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Dr. Steven Galson, Acting Director
Center for Drug Evaluation and Research
Food and Drug Administration
C/o Dockets Management Branch (HFA-305)
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: NDA 21-045/S-011

Dear Dr. Galson,

In response to my letter of October 20, 2004 to The Honorable Tommy G. Thompson, Secretary of Health and Human Services, Dr. Duane Alexander, Director of the National Institute of Child Health and Human Development, states in his letter of November 8, 2004, "We are unaware of any studies of typical use rates for the morning-after pill." Importantly, typical use includes non-use after planned use. I find it unconscionable that a consensus of experts would recommend the morning-after pill for over-the-counter use without any estimate of typical use rates.

Also, I note that a problem of substituted reliance (substituted use) will occur when a couple foregoes a traditional "Plan A" method based on plans to use a morning-after pill (e.g., Plan B) post-coitally. The morning-after pills are based on a doubling-down on birth control pills post-coitally, usually with a follow-up dose. It has long been known that this practice is less effective than traditional methods. Therefore, substituted reliance will result in more unplanned pregnancies. It is also important to emphasize that in a typical use scenario substituted reliance includes cases where the end result is non-use despite planned use. Where Plan A was the condom, substitution means more unplanned pregnancies and an increased transmission of sexually transmitted diseases, affecting both partners and offspring.

Although first year pregnancy rates (referred to elsewhere as first year contraceptive failure rates) for perfect use are known for both the morning-after pills and the traditional methods, single use pregnancy reduction rates do not appear to have been reported for the traditional methods. Confusion arises because authorities stress that the morning-after pill is not likely to be used continuously, and therefore they mistakenly discount the comparison of first year statistics. However, this confusion is unnecessary because regarding perfect use rates a method with a higher first year pregnancy rate must therefore reduce fewer pregnancies per single use. Nevertheless, confusion continues to arise because single use rates for the traditional methods are not available for comparison and so the rates published for the morning-after pills are left to appear deceivingly significant when looked at alone.

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The following report on the pregnancy reduction curve clears up this confusion by showing that the relationship between single use rates and first year rates is an exponential one. The pregnancy reduction curve allows us to estimate the single use rate from the first year rate, whether for perfect use or for typical use, the latter implying an average single use rate including factors such as non-use after planned use. Notably, the single use rates are linearly proportional to woman-year rates. Note also that the order among methods is such that a method with a higher first year pregnancy rate allows more pregnancies per woman-year of use as well as per single use. Importantly, the pregnancy reduction curve helps us to understand, for example, why Preven allows twice as many pregnancies in the first year of perfect use compared to Plan B even though the single use rates seem roughly similar on a linear basis. In other words, the pregnancy reduction curve allows us to see the exponential nature of the relationship. Accordingly, noting that typical use rates for the morning-after pills will be worse than perfect use rates, it becomes clear that even occasional reliance on the morning-after pill is contraindicated compared to traditional methods.

I alert you to these problems to avert the inevitable epidemic of unplanned pregnancies that will result from over-the-counter popularization of the morning-after pill, or any form of popularization for that matter, including by loose prescription.

Pregnancy Reduction Curve

In this brief report, I present the Pregnancy Reduction Curve (PRC). The PRC relates the first year pregnancy rate for a pregnancy reduction method to the single use reduction rate for the same method. In my estimation, the PRC appears to be the most fundamental curve relating to pregnancy reduction methods.

This report does not consider the accuracy of the sample data used. Instead, the purpose of this report is to present the PRC and the methodology behind it.

The first datum used is that the first year pregnancy rate for using no method is 85 pregnancies per 100 women. (1) The second datum is expressed this way: "On average, if 100 women have unprotected intercourse once during the second or third week of their cycle, 8 will become pregnant." (2) I will call this the two-week fertility window.

Using this data, the following program approximately answers the question, "On average, how often do women have intercourse during the two-week fertility window?" The approximation is due to pregnancies occurring outside this window. The program is written in Microsoft Excel's Visual Basic programming language.

```
Sub CoitivityRate()
NonpregnantWomen = 100
SomeNumber = 23
For TimesHavingIntercourse = 1 To SomeNumber Step 1
   NewPregnancies = (8 / 100) * NonpregnantWomen
   NonpregnantWomen = NonpregnantWomen - NewPregnancies
   Next
Pregnancies = 100 - NonpregnantWomen
MsgBox Pregnancies
End Sub
```

The program says: We start with 100 non-pregnant women; each time they have intercourse in the two-week fertility window, the number of new pregnancies equals the number of non-pregnant women times 8/100, which reflects the likelihood of becoming pregnant using no method; each time they have intercourse, the number of non-pregnant women is reduced by the number of new pregnancies. The program leaves variable the number of times the women have intercourse, ranging from 1 to some number. The value for "SomeNumber" is varied manually until the data is matched, namely, that there have been 85 pregnancies. It turns out that SomeNumber = 23 provides the best match.

Since there are roughly 12 of these two-week fertility windows in a year, this means women are having intercourse on the order of about once a week during that window. In other words, given the odds of becoming pregnant, i.e., 8/100 per instance of intercourse in the two-week fertility window, women would have to be having intercourse about once a week during that window in order for 85 out of 100 women to become pregnant during the first year.

Although discussions of intercourse can be somewhat embarrassing, I call the average number of times women are having intercourse the coitivity (L. *coitus*) rate. Notably, regarding intercourse using no method of pregnancy reduction, changes in the coitivity (co-it-iv'it-e) rate relate directly to changes in the pregnancy rate.

Taking the odds of getting pregnant for granted, the above determination of the coitivity rate relies on a single datum for pregnancy expectation. The PRC is derived by expanding the program to accommodate more data. The additional data available happens to be the first year pregnancy rates and single use reduction rates for the combination (estrogen plus progestin) (Preven) and progestin-only (Plan B) morning-after pills.

The single use reduction rate for a given pregnancy reduction method answers the question: If women using no method can expect 8 pregnancies per 100 women for having intercourse once during the two-week fertility window, what percent of those 8 pregnancies will be reduced (prevented or terminated) by a single use of a given method?

The additional data is as follows: Assuming perfect use for every act of intercourse throughout the year, there will be 38 pregnancies per 100 women using Preven and 19 for Plan B. Preven's single use reduction rate is 75% (75% of the 8 pregnancies expected for using no method are reduced by making perfect use of Preven after a single act of intercourse); Plan B's single use reduction rate is 89%. (2)

The basic formula for new pregnancies per single act of sex during the two-week window is:

NewPregnancies = (8 / 100) * NonpregnantWomen

The factor (8/100) means 8 out of 100 women will get pregnant. So, given 100 non-pregnant women, this means 8 new pregnancies. But given a method that reduces pregnancy, we multiply by one minus the fraction given by the single use reduction rate (i.e., if 75% are eliminated, then 25% (fraction 0.25) are left):

NewPregnancies = (1 – SingleUseRateFraction) * (8 / 100) * NonpregnantWomen

For example, if the single use reduction rate equals 75% (i.e., for Preven) then the formula becomes:

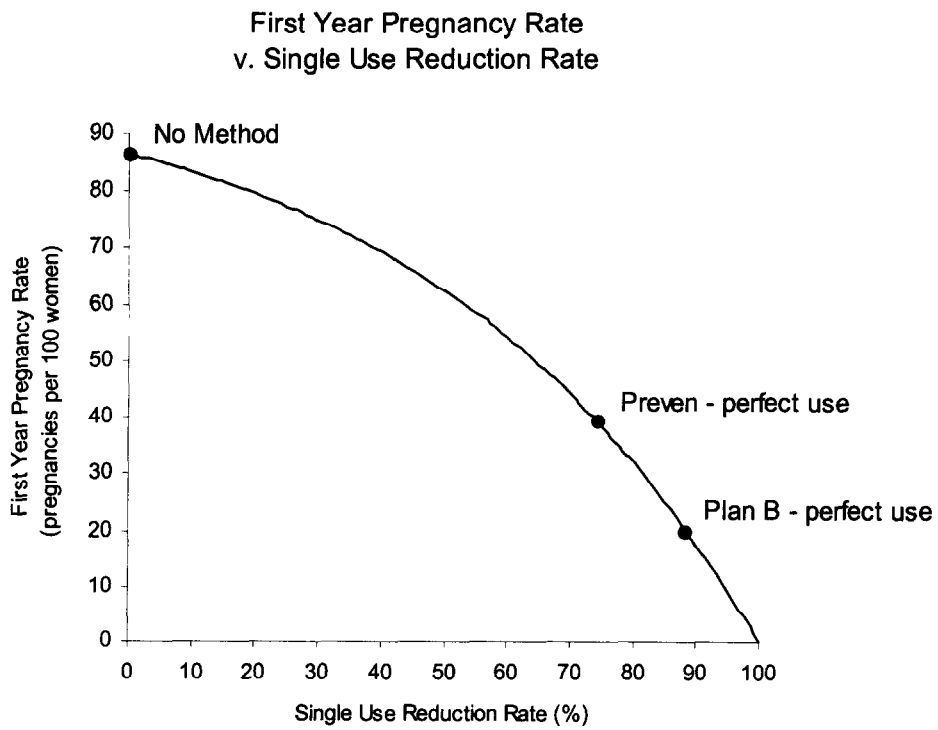
NewPregnancies = (1 - 0.75) * (8/100) * NonpregnantWomen

The PRC is obtained in two steps. First, a program is written to permute the new pregnancy formula for all percentages of the single use reduction rate, from 0% to 100% going by 1% steps. Second, different values for "SomeNumber" are tried manually to see which value best matches the data.

Here is what the program looks like:

```
Sub PregnancyReductionCurve()
For SingleUseRate = 0 To 100 Step 1
SingleUseRateFraction = SingleUseRate / 100
NonPregnantWomen = 100
SomeNumber = 24
For TimesHavingIntercourse = 1 To SomeNumber Step 1
  NewPregnancies = (1 - SingleUseRateFraction) * (8 / 100) * NonPregnantWomen
  NonPregnantWomen = NonPregnantWomen - NewPregnancies
  Next
Pregnancies = 100 - NonPregnantWomen
Cells(2 + SingleUseRate, 1) = SingleUseRate
Cells(2 + SingleUseRate, 2) = Pregnancies
  Next
End Sub
```

The graph of the output, with SomeNumber = 24, looks like this:



Our correlation, with SomeNumber = 24, looks like this:

	No Method	Preven	Plan B
First Year Pregnancy Rate (data)	85	38	19
First Year Pregnancy Rate (calc.)	86.48	38.42	19.11
Single Use Reduction Rate (data)	0%	75%	89%

SomeNumber = 24 fits the data the best. This implies a coitivity rate of about once a week during the two-week fertility window, neglecting fertility outside this window. Inclusion of fertility outside this window would reduce the figure for the coitivity rate. This simplistic methodology assumes all methods involve the same coitivity rate; however, individual coitivity rates can be calculated (e.g., to yield comparative measures of spontaneity based on differences in coitivity) if the first year pregnancy rate and single use reduction rate are known. We might have also considered that 8 pregnancies per 100 women per single act of intercourse during the two-week fertility window using no method is not exact. For example, it might be 7.9 or 8.1 pregnancies per 100 women. But the object here is simply to outline the methodology, not to criticize data. However, note that the data do appear to correlate fairly well.

Here is the (unrounded) output for the PRC program in Microsoft Excel:

Col. A: Single Use Reduction Rate (%)
Col. B: First Year Pregnancy Rate (pregnancies per 100 women)

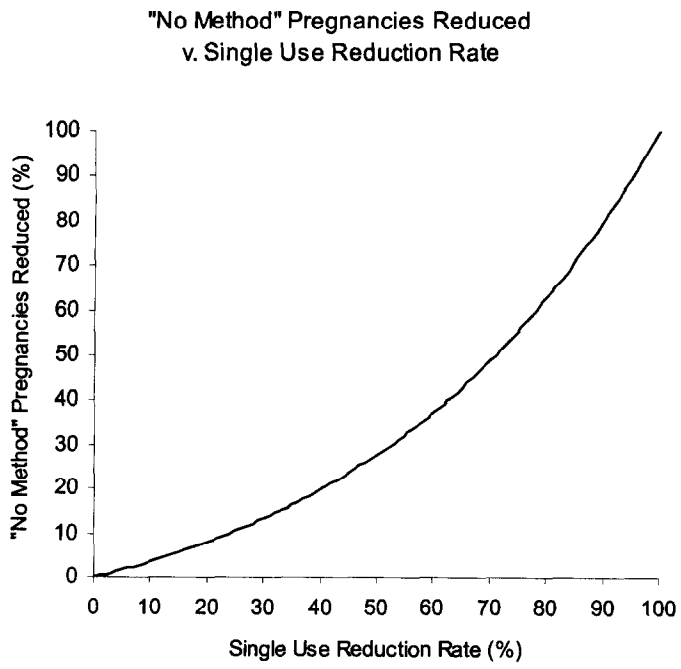
A	B	A	B	A	B	A	B
0	86.48214	26	76.88279	52	60.92789	78	34.6989
1	86.19719	27	76.40637	53	60.14023	79	33.41063
2	85.90649	28	75.92054	54	59.33738	80	32.09803
3	85.60992	29	75.42514	55	58.51904	81	30.76065
4	85.30738	30	74.91998	56	57.68493	82	29.39805
5	84.99875	31	74.40488	57	56.83476	83	28.00978
6	84.68392	32	73.87964	58	55.96823	84	26.59536
7	84.36275	33	73.34409	59	55.08505	85	25.15433
8	84.03514	34	72.79802	60	54.18491	86	23.68622
9	83.70096	35	72.24124	61	53.26749	87	22.19053
10	83.36007	36	71.67355	62	52.33248	88	20.66677
11	83.01236	37	71.09474	63	51.37956	89	19.11443
12	82.6577	38	70.5046	64	50.40839	90	17.53301
13	82.29594	39	69.90293	65	49.41866	91	15.92199
14	81.92696	40	69.28951	66	48.41	92	14.28082
15	81.55061	41	68.66412	67	47.38209	93	12.60899
16	81.16677	42	68.02653	68	46.33457	94	10.90593
17	80.77527	43	67.37652	69	45.26708	95	9.171086
18	80.37598	44	66.71385	70	44.17926	96	7.403898
19	79.96875	45	66.0383	71	43.07073	97	5.603787
20	79.55343	46	65.34962	72	41.94112	98	3.770166
21	79.12987	47	64.64757	73	40.79006	99	1.902439
22	78.6979	48	63.9319	74	39.61714	100	0
23	78.25737	49	63.20235	75	38.42197		
24	77.80812	50	62.45868	76	37.20415		
25	77.34999	51	61.70061	77	35.96326		

A great importance of the PRC is that it enables us to relate first year pregnancy rates to single use reduction rates. For example, with perfect use, the male condom has a first year pregnancy rate of 3 pregnancies per 100 women. (3) So, what is the single use reduction rate? Looking at the PRC, a first year pregnancy rate of 3 pregnancies per 100 women correlates with a single use reduction rate of over 98%.

Another great importance of the PRC is that it enables us to recognize that the relationship is not linear between first year pregnancy rates and single use reduction rates. This is true for both perfect use and typical use scenarios, since either way one will be treating single use reduction rates as average rates. To illustrate the importance, at first glance Preven's 75% single use reduction rate with perfect use may sound appealing. But how does that compare to, say, the withdrawal method with typical use? For typical use of the withdrawal method, the first year pregnancy rate is 27 pregnancies per 100 women. (3) Looking at the PRC, this correlates with an average single use reduction rate of greater than 83%. In other words, a 75% single use reduction rate, such as for perfect use of Preven, is even less than the single use reduction rate for something as dismal and unadvisable as the withdrawal method with typical use!

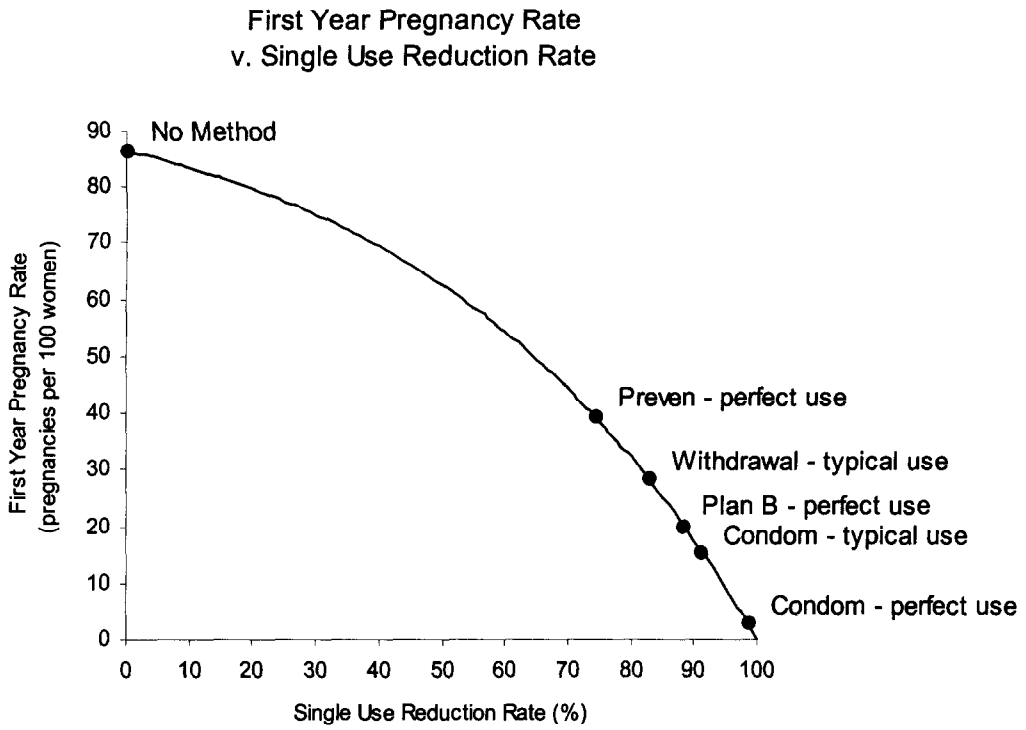
The PRC shows us that the relationship between first year pregnancy rates and single use reduction rates is non-linear. Note that as the single use reduction rate approaches 100% the slope of the curve gets steeper and steeper. This means that small changes in the single use reduction rate become more and more significant in reducing the first year pregnancy rate as we approach 100%.

We can arrange the data from the PRC curve in a slightly different way in order to clarify the exponential nature of the curve. Instead of graphing the PRC in terms of first year pregnancies, we can graph it in terms of the percentage of "no method" pregnancies reduced. The "no method" pregnancies are the number of pregnancies (i.e., 85-86) expected in the first year for using no method. Thus, the "no method" pregnancies reduced (%) tells us what percent of those pregnancies are reduced. This curve is graphed below.



Note how the curve shoots up as we approach 100%. The exponential nature of the curve means that small changes in the single use reduction rate become increasingly significant as we approach 100%. The reason is that intercourse is repeated and so the probability adds up, making it necessary to have a very high single use reduction rate, i.e., >90%, in order to reduce pregnancies by a reasonably reliable amount.

This situation can be understood graphically by examining the PRC in relationship to various known methods:



Note that even with perfect use, Plan B is less effective at reducing pregnancies than even typical use of the condom. However, the rates for Preven and Plan B will worsen substantially with typical use. This is because, unlike perfect use, typical use rates include non-use after planned use. Also, planned use of the morning-after pill will increase in the form of substituted reliance. Substituted reliance occurs, for example, when a woman lets her partner skip condom use (Plan A) because she plans to take the morning-after pill (Plan B) after intercourse. Since the rates for condom use are better than even perfect use rates for the morning-after pills, substituted reliance, even if only occasional, will mean more unplanned pregnancies. Not only that, but typical use means a woman may not even follow through with her plans to take Plan B after intercourse. Combined with substituted reliance, this makes a woman subject to the pregnancy rates for using no method, as well as the rates of sexually transmitted diseases for using no condom. On top of this, misunderstanding about the effectiveness of the morning-after pills will warp the expectations that men have for girls and women in view of the misguided prospect of relying on the pills as a "Plan B". Indeed, as a testament to shameful marketing, even the brand name "Plan B" anticipates a culture of substituted reliance, by suggesting itself as a replacement for "Plan A" methods such as the condom.

Thus, typical use scenarios for the morning-after pill, including non-use after substituted reliance, will make the rates for these methods fall way back on the pregnancy reduction curve compared to perfect use rates. And since the rates for these methods are already inferior even with perfect use, this will mean an epidemic of unplanned pregnancies. This epidemic will be fueled not only by the dismal rates themselves but also by popular illusions about the effectiveness of the morning-after pill. These illusions will in turn create pressure to rely on the morning-after pill as a substitute for traditional methods such as the condom, which are more effective. On top of this, in many instances women will not actually follow through and take the pills despite planned use (i.e., non-use after planned use will be a factor in typical use). Notably, the morning-after pills cater to the "play now, pay later" crowd, and this crowd can be expected not to show "perfect use" behaviors when it comes to following through and taking the pills.

Finally, it may be noted that unlike the condom for example, the morning-after pills have a concepticidal component. Concepticide (L. *conceptus* + *caedere*, to kill) means the taking of the life of a conceptus. As more and more women become aware that the pills can kill a conceptus at least up until implantation, they will be more and more averse to following through and taking the pills after intercourse, for reasons of conscience.

Notably, an inherent problem with any kind of morning-after pill has simply to do with its post-coital application. Since the probability of getting pregnant is 8% for having intercourse once in the two-week fertility window, this means no fewer than 92% of women will be making unsubstantiated use of the pills since they have no way of knowing what their pregnancy situation will be in advance. In contrast, abortion companies are required to perform a pregnancy test first, so as to avoid unsubstantiated use of the abortion procedures. Thus, the problem of unsubstantiated use of any drug should be taken seriously. This emphasizes why pre-coital discipline is needed for public health. In contrast, post-coital methods like the morning-after pill run added risks of concepticide, non-use after planned use, and unsubstantiated use; alarmingly, they also encourage a "play now, pay later" mentality that warps expectations, defeats discipline, and supports substituted reliance. Notably, even if the norm is occasional substituted reliance, the woman-years of use will add up statistically based on inferior rates, thus implying more unplanned pregnancies.

For reasons such as these, it is obvious that the morning-after pills are dangerous and ineffective for popular use. Instead, public health requires us to focus on competent means that are not harmful to the members of society. Although these means often require a fair amount of discipline, it is important not to wreck this discipline by introducing an illusory means such as the morning-after pill. This is not to condemn those who have their hopes set on effective methodologies. Instead, it is to emphasize that illusory methods are of no benefit, other than for those who profit from unplanned pregnancies. In this regard, it should not be surprising that abortion company Planned Parenthood pushed Preven over Plan B, even though Preven with perfect use has rates more dismal than even typical use of the withdrawal method, and even though Preven allows twice as many unplanned pregnancies as Plan B with perfect use. Notably, even Plan B with perfect use reduces fewer pregnancies than the condom with typical use!

It helps no one to be naïve about the motives behind efforts to popularize these pills. It helps no one to place faith in politically formed consensuses that fail to account for the facts. The morning-after pill is an illusion and the statistics clearly show why this is the case. It would seriously harm public health to allow this illusion to be popularized.

Serious considerations need to be raised based on the extent to which the morning-after pills have recently been promoted. These pills are nothing new. They are based on a doubling-down on birth control pills taken after intercourse with a suggested follow-up dose. Although the pills are now referred to by brand names, it does nothing to change the fact that the dangerous ineffectiveness of the morning-after pill has long been known. It is worrisome to observe that not only has support for the pills grown in recent times to contradict this knowledge, but furthermore that a large consensus has come out in support of them. For it is truly worrisome to note that so large a consensus could have been established in favor of something so harmful to the public health, especially since it has been known for decades that the morning-after pills are dangerously ineffective. Indeed, even with perfect use, doubling down on the combination pill is less effective than even typical use of the withdrawal method.

In addition to condemning popularization of the morning-after pills, I would ask you to investigate a conflict of interest associated with Planned Parenthood's support for the morning-after pill brand Preven. Notably, the makers of Preven have voluntarily withdrawn it from the U.S. market, presumably based on growing awareness of its ineffectiveness compared to Plan B. However, Plan B must also be withdrawn, because it, too, is dangerously ineffective compared to "Plan A" methods; moreover, the whole notion of a "Plan B" will warp popular expectations so as to combine with typical use and substituted reliance to spell complete disaster for public health.

Please do everything in your power to avert the epidemic of unplanned pregnancies that will result from popularizing the morning-after pill. Please confront the professional community for its faulty consensus of support for these dangerously ineffective pills. Please deny these illusory and outdated pills a place on the U.S. market. We must not be naïve about drugs. The idea of women making unsubstantiated use of a drug with illusory and dangerously ineffective benefits is totally shocking, especially since the morning-after pill is statistically doomed to have an overall opposite effect on unplanned pregnancies compared to the one users intend. We must not let greedy abortion companies derail our true progress in reproductive discipline with their political rants, especially since young people are finally beginning to show improvements in discipline. In this regard, I feel you must be commended for considering the impact of these pills on the lives of young teenagers, despite formidable opposition from a faulty consensus of experts who recommended the contrary. I also ask you to have the courage to identify and prevent the problem of concepticide wherever it may occur.

As a closing thought, imagine how absurd it would be if someone said, "I know how to reduce unplanned pregnancies. Let's popularize something that with perfect use is less effective than typical use of the withdrawal method." In effect, this is precisely what abortion company behemoth Planned Parenthood said by advocating Preven! Why should we be naïve about abortion company politics? As young people have begun taking more responsibility, abortion company profits have started feeling the pinch. Yet if the suggestion that the morning-after pill should be popularized is absurd even with perfect use rates, imagine what it would be like with typical use over-the-counter!

Notice that with perfect use, the rates for the condom and withdrawal method are similar. But with typical use, the withdrawal method is grossly inferior, due to the problem of non-use after planned use. The single use reduction rate for the withdrawal method falls from almost 98% with perfect use to 83-84% with typical use. Accepting the approximation that non-use after planned use accounts for this difference, this implies

that non-use after planned use is occurring roughly 15% of the time with typical use of the withdrawal method, i.e., the single use rate for typical use is 15% less than the rate for perfect use. In other words, the single use rate for typical use can be viewed as the average given by making perfect use 85% of the time and using no method 15% of the time due to non-use after planned use, i.e., non-withdrawal.

The withdrawal method is not a pre-coital method since the discipline of its practice must take place during intercourse. So it is not surprising that an inter-coital method such as this fares much worse with typical use than a pre-coital method such as the condom, despite similar perfect use rates. Predictably, we should expect the likelihood of non-use after planned use to worsen even much further with a post-coital method.

Thus, if popularized over-the-counter, I do not think it would be unreasonable to anticipate non-use after planned use to occur anywhere from 50-75% of the time or more with the morning-after pill in a typical use scenario. This would imply a single use reduction rate of 22-45% for Plan B with typical use; examining the pregnancy reduction curve, this would imply pregnancy rates in the close neighborhood of using no method! The reason why this dramatic upturn in non-use after planned use should be expected is because the morning-after pill is a post-coital method, and thus caters to people who do not exhibit discipline before or during intercourse. Procrastination, disputes over who should pay for the pills, and worries about the concepticidal potential of the pills will be heavy contributors. There will be creative contributions as well. For example, some couples will undoubtedly try to save money by having intercourse on successive days before taking the pills, given that the pills do not have to be taken immediately. This in turn will lead to a general loss of discipline, especially when compounded by forgetfulness. Also, the realization that pregnancy is limited in its likeliness on any single occasion will contribute to non-use after planned use. People will try saving money by gambling with not taking the pills, while at the same time losing the discipline of pre-coital methods. Another factor contributing to the willingness to gamble will be the idea that girls and women can simply fall back on an abortion. Yet even if they follow through with plans to take the pills, the rates will be inferior to traditional pre-coital methods like the condom. Thus, abortion companies stand to profit. Since the morning-after pill is a post-coital regimen, other problems can occur, especially with young girls. For example, a girl might get sick the next day and be afraid to ask her mother to go and purchase the pills for her.

Thus, to underscore the liabilities associated with post-coital methods, even if a morning-after pill offered a single use reduction rate of 100% with perfect use, the great problem of typical use would still make it contraindicated for popular use. Although this might seem implausible, it stands to reason. With perfect use, the male condom has a single use reduction rate of over 98%, but with typical use this rate drops to 91-92%. This is a pre-coital method, so in most cases, having intercourse will be contingent on use. But the morning-after pill is a post-coital method; thus, having intercourse is only contingent upon planned use, and therefore the problem of non-use after planned use can be expected to dramatically increase. There is a big difference between pre-coital and post-coital. Perceptions of responsibility often change after intercourse. The plans people make before intercourse can be much different than the ones they follow through with after. So even if a magical morning-after pill were 100% effective in reducing pregnancy based on single use in a perfect use scenario, a rate of non-use after planned use of even 10% would be enough to make the typical use rate inferior to the condom!

Yet regarding Plan B and Preven, this "magic pill" scenario is not even a question since even the perfect use rates for these drugs are inferior to typical use rates for traditional methods like the condom. This simply confirms what has already been known for decades, namely, that relying on a doubling-down on birth control pills after intercourse is an ineffective strategy for reducing pregnancy. Yet, in what has unfortunately become a culture of rationalization, the morning-after pill, i.e., doubling down on birth control pills after intercourse, now finds itself recommended by an astonishing consensus of experts!

Proponents of popularizing the morning-after pill argue that the pills can be used discerningly by some women, who therefore have a right to expand their reproductive choices. But public health dictates that we consider the total impact of these drugs on society. But proponents may argue that women who rely on the pills without the desired results nonetheless have the option of having an abortion. They may even introduce the argument that an abortion is safer for women than a full term pregnancy. But statistics show that abortion largely indicates a compounding risk factor rather than a mitigating one. This is evident because women generally have their abortions before completing the average number of births for women giving birth in their lifetimes. Thus, on average, having an abortion only temporarily forestalls the natural inclination to bearing children, for in the long run abortion (spontaneous or induced) tends to increase the pregnancy rate per woman as women have replacement pregnancies to achieve their lifetime number of births. For this reason, the risks of an abortion tend to add, not subtract, from the overall risks of bearing children that women face according to their pregnancies. In other words, abortion tends to be a compounding risk factor rather than a mitigating one.

Thus, to conclude this closing thought, we must reject the false claims of abortion industry leaders who are pushing for popular use of the morning-after pill. For simply put the morning-after pill is dangerously ineffective and grossly misleading.

For your convenience, I have attached a copy of my brief report entitled "Rates, human factors, and the morning-after pill: why a case of analytical malpractice points to an epidemic of unplanned pregnancies". The report comes with a helpful table comparing what was known and unknown about the various methods, though single use rates have now been estimated by the present report. I have also attached a copy of Dr. Alexander's letter confirming the absence of data on typical use rates for the morning-after pill.

Sincerely,

Mr. Eurica Californiaa, Amb.
Juridic Embassy, Micro ICU Project

Attachments: as stated.

References:

1. Hatcher RA et al., eds., Contraceptive Technology, 17th rev. ed., New York: Ardent Media, 1998, Table 9-2, p. 216.
2. Princeton University. Emergency Contraception. http://ec.princeton.edu/questions/eceffect.html.
3. Alan Guttmacher Institute. Contraceptive Use. http://www.agi-usa.org/pubs/fb_contr_use.html

Rates, Human Factors, and the Morning-After Pill: Why a Case of Analytical Malpractice Points to an Epidemic of Unplanned Pregnancies

Eurica Californiaa*

Analytical malpractice regards professional failure to make competent analysis. Although any malpractice may be hard to admit, this is especially true when faulty judgment is compounded by social pressure to accept the analysis. Consideration of unsubstantiated use, single use rates versus first year failure rates, substituted use, and typical use for the morning-after pill reveals a trend of analytical malpractice in this debate.

Princeton University's website for the morning-after pills describes fertile capacity this way: "On average, if 100 women have unprotected intercourse once during the second or third week of their cycle, 8 will become pregnant." (1) Because the pills are taken post-coitally and 92% will not get pregnant anyway, no fewer than 92% will be making unsubstantiated use. Thus, it suffices to say that pre-coital discipline is indicated because the problem of unsubstantiated use of any kind of drug is a serious one.

The morning-after pills tout their ability to reduce the aforementioned 8 pregnancies by 75% (Preven) and 89% (Plan B) based on single use. (1) Unfortunately, these dismal rates may seem deceivingly favorable apart from comparison to single use statistics for traditional methods, which are not available. However, by comparing statistics on failure rates for perfect use, it must be inferred that the single use rates for traditional methods (e.g., condom, diaphragm, and withdrawal) are far superior.

As the name "Plan B" cleverly implies, the morning-after pill suggests itself as an occasional substitute for traditional "Plan A" methods. Substituted use occurs when a couple decides to forego Plan A in favor of Plan B. Statistics based on woman-years do not necessarily imply continuous use. For example, 1000 women using X one-tenth of the year implies the same number of woman-years of use as 100 women using X all year round. Thus, even though the substitution is not continuous, the woman-years of use add up. Consequently, substituted use implies an <u>increase</u> in unplanned pregnancies because the failure rate for Plan B is greater than for Plan A!

Importantly, typical use includes non-use after planned use. If Jack tells Dianne not to worry that he forgot a condom because he will pay for Plan B tomorrow, but when he does not provide the money she gets upset and does not follow through and take the pills, then she exhibits a "typical use" scenario combining substituted use, and the rates of pregnancy and sexually transmitted diseases for using no condom apply. Statistics on typical use for the morning-after pill are unavailable. One should not assume typical use rates for the morning-after pill worsen any less compared to perfect use rates than for traditional methods. Notably, first year failure rates for perfect use of Plan B or Preven are greater than even the typical use rates for the condom or diaphragm. (1,2) Also, the incidence of substituted use and non-use after planned use will increase as pressure forms to make reliance on the morning-after pill seem "expected" based on popular myths about effectiveness, leading to an epidemic of unplanned pregnancies.

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Table

	I.[1,a]	II.[1,2]	III-A.	III-B.	IV.[2]
Preven[b]	75%	38	-	-	?
Plan B[b]	89%	19	-	-	?
Diaphragm	?	6	32	13	16
Withdrawal	?	4	34	15	27
Condom	?	3	35	16	15

Morning-After Pill Versus Traditional Methods. I. Reduction in fertile capacity per single use. II. First year contraceptive failure rates for perfect use, in pregnancies per 100 women. III. Increase in failure rate, i.e., added pregnancies, caused by substituting Preven (III-A) or Plan B (III-B) for the selected method, i.e., the respective differences between col. II rates. IV. First year contraceptive failure rates for typical use. Notes: a) Though data for col. I is absent, inferred is that the selected traditional methods reduce fertile capacity per single use by more than Plan B's 89% since in view of the failure rates for perfect use (col. II) there are fewer pregnancies, meaning, an 89% rate is strikingly dismal. As the single use rate tends to 100%, a unit increase in this rate implies increasingly larger decreases in the failure rate, e.g., Plan B's failure rate is half of Preven's (19 v. 38) even though its single use rate is less than 20% greater (89% v. 75%), meaning, even small increases in the single use rate become highly significant. b) Concepticide (L. *conceptus* + *caedere*, to kill) is the taking of the life of a conceptus. As an ethical remark, note that for a morning-after pill, unlike for a method such as the condom, the overall reduction in fertile capacity has a concepticidal component. In view of this, note that the pregnancies referred to here are those that have neither been averted nor ended by the given method.

References

1. Emergency Contraception. Princeton University. http://ec.princeton.edu/questions/eceffect.html (accessed 10/23/2004)
2. Contraceptive Use. The Alan Guttmacher Institute. http://www.agi-usa.org/pubs/fb_contr_use.html (accessed 10/23/2004)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
National Institutes of Health

National Institute of Child Health
and Human Development
Bethesda, Maryland 20892

November 8, 2004

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Dear Amb. Californiaa:

This letter is in response to your letter of October 20, 2004 to The Honorable Tommy G. Thompson, Secretary of Health and Human Services. Dr. James Trussell and colleagues at Princeton University produced the estimates of contraceptive effectiveness and the methodology used to derive these estimates. His address is:

Dr. James Trussell
Office of Population Research
Princeton University
Wallace Hall
Princeton, NJ 08544

We are unaware of any studies of typical use rates for the morning-after pill. Thank you for your letter.

Sincerely yours,

Duane Alexander, M.D.
Director