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FDA Regulation of Condoms:

Minimal Scientific Uncertainty Fuels the Moral Conservative Plea to Rip a Large Hole in the Public's Perception of Contraception

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I. Introduction

Condoms have long been used to prevent disease and pregnancy. Many people, but not all, support ending the spread of sexually transmitted diseases (“STDs”) and a significant reduction in unwanted pregnancy rates. Condom opponents dispute the extent to which condoms are the solution to these two problems. While some condom opponents argue that abstinence is the only viable method to prevent disease and pregnancy, other opponents at least question the extent to which sexually active teenagers and adults should rely on condoms’ effectiveness and whether the Food and Drug Administration has the obligation to label condoms in a more conservatively to better disclose risks inherent in condom use.

The public use of condoms to prevent disease and pregnancy can have two possible opposing effects. On one hand, condoms can prevent bad outcomes associated with each act of risky sex, and on the other, condom use can promote more acts of risky sex (by making people less fearful about bad consequences). One question is how to weigh the two factors together. For instance, if condoms are 1% effective, but lead to a 300% increase in risky conduct, then the net increase in overall risk is $(.99)(3.0) = 2.97$, or a 197% increase. In that case, encouraging condoms as a preventive might increase STD transmission rates, in addition to any “moral harm” caused increased promiscuity. Now, say condoms are 90% effective, and lead only to a 10% increase in risky sex. Then, the net change in risk is $(.1)(1.1) = .11$, which is a 89% decrease. Even considering the second scenario, a society may not approve of condoms if it feels that the increase in risky sex is moral unacceptable, or if it feels that bad outcomes are the right price to pay for immorality.

Thus, debates over promoting or allowing condom use raise questions of whether bad outcomes (unwanted pregnancy, disease) are increased or decreased, apart from the inherent morality of non-marital sex. Over the

last two decades, the FDA position on condoms has traditionally assumed the first scenario, that condom use on the whole reduces the STD rates. The FDA's position has been in accord with the widespread scientific consensus. However, under increasing political pressure from pro-abstinence conservatives over the last five year, the FDA may be shifting its view closer towards the second scenario and adopting a more caution approach in regulating condoms. Such pressure is exemplified by the recent movement toward including warning labels on condoms packaging.

Given the lack of certainty whether condoms are an effective public health solution, the political debate becomes focused upon values and morality. As Linda Gordon, Professor of History at New York University who specializes in examining the historical roots of contemporary social policy debates, argues,¹ even today, debates over reproductive rights are political, rather than scientific conflicts. Thus, Gordon claims that even technological developments and facially neutral scientific discoveries must be understood in political context. The key political question is: Should two consenting adults have the freedom to choose traditionally "immoral" sexual behaviors such as non-marital and non-procreative sex. Historically, such immorality carried risks of suffering that served as disincentives. The conservative fear is that once the disincentive is removed, society will drown in an ocean of licentiousness and vice.

As other more effective forms of birth control are widely used, the debate over condoms has shifted to their effectiveness in preventing disease. Condoms are the only method, apart from abstinence, that may prevent transmission of certain STDs.

This paper surveys the history of condom use, the underlying science, the FDA regulation of condoms and the recent debate on condoms and their effectiveness in preventing disease. In articulating the debate, perspectives of the Catholic Church are propounded as examples of arguments hinging exclusively on religious

¹LINDA GORDON, *MORAL PROPERTY OF WOMEN*, at vii (Univ. of Ill. Press 2002).

moral premises. The Church's perspectives are revealing in the way that they shape so called "medical" or "scientific" recommendations against condom use. Accordingly, this paper explores the conclusions of social conservatives that, assuming condoms should be prohibited; the key alternative is abstinence and chastity.

II. Historical Perspectives and Scientific Underpinnings: The Early Years

Egyptian art dating back to 1350 B.C. depicts males who have barriers covering the tip of the penis.² In actuality, however, such barriers were used, not as contraceptives, but as protection against tropical diseases or insect bites, as insignia of rank or status, as decorations or for clothing.³ It was a small step from these penis-specific coverings to modifying them for use to prevent pregnancy or STDs.⁴

As early as the 16th century, condoms were used for the prevention of infection,⁵ providing evidence non-marital promiscuous sexual activities were key facilitators of this innovation. The first written description of the condom and its utility is found in *De morbo gallico*, written by the great Italian anatomist and syphilis expert Fallopius.⁶ Fallopius described the condom as a linen sheath that is cut to cover the head of the penis and worn to prevent against "French Caries" or syphilis infection.⁷ Fallopius explained that he had "tried the experiment on eleven hundred men, and . . . call[ed] immortal God to witness that not one of them was infected."⁸ While Fallopius noted its convenience (men could carry sheaths in their pocket), an early

²NORMAN E. HIMES, MEDICAL HISTORY OF CONTRACEPTION 186 (Williams & Wilkins 1936).

³*Id.* Today, by way of comparison, the highland inhabitants of West Papua, Indonesia, wear elaborate penis gourds. One can see pictures of these penis gourds, similar to those used in Egypt, at <http://www.rhymer.net/New%20Folder/penisgourdgallery/gallery.htm>.<http://www.rhymer.net/New%20Folder/penisgourdgallery/gallery.htm>

⁴HIMES, *supra* note 3, at 186.

⁵*Id.* at 187.

⁶*Id.* at 188.

⁷*Id.* at 188-190.

⁸*Id.* at 190.

18th century physician noted its disadvantages:

...the *Condom* being the best, if not the only Preservative our Libertines have found out at present; and yet by reason of its blunting the Sensation, I have heard some of them acknowledge, that they had often chose to risk a *Clap*, rather than engage *cum Hastis sic clypeatis*. [With spears thus sheathed.]”⁹

Condoms were not used for contraception until as late as the 18th century.¹⁰ Condom merchants in 18th century England printed bill board advertising condoms as “implements of safety.”¹¹ The bills used the following blurb – “To guard yourself from shame or fear, Votaries to Venus, hasten here, None in our ware e’er found a flaw, Self-preservation’s nature’s law.”¹² Casanova, writing extensively about condoms,¹³ called the devices “The English Riding Coat,” “preservative sheaths” and “assurance caps.”¹⁴ He used condoms not only to prevent pregnancy, but also to avoid STDs.¹⁵ For instance, before having sex with a “public woman” with whom he was concerned with the risk of acquiring a STD, he would insist that she offer him a condom.¹⁶ Similar to modern testing techniques, Casanova would inflate his condoms with air to check whether it had any holes or weaknesses.¹⁷

The key innovation in condom technology occurred when the Vulcanization of rubber was discovered by Goodyear and Hancock in 1843.¹⁸ The use of vulcanized rubber, as opposed to animal tissue, lowered costs and increased condom quality. Literally hundreds of publications, treatises and handbills attested to the utility of this new invention.¹⁹ Today’s latex condom is a direct descendant of the vulcanized rubber condom

¹⁰HIMES, *supra* note 3, at 187.

¹¹*Id.*

¹²*Id.* at 200, *citing* F. GROSE, GUIDE 12 (1796).

¹³HIMES, *supra* note 3, at 195.

¹⁴*Id.*

¹⁵*Id.*

¹⁶*Id.*

¹⁷*Id.*

¹⁸*Id.* at 201.

¹⁹*Id.*

that took the world by storm in the 19th century.

A condom is the only reversible male contraceptive method. It is a thin sheath of latex, plastic or lambskin²⁰ that covers the penis during intercourse.²¹ ²² Condoms work as contraceptives by collecting semen and other male secretions that may contain sperm and thus preventing the insemination of the woman.²³ For the condom to achieve its beneficial purpose it must not break, slip or otherwise allow sperm to pass the latex barrier. In order to achieve its maximum preventive capacity, the condom must also be used correctly and consistently.²⁴ Condoms, including the material they are made from, are engineered so as to be easily placed on the penis, to contain the collected fluid and to minimize breakage and slippage.²⁵

Rubber condoms have been mass-produced since the 19th century²⁶ and are widely used today both in the United States and internationally. In 1995, approximately 13% of women of reproductive age reported using condoms for contraception.²⁷ Young men aged fifteen through nineteen showed that only 9.5% had never used condoms.²⁸ However, despite being widely used, few people prefer using condoms as contraception.²⁹

²⁰A small proportion (about 5% in the US) are made of the intestinal caecum of the lamb. MURPHY JS: THE CONDOM INDUSTRY IN THE US (McFarland and Company, Inc. 1990). These natural membrane or “lambskin” condoms are not as effective as contraceptives or as disease prevention devices. *See id.*

²¹PLANNED PARENTHOOD, FEDERATION OF AMERICA, INC., *The Condom*, at <http://www.plannedparenthood.org/pp2/portal/files/portal/medicalcondom.xml> (last visited May 23, 2005).

²²21 C.F.R. § 884.5300 (2004) (“A condom is a sheath which completely covers the penis with a closely fitting membrane. The condom is used for contraceptive and for prophylactic purposes (preventing transmission of venereal disease). The device may also be used to collect semen to aid in the diagnosis of infertility.”)

²³PLANNED PARENTHOOD, *supra* note 22, at <http://www.plannedparenthood.org/pp2/portal/files/portal/medicalinfo/birthcontrol/pubcondom.xml>.

²⁴NAT’L INST. OF ALLERGY AND INFECTIOUS DISEASES, NAT’L INST. OF HEALTH, US DEPT. OF HEALTH AND HUMAN SVCS., Workshop Summary, *Scientific Evidence on Condom Effectiveness for Sexually Transmitted Disease Prevention*, at 6, available at <http://www.niaid.nih.gov/dmid/stds/condomreport.pdf> (last visited May 23, 2005) [hereinafter *Scientific Evidence on Condom Effectiveness*].

²⁵<http://www.niaid.nih.gov/dmid/stds/condomreport.pdf>Id. at 26.

²⁶Jefferson, Id. [HBS article, Gallo paper]

²⁷Abma JC, Chandra A, Mosher WD, Peterson LS, Piccinino LJ. Fertility, family planning, and women’s health: new data from the 1995 National Survey of Family Growth. *Vital Health Stat* 1997;23:1-114. (Cited in MF Gallo et al, *Contraception* 68 (2003) 319-326.

²⁸Sonenstein FI et al., *Changes in Sexual Behavior and Condom Use Among Teenaged Males: 1988 to 1995*, 88 AM. J. PUBLIC HEALTH 956, 956-959 (1998).

²⁹ERIN T MCNEIL ET AL., FAMILY HEALTH INTERNATIONAL, MONOGRAPH, THE LATEX CONDOM: RECENT ADVANCES, FUTURE DIRECTIONS, at ch. 2, available at <http://www.fhi.org/en/RH/Pubs/booksReports/latexcondom/condomaccept.htm>.

For instance, only 5% of married women of reproductive age use condoms as contraception.³⁰

III. Condom Reliability

Contraception

Condoms are safe, effective, user-controlled, non-prescription, easy to use and relatively cheap. As contraceptives, condoms have a perfect-use failure rate of 3% and a typical use failure rate³¹ of 14%.³² This means if one hundred women use condoms for a year, three will be pregnant assuming each used the condom perfectly. Typical use, however, would theoretically yield fourteen pregnant women.³³ Significant variations in a condom's effectiveness for preventing pregnancy arise from whether the condom is correctly and consistently used.³⁴ The average failure rate is likely closer to 14% rather than 3% because of the various negative sentiment concerning condoms that discourages correct and consistent use. Such negatives decreased sensitivity and sexual enjoyment. Three-quarters of men surveyed in the United States allege that condoms decrease pleasurable sensation.³⁵ Given the wide availability of more pleasurable, non-barrier contraception such as the pill, people are reluctant to use condoms if they perceive, even inaccurately, that they are at a low risk for contracting an STD.³⁶ Requesting that a partner use a condom also can be embarrassing. Condoms

³⁰*Id.*<http://www.fhi.org/en/RH/Pubs/booksReports/latexcondom/condomaccept.htm>

³¹*Id.* These rates refer to the risk that a woman will become pregnant in her first year of use, assuming perfect use (consistently) and typical use. For example, less than half of condom users report using condoms consistently at every act of intercourse. *Id.*

³²R.A. HATCHER ET AL., *CONTRACEPTIVE TECHNOLOGY* (17th ed., Ardent Media Inc. 1998).

³³"Typical use" entails either a properly executing the instructions and properly using the condom during each sexual encounter.

³⁴MCNEIL, *supra* note 30, at ch. 1 *available at* <http://www.fhi.org/en/RH/Pubs/booksReports/latexcondom/pregandstdprev.htm>.

³⁵Other factors include: reducing sensation, requiring care to avoid breakage, requiring withdrawing quickly, embarrassing to buy, difficult to put on, often comes off during sex, embarrassing to discard, indicates that partner requesting to use the condom either has HIV or an STD or believes that the other partner has HIV or an STD. W.R. Grady et al., *Condom Characteristics: The Perceptions and Preferences of Men in the U.S.*, 25 *Family Planning Perspectives*, at 67-73 (1993).

³⁶MCNEIL, *supra* note 30, at ch. 1, *available at* <http://www.fhi.org/en/RH/Pubs/booksReports/latexcondom/pregandstdprev.htm>.
<http://www.fhi.org/en/RH/Pubs/booksReports/latexcondom/condomaccept.htm>

are sometimes not easy to apply and remove during sex; they may fit uncomfortably tight during sex,³⁷ and allergies may prevent the use of latex condoms. For these reasons, both male and female partners are sometimes reluctant to agree to correct and consistent condom use during sex.

When used correctly, condoms as medical devices are highly reliable contraceptives. A 10% pregnancy rate in typical use does not mean condoms fail 10% of the time.³⁸ Human factors by far account for most pregnancies as opposed to product defects in condoms. According to Family Health International, studies show that the inconsistent and incorrect use of condoms is a far greater explanatory factor for pregnancy than is condom failure (breakage and slippage).³⁹ Mathematical models of inconsistent use and condom failure confirm this result. When condoms do fail because of apparent product defects, such failures are also generally the result of the user's behavior or physical, mental or sociological characteristics.⁴⁰ Not surprisingly, those who have experienced condom failure are twice as likely to experience it again as compared to those who have no experience with condom failure.⁴¹ Accordingly, in a study of forty-four Nevada prostitutes who had sex 41,000 times, one woman reported that 41% of condoms she used broke while three reported that 47% of condoms each used slipped.⁴²

User characteristics that have been studied for association with failure include: history of failure, less experience with condom use, youth, less education, larger penis and/or circumcised penis. User behaviors that have been studied for links with condom failure include: (i) opening condom packages with sharp objects,

³⁷M.F. Gallo et al., *Non-latex vs. Latex Male Condoms for Contraception: A Systematic Review of Randomized Controlled Trials*, 68 *Contraception*, at 319-326 (2003).

³⁸MCNEIL, *supra* note 30, at ch.1, available at <http://www.fhi.org/en/RH/Pubs/booksReports/latexcondom/pregandstdprev.htm>.<http://www.fhi.org/en/RH/Pubs/booksReports/latexcondom/pregandstdprev.htm>

³⁹<http://www.fhi.org/en/RH/Pubs/booksReports/latexcondom/pregandstdprev.htm>*Id.*

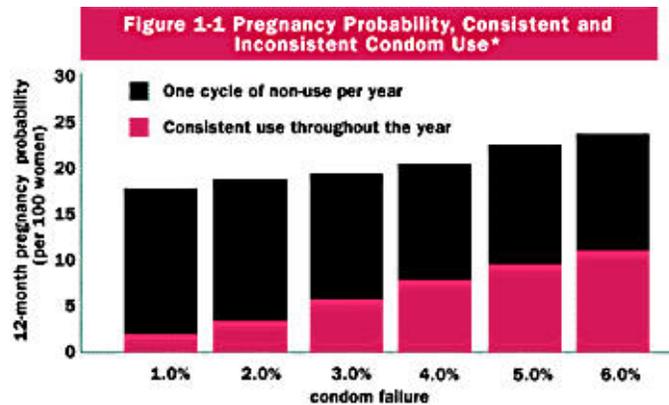
⁴⁰*Id.* Using oil as a lubricant (it destroys latex) during sex or having anal sex would be an example of user behavior that promotes condom failure. Having a genital piercing or long fingernails that rip latex would be a user attribute that results in condom failure. *Id.* at ch. 3, available at <http://www.fhi.org/en/RH/Pubs/booksReports/latexcondom/behavcharac.htm>.<http://www.fhi.org/en/RH/Pubs/booksReports/latexcondom/behavcharac.htm>

⁴¹See *id.*<http://www.fhi.org/en/RH/Pubs/booksReports/latexcondom/behavcharac.htm>

⁴²A.E. Albert et al., *Condom use among female commercial sex workers in Nevada's legal brothels*, 85 *AM. J. PUBLIC HEALTH* 1514, 1514-1520 (1995).

(ii) unrolling the condom before donning, (iii) lengthy or vigorous sex, (iv) using too much lubrication, (v) reducing natural vaginal lubrication by drying agents, (vi) engaging in anal and/or oral intercourse, (vii) engaging in intercourse in specific unnatural positions and/or (viii) re-using condoms.⁴³ More detailed research is needed to understand precisely which behaviors and user characteristics contribute most significantly to higher rates of condom failure in some users. Perhaps some practices, such as using oil-based lubrication or employing sharp objects to open condom wrappers, might be addressed through improved package labeling. It is unknown (but perhaps an interesting research question) whether counseling or instruction could reduce condom failure rates that some users experience.

Figure 1
Inconsistent condom use contributes more to pregnancy than condom failure⁴⁴
 (derived from Family Health International)



Disease Prevention

⁴³MCNEIL, *supra* note 30, at ch. 3, available at <http://www.fhi.org/en/RH/Pubs/booksReports/latexcondom/behavcharac.htm>.

⁴⁴*See id.* at ch. 1, available at <http://www.fhi.org/en/RH/Pubs/booksReports/latexcondom/pregandstdprev.htm>.

Condoms also may reduce the risk of contracting sexually transmitted infection by preventing contact with infectious secretions and skin lesions. Condoms, when used correctly and consistently, are eighty five through 100% effective in preventing the transmission of HIV, the virus that causes AIDS. Studies show that in relationships containing one HIV positive partner consistent condom use is extremely effective in preventing transmission of the virus with zero to two persons infected for every one hundred persons per year of exposure,⁴⁵ implying a near-zero risk of infection. Such studies, however, also indicate that *inconsistent* condom use yields a similar risk of infection as a person that does not use condoms at all.⁴⁶ Though studies are not as advanced, condoms' efficacy in preventing other sexually transmitted infections, such as gonorrhea, syphilis, Chlamydia, chancroid, trichomoniasis, HPV, herpes (HSV), and pelvic inflammatory disease is probable.

In Vitro testing shows that condoms are “virtually certain” of blocking passage of genital fluids between partners.⁴⁷ Scanning electron microscope pictures show pits and imperfections but no pores that cross the entire membrane.⁴⁸ FDA researchers have created a test model for condom leakage using a highly concentrated solution of a laboratory virus.⁴⁹ While this test is not routinely used to test condoms, it is perhaps more sensitive and therefore more precise than the conventional water leakage test. Using this test model, FDA scientists testing many different types of condoms found that condoms were very effective

⁴⁵PLANNED PARENTHOOD, *supra* note 22, at <http://www.plannedparenthood.org/pp2/portal/files/portal/medicalinfo/birthcontrol/pub-condom.xml>, citing Alberto Saracco et al., *Man-To-Woman Transmission of HIV: Longitudinal Study of 343 Steady Partners of Infected Men*, 6 JOURNAL OF ACQUIRED IMMUNE DEFICIENCY SYNDROMES, at 497-502 (Raven Press Ltd., New York 1993); also Isabelle De Vincenzi, *Heterosexual Transmission of HIV in European Cohort of Couples*, EUROPEAN CENTRE FOR THE EPIDEMIOLOGICAL MONITORING OF AIDS (Paris, France 1993), reported in, U.S. CENTERS FOR DISEASE CONTROL AND PREVENTION, MORBIDITY AND MORTALITY WEEKLY REPORT 42, at 30 (Aug. 6, 1993).

⁴⁶These results reinforce the point that perhaps most bad outcomes that occur with condom use are due to condoms not being used correctly and consistently. See MCNEIL, *supra* note 30, at ch.1, available at <http://www.fhi.org/en/RH/Pubs/booksReports/latexcondom/pregandstdprev.htm>.<http://www.fhi.org/en/RH/Pubs/booksReports/latexcondom/pregandstdprev.html>.

⁴⁷<http://www.fhi.org/en/RH/Pubs/booksReports/latexcondom/pregandstdprev.html>.

⁴⁸<http://www.fhi.org/en/RH/Pubs/booksReports/latexcondom/pregandstdprev.html>.

⁴⁹C.D. Lytle et al., *A Sensitive Method for Evaluating Condoms as Virus Barriers*, 80 J. AOAC Int. 319, 319-324 (1997); also *Scientific Evidence on Condom Effectiveness*, *supra* note 25, at 7, available at <http://www.niaid.nih.gov/dmid/stds/condomreport.pdf>.<http://www.niaid.nih.gov/dmid/stds/condomreport.pdf>

as barriers to virus transmission notwithstanding a small chance of leakage.⁵⁰ Leakage was typically on the order of 0.1 microliter or less, or about 1/10,000 of a typical ejaculation which in such small amounts would typically be virus-free in an HIV-infected person.⁵¹ Condoms that are intact, without major holes are essentially impermeable to particles the same size as STD pathogens. These studies also show that fluid flow, as opposed to virus size, is the most important determinant of viral transmission. Condoms with holes many times larger than the virus impeded fluid flow to the extent that few of the test particles were transmitted.⁵² Of course, for many STDs such as those transmitted by skin-to-skin contact the risk of acquiring an infection might not be proportional to the volume of fluid passing through a permeable condom.

IV. Regulation

Condoms are regulated by the FDA as Class II medical devices.⁵³ They were marketed and sold before the Medical Device Amendments of 1976⁵⁴ were enacted and were therefore grandfathered into newly created Class II as part of the initial classification of all existing devices.⁵⁵ The Amendments anticipated that the FDA would establish mandatory performance standards for each Class II device, but such detailed regulation proved unduly burdensome for the FDA and was never fully implemented.⁵⁶ More recently, as part of the Safe

⁵⁰C.D. Lytle et al., *An in vitro evaluation of condoms as barriers to small virus* in SEXUALLY TRANSMITTED DISEASES, at ch. 24, 161-164 (March 1997).

⁵¹McNEIL, *supra* note 30, at ch.1, available at <http://www.fhi.org/en/RH/Pubs/booksReports/latexcondom/pregandstdprev.htm>; See also R.F. Carey et al., *Effectiveness of latex condoms as a barrier to HIV-sized particles under conditions of simulated use* in SEXUALLY TRANSMITTED DISEASES, at ch. 19, 230-234 (1992).

⁵²*A Sensitive Method for Evaluating Condoms as Virus Barriers*, *supra* note 51, at 319-324.

⁵³See *Subcommittee on Criminal Justice, Drug Policy and Human Resources, Committee on Government Reform*, US House of Representatives (March 11, 2004) (Statement of Daniel G. Shultz, Director, Office of Device Evaluation, Center for Devices and Radiological Health, Food and Drug Administration), at <http://www.fda.gov/ola/2004/condoms0311.html>; see also 21 C.F.R. §§ 884.5300, 884.5310 (condoms with spermicidal lubricant).

⁵⁴[Cite]

⁵⁵See Statement of Daniel G. Shultz, *supra* note 55, at <http://www.fda.gov/ola/2004/condoms0311.html>.

⁵⁶<http://www.fda.gov/ola/2004/condoms0311.html> *Id.*

Medical Devices Act of 1990, Congress made Class II medical devices subject to FDA established optional special controls, which are broader and less particular than mandatory performance standards. Thus far, the FDA has not specified special control measures in connection with condoms.⁵⁷ FDA regulation does extend, however, to condom-makers marketing and selling condoms in the United States. Such regulations encompass two regulatory regimes:⁵⁸ pre-market controls which regulate condoms when they are first introduced to the market and post-market controls. The former regulatory structure relies upon 510(k) pre-market notification procedures⁵⁹ while for the latter the FDA requires compliance with Quality System Regulation.

Pre-marketing notification under Section 510(k)

The 1976 Amendments allow the FDA to control market introduction of all medical devices.⁶⁰ One of the three ways a new device may be legally marketed is when it is “substantially equivalent” to a device that is already marketed.⁶¹ Specifically, every manufacturer or importer of a new medical device must provide pre-market notification (“PMN”) to the FDA under Section 510(k)⁶² with information to enable the agency to determine whether the item is “substantially equivalent” to a legally marketed device that is already on the market.⁶³ Unless exempted from PMN requirements, a producer may not market a new device under

⁵⁷ *Id.* <http://www.fda.gov/ola/2004/condoms0311.html>

⁵⁸ *Scientific Evidence on Condom Effectiveness*, *supra* note 25, at 6, available at <http://www.niaid.nih.gov/dmid/stds/condomreport.pdf>.

⁵⁹ 21 U.S.C. § 510(k) (2004); *see also Scientific Evidence on Condom Effectiveness*, *supra* note 25, at 6, available at <http://www.niaid.nih.gov/dmid/stds/condomreport.pdf>. <http://www.niaid.nih.gov/dmid/stds/condomreport.pdf>

⁶⁰ PB Hutt, at 745.

⁶¹ “Substantially equivalent” is a defined term that can be found in Section 513(i). 21 U.S.C. § 513(i).

⁶² “Section 510(k) of the Act and the implementing regulation, 21 CFR Part 807, require persons who intend to market a new device to submit a premarket notification containing information that enables the FDA to determine whether the new device is substantially equivalent within the meaning of Section 513(i) of the Act to a legally marketed device that does not require premarket approval.” 21 U.S.C. § 510(k); 21 C.F.R. pt. 807.

⁶³ *Scientific Evidence on Condom Effectiveness*, *supra* note 25, at 6, available at

Section 510(k) without receiving a “substantially equivalent” order or an order classifying the device as a Class I or Class II device.⁶⁴

Male condoms, as noted previously, are Class II devices and are not exempt from 510(k) requirements, thus 510(k) PMN must be submitted to the FDA before a new male condom, or an existing condom that has been substantially changed or modified, is introduced.⁶⁵ Most new latex condoms meet the “substantially equivalent” requirement with respect to condoms that were on the market before the 1976 Amendment. Consequently, most new latex condoms are approved through the “substantially equivalent” requirements contained in Section 513(i).

Office of Device Evaluation – Abbreviated 510(k) requirements

The FDA also allows abbreviated submissions for male condom PMN using consensus standards. Conforming to recognized consensus standards reasonably assures the FDA of the safety and effectiveness of several aspects of medical devices, including male latex condoms. A 510(k) PMN that states that a device conforms to recognized consensus standards will in most instances mean that the FDA will not need to review the actual test data for those aspects of the product that the standards deal with. The FDA can still seek such data if otherwise permitted by statute or regulation. Compliance with consensus standards may not always

<http://www.niaid.nih.gov/dmid/stds/condomreport.pdf>; see also CENTER FOR DEVICES AND RADIOLOGICAL HEALTH, FDA, *Latex Condoms for Men – Information for 510(k) Premarket Notifications: Use of Consensus Standards for Abbreviated Submissions*, Guidance for Industry, July 23, 1998, available at <http://www.fda.gov/cdrh/ode/ltxcondm.pdf> (abbreviated 510(k) for male condoms) [hereinafter *Latex Condoms for Men*].

⁶⁴ See *id.* <http://www.fda.gov/cdrh/ode/ltxcondm.pdf>

⁶⁵ *Id.* <http://www.fda.gov/cdrh/ode/ltxcondm.pdf>

be a sufficient basis for regulatory decisions. Specifically, if a new device or intended use raises safety and effectiveness concerns that are not addressed by a consensus standard, or if regulations are more rigorous than consensus standards, compliance with consensus standards will not be adequate for marketing approval.

The FDA recognizes voluntary consensus standards for male latex condoms, as well as other standards, such as the ISO 10993 standard for cytotoxicity, which is relevant to a 510(k) application for a latex condom.⁶⁶

An annually updated list of approved consensus standards is posted on the FDA website.⁶⁷ Manufacturers can choose to make a declaration of conformity to any of the listed standards.⁶⁸

The FDA-drafted guidance document for a PMN⁶⁹ refers to the ASTM voluntary consensus standard for condoms⁷⁰ and the ISO voluntary consensus standard⁷¹ for biological evaluation of medical devices. The guidance document serves as a structure for a producer to show compliance with these consensus standards for male latex condoms. When the declaration of compliance with consensus standards is included in a complete and accurate 510(k) PMN it can serve as the basis for an FDA finding of substantial equivalence.

ASTM and ISO voluntary standards for condoms

The FDA's abbreviated guidance under a 510(k) PMN specifically requires the producer or importer to show conformance with the ASTM Standard Specification for Rubber Contraceptives (Condoms), D3492,⁷² and

⁶⁶ *Id.*

⁶⁷ See also *Latex Condoms for Men*, *supra* note 65, available at <http://www.fda.gov/cdrh/ode/ltxcondm.pdf>. <http://www.accessdata.fda.gov/sc>

⁶⁸ *Id.*; see also FDA GUIDANCE ON THE RECOGNITION AND USE OF CONSENSUS STANDARDS (Feb. 19, 1998)

⁶⁹ See also *Latex Condoms for Men*, *supra* note 65, available at [http://www.fda.gov/cdrh/ode/ltxc](http://www.fda.gov/cdrh/ode/ltxcondm.pdf)

⁷⁰ [Cite]

⁷¹ [Cite]

⁷² ASTM refers to the American Society for Testing and Materials, 100 Barr Harbor Drive, West Conshohocken, PA 19428. ASTM's website is <http://www.astm.org>.

the ISO Standard 10993⁷³ or Biologic Evaluation of Medical Devices.⁷⁴ The ASTM standards are specific for condoms, whereas the ISO standards apply to medical devices that are in contact with the body.

ASTM Condom standards deal with the physical properties of the condom, requiring that condoms are made from natural rubber latex, are of certain dimensions and thickness,⁷⁵ meet toxicity criteria, meet air burst pressure and volume criteria and meet criteria for leakage and package integrity. Condoms must conform in all respects to these requirements, unless variance is specifically noted. Where such a variance is disclosed, the FDA requires separate disclosure that identifies the variance from each standard and that explains how the variation does not materially impact the condom's "substantial equivalence." Appendix 1 lists the ASTM standards as well as other international condom standards.

The FDA standards are arguably inadequate given the technology that is available for condom testing. For example, the ASTM standards only require visual leak testing, not electronic testing which is the standard practice of condom producers.⁷⁶ ASTM standards specify that the tester must fill a sample of condoms from each batch with water and look for water leaks using the naked eye.⁷⁷ According to the FDA, the ASTM water leak test, detects tiny holes in tested condoms, but does not assure that condoms are strong enough to resist being broken during sex.⁷⁸

⁷³See *A practical guide to ISO 10993: Part I – Introduction to the standards*, MED. DEVICE & DIAGNOSTIC IND. MAG., Jan. 1998, available at <http://www.devicelink.com/mddi/archive/98/01/023.html>.

⁷⁴See *Id* [27] at Page 9.

⁷⁵With regard to condom dimensions, ASTM standards require condoms to have a minimum thinness of 0.3 mm and, when laid-flat, a maximum width of 54 mm and minimum length of 160 mm. MCNEIL, *supra* note 30, at ch. 5, available at <http://www.fhi.org/en/RH/Pubs/booksReports/latexcondom/standspectests.htm>. It is noteworthy that the comparable Japanese and European condom standards, as given by the ISO and CEO, do not specify a minimum condom thickness.

⁷⁶*Id.* With regard to leakiness of condoms or detecting tiny holes, producers test every condom electronically too see if they allow electricity through. *Id.* <http://www.fhi.org/en/RH/Pubs/booksReports/latexcondom/standspectests.htm> Rubber is an electric insulator, so if current passes across a condom, that means there is a hole. *Id.*

⁷⁷See *id* <http://www.fhi.org/en/RH/Pubs/booksReports/latexcondom/standspectests.htm>.

⁷⁸See FDA, OFFICE OF REGULATORY AFFAIRS, 5 Compliance Policy Guide § 345.100, *Male Condom Defects* (March 29, 2002) (draft for comment), at www.fda.gov/ora/compliance_ref/cpg/cpgdev/cpg345-100_draft.html [hereinafter *Male Condom Defects*].

To understand how well condoms can stretch and expand, ASTM standards also require an air burst test.⁷⁹ The air burst tests required by the ASTM standard are destructive tests that blow condoms up like balloons. During testing the pressure and volume of air that condoms are inflated with is increased until they burst.⁸⁰ The air burst test thus measures the maximum strength of the weakest part of the entire condom.⁸¹ Research indicates that the air burst test results correlate with how well condoms actually perform during sex.⁸² Conversely, when used during sex, condoms might not commonly burst at their weakest point, but rather at their most stressed point, such as the closed end and tip of the condom. So there are proposals to have an additional inflation testing component with higher performance standards for the closed end and tip of the condom.⁸³

Acceptable Quality Level

The tests do not require every condom in a sample to pass. Rather, each test, whether for size, leaks or inflation, comes with an acceptable quality level (AQL) specification.⁸⁴ The AQL level and number of allowable defects depends on the sample size tested.⁸⁵ For example, using the ASTM leak test and applying a 0.40 AQL would require gathering a random sample of 315 condoms from a batch of 150,000 to 500,000

⁷⁹MCNEIL, *supra* note 30, at ch. 5, available at <http://www.fhi.org/en/RH/Pubs/booksReports/latexcondom/standspectests.htm>.<http://www.fh>

⁸⁰See *Male Condom Defects*, *supra* note 80, at www.fda.gov/ora/compliance_ref/cpg/cpgdev/cpg345-100_draft.html; see also ISO 4074 and ASTM D3492 standards. Air burst tests have been adopted by many other countries, such as Canada, Australia and the member countries of the European Union. *Id.* The ASTM standard requires condoms to be inflated to a minimum volume of sixteen liters and to a minimum pressure of one kiloPascal. See <http://www.fhi.org/en/RH/Pubs/booksReports/latexcondom/standspectests.htm>MCNEIL, *supra* note 30, at ch. 5, available at <http://www.fhi.org/en/RH/Pubs/booksReports/latexcondom/standspectests.htm>.

⁸¹When a condom is inflated to bursting, it will typically break at its weakest part. MCNEIL, *supra* note 30, at ch. 5, available at <http://www.fhi.org/en/RH/Pubs/booksReports/latexcondom/standspectests.htm>.

⁸²M.J. Free et al., *An assessment of burst strength distribution data for monitoring condom stocks in developing countries*, *Contraception* 1986; 33:285-99; see also MCNEIL, *supra* note 30, at ch. 5, available at <http://www.fhi.org/en/RH/Pubs/booksReports/latexcondom/standspectests.htm>, citing M.J. Free et al., *Relationship between condom strength and failure during use*, *Contraception* 1980;22:31-37. <http://www.fhi.org/en/RH/Pubs/booksReports/latexcondom/standspectests.htm>

⁸³MCNEIL, *supra* note 30, at ch. 5, available at <http://www.fhi.org/en/RH/Pubs/booksReports/latexcondom/standspectests.htm>.<http://www.fh>

⁸⁴*Id.*

⁸⁵*Id.*

manufactured condoms. The batch passes the ASTM water leak test if no more than 3 condoms in the sample have visible water leaks. If more than three condoms in the sample fail the test, then the entire manufacturer batch of condoms is destroyed. If the AQL for the ASTM water leak test was tightened to 0.25, as has been proposed, this would require no more than two condoms to fail in the sample of 315.⁸⁶

ISO Standards

The twelve part ISO standards generally aim to test and evaluate the effects of medical device materials on the body.⁸⁷ In particular, four of the twelve ISO 10993 standards apply to male condoms.⁸⁸ The ISO 10993 standards and the FDA ODE Bluebook Guidance memorandum #G95-1⁸⁹ demonstrate that the condom is not cytotoxic,⁹⁰ systemically toxic,⁹¹ sensitizing or locally irritating,⁹² or otherwise harmful.⁹³ Unlike the ASTM standards, the ISO standards describe test procedures and not performance thresholds or “passing grades.”⁹⁴ Therefore summaries of the testing results must be included with the PMN.⁹⁵

Quality System Regulation of Condoms

The Quality System Regulation⁹⁶ is a post-market regulatory control, which means that it applies to condoms that are already being sold on the market.⁹⁷ The Regulation sets forth requirements to comply with

⁸⁶ *Id.* <http://www.fhi.org/en/RH/Pubs/booksReports/latexcondom/standspectests.htm>

⁸⁷ See *Latex Condoms for Men*, *supra* note 65, available at <http://www.fda.gov/cdrh/ode/ltxcondm.pdf>. <http://www.fda.gov/cdrh/g951.html>

⁸⁸ See <http://www.fda.gov/cdrh/ode/ltxcondm.pdf> *id.*, at 9.

⁸⁹ FDA, *Required Biocompatibility Training and Toxicology Profiles for Evaluation of Medical Devices*, (G95-1) (May 1, 1995), at <http://www.fda.gov/cdrh/g951.html>.

⁹⁰ ISO 10993-5 – Cytotoxicity.

⁹¹ ISO 10993- 11 Systemic Toxicity.

⁹² ISO 10993-10 – Irritation and Sensitization.

⁹³ *cite*

⁹⁴ *Latex Condoms for Men*, *supra* note 65, at 9, available at <http://www.fda.gov/cdrh/ode/ltxcondm.pdf>. <http://www.fda.gov/cdrh/ode/ltxcondm.pdf>

⁹⁵ *Id.*

⁹⁶ See 21 C.F.R. pt. 820, available at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=820&showFR=1>.

⁹⁷ *Scientific Evidence on Condom Effectiveness*, *supra* note 25, at 6, available at <http://www.niaid.nih.gov/dmid/stds/condomreport.pdf>. <http://www.niaid.nih.gov/dmid/stds/condomreport.pdf>

current desirable manufacturing practice.⁹⁸ The Regulation requires condom manufacturers to adhere to the following standards: (i) manufacturers must use quality assurance standards for new condom designs; (ii) manufacturers must use valid processes in condom manufacture, so that they conform to their design specifications; and (iii) manufacturers must apply strict product release criteria to condoms.⁹⁹

Shipments and imports of condoms to the United States

When shipments of condoms contain defects or holes, they may be refused entry into the United States under section 801(a)(3)¹⁰⁰ because they appear to be of substandard quality.¹⁰¹ Essentially, these defective condoms are considered adulterated pursuant to section 501(c).¹⁰² If these imported condoms are labeled for the prevention of disease, then they are also considered misbranded under section 502(a), as the holes and defects in the condoms make them ineffective at disease prevention.¹⁰³

The FDA also holds imported condoms to similar quality standards.¹⁰⁴ The FDA is permitted to seize condoms that do not meet the ASTM D3492 water leak test¹⁰⁵ and ISO 4074 and ASTM D3492 airburst test specifications.¹⁰⁶ Such condoms that do not provide an adequate barrier are considered adulterated.

Condoms that do not pass these tests satisfactorily may be considered adulterated and misbranded and may be subject to direct reference seizure.¹⁰⁷ The FDA lists sample charges that include the following:¹⁰⁸

⁹⁸21 C.F.R. § 820.1(a).

⁹⁹*Id.*

¹⁰⁰*Id.*

¹⁰¹*Id.*

¹⁰²Cite

¹⁰³See 502(a).

¹⁰⁴See *Male Condom Defects*, *supra* note 80, at www.fda.gov/ora/compliance_ref/cpg/cpgdev/cpg345-100_draft.html.

¹⁰⁵*Id.* Specifically, if more than 0.25% (that is twenty-five out of ten thousand) condoms are leaky, then the batch fails the test. *Id.* In 1987, when the ASTM standard was first used by the FDA, the leakiness standard was just 0.4%. *Id.*

¹⁰⁶*Id.*

¹⁰⁷*Id.*

¹⁰⁸See specimen charges at www.fda.gov/ora/compliance_ref/cpg/cpgdev/cpg345-100_draft.html.

1.

For lots that FDA determines are adulterated on the basis of the water leak test AQL or other factors, the FDA finds, [t]hat the article of device is adulterated within the meaning of the Act, 21 U.S.C. 351(c), in that it is not subject to 21 U.S.C. 351(b) and its quality falls below that which it purports or is represented to possess in that the devices contain defects/holes;

2. If the condoms contain holes and are labeled for the contraception, the FDA may find a violation of 21 U.S.C. 351(c) and may also find, [t]hat the article of device is misbranded within the meaning of the Act, 21 U.S.C. 352(a), in that its labeling [for the prevention of pregnancy] is false or misleading, because the labeling fails to reveal a material fact in light of such representations, that the article contains holes;

3. If the seized lot was repacked by the dealer and it is believed that holes may have occurred during repacking, the FDA may add a statement to the examination paragraph of the complaint finding, (Insert name of firm) repacked the article of device from bulk stock after receipt in interstate commerce.¹⁰⁹

Labeling

The FDA generally regulates condom labeling through medical device labeling requirements¹¹⁰ and uniform contraceptive labeling requirements¹¹¹ and more specifically through condom labeling regulations that require condom expiration dating¹¹² and warnings about allergies to rubber latex.¹¹³

As far back as 1987, the FDA has issued guidance related to condom labeling in connection with protection against sexually transmitted disease.¹¹⁴ Condom packaging is typically labeled on an external box, which

¹⁰⁹Cite

¹¹⁰21 C.F.R. pt. 801.

¹¹¹FDA, GUIDANCE FOR INDUSTRY, UNIFORM CONTRACEPTIVE LABELING, July 23, 1998, at <http://www.fda.gov/cdrh/ode/contrlab.html>.

¹¹²21 C.F.R. § 801.435.

¹¹³*Id.* § 801.437. The standard warning says: “Warning: This product contains natural rubber latex which may cause allergic reactions.” See also *Latex Condoms for Men*, *supra* note 65, at 12, available at <http://www.fda.gov/cdrh/ode/ltxcondm.pdf>.

¹¹⁴See Statement of Daniel G. Shultz, *supra* note 55, at <http://www.fda.gov/ola/2004/condoms0311.html>.

is called the “principal display panel.”¹¹⁵ The box must display the product’s “principal intended action.” Condom packaging also contains more detailed information including user directions and other important information, either on the box or on a package insert inside the box.¹¹⁶ FDA guidance suggests the “principal intended action” include statements as to contraception and STD risk reduction. With respect to STD risk reduction, recommended statements include the following:¹¹⁷

“Protection against sexually transmitted diseases (STDs).”

“If used properly, latex condoms will help to reduce the risk of transmission of HIV infection (AIDS) and many other sexually transmitted diseases.”

“If used properly, latex condoms will help to reduce the risk of transmission of HIV infection (AIDS) and many other sexually transmitted diseases, including chlamydia infections, genital herpes, genital warts, gonorrhea, hepatitis B, and syphilis.”

Condoms with spermicidal lubricant must also carry special labeling, describing the contraceptive function of the spermicidal lubricant nonoxynol-9. Such labeling must explain that the reduced risk of pregnancy has not been quantified and that a condom coupled with spermicidal is not a substitute for a vaginal spermicide and a condom.¹¹⁸

Condom package inserts must also include a contraceptive effectiveness table with pregnancy rates for all contraceptive methods.¹¹⁹ The FDA explains that requiring such a table will enable contraceptive users to compare contraceptive alternatives and thereby make informed and educated choices. The FDA has developed such a table for this purpose¹²⁰ based on a leading textbook.¹²¹

Labeling must also incorporate suggested directions and precautions to follow including indications that

¹¹⁵ See *id* <http://www.fda.gov/ola/2004/condoms0311.html>.

¹¹⁶ See *id*.

¹¹⁷ <http://www.fda.gov/ola/2004/condoms0311.html> See *id*.

¹¹⁸ See also *Latex Condoms for Men*, *supra* note 65, at 12, available at <http://www.fda.gov/cdrh/ode/ltxcondm.pdf>. <http://www.fda.gov/cdrh/ode>

¹¹⁹ *Id.* <http://www.fda.gov/cdrh/ode/ltxcondm.pdf>

¹²⁰ FDA, OFFICE OF WOMEN’S HEALTH, PREGNANCY RATES FOR BIRTH CONTROL DEVICES (DATE).

¹²¹ CONTRACEPTIVE TECHNOLOGY (17th ed. Hatcher et al. YEAR). The table is available at <http://www.fda.gov/cdrh/ode/contrlab.html>.

condoms should be stored in a cool dry place, and also advice forewarning users not to reuse condoms, use obviously damaged condoms or use oil-based lubricants which may damage condoms.¹²²

V. Studies and Debates Fueling Condom Regulation and Social Policy

Activist groups often argue that the deterioration of America's moral values is the result of government sanctioning of "immoral" behavior such promoting condom use instead of abstinence. By promoting condoms, such groups state, the government gives its citizens the impression that pre-marital sex or irresponsible sex is acceptable and the proper way to protect against disease and pregnancy is to use protection rather than practice abstinence. The American Social Hygiene Association, for instance, fought to ban condom use in the early part of the twentieth century, particularly during World War I.¹²³ The association felt that negative consequences such as STDs and unwanted pregnancy that are inherent in non-marital sex and promiscuity already served as deterrents to immoral behavior. Without this disease-based deterrence, it argued, America's morals would surely decline. During World War I, in a reflection of this ethos, American armed forces were the only troops in Europe that were not provided condoms.¹²⁴ This led to a 70% STD infection rate, the highest of any fighting force in Europe. Fundamentalist Secretary of the Navy Josephus Daniels was one of many military leaders who believed condom use was immoral and "Un-Christian."¹²⁵ Pragmatics won over moral scruples, and by 1919 the US Army was spending a million dollars each year on prevention of venereal disease, including distribution of condoms.¹²⁶ The medical endorsement and wide

¹²²See *See also Latex Condoms for Men*, *supra* note 65, at 13, available at <http://www.fda.gov/cdrh/ode/ltxcondm.pdf>.<http://www.fda.gov/cdrh/ode/ltxcondm.pdf>

¹²³PLANNED PARENTHOOD FEDERATION OF AMERICA, INC., *A History of Contraceptive Methods* citing ALLAN M. BRANDT, NO MAGIC BULLET: A SOCIAL HISTORY OF VENEREAL DISEASE IN THE UNITED STATES SINCE 1880 (Oxford Univ. Press. 1985), at <http://www.plannedparenthood.org/pp2/portal/files/portal/medicalinfo/birthcontrol/fact-020709-contraception-history.xml>.

¹²⁴See BRANDT, *supra* note 125.

¹²⁵See *id.*

¹²⁶LINDA GORDON, WOMEN'S BODY, WOMEN'S RIGHT: BIRTH CONTROL IN AMERICA 63-64 (Penguin Books USA 1990)

distribution of condoms helped popularize them with the 4.8 million American men who served in World War I.¹²⁷

The moral debate again reared its head in the wake of the global AIDS epidemic. From 1987 the FDA has issued various guidance documents on condom labeling related to STD protection.¹²⁸ The FDA also increased testing and quality standards for condoms.¹²⁹ Through the FDA's public outreach efforts, it has also promoted condom use, even to teenagers, as a way of protecting against STDs.¹³⁰ For instance, an FDA booklet promoting condoms, titled "Condoms and Sexually Transmitted Diseases ... Especially AIDS," states that "it's important to use condoms (rubbers, prophylactics) to help reduce the spread of sexually transmitted diseases."¹³¹ The booklet qualifies this recommendation by noting that abstinence and monogamous intercourse with a non-infected monogamous partner are the only sure ways of avoiding STDs. The booklet went on to note that condoms are not 100% safe in preventing STD infection. In another article in its consumer magazine, the FDA quotes Herbert Peterson, M.D., chief of the Center for Disease Control's ("CDC") women's health and fertility branch, as saying that "[t]he scientific evidence [as to condom efficacy in preventing STD transmission] is compelling."¹³²

The government's role in promoting condom use under the earlier rubric of "safe sex" and the later term "safer sex," generated social¹³³ and political opposition¹³⁴ from social conservatives. The opposition was not

¹²⁷ *Id.*

¹²⁸ See Statement of Daniel G. Shultz, *supra* note 55, at <http://www.fda.gov/ola/2004/condoms0311.html>.

¹²⁹ [Cite.]; also see, CONSUMER REPORTS, *Feature Report: Condoms Get Better*, June 1999, at http://www.consumerreports.org/main/detail.jsp?CONTENT%3C%3Ecnt_id=19263&FOLDER%3C%3Efolder_id=18151.

¹³⁰ See e.g., FDA, *On the teen scene: Preventing STDs*, FDA CONSUMER MAG., June 1993, at http://www.fda.gov/fdac/reprints/ots_stds.html; see also Judith Levin Willis, US FDA, *Latex Condoms Reduce the risk of STDs*, FDA CONSUMER MAG., September 1990, at <http://www.fda.gov/bbs/topics/CONSUMER/CN00042c.html>; see also Tamar Nordenberg, *Condoms: Barriers to Bad News*, FDA CONSUMER MAG., March – April 1998, at <http://www.thebody.com/fda/condoms.html>.

¹³¹ See FDA, *CONDOMS AND SEXUALLY TRANSMITTED DISEASES ... ESPECIALLY AIDS*, Brochure, at <http://www.fda.gov/oashi/aids/condom.html>.

¹³² See Nordenberg, *supra* note 132, at <http://www.thebody.com/fda/condoms.html>.

¹³³ For example, consider 'The Pure Love Club,' a Catholic chastity outreach program that can be found at www.pureloveclub.com.

¹³⁴ See Heather Boonstra, *Public Health Advocates Say Campaign to Disparage Condoms Threatens STD Prevention Efforts*,

a new phenomenon, but rather was similar to the opposition to condom use (to stop venereal disease) before and during World War I.¹³⁵ The moral debate persists today where promotion and easy access to condoms are feared as a “license to sexual immorality.”¹³⁶ For social conservatives, easy access to a contraceptive that is effective, cheap, safe, prescription-free, anonymous “not only encourages but signals acceptance of nonmarital, nonreproductive sex.”¹³⁷

Condom opponents today cast their arguments in both scientific and moral terms.¹³⁸ Morally, they have argued that religion and tradition favored strict, reciprocal monogamy or abstinence. Scientifically, they have publicly attacked the efficacy of condoms in preventing STD infection,¹³⁹ and called on the government to limit or at least require condom promoters to teach abstinence in conjunction with safe sex marketing campaigns.¹⁴⁰ In addition, social conservatives have indirectly accused safer sex advocates of fraud for in knowingly promoting condoms despite knowing of condoms’ inefficacy for disease prevention. For instance, conservative commentator Patrick J. Buchanan writes in *The Great Condom Fraud and Cover-Up*¹⁴¹ that “. . . [Secretary of State Colin] Powell’s testimonial to condoms as offering protection against disease, . . . appears to be one of the frauds of our time.”¹⁴² James Dobson, a prominent conservative and president of Focus on the Family, noted that “[Powell] is talking about a subject he doesn’t understand. He clearly doesn’t understand the science regarding condom efficacy.”¹⁴³ These comments were in response to former

THE GUTTMACHER REPORT ON PUBLIC POLICY, March 2003, at 1, at <http://www.guttmacher.org/pubs/tgr/06/1/gr060101.pdf>.

¹³⁵ See *id.* at 477; GORDON, *supra* note 128, at 63-64, 309-310.

¹³⁶ GORDON, *supra* note 128, at 309-310.

¹³⁷ LINDA GORDON, *THE MORAL PROPERTY OF WOMEN: A HISTORY OF BIRTH CONTROL POLITICS IN AMERICA* 355 (Univ. of Ill. Press 2002).

¹³⁸ The new government website for parents – www.4parents.gov – is designed for parents who are too shy to speak to their children about sex. It clearly promotes the message that “abstinence is the healthiest choice.” It clearly illustrates that condoms provide poor protection against many STDs and lists the high mean failure rates for various contraceptives. The site does not have any advice on “safe sex.”

¹³⁹ See the table at <http://www.4parents.gov/talktopics/table.htm>.

¹⁴⁰ “Government spends \$12 on Safe Sex and Contraceptives for Every \$1 Spent on Abstinence: Heritage Foundation Backgrounder #1718.” Melissa G. Pardue, Robert E. Rector, and Shannan Martin.

¹⁴¹ See Patrick J. Buchanan, *THE AMERICAN CAUSE, The Great Condom Fraud Cover-Up*, March 1, 2002, at www.theamericancause.org (search title in archives).

¹⁴² See *id.*

¹⁴³ See BBC NEWS, *Powell’s condom comments draw ire*, Feb. 16 2002, at

Secretary of State Colin Powell's remarks on MTV that "condoms are a way to prevent infection and therefore [he] not only support[s] their use [but he] encourage[s] their use among people who are sexually active and need to protect themselves."¹⁴⁴

Catholic Church Discourages Condom Use to Fight AIDS in Third World

The Catholic Church has a long history of involvement in the controversy over whether promoting condoms or abstinence is preferable to fight the global AIDS epidemic, a problem especially severe in sub-Saharan Africa and elsewhere in the Third World. Cardinal Alfonso Lopez Trujillo of Colombia, President of the Vatican's Pontifical Council on the Family, publicly remarked in 2003 that condoms don't prevent AIDS and may actually help spread the disease by creating a false sense of security.¹⁴⁵ The Cardinal made these remarks in a BBC Panorama program, "Sex and the Holy City."¹⁴⁶ Cardinal Lopez Trujillo defended these extemporaneous remarks with a detailed twenty page statement (with eighty-four footnotes, including citations to multiple scientific sources) titled "Family Values versus Safer Sex."¹⁴⁷ In Cardinal Lopez Trujillo's words,

<http://news.bbc.co.uk/1/hi/world/americas/1823739.stm>.

¹⁴⁴See *id.*

¹⁴⁵See Nicole Winfield, ASSOCIATED PRESS, *What is the Vatican Position on condoms to fight AIDS?*, March 20, 2004, at <http://www.aegis.com/news/ap/2004/AP040334.html>. In a more detailed statement, Cardinal Lopez Trujillo says, "I am quite concerned because people, especially the young, are misled when total protection is seemingly offered to them, while in fact there is no such total protection." See CARDINAL LOPEZ TRUJILLO, CATHOLIC CULTURE, *Family Values Versus Safe Sex*, at http://www.catholicculture.org/docs/doc_view.cfm?recnum=5836 (last visited May 23, 2005); See Interview by BBC on Vatican Radio with Cardinal Lopez Trujillo President of Pontifical Council for the Family, Vatican City (Nov. 23, 2003) (effectiveness of condoms to curb AIDS), at <http://www.catholic.org/featured/headline.php?ID=488><http://www.catholic.org/featured/headline.php?ID=488>.

¹⁴⁶See STEVE BRADSHAW, THE GUARDIAN, *Vatican: Condoms don't stop AIDS*, October 9, 2003, at <http://www.guardian.co.uk/aids/story/0,7369,1059068,00.html>.

¹⁴⁷*Family Values Versus Safe Sex*, *supra* note 147, at http://www.catholicculture.org/docs/doc_view.cfm?recnum=5836.

One cannot really speak of safe sex, leading people to believe that the use of condoms is the formula to avoid the risk of HIV and thus to overcome the AIDS pandemic. Nor should people be led to believe that condoms provide absolute safety. They do not mention that there is a percentage of grave risk, not only of AIDS, but also of the different sexually transmitted diseases, and that the rate of failure is quite high.¹⁴⁸

The Cardinal understands that the World Health Organization estimates that using condoms reduces 90% of the risk of acquiring HIV and that it estimates that 99% of new HIV cases come from unprotected sex, but his position claims that the residual risk is still unacceptably high for a mortal disease like AIDS.¹⁴⁹ In place of condoms, the Cardinal advocates “moral values of mutual fidelity of spouses and chastity,”¹⁵⁰ which he says provide “absolute protection”¹⁵¹ in preventing disease. To discourage condom use (and presumably promote chastity and fidelity), the Cardinal recommends a mandatory warning notice on condom packaging, similar to the warning on cigarettes that filters do not make the product safer, that states that condoms are unsafe.¹⁵²

Cardinal Lopez Trujillo’s written statement also offers a detailed critique of safer sex, which he argues promotes sexual promiscuity and condom use, which in his view are so ineffective as to be harmful.¹⁵³ He cites research showing that “HIV/AIDS cases increase as the number of condoms distributed also increases.”¹⁵⁴ He also cites anecdotal reports that where abstinence and marital fidelity has been promoted (Uganda for example) the HIV/AIDS pandemic has “dramatically decreased”¹⁵⁵ In Uganda, he cites a US Agency for International Development (“USAID”) study that attributes falling HIV prevalence “more to reduction in

¹⁴⁹ *Family Values Versus Safe Sex*, *supra* note 147, at http://www.catholicculture.org/docs/doc_view.cfm?recnum=5836.
http://www.catholicculture.org/docs/doc_view.cfm?recnum=5836

¹⁵⁰ See Interview with Cardinal Lopez Trujillo, *supra* note 147, at <http://www.catholic.org/featured/headline.php?ID=488>.<http://www.catholic.org/featured/headline.php?ID=488>

¹⁵¹ *Family Values Versus Safe Sex*, *supra* note 147, at http://www.catholicculture.org/docs/doc_view.cfm?recnum=5836.http://www.catholicculture.org/docs/doc_view.cfm?recnum=5836

¹⁵² See Interview with Cardinal Lopez Trujillo, *supra* note 147, at <http://www.catholic.org/featured/headline.php?ID=488>.<http://www.catholic.org/featured/headline.php?ID=488>

¹⁵³ See *id.* <http://www.catholic.org/featured/headline.php?ID=488>

¹⁵⁴ See <http://www.catholic.org/featured/headline.php?ID=488>. He references the graph showing an almost parallel increase of condoms distributed by USAID and the spread of HIV/AIDS from 1984 - 2003, in the Population Research Institute Review (May-Jun 2003), page 10, summarizing data from the Harvard School of Public Health, UNAIDS, and the Kaiser Family Foundation. See *id.*

¹⁵⁵ See *Family Values Versus Safe Sex*, *supra* note 147, at http://www.catholicculture.org/docs/doc_view.cfm?recnum=5836.
http://www.catholicculture.org/docs/doc_view.cfm?recnum=5836

sex partners than condoms.”¹⁵⁶ As a result of condoms taking a back-seat to moral behavior, he notes that Kampala has achieved an 80% HIV prevalence rate, which no other sub-Saharan country has matched.¹⁵⁷ He also contrasts the much higher prevalence of HIV in Thailand than the Catholic Philippines, explaining the difference by the Philippines’ low rates of condom promotion and staunch opposition from the Church and government against promiscuity. In further support of his anti-condom views, Lopez Trujillo cites a grouping of US doctors who accused the CDC of covering up its own research showing the ineffectiveness of condoms to prevent the transmission of sexually transmitted diseases.”¹⁵⁸ Also, Cardinal Lopez Trujillo claimed that condoms have tiny holes through which the HIV virus can pass through.¹⁵⁹

The Catholic Church has opposed condoms and contraception in general as it believes that every act of sex should be open to conception.¹⁶⁰ Contraception and condoms separate sex from procreation and signify a society where life is not inherently valued. Thus, contraception and abortion are linked as pillars of a “culture of death.” One of the doctors¹⁶¹ of the Catholic Church, St Augustine, condemned contraception as against natural law saying, “[i]ntercourse even with one’s legitimate wife is unlawful and wicked where the conception of the offspring is prevented. Onan, the son of Juda, did this and the Lord killed him for it.”¹⁶²

¹⁵⁶See <http://www.catholicculture.org/docs/doc.view.cfm?recnum=5836>*id.*

¹⁵⁷USAID, PROJECT LESSONS LEARNED, Case Study, Sept. 2002, at 11 (Table: Simulation of Uganda HIV Dynamics: Potential impact of similar behavior change in South Africa by 2000). On the same page, the Case Study report adds, “[i]t must be remembered that many of the elements of Uganda’s response, such as high-level political support, decentralized planning, and multi-sectoral responses, do not affect HIV infection rates directly. Sexual behavior itself must change in order for seroincidence to change. According to [the author of the study,] the effect of HIV prevention interventions in Uganda (particularly partner reduction) during the past decade appears to have had a similar impact as a potential medical vaccine of 80 percent efficacy.” *Id.*

¹⁵⁸This is the same study that Rep. Coburn requested the CDC to conduct. See Interview with Cardinal Lopez Trujillo, *supra* note 147, at <http://www.catholic.org/featured/headline.php?ID=488>.

¹⁵⁹Cardinal Lopez Trujillo stated: “Two years later, the same reporter wrote in an article, 4 *Popular Condoms Leak AIDS Virus in Clinical Tests*, that ‘[f]our of the nation’s most popular condom brands permitted the AIDS virus to escape in laboratory tests conducted for UCLA, prompting researchers to warn users they should not assume that all condoms work equally well in preventing spread of the disease. . . .’ Overall, among the thousands of condoms tested, the study found that 0.66% of condoms—more than one of every 200—failed, either allowing water or air to escape, breaking in tensile strength tests or leaking the AIDS virus.” Cardinal Lopez Trujillo, *Article*, LOS ANGELES TIMES, at ?? (Sept. 12, 1989).

¹⁶⁰See ENCYCLICAL HUMANAЕ VITAE, *Of Human Life*.

¹⁶¹A doctor of the Catholic Church is a key contributor to its doctrine.

¹⁶²PIUS XI, ENCYCLICAL LETTER NO. 54, CASTI CONNUBII, ON CHRISTIAN MARRIAGE, at n. 45, *citing* ST. AUGUST., *De coniug. adult.*, lib. II, n. 12, *Gen*, XXXVIII, at 8-10.

Pope Pius XI also condemned contraception in his encyclical *Casti Connubii* (December 31, 1930) stating that “the conjugal act is destined primarily by nature for the begetting of children, those who in exercising it deliberately frustrate its natural power and purpose sin against nature and commit a deed which is shameful and intrinsically vicious.”¹⁶³

Notwithstanding these moral teachings against condoms and contraception, the Catholic Church permits a limited “defense” of necessity, similar to the criminal law defense of necessity.¹⁶⁴ Catholic Cardinal Godfried Danneels of Belgium opined that if a person with HIV insisted on having sex, then he must use a condom, or sin by risking transmission of a potentially fatal illness.¹⁶⁵ Another Cardinal, Javier Lozano Barragan of Mexico, stated that condom use was sometimes acceptable, as when a wife was forced to accept her HIV-positive husband’s sexual advances.¹⁶⁶ His rationale was that preserving life is paramount. As an illustration of the complexities of a necessity defense, the Rev. Prof. Angel Rodriguez Luno, a moral theologian at the Pontifical University of the Holy Cross in Rome, gave two examples.¹⁶⁷ On one hand, she noted that a Catholic priest cannot promote condoms in school, for this would be incitement of their use. But on the other hand, she went on to find that if the same priest was working as a social worker with prostitutes, advising them to use condoms to avoid contracting AIDS, he is not encouraging an evil, but rather lessening an evil that is already occurring. Rev. Prof. Rodriguez Luno acknowledges that a “lesser of two evils” defense to condom use is supported by church documents going back 200 years.¹⁶⁸

¹⁶³PIUS XI, *supra* note 164.

¹⁶⁴Linked to the “necessity defense,” is the idea of the “lesser of two evils.” For example, according to Rev. Charles Curran, a Catholic Professor of Human Values at Southern Methodist University, in the 1960s, the Vatican allowed nuns working in the Congo who were at risk of rape to take contraceptive pills to prevent pregnancy. See Winfield, *supra* note 147, at <http://www.aegis.com/news/ap/2004/AP040334.html>.

¹⁶⁵See <http://www.aegis.com/news/ap/2004/AP040334.html> *id.*

¹⁶⁶See *id.*

¹⁶⁷See *id.*

¹⁶⁸See *id.*

To little avail, local groups of Catholic Bishops have strived to formulate policy that balances a strong condemnation of contraception against a need to defend against HIV. In 2001, despite soaring AIDS infection rates, the Southern African Catholic Bishops' Conference condemned HIV-prevention programs that encouraged condom use.¹⁶⁹ The Conference stated the following:

[the Bishops] regard the widespread and indiscriminate promotion of condoms as an immoral and misguided weapon in our battle against HIV/AIDS for the following reasons: [1] The use of condoms goes against human dignity. [2] Condoms change the beautiful act of love into a selfish search for pleasure — while rejecting responsibility. [3] Condoms do not guarantee protection against HIV/AIDS. [4] Condoms may even be one of the main reasons for the spread of HIV/AIDS. Apart from the possibility of condoms being faulty or wrongly used they contribute to the breaking down of self-control and mutual respect.¹⁷⁰

The Conference would permit married couples where one partner is HIV-positive to use condoms if they avoid sex while the woman is ovulating, so that condoms would not prevent the creation of life.¹⁷¹

Bishop Kevin Dowling of South Africa has urged the conference to be more tolerant of condom usage.¹⁷² In an article in the US Catholic Magazine, he notes that there are thirty million people living with HIV in sub-Saharan Africa, many of which are abused and vulnerable women.¹⁷³ He suggests that the use of condoms, not as contraception, but to prevent HIV infection deserves serious consideration.¹⁷⁴ Such promotion, he argues, does not go against traditional church teaching which is limited to the topic of contraceptive action.

Rather, the use of condoms to deal with AIDS is,

¹⁶⁹ See *id.*

¹⁷¹ See *A Message of Hope*, *supra* note 172.

¹⁷² Winfield, *supra* note 147, at <http://www.aegis.com/news/ap/2004/AP040334.html>; See also US CATHOLIC MAG., November 2003, at 20-25, available at <http://www.uscatholic.org/2003/11/USCathHIV.pdf>.

¹⁷³ Bishop Dowling opens his story with a heart-rending account of Lydia, a 22 year old prostitute dying of AIDS. US CATHOLIC MAG., *supra* note 174, at 21, available at <http://www.uscatholic.org/2003/11/USCathHIV.pdf>.

¹⁷⁴ See *id.*

skin to the moral teaching that one can remove a diseased fallopian tube containing an ectopic pregnancy since it was done for health reasons, thus allowing the secondary effect of abortion of the fetus. Or doctors can prescribe birth-control pills to stop dysfunctional uterine bleeding or to correct irregular menstrual cycles.¹⁷⁵

The Church, he says, citing the 1968 Papal Encyclical *Humane Vitae*,¹⁷⁶ regards these actions as licit, even though their effect is the suppression of fertility.¹⁷⁷ Thus, he argues, “[i]f one were to use [condoms] to promote health – life rather than death – then one is not grudgingly accepting one evil to prevent a greater one but rather one is promoting something that in the context is not simply good but a moral imperative.”¹⁷⁸

Famously, Anglican Archbishop Desmond Tutu endorsed condom use on South African Television as a means of combating the HIV/AIDS rate that is epidemic in sub-Saharan Africa.¹⁷⁹ Tutu said that the Catholic Church must be realistic in the matter of condom use, adding that it was irresponsible for the Church to suggest that sex education and condom dissemination promoted promiscuity.¹⁸⁰

The US Catholic Conference, an association of bishops, has criticized condom promotion as safer sex as far back as 1987. It notes,

Abstinence outside of marriage and fidelity within marriage as well as the avoidance of intravenous drug abuse are the only morally correct and medically sure ways to prevent the spread of AIDS. So-called safe sex practices are at best only partially effective . . . As the National Academy of Sciences has noted in its study of AIDS, ‘many have argued that it is more accurate to speak in terms of ‘safer’ sex because the unknowns are still such that it would be irresponsible to certify any particular activity as absolutely safe.’¹⁸¹

¹⁷⁶ *See id.*

¹⁷⁷ *See* <http://www.uscatholic.org/2003/11/USCathHIV.pdf> *id.*

¹⁷⁸ Winfield, *supra* note 147, at <http://www.aegis.com/news/ap/2004/AP040334.html>; <http://www.aegis.com/news/ap/2004/AP040334.html>

See also US CATHOLIC MAG., *supra* note 174, at 21, *available at* <http://www.uscatholic.org/2003/11/USCathHIV.pdf>; <http://www.uscatholic.org/>

¹⁷⁹ MCNEIL, *supra* note 30, at ch.2, *available at*

<http://www.fhi.org/en/RH/Pubs/booksReports/latexcondom/condomaccept.htm>.

¹⁸⁰ *Id.*

The issue of the legitimacy of condoms for AIDS prevention, as opposed to contraception, is still not settled. The Vatican has not issued an encyclical, which is its most authoritative form of teaching and is held out to the congregation as morally infallible, specifically about condoms and AIDS.¹⁸² Interviews with several churchmen and theologians remarked that the issue was still being debated within the Vatican and is still unresolved.¹⁸³

Coburn's Attempt to Put Warning Labels on Condoms

The “safe sex vs. abstinence” political battle has extended to the FDA’s regulation of condom labeling. Social conservatives argue that condoms do not protect against STDs and that FDA-mandated condom labeling should include warnings to this effect. In 2000, in an effort to require such labels, then-Rep Tom Coburn¹⁸⁴ (R-OK), a Catholic obstetrician and opponent of government-funded family planning programs, tried unsuccessfully¹⁸⁵ to amend Breast and Cervical Cancer Treatment Act¹⁸⁶ to mandate labeling on condoms that cautioned that condoms provide “little or no protection” against an extremely common STD, human papillomavirus (HPV).¹⁸⁷ In addition, condom labels would have to state that HPV was the cause of cervical cancer.¹⁸⁸ Also, federally funded sex education campaigns would have to issue similar warnings.¹⁸⁹ Coburn pushed for the inclusion of the mandatory warning provisions in a bill that was primarily intended to extend Medicaid coverage for breast and cervical cancer treatment for low-income women diagnosed under a CDC-run early detection program.¹⁹⁰ Coburn stated that the link between HPV and cervical cancer was

¹⁸²Winfield, *supra* note 147, at <http://www.aegis.com/news/ap/2004/AP040334.html><http://www.aegis.com/news/ap/2004/AP040334.html>.

¹⁸³*See id.*

¹⁸⁴*See* Senator Tom Coburn, Homepage, at http://www.senate.gov/pagelayout/senators/one_item_and_teasers/coburn.htm (last visited May 24, 2005).

¹⁸⁵Rep Coburn was successful in getting his warning on the House version of the bill, but not in its final enacted form.

¹⁸⁶The legislative history of the bill can be seen online at <http://thomas.loc.gov/cgi-bin/query/z?c106:H.R.+4386>.

¹⁸⁷[Do some research and cite this]

¹⁸⁸House approves labeling condoms with warnings about HPV infection. AIDS Policy and Law. May 26, 2000.

¹⁸⁹House approves labeling condoms with warnings about HPV infection. AIDS Policy and Law. May 26, 2000.

¹⁹⁰House approves labeling condoms with warnings about HPV infection. AIDS Policy and Law. May 26, 2000.

as clear as the link between smoking and lung cancer, but less than one third of Americans are familiar with the disease.¹⁹¹ He argued that Congress was obliged to “educate the American people about the risk of contracting this dreaded virus,” adding that warning labels would “save lives and end the conspiracy of silence surrounding HPV.”¹⁹² Specifically, he pushed to insert the following provision into the law:¹⁹³

Part B of title III of the Public Health Service Act (42 U.S.C. 243 et seq.) is amended by inserting after section 317G the following section: . . .

(1) **IN GENERAL.**—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall— . . .

(c) **CONDOM EFFECTIVENESS; EDUCATION.**—The Secretary shall require that the Department of Health and Human Services and all contractors, grantees, and subgrantees of such Department specifically state the effectiveness or lack of effectiveness of condoms in preventing the transmission of HPV, herpes, and other sexually transmitted diseases in all informational materials related to condoms or sexually transmitted diseases that are made available to the public. The Secretary shall assure that such information is made available to relevant operating divisions and offices of the Department of Health and Human Services. This subsection shall be effective within 6 months of the date of its enactment.”. . .

SEC. 4. LABELING OF CONDOMS WITH RESPECT TO HUMAN PAPILLOMAVIRUS.

(a) **IN GENERAL.**—Section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352) is amended by adding at the end the following: . . .

(u) If it is a condom, unless its label and labeling bear information providing that condoms do not effectively prevent the transmission of the human papillomavirus and that such virus can cause cervical cancer.

In May, the House voted 421-1 to pass the bill with these provisions included.¹⁹⁴ The Senate, however, removed the provision from its version of the bill and sent it back to the House in early October.¹⁹⁵ Apart from opposition within the Senate, there was also opposition from several medical groups, including the American Cancer Society and the American College of Obstetricians and Gynecologists, as well as the

¹⁹¹House approves labeling condoms with warnings about HPV infection. AIDS Policy and Law. May 26, 2000.

¹⁹²House approves labeling condoms with warnings about HPV infection. AIDS Policy and Law. May 26, 2000. Four types of HPV are linked to 80% of cervical cancer deaths, which kills more than 4,500 US women each year. Current tests are costly and error-prone, and annual Pap smear screenings are the best way of detecting the presence of precancerous cells. Condoms may not work to prevent HPV as the virus is present on areas not covered by condoms, including stomach and groin skin. Infections can spread from there to the cervix.

¹⁹³House of Representatives, May 09, 2000. on page H2689.

¹⁹⁴*Condom-Labeling plan is deleted from cervical cancer bill*, AIDS POLICY AND LAW (Oct. 27, 2000) [hereinafter *Condom-Labeling plan is deleted*], citing, AIDS LAW AND POLICY 1 (May 26, 2000).

¹⁹⁵*Condom-Labeling plan is deleted*, supra note 196.

Clinton administration who feared the provision would discourage condom use.¹⁹⁶ On October 12, 2000, the House agreed to strip the provisions requiring condom warning labels from the bill.¹⁹⁷

In the final version of the law, PL 106-554 the “Breast and Cervical Cancer Treatment Act,” Coburn and his allies in Congress inserted provisions requiring the Centers for Disease Control and the FDA to educate the public about HPV.¹⁹⁸ Part of the law also required that government-sponsored educational materials shall “contain medically accurate information regarding the effectiveness or lack of effectiveness of condoms in preventing the STD the materials are designed to address.”¹⁹⁹ The CDC was given until December 21, 2003 to issue a report “including a detailed summary of the significant findings and problems and best strategies to prevent future infections, based on available science.”²⁰⁰

Coburn’s efforts, according to Heather Boonstra of the Guttmacher Institute, were part of “a campaign to disparage the value of condom use . . . the cornerstone of an effort to undermine the very notion of sexual risk-reduction, or ‘safer sex.’”²⁰¹ Experts in HIV and STD prevention were concerned that the conservative effort to promote chastity by cautioning the public as to condoms’ inadequacies would backfire.²⁰² Decreased public confidence in condoms might lead to decreased condom use, which would lead to increased STD and HIV infection rates if sexual behavior was otherwise unaffected. Of course, if abstinence advocates were correct and frightening the public into accepting the alleged inadequacy of the condom to assure “safer sex” led to more abstinence and monogamy, then STD and HIV infection rates might fall. Disease prevention experts nevertheless maintain that a “conclusion that correct condom use does not offer a high degree of

¹⁹⁶ *Id.*

¹⁹⁷ *Id.*

¹⁹⁸ [Cite]; see Boonstra, *supra* note 136, at 1, at <http://www.guttmacher.org/pubs/tgr/06/1/gr060101.pdf>.

¹⁹⁹ See Boonstra, *supra* note 136, at 1, at <http://www.guttmacher.org/pubs/tgr/06/1/gr060101.pdf>.

²⁰⁰ See *id.*

²⁰¹ See *id.*

²⁰² See *id.*

protection against the vast majority of STDs, not to mention HIV and unintended pregnancy, is simply not warranted by the science. . . .”²⁰³ In addition, these experts say that condom critics are “selectively citing and intentionally misrepresenting” findings from the National Institute of Health (“NIH”) workshop report to support their case.²⁰⁴

June 2000: NIH Workshop Conducted by the FDA, NIH, USAID, and CDC

As required by federal law,²⁰⁵ in June 2000 the National Institute of Allergy and Infectious Diseases, part of the NIH, convened a workshop entitled “Scientific Evidence on Condom Effectiveness for Sexually Transmitted Disease Prevention.”²⁰⁶ The workshop was tasked with answering the following specific question: “What is the scientific evidence on the effectiveness of latex male condom-use to prevent STD transmission during vaginal intercourse?”²⁰⁷ Over 180 persons attended the workshop including twenty-eight experts²⁰⁸ who subsequently wrote the report that was presented to Congress. The report examined the published peer-reviewed scientific data²⁰⁹ on the effectiveness of condoms in preventing eight specific STDs:²¹⁰ HIV, gonorrhea, Chlamydia, syphilis, chancroid, trichomoniasis, genital herpes, and human papillomavirus.²¹¹ The meeting and report, however, only discussed the scientific literature and were explicitly “not intended to make public health policy recommendations regarding the role of condoms in HIV and STD prevention policy and program.”²¹²

²⁰³ *See id.*

²⁰⁴ *See* <http://www.guttmacher.org/pubs/tgr/06/1/gr060101.pdf> *id.*

²⁰⁵ *See id.*

²⁰⁶ *Scientific Evidence on Condom Effectiveness, supra* note 25, available at <http://www.niaid.nih.gov/dmid/stds/condomreport.pdf>.

²⁰⁷ *Id.* at i.

²⁰⁸ *See id.* at i Appendix A <http://www.niaid.nih.gov/dmid/stds/condomreport.pdf>.

²⁰⁹ *Id.* One hundred thirty-eight peer-reviewed scientific articles published before June 2000 were compiled and reviewed, and were cited in the report’s bibliography. *See id.* at ii Appendix B, Bibliography, 1-14. <http://www.niaid.nih.gov/dmid/stds/condomreport.pdf>

²¹⁰ *Id.* at i.

²¹¹ *Id.*

²¹² <http://www.niaid.nih.gov/dmid/stds/condomreport.pdf> *Id.*

The report starts by noting that STDs are “common, important and preventable” diseases in the United States with considerable social impact, including death, illness, infertility, adverse pregnancy outcomes²¹³ and lost work and health care costs. Over 65 million people in the US are living with an STD, most of which are incurable viral infections and over 15 million new infections occurs each year.²¹⁴ Over 493,000 individuals have died from AIDS, and over 800,000 people are living with HIV.²¹⁵ In particular, and in reference to the congressional inquiry and proposed condom safety warning,²¹⁶ the report notes that HPV can cause cervical and anogenital cancer.²¹⁷ The report then notes that in the absence of STD vaccines and effective microbicides²¹⁸ there are only three ways for reducing the risk of STD acquisition: (i) not having sex, (ii) lifelong monogamy among uninfected couples, and (iii) using condoms.

In discussing the condom literature, the report distinguishes between condom efficacy and effectiveness.²¹⁹ Efficacy refers to the protection that “users received under ideal circumstances” that is when condoms are used “correctly and consistently,” while effectiveness refers to the protection users receive under actual or typical conditions of use.²²⁰ Efficacy primarily depends on the characteristics and properties of the condom, whereas effectiveness also depends on user behavior and attributes.²²¹ A key issue in interpreting research and in determining whether it is prudent to promote or discourage condom use is disentangling these two measures of protection. Thus, a key source of condom failure to prevent disease transmission might be incorrect or inconsistent use, such as failing to use a condom for each act of sex from start to finish. If this is the case, the increased funding for condom promotion and safer sex education, rather than attacking

²¹³ *Id.* (including miscarriage, entopic pregnancy, stillbirth, intrauterine growth retarded and transmission of illness to the baby).<http://www.niaid.nih.gov/dmid/stds/condomreport.pdf>

²¹⁴ <http://www.niaid.nih.gov/dmid/stds/condomreport.pdf> *Id.*

²¹⁵ *Id.*

²¹⁶ Note that in the House version of the bill, then-Rep. Coburn has proposed a warning that 1) condoms don’t prevent HPV transmission, and 2) HPV leads to cancer of the cervix.

²¹⁷ <http://www.niaid.nih.gov/dmid/stds/condomreport.pdf> *Id.*

²¹⁸ *Id.*

²¹⁹ *Id.* at 3.

²²⁰ <http://www.niaid.nih.gov/dmid/stds/condomreport.pdf> *Id.*

²²¹ *Id.* at 4.

condoms, could help reduce STD transmission. On the other hand, denigrating condom effectiveness might lead to inconsistent or no use which would reduce the net effect on STD prevention.

The best method to assess protection is through a prospective randomized controlled clinical trial, however, such a method cannot be employed due to the ethical issues involved with exposing people to a high risk of STD acquisition.²²² The published studies are a poor substitute. The studies that the expert panel were able to review were fraught with various of flaws, including the following: (i) looking to clinical manifestations of disease, rather than precise diagnostic tests; (ii) insufficient subjects to assure statistical accuracy; (iii) study populations, such as commercial sex workers, were not representative of the general population; (iv) gender differences were ignored in the studies; (v) methods to detect infection were poor; (vi) failure to elicit full information on condom use behavior and sexual history; (vii) imprecise quantification of condom use, including breakage and slippage events; and (viii) inability to document exposure to disease during condom use.²²³

The panel found that the data most strongly supported the effectiveness of condoms in preventing HIV infection.²²⁴ The data²²⁵ show that among couples²²⁶ who report always using condoms, there is are 0.9 infections per one hundred persons per year, whereas among those couples that do not use condoms, there are 6.7 infections per one hundred persons per year.²²⁷ Thus, always using condoms (a component of complete and consistent condom use) reduces the risk of HIV transmission by 85%. There was also strong data available for gonorrhea, with various studies supporting a 40-75% relative reduction in risk of a man

²²²*Id.* at 5-6.<http://www.niaid.nih.gov/dmid/stds/condomreport.pdf>

²²³*Id.*<http://www.niaid.nih.gov/dmid/stds/condomreport.pdf>

²²⁴*Id.* at i, 13.

²²⁵*Id.* at 14.; See also note 28 on page 3 of Appendix B, listing, Davis KR and Weller SC. The Effectiveness of Condoms in Reducing Heterosexual Transmission of HIV. *Fam Plann Perspect.* 1999; 31(6): 272-279.

²²⁶Couples where one has HIV and the other does not.

²²⁷*Scientific Evidence on Condom Effectiveness*, *supra* note 25, at 15, available at <http://www.niaid.nih.gov/dmid/stds/condomreport.pdf>.

acquiring gonorrhea from an infected woman.²²⁸ Only one study specifically looked at the protective effect of condoms against the transmission of Chlamydia to men, which found a 0% (0/72) infection rate in men consistently using a condom, as compared with a 6.3% (16/251) infection rate in men who did not always use a condom.²²⁹ Taken as a whole, the studies concerning Chlamydia infections do “not allow an accurate assessment of the degree of potential protection against [infection] offered by correct and consistent condom use.”²³⁰ With regard to trichomoniasis, one limited study showed a 30% protective effect for women, but as with chlamydia, the data does not allow an accurate assessment of risk reduction associated with condom use.²³¹

Genital ulcerative diseases examined included genital herpes, syphilis, and chancroid, where infectious agents are present in sores or ulcers, as well as in human secretions.²³² The studies show that condoms may work to reduce the risk of disease transmission if they fully cover the site where sores and ulcers are present. With regard to genital herpes, the most common ulcerative disease, five studies²³³ showed some reduction in risk with condom use.²³⁴ Limitations in the design of these studies, however, and a lack of “primary outcome measurements” meant that no conclusions could be drawn as to the effectiveness of condoms to prevent the transmission of genital herpes when correctly and consistently used.²³⁵ Chancroid is a very rare disease in the US, with just 1000 cases each year. Only two studies were relevant to assessing prevention rates, but neither included microbiological confirmation of the disease, therefore conclusions as to condom effectiveness could not be drawn.²³⁶ With regard to syphilis, another rare disease,²³⁷ various studies showed condom

²²⁸ *Id.* <http://www.niaid.nih.gov/dmid/stds/condomreport.pdf>

²²⁹ *Id.* at 17. <http://www.niaid.nih.gov/dmid/stds/condomreport.pdf>

²³⁰ *Id.* <http://www.niaid.nih.gov/dmid/stds/condomreport.pdf>

²³¹ *Id.* at 18. <http://www.niaid.nih.gov/dmid/stds/condomreport.pdf>

²³² *Id.* <http://www.niaid.nih.gov/dmid/stds/condomreport.pdf>

²³³ *Id.*

²³⁴ *Id.*

²³⁵ *Id.* at 20.

²³⁶ *Id.* at 21. <http://www.niaid.nih.gov/dmid/stds/condomreport.pdf>

²³⁷ *Id.* (a rate of 2.2 / 100,000). <http://www.niaid.nih.gov/dmid/stds/condomreport.pdf>

effectiveness, but poor study design prevented the panel from properly assessing the degree of risk reduction afforded by correct and consistent condom use.²³⁸

HPV infection, singled out initially in the bill that Rep Coburn proposed,²³⁹ could not be neatly categorized in the ulcerative or discharge STD dichotomy that the panel used to classify other STDs.²⁴⁰ Currently, about twenty million adults in the United States are infected with genital HPV, while more than 50% of sexually active adults have been infected in the past.²⁴¹ “Significant majorities” of these infections are “asymptomatic, unrecognized and benign.”²⁴² Types of genital HPV infections, denoted as high-risk, are associated with cancer of the cervix, as well as anal and genital cancer and pre-cancerous tissue changes of the cervix. Other types are not associated with cancer, but cause genital warts and flat lesions on the cervix and low-grade Pap smear abnormalities.²⁴³ HPV infections occur inside the genitals and also infect the skin surrounding the genitals and may be transmitted by the hands and nails of an infected person.²⁴⁴ Thus, while transmitted by sexual contact, HPV can be also be transmitted by areas not covered or protected by the condom, suggesting that condoms at best only partly reduce the risk of disease transmission.²⁴⁵

Of the twenty-four papers the panel initially considered, it found the sixteen were sufficient for further discussion in its report.²⁴⁶ None of the four studies which examined condom use as a factor in reducing the

²³⁸ *Id.* at 23.<http://www.niaid.nih.gov/dmid/stds/condomreport.pdf>

²³⁹ *Id.*

²⁴⁰ *Id.* (“Genital HPV infection cannot be classified exclusively as an STD which is transmitted by genital secretions or which is transmitted through contact with open sores. HPV is probably transmitted through contact with infected epithelial surfaces and/or genital fluids containing infective viruses.”). <http://www.niaid.nih.gov/dmid/stds/condomreport.pdf>

²⁴¹ *Id.*, citing <http://www.niaid.nih.gov/dmid/stds/condomreport.pdf> W. CATES, AMERICAN SOCIAL HEALTH ASSOCIATION PANEL, *Estimates of the incidence and prevalence of sexually transmitted disease in the United States* in SEXUALLY TRANSMITTED DISEASES, at ch. 26, 52-57 (suppl. 1999).

²⁴² N.B. Kiviat et al., *Cervical neoplasia and other STD-related genital tract neoplasias* in SEXUALLY TRANSMITTED DISEASES, at ch. 59 (3rd ed. Holmes et al., eds., McGraw-Hill 1999).

²⁴³ *Scientific Evidence on Condom Effectiveness*, *supra* note 25, at 24, available at <http://www.niaid.nih.gov/dmid/stds/condomreport.pdf>. <http://www.niaid.nih.gov/dmid/stds/condomreport.pdf>

²⁴⁴ *Id.* <http://www.niaid.nih.gov/dmid/stds/condomreport.pdf>

²⁴⁵ *Id.* <http://www.niaid.nih.gov/dmid/stds/condomreport.pdf>

²⁴⁶ *Id.* The sixteen studies included one cohort study, four cross-sectional studies and eleven case-control studies. *Id.*

risk of HPV transmission found any risk reduction.²⁴⁷ In specifically analyzing genital warts, a subtype of HPV infections, two retrospective studies found that condoms gave some risk reduction of 30% and 52% for warts in men.²⁴⁸ In women, one study examining the protective effect of condoms showed a 30% risk reduction in acquiring genital warts, but this was not statistically significant. Ten studies in women measured the risk reduction in acquiring dysphasia and cancer of the cervix with the following results: (i) six showed condom users having a statistically significant reduction in risk, (ii) two did not show statistically significant risk reductions, and (ii) two showed no evidence of even partial protection.²⁴⁹

In reviewing these studies, the panel reported difficulties in achieving the congressionally mandated “coherent and actionable interpretation.”²⁵⁰ Studies differed not only in their methodology and measured outcomes, but also in results for those with similar objectives.²⁵¹ In addition, most of the studies did not track condom use carefully.²⁵² Retrospective studies suffered from uncertainties as to how accurately subjects reported their condom use behavior for several years back. The panel concluded that “there was no evidence that condom use reduced the risk of HPV infection, but study results did suggest that condom use might afford some reduction in risk of HPV-associated diseases, including genital warts in men and cervical dysphasia in women.”²⁵³

The panel concluded by asking for more research, noting the need for “better-designed studies to assess condom effectiveness for STD prevention,”²⁵⁴ despite the difficulties in designing a study that is both scientifically valid and ethically sound.²⁵⁵ The panel found that their ability to draw conclusions as to the

²⁴⁷ *Id.* at 25.<http://www.niaid.nih.gov/dmid/stds/condomreport.pdf>

²⁴⁸ *Id.*<http://www.niaid.nih.gov/dmid/stds/condomreport.pdf>

²⁴⁹ *Id.*<http://www.niaid.nih.gov/dmid/stds/condomreport.pdf>

²⁵⁰ *Id.*<http://www.niaid.nih.gov/dmid/stds/condomreport.pdf>

²⁵¹ *Id.*<http://www.niaid.nih.gov/dmid/stds/condomreport.pdf>

²⁵² *Id.*<http://www.niaid.nih.gov/dmid/stds/condomreport.pdf>

²⁵³ *Id.* at 26.<http://www.niaid.nih.gov/dmid/stds/condomreport.pdf>

²⁵⁴ *Id.*<http://www.niaid.nih.gov/dmid/stds/condomreport.pdf>

²⁵⁵ *Id.* Ethical considerations discussed by the panel included: 1) Timely diagnosis and treatment of research subjects with curable STDs, and provision of the best available preventive services, including condoms and condom counseling, to couples

protective effect of condoms was, at best,

significantly hampered by the lack of adequate study design in most, but not all studies under review. Exceptions to this generalization are the studies that demonstrated that the consistent use of male condoms protects against HIV/AIDS transmissions between women and men. Gonorrhea transmission to men was also found to be reduced with consistent and correct condom use. Better research is necessary to adequately answer the question about condom effectiveness in reducing the risk of acquiring other STDs.²⁵⁶

Of course, the panel noted that “inadequacies of the evidence available . . . should not be interpreted as proof of the adequacy or inadequacy of the condom.”²⁵⁷

Responses to the NIH Studies

On July 19, 2001,²⁵⁸ Coburn issued a press release, “Safe Sex Myth Exposed by Scientific Report; Condoms Do Not Prevent Most STDs.”²⁵⁹ His report commended the NIH report for “finally exposing the ‘safe’ sex myth for the lie that it is.”²⁶⁰ While no longer a Congressman, Coburn was now Co-chair of the Presidential Advisory Council of HIV/AIDS,²⁶¹ and advocated that “the American people should know the truth of condom ineffectiveness.”²⁶² He argues that the only way to achieve safe sex is to continue promoting policies favoring abstinence.²⁶³ In an interview he gave to the Advocate, Coburn said he believed in condoms to prevent HIV infection, but he qualified this belief reiterating his belief in “informed consent about the

where one member has an incurable STD; 2) All subjects must be told of and given access to the “best available preventive measures”; 3) As the consistent use of condoms has been shown to reduce the risk of acquiring some STDs, research subjects cannot ethically be randomized into condom use and non-use groups; denying persons at risk of STDs from an effective preventive device is tantamount to withholding available treatment. *Id.* at 27.<http://www.niaid.nih.gov/dmid/stds/condomreport.pdf>

²⁵⁷*Id.* at ii.<http://www.niaid.nih.gov/dmid/stds/condomreport.pdf>

²⁵⁸See Jan LaRue, Esq., CONCERNED WOMAN FOR AMERICA, *Porn Industry Plagued by HIV and DOJ*, Apr. 29, 2004, at <http://www.cwfa.org/printerfriendly.asp?id=5585&department=legal&categoryid=pornography>.

²⁵⁹*Id.*

²⁶⁰See Boonstra, *supra* note 136, at 2, at <http://www.guttmacher.org/pubs/tgr/06/1/gr060101.pdf>.<http://www.guttmacher.org/pubs/tgr/06/1/gr060101.pdf>

²⁶¹See Louis W. Sullivan, M.D. & Thomas A. Coburn, M.D., PRESEDENTIAL ADVISORY COUNSEL ON HIV/AIDS, Letter, May 1, 2002, at http://www.pacha.gov/actions/correspondence/pres/corr_pres5_02/corr_pres5_02.html.

²⁶²*Id.*

²⁶³*Id.*

effectiveness of condoms” stating, “[a]sk any expert you want, and they will tell you that condoms are not always effective, and people have a right to know this.”²⁶⁴

Another pro-abstinence group, the Medical Institute for Sexual Health, summarized and analyzed the NIH report. It concluded that condoms are so inherently unreliable that the government should not promote their use for STD prevention.²⁶⁵ Rather, the government should advance marriage and abstinence as lifestyles that effectively prevent STDs.²⁶⁶ A consortium of groups, specifically the Physicians’ Consortium, accused the CDC for concealing research on condom ineffectiveness.²⁶⁷ The Consortium, with nearly 10,000 physicians represented, stated that the CDC has “systematically hidden and misrepresented vital medical information regarding the ineffectiveness of condoms to prevent the transmission of STDs.”²⁶⁸ Further, “[t]he CDC’s refusal to acknowledge clinical research has contributed to the massive STD epidemic.”²⁶⁹

Attacks on condom efficacy have reached at least some people resulting in a decrease in condom use during risky sex. According to Bill Smith, Director of Public Policy for the Sexuality Information and Education Council of the United States (SIECUS),

Time and time again, we learn in focus groups with young people that they are being taught that condoms don’t work, that HIV can get through holes in them. So they don’t even bother using them. While it is true that condoms are not effective 100% of the time, we know for a fact that they are effective against the transmission of HIV.²⁷⁰

The CDC initially responded to the attack on condom efficacy by withdrawing a fact sheet on condom

²⁶⁴ *Bush’s abstinence man: Tom Coburn, head of the president’s AIDS advisory council, preaches his preference for just say no over condom-based HIV education*, THE ADVOCATE, May 28, 2002, at http://www.findarticles.com/p/articles/mi_m1589/is_2002_May_28/ai_86128322 [hereinafter *Bush’s abstinence man: Tom Coburn*].

²⁶⁵ *Id.*

²⁶⁶ See Boonstra, *supra* note 136, at 1, at <http://www.guttmacher.org/pubs/tgr/06/1/gr060101.pdf>. <http://www.guttmacher.org/pubs/tgr/06/1/gr060101.pdf>

²⁶⁷ See PURE LOVE CLUB, Chastity Q & A, at <http://www.pureloveclub.com/chastity/index.php?id=7&entryid=284> (last visited May 24, 2005)

²⁶⁸ *See id.*

²⁶⁹ *See id.* <http://www.pureloveclub.com/chastity/index.php?id=7&entryid=284>

effectiveness²⁷¹ from its public website in October 2002.²⁷² A group of House Democrats, led by Henry Waxman, on October 21, 2003, wrote to the then Secretary of Health and Human Services explaining that he was concerned that “scientific information that doesn’t fit the Administration’s political agenda is being suppressed.”²⁷³ In addition to removing the information about condoms, the National Cancer Institute had also removed a page on its site denying any link between breast cancer and abortion, as well as a CDC page that included advice on helping at-risk children avoid HIV and STD infection.²⁷⁴

Condom opponents continued to gear-up attacks on condom use, trying to get HPV warning labeling on condoms. On February 12, 2004, Indiana Representative Souder, Chairman of the Subcommittee on Criminal Justice, Drug Policy and Human Resources, wrote to FDA Commissioner Mark McClellan to express his concern regarding condom labeling.²⁷⁵ The letter asked the Commissioner to look into revising what he called inaccurate condom labeling as to HPV prevention in light of the CDC Report. Rep Souder cited recent research, including a meta-analysis of research studies published in the journal Sexually Transmitted Diseases²⁷⁶ that showed no consistent evidence of the protective effect of condom use on HPV DNA detection.²⁷⁷ Souder also noted that some studies examined actually indicated a slightly increased risk of lesions.²⁷⁸ Rep Souder demanded action stating the following:

²⁷¹A comparison of the two versions of the CDC website in connection with condoms can be viewed online. The original website: CDC, *Condoms and Their Use in Preventing HIV Infection and Other STDs* (Sept. 1999) is available on-line at www.house.gov/reform/min/pdfs/pdf_inves/pdf_admin_hhs_info_condoms_fact_sheet_orig.pdf.

For the current sheet, see CDC, *Fact Sheet for Public Health Personnel: Male Latex Condoms and Sexually Transmitted Diseases*, available at <http://www.cdc.gov/hiv/pubs/facts/condoms.htm> (Updated Jan. 23, 2003).

²⁷²See CBS NEWS, *Critics: Feds Hiding Health Data*, Nov. 26, 2002, at <http://www.cbsnews.com/stories/2002/11/26/politics/main530888.shtml>; see also, Adam Clymer, *U.S. Revises Sex Information, and a Fight Goes On*, THE NEW YORK TIMES, Dec. 27, 2002.

²⁷³See AUTHOR, *Drug Discovery and Development*, “science Pulled in Political Struggle”, at <http://www.dddmag.com/ShowPR.aspx?PUBCODE=016&ACCT=1600000100&ISSUE=0409&RELTYPE=PR&ORIGRELTYPE=PNP&PROD> (last visited on May 24, 2005).

²⁷⁴See CBS NEWS, *supra* note 274, at <http://www.cbsnews.com/stories/2002/11/26/politics/main530888.shtml>.

²⁷⁵See PURE LOVE CLUB, *supra* note 269, at <http://www.pureloveclub.com/chastity/index.php?id=7&entryid=284>.

²⁷⁶[Cite] in November 29, 2002 edition.

²⁷⁷*Id.*

²⁷⁸*Id.*

Three years after Public Law 106-554 was signed by President Clinton, condom labels still do not warn consumers about the lack of protection against HPV infection. The Subcommittee urges FDA to act on the release of CDC's HPV prevention report and immediately re-label condoms to alert consumers that condoms do not provide effective protection against HPV infection.²⁷⁹

At about this time, in February 2004, the Union of Concerned Scientists released a statement titled "Restoring Scientific Integrity in Policymaking," arguing that when science conflicts with political expediency, the administration has "often manipulated the process through which science enters into its decisions."²⁸⁰ The Union included allegations of suppression and censorship of the government's own scientist.²⁸¹ Distinguished scientists including forty-eight Nobel laureates, and 127 members of the National Academy of Sciences signed the statement.²⁸² The Union noted in an accompanying special report that factual information on the CDC website has been "altered to raise scientifically questionable doubts about the efficacy of condoms in preventing the spread of HIV/AIDS."²⁸³ It noted that the earlier CDC fact sheet had been rewritten in October 2002 to highlight condom failure rates and the effectiveness of abstinence and monogamy.²⁸⁴ Relying on an interview with a confidential source within the CDC, the Union's report noted that the changes were directed by Bush political appointees at the Department of Health and Human Services.²⁸⁵ The Union followed this up with a later general finding in June 2004 that "the Bush administration continues to suppress and distort scientific knowledge and undermine scientific advisory panels."²⁸⁶

The CDC later introduced a revised version of the condom fact-sheet, adding in bold letters (the only bolded text on the page) that "[t]he surest way to avoid [...] [STDs] is to abstain from sexual

²⁸⁰UNION OF CONCERNED SCIENTISTS, *Restoring Scientific Integrity in Policymaking*, Statement (Feb. 18, 2004), at http://www.ucsusa.org/global_environment/rsi/page.cfm?pageID=1320.

²⁸¹http://www.ucsusa.org/global_environment/rsi/page.cfm?pageID=1320 *Id.*

²⁸²*Id.*

²⁸³See UNION OF CONCERNED SCIENTISTS, *Scientific Integrity in Policymaking: An Investigation into the Bush Administration's Misuse of Science*, at 12 (March 2004), available at <http://www.ucsusa.org/rsi>.

²⁸⁴*Id.* <http://www.ucsusa.org/rsi>

²⁸⁵See *id.* <http://www.ucsusa.org/rsi>

²⁸⁶See UNION OF CONCERNED SCIENTISTS, *New Cases of Scientific Abuse by Administration Emerge*, Press Release (July 8, 2004), at http://www.ucsusa.org/news/press_release.cfm?newsID=405.

intercourse, or to be in a long-term mutually monogamous relationship with a partner who has been tested and you know is uninfected.”²⁸⁷ While it notes that correct and consistent condom use can protect against STDs, the fact sheet emphasizes that condom use cannot guarantee absolute protection.²⁸⁸

The site also includes a suggested boxed notice about the protective effect of condoms, perhaps as a summary for clinicians or to substitute for the current FDA-required condom labeling.²⁸⁹ It reads,

Sexually transmitted diseases, including HIV

Latex condoms, when used consistently and correctly, are highly effective in preventing transmission of HIV, the virus that causes AIDS. In addition, correct and consistent use of latex condoms can reduce the risk of other sexually transmitted diseases (STDs), including discharge and genital ulcer diseases. While the effect of condoms in preventing human papillomavirus (HPV) infection is unknown, condom use has been associated with a lower rate of cervical cancer, an HPV-associated disease.²⁹⁰

**VI. The Current Debate:
Hyping Condom Ineffectiveness to Strengthen Pro-Abstinence Policies²⁹¹**

The current political climate is ripe to facilitate the “safe sex vs. abstinence” debate. The Bush administration strongly promotes abstinence outside marriage assuring pressure on the FDA to revise its pro-condom policies. On March 25, 2005, the Department of Health and Human Services, led by former Utah Governor Michael O. Leavitt,²⁹² joined the debate with a controversial pro-abstinence website for parents, www.4parents.gov.²⁹³ Secretary Leavitt points out that “[p]arents have a tremendous amount of influence

²⁸⁷ See *Fact Sheet for Public Health Personnel*, *supra* note 273, available at <http://www.cdc.gov/hiv/pubs/facts/condoms.htm>.

²⁸⁸ *Id.*

²⁸⁹ *Id.*

²⁹¹ Phrasing derived from Chris C. Mooney’s web blog, entry dated Nov. 3, 2004, *More on Tom Coburn’s Campaign Against Condoms*, at <http://www.chrisccooney.com/blog.asp?Id=1332>.

²⁹² “Michael O. Leavitt was sworn in as the 20th Secretary of the U.S. Department of Health and Human Services on January 26, 2005.” U.S. DEPT. OF HEALTH AND HUMAN SERVICES, *Biography of Mike Leavitt*, at <http://www.hhs.gov/about/bios/dhhssec.html> (last revised Jan. 26, 2005).

²⁹³ See DEPARTMENT OF HEALTH AND HUMAN SERVICES, *HHS Announces New Communication Tools to Help Parents Talk to Their Teens About Abstinence*, Press Release, March 25, 2005, at <http://www.hhs.gov/news/press/2005pres/20050325.html>.

on their children and we (speaking on behalf of society in general) want them to talk with their teens about abstinence so that they can stay safe and healthy.”²⁹⁴ The site prominently warns against the dangers of sex noting deleterious results of extra-marital sexual activity including poverty, crime, pregnancy and STDs all despite condom use.²⁹⁵ It argues that condoms are too unreliable to protect our teenagers from these socially undesirable consequences.²⁹⁶ Thus, it advises parents: “What do you tell your teen? Be firm in your decision to delay sex.”²⁹⁷

The site emphasizes abstinence and chastity over condom use, which it denigrates as being ineffective.²⁹⁸ The site also includes a table included from a government website that states that condoms are largely ineffective, not even 50% effective, in preventing most STDs, with the exceptions of HIV/AIDS, where condoms are noted as having an 85% effective rate.²⁹⁹ The table is included herein as Appendix 2.

The controversial website was greeted on March 31, 2005, with written condemnation from 145 public health and advocacy groups.³⁰⁰ Monica Rodriguez, vice president for education and training of SIECUS, remarked that “[u]nfortunately, 4parents.gov is not about educating parents, it is about scaring them. This Web site relies on fear to motivate and contains misinformation and biases that undermine its intent of encouraging parent-child communication around sex and sexuality.”³⁰¹

President Bush (together with his administration) has been a strong advocate for abstinence-only sex ed-

²⁹⁴ See *id.* <http://www.hhs.gov/news/press/2005pres/20050325.html>

²⁹⁵ See *id.*

²⁹⁶ See *id.*

²⁹⁷ See <http://www.4parents.gov/facts/index.htm>.

²⁹⁸ See <http://www.4parents.gov/facts/index.htm>.

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³⁰⁰ US NEWSWIRE, *145 Public Health and Advocacy Organizations Seek Removal of 4Parents.gov, a New HHS Web Site; Web Site Includes Medical Inaccuracies, Biases, Fear-Based Messages, Groups Say*, (last visited March 31, 2005); at <http://releases.usnewswire.com/GetRelease.asp?id=45145>.

³⁰¹ *Id.* <http://releases.usnewswire.com/GetRelease.asp?id=45145>

ucation.³⁰² White House spokesman Ari Fleischer has stated that “abstinence is more than sound science, it’s a sound practice. . . . [A]bstinence has a proven track record of working.”³⁰³ According to a 2003 House Minority Committee on Government Reform Report entitled “Politics and Science in the Bush Administration,” the administration is distorting scientific evidence in claiming that abstinence-only sex education is scientifically proven as effective.”³⁰⁴ The Committee further argues that rather than relying on solid science, the administration has “changed [the] performance measure for abstinence-only education to make the programs appear successful, censored information on effective sex education programs, and appointed to a key panel an abstinence-only proponent with dubious credentials.”³⁰⁵ For instance, rather than tracking pregnancy, STD infection or sexual activity as outcomes, measures adopted by the Bush administration track the attendance, attitudes and “understanding” of participating youths.³⁰⁶ The fallacy of such measurements is that beliefs, attitudes and intentions in young adults are weak indicators of what they will do sexually.³⁰⁷ In other words, teens may promise and sincerely desire to avoid sex, but in actuality many will fail to do so.

The administration’s promotion of abstinence appears to be based solely on faith or moral principle. A public health policy based solely on abstinence has not been shown to be effective.³⁰⁸ Simulation studies have indicated that given likely compliance rates, the promotion of abstinence may possibly yield a similar efficacy rate when compared to condoms for preventing STDs.³⁰⁹ Further, the negative effects, if any, of

³⁰² See, e.g., President George W. Bush, President Discusses Welfare Reform and Job Training, Address before the Chamber of Commerce (Feb. 27, 2002), at <http://www.whitehouse.gov/news/releases/2002/02/print/20020227-5.html>.

³⁰³ Rep. Henry A. Waxman, U.S. HOUSE OF REPRESENTATIVES, COMMITTEE ON GOVERNMENT REFORM, *Politics and Science in the Bush Administration*, House Investigative Rep., at n. 10 & 11 (Updated Nov. 13, 2003), at http://www.house.gov/reform/min/politicsandscience/pdfs/pdf_politics_and_science_rep.pdf, citing Ari Fleischer, Press Briefing at the White House (Jan. 27, 2003), at <http://www.whitehouse.gov/news/releases/2003/01/20030127-2.html>. http://www.house.gov/reform/min/politicsandscience/pdfs/pdf_politics_and_science_rep.pdf

³⁰⁴ Waxman, *supra* note 306, at http://www.house.gov/reform/min/politicsandscience/pdfs/pdf_politics_and_science_rep.pdf.

³⁰⁵ *Id.* at 4. http://www.house.gov/reform/min/politicsandscience/pdfs/pdf_politics_and_science_rep.pdf. at page 4

³⁰⁶ *Id.* at 5; see also D. KIRBY, NATIONAL CAMPAIGN TO PREVENT TEEN PREGNANCY, EMERGING ANSWERS: RESEARCH FINDINGS ON PROGRAMS TO REDUCE TEEN PREGNANCY 88 (May 2001). http://www.house.gov/reform/min/politicsandscience/pdfs/pdf_politics_and_science_rep.pdf

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³⁰⁸ J.D. Fortenberry, *Editorial: The Limits of abstinence-only in preventing sexually transmitted infections*, 36 J. OF ADOLESCENT HEALTH 269, 269-270 (2005); see also, Kirby, *supra* note 309, at 88 (“[T]here do not currently exist any abstinence-only programs with reasonably strong evidence that they actually delay the initiation of sex or reduce its frequency”).

³⁰⁹ S.D. Pinkerton, *A relative risk-based, disease-specific definition of sexual abstinence failure rates* in HEALTH EDUC. BE-

abstinence promotion are not known.

A recent paper by two sociologists³¹⁰ has shown that virginity pledges, a form of promoting abstinence, are not effective in lowering STD infection rates in adolescents.³¹¹ Virginity pledges, sponsored by the organization “True Love Waits,” typically involve teenagers publicly promising their parents and community not to have sex before marriage.³¹² The pledger then receives a ring or other jewelry to commemorate his or her pledge.³¹³

Most pledgers break their promise – of those pledgers who have had sex, only 12% waited until marriage in contrast to 1% of non-pledgers.³¹⁴ An earlier study by the same authors does in fact indicate that virginity pledgers as a group do not have sex until they have attained an older age on average than those who do not pledge.³¹⁵ Relative to their non-pledge counterparts, pledgers have fewer sex partners and are sexually active for shorter time periods.³¹⁶ Data reveals that up to 25% of consistent pledgers remain virgins until age twenty-five and that pledgers marry younger than non-pledgers.³¹⁷ It appears that pledgers as opposed to non-pledgers may be exposed to less risk of contracting STDs because on average they have sex with fewer partners and therefore reduce a significant risk component of STD transmission.

Based on a significant reduction in exposure to risk factors, one might expect pledgers to have lower STDs

HAVIOR, at ch. 28, 10-20 (2001).

³¹⁰H. Brückner & P.S. Bearman, *After the promise: the STD Consequences of adolescent virginity pledges*, 36 J. ADOLESCENT HEALTH 271-278 (2005).

³¹¹*Id.*

³¹²*Id.*

³¹³See, for example, *Lifeway, Biblical Solutions for Life, Leaders Tools – Ring Ceremony*, at http://www.lifeway.com/tlw/ldr_tools_ceremony.asp. By 1995, an estimated 2.2 million adolescents (12% of all adolescents) had taken such pledges.

³¹⁴Brückner, *supra* note 313, at 275.

³¹⁵*Id.* at 859-912.

³¹⁶*Id.* at 271-278. Female pledgers have an average of 1.9 sex partners and are sexually active for 4.2 years compared to their non-pledge counterparts who have an average of 2.7 sex partners and are sexually active for 5.9 years. *Id.* at 277.

³¹⁷*Id.* at 271-278; table 3 at 275.

rates than non-pledgers. Despite such a theoretical assumption, the data shows that in reality pledging has no statistically significant effect on STD rates.³¹⁸ As a possible explanation for this surprising contradiction, the authors cite data showing that pledgers are less likely to use condoms during intercourse or to be tested and treated for STDs.³¹⁹ In addition, virginity pledgers have higher rates of oral and/or anal sex than their non-pledge counterparts.³²⁰ The authors conclude that given equivalent STD rates among pledgers and non-pledgers, “abstinence as intervention may not be the optimal approach” to preventing STDs among adolescents.³²¹ Among children and young adults, the debate whether to teach abstinence or safer sex, including condom use, has not significantly changed since the early 20th century.³²²

VII.

Conclusion

Promoting abstinence rather than condom use is akin to recommending self-disciplined and unassisted so called “cold-turkey” tactics to deal with smoking habits and self-guided dieting to deal with obesity. Both smoking-related diseases and obesity are widespread public health problems caused by unhealthy lifestyles, which can be ameliorated if not eliminated by life-style changes. In principle, self-control and discipline could lead to cheap and lasting changes in harmful behavior. A cursory glance at today’s society reveals that such disciplined life-style choices are not headed by many, despite widely known risks. Neither a conspicuous Surgeon General’s warning advising smokers to stop smoking nor a glaringly apparent health risk associated with both smoking and obesity has led to a significant reduction in smokers or wide spread acceptance of healthy dieting. If one were to measure the efficacy of dieting by those who adhere to a diet, then it is 100%.

If one were to measure the efficacy of dieting accounting for long-term success rates of all of those that begin

³¹⁸ *Id.* For instance, the study showed that non-pledgers (n=9072) had a 26.5% incidence of HPV infection, while consistent pledgers (n =777) had a 26.7% infection rate. *Id.*

³¹⁹ *Id.*

³²⁰ *Id.*

³²¹ *Id.* at 271.

³²² See J.P. MORAN, TEACHING SEX: THE SHAPING OF ADOLESCENCE IN THE 20th CENTURY (Harvard Univ. Press 2000); also see Fortenberry, *supra* note 311, at 269-270.

a diet, some of which fail, then the figures are much more disappointing.

Such a phenomenon is identical to what one should expect in connection with abstinence. Thus, abstinence is completely effective, provided that one embarking upon the mission will perfectly follow the “diet.” Abstinence is far less effective, however, when one factors in individual human fallibility across over the long-term. In sum, the personal choice of abstinence may be effective, but it might not be effective as a viable public health policy.

Both history and data strongly suggest that abstinence alone does not work to prevent pregnancy or STDs. However, given the strong moral opposition many conservatives have to promoting condoms and safer sex, the issue is likely to be a subject of political debate for years to come.

Appendix 1

Table 5-1. Comparison of International Latex Condom Standards/Specifications, 1997

	ISO	CEN	ASTM	WHO	USAID			
Dimensions In- spec- tion Level/AQL Length, mm Width, mm Thick- ness, mm	S- 2; 4.0 160 min. 50- 54 N/A	min.10Spls/ 170 min. 50- 54 N/A	NSA 2; 4.0 160 min. 54 max. .03 min.	(53mm Width) S- 2; 1.0 180min. 51- 55 .04 - .08	(49mm Width)			(52mm Width)
					S-2; 1.0 170 min. 47-51 .04 -.08	S- 2; 2.5 170 min.	S- 2; 2.5 160 min.	
Leakage/Freedom from Holes In- spec- tion Level/AQL Test Method De- fect Area	G- I;.25 min. Hang & Roll Ex- clude area >150 mm from closed end	315 Spls/.25 Hang & Roll En- tire Condom	G- I;.40 Hang Ex- clude area 25mm be- low open end	G- I;.25 Hang & Roll Ex- clude area 25 mm be- low open end	G- I;.40 Hang Ex- clude area 25 mm be- low open end	50- 54 .05 min.	47 - 51 .05 min.	

Air Burst Inspection Level/AQL Volume, L Pressure, kPa Note:	G-I; 1.0 16.0 min. 1.0 min.	G-I; 1.5 18.0 min. 1.0 min.	G-I; 1.5 16.0 min. 1.0 min. (Exclude Leak- ers)	G-I; 1.0 18.0 min. 1.0 min. (Exclude Leak- ers)	G-I; 1.5 (Dou- ble) 16.0 min. 1.0 min. (Exclude Leak- ers)	
Air Burst (after 2 days @ 70C) Re- quire- ments	Same as before aging	Not re- quired	Not re- quired	Not re- quired	Same as be- fore ag- ing	
Air Burst (af- ter 7 days @ 70C) In- spec- tion Level Vol- ume, L Pres- sure, kPa						

	Not required	Not required	Not required	min. 80 Spls 27.0 min. (mean) 1.0 min.	Not required	
Tensile In- spec- tion Level/AQL Force, N Break- ing Str., MPa % Elon- ga- tion	Not re- quired	min.13Spls/ 39 (me- dian) N/A 700 (me- dian)	Not re- quired	Not required	S-2; 2.5 35 min. 17 min. 650 min.	
Tensile (after 2 days @ 70C) Inspection Level Force, N % Elonga- tion	Not re- quired	13 Spls 39 (median) 700 (median)		Not required		

Tensile (after 7 days @ 70C) In- spec- tion Level Force, N Break- ing Str., MPa % Elon- ga- tion	Not re- quired	Not re- quired	Not re- quired	Not required	S-2 35 (mean) 17 (mean) 650 (mean)	
Package Integrity Inspection Level/AQL	Not re- quired	Not required		S-3; 2.5		
Lubricant Quantity Inspection Level/AQL Quantity, mg	Not re- quired	Not required		Not required	S- 2, 4.0 350 -	S- 2; 1.5 250 min.
					550	

Inspection Levels – G (general sampling level); S (special sampling level). The higher the number, the larger the sample. AQL – Acceptable Quality Level; Spls – Sample Size

Appendix 2

Table 1: from <http://www.4parents.gov/talktopics/table.htm>

WHAT PARENTS NEED TO KNOW ABOUT STDs

	Bacterial Sexually Transmitted Diseases			Viral Sexually Transmitted Diseases					
Common STDs	Chlamydia	Gonorrhea					Syphilis	HSV: Herpes Simplex	Human Papilloma Virus (HPV) and Genital Warts
Where is it found?	Vagina, cervix, urethra, throat and anus	Vagina, cervix, urethra, throat and anus	Genital area and/or on mouth	Vagina, cervix, urethra, anus, mouth, throat and all genital areas	Vagina, cervix, urethra, anus, scrotum, mouth, throat and all genital areas	Blood, semen, vaginal fluid, breast milk			

<p>What are the possible symptoms?</p>	<p>May or may not have early symptoms, discharge from penis and vagina, chronic low stomach pain, pelvic infection/fever, infertility may result (mostly in women), can infect babies</p>	<p>Vaginal or penile pain and discharge, chronic low stomach pain, pelvic infection/fever, infertility may result (mostly in women), can infect babies</p>	<p>Painless chancre (sore), untreated it can spread to the brain and/or heart, can cause birth defects and lesions on infants' skin and other problems with their organs</p>	<p>Painful blisters, fever, swollen glands, symptoms reoccur throughout life, can infect babies</p>	<p>Few early symptoms, may cause warts, can cause cancer of the cervix, anus and penis, can infect babies</p>	<p>No early symptoms, destroys immune system, multiple severe infections, no known cure, fatal illness, can infect babies</p>
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How can it be spread?	Oral, anal and vaginal sex, and mother to child	Oral, anal and vaginal sex, and mother to child				
Can condoms help if always used (100% of the time and correctly)?	Condom use is associated with some decreased risk. (Risk reduction is 50% or less.)	Condom use is associated with some decreased risk. (Risk reduction is 50% or less.)	Condom use is associated with some decreased risk. (Risk reduction is 50% or less.)	Condom use is associated with some decreased risk. (Risk reduction is 50% or less.)*	No evidence that condom use reduces risk of HPV infection. Some evidence that condoms reduce the risk of HPV-associated diseases.	Condom use decreases the risk of HIV/AIDS transmission by approximately 85%.

How many infected teens are reported?	3-14% of women age 15-24 who visited family planning clinics (2002)	0.1 to 2.8% of women age 15-24 who visited family planning clinics (based on reporting states)
What are the treatments?	Antibiotics (permanent damage may have occurred)	Antibiotics (permanent damage may have occurred)

Notes:
*This takes into account as yet unpublished data, which were presented at the 2002 National STD Conference, sponsored by the CDC. See below for citation.