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January 30, 2005

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

Re: Docket No. 2004D-0555

To Whom It May Concern:

Catholics for a Free Choice (CFFC) is an independent and non-partisan international organization which shapes and advances sexual and reproductive ethics that are based on justice, reflect a commitment to women's well being and respect and affirm the moral capacity of women and men to make sound decisions about their lives. Through discourse, education and advocacy, CFFC works in the US and internationally to infuse these values into public policy, community life and Catholic social thinking and teaching.

Thank you for the opportunity to comment on the Food and Drug Administration's draft guidance on latex condoms, both with and without nonoxynol-9 (N-9), entitled "Class II Special Controls Guidance Document: Labeling for Male Condoms Made of Natural Rubber Latex."

A major programmatic initiative of CFFC is its international and domestic campaign entitled, Condoms4Life which encourages Catholics and all people of faith to use condoms as a method of both preventing the spread of sexually transmitted diseases and unintended pregnancies. While some of the hierarchy of the Catholic church has discouraged the use of condoms, CFFC is working across around the country and across the globe through media campaigns and the distribution of public education materials to disseminate accurate and thorough information about the use of condoms to prevent HIV transmission. In the United States alone, 38% of Catholic women report using condoms for family planning and the prevention of sexually transmitted diseases— a significant percentage given the false and misleading campaign against condoms waged by some within the church hierarchy.

In light of our "Condoms4Life" campaign, our comments on the proposed guidelines regarding N-9 are below.

- Since the FDA has decided to proceed with the labeling of condoms with N-9, we believe that a warning statement addressing vaginal irritation, damage to the rectal epithelium and HIV/AIDS transmission must appear on the retail package. The warning on vaginal irritation, however, should clarify that *frequent use* can increase vaginal irritation, and it should quantify what "frequent use" is as defined by the FDA.

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- Additionally, all information on the retail package about N-9 should be concisely grouped together. It is vitally important that all critical information about N-9 be readily accessible and focused.
- The warnings for N-9 are sufficiently important to be included, by themselves, on the individual condom packages. Many condoms are distributed both domestically and internationally without the retail package, thus, entire populations would be at risk and not aware of the potential problems with N-9.

Our comments regarding the labeling of latex condoms regarding their effectiveness in reducing the spread of sexually transmitted diseases and decreasing the risk of pregnancy are below.

- The draft package insert appropriately states that male latex condoms used consistently and correctly can greatly reduce, but do not eliminate, the risk of pregnancy and the risk of contracting or spreading HIV, and that condoms can also reduce the risk of other STIs, such as chlamydia and gonorrhea, that are spread to or from the penis by direct contact with the vagina and genital fluids.
- However, the suggested statement on condom effectiveness against those STIs that also can be spread through skin-to-skin contact, as written, is not clear. It is true that these STIs cannot be entirely prevented by condom use. However, they do afford some protection and the language should reflect that reality.

Our comments regarding the effectiveness rates for condoms regarding preventing pregnancy are below.

The table of method effectiveness rates is an important tool for couples, and no doubt many health professionals as well, in evaluating which contraceptive method will best meet the their needs and the needs of their families. Because of the importance of this tool, it is disappointing that the draft guidance includes a table that is out-of-date and significantly reduced from that which appears in the current labeling for combined oral contraceptives. This should be remedied with the full scope of scientific information on contraceptive services and their efficacy.

Moreover, we believe that both the perfect-use and typical-use effectiveness rates should be presented for every method. Couples need to be informed about what can be achieved with perfect use so that they can determine for themselves how “typical” or “atypical” they may be in terms of their ability to comply with a particular contraceptive regimen.

We thank the FDA for the opportunity to provide these comments and would be happy to respond to any questions it may have.

Sincerely,

A handwritten signature in black ink, appearing to read 'Jon O'Brien', with a long horizontal line extending to the right.

Jon O'Brien
Executive Vice President