The Morning-After Pill

By Wendy Wright, Carol Denner, R.N. and Jill Stanek, R.N.

A pill that would make abortions rare?

If this sounds too simple to be true, you are right. Backers of the morning-after pill claim that easy access to the drug will lower the number of abortions. But the first clue that makes this suspect is the campaigners themselves: abortion advocates. One of their top priorities is to make the morning-after pill available to anyone, with no age restriction, parental involvement or qualified medical oversight.

But will the morning-after pill be the solution for the night-before’s mistakes? Or another false promise that causes more problems for the consumers and society?

Women’s Capital Corporation, the creator of the morning-after pill Plan B, and Barr Labs, which bought the drug, petitioned the Food and Drug Administration (FDA) to make Plan B available over-the-counter, without a prescription. On May 6, 2004, the FDA declined, concluding it had not been adequately tested to determine how easy access to the drug would affect adolescents.

In its non-approval letter to Barr Research, the FDA stated:

Based on a review of the data, we have concluded that you have not provided adequate data to support a conclusion that Plan B can be used safely by young adolescent women for emergency contraception without the professional supervision of a practitioner licensed by law to administer the drug.1

Questions had been raised about the effect of easy access to the morning-after pill on adolescents and on sexually transmitted disease (STD) rates. Notably, a groundbreaking study in the United Kingdom released in April, 2004, found that “the shift towards greater promotion of emergency birth control appears to have worsened the impact on STI [sexually transmitted infection] rates since 2000.” In 2000, regulations were passed

that made it easier to dispense the morning-after pill without a doctor’s prescription and initiatives introduced to promote the drug to young people.

The study concludes “it appears that some measures aimed at reducing adolescent pregnancy rates induced changes in teenage behavior that were large enough not only to negate the intended impact on pregnancy rates but to have an adverse impact on another important area of adolescent sexual health: sexually transmitted infections.”

State officials should share the FDA’s discomfort when asked to make the morning-after pill easily available.

Medical and public health issues with easy access to the morning-after pill include:

- inadequate scientific studies on: its specific effects on adolescents; long-term effects; the high dosage; repeated usage; and use by females not screened for medical contraindications;

- increases in sexually transmitted disease rates where the drug is easily available;

- the potential for the morning-after pill to be slipped to women without their knowledge or consent;

- teenagers – and those below the age of consent – would be less confident in resisting sexual pressure. It would also be a tool for statutory rapists to cover their crimes.

State officials should not allow a drug to be sold without a doctor’s oversight that lacks testing, that will increase public health problems, and could be used detrimentally on women without their knowledge or consent.

**Oral Contraceptives Require Medical Oversight**

Whenever oral contraceptives are used, including the morning-after pill, physical and clinical examinations by a physician are essential to good health care. Exams enable doctors to counsel patients, detect medical contraindications, determine STDs, abusive relationships and related health issues, and obtain forensic evidence in the case of rape. Availability of the morning-after pill without this puts women and girls at higher risk for disease, health problems and continued abuse.

The morning-after pill is a high dose of the birth-control pill. Ironically, manufacturers have reduced the hormone content of oral contraceptives due to women experiencing serious side effects and health risks.

Birth control pills are available only be prescription for sound medical reasons: They can

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cause significant or life-threatening conditions such as blood clots, stroke and liver disease. Existing medical problems, that may be unknown to the woman, can worsen.³

Both the American Medical Association (AMA) and the American College of Obstetricians and Gynecologists (ACOG) recommend that low-dose oral contraceptives be available only with a prescription from a licensed health-care provider. Yet activists within these organizations recommend that Plan B and other higher-dose hormone regimens be available without one.

Non-prescription access would extend the availability of the morning-after pill to a broader population than any trial has included — females who have not been counseled or screened and may not have access to a physician to assist when complications occur.⁴

Non-prescription access conveys the impression that a drug has been determined safe if used as labeled. However, the approval of high-dose hormone therapy (such as Plan B) was not based on controlled scientific studies, but on unscientific, anecdotal evidence. All studies (including those cited in Plan B’s over-the-counter application) focus attention on the drug’s relative reliability in decreasing the expected birth rate, not on the effect on the women who have taken the drug regimen.

The safety of medications can only be determined if health professionals trained to identify side effects follow individuals receiving the medications over an extended time period. A serious side effect may not be immediately apparent.

The highly-touted effectiveness of the morning-after pill leaves much to be desired, with only between 75 to 89 percent efficacy in decreasing the naturally occurring pregnancy rate.⁵ Up to one out of four pregnancies may still occur when it is used. Easy access to the pill may make couples more likely to engage in risky sexual activity; failure of the morning-after pill would make women more susceptible to abortion.

³ Some side effects necessitate medical input. MayoClinic.com states, “If you are receiving levonorgestrel tablets for emergency contraception and vomiting occurs within 1 hour of taking either dose of the medicine, contact your physician to discuss whether the dose should be repeated.” Introducing a list of side effects of progestin oral contraceptives, including Plan B, it states, “Although not all of these side effects may occur, if they do occur they may need medical attention. Check with your doctor as soon as possible if any of the following side effects occur …”:

http://www.mayoclinic.com/invoke.cfm?objectid=5A236570-60AA-447C-BFF244AF15E011AE#g20275701.

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⁵ Plan B (Levonorgestrel) Emergency Contraception: Prescribing Information, found at:
http://www.go2planb.com/section/prescribing_info/?PHPSESSID=50065b3cd1c2d512226d7230b5596
Unknown Effects of Repeat Usage

Advocates argue that women know better than to use the morning-after pill often, so there is no risk of over-use of this high-dose drug. Yet, in the label comprehension study submitted by Barr Labs to the FDA, a full one-third of adult women who read the instructions for Plan B did not understand that the morning-after pill is not to be used as a regular form of birth control. The number increased among those with low literacy and less than high school education. Over one-third did not understand the need to take the second pill at 12 hours after the first. The chairman of the FDA Advisory Committee that reviewed the comprehension study called it an “overall failure.”

The maximum safe dose for levonorgestrel (the active ingredient in Plan B) has not been determined by scientific study, or the effects of overdose. It is unknown whether there is a maximum safe daily dose, monthly dose or yearly dose. The health risks for those who may use Plan B repeatedly (ranging in age from menarche—as young as 9—to women in their 50s) at one time or over years are unknown.

While advocates brush away concern over repeated use, stating that women will use it only in “emergencies,” experience shows that, when easily available, the morning-after pill is relied upon often. In fact, promoters of the morning-after pill describe “emergencies” as suspected contraceptive failure or “any time unprotected sexual intercourse occurs.” Repeat use is only discouraged based on its insufficient efficacy as a birth control method, not due to safety concerns.

Dr. Ben-Maimon of Barr testified at an FDA Advisory Committee hearing: “Well, I think that there is no question that the data suggests that women who have emergency contraception use it more frequently.”

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6 Summary, Clinical Review of Plan B (Levonorgestrel) sNDA 21-045. Author’s copy.


8 “There are no data on overdosage of Plan B,” Plan B (Levonorgestrel) Emergency Contraception: Prescribing Information, found at http://www.go2planb.com/section/prescribing_info/?PHPSESSID=50065b3c473d1e2d512226d7230b5596.


A study conducted at Albert Einstein School of Medicine found that 19 percent of women
given Plan B used it, while none of the women given a prescription for Plan B used it.\textsuperscript{12}

Adolescents, whose bodies are developing and undergoing rapid hormonal changes, are
among those most likely to use this hormonal drug repeatedly. The ability to use it
secretly would attract adolescents, also making them averse to seeking medical help
when complications arise. They are less likely to follow directions for administration or
to read through or fully understand the medication label. Those fearful of a pregnancy
may take more than one dosage, either in response to the side effect of vomiting or in the
all-too-common rationalization that it would increase its chances of working.

Because the morning-after pill has not been adequately tested, the women who use it will
serve as unsuspecting “guinea pigs.”\textsuperscript{13}

**FDA Cites Pill’s Marketers for False Advertising**

In November 2002, the FDA Division of Drug Marketing, Advertising and
Communications (DDMAC) cited Women’s Capital Corporation for false advertising of
Plan B. The FDA Warning Letter expresses strong concerns over the use and misuse of
the drug—concerns that warrant the prescription status. The violations highlight the
practice of proponents to minimize risks, side effects, proper precautions and indications
for use. The letter states:

DDMAC has concluded that [Women’s Capital Corporation’s] ads are false,
lacking in fair balance, or otherwise misleading in violation of the Federal Food,
Drug and Cosmetic Act and applicable implementing regulations. Specifically,
the DTC [direct to consumer] radio and print ads overstate efficacy, fail to convey
important limitations on use, and minimize important information about risks
associated with the use of Plan B Tablets emergency contraception. As a result,
the ads raise significant public health and safety concerns.\textsuperscript{14}

A different ad campaign for Plan B, placed in newspapers and on college campuses,
makes sex with multiple partners the ideal:

- One ad portraying 13 young men with the caption, “So many men. So many reasons
to have back up contraception.”

\textsuperscript{12}“Study Ties ‘Morning-After’ Pill Use to Supply Ease,” Reuters, April 28, 2003.

\textsuperscript{13}Official Web site of Plan B admits, “Progestin-only contraceptive pills (POPs) are used as a routine
method of birth control over longer periods of time, and are contraindicated in some conditions. It is not
known whether these same conditions apply to the Plan B regimen consisting of the emergency use of two
progestin pills.” Plan B (Levonorgestrel) Emergency Contraception: Prescribing Information, found at
http://www.go2planb.com/section/prescribing_info/?PHPSESSID=50065b3e473d1c2d512226d7230b5596.

\textsuperscript{14}Letter to Sharon L. Camp, Ph.D., President and CEO of Women’s Capital Corporation, RE: NDA 21-045
Plan B (levonorgestrel) Tablets, 0.75 mg, FDA Warning Letters, released November 19, 2002.
Another pictures a cheering fraternity, with the words, “Delta Delta Thi. 27 upstanding young men. 34 billion sneaky little sperm.”

Another campaign, designed like celebrity posters for adolescents, displays a shirtless teenager and the autograph, “Love, Ernesto.” The tag line reads, “Of all the things you’d love to hear him whisper in your ear, ‘Oops – the rubber broke,’ isn’t one of them.” The next poster, signed, “Damian XOXO,” describes the object of affection as “A Renaissance Guy, a Deep Thinker, an Ancient Soul, a Walking Sperm Factory.”

Additionally, while admitting that Plan B inhibits implantation, morning-after pill promoters claim it does not end a pregnancy. Something must exist in order to implant. That something is a newly formed human life, with 23 chromosomes from mom and 23 from dad - the full genetic information of a distinct human being. Nearly half of Americans (46 percent) believe life begins at fertilization. Because this knowledge, that the morning-after pill can terminate a new life, could affect a woman’s decision to use it, obscuring such information violates the principle of informed consent.

**Easy Access Has Led to an Increase in Sexually Transmitted Diseases, No Reduction in Abortions, and Repeat Use**

- **Scotland** – Scotland has made the morning-after pill accessible for years. In Glasgow, morning-after pill prescriptions increased 300 percent from 1992 to 1999. Yet, abortions did not decrease. In Lothian, where schools handed out condoms and sent pupils to clinics for morning-after pills, teenage pregnancies among 13- to 15-year-olds soared 10 percent in one year.

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18 “The ‘morning-after pill’, abortion and informed consent,” by Gene Rudd, MD, found at [http://www.cmdahome.org/fastmedia/Issues_Abortion/Abortion_MorningAfterPill_GRudd/media/Abortion_and_the_morning-after_pill_-_Rudd.pdf?id=335&type=f&station=CMDS2&slow=http%3a%2f%2fwww%2ecmdahome%2eorg%2findex%2ehtml%2fIssues_Abortion%2fAbortion_MorningAfterPill_GRudd%2fmedia%2fAbortion_and_the_morning-after_pill_-_Rudd.pdf&file=Abortion_and_the_morning-after_pill_-_Rudd.pdf](http://www.cmdahome.org/fastmedia/Issues_Abortion/Abortion_MorningAfterPill_GRudd/media/Abortion_and_the_morning-after_pill_-_Rudd.pdf?id=335&type=f&station=CMDS2&slow=http%3a%2f%2fwww%2ecmdahome%2eorg%2findex%2ehtml%2fIssues_Abortion%2fAbortion_MorningAfterPill_GRudd%2fmedia%2fAbortion_and_the_morning-after_pill_-_Rudd.pdf&file=Abortion_and_the_morning-after_pill_-_Rudd.pdf).


United Kingdom – Making the morning-after pill available through pharmacists (without a prescription) coincides with surges in STD rates. In areas where a limited program began in 1999 (which was then expanded nationwide in January 2001), chlamydia cases rose from 7,000 in 1999 to 10,000 cases in 2002. Gonorrhea cases climbed nearly 50 percent, to nearly 3,000 cases in 2002, up from 2,000 in 1999. The highest increases were among 16-to 19-year-olds. Abortions increased by nearly 6,000 in a one year period, jumping 3.2 percent in 2003 from 2002, with the largest leap among girls under the age of 16.

An official survey of pharmacies, family planning clinics and schools revealed that 25,200 girls under 16 (the age of consent in England) were given the morning-after pill in 2001. Among them were girls as young as 12.

Morning-after pill use among teenage girls in the United Kingdom has more than doubled since it became available in pharmacies, increasing from one in 12 teenagers to one in five. “Women aged under 20 were twice as likely as those aged 20 and over to have used the morning-after pill at least once in the past year.” Of the more than 20 percent of 18 to 19-year-olds who used the morning-after pill, nearly a quarter had taken it more than once in the same year. One in seven of all women used the morning-after pill repeatedly in the same year.

Nurses at the Royal College of Nursing’s annual conference in 2003 called for tighter regulations, warning that suppliers (pharmacists) were failing to warn customers of possible complications or carry out routine medical assessments.

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28 Ibid.

In a study published in *Social Science & Medicine*, pharmacists and users of the morning-after pill expressed major concerns about the easy access. These included the potential for misuse, changes in contraceptive use (relying on morning-after pill rather than regular birth control), and the impact on STDs.\(^{30}\)

The study cites revealing comments from pharmacists:

- “I think we have to hammer home the message with some of them. I’ve felt that those who come in giggling about it, it’s important to underline that this isn’t a joke. One girl had been in three times, and then you start to get the thumbscrews out with them. If they’re not getting the message that it’s only for occasional use, then we have to tell them.”

- A girl who said she was 10 years old told the pharmacist “she had already used it [Emergency Hormonal Contraception] four times.” The pharmacist declined her request and referred her to a sexual health clinic.

- “I think the pharmacy service offers anonymity for those who don’t want their doctors to know they have taken EHC [Emergency Hormonal Contraception].” [Anonymous use thwarts physicians from accurately diagnosing later complications.]

- Female pharmacists expressed concern that easy access to the morning-after pill would result in men coercing women, particularly young or less assertive women, into having sexual intercourse against their will.

In response to concern that providing the morning-after pill through pharmacists would lead to more unprotected sex, a user of the pill disclosed:

> To be honest, in a way, that is what happened to me. I did previously know that X chemist was just over the road and I think … if I hadn’t have known I could have got it so easily, I would have been more careful, to be honest.

In regard to repeat use, pharmacists conceded they would not know how often customers obtained the drug from other stores and clinics.

In a different study among users of the pill, four out of the 12 women interviewed said their choice to have unprotected sexual intercourse was influenced by the knowledge that they could obtain the pill from a pharmacy.\(^{31}\)

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### Australia
On January 1, 2004, Australia made the morning-after pill available without prescription, against the objections of the Australian Medical Association (AMA). Only doctors can adequately counsel teenagers about under-age sex, contraception and sexually-transmitted infections, the AMA stated. A survey of general practitioners found that more than half of the 104 doctors questioned were opposed to the over-the-counter availability to women of any age. By June 2004, Federal Health Minister Tony Abbott announced he was considering tightening access after disturbing reports that the drug was being sold to young teenagers without concern for age of consent or unprotected sex.\(^\text{32}\)

### Jamaica
Pharmacists complained that the morning-after pill “is being abused by persons including schoolchildren, and they are calling on officials in the Ministry of Health to rethink the decision which made the pill available over the counter some six months ago” it was announced in November 2003. Pharmacists also reported falling condom sales, which they attributed to easier access to the morning-after pill. “Down here,” said one pharmacist, “one person will go to three, four different pharmacies and you can’t stop them because you can only go by what they tell you during counseling.” Some pharmacists are so angry at the situation that they don’t even keep the drug in stock.\(^\text{33}\)

### Washington State
A pilot program to provide morning-after pills through pharmacists (with no prescription) since February 1998 focused on increasing access and use. However, it did not review STD or abortion rates, nor did it record complications suffered by morning-after pill users.\(^\text{34}\) Washington Center for Health Statistics reports abortion rates that reflect only the same small decrease in abortions reported nationwide where the morning-after pill was not as easily accessible.

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**Men are the Most Frequent Buyers of the Morning-After Pill in Thailand**

A study of morning-after pill use in Thailand, where it has been available through pharmacists (without prescription) since 1984, found “the majority of purchasers are men buying EC [emergency contraceptives] for women, and it is generally men who select the method for their girlfriends.” Most young people (17 out of 22) had purchased EC more than once. Nine out of 17 respondents who had purchased morning-after pills in the past

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\(^\text{36}\) “Situational analysis of emergency contraceptive use among young people in Thailand,” found at
reported that “they or their partners used more than two tablets of EC per month, which suggests that they may use it regularly, contrary to its intended purpose.”

The Bangkok Post elaborated on the disturbing consequences of easy availability:

- Men “buy the pills for their girlfriends or wives so that they don’t have to wear condoms and feel they’re at no risk of becoming a father afterwards. Some women I’ve spoken to said that they didn’t even know what they were taking; that the guy just said it was a health supplement,” said Nattaya Boonpakdee, program assistant at the Population Council (an agency that promotes and develops contraception and abortion methods).

- “Many women take three pills in a single week. Obviously, those can’t all be emergencies,” said Nattaya Boonpakdee.

- It was not uncommon for women to take more than 10 pills a month, although the maximum recommended monthly dose is four tablets (two occasions of unprotected sex), according to clinic worker Waranya Pitaktepsombat.

- “A woman taking the emergency pill is probably not insisting on the use of a condom and this practice is likely to be more common now among youngsters and married couples. This inevitably puts them at high risk of contracting sexually transmitted diseases. And, as statistics show, a high percentage of AIDS victims contracted the virus from their [long-term] partners,” stated Dr. Niyada Kiating-Angsulee of the Faculty of Pharmaceutical Sciences at Chulalongkorn University.

The article notes, “Although many feminists believe that the morning-after pill gives them more control over their own bodies, it would seem, judging from the few studies conducted so far, that it is actually being used by men to exploit women.”

“Forcing women to use oral contraceptives on a regular basis, especially these highly concentrated morning-after pills, is likely to put women’s health at risk,” said Dr. Niyada Kiating-Angsulee of the Faculty of Pharmaceutical Sciences at Chulalongkorn University.

**Tool for Abusers and Statutory Rapists**

Congress passed a law to require reporting of suspected statutory rape by those dispensing federally funded contraception. This legislation was fueled by accounts of


adult men relying on contraception from family planning clinics to cover up their sexual abuse of minor girls. Allowing access to the morning-after pill without a prescription would thwart national efforts to protect minors from sexual abuse.

Even morning-after pill supporters agree that sexually active girls are likely victims of sexual abuse, and interaction with medical professionals is an important defense.

The Alan Guttmacher Institute reported: “The younger women are when they first have intercourse the more likely they are to have had unwanted or nonvoluntary first sex, seven in 10 of those who had sex before age 13, for example.”

Dr. Joycelyn Elders co-authored a 1998 commentary in the *Journal of the American Medical Association* on adolescent pregnancy and sexual abuse. She expressed concern that even in the clinical setting, the rush to choose “pregnancy outcome options” may pre-empt efforts to rule out sexual abuse.

Girls who are pregnant under questionable circumstances are potential victims of sexual abuse, as Dr. Elders and her co-author Alexa Albert stated: “Sexual abuse is a common antecedent of adolescent pregnancy, with up to 66 percent of pregnant teens reporting histories of abuse. … Pregnancy may also be a sign of ongoing sexual abuse. … Boyer and Fine found that of 535 young women who were pregnant, 44 percent had been raped, of whom 11 percent became pregnant as a result of the rape. One half of these young women with rape histories were raped more than once.”

Dr. Elders and Albert concur with the Guttmacher Institute: “The younger the mother, the greater the partner age gap.” They reported that “fathers are on average 9.8 years older than mothers 11 to 12 years of age.”

Dr. Elders and Albert concluded, “Health care professionals need to improve their abilities to identify and support adolescent girls who are experiencing nonvoluntary sex and are subsequently at risk for unplanned pregnancies. The possibility of sexual abuse should be considered routinely in every adolescent female patient who has initiated sexual activity.”

Making the morning-after pill available without a prescription would pre-empt Dr. Elders’ recommendations. Pharmacists are not capable of doing an exam that would detect abuse, nor counsel on private matters in the open setting of a store. Easy access to the morning-after pill would assist sexual perpetrators in hiding their rapes.

Although adult women may be less susceptible to coercion, they can become victims of those who do not want them to be pregnant. In one example, Gary Bourgeois tried to convince his pregnant girlfriend to have an abortion, which she refused. During sexual

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relations, he inserted misoprostol, used in the RU-486 abortion regimen. Later she experienced violent cramps then felt a partially dissolved pill drop from her vagina. Her baby died. He pled guilty to aggravated assault and administering a noxious substance.40

In another incident, Dr. Stephen Pack pled guilty to injecting Joy Schepis with an abortion-inducing drug in April 2000. The Bronx, New York, doctor jabbed his former lover with a syringe filled with methotrexate because she refused to have an abortion.41

The morning-after pill, unlike an injection or vaginal insertions, can easily be administered without a woman’s knowledge. Without requiring a prescription, the person who buys the drug may not be the person who consumes it. Since it needs only to be swallowed, it can simply be slipped to women without their consent or knowledge. When complications occur, victims and their doctors will not know the cause.

Morning-After Pill Linked to Ectopic Pregnancy

The World Health Organization has warned: “There may be a higher percentage of ectopic pregnancies among emergency contraceptive pill failure cases than among a normal pregnant population.”43 Scientists believe that the pill may slow the journey of the egg to the womb in some women by affecting cilia, tiny hairs that help transport the egg inside the fallopian tubes.

Britain’s Chief Medical Officer, Sir Liam Donaldson, sent a letter to doctors in January 2003, warning that 12 cases of ectopic pregnancy out of 201 pregnancies followed failure of Levonelle (levonorgestrel 0.75 mg). The letter noted that ectopic pregnancies are more likely to occur in women taking progestogen-only pills.44 Schering Health Care, the

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40 Tu Thanh Ha, “Man admits inducing woman’s miscarriage; Montrealer pleads guilty in case where anti-ulcer drug was slipped to girlfriend who had refused to have an abortion,” The Globe and Mail, September 17, 2003. “Montreal man sentenced to one year in jail for inducing miscarriage,” CNEWS, May 18, 2004, found at http://cnews.canoe.ca/CNEWS/Law/2004/05/18/464589-cp.html.


maker of Levonelle, was ordered to change the wording of patient information leaflets to clarify the potential risk of ectopic pregnancy.\textsuperscript{45}

Dr. Terri Foran, medical director of FPA Health (Family Planning Australia) in Sydney, said, “Of those pregnancies that are not prevented by the [contraceptive] method, it would appear likely that an increased proportion of these might be ectopic.”\textsuperscript{46}

Similarly, the Lis Maternity Hospital in Tel-Aviv reported three cases of ectopic pregnancies occurring in women who ingested levonorgestrel. The women, aged 19, 20 and 34, were “without apparent risk for ectopic pregnancy.”\textsuperscript{47}

**Conclusion**

The evidence is clear. Easy access to the morning-after pill encourages frequent use and will cause STD rates—already at epidemic levels—to increase. It may carry medical risks to women, including those who have not consented to it. Statutory rapists will rely upon it to cover up continuing abuse.

While wider availability may result in some businesses profiting from the consequences of sexual activity, it will be at the cost of women’s and public health.

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\textsuperscript{46} Ibid.