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## Potency and Pregnancy in Japan: Did Viagra Push the Pill

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# POTENCY AND PREGNANCY IN JAPAN: DID VIAGRA PUSH THE PILL?

## I. INTRODUCTION

For the first time in history, Japanese women can legally buy birth control pills ("the Pill") for contraceptive purposes.<sup>1</sup> The Pill was offered on the market to the Japanese public beginning in September 1999, thus culminating a nine-year battle by Japanese pharmaceutical companies to gain approval from the Japanese government for the sale of the "low-dose" contraceptive.<sup>2</sup> In June 1999, the manufacturers of oral contraceptives finally received approval from the Japanese Ministry of Health and Welfare ("MHW") for sale of the Pill by prescription.<sup>3</sup>

The approval process through this nine-year period is best described as a slow moving train which gained unexpected speed as it neared its destination, fueled by an unexpected source. Rumors abound that approval of the Pill in Japan was spurred by the swift approval of Viagra in that country.<sup>4</sup> In contrast to the approval process for the Pill, the wonder-impotency drug for men gained approval from the same MHW in a record six months,<sup>5</sup> a bullet train of bureaucratic speed and need.<sup>6</sup> Although the Pill has been available in the United States for almost forty years, Japan is the last industrialized nation to approve the safety and legality of the pill for its citizens.<sup>7</sup>

The contrast between the slow rate of approval of the Pill and the speedy approval of Viagra certainly highlights the vagaries of the Japanese government's drug approval process. Even more importantly, in light of the fact that birth control issues are so closely related to human sexuality, gender equality, reproductive rights, abortion, and population control, the contrast focuses attention on several areas where Japan may face change or criticism.<sup>8</sup> The Japanese government's inconsistency in the approval process of the Pill and Viagra is not easily explained

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1. See *Drug Makers Introduce Birth Control Pills in Japan*, NATIONAL POST, Sept. 3, 1999, at C02. News of the legal sale of birth control pills was reported worldwide on Sept. 3, 1999. See, e.g., *News in Brief*, THE CHRISTIAN SCIENCE MONITOR, Sept. 3, 1999, at 24; *World News Tonight* (ABC television broadcast, Sept. 2, 1999) (transcript #99090203-j04); THE TIMES (London), Sept. 3, 1999.

2. See *Birth Control Pill Goes on Sale in Japan*, DEUTSCHE PRESSE-AGENTUR, Sept. 2, 1999, available in LEXIS, News Group Files.

3. See *Japan Health Ministry Approves Birth Control Pills*, ASIA PULSE, June 17, 1999, available in LEXIS, News Group Files.

4. See *World Watch*, TIME, Sept. 13, 1999, at 16.

5. The link between birth control pill approval and Viagra was made on *ABC World News This Morning*, Sept. 3, 1999 (transcript #99090303-j03) and in newspapers. See, e.g., *Popularity of Pill Not Likely to Soar in Japan*, THE DESERET NEWS, Sept. 1, 1999, at A06. One theory suggests that Viagra won approval in record time because "the country's mostly male politicians wanted access to the drug for their own use." Kay Itoi, *The Great Viagra Emergency*, NEWSWEEK, Feb. 8, 1999, at 39.

6. The bullet train, or *shinkansen*, is the high speed express train linking major cities in Japan.

7. See *Birth Control Pill Goes on Sale In Japan*, supra note 2.

8. See Anika Rahman, *Symposium: Women's Rights as International Human Rights: Toward Government Accountability for Women's Reproductive Rights*, 69 ST. JOHN'S L. REV. 203 (1995) (discussing the relationship between access to birth control and reproductive rights).

or harmonized. Any explanation, in fact, points a finger at the schizophrenic role Japan plays as a world leader,<sup>9</sup> and the double standards and paradoxes that permeate Japanese life and culture.<sup>10</sup> Why is an explanation for Japan's reaction to the Pill important? First, as Japan grapples with the fallout from this latest blunder in the equal rights arena,<sup>11</sup> the world, specifically the United Nations, will be watching for the Japanese response to pressure for a more sexually egalitarian society. Second, another legal issue which will surface based upon Japan's approval of the Pill and the contrast with approval of Viagra is informed consent in the context of reproductive health, an area where the Japanese may consider emulating the United States or other countries. Third, as Japan attempts to reconcile new contraceptive techniques with its abortion policies, Japan's struggle may enlighten those seeking a compromise on abortion in the United States.<sup>12</sup> Approval of the Pill will not automatically create gender equality, reduce abortion, or implement informed consent; rather, the approval of the Pill will force the Japanese to seek legal and social solutions to these issues under international scrutiny.

Until the Pill was approved, abortion was the only available option for a Japanese woman to prevent the birth of an unwanted child.<sup>13</sup> As this comment will indicate, past comparisons of Japanese and American abortion laws are thoughtful and enlightening.<sup>14</sup> Those comparisons, however, were based on the unavailability of oral contraceptives to Japanese women; therefore, abortion was not only an option for terminating a pregnancy, but was the primary method of birth control when condoms failed.<sup>15</sup> This comment goes beyond the previous comparisons to focus on some future areas of change in Japanese society and Japanese law relating to the abortion issue now that the Pill is legal.

Specifically, Japan's leaders and policy-makers must consider, as Japanese women begin to choose the Pill as a contraceptive option, what concurrent changes the Pill will provoke. Currently in Japan, abortion does not divide society on moral

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9. See *id.* at 209 n.19. Japan contributes to family planning through the United Nations and the International Conference on Population and Development (ICPD) and other organizations.

10. See Sam Jameson, *Viagra vs. Birth Control Case Shows Japan's Double Standard*, THE DENVER POST, Feb. 17, 1999, at B-09. It is always a temptation to explain what the west sees in Japan as inconsistencies as "duality", "opaqueness" or "cultural differences." This is too simplistic. Japan is a complicated society with a long and distinguished history which has shaped its response to non-Japanese conventions, rules and norms.

11. Maya Kaneko, *Viagra's Speedy Approval Contrasts with Ban on Pill*, JAPAN ECONOMIC NEWSWIRE, Jan. 31, 1999.

12. See generally Anita L. Allen, *Review Essay: Tribe's Judicious Feminism*, 44 STAN. L. REV. 179, 198-200 (1991).

13. See Willis Witter, *Japanese Panel Oks Sale of the Pill; Viagra Approval Spurred Uproar*, THE WASH. TIMES, March 4, 1999, at A1. The condom and abortion have been the two major methods of "birth control" in Japan, since the IUD is not allowed in Japan. Women have little control over use of the condom in preventing pregnancy.

14. See, e.g., Sara L. Walsh, *Liquid Lives and Liquid Laws: The Evolution of Abortion Law in Japan and the United States*, 7 INT'L LEGAL PERSPECTIVES 187, (1995); Lynn D. Wardle, "Crying Stones": A Comparison of Abortion in Japan and the United States, 14 N.Y.L. SCH. J. INT'L & COMP. L. 183 (1993).

15. See Aya Furata, *Latest Attack on the Pill Comes from Environmental Groups*, THE NIKKEI WEEKLY, July 13, 1998, at 19 (stating that in 1996, 340,000 abortions were reported, 8.3 % on teenagers, and that the percentage is increasing). See also Suvendrini Kakuchi, *Population-Japan: Too Quick on Viagra, Too Slow on the Pill*, INTER PRESS SERVICE, Feb. 9, 1999, available in LEXIS, News Group Files [hereinafter Kakuchi, *Viagra*].

and religious grounds as it does in the United States.<sup>16</sup> Rather, abortion is a socially acceptable practice domestically which receives criticism internationally.<sup>17</sup> Will the lessened need for abortion in Japan due to increased use of the Pill spark an interest in the rights of the unborn child? Will Japanese religious groups begin to rally around the child and the preservation of the family as a political force to change abortion laws? What issues will be the focus in the future? Can Japan avoid the divisive, angry, and at times, violent debate concerning abortion that has been a part of American culture and political life since even before the landmark Supreme Court decision in *Roe v. Wade*?<sup>18</sup> Intersecting with the issues of informed consent will be reproductive rights: How will Japan respond to international and domestic challenges in this area of obvious inequality? In general, will Japan be able to continue to keep its paradoxical double standard on issues that face much of the industrialized world?<sup>19</sup>

To put these issues in a historical and contextual framework, this comment explores the history of the efforts by pharmaceutical companies to introduce the Pill in Japan, and, in Section III, suggests reasons for the slow approval of the Pill. Section IV discusses the history of abortion law and current law in Japan. The issues of medical informed consent in relation to the Pill appear in Section V, and the current state of gender equality laws and reproductive rights are discussed in Section VI. Section VII provides a conclusion with predictions for the future.

## II. HISTORY OF EFFORTS TO PROVIDE THE PILL TO JAPANESE WOMEN

The Pill gained approval for use in the United States in 1965 from the Federal Drug Administration (FDA) despite its link to thrombosis and its other possible side effects.<sup>20</sup> Since 1965, more than 185 United Nations member countries have approved the Pill,<sup>21</sup> and 300 million women worldwide have used the Pill.<sup>22</sup> Japan is the last industrialized nation to approve the Pill for use as a contraceptive.<sup>23</sup> High dose pills,<sup>24</sup> however, have been available by prescription in Japan for the relief of menstrual irregularity, and approximately 200,000 women actually use these pills for contraceptive purposes.<sup>25</sup> Consequently, with access to

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16. See generally Wardle, *supra* note 14, at 233-241 (summarizing the climate in Japan towards abortion).

17. See *id.* at 220, 228-31.

18. *Roe v. Wade*, 410 U.S. 113 (1973). See also Bill Baird, *The Politics of God, Government and Sex: A Thirty-One-Year Crusade*, 13 ST. LOUIS U. PUB. L. REV. 139 (1993).

19. See Jameson, *supra* note 10.

20. See Miyuki Nakamura, *Japan Still Finds the Pill Hard to Swallow*, THE NIKKEI WEEKLY, Oct. 21, 1996, at 16. The safety of prescription drugs is monitored by the FDA under the Food Drug and Cosmetic Act of 1938, U.S.C. §§301-393; Rachel F. Ochs, *Pharmaceuticals: The Battle for Control in the 21<sup>st</sup> Century*, 10 J.L. & HEALTH 298, at 10 n.59 (1995-96).

21. See Kaneko, *supra* note 11.

22. See Mina Hasegawa, *Japan Ends Hold-Out on Birth Control Pill: Women Applaud Move But Fears Remain*, THE NIKKEI WEEKLY, June 7, 1999, at 19. *Early Lifting of Ban on Birth Control Pills Unlikely*, JAPAN ECONOMIC NEWSWIRE, Aug. 12, 1997 (stating that ninety million women worldwide now use the low-dose pills).

23. See *Birth Control Pill Goes on Sale in Japan*, *supra* note 2.

24. Higher dose pills have the same compound but higher dosages of ethynyl estradiol and produce side effects such as nausea, which can be avoided or lessened if taken in lower dosages. Furata, *supra* note 15, at 19.

25. See *id.*

other contraceptive methods limited, the abortion rate in Japan has been quite high<sup>26</sup> since abortion was legalized under certain conditions in 1947.<sup>27</sup>

### A. *The Approval Process*

Generally the approval process for a new drug in Japan takes eighteen months.<sup>28</sup> Even if a drug meets Food and Drug Administration (FDA) standards in the U.S., the Japanese MHW must approve the drug through its own internal approval and licensing procedures.<sup>29</sup> Japanese standards are similar to the FDA standards,<sup>30</sup> to better allow pharmaceuticals to compete in the global market. Sales and distribution by pharmaceutical companies are regulated by Pharmaceutical Affairs Law,<sup>31</sup> laws which are proposed and administered by the MHW.<sup>32</sup> The Central Pharmaceutical Affairs Bureau (CPAC) is charged with investigating and advising the Ministry on scientific aspects of drugs, and various subcommittees of the "CPAC evaluate the safety, quality and efficacy of new drugs."<sup>33</sup> The CPAC secretariat oversees, coordinates, and harmonizes the efforts of the CPAC and its subcommittees.<sup>34</sup> After approval by the MHW based on this system of review within the MHW, pharmaceutical companies must apply for a license from the MHW in order to manufacture or import a drug.<sup>35</sup> Although the process appears comprehensive, encompassing several reporting bodies and an oversight function, the safety and scientific standards in Japan are not as high as those in the U.S. through FDA regulation.<sup>36</sup>

### B. *Pharmaceutical Companies Promote the Pill*

Early efforts to bring the Pill to Japan started in 1961 with clinical tests on oral contraceptives.<sup>37</sup> Japanese pharmaceutical companies sought approval of the early version of the Pill, which was a higher dosage drug in 1965.<sup>38</sup> The Japanese Ministry of Health and Welfare signaled that it would approve the drug, but later in 1965 the Ministry terminated the authorization procedure with no explanation.<sup>39</sup>

In 1990, Japanese pharmaceutical companies again sought to sell and market the new, lower dosage birth control pills after conducting clinical trials on 5,000

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26. See Wardle, *supra* note 14, at 244 (stating that Japan's abortion rate is in the 30-40% range per number of pregnancies).

27. See *id.* at 195.

28. See Ochs, *supra* note 20, at 10.

29. See *id.* at 38.

30. See *id.*

31. See *id.* at n. 225.

32. See *id.* at 38.

33. Ochs, *supra* note 20, at 38.

34. See *id.*

35. See *id.* at 39.

36. See *id.*

37. See Itoi, *supra* note 5, at 39.

38. See *Japan Having a Hard Time With Oral Contraceptives*, JAPAN POLICY & POLITICS, Dec. 28, 1998.

39. See *id.* Some speculate that the ministry halted the process because of "concern about the corruption of sexual mores." Nakamura, *supra* note 20, at 16.

Japanese women.<sup>40</sup> Little did the companies know that they would be stuck in this bureaucratic web for nine years.<sup>41</sup> Negotiations began between the Central Pharmaceutical Affairs Bureau (CPAC) and pharmaceutical companies in early 1991, and by 1992 it looked likely that the Ministry would consider lifting the ban on the Pill.<sup>42</sup> However, fears of the AIDS pandemic,<sup>43</sup> and the prediction that the Pill would lead to less condom usage in the country abruptly halted the approval process.<sup>44</sup> The issue of approval was returned to the subcommittee for additional study.

Finally in February 1997, the MHW accepted a report that declared the new low dosage birth control pills safe, and MHW drafted a report in June 1997, conditionally advocating the Pill.<sup>45</sup> As a result, the Pill again appeared close to approval when the Ministry's Public Health Council backed the legality of the Pill with conditions.<sup>46</sup> A major setback occurred in August 1997, when a subcommittee of the CPAC postponed its decision on approval, again citing concerns regarding AIDS prevention measures.<sup>47</sup> By this time, many women were outraged enough to protest the delay in approving the Pill. The Professional Women's Coalition for Sexuality and Health, composed of gynecologists, scientists, midwives, health workers, and teachers, convened November 8, 1997,<sup>48</sup> to push approval of the Pill,<sup>49</sup> and joined pharmaceutical companies as a faction seeking approval of the Pill. Support for the approval of the Pill also came from the United Nations Population Fund (UNFPA).<sup>50</sup>

In April 1998, another unexpected hurdle arose in the paths of the

40. See Furata, *supra* note 15, at 19.

41. See *id.*

42. See *id.*

43. See *Early Lifting of the Ban Unlikely, supra* note 22; *Japan Having a Hard Time, supra* note 38. Japan was not over-reacting to the threat of AIDS.

The HIV/AIDS pandemic, now in its second decade, continues to grow at an extraordinary rate . . . [d]iscussion of reproductive health and reproductive rights matters at the international level has generally failed to take into account the breadth of related HIV/AIDS concerns. In particular, consideration for the reproductive health and reproductive rights of women effectively disappears in the context of HIV/AIDS.

Sofia Gruskin, *The Impact of Reproductive Subordination on Women's Health: Negotiating the Relationship of HIV/AIDS to Reproductive Health and Reproductive Rights*, 44 AM. U.L. REV. 1191 (1995). "[W]omen as a group are more vulnerable to HIV infection because of social, cultural, economic, and political realities at the international, national, and community level, not simply because of their immune systems or biology." *Id.* at 1193. As of January 1, 1994, 11.3 million men, 8.7 million women and 2.2 million children had been infected with HIV since the start of the epidemic in the 1980s. During 1993, over 10,000 new infections occurred each day. *Id.* at 1191.

44. See Michael A. Lev, *Japan Quick to OK Viagra; Women Still Await the Pill*, THE CHICAGO TRIBUNE, Feb. 1, 1999, at 1 (stating "Japan has highest usage rate of condoms in the world and the lowest rate of AIDS.").

45. See Jon Herskovitz, *Japan Starts Process to End 30-Year Ban on the Pill*, JAPAN ECONOMIC NEWSWIRE, June 19, 1997.

46. See *id.* (stating the conditions set by the MHW for approval of the Pill which included measures to prevent/decrease STDs).

47. See *id.* The link between AIDS and the Pill relates to condom use. The fear was that couples would stop using condoms if the Pill were available to women, thus no longer preventing the spread of AIDS.

48. See *Writer Pushes to Legalize Low-dose Pill*, THE NIKKEI WEEKLY, Nov. 3, 1997, at 17.

49. See Furata, *supra* note 15, at 19.

50. See Suvendrini Kakuchi, *Population-Japan: Birth Control Pill Coming Soon, At Last?* INTER PRESS SERVICE, Dec. 15, 1997, [hereinafter Kakuchi, *Birth Control*].

proponents of the Pill. A study released in the United Kingdom on the feminization of fish near a sewage treatment plant hypothesized that hormones from waste products of birth-control-ingesting-humans were affecting the fish.<sup>51</sup> This study sparked fear in Japan<sup>52</sup> and the group "Stop! Dioxin Pollution Kanto Network," opposed the Pill because "[t]he waste from pill takers can go into polluted waters and have harmful effects on wild animals."<sup>53</sup> The issues raised by the fish study resulted in another postponement by Japanese officials while a subcommittee reviewed the specific environmental hazards associated with the Pill,<sup>54</sup> and commissioned a study on the Pill as an endocrine disrupter.<sup>55</sup>

### C. *Viagra Pushes the Pill*

Ironically, it may have been the success of Viagra, the wonder-drug to counteract erectile dysfunction and impotence, that pushed the Pill over the barriers to approval. In December 1998, a MHW advisory panel approved the sale of Viagra based upon clinical trials from the United States submitted by the drug's manufacturer, Pfizer Pharmaceuticals.<sup>56</sup> The MHW gave its approval of Viagra on January 25, 1999,<sup>57</sup> to combat the "health emergency for men in need of immediate treatment."<sup>58</sup> The unprecedented swiftness of approval<sup>59</sup> astounded pharmaceutical experts and sparked demonstrations and angry reactions from women's groups and other proponents of the Pill.<sup>60</sup> By March 23, 1999, Viagra was available by prescription in Japan, after only six months of deliberation by the MHW concerning this new drug which has several dangerous side effects.<sup>61</sup> Authorities claimed they rushed approval of the drug to ensure that Viagra users obtained the drug by prescription to "prevent deaths that could occur among heart and liver patients who obtain[ed] [the drug] surreptitiously."<sup>62</sup> Cries of Japan's double standard, male-centered way of thinking, sexual inequality, gender bias and the like seemed to have spurred the MHW at last on the Pill issue.<sup>63</sup> This was evidenced by the fact that on February 22, 1999, approval of the Pill was predicted to take place at the March meeting of the Pharmaceutical Council.<sup>64</sup> The MHW

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51. See Furata, *supra* note 15.

52. See Lev, *supra* note 44.

53. See Furata, *supra* note 15, at 19.

54. See *id.*

55. See Witter, *supra* note 13.

56. See Jameson, *supra* note 10.

57. See MAINICHI DAILY NEWS, Feb. 5, 1999, at 2.

58. In *Japan You Can Buy Viag[a]ra, but Not the Birth Control Pill*, CTV NATIONAL NEWS, March 23, 1999, 23:00 available in LEXIS, News Group Files.

59. The usual approval process is 18 months. See Ochs, *supra* note 20, at 30.

60. See *Japan's Viagra Ok Angers Pill Advocates*, MINNEAPOLIS STAR TRIBUNE, Feb. 11, 1999. See also Jameson, *supra* note 10.

61. See Kaneko, *supra* note 11. See also Witter, *supra* note 13, at A1. One theory for the swift approval was that the government wanted to circumvent the black market where one Viagra pill cost \$300 compared to \$10 in the U.S. Other methods of obtaining the drug were by travel abroad to Hawaii and San Francisco and sales through the Internet. *Id.*

62. Jameson, *supra* note 10.

63. See Kakuchi, *Viagra*, *supra* note 15.

64. See *Drug Makers Introduce Birth Control Pill*, *supra* note 1.

advisory panel did indeed recommend legal approval of the Pill at its March 3, 1999 meetings, pending a final decision based on a report submitted by the CPAC to the MHW.<sup>65</sup> The CPAC closed discussion on the issue of the Pill, March 4, 1999, and its report went to the standing committee recommending approval.<sup>66</sup> On June 7, 1999, the Health Minister, Sohei Miyashita, accepted the CPAC report and the nine-year old approval request from the pharmaceutical companies.<sup>67</sup> On September 2, 1999, the Tsumura Company launched sales of the Pill, joined by ten other pharmaceutical companies in the widely reported event.<sup>68</sup>

Despite approval of the Pill after the push from Viagra, the slow train ride is not yet over for Japanese society. Pharmaceutical companies may now legally sell the Pill in Japan, but Japanese women are not rushing to their doctors for prescriptions.<sup>69</sup> Although the Pill is legal, Japanese women must still overcome significant social, cultural, and economic barriers before the Pill will be widely accepted and properly used.<sup>70</sup> A ten-year post-approval study on the effects of the Pill is required by the Ministry of Health, and the Pill probably will not be covered by health insurance providers.<sup>71</sup> While some of these barriers to use of the Pill were created during the course of the approval process, others are imbedded in Japanese culture, history, and tradition.<sup>72</sup> The legal and regulatory barriers to use of the Pill are broken, but as the Pill becomes common in use, other legal areas ripe for change include abortion law, informed consent laws and a recognition of reproductive rights for Japanese women.

### III. WHY DID APPROVAL OF THE PILL TAKE SO LONG IN JAPAN?

Japan's ban on the birth control pill has been a source of international social, and political embarrassment,<sup>73</sup> yet this embarrassment alone was not enough

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65. See *Further Delay in Japan OC Approval*, MARKET LETTER, 0951-3175, March 8, 1999, available in LEXIS, News Group Files.

66. See *Low Dose Pill Could Be Available in Japan By Fall*, COMLINE DAILY NEWS, BIOTECHNOLOGY AND MEDICAL TECHNOLOGY, Mar. 4, 1999.

67. See *Ministry of Health and Welfare Officially Ok's Low-dose Birth-control Pill*, COMLINE-EMERGING MARKET OF JAPAN AND EASTERN ASIA: HEALTH CARE AND BIOTECHNOLOGY, July 1, 1999. See also Witter, *supra* note 13.

68. See *11 Firms Set to Launch Birth Control Pills Thurs.*, JJI PRESS TICKER SERVICE, Sept. 1, 1999; *Tsumura to Start Selling Birth Control Pills September 2*, JJI PRESS TICKER SERVICE, Aug. 25, 1999. The companies include Tsumura, Yamanouchi, Nihon Schering K.K., Janssen-Kyowa Co, Mochida Pharmaceutical Co., Teikoku Hormone Mfg. Co., Monsanto Japan Ltd. and Daiichi Pharmaceutical Co.

69. See *Popularity of 'Pill' Not Likely to Soar*, *supra* note 5, at A06.

70. See Hasegawa, *supra* note 22.

71. See Kevin Sullivan, *The Pill Is Approved in Japan; Women's Groups Hail Long-Delayed Action*, THE WASHINGTON POST, June 3, 1999, at A19.

72. See Matt E. Antell, *Birth Control Pill in Japan*, UNITED PRESS INTERNATIONAL, Dec. 30, 1998. One of the excuses for slow approval was the "importance on first achieving public consensus on the issues" according to Toshiki Hirai, a Ministry official.

73. See Nicole Gaouette, *Japan's Low Birthrate Slows Birth-control Approval*, THE CHRISTIAN SCIENCE MONITOR, Mar. 11, 1999, at 8 (explaining that the embarrassment led to changes in abortion law rather than the approval of the Pill when the 1994 Cairo Conference on Population and Development Conference questioned Japan's restrictions on the Pill and in Sept of 1995, the World Conference On Women in Beijing had the same issue come up); See also Sonni Efron, *World Perspective: Japan: Women Find Viagra's Speedy Ok is Bitter Pill to*



to spur the MHW to faster action on approval.<sup>74</sup> When no government explanation for opposition to the Pill was forthcoming, speculation and rumor substituted for facts.<sup>75</sup> The slowness with which Japan approved the Pill is even more baffling when confronted with the statistic that Japan is the world's largest user of prescription drugs.<sup>76</sup> Five possible explanations for the reluctance to approve the Pill include (1) fear; (2) entrenched medical and business interests; (3) religious pressures; (4) Japan's low birth rate; and (5) the prevalence and acceptance of abortion as a contraceptive method. Of these explanations, the availability of legal abortion as a contraceptive method has been a dominant factor in the pattern of birth control in Japan, and therefore is treated in depth in Section IV of this comment.

#### A. Health and Social Fears

As noted earlier, the fear of the spread of AIDS and the fear of environmental harms and potential side effects from use of the Pill contributed to the delay in the approval process of this drug.<sup>77</sup> Of these, fear of potential side effects was (and still is) the greatest barrier faced by manufacturers of the Pill. Japanese women feared using the Pill because actual knowledge and facts about the side effects and safety of the newer, low dosage pills was not adequately disseminated to women in Japan, and the dangers of its use were exaggerated. These fears were clearly not allayed in 1995 when Japan's top health official, Junichiro Koizumi (the Minister of Health), said in an interview "[t]he pill distorts the natural physiological function of women. It is unusual when women have no side effects."<sup>78</sup> A daily Japanese paper conducted a poll in 1998, in which 54 percent of the women surveyed said they would not use the Pill even if approved, and 70 percent of those women admitted fear of the side effects.<sup>79</sup> Other fears of potential side effects arose among women based upon past drug company nightmares such as the DES babies in the 1940s and 1950s, and the thalidomide birth defects in the 1960s,<sup>80</sup> which were well-publicized in Japan.<sup>81</sup> The publicity regarding possible links between increased risk of thrombosis (blood clots), breast cancer, and the Pill in 1995<sup>82</sup> also made Japanese women leery of the risks.<sup>83</sup> Furthermore, the same fears that existed before the Pill was approved remain prevalent today due to a lack of information

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Swallow, L.A. TIMES, Jan. 30, 1999, at A2.

74. See generally Meredith Marshall, *Recent Development: United Nations Conference on Population and Development: The Road to a New Reality for Reproductive Health*, 10 EMORY INT'L L. REV. 441 (1996); Mahmoud F. Fathalla, *The Impact of Reproductive Subordination on Women's Health: Family Planning Services*, 44 AM. U.L. REV. 1179, 1187 (1995).

75. See Nakamura, *supra* note 20.

76. See Ochs, *supra* note 20, at 5. (stating "Japan has the world's highest per capita consumption of drugs, more than double that of the U.S. or Western Europe.").

77. See Furata, *supra* note 15, at 18.

78. *Id.*

79. See *id.*

80. See *id.*

81. See *id.*

82. See Nakamura, *supra* note 20.

83. See Furata, *supra* note 15, at 18.

and education on birth control options. For example, a recent article in *More*, a fashion magazine for young women, explained the methods and advantages of the Pill.<sup>84</sup> Although the “spin” on the article was that weight gain (and its effect on health and beauty) was a side effect of birth control pills,<sup>85</sup> the subject of birth control was at last addressed in a popular forum. This was one of the first articles geared toward educating young Japanese women on their contraceptive options.<sup>86</sup> The scarcity of popular materials on contraception is significant, since other sources of information are also lacking. Family planning sources characterize the lack of information as follows: “Sex education in schools is poor, and teenagers are often left without sufficient family planning information and services.”<sup>87</sup>

Fears were not restricted to the potential physical side effects on women. The social fear of increased promiscuity, especially among teenagers and unmarried women, the fear of “the corruption of social mores,”<sup>88</sup> and fear of an increase in the spread of AIDS were all pressures fighting against approval.<sup>89</sup> Indeed, advocates of the Pill have said that the failure to distinguish between medical and social problems associated with the drug was an error on the part of CPAC during the approval process.<sup>90</sup> Critics of the Japanese government believed that the greatest concern of the government and politicians was the “sexual freedom the pill would offer to Japanese women, a right long considered the prerogative of men.”<sup>91</sup> In other words, it was a fear that “all women would somehow become sex fiends.”<sup>92</sup>

The Japanese government did little during the approval process to lessen these physical and societal fears, but rather used these fears as reasons for delay and further study. Female activist Akiko Domoto, a member of the upper house of the Diet (the Japanese Parliament), contended that there was “constant pressure to not approve the Pill from all parties in the Diet.”<sup>93</sup> Domoto believed the way the approval process was handled indicated that the Pill was “an issue deeply rooted in Japan’s male-oriented traditions.”<sup>94</sup> Remarking on the process, a Japanese female politician stated, “[t]he committee deliberating on the Pill is very closed . . . and mostly male.”<sup>95</sup> Indeed, the Ministry of Health had “six women among its 204

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84. See Philip Brasor, ‘Liberation’ of Birth Control Proves a Bitter Pill to Swallow, THE JAPAN TIMES, July 1, 1999.

85. See *id.*

86. *Id.* The lack of information about sex and birth control is in stark contrast to the overload of information on every other subject in Japan. With one of the world’s high literacy rates, at 99%, several major daily national newspapers, and a huge publishing industry, it is hard to believe that the subject has not been adequately covered in the press. See *The Denver Post Online* (visited Oct. 24, 1999) <<http://www.Denverpost.com/news/jainfor.htm>>. “Bookstores thrive on sales of health related publications.” Robert B. Leflar, *Informed Consent and Patients’ Rights in Japan*, 33 HOUS.L. REV.1, (1996), at 85.

87. *International Planned Parenthood Federation*, Japan Country Profiles, (visited Sept. 26, 1999) <<http://www.ippf.org/regions/countries/jpn/index.htm>>.

88. Nakamura, *supra* note 20.

89. See Furata, *supra* note 15, at 18.

90. See *Japan Having a Hard Time*, *supra* note 38.

91. *The Promise of the Pill—At Last*, THE JAPAN TIMES, March 7, 1999.

92. Brasor, *supra* note 84.

93. Hasegawa, *supra* note 22.

94. *Id.*

95. *Condom Makers Braced for Bitter Pill: Bayan Rahman on the Battle for the Lucrative Contraceptive Market*, FIN. TIMES (London), Sept. 3, 1999, at 4, available in LEXIS, News Group Files.

bureaucrats,"<sup>96</sup> and the committee making the decision was made up of three women and twenty-one men.<sup>97</sup> Fear of physical and social side effects from potential use of the Pill delayed its approval and still remains as a barrier to its widespread use.

### B. Entrenched Interests

Entrenched interests in the medical and business communities are the second possible explanation for the delay in approving the Pill. Obstetricians and gynecologists, who draw much of their income from legal abortions, may have exerted considerable pressure to resist lifting the ban on the Pill.<sup>98</sup> Because the cost of abortions is not covered by insurance, doctors' fees are controlled only by the market<sup>99</sup> in this "quick and profitable kind of medical practice."<sup>100</sup> Condom manufacturers may also begin to suffer financially if the Pill is widely accepted by Japanese women. Okamoto Industries, Inc. for example, controls about 60 percent of the domestic condom market in a country that has been the leader among industrialized nations in the use of condoms.<sup>101</sup> About 600 million condoms are sold each year in Japan,<sup>102</sup> yet surprisingly, Okamoto's spokesmen said the company was not opposed to lifting the ban on the Pill.<sup>103</sup> Okamoto expects sales to fall by only 10 percent.<sup>104</sup>

One versed in U.S. politics and drug policy might have expected the pharmaceutical companies to have exerted more pressure and influence during the nine-year period of approval in Japan. However, in contrast to the U.S. market for the Pill which is estimated at U.S.\$1.64 billion (approximately 200 billion yen), the market in Japan is expected to start slowly and grow to about U.S.\$164 million.<sup>105</sup> Still, at 2000-3000 yen (U.S.\$20-30) per month per person,<sup>106</sup> this is not just a niche market.<sup>107</sup> "Ironically, Japanese pharmaceutical firms have been *manufacturing* the Pill for years, solely for *export* to Asian countries, and the United States."<sup>108</sup> Adding the Japanese domestic market would not have increased pharmaceutical company costs significantly; rather, sales of the Pill would become a major profit

96. Sheryl Wu Dunn, *Japan's Tale of Two Pills, Different Fates for Viagra and Birth Control*, INT'L HERALD TRIB., May 3, 1999.

97. See Efron, *supra* note 73, at A2.

98. See Brasor, *supra* note 84; See also, *Condom Makers Braced for Bitter Pill*, *supra* note 95.

99. See Ginny Parker, *Japan, at Last, Allows Pill Months After Viagra OK'd.*, THE BOSTON GLOBE, June 3, 1999, at A2; See also Wardle, *supra* note 14, at 218, 234.

100. *Id.* at 243.

101. See Herskovitz, *supra* note 45.

102. See *id.*

103. See *id.*

104. See *Condom Makers Braced for Bitter Pill*, *supra* note 22.

105. See Hasegawa, *supra* note 22. Some sources estimate the Japanese market to be as low as 10-15 billion yen (U.S.\$100-150 million) over the next 3-5 years. See generally, Antell, *supra* note 72; while others put this market at U.S.\$862 million based on the population of women in child bearing years. See *Condom Makers Braced for Bitter Pill*, *supra* note 95.

106. See Junko Takahashi and Mayumi Negishi, *Rousing Reception Unlikely for Pill*, THE JAPAN TIMES, June 3, 1999; See also, Herskovitz, *supra* note 45. If 10 percent of women were to start using the Pill, the yearly market could reach 114 billion yen (US\$1.14 billion).

107. See Takahashi and Negishi, *supra* note 106.

108. See Kakuchi, *Birth Control*, *supra* note 50.

area since the distribution system is already in place. Perhaps the explanation lies elsewhere, for, concomitant with the slow process of birth control pill approval was a push by the Japanese government to increase pharmaceutical exports and increase new drug research and development.<sup>109</sup> This tends to indicate that selling and marketing the Pill in Japan was not a purely economic issue. Japanese drug companies might have traded early approval in the Japanese domestic market for substantial government support in a push for world-wide market domination in all pharmaceuticals, a U.S.\$130-140 billion industry overall.<sup>110</sup>

### C. Japan's New Religions

The so-called "New Religions" in Japan may have opposed approval of the Pill, a drug often linked to feminism and the sexual liberation of women. The new religious groups can be described in "fundamentalist" terms and are part of a world-wide movement to use legal structures to ensure "women's obedience to their husbands and confine them to the role of wife and mother."<sup>111</sup> These New Religions of Japan have their origins in Shintoism and Buddhism and include one-third to one-fourth of the Japanese population among their members.<sup>112</sup> Groups such as the *Soka Gakkai*, *Seicho no Ie*, and *Reiyukai Kyodan* have close ties with political parties and influence legislation in the Diet and policy-making in the ministries.<sup>113</sup> These groups oppose and lobby against contraception because of their position that "it's men who are superior, and the women who are behind all the trouble in the world."<sup>114</sup> Japan's new religious groups are lobbying the Diet to return to the Meiji Civil Code which was enacted following the overthrow of Japan's feudal regime in 1868,<sup>115</sup> which derived from French and German law systems.<sup>116</sup> The Meiji Civil Code forbids contraception and contraceptive education. By bringing back the Meiji Civil Code, the fundamentalist groups would reinforce the model of patriarchal, male dominated life that prevailed in Japan under the Meiji emperor and until World War II.<sup>117</sup> They see the repeal of the Meiji Civil Code and the "gift" of an American composed and imposed constitution after World War II<sup>118</sup> as the beginning of many of the reforms in postwar Japan and a

109. See Ochs, *supra* note 20, at 1-2.

110. See *id.* at 1.

111. Courtney W. Howland, *The Challenge of Religious Fundamentalism to the Liberty and Equality Rights of Women: An Analysis Under the United Nations Charter*, 35 COLUM. J. TRANSNAT'L L. 271 (1997).

112. See *id.* at 286 n.46.

113. See *id.* at 276.

114. *Id.* at 288.

115. See generally Peter Duus, THE RISE OF MODERN JAPAN 73-89.

116. See Wardle, *supra* note 14, at 193.

117. See Howland, *supra* note 111, at 288-89. Specifically, the Meiji Civil Code that applied to family life provided for the eldest male to be head of the family, and as household head he had authority over the family property. Women's rights to real and personal property were strictly limited and could be disposed of by the husband without the wife's consent. Likewise, divorce rights were closely circumscribed, while men could divorce for any number of reasons, including "adultery or failure to produce a male child." *Id.* A wife could not expect to receive alimony or custody of her children under the Code. *Id.* at 289.

118. See generally Mark Gayn, *Drafting the Japanese Constitution*, THE ORIGINS OF THE MODERN JAPANESE STATE, (Jon Livingston, ed.) at 19-24 (describing the creation of the Japanese Constitution and the societal reforms that it endeavored to impose on Japan).

subsequent rise in the power of women.<sup>119</sup> The approval of the birth control pill, which gives women more control of their reproductive health decisions, obviously thwarts the fundamentalist thrust of the new religions.

#### D. Low Birth Rate

Japan's current low birth rate is the fourth factor that might have created reluctance to speed the availability of the Pill.<sup>120</sup> Japan has the world's longest life expectancy and one of the lowest birth rates.<sup>121</sup> Thus, Japan has been grappling with the potential consequences of both of these trends since the early 1980s because of their enormous impact on social and economic systems.<sup>122</sup> Issues of paying for an aging workforce and financing medical care, retirement, and social security might have been balanced against women's reproductive rights in the approval process of the Pill.<sup>123</sup> Discouraging use of the Pill might cause the birth rate to rise, rather than decline, as it has in many other countries which introduced the Pill. Other developed Asian countries such as Singapore,<sup>124</sup> have faced a declining birthrate.<sup>125</sup> Singapore's answer was to provide government incentives to encourage larger families and thus "grow" a future workforce. Government incentives to encourage larger families are not a new idea for Japan.<sup>126</sup> The linkage between population control (including abortion) and the economic condition and well-being of the country has a long history.<sup>127</sup> During the battle for approval of the Pill in Japan it was postulated that the Diet members who recognized the danger in Japan's low birth rate, already below population replacement levels, might have "quashed approval . . . in order to keep the birthrate from falling farther."<sup>128</sup> By dragging its feet in the approval of the Pill, the Japanese government *de facto* legislated population policy in Japan through the 1990s without facing the disadvantages of public debate over family size.

#### E. High Rate of Abortion

Finally, the high rate of abortion, the legality of abortion, and the lack of

119. See Howland, *supra* note 111, at 289.

120. See *Condom Makers Braced for Bitter Pill*, *supra* note 95.

121. See *Japan Country Profiles*, *supra* note 87. Life expectancy for women in Japan is 84 years for women, 77 years for men. See *id.*

122. See *Condom Makers Braced for Bitter Pill*, *supra* note 95.

123. See *id.* When this concern first surfaced in the 1980s the ruling political party (Liberal Democratic Party or "LDP"), attempted to amend the abortion laws to make them less liberal, but failed in their attempt.

124. See Ken J. Moyle, Comment, *A Cultural Exchange: Singapore and the United States Can Learn From Each Other in Restructuring Social Security Plans*, 6 PAC. RIM L. & POL'Y J. 449, 451, 454 (1997).

125. See generally Sandra O'Malley, *VIC: Expert Warns of Population Decline*, AAPNEWSFEED, Aug. 7, 1999, available in LEXIS, News Group Files. (Stating "[n]ational identities [are] at risk, enormous fiscal problems develop as aging populations seek to maintain social security systems premised on intergenerational solidarity and moderate population growth.").

126. See Walsh, *supra* note 14, at 189, and text accompanying note 150.

127. See Wardle, *supra* note 14, at 190.

128. See Nakamura, *supra* note 20.

social stigma attached to abortion may have reduced the urgency or need for women to push for approval of the Pill. Conversely, the “unavailability of the low-dose [P]ill directly contribute[d] to the high rate of abortion as a solution to unwanted pregnancy in [Japan].”<sup>129</sup> According to *The Japan Times*, quoting a MHW report, doctors performed and reported 338,000 abortions to municipal governments in 1997.<sup>130</sup> The actual number, including illegal abortions, may be two to three times that number.<sup>131</sup> More than one million births were registered in Japan in 1997, meaning that 30-40 percent of all pregnancies may have terminated in abortion. This percentage is one of the highest in the world.<sup>132</sup> *The Japan Times* article reflects that these numbers indicate that

[C]ondom use is not always successful; and second that performing abortions is a highly rewarding business for a large segment of the medical profession. The debate over the Pill here has consistently overlooked the risk to women’s health of repeated abortions and the fact some are left infertile as a result.<sup>133</sup>

Additionally, as mentioned earlier, abortion is a lucrative practice. Only doctors can perform abortions in Japan, and they are free to set their own fees for the procedures with no government-imposed limits.<sup>134</sup>

#### IV. WHY IS ABORTION SO PREVALENT IN JAPAN?

If, as has been suggested, “the incident of abortion reflects the state of contraception,”<sup>135</sup> changes in the availability of the oral contraceptives may move Japan down from its spot as the country with the third or fourth highest abortion rate in the world.<sup>136</sup> A prediction of the future may be found in the past, specifically in Japan’s legal history regarding abortion. As noted earlier, many proponents of oral contraceptives, although pleased to have the approval process finished and the oral contraceptives legally available, do not expect great changes in the habits of

129. *The Promise of the Pill*, *supra* note 91.

130. *See id.*

131. *See id.*

132. *See* Wardle, *supra* note 14, at 266. (Proposing that although difficult to compare with other countries where illegal abortions are not reported, Japan ranks third or fourth in the rate of abortion and number of abortions performed.). *See also*, Sullivan, *supra* note 71. (Describing this amounts to approximately 1,000 reported abortions each day, according to a women’s health group.).

133. *The Promise of the Pill*, *supra* note 91.

134. *See* Wardle, *supra* note 14, at 197, n.81; 220 n.189.

135. Djerrassi, *The Bitter Pill*, 245 *SCIENCE* 356 (1989) (quoting Walter Dellinger and Gene B. Sperling, *Colloquy: Webster v. Reproductive Health Services: Abortion and the Supreme Court: The Retreat From Roe v. Wade*, 138 U. PA. L. REV. 83, at 115, n.104).

136. *See* Dellinger, *supra* note 135 at 115, n.104. Worldwide, statistics vary on abortion rates. China reports the highest number (10,394,500 in 1987), while the rate is high in Russia, 181 abortions per 1,000 women. Roughly 60 percent of pregnancies in Russia end in abortion. This rate is four times that of the U.S.. Romania also has a high rate, 78 percent. *Worldwide Abortion Statistics*, Baptists For Life, (visited Nov. 20, 1999) <<http://www.bfl.org/worldstat.html>> (citing Alan Guttmacher Institute statistics); *see also* Allen, *supra* note 12, at 198.

Japanese women.<sup>137</sup> Fear of side effects and safety go hand-in-hand with social obstacles to using the Pill.<sup>138</sup> For example, a Japanese gynecologist, Tomoko Satome, states, “[I]t’s easier for a Japanese woman to come out and say she’s had an abortion than to say she’s on the Pill.”<sup>139</sup> Why has abortion gained so much social acceptance in Japan when it is still such a difficult and emotionally charged issue in the United States? Unlike the birth control pill approval process, the history of abortion law in Japan has remained fluid, responding to cultural and economic conditions.<sup>140</sup>

Abortion in Japan dates back to the Heian period (A.D. 794-1185) and was most often associated with the elite.<sup>141</sup> Peasants resorted to infanticide of their unwanted or unaffordable children, thinning them out like the young plants in a field.<sup>142</sup> Although sporadic and usually connected with natural disasters, abortion and infanticide became widespread for two reasons<sup>143</sup> in Japan’s feudal era, known as the Tokugawa period (1615-1867).<sup>144</sup> Extreme poverty and sexual immorality were commonplace in this period, while the mores of the time proscribed fornication and adultery.<sup>145</sup> The evidence of immorality, an unexpected and unplanned child, resulted in severe consequences; therefore, abortion and infanticide were practiced to preserve appearances among the upper class and gentry.<sup>146</sup> At the same time the elite were engaging in promiscuous and immoral behavior, poverty overwhelmed most of the population.<sup>147</sup> Because of the tax system imposed by the feudal lords, (the *daimyo*), and the stipend system that rationed rice to a fixed amount per household, it was more advantageous for a family to remain small. A practical and accepted response to severe poverty was infanticide or abortion. Toward the end of the eighteenth century, as the population stabilized<sup>148</sup> (in response to abortion and infanticide for social reasons, poverty induced by the stipend system, and as work became available in the cities), the production of rice and the number of farmers dropped.<sup>149</sup> Worried about the

137. See Maureen Tkacik, *Of Campaigners On a Long March*, ASIA WEEK, Aug. 6, 1999 at 36. Some surveys suggest that only 7% of women between ages 16 and 49 will take the Pill, while THE CHRISTIAN SCIENCE MONITOR reports that 2% of women of child bearing age will buy the Pill, now that it is legal. *World*, CHRISTIAN SCIENCE MONITOR, Sept. 3, 1999, at 24.

138. See Furata, *supra* note 15, at 18.

139. See, e.g., *Popularity of the Pill Not Likely to Soar*, *supra* note 5, (DESERET NEWS), *World Watch*, *supra* note 6 (TIME); Itoi, *supra* note 5, at 39, (NEWSWEEK); *Smart-Talk*, CHI. TRIB., Sept. 15, 1999, at 6.

140. See Walsh, *supra* note 14, at 188.

141. See Wardle, *supra* note 14, at 187.

142. See *id.*

143. See *id.* at 188.

144. See G. B. SANSOM, *JAPAN: A SHORT CULTURAL HISTORY viii* (Stanford Univ. Press 1978) (1931).

145. See Wardle, *supra* note 14, at 187.

146. See *id.* at 198.

147. See *id.* at 187.

148. See Walsh, *supra* note 14, at 191.

149. See SANSOM, *supra* note 144 at 520. The reader may question the traditional role of religion during this period. According to Wardle, “[W]hile traditional religious beliefs such as Buddhism have opposed the destruction of life, religious practices and principles have been of only occasional, secondary significance in the establishment of Japan’s abortion policy.” Wardle, *supra* note 14, at 212. Currently, religious recognition of abortion policy in Japanese is prevalent in the Buddhist practice of observing *mizuyo kuyo* (requiems for the unborn). *Id.* at 229. This practice is a formal expression of grief, sorrow, mourning and mercy seeking. *Id.* at 229-230. The practice results

decrease in agricultural output, the central government, based in Tokyo (Edo at the time) instituted financial incentives, such as rice or monetary subsidies, to encourage larger families and to discourage abortion and infanticide.<sup>150</sup>

The first “laws” prohibiting abortion appeared in this period, beginning in 1646 and progressively becoming stricter through the period as the population stabilized.<sup>151</sup> These laws were in force only in the capital city, and many of the laws were easily evaded.<sup>152</sup> In 1667, for example, the government “prohibited advertising abortions and performing private or secret abortions, holding such acts punishable by expulsion from the city of Edo.”<sup>153</sup> However, “the restrictions were weak, the punishments modest or nonexistent, and the enforcement lax.”<sup>154</sup>

After 700 years of feudal rule by the *shogun* and *daimyo*, the Tokugawa regime was defeated and overcome. The emperor was “restored” to his throne in 1867 through the efforts of lower level samurai and the merchant class,<sup>155</sup> and Japan flung itself open to the world for “civilization and enlightenment” during the “Meiji Restoration.”<sup>156</sup> The new government, an oligarchy led by many of the same former samurai warriors and the old merchant class, began to reshape Japan from “top to bottom.”<sup>157</sup> A new legal system was necessary, and the Meiji regime sent scholars to France and Germany to gather information and “write a modern legal code.”<sup>158</sup> Thus, the prohibitions (on the books)<sup>159</sup> on abortion from the Tokugawa period were codified when Japan adopted a western legal system from France and Germany.<sup>160</sup> The code that took effect in 1882 closely followed the French code and prohibited abortion in this manner: “A woman who had an abortion was subject to one to six months of imprisonment, and the person who performed the abortion was

in a “healthy” attitude toward abortion in Japan. *Id.* at 230.

150. See SANSOM, *supra* note 144 at 520.

151. See *id.*

152. See Wardle, *supra* note 14, at 192. Although the laws were in effect only in Edo, many of the local feudal lords adopted similar policies in the local provinces or *han*.

153. *Id.* at 191.

154. *Id.* at 192. This economic loophole is huge, as over 90% of abortions fall into the “economic need” category. *Condom Makers Braced for Bitter Pill*, *supra* note 95.

155. See E.H. Norman, *Japan’s Emergence as a Modern State*, ORIGINS OF THE MODERN JAPANESE STATE 156 (John W. Dower, ed. 1975).

156. See Duus, *supra* note 115, at 73-89. The Meiji era was 1868-1912.

157. *Id.* at 72. This is a cursory overview of the dramatic events that took place during the “revolution from above”. Led by an “oligarchy” determined to catch Japan up with the rest of the modern world, the Japanese made sweeping changes and reforms in a remarkably short period. This same oligarchy felt that for Japan to be a modern nation, a modern legal system was necessary (along with many other systems) and sent scholars to gather information from the west and then modify a system to suit Japanese culture.

158. Wardle, *supra* note 14, at 193.

159. These “laws” were “not statutory enactments or codes as we understand them,” according to Sansom, *supra* note 144 at 462.

They were merely statements in writing of the principles underlying customary laws, which they did not replace but only supplemented . . . [I]n general the Tokugawa rulers did not regard it as part of their function to compile and enforce a coherent and specific body of laws, civil or criminal . . . [T]hey seem to have preferred to work upon empiric lines, promulgating laws to meet occasions as they arose but not anticipating them.

*Id.* at 462-63. In interpreting the “law” a Japanese judge was often told the intention of the law, and had discretion to give it effect, in contrast to the English and American tradition of deciding the intention of the law from its text. See *id.* at 462.

160. See Wardle, *supra* note 14, at 192-93.



subject to one to three years of imprisonment. A doctor or midwife who performed an abortion was deemed guilty of a first-degree crime.”<sup>161</sup> The revised penal code instituted in 1908, modeled after German law, forms the basis for current law.<sup>162</sup> Under the 1908 Penal Code, “any professional who performed an abortion, including doctors, midwives or druggists, could be imprisoned for three months to five years.”<sup>163</sup> However, since this was the “bright era” of Japanese development under the Emperor Meiji, prosperity increased, as did the size of families.<sup>164</sup> Following the pattern of the past, the number of abortions and infanticides fell markedly as the nation prospered.<sup>165</sup> When fortunes fell after the death of Emperor Meiji in 1912 and the worldwide depression of the late 1920s and 1930s hit Japan, abortion rates again rose, as did enforcement of the anti-abortion laws.<sup>166</sup>

In 1940, after a decade of militarism and in a wartime climate, the Diet adopted the National Eugenic Law.<sup>167</sup> Again patterned after Germany, then under control of the Nazi party, the purpose of the law was to limit abortion to narrow circumstances, to preserve the purity of the race and authorize abortion of “defective” children.<sup>168</sup> The law required a second doctor’s opinion as well as governmental reporting when an abortion was performed.<sup>169</sup> In part because of this policy, characterized by the slogan “Bear Children, Swell the Population,”<sup>170</sup> by the end of World War II in the Pacific theater, the Japanese population rose just as the resources and the rice to feed it became depleted.<sup>171</sup> Widespread suffering of Japanese women and children made it imperative to relax the abortion laws.<sup>172</sup> As Americans poured into Japan for the Occupation, the number of Amerasian children became an embarrassment for the occupying government—another reason to push for relaxation of the laws.<sup>173</sup> As a response to these changing social conditions, the Eugenic Protection Law (EPL) passed in 1948.<sup>174</sup> Amendments were made to the law in 1949 and 1952.<sup>175</sup> The 1952 amendment was especially significant, because

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161. *Id.* at 193.

162. *See id.*

163. *Id.* (stating that if the woman was injured during the abortion, the penalty was increased, ranging from six months to seven years).

164. *Id.*

165. *See* Wardle, *supra* note 14, at 193.

166. *See id.*

167. *See id.* For a discussion of militarism in Japan, *see generally* Duus, *supra* note 115, at 206-223.

168. *See* Wardle, *supra* note 14, at 194.

169. *See* Walsh, *supra* note 14, at 202.

170. Gaouette, *supra* note 73, at 8.

171. *See* Wardle, *supra* note 14, at 195. Other factors contributing to the rise in the population included the fact that thousands of Japan’s expatriates returned from former colonies, and the troops returned to the home islands after their defeat, accompanied by the inevitable post-war baby boom. *Condom Makers Braced For Bitter Pill*, *supra* note 95.

172. *See* Walsh, *supra* note 14, at 203.

173. *See id.*

174. *See id.*; *see also*, Wardle, *supra* note 14, at 195. The Eugenic Protection Law, Law No. 156 of 1948, art. 14, *reprinted in* Eugenic Protection Law in Japan, English Pamphlet Ser. No. 68 (Ministry of Health and Welfare, Inst. Of Population Probs., Tokyo Japan) March 1, 1989 at 10. Wardle cites the five instances in which abortion was allowed: 1) if the woman’s physical health could be seriously affected if she continued in the pregnancy or delivers; 2) in cases of rape; 3) leprosy; 4) hereditary illness; and 5) mental illness. *Id.* at 195, n.65.

175. *See* Walsh, *supra* note 14, at 204.

in addition to the five narrow categories in the EPL,<sup>176</sup> abortion was permitted for “a mother whose health may be seriously affected by the continuation of the pregnancy or subsequent delivery because of physical or *economic* reasons,”<sup>177</sup> essentially allowing abortion on demand. Also, the procedural hurdle of the 1948 law, the requirement that a doctor file an application with a local committee and receive approval before performing the abortion, was eliminated in 1952, leaving the decision in the hands of one doctor.<sup>178</sup> Thus, in practical terms the “artificial interruption of pregnancy,”<sup>179</sup> the euphemism for abortion, was regulated as follows:

The EPL and Ministry of Health regulations require doctors to complete extensive records on each abortion. Technically, abortion is authorized only for married women. The consent and “personal seal” of the husband of the woman seeking abortion is required in each case. However, for a nominal cost any woman can buy a copy of her husband’s “seal” stamp and “forge” his approval . . . . Abortions may only be performed by “designated physicians,” but virtually all obstetricians and gynecologists are designated physicians; there are approximately 13,000 designated physicians in Japan.<sup>180</sup>

As a result of the liberal “economic grounds” loophole, between 1952 and 1953, the number of abortions increased 34% to 1,068,066.<sup>181</sup> The abortion law has remained virtually unchanged since 1952,<sup>182</sup> and the rate of abortion remains high, despite the revolution in reproductive rights and family planning methods in the latter part of the twentieth century.<sup>183</sup>

The high rate of abortion in Japan has caused little political dissent or controversy in Japan since the passing of the EPL and its amendments in 1952,<sup>184</sup> except in the international arena of reproductive rights and family planning.<sup>185</sup> Whereas abortion has been highly divisive in the U.S., other medical, social and ethical issues, such as assisted conception and organ transplants, have been much more controversial in Japan than abortion.<sup>186</sup> A number of factors contribute to the

176. See Wardle, *supra* note 14, at 196. According to Wardle, June 24, 1949 “marks the point of adoption of liberal ‘grounds’ for abortion in Japan.” *Id.* at 196.

177. See *id.* (quoting Takishi Wagatsuma, *Induced Abortion in Japan*, in BASIC READINGS ON POPULATION AND FAMILY PLANNING IN JAPAN 101, 102 (M. Muramatsu ed., 3d ed. 1985)).

178. See *id.*

179. *Id.* at 197.

180. *Id.*

181. See Wardle, *supra* note 14, at 196, (citing Samuel Coleman, FAMILY PLANNING IN JAPANESE SOCIETY 19 (1983)).

182. See *id.* at 197 (summarizing Wardle, changes in the law since 1952 have been made in the definition of viability. Further stating, the original regulation from the Ministry of Health declared viability existed after eight months of pregnancy; in 1976 it was reduced to seven months, in 1978 to twenty-four weeks. Currently, Japanese law permits abortion during the first 23 weeks of gestation (or 21 weeks measured from conception)). The law was amended March 1, 1991, to reduce viability to 22 weeks. Walsh, *supra* note 14, at 205.

183. The rate of married women who have abortions in Japan is 70 percent, whereas 80 percent of abortions in the U.S. are performed on unmarried women. Wardle, *supra* note 14, at 224.

184. Abortion is still a crime in Japan. See *id.* at 210.

185. See *id.* at 223.

186. See Leflar, *supra* note 86, at 85.

way abortion has been accepted differently in Japan than in the U.S. A major difference is that the Japanese *legislature* defined and implemented abortion laws, whereas abortion law was imposed by *judicial fiat* in the U.S., in spite of state legislative action on the issue.<sup>187</sup> As a consequence, Japanese law on abortion may be more representative of the national consensus or majority of opinion on the practice than in the U.S. Additionally, abortion policy in Japan historically has responded to the economic and social needs of the population.<sup>188</sup> Widespread use of the Pill by Japanese women, if they can overcome the significant anti-Pill propaganda of the past forty years and other barriers to use, may stimulate change in the Japanese contraceptive habits, and then Japanese abortion law. If Japan follows its historical pattern on abortion, and the need for abortion subsidies, the laws will change *through the legislature*, and better reflect the norms of social reality.<sup>189</sup>

## V. INFORMED CONSENT

Abortion law may not be the only area of law that will be forced to change with the advent of availability of the Pill to women in Japan. Legal availability of the Pill now gives women a right to choose among contraceptive alternatives, and the right to choose creates the issue of informed consent.<sup>190</sup> In order for a Japanese woman to use the Pill, she must have a doctor's prescription, which will require a visit to the doctor's office and a discussion of the woman's reproductive needs. As in the United States, this visit to the physician will create a nexus in which the doctor will need to inform the woman about her reproductive medical choices, and the doctors will be required by law to describe these choices.<sup>191</sup> Generally, the standard for informed consent for contraception world-wide suggests that "physicians should be required to inform patients of the benefits, risks, alternatives

187. See Wardle, *supra* note 14, at 211.

188. See *id.* at 212.

189. See generally *id.* at 217 (explaining the differences between the U.S. and Japanese law and the cultural differences). Briefly summarizing, five major differences can be explained as follows: 1) Abortion policy in Japan has been legislated, and current policy in the U.S. was created by judicial decisions such as *Roe v. Wade*. 2) Japanese abortion policy reflects historical government policy and regulation as a means of population control and contributing to national economic goals, whereas today's policy in the US. is a major departure from traditional Judeo-Christian view of the value and worth of human life. 3) Japan's policy toward abortion is nationwide and consistent. State's rights and federalism in the U.S. still allow for a great variety in implementation and restriction from jurisdiction to jurisdiction, although states laws must conform to the constitutionality requirements set by the U.S. Supreme Court rulings on abortion. 4) The ideology and motivations for implementing abortion vary widely between the two countries.

In Japan, permissive abortion laws were adopted primarily because of a severe economic crisis and as a means to achieve national economic recovery and development. In the United States, the motivating ideology stemmed from radical individualism and the desire to eliminate encumbrances to promiscuous lifestyles and to escape from restrictive personal responsibilities.

*Id.* at 213. 5) The policies in the two countries reflect battles in two socially different contexts. Wardle believes that in the U.S., *Roe v. Wade* reflects the triumph of upper class "superconventional" values, and its influence on the judiciary over the moral traditional middle class with legislative representation. *Id.* at 214.

190. See Takahashi and Negishi, *supra* note 106.

191. See *id.*

and all major information regarding the contemplated method of contraception.”<sup>192</sup> Specifically in Japan, informed consent cannot be ignored in regard to the Pill because the Ministry of Health and Welfare expects doctors to provide patients with accurate information about the Pill and has issued guidelines for prescribing the Pill.<sup>193</sup> However, some believe that the medical profession will not inform the women using the Pill of proper usage and all available alternatives, since doctors in a three-year test in 1987 “sometimes failed to give information on the correct use of the Pill.”<sup>194</sup> The need for firm informed consent law in this context is critical when one considers that “Japanese women . . . are reluctant to discuss birth control and other sexual matters with doctors,”<sup>195</sup> even though MHW approval of the Pill *requires* that doctors inform women of the added risks of AIDS and other sexually transmitted diseases if they stop using the condom while on the Pill.<sup>196</sup> For women to receive appropriate information and make informed choices about their reproductive health care, the current status of informed consent law will face change.

The issue of informed consent (*infomudo konsento* in Japanese) is debated widely in Japan today in other medical contexts such as treating terminal cancer patients and organ donation,<sup>197</sup> but the approval of the Pill will force the Japanese medical community to face the issue of informed consent in the context of reproductive choice and contraceptive information. The legal concept of informed consent in Japan is still in the developmental stages, fighting against cultural biases and a reluctant medical profession. The status of informed consent law was reported in January 1990, by the Japan Medical Association’s Bio-ethics Roundtable. Although “the principle of informed consent has become a necessary basis for the construction of a trusting relationship between doctor and patient,”<sup>198</sup> the doctors of the Roundtable insisted that the law of informed consent cannot be imported into Japan unaltered by Japanese history, culture, character and background.<sup>199</sup>

Informed consent in Japan does not hold the same position in the legal system as it does in the United States.<sup>200</sup> Judge-made law and legislative efforts have had minimal success in imposing strict standards on the medical community.<sup>201</sup> However, the physician does have a duty of explanation derived from the Japanese legal code; specifically from the Medical Practitioners Law, basic negligence

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192. Stacey L. Arthur, *The Norplant Prescription: Birth Control, Woman Control or Crime Control?* 40 UCLA L. REV. 1, 94 (1992) (cited in Rahman, *supra* note 8 at n.30).

193. See Takahashi and Negishi, *supra* note 106.

194. *Id.*

195. Sullivan, *supra* note 71.

196. See *id.* Concomitant with approval of the Pill was the enactment of the Infectious Disease Protection Law, in April 1999, which requires that the MHW monitor and report the spread of sexually transmitted diseases. *MHW Officially OK's Low-Dose Birth-Control Pill*, COMLINE EMERGING MARKETS, JAPAN AND EASTERN ASIA: HEALTH CARE AND BIOTECHNOLOGY, July 1, 1999, available in LEXIS Group Files.

197. See generally Leflar, *supra* note 86.

198. See *id.* at 10.

199. See *id.* at 11.

200. See *id.* at 44.

201. See *id.*

provisions and contract provisions of the Civil Code.<sup>202</sup> The duty has been enhanced and formalized by court decisions, and in general, the Japanese Supreme Court "stated that the physician's duty of disclosure encompassed the nature of the operation and the risks involved."<sup>203</sup> This view continues to defer to the medical profession and its existing practices of information disclosure,<sup>204</sup> where disclosing the risks or diagnosis is often the doctor's prerogative. Japanese informed consent does not extend as far as the American jurisprudential concept of a patient's right to self-determination or choice.<sup>205</sup>

In sum, one Japanese law professor states, regarding Japanese case law on informed consent:

The majority of the cases seem to allow patients only to accede to or refuse the course of treatment proposed by their doctors. In this respect . . . most Japanese courts are willing to recognize the inviolability of the patient's body but this willingness does not extend to the patient's right to self-determination or autonomy with respect to the selection of . . . treatment . . . ."<sup>206</sup>

Not surprisingly, the exact definition of informed consent as practiced in Japan is impossible to state. It could mean anything from a patient's polite conversation with her doctor, to a choice among many treatment options explained in full by the health professional.<sup>207</sup> Informed consent is most notably an issue with the Pill because the paternalism of the medical community is most blatant when dispensing prescription drugs. Doctors routinely prescribe (and over-prescribe) drugs without giving an explanation of the purpose, use, side effects, or drug interactions.<sup>208</sup> Many patients fear a doctor's anger if they ask if a drug is safe or even what the drug is,<sup>209</sup> and doctors often go so far as to cut the tag or label off the carton with the drug's name on it before dispensing it to the patient.<sup>210</sup>

All of this may be changing. The public is becoming increasingly more informed by the media and other sources and is therefore less content with the quality and quantity of information it receives from health care providers.<sup>211</sup> The timing of the need for informed consent law to evolve in the area of dispensing birth control pills coincides with the movement in Japanese society which is pushing for a change in the doctor-patient relationship, a relationship which has been characterized as "dominant paternalism" until recently.<sup>212</sup> Reform groups are

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202. *See id.* at 45.

203. *See* Leflar, *supra* note 86, at 47.

204. *See id.* at 44, 51-62, (discussing exceptions and the specific cases where the duty principle has been applied).

205. *See id.* at 48.

206. *Id.* at 60 (quoting Eiji Maruyama, *Japanese Law of Informed Consent*, 26 KOBE U.L. REV. 39, 43 (1991)).

207. *See id.* at 11.

208. *See* Leflar, *supra* note 86, at 27-28.

209. *See id.* at 28.

210. *See id.* at 28. Most prescription drugs are dispensed by doctors, not pharmacists. *Id.* at 41.

211. *See id.* at 85, 90 n.418.

212. *Id.* at 7 n.16.

attempting to push for legislated informed consent requirements.<sup>213</sup> Other groups are using mass media, books, and television to express their discontent with the medical establishment's paternalistic attitude.<sup>214</sup> The prominence of the public debate over brain death and organ transplantation has focused on informed consent, which has been used by both sides of the controversy as a "weapon of convenience."<sup>215</sup> Adding the ministerial requirement that all patients receiving the Pill must have a doctor's prescription, will likely provoke more scrutiny of the doctor-patient relationship and be another force pushing for more transparency and patient self-determination in the area of reproduction and informed consent.

The issue of informed consent will not be limited to the Pill. As more reproductive measures such as Norplant<sup>216</sup> and long-lasting contraceptives become available in Japan, now that the Pill has been approved,<sup>217</sup> the Japanese medical profession perhaps will face similar claims to those in the United States that patient's "rights to informed consent are being violated."<sup>218</sup> For example, the issue has arisen in the U.S. where Norplant was promoted for use among Native Americans without a "system of informed consent, monitoring or guidelines for removal."<sup>219</sup> Lawsuits have increased in the U.S. claiming that Norplant is unsafe and has serious side effects.<sup>220</sup> Thus, the right to informed consent in this context is closely linked to reproductive rights. If the right to informed consent actually becomes part of a patient's care from her doctors, and is part of the discussion among the medical community and family planning advocates, this will necessarily focus attention on Japan's record in the area of reproductive rights for women, because often a violation of a reproductive right is also a violation of informed consent rights.<sup>221</sup> This link between informed consent and reproductive rights can also be demonstrated when viewed from the perspective of Japan's position in the area of gender equality, as shown in the following section.

## VI. GENDER EQUALITY AND REPRODUCTIVE RIGHTS

Gender equality is not a new issue for Japan. Although the Constitution

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213. See Leflar, *supra* note 86, at 60.

214. See *id.*

215. *Id.* at 66.

216. See Rahman, *supra* note 8, at 212 n.27.

217. The morning after pill has been available in Japan for some time. See Sumiko Oshima, *Morning After Pill Legal, But Rarely Used*, THE JAPAN TIMES, June 24, 1999.

218. See Rahman, *supra* note 8, at 211-12.

219. *Id.* at 212, n.28. Norplant is "tiny hormone (progestin) sticks implanted in the upper arm to prevent pregnancy for up to five years." Carolyn Poirot, *The Birth Control Explosion*, THE FORT-WORTH STAR-TELEGRAM, Aug. 29, 1999, Life Section at 1.

220. See *id.* at 212 n.27.

221. See Bharati Sadasivim, *The Rights' Framework in Reproductive Health Advocacy—A Reappraisal*, 8 HASTINGS WOMEN'S L. J. 313 (1997). "The right to reproductive health care entails a right of access to health services, including family planning and quality of care, which can be exercised on the basis of informed consent, free of discrimination, coercion, and violence." *Id.* at 313.

imposed by General MacArthur in 1946 guaranteed equal rights to women<sup>222</sup> that were unheard of in pre-World War II society, Japan lags behind other post-industrialized societies in the area of women's rights.<sup>223</sup> Most specifically, the area of gender equality that has moved to the forefront domestically and internationally is the lack of equality in reproductive rights. Japan recently made legal changes in domestic social equality issues,<sup>224</sup> but the stark contrast between approval of the Pill, a nine-year process, and Viagra, a six-month process, highlighted the lack of gender equality in Japan in 1999.<sup>225</sup>

Internationally, Japan has a poor record and reputation in the area of reproductive rights, an important measure of gender equality. A 1992 study measuring access to family planning and reproductive health in over 124 countries placed Japan in the "poor to very poor category."<sup>226</sup> As a leader in the United Nations, Japan was criticized at both the 1994 International Conference on Population and Development in Cairo (ICPD) and the 1995 Beijing Conference on Women, for its dilatory approval of the Pill, although Japan contributes billions of dollars to population programs in other countries, programs which include the Pill as part of their family planning programs.<sup>227</sup> The 1994 Cairo ICPD conference recognized that the "difficulty of discussing reproductive rights and health in many countries stems from the subtle male preference seen in the law, coercive stereotypes, religious norms and lack of financial resources aimed at enhancing a woman's right to reproductive self-determination."<sup>228</sup> Japan would have to plead guilty on these counts. "Bureaucrats returned from the 1996 International Women's conference chagrined after realizing how far behind Japanese society was."<sup>229</sup> The U.N. Population Fund (UNPD) criticized Japan for failing to approve the birth control Pill in a 1998 White Paper.<sup>230</sup> More international pressure to approve the Pill may have come from the UNPD early in 1999, in the form of a scheduled review in Japan in June of the Programme and Implementation plan of the 1994 Cairo conference.<sup>231</sup> The announcement of the review coincided with the approval

222. See Nihonkoku Kenpo, (*The Japanese Constitution*), (1946), art. 14, 24, (last visited Nov. 14, 1999) <<http://www.nt.com/japan/constitution/english-constitution.html>>. See also Mark Magnier, *Equality Evolving in Japan*, LOS ANGELES TIMES, Aug. 30, 1999, at A1, Foreign Desk.

223. See Magnier, *supra* note 222. International comparisons show that women in Japan rank nineteenth out of twenty-third world wide for work place conditions, thirty-eighth out of 102 in parliamentary representation. Only 9.3% of administrative and managerial jobs are held by women.

224. See *id.*

225. Carey Goldberg, *Insurance for Viagra Sparks Coverage for Birth Control*, NEW YORK TIMES, June 30, 1999, A1 Col. 5. Japan is not the only country facing political flack for gender/social inequality. At least 30 U.S. state legislatures are requiring that insurance carriers who cover prescription drugs provide coverage for women's contraceptives if they cover Viagra. Apparently, "Viagra made any argument against mandated contraception coverage 'laughable, really,'" says California State Senator Jackie Speier. *Id.*

226. Fathalla, *supra* note 74, at 1187.

227. See Marshall, *supra* note 74, at 489. Japan has been second in donor assistance to population programs in the 1990s, and Japan pledged political and financial support for the International Conference on Population and Development Programme of Action goals. *Id.*

228. *Id.* at 451.

229. Magnier, *supra* note 222.

230. Kakuchi, *Viagra*, *supra* note 15.

231. See Setsugo Ogawa, MAINICHI SHIMBUN Dec. 17, 1998 at 12.

of Viagra and the MHW may have decided to approve the Pill to dispel criticism at the time of the review.<sup>232</sup> Many Japanese women would agree with the international critics: "Everything points to the sad situation that women's health and their right to enjoy safe contraception is ignored by the government. That's because men are in charge of our lives," says Tomoko Satome, a leader in the push to approve the Pill.<sup>233</sup>

Domestically, Japan has progressed in gender equality, where legal changes include the "Gender Equality Law which 'sets out broad new principles for Japanese society.'"<sup>234</sup> The government finally defined sexual harassment (*seku hara*) and prohibited discrimination in the workplace in the revised Equal Employment Opportunity and Labor Laws.<sup>235</sup> But the slowness of approval of the Pill, contrasted with the rapid incorporation of Viagra, shows that Japan still lags behind in reproductive rights when one considers access to and quality of healthcare for women in the area of reproductive and sexual health in contrast to that of men. The furor and contrast over Viagra and Pill approval processes threw the health issue into sharp relief, because the strongest public argument the government made against approval of the Pill was that it would endanger the safety<sup>236</sup> and the health of women.<sup>237</sup> The argument against approval was that since the Pill is given to healthy women, it was imperative that the drug be completely safe. Also, since birth control Pills are for healthy women, women could "afford to wait a little more."<sup>238</sup> In contrast, regarding the Viagra approval process, not only were the "needs" of men met in a timely, even speedy fashion, but the argument for approval of Viagra was that it was a "medical treatment for sick men," and would contribute to their "quality of life."<sup>239</sup> The health risks associated with Viagra, including heart attacks and death, in comparison with the relative safety of the low dose Pill, fueled the gender-bias argument.<sup>240</sup> For example, a women's health group spokeswoman stated "Viagra's approval showed clearly that what the Health Ministry is doing is incoherent; women in Japan have been unable to plan their lives because they haven't had control over childbirth."<sup>241</sup> Additionally, "if you look at the issue in terms of safety, it's strange that Viagra got approved so fast," according to Tomoko

232. See *Further Delay*, *supra* note 65.

233. Kakuchi, *Viagra*, *supra* note 15.

234. Equality Evolving in Japan, *supra* note 221.

235. See *id.*

236. See Ochs, *supra* note 20, at 40. Safety has not always been the driving force behind drug approval. Double standards and inconsistencies have been even more obvious in approval of other drugs. This may have its roots in Japanese public policy of promoting economic welfare over individual safety. *Id.* at 40. In 1985 the Japanese Ministry of Health and Welfare allowed imported blood products into Japan even though they were possibly tainted with the HIV virus. The government protected a local manufacturer developing a heat treatment to kill the AIDS virus, and did not allow a foreign manufacturing company, which had already developed a process to kill the virus, to enter the Japanese market. The delay in instituting the heat treatment process contributed to the spread of the AIDS virus to 1800 hemophiliacs in Japan, 400 of whom had died by 1994. Leflar, *supra* note 86, at 8 n.19. This type of policy makes the birth control policy approval delays all the more mystifying.

237. *Id.*

238. CTV NATIONAL NEWS, *supra* note 58.

239. *Id.*

240. Takahashi and Negishi, *supra* note 106.

241. Sullivan, *supra* note 71, at A19.



Adachi, a gynecologist at Tokyo Women's Medical University.<sup>242</sup> Clearly a strict analysis on a health risk/benefit basis would not have had the same result: Japan would have had the Pill thirty years ago, and Viagra would still be a coveted item on the black market.

Furthermore, an argument that refutes the "health" concerns of the government is that the abortion rate and health risks associated with abortion were not addressed as part of the debate on the Pill approval process. Abortion is a genuine health risk for women, especially when contrasted with the Pill as a birth control method. For Japanese women to have tolerated abortion without the option of the Pill indicates, in part, the effectiveness of the propaganda against the Pill.<sup>243</sup> Societal pressures and fears against women's reproductive freedoms were part of the misinformation. The rate of abortion in Japan is consistent with the worldwide trend that "women's accessibility to contraception frequently is reflected in abortion statistics . . . ."<sup>244</sup>

Currently in Japan, 400,000 abortions are performed each year - more than 1,000 procedures each day.<sup>245</sup> Statistics vary, but according to Japanese gynecologist Masako Moriguchi, at least 20 percent of all pregnancies are aborted every year. About 40-46 percent of women have repeat abortions.<sup>246</sup> Two abortions in a five year period is not an unusual medical history.<sup>247</sup> Furthermore, at the time of the abortion, the woman is not informed that abortion can result in infertility and other complications.<sup>248</sup> Studies show that planned pregnancies account for only 35 percent of the total pregnancies each year, indicating that abortion is being used as a primary method of birth control.<sup>249</sup> This means that 65 percent of the pregnancies in Japan result in abortion or a full-term pregnancy—these are unanticipated consequences which are risky to the health of the mother and may lead to unexpected complications. If women are not informed of the risks of abortion and unplanned pregnancies compared to the safety of the Pill, her reproductive and informed consent rights are being violated.

This is again where the legal principles upholding reproductive rights and informed consent intersect, as the 1994 Cairo ICPD made clear. The abortion policy and rate in Japan conflicts with most international goals on abortion and family planning. The ICPD "Programme of Action" developed in Cairo in 1994 "deemed abortion a major public health concern" and said that it "does not promote the use of abortion in family planning programs."<sup>250</sup> In implementing the Programme of Action in Cairo, the conference adopted the following wording on abortion:

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242. WuDunn, *supra* note 96.

243. See CTV NATIONAL NEWS, *supra* note 58.

244. Marshall, *supra* note 74, at 456.

245. See *supra*, note 15.

246. See Wardle, *supra* note 14 at 223.

247. See Kakuchi, *Birth Control*, *supra* note 108.

248. See Itoi, *supra* note 5, at 39.

249. See Kakuchi, *Birth Control*, *supra* note 108.

250. Marshall *supra* note 74, at 473, 457.

In no case should abortion be promoted as a method of family planning. All Governments and relevant intergovernmental and non-governmental organizations are urged to strengthen their commitment to women's health, to deal with the health impact of unsafe abortion as a major public health concern and to reduce the recourse to abortion through expanded and improved family planning services. Prevention of unwanted pregnancies must always be given the highest priority and all attempts should be made to eliminate the need for abortion. Women who have unwanted pregnancies should have ready access to reliable information and compassionate counseling. Any measures or changes related to abortion within the health system can only be determined at the national or local level according to the national legislative process. In circumstances in which abortion is not against the law, such abortion should be safe. In all cases, women should have access to quality services for the management of complications arising from abortion. Post-abortion counseling, education and family planning services should be offered promptly which will also help to avoid repeat abortions.<sup>251</sup>

Japan's continuation of its abortion policies in light of the unavailability of the Pill was clearly inconsistent with the goals of the U.N. and major developed and developing countries. For Japan to meet the goals of the Cairo conference, and escape more international criticism, Japan will need to insure a comprehensive domestic health delivery program appropriate to its position as an economic leader and major donor to population programs in developing countries. Japanese law, whether judicial or legislative, should require the medical community to give women informed choices and obtain consent for treatment. The 1994 ICPD conference focused on "the need for greater access to education and information so that women can be in better positions to make informed decisions about their lives and their families."<sup>252</sup> The ICPD program called for "education and communication at all levels of society."<sup>253</sup> It specifically urged service providers (including medical providers), to give "correct and complete information" to clients and patients to encourage an informed decision.<sup>254</sup> Indeed, at least one author, in evaluating women's rights in this area, stated that countries and government policies that promote specific methods or disincentives to other specific contraceptives did not "promote choice or informed consent."<sup>255</sup> Thus, the focus on gender equality issues faced by Japan in light of approval of the Pill will center on equal access for men and women in the area of reproductive and sexual health. By approving the Pill, Japan has made major strides in allowing a choice in contraceptives the foundation of a comprehensive reproductive rights agenda. With choice comes the need for enforceable informed consent laws for medical practitioners to follow. The benefits for Japanese women are numerous. To name just one, a lower abortion

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251. Mona Zulficar, *Keynote speaker: From Human Rights to Program Reality: Vienna, Cairo, and Beijing in Perspective*, 44 AM. U.L. REV. 1017 at 1028-29.

252. Marshall, *supra* note 74, at 443.

253. *Id.* at 481.

254. *Id.* at 480.

255. Rahman, *supra* note 8, at 213.

rate would lower the health risks faced by women in the child-bearing years.

## VII. CONCLUSION

Access to the Pill has been a foundation of family planning programs, gender equality, and reproductive and health rights since the Pill first became available to women in the 1960s. Only in 1999 did the Japanese government bow to international and domestic pressure to allow access to and attach legality<sup>256</sup> to the Pill for its own population.<sup>257</sup>

Like any other social, medical or scientific innovation, Japan will have to confront the changes that will result from the introduction of a (lifechanging) pharmaceutical and contraceptive. In Japan, the use of the Pill will most likely promote and provoke change in many areas: Abortion practices and eventually abortion law; gender and equality of women issues; and in the medical area, informed consent regarding reproductive choices. Segments of Japanese society will continue to resist change in these areas. The medical community, because of its financial interest in performing abortions and paternalistic patterns in providing patients with information in medical care, may continue to be a stumbling block to women who desire to use the Pill to prevent pregnancy. Likewise, gender and social equality issues will continue to plague Japanese society as international and internal pressures push for more than lip service to the laws already on the books. The swift approval of Viagra domestically, and scrutiny by U.N. organizations internationally, will perhaps provoke substantive change in this area, overcoming tremendous social and legal pressures such as the traditional role of women in Japan, the rise of new fundamentalist religions, and a male-dominated legislature and policy-making bureaucracy.

Abortion law and public attitudes towards abortion may change as well. Although the medical community may resist change, the "economic necessity" loophole in the law through which most abortions are performed may no longer be necessary with availability of the Pill. Alternatives to abortion may result in a more rational rate of abortion if Japan follows international trends in family planning statistics that relate access to contraceptives to the rate of abortion. As necessity for abortion abates, the law may change, since historically Japanese laws have followed social practice.

Despite domestic and international pressures in all of these areas, the approval of the Pill may not provoke or spark any change in Japan. As many scholars and journalists have pointed out, Japan as a society is able to prosper economically and socially in the midst of duality, inconsistency and paradox.<sup>258</sup> What is inconsistent

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256. See *Pharmacist Held for Selling Pills Without a Prescription*, JAPAN ECONOMIC NEWSWIRE, July 7, 1999.

257. Those familiar with Japanese history may think of Admiral Perry's American black ship in Tokyo Bay. Although Japan did eventually bow to outside pressure, its leaders opened their nation to the West in a selective and unique way. See Kenneth B. Pyle, *THE MAKING OF MODERN JAPAN* 47-54 (1978).

258. See, e.g., Jameson, *supra* note 10.

behavior to one country or to an outsider is comfortable for Japan. In fact, this “schizophrenic” nature of Japanese public and social policy may allow the Pill to exist side by side the little blue Viagra pill with no ripple effect. Just as the *shinkansen* (bullet train) and the local milk run depart from neighboring tracks in Tokyo Station, so may the Pill and Viagra continue to exist side by side on the pharmacy shelves and in doctor’s offices, a tangible reminder of the way Japan has integrated foreign products into a uniquely Japanese setting.

*Patricia L. Martin*

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