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Proposed Condom Label Changes Raise More Controversy than They Settle

In its first public response to a 2000 law, the FDA is proposing a revised set of condom labeling requirements. The law mandates that the Secretary of Health and Human Services “determine whether the labels are medically accurate regarding the overall effectiveness or lack of effectiveness of condoms in preventing sexually transmitted diseases, including HPV [human papillomavirus].”

After five years of review, the agency is proposing adding the following messages on condom packages:

- When used correctly, condoms “greatly reduce but do not eliminate” the risk of pregnancy and of transmitting HIV.
- Condoms also “reduce the risk” of spreading STDs transmitted through genital fluid (chlamydia and gonorrhea).
- Condoms “cannot protect” against herpes and HPV, which can be transmitted by skin-to-skin contact outside covered areas. Still, “using condoms every time” will provide “some benefit.” They may reduce the risk of herpes as well as the appearance of HPV-related genital warts and cervical cancer.
- Use of condoms lubricated with nonoxynol-9 may help to kill sperm but the added protection against pregnancy is unknown. Nonoxynol-9 does not provide extra protection against HIV or other STDs. Rather, nonoxynol-9 causes vaginal and rectal irritation that increases the risk of contracting HIV. Condoms with nonoxynol-9 should not be used with sex partners who have HIV or are of undetermined HIV status.

- The requirements also include a chart comparing the effectiveness of condoms and other barrier methods in preventing pregnancy.

The dangers of nonoxynol-9 have been under discussion for many years. Problems with this agent were reported in 2000, when the results of a trial of this agent as a microbicide found that women had a higher rate of acquiring HIV when they used it. The other label requirements are more controversial. It is notoriously difficult to design studies that accurately measure condom effectiveness (see HHSWatch, July 2005). An adequate trial would compare high-risk populations that do or do not use condoms consistently. Carefully structured studies have recently reported a substantial protection against a variety of STDs, including herpes and HPV (again, see the July 2005 HHSWatch).

The FDA further is proposing that condom packages report that the condom failure rate in preventing pregnancy is 12% per year. This assumes typical use, which ordinarily would be the best way to evaluate performance. “Correct and consistent” condom use has much higher efficacy, though. An 800-couple study published a year ago in the journal *Contraception* found a 1% pregnancy rate over six menstrual cycles for consistent condom use compared with a 7% rate for typical use. Stating only the higher number obscures the fact that better trained, more adept condom users will be much more successful. Overall, excessively cautious messages can discourage condom use at a time when abstinence promoters are vigorously attacking condom use (see the rest of this issue). They enhance the public’s widespread misperceptions about the role condoms can play in limiting STDs and pregnancy.

To be fair, the FDA's has resisted heavy pressure from religious conservatives to go much further. On November 10, the day the FDA's proposal first became public, Sen. Tom Coburn (R-OK) responded with a highly critical statement. Coburn said, "Today's misleading recommendations by the FDA are the latest example where the agency has put the public at risk by providing inaccurate information about condoms... The FDA should stop playing political games with the health and lives of Americans and immediately comply with the law by ensuring only medically accurate information that is irrefutable on condom labels."

The public has 90 days to comment on the FDA proposal. Its full text and instructions on how to comment may be found on the Internet at <http://www.fda.gov/cdrh/comp/guidance/1548.pdf>.

Maine Rejects Abstinence Funding

In September, the state of Maine notified the federal government that it was refusing education grants for abstinence only education. Maine joins California and Pennsylvania in turning down abstinence funding. Together the three states represent 20% of all US public school students.

Maine would have received \$161,000 in the current fiscal year. It previously used the money for television spots aimed at avoiding pregnancy, STDs and "premature" sexual activity. The state department of education was already embroiled in controversy stemming from its refusal to fund school programs run by Heritage of Maine, a Christian-based group that receives \$500,000 a year from the federal government for its workshops. The workshops take the position that sex outside of marriage is unsatisfying and dangerous physically and emotionally. In August, state education commissioner Susan Gendron refused to work with the Heritage of Maine curriculum because its programs are inconsistent with Maine's Comprehensive Family Life legislation. State law mandates that public school sex education programs

include instruction in contraceptive use as well as "an emphasis on abstinence. "

Maine's acceptance of the federal abstinence monies put it in an increasingly difficult position as the Bush administration has tightened the rules under which those funds are administered. The 1996 law establishing the abstinence education grants named eight principles that funded programs had to follow. These principals stress the "harmful" effects of extramarital sex and that abstinence is the only sure way to avoid disease and pregnancy.

Previously, states had gotten away with picking and choosing among the principles, hence Maine's television ads. This is no longer true – the abstinence programs cannot exist within a broader sex ed framework that also supports unmarried sexually active young people, homosexual as well as heterosexual. Oversight of the abstinence grants was shifted last year to HHS's Administration for Children and Families under Assistant Secretary Wade Horn. This year's state grant application stresses, "A project may not be inconsistent with any aspect of the abstinence education definition. " It specifically forbids the use of these funds or matching funds to promote contraception.

Quality of Abstinence Programs Challenged

While Maine was turning down the funds on a state level, others were challenging the quality of abstinence education programs nationwide. Rep. Henry Waxman (D-CA) sent a letter to the Government Accountability Office (GAO) requesting an investigation of the National Abstinence Clearinghouse. The Clearinghouse is winding up a \$2.7 million, three-year contract with HHS to evaluate abstinence education programs – including their compliance with the definition of abstinence only education – and support grant recipients' understanding of accurate medical information. Waxman cited instances of false information in the Clearinghouse's own literature as well as the conflict of interest arising from the

sponsorships that the organization solicits from abstinence education providers. He asked for the GAO to look at how the HHS awarded the contract in the first place and the quality of the information training provided under the contract.

Waxman last December, issued a report challenging the accuracy of popular abstinence curricula. With students coming back to school this September, the Sexuality Information and Education Council of the United States (SIECUS) made its own review of several of the programs. After noting such egregious statements as, "Condoms can never protect someone from the emotional problems that can result from multiple sexual partners and premature sexual activity," Will Smith, SEICUS Vice-president for public policy, stated, "Programs that disparage condom use, instill fear and shame in young people, perpetuate gender stereotypes, and contain anti-abortion messages, among other deplorable statements, have no place in any program for school-aged young people, let alone programs sanctioned by the federal government, and paid for with hard-earned tax dollars."

SIECUS and Advocates for Youth recently filed a challenge to the direct federal grants to such programs under the Data Quality Act of 2000. The Act requires the government to create guidelines ensuring the quality and objectivity of information issued by federal agencies. It previously has served mainly as a vehicle for corporations who want to block bad news. The HHS is required to respond by mid-November. It is not at all clear what the outcome of this action will be, but it does continue the public discussion about the effects of current abstinence-only education.

That heightened awareness was immediately apparent during the October 27 Senate debate over this year's HHS budget. The body, by a voice vote, accepted an amendment from Frank Lautenberg (D-NJ) stipulating that no funds could go "to provide abstinence education that includes information that ... is unsupported or contradicted by peer-reviewed research..."

The Incredible Shrinking C

By the summer of 2004, President Yoweri Museveni of Uganda was making a series of comments attacking the utility of condom promotion as part of AIDS prevention. For example, in June of that year he told the kaisernetwork.org, "...if you are young and you are not married; what sex are you talking about? That's [why] I couldn't accept so I cannot recommend condoms for the young people; that's why we said abstinence until you get married." Condoms, Museveni said, are a measure of last resort use them if you cannot "manage" abstinence or monogamy.

By last fall, Ugandans found condoms were in increasingly short supply. First, the government withdrew its own free brand, citing quality control problems (which were denied by the German and Chinese manufacturers). The government then insisted that samples of all condom shipments, including those from private agencies, be sent to Sweden for "post-import" testing. It increased taxes on condom sales, too. As condom supplies collapsed, retail prices tripled. Distribution sank from 90 million condoms in fiscal year 2004 to 30 million this year.

A major factor accompanying this sudden shortage was the growing assistance from the US administration's Presidential Emergency Plan for AIDS Relief (PEPFAR). PEPFAR, in accordance with its Congressional mandate, has relegated condom promotion to a secondary role focusing on "high-risk" groups such as commercial sex workers and couples in which only one partner in HIV-positive. PEPFAR's version of ABC contains a special caveat about condoms:

"Abstinence, Be faithful, and as appropriate, correct and consistent use of Condoms."

According to PEPFAR's 2005 country report, PEPFAR is helping Uganda make condoms an afterthought: "US programming is increasingly emphasizing both A and B. Adolescents are targeted as a key group for abstinence messages... Uganda's First Lady

[Janet Museveni] is a charismatic champion of AB programming and a strong supporter of risk avoidance. Her office is collaborating to articulate a national AB strategy, which is expected to enhance effective planning and coordination of A and B programs. The USG [United States government] is the only donor of the national school-based abstinence program, and this support will continue in FY 2005. "

This year, PEPFAR canceled its grant to one of the two private agencies supplying condoms. At the same time, pro-abstinence billboards belittling condom use have appeared around the country. These replace the former exhortations to delay sexual initiation, have fewer sex partners, and use condoms.

Stephen Lewis, the UN special envoy for HIV/AIDS in Africa, told a recent press conference held by the Washington-based Center for Health and Gender Equality (CHANGE), "There is no question in my mind that the condom crisis in Uganda is being driven and exacerbated by PEPFAR and by the extreme policies that the administration in the United States is now pursuing in the emphasis on abstinence, far and away beyond that of condoms. And that distortion of the preventive apparatus of ABC, with which we're all familiar, is resulting in great damage and undoubtedly will cause significant numbers of infections, which should never have occurred.

Uganda has gained international acclaim for greatly reducing HIV rates, but HIV prevalence has stubbornly plateaued in recent years at the 6%-7% range. The reasons for the original decline and current persistence are controversial. A report at the Conference on Retroviruses and Opportunistic Infections last February found that in the Rakai district of southern Uganda, age of sexual initiation was decreasing and nonmarital relations increasing. Condom use increased, too, and the rate of new infections held steady since 1994. Overall HIV levels decreased only because the extraordinary mortality outbalanced new infections. In this study's view, the HIV epidemic in Uganda is in a state of precarious equilibrium. Small increases in risk could hoist HIV levels considerably.

The Uganda Ministry of Health's "HIV/AIDS Sero-Behavioural Survey 2004-2005" found that both nonmarital sex and use of condoms increase with educational level. To the extent that they are able, Ugandans have improvised their way through the HIV epidemic. The shortage and criticism of condoms threatens to undermine the delicate balance that now exists, replacing an eclectic mix of prevention resources with morals-based programming.

This issue of HHS Watch was written by David Gilden

HHSWatch, a watchdog newsletter from CHAMP, monitors and reports on activities related to HIV prevention at Health and Human Services agencies, including CDC, NIH, HRSA and SAMHSA. HHSWatch is a resource for community members, policy advocates, researchers and anyone interested in more fully understanding and tracking the committees, panels and administrators whose recommendations and decisions affect our work. HHSWatch is committed to providing an outlet for those concerned about infringements upon science-based HIV prevention and treatment, and will respect your wishes for confidentiality. If you are interested in contributing information or suggesting a story, please contact champ@champnetwork.org.



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