

NONPRESCRIPTION MEDICINES DIGEST



November 15, 2002

Welcome to the new edition of *Nonprescription Medicines Digest*. This month, a controversial perspective on over-the-counter emergency contraception and the dangers of frequent use of nonoxynol-9 are discussed. In addition, we also feature a report on the Consumer Healthcare Products Association's FDA free speech allegations.

NMA Faculty Resources

You probably already know that the mission of the NMA newsletter is to promote discussion of OTC products, but did you know that the NMA website also offers a faculty-only area of the website that is designed to facilitate the exchange of course materials such as syllabi, cases, and exam questions? Become part of the online academy and help foster the exchange of ideas when you [register](#) to join this free service.

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Over-the-Counter Emergency Contraception: A Newsmaker Interview with David A. Grimes, MD

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Editor's Note: *Dr. Grimes is vice president of biomedical affairs at the Family Health Institute of Family Health International in Research Triangle Park, North Carolina.*

In the September 12, 2002, issue of the *New England Journal of Medicine*, David A. Grimes, MD, argued in favor of immediate switch to over-the-counter (OTC) availability for emergency contraception (EC).

In February 2001, more than 70 organizations filed a Citizen's Petition with the FDA requesting that emergency contraception be made available without a prescription, as it is in other countries. Those who object claim that reliance on EC could have the unintended effect of increasing unwanted pregnancies, and many believe that is merely a euphemism for early abortion. EC is currently available nationwide by prescription and in Washington and California without a prescription under strict guidelines.

According to Grimes, almost all objections to OTC EC are social rather than medical. He doesn't know what exactly is delaying the FDA, but an editorial in a Florida newspaper suggests that abortion politics have stalled OTC status. Grimes has written the FDA several times inquiring about the reasons for the delay and received a generic letter saying that the subject raises "serious issues." Grimes is curious as to the "serious issues," as there have been no reported deaths or serious adverse events from EC.

Grimes claims that many are worried that if available OTC, EC would become a substitute for regular contraception and decrease condom use or abstinence, thereby increasing sexually transmitted diseases (STDs). Grimes cites four studies that suggest that advance access to EC does not prevent use of regular birth control. When discussing STDs, Grimes asserts that the sole purpose of contraception is to prevent pregnancy, and we should not expect it to prevent STDs. "Condoms should be used by those who are at risk of contracting STDs, but this doesn't mean they shouldn't have easy access to EC," he says.

Others suggest that socioeconomic factors might play a role in the ability to follow instructions correctly. Grimes states that questions such as these are demeaning and patronizing to women. "When people are scared, their behavior changes dramatically," he says. "A pregnancy scare could be enough for users to follow instructions to the letter."

According to Grimes, each day that goes by without OTC access to EC hurts women's health. There's no data on the efficacy of having EC available without a prescription. However, Grimes says that the projections of the number of women who would use it and the number of unwanted pregnancies suggest that it could decrease induced abortions by about 800,000 a year.

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Accessed: Medscape Medical News

Full text of article: <http://mp.medscape.com/cgi-bin1/flo?y=hYLq0EKC3h0D2d0FPCh0AA>

Frequent Use of Nonoxynol-9 Increases Risk of HIV Transmission

Van Damme L, et al.

According to the authors of a randomized trial reported in the September 28 issue of *The Lancet*, frequent use of the common spermicide gel nonoxynol-9 potentiates transmission of HIV-1 but not of gonorrhea or chlamydia.

This placebo-controlled, triple-blinded trial analyzed data from 765 female sex workers in South Africa, Côte d'Ivoire, Benin, and Thailand. Incidence of HIV-1 infection was 16 percent (59 of 376) in women who used nonoxynol-9 and 27 percent (104 of 389) in users of placebo gel (402.5 vs 435 woman-years; hazard ratio [HR] adjusted for center 1.5; 95% confidence interval [CI] 1-2.2; P=0.047).

In 239 women (32%) who used more than 3.5 applicators per working day, risk of HIV-1 infection in the nonoxynol-9 group was almost twice that in placebo users (HR 1.8; 95% CI 1-3.2). According to lead author Lut van Damme, low frequency use of nonoxynol-9 causes neither harm nor prevention of HIV-1, but frequent use increases a woman's risk of HIV-1 by causing lesions. According to the *Lancet* report, "At low frequency use, nonoxynol-9 had no effect, either positive or negative, on HIV-1 infection. This conclusion did not change after adjustment for sexual behaviour (frequency of vaginal sex not protected by condoms or unprotected anal sex)".

In accompanying commentary by David Wilkinson from Adelaide, Australia, the importance of a global effort to develop an effective vaginal microbicide that reduces the risk of HIV and other sexually transmitted diseases is stressed.

Article originally published: *Lancet* 2002;360:971-977.

Full text available through <http://www.thelancet.com/>.

Summary Accessed: Medscape Medical News

Full text of summary: <http://www.medscape.com/viewarticle/442147?mpid=4569>

CHPA Raises First Amendment Concerns to FDA

On September 13, the Consumer Healthcare Products Association (CHPA) filed comments with the FDA regarding how recent court rulings on commercial free speech rights impact its activity. CHPA's comments focused on the FDA's exclusivity policy for over-the-counter (OTC) labeling, the disparity between dietary supplement and conventional food labeling, and the FDA's lack of a substantial evidence policy for regulations that affect commercial speech.

The regulation affecting commercial speech explicitly requires the specific wording articulated in FDA's monographs in OTC labeling. However, a recent Supreme Court doctrine mandated that restrictions on commercial speech not be more extensive than necessary. The policy is unsupported by evidence that broader flexibility in labeling would fail to achieve the FDA's interests.

In addition, the CHPA objects to the restrictive ruling prohibiting dietary supplements having nutritive value from making structure/function claims on a parity base with conventional foods without a disclaimer. The CHPA urged the agency to adopt a policy that would require substantial evidence as to how restrictions directly advance the governmental interest asserted rather than its "arbitrary and capricious" standard.

CHPA Executive Newsletter Sept. 13, 2002;19-02.

Full text of article: http://www.chpa-info.org/newsletter/archived/2002/9_13_02_XNL.html