



Ibis  
Reproductive Health  
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15 April 2003

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

Re: Docket number 80N-0280 in the *Federal Register* 16 January 2003 (Volume 68, Number 11)

Dear Sir/Madam:

I am pleased to submit a comment about the proposed new labeling warning for over-the-counter vaginal contraceptives containing nonoxynol-9. I comment on behalf of Ibis Reproductive Health, a non-profit organization based in Cambridge, MA, that conducts clinical and social sciences research, analyzes policy, and advocates for medical reform – all as ways to better reproductive autonomy and health.

While we do not now take a position for or against the proposed warning *per se*, we call the FDA's attention to four points.

1. It is a reasonable hypothesis, but as yet only a hypothesis, that the irritation and epithelial disruption caused by frequent N-9 use actually increase the risk of HIV or other sexually transmitted infections (STIs). The FDA should not imply that there is firm evidence to support this hypothesis and should not imply that *all* STIs would necessarily be implicated.
2. The studies cited as supporting the proposed warning typically investigated the safety and effectiveness of N-9 used alone. In fact, most N-9 products are labeled for use with a diaphragm or other physical barrier of the cervix,<sup>1</sup> and at least in the United States, most spermicide use occurs together with such physical barriers.<sup>2</sup> It is quite possible that these devices themselves protect women against the cervical STIs, and perhaps against HIV and other STIs as well. At least three prospective, randomized, controlled trials are underway to investigate the role of diaphragms in STI prevention. Unfortunately, however, the results are still years away and cannot inform the present discussion.

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<sup>1</sup> See for instance the labels for Gynol II<sup>®</sup> Contraceptive Jelly, Delfen<sup>®</sup> II, and approximately twenty other N-9 spermicidal jellies and cremes.

<sup>2</sup> Piccinino LJ, Mosher WD. Trends in contraceptive use in the United States: 1982-1995. *Family Planning Perspectives* 1998; 30(1): 4-10, 46.

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3. The women who select N-9 as part of their fertility regulation strategy may face a different STI risk profile than the women studied in the trials of N-9's ability to prevent HIV and other STIs. Approximately one million American women,<sup>2</sup> perhaps 100,000 of them attending Title X clinics,<sup>3</sup> rely on N-9 as a primary component of their family planning strategy. A recent report from the Centers for Disease Control estimates that N-9 used together with diaphragms prevents approximately 460,000 pregnancies each year.<sup>3</sup> If the studies motivating the FDA to propose the warning, in fact, should not properly be extrapolated to the women who now use N-9 successfully to prevent pregnancy, the warning might exert a harmful net effect on women's health, even if the underlying causal hypothesis motivating the warning proves correct. For instance, the warning could have the unfortunate effect of increasing unintended pregnancy, and perhaps even STIs, among women who would otherwise use cervical barriers plus N-9 safely, but might switch because of the warning to a method that serves them less well, or to no method at all. It would be a particular shame if the warning drove N-9 from the market, depriving many women at low STI risk of an excellent contraceptive.

4. As a rule, Ibis Reproductive Health supports efforts to inform women of any safety and effectiveness information relevant to their decisions about preventing pregnancy and preventing STIs. But we also support limiting the role of physicians to areas in which it improves health outcomes enough to justify the costs. For this reason we support clear, informative labels, whether products are sold over-the-counter or by prescription. But in the case of N-9, we question the need for urging women to ask their doctors about the role for N-9 in their STI or pregnancy prevention strategies. (The proposed warning states in part "Ask a doctor before use if you have a new sex partner, multiple sex partners, or unprotected sex.") We doubt that the average physician can deliver enough special expertise or insight about the role for N-9 in a planned sexual encounter with a new partner to offset the inconvenience, discomfort, or cost to women of involving a health professional in this arena in the timeframe generally applicable in such situations. We are also concerned about the implied message that N-9 must be quite dangerous to merit such an exhortation. We believe that women can appropriately comprehend and put into context the needed information without physician assistance. We consider it particularly illogical, moreover, to urge women to "Ask a doctor before use if you have ... unprotected sex." Sex with N-9 is not unprotected sex.

Thank you for the opportunity to comment.

Sincerely,



Charlotte Ellertson, MPA, PhD  
President

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<sup>3</sup> Nonxynol-9 spermicide contraception use – United States, 1999. *Morbidity and Mortality Weekly Review* May 10, 2002; 51(18): 389-392.