UNDER THE TABLE

Why the U.S. Food and Drug Administration Should Not Approve the Over-the Counter Distribution of Morning After Pills

Population Research Institute

Backgrounder No. 5

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Why the U.S. Food and Drug Administration Should Not Approve the Over-the Counter Distribution of Morning After Pills

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Executive Summary

In May 2004, the U.S. Food and Drug Administration will act on Women's Capital Corporation/Barr Laboratories application for over-the-counter (OTC) status for so-called "emergency contraception" (EC), the morning-after pill (MAP). Opposition to OTC/MAP involves moral and medical safety/efficacy issues, plus controversies concerning international organizations. Efforts in America to obtain OTC/MAP status are a final step in a coordinated campaign undertaken by international abortion advocacy/population control organizations.

Moral Concerns – Organizations both opposed to and in favor of OTC/MAP have acknowledged the importance of considering the abortion-inducing nature of MAP. Its abortion-inducing function was admitted openly at first by proponents of MAP. As moral opposition intensified, proponents generated new "studies" which attempted to question scientific evidence pointing to the abortion-inducing function of MAP. This moral controversy will worsen if OTC/MAP is approved.

Dangers of MAP – The dangers of MAP were ignored at the December 2003 FDA advisory committee meeting on OTC/MAP. Risks include: ectopic pregnancy; long-term use; pregnancy-related risks; risks of misuse and overdose; increased rates of STD/HIV infection; increased rates of induced abortion; increased rates of sexual violence, and risks associated with interactions with other drugs. Post-marketing surveillance of OTC/MAP will not mitigate these risks.

False and Provocative Advertising – Claims of widespread demand for OTC/MAP appear to have emerged almost overnight. For many years, however, global social marketing campaigns have been quietly laying this foundation. Ad campaigns include strategies to obfuscate its abortion-inducing nature, and make inroads into public school populations. Advertising themes, supported by both USAID and a host of international and domestic abortion groups, have ranged from promoting promiscuity to selling MAP as a solution to rape.

MAP and the International Controversy – In 1995, Dr. Sharon Camp, founder of FDA OTC/MAP applicant Women's Capital Corporation, convened global regional groups for MAP social marketing campaigns, pursuant to a consensus statement ratified by international abortion groups at a special conference in 1995 at Bellagio, Italy. The next year, an International Consortium at which USAID participated succeeded in securing the manufacture of MAP for social marketing worldwide. USAID-funded groups have promoted MAP, to girls as young as 10 years old, in nations where it is illegal to do so.

The Bush Administration should not permit MAP to become standardized by the Department of Health and Human Services. FDA approval for OTC/MAP status should be denied. In addition, the Bush Administration should not include MAP as a method of family planning in foreign programs because of its known health risks and because its action includes an abortion-inducing function.

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MORNING-AFTER PILL/ INTERNATIONAL ORGANIZATIONS TIMELINE

FDA's current consideration of Plan B's application for OTC status represents the final step in a worldwide campaign launched by international abortion advocacy/population control organizations a decade ago. The Consensus Statement on Emergency Contraception, produced at the 1995 Rockefeller Foundation summit in Bellagio, Italy, called for stimulation of demand for and acceptance of EC and specifically targeted adolescents for EC use.

1993—Princeton University Office of Population Research launched Emergency Contraception website with list of providers willing to prescribe MAP off-label.[1] [*Question: If MAP demand was driven by women as a health issue, why did EC promotion originate in a scholarly population research program?*]

1994—International Planned Parenthood Federation survey found that (a) providers are reluctant to offer emergency contraception fearing it would be linked with abortion; (b) their staffs are not trained to offer MAP; and (3) women have not requested MAP.[2] Demand would have to be generated.

1994—Cairo, Egypt "International Conference on Population and Development," marked a new era in strategies for worldwide population control by abandoning specific demographic targets and instead reframing population issues as a matter of individual rights, personal health and well-being, and national economic development.[3] The benefits of this strategy appeared almost immediately in the 1995 Bellagio meeting where the morning-after pill is framed as a women's health issue, thereby avoiding a perception of MAP as another coercive population control measure.

1995—Bellagio, Italy - Rockefeller Foundation held an international summit among seven abortion advocacy/population control groups.[4] Meeting was hosted by South-to-South Cooperation in Reproductive Health, a major international organization working to implement the Cairo Plan of Action, which calls for sexual and reproductive healthcare to be available to all, including adolescents.[5]

1995—Dr. Sharon L. Camp emerged at 1995 Bellagio meeting as "volunteer coordinator" for ongoing working group.[6] Dr. Camp's professional background is almost exclusively focused in population control organizations, with a special emphasis in reproductive health.

1995—Consensus Statement on Emergency Contraception[7] published in *Contraception* served as a rallying cry for international abortion advocacy/population control organizations to work cooperatively toward awareness and acceptance of MAP. Consensus Statement sets forth the international vision, focusing on: (a) increasing worldwide awareness of/demand for MAP; and (b) increasing worldwide access to MAP. Consensus Statement recommendations included targeting of adolescent populations and encouraging worldwide stimulation of demand for MAP.[8]
The Statement also called for data collection on MAP use.[9]

1995—WHO Model List of Essential Drugs added the combined estrogen-progestin (Yuzpe) regimen of the morning-after pill.[10]

1995 to 1996—International Consortium for Emergency Contraception became an international coordination vehicle Dr. Camp established as outcome of 1995 Bellagio meeting. Each region of the world established its own working group to promote MAP. Regions collaborated by sharing challenges and success stories via the international consortium. Thus, a highly questionable abortion advocacy/population issue was transformed at the local level into a "women's health" issue. Each region utilized different rationale to promote MAP by addressing specific regional/national/local concerns.[11]

1996—Postinor-2 morning-after pill became first MAP product developed by Gedeon Richter in consultation with International Consortium for Emergency Contraception.[12] Less than a year after Rockefeller Foundation summit in Bellagio, the International Consortium succeeded in securing the manufacture of a dedicated product for social marketing of MAP worldwide.

1996—Family Health International study outlined plan for *changing attitudes* towards MAP. Communicating with providers, policy-makers and women was identified as crucial step.[13] Study targeted adolescents as group in special need of MAP due to possible sexual assault or first sexual encounter.

1996—Kenya EC Consortium began pilot project for social marketing of MAP. Ministry of Health and public leaders anticipated community backlash and controversy, and asked the Consortium "to avoid media contact during the initial stages of the project." [14]

1996—Princeton University Office of Population Research launched MAP hotline 1-888-NOT-2-LATE.[15]

MORNING-AFTER PILL / INTERNATIONAL ORGANIZATIONS TIMELINE

1996 to present—Worldwide acceptance/demand for MAP continued to be stimulated through International Consortium on Emergency Contraception. Success stories and strategies were shared through global internet newsletter at ICEC's website.[16]

1997—WHO Model List of Essential Drugs added levonorgestrel (progestin) only regimen of the morning-after pill.[17]

1997—American Society for Emergency Contraception became U.S. "voluntary collaboration of organizations working to improve women's access to emergency contraception."[18] Influence of abortion advocacy/population control organizations was not obvious.

1997—Dr. Sharon L. Camp founded Women's Capital Corporation, a privately held for-profit corporation whose shareholders are mainly private foundations. WCC's corporate mission is to purchase existing, orphaned contraceptive technology avoided by mainstream pharmaceuticals due to fears of bad publicity.[19] WCC describes itself as "unique" among pharmaceutical companies in that "*financing for [WCC] came almost entirely from foundations and other non-profit organizations*."[20] Five Planned Parenthood affiliates made equity investments in Plan B.[21] Through WCC, the ideological goals of special-interest groups are masked and MAP issues are framed as science, medicine and women's health concerns, with little awareness of organizational involvement in WCC.

1997—George Soros, through his philanthropic Open Society Institute, provided $1.5 Million funding for WCC.[22] Open Society Institute Program on Reproductive Health and Rights promotes "the development of policies and practices to protect women's comprehensive sexual and reproductive healthcare, including abortion, both in the United States and in the countries and regions where the Open Society Institute operates."[23]

1997—Sri Lanka EC Consortium began pilot project for social marketing of MAP.[24]

1997—Princeton University's Office of Population Research launched first multimedia public awareness campaign in six U.S. cities.[25]

1997—FDA Declared morning-after pills safe and effective. According to International Consortium on Emergency Contraception, "The move is considered highly unusual. The FDA rarely sanctions a drug's use for new medical indications without an application from the drug's manufacturer."[26]

1997 to 2004—George Soros' Open Society Institute provided over $4.5 Million in funding for Emergency Contraception projects conducted by eighteen organizations.[27]

1998—Washington State became first state to allow women to get EC directly from pharmacist. Planned Parenthood announced "EC to Go," providing prescriptions in advance and over-the-phone.[28]

1999—Plan B approved for Prescription by FDA on July 28, 1999.[29]

2001—Center for Reproductive Law and Policy (now Center for Reproductive Rights, an abortion/reproductive rights advocacy group) petitioned FDA to switch MAP to OTC status.[30]

2002—California became second state to allow direct access to MAP through pharmacists.[31]

2002—FDA Issued Warning Letter to Women's Capital Corporation concerning unproven advertising/marketing claims.[32]

2003—Women's Capital Corporation filed for OTC Switch Status with FDA for Plan B only one year after FDA Warning Letter concerning unproven claims.[33]

2003—Alaska and New Mexico allowed pharmacist-direct distribution of MAP.[34]

2003—Women's Capital Corporation sold to Barr Laboratories for $24 Million plus retention of some sales rights in Canada.[35]

2004—Dr. Sharon L. Camp became Chief Executive Officer of Alan Guttmacher Institute after negotiating sale of Women's Capital Corporation to Barr Laboratories.[36]

2004—Women's Capital Corporation new chairman, Ellen Chesler, Ph.D. is senior fellow at George Soros' Open Society Institute.[37] Many non-profit organizations are WCC shareholders.[38]

2004—Private Foundations and certain abortion-providing organizations achieved significant returns on investment.[39] These abortion advocacy/population control organizations, with an ideological devotion to EC, provided the seed money for Women's Capital Corporation's acquisition of little-used contraceptive technology, orphaned because of its controversial nature.

(See page 40-43 for Timeline Endnotes)

Introduction

In May 2004, the Food and Drug Administration (FDA) will act on Women's Capital Corporation/Barr Laboratories' application for over-the-counter (OTC) status for so-called "emergency contraception" (the morning-after pill, MAP). Their submission, commonly called "Plan B," has been widely criticized on multiple grounds. Opposition to OTC/MAP status involves not only moral and medical safety/efficacy issues, but also a largely overlooked controversy concerning the international organizations behind this pressure for OTC/MAP status. In fact, current U.S. efforts to obtain OTC/MAP status are merely the final step in a coordinated worldwide campaign quietly undertaken by international abortion advocacy/population control organizations a decade ago.

Summary/Recommendations

We recommend that:

1. **The Bush Administration should not permit MAP to become a standard treatment for suspected pregnancy by the Department of Health and Human Services.**
2. **The FDA approval for OTC/MAP status should be denied.**
3. **The Bush Administration should not include MAP as method of family planning in foreign programs because of known health risks and because its action includes an abortifacient (abortion-inducing) function.**

Moral Concerns

- ***Abortion-inducing function*** – There are a host of moral concerns surrounding MAP itself, beginning with its abortifacient effect. Although the abortifacient function (prevention of implantation) of MAP is obscured in Plan B's submissions to FDA, The Plan B package insert admits MAP "may inhibit implantation (by altering the endometrium)."[1] Promoters of MAP decided upon a strategy to deny MAP's abortifacient effect in order to stifle moral opposition.[2] However, various studies and medical experts have confirmed MAP's abortifacient effect.[3] MAP is promoted by many organizations other than the manufacturers and these representations, more often than not, do not make clear MAP's abortifacient action.[4]

- ***Coercive violation of conscience*** – The proponents of Plan B have sought to define its abortifacient effect out of existence by redefining "conception" and "pregnancy" to begin at "implantation" rather than "fertilization."[5] This, in turn, permitted them to claim that MAP, which inhibits implantation, was merely "contraceptive" rather than "abortifacient."

  The stakes in these semantic games are about to be raised even higher. The science demonstrating MAP's abortifacient function cannot be forever disregarded. If Plan B is approved, tens of thousands of healthcare workers and facilities may find themselves pressured either to violate their consciences by stocking, dispensing, or selling MAP or face job dismissal.[6] In February 2004, three pharmacists working for Eckerd Pharmacy in Texas were fired after refusing to fill prescriptions for the morning-after pill. Eckerd does not allow pharmacists to refuse to fill prescriptions on religious, moral, or ethical grounds.[7]

- ***Violation of informed consent standard*** – Because Plan B patient information does not disclose clearly and unambiguously that MAP, by preventing implantation, is abortifacient, women by definition cannot provide informed consent.[8] Prescription-only MAP at least allows an opportunity for physicians to fully inform a woman of abortifacient action of MAP, which, in turn, allows her to object to its use.

- ***Women as guinea pigs*** – The December 2003 FDA advisory committee meeting revealed that certain

MAP research issues were not resolved. These include evidence on long-term safety, especially as to ectopic pregnancy; safety in pregnant women and MAP-exposed fetuses; use as primary form of contraception; change in contraceptive practices; change in rates of STD/HIV or induced abortion; adolescent patterns of use/abuse; safety in adolescents; and interactions with other drugs.[9] To leave such vital questions for post-marketing surveillance amounts to what the U.S. Conference of Catholic Bishops calls, "reckless experimentation on women."[10] In fact, Plan B's own medical expert once admitted in an interview that certain postmarketing studies would amount to "an ecological fallacy."[11]

- ***Circumvention of parental consent/notification*** – Minors have access to contraception without parental involvement, but many states have parental consent/notification laws for abortion. Labeling MAP as non-abortifacient blurs these lines and circumvents the intent of legislators that parents be involved in decisions having to do with the abortion of their children and grandchildren.[12] In fact, medical articles and school programs even encourage strategies to prevent parental knowledge of MAP use by their own children.[13]

- ***Societal abandonment of sexually assaulted women*** – OTC/MAP status is falsely promoted as appropriate treatment for rape/involuntary sexual intercourse.[14] Emotional/physical/spiritual support for sexually abused women is complex. OTC provision of MAP does not address these needs adequately and constitutes societal abandonment of abused women—a moral failure.

- ***Lowered threshold for refusal of sexual pressure*** – Numerous studies indicate that adolescents often succumb to pressure to engage in sexual acts against their own desires.[15] OTC/MAP will increase pressure on adolescents who attempt abstinence because OTC/MAP removes barriers such as: hesitation to ask for contraception, possibility of parental/physician oversight, and reduction in perceived fear of pregnancy/need for induced abortion. Potential sexual partners will exploit these perceptions to exert increased pressure upon abstinent youth.

- ***Potential Public Funding Issues*** - Plan B's distributor, Women's Capital Corporation, may rejoin the Medicaid program in the future, which would effectively force taxpayers who object in conscience to abortifacient contraception to subsidize MAP's routine use.[16] In some instances, MAP may already be publicly funded.[17] Objections to Title X funding for MAP were anticipated in early articles promoting MAP.[18]

General Comments and Concerns

MAP does not protect against HIV and other STDs. MAP by prescription insures at a minimum that a physician can provide oversight for STD risk, testing, and treatment.

Oversight by medical professionals ensures that MAP does not become routine method of contraceptive use.[19] The cost of OTC/MAP is an insufficient barrier against misuse in light of provocative advertising campaigns and adolescent tendency towards risky sexual behavior and "self-deception."[20] MAP appeals psychologically because it requires neither a conscious decision to remain abstinent nor advance planning for a sexual act.[21]

A World Health Organization study expressed concern over the fact that married women use abortion in order limit family size, even in countries where fertility regulation methods are easily available.[22] This disturbing situation suggests that legalized abortion has changed sexual attitudes/behaviors, resulting in high rates of unintended pregnancy, abortion, and HIV/STDs.[23] However, WHO did not question the legalization of abortion as a causative factor, but merely concluded that such abortions indicate need for greater contraceptive options; MAP emerged as most promising new option.

Divergent views about cause-and-effect of increase/decrease in abortion rates indicate the need for long-

term, in-depth study. If changed sexual behaviors and attitudes are in fact statistically linked to increased HIV/STD and abortion rates, then it is reasonable to conclude that OTC/MAP status will further coarsen sexual behaviors and attitudes, resulting in increased rates of HIV/STD infection and abortion. Approving OTC/MAP status without such studies would endorse unproven, unstudied *assumptions* about MAP based on little more than wishful thinking. These assumptions may ultimately be proven erroneous as the great social experiment of MAP plays out—at great personal cost—in the lives of the adolescents, women, and families who will become unwitting "guinea pigs."

Women's risk of future psychological trauma is increased by lack of informed consent.[24] Since Plan B marketing/packaging does not clearly and unambiguously reveal its abortifacient function, women may not realize that MAP can act to expel a new developing human being at the time of implantation. At a later stage in life, women may feel deep regret and guilt. If infertility issues develop, such women may berate themselves, wondering if MAP perhaps destroyed the only child(ren) they ever conceived. For some women, these grief issues may become so profound that counseling or treatment for clinical depression may be necessary.

At the 2000 meeting of the American Pharmacists Association, the House of Delegates adopted a policy that, "The American Pharmacists Association supports the voluntary involvement of pharmacists, in collaboration with other health care providers, in emergency contraceptive programs that include patient evaluation, patient education, and direct provision of emergency contraceptive medications."[25] This at least would facilitate informed consent and help avoid future psychological trauma for uninformed women. Others, including the Plan B website itself, have discussed the important role of pharmacists in overseeing patient use of MAP.[26]

Social Marketing to Create a Worldwide Demand for MAP

Dr. Sharon L. Camp (former coordinator of the International Consortium for Emergency Contraception, founder of Women's Capital Corporation and current Chief Executive Officer of Alan Guttmacher Institute) described how 15 developing countries were targeted to introduce MAP in 1996: "The thing that has surprised us the most is the extraordinary level of interest in these methods and the relative lack of controversy."[27] By quietly targeting developing countries eight years ago, MAP was largely overlooked in the U.S. where it was perceived as a sexual assault treatment by medical professionals in a hospital setting. Foreign countries' experiences in social marketing of MAP provided a roadmap for others.[28] From the inception of MAP's social marketing campaign, objections to MAP were anticipated by international experts.[29]

According to a member of the American College of Obstetricians and Gynecologists "Time is of essence for women who need emergency contraception, yet many pharmacies refuse to provide it or they don't know about it." Should it be sold as an over-the-counter drug? The FDA will decide in May 2004

Within the U.S., a seeming demand for OTC/MAP appeared to burst forth suddenly as a purported major public health issue only a year ago. In fact, "social marketing" initiatives had been laying the groundwork for what was later portrayed as a women's health imperative. Social marketing purports to "influence social behaviors not to benefit the marketer, but to benefit the target audience and the general society."[30] Of course,

the crucial question in social marketing is: *Who* decides which *social behaviors* will benefit the *target audience* and *general society*? With regard to MAP, it is abortion advocacy/international organizations who are targeting young women, especially adolescents, with a new abortifacient product, under the pretext that widespread use of MAP will benefit all of society. These unproven assumptions portend a medical and social experiment of historic proportions upon adolescent girls and women.

The International Consortium for Emergency Contraception adopted a "unique collaborative approach" to promote MAP worldwide through "an unprecedented partnering of international organizations and a private-sector pharmaceutical company."[31] The Consortium's approach was unique because "never before had a group of organizations come together around this compelling health issue, formed a plan to address it, and gone to donors seeking support." In fact, "by joining forces to implement the project, the [Consortium] group achieved a level of influence that exceeded that of the sum of its individual members." Since no single Consortium member took a lead, "donors were very responsive to this model of collaborating, noting that 'it was exciting to see Consortium members work together toward a common goal and not compete with each other.'" As one Consortium member stated, "If the various member organizations had just done their own thing, we would not have advanced the cause of emergency contraception so quickly."

A frequent theme in International Consortium for Emergency Contraception efforts is the absolute necessity of distinguishing MAP from abortifacient methods of contraception.[32] In fact, the abortifacient issue had been identified as a potential problem at an international strategy meeting even prior to the formation of the International Consortium for Emergency Contraception.[33]

The Consortium also recognized that opposition to MAP could result from concerns that MAP would increase STDs and/or cause women to abandon other contraceptives.[34] As controversy and opposition have increased, counterstrategies continue to be developed to "build strategic alliances, mobilize market demand, educate and communicate with consumers, and use innovative delivery mechanisms to help manage controversy and/or to make contraceptive products available to consumers in spite of controversy."[35]

Although packets of regular oral contraceptive pills were being divided and used as MAP, the lack of a dedicated MAP product or brand name hindered social marketing efforts. The Consortium's first task was to "convince a manufacturer" to "create a dedicated product for emergency contraception (based on proven formulations), seek registration of this product in selected developing countries, and provide a preferential price to public-sector agencies wishing to purchase the product in these countries."[36] Numerous manufacturers were consulted but only one, Gedeon Richter, Budapest, Hungary, proved willing.

With a dedicated brand name product available, the Consortium designed a "basic introduction framework" for social marketing of MAP in four selected countries: Kenya, Sri Lanka, Mexico and Indonesia. Two of the steps in this framework included: (a) building in-country support for MAP; and (b) claiming that MAP is not abortifacient.[37] Successes in these countries were expanded upon as social marketing of MAP quickly spread around the world.

Medical Efficacy

Unproven Claims Concerning MAP's Prevention of Induced Abortions

1. *Claims Made by Alan Guttmacher Institute in 2001*

A 2001 Alan Guttmacher Institute (AGI) study states that no conclusions can be made about the impact of MAP on abortion rates in Washington State, home of the first U.S. pharmacy-direct access to MAP. "If the increased accessibility of emergency contraception reduces unintended pregnancy, there should be evidence of reduced pregnancy and abortion rates. To be sure, abortions in Washington reached the lowest level in two decades ... . However, the national abortion rates were also declining during this period, reaching their lowest levels since 1978. **Therefore, before one can make a definitive statement about whether improved access**

to emergency contraception can reduce pregnancy and abortion rates, it is necessary to observe a longer period than is currently possible, as well as to conduct research that controls for all potential confounding variables." [Emphasis added.][38] This study is based on data from a pilot project examining 11,969 prescriptions from 130 pharmacies. The pilot project was clearly designed, carefully controlled, involved close coordination and feedback among participants, and provided many opportunities for data quantification.

2. *Claims Made by Alan Guttmacher Institute in 2002*

Only one year later—as efforts were intensifying to make MAP available OTC[39]—a 2002 study by the Alan Guttmacher Institute made broad claims that MAP use nationally prevented 51,000 induced abortions in 2000. Of course, this claim disregards early abortions induced by the morning-after pill itself. AGI's new claim is based on an analysis of a national survey of 10,000 women obtaining abortions in 2000-2001.[40]

3. *Analysis of 2002 Contraceptive Use Study by Alan Guttmacher Institute*

Claims that OTC/MAP will cut in half the number of induced abortions resonate powerfully with many health professionals. Therefore, it is important to carefully examine the methodology, findings, and conclusions of the 2002 AGI study claiming that MAP prevented 51,000 induced abortions. (It should be noted that the methodology of the 2002 study, as explained below, stands in marked contrast to the 2001 study which drew no conclusions about MAP's role in reducing abortion rates.)

Study Methodology

The 2002 AGI Contraceptive Use study provided a self-administered questionnaire at 100 abortion facilities, usually completed by the woman ***while she waited for her abortion***. There were 10,683 usable questionnaires returned to AGI and, assuming a representative sample, national estimates were made concerning prevented abortions.[41] Study data were gathered under circumstances of extreme stress, emotion, and possible confusion. One can hardly imagine a survey environment less conducive to collecting reliable data than a self-administered questionnaire completed by a woman waiting for an abortion procedure. Collecting what amounts to market research data under such conditions appears callous and extremely insensitive to the women involved.

The Contraceptive Use study repeatedly explained that inferences were drawn concerning study data and, where data were missing from questionnaire responses, the survey authors **"examined responses to other relevant questions when possible; otherwise, [they] imputed missing items."**[42] Naturally, a methodology of "imputing" missing data is highly troubling, especially considering that this is one study upon which are based claims that MAP will cut abortion numbers in half. And this claim, in turn, is pivotal to a major national policy decision concerning OTC/MAP.

The study does not explain **how much** data were imputed, although it does describe how data were imputed:[43]

- Some missing data were imputed based on "responses given by women with similar characteristics" by using a "hot-deck" procedure. Data were cross-tabulated to identify variables most strongly associated with missing item. Respondents were sorted so that similar cases were adjacent to each other. "A missing value was then replaced by the value of the preceding case in the file with available data," according to the study.

- Other missing data were imputed on a case-by-case basis, presuming that "women who did not provide responses to these items resembled women who did provide responses."

- Data on contraceptive use were imputed for 12% of aborting women who reported using more than one method. For 5%, the data were imputed based on answers to other questions by same survey respondent; for 7%, the study "assumed that [they] had been using the most effective method they

reported."

The aborting women were asked "whether they had used emergency contraceptive pills to prevent the current pregnancy."[44] The survey instrument itself is not provided within the article, so it is unclear whether this question was left vague and open to individual interpretation or whether the actual questionnaire clearly explained what was meant by "emergency contraceptive pills." In 2000-2001, this term might have had a wide variety of meanings to different women, especially adolescents and women of low-literacy levels and/or non-English speaking. Even health food stores sell herbs that could be considered "emergency contraceptive pills" in some cultural contexts and by adolescents.

The study found that 1.3% of the 10,683 aborting women surveyed reported use of MAP.[45] The study concluded that nationwide, 1.3% would represent 17,000 women obtaining abortions that year. However, if the MAP question was misunderstood and answered incorrectly, or if the survey authors incorrectly "imputed" responses to this question, then this estimate of MAP use is not reliable.

The study then claimed that MAP use had prevented 51,000 induced abortions, by relying on an estimate by Dr. James Trussell that for every MAP failure resulting in pregnancy, three unintended pregnancies are avoided.[46]

Non-Use of Contraception

AGI's Contraceptive Use study found that MAP had been used by only 3% of women who had experienced condom breakage, 2% of inconsistent condom users, and 1% of inconsistent pill users.[47] Since OTC/MAP is promoted primarily for a "contraceptive accident," such low rates of MAP usage for that purpose appear to call into question the true importance of MAP for "contraceptive failure."

AGI's Contraceptive Use study found that 35% of aborting women who used MAP had not used any birth control method in the month they became pregnant

AGI's Contraceptive Use study found that 35% of aborting women who used MAP *had not used any birth control method in the month they became pregnant.*[48] This high percentage of non-use contradicts claims made by advocates for OTC/MAP that MAP is reserved for use after sexual assault and "contraceptive accident."

However, actual non-use of contraception by MAP users may be even higher than 35% for a number of reasons. The Contraceptive Use study indicated that:

- A survey question about "last method used" for contraception did not include MAP as a category, which may have led to confusion in responses: "Some women who indicated both use of emergency contraception and pill use may have used only emergency contraceptive pills."[49]

- The study changed how data were tabulated for women who confusingly "reported both that they had used a contraceptive method in the month they became pregnant and that they had stopped method use before becoming pregnant." In previous Alan Guttmacher Institute studies, such women were classified as "non-users" of contraception; in this study, such women were classified as "users" of contraception.[50]

- "Withdrawal" and "periodic abstinence" were counted as methods of contraception.[51] Most persons would not classify either "withdrawal" or "periodic abstinence" as contraception in the sense that such

should be included in studies of contraceptive/MAP use/nonuse patterns and rates of abortion.

- Confusing and somewhat arbitrary guidelines were established for what was considered a "use" of contraception during particular time periods.[52] For example, women were considered to have been contraceptive users if they had been using contraception *during the calendar month* in which they became pregnant (apparently at any time during that month) and had not *intentionally* stopped doing so before becoming pregnant. Apparently, if a woman *unintentionally* stopped using contraception, she was counted as a contraceptive user.

- Women who were not sure of date of conception were counted as users of contraception if they used contraception up until *three months before the abortion*.[53] In other words, a woman obtaining an abortion on March 31 apparently would have been counted as a contraceptive user even if she had stopped using contraception on January 1.

Unreliability of 51,000 Figure

Even the Contraceptive Use study itself qualified its claims that 51,000 induced abortions had been prevented by admitting that if MAP *had not been used correctly*, the number of prevented induced abortions would be lower than the 51,000 estimate.[54] Yet the 51,000 figure is repeatedly referenced in medical and media reports as if it were a proven fact.

Considering the grave importance attributed to claims that MAP prevents induced abortion, it is reasonable to call into question the data underlying that assumption. As described above, the way in which data were collected, tabulated, imputed and interpreted may have resulted in an unwarranted and unprovable claim that 51,000 induced abortions were prevented by MAP in 2000-01.

4. *Additional Unproven Claims Concerning MAP's Prevention of Induced Abortion*

An MAP researcher stated in a recent abstract for a presentation to the American Public Health Association that "No studies to date have demonstrated reductions in unintended pregnancy rates among women who have easy access to emergency contraception."[55] This study was supported by a research grant from Women's Capital Corporation, manufacturer of Plan B.

Despite this statement that *no studies* have proven a reduction in unintended pregnancy rates, conflicting claims have been made—even by the manufacturer of Plan B, Women's Capital Corporation/Barr Laboratories. The Plan B Briefing Document submitted to the FDA advisory committee in December 2003 stated that "up to 70% of unintended pregnancies" could be prevented by the morning-after pill.[56]

At the FDA advisory committee meeting on December 16, 2003, Dr. Carole Ben-Maimon, representing Plan B's manufacturer, gave a different figure. She stated, "It is estimated that up to 50 percent of [unintended] pregnancies could be prevented with greater access and use of emergency contraception."[57]

David A. Grimes, MD, a presenter on behalf of Plan B's manufacturer before the 2003 FDA advisory committee, made a very specific correlation between MAP and induced abortion: **"[D]espite limited use of emergency contraception, it has averted over 50,000 abortions that would have taken place without its use. Think what we can do together with easier, wider access to this safe product."[58]**

However, Dr. Grimes had stated an apparently contradictory position during a 2002 media interview when he said that no study could correlate OTC/MAP with any change in rate of unplanned pregnancy or STD infection: **"How would you do such a study, and how would you interpret the results? Finding a change in rate of unplanned pregnancy or of STD and attributing it to OTC availability of EC would be an ecological fallacy. That would be like finding that the number of telephone poles in a city is correlated with the number of heart attacks, and concluding that telephone poles cause coronary artery disease."[59]**

Dr. Grimes is a notorious abortionist who once worked at the Midtown Hospital in Atlanta, an abortion-only facility that was shut down after 14 babies were born alive following failed abortions.[60]

Conflicting reports concerning MAP's impact on induced abortion rates continue. A new Alan Guttmacher Institute report claims that 43% of the decline in abortion from 1994 to 2000 is attributable to MAP use.[61]

5. *Claims that MAP Prevents Three Induced Abortions for Each Failure Resulting in Pregnancy*

MAP efficacy studies and media reports rely on an estimate that for every MAP failure resulting in pregnancy, three pregnancies/induced abortions are prevented. Considering claims that MAP can cut in half the number of induced abortions, it is most vital that this 75% effectiveness claim be carefully examined.

At the December 2003 FDA review committee hearing, Dr. Chris Kahlenborn made the following observation during the public comment portion of the hearing: "The claim that emergency contraception has a 75 percent efficacy rate could be artificially inflated since it is based on studies whose control groups are not properly matched against the case groups. Usually older control groups or control groups that had lower rates of infertility are not properly matched. That would overinflate the statistic."[62]

When Dr. David Grimes, a presenter for Plan B's manufacturer, represented to the FDA advisory committee that over 50,000 abortions had been prevented by MAP, he was relying on the Alan Guttmacher Institute study.[63]

In turn, the Alan Guttmacher Institute study relies on the James Trussell report, "Updated Estimates of the Effectiveness of the Yuzpe Regimen of Emergency Contraception," to support a claim that three abortions are prevented for every MAP failure resulting in pregnancy.[64] In 1999, Dr. Trussell examined eight different MAP regimens and described MAP's effectiveness as ranging from 63.7% to 86.8%:[65]

- In explaining the wide divergence, Dr. Trussell stated that, "this considerable variation may be attributable to several sources: chance, differences in underlying fecundity (perhaps due to ethnic origin), differences in the interval between unprotected intercourse and treatment, differences in completeness of reporting of pregnancy following treatment, or . . . differences in the proportions of women pregnant at treatment or becoming pregnant from acts of intercourse in the same cycle subsequent to treatment."[66]

- It is possible that MAP efficacy estimates are too high because certain conceptions and pregnancies were not included in existing studies. This is evident from how pregnancy is defined in a study by Dr. James Trussell: "conception is used synonymously with implantation, not fertilization."[67] This, of course, lies at the very heart of the dispute over whether or not MAP has an abortifacient (abortion-inducing) effect and all the moral implications and controversies thereof. If MAP has no abortifacient effect, then this controversial, modified definition of "conception" would not be necessary.

- Raw data for each of the studies analyzed by Dr. Trussell yielded an MAP efficacy rate significantly lower; Dr. Trussell's overall calculated estimate was 74.1%, while the raw data yielded a figure of 65.7%.[68]

- The studies involved "were not comparing contemporaneous cohorts and controls. This major design problem may render the conclusions of the studies uncertain," according to a 2002 analysis published in *The Annals of Pharmacotherapy*.[69] First, infertility rates were lower in 1960s than in recent years; therefore, "the rate of infertility would be expected to be lower for the [historical control study] than for the study cohorts (women using EC)." Second, there were differences among exclusions for serious chronic illness or history of fertility problems. "It is therefore probable that both of the historical control studies had a lower rate of infertility than the case studies. If this is true, then studies

of EC use that employ historical controls for comparison may overestimate the effectiveness of EC use in preventing or ending a pregnancy."

- Additionally, the study's results may have been affected by using a historical control comprised of women who were not seeking to prevent or end pregnancy (in fact, some were attempting to achieve pregnancy) compared to women under the stress of an unwanted pregnancy for which they used MAP. "Fertility rates in each group may have varied markedly, because it is possible that under extreme stress, the secretion of ovulatory hormones from the pituitary gland could be inhibited."[70]

- Finally, all of the MAP studies in Dr. Trussell's analysis "are based on a fixed timing of ovulation relative to cycle length (e.g., 14 d before the next menstrual cycle). However, the length of the luteal phase varies significantly, both between women, and to a lesser extent, within the same woman . . . ."[71]

One study questioning reliability of MAP efficacy data found that "calculations [of the efficacy of MAP] are likely to be inaccurate for a significant minority of women."[72]

Another study matched menstrual data with hormonal measurements in an attempt to better determine the efficacy of MAP.[73] This study acknowledged that MAP's "real effectiveness remains uncertain. . . . Effectiveness has to be estimated indirectly." This study concluded that, **"Hormonal studies suggest that methods based on pregnancy risk calculated by cycle day do not faithfully reflect the real exposure. . . .** The effectiveness of postcoital contraception remains elusive to ascertain." [Emphasis added.]

Although the menstrual data study suggested that the efficacy of MAP may be higher than reported previously, the study noted that an unusually large number of women in the study received MAP within 24 hours following sexual intercourse and that this "could explain the high effectiveness rate of the treatment in this study."[74]

The menstrual data study does not replicate OTC/MAP usage in that it excluded women who likely will be MAP users in an OTC setting. For example, **t**he study excluded women who requested MAP more than 72 hours after sexual intercourse, women with irregular menstrual cycles, women taking drugs able to modify the metabolism of hormones, women in the puerperal or post-abortion period or lactating women, women reporting unprotected sexual intercourse more than once in that cycle, women who did not comply with treatment regimen, and women lost to follow-up.[75] With unrestricted access in OTC setting, the efficacy of MAP would likely be lower than current estimates.

The International Consortium for Emergency Contraception now recommends MAP usage up to 120 hours after intercourse even though it acknowledged that studies show "a significant trend towards a lower efficacy the longer the delay between treatment and unprotected intercourse."[76] MAP advertisements and pharmacy-direct protocols now specify 120 hours as a time limit.[77] Actual OTC/MAP usage, therefore, is likely to result in efficacy rates *lower* than current estimates of 75%. Furthermore, since pregnancy is more likely to result under a longer timeframe for MAP use, the 120-hour recommendation may actually result in an increased number of abortions; those women who rely on MAP may not wish to risk fetal abnormalities. In clinical trials, most women who became pregnant obtained abortions.[78]

The 1998 World Health Organization Randomized Trial Study (considered a pivotal study) claimed that the levonorgestrel regimen was 85% effective in preventing pregnancy.[79] However, this rate of efficacy is not likely in OTC context since the WHO study excluded women who likely will take MAP in OTC setting. For example, the WHO study excluded: women already pregnant; women with irregular menstrual cycles; women who had more than one act of unprotected intercourse during last menstrual cycle prior to MAP use; women who had sexual intercourse more than 72 hours prior to MAP treatment; women who took the second dose of MAP more than 24 hours after the first dose; women who had used regular oral hormonal contraception since last menstrual cycle; women who used regular oral hormonal contraception later in that menstrual cycle;

women recently pregnant; breastfeeding women; women with contraindications to regular oral hormonal contraception; women uncertain about date of last menses; women who had additional acts of sexual intercourse (with or without barrier protection) prior to next menses. Clearly, women in all these situations will use OTC/MAP and the effectiveness in preventing pregnancy will likely be much lower than 85%.

The Plan B Briefing Document submitted by Women's Capital Corporation stated that postmarketing surveillance data probably *understate* numbers of unintended pregnancies because pregnancy "is not usually considered a serious or unexpected adverse event, but a product failure." [80]

Not all researchers deny MAP's abortifacient effect. A 1999 study actually described "the optimal contraceptive method as one which disturbs endometrial development enough to prevent implantation without affecting ovulation and thus the bleeding pattern."[81] Clearly, this describes an abortifacient. In this particular study, 0.5 mg mifepristone (RU-486) was used daily as a contraceptive (or an abortifacient in the event fertilization occurred). Significantly, the study utilized the same markers for measuring endometrial receptivity (which determine whether a particular contraceptive has an abortifacient effect) that other MAP researchers have used.

By December 2002, almost two years after the Center for Reproductive Rights (formerly the Center for Reproductive Law and Policy) had petitioned the FDA for OTC/MAP approval, an International Planned Parenthood Federation study stated there was "no evidence that EC pills prevent pregnancy by interfering with implantation of fertilized eggs."[82]

Usage Concerns

Usage Data on Plan B - Inadequate/Contradictory/Troubling

1. *Plan B Actual Use Study*

The Briefing Document submitted by Plan B's manufacturer to FDA reveals some significant limitations in any attempt to apply the study's findings to the general population:

- 40% of the women participating in the Actual Use Study had used the morning-after pill previously; 14% of the women had used MAP more than once previously.[83] In comparison, only 6% of women nationally have ever used MAP.[84] Therefore, Plan B Actual Use study did not simulate OTC environment.

- 94% of women in Actual Use Study were recruited from family planning clinics.[85] This does not simulate MAP's actual use OTC environment, which is more likely to attract new users, including especially young adolescents.[86]

FDA's Executive Summary of the Actual Use Study noted additional limitations as follows:[87]

- Women were observed for only four weeks; this does not predict long-term use or patterns of re-use.

- Only 5% of the women were aged 14-16; This small sample size precludes conclusions about this population group.

- Upon enrollment, women were allowed to purchase only one package of Plan B. They could not purchase additional package of Plan B unless they re-enrolled. This requirement minimized the number of women who otherwise might have re-used MAP.

2. *Frequency of Use/Repeated Use*

Many pro-OTC/MAP organizations strongly advocate for unlimited, unquestioning, non-judgmental

provision of MAP to any adolescent or woman upon request. One advocacy group promoting MAP for adolescents stated that, "a recent article about repeated use concluded that it is reasonable for women who have infrequent sex to use [MAP] as a primary method of birth control."[88]

No limit of any kind is stated or recommended on Plan B website. Instead, Plan B's clinical information for health professionals states, "Plan B can be provided as frequently as needed."[89] Considering that more income is generated by repeat sales, the vague caution, "not for routine use," appears quite meaningless in light of "can be provided as frequently as needed."

Plan B's claim that it may be used "as frequently as needed" contradicts some studies which placed a maximum usage of "four times a month. That means that women with regular intercourse should choose another method."[90] However, these high limits or lack of limits contradict the general public's perception that MAP is for emergency use only, such as "contraceptive accidents" or sexual assault. Moreover, MAP usage at four times per month would result in a questionable level of exposure, according to an International Consortium for Emergency Contraception policy statement.[91]

The International Consortium for Emergency Contraception's policy statement on repeated use of the morning-after pill recommends, "Medical and behavioral research conducted to date does not provide any basis for limiting the number of times that women use ECPs, in a year or in a month. . . . *Women should use ECPs as often as needed.*" [Emphasis added.][92]

A World Health Organization study found that routine postcoital contraception (levonorgestrel 0.75 mg) was "unsuitable primarily because of the high incidence of cycle disturbances."[93] David A Grimes, MD, himself an abortionist, was a presenter for Plan B's manufacturer before the FDA advisory committee in December 2003. Grimes had previously acknowledged in a 2002 media interview that MAP has a powerful effect on women's menstrual cycles: "Repeated use of EC *wreaks havoc* on a woman's cycle, so the resulting *menstrual chaos* acts as a powerful deterrent to using this method too often." [Emphasis added.][94] Dr. Grimes may speak authoritatively concerning "menstrual chaos" caused by MAP, but his conclusion that this is a powerful deterrent to routine use of MAP is personal speculation.

Dr. Carole S. Ben-Maimon, president and COO of Barr Research and Plan B manufacturer's representative

A conference presentation by a director of a family planning clinic described a social marketing program that introduced MAP in Albania. The clinic director described Albania as a "pronatalist" country with a low Contraceptive Prevalence Rate at 15%.[95] Although she supported MAP, the clinic director lamented that young people especially "use it [MAP] every time they have sexual intercourse."

Statistics quoting rates of MAP use and repeated use in pharmacy-direct states (such as Washington, California and New Mexico) do not simulate OTC/MAP environment. **Pharmacists' assessment tools or screening checklists (called "encounter forms") used in all three states collected personal information including woman's name, address, telephone number, age, and personal questions about contraceptive use, possible STDs, and reasons for requesting MAP.[96]** Clearly, the requirement to answer such questions created a disincentive for MAP use/repeat use, especially among adolescents. Such disincentive will be non-existent under OTC/MAP conditions.

Plan B manufacturer's representative, Dr. Carole Ben-Maimon, described these pharmacist assessment

tools as "significant barriers" to access to MAP.[97] It is not clear why assessments by trained medical professionals should be considered *barriers* rather than helpful and necessary safeguards for women's health and safety.[98] At the December 2003 review committee meeting, Dr. Ben-Maimon was asked about situations where pharmacists did not dispense MAP: "What reasons [did] they give that they don't fill the prescription? Do you have that any of that type of information?" Dr. Ben-Maimon replied, "The women may not meet the criteria."[99]

3. *Contraceptive Behavior Affected by MAP Use*

In discussing changes in contraceptive practices, the Briefing Document submitted by Plan B's manufacturer stated that "the change to OTC availability of Plan B *should not* encourage the inappropriate use of this product . . . ."[100] [Emphasis added.] Dr. David A. Grimes stated in regard to concerns that "easy access to [MAP] . . . would in some way sabotage or undermine ongoing traditional contraception, . . . there are studies around the world refuting this. It doesn't happen."[101]

However, these studies appear to have little relevance to OTC/MAP setting. Eight literature reports regarding contraceptive behavior submitted by Plan B's manufacturer were critiqued by Dr. Jin Chen, FDA medical reviewer.[102] Dr. Chen described these behavior studies as having limitations relevant to OTC/MAP in that: all studies were conducted in clinics rather than simulated OTC setting; all of the study subjects received MAP education; three studies were conducted in foreign countries; most of the studies were not randomized (using a random number generator); and six of the studies provided only one course of MAP in advance.

An FDA Clinical Review on contraceptive behavior and Plan B reported that one study "suggests that the advance, pharmacy and standard EC access groups plus EC education had . . . a decrease in condom use."[103] This study was sponsored by Women's Capital Corporation. Since condoms offer some protection against the transmission of HIV/STDs, this trend away from condom use may result in increased rates of HIV/STD infection.

The FDA Clinical Review on contraceptive behavior and Plan B also reported that "women with advance EC access are more likely to use less-effective contraception." Another U.S. study showed "higher frequency of missing oral contraceptive pills in subjects provided with advance EC than those in control."[104]

4. *Potential for Misuse/Overdose*

In a 2002 media interview, Dr. Grimes, vice president of Biomedical Affairs, Family Health International, had been asked some critically important questions about how likely OTC/MAP users would be to follow label directions, take a pregnancy test first, understand decreased efficacy if they are taking antibiotics or anti-epileptic drugs, remember to take the second dose 12 hours later, realize that they might be unprotected if they vomit either dose, have access to medicine or other antiemetic if needed, and see a doctor or take a pregnancy test if their period doesn't resume in three weeks. **Dr. Grimes' response to these important questions was to brush them off: "Questions like this are demeaning and patronizing to women. Why shouldn't they be able to use the product correctly?"[105]**

A follow-up question asked whether socioeconomic factors might play a role in the likelihood of OTC/MAP users correctly using the medication. **Dr. Grimes' response was, "When people are scared, their behavior changes dramatically. A pregnancy scare could be enough for users to follow instructions to the letter."[106]** Dr. Grimes' personal opinion that MAP users will likely change their behavior appears at odds with abortion statistics, which consistently indicate that almost half of the women obtaining abortions did not use contraception. Additionally, according to 2003 Alan Guttmacher Institute data, 48% of women obtaining abortions each year already have had at least one previous abortion.[107] In light of these facts, and considering that abortion is a more traumatic experience than the use of MAP, Dr. Grimes' belief that a "pregnancy scare" could result in correct and responsible use of MAP appears to run contrary to the actual behavior and experience of women.

In fact, adult women have *intentionally* taken large doses of levonorgestrel-MAP "due to enormous fear of unwanted pregnancy." One study from Hungary reported on three women who took 4-5 pills (3.0 to 3.75 mg total, which is 4-5 times the approved dose) as a first dose, followed by one .75 mg pill 12 hours later.[108] These women were all adults ranging in age from 18 to 37, and none had used oral contraceptives or the IUD. Clearly, OTC/MAP presents the danger that any women, but especially adolescents, who may be panicked at the possibility of pregnancy, may ingest MAP at 4-5 times the recommended dosage in a desperate and ill-advised attempt to avoid pregnancy.

Sri Lanka's social marketing program introducing MAP identified a problem: "many women request[ed] [MAP] *after the 72-hour window of treatment opportunity*." [Emphasis added.][109] The window of treatment for MAP is now considered to be 120 hours following sexual intercourse.[110] Regardless of any particular deadline established, many women and adolescents are likely to use OTC/MAP beyond the deadline in a panicked attempt to avoid pregnancy. Women may rationalize that four or five packets of Plan B cost less and are more private than an induced abortion. This prospect raises serious health and safety concerns. What is the likely MAP failure rate for such women who are further along in pregnancy? How large of a dose might they ingest as a megadose of MAP? Are such women and girls likely to seek medical attention afterwards? What short-term and long-term effects might a megadose of MAP have upon the woman's health? Upon the fetus? Unfortunately, if OTC/MAP is approved, the answers to these questions will be found "the hard way" in the lives of women who use MAP in unsupervised OTC setting.

Despite these facts, presenters for Women's Capital Corporation/Barr Laboratories assured the FDA advisory committee that Plan B is completely safe with no potential for overdose. Dr. Vivian Dickerson, president-elect of American College of Obstetricians and Gynecologists, stated, "Plan B . . . is not teratogenic [that is, it does not cause birth defects]. It has no potential for overdose."[111] FDA medical officer also told the advisory committee that, "For overdose, there were no reports in the literature or safety databases of an overdose. Overdose is also unlikely with the expected cost of Plan B."[112]

5. Other Concerns Over Plan B Actual Usage

- MAP is acknowledged to be less effective than other methods of contraception.[113] Plan B's clinical information states: "Emergency contraceptives are not as effective as routine contraception since their failure rate, while low based on a single use, would accumulate over time with repeated use."[114]
- Following use of Plan B, some women may experience difficulty ascertaining whether they are pregnant or are experiencing normal menses. Plan B clinical information states, "Menstrual bleeding patterns are often irregular . . . in clinical studies of levonorgestrel for postcoital and emergency contraceptive use."[115] For women who find themselves using Plan B on a regular basis, accurately dating last menses and self-determining risk of pregnancy may become very difficult due to irregular menses.[116]

- Women's Capital Corporation states about **60% of women enrolled in the Plan B Actual Use Study "had sex without contraception at least once in that month (including the act that prompted the subject's use of emergency contraceptive pills)."[117]** This contradicts general public perception that MAP use will be limited to emergencies such as "contraceptive accidents" and rape.

- Finally, it should be seriously considered that OTC/MAP is likely to unnecessarily provide high hormone doses to many women for whom MAP would be ineffective and completely unnecessary due to ovulation patterns in that particular menstrual cycle. In fact, a 1996 study in International Family Planning Perspectives reported that in the Netherlands, where MAP was widely available, **"Slightly fewer than half of the women in these studies had unprotected intercourse at midcycle, suggesting that many women seek emergency contraception even when the risk of pregnancy is slight."[118]** At the December 2003 FDA review committee meeting, Dr. David Hager expressed concern over a perception that MAP should be used after every unprotected intercourse, stating, "It would be my contention that the diagnosis is not unprotected intercourse, but rather

unprotected intercourse just prior to and at the time of ovulation. So my question is, are there data available on the unnecessary uses." An FDA representative replied, "We're not aware of any."[119] Dr. Hager asked Dr. Ben-Maimon, representative for Plan B's manufacturer, "The recommendation is to take [Plan B] with every act of unprotected intercourse, is that correct?" Dr. Ben-Maimon replied, "That's correct."[120]

- Pharmacists in the Washington State emergency contraception pilot project sometimes encountered patients who requested MAP but did not need it for various reasons.[121] OTC/MAP will remove any possibility of physician oversight to prevent such misuse of MAP. Thus, adolescents and women who do not even need MAP will be among the millions of women whose very lives ultimately will provide the data on the long-term health risks of high-dose hormones.

OTC/MAP - Inappropriate Treatment for Sexual Assault

At the December 16, 2003, FDA hearing, all of the presenters for Women's Capital Corporation/Barr Laboratories, described MAP in *over-the-counter* setting as essential for women who have been victims of sexual assault.[122] These presenters were: Dr. Carole Ben-Maimon, President/COO, Barr Laboratories; Dr. Vivian Dickerson, president-elect, American College of Obstetricians and Gynecologists; and Dr. David A. Grimes, vice president, Biomedical Affairs, Family Health International.

OTC/MAP status will likely result in increased incidence of unreported rapes. OTC/MAP is not an appropriate mode of treatment for rape/incest/involuntary sexual act. Sexually abused women deserve intense emotional, physical, and spiritual support. OTC setting does not permit these needs to be addressed. Knowledge that MAP is available OTC may encourage a rape victim's mistaken feeling that she bears responsibility and that her sexual violation can easily be remedied at the pharmacy. Some advertisements even encourage OTC use of MAP for sexual assault.[123]

Sexual assault victims need a wide range of services, including police report, rape evidence collection, HIV/STD testing, counseling, possible court order of protection, etc.[124] Such vitally necessary measures are a routine part of comprehensive post-rape procedures in hospital setting. MAP as an OTC treatment for sexual assault denigrates women by neglecting to provide of these services.

OTC/MAP places incest victims at risk of continued exploitation. Prescription-only MAP is a last-chance lifeline for a physician to discover and report incest/molestation of the young patient. OTC/MAP would enable the perpetrator to erase evidence of abuse (possible pregnancy) by conveniently providing MAP directly to the victim. A visit to a physician provides the victim with a chance that the incest/molestation will be discovered and stopped. Those who support OTC/MAP seem to realize that even incest victims may be MAP users.[125] One MAP clinicians' guide stated, "Because rape is often perpetrated by relatives, friends and acquaintances, victims are frequently reluctant to go to an emergency room for fear that they will have to officially report the incident." Recommending a non-intrusive approach, the guide states, "if the victim is reluctant to report the rape, her needs for ECPs [Emergency Contraceptive Pills], contraception and screening/treatment of STDs still must be addressed."

The Rape, Abuse & Incest National Network (RAINN) reported that the 2002 National Crime Victimization Survey found that sexual assaults reported to police rose to 53.7%, up from 30% in 1999. The Survey also found that there were 248,000 sexual crimes in 1999, down from 485,000 in 1993.[126] RAINN attributes these developments to greater willingness by victims to report sexual assault and tougher sentences for offenders. *OTC/MAP would reverse these trends and undermine these achievements.* OTC/MAP enables offenders to manipulate victims who may fear revealing the sexual assault, which statistically is most likely by someone they know.[127] OTC/MAP helps perpetrators send the message to victims: "You don't have to tell anyone. It's easy to take care of this yourself at the pharmacy with a simple regimen of pills."

RAINN, the largest U.S. anti-sexual assault organization, also recommends that sexual assault victims *get medical attention for STDs, determine risk of pregnancy, ask hospital to preserve forensic evidence via a rape kit exam, ask for a urine sample to be collected if victim suspect s/he has been drugged, report the rape to law enforcement, and seek counseling*.[128] These interventions seem highly unlikely in OTC/MAP setting.

According to RAINN, 44% of all sexual assault victims are under age 18.[129] Our nation's sexual assault victims—especially adolescents—deserve a better societal response than OTC/MAP.

Label Comprehension Problems

The Briefing Document submitted to FDA for the Plan B/OTC application revealed that women of all ages scored very low in questions presenting specific situations where MAP use may or may not be appropriate.[130] These situational questions closely resemble real-world decisions that women will make concerning OTC/MAP use:

A. **Question:** *A woman is planning to have sex tonight. She usually uses condoms to prevent pregnancy. This time she plans to use Plan B instead because her husband complains about using condoms. Is this a correct use of Plan B?*

Correct response*	Age Group – Years
50.0%	12-16
49.6%	17-25
40.9%	26-50

*Correct response to this question = No.

B. **Question:** *A woman and her husband do not like using condoms, and the woman does not want to take birth control pills. They decide to use Plan B as their main contraceptive method. Is this a correct use of Plan B?*

Correct Response*	Age Group – Years
59.2%	12-16
65.6%	17-25
75.6%	26-50

*Correct response to this question = No.

C. **Question:** "*A woman used Plan B every day instead of her usual birth control pills. Was this a correct use of Plan B? (Correct answer = No)"* Approximately 10% of women of all age groups incorrectly responded, "yes."

Dr. Karen Lechter, FDA social science analyst, explained that in label comprehension studies, the FDA encourages, "the use of scenario questions to which participants have to apply the labeling information to hypothetical situations."[131] Thus, these low scores reveal significant problems in the label comprehension study. In response, Plan B's manufacturer intends to put in boldface on the Plan B package, "Plan B should not be used in place of regular contraception."[132] However, this seems to conflict with Plan B clinical information which states, "Plan B can be provided as frequently as needed."[133]

FDA reviewer Dr. Karen Lechter stated that in label comprehension studies, the FDA asks "sponsors to include a substantial number of low literate participants."[134] According to the FDA, Plan B's label comprehension study revealed that participant**s did not clearly understand (or data was inconclusive)** that: [135]

- Plan B is not for regular contraceptive use;
- The first tablet is to be taken as soon as possible after intercourse;
- The second tablet is to be taken 12 hours after the first one;
- Plan B is to be used **after** intercourse [emphasis theirs].

These are significant concerns for OTC status for Plan B, which improved product packaging/labeling may not resolve adequately.

Low literacy levels on MAP use were also considered in an unrelated study at a Title X low-income clinic which concludes: "Emergency contraception utilization was far lower than anticipated, suggesting that ready access is not the only issue. Many of the women did not administer ECP correctly or could not state how they would use it in the future ***despite extensive instruction.*** Patients will require new and creative approaches to encourage their appropriate use of emergency contraception." [Emphasis added.][136] Although this study was not on the Plan B product, it is not readily apparent that OTC/MAP will result in greater understanding and compliance. Further, OTC/MAP does not provide the opportunity for "extensive instruction" to encourage appropriate use of MAP.

Manufacturers Recommend Medical Professional Involvement

Plan B/Women's Capital Corporation website discusses pharmacist involvement as essential for: counseling and educating patients; identifying patients that are candidates for MAP and comparing available MAP therapies.[137] These interventions are not possible in OTC/MAP setting.

Screening protocol on Plan B/Women's Capital Corporation website asks: Have you had unprotected sex in last 3 days? Was the first day of your last menstrual period less than 4 weeks ago? Was this period normal in both its length and timing? *If the response is yes to all 3 questions, you may prescribe Plan B. If the response to any of the questions is no, or you suspect that the sexual history may be inaccurate, the client . . . will require a pregnancy test first.*[138] A screening protocol is not possible with OTC/MAP.

Berlin-based Schering, manufacturer of two MAP products primarily used in Western Europe, has stated that MAP should be available by prescription only.[139] Schering has refused to sell MAP in countries where it is available without a prescription.

Medical Safety

Safety of Plan B in Postmarketing Safety Review

In researching Plan B, FDA ODS Postmarketing Safety Review stated "databases usually used by ODS were deemed inadequate to determine the use of Plan B," because product was not dispensed primarily through pharmacies or office-based physicians, but rather through family planning clinics.[140] Presumably, family planning clinics would have been difficult to survey for utilization data.

FDA ODS Postmarketing Safety Review stated that it is impossible to know how many Plan B kits were actually distributed to patients.[141] It is also impossible to know how many distributed kits actually were used by patients. These variables affect whether or not the number and seriousness of Plan B Adverse Events reports have any meaningful statistical correlation to number of Plan B kits used during a four-year period.

FDA ODS Postmarketing Safety Review stated that FDA researchers searched only for trade name "Plan B" and foreign equivalent trade names. They did not search for **levonorgestrel**, the generic name of Plan B's active ingredient, because they wished to avoid "capture" of Norplant class action data.[142] However, this research decision dismissed all generic levonorgestrel Adverse Events data out-of-hand and deprived the FDA advisory committee of all AEs reported generically for levonorgestrel. FDA researchers should have conducted a routine AERS search of generic name for levonorgestrel and presented a summary to FDA advisory committee for review. (Captured Norplant class action data could have been easily separated.)

In fact, a 1995 FDA Annual Adverse Drug Experience Report ranked Norplant second on the list of drugs described as "suspect drugs" approved within the past three years.[143] Norplant's sole active ingredient is levonorgesetrel, which is also the sole active ingredient of Plan B.

The most common, most troublesome side effect of Norplant is irregular, frequent, excessive, prolonged

or altogether absent menstrual bleeding.[144] According to Plan B's website, menstrual disturbances are among most common adverse events, although nausea tops Plan B's list. However, if "menstrual disturbance" (both heavier and lighter menstrual bleeding) were combined into one Adverse Event category, then menstrual disturbance would actually top the list of most common Adverse Events for Plan B (26.3%) with nausea second (23.1%).[145] There may be possible parallels between Norplant and Plan B Adverse Events due to common active ingredient of levonorgestrel.

At the December 2003 FDA review committee meeting, Dr. Carol Ben-Maimon, a representative for Plan B's manufacturer, stated that "the most common side effects [of Plan B] are nausea, abdominal pain, fatigue." [146] Later during the hearing, Dr. Ben-Maimon was asked about data concerning irregular bleeding and its public health impact. Dr. Ben-Maimon replied, "No, I don't have data. . . . With repeat use, . . . intermenstrual bleeding occurs in about 40 percent of women."[147]

Plan B's Briefing Document submitted to the FDA reported that menstrual disturbances affected only 6.6% of women in Actual Use Study.[148] It is unclear why there is such a significant discrepancy concerning the incidence of menstrual disturbances in the Actual Use Study/Briefing Document versus the incidence reported on the Plan B website and by Dr. Ben-Maimon during the FDA review committee meeting. The Briefing Document did not include a copy of the actual data card form which women completed following use of the Plan B product.[149]

A 2002 study in Hungary, where levonorgestrel MAP was first developed commercially, described breakthrough bleeding as "frequent" and underscored the need for counseling due to this side effect.[150] Such counseling is not possible in an OTC/MAP context.

It is unknown how adolescent use/abuse of Plan B might increase rate or severity of menstrual disturbances. It is further unknown how adolescents will respond to such menstrual disturbances, particularly in terms of confusion about possibility of pregnancy.

Additional common complaints about Norplant include: ovarian cyst enlargement (well-documented, according to World Health Organization), headaches, weight gain, dizziness, acne and other skin problems, and mood changes, including nervousness and depression. Other possible effects (described as "weak but statistically significant") of Norplant include: gallbladder disease, high blood pressure and respiratory disorders.[151]

Limiting the safety review Adverse Event search to "Plan B" product name (and foreign equivalent names) yielded far fewer AE reports than levonorgestrel generic search would have yielded. Even so, 116 Averse Events were reported for Plan B, including serious and potentially serious cases.[152]

Abortion-Inducing Effect of the Morning After Pill

A pivotal 1998 World Health Organization study of the morning-after pill was conducted by the World Health Organization Task Force on Postovulatory Methods of Fertility Regulation.[153] It is self-evident that studying fertility regulation methods that are *postovulatory* would mean, in fact, studying methods that are *abortifacient.* A postovulatory effect could not be denied by the Task Force since this was precisely the purpose of the Task Force. Later, however, the denial of *any abortifacient effect* was deemed essential to widespread use of MAP.[154]

Controversy over reproductive health technologies led to a redefinition of scientific terms. Redefining "conception" as beginning at "implantation" rather than "fertilization" was an attempt to stifle opposition: fertilization may occur but since conception was now deemed to occur at implantation, no early abortion was said to occur.[155] However, as moral opposition intensified, even this definition did not suffice and new studies emerged purporting to find that whether or not MAP alters the endometrium cannot be proved and may never be proved.[156]

Among human embryologists globally, "there is 100% consensus" that a new human being begins to exist at fertilization.[157] An especially comprehensive scientific review of the issues surrounding MAP's abortifacient effect was provided to the December 2003 FDA advisory committee by Dr. Dianne Nutwell Irving, a former research biochemist/biologist. Dr. Nutwell Irving explained that, "By the time of implantation, the living human embryo is approximately already 5-7 days old. This is not a . . . 'belief' or 'opinion', but rather it is an objective scientific fact that has been known scientifically for over a hundred years." Dr. Irving stated, "If other scientists and physicians are not aware of these scientific facts, that is more a reflection of their lack of knowledge and/or credentials, rather than a reflection of any 'confusion' on these scientific facts."[158]

Scientist redefining conception as beginning at implantation rather than fertilization allows for MAP-use as being non-abortive

The Scottish Council on Human Bioethics published a briefing paper on the Morning-After-Pill.[159] In discussing how conception was redefined to begin at implantation rather than fertilization, the briefing paper disparaged this as "new biology" in contrast to centuries of biological scholarship. Dr. John Ling described these semantic games as "an example of lexical engineering preceding social engineering." The briefing paper quoted standard textbooks on embryology which affirm that "human development begins after the union of male and female gametes or germ cells during a process known as fertilization (conception). . . . Implantation has been described as the 'fourth stage' of human embryonic development. By this time (implantation), the conceptus has undergone eight of the forty-one cell doublings that occur before birth."

Members of the December 16, 2003, FDA review committee discussed whether or not MAP has an abortifacient effect and/or is understood by MAP users to have an abortifacient effect:

- Dr. Joseph Stanford referred to the Plan B Label Comprehension Study, which tabulated answers to the question, "What is Plan B used for?" Plan B's manufacturer included as correct answers: **"an abortion type of thing if you think you are pregnant" and "an abortion type thing for the day after."**[160]

- Dr. Valerie Montgomery Rice explained that, "There is some data out there that really does suggest at very high dosages that there may be the possibility that you're interfering with the implantation."[161]

- Dr. Charles Lockwood explained that, "We know that progesterone given at around the time of attachment can affect HOXA-10 expression. It can affect integrin expression. It can affect Lith expression by endometrial glands, et cetera. So the issue becomes . . . does it affect attachment, and does it act, in other words, like an IUD rather than an anti-fertilization agent. And it sounds like you're telling me that no one has done the studies." Plan B's manufacturer's representative, Dr. Ben-Maimon, replied, "The studies are not available."[162]

- Dr. Joseph Stanford replied, "I don't think it's quite as clear-cut as has been presented here that there's no data on one side and all data on the other side. . . . I would like to point out what I think is the most to date compelling piece of data on the side that says this may work after fertilization at times, and that is the data that it's effective up to four or five days after. . . . There's certainly some epidemiologic evidence from there that suggests that it is working after fertilization some of the time, and I think it is misleading to say we have no suggestion of that happening."[163]

Despite these questions about MAP's abortifacient function and implications for informed consent issues, these concerns were left unresolved at the FDA hearing.

Unclear Risks to Fetus During Pregnancy

The FDA found possible fetal anomalies/miscarriages for users of Plan B or foreign equivalent levonorgestrel MAP.[164] Although incidence of fetal anomalies was described as statistically insignificant, the general reliability of postmarketing surveillance data was downplayed during December 16, 2003, advisory committee meeting.[165]

The FDA found "very limited information specifically on MAP use during pregnancy" and instead relied on data on regular oral contraceptives in general.[166] It cannot be assumed that oral contraception data is directly applicable to MAP, especially in light of potential for adolescent use/repeated use in OTC context and actual incidents of intentional MAP overdoses.

The FDA found possible fetal anomalies/ miscarriages for users of Plan B

Dr. James Trussell, an MAP expert, stated in a 2000 report that, "There have been no conclusive studies of births to women who were already pregnant when they took combined ECPs [emergency contraceptive pills] or following failure of combined ECPs."[167]

At the December 2003 FDA review committee meeting, Dr. Carole Ben-Maimon, a representative for Plan B's manufacturer, reported that in six clinical trials there were 133 pregnancies.[168] Later during the hearing, when Dr. Ben-Maimon was asked if she had follow-up data on the outcomes of those pregnancies, she replied, "Actually, I don't."[169] Despite a lack of such data, representatives of Plan B's manufacturer told the FDA advisory committee that Plan B "is not teratogenic," that is, that it does not cause birth defects.[170]

FDA medical officer reported to December 16, 2003, advisory committee meeting that, "Use during pregnancy shows no clear evidence that inadvertent use of levonorgestrel during a pregnancy will result in abortion or cause fetal problems."[171]

A major World Health Organization study is often cited by pro-OTC/MAP sources as purportedly demonstrating MAP safety during pregnancy.[172] **In fact, the WHO study does not demonstrate safety during pregnancy at all. The study was not designed for this purpose and actually excluded women who were known to be pregnant.** The WHO study was designed to study effectiveness of the Yuzpe MAP regimen versus levonorgestrel MAP regimen, particularly by extending the maximum delay between intercourse and MAP treatment to 72 hours. **Because pregnant women were excluded from the WHO study, it provides no foundation for a conclusion that MAP is safe during pregnancy.**

The WHO study also excluded women who "were uncertain about the date of their last menses," presumably as another precaution against including women possibly pregnant.[173]

Adolescents are universally acknowledged to have special needs during pregnancy. Yet, there appear to be no studies of the health risks to adolescents or fetuses where pregnancy continued following MAP failure, where fetuses were unintentionally exposed to MAP in mothers already pregnant, nor the outcomes of such pregnancies.[174] All of these situations will occur with unknown frequency in adolescent use of OTC/MAP.

HIV/STD Rates of Infection

A 2003 study by Jonathan Klick and Thomas Stratmann examined the effect of legalized abortion on sexual behavior and rates of Sexually Transmitted Disease infection.[175] The study described unwanted pregnancy as representing "a major cost of sexual activity" and suggested that this cost was a significant disincentive to sexual activity prior to the legalization of abortion. The study predicted that, "abortion legalization generated incentives leading to an increase in sexual activity," and that this was followed by an increase in STDs as well. Using Centers for Disease Control data for gonorrhea and syphilis, the study found that increases in STD rates positively correlated with legalization of abortion.[176] The study also found a divergence in STD rates between those states which legalized abortion early and the national legalization of abortion in 1973. After abortion was legalized nationally, STD rates among all states converged.

If the "cost of unwanted pregnancy" was reduced by legalized abortion which resulted in significantly increased rates of STD infection, then it is reasonable to conclude that MAP, perceived as further reducing the "cost of unwanted pregnancy," is likely to result in further increases in STD infections. Changing sexual attitudes and behaviors are variables challenging fixed assumptions about MAP's effect on unwanted pregnancy and STD rates of infection.

An FDA Clinical Review on contraceptive behavior and Plan B reported that one study "suggests that the advance, pharmacy and standard EC access groups plus EC education had . . . a decrease in condom use."[177] This study was sponsored by Women's Capital Corporation, the manufacturer of Plan B. Since condoms offer some protection against transmission of HIV/STDs, this trend away from condom use may result in increased rates of HIV/STD infection.

One study examined the influence of male partners in the use of MAP. This study focused on low-income population at high risk for pregnancy and Sexually Transmitted Diseases. The study looked at factors such as perceived risk for STDs, perceived risk for pregnancy, motivation to use protection, condom attitudes, multiple partners, sexual history, and relationship issues, such as decision-making, pressure for sex, and contraceptive use. The study found that MAP use depends not only upon the woman's knowledge, but also varies with male attitudes, concluding, "Implications for EC provision are that *partner factors should be integrated into routine counseling.*"[178] Routine counseling for couples simply is not possible in OTC/MAP setting. Yet, the male partner's sexual behavior and attitudes was found to play a significant/determinant role in STD risk.

Ongoing Monitoring of Plan B Post-OTC

Plan B's manufacturer, Barr Laboratories, designed a postsurveillance program called C.A.R.E. (Convenient, Access, Responsible Education). Plan B's Briefing Document stated that ongoing monitoring of actual use of Plan B "is complex, due to the difficulties inherent in identifying women who have purchased the product and in gathering useful, generalizable information." Barr Laboratories proposed that the ongoing monitoring of Plan B would be done in a rather indirect manner: (a) surveying healthcare professionals to determine attitudes towards and trends in MAP; (b) collaborating with professional groups to evaluate Barr Laboratories "Convenient, Access, Responsible Education" program; (c) using others' data [NGOs, CDC, etc.] to "monitor" whether Plan B is being used in an inappropriate manner; and (d) possibly asking these unrelated organizations to include certain questions in their future surveys such as: increased STDs in areas with high Plan B sales; increased rates of pregnancy/induced abortion in rates with high Plan B sales.[179]

The Briefing Document states that "gathering data from actual users of Plan B is difficult because the number of users will be relatively small and because the decision to use emergency contraception is a private and emotional one. Women choosing to use the product are expected to wish to remain anonymous and are entitled to maintain their privacy."[180] It is not clear why privacy issues are a barrier to gathering data; as part of the Plan B/OTC application, an actual use study was conducted by Women's Capital Corporation on the women using Plan B. It is not clear why is the number of Plan B users is described as "relatively small" when

the number would be expected to increase dramatically upon OTC approval.

The unrelated organizations upon which Barr Laboratories would be relying for data may be the Foundations and NGOs advocating for MAP, abortion rights, and population control. The Briefing Document vaguely states that "it is hoped" that the studies conducted by these Foundations and NGOs can provide a sufficient base for a study of Plan B users to determine trends on pregnancy rate, abortion rate, HIV/STD infection rates.[181] Some of the Foundations also may be the same organizations who invested in Women's Capital Corporation and/or are active members of the International Consortium for Emergency Contraception. If so, this should be disclosed.

On one hand, the general public is assured that after OTC approval, adverse effects of Plan B will be carefully monitored via Barr Laboratories' postmarketing surveillance program (C.A.R.E.). On the other hand, it appears that even the FDA medical officer considers postmarketing surveillance data of limited use because "there is considerable underreporting of adverse events in general. . . . The likelihood of reporting adverse events may be greater or lesser, depending on the nature of the event."[182] MAP use involves sexual activity and unintended pregnancy. Arguments in favor of OTC/MAP emphasize the need for privacy and secrecy. Adolescents and young women are identified as the primary users of Plan B.[183] Therefore, OTC/MAP appears to involve exactly the type of situations in which postmarketing adverse events are *likely to be underreported*.

Contraindications to Emergency Contraception

A pivotal World Health Organization study is often cited to support lack of contraindications for MAP.[184] **In fact, the WHO study did not make this determination because the study design specifically excluded "women who were breast-feeding or had used hormonal contraception within the current menstrual cycle . . . [or] those who had contraindications to hormonal contraception."** [Emphasis added.] The purpose of the WHO study was to determine rates of effectiveness between the Yuzzpe MAP regimen and the levonorgestrel MAP regimen. **Because women with possible contraindications were excluded from WHO study, it provides no foundation for a conclusion that MAP has no contraindications.** Yet women with contraindications to oral contraceptives, women currently using oral contraceptives, and breastfeeding women would have access to OTC/MAP without medical oversight.

In 1995, in the Consensus Statement on Emergency Contraception, international abortion advocacy/population control organizations acknowledged that MAP contraindications exist.[185]

Annals of Internal Medicine states, "No studies have directly compared the risk for complications after emergency contraception in women who have medical illnesses or other risk factors and women without these conditions."[186] The same article continues, "No data are available specifically about interactions between hormonal emergency contraception regimens and other drugs."[187]

At the December 2003 FDA hearing, Dr. Neal Benowitz asked whether Plan B's manufacturer had looked at the effect of enzyme-inducing drugs and drug interactions. Dr. Carole Ben-Maimon, representing Plan B's manufacturer, stated, "clearly there is data on levonorgestrel, and there is an interaction with some [anticonvulsant drugs]. We have not specifically done it with this particular dose and two doses."[188]

British Medical Journal reported on apparent interaction between warfarin and levonorgestrel MAP.[189]

Plan B package insert states, "No formal studies have evaluated the effect of hepatic insufficiency or renal insufficiency on the disposition of emergency contraceptive tablets." Further, "No formal studies of drug-drug interactions were conducted."[190]

The Mexican Family Planning Association (MexFam) stated that, despite the World Health Organization's

lack of absolute contraindications to MAP, "it is advisable to consult a physician before taking emergency contraceptives if a woman has had: breast cancer; cancer in the sex organs; a heart attack; blood clots in the legs or lungs; serious diseases such as diabetes, hepatitis, cardiopathies, kidney diseases, severe high blood pressure."[191]

The International Consortium for Emergency Contraception's policy statement on repeated use of MAP states that, "There are no medical contraindications to ECPs when used occasionally, for example, once a month or less. If use exceeds this amount, the **contraindications to regular combined or progestin-only oral contraceptives might apply.**" [Emphasis added.][192] However, ICEC's own policy statement appears self-contradictory on this point as elsewhere it states, **"Women should use ECPs as often as needed"** and, "Medical and behavioral research conducted to date **does not provide any basis for limiting the number of times that women use ECPs, in a year or in a month.**" [Emphasis added.] Taken together, these statements seem to imply that those women and adolescents who use OTC/MAP more frequently than once a month will themselves provide the new body of medical evidence as to MAP's safety or non-safety with frequent or repeated use.

Ectopic Pregnancy

1. *Plan B Package Insert*

Plan B Package Insert acknowledges that abdominal pain is second most common adverse reaction in clinical trials.[193] If Plan B increases risk of ectopic pregnancies, then confusion over abdominal pain following Plan B use could significantly reduce timeliness in seeking treatment for life-threatening ectopic pregnancies.

In adolescent populations, this confusion over the cause of abdominal pain could be exacerbated by fear of informing parents that MAP was used. The recent RU-486 death of Holly Patterson illustrates that adolescents may even turn to medical personnel for unsuccessful treatment of life-threatening complications but still not inform parents. Privacy has been emphasized as justification for OTC/MAP availability; that very same privacy motivation may lead adolescents to carry secrecy to life-threatening extremes.[194]

2. *Plan B Submissions/Presentation to FDA*

The Plan B Briefing Document submitted to the FDA stated that clinical studies for Plan B found an ectopic pregnancy rate of 1.5%, which is lower than the ectopic pregnancy rate for the U.S. general population at 2%.[195] The Briefing Document goes on to state that in post-marketing reports, ectopic pregnancies are reported as high "as compared to the number of unintended pregnancies reported to pharmacovigilance authorities."[196] No statistics are provided. However, the Briefing Document dismissed this increased risk of ectopic pregnancy as "probably due to less reporting of unintended pregnancy because it is not usually considered a serious or unexpected adverse event, but a product failure. . . . These data suggest no increased risk of ectopic pregnancy for levonorgestrel emergency contraception."[197] Thus, relying on general assumptions, that normal pregnancies were underreported, postmarketing reports of increased risk of ectopic pregnancy seemed to be dismissed.

At the December 16, 2003, FDA advisory committee meeting on Plan B switch status, Dr. Carole Ben-Maimom, COO for Barr Laboratories, represented to the advisory committee that "there is no increase in the incidence of ectopic pregnancy."[198] She described progestin-only oral contraceptives as being "questionably associated" with an increased incidence of ectopic pregnancy and referred to clinical trials which did not find an increased risk. However, Dr. Ben-Maimom's presentation to the FDA committee did not include information about findings of postmarketing surveillance in the United Kingdom and New Zealand (explained below).

Dr. David Grimes, whose role at the FDA committee meeting was to present the health consequences of Plan B/OTC on behalf of Plan B's manufacturer, did not address ectopic pregnancy in his presentation. Dr. Grimes did describe Plan B's benefits as, "Seldom in medicine do we see the scale so forcibly tipped and permanently tipped in favor of benefit . . . ."[199] He unequivocally stated, "There are no outstanding medical

issues," regarding Plan B.[200] In concluding his presentation, Dr. Grimes stated, "The public health and the medical evidence is clear and incontrovertible."[201]

3. *Overseas Postmarketing Surveillance Finds Increased Ectopic Pregnancy Risk*

Postmarketing surveillance of levonorgestrel MAP in the United Kingdom found a significantly increased risk of ectopic pregnancy. Out of 201 unintended pregnancies, 12 were ectopic, following failure of Levonelle (brand name for levonorgestrel MAP). This represents an incidence of 6%, which is triple the typical rate of ectopic pregnancy. A U.K. Department of Health report states, "Since pregnancies that occur in women taking progestogen-only pills [oral contraceptives] are more likely to be ectopic than those occurring in women who use other methods of contraception, this [increased ectopic risk with MAP] is not unexpected."[202]

Increased risk of ectopic pregnancy is a problem when using MAP

In light of the increased risk of ectopic pregnancy discovered by postmarketing surveillance, the U.K. Department of Health then issued the following advice to physicians: "The possibility of an ectopic pregnancy should be considered, particularly in women with a previous ectopic pregnancy, fallopian tube surgery or pelvic inflammatory disease."[203]

Three ectopic pregnancies were reported to the New Zealand Centre for Adverse Reactions Monitoring. Vigilant caution by New Zealand's Ministry of Health resulted in a Prescriber Update as "a reminder that women who have amenorrhoea (or other symptoms suggestive of pregnancy) following use of progetogen-only emergency contraception should have a pregnancy test. If the result if positive, the possibility of ectopic pregnancy should be considered."[204]

Since Plan B's manufacturer has denied or downplayed any increased risk of ectopic pregnancy, it is unlikely that U.S. physicians are prepared to exercise the same vigilance concerning possible ectopic pregnancy as their U.K. or N.Z. counterparts.

4. *FDA Presentation on Ectopic Pregnancy Risk*

FDA's ODS Postmarketing Safety Review did not report the U.K. Chief Medical Officer's new guidance concerning monitoring for ectopic pregnancy, even though the U.K. experience with levonorgestrel MAP had been researched and a priority had been placed on ectopic pregnancy reports.[205] While the ODS Postmarketing Safety Review did note 5 ectopic pregnancies with Levonelle and 16 with Levonelle-2 (both levonorgestrel MAP), without a statistic for the total number of pregnancies, these figures are not meaningful in terms of ectopic risk. Presumably, the figure for the total number of pregnancies could have been obtained to clarify risk.

The FDA's Medical Officer Safety Review is the comprehensive review, which actually incorporates the ODS Postmarketing Safety Review described above. The Medical Officer Safety Review on Plan B examined ectopic pregnancy risk.[206] The review examined databases through October 2003 and reported 28 ectopic pregnancies, 10 of which were from the U.K. The FDA medical officer described the postmarketing reports of ectopic pregnancies as "hard to interpret" because the total number of pregnancies are not known, a bias is presumed in favor of reporting ectopic over interuterine pregnancies as adverse events and "there is considerable underreporting of adverse events in general." (At least in the U.K., more definitive information concerning ectopic pregnancy risk was available for review, including especially the U.K. Chief Medical Officer's revised guidance to physicians. More specific information may have been available from other countries as

well.) Finally, the FDA medical officer report concluded that "there is no evidence that history of a previous ectopic pregnancy is a contraindication to the use of Plan B or that the risk of an ectopic pregnancy is greater with the use of levonorgestrel emergency contraception."[207]

Morning After Pill and Adolescents

International organizations representing abortion advocacy and population control interests targeted adolescents from very beginning of worldwide campaign to standardize MAP.[208] Adolescent use of OTC/MAP is a very serious public health concern.

Adolescent Health/Safety Risk Not Adequately Studied

Women's Capital Corporation has funded some studies intended to test Plan B's safety and pharmacokinetics in adolescents 16 and younger.[209] However, the studies excluded adolescents with irregular menstrual cycles, adolescents who had used sex steroids within last two months, and those adolescents who were sexually active within last menstrual cycle with any inconsistent use of condoms. In adolescent actual use of OTC/MAP, all of these factors will be involved. **None of the adolescents studied used MAP within 72 hours after unprotected sexual intercourse to prevent pregnancy. Further, it is not clear whether the adolescents were counseled or supervised in use of Plan B.** The abstract of the study noted that "adolescents had lower plasma concentrations of levonorgestrel than adults, which may be due to faster clearance or lower bioavailability."[210]

Another study on "Sexual Risk-Taking and Emergency Contraception" may reveal attitudes towards opposition to MAP, as stated in the following introduction to a presentation of the study: "Emergency contraception has become increasingly available in the United States, due to sustained public health efforts to improve service delivery. **These efforts, however successful, continually face challenges from groups reluctant to increase access. In surveys, both providers and the public have expressed their concerns about sexual risk-taking and STDs."** [Emphasis added.][211] It is unclear whether this study has been completed. The study's findings, conclusions and recommendations should be considered carefully in light of implied concerns. The study may consider public and provider opposition to MAP an obstacle to be overcome.

In Plan B label comprehension study submitted to FDA by Women's Capital Corporation, only 11.6% (76) of the 656 participants were teenagers 16 or under.[212] A label comprehensive study does not, of course, provide data on health risks. In WCC's Plan B actual use study, an even smaller group (only 4% or 22 out of 540) of Plan B users were age 16 or under.[213] For unclear reasons, both studies grouped adolescents aged 17 and 18 with women of older ages. In comparison, CDC data on Sexually Transmitted Diseases groups ages as follows: 10-14, 15-19, 20-24 years old.[214] Inconsistent methods of age groupings may make comparisons of various data difficult.

Norplant (a progestin-only hormonal contraceptive with same active ingredient as Plan B) has a well-documented history of adverse effects. Should Plan B's use by adolescent population result in adverse effects similar to Norplant's, some typical complaints considered "minor" in other populations could actually significantly impact adolescent health. For example, efforts to control weight gain could contribute to development of bulimia or anorexia; acne/skin problems can lower self-esteem; and adolescent mood changes could increase in severity to clinical depression. Additionally, adolescents should not be exposed to risks for serious medical problems such as ovarian cyst enlargement, gallbladder disease, high blood pressure, and respiratory disorders.[215] Because the use/abuse of Plan B by adolescents has not been adequately studied, OTC/MAP approval would inflict upon our nation's youth a great medical and social experiment.

If OTC status for MAP is approved, MAP will be available to adolescents of all ages without supervision. Therefore, limiting future Plan B studies to 16 and 17 year old adolescents will fail to provide information about likely actual adolescent MAP usage in OTC setting. *If there are concerns about studying Plan B effects*

in sexually active adolescent females younger than 16, then there certainly should be even greater concerns about actually making OTC/MAP available to sexually active young adolescent females without supervision.

Rate of HIV/STD Infection Among Adolescents Rapidly Increasing

Adolescents age 15-19 represent 46% of all cases of Chlamydia; 1 in 4 sexually active teenagers will contract an STD. Girls and young women acquire HIV an average of 10 years earlier than young men. In the U.S., women account for 30% of new HIV infections each year. Half of new HIV cases are in those younger than 25 years, and half of those are in women.[216] OTC/MAP fails to protect against HIV/STDs and likely will increase the dimensions of the HIV/STD public health disaster among youth by encouraging increased sexual risk-taking.

A new study found that sexually active persons aged 15-24 represent only 25% of all sexually experienced persons. However, this group represents 48% of all new cases of STDs in 2000. Three STDs—human papillomavirus, trichomoniasis and Chlamydia—accounted for 88 percent of new STD cases in the 15-24 year old age group.[217]

Chlamydia is the most common Sexually Transmitted Disease, disproportionately affecting sexually active adolescents and young adults.[218] Adolescents are considered at greatest risk for Chlamydia because they are more likely to take sexual risks, have multiple partners, and may be more biologically susceptible to infection.[219] Unlike other STDs which exhibit obvious symptoms, 75% of females and 50% of males infected with Chlamydia have no symptoms.[220] Because Chlamydia infection is a "silent" epidemic, it is now recommended that sexually active adolescents be screened twice yearly.[221] Persons infected with Chlamydia often have gonorrhea and are also at increased risk of contracting HIV infection.[222]

Johns Hopkins researchers studied over 3,000 sexually active females aged 12-19 who visited family planning, STD or school-based clinics, finding 14-year-olds with the highest rate of Chlamydia infection.[223] The researchers said they could not predict which females in the study would be at increased risk for Chlamydia based upon usual risk factors. "The only risk factor we found for Chlamydia infection was being a teenager," the study team concluded.

Pro-MAP groups portray MAP as an important "bridge" to regular use of contraception by adolescents beginning to engage in sexual intercourse.[224] As a measure of how pathetically low our nation's expectations have already fallen concerning adolescent sexual behavior, consider that a Centers for Disease Control Survey on trends in sexual risk behaviors among **high school students** defines "having multiple sex partners . . . as having had four or more sex partners during [the student's] lifetime."[225] Over 14% of high school students nationwide have had sexual intercourse during their lifetime with 4 or more sexual partners.[226]

The CDC survey on trends in sexual risk behaviors states that a 2010 national health objective is to increase the number of adolescents in grades 9-12 who used a condom the last time they had sexual intercourse during the preceding 3 months.[227] Given these disturbing statistics on adolescent risky sexual behavior, it is a compelling question to consider whether OTC/MAP will move our nation in the right direction or simply provide "more of the same" at an even more accelerated pace.

A 2004 Alan Guttmacher Institute study examined 399 adolescent females aged 13-19 who visited clinics for birth control to determine the degree to which support from the mother, a male partner or a friend influenced contraceptive choices.[228] The study found that younger teenagers relied more on friends for advice than did older teenagers. From this, the study concludes that younger teenagers "may be in greater need of counseling to make healthy choices." OTC/MAP precludes the possibility of counseling younger teenagers. The study acknowledged that due to lack of support from mothers or male partners, it is likely that "many teenagers [were prevented] from ever making it to the clinic [for contraception]." This implies that OTC/MAP would be a *more likely* choice for younger teenagers.

The abstract of a **"Sexual Risk-Taking and Emergency Contraception"** conference presentation makes an intriguing statement under learning objectives for the session participant concerning MAP: "Discuss trade-offs in pregnancy and STD protection."[229] If Emergency Contraception does not lead to increased rates of HIV/STD infection, there are no "trade-offs" between pregnancy and STD protection.

At the December 2003 FDA advisory committee meeting, Dr. David A. Grimes presented "Health Consequences of Plan B OTC," on behalf of Barr Laboratories. However, Dr. Grimes did not address HIV/STD infection rates in relation to OTC status for Plan B.[230] No other presenter on behalf of Barr Laboratories addressed this issue either.[231]

The economic burden of treating STDs among the youth is staggering. A recent Alan Guttmacher Institute report estimated the lifetime medical costs per STD case and then multiplied the cost-per-case estimates by the number of new STDs acquired by youth aged 15-24 (9 million new STD cases among youth in 2000). The estimated total burden for treatment of STD disease occurring among 15-24 year olds in 2000 was estimated to cost $6.5 billion.[232]

Adolescents age 15-19 represent 46% of all cases of Chlamydia; 1 in 4 sexually active teenagers will contract an STD

STD/Chlamydia Infection Rates in Washington State

Before policymakers consider making MAP available over-the-counter nationwide, special attention should be given to the STD infection rates experienced in Washington State. A pharmacist-direct pilot project for MAP was begun in 1998 with the expressed purpose of increasing access to MAP for women of all ages, including adolescents.[233]

Young adults—but especially adolescent girls—are disproportionately harmed by Chlamydia infection. Washington State Department of Health reports that for 2002:[234]

- over 73% of all reported cases of Chlamydia occur among 15-24 year old women and men
- peak female rates occur among 15-19 year olds at 2,039 per 100,000
- peak male rates occur among 20-24 year olds at 695 per 100,000
- increase in age-specific incidence rates of 6.3% noted among females 15-24
- rate of Chlamydia infection among adolescent females 15-19 is 2,039 per 100,000 (compared to women of all ages at 363 per 100,000)

In Washington State, the overall male rate (131 per 100,000) of Chlamydia infection is only one-third the overall female rate (363 per 100,000).[235]

Prior to the MAP pilot project, rates of infection for Chlamydia and other STDs had been in a long-term pattern of steady decline. By 1997, the overall Chlamydia rate per 100,000 (women and men, all ages) was 170, down from 275 in 1988.[236]

Washington State's Chlamydia rates of infection have climbed steadily since the MAP pilot project was introduced five years ago. From the 1997 rate of 170, the Chlamydia rate per 100,000 men and women is now 247.[237] This represents an increase of 45% since MAP was made available pharmacist-direct.

Following chart demonstrates the increase in Chlamydia infection for young women and adolescent girls since MAP was made available in 1998: [238]

WASHINGTON STATE
CHLAMYDIA INCIDENCE RATES
AMONG SOME WOMEN

	Rate per 100,000		
Year	15-19 y/o Women	20-24 y/o Women	All Women
1997	1,656	1,383	260
*1998**	*1,799*	*1,565*	*292*
1999	1,797	1,734	307
2000	*1,947*	*1,824*	*328*
2001	1,979	1,824	339
2002	*2,039*	*1,983*	*363*

*Year Emergency Contraception Pilot Project began in Washington State

Over the years, Washington State Department of Health public health officials have explained the sudden trend reversal and increased rates of Chlamydia infection as follows:[239]

1997—The incidence of Chlamydia in Washington State has shown a 40% decline over the past 10 years from 275 cases per 100,000 in 1988 (the beginning of the Region X Chlamydia Project)

1998—The number of [Chlamydia] cases increased 15% over the 1997 total and the state Chlamydia incidence rate in 1998 jumped 13% from previous year. An estimated 67% of the increase in reported Chlamydia cases may be attributable to more sensitive testing methods. The next two years will either confirm increasing Chlamydia incidence or reveal that 1998 may have deviated from the expected trend.

1999—After nearly a decade of decline, reported Chlamydia case have increased 25.6% and rates have increased 22.3% from 1997 to 1999. Laboratory, surveillance, screening and increased transmission risk behaviors were considered as causes of increase.

2000—Reported Chlamydia cases have increased 41.5% and calculated rates have increased 34.1% from 1996 to 2000. Again, laboratory, surveillance, screening and increased sexual-risk behaviors were considered as causes of increase.

2001—After significant declines through the mid-1990s, reported Chlamydia cases have increased 47.6% and calculated rates have increased 36.3% since reaching a low in 1996. [1996 and 1997 rates were nearly identical.]

2002—After significant declines through the mid-1990s, reported Chlamydia cases have increased steadily since 1996. In 2001, Washington State initiated a public awareness campaign in six counties encouraging asymptomatic men 15-29 years old to be screened for Chlamydial infection.

It should be noted that the Centers for Disease Control have adjusted rates of Chlamydia infection based on increased sensitivity laboratory testing. The CDC finds that Region X's rate of infection for Chlamydia is in a trend of positivity rather than decline even after such adjustment.[240]

Washington State gonorrhea rates of infection have also been increasing steadily each year, following an all-time low in 1998:[241]

1998 – 34 /100,000
1999 – 39 /100,000
2000 – 42 /100,000
2001 – 50 /100,000
2002 – 48 /100,000

Washington State Department of Health cautions that, "While [2002 rates are] somewhat lower than rates observed in 2001, it would be premature to interpret this decrease as indicative of a broad reversal in increasing disease trends."[242]

The Washington State pharmacist-direct pilot project does not simulate an OTC setting for MAP due to use of protocols and pharmacist supervision. Therefore, OTC/MAP will likely result in even greater increases in rates of STD transmission.

Adolescent STD Infection Rates in Sweden

Sweden serves as another example of increased rates of adolescent STD infection following introduction of MAP. Sweden was one of the first countries to introduce the morning-after pill in the late 1990s. In 1998-99, a study was conducted of 134 young women aged 15-25 obtaining MAP at a youth clinic.[243] The women were monitored for 12 months. **None of the women had a positive Chlamydia test.**

By 2001, however, the impact of MAP was clearly observable in STD and abortion statistics for Sweden. A study published 2002 found that:[244]

- Teenage abortion rates had increased, from 17/1000 to 22.5/100

- Overall, Chlamydia infections had increased as follows:
  - 14,000 in 1994
  - 16,711 in 1999
  - 19,284 in 2000
  - 22,263 in 2001

- 60% of Chlamydia cases occurred among young people with the steepest rise among teenagers

- A 1999 questionnaire of 17 year olds found that having a steady partner or being in love were becoming less prerequisites for having sex, compared to prior surveys.

The study stated that, "a question of major concern is whether and how adolescent sexual behavior has shifted towards more risky practices during the late 1990s."

Swedish Institute for Infectious Disease Control (SMI) statistics for 2002 and 2003 show continuing trends of high rates of Chlamydia infection among young people:[245]

% of all Chlamydia infections: 15-19 year olds

- 2002 – 23.4%
- 2003 – 27.7%

% of all Chlamydia infections: 20-29 year olds

- 2002 – 61.4%
- 2003 – 58.1%

Gonorrhea infections have also increased among 15-19 year olds. In 2002, this age group represented

4.7% of all Gonorrhea infections; in 2003, this age group represented 7.8%.[246]

Syphilis infections have also increased among 15-19 year olds. In 2002, this age group represented 1.5% of all Syphilis infections; in 2003, this age group represented 3.8%[247]

Like Washington State, Sweden has experienced rapidly increasing rates of STD infection among young persons, especially adolescents, since MAP was introduced on a widespread basis.

Repeat Use/Abuse of MAP Poses Significant Risk

In his presentation to the FDA advisory committee reviewing Plan B's application for OTC status, FDA medical officer Dr. Daniel Davis discussed the risks of repeat use based upon a United Kingdom study published in *The British Journal of Family Planning*, which claimed it "disproved the notion of widespread repeated use of emergency contraception."[248] Since it was relied on by Dr. Davis and the FDA advisory committee, it is important to examine this study carefully.

The U.K. study on repeat MAP use examined patient files of 95,007 women aged 14-29 in the General Practice Research Database over a 4-year period starting in 1993, searching for evidence of use of MAP and regular contraception. Of the 95,007 records examined, 15,105 women had received MAP. The study admits that "possible sources of inaccuracy in the data used in the study" may have affected the study's results. Particular problems included: (a) possibility of incomplete GP records concerning MAP/contraceptive use; (b) inability to identify patients who switched use between GP and family planning clinic for services (family planning clinics not included in database); (c) only 29% of teenagers under age 16 receive contraceptives from GP (which was the database searched in this study); (d) the extent that emergency departments were used to obtain MAP (not in database); (e) steady increase in use of family planning clinics by teenagers under 16; and (f) changes in MAP use from year to year were not fully considered in the 14-19 age group because data on the youngest women were available only for the first year. **These numerous variables and possible inaccuracies in the study data do not permit any clear conclusions to be drawn.**

Additional considerations concerning findings of U.K. repeated use study: (a) Data are more than a decade old, when general MAP awareness and use was limited; (b) In fact, study period mostly precedes international campaign to increase acceptance, awareness and use of MAP (with special emphasis on denying any abortifacient effect). For these reasons, MAP use/repeated use was likely much lower in 1993 than an equivalent study would reveal today; (c) In this study, MAP was available by prescription only, making the study's findings irrelevant to a discussion of OTC/MAP; (d) Prescription-only availability of MAP in this study provided medical supervision and oversight which likely minimized patient requests for and physician provisions of repeat MAP; and (e) In a survey of physician attitudes contemporaneous with (and referenced in U.K. MAP repeat use study), most physicians had a personal limit as to the number of times they would provide MAP for a particular patient.

Important relevant findings of U.K. MAP repeated use study: (a) Use of MAP by adolescents aged 14-19 (21.1%) was almost twice as frequent as women aged 25-29 (11.5%); (b) Family planning clinic statistics show peak use in the 16-19 age group; (c) For all groups, use of MAP increased during the 4 years of the study and this was only due in part to an aging effect; and (d) The Study found that, "Use of EC is predominantly by teenagers likely to be initiating sexual relationships. . . . Both use and repeat use of EC was more common in the 14-19 age group. This fits with exploratory sexual behavior in teenagers. Teenagers' use of EC may often have been their first experience of accessing contraceptive services; the majority was subsequently using regular contraception soon afterwards," which is defined in the study as within one year. Some may conclude that this study suggests that MAP is not so much a "bridge" to regular contraception as it is an encouragement for youth to become sexually active.

OTC/MAP Promoted as Response to Sexual Assault of Children, Adolescents

At December 2003 FDA advisory committee meeting on Plan B/OTC application, Vivian Dickerson, MD, president-elect, American College of Obstetricians and Gynecologists (ACOG), was one of three individuals who made presentations on behalf of Plan B's manufacturer, Women's Capital Corporation/Barr Laboratories. Dr. Dickerson said adolescents should have access to OTC/MAP because they, "in particular, [do not] have control over the occurrence of intercourse or the use of contraception. Examples of such cases are **rape, date rape, partner pressure,** or other socio-cultural pressures to engage in sex without contraception." [Emphasis added.][249] It is simply astounding that ACOG considers OTC/MAP an appropriate response to sexual assault of adolescents. Our nation's adolescents deserve a better response to **rape, date rape and partner pressure** than OTC/MAP.

According to Family Health International, "For young people who are not prepared for a sexual experience or who had **involuntary sex**, ECPs offer a second chance at contraception." [Emphasis added.][250] An Advocates for Youth report found that seven percent of students ages 12 through 16 **were forced against their will to do something sexual with an adult**. Seventeen percent of students ages 12 through 16 **were forced to do something sexual with another teenager.**[251] Our nation's adolescents who have been victims of **involuntary sex** deserve a better societal response than OTC/MAP.

A Johns Hopkins Bloomberg School of Public Health report advocated in favor of OTC/MAP stating, "women abused by their husbands or boyfriends often are unable to negotiate the timing or the terms of sexual intercourse."[252] In support of this claim, the report referenced a Population Reports article which stated: "Two of the most common forms of violence against women are abuse by intimate male partners and **coerced sex**, whether it takes place in **childhood, adolescence**, or adulthood."[253] Our nation's children and adolescents who have been victims of coerced sex deserve a better societal response than OTC/MAP.

The USAID Fact Sheet on Emergency Contraception describes adolescent women as falling into a category that needs MAP because these adolescent women might **"have been raped, . . .** [they] were **not expecting to have sex."**[254] These situations present serious concerns about sexual coercion facing adolescents. OTC/MAP status will magnify these serious problems. Our nation's adolescents deserve a better response.

The CDC Youth Risk Behavior Surveillance (2001) reported that nationwide 7.7% of students had ever been forced to have sexual intercourse they did not want. Female students (10.3%) were twice as likely as male students (5.1%) to have been forced.[255]

Advertisements targeting teenagers encourage them to use OTC/MAP if they have been victims of sexual assault.[256]

MAP "Toolkit" for Schools Targets Adolescents

The Academy for Education Development has published an MAP toolkit for use in schools and community-based organizations: "Building Emergency Contraception Awareness Among Adolescents: A Toolkit for Schools and Community-based Organizations." Bearing in mind that the ultimate target audience of the Toolkit is adolescents, the strategies contained in the Toolkit are an insightful look into the beliefs, motives and methodologies of those organizations who wish to promote MAP to our youth. All of the following points are contained within the Toolkit:[257]

- MAP is helpful in situations where "sex was forced."
- Some providers (e.g., Planned Parenthood affiliates) will phone an MAP prescription to a local pharmacy without a visit; MAP is available on the internet via Planned Parenthood websites; Planned Parenthood will reduce fees for teenagers.

- If fertilization has occurred, MAP will “inhibit a fertilized egg from implanting in the uterine wall.”

- Title X clinics are required to provide confidential services to teens; outside of Title X clinics, state laws govern whether MAP can be provided to minors without parental notification/consent.

- Teens can contact the Alan Guttmacher Institute, the ACLU Reproductive Freedom Project or local Planned Parenthood affiliate for information about state laws on MAP.

- The national Emergency Contraception hotlines and websites are provided repeatedly to students in school.

- Teachers, guidance counselors, youth workers and others should not wait until the teenager asks. Discuss MAP before s/he asks. Repeat the information on different occasions. Make sure adolescents know where to obtain MAP in local area. Help teenagers get MAP immediately.

- If a teen is worried that she may be pregnant, help her decide whether to ask parent to help her make a decision. However, if the teen decides not to involve the parent, teacher is under no legal obligation to notify the parent.

- More than half of the women who experience rape or attempted rape were under age 18. Child/ adolescent rape victims are usually assaulted by a relative or acquaintance.

- Use teens who already know about MAP to disseminate information to peers, possibly by handing out materials, writing newspaper editorials, writing to legislators.

- Lay the groundwork for in-school MAP initiatives by attempting to obtain a letter of permission from the district superintendent; failing that, some districts will allow MAP information in the schools so long as no controversy ensues; failing this, work with key leaders to attempt to change school policies.

- If middle schools are teaching sex education that includes pregnancy prevention, then it is appropriate to include MAP in the curriculum.

- If outside speakers provide school sex education, ask them to discuss MAP.

- School-based health center should have a protocol for providing MAP when clinic is closed.

- Counselors are to be nonjudgmental and nondirective and avoid personal bias.

- Measuring how many pregnancies were avoided by MAP use is “tricky” and the research is “impractical” for schools and CBOs.

- Integrate MAP into the health curriculum. Find creative ways to integrate MAP into academic curricula (History/Social studies – discuss freedom and human rights; Math – take a poll of student knowledge about MAP, breaking down responses by age and gender; English/Language Arts – write papers and essays; Art – develop posters and videos; Biology – describe how MAP works)

- MAP Consent Form *to be signed by the child* lists contraindications for MAP as: pregnancy, thrombophlebitis or emboli; controlled hypertension. *The Medical Director—not the parent—is to assess potential benefits versus potential risks for particular child*.

- MAP Consent Form *to be signed by the child* acknowledges that she is aware that MAP reactions may include nausea/vomiting, breast tenderness, irregular vaginal bleeding and headache. Ectopic

pregnancy is not mentioned, except obliquely: "I understand that I need to seek immediate health care if I have severe new pain in any part of my body, particularly severe headaches or severe pain in my abdomen, chest or legs."

- School administrators may be supportive of MAP in their schools, but fearing controversy, may provide only "tacit approval." That may be all that is needed to begin MAP program.

In summary, the Toolkit is a strategic roadmap for introducing MAP into the school system by circumventing parental knowledge/approval and by obtaining quiet acceptance from administration, rather than overt approval which might generate controversy threatening the program.

Additional Concerns About Adolescent MAP Use/Abuse

A December 2003 report from Scotland provides evidence that adolescent use of contraception and MAP actually *increases* teen pregnancy rates.[258] MAP and condoms were provided free confidentially to students. The pilot project resulted in a 10% increase in teen pregnancy rates among 13 to 15 year olds, which occurred at a time that teenage pregnancy rates were falling across Scotland.

One study observed a troubling effect when MAP was provided in advance: "Changes to less effective contraceptive methods and patterns of pill use were potentially negative effects that need to be explored . . . ."[259]

Survey of pediatricians found reluctance to prescribe MAP for adolescents. More than half of surveyed pediatricians said they would restrict number of times they would dispense MAP to a particular patient; 12% cited moral/religious reasons for not prescribing MAP; and 17% of pediatricians were concerned about teratogenic effects.[260] Medical oversight is not possible in OTC/MAP context. These concerns of pediatricians argue powerfully against OTC/MAP.

British Medical Journal found that teenagers whose pregnancies ended in induced abortion were *more likely* to have used MAP before conception.[261] The study surmises that MAP use is an indicator of willingness to engage in "risk-taking" behavior. The study also concludes need for "appropriate follow-up to address long term needs for contraception whenever a teenager consults for emergency contraception. It also raises questions about the possible supply of emergency contraception by agencies which are unable to provide such follow-up." The results of this study argue against OTC/MAP status.

According to Dr. Daniel Davis, medical officer, FDA Division of Reproductive & Urologic Drugs, only Norway and Sweden have true OTC status for MAP (66 countries have MAP available by prescription; 33 countries have MAP available direct from pharmacist).[262] Netherlands experience offers insight on possible future rate of U.S. adolescent use of MAP: 34 percent of Dutch women using MAP are teenagers under 20 years old. However, at the Rutgers Stichting clinics (youth-specific sexual health services clinics), the proportion of MAP prescriptions for adolescents is even higher at 51%.[263]

Some pro-MAP organizations believe even men are entitled to obtain MAP.[264] OTC status will make MAP available to men of all ages, presenting a perhaps irresistible opportunity for sexual coercion of young females. ***MAP is not prescribed to males.*** Prescription-only status is the only way to keep MAP available to females only, thereby minimizing opportunities for MAP to be used as a cover-up for sexual coercion or assault.[265]

Misleading Ads Promote Dangerous Sexual Behavior

OTC/MAP raises serious concerns over possibility of encouraging increased sexual activity among adolescents, leading to increased rates of HIV/STD infection and even induced abortion. In part, such concerns stem from U.S. experience post-legalization of abortion.[266]

MAP is portrayed as a solution for sexual assault and "contraceptive accidents" with no negative societal/ public health implications. However, Women's Capital Corporation advertising for MAP actually promotes provocative themes of dangerous and risky sexual behavior.[267] These advertisements encourage sexual attitudes of promiscuity and multiple partners, risking HIV/STD infection, pregnancy and abortion. These ads undermine MAP's stated purpose that MAP is for "contraceptive accidents" and sexual assault.

- **"So Many Men. So Many Reasons to Have Back-up Contraception."**[268] Plan B newspaper ad featuring picture of 13 college-age men.

- **"Delta Delta Thi. 27 Upstanding Young Men. 34 Billion Sneaky Little Sperm."**[269] Plan B newspaper ad featuring picture of more than 20 college-age men.

- **"A Renaissance Man, A Deep Thinker, An Ancient Soul, A Walking Sperm Factory."**[270] Plan B poster advertisement.

Other MAP advertising themes employ crude language inappropriate for broadcast via mass media:

- **Sperm Happens.**[271] Billboard.

- **Oh $#*!**[272] Picture of two pills imprinted with these words. Bus shelter ads, newspaper/magazine ads.

Population Services International produced a 10 minute video on MAP, which features sexually active young persons explaining why they do not wish to become pregnant. A preview clip available on-line ends with a young man's irresponsible, gratuitous comment revealing his "have fun" attitude towards sexuality:

> **"I don't think that a lot of people my age want to get pregnant. They realize that there's a lot of time to have children. This is the time to be young and have fun."**[273]

A particularly disturbing advertisement promoting OTC/MAP treatment for rape appears on Population Council website.

> **"Were you forced? Help is available if you act now. See your chemist or clinic about emergency contraception."**[274]

OTC/MAP is a completely inadequate response to sexual assault. Women who have been sexually assaulted deserve much more than a pill from the pharmacy.

Another advertising tool directed at adolescents and young adults also encouraged OTC/MAP after sexual assault. A wallet card asks,

> **"When Can I use Emergency Contraception Pills? You were forced to have sex."**[275]

A California Family Health Council's bus poster advertising MAP features a scene of **bathroom/shower with a woman's brassiere hanging from the showerhead and high heels abandoned on the floor.** A subliminal message of a casual sexual encounter is conveyed visually. The poster is captioned,

> **"When things don't go as planned . . ."**[276]

This bus poster is part of California Family Health Council's "provocative, attention grabbing campaign using cutting edge artwork."[277]

Provocative advertising for MAP is likely to increase. **"Let's Get It On: Making Teen Pregnancy**

Prevention Hot," is the title of an American Public Health Association presentation described as "social marketing."[278] This campaign follows the cutting-edge trend of "looking for new and innovative projects that engage youth" and countering opposition in conservative, rural communities. The project created "informative and on-the-edge media that teens would respect."

OTC/MAP places incest victims at risk of continued exploitation; they deserve better from society

USAID's Arguably Illegal Distribution of MAP Overseas

The United State Agency for International Development (USAID) has been actively involved in promoting and distributing MAP to poor women in developing nations for years. USAID has funded events designed to expand global access to MAP.[279]

In Uganda, for example, USAID initiated a "new Commercial Market Strategies project (CMS)" to introduce emergency contraception. With the help of Population Services International (PSI) and Pathfinder International, social marketing campaigns were carried out. PSI led focus groups among African women to increase use.[280]

In a Fact Sheet distributed to all of its overseas missions, USAID declared that morning-after pills are safe and effective, do not cause abortion, and "constitute an integral part of the voluntary service delivery mix that USAID supports."[281]

This OTC distribution of MAP, which occurred in the absense of an FDA ruling, suggests, a double standard in medical care. Women in the developing world are not accorded the same protections as women in the U.S. It is arguably a violation of the Tiahrt Amendment, which forbids the use of experimental methods on developing world women.

USAID employees have promoted MAP overseas in countries where such chemical abortifacients are illegal under the law. In Peru, a USAID official actively lobbied for the legalization of MAP, knowing that Peru's pro-life laws prohibit MAP.[282] While this USAID employee was disciplined for her actions, USAID's promotion of MAP throughout Latin America apparently continues. USAID-funded Family Health International, ignoring El Salvadorian law which defines life as beginning at fertilization, launched massive efforts in that country to promote MAP to girls as young as 10 years of age.[283]

Conclusion

1. **The Bush Administration should not permit MAP to become a standard treatment for suspected pregnancy by the Department of Health and Human Services.**

2. **The FDA approval for OTC/MAP status should be denied.**

3. **The Bush Administration should not include MAP as method of family planning in foreign programs because of known health risks and because its action includes abortifacient function.**

NOTE: All information documented above was obtained primarily from pro-OTC/MAP sources as well as FDA website. All websites referenced in these endnotes were accessed on February 15, 2004.

ENDNOTES
EMERGENCY CONTRACEPTION / INTERNATIONAL ORGANIZATIONS TIMELINE (Page 4-5)

[1] Princeton University Office of Population Research Institute. EC website was later moved to http://ec.princeton.edu.

[2] P. Senanayake, "Emergency Contraception: The International Planned Parenthood Federation's Experience." *Int.Fam. Plann. Perspect.* 1996; 22(2):69-70. As cited in "OCs Provide Emergency Contraception Option." Family Health International. *Network*, Summer 1996, Vol. 16 No. 4. Available at www.reproline.jhu.edu/english/6read/6issues/6network/v16-4/nt1645.html.

[3] "International Conference on Population and Development," United Nations ICPD Programme of Action, Cairo, Egypt, September 1994. Available at www.un.org/ecosocdev/geninfo/populatin/icpd.htm The Summary of Programme of Action states, "The 115-page document, adopted by acclamation on 13 September, endorses a new strategy which emphasizes the numerous linkages between population and development and focuses on meeting the needs of individual women and men rather than on achieving demographic targets."

[4] International Consortium for Emergency Contraception. Available at: http://www.cecinfo.org/html/ab-unique-approach.htm The original seven international abortion advocacy/population control groups were: *The Concept Foundation; International Planned Parenthood Federation; Pacific Institute for Women's Health; Pathfinder International; PATH (Program for Appropriate Technology in Health); Population Council; World Health Organization's Special Programme of Research, Development and Research Training in Human Reproduction.* Membership was later expanded but remains comprised predominantly of abortion advocacy and population control groups.

[5] "International Conference on Population and Development." United Nations ICPD Programme of Action, Cairo, Egypt, September 1994. The Programme specifically urged the provision of reproductive services to adolescents: "The text stresses that countries must ensure that programmes and attitudes of health-care providers do not restrict adolescents' access to the services and information they need. These services must safeguard the right of adolescents to privacy, confidentiality, respect and informed consent . . . . Countries, with the support of the international community, should protect and promote the rights of adolescents to reproductive health education, information and care, and greatly reduce the number of adolescent pregnancies. Governments are urged, in collaboration with NGOs, to establish appropriate mechanisms to respond to the special needs of adolescents."

[6] Dr. Sharon L. Camp's resume is available at www.guttmacher.org/pipermail/agi/2003-July/000080.html Dr. Camp was formerly senior vice president at Population Action International. Dr. Camp founded Women's Capital Corporation for the expressed purpose of bringing EC to over-the-counter market. After negotiating the sale of WCC to Barr Laboratories in anticipation of EC/OTC approval, Dr. Camp became new president/CEO of Alan Guttmacher Institute.

[7] "Consensus Statement on Emergency Contraception" *Contraception*, 1996; 52:211-212. The Consensus Statement (in an incomplete version) is available at www.path.org/outlook/html/13_3.htm The Consensus Statement included findings and recommendations that undermine support for EC/OTC status. For example, Consensus Statement: (a) targeted adolescents; (b) acknowledged contraindications to EC and indicated they should be respected; (c) desired EC availability to women "who are not currently using a family planning method," indicating a willingness to rely on EC for regular use, as opposed to emergency use only; (d) identified sexual violence/coercion as reason to provide EC "in context of STD clinics, rape crisis centers, police stations and hospitals" (such support systems/services are not possible in OTC context); (e) urged training for EC providers to include "counseling, treatment regimens, management of side effects and proper follow-up (none of which are possible in OTC context); and (f) urged that "women seeking EC should also be counseled and offered a choice of effective and reliable methods of contraception for regular use," (which is not possible in OTC context).

[8] Anna Glasier, Evert Ketting, V.T. Palan, "Case Studies in Emergency Contraception from Six Countries." *International Family Planning Perspectives.* June 1996. 22(2).p.57-61. Available at http://www.hsph.harvard.edu/Organizations/healthnet/SAsia/suchana/0507/glasier_etc.html Only one year later after Consensus Statement is published, this *International Family Planning Perspectives* report studied countries where EC was offered, concluding, "The experiences of these six countries suggest that family planning researchers and practitioners must be *both persistent and innovative* as they work to make emergency contraception available to more women in more countries around the world." [Emphasis added]

[9] "Consensus Statement on Emergency Contraception." The Consensus Statement called for "innovative service delivery options," which seems to indicate artificial stimulation of demand for/acceptance of EC."

[10] Elisa Wells and Michele Burns, "Expanding Global Access to Emergency Contraception: A Collaborative Approach to Meeting Women's Needs," International Consortium for Emergency Contraception. Available at www.cecinfo.org/files/Expaning-Global-Access-to%20EC.rtf Inclusion of this EC regimen "greatly enhanced the Consortium's introduction efforts," in social marketing of EC in selected countries.
[11] International Consortium for Emergency Contraception. Available at www.cecinfo.org. Website contains archive of ICEC internet newsletters, providing a historical overview of how EC awareness/acceptance/demand was coordinated worldwide. ICEC serves as advocate for expanded access to EC, strategic planning forum, facilitator of information sharing/networking, developer of public-private partnerships to make EC available to large numbers of women worldwide.
[12] Elisa Wells and Michele Burns, "Expanding Global Access to Emergency Contraception: A Collaborative Approach to Meeting Women's Needs." Through this collaborative agreement with Gedeon Richter, Budapest, Hungary, the Consortium promised to pave the way for a successful EC product by "gaining the support of government policy makers, providers, and community leaders, and helping family planning programs incorporate emergency contraception into their services." Grant monies from the David and Lucile Packard Foundation (and other private foundations) enabled the Consortium to test an EC introduction strategy in four countries (Indonesia, Kenya, Mexico and Sri Lanka).
[13] "OCs Provide Emergency Contraception Option," Family Health International, *Network*, Summer 1996, Vol. 16 No. 4. Available at: www.reproline.jhu.edu/english/6read/6issues/6network/v16-4/nt1645.html Article emphasizes that communication can increase access by "strengthening providers' knowledge of emergency contraception, increasing awareness of its availability and where to obtain it, and overcoming political obstacles." Article makes special mention of adolescents: "Women who seek emergency contraception are often embarrassed and frightened: *They may be adolescents who have had their first sexual contact, or* ***women who have been sexually assaulted.***" [Emphasis added.] Describing these situations as special circumstances, article continues, "providers' attitudes are very important. . . . Avoid prolonged counseling that might make the woman uncomfortable."
[14] Elisa Wells and Michele Burns, "Expanding Global Access to Emergency Contraception: A Collaborative Approach to Meeting Women's Needs." The Consortium first made EC available only through small number of family planning clinics, but EC requests quickly tapered off. Distribution was then expanded through public and private sector organizations, including 375 pharmacies. Controversy in Kenya's experience involved EC's abortifacient effect.
[15] "Emergency Contraception Timeline." Reproductive Health Technologies Project. Available at www.rhtp.org/ec/ec_timeline.htm.
[16] Elisa Wells and Michele Burns, "Expanding Global Access to Emergency Contraception: A Collaborative Approach to Meeting Women's Needs."
[17] Ibid. Inclusion of this EC regimen "greatly enhanced the Consortium's introduction efforts," in social marketing of EC in selected countries.
[18] American Society for Emergency Contraception. Available at www.emergencycontraception.org ASEC's membership list reads like a "Who's Who" of abortion advocacy and population control organizations. ASEC's purpose is to serve as national clearinghouse for EC information/promotion.
[19] "Daily Reproductive Health Report: Contraception and Family Planning, Barr Laboratories Acquires Emergency Contraceptive Plan B," *Kaiser Daily Network Reports.* October 6, 2003. Available at www.kaisernetwork.org/daily_reports/rep_index.cfm?DR_id=20191.
[20] "Newsroom," Women's Capital Corporation. Available at www.go2planb.com Newsroom section of website states: "How is the company financed? WCC is financed largely through loans and equity investments from U.S. foundations and nonprofit organizations. The David and Lucille Packard Foundation has provided the largest share of financing. A number of other foundations and nonprofit organizations hold equity shares in WCC. In addition, there are individual shareholders, including the company founders, directors and staff."
[21] "Press Release," Women's Capital Corporation. Available at http://ec.princeton.edu/news/planbpressrelease.html This 1999 press release from Women's Capital Corporation states that "Financing for Plan B has come, in large part, from U.S. foundations, such as the **David and Lucile Packard Foundation, the Wallace Alexander Gerbode Foundation and the Compton Foundation. Robert Wallace, Chairman of the Wallace Global Fund, was the project's "angel investor." Five Planned Parenthood affiliates also made equity investments in Plan B, including Planned Parenthood of Western Washington."**
[22] "About Women's Capital Corporation." Available at: www.go2planb.com/section/newsroom/about_wcc.
[23] "About this Initiative," Program on Reproductive Health and Rights, Open Society Institute. Available at www.soros.org/initiatives/repro/focus_areas/advocacy_litigation As a measure of its commitment to abortion rights,

the Open Society Institute states that the right to abortion, "has been seriously compromised by the imposition of often disabling burdens," such as mandatory waiting periods and parental consent laws for minors. (A majority of Americans strongly support these minimal safeguards to protect women and adolescent girls.) OSI also notes that "only 15 states today provide publicly-funded abortions in all or most circumstances." Fellowships offered by OSI encourage strategies for "tackling cultural, political and financial barriers to the free expression of reproductive rights . . . even when those rights contradict local, cultural or religious norms . . . ."

[24] Elisa Wells and Michele Burns, "Expanding Global Access to Emergency Contraception: A Collaborative Approach to Meeting Women's Needs."

[25] "Emergency Contraception Timeline," Reproductive Health Technologies Project.

[26] International Consortium for Emergency Contraception, "Emergency Contraception Highlights Update: 10/96 to 10/97." Available at: www.cecinfo.org/files/ecupdateHilights-96-97.rtf In 1995, the "Consensus Statement on Emergency Contraception" had called upon drug regulatory authorities to "require explicit description of emergency use in the labeling of . . . oral contraceptives." Less than two years after Bellagio conference, FDA took unusual step of permitting re-labeling oral contraceptives for emergency use without specific request from drug manufacturer. About this FDA action, ICEC stated," "On February 25, 1997, the U.S. Food and Drug Administration pronounced six U.S. brands of combined oral contraceptives safe and effective for use as emergency contraceptives and urged the pharmaceutical industry to apply for approval of new dedicated products."

"History of EC," Planned Parenthood of Amarillo and Texas Panhandle. Available at: http://www.ppatp.org/HistoryofEC.htm "In February 1997, the FDA did take a step that is most unusual in the absence of an application from a drug manufacturer. In response to the CRLP citizen petition, the FDA issued an official notice in the *Federal Register* declaring common regimens of emergency contraception to be safe and effective. The FDA also said it would accept applications to manufacture and market ECPs without requiring expensive new drug trials, because the safety and efficacy of emergency contraception had already been demonstrated (FDA, 1997).

[27] "Innovations in Service Delivery Grants Awarded, 1997-2004: Emergency Contraception," Open Society Institute. Available at: www.soros.org/initiatives/repro/focus_areas/innovations/grantees/grantee_list Recipients of the $4.5 Million in grant awards include some of the organizations who made presentations at the FDA advisory committee meeting in December 2003: Planned Parenthood Federation of America, Association of Reproductive Health Professionals, Reproductive Health Technologies Project (4 separate grant awards) and Public Health Initiative. From 1998 to 2004, the Open Society Institute also provided over $6.5 Million in funding for Early Options in Pregnancy Termination projects conducted by twenty-two organizations, including the National Abortion Federation, Abortion Rights Mobilization, Abortion Access Project, NARAL/NewYork, Population Council, and Planned Parenthood Federation of America.

[28] "Emergency Contraception Timeline," Reproductive Health Technologies Project.

[29] Transcript, Nonprescription Drugs Advisory Committee in Joint Session with the Advisory Committee for Reproductive Health Drugs Meeting, Food & Drug Administration, December 16, 2003, P. 21. Available at: www.fda.gov/ohrms/dockets/ac/03/transcripts/4015T1.pdf.

[30] "Center for Reproductive Rights Petitions FDA Petitions FDA to Change Emergency Contraception from Prescription to Over the Counter," Center for Reproductive Law and Policy [now Center for Reproductive Rights], February 14, 2001. Available at: http://www.crlp.org/pr_01_214ecpetition.html

[31] "Emergency Contraception Timeline," Reproductive Health Technologies Project.

[32] FDA Warning Letter to Women's Capital Corporation. Available at www.fda.gov/cder/warn/2002/11214.pdf. Copy of FDA Warning Letter also available at http://www.pharmcast.com/WarningLetters/Yr2002/November2002/WomensCapital120302.htm.

[33] Women's Capital Corporation website. Available at: http://www.go2planb.com/section/newsroom/in_the_news/.

[34] "Emergency Contraception Timeline," Reproductive Health Technologies Project.

[35] "Barr Signs Letter of Intent to Acquire Plan B Emergency Contraceptive," Barr Laboratories, Inc., Press Release, October 2, 2003. Available at: http://www.barrlabs.com/pages/nprpr.html.
"Barr Says FDA Extends Plan B Emergency Contraceptive PDUFA Date: FDA Reviewing Additional Information on Application for Over-the-Counter Status," *Press Release*, Barr Pharmaceuticals, Inc., February 13, 2004. Available at www.go2ec.org/pdfs/Barr%20Press%20Release.doc.

[36] Press release, The Alan Guttmacher Institute. Available at: www.guttmacher.org/pipermail/agi/2003-July/000080.html.

[37] "About Women's Capital Corporation," Plan B website. Available at: www.go2planb.com/section/newsroom/about_wcc.

"New OSI 'Ideas' Paper Urges Common Ground," Open Society Institute. Available at www.soros.org/

initiatives/repro/press/ideasabortion_20010426. The convergence of abortion advocacy with EC advocacy is illustrated by Dr. Chesler's leadership on both issues. Dr. Chesler is author of *Woman of Valor*, a biography of Margaret Sanger, founder of Planned Parenthood. In her position with Open Society Institute, Dr.Chesler authored "The Abortion Debate: Finding Common Ground," which advocates lifting legal restrictions on surgical abortion. Open Society Institute states that it "debates provocative and innovative ideas and strategies for social change."

[38] "About Women's Capital Corporation," Women's Capital Corporation. Available at: www.go2planb.com/section/newsroom/about_wcc/wcc_faqs. The David and Lucille Packard Foundation provided the largest share of financing. WCC Board of Directors are: Ellen Chesler, Ph.D., chair; Gordon W. Duncan, Ph.D.; Mark D. Duncan, MBA; Dell E. Keehn, MBA; Gordon W. Perkin, MD; J.Joseph Speidel, MD.

"Press Release," Women's Capital Corporation. Available at http://ec.princeton.edu/news/planbpressrelease.html. This 1999 press release from Women's Capital Corporation states that "Financing for Plan B has come, in large part, from U.S. foundations, such as the **David and Lucile Packard Foundation, the Wallace Alexander Gerbode Foundation and the Compton Foundation. Robert Wallace, Chairman of the Wallace Global Fund, was the project's "angel investor." Five Planned Parenthood affiliates also made equity investments in Plan B, including Planned Parenthood of Western Washington."**

[39] Newsroom, Women's Capital Corporation. Available at: www.go2planb.com/section/newsroom.

ENDNOTES
EMERGENCY CONTRACEPTION / INTERNATIONAL ORGANIZATIONS

[1] Plan B Package Insert, "Clinical Pharmacology." Available at: www.go2planb.com/section/about/package_insert.

"Briefing Document: Nonprescription Drugs and Reproductive Health Drugs Advisory Committee Meeting," Women's Capital Corporation, Plan B for Emergency Contraception Rx-to-OTC Switch, 14 November 2003, Appendix 1: Mechanism of Action. See www.fda.gov/ohrms/dockets/ac/03/briefing/4015B1_01_WCC-Briefing%20Document.pdf. To supports its claims that Plan B is not abortifacient, Women's Capital Corporation's Briefing Document included a Medical Bulletin from International Planned Parenthood Federation entitled, "Emergency Contraception Pills: How Do They Work?" The Medical Bulletin begins by acknowledging that "the mode of action of emergency contraception has become the subject of heated debate in several countries. The main question centres on whether or not EC prevents pregnancy by interfering with post-fertilization events. This issue is of importance for many people who believe that a new human life begins at the time fertilization is completed; thus, interference with post-fertilization events would lead to loss of human life." This introduction makes apparent that the stakes are high: Should studies prove that MAP has an abortifacient function, many persons – even entire nations – will have a moral abhorrence to MAP that may prove fatal to its widespread use. The report asks a very simple question: What if MAP is taken too late to prevent fertilization? It answers that question: either MAP fails and pregnancy occurs or MAP "prevents pregnancy, in which case it acts after fertilization." Since no MAP user knows whether the pills were taken before or after ovulation and since no study could ethically or logistically make such determinations, the report finds, "there is no direct evidence for or against the hypothesis that MAP pills prevent pregnancy by interference with post-fertilization events." The report seems to admit that MAP is sometimes taken too late to prevent ovulation and fertilization may occur. However, since this effect cannot be proved in any particular woman's use of MAP, there is no direct evidence. The report also discusses studies of endometrium alterations where endometrium biopsies were obtained. The report states that "treated cycles in which the ovulatory process is believed to be abnormal or suppressed are excluded since endometrial development would reflect abnormal ovarian function rather than a direct effect of the EC pill." However, where abnormal or suppressed ovulation occurs, consequent changes in endometrial development would be an indirect but still abortifacient effect of MAP.

[2] Anna Glasier, Evert Ketting, V.T. Palan, "Case Studies in Emergency Contraception from Six Countries." *International Family Planning Perspectives.* June 1996; 22(2) p.57-61. Available at http://www.hsph.harvard.edu/Organizations/healthnet/SAsia/suchana/0507/glasier_etc.html. As a strategy to overcome opposition to emergency contraception, this report found that, "A clear distinction must be drawn between emergency contraception and abortion, especially in countries where abortion is legally restricted or carries a moral stigma. A confusion of emergency contraception with abortion can seriously impede efforts to prevent unintended pregnancy through use of emergency methods . . . . Emergency contraception should be cast as an important way to reduce the need for abortion."

[3] Horacaio B. Croxatto, et al., "Mechanism of Action of Hormonal Preparations for Emergency Contraception: A Review of the Literature." 63 *Contraception* 111-121 (2001). This review was funded by UNDP/UNFPA/WHO/World Bank Special Programme of Research, Development and Research Training in Human Reproduction. **The review seemed to acknowledge that a particular point of view on MAP's abortifacient effect was important**. First, the review states that determining how MAP impedes pregnancy is an important question "**in order to attain an informed choice**" and it "**should contribute to overcome barriers in many settings, facilitate the widespread utilization of preparations for EC**, and lead toward further improvements. **The mode of action is important for some users, health providers, policy makers, developers and manufacturers because of sensitive ethical issues**." [Emphasis added.] These ethical issues are identified as whether MAP works "before or after fertilization," and "before or after implantation." This review found that there are "few studies designed to look at the mechanism of action of [levonorgestrel] and its exact mode of action remains unknown." The review referenced a study which found that levonorgestrel's effect was "preovulatory administration had no effect on ovulation, whereas at the level of the endometrium, it caused divergent effects **depending on the time of drug intake.** Factors believed to be critical for implantation . . . were changed in ways which are likely to alter endometrial receptivity." The review itself admitted that "one of the complexities that researchers have to deal with . . **. is that the mechanism may differ . . . depending upon when [MAP] is given relative to the time of intercourse and relative to time of ovulation**." [Emphasis added.]

G. Ugocsai, et al., "Scanning Electron Microscopic (SEM) Changes of the Endometrium in Women Taking High Doses of Levonorgestrel as Emergency Postcoital Contraception." 66 *Contraception* 433-437 (2002). This is a

recent study from Hungary, where levonorgestrel emergency contraception was first developed commercially (Gedeon Richter, Budapest). In this study, three women intentionally took high doses of levonorgestrel as emergency postcoital contraception, because they were panicked at the possibility of pregnancy. After later seeking medical treatment, these women provided scientists a rare opportunity to study and diagnose endometrial changes in humans. The study found that Scanning Electron Microscopic analysis "confirmed *unambiguous* changes on the endometrial surface compared to control specimens. The changes seemed to be exclusively attributable to the effect of the external levonorgestral load. . . . Our results revealed marked endometrial changes both in the proliferative and secretory phases of the cycle. . . . The surface alterations seen with high doses may not be detected under the influence of recommended doses, but the underlying molecular changes, caused by levonorgestrel, may correspond to the contraceptive effect. With the application of other, more selective gestogens or progesterone antagonists, as a consequence, the "phasing-out" of the endometrium ensues, so accomplishing effective endometrial contraception."

Elizabeth G. Raymond, et al., "Effect of the Yuzpe Regimen of Emergency Contraception on Markers of Endometrial Receptivity." *Human Reproduction*, November 2000, Vol. 15, No. 11, 2351-2355. Available at http://humrep.oupjournals.org/cgi/content/full/15/11/2351. This study examined combined estrogen/progesterone MAP known as the Yuzpe regimen. This study appears inconclusive at best and may even confirm MAP's abortifacient effect, depending upon interpretation of data. After noting various shortcomings in the data, the study admits, "we did note five statistically significant differences in treated cycles compared with untreated cycles. However, the relationship between these changes and the contraceptive action of the emergency contraception is unclear." The study goes on to report, "The reason for the differences between our primarily negative findings and the striking structural endometrial abnormalities seen by early researchers is not clear. . . . Our results leave a puzzling gap in our understanding of the mechanism of action of this therapy."

James Trussell, Ph.D., et al., "Statistical Evidence About the Mechanism of Action of the Yuzpe Regimen of Emergency Contraception." *Obstetrics & Gynecology*, 1999; 93:872-876. Available at www.greenjournal.org/cgi/content/full/93/5/872. The study found that ovulation is not always prevented under the Yuzpe regimen for MAP and that women "were more likely to request [MAP] treatment after unprotected intercourse that occurred on the day of ovulation or the preceding or subsequent day," which would increase risk of fertilization. The report concluded: "The best information currently available indicates that the Yuzpe regimen could not be as effective as it appears to be if it worked only by preventing or delaying ovulation."

Laurie Barclay, MD, "Over-the-Counter Emergency Contraception: A Newsmaker Interview with David A. Grimes, MD.: *MedScape Medical News*, October 1, 2002. See www.medscape.com/viewarticle/442258. In the interview, Dr. Grimes, Vice President of Biomedical Affairs at Family Health International, Research Triangle Park, North Carolina, stated, **"[MAP's] mechanism of action is to prevent implantation of the fertilized egg into the uterine lining**." This admission is especially significant considering that Dr. Grimes was one of only three individuals whom Plan B's manufacturer chose to make formal presentations to the Dec. 2003 FDA advisory committee. Plan B's application for over-the-counter status was filed by Women's Capital Corporation and was presented by Barr Laboratories.

James Trussell, Ph.D., et al., "Updated Estimates of the Effectiveness of the Yuzpe Regimen of Emergency Contraception," *Contraception*, 1999;59:147-151. Available at www.ibisreproductivehealth.org. This study's definition of pregnancy is very revealing: "conception [is] used synonymously with implantation, not fertilization." If MAP has no abortifacient effect, then it would not be necessary to rely upon this modified and controversial definition of conception and pregnancy. If MAP has no abortifacient effect, MAP would prevent all pregnancies before fertilization which would obviate the dispute over the definition of conception, at least as to this study.

Chris Kahlenborn, et al., "Postfertilization Effect of Hormonal Emergency Contraception," *The Annals of Pharmacotherapy*, Vol. 36, No. 3, Pp. 465-470, 2002. www.polycarp.org/postfertilization_polycarp_1.htm.

[4] "Key Facts About Emergency Contraception," California State Board of Pharmacy, October 2003. Available at: http://www.pharmacyaccess.org/PrintedMaterials.htm. This Fact Sheet states: "EC won't cause an abortion. Emergency Contraceptive pills are NOT the same as RU-486 (the abortion pill). Emergency Contraceptive pills are not effective after pregnancy has occurred and cannot interrupt it." This does not make clear that MAP may alter the endometrium and thereby prevent implantation.

"The Emergency Contraception Program: An Informational Brochure for Pharmacists," *Pharmacy Access Partnership*, Public Health Institute. Available at: www.pharmacyaccess.org/PromotingECServ.htm. This brochure for pharmacists states: "EC works before implantation and therefore stops a pregnancy before it begins." Pharmacists who consider human life to begin at *fertilization* and not *implantation* are not provided an opportunity to exercise conscience objection. Pharmacists relying on this brochure cannot provide accurate information to patients to enable informed consent.

[5] "Contraception, Not Abortion – An Analysis of Laws and Policy Around the World," Center for Reproductive Rights, April 2002, Item: B012. Available at: www.reproductiverights.org/pub_bp_icpdec2_endnotes.html. This briefing paper provides an overview of the status of law and medicine concerning MAP. Unlike other arguments supporting MAP, this briefing paper does not deny the fact that MAP sometimes acts by permitting fertilization but preventing implantation. Instead, this report relies on revised definitions of conception and pregnancy: "Methods that delay or inhibit ovulation, block fertilization *or prevent implantation of the fertilized egg* are means of preventing pregnancy." [Emphasis added.] The report quotes a *New England Journal of Medicine* article describing MAP as "delaying or inhibiting ovulation, by inhibiting fertilization, or *by inhibiting implantation of a fertilized egg."* [Emphasis added.]

Chris Kahlenborn, et al., "Postfertilization Effect of Hormonal Emergency Contraception," *The Annals of Pharmacotherapy*, Vol. 36, No. 3, Pp. 465-470, 2002. www.polycarp.org/postfertilization_polycarp_1.htm

[6] *Kathleen Brownfield v. Daniel Freeman Marina Hospital*, 208 Cal.App.3d 405 (Ct.App. 1989). Available at www.courtinfo.ca.gov/opinions. *Brownfield* held that a Catholic hospital could be held liable for medical malpractice for failing to provide a rape victim with information about emergency contraception. The court found that emergency contraception constitutes pregnancy prevention rather than termination and, therefore, conscience objection protections under state abortion statutes did not apply. Many state legislatures are currently grappling with conscience objection protections for pharmacists. However, store managers, clerks, cashiers, etc. have no protections in law for their abortion conscience objections. Until now, such protections have not been needed for persons employed outside of the healthcare field. Should legal and medical attempts to redefine emergency contraception as non-abortifacient become standardized, OTC/MAP status threatens to place ordinary working Americans in coercive employment situations in violation of their consciences. "Service to Minors," Washington State Pharmacy Association. Available at www.go2ec.org/pdfs/WA_ServiceToMinors.pdf. *Brownfield v. Daniel Freeman Marina Hospital* is referenced in Washington State's "Service to Minors" guidelines. The guidelines suggest that when pharmacists are confronted by angry parents of a minor who received MAP, *Brownfield* should be cited as a legal precedent requiring pharmacists either to provide MAP/contraceptive services or to face liability.

[7] "Texas Pharmacists Fired by Eckerd Corporation for Ethical Stand on Morning After Pill," LifeSiteNews.com, 4 February 2004.

[8] Walter L. Larimore, MD, et al, "Postfertilization Effects of Oral Contraceptives and Their Relationship to Informed Consent." *Archives of Family Medicine*, Vol. 9 February 2000 http://archfami.ama-assn.org/cgi/reprint/9/2/126.pdf. Although this article is an analysis of oral contraceptives, its conclusions concerning informed consent are applicable to MAP: "Despite the lack of quantitative data, the principles of informed consent suggest that patients who may object to any postfertilization loss should be made aware of this information so that they can give fully informed consent . . . ."

U.S. Conference of Catholic Bishops, "Bishops' Official Calls FDA Ruling on 'Plan B' a 'Reckless Experiment' on Women." http://www.usccb.org/comm/archives/2003/03-245.htm.

Horacio B. Croxatto, et al, "Mechanism of Action of Hormonal Preparations for Emergency Contraception: A Review of the Literature." 63 *Contraception* 111-121 (2001). This study acknowledges that determining how MAP impedes pregnancy is an important question "in order to attain an informed choice."

[9] Transcript, Nonprescription Drugs Advisory Committee in Joint Session with the Advisory Committee for Reproductive Health Drugs Meeting, Food and Drug Administration, December 16, 2003. Transcript at: www.fda.gov/ohrms/dockets/ac/03/transcripts/4015T1.pdf.

[10]U.S. Conference of Catholic Bishops, "Bishops' Official Calls FDA Ruling on 'Plan B' a 'Reckless Experiment' on Women." http://www.usccb.org/comm/archives/2003/03-245.htm.

[11] Laurie Barclay, MD., "Over-the-Counter Emergency Contraception: A Newsmaker Interview with David A. Grimes, MD," *MedScape Medical News*, 2002, at www.medscape.com/viewarticle/442258. In response to a question about the experiences of other countries concerning MAP's effect on the rate of unplanned pregnancies and STDs, Dr. Grimes replied, "[N]o postmarketing surveillance studies or epidemiologic studies are planned. How would you do such a study, and how would you interpret the results? **Finding a change in the rate of unplanned pregnancy or of STD and attributing it to OTC availability would be an ecological fallacy.** That would be like finding that the number of telephone poles in a city is correlated with the number of heart attacks, and concluding that telephone poles cause coronary artery disease." [Emphasis added.]

Transcript, Nonprescription Drugs Advisory Committee in Joint Session with the Advisory Committee for Reproductive Health Drugs Meeting, Food and Drug Administration, December 16, 2003, P. 104. The FDA's own medical officer seemed to call into question the reliability of certain postmarketing surveillance data. Dr. Daniel Davis stated with regard to ectopic pregnancy reports, "The use or exposure data is often estimated. The likelihood

of reporting adverse events may be greater or lesser, depending on the nature of the event. . . . [T]here's considerable underreporting of adverse events. And . . . many of the postmarketing AE reports lack complete clinical information. . . . [O]verlapping of the reports often makes it difficult to interpret the data."

[12] "Service to Minors," Washington State Pharmacy Association. Available at www.go2ec.org/pdfs/WA_ServiceToMinors.pdf. This guidance for pharmacists explains how to deal with parents who discover their daughter has received emergency contraception from the pharmacy. First, it is stated that MAP is "considered the accepted standard of treatment to prevent an unintended pregnancy after unprotected intercourse" and equates MAP with contraceptives. The guidance explains that, "Minors are assured the same confidentiality rights as others. *A breach in confidentiality may arise when the insurance company bills the parent for contraceptive services provided or the minor uses the family's medical coupon."* [Emphasis added.] The guidance explains that, "Parents' reactions to learning that their child has received contraceptive services vary and range from being upset to feeling displaced and sad. For instance, they may feel upset when discovering . . . an ECP [Emergency Contraception Pill] prescription in the child's personal belongings because it indicates a level of sexual activity of which they were not aware." The guidance recommends that, "if appropriate, inform parents that minors can consent to contraceptive and family planning services under state laws and it is the pharmacist's obligation to provide them."

[13] Enitza D. George, M.D., "Challenges in Adolescent Female Contraception," American Academy of Pediatrics 1999 Annual Meeting, as reported in *Medscape WebMD*. Available at www.medscape.com/viewarticle/423493. In an article for pediatricians, Dr. George recommends, "If the adolescent insists on keeping her [contraceptive] choices a secret, the clinician should assure the patient of confidential care, bearing in mind that reports to third-party payers may make parents aware of their child's diagnosis and of the clinician's diagnosis and therapeutic procedures. To ensure absolute confidentiality, it may be necessary to refer the [adolescent] patient to a planned parenthood agency or other community resources. Public agencies provide oral contraceptive pills (OCPs) at a reduced cost, which obviates the need to request monies from the parent to fill prescriptions." Dr. George also recommends various strategies to get the adolescent to submit to a pelvic exam and to keep parents unaware that their child is sexually active: "When justifying the pelvic exam to parents who are unaware of their adolescent's sexual activity, tell them that the exam is needed to differentiate primary and secondary causes of dysmenorrhea."

"Building Emergency Contraception Awareness Among Adolescents: A Toolkit for Schools and Community-Based Organizations," Academy for Educational Development, 2003. Available at: www.aed.org/publications/ECtoolkit3283.pdf. Toolkit states, "ECP use is strictly confidential and parental consent is not necessary to receive a prescription or purchase the pills."

[14] "Emergency Contraceptive Pill," Population Reports, Series A, Number 9. Available at: www.infoforhealth.org/pr/a9/a9ecp.shtml. Article states: "Emergency contraception is a pressing need for many battered women. Women abused by their husbands or boyfriends often are unable to negotiate the timing or the terms of sexual intercourse. . . . A violent sexual partner may prevent a woman from using ongoing contraception . . . . Thus access to ECPs is especially critical for battered women." While it argues for OTC/MAP availability especially for battered women, the article appears self-contradictory in that it recognizes that abused/battered women have serious needs, which needs are not addressed by OTC/MAP.

Transcript, Nonprescription Drugs Advisory Committee in Joint Session with the Advisory Committee for Reproductive Health Drugs Meeting, Food and Drug Administration, December 16, 2003. Presentations by Women's Capital Corporation/Barr Laboratories representatives included sexual assault as a reason for OTC/MAP. See Carole Ben-Maimon, MD, Vivian Dickerson, MD, and David Grimes, MD, at pp. 28, 32, 38, 63, 81.

"What Can You Do If An Accident Happens?" *Accidents Happen, Pregnancy Doesn't Have To Marketing Campaign*, Population Services International (PSI). Available www.go2ec.org/pdfs/PSI_EC_Wallet.pdf. This wallet card urges adolescents and young persons to use MAP in various situations, including sexual assault: "**When can I use Emergency Contraception Pills? You were forced to have sex.**"

[15] Kristin A. Moore, et al. "Beginning Too Soon: Adolescent Sexual Behavior, Pregnancy and Parenthood, A Review of Research and Interventions," U.S. Department of Health and Human Services under Contract No. DHHS-100-92-0015, D.O.08. Available at: http://aspe.os.dhhs.gov/hsp/cyp/xsteesex.htm. This study found that "before age 15, a majority of first intercourse experiences among females are reported to be non-voluntary." The study also found that the younger the age of first sexual intercourse, the more likely that the experience was coercive. The study also found that sexually active adolescents have extremely high rates of STD infection and risk exposure to HIV.

Katie Dillard, "Adolescent Sexual Behavior. 1: Demographics," Advocates for Youth, November 2002. Available at www.advocatesforyouth.org/publications/factsheet/fsbehdem.pdf. This report stated that, "In a study of students ages 12 through 16, seven percent had been forced against their will to do something sexual with an adult; 17 percent with a teenager. . . . 47 percent of teens who had experienced sexual intimacy said they had done something

sexual or felt pressure to do something they weren't ready to do. Teenage women were more likely than teenage men to have had these experiences."

[16] "Health Professionals," Plan B Clinical Information. Available at: http://www.go2planb.com/section/health_professionals.

[17] "Building Emergency Contraception Awareness Among Adolescents: A Toolkit for Schools and Community-Based Organizations," Academy for Educational Development, 2003. Available at: www.aed.org/publications/EDtoolkit3283.pdf. The Toolkit states: "Prescriptions for ECPs [emergency contraceptive pills] and medical visits are covered by Medicaid and some private insurance companies."

"Washington State Profile," *Pharmacy Access Partnership*, Public Health Institute, 2003. Available at www.go2ec.org/ProfileWashington.htm. Profile states that Washington State Department of Health and Department of Social & Health Services "have successfully worked together at the local level and have jointly trained staff at Community Services Offices (welfare centers) about EC. . . . DSHS houses the state's Medicaid program, and Washington is the only state thus far that allows government MAA reimbursement for pharmacist initiation of EC. Pharmacists are paid $13.50 per encounter for the counseling portion of EC service and must bill using a HCFA claim form."

[18] James Trussell, Ph.D., et al., "Emergency Contraceptive Pills: A Simple Proposal to Reduce Unintended Pregnancies," *Family Planning Perspectives*, Nov-Dec. 1992; 24(6):269-73. Abstract available through Pub Med, National Library of Medicine, at www.ncbi.nlm.nih.gov/PubMed. Dr. Trussell was a voting member of the December 16, 2003, FDA advisory committee on Plan B's application for OTC switch status.

[19] Heidi Welborn, "Expanding the Pharmacist's Role in Providing Emergency Contraception," *Journal of the American Pharmaceutical Association*, Vol. 41, No. 5, September/October 2001. Available at www.aphanet.org.

[20] Peter A. Hall, PhD, et al., "Risky Adolescent Sexual Behavior: A Psychological Perspective for Primary Care Clinicians," *Advanced Practice Nursing eJournal*, 4(1), 2004, available at www.medscape.com/viewarticle/467059_1. The article states, "The majority of older adolescents in North America are sexually active, yet many do not take appropriate precautions to prevent pregnancy or the spread of sexually transmitted infections. . . . Adolescents, like adults, may be prone to engaging in risky sexual behavior due to perceptions of invulnerability and their tendency to focus on the immediate, rather than long-term, consequences of their behavior. Mentally ill adolescents may be particularly at risk and warrant special consideration. . . . The majority of adolescents aged 15 to 19 years in Canada and the United States report having had sexual intercourse at least once. In addition, 23.9% and 45.5% of adolescent females from Canada and the United States, respectively, report having had 2 or more sexual partners in the past year." The article explains that STD treatment of adolescents is frustrating for clinicians because adolescents often are treated repeatedly for STD infection even after they have been counseled to use protection or abstain from sexual activity completely.

"EC Outreach Materials," *Pharmacy Access Project*, Public Health Institute. Available at: www.go2ec.org/ECOutreachMaterials.htm. Advertisements and promotional materials utilize provocative advertising themes.

[21] "Emergency Contraceptive Pills," Population Reports, Series A, Number 9. Available at: www.infoforhealth.org/pr/a9/a9ecp.shtml.

"Emergency Contraceptive Pills: An Important Option for Young Adults," Family Health International. Available at: www.fhi.org/en/Youth/YouthNet. This article states, "ECPs aid sexually active young people as they move to sustained contraceptive use. ECPs should be viewed as a bridge to regular contraception. . . ." This article considers MAP "particularly important for adolescents. As young people establish their sexual identity, and contraceptive practice, they may be likely to use contraceptives ineffectively and subsequently experience contraceptive failure. For them, emergency contraception may provide a crucial safety net in the event of intercourse they did not expect or adequately prepare for, as well as a bridge to more regular and sustained contraceptive use."

[22] "Fuller Information and More Choice – The Responsible Way Ahead," *Progress in Reproductive Health Research*, 1995, No. 35, part 2. World Health Organization. Available at: www.who.int/reproductive-health/hrp/progress/35/news35_2.en.html.

[23] "Trends in Sexual Risk Behaviors Among High School Students – United States, 1991-2001," *Morbidity and Mortality Weekly Report*, September 27, 2002, Centers for Disease Control and Prevention. Available at www.cdc.gov/mmwr/preview/mmwrhtml/mm5138a2.htm. CDC report states, "During 1971-1979, the percentage of females aged 15-19 years living in metropolitan areas nationwide who ever had sexual intercourse increased from 30% to 50%." This dramatic increase in sexual activity among adolescent females coincided with the legalization of induced abortion in 1973, which provided a back-up measure for unintended pregnancy. Some see a similar parallel in that OTC/MAP will further reduce perceived concerns about pregnancy or a need for induced abortion. This, in turn, may lead to new increases in rates of adolescent sexual activity, with increased risks of STD/HIV infection.

Jonathan Klick and Thomas Stratmann, "The Effect of Abortion Legalization on Sexual Behavior: Evidence from Sexually Transmitted Disease," *Journal of Legal Studies*, The University of Chicago, June 2003, Vol. 32. Available at George Mason University, www.gmu.edu/jbc/stratmann.std18.pdf. The study describes unwanted pregnancy as "a major cost of sexual activity" and posits that this cost was a significant disincentive to sexual activity prior to the legalization of abortion. After legalized abortion, the cost of sexual activity was reduced, generating increased sexual activity accompanied by increased rates of STDs. The study finds that "gonorrhea and syphilis incidences are significantly and positively correlated with abortion legalization." Using a double quasi-experiment, the study proved that STD rates rose quickly among states which first legalized abortion; STD rates among all states later converged when abortion was legalized nationally in 1973.

[24] Chris Kahlenborn, et al., "Postfertilization Effect of Hormonal Emergency Contraception."

[25] "2000 Action of the APhA House of Delegates, Washington, DC, March 10-14, 2000," American Pharmacists Association, available at www.aphanet.org/govt/2000actionhod.html.

[26] Don F. Downing, B.S. Pharm., "Helping Pharmacists Determine their Role in Emergency Contraception," *Supplement to U.S. Pharmacist*, 1 Dec. 2000. Also, "American Pharmaceutical Association Special Report on Emergency Contraception: The Pharmacist's Role." Available at: www.go2planb.com/content/article/detail554.

[27] "OCs Provide Emergency Contraception Option," Family Health International, *Network*, Summer 1996, Vol. 16 No. 4. Available at: http://www.reproline.jhu.edu/english/6read/6issues/6network/v16-4/nt1645.html.

[28] "Spotlight on Emergency Contraception: Lessons Learned from Colombia," *IPPF/WHR Spotlight Series*, International Planned Parenthood Federation, March 2003. Available at www.ippfwhr.org/publications/serial_issue_e.asp?PubID=50&SerialIssuesID=133. This article described the social marketing process which succeeded in obtaining MAP approval in Colombia. A roadmap for other countries and other organizations, the article describes four key strategies for success: "sensitizing" internal staff to build consensus in favor of MAP; framing the MAP issue as a matter of sexual and reproductive right relying upon international treaties; building alliances with media, women's groups, medical organizations and youth groups; marginalizing religious opposition to MAP as an abortifacient.

Etlava Sahatci, "Lessons Learned From Family Planning and Contraception Programs in CEE/NIS Region," *2002 Schweitzer Seminar Series*, Albert Schweitzer Institute/Open Society Institute, Quinnipiac University. Available at www.quinnipiac.edu/x3363.xml. Reporting on a social marketing program that introduced MAP in Albania, Dr. Sahatci gave praise for MAP, but lamented that young people especially "use it [MAP] every time they have sexual intercourse."

[29] James Trussell, Ph.D., et al., "Emergency Contraceptive Pills: A Simple Proposal to Reduce Unintended Pregnancies," *Family Planning Perspectives*, Nov-Dec. 1992; 24(6):269-73. Abstract available through Pub Med, National Library of Medicine, at www.ncbi.nlm.nih.gov/PubMed In 1992, as director of Office of Population Research at Princeton University, Dr. Trussell was at the forefront of population organizations' support for MAP. Dr. Trussell anticipated possible objections to MAP as: encouraging sexual risk-taking; health risks of repeated use; public funding through Title X; discouraging women from seeking regular checkups and Pap smears; use by women with contraindications to MAP; and moral objections to MAP's abortifacient effect. Recommended responses to these objections were: making MAP available over-the-counter or in vending machines; changing prescription laws; and proper package labeling. Objection to MAP was dismissed as "paternalism [that] is not a sufficient justification for requiring prescription of contraceptives and medical visits."

[30] Nedra Kline Weinreich, "What is Social Marketing?" Weinrich Communications. Available at www.social-marketing.com Quoting work of Philip Kotler and Gerald Zaltman, social marketing pioneers.

[31] Elisa Wells and Michele Burns, "Expanding Global Access to Emergency Contraception: A Collaborative Approach to Meeting Women's Needs," International Consortium for Emergency Contraception. Available at www.cecinfo.org/files/Expaning-Global-Access-to%20EC.rtf. The story of how the International Consortium quickly and successfully introduced MAP around the world, often despite stiff moral opposition, is published in so that "lessons learned from this experience can provide valuable insight to other groups also working to expand women's access to this important contraceptive option."

[32] Ibid.

[33] "Consensus Statement on Emergency Contraception," *Contraception*, 1995 Oct; 52(4): 211-3. The Consensus Statement (in an incomplete version) is available at www.path.org/outlook/html/13_3.htm The Consensus Statement admits, "service providers are too often reluctant to provide this method. **In case there is any misunderstanding, emergency contraceptives are not abortifacient.** Emergency contraceptives prevent unwanted pregnancy." [Emphasis added.]

[34] Elisa Wells and Michele Burns, "Expanding Global Access to Emergency Contraception: A Collaborative

Approach to Meeting Women's Needs."

[35] Sujata Bose, MS, et al., "Managing Contraceptive Controversies," *American Public Health Association Annual Meeting 2003*, November 17, 2003, Abstract #71653. Available at http://apha.confex.com/apha/131am/techprogram/meeting_131am.htm. Although this abstract doesn't specifically name Emergency Contraception, its timing and content may appear relevant to the MAP controversy. The authors summarized contraceptive controversies as involving four main objections: religious/ethical, marketing to adolescent audiences, health and safety concerns, and fear of coercive use/hidden political agenda. The authors identified "strategies to address, anticipate and prepare for contraceptive-related controversy" and provided specific examples from non-governmental organizations, private manufacturers, and national governments as to how international and domestic controversies were managed.

[36] Elisa Wells and Michele Burns, "Expanding Global Access to Emergency Contraception: A Collaborative Approach to Meeting Women's Needs."

[37] Ibid. The local in-country contacts kept in close communication with the global Consortium, attending meetings as frequently as possible to exchange information and enhance project planning.

[38] Jacqueline S. Gardner, et al., "Increasing Access to Emergency Contraception Through Community Pharmacies: Lessons from Washington State," *Family Planning Perspectives*, July/August 2001, Vol. 33 No. 4. Available at: http://www.agi-usa.org/pubs/journals/3317201.html This study examined 1998-1999 data.

[39] "Center for Reproductive Rights Petitions FDA Petitions FDA to Change Emergency Contraception from Prescription to Over the Counter," Center for Reproductive Law and Policy [now Center for Reproductive Rights], February 14, 2001. Available at: http://www.crlp.org/pr_01_214ecpetition.html.

[40] Rachel K. Jones, et al., "Contraceptive Use Among U.S. Women Having Abortions in 2000-2001," *Perspectives on Sexuality and Reproductive Health*, The Alan Guttmacher Institute, Vol. 34, No. 6, November/December 2002. Available at: http://www.agi-usa.org/pubs/journals/3429402.html. The study reported that 46% of the aborting women were described as not using contraception in the month they became pregnant.

[41] Ibid.

[42] Ibid.

[43] Ibid.

[44] Ibid.

[45] Ibid.

[46] Ibid. Interestingly, James Trussell, whose studies claim a 75% effectiveness rate for MAP, was a voting member of the December 16, 2003, FDA advisory committee which recommended OTC status for MAP.

[47] Ibid.

[48] Ibid. In contrast, the Actual Use Study conducted for the FDA by Plan B's manufacturer found that 60% of the women requesting MAP had not used contraception.

[49] Ibid.

[50] Ibid.

[51] Ibid. According to the study, 10% of women obtaining abortions reported using "periodic abstinence" or "withdrawal." Including these in a study of contraceptive use and abortion rates is misleading and would inaccurately increase the number and rate of reported contraceptive users. Certainly, there is a public perception that "contraceptive use" involves some actual contraceptive product, such as condoms, diaphragms or medication.

[52] Ibid.

[53] Ibid.

[54] Ibid.

[55] Tina Raine, MD, MPH, et al., "Does Improving Access to Emergency Contraception Through Pharmacies Make a Difference in Unintended Pregnancy Rates?" *American Public Health Association 2003 Annual Meeting*, November 19, 2003, Abstract #70869. Available at http://apha.confex.com/apha/131am/techprogram. It is unclear whether the results of this study have been published. This study was supported by a research grant from Women's Capital Corporation, manufacturer of Plan B.

[56] Briefing Document: Nonprescription Drugs and Reproductive Health Drugs Advisory Committee Meeting," Women's Capital Corporation, Plan B for Emergency Contraception Rx-to-OTC Switch, 14 November 2003, P. 8. Available at: www.fda.gov/ohrms/dockets/ac/03/briefing/4015B1_01_WCC-Briefing%20Document.pdf. The Briefing Document supported this claim with a study by Dr. James Trussell, who actually was a voting member of the FDA advisory committee.

[57] Transcript, Nonprescription Drugs Advisory Committee in Joint Session with the Advisory Committee for Reproductive Health Drugs Meeting, Food and Drug Administration, December 16, 2003, p. 29. Transcript available at: www.fda.gov/ohrms/dockets/ac/03/transcripts/4015T1.pdf.

[58] Ibid., p. 62.
[59] Laurie Barclay, MD., "Over-the-Counter Emergency Contraception: A Newsmaker Interview with David A. Grimes, MD."
[60] "The Two Sides of the Culture of Death," PRI Weekly Briefing Vol. 5, No. 30, 10 October 2003. See www.pop.org.
[61] "Facts in Brief: Induced Abortion," The Alan Guttmacher Institute, 2003. Available at www.guttmacher.org/pubs/fb_induced_abortion.html.
[62] Transcript, Nonprescription Drugs Advisory Committee in Joint Session with the Advisory Committee for Reproductive Health Drugs Meeting, Food and Drug Administration, December 16, 2003, p. 198. Transcript available at: www.fda.gov/ohrms/dockets/ac/03/transcripts/4015T1.pdf.
[63] Ibid., p. 62.
[64] Rachel K. Jones, et al., "Contraceptive Use Among U.S. Women Having Abortions in 2000-2001.".

James Trussell Ph.D., et al., "Updated Estimates of the Effectiveness of the Yuzpe Regimen of Emergency Contraception." It should be noted that while this particular study examined data for the Yuzpe Regimen for MAP (combined estrogen/progesterone hormones), this study is widely quoted to support claims that levonorgestrel MAP prevents 3 pregnancies/induced abortions for every failure resulting in pregnancy.
[65] James Trussell, Ph.D., et al., "Updated Estimates of the Effectiveness of the Yuzpe Regimen of Emergency Contraception."
[66] Ibid.
[67] Ibid.
[68] Chris Kahlenborn, et al., "Postfertilization Effect of Hormonal Emergency Contraception."
[69] Ibid.
[70] Ibid.
[71] Ibid.
[72] Alex Stirling, et al., "Estimating the Efficacy of Emergency Contraception – How Reliable Are the Data?" *Contraception*, Vol. 66, Issue 1, July 2002, Pp. 19-22. Available at http://www.sciencedirect.com/science/article/B6T5P-46H6JTJ-4/2/1b08d90a8ddeb5d793cf2de995374e5d. Authors found that of 94 women using MAP, only "45 were certain of date of LMP. Twenty-one women had urinary pregnanediol concentrations inconsistent with their cycle day. Calculations of the efficacy of EC depend on knowing the timing of intercourse in relation to the estimated day of ovulation."
[73] Juan J. Espinos, et al., "The Role of Matching Menstrual Data With Hormonal Measurements in Evaluating Effectiveness of Postcoital Contraception," *Contraception*, 1999 Oct; 60(4):243-7. Abstract available at http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=10640171&dopt=Abstract. In the study, 64 women with irregular periods were excluded leaving a final sample of 382 women, only 99 of whom were between -5 and 0 days (in relation to ovulation) at the moment of unprotected intercourse. Only 2 pregnancies were recorded; however, the study also acknowledged that the study had a "large number of women presenting . . . within the first 24 h after unprotected intercourse," which may have increased the efficacy of MAP.
[74] Ibid.
[75] Ibid.
[76] "Regimen Update: Policy Statement," International Consortium for Emergency Contraception, July 2003. Available at www.cecinfo.org/files/ICEC%20-%20Dosage%20and%20Timing%20Policy%20Statement%202003.pdf.
[77] "When Things Don't Go As Planned . . ." *Bus Poster*, California Family Health Council, Spring 2003, Los Angeles Public Bus Advertising Campaign. Available at: www.go2ec.org/pdfs/CFHC_Bus_Poster2003.pdf. Advertising campaigns for MAP, including this bus poster, promote off-label use of MAP up to 120 hours.

"Does Emergency Contraception Work the Morning After?" *Billboard*, Planned Parenthood New York City, 2003. Available at: www.go2ec.org/pdfs/PP_NYCSummer_Billboard%202003.pdf. Advertising campaigns for MAP, including this billboard, promote off-label use of MAP up to 120 hours.

"Encounter Forms: EC Protocols & Other Tools," *Pharmacy Access Partnership*, Public Health Institute. Available at: http://www.go2ec.org/ECProtocolsAndOtherTools.htm#Encounter_Forms. The screening checklists and assessment questionnaires used in pharmacy-direct states such as Washington and New Mexico permit MAP within 120 hours.
[78] "Randomised Control Trial of Levonorgestrel Versus the Yuzpe Regimen of Combined Oral Contraceptives for Emergency Contraception," *The Lancet*, Aug. 8, 1998, Vol. 352:428-433. This study was sponsored by the Task Force on Postovulatory Methods of Fertility Regulation, World Health Organization, Special Programme of

Research, Development, and Research Training in Human Reproduction, 42 women were found to be pregnant after MAP treatment; all but 5 obtained abortions.
[79] Ibid.
[80] Briefing Document: Nonprescription Drugs and Reproductive Health Drugs Advisory Committee Meeting," Women's Capital Corporation, Plan B for Emergency Contraception Rx-to-OTC Switch, 14 November 2003, P. 26. Available at: www.fda.gov/ohrms/dockets/ac/03/briefing/4015B1_01_WCC-Briefing%20Document.pdf.
[81] Lena Marions, et al., "Contraceptive Efficacy of Daily Administration of 0.5 mg Mifepristone," *European Society of Human Reproduction and Embryology*, Vol. 14 No. 11, Pp. 2788-2790 (1999). This study was supported by UNDP/UNFPA/WHO, World Bank Special Program of Research Development and Research Training in Human Reproduction. Study subjects were recruited from Hungary and Sweden. The reason this would be considered "optimal contraception" is because ovulation permits menstruation, while blocking implantation stops pregnancy. The study concluded that daily low-dose mifepristone is not "sufficient to act as a contraceptive [and] it is probably not possible to increase the dose without disturbing ovulation and bleeding pattern."
[82] Horacio B. Croxatto, et al., "Emergency Contraception Pills: How Do They Work?" *IPPF Medical Bulletin*, Vol. 36, No. 6, December 2002. International Planned Parenthood Federation. Contained in Plan B Briefing Document available at: "Briefing Document: Nonprescription Drugs and Reproductive Health Drugs Advisory Committee Meeting," Women's Capital Corporation, Plan B for Emergency Contraception Rx-to-OTC Switch, 14 November 2003, Appendix 1: Mechanism of Action. Available at: www.fda.gov/ohrms/dockets/ac/03/briefing/4015B1_01_WCC-Briefing%20Document.pdf.
[83] "Briefing Document: Nonprescription Drugs and Reproductive Health Drugs Advisory Committee Meeting," Women's Capital Corporation, Plan B for Emergency Contraception Rx-to-OTC Switch, 14 November 2003, P.64. Available at www.fda.gov/ohrms/dockets/ac/03/briefing/4015B1_01_WCC-Briefing%20Document.pdf.
[84] Ibid., p. 11.
[85] "Executive Summary of Actual Use Study," Food & Drug Administration, Study #9727: Plan B Actual Use Study," sNDA #21-045, January 30, 2003. Available at www.fda.gov/ohrms/dockets/ac/03/briefing/4015b1.htm.
[86] Cynthia Harper, et al., "Adolescent Clinic Visits for Contraception: Support from Mothers, Male Partners and Friends," *Perspectives on Sexual and Reproductive Health*, Vol. 36 No. 1, January/February 2004. Available at: www.agi-usa.org/journals/toc/psrh3601toc.html. The study found that younger teenagers relied more on friends for advice than did older teenagers. The study surmised that due to lack of support from mothers or male partners, it is likely that "many teenagers [were prevented] from ever making it to the [family planning] clinic." This implies that OTC/MAP would be a *more likely* choice for younger teenagers.
[87] "Executive Summary of Actual Use Study," Food & Drug Administration, Study #9727: Plan B Actual Use Study," sNDA #21-045, January 30, 2003. Available at www.fda.gov/ohrms/dockets/ac/03/briefing/4015b1.htm.
[88] L. Simkin, M.Phil., et al., "Building Emergency Contraception Awareness Among Adolescents: A Toolkit for Schools and Community-Based Organizations," 2003, Academy for Educational Development. Available at: http://www.aed.org/publications/ECtoolkit3283.pdf.
[89] "Health Professionals," Plan B Clinical Information.
[90] G. Ugocsai, et al., "Scanning Electron Microscopic (SEM) Changes of the Endometrium in Women Taking High Doses of Levonorgestrel as Emergency Postcoital Contraception." 66 *Contraception* 433-437 (2002). The study also urges counseling for MAP users "as the main side effect of breakthrough bleeding frequently occurs."
[91] "Repeated Use of Emergency Contraception: The Facts," *Policy Statement*, International Consortium for Emergency Contraception, July 2003. Available at www.cecinfo.org "There are no medical contraindications to ECPs when used occasionally, for example, once a month or less. If use exceeds this amount, the contraindications to regular combined or progestin-only oral contraceptives might apply."
[92] Ibid.
[93] Mitchell D. Creinin, MD, "Emergency Contraception: More Than a Morning After Pill," *Medscape General Medicine*, 1999. Available at: www.medscape.com/viewarticle/408799. Without oversight of any medical professional, OTC/MAP will enable possible routine use by women and adolescents.
[94] Laurie Barclay, MD, "Over-the-Counter Emergency Contraception: A Newsmaker Interview with David A. Grimes, MD," *Medscape Medical News*, 2002. Available at: www.medscape.com/viewarticle/442258. Dr. Grimes is Vice President of Biomedical Affairs, Family Health International, Research Triangle Park, North Carolina.
[95] Etlava Sahatci, "Lessons Learned From Family Planning and Contraception Programs in CEE/NIS Region," *2002 Schweitzer Seminar Series*, Albert Schweitzer Institute/Open Society Institute, Quinnipiac University. Available at www.quinnipiac.edu/x3363.xml. Dr. Sahatci is director of the Marie Stopes Clinic, a family planning clinic in Tirane, Albania. The Albert Schweitzer Institute at Quinnipiac University convenes regular conferences sponsored

by George Soros' **Open Society Institute**. These conferences in Central and Eastern Europe and the Former Soviet Union comprise the most extensive health education series in that region and frequently promote abortion and MAP.

[96] "Encounter Forms: EC Protocols & Other Tools," *Pharmacy Access Partnership*, Public Health Institute. Available at: http://www.go2ec.org/ECProtocolsAndOtherTools.htm#Encounter_Forms.

[97] Transcript, Nonprescription Drugs Advisory Committee in Joint Session with the Advisory Committee for Reproductive Health Drugs Meeting, Food and Drug Administration, December 16, 2003, P. 72. Transcript available at: www.fda.gov/ohrms/dockets/ac/03/transcripts/4015T1.pdf. Dr. Carole Ben-Maimon stated, "The need to consult with the pharmacist, at least be interviewed by the pharmacist . . . and meet certain criteria, could act as a significant barrier for women to seek emergency contraception through pharmacy access."

[98] Ibid., p. 32, 33. In describing why she opposes prescription-only MAP, Dr. Ben-Maimon stated, "If a woman does not have a physician that she sees regularly, . . . doctors are reticent sometimes to calling in prescriptions to patients who they don't know and *probably for good reason.*" [Emphasis added.]

[99] Ibid., p. 258.

[100] "Briefing Document: Nonprescription Drugs and Reproductive Health Drugs Advisory Committee Meeting," Women's Capital Corporation, Plan B for Emergency Contraception Rx-to-OTC Switch, 14 November 2003, P. 20. Available at www.fda.gov/ohrms/dockets/ac/03/briefing/4015B1_01_WCC-Briefing%20Document.pdf

[101] Transcript, Nonprescription Drugs Advisory Committee in Joint Session with the Advisory Committee for Reproductive Health Drugs Meeting, Food and Drug Administration, December 16, 2003, Pp. 62, 63.

[102] Ibid., pp. 132-135.

[103] "Sexual and Contraceptive Behavior Studies on Plan B: A Literature Review," FDA, sNDA #21-045, P. 2. Available at: www.fda.gov/ohrms/dockets/ac/03/briefing/4015B1_09_FDA-Tab%204-1-Summary%20of%20Literature.pdf.

[104] Ibid.

[105] Laurie Barclay, MD, "Over-the-Counter Emergency Contraception: A Newsmaker Interview with David A. Grimes, MD," *Medscape Medical News*, 2002. Available at www.medscape.com/viewarticle/442258 Dr. Grimes was one of three presenters for Plan B's manufacturer before the December 2003 FDA hearing.

[106] Ibid.

[107] "Facts in Brief: Induced Abortion," The Alan Guttmacher Institute, 2003. Available at www.guttmacher.org/pubs/fb_induced_abortion.html.

[108] G. Ugocsai, et al., "Scanning Electron Microscopic (SEM) Changes of the Endometrium in Women Taking High Doses of Levonorgestrel as Emergency Postcoital Contraception," *Contraception* 66:433-437 (2002). The short-term and long-term safety risks of such overdoses are unknown. Whether most women, especially adolescents, who overdose would seek medical care afterward is also unknown.

[109] Elisa Wells and Michele Burns, "Expanding Global Access to Emergency Contraception: A Collaborative Approach to Meeting Women's Needs."

[110] "Regimen Update: Policy Statement," International Consortium for Emergency Contraception, July 2003. Available at www.cecinfo.org/files/ICEC%20-%20Dosage%20and%20Timing%20Policy%20Statement%202003.pdf.

[111] Transcript, Nonprescription Drugs Advisory Committee in Joint Session with the Advisory Committee for Reproductive Health Drugs Meeting, Food and Drug Administration, December 16, 2003, P. 35. Transcript available at: www.fda.gov/ohrms/dockets/ac/03/transcripts/4015T1.pdf.

[112] Ibid., p. 108. At P.113, the FDA medical officer named specific dosages for Plan B's safety profile stating, "repeated doses up to 2.25 milligrams in a 24-hour period of time have been studied." However, the women in the Hungarian study had taken doses up to twice that amount within a 24-hour period.

[113] Laurie Barclay, MD, "Over-the-Counter Emergency Contraception: A Newsmaker Interview with David A. Grimes, MD." Dr. David A. Grimes, Vice President of Biomedical Affairs, Family Health International, said, "Relying exclusively on EC is a bad idea . . . ."

[114] "Health Professionals," Plan B Clinical Information. Available at: http://www.go2planb.com/section/health_professionals.

[115] Plan B Package Insert. Available at: www.go2planb.com/section/about/package_insert. "Menstrual bleeding patterns are often irregular among women using progestin-only oral contraceptives and in clinical studies of levonorgestrel for postcoital and emergency contraceptive use. Some women may experience spotting a few days after taking Plan B. At the time of expected menses, approximately 75% of women using Plan B had vaginal bleeding similar to their normal menses. 12-13% bled more than usual, and 12% bled less than usual. The majority of women (87%) had their next menstrual period at the expected time or within +/- 7 days, while 13% had a delay of

more than 7 days beyond the anticipated onset of menses. If there is a delay in the onset of menses beyond 1 week, the possibility of pregnancy should be considered."

[116] "Repeated Use of Emergency Contraception: The Facts," International Consortium for Emergency Contraception, Policy Statement, July 2003. Available at: www.cecinfo.org. "The most common side effects are menstrual irregularities and nausea. In a study of repeat postcoital use . . . 70% of the participants reported menstrual irregularities. A high proportion of the women in this study dropped out early because of the side effects."

[117] "Briefing Document: Nonprescription Drugs and Reproductive Health Drugs Advisory Committee Meeting," Women's Capital Corporation, Plan B for Emergency Contraception Rx-to-OTC Switch, 14 November 2003, P. 20. Available at www.fda.gov/ohrms/dockets/ac/03/briefing/4015B1_01_WCC-Briefing%20Document.pdf.

[118] A. Glasier, et al., "Case Studies in Emergency Contraception from Six Countries," *International Family Planning Perspectives*, June 1996, 22(2):57-6. Study available at http://www.hsph.harvard.edu/Organizations/healthnet/SAsia/suchana/0507/glasier_etc.html. Since MAP is included in the health insurance system in the Netherlands, it is easily accessible and widely used.

[119] Transcript, Nonprescription Drugs Advisory Committee in Joint Session with the Advisory Committee for Reproductive Health Drugs Meeting, Food and Drug Administration, December 16, 2003, P. 25. Transcript available at: www.fda.gov/ohrms/dockets/ac/03/transcripts/4015T1.pdf.

[120] Ibid., p. 253.

[121] Janet P. Engle, Pharm.D., "Statement of the American Pharmacists Association to the Food and Drug Administration's Nonprescription Drugs Advisory Committee and Advisory Committee for Reproductive Health Drugs, Over-the-Counter Use of Levonorgestrel," December 16, 2003. Available through www.aphanet.org. Examples of patients who mistakenly thought they needed MAP included women who: (1) took oral contraceptives an hour later than usual; (2) swam in same swimming pool with men.

[122] Ibid. Presentations supporting OTC/MAP for sexual assault were made by Women's Capital Corporation/Barr Laboratories representatives Carole Ben-Maimon, MD, Vivian Dickerson, MD, and David Grimes, MD, at pp. 28, 32, 38, 63, 81.

[123] "Were You Forced?" Advertisement, Population Council, Reproductive Health and Family Planning, Contraception, Emergency Contraception. Available at http://www.popcouncil.org/rhfp/ec.html.

"What Can You Do If An Accident Happens?" *Accidents Happen, Pregnancy Doesn't Have To Marketing Campaign*, Population Services International (PSI). Available at: www.go2ec.org/pdfs/PSI_EC_Wallet.pdf. This wallet card urges adolescents and young persons to use MAP in various situations, including sexual assault: "When can I use Emergency Contraception Pills? You were forced to have sex."

[124] Vaughan I. Rickert, PsyD., et al., "Violence Against Young Women: Implications for Clinicians," *Contemporary Ob/Gyn*, 48(2):30-45, 2003. Available at www.medscape.com/viewarticle/449862_6. Author finds, "Obstetricians and gynecologists should not assume that their patients will spontaneously and accurately report all victimization events. . . . Screening for intimate partner violence is an important component of providing comprehensive care and an activity advocated by several prominent medical and public health organizations." The clinician's role in responding to sexual assault is vital: "Although research suggests that adolescent and young adult women delay seeking medical care after sexual assault, some may present for care within 72 hours. When that is the case, forensic evidence (rape kit) can be collected, medical treatment given for STDs, and emergency contraception provided as well as counseling for HIV prophylaxis. Data suggest adolescent victims are less likely to sustain physical injuries during an assault than are adult victims of sexual violence. . . . Issues of personal safety should be addressed . . . . Finally, evaluate your patient's need for referral for psychologic or psychiatric treatment . . . ."

[125] Mary Ann Castle and Francine Coeytaux, "A Clinician's Guide to Providing Emergency Contraceptive Pills," Pacific Institute for Women's Health. Available at www.piwh.org/pdfs/EC_guide.pdf. The Guide was originally written for all clinicians, including pharmacists, nurse practitioners, nurses, physician assistants, midwives, school-based health clinics, teen outreach programs, clinic administrators and staff. The publisher, Pacific Institute for Women's Health, now supports OTC/MAP. The Guide reminds clinicians that most states mandate the reporting of abuse against minors. OTC availability of MAP for minors will make less likely reporting of incest.

[126] "New Report Shows Dramatic Increase in Willingness to Report Rape to Police: Sexual Assaults Down by Half Over Last Decade," Rape, Abuse and Incest National Network, *RAINN News*. Available at: www.rainn.org/news/ncvs2002.html. "Experts believe two trends are largely responsible for the tremendous decline in sexual violence over the last decade. 'First, tough-on-crime policies of recent years . . . ,' said Scott Berkowitz, president and founder of the Rape, Abuse & Incest National Network (RAINN), America's largest anti-sexual assault organization. "The second trend is generational. Rape victims are overwhelmingly young—80% are under 30 years old. This generation has grown up knowing that 'No Means No,' and young women today are both more careful about entering into

potentially dangerous situations and more willing to forcefully express their own desires," Berkowitz continued. "This generational shift, combined with increased media attention and a greater societal openness about the issue, are likely the key factors in the increased willingness to report to police." RAINN News also reported that women are seven times more likely than men to be victims of sexual assault; victim/offender relationship is usually non-stranger: 57% of offenders are friends/acquaintances of victim.

[127] Callie Marie Rennison, Ph.D., et al. "Criminal Victimization, 2002," *National Crime Victimization Survey*, Bureau of Justice Statistics, August 2003. Available at www.rainn.org/ncvs.2002.pdf. "Females were most often victimized by someone they knew . . . . Of those offenders victimizing females, 40% were described as friends/ acquaintances, 20% as intimates, and 7% as some other relative [69% total non-stranger victim-offender relationship]. Strangers to the victims committed 31% of the violence against females."

[128] "What Should I Do If I am Sexually Assaulted?" Rape, Abuse and Incest National Network. Available at: www.rainn.org/whatshould.html.

[129] "Before & After 2004," Rape, Abuse and Incest National Network. Available at: www.rain.org/before&after.html.

[130] "Briefing Document, "Nonprescription Drugs and Reproductive Health Drugs Advisory Committee Meeting," December 16, 2003, Plan B (Levonorgestrel) for Emergency Contraception Rx-to-OTC Switch, 14 November 2003, Women's Capital Corporation, Table 10, p. 46. Available at www.fda.gov/ohrms/dockets/ac/03/briefing/ 4015B1_01_WCC-Briefing%20Document.pdf.

[131] Transcript, Nonprescription Drugs Advisory Committee in Joint Session with the Advisory Committee for Reproductive Health Drugs Meeting, Food and Drug Administration, December 16, 2003, p. 116. Transcript available at: www.fda.gov/ohrms/dockets/ac/03/transcripts/4015T1.pdf.

[132] Ibid., p. 50.

[133] "Health Professionals," Plan B Clinical Information.

[134] Transcript, Nonprescription Drugs Advisory Committee in Joint Session with the Advisory Committee for Reproductive Health Drugs Meeting, Food and Drug Administration, December 16, 2003, p. 115.

[135] Plan B OTC Label Comprehension Study, FDA Study #9728, June 18, 2001 to July 18, 2001. Available at: www.fda.gov/ohrms/dockets/ac/03/briefing/4015B1_05_FDA-Tab%202-1-DSRCS%20REVIEW.pdf.

[136] Loraine K. Endreds, MD, Matthew Beshara, MD, Steven Sondheimer, MD. "Experience with Self-Administered Emergency Contraception in a Low-Income, Inner-City Family Planning Program," *Journal of Reproductive Medicine*, 10 Nov 2000, Vol. 45, Pp. 827-30. Available at www.reproductivemedicine.com/Search/index.html. Only 24% of women in this study could recall how to use MAP correctly. 33% of the women could not even locate their MAP package.

[137] Don F. Downing, B.S., Pharm. "Helping Pharmacists Determine their Role in Emergency Contraception," *Supplement to U.S. Pharmacist*, 1 Dec. 2000. www.uspharmacist.com/index.asp?show=static&page=about.htm. Available at: www.go2planb.com/content/article/detail/555.

American Pharmaceutical Association. Special Report on Emergency Contraception: The Pharmacist's Role, A Continuing Education Program for Pharmacists (21 pages, geared for pharmacists) 1 Oct. 1999 www.go2planb.com/ content/article/detail/554.

[138] "Screening Protocols," Plan B. Available at: www.go2planb.com/section/health_professionals/ screening_protocols.

[139] "OCs Provide Emergency Contraception Option," Family Health International, *Network*, Summer 1996, Vol. 16 No. 4. Available at: www.reproline.jhu.edu/english/6read/6issues/6network/v16-4/nt1645.html. The article states, "'Schering believes ECPs should be offered by prescription only,' says Lutz Schaffran, Schering's head of international family planning. For that reason, the pharmaceutical company does not sell ECPs in Asia and Latin America, where oral contraceptives are typically bought in pharmacies without prescription."

[140] FDA ODS, Postmarketing Safety Review, Dept. of Health & Human Services, ODS PID # D030586, October 31, 2003, at http://www.fda.gov/ohrms/dockets/ac/03/briefing/4015B1_13_FDA-Tab%205-2-ODS%20Safety%20Review.pdf. Sales data were requested from non-FDA sources, resulting in vague usage reports.

[141] Ibid. Review provides number of Plan B kits sold between approval of the drug in July 1999 and August 2003. It is unknown how many kits were distributed to or used by patients.

[142] Ibid. Review states "a typical AERS search using the drug active ingredient (generic name), levonorgestrel, would capture all the Norplant cases as well as those associated with Plan B. Thousands of Norplant cases have been received in association with class action lawsuits. Therefore, AERS was searched using only the trade name Plan B" and equivalent foreign trade names.

[143] "Annual Adverse Drug Experience Report: 1995," Food and Drug Administration, Center for Drug Evaluation and Research, Office of Epidemiology and Biostatistics. Available at: www.fda.gov/medwatch/safety/ar95.pdf.

[144] "Study Finds Levonorgestrel Contraceptive Implant is as Safe and Effective as IUDs and Sterilization," World Health Organization/Population Council, 2 April 2001. Available at: www.popcouncil.org/mediacenter/newsreleases/NorplantPMS.html.

"Contraceptive Implants Come of Age," Progress in Reproductive Health Research No. 61, World Health Organization. Available at: www.who.int/reproductive-health/hrp/progress/61/news61.html.

[145] "Side Effects of Plan B." Available at www.rxlist.com/cgi/generic3/levonorgestrel_ad.htm.

"What Are the Side Effects of Plan B?" About Plan B, Available at www.go2planb.com/section/about. According to Plan B website: "What are the side effects of Plan B? Some women experience one or more side effects after taking Plan B. Approximately 23.1 percent of women taking Plan B experience nausea (compared to 50.5 percent with the Yuzpe regimen of high-dose estrogen-progestin pills) and 5.6 percent vomit (compared to 18.8 percent with the Yuzpe regimen). Other side effects may include lower abdominal pain (17.6 percent), fatigue (16.9 percent), headache (16.8 percent), dizziness (11.2 percent), breast tenderness (10.7 percent), and menstrual changes, including heavier bleeding (13.8 percent) and lighter bleeding (12.5 percent)." Almost 40% of Plan B users will not menstruate on or near the expected time, according to Plan B website.

[146] Transcript, Nonprescription Drugs Advisory Committee in Joint Session with the Advisory Committee for Reproductive Health Drugs Meeting, Food and Drug Administration, December 16, 2003, P.42. Transcript available at: www.fda.gov/ohrms/dockets/ac/03/transcripts/4015T1.pdf

[147] Ibid.

[148] "Briefing Document: Nonprescription Drugs and Reproductive Health Drugs Advisory Committee Meeting," Women's Capital Corporation, Plan B for Emergency Contraception Rx-to-OTC Switch, 14 November 2003, P.71. Available at www.fda.gov/ohrms/dockets/ac/03/briefing/4015B1_01_WCC-Briefing%20Document.pdf

[149] Ibid., Appendix 8. A copy of the Study Data Card Transcription Form (used to transcribe the patient data cards) is included in the Briefing Document at Appendix 8. (Appendix 8 appears to be mislabeled as "Label Comprehension Study" rather than "Actual Use Study.")

[150] G. Ugocsai, et al., "Scanning Electron Microscopic (SEM) Changes of the Endometrium in Women Taking High Doses of Levonorgestrel as Emergency Postcoital Contraception." 66 *Contraception* 433-437 (2002).

[151] "Contraceptive Implants Come of Age," Progress in Reproductive Health Research No. 61, World Health Organization. Available at: www.who.int/reproductive-health/hrp/progress/61/news61.html.

[152] FDA ODS, Postmarketing Safety Review, Dept. of Health & Human Services, ODS PID # D030586. Adverse Events reports include: (a) three cases of convulsions including a possible grand mal seizure in woman with no history of seizures; (b) ten cases of hypersensitivity reactions, seven of which were considered life-threatening; (c) one case of Thrombocytopenia; and (d) twenty-eight cases of ectopic pregnancy. Additional reported Adverse Events included: ruptured corpus luteum cyst; numbness/tingling of the fingers, jaw tightening, shakiness, sore throat, nausea; breast soreness/tenderness; headache; urinary frequency/pain; abdominal bloating/cramping; disorientation; dizziness.

Transcript, Nonprescription Drugs Advisory Committee in Joint Session with the Advisory Committee for Reproductive Health Drugs Meeting, Food and Drug Administration, December 16, 2003, P. 106. Transcript available at: www.fda.gov/ohrms/dockets/ac/03/transcripts/4015T1.pdf. Dr. Daniel Davis, medical officer, Division of Reproductive & Urologic Drugs, FDA, stated at the December 2003 FDA hearing that, "Many of the [AE] reports had incomplete information and are, therefore, hard to interpret."

[153] Task Force on Postovulatory Methods of Fertility Regulation, "Randomised Controlled Trial of Levonorgestrel versus the Yuzpe Regimen of Combined Oral Contraceptives for Emergency Contraception," *The Lancet*, Vol. 352:428-33, August 8, 1998. Study sponsored by UNDP/UNFPA/WHO/World Bank Special Programme of Research, Development and Research Training in Human Reproduction, World Health Organization.

[154] Anna Glasier, Evert Ketting, V.T. Palan, "Case Studies in Emergency Contraception from Six Countries." *International Family Planning Perspectives.* June 1996; 22(2) p.57-61. Available at http://www.hsph.harvard.edu/Organizations/healthnet/SAsia/suchana/0507/glasier_etc.html. As a strategy to overcome opposition to emergency contraception, this report found that, "A clear distinction must be drawn between emergency contraception and abortion, especially in countries where abortion is legally restricted or carries a moral stigma. A confusion of emergency contraception with abortion can seriously impede efforts to prevent unintended pregnancy through use of emergency methods . . . . Emergency contraception should be cast as an important way to reduce the need for abortion."

[155] "Contraception, Not Abortion – An Analysis of Laws and Policy Around the World," Center for Reproductive Rights, April 2002, Item: B012. Available at: www.reproductiverights.org/pub_bp_icpdec2_endnotes.html.

[156] "Briefing Document: Nonprescription Drugs and Reproductive Health Drugs Advisory Committee Meeting,"

Women's Capital Corporation, Plan B for Emergency Contraception Rx-to-OTC Switch, 14 November 2003, Appendix 1: Mechanism of Action. See www.fda.gov/ohrms/dockets/ac/03/briefing/4015B1_01_WCC-Briefing%20Document.pdf. To supports its claims that Plan B is not abortifacient, Women's Capital Corporation's Briefing Document included a Medical Bulletin from International Planned Parenthood Federation entitled, "Emergency Contraception Pills: How Do They Work?" According to the report, since it is never known whether MAP pills were taken before or after ovulation and since no study could ethically or logistically make such determinations, "there is no direct evidence for or against the hypothesis that EC pills prevent pregnancy by interference with post-fertilization events." The report discusses studies of endometrium alterations where endometrium biopsies were obtained. The report states that "treated cycles in which the ovulatory process is believed to be abnormal or suppressed are excluded since endometrial development would reflect abnormal ovarian function rather than a direct effect of the EC pill." However, where abnormal or suppressed ovulation occurs, consequent changes in endometrial development would be an *indirect* but still abortifacient effect of MAP.

[157] Dianne Irving, "New Drug Application 21-045 Levonorgestrel ("Plan B", and "Preven"), ("Emergency Contraceptives") and Their Possible Abortifacient Effects," *Letter to FDA Advisory Committee*, December 5, 2003. Available at: www.lifeissues.net/writers/irvi/irvi_19newdrug21-045.html.

[158] Ibid.

[159] Anne Williams, "Briefing Paper: The Morning-After-Pill," The Scottish Council on Human Bioethics, January 2002. Available at: http://www.schb.org.uk. The briefing paper noted that the motivation to ignore long-understood biological facts and to attempt to redefine conception is purely political: "These facts are ignored by scientists engaged in the family planning industry, who have initiated a subtle campaign against the established and scientifically proven definition of conception."

[160] "Briefing Document: Nonprescription Drugs and Reproductive Health Drugs Advisory Committee Meeting," Women's Capital Corporation, Plan B for Emergency Contraception Rx-to-OTC Switch, 14 November 2003, Appendix 6. Available at www.fda.gov/ohrms/dockets/ac/03/briefing/4015B1_01_WCC-Briefing%20Document.pdf.

Transcript, Nonprescription Drugs Advisory Committee in Joint Session with the Advisory Committee for Reproductive Health Drugs Meeting, Food and Drug Administration, December 16, 2003, P. 288, 289. Transcript available at: www.fda.gov/ohrms/dockets/ac/03/transcripts/4015T1.pdf.

[161] Transcript, Nonprescription Drugs Advisory Committee in Joint Session with the Advisory Committee for Reproductive Health Drugs Meeting, Food and Drug Administration, December 16, 2003, P. 291.

[162] Ibid., p. 268, 269.

[163] Ibid., pp. 269-271.

[164] FDA ODS, Postmarketing Safety Review, Dept. of Health & Human Services, ODS PID # D030586. Fetal anomalies/miscarriages included: (a) 36-year-old U.S. woman reported that fetus was detached from uterine wall, D&C performed, following use of Plan B; (b) 30-year-old woman used MAP and erythromycin together; unintended pregnancy resulted in birth of baby with translocated Down syndrome; (c) 29-year-old woman experienced fetal death at 15 weeks' gestation following use of MAP; fetus may have had "Edward's syndrome (trisomy) on triple testing; (d) Four women had unintended pregnancies resulting in miscarriages; (e) 14-year-old U.K. teenager took MAP 10 days after conception had occurred. She received x-rays at 12 weeks' gestation after complaints of abdominal pain; at 14 weeks, pregnancy diagnosed; at unspecified time, major fetal anomalies diagnosed: extensive abdominal wall defects, thoracic wall defects, amputation of left arm, loss of bony rib cage and scoliosis.

[165] Transcript, Nonprescription Drugs Advisory Committee in Joint Session with the Advisory Committee for Reproductive Health Drugs Meeting, Food and Drug Administration, December 16, 2003, P. 104. FDA Medical Officer stated stated that "The use or exposure data is often estimated. . . . We know that there's considerable underreporting of adverse events. . . . Many of the postmarketing AE reports lack complete clinical data. . . . Overlapping of the reports often makes it difficult to interpret the data."

[166] "Teratogenic Risk of Hormonal Products for Contraception: A Review of the Literature." Available at www.fda.gov/ohrms/dockets/ac/03/briefing/4015B1_14_FDA-Tab%205-3-Teratogenic%20Review.pdf.

[167] James Trussell, Ph.D., "Emergency Contraception: A Cost-Effective Approach to Preventing Unintended Pregnancy," *Medscape Ob/Gyn & Women's Health*, 5(2), 2000. Available at www.medscape.com/viewarticle/408916. "Combined ECPs" contain both estrogen and progestin hormones and have been in use longer than progestin-only MAP, such as Plan B.

[168] Transcript, Nonprescription Drugs Advisory Committee in Joint Session with the Advisory Committee for Reproductive Health Drugs Meeting, Food and Drug Administration, December 16, 2003, P. 44. Transcript available

at: www.fda.gov/ohrms/dockets/ac/03/transcripts/4015T1.pdf
[169] Transcript, Nonprescription Drugs Advisory Committee in Joint Session with the Advisory Committee for Reproductive Health Drugs Meeting, Food and Drug Administration, December 16, 2003, P. 296.
[170] Ibid., p. 35. Presentation of Vivian Dickerson, M.D., president-elect, American College of Obstetricians and Gynecologists.
[171] Ibid., P.110.
[172] Task Force on Postovulatory Methods of Fertility Regulation, "Randomized Control Trial of Levonorgestrel Versus the Yuzpe Regimen of Combined Oral Contraceptives for Emergency Contraception," *The Lancet*, Vol. 352:428-33, August 8, 1998. Study summary available at "Improving Methods of Emergency Contraception," *Progress in Reproductive Health Research*, No. 51, 1999. Available at: www.who.int/reproductive-health/hrp/progress/51/news51_1.en.html. Out of 1,998 women in WHO study, "42 were found to be pregnant after treatment. However, retrospective urine analysis showed that four had already been pregnant on enrolment and the pregnancy status at admission of a further five could not be determined. Five women continued their pregnancies with normal outcomes and the others opted for termination." Since 90% of the pregnant women obtained abortions, no conclusions can be drawn that this study proved MAP safety in pregnancy.
[173] Ibid.
[174] Cynthia C. Harper, Ph.D, "Safety and Pharmacokinetics of Emergency Contraception in a Pediatric Population (Aged 12-16)," *2003 Annual Meeting*, American Public Health Association, November 17, 2003, Abstract #71417. Abstract available at: http://apha.confex.com/apha/131am/techprogram Study funded by Women's Capital Corporation, manufacturer of Plan B.
[175] Jonathan Klick and Thomas Stratmann, "The Effect of Abortion Legalization on Sexual Behavior: Evidence from Sexually Transmitted Diseases," *Journal of Legal Studies*, June 2003, Vol. 32. Available at www.gmu.edu/jbc/stratmann.std18.pdf. The study describes unwanted pregnancy as "a major cost of sexual activity" and posits that this cost was a significant disincentive to sexual activity prior to the legalization of abortion. After legalized abortion, the cost of sexual activity was reduced, generating increased sexual activity accompanied by increased rates of STDs. The study finds that "gonorrhea and syphilis incidences are significantly and positively correlated with abortion legalization." Using a double quasi-experiment, the study proves that STD rates rose quickly among states which first legalized abortion; STD rates among all states later converged when abortion was legalized nationally in 1973.
[176] "1993 Sexually Transmitted Disease Surveillance Report," Centers for Disease Control. Available at: http://wonder.cdc.gov/wonder/STD/Title3000.html. CDC statistics published on-line are available for: Syphilis beginning in 1941; Gonorrhea beginning in 1970; Chlamydia beginning in 1984.
[177] "Sexual and Contraceptive Behavior Studies on Plan B: A Literature Review," FDA, sNDA #21-045, P. 2. Available at: www.fda.gov/ohrms/dockets/ac/03/briefing/4015B1_09_FDA-Tab%204-1-Summary%20of%20Literature.pdf.
[178] Cynthia C. Harper, Ph.D., et al., "Male partners and Use of Emergency Contraception," *2000 Annual Meeting*, American Public Health Association, November 13, 2000, Abstract #15575. Abstract available at: http://apha.confex.com/apha/128am/techprogram.
[179] "Briefing Document: Nonprescription Drugs and Reproductive Health Drugs Advisory Committee Meeting," Women's Capital Corporation, Plan B for Emergency Contraception Rx-to-OTC Switch, 14 November 2003, P. 86. Available at www.fda.gov/ohrms/dockets/ac/03/briefing/4015B1_01_WCC-Briefing%20Document.pdf.
[180] Ibid., p. 87.
[181] Ibid.
[182] Transcript, Nonprescription Drugs Advisory Committee in Joint Session with the Advisory Committee for Reproductive Health Drugs Meeting, Food and Drug Administration, December 16, 2003, P. 104. Transcript at: www.fda.gov/ohrms/dockets/ac/03/transcripts/4015T1.pdf.
[183] Ibid., p. 54.
[184] Task Force on Postovulatory Methods of Fertility Regulation, "Randomized Control Trial of Levonorgestrel Versus the Yuzpe Regimen of Combined Oral Contraceptives for Emergency Contraception," *The Lancet*, Vol. 352:428-33, August 8, 1998. Study summary available at "Improving Methods of Emergency Contraception," *Progress in Reproductive Health Research*, No. 51, 1999, at www.who.int/reproductive-health/hrp/progress/51/news51_1.en.html.
[185] "Consensus Statement on Emergency Contraception," *Contraception*, 1995 Oct; 52(4): 211-3. The Consensus Statement (in an incomplete version) is available at www.path.org/outlook/html/13_3.htm. "Emergency contraception should be made available to all women who seek it, *provided no contraindications are present*."

[Emphasis added.]
[186] David A. Grimes, MD, and Elizabeth G. Raymond, MD, MPH., "Review: Emergency Contraception," *Annals of Internal Medicine*, 6 August 2002, Vol. 137 Issue 3, Pp. 180-189. Available at: www.annals.org/cgi/content/full/137/3/180.
[187] Ibid.
[188] Transcript, Nonprescription Drugs Advisory Committee in Joint Session with the Advisory Committee for Reproductive Health Drugs Meeting, Food and Drug Administration, December 16, 2003, p. 286-287. Transcript available at: www.fda.gov/ohrms/dockets/ac/03/transcripts/4015T1.pdf
[189] J. Ellison, et al. "Apparent interaction between warfarin and levonorgestrel used for emergency contraception," *British Medical Journal*, 2000 December 2; 321 (7273): 1382. Available at http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=27541. Article concludes, "women receiving warfarin treatment may be at risk of an interaction between warfarin and levonorgestrel if they are prescribed the progestogen only regimen because of its apparent safety. The manufacturer of levonorgestrel (Wyeth) has not received any reports describing such an interaction with warfarin. This potential interaction requires prompt investigation, particularly in light of recommendations that emergency contraception be made available over the counter. If patients are fully anticoagulated with warfarin, the conventional Yuzpe regimen may be effective without being associated with any increased risk of venous thromboembolism."
[190] Plan B Package Insert, "Hepatic Insufficiency and Renal Insufficiency" and "Drug-Drug Interactions." Available at: www.go2planb.com/section/about/package_insert.
[191] "Precautions," Mexican Family Planning Association. Available at: www.mexfam.org.mx/ing_anti_em_7.htm.
[192] "Repeated Use of Emergency Contraception: The Facts," International Consortium for Emergency Contraception, Policy Statement, July 2003. Available at: www.cecinfo.org.
[193] Plan B Package Insert, "Adverse Reactions." Available at: www.go2planb.com/section/about/package_insert. 18% of Adverse Events involved abdominal pain.
[194] "Letter from Monty and Helen Patterson to Congress Endorsing Halt of RU486," *LifeNews.com*, November 6, 2003. Available at: www.prolifeinfo.com/nat192b.html.
[195] "Briefing Document: Nonprescription Drugs and Reproductive Health Drugs Advisory Committee Meeting," Women's Capital Corporation, Plan B for Emergency Contraception Rx-to-OTC Switch, 14 November 2003, Pp. 25-26. Available at www.fda.gov/ohrms/dockets/ac/03/briefing/4015B1_01_WCC-Briefing%20Document.pdf.
[196] Ibid., p. 26.
[197] Ibid.
[198] Transcript, Nonprescription Drugs Advisory Committee in Joint Session with the Advisory Committee for Reproductive Health Drugs Meeting, Food and Drug Administration, December 16, 2003, p. 43. Transcript available at: www.fda.gov/ohrms/dockets/ac/03/transcripts/4015T1.pdf
[199] Ibid., p. 61.
[200] Ibid., p. 63.
[201] Ibid., p. 64.
[202] "A Communication to All Doctors from the Chief Medical Officer," *Chief Medical Officer Update No. 35*, U.K. Department of Health, January 2003. Available at www.doh.gov.uk/cmo/cmo_35.htm#20
[203] Ibid.
[204] Mira Harrison-Woolrych, "Progestogen-Only Emergency Contraception and Ectopic Pregnancy," *Prescriber Update 2002*, Medsafe New Zealand Ministry of Health, November 2002, Vol. 23 No. 3. Available at www.medsafe.govt.nz/PUArticlesPage.htm. The number of total pregnancies is not stated in the report.
[205] FDA ODS, Postmarketing Safety Review, Dept. of Health & Human Services, ODS PID # D030586, October 31, 2003. Available at: http://www.fda.gov/ohrms/dockets/ac/03/briefing/4015B1_13_FDA-Tab%205-2-ODS%20Safety%20Review.pdf.
[206] Daniel Davis, MD, "Medical Officer Safety Review," Food & Drug Administration, November 15, 2003. Available at www.fda.gov/ohrms/dockets/ac/03/briefing/4015B1_12_FDA-Tab%205-1-Medical%20Officer%20Review.doc.
[207] Ibid.
[208] "Consensus Statement on Emergency Contraception," *Contraception*, 1995 Oct.; 52(4):211-3. The Consensus Statement (in an incomplete version) is available at www.path.org/outlook/html/13_3.htm. Consensus Statement stated, "IEC [information/education/communication] strategies should consider groups with special needs, such as adolescents." Consensus Statement also encouraged MAP providers to "think broadly about women for whom emergency contraception is appropriate, including . . . adolescents and single women. Each group should be

considered in formulating . . . strategies."

[209] Cynthia C. Harper, Ph.D, et al., "Safety and Pharmacokinetics of Emergency Contraception in a Pediatric Population (Aged 12-16)," *2003 Annual Meeting*, American Public Health Association, November 17, 2003, Abstract #71417. Abstract available at: http://apha.confex.com/apha/131am/techprogram. Study funded by Women's Capital Corporation, manufacturer of Plan B. This study did not claim effectiveness in preventing pregnancy in adolescents. Study reported Plan B's safety in only 60 adolescent females age 16 or under, finding, "Emergency contraception was safe and well-tolerated by teenage girls." In this study, pharmacokinetics was examined in only 22 adolescent females age 16 or under.

"Plan B Emergency Contraception: An Open Observational Study in A Healthy Female Pediatric Population," and "Plan B Emergency Contraception: An Open-Label Pharmacokinetic Study in a Healthy Female Pediatric Population," *Adolescent Reproductive Health, Epidemiological & Behavioral Research, Research Summaries*, Center for Reproductive Health Research & Policy, University of California-San Francisco. Available at http:/reprohealth.ucsf.edu/Research—ARH—epi.htm. Both studies also excluded adolescents with history of psychiatric conditions or use of psychotropics, which would not be excluded in OTC/MAP setting. The pharmacokinetic study also excluded smokers and those adolescents more than 15% over/under ideal body weight. Smoking is a recognized indicator of adolescent risk-taking behavior; therefore, the study excluded those adolescents most likely to use OTC/MAP.

[210] Cynthia C. Harper, Ph.D, et al., "Safety and Pharmacokinetics of Emergency Contraception in a Pediatric Population (Aged 12-16)." Study funded by Women's Capital Corporation, manufacturer of Plan B. The study's abstract (APHA annual meeting) does not indicate whether any test subjects were pregnant at the time of MAP use or became pregnant due to MAP failure, the outcomes of such pregnancies, nor any information on health risks to fetuses unintentionally exposed to Plan B in adolescents.

[211] Cynthia C. Harper, Ph.D., et al., "Sexual Risk-Taking and Emergency Contraception," *2003 Annual Meeting*, American Public Health Association, November 19, 2003. Abstract #69864. Available at: http://apha.confex.com/apha/131/am/techprogram. The study's abstract states that, "Study results will be an important resource for many states debating legislation on access to emergency contraception."

[212] Plan B OTC Label Comprehension Study, FDA Study #9728, June 18, 2001 to July 18, 2001. Available at: http://www.fda.gov/ohrms/dockets/ac/03/briefing/4015B1_06_FDA-Tab%202-2-Label%20Conprehension%20Study.htm.

[213] Plan B OTC Actual Use Study, FDA Study #9727, November 5, 2001 to April 11, 2002. Available at: http://www.fda.gov/ohrms/dockets/ac/03/briefing/4015B1_08_FDA-Tab%203-3%20Actual%20Use%20Review.htm.

[214] "1993 Sexually Transmitted Disease Surveillance Report," Centers for Disease Control, 1993. Available at: http://wonder.cdc.gov/wonder/STD/Title3000.html.

[215] "Contraceptive Implants Come of Age," Progress in Reproductive Health Research No. 61, World Health Organization. Available at: www.who.int/reproductive-health/hrp/progress/61/news61.html.

[216] John R. Roberts, MSN, RNCS, ANP. "HIV Prevention: Are We Making Progress?" Association of Nurses in AIDS Care 15th Annual Conference. Available at www.medscape.com/viewarticle/445634.

[217] Hillard Weinstock, et al., "Sexually Transmitted Diseases Among American Youth: Incidence and Prevalence Estimates," *Perspectives on Sexual and Reproductive Health*, Vol. 36 No. 1, January/February 2004. Available at: www.agi-usa.org/pubs/journals/3600604.pdf.

[218] "ASHA Fact Sheet: Chlamydial Infection," *American Social Health Association*, Research Triangle Park, North Carolina. Available at: www.ashastd.org/news/fschlamydia.html.

[219] "Sexually Transmitted Disease Morbidity, Washington State," Infection Disease and Reproductive Health, STD/TB Services& IDRH Assessment Unit, Washington State Department of Health, 1997. Available at www.doh.wa.gov. The report states, "There is some evidence that younger females are more at risk of acquiring Chlamydia if exposed because of the immaturity and friability of the cervix (CDC, 1997)."

[220] "ASHA Fact Sheet: Chlamydial Infection," *American Social Health Association*, Research Triangle Park, North Carolina. Available at: www.ashastd.org/news/fschlamydia.html. Serious complications can develop if Chlamydia is left untreated, including: pelvic inflammatory disease, increasing risk of infertility or ectopic pregnancy.

[221] "Screening All Sexually Active Adolescent Females for Chlamydia Every 6 Months: A New Guideline," Evidence-Based Pediatrics Web Site, Department of Pediatrics, University of Michigan Health System. Available at: www.med.umich.edu/pediatrics/ebm/cats/chlam.htm.

[222] "ASHA Fact Sheet: Chlamydial Infection."

[223] "Hopkins Researchers Urge Regular Chlamydia Testing for All Sexually Active Teenage Women," Office of Communications and Public Affairs, Johns Hopkins Medical Institute, August 1998. Available at: www.hopkinsmedicine.org/press/1998/AUGUST/980811B.HTM. Researchers stated they couldn't predict infection

only by determining symptoms, since Chlamydia often has no symptoms. The study utilized a highly-sensitive urine-based DNA test that amplified DNA Chlamydia. Study published as: Gale R. Burstein, et al., "Incident Chlamydia Trachomatis Infections Among Inner-City Adolescent Females," JAMA, 280 (12 August 1998): 521-526.

[224] "Special Feature: Emergency Contraceptive Pill," *Population Reports*, Series A, Number 9, The Information & Knowledge for Optimal Health (INFO) Project, Johns Hopkins Bloomberg School of Public Health, Baltimore, Md. Available at: www.infoforhealth.org/pr/a9/a9ecp.shtml. The report states, "Sexual activity among youth tends to be more sporadic and less likely to be planned for than among adults, and young people may be more likely to take risks. . . . Not only can emergency contraception help prevent unwanted pregnancies and abortions in this vulnerable group, but also providing ECPs sometimes can create opportunities to offer other reproductive health services and counseling about healthy sexual behavior." It is self-evident that OTC/MAP will *fail* to create opportunities to offer other services or counseling.

[225] Trends in Sexual Risk Behaviors Among High School Students – United States, 1991 – 2001," *Morbidity and Mortality Weekly Report*, September 27, 2002. Centers for Disease Control and Prevention. Available at www.cdc.gov/mmwr/preview/mmwrhtml/mm5138a2.htm.

[226] JoAnne Grunbaum, Ed.D., et al., "Youth Risk Behavior Surveillance – United States, 2001," Centers for Disease Control, June 2, 2002/51(SS04);1-64. Available at www.cdc.gov/mmwr/preview/mmwrhtml/ss5104a1.htm.

[227] Trends in Sexual Risk Behaviors Among High School Students – United States, 1991 – 2001."

[228] Cynthia Harper, Ph.D., et al., "Adolescent Clinic Visits for Contraception: Support from Mothers, Male Partners and Friends," *Perspectives on Sexual and Reproductive Health*, Vol. 36, No. 1, January/February 2004. Available at: www.agi-usa.org/pubs/journals/3602004.pdf. In this study of pregnancy prevention, teenage users of implant hormonal contraception were far more likely to continue using contraception after one year. However, implant contraception provides no protection against HIV/STDs. The study found that younger teenagers relied more on friends for advice than did older teenagers. From this, the study concludes that younger teenagers "may be in greater need of counseling to make healthy choices."

[229] Cynthia C. Harper, Ph.D., et al., "Sexual Risk-Taking and Emergency Contraception," *2003 Annual Meeting*, American Public Health Association, November 19, 2003. Abstract #69864. Available at: http://apha.confex.com/apha/131/am/techprogram. It is not clear whether results of this study are published or available.

[230] Laurie Barclay, MD, "Over-the-Counter Emergency Contraception: A Newsmaker Interview with David A. Grimes, MD." In this media interview, Dr. Grimes described correlating STD rates and OTC/MAP availability as "an ecological fallacy. That would be like finding that the number of telephone poles in a city is correlated with the number of heart attacks, and concluding that telephone poles cause coronary heart disease."

[231] Transcript, Nonprescription Drugs Advisory Committee in Joint Session with the Advisory Committee for Reproductive Health Drugs Meeting, Food & Drug Administration, December 16, 2003. Available at: www.fda.gov/ohrms/dockets/ac/03/transcripts/4015T1.pdf.

[232] Harrell W. Chesson, et al., "The Estimated Direct Medical Cost of Sexually Transmitted Diseases Among American Youth, 2000," *Perspectives on Sexual and Reproductive Health*, Vol. 36, Number 1, January/February 2004. Available at: www.agi-usa.org/pubs/journals/3601104.pdf.

[233] "EC and Pharmacies: States with Direct Access – Washington," *Pharmacy Access Partnership*, Public Health Institute, 2003. Available at www.go2ec.org/ModelWashington.htm. According to the on-line article, "The highly successful pilot project ended in 1999 and has since then become self-sustaining."

[234] "Sexually Transmitted Disease Morbidity, Washington State," Infection Disease and Reproductive Health, STD/TB Services& IDRH Assessment Unit, Washington State Department of Health, 2002. Available at www.doh.wa.gov.

[235] Ibid.

[236] "Sexually Transmitted Disease Morbidity, Washington State," Infection Disease and Reproductive Health, STD/TB Services& IDRH Assessment Unit, Washington State Department of Health, 1997. Available at www.doh.wa.gov.

[237] "Sexually Transmitted Disease Morbidity, Washington State," Infection Disease and Reproductive Health, STD/TB Services& IDRH Assessment Unit, Washington State Department of Health, 2002.

[238] "Sexually Transmitted Disease Morbidity, Washington State," Infection Disease and Reproductive Health, STD/TB Services& IDRH Assessment Unit, Washington State Department of Health, 1997 through 2002. Available at www.doh.wa.gov.

[239] Ibid.

[240] "National Profile: STD Surveillance 2002," Centers for Disease Control, 2000. Available at www.cdc.gov/std/stats/toc2002.htm.

[241] "Sexually Transmitted Disease Morbidity Reports," Washington State Department of Health. Available at: www.doh.wa.gov/cfh/STD/morbidity.htm.
[242] Ibid. WSDH reports that the increasing trend can be explained only in part by MSM (Males-having-sex-with-Males) statistics.
[243] Gabriella Falk, et al., "Young Women Requesting Emergency Contraception Are, Despite Contraceptive Counseling, A High Risk Group for New Unintended Pregnancies," *Contraception*, Vol. 64 Issue 1, July 2001, Pp. 23-27. Abstract available at www.sciencedirect.com. 54% of women requesting MAP had used **no contraception.** At follow-up, there were 10 pregnancies among the 134 women, 9 of which were terminated in abortion. All of the women who became pregnant failed to use routine contraception.
[244] K. Edgardh, "Adolescent Sexual Health," *Sexually Transmitted Infections*, 19 July 2002; 78:352-356. Available at: http://sti.bmjjournals.com/cgi/content/full/78/5/352.
[245] "Statistics: Notifiable Diseases, Genetal Chlamydia Infection," Swedish Institute for Infectious Disease Control (SMI). Available at www.smittskyddsinstitutet.se.
[246] Ibid.
[247] Ibid.
[248] Sam Rowlands, MD, et al., "Repeated Use of Hormonal Emergency Contraception by Younger Women in the U.K.," *The British Journal of Family Planning*, 2000: 26(3):138-143. Available at http://lysander.ingentaselect.com/vl=4762564/cl=64/nw=1/rpsv/cgi-bin/linker?ini=ffp&reqidx=/cw/ffp/14711893/v26n3/s5/p138.
[249] Transcript, Nonprescription Drugs Advisory Committee in Joint Session with the Advisory Committee for Reproductive Health Drugs Meeting, Food and Drug Administration, December 16, 2003, P.38 Transcript available at: www.fda.gov/ohrms/dockets/ac/03/transcripts/4015T1.pdf. Presentation by Women's Capital Corporation/Barr Laboratories representative Vivian Dickerson, MD, president-elect, American College of Obstetricians and Gynecologists.
[250] "Emergency Contraceptive Pills: An Important Option for Young Adults," Family Health International. Available at: www.fhi.org/en/Youth/YouthNet. Article also stated, "ECPs aid sexually active young people as they move to sustained contraceptive use. ECPs should be viewed as a bridge to regular contraception, because regular contraceptives have higher efficacy rates." This seems to presume that adolescents who are not prepared for sexual intimacy or who are sexually coerced (typical justifications for OTC/MAP for adolescents) should be "bridged" into becoming sexually active on a regular basis.
[251]Katie Dillard, "Adolescent Sexual Behavior. 1: Demographics," Advocates for Youth, November 2002. Available at: www.advocatesforyouth.org/publications/factsheet/fsbehdem.pdf .
[252] "Special Feature: Emergency Contraceptive Pill," *Population Reports*, Series A, Number 9, The Information & Knowledge for Optimal Health (INFO) Project, Johns Hopkins Bloomberg School of Public Health, Baltimore, Md. Available at: www.infoforhealth.org/pr/a9/a9ecp.shtml.
[253] "Ending Violence Against Women," *Population Reports*, Series L, No. 11, December 1999. Available at: http://www.infoforhealth.org/pr/l11edsum.shtml. This report quoted a Center for Health and Gender Equity study which found in an anonymous self-report survey of 317 teenagers in the U.S. (South) that 13% of adolescent girls in grades 8 and 10 reported they had been forced to have intercourse.
[254] "U.S. AID Fact Sheet on Emergency Contraception," October 1999. Available at Albert Schweitzer Institute, Quinnipiac University, at: www.quinnipiac.edu/prebuilt/pdf/asi/asi-3212002usaid-fact-sheet.pdf.
[255] JoAnne Grunbaum, Ed.D., et al., "Youth Risk Behavior Surveillance – United States, 2001," Centers for Disease Control, June 2, 2002/51(SS04);1-64. Available at www.cdc.gov/mmwr/preview/mmwrhtml/ss5104a1.htm.
[256] "Teen Card: Emergency Contraception," *Pharmacy Access Partnership*, Public Health Institute. Available at: www.pharmacyaccess.org/PromotingECServ.htm. This tri-folded pocket-sized brochure states, "EC is a safe and effective way to prevent pregnancy if: . . . **You were forced to have sex.**" Brochure was developed at a 6th-7th grade reading level.
[257] Linda Simkin, M.Phil., et al., "Building Emergency Contraception Awareness Among Adolescents: A Toolkit for Schools and Community-Based Organizations," Academy for Educational Development, 2003. Available at: http://www.aed.org/publications/ECtoolkit3283.pdf. The Toolkit was funded by the David and Lucille Packard Foundation, General Service Foundation and the Child Welfare Fund. The Toolkit also thanked the George Soros' Open Society Institute and the Turner Foundation for past funding of AED's MAP/adolescent work
[258] "Birth control for teens so pregnancies go up by 10pc." *Daily Mail (London)*, Dec. 1, 2003. "A controversial sex education programme that hands out condoms in school was branded a failure last night after figures showed a [10%] rise in teenage pregnancy rates. . . . Under the initiative, schools hand out condoms and pupils are sent to clinics for the morning-after-pill. . . . But, while teenage pregnancy rates have fallen across Scotland, they have risen

sharply in the Lothians area [area providing contraception and MAP to teens]. . . . Last night, critics called for Healthy Respect to be scrapped amid growing concerns that it has dramatically backfired. . . . Under a scheme set up in Lothian in June, free morning-after-pills are dished out through 24 pharmacies, including Boots, under the title EC72. The Healthy Respect website directly invites underage girls to take up the offer, stating: 'EC72 is free and completely confidential. We will not tell anyone that you have used the service." Responding to these criticisms, a program spokesman retorted, "To suggest, at this stage, that Healthy Respect is failing because it has not achieved specific, long-term health outcomes, undermines the important work of the project." The project's important work is then described as, "*[T]he majority of young people in Lothian are making mature, well-informed decisions about their sexual health as a direct result of the education, information and services provided by Healthy Respect and health promotion specialists*." The Lothian teenage pregnancy rate is 59.1 pregnancies for every 1,000 females.

[259] Tina Raine, MD, MPH, et al., "Emergency Contraception: Advance Provision in a Young, High-Risk Clinic Population," *Obstetrics & Gynecology*, 1 July 2000, Vol. 96, No. 1, Pp. 1-7. Available on Plan B/Women's Capital Corporation website at: http://www.go2planb.com/content/article/detail/553. "Women in the treatment group (28%) were more likely than those in the control group (17%) to report using less effective contraception at follow-up compared with enrollment."

[260] Neville H. Golden, et al., "Emergency Contraception: Pediatricians' Knowledge, Attitudes and Opinions," *Pediatrics*, 2 February 2001, Vol. 107, Pp. 287-292. Available at: http://pediatrics.aappublications.org/cgi/content/abstract/107/2/287. Study authors conclude, "Despite the safety and efficacy of EC, the low rate of use is of concern. Pediatricians are being confronted with the decision to prescribe EC but do not feel comfortable prescribing it because of inadequate training in its use." Lack of pediatrician willingness to prescribe MAP for adolescents may be "of concern" to study's authors, but it is a comfort to parents who object to use of MAP by their children. Perhaps OTC/MAP is proposed means to resolve this "concern" because adolescents can obtain MAP themselves directly.

[261] Dick Churchill, et al., "Consultation Patterns and Provision of Contraception in General Practice Before Teenage Pregnancy: Case-Control Study," *British Medical Journal*, 2000 August 19; 321 (7259): 486-489. Available at: http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=27465&rendertype=abstract.

[262] Transcript, Nonprescription Drugs Advisory Committee in Joint Session with the Advisory Committee for Reproductive Health Drugs Meeting, Food & Drug Administration, December 16, 2003, P.101, 102.

[263] A. Glasier, et al., "Case Studies in Emergency Contraception from Six Countries," *International Family Planning Perspectives*, June 1996. 22(21):57-61. Available at http://www.hsph.harvard.edu/Organizations/healthnet/SAsia/suchana/0507/glasier_etc.html.

[264] Mary Ann Castle and Francine Coeytaux, "A Clinician's Guide to Providing Emergency Contraceptive Pills," Pacific Institute for Women's Health. Available at www.piwh.org/pdfs/EC_guide.pdf. "Special attention and education should be paid to men requesting ECPs. . . . Have available information and materials specifically designed for men and hand out condoms when appropriate."

[265] Heidi Welborn, "Expanding the Pharmacist's Role in Providing Emergency Contraception," *Journal of the American Pharmaceutical Association*, Vol. 41 No. 5, September/October 2001. Available at www.aphanet.org. Note, however, that pharmacists who object in conscience to MAP must be specifically exempted from any job-related duty to dispense MAP.

[266] "Trends in Sexual Risk Behaviors Among High School Students – United States, 1991 – 2001," *Morbidity and Mortality Weekly Report*, September 27, 2002. Centers for Disease Control and Prevention. Available at www.cdc.gov/mmwr/preview/mmwrhtml/mm5138a2.htm. CDC report states, "During 1971-1979, the percentage of females aged 15-19 years living in metropolitan areas nationwide who ever had sexual intercourse increased from 30% to 50%." This dramatic increase in sexual activity among adolescent females coincided with the legalization of induced abortion in 1973, which provided a back-up measure for unintended pregnancy. Some see a similar parallel in that OTC/MAP will further lessen perceived concerns about pregnancy and the need for induced abortion. This, in turn, may lead to new increases in rates of adolescent sexual activity, with increased risks of STD/HIV infection.

Jonathan Klick and Thomas Stratmann, "The Effect of Abortion Legalization on Sexual Behavior: Evidence from Sexually Transmitted Disease," *Journal of Legal Studies*, The University of Chicago, June 2003, Vol. 32. Available at George Mason University, www.gmu.edu/jbc/stratmann.std18.pdf. The study describes unwanted pregnancy as "a major cost of sexual activity" and posits that this cost was a significant disincentive to sexual activity prior to the legalization of abortion. After legalized abortion, the cost of sexual activity was reduced, generating increased sexual activity accompanied by increased rates of STDs. The study finds that "gonorrhea and syphilis incidences are significantly and positively correlated with abortion legalization." Using a double quasi-experiment, the study proves that STD rates rose quickly among states which first .legalized abortion; STD rates among all states later converged when abortion was legalized nationally in 1973

[267] "EC Outreach Materials," *Pharmacy Access Project*, Public Health Institute. Available at http://www.go2ec.org/ECOutreachMaterials.htm. According to Pharmacy Access Project, the Women's Capital Corporation advertisements ran in 30 college newspapers in early 2002.
[268] "So Many Men. So Many Reasons to Have Back-Up Contraception." Plan B newspaper ad. Women's Capital Corporation. DDB Bass & Howes. Available at: http://www.basshowes.com/ia_portfolio_item.asp?id=186.
[269] "Delta Delta Thi. 27 Upstanding Young Men. 34 Billion Sneaky Little Sperm." Plan B newspaper ad. Women's Capital Corporation. DDB Bass & Howes. Available at: http://www.basshowes.com/ia_portfolio_item.asp?id=186.
[270] "A Renaissance Man. A Deep Thinker. An Ancient Soul. A Walking Sperm Factory." Plan B poster ad. Women's Capital Corporation. DDB Bass & Howes. Available at: http://www.basshowes.com/ia_portfolio_item.asp?id=185.
[271] "Sperm Happens," *Billboard Campaign*, Population Services International. Available at: www.psi.org/resources/pubs/usp.html.
[272] "Oh $#*!" *Emergency Contraception: Because $#*! Happens*, Media Campaign, Pacific Institute for Women's Health. Available at www.piwh.org/unitedstates.html. McCann-Erickson and cruz/kravetz:IDEAS. Bus shelter ads, magazine and newspaper ads and "GoCards" featured this advertising theme [delete: them] in Los Angeles, San Francisco and New York.
[273] "Advocacy Tool Kit Video," *Accidents Happen, Pregnancy Doesn't Have To Marketing Campaign*, Population Services International (PSI). Available at: www.go2ec.org/AccidentsVideoLow.htm. This video encourages the sexual attitudes which risk HIV/STDs and pregnancy.
[274] "Were You Forced?" Advertisement, Population Council, Reproductive Health and Family Planning, Contraception, Emergency Contraception. Available at: http://www.popcouncil.org/rhfp/ec.html.
[275] "What Can You Do If An Accident Happens?" *Accidents Happen, Pregnancy Doesn't Have To Marketing Campaign*, Population Services International (PSI). Available at: www.go2ec.org/pdfs/PSI_EC_Wallet.pdf. This wallet card urges adolescents and young persons to use MAP in various situations, including sexual assault: "When can I use Emergency Contraception Pills? You were forced to have sex." The wallet card is one tool in MAP marketing campaign developed through PSI pilot project in Sacramento, California, with the Emergency Contraception Promotion Project.
[276] "When Things Don't Go As Planned . . ." *Bus Poster*, California Family Health Council, Spring 2003, Los Angeles Public Bus Advertising Campaign. Available at: www.go2ec.org/pdfs/CFHC_Bus_Poster2003.pdf.
[277] Anna L. Garcia, et al., "Caution: Provocative Artwork Ahead! Getting Attention for Emergency Contraception," *American Public Health Association Annual Meeting 2003*, November 17, 2003, Abstract #72030. Available at http://apha.confex.com/apha/131am/techprogram. A presentation stated that an evaluation of the campaign is planned: "A comparison will be made of the community response to the emergency contraception messages and graphic designs from the current provocative campaign to the *earlier conservative campaign*." It is unclear how success will be measured in the evaluation. For example, an increased number of calls to an MAP hot line could indicate increased sexual activity due to the provocative ad campaign itself. Will the evaluation consider changed rates of HIV/STD infection and abortion as well as possible adverse health events such as ectopic pregnancies?
[278] Nan Frances Lewicky, MA, MPH, et al., "Let's Get It On: Making Teen Pregnancy Prevention Hot," *American Public Health Association Annual Meeting 2003*, November 17, 2003, Abstract #65242. Available at http://apha.confex.com/apha/131am/techprogram. The abstract describes the project as a "youth-empowered teen pregnancy program in a semi-rural agricultural community" with a "conservative political and socio-economic environment. . . . Trendy condom vending machines [were] placed in local shops and youth hangouts." Although it is not clear whether MAP was included in this campaign, future social marketing undoubtedly will promote MAP should it become standardized.
[279]"Expanding Global Access to Emergency Contraception: A Collaborative Approach to Meeting Women's Needs;" www.cecinfo.org/files/ see: link titled Expaning-Global-Access-to EC.rtf.
[280]"The Emergency Contraceptive Newsletter," Spring 1999, Vol. 4, No. 1.
[281] Emergency Contraception Update Highlights: October, 1996 to October 1997; "USAID *Promotes 'Vital Choice for Women.'*"
[282] May 17, 2002 letter to Peruvian Minister of Health Fernando Carbone, from 21 pro-abortion activists, including signature of Maria Angelica Borneck of USAID/Peru.
[283] USAID El Salvador, "Family Planning Guidelines," July 1999.