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May 25, 2010

To: Representative Ryan Yamane, Chair, and Representative Scott Nishimoto, Vice Chair, and Members of the House Committee on Health

From: Katie Reardon, Vice President of Government & Public Affairs Planned Parenthood of Hawaii.
Andrea Anderson, CEO, Planned Parenthood of Hawaii

Re: Informational Briefing on the current system of care for sexual assault victims in Hawaii's hospitals and emergency rooms

In the aftermath of rape, victims find themselves dealing with a host of reproductive and sexual health issues, including pregnancy. Though statistics vary, the average rate of pregnancy resulting from rape is somewhere between 5-8% with an estimated 32,000 rape related pregnancies occurring every year.[1] For many years, legislation proposing to provide information and access about Emergency Contraception to sexual assault victims reporting to Hawaii's emergency rooms has been unsuccessful. Most recently, important questions have been raised regarding the need for such legislation and its impact on Hawaii. Discussed below, Planned Parenthood of Hawaii presents information regarding the safety and efficacy of Emergency Contraception, its wide acceptance as the standard of care for treating sexual assault patients, and its economic impact on providers, patients, and the greater community. We express our thanks to the House Health Committee for hearing reviewing this information.

I. Emergency Contraceptives (EC) are Safe and Effective

Emergency contraceptives (EC) are a safe and effective way to prevent a pregnancy as the result of a rape. EC, also known as Levonorgestrel, is a high dose contraceptive that, when taken within 120 hours (or 5 days) of unprotected sex, can prevent pregnancy. It is most effective the earlier it is taken, with a 99% efficacy rate when taken within 12 hours, 82% within 72 hours, and decreasing thereafter.

EC is a contraceptive and is not an abortifacient. EC works in two ways. Primarily, EC delivers hormones to the body that prevent ovulation from occurring. When ovulation is prevented, there is no egg to be fertilized, and a pregnancy will be prevented. EC may also be effective even if ovulation has occurred. The hormones in EC cause a thickening to the cervical mucus, which prevents sperm from entering the uterus and fertilizing the egg, thereby preventing pregnancy.

EC will not terminate an existing pregnancy. According to medical authorities, such as the American College of Obstetrics and Gynecology and the National Institutes on Health, a pregnancy occurs when a fertilized egg implants itself on the uterine lining. Whether a woman became pregnant prior to being sexually assaulted or as a result of it, EC will not terminate or otherwise affect that pregnancy.

[1] Holmes, Melissa and Resnick, Heidi A. and Kirkpatrick, Dean G. and Best, Connie L. *Rape-related Pregnancy: Estimates and Descriptive Characteristics from a National Sample of Women.* American Journal of Obstetrics and Gynecology, Vol. 175, 2, pp. 320-325. (1995).

In the past there has been uncertainty as to whether EC will prevent a fertilized egg from implanting onto the uterine lining, and no conclusive data has been able to support that effect. In fact, more recent studies have suggested that it is unlikely that EC will prevent a fertilized egg from implanting or have any effect post-fertilization.[2] For those who disagree with medical experts and believe that life begins when an ovum is fertilized by a sperm, this new research should be reassurance that EC is not abortifacient.

II. Providing EC in Emergency Rooms is the Standard of Care

Providing EC in the Emergency Rooms is the accepted standard of care. The American Medical Association's Guidelines for treating sexual assault victims states that victims should be informed about and provided EC.[3] The American College of Obstetrics and Gynecology also supports this standard of care. [4]

Fifteen states and the District of Columbia have adopted legislation requiring the provision of information about and/or access to EC to sexual assault victims in emergency rooms.[5] This past year, the Federal Government also standardized rules regarding EC and now requires that all military and federal hospitals stock EC.[6] The Army Medical Command Regulations advise discussing and providing EC to sexual assault victims.[7] Federal legislation, the Compassionate Care for Service Women Act, is currently pending and would ensure that all servicewomen reporting sexual assaults are informed about and provided EC. The Religious and Ethical Directives for Catholic Health Care also call for provision of EC to sexual assault victims in most circumstances.[8]

While EC is available over the counter in most pharmacies, in cases of sexual assault, it is important that victims receive access on site and immediately. Emergency rooms help victims avoid various difficulties that come along with accessing EC at a pharmacy or clinic. First, while EC is over the counter, it must be requested at the pharmacist counter. Since the efficacy of EC decreases over time, the longer a victim must wait for her local pharmacy to open, the less effective the drug will be. Similarly, while EC is available at clinics such as Planned Parenthood, our clinics have limited hours, and victims could potentially wait as long as 36 hours on Oahu for our clinic to re-open, or as long as 60 hours at our neighbor island clinics.[9]

Emergency room access can guarantee EC access to younger victims who require a prescription for EC. According to FDA regulations women and girls under the age of 17 need a prescription for EC. In Hawaii, girls aged 14-16 may obtain a prescription after consultation with a pharmacist at some pharmacies. The level of care provided in emergency rooms would ensure that sexual assault victims of any age have access to EC immediately and without complication or having to disclose the traumatic details of their assault to yet another person.

III. EC is Low Cost and Saves Our State Money

Providing EC at emergency rooms saves patients and the community money at little cost to providers. Currently, there are both brand name and generic options for EC. Next Choice, the generic form of EC, is

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[2] Rev. Nicanor Pier Giorgio Austriaco, "*Is Plan B an Abortifacient? A Critical Look at the Scientific Evidence*", The National Catholic Bioethics Quarterly, (Winter 2007).

[3] See, American Medical Association, Strategies for the Treatment and Prevention of Sexual Assault (1995).

[4] American College of Obstetricians and Gynecologists, Violence Against Women: Acute Care of Sexual Assault Victims (2004), at http://www.acog.org/departments/dept_notice.cfm?recno=17&bulletin=1625.

[5] States Include: AR, CA, CO, CT, DC, IL, MA, MN, NJ, NM, NY, OR, SC, UT, WA, WI.

[6] See, Department of Defense, *Pharmacy and Therapeutics Committee Recommendations*, November 2009, Signed February 2010.

[7] See, Army Medical Command Regulation, 40-36, Part 17, January 2009.

[8] See, Ethical and Religious Directives for Catholic Health Care Services, Fourth Edition, Part Three, Dir. 36.

[9] Planned Parenthood of Hawaii's Honolulu Health Center is open Mon-Sat. Our Kailua-Kona Health Center on Hawaii Island is open M-W, F, and the Kahului Health Center on Maui is open M-F.

widely used. As of May 21, 2010, the wholesale price of a single dose of Next Choice is $26.13.[10] It should be noted that most hospitals and pharmacies negotiate significantly lower rates, and facilities with certain types of funding are guaranteed lower rates.

Patients paying out of pocket for EC pay higher costs. EC is available in pharmacies in Hawaii as an over the counter drug for women aged 17 and over. Typically, health insurance plans do not cover non-prescription medication. Hawaii's Medicaid program has opted to cover the cost of non-prescription EC for recipients. For those who do not receive Medicaid benefits, the cost of purchasing EC at a pharmacy is between $40 and $52 for a single dose, depending on pharmacy and brand of pill. [11]

Access to EC saves victims and the community the high costs of unplanned pregnancies. Were a victim to become pregnant as a result of a sexual assault, whether she chooses to terminate or continue her pregnancy, her medical costs would soar. The average cost of childbirth is approximately $7,600.[12] If a woman chooses an abortion early in her first trimester, she may pay anywhere between $350 and $500 out of pocket.[13]

Finally, EC saves our community money by preventing unwanted pregnancy. For women who continue pregnancy after a rape, costs are high to the community. Unplanned pregnancies cost the United States $5 billion each year.[14] Funds spent on prevention are well spent. In fact, for every $1 spent on EC, we save $1.43.[15] According to a recent report from the Guttmacher Insitute the Medicaid cost in Hawaii for a single birth is in excess of $11,400. That includes prenatal care, delivery, postpartum care and infant care for one year. State Medicaid funds also cover medically necessary abortion. In Hawaii, Medicaid provides coverage for 27% of all births.[16]

IV. Conclusion

EC is low cost and saves patients and the community money at a low cost to providers. More importantly, providing access to Emergency Contraception is the best standard of care we can offer sexual assault victims- one that helps prevent unwanted rape-related pregnancy, aids in recovery, and benefits not only victims but the community as a whole.

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[10] Based on phone call with Next Choice Representative.

[11] Based on phone calls placed to local major pharmacies. Longs Pharmacy charged $49.99 for Plan B and $39.00 for the generic Next Choice. Walgreens Pharmacy charges $52.00 for Plan B and $44.99 for the generic. Safeway Pharmacies charge $43.00 for the generic pill and require ID to be given. Target Pharmacy sells Plan B for $40.00.

[12] The Kaiser Family Foundation, accessed at: http://www.kaisernetwork.org/daily_reports/rep_index.cfm?DR_ID=48370

[13] National Abortion Federation, *Economics of Abortion*, accessed at: http://www.prochoice.org/about_abortion/facts/economics.html

[14] Trussell, J (2007) The cost of unintended pregnancy in the United States, *Contraception, 75*: 168-170.

[15] Id.

[16] The Kaiser Family Foundation, Hawaii: Births Financed by Medicaid, accessed at: http://www.statehealthfacts.org/profileind.jsp?cat=4&sub=57&rgn=13

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Frequently Asked Questions about Hormonal Approaches to Emergency Contraception

1. What is emergency contraception?

Emergency contraception (EC) is a term that describes the use of contraceptive methods to prevent pregnancy after unprotected or incompletely protected intercourse. The approach most often used is the ingestion of combined oral contraceptives (COC) or progestin-only pills (POP) within 72 hours of unprotected intercourse. Several regimens of different formulations can be used for EC:

Yuzpe regimen: Two tablets of Ovral (50 mcg ethinyl estradiol plus 0.5 mg norgestrel) followed in 12 hours by 2 additional tablets.
Formulations of sub-50 mcg COCs.
"Preven": The equivalent of the 2 Ovral doses of 2 tablets each).
"Plan B": One tablet of 0.75 mg levonorgestrel followed in 12 hours by 1 additional tablet.

As an alternative to the hormonal approach, an intrauterine device can be very effective for EC when it is inserted within 5 days of unprotected intercourse. IUDs must be inserted and removed by a physician. This method may be appropriate for women seeking long-term contraception; however, it is not advisable for women at high risk for sexually transmitted diseases or for adolescents. Furthermore, insertion of an IUD is not recommended for EC in cases of rape.

2. What is meant by "incompletely protected" intercourse?

Approximately half of unintended pregnancies in the U.S. result from a contraceptive method failure. Commonly experienced examples of such failure are condom slippage or breakage or multiple missed pills in a cycle of pill use.

3. What is the mechanism of action of COCs or POPs in providing emergency contraception?

Before ovulation, treatment with EC is believed to disrupt follicular maturation and consequently inhibit or delay of ovulation. After ovulation, treatment appears to have no effect on ovarian hormone levels. Thus, prevention of implantation may be a secondary mechanism of action. In addition, POPs alter tubal motility.

4. Does this mean that emergency contraception can cause an abortion?

Emergency contraception will not disrupt an established pregnancy. Women often are exposed to exogenous hormones in early pregnancy without adverse outcome. Some women undergoing assisted reproductive technology procedures to achieve pregnancy are routinely prescribed progesterone to support the pregnancy. It is also a common occurrence to interview patients in early pregnancy who were not aware that their missed pills had resulted in contraceptive failure and who thus had continued taking their pills.

5. How effective is emergency contraception?

Effectiveness is determined by comparing the number of pregnancies observed with treatment to the number that would have been expected without treatment. Women who utilize emergency contraception in the most fertile segment of the menstrual cycle (6 days preceding ovulation to the day after ovulation) will have a higher failure rate than women who utilize the method during another part of the cycle. The proportion of pregnancies prevented with the Yuzpe regimen has

been calculated to be between 57-75%. The effectiveness of the levonorgestrel regimen is reported to be 85%. The effectiveness of all regimens decreases after the first 12-24 hours after unprotected or incompletely protected intercourse.

6. Is there any point in using EC after 24 hours?

Although the reduction in the risk of pregnancy is most striking in the first 12-24 hours, EC can be effective for up to 72 hours. Based on combined COC and POP method use, the World Health Organization (WHO) has reported pregnancy rates of 0.5%-1.5% in the first 12-24 hours compared to approximately 2.6% at 48hours and 4.1% at 72 hours. To reduce unintended pregnancies it is critical to find ways to make EC as readily available as possible to women as soon as the need is recognized.

7. What about having emergency contraception available in advance?

The correlation of low pregnancy rates with early utilization of emergency contraception supports advance prescribing of the dedicated products along with detailed instructions for their use. In addition, it is well known that users of barrier methods and OCPs would benefit from this kind of intervention. Users of OCPs are routinely advised to take a missed pill along with the current pill. Studies have shown that women can identify their risks and needs quickly, will utilize the regimen appropriately when it is provided in advance, and are not inclined toward repetitive use patterns for EC.

8. What are the side effects associated with EC use?

The most common side effects of EC use are nausea and vomiting. At least 50% of the COC regimen users will experience nausea and 18-20% will have vomiting. The Plan B (levonorgestrel) regimen is associated with less than 25% frequency of nausea and about 5% vomiting. An antiemetic should be offered in conjunction with the EC prescription. Products such as those used for motion sickness are generally sufficient. The dose may need to be repeated if an EC user vomits within 1 hour of taking the medication. An episode of vomiting after 2 hours does not require a replacement dose.

9. In addition to temporary side effects, are there any serious complications of EC?

The short-term nature of the regimen makes any vascular complications such as thrombosis highly unlikely. Menstrual cycle changes such as heavier bleeding, headache, dizziness, and breast tenderness may be experienced by as many 16 % of EC users. Because of the presumed effects on tubal motility with POP regimens, caution should be exercised in evaluating the possibility of ectopic pregnancy in users who experience abnormal bleeding for. There are very few contraindications to using EC: women should not use EC who are already pregnant or who have genital bleeding of unknown cause.

10. What if a women is already pregnant or if EC fails to prevent pregnancy? What problems may occur?

The use of EC is contraindicated during pregnancy. A woman with a problem pregnancy needs evaluation, counseling, and advice. A woman with an unplanned but desired pregnancy needs exactly the same care from her physician. Menses may be delayed after EC use, and a follow-up visit should be scheduled within 1-3 weeks to check for possible pregnancy. Based on studies of pregnancies where EC failed to prevent pregnancy, there is no that there is any increased risk of birth defects or other problems for the ongoing pregnancy. This finding is consistent with the knowledge that early exposure to estrogen or progestin formulations does not produce adverse embryonic or fetal effects.

11. Should a pregnancy test be performed before using EC?

A pregnancy test is not a prerequisite to the use of EC. It can be useful in determining the need for EC if the woman has experienced more than one episode of unprotected or incompletely protected intercourse in the cycle and at least one episode was greater than 72 hours preceding evaluation. A positive test will allow the women or her physician to begin the appropriate care for early pregnancy.

12. When should the regular method of contraception be resumed after EC use?

Since EC (both the COC and the POP methods) can delay ovulation, it is important for a woman who is at continued risk for pregnancy to use an effective method of contraception for the remainder of the current cycle. Barrier methods and spermicide can be used immediately. A woman who is using OCPs can start a new pack after beginning the next menstrual cycle or she could even begin with one pill a day of her regular OC on the day after completing the EC treatment regimen.

13. Do EC users become less effective contraceptive users?

Most couples would like to increase their ability to effectively prevent and plan pregnancy. Many EC users are currently using a contraceptive method the best way they can under the circumstances of their lives. Identifying the need for EC and providing it gives a woman an opportunity to enhance personal decision-making for ongoing effective contraception.

The Scientific Evidence Suggests that Plan B is not an Abortifacient

Posted By Fr. Nicanor Pier Giorgio Austriaco O.P. On August 8, 2008 @ 8:33 pm In Bioethics at the Beginning of Life, Fr. Nicanor Pier Giorgio Austriaco, O.P., Matters Arising | 3 Comments

In recent weeks, there has been much controversy surrounding the possible abortifacient effect of some contraceptives given the Bush administration's proposal to redefine some forms of hormonal contraception as abortion. A year ago, I authored an essay published in the *National Catholic Bioethics Quarterly*, which summarized the scientific evidence that suggested that Plan B is not an abortifacient. [1] I would like to update my analysis and conclusions to date.

I open with a brief overview of the menstrual cycle because knowledge of the cycle is important to properly understand the debate over the mode of action of Plan B. A typical cycle lasts about twenty-eight days counting from the first day of menstrual flow. A woman's period, which typically lasts about four days (days 1–4), is followed by the follicular or proliferative phase, which lasts about eight days (days 5–13). During this phase, a single egg matures in the ovary in a structure called the follicle. The follicular phase is followed by the peri-ovulatory phase, the period flanking ovulation. Ovulation takes place on day 14 when the mature egg is released from the ovary. It is preceded by a surge of lutenizing hormone (LH) in the woman's blood that triggers the release of the egg. Ovulation is followed by the luteal or secretory phase, which lasts thirteen days or so (days 15–28). During this phase, the woman's uterus matures so that it would be ready to nourish an embryo if conception occurs. The development of the uterus is supported by hormones secreted by the remnant of the ovarian follicle called the corpus luteum. If an egg is not fertilized, the cycle ends and begins again with the onset of menses. In contrast, if an egg is fertilized, the embryo implants into his mother's uterus and the pregnancy continues.

If Plan B is taken during the follicular phase of a woman's cycle, it prevents ovulation. [2]This is not controversial. Clearly, the drug is a contraceptive. However, if Plan B is taken during the periovulatory or the luteal phase, some have suggested that it can act as an abortifacient. In support of this claim, proponents have appealed to statistical studies that report an effectiveness rate for Plan B between 58 percent and 95 percent, depending upon the delay in administration after intercourse. [3]They have argued that the high effectiveness rates for LNG point to a post-fertilization effect: If ovulation disruption is taken to be the only significant mechanism of action of Plan B, the total effectiveness should not be much higher than 50 percent if it is administered immediately after intercourse. [4] Similarly, without post-fertilization effects, if Plan B is administered with a twenty-four-hour delay, the highest possible effectiveness would be about 60 percent.

In response, critics have criticized the studies that report a high effectiveness rate for Plan B because they relied on a flawed methodology that was based on a woman's self-report of her ovulation date. A recent paper has shown that only 40 percent of women can accurately determine their correct stage in the menstrual cycle. [5] Because of their flawed methodology, it is likely that the earlier studies noted above may have overestimated the effectiveness of Plan B. This critique has now been supported by a recent systematic review of twenty-three different studies that evaluated various strategies designed to enhance women's access to emergency contraceptive pills. This review revealed that increased access to emergency contraception including the levonorgestrel-only regimen has *not* reduced the rates of unintended pregnancy. [6]To explain this unexpected finding, the authors believe that earlier studies that had estimated the efficacy rates for emergency contraception, including Plan B, were probably overstated, possibly quite substantially. They conclude: "Clearly, if the method [of emergency contraception] is weakly efficacious, it is unlikely to produce a major reduction in unintended pregnancy rates no matter how often women use it." [7] A substantially lower effectiveness rate that could account for the unexpected absence of reductions in the pregnancy rates seen in these population studies of emergency contraception would undermine the validity of the argument that Plan B is an abortifacient. At the very least, these studies cast serious doubt on

the statistical claim that Plan B has a post-fertilization effect: If the drug is an abortifacient with a high effectiveness rate, how could these population studies—despite their poor design in some cases—be systematically erroneous?

Next, I turn to reports that more directly determine the mode of action of Plan B. In theory, these studies should be more informative than the statistical studies described above since they are investigating particular biological mechanisms for LNG's mode of action.

If Plan B is an abortifacient, it could be an abortifacient in three primary ways: First, it could be an abortifacient by increasing the risk of ectopic pregnancies. In support of this possibility, isolated case studies had linked the drug to ectopic pregnancies. [8]However, combined data from five clinical trials with nearly six thousand women showed that the rate of ectopic pregnancies in women who have used Plan B is 1.02 percent as compared to the overall national ectopic pregnancy rate between 1.24 percent and 1.97 percent. [9]In light of this finding, it is unlikely that Plan B increases the ectopic pregnancy rate, suggesting that the isolated case studies in the literature are atypical. This conclusion is supported by a study that has shown that the standard dose of Plan B as an emergency contraceptive does not affect the biology of the fallopian tube. [10] In contrast, the same study showed that RU-486 or mifepristone—a bona fide abortifacient—taken as emergency contraception did change the biology of that tissue.

Next, Plan B could be an abortifacient by preventing the implantation of an embryo into the uterine wall. It could do this in at least three different ways. First, it could prevent implantation by undermining the development of the endometrium making it inhospitable for embryo implantation. However, morphological and biochemical analyses of endometrial biopsies of women who had taken Plan B eight or nine days prior to the biopsy have revealed that the drug does not dramatically alter the structure of this tissue. [11]This suggests that the drug does not compromise endometrial development. In contrast, there is clear evidence that the abortifacient RU-486 or mifepristone does alter the structure of the endometrium in ways that could be detrimental to an embryo. [12]

Second, the drug could prevent implantation by disrupting the function of the corpus luteum, indirectly interfering with endometrial function. Recall that the corpus luteum is the remnant of the ovarian follicle that gave rise to the egg. During the luteal phase, the corpus luteum releases hormones that are required for the maintainence of the endometrium so that it will remain hospitable for implantation for several days. If Plan B impaired corpus luteum function, the endometrium would fail, leading to the onset of an earlier menstrual period. Failure of the endometrium would prevent embryo implantation and thus lead to death. In support of this possible mode of action for Plan B, there are studies that have shown that menstrual bleeding begins earlier than usual in some women who use Plan B at the time of expected ovulation. [13] One particular study by Durand et al. has shown that taking Plan B during the LH surge one or two days *prior* to ovulation would blunt the surge but not prevent ovulation. [14] According to this study and a subsequent paper from the same group using the same data set, this would impair corpus luteum function leading to diminished levels of endometrial glycodelin A. [15] Since glycodelin A may play a role in adhesion of the embryo to the endometrium, this could potentially disrupt embryo implantation.

In response, a recent paper by Tirelli et al. has clarified the findings of these earlier studies. [16] It reported that shortened menstrual cycles are only seen in women who had not ovulated. In fact, in the one case when Plan B was taken during the LH surge, the woman showed a regular ovulatory cycle characterized by normal levels of hormones during the luteal phase. This one subject, whose response to Plan B is at odds with the findings of the Durand et al. study noted above, demonstrates that the use of the drug does not necessarily impair luteal function even if it is taken prior to ovulation during the LH surge. At most, if it does, it only does so in some women and only some of the time. Significantly, it is important to note that eggs released after a delayed or a partially suppressed LH surge—the conditions presupposed by the studies described above—are resistant to fertilization with a resistance proportional to the degree that the LH surge was blunted. [17] Together, this data suggests that the risk of a post-fertilization effect from this mode of action for any particular individual woman, if it is real, would be

vanishingly small.

Third, the drug could prevent implantation by directly interfering with the implantation process itself. As I discussed in detail in my earlier writings on this subject, one study that directly tested the ability of human embryos to implant on endometrial tissue exposed to LNG—though grossly immoral—does not support this mode of action for Plan B. [18] Incidentally, a more recent study from this same group has shown that Plan B, unlike RU-486, did not affect the expression of endometrial receptivity markers on their cell culture model of the human endometrium, a finding consonant with their earlier work. [19] Finally, this mode of action for LNG is also unlikely, given one small clinical study with an improved methodology in comparison to the earlier studies noted above that showed that the rate of pregnancy of women who had taken Plan B after ovulation was not reduced. [20]

Finally, Plan B could be an abortifacient by killing an already implanted embryo. Clearly, RU-486 has this post-implantation effect. It is routinely used to terminate established pregnancies in so-called medical abortions. [21]However, a report from the FDA shows that Plan B does not increase the rate of pregnancy loss nor the frequency of fetal abnormalities once a pregnancy has been established. [22]

In sum, recent population-based studies with Plan B suggest that its effectiveness rate was probably overstated. A substantially lower effectiveness rate would undermine the statistical argument that Plan B is an abortifacient. Moreover, all the mode of action studies show that it is unlikely that Plan B increases the risk of ectopic pregnancies, prevents the implantation of the embryo into the uterine wall, or kills an already implanted embryo. At most, if the finding of the Durand et al. study is real, one could say that it could increase the risk of a miscarriage in *some* women *some* of the time *only* if they take the drug during the brief interval of the LH surge prior to ovulation, and *only* if this blunting of the LH surge leads to the ovulation of an egg that is amenable to fertilization, and *only* if this egg is fertilized. As already noted above, fulfilling these conditions is very unlikely, given that eggs that are released after a blunting of the LH surge are themselves refractory to fertilization. In light of the available scientific evidence and given the inherent limitations of the studies, it is unlikely that Plan B is an abortifacient.

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[2] For data analysis and discussion, see the following studies, among others: L. Marions et al., "Emergency Contraception with Levonorgestrel and Mifepristone: Mechanism of Action," *Obstetrics and Gynecology* 100.1 (July 2002): 65–71; L. Marions et al., "Effect of Emergency Contraception with Levonorgestrel or Mifepristone on Ovarian Function," *Contraception* 69.5 (May 2004): 373–377.

[3] For data analysis and discussion, see the following studies, among others: A. O. Arowojolu, I. A. Okewole, A. O. Adekunle, "Comparative Evaluation of the Effectiveness and Safety of Two Regimens of Levonorgestrel for Emergency Contraception in Nigerians," *Contraception* 66.4 (October 2002): 269–273; and S. W. Ngai et al., "A Randomized Trial to Compare 24 h versus 12 h Double Dose Regimen of Levonorgestrel for Emergency Contraception," *Human Reproduction* 20.1 (January 2005): 307–311.

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[5] N. Novikova et al., "Effectiveness of Levonorgestrel Emergency Contraception Given Before or After Ovulation—A Pilot Study," *Contraception* 75.2 (February 2007): 112–118.

[6] E. G. Raymond et al., "Population Effect of Increased Access to Emergency Contraceptive Pills: A Systematic Review," *Obstetrics and Gynecology* 109.1 (January 2007): 181–188.

[7] Ibid., 187.

[8] For one example, see H. Matsushita, T. Takayanagi, and H. Ikarashi, "Ectopic Pregnancy Following Emergency Contraception with Ethinyloestradiol-Levonorgestrel: A Case Report," *European Journal of Contraception and Reproductive Health Care* 12.2 (June 2007): 184–186.

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[13] E. Gainer et al., "Menstrual Bleeding Patterns Following Levonorgestrel Emergency Contraception," *Contraception* 74.2 (August 2006): 118–124; E.G. Raymond et al., "Bleeding Patterns after Use of Levonorgestrel Emergency Contraceptive Pills," *Contraception* 73.4 (April 2006): 376–381; and D. Hapangama, A.F. Glasier, and D.T. Baird, "The Effects of Peri-Ovulatory Administration of Levonorgestrel on the Menstrual Cycle," *Contraception* 63.3 (March 2001): 123–129.

[14] Durand et al., "On the Mechanism of Action." Also see Gemzell-Danielsson and Marions, "Mechanisms of Action"; and Croxatto et al., "Pituitary-Ovarian Function Following the Standard Levonorgestrel Contraceptive Dose or a Single 0.75 mg Dose Given on the Days Preceding Ovulation," *Contraception* 70.6 (December 2004): 442–450.

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[16] A. Tirelli, A. Cagnacci, A. Volpe, "Levonorgestrel Administration in Emergency Contraception: Bleeding Pattern and Pituitary-Ovarian Function," *Contraception* 77.5 (May 2008): 328–332.

[17] W. M. Verpoest et al., "Relationship between Midcycle Luteinizing Hormone Surge Quality and Oocyte Fertilization," *Fertility and Sterility.* 73.1 (January 2000): 75–77.

[18] P. G. L. Lalitkumar et al., "Mifepristone, but not Levonorgestrel, Inhibits Human Blastocyst Attachment to an *In Vitro* Endometrial Three-Dimensional Cell Culture Model," *Human Reproduction* 22.11 (November 2007): 3031–3037.

[19] C. X. Meng et al., "Effect of Levonorgestrel and Mifepristone on Endometrial Receptivity Markers in a Three-Dimensional Human Endometrial Cell Culture Model," *Fertility and Sterility*, published online January 16, 2008.

[20] Novikova et al., "Effectiveness of Levonorgestrel."

[21] H. Hamoda and G. M. Flett, "Medical Termination of Pregnancy in the Early First Trimester," *Journal of Family Planning and Reproductive Health Care* 31.1 (January 2005): 10–14.

[22] Medical Officer's Safety Review of Supplemental NDA for Plan B: Division of Reproductive and Urologic Products, Food and Drug Administration.

Available at www.fda.gov/OHRMS/DOCKETS/AC/03/briefing/4015B1_

12_FDA-Tab 5-1-Medical Officer Review.doc. Last accessed on July 26, 2008.

Fr. Austriaco currently serves as an Assistant Professor of Biology and an Instructor of Theology at Providence College in Providence, RI. He is also an Investigator of the Rhode Island-INBRE Program funded by the National Institutes of Health (NIH) and a staff ethicist at the Dominican Friars Health Care Ministry of New York, New York, NY.

AMERICAN CIVIL LIBERTIES UNION of HAWAI'I

Committee:	Committee on Health
Hearing Date/Time:	Tuesday, May 25, 2010, 10:30 a.m.
Place:	Room 325
Re:	*Testimony of the ACLU of Hawaii re the Current System of Care for Sex Assault Victims in Hawaii's hospitals and Emergency Rooms*

Dear Chair Yamane and Members of the Committee on Health:

The American Civil Liberties Union of Hawaii ("ACLU of Hawaii") reports on the current system of care for sex assault victims in Hawaii's hospitals and emergency rooms, particularly with regard to emergency service providers' provision of emergency contraception to sex assault victims.

For the past 10 years, reproductive health advocates have unsuccessfully lobbied the Hawaii State Legislature to mandate that hospitals provide sex assault victims with emergency contraception. Legislators have cited at least four reasons for the bills' failure to pass: 1) there is no need for legislation, 2) the state and private hospitals may incur monetary liability for contract violations if legislation is passed, 3) economic impact, and 4) lack of information about emergency contraception. The ACLU of Hawaii, Planned Parenthood, Healthy Mothers Healthy Babies and the Sex Abuse Treatment Center are working together as Compassionate Care for Sexual Assault Victims ("CCSAV") to initiate and complete a number of projects designed to address these concerns. As Katie and Adriana have already discussed the economic impact and EC information, I will discuss the need for legislation and the liability issue.

The Need for Legislation

According to the most recent Crime in Hawaii report, there were 363 forcible rapes reported to law enforcement in Hawaii in 2008.[1] However, we know that this is only the tip of the iceberg given that the large majority of sex assaults are not classified as "forcible rapes" and/or aren't reported at all. Many of these survivors required and/or sought emergency medical care at one of Hawaii's emergency rooms.

CCSAV, with the assistance of the Healthcare Association of Hawaii, is currently conducting a survey of Hawaii's twenty-six emergency care providers regarding their provision of emergency contraception to sex assault victims. So far, we have received 14 responses and anticipate

[1] *Crime in Hawaii 2008: A Review of Uniform Crime Reports,* Crime Prevention & Justice Assistance Division, Research & Statistics Branch (Aug. 2009), also available at www.hawaii.gov/ag/cpja.

American Civil Liberties Union of Hawai'i
P.O. Box 3410
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receiving the outstanding responses shortly. Out of the responses that we have received, one thing is abundantly clear: most emergency service providers do not have clear and consistent policies with regard to the provision of emergency contraception to sex assault victims. The inherent danger of not having a clear and consistent statewide policy is that a sex assault victim may not receive the care that she needs to avoid a pregnancy as a result of a sex assault. A sex assault victim will have no way of knowing whether the hospital she is choosing to go to will provide her with emergency contraception or even inform her that emergency contraception exists. Moreover, our geography presents further difficulties because some entire islands may not have an emergency service provider who will offer EC. For instance, it remains to be seen whether residents of Maui, Molokai, Lanai and Hawaii Island have access to emergency contraception in emergency rooms. Further, if there is only one local hospital in a rural community, like Kahuku, for instance, it may be extremely difficult or even impossible for a sex assault victim to access emergency contraception, particularly if she is unwilling to go through the sex assault treatment center examination and interview process.

CCSAV will continue to review and compile the survey responses and report our final results to this Committee as soon as the survey project is completed. With this testimony I am submitting copies of our survey and cover letter, a summary of the responses received so far and maps indicating the location of each emergency service provider so as to demonstrate the problems with lack of access due to geographical difficulties.

Civil Liability

CCSAV has obtained the assistance of the law firm Paul Johnson Park & Niles ("PJPN") to analyze the legal claims with regard to a local hospital's objection to a law requiring it to distribute EC. The hospital has stated that it objects on the basis that the law would force it to violate a pre-existing contract and expose them and the state of Hawaii to civil liability. Unfortunately, the attorneys from PJPN are unable to be here today to present their findings but have agreed to do so at a later date.

Thank you for agreeing to host this informational briefing. We are pleased to provide you with this information and look forward to presenting you with the final results at a later date.

The mission of the ACLU of Hawaii is to protect the fundamental freedoms enshrined in the U.S. and State Constitutions. The ACLU of Hawaii fulfills this through legislative, litigation, and public education programs statewide. The ACLU of Hawaii is a non-partisan and private non-profit organization that provides its services at no cost to the public and does not accept government funds. The ACLU of Hawaii has been serving Hawaii for over 40 years.

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Thank you for this opportunity to testify at this informational briefing.

Sincerely,

Laurie A. Temple
Staff Attorney

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Date

Chief Nursing Officer
Emergency Service Provider
Address
City, HI ZIP

Dear Chief Nursing Officer,

Compassionate Care for Sexual Assault Victims ("CCSAV") is a group of organizations and individuals committed to ensuring that sexual assault victims are informed about and given access to emergency contraception ("EC"). To further this goal, CCSAV is conducting a survey of Hawaii emergency service providers' EC protocol when treating sexual assault patients.

Enclosed is a survey regarding your facility's EC policies and procedures. Please take a few minutes to review and complete the form and send it to CCSAV via fax at (808) 522-5909 or email at jackieb@hmhb-hawaii.org. Please also fax or email a copy of your EC policies and procedures, if they are available.

CCSAV greatly appreciates your assistance with the EC survey process. If you have questions about the survey or about EC, please contact Jackie Berry at (808) 951-5805.

Thank you for your cooperation.

Sincerely,

Compassionate Care for Sexual Assault Victims

Emergency Service Provider Survey Form
Emergency Contraception for Sexual Assault Patients

1. Please indicate which description best reflects the practices of your facility in treating sexual assault patients. CHECK ALL THAT APPLY

a) ☐ Generally, patients are referred somewhere else for all treatment related to sexual assault.

Please specify facility that patients are referred to:_____

b) When a patient declines a referral elsewhere, do you provide care on site? ☐ Yes ☐ No

Is Emergency Contraception ("EC") offered or provided? ☐ Yes ☐ No

2. Does your facility have a clear policy on the provision of EC to sexual assault patients?

☐ Yes ☐ No

3. Please indicate which description below best reflects the pregnancy prevention practices of your facility in treating sexual assault patients. CHECK ALL THAT APPLY

a) EC is offered on-site in the emergency department.

☐ Always ☐ Sometimes ☐ Never

b) Patients are given only information about EC.

☐ Always ☐ Sometimes ☐ Never

c) EC is kept in stock.

☐ Always ☐ Sometimes ☐ Never

d) ☐ Only referrals for EC are offered.

e) ☐ Patients are referred elsewhere for EC.
Please specify EC provider: _____

f) ☐ No information about EC, prescriptions for EC, or EC are provided on-site.
Please explain: _____

OVER

4. If your policy includes the provision of EC, is there a system in place to carry out that policy if the attending physician declines to provide EC?
☐ Yes ☐ No

5. Does your policy prohibit the provision of EC under some or all circumstances? ☐ Yes ☐ No
If Yes, please explain: _____

6. If you provide EC, what medication is used? ☐ Plan B ☐ Plan B One Step
☐ Other:_____

7. Additional comments:

Name: _____

Title: _____

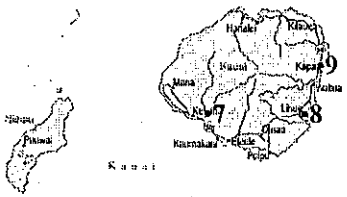
Signature: _____

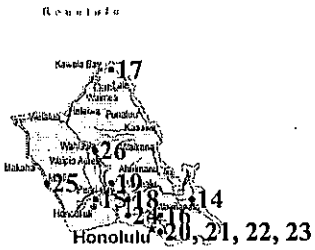
Thank you for your assistance with this survey.

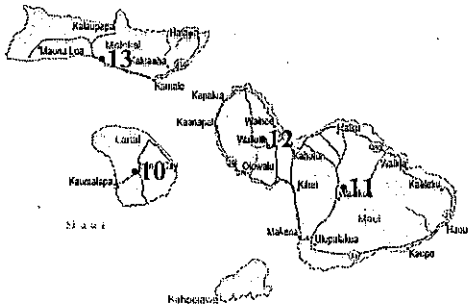
Please Return to Compassionate Care for Sexual Assault Victims via fax at (808) 522-5909 or via email at jackieb@hmhb-hawaii.org.

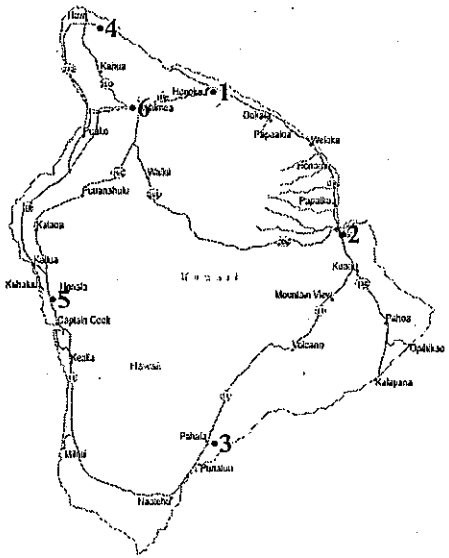
Facility	1a (refer to provider)	1b (on-site treatment/EC provided)	2 (policy)	3a (EC offered)	3b (info only)	3c (in stock)
1. Hale Hoola Hamakua	North Hawaii Community Hospital	on care site provided, dependent on doctor to provide info and/or access to EC	No	No - only prescription	Sometimes (depends on the doctor)	No
4. Kohala	Kona Community Hospital	No (can't decline); dependent on doc to provide EC	No	Sometimes if docs choose	no knowledge that it has ever been asked for in the 7 yrs she has been there	Always
5. Kona Community Hospital	IDK	IDK, EC offered if physician chooses	No	Sometimes	Sometimes	IDK
6. North Hawaii Community Hospital	No SANE person so no SA program. Sometimes refer to hospital with SANE nurse.	Yes, ER does assessment and treats injuries, advises counselling. I believe we have info about getting EC but idk whether we provide it.	No	No - only prescription	always	IDK - advise to cross street to drugstore
7. West Kauai Medical Center	SART team	Yes, provide medical only if needed. No EC offered or provided	No - work in progress	Never	Always	Never
8. Wilcox Memorial	SANE nurses called	EC provided	Yes	Always	Always	Always
9. Samuel Mahelona	No SA victims this year, bring to police dept/wilcox, not equipped	Yes; IDK	IDK	IDK	IDK	IDK
16. Hawaii Medical Center East	Kapiolani Rape Team, SATC	Yes (stablize, x-rays, labs, rape team called). NO EC	Yes - provide info only	Never	Always	Never
17. Kahuku	Kapiolani W&C		No	Never	Never	Never
19. Kapiolani - Pali Momi	Kapiolani W&C (gives meds)					
20. Kapiolani Women's and Children's Hospital		Yes	Yes	Always		
22. Queen's Medical Center	Kapiolani W&C	Yes	Yes	No		Always
24. Tripler Army Medical Center		TAMC has in-house SANE on-call 24/7; Yes, Yes	Yes, fed mandate to offer EC	Always		Always
25. Waianae Comprehensive Health Center	Kapiolani W&C	Clear medically, Yes	Yes. Offer only if assaulted	Always	Always. Urinate first, given teaching	Always

Facility	3d (referal only)	3e (refer to another provider)	3f (provide nothing)	4 (policy re doctor declines)	5 (policy prohibiting)	6 (medication)	Comments
1. Hale Hoola Hamakua				No	No		Have not addressed this issue but would like to address with medical director
4. Kohala	if someone asks for it we have it, up to docs to provide		if someone asks then they may get verbal info, case by case	No, only 1 doc on call at a time but can't imagine doc not providing it.	No	Other	
5. Kona Community Hospital				IDK	IDK		
6. North Hawaii Community Hospital				Yes	No	Plan B	
7. West Kauai Medical Center	Only referrals offered	Referred to SART for resources. Not doable in ER		No	Yes		Encourage statewide. Nurses need to keep up on skills; doesn't work in ER; need care that doesn't work in ER; need space for them to go, don't have
8. Wilcox Memorial				Yes	No	IDK	
9. Samuel Mahelona	IDK		IDK	IDK	IDK		Permanent managers are currently out. Responder is termporary so she doesn't really know and they haven't had a case since she's been there.
16. Hawaii Medical Center East	Yes	Kapiolani, patient's ob/gyn or other			Yes, operate under Catholic Directives		
17. Kahuku		Kapiolani					
19. Kapiolani - Pali Momi							No eversion to writing medication, not in policy, individual case.
20. Kapiolani Women's and Children's Hospital				Yes	No	Plan B One Step	
22. Queen's Medical Center					No		
24. Tripler Army Medical Center				Yes	No	Plan B	There is a federal mandate requiring all military facilities to offer EC to SA patients. Additionally, any female patient over age 18 may receive OTC EC from the pharmacy without seeing a provider.
25. Waianae Comprehensive Health Center				Physician can't decline because of federal funds	No	Plan B	









HAWAII

- Hale Ho`ola Hamakua
- Hilo Medical Center
- Kau Hospital
- Kohala Hospital
- Kona Community Hospital
- North Hawaii Community Hospital

KAUAI

7. West Kauai Medical Center
8. Wilcox Memorial Hospital
9. Samuel Mahelona Memorial Hospital

LANAI

10. Lanai Community Hospital

MAUI

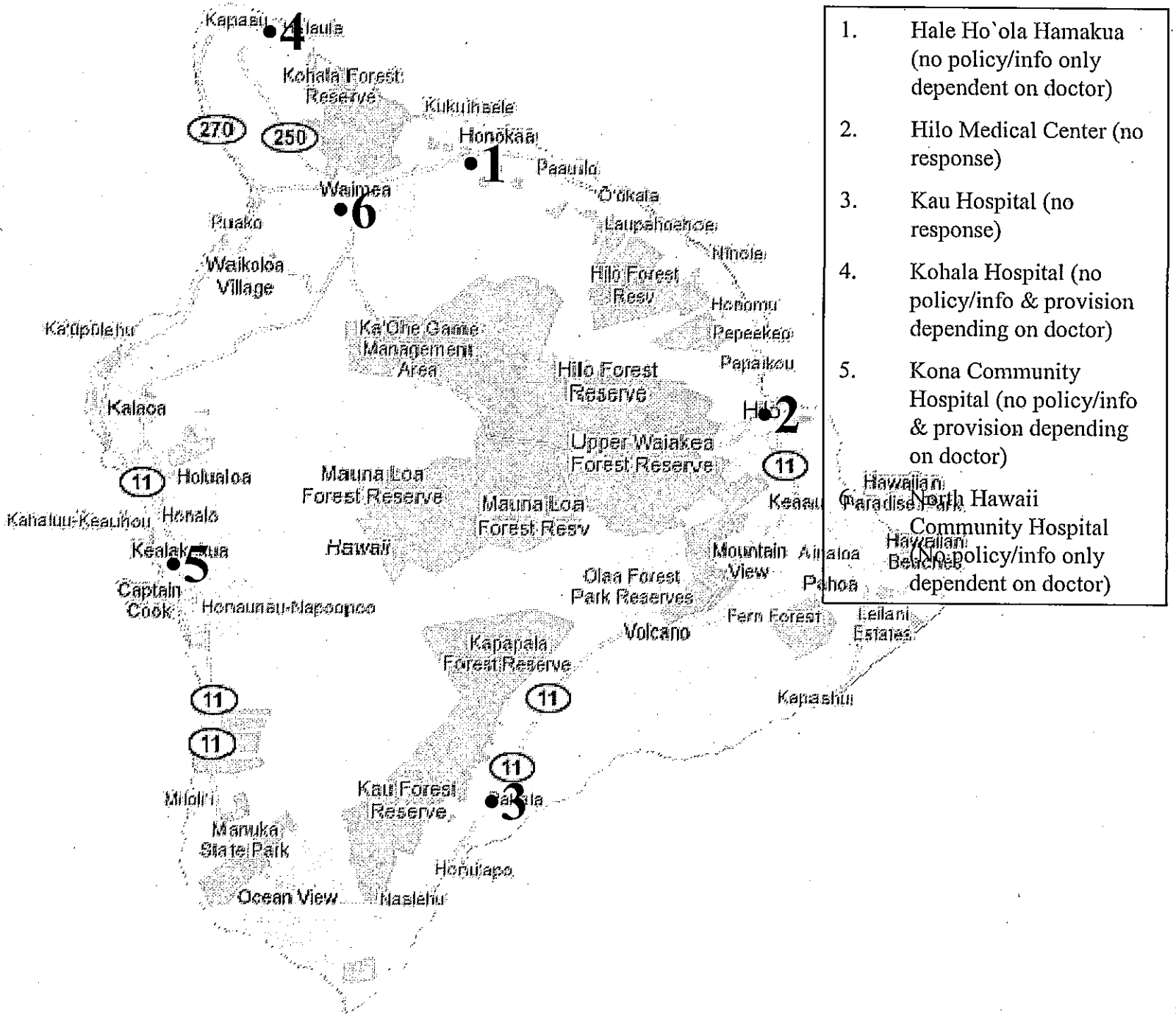
11. Kula Hospital
12. Maui Memorial Medical Center

MOLOKAI

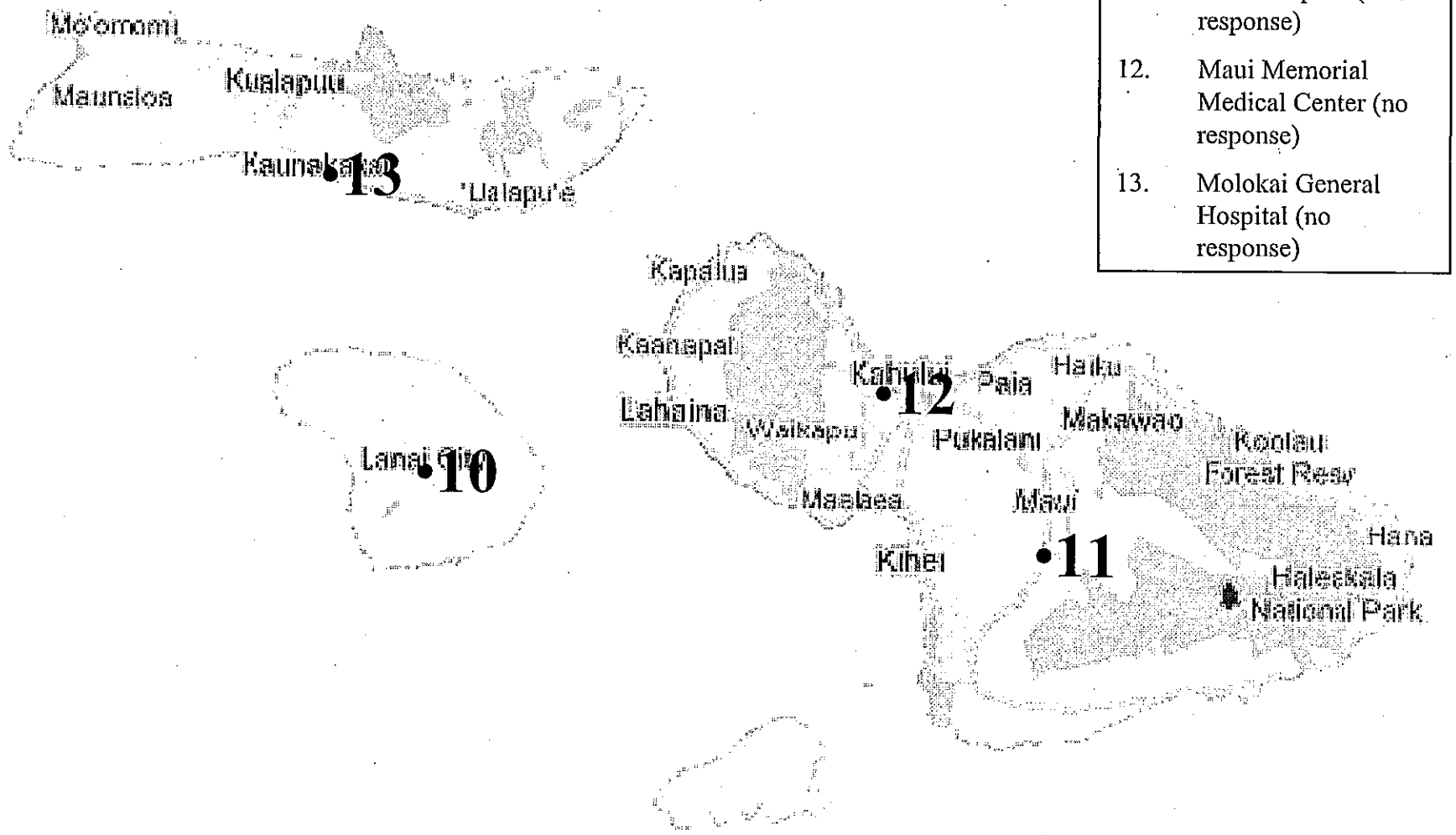
13. Molokai General Hospital

OAHU

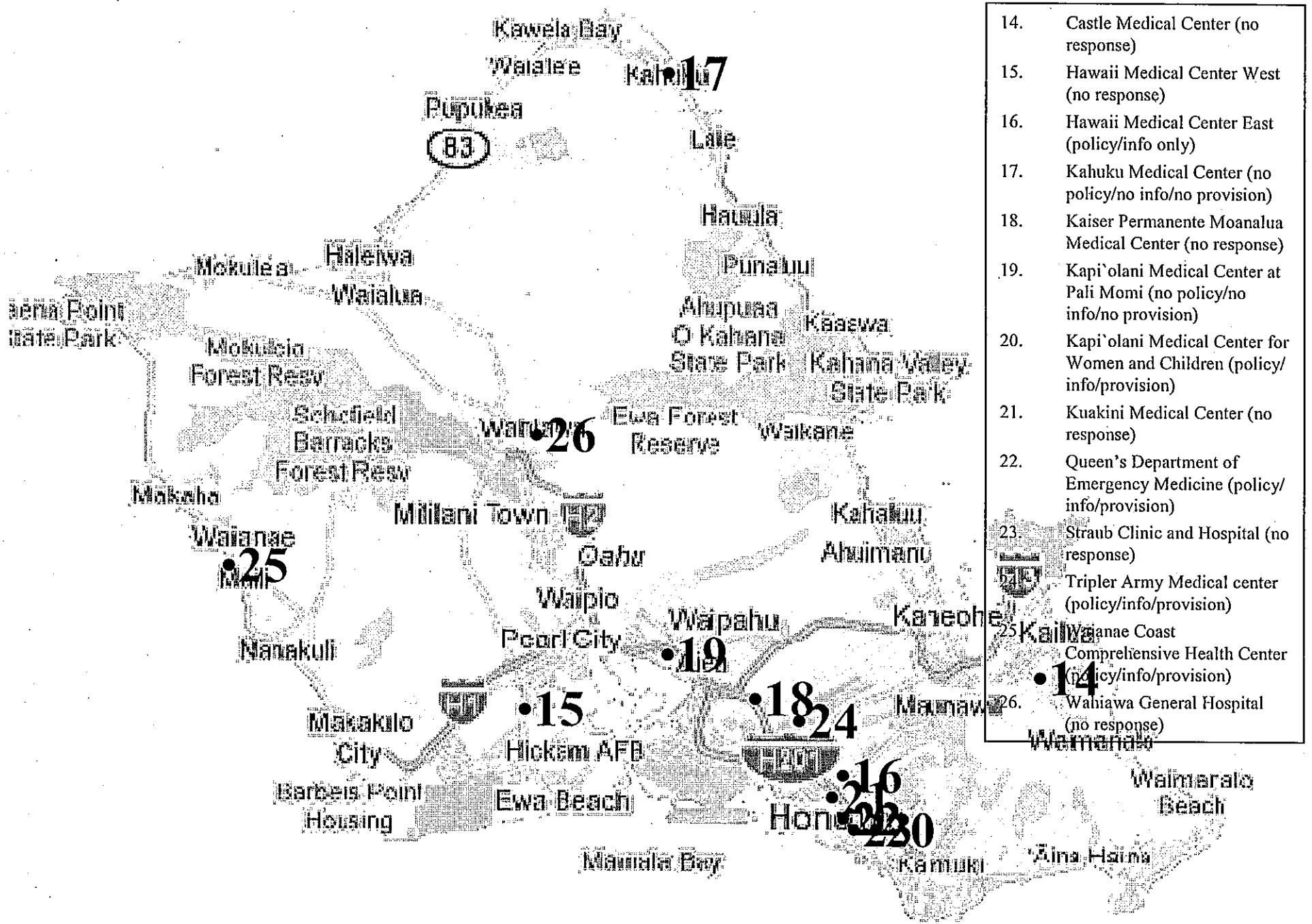
14. Castle Medical Center
15. Hawaii Medical Center West
16. Hawaii Medical Center East
17. Kahuku Medical Center
18. Kaiser Permanente Moanalua Medical Center and Clinic
19. Kapi`olani Medical Center at Pali Momi
20. Kapi`olani Medical center for Women and Children
21. Kuakini Medical Center
22. Queen's Department of Emergency Medicine
23. Straub Clinic and Hospital
24. Tripler Army Medical Center
25. Waianae Coast Comprehensive Health Center
26. Wahiawa General Hospital


1. Hale Ho`ola Hamakua (no policy/info only dependent on doctor)
2. Hilo Medical Center (no response)
3. Kau Hospital (no response)
4. Kohala Hospital (no policy/info & provision depending on doctor)
5. Kona Community Hospital (no policy/info & provision depending on doctor)
6. North Hawaii Community Hospital (No policy/info only dependent on doctor)
Kapaau
Kohala Forest Reserve
Kukuihaele
Honokaa
Paauilo
Waimea
Puako
Waikoloa Village
Ka'upulehu
Ka'Ohe Game Management Area
Hilo Forest Resv
Hilo Forest Reserve
Upper Waiakea Forest Reserve
Mauna Loa Forest Reserve
Mauna Loa Forest Resv
Hawaii
Kalaoa
Holualoa
Kahaluu-Keauhou
Honalo
Kealakekua
Captain Cook
Honaunau-Napoopoo
Olaa Forest Park Reserves
Volcano
Kapapala Forest Reserve
Kau Forest Reserve
Miloli'i
Manuka State Park
Ocean View
Naalehu
Honuapo
Kapaahu
Fern Forest
Leilani Estates
Mountain View
Pahoa
Hawaiian Paradise Park
Hawaiian Beaches
Keaau
Papaikou
Pepeekeo
Honomu
Hilo
Laupahoehoe
Hinale
Ookala
270
250
11

7. West Kauai Medical Center (no policy/info only)
8. Wilcox Memorial Hospital (policy/info/provision)
9. Samuel Mahelona Memorial Hospital (no policy/no info/no provision)



10. Lanai Community Hospital (no response)
11. Kula Hospital (no response)
12. Maui Memorial Medical Center (no response)
13. Molokai General Hospital (no response)



14. Castle Medical Center (no response)
15. Hawaii Medical Center West (no response)
16. Hawaii Medical Center East (policy/info only)
17. Kahuku Medical Center (no policy/no info/no provision)
18. Kaiser Permanente Moanalua Medical Center (no response)
19. Kapi`olani Medical Center at Pali Momi (no policy/no info/no provision)
20. Kapi`olani Medical Center for Women and Children (policy/info/provision)
21. Kuakini Medical Center (no response)
22. Queen's Department of Emergency Medicine (policy/info/provision)
23. Straub Clinic and Hospital (no response)
24. Tripler Army Medical center (policy/info/provision)
25. Waianae Coast Comprehensive Health Center (policy/info/provision)
26. Wahiawa General Hospital (no response)

THE SEX ABUSE TREATMENT CENTER

A Program of Kapi'olani Medical Center for Women & Children

DATE: Mary 25, 2010

TO: The Honorable Ryan I. Yamane, Chair
The Honorable Scott Y. Nishimoto, Vice Chair
Committee on Health

FROM: Adriana Ramelli, Executive Director
The Sex Abuse Treatment Center

RE: Emergency Contraception for Sexual Assault Victims

Good morning Representatives Yamane and Nishimoto and members of the House Committee on Health. My name is Adriana Ramelli and I am the Executive Director of the Sex Abuse Treatment Center (SATC), a program of the Kapi'olani Medical Center for Women & Children (KMCWC), an affiliate of Hawai'i Pacific Health.

Sexual assault is a horrific act of violence; and following an attack, women are left to cope with the raw painful emotions of a situation that was forced upon them. In addition, these women are forced to cope with and manage the many physical consequences of sexual violence. One very serious physical consequence is a rape-related pregnancy. Every year, approximately 300,000 women are raped and about 25,000 women of them become pregnant as a result of the sexual assault (Steward, Russell American Journal of Preventive Medicine Nov. 2000). Though statistics vary, the average rate of pregnancy resulting from rape is somewhere between 1 to 5% with an estimated 32,000 rape related pregnancies occurring every year.

Victims of sexual assault should have the right to access therapeutic and medical care following an assault as well as the right to determine their own course of action after an event that stripped them of all of their control.

The SATC is a community program designed to support the needs of victims and is available to them following an assault. The KMCWC is the designated hospital for sexual assault victims to receive a comprehensive medical-legal examination. This examination entails the detection and treatment of injuries, collection of legal evidence, testing for sexually transmitted diseases, and pregnancy testing. If a victim is concerned about or at risk for an unwanted pregnancy, the examining physician will offer information about and discuss the option of prescribing the emergency contraceptive pill. Medical Centers on O'ahu are aware of the forensic medical services of the SATC and do refer victims to the KMCWC Emergency Department for the comprehensive examination. This system works when victims want the comprehensive forensic examination services of the SATC. However, not all choose this method of care and may be concerned only about becoming pregnant from the assault.

If this is the case, the system works when a victim can walk into any emergency room, be evaluated for the risk of pregnancy, and offered the option of emergency contraception.

Offering emergency contraception is also a time-sensitive issue. The medication needs to be administered within 72 hours of the sexual attack to be effective. It is not uncommon for victims to delay seeking immediate medical care because the realities of a sexual assault are often too painful to face. In addition, it is not uncommon for sexual assault victims to be faced with transportation issues and be forced to seek care for the unwanted pregnancy at a medical facility nearest their home.

The SATC supports establishing public policy to ensure that victims of sexual assault who seek medical treatment at hospitals are provided information on emergency contraceptives and, if the victim so chooses, make it available to them. Victims of sexual assault deserve to receive the best standard of emergency medical care and promoting sound and compassionate legislation will ensure that victims of sexual assault are protected from the devastating fear of an unwanted pregnancy resulting from a sexual assault.

Thank you for this opportunity to testify.

Healthcare Association
of Hawaii

HOUSE COMMITTEE ON HEALTH
Rep. Ryan Yamane, Chair

Conference Room 325
May 25, 2010 at 10:30 a.m.

Comments on the system of care for sexual assault victims in Hawaii's hospitals and emergency rooms.

The Healthcare Association of Hawaii advocates for its member organizations that span the entire spectrum of health care, including all acute care hospitals, as well as long term care facilities, home care agencies, and hospices. Thank you for this opportunity to provide comments on the current system of care for sexual assault victims in Hawaii's hospitals and emergency rooms.

Emergency departments are complex, dynamic environments that must comply with regulations established by the Department of Health. Legislating requirements on top of existing regulations would place an unnecessary burden on the licensed and trained professionals who must make decisions in critical situations. For these reasons, the Association does not support legislation that would mandate protocol in emergency departments. It would be our preference to work collaboratively with all interested parties on matters such as these so that we could create solutions without legislation.

Sexual assault victims present complex cases to health care providers because deep emotional issues, as well as legal issues, are typically involved. Emergency contraception is an issue associated with sexual assault victims, and the Healthcare Association has been working with Healthy Mothers Healthy Babies (HMHB) and the American Civil Liberties Union of Hawaii (ACLU) to identify standard operating procedures in Hawaii emergency departments. To this end, the Association facilitated a survey of hospitals on the subject, for the use of the above parties, which is in progress and not yet complete.

The Association looks forward to continue working with HMHB and the ACLU on this issue. We would like to utilize the results of the survey to identify issues and, without legislation, to address issues identified by the survey to ensure that all sexual assault victims receive appropriate care in all of Hawaii's hospitals and emergency rooms. We look forward to continuing to collaborate with these organizations and all other interested parties on this issue.

St. Francis

HEALTHCARE SYSTEM OF HAWAII
A Legacy of Caring for Hawaii's People

May 25, 2010

Rep. Ryan I. Yamane
37th Representative District
Hawaii State Capitol, Room 419
415 South Beretania Street
Honolulu, HI 96813

Dear Representative Yamane:

Thank you for your interest in exploring all of the different perspectives relating to emergency contraceptives for sexual assault survivors.

The St. Francis Healthcare System of Hawaii is strongly opposed to any legislation mandating the provision of emergency contraceptives to any patient in our care. We join our diocese, the United States Conference of Catholic Bishops, and the Catholic Health Assembly in our objection to violating our rights of conscience. As the only Catholic Healthcare organization in Hawaii we are obligated to oppose any effort to undermine the ability of faith-based groups to preserve their identity as partners with government.

You will find attached the position paper prepared by St. Francis Healthcare System of Hawaii. It provides the rationale for our position, explaining not only our ethical and religious reasons, but also our medical concerns about emergency contraceptives – something I think you will appreciate as a former medical social worker in a hospital setting.

We also provide our view of the issues from an economic and community health resource planning perspective, which the House Health Committee may find valuable. We also disclose some of the grave implications for St. Francis and the community if such a bill were to be passed and become law.

I also call your attention to the attached statement from the Diocese of Honolulu, The Ethical and Religious Directives for Catholic Health Care Services (especially sections 23, 33 and 36 on pages 7 and 8), and information from the Mayo Clinic website regarding the Plan B pill.

If you have any questions or would like more details, I would be glad to discuss them with you, your staff or members of the committee. I thank you for this opportunity to share our views.

Mahalo for your support,

Joy Yadao, R.N.
Director of Advocacy and Business Development

St. Francis

HEALTHCARE SYSTEM OF HAWAII

A Legacy of Caring for Hawaii's People

POSITION PAPER

Emergency Contraceptives for Sexual Assault Survivors

Proposed Legislation:
There are bills in the legislature that currently propose that healthcare organizations, including Catholic healthcare organizations, must offer "emergency contraceptive" pills to victims of sexual assault.

St. Francis Healthcare System's Position:
St. Francis Healthcare System is opposed to bills that would mandate healthcare organizations to provide "emergency contraceptive" pills to patients who have been sexually assaulted. As a Catholic healthcare organization, affirming and protecting life and providing quality care for the whole patient are important to us. Being forced to offer or withhold services or products that run counter to our ethical and religious values would violate our conscience.

Rationale:
St. Francis Healthcare System opposes these bills not only on the grounds that they go against our ethical and religious values, but also because of medical, economic and health resource planning concerns.

Ethical and Religious Reasons:

- **Against Our Catholic Values**
  A sexual assault is a traumatic experience for a woman. Forcing us to provide emergency contraceptives in these cases would be an assault to our conscience as a Catholic healthcare organization. Imposing this requirement and penalizing us for not complying with these proposed laws would attack the values that are important to us. We are also accountable to our "stakeholders," the thousands of donors in the community who provide financial and other types of support because they believe in our mission.

- **"Plan B" Is Designed to Cause Chemically-Induced Abortions**
  The term, "emergency contraceptive," is misleading and has been used to promote acceptance of Plan B, the product manufactured by Barr Pharmaceuticals. On its product insert, the company clearly states: "This product works mainly by preventing ovulation (egg release). It may also prevent fertilization of a released egg (joining of sperm and egg) or attachment of a fertilized egg to the uterus (implantation)." As a Catholic healthcare organization, we believe life begins at conception and preventing implantation is abortion.

The *Pontifical Academy for Life* has made a clear prohibition on the use of emergency contraceptives: "Consequently, from the ethical standpoint the same absolute unlawfulness of abortifacient procedures also applies to distributing, prescribing and taking the morning-after pill. All who, whether sharing the intention or not, directly co-operate with this procedure are also morally responsible for it."

Medical Reasons:

- **The Bill Trivializes the Act of Rape**
  As a Catholic healthcare organization, we are concerned about the welfare of every individual who comes to our facilities. We focus on caring for the whole person – body, mind and spirit. When a woman or girl has been sexually assaulted, the response to her traumatic experience must encompass much more than a concern about pregnancy. Counseling, testing for sexually transmitted diseases, filing a police report, and preservation of forensic evidence to incarcerate the perpetuator of the assault are also important. This bill fails to take into account the wide range of support services required to adequately deliver quality care to these sexual assault victims.

- **Lack of Medical Precautions**
  It is important to note that emergency contraceptives are essentially mega-doses of birth control pills, containing high levels of progestin. Before prescribing birth control pills, a physician conducts a thorough health assessment of a woman; yet, there are no required protocols for administering "emergency contraceptives."

- **Health Risks Associated with Emergency Contraceptives**
  The risks associated with the use of Plan B have not been adequately documented. Norplant, the progestin-only hormonal contraceptive, has the same active ingredient as Plan B. Norplant is no longer available for use in the United States because of its health risks. Some of the documented risks associated with Plan B include significant weight gain, depression, ovarian cyst enlargement, gallbladder disease, high blood pressure, and respiratory disorders.

Economics and Community Health Resource Planning Reasons:

- **Service Limitations**
  No healthcare organization can be all things to all people. St. Francis is aware of its limitations and routinely makes referrals to other healthcare organizations in the community when a patient's condition is beyond the expertise or experience of our staff. This would apply to cases involving sexual assault victims.

  St. Francis is simply not equipped to manage these types of instances. Would Hawaii lawmakers require that all emergency rooms have the capabilities to care for burn victims? No, because patients can best be served by Straub Clinic & Hospital, which specializes in burn treatment. Should all hospitals be required to deliver babies? No, the twoSt. Francis Medical Centers (now known as Hawaii Medical Centers) have not delivered babies for years. Then, Hawaii legislators should not impose laws that would require us to provide a service that we know we cannot adequately deliver and that would violate our conscience.

- **No Justification for State Funding of Redundant Services**
  At a time when the State of Hawaii is seeking ways to reduce costs because of budget constraints, the legislature should not mandate requirements that will increase costs for services already provided in the community – especially at the expense of Hawaii taxpayers. Providing funding for emergency contraceptives as a way to ensure they are dispensed by healthcare organizations is an irresponsible use of State funds, particularly if emergency contraceptives can be obtained at another healthcare organization or over the counter at a drugstore.

Future Ramifications:

- **Potential Litigation for Breach of Contract**
  While St. Francis certainly hopes these bills die and never resurface, we are fully prepared to act upon our convictions should they become law. St. Francis Healthcare System sold its two hospitals in Liliha and Ewa to Hawaii Medical Center (HMC) in early 2007, with the stipulation that HMC continue to abide by the Ethical and Religious Directives of Catholic Health Care Services that were developed and adopted by the U.S. Conference of Catholic Bishops. It would be unthinkable if these activities were allowed on the land we own and that God has entrusted to our care. If HMC does not to honor its word, St. Francis Healthcare System would have no alternative but to pursue litigation for breach of contract. Time-consuming litigation and legal fees would only distract us from our core mission of creating healthy communities in the Spirit of Christ's healing ministry. Already, the litigation involved with HMC's bankruptcy is depriving St. Francis of significant resources and time from its healthcare ministries.

- **Potential Closure of Emergency Rooms**
  If St. Francis regains control of the two hospitals and these bills become law, we would have to abide by our convictions and may have to reluctantly close our emergency rooms. We realize this would cause great harm in the community since there would be fewer emergency rooms to serve Hawaii's people. This is especially important for the Ewa hospital, which serves as a critical-access facility for West Oahu residents.

Desired Outcome

The core values of St. Francis are charity, peacemaking, simplicity and joy, and we base our decisions and operations on these values. More than 125 years ago, the Sisters of St. Francis came to the Islands in response to a plea from King David Kalakaua to care for those with Hansen's disease. The Sisters have faithfully worked in collaboration with government leaders to deliver compassionate care and healing, affirming life wherever they went and with whomever they touched. Our desire is to continue carry on this long-standing tradition in the Islands.

St. Francis

HEALTHCARE SYSTEM OF HAWAII
A Legacy of Caring for Hawaii's People

Questions and Answers

Emergency Contraceptives for Sexual Assault Survivors

Q: If emergency contraceptives are already available over the counter in drug stores without a prescription, why can't St. Francis dispense them at its facilities?

A. St. Francis Healthcare System currently does not operate emergency rooms, and therefore, is not equipped to care for sexual assault victims. We sold our two hospitals in Liliha and Ewa to Hawaii Medical Center (HMC) in early 2007. However, we have an agreement with HMC that they must abide by the Ethical and Religious Directives of Catholic Health Care Services. As a Catholic healthcare organization, affirming and protecting life and providing quality care for the whole person are important to us. A sexual assault is a traumatic experience for a girl or woman, and there are many aspects to her care besides concern about pregnancy. Counseling, testing for sexually transmitted diseases, filing a police report, and preservation of forensic evidence to incarcerate the perpetuator of the assault are also important.

No healthcare organization can be all things to all people. St. Francis is aware of its limitations and routinely makes referrals to other healthcare organizations in the community when a patient's condition is beyond the expertise or experience of our staff. This would apply to cases involving sexual assault victims.

Q. Other Catholic hospitals have made an exception and offered emergency contraceptives in cases which involve rape. Why not St. Francis?

Catholic hospitals that dispense emergency contraceptives do so only in conjunction with testing for ovulation, and there must be an accurate understanding on how these hormonal medications work. As a Catholic healthcare organization, we believe the use of artificial contraceptives and abortions goes against our conscience. The term, "emergency contraceptive," is misleading and has been used to promote acceptance of Plan B, the product manufactured by Barr Pharmaceuticals.

On its product insert, it clearly states: "This product works mainly by preventing ovulation (egg release). It may also prevent fertilization of a released egg (joining of sperm and egg) or attachment of a fertilized egg to the uterus (implantation)." As a Catholic healthcare organization, we believe life begins at conception and preventing implantation is a chemically-induced abortion. Being forced to offer

products or services that run counter to our ethical and religious values would violate our conscience.

Q. Emergency contraceptive is effective in preventing pregnancy for up to five days after the assault, but is most effective if taken as soon as possible. Emergency contraceptives have also been proven to be safe. Why would St. Francis want to aggravate a sexual assault victim by making her seek emergency contraceptives from somewhere else?

Medical science has shown there is no longer a sense of urgency and that emergency contraceptives are no longer an "emergency." No medical treatment is without some risk and this is true for emergency contraceptives. Some of the documented risks associated with Plan B include significant weight gain, depression, ovarian cyst enlargement, gallbladder disease, high blood pressure, and respiratory disorders.

Emergency contraceptives are essentially mega-doses of birth control pills, containing high levels of progestin. Before prescribing birth control pills, a physician conducts a thorough health assessment of a woman; yet there are no required protocols for administering "emergency contraceptives."

Q. What would happen if this bill were to be passed and St. Francis would be required to dispense emergency contraceptives in its emergency rooms?

A. St. Francis Healthcare System currently does not operate emergency rooms. We sold our two hospitals in Liliha and Ewa to Hawaii Medical Center in early 2007. However, we have an agreement with Hawaii Medical Center that they must abide by the Ethical and Religious Directives of Catholic Health Care Services, which was developed and adopted by the U.S. Conference of Catholic Bishops. HMC must comply with this obligation. If HMC does not to honor its word, St. Francis Healthcare System would have no alternative but to pursue litigation for breach of contract.

Q. What would happen if St. Francis were to take back the hospitals?

A. If St. Francis regains control of the two hospitals and these bills become law, we would have to abide by our convictions and may have to reluctantly close our emergency rooms, even though we realized this would cause harm to our community since there would be fewer emergency rooms to serve Hawaii's people. This is especially important for Ewa hospital, which serves as a critical-access facility for West Oahu residents.

Q. Is cost of emergency contraceptives an issue for St. Francis?

A. Our understanding is that these abortifacients would be paid for by the State, Hawaii's taxpayers' money. At a time when the State of Hawaii is seeking ways to reduce costs because of budget constraints, it is puzzling why the legislature would want to have mandates that increase the costs for the State. Providing funding for emergency contraceptives as a way to ensure they are dispensed by healthcare

organizations is an irresponsible use of State funds, particularly if they can be obtained at another healthcare organization or over the counter at a drugstore.

Q. What would St. Francis like to see happen?

A. The core values of St. Francis are charity, peacemaking, simplicity and joy, and we base our operations on these values. We would like all bills that impose another set of values upon us be killed and never resurface. More than 125 years ago, the Sisters of St. Francis came to the Islands in response to a plea from King David Kalakaua to care for those with Hansen's disease. The Sisters have faithfully worked in collaboration with government leaders to deliver compassionate care and healing, affirming life wherever they go and with whomever they touch. Our desire is to continue carry on this long-standing tradition in the Islands.

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3 February 2010

Statement of Bishop Larry Silva on Emergency Contraceptives

As Bishop of Honolulu, I offer this statement with respect to proposed legislation which would require hospitals to provide information about emergency contraception to women who are sexually assaulted and to provide emergency contraception when requested. I respectfully request that you do NOT approve such legislation in any form, especially if it does not contain an exemption for the Hawaii Medical Center – and anyone else who shares its beliefs.

GOVERNMENT COMPULSION TO VIOLATE RELIGIOUS BELIEFS

First and foremost, we operate our hospitals guided by our belief that compassionate and understanding care should be given to sexual assault victims. At the same time, we are bound by ethical and religious principles which set forth the parameters of treatment.

Because of its religious tenets, the St. Francis Healthcare System does not provide abortion services, including "emergency contraception," which is almost always an agent of chemical abortion. A very large portion of the people of Hawaii, both Catholics and others, oppose abortion because it violates the human rights of unborn children. The "emergency contraceptive" is, in effect, a non-surgical method of abortion.

While it is true that the former St. Francis hospitals are now the Hawaii Medical Centers (HMCs), there are two crucial legal items that merit attention:

- St. Francis Healthcare System still owns the land upon which the HMC's operate.
- The legal relationship between HMC and St. Francis is governed by a contract binding HMC to operate the hospitals in a manner consistent with Catholic ethical and religious directives. Those directives prohibit complicity in the termination of life, beginning at the moment of conception, fertilization. Emergency contraceptives sometimes work post-fertilization, resulting in the termination of the new young life and the ending of the pregnancy. This violates a core religious directive. Passage of any legislation on emergency contraception would use government force to effectively compel St. Francis Healthcare Sytems to condone, on its own property, this procedure which can act as an abortifacient – something that would be directly contrary to St. Francis Healthcare System's beliefs in the sanctity of human life, contained in natural law and articulated clearly by our religious beliefs.

St. Francis has publicly stated in previous testimony that they will close existing emergency rooms rather than be forced to act contrary to their religious tenets. Although I oppose its use in any place, if you insist on passing such legislation, I urge you to allow at least the Hawaii Medical Center to honor the terms of its lease with the St. Francis Healthcare System by granting an exemption from the requirement that it dispense emergency contraceptives. It would be ironic if "pro-Choice" legislation were to eliminate a crucial choice of conscience.

FIRST AMENDMENT ISSUES AT STAKE - DISCONCERTING LEGAL PRECEDENT

One need not support the position of St. Francis and HMC on emergency contraception to support their rights to assist the community in a manner that comports with their religious beliefs.

If the government can compel that which religion prohibits in this instance, there is no legal or public policy justification left to stop this state legislature from requiring religious hospitals to perform surgical abortions, for example. Catholic hospitals must always be free to rely on the best and most up-to-date facts and the moral obligations those facts place on them in accord with their respect for nascent human life.

DIVERSITY & TOLERANCE ACHIEVED WITH A RELIGIOUS EXEMPTION

Indeed, the Hawaii legislature has recognized the importance of religious freedom protections as a part of otherwise generally applicable law. For example, Hawaii's employment non-discrimination law (H.R.S. 378-3) contains a religious exemption. This balance in the law reflects Hawaii's tradition of tolerance and pluralism. Through the religious exemption, consideration is given to diverse points of view.

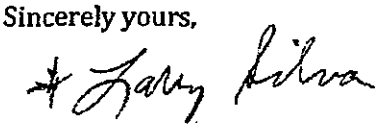
Legislation can be crafted to accommodate the broader public policy goal, while at the same time respecting the constitutionally protected sincerely held religious beliefs of others in the community. At issue is the balancing of rights – the constitutional right to freely exercise one's religion versus what some are hoping to make a statutory right to force religious institutions to violate their core beliefs. We believe that this right can be balanced through the adoption of a religious exemption.

RELIGIOUS EXEMPTION LANGUAGE

Consistent with the spirit and intent of a religious exemption, we submit that if such legislation is considered it should include a conscience clause protection covering those kinds of emergency contraception which are abortifacient. The text of such a conscience clause should read as follows:

"Nothing in this act shall compel a nonprofit hospital to provide any emergency contraception which has as its purpose or direct effect the removal, destruction or interference with the implantation of a fertilized ovum when such action violates its ethical, moral or religious beliefs, and the refusal to so provide shall not constitute grounds for civil or criminal liability, disciplinary action or discriminatory treatment."

Sincerely yours,



Most Reverend Larry Silva
Bishop of Honolulu

Today, a patient often receives health care from a team of providers, especially in the setting of the modern acute-care hospital. But the resulting multiplication of relationships does not alter the personal character of the interaction between health care providers and the patient. The relationship of the person seeking health care and the professionals providing that care is an important part of the foundation on which diagnosis and care are provided. Diagnosis and care, therefore, entail a series of decisions with ethical as well as medical dimensions. The health care professional has the knowledge and experience to pursue the goals of healing, the maintenance of health, and the compassionate care of the dying, taking into account the patient's convictions and spiritual needs, and the moral responsibilities of all concerned. The person in need of health care depends on the skill of the health care provider to assist in preserving life and promoting health of body, mind, and spirit. The patient, in turn, has a responsibility to use these physical and mental resources in the service of moral and spiritual goals to the best of his or her ability.

When the health care professional and the patient use institutional Catholic health care, they also accept its public commitment to the Church's understanding of and witness to the dignity of the human person. The Church's moral teaching on health care nurtures a truly interpersonal professional-patient relationship. This professional-patient relationship is never separated, then, from the Catholic identity of the health care institution. The faith that inspires Catholic health care guides medical decisions in ways that fully respect the dignity of the person and the relationship with the health care professional.

Directives

23. The inherent dignity of the human person must be respected and protected regardless of the nature of the person's health problem or social status. The respect for human dignity extends to all persons who are served by Catholic health care.

24. In compliance with federal law, a Catholic health care institution will make available to patients information about their rights, under the laws of their state, to make an advance directive for their medical treatment. The institution, however, will not honor an advance directive that is contrary to Catholic teaching. If the advance directive conflicts with Catholic teaching, an explanation should be provided as to why the directive cannot be honored.

25. Each person may identify in advance a representative to make health care decisions as his or her surrogate in the event that the person loses the capacity to make health care decisions. Decisions by the designated surrogate should be faithful to Catholic moral principles and to the person's intentions and values, or if the person's intentions are unknown, to the person's best interests. In the event that an advance directive is not executed, those who are in a position to know best the patient's wishes—usually family members and loved ones—should participate in the treatment decisions for the person who has lost the capacity to make health care decisions.

26. The free and informed consent of the person or the person's surrogate is required for medical treatments and procedures, except in an emergency situation when consent cannot be obtained and there is no indication that the patient would refuse consent to the treatment.

27. Free and informed consent requires that the person or the person's surrogate receive all reasonable information about the essential nature of the proposed treatment and its benefits; its risks, side-effects, consequences, and cost; and any reasonable and morally legitimate alternatives, including no treatment at all.

28. Each person or the person's surrogate should have access to medical and moral information and counseling so as to be able to form his or her conscience. The free and informed health care decision of the person or the person's surrogate is to be followed so long as it does not contradict Catholic principles.

29. All persons served by Catholic health care have the right and duty to protect and preserve their bodily and functional integrity.[16] The functional integrity of the person may be sacrificed to maintain the health or life of the person when no other morally permissible means is available.[17]

30. The transplantation of organs from living donors is morally permissible when such a donation will not sacrifice or seriously impair any essential bodily function and the anticipated benefit to the recipient is proportionate to the harm done to the donor. Furthermore, the freedom of the prospective donor must be respected, and economic advantages should not accrue to the donor.

31. No one should be the subject of medical or genetic experimentation, even if it is therapeutic, unless the person or surrogate first has given free and informed consent. In instances of nontherapeutic experimentation, the surrogate can give this consent only if the experiment entails no significant risk to the person's well-being. Moreover, the greater the person's incompetency and vulnerability, the greater the reasons must be to perform any medical experimentation, especially nontherapeutic.

32. While every person is obliged to use ordinary means to preserve his or her health, no person should be obliged to submit to a health care procedure that the person has judged, with a free and informed conscience,

not to provide a reasonable hope of benefit without imposing excessive risks and burdens on the patient or excessive expense to family or community.[18]

33. The well-being of the whole person must be taken into account in deciding about any therapeutic intervention or use of technology. Therapeutic procedures that are likely to cause harm or undesirable side-effects can be justified only by a proportionate benefit to the patient.

34. Health care providers are to respect each person's privacy and confidentiality regarding information related to the person's diagnosis, treatment, and care.

35. Health care professionals should be educated to recognize the symptoms of abuse and violence and are obliged to report cases of abuse to the proper authorities in accordance with local statutes.

36. Compassionate and understanding care should be given to a person who is the victim of sexual assault. Health care providers should cooperate with law enforcement officials and offer the person psychological and spiritual support as well as accurate medical information. A female who has been raped should be able to defend herself against a potential conception from the sexual assault. If, after appropriate testing, there is no evidence that conception has occurred already, she may be treated with medications that would prevent ovulation, sperm capacitation, or fertilization. It is not permissible, however, to initiate or to recommend treatments that have as their purpose or direct effect the removal, destruction, or interference with the implantation of a fertilized ovum.[19]

37. An ethics committee or some alternate form of ethical consultation should be available to assist by advising on particular ethical situations, by offering educational opportunities, and by reviewing and recommending policies. To these ends, there should be appropriate standards for medical ethical consultation within a particular diocese that will respect the diocesan bishop's pastoral responsibility as well as assist members of ethics committees to be familiar with Catholic medical ethics and, in particular, these Directives.

PART FOUR

Issues in Care for the Beginning of Life

Introduction

The Church's commitment to human dignity inspires an abiding concern for the sanctity of human life from its very beginning, and with the dignity of marriage and of the marriage act by which human life is transmitted. The Church cannot approve medical practices that undermine the biological, psychological, and moral bonds on which the strength of marriage and the family depends.

Catholic health care ministry witnesses to the sanctity of life "from the moment of conception until death."[20] The Church's defense of life encompasses the unborn and the care of women and their children during and after pregnancy. The Church's commitment to life is seen in its willingness to collaborate with others to alleviate the causes of the high infant mortality rate and to provide adequate health care to mothers and their children before and after birth.

The Church has the deepest respect for the family, for the marriage covenant, and for the love that binds a married couple together. This includes respect for the marriage act by which husband and wife express their love and cooperate with God in the creation of a new human being. The Second Vatican Council affirms:

> This love is an eminently human one. . . . It involves the good of the whole person. . . . The actions within marriage by which the couple are united intimately and chastely are noble and worthy ones. Expressed in a manner which is truly human, these actions signify and promote that mutual self-giving by which spouses enrich each other with a joyful and a thankful will.[21]
>
> Marriage and conjugal love are by their nature ordained toward the begetting and educating of children. Children are really the supreme gift of marriage and contribute very substantially to the welfare of their parents. . . . Parents should regard as their proper mission the task of transmitting human life and educating those to whom it has been transmitted. . . . They are thereby cooperators with the love of God the Creator, and are, so to speak, the interpreters of that love.[22]

For legitimate reasons of responsible parenthood, married couples may limit the number of their children by natural means. The Church cannot approve contraceptive interventions that "either in anticipation of the marital act, or in its accomplishment or in the development of its natural consequences, have the purpose, whether as an end or a means, to render procreation impossible."[23] Such interventions violate "the inseparable connection, willed by God . . . between the two meanings of the conjugal act: the unitive and procreative meaning."[24]

Drugs

FDA's Decision Regarding Plan B: Questions and Answers

Please see Questions and Answers, August 24, 2006 [1]

1. What is emergency contraception?

Emergency contraception is a method of preventing pregnancy to be used after a contraceptive fails or after unprotected sex. It is not for routine use. Drugs used for this purpose are called emergency contraceptive pills, post-coital pills, or morning after pills. Emergency contraceptives contain the hormones estrogen and progestin (levonorgestrel), either separately or in combination. FDA has approved two products for prescription use for emergency contraception – Preven (approved in 1998) and Plan B (approved in 1999).

2. What is Plan B?

Plan B is emergency contraception, a backup method to birth control. It is in the form of two levonorgestrel pills (0.75 mg in each pill) that are taken by mouth after unprotected sex. Levonorgestrel is a synthetic hormone used in birth control pills for over 35 years. Plan B can reduce a woman's risk of pregnancy when taken as directed if she has had unprotected sex. Plan B contains only progestin, levonorgestrel, a synthetic hormone used in birth control pills for over 35 years. It is currently available only by prescription

3. How does Plan B work?

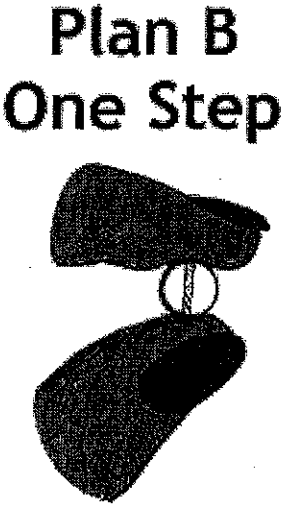
Plan B works like other birth control pills to prevent pregnancy. Plan B acts primarily by stopping the release of an egg from the ovary (ovulation). It may prevent the union of sperm and egg (fertilization). If fertilization does occur, Plan B may prevent a fertilized egg from attaching to the womb (implantation). If a fertilized egg is implanted prior to taking Plan B, Plan B will not work.

4. What steps did FDA take in considering switching Plan B from prescription to nonprescription (over-the-counter (OTC)) status?

FDA received an application to switch Plan B from prescription to nonprescription status. FDA staff reviewed the scientific data contained in the application which included among other data, an actual use study and a label comprehension study.

On December 16, 2003, we held a public advisory committee meeting with a panel of medical and scientific experts from outside the federal government. The members of the Nonprescription Drugs Advisory Committee and the Advisory Committee for Reproductive Health, met jointly to consider the safety and effectiveness data of nonprescription use of Plan B. Although the joint committee recommended to FDA that this product be sold without a prescription, some members of the committee, including the Chair, raised questions concerning whether the actual use data were generalizable to the overall population of nonprescription users, chiefly because of inadequate sampling of younger age groups.

Following the advisory committee meeting, FDA requested additional information from the sponsor pertaining to adolescent use. The sponsor submitted this additional information to FDA in support of their pending application to change Plan B from a prescription to an over-the-counter product. This additional information was extensive enough to qualify as a major amendment to the NDA. Under the terms of the Prescription Drug User Fee Act (PDUFA) performance goals, major amendments such as this may trigger a 90-day extension of the original PDUFA deadline.



Emergency Contraception

You can **prevent pregnancy *after* intercourse** by taking Emergency Contraceptive pill (also known as the Morning After Pill or EC). The most common is brand name "Plan B One Step."

Plan B, the one-step Emergency Contraception (EC) Pill, works by giving the body a short, high, burst of synthetic hormones. This disrupts hormone patterns needed for pregnancy. Plan B affects the ovaries and the development of the uterine lining, making pregnancy less likely. Depending upon where the woman is in her menstrual cycle, the hormones prevent pregnancy in different ways. It prevents ovulation (the egg leaving the ovary and moving into the fallopian tube). It blocks the hormones needed for the egg to be able to be fertilized. It may affect the lining of the uterus and alters sperm transport which prevents sperm from meeting the egg and fertilizing it.

EC may be effective up to **120 hours (5 days)** after intercourse. **But, it is most effective within the first 24 hours**. Emergency Contraception reduces the risk of pregnancy by 75 - 89%. EC does not protect against reproductive tract infections, including HIV/AIDS.

Use • Your Health • Side Effects • Danger Signs • Future Fertility Access • Advantages • Disadvantages • More Info • PDF Version

Use

Take as soon as possible and within 120 hours of unprotected intercourse. EC (plan B) may be taken after 120 hours, but its effectiveness is much lower.

If you vomit within a half hour, it might not work and you should take another dose. You might want to take it with food and some anti-nausea medication.

How Well Does It Work?

Morning-after pill

Definition

By Mayo Clinic staff

The morning-after pill is a type of emergency birth control that contains the hormone levonorgestrel, a progestin.

Plan B One-Step

The morning-after pill can be used after you've had unprotected sex. Depending on where you are in your menstrual cycle, the morning-after pill can prevent ovulation, block fertilization or keep a fertilized egg from implanting in the uterus. If you're already pregnant when you take the morning-after pill, the treatment will be ineffective and won't harm the developing baby.

Plan B One-Step and Next Choice are the only morning-after pills that