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path
Program for Appropriate Technology in Health

December 1, 2003

Dockets Management Branch
HFA-305
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

To Whom It May Concern:

Program for Appropriate Technology in Health (PATH) is a nonprofit, international health organization that works to to improve health, especially the health of women and children. PATH places an emphasis on improving the quality of reproductive health services and on preventing and reducing the impact of widespread communicable diseases. PATH identifies, develops, and applies appropriate and innovative solutions to public health problems. Unintended pregnancy is a critical health and social problem in the U.S. and throughout the world. Emergency contraceptive pills can play an important role in reducing unintended pregnancy by enabling women to prevent pregnancy after unprotected intercourse. Since 1996, PATH has collaborated with public health programs in the United States and in the developing world to reduce unintended pregnancy by increasing awareness of and access to emergency contraception, particularly emergency contraceptive pills (ECPs). We have had several successful collaborations with organizations and public health agencies in Washington State, with the result that emergency contraception is widely and easily available to women. Our experience, especially the results of a pilot project conducted in 1997-1999, has provided convincing evidence that making ECPs more easily and conveniently available to women through pharmacies is a safe and effective way of reducing unintended pregnancy.

From 1997 through July 1999, PATH collaborated with several partners in Washington State on a pilot project that enabled women to receive ECPs directly from pharmacists through the promotion and facilitation of agreements between pharmacists and other contraceptive care providers such as physicians. Because of the limited timeframe within which ECPs are effective (to maximize effectiveness, they should be taken as soon as possible after unprotected sex),

access becomes an especially critical issue. Data collected through surveys[1] during the pilot project, as well as a cost benefit analysis,[2] revealed that direct pharmacy access to ECPs was not only an effective and viable approach for meeting women's needs, but also a service that resulted in savings of health resources.

- Women went directly to the pharmacy for ECPs because of convenience (76%), because their regular doctor's office was closed (20%), because they had no regular doctor or clinic (15%), 13% because they did not want their regular doctor to know of their need for ECPs, and 7% because their regular doctor or clinic did not prescribe ECPs. Twenty-six percent of women surveyed indicated that they would wait to see whether or not they got pregnant had they been unable to get ECPs from their pharmacist.

- Many women (42%) received ECPs through participating pharmacies after regular business hours—in the evening, on a weekend or on a holiday, and 70% of women received ECP services within one day of unprotected intercourse.

- Although the service was available to women of all ages, an overwhelming majority—79%—were 18-35, the age group that experiences the greatest number of unintended pregnancies.

- The 11,969 ECP prescriptions provided during the 16 months of the pilot could have prevented 677 pregnancies. Assuming an unintended pregnancy resulted in one of four possible outcomes, this number of pharmacist ECP prescriptions prevented 315 induced abortions, 272 births, 83 miscarriages, and 7 ectopic pregnancies.

- Obtaining ECPs from pharmacies resulted in a $158 reduction in cost for private payers and a $48 reduction in cost for public payers. The basic cost of estimates for the payer models were derived from the literature and other sources, and were: $30 for pharmacy prescription and dispensing of ECPs, $558 (private)/$412 (public) for an induced abortion, $11,565 (private)/$4,323 (public) for a birth, $1,392 (private)/$496 (public) for a spontaneous abortion, and $6,696 (private)/$3,346 (public) for an ectopic pregnancy. One assumes that these cost savings would be more pronounced if the ECPs were available over the counter.

This approach of providing women with direct access to ECPs through pharmacies has now been institutionalized in Washington State, and it has had a resounding impact on other states and other countries. Based on our experience and the data above, we believe that the approach has

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[1] Including an anonymous mail-in survey of women receiving ECPs from a pharmacist and surveys of pharmacists and licensed prescribers, as well as a review of 3,775 pharmacy records. (Gardner J.S. et al. Increasing access to emergency contraception through community pharmacies : lessons from Washingon State. *Family Planning Perspectives* 33(4) 2001.

[2] Marciante, K.D., et al. Modeling the cost and outcomes of pharmacist-prescribed emergency contraception. *American Journal of Public Health* 91(9):1443-1445 (2001).

contributed to a reduction in unintended pregnancy and abortion in Washington State. Although ECPs retained prescription status under this collaborative agreement approach, the convenience of going directly to a pharmacy was appealing to many women and also appeared to have enabled them to initiate ECP therapy soon after unprotected intercourse, when the pills are most effective. OTC availability could even more greatly enhance the capacity of ECPs to reduce unintended pregnancy and prevent abortion in the United States.

If you have any questions, please contact me or Ms. Jane Hutchings, Associate Director of PATH's Reproductive Health Unit, at (206) 285-3500.

Best regards,

Christopher J. Elias, M.D., M.P.H.
President

cc: Jane Hutchings
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