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Reproductive
Health

November 2, 2005

Division of Dockets Management
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket Number 2005N-0345

Dear Acting Commissioner von Eschenbach,

We write in response to the Advance Notice for Proposed Rulemaking (ANPR) in docket number 2005N-0345. Ibis Reproductive Health is a non-governmental research organization that aims to improve women's reproductive health, choices, and autonomy in the U.S. and worldwide. Our work includes clinical and social science research, policy analysis, and informing public and regulatory debate.

We believe that the proposed rulemaking process is unnecessary and is being used as a politically-motivated tactic to forestall a final decision regarding the emergency contraceptive Plan B. The peer-reviewed literature clearly demonstrates that adolescents under the age of sixteen can safely use emergency contraception (EC), and increased access to EC in this age group does not lead to more risky sexual behavior.¹ Based on these and other scientific results, over seventy professional medical and public health associations support an over-the-counter (OTC) switch for Plan B. These groups include American Medical Association, the American College of Obstetricians and Gynecologists, and the Society for Adolescent Medicine, as well as the FDA's own advisory committees. Plan B should be immediately approved for OTC status with no age restriction.

Many of our colleagues have argued these points in their responses to the ANPR. We would like to add to the discussion by placing the FDA's decision on EC in the broader context of ensuring reproductive health for young women.

The FDA's Division of Urologic and Reproductive Health Products does not distinguish between post-pubescent adolescents and adult women with respect to contraceptive products. We argue further that post-pubertal age should never be a basis for determining the regulatory status of *any* reproductive health product. According to the most recent National Survey of Family Growth,

¹ Harper CC, Cheong M, Rocca CH, Darney PD, Raine TR. The effect of increased access to emergency contraception among young adolescents. *Obstetrics and Gynecology* 2005;106(3):483-91.

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49% of women have had vaginal intercourse by age seventeen, and 56% of sexually active women aged 15-19 did not use a condom at last intercourse.² Regardless of the ethical judgment some may place on these activities, young women, like women of all ages, are in need of full access to products that protect their reproductive health.

Adolescents' access to reproductive health products is already tightly constrained. Compared with older women, adolescents may have less control over their finances, schedules, and transportation options. As a result, current service delivery models often do not provide the confidentiality, office hours, payment plans, and other flexible options that can meet adolescents' special circumstances.³ Additionally, cultural and family norms frequently condemn adolescent sexual behavior in strict terms, which can result in covert sexual activity. One of the main reasons adolescents delay seeking contraceptive supplies is fear of discovery by a parent.⁴ Adolescents also report that they would stop using prescription contraceptives if their parents had to be notified, although they would not discontinue having intercourse.^{5,6} Women of all ages need medically accurate contraceptive information, but the current "abstinence-only" environment threatens basic contraceptive knowledge among adolescents in particular.⁷ These structural, social, and educational norms constrain adolescents' access to a range of reproductive health products.

This range includes long-term contraception, effective female-controlled HIV/STI prevention, HIV/STI screening, and so on. Restricting adolescents' access to EC would set a precedent with potentially dire consequences for other products. Many reproductive health products -- condoms, sponges, spermicides, pregnancy tests and vaginal antifungals, to name a few -- are currently sold OTC without an age restriction. If the sale of an OTC EC product is restricted based on age, such action would open the door to restricting other OTC products similarly. Further, contraceptive products such as diaphragms and oral contraceptive pills may be considered for OTC status in the future and microbicides may come to market in the near term. If a microbicide formulation is sold OTC, an age restriction would be unconscionable given the potential power of microbicides to prevent the transmission of HIV and other STIs. In short, a misguided age-based restriction on EC today may have sweeping repercussions for adolescent reproductive health in the future.

EC, which has been proven safe and effective among adolescents, is but one crucial reproductive health product that young people must be able to access without obstacle or impediment. Placing

² Mosher WD, Chandra A, Jones J. Sexual behavior and selected health measures: Men and women 15-44 years of age, United States, 2002. Advance data from vital and health statistics; no 362. Hyattsville, MD: National Center for Health Statistics. 2005.

³ Brindis C. Advancing the adolescent reproductive health policy agenda: Issues for the coming decade. *Journal of Adolescent Health* 2002;31:296-309.

⁴ Zabin LS, Clark SD. Why they delay: A study of teenage family planning clinic patients. *Family Planning Perspectives* 1981;13(5):205-7,211-17.

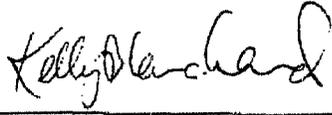
⁵ Jones RK, Boonstra H. Confidential reproductive health services for minors: The potential impact of mandated parental involvement for contraception. *Perspectives on Sexual and Reproductive Health* 2004;36(5):182-191.

⁶ Stevens-Simon C, Kelly L, Singer D, Cox A. Why pregnant adolescents say they did not use contraceptives prior to conception. *Journal of Adolescent Health* 1996;19:48-53.

⁷ Bennet SE, Assefi NP. School-based teenage pregnancy prevention programs: a systematic review of randomized controlled trials. *Journal of Adolescent Health* 2005;36:72-81.

unwarranted barriers to EC access for adolescents will only lead to deterioration in their reproductive health in the future.

Sincerely,



Kelly Blanchard, MSc
President