# **CONDOMS**

#### "CONDOMS HELP PROTECT AGAINST CANCER"

"Human papilloma virus – which can cause cervical cancer, genital warts and vaginal, vulvar, anal and penile caners – is the most common sexually transmitted disease, infecting about 80 percent of young women within five years of becoming sexually active. An estimated 630 million people worldwide are infected."

("Condoms help protect against cervical cancer," MSNBC.com, June 2006, www.msnbc.msn.com/id/13461194/print/1/displaymode/1098/)

"Condoms with a 20% to 50% failure rate for teen pregnancy are such a poor contraceptive that teens are encouraged to use the pill or five year Norplant. Only 3% of girls on the pill also use condoms. The 'belts and suspenders' (condoms and the pill) approach...has been a complete failure-in spite of billions of dollars already spent on condom and contraceptive programs."

## "SEX, CONDOMS & STDs: WHAT WE NOW KNOW"

"Key Findings:"

(Archer, 1993, p. 22)

- "Consistent (always) condom use is defined as 100 percent condom use during all sex acts indefinitely."
- "To provide any reasonable hope of avoiding most STD infections condoms must be used 100 percent of the time by individuals outside of lifelong mutually faithful monogamous relationships (usually found in marriage)."
- "Even 100 percent condom use does not eliminate the risk of any STD including HIV."
- "Condoms slip or break on average 1.6 percent to 3.6 percent of the time even when used 100 percent of the time, potentially exposing sexual partners to STD infection." [72, 34, 35, 46]

- "Protection' is the term often applied to condom use. This can be misleading because condoms only reduce the risk of infection. They do not "protect" 100 percent of the time from any STD."
- "Condoms do not prevent the transmission of STD's from lesions outside the areas covered by, or 'protected' by, condoms." [72]
- "All studies of condom use are done for a limited period of time from a few acts of sex to two or three years of activity. Single individuals who are sexually active usually continue sexual activity year after year. With an increasing number of sexual partners and sex acts comes an increasing risk of STD infection, even with 100 percent condom use." (See discussion in the section "The Impact of Cumulative Effectiveness.")
- "One hundred percent use of condoms for many years is so uncommon that it is almost a purely theoretical concept except for very few, very meticulous individuals. Even among adults who knew that their partner had HIV, only 56 percent used condoms every time (and the median follow up was only 24 months)." [61]
- "There is no evidence of any risk reduction for sexual transmission of human papillomavirus infection (HPV) even with 100 percent condom use. There is some evidence that condom use 'might afford some reduction in risk of HPV associated disease including genital warts in men and cervical neoplasia in women.' Neoplasia means cervical precancer or cervical cancer." [72] (The scientific explanation for this phenomenon is beyond the scope of this paper.)
- "Current evidence does not show that Trichomonas vaginalis sexual transmission is reduced even with 100 percent condom use." [1, 72]
- "Syphilis transmission is reduced by 29 percent to 50 percent with 100 percent condom use. Although the data about syphilis transmission is limited, current data show that even with 100 percent condom use, there remains a 50 percent to 71 percent relative risk of syphilis infection." [1, 9] (See the definition of relative risk in the section "Scientific Language and the Discussion of Condom Effectiveness.")
- "Gonorrhea transmission is reduced by approximately 50 percent with 100 percent condom use. Although the data about gonorrhea transmission is limited, current evidence shows that even with 100 percent condom use there remains a 50 percent relative risk of gonorrhea infection." [72, 1, 9]
- "Chlamydia transmission is reduced by approximately 50 percent with 100 percent condom use. Although the data about chlamydia transmission is limited, current

- evidence shows that even with 100 percent condom use, there remains a 50 percent relative risk of chlamydia infection." [1, 9]
- "Genital herpes sexual transmission: A recent study showed that with 25 percent or more condom use, there was risk reduction for females but not for males. [70] Expanded data by the same author, as yet unpublished but presented at a national conference, show risk reduction of approximately 40 percent for both males and females when condoms were used for 65 percent or more of sex acts. Although the data about herpes transmission is limited, current evidence shows that even with condom use there remains a 60 percent relative risk of herpes infection." [69]
- "HIV sexual transmission is reduced by approximately 85 percent with 100 percent condom use, leaving approximately 15 percent relative risk even with 100 percent condom use. [72, 26] Inconsistent condom use affords significantly less risk reduction. As discussed later in this monograph, 85 percent risk reduction rates were found in an ideal situation for condoms reducing the risk of HIV transmission."
- "For the approximately twenty other STDs, not enough data exist to say whether or not condoms offer any risk reduction from sexual transmission."
- "Approximately 25 percent of adolescents report alcohol or drug use during their most recent sexual behavior, compromising their ability to use condoms correctly or at all." [23]
- "There are certain groups that are more susceptible to some STDs. These groups include those already infected with an STD. For example, the presence of another STD, particularly an ulcerative disease, can significantly increase the risk of acquiring (or transmitting) HIV if an individual is exposed to a sexual partner who is HIV positive." [30, 38]
- "Females are more susceptible to many STDs than are males because they have a larger surface susceptible to infection (the lining of the vagina) than males (the lining of the urethra). Mucous membranes provide an easier route of entry for most STDs than intact skin. In addition, adolescent females are at higher risk of certain STDs than are adult women, due to anatomical differences of the uterine cervix associated with age. [30] Condom effectiveness is decreased due to the increased susceptibility of the individual. In addition, women suffer more of the severe complications of STDs than men do (e.g., cervical cancer, infertility)."
- "Most people infected with an STD do not know it. For example, a study of adolescent females who had one or more of six STDs studied (genital herpes, chlamydia, gonorrhea, syphilis, hepatitis B, trichomoniasis) showed that 87 percent had no

symptoms. [13] Individuals and their partners who do not think they have an STD may not be highly motivated to use condoms consistently."

# "Report's Bibliography:"

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- "9. Baeten JM, Nyange PM, Richardson BA, et al. Hormonal contraception and risk of sexually transmitted acquisition: Results from a prospective study. Am J Obstet Gynecol. 2001;185:380-385."
- "13. Bunnell RE, Dahlberg L, Rolfs R, et al. High prevalence and incidence of sexually transmitted diseases in urban adolescent females despite moderate risk behaviors. J Infect Dis. 1999;180:1624-1631."
- "23. Centers for Disease Control and Prevention. Youth Risk Behavior Surveillance United States, 2001. MMWR. 2002;51:1-64."
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- "30. Eng TR, Butler WT, eds. The Hidden Epidemic: Confronting Sexually Transmitted Disease. Institute of Medicine. Washington, DC: National Academy Press; 1997."
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- "61. Saracco A, Musicco M, Nicolosi A, et al. Man-to-woman sexual transmission of HIV: Longitudinal study of 343 steady partners of infected men. Journal of Acquired Immune Deficiency Syndromes. 1993;6:497-502."
- "69. Wald A, Langengerg A, Kexel E, Izu AE, Ashley R, Corey, L. Condoms protect men and women against Herpes Simplex Virus Type 2 (HSV-2 Acquisition). Abstract B09E, 2002 National STD Prevention Conference, San Diego, CA, March 4-7, 2002. Available at http://www.stdconference.org "
- "70. Wald A, Langengerg AG, Link K, et al. Effect of condoms on reducing the transmission of herpes simplex virus type 2 from men to women. JAMA. 2001;285:3100-3106."
- "72. Workshop Summary: Scientific Evidence on Condom Effectiveness for Sexually Transmitted Disease (STD) Prevention. July 20, 2001. National Institute of Allergy and Infectious Diseases, National Institutes of Health, Department of Health and Human Services. Available at: <a href="http://www.niaid.nih.gov/dmid/stds/condomreport.pdf">http://www.niaid.nih.gov/dmid/stds/condomreport.pdf</a>"

(This excerpt from The Medical Institute's report, *Sex, Condoms & STDs: What We Now Know*, provides a quick reference and offers an easy-to-understand look at the currently available research conducted on condom effectiveness. However, we cannot overstate the importance of reading the entire report – only then can the reader gain a complete appreciation for the impact and importance of this research. To get a copy of the 2003 monograph, please call (900) 892-9484. The cost is \$10 plus shipping.)

#### "DO CONDOMS MAKE SEX SAFE ENOUGH?"

"Genital Herpes"

"Based on the limited studies, it appears condoms only reduce the risk of herpes by half at best. Genital herpes infects nearly a quarter of Americans 12 and older and almost half of all African Americans. Because there is no cure, once you're infected with genital herpes, you have it for life."

("Do Condoms Make Sex Safe Enough?" The Medical Institute brochure, 2003 <a href="https://www.medinstitute.org">www.medinstitute.org</a>)

#### "THE TRUTH ABOUT CONDOMS"

"Condoms are a barrier method of contraception that, when used consistently and correctly, can prevent pregnancy by blocking the passage of semen into the vaginal canal. Condoms can also prevent the exchange of blood, semen, and vaginal secretions, which are the primary routes of STD transmission."

"In recent years, as a result of misinformation and insufficient research, the efficacy of condoms, especially in terms of STD prevention, has been debated in many forums."

"Research continues to show that condoms are one of the best methods of preventing unwanted pregnancy and are one of the only methods for sexually active individuals to protect themselves against STDs, including HIV."

"This updated Fact Sheet includes information on both the male and female condom; on their effectiveness in protecting against unplanned pregnancies and STDs, including HIV; and on condom breakage and slippage, regulations and tests, and consistent and correct use."

"This Fact Sheet is designed to provide the most recent information about condoms and to clear up confusion and misunderstandings."

#### "Male Condom"

"The male condom is a barrier method of contraception that is placed over the glans and shaft of the penis. Male condoms are available in latex, lambskin, and polyurethane."

"Condoms manufactured from latex are the most popular, and studies conducted on the ability of condoms to prevent the transmission of STDs and HIV most often involve latex condoms."

"Condoms manufactured from lambskin, also known as 'natural skin,' or 'natural membrane,' are made from the intestinal lining of lambs. While these condoms can prevent pregnancy, they contain small pores that may permit passage of some STDs, including HIV, the hepatitis B virus, and the herpes simplex virus." (1)

"Condoms manufactured from polyurethane are thinner and stronger than latex condoms, provide a less constricting fit, are more resistant to deterioration, and may enhance sensitivity." (2)

"Polyurethane condoms are also recommended for those who have latex allergies. Polyurethane condoms have not been studied for their effectiveness in the prevention of STD transmission. (3) In addition, condoms made of polyurethane are compatible with oilbased lubricants, unlike latex condoms which must be used with water-based lubricants."
(4)

## "Pregnancy Prevention"

"Studies have shown that condoms are one of the most reliable methods for preventing unwanted pregnancy. In addition to being effective, condoms are also inexpensive and are available without a prescription."

#### "Facts in Brief"

• "Condoms are 98 percent effective in preventing pregnancy when used consistently and correctly." (5)

#### "Condoms and STDs: CDC Prevention Messages"

"The following are prevention messages recently developed by the CDC:"

- "Latex condoms, when used consistently and correctly, are highly effective in preventing the transmission of HIV, the virus that causes AIDS. In addition, correct and consistent use of latex condoms can reduce the risk of other STDs."
- "Latex condoms, when used consistently and correctly, can reduce the risk of transmission of gonorrhea, chlamydia, and trichomoniasis."
- "Latex condoms, when used consistently and correctly, can reduce the risk of genital herpes, syphilis, chancroid, and HPV only when the infected areas are covered or protected by the condom."
- "The use of latex condoms has been associated with a reduction in the risk of HPV-associated diseases, such as cervical cancer."

#### Reference

Latex Condoms and Sexually Transmitted Diseases—Prevention Messages, National Center For HIV, STD, & TB Prevention, Centers for Disease Control and Prevention, Atlanta, GA (undated document).

• "The first-year effectiveness rate in preventing pregnancy among typical condom users on average is 86 percent. This includes pregnancies resulting from errors in condom use." (6)

#### "HIV Prevention"

"Latex condoms, when used consistently and correctly, are highly effective in preventing transmission of HIV, the virus that causes AIDS." (7)

#### "Facts in Brief"

- "Using a latex condom to prevent transmission of HIV is more than 10,000 times safer than not using a condom." (8)
- "A study published in *The New England Journal of Medicine* observed heterosexual couples where one was HIV-positive and the other was HIV-negative, for an average of 20 months. (These couples are referred to as serodiscordant.) (9) Findings included:"
- -- "No sero-conversion occurred among the 124 couples who used latex condoms consistently and correctly for vaginal or anal intercourse." (10)
- -- "Ten percent of the HIV-negative partners (12 of 121) of couples became infected when condoms were used inconsistently for vaginal or anal intercourse. In contrast, 5 negative partners became infected when condoms were not used." (11)

#### "Condoms & Pregnancy -- understanding condom effectiveness"

"To fully understand research on condom effectiveness, one must understand the differences between *method failure* and *user failure*. *Method failure* refers to failure that results from a defect in the product. *User failure* refers to failure that results from incorrect or inconsistent use."

"In its fact sheet on condoms, the U.S. Centers for Disease Control and Prevention explains that the term *condom failure* often imprecisely refers to the percentage of women who become pregnant over the course of a year in which they reported using condoms as their primary method of birth control – even if they did not use condoms every time they had intercourse. The CDC concluded that 'clearly these statistics don't report *condom failure* but *user failure*." (1)

"Method failure" of male condoms is uncommon. In fact, it is estimated to occur among only three percent of couples using condoms consistently and correctly during the first year of use. To help individuals understand this estimate, Contraceptive Technology explains that 'only three of 100 couples who use condoms perfectly for one year will experience an unintended pregnancy." (2)

"It goes on to say that 'if each [of these 100 couples] had intercourse at the average coital frequency of 83 acts per year, then 100 couples would have intercourse a combined 8,300 times a year. Three pregnancies resulting from 8,300 acts of condom use is a remarkably low pregnancy rate (.04 percent) when calculated on a per-condom basis." (3)

"In truth, condom failures are most often caused by errors in use, 'most notably the failure of couples to use condoms during every act of sexual intercourse.' (4) It is therefore important to look at the data on typical condom use or *user failure*."

"Among those couples using condoms as their primary method of contraception, approximately 14 percent will experience an unintended pregnancy during the first year. It is important to remember that they may not have used a condom or may have used one incorrectly during the act of intercourse that resulted in pregnancy." (5)

"To put this in perspective, individuals need to understand that 85 percent of women using no method of birth control will become pregnant in the first year as will 25 percent of women using periodic abstinence." (6)

#### References

- 1. CDC Update, Questions and Answers on Condom Effectiveness, January 1997.
- 2. R.A. Hatcher, et al., *Contraceptive Technology*, 17<sup>th</sup> revised edition (New York: Irvington Publishers, Inc., 1998), p. 328.
- 3. Ibid, p. 329.
- 4. CDC Update, Questions and Answers on Condom Effectiveness, January 1997.
- 5. R.A. Hatcher, *Contraceptive Technology*, p. 329.
- 6. Ibid., p. 216

# **Update on Nonoxynol-9**

"In the past, public health experts recommended using condoms combined with Nonoxynol-9 (N-9), a spermicide, for increased protection against pregnancy, HIV, and STDs. Two recent studies, however, call into question the effectiveness and safety of N-9."

"A study published by UNAIDS found that N-9 used without condoms was ineffective against HIV transmission. This study actually showed some evidence that N-9 increased the risk of HIV infection."

"Researchers note that this study was conducted among commercial sex workers in Africa who are at increased risk and used a N-9 gel on a frequent basis. The adverse effects might not be seen at the same level among women who are using N-9 less frequently or in a different formulation."

"As a result of this study, however, the CDC concluded that 'given that N-9 has been proven ineffective against HIV transmission, the possibility of risk, with no benefit, indicates that *N-9 should not be recommended as an effective means of HIV-prevention.*" \( \frac{1}{2} \)

"A similar study published in the *Journal of the American Medical Association* found that N-9, when used with condoms, did not protect women from the bacteria that causes gonorrhea and chlamydial infection any better than condoms used alone."<sup>2</sup>

#### References

- 1. Letter to Colleagues from Helene D. Gayle, M.D., M.P.H., director, National Center for HIV, STD, and TB Prevention, U.S. Centers for Disease Control and Prevention, August 4, 2000.
- 2. R. E. Roddy, L. Zekeng, K. A. Ryan, U. Tamoufé, and K. G. Tweedy, "Effect of Nonoxynol-9 Gel on Urogenital Gonorrhea and Chlamydial Infection: A Randomized Controlled Trial," *Journal of the American Medical Association*, March 6, 2002, pp. 1117-22.

#### "STD Prevention"

"Condoms can be expected to provide different levels of risk reduction for different STDs. There is no definitive study about condom effectiveness for all STDs. Definitive data are lacking on the degree of risk reduction that latex condoms provide for some STDs; for others, the evidence is considered inconclusive."

"The U.S. Centers for Disease Control and Prevention (CDC) states, 'It is important to note that the lack of data about the level of condom effectiveness indicates that more research is needed -- not that latex condoms do not work." 13

#### "Facts in Brief"

• "Several studies have demonstrated that condoms can protect against the transmission of chlamydia, gonorrhea, and trichomoniasis, and may protect against genital herpes and syphilis." 14

## "Condom Breakage and Slippage"

"Although people fear that condoms may break or fall off during use, studies indicate this rarely occurs when condoms are properly used. <sup>15</sup> It is also important to note that not all condom breaks are equally risky. As many as 24 to 65 percent occur before intercourse and pose no biological risk of pregnancy or infection if a new condom is used for intercourse." <sup>16</sup>

#### "Facts in Brief"

- "A study published in the *American Journal of Public Health* observed female sex workers in Nevada brothels, where condom use is required by law, and found that of 353 condoms used by the sex workers during the study, none broke or fell off during intercourse, and only two (0.6 percent) slipped off during withdrawal." <sup>17</sup>
- "Studies have reported breakage rates during vaginal intercourse ranging from zero percent to 6.7 percent. Most studies report that condoms break less than two percent of the time during intercourse or withdrawal." 18
- "Condoms fall off the penis in 0.6 percent to 5.4 percent of acts of vaginal intercourse and may slip down the penis without falling off in 3.4 percent to 13.1 percent of acts of vaginal intercourse." 19
- "Breakage rates during anal sex for gay men in four prospective studies ranged from 0.5 percent to 12 percent, with rates less than two percent in three of the studies." 20

#### "Condom Use"

"Research shows that consistent condom use among sexually active individuals has increased."

#### "Facts in Brief"

• "In 2001, the Centers for Disease Control and Prevention's *Youth Risk Behavior Surveillance Summaries* found that among currently sexually active students in grades nine through 12 nationwide, 57.9 percent reported that either they or their partner had

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used a condom during last sexual intercourse compared to 58.0 percent in 1999, 56.8 percent in 1997, 54.4 percent in 1995, and 52.8 percent in 1993."<sup>21</sup>

• "The *National Survey of Family Growth* reported that 20 percent of American women 15 to 44 years of age reported using a condom in 1995 compared to 15 percent in 1988 and 12 percent in 1982."<sup>22</sup>

# "Consistent and Correct Condom Use"

"In order to benefit from the protection that condoms provide, individuals must use them *consistently* and *correctly*. This means they must use a condom with every act of sexual intercourse, from start to finish, including penile-vaginal intercourse as well as oral and anal intercourse. In addition, individuals must understand how to properly use a condom. Studies of hundreds of couples show that consistent condom use is possible when sexual partners have the skills and motivation to use them."<sup>23</sup>

# "Correct Use of the Male Condom"24

- "Store condoms in a cool place out of direct sunlight (not in wallets or glove compartments). Latex will become brittle from changes in temperature, rough handling, or age. Don't use damaged, discolored, brittle, or sticky condoms."
- "Check the expiration date."
- "Carefully open the condom package -- teeth or fingernails can tear the condom."
- "Use a new condom for each act of sexual intercourse."
- "Put on the condom before it touches any part of a partner's body."
- "Hold the condom over an erect penis."
- "If a penis is uncircumcised, pull back the foreskin before putting on the condom."

  Josh McDowell Research Condoms

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- "Put on the condom by pinching the reservoir tip and unrolling it all the way down the shaft of the penis from head to base. If the condom does not have a reservoir tip, pinch it to leave a half-inch space at the head of the penis for semen to collect after ejaculation."
- "In the event that the condom breaks, withdraw the penis immediately and put on a new condom before resuming intercourse."
- "Use only water-based lubrication. Do not use oil-based lubricants such as cooking/vegetable oil, baby oil, hand lotion, or petroleum jelly -- these will cause the condom to deteriorate and break."
- "Withdraw the penis immediately after ejaculation. While the penis is still erect, grasp the rim of the condom between the fingers and slowly withdraw the penis (with the condom still on) so that no semen is spilled."
- "Remove the condom, making certain that no semen is spilled."
- "Carefully dispose of the condom. Do not reuse it."
- "Do not use a male condom along with a female condom. If the two condoms rub together, the friction between them can cause the male condom to be pulled off or the female condom to be pushed in."

# "Regulations and Tests"

"The U.S. Food and Drug Administration (FDA) regulates manufacturers who sell condoms in the United States."

"As a quality assurance step, condom manufacturers sample each lot of finished packaged

condoms and examine them for holes using a water leak test. The FDA recognizes domestic and international standards that specify that the rate of sampled condoms failing the water leak test, for each manufactured lot of condoms, must be less than one in 400."

"Manufacturers also test lots for physical properties using the air burst test and the tensile (strength) property test."

"In order to test condoms' ability to prevent the passage of viruses, FDA researchers developed a test using high concentrations of a laboratory created "virus" that is the same size as STD pathogens."

"The FDA tested many different types of male condoms and showed that they are highly effective barriers to virus passage with a very small chance of leakage. Intact condoms (those that pass the water leak test) are essentially impermeable to particles the size of STD pathogens. Moreover, these studies show that fluid flow, not virus size, is the most important determinant of viral passage through a hole."

#### Reference

1. National Institute of Allergy and Infectious Diseases, National Institutes of Health, U.S. Department of Health and Human Services, *Workshop Summary: Scientific Evidence on Condom Effectiveness for Sexually Transmitted Disease (STD) Prevention*, July 12-13, 2000, Hyatt Dulles Airport Herndon, VA. (Released July 20, 2001)

#### "Female Condom"

"Available under the brand name Reality®, the female condom is made of polyurethane and provides protection against pregnancy and STDs, including HIV. Lt consists of a tube-like sheath with one flexible polyurethane ring at each end. One ring is placed inside the vaginal canal and is closed off by polyurethane, collecting the ejaculate. The other ring remains outside the vagina and the penis enters the vagina through this ring. The female condom is coated with a silicone-based lubricant. Additional lubricant can be added as necessary. The female and male condom should not be used together as they can adhere to each other, causing slippage or displacement."

#### "Facts in Brief"

• "The first-year effectiveness rate of preventing pregnancy among typical condom users averages about 79 percent for female (Reality®) condoms. This includes pregnancies resulting from errors in condom use."

- "The female condom Reality® is estimated to reduce the risk of HIV infection for each act of intercourse by 97.1 percent when used consistently and correctly."
- "Laboratory studies have shown Reality® to be an effective barrier to microorganisms including HIV and including a bacteriophage smaller than hepatitis B, the smallest virus known to cause an STD."

#### References

- 1. www.femalehealth.com/yourquests.html.
- 2. R.A. Hatcher, et al., (1998), p. 328.
- 3. www.femalehealth.com/yourquests.html.
- 4. Ibid.

## "Correct Use of the Female Condom" 25

- "Do not use damaged, discolored, brittle, or sticky condoms."
  "Check the expiration date."
- "Carefully open the condom package -- teeth or fingernails can tear the condom."
- "Use a new condom for each act of sexual intercourse."
- "First, inspect the condom and make certain it is completely lubricated on the outside and the inside."
- "The female condom is inserted into the vagina with fingers, much like a tampon that has no applicator. To do so:"

- o "Hold the condom at the closed end and squeeze the flexible inner ring with thumb and middle finger so it becomes long and narrow. With the other hand, separate the outer lips of the vagina."
- "Gently insert the inner ring end as far into the vagina as possible, using the index finger to push up the inner ring until the finger reaches the cervix (similar to how a diaphragm would be inserted)."
- "Before having intercourse, make certain the condom is in place. When in place, it will cover the opening of the cervix and line the vaginal walls. A general indicator of correct insertion is that the individual will no longer feel the ring. The open end of the condom must always remain outside the vaginal opening. Before having intercourse, make certain that the condom is straight and not twisted."
- "Add water-based lubricant onto the penis and/or the inside of the female condom to increase comfort and decrease noise. It is important to use enough lubricant so that the condom stays in place during sex. If the condom is pulled out or pushed in, that is an indicator that there is not enough lubricant."
- "Be sure that the penis is not entering the vaginal canal outside of the condom before intercourse."
- "To remove the condom, twist the outer ring and gently pull the condom out to avoid any spillage."
- "Carefully dispose of the condom. Do not reuse it."

"Do not use a male condom along with a female condom. If the two condoms rub together, the friction between them can cause the male condom to be pulled off or the female condom to be pushed in."

#### "References"

- 1. "R.A. Hatcher, et al., Contraceptive Technology, 17th revised Edition (New York: Ardent Media, Inc., 1998), p.326.
- 2. Ibid"
- 3. Ibid.
- 4. Ibid, p. 343.
- 5. J. Trussel, et al., "Contraceptive Failure in the United States: An Update," Studies in Family Planning, January/February 1990, vol. 21, no. 1, p. 52.
- 6. R.A. Hatcher, et al., 1998, p. 328.
- 7. R.F. Carey, et al., "Effectiveness of Latex Condoms As a Barrier to Human Immunodeficiency Virus-sized Particles under the Conditions of Simulated Use," Sexually Transmitted Diseases, July/August 1992, vol. 19, no. 4, p. 230.
- 8. Ibid.
- 9. I. De Vincenzi, "A Longitudinal Study of Human Immunodeficiency Virus Transmission by Heterosexual Partners," The New England Journal of Medicine, 331, no. 6 (Aug. 11, 1994), p. 341-6.
- 10.Ibid, p. 341.
- 11.Ibid, p. 343.
- 12.A. Saracco, et al., "Man-to-Woman Sexual Transmission of HIV: Longitudinal Study of 343 Steady Partners of Infected Men," Journal of Acquired Immune Deficiency *Syndromes*, vol. 6, no. 5, 1993, p. 499.
- 13.U.S. Centers for Disease Control and Prevention (CDC), Latex Condoms and Sexually Transmitted Diseases -- Prevention Messages (Atlanta, GA: CDC, 2001), p. 2.
- 14.Ibid.
- 15.R.A. Hatcher, et al., 1998, p. 329.
- 16.Ibid.
- 17.Ibid.
- 18.Ibid.
- 19.Ibid.
- 20.Ibid.
- 21.U.S. Centers for Disease Control and Prevention (CDC), "Youth Risk Behavior Surveillance (YRBS) -- United States, 2001," Morbidity and Mortality Weekly Report, vol. 51, no. SS-4, June 28, 2002, Table 32; "Youth Risk Behavior Surveillance (YRBS) -- United States, 1999," Morbidity and Mortality Weekly Report, vol. 49, no. SS-5 (June 9, 2000), Table 32; CDC, "Youth Risk Behavior Surveillance (YRBS) -- United States, 1997," Morbidity and Mortality Weekly Report, vol. 47, no. SS-3 (August 14, 1998), Table 28; "Youth Risk Behavior Surveillance (YRBS) -- United States, 1995," Morbidity and Mortality Weekly Report, vol. 45, no. SS-4 (September 27, 1996), Table

- 20; "Youth Risk Behavior Surveillance (YRBS) -- United States, 1993," *Morbidity and Mortality Weekly Report*, vol. 44, no. SS-1 (March 24, 1995), Table 20.
- 22. National Institute of Allergy and Infectious Diseases, National Institutes of Health, U.S. Department of Health and Human Services, *Workshop Summary: Scientific Evidence on Condom Effectiveness for Sexually Transmitted Disease (STD) Prevention*, July 12-13, 2000, Hyatt Dulles Airport Herndon, VA, p. 8. (Released July 20, 2001.)
- 23.U.S. Centers for Disease Control and Prevention (CDC), "Questions and Answers About Male Latex Condoms to Prevent Sexual Transmission of HIV," *CDC Update* (CDC: Atlanta, GA: April 1997), pp. 1-2.

24.Ibid.

25.www.femalehealth.com/yourquests.html."

("The Truth About Condoms," Siecus Fact Sheet, November, 2002, www.siecus.org)

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### "STUDY LOOKS AT CONDOMS, WART VIRUS TRANSMISSION"

"HPV can cause genital warts in men and women, and some types – usually the ones that do not cause warts – have been linked to an increased risk of cancers of the cervix, vulva, vagina, anus and penis. Up to 50% of the sexually active men and women between the ages of 15 and 49 are believed to be infected with HPV at some point in their life, although most people clear the infection on their own and never develop cancer."

"Complete protection from genital HPV infection may be impossible because infections may occur at...sites not covered by the condom,' they write. (emphasis added.)" (SOURCE: Sexually Transmitted Diseases 2002;29:725-735.)

("Study Looks at Condoms, Wart Virus Transmission," www.abstinence.net/library/index.php?entryid=337)

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# "SCIENTIFIC REVIEW PANEL CONFIRMS: NO EVIDENCE CONDOMS ARE HIGHLY EFFECTIVE AGAINST STDS"

"However, the review panel concluded that epidemiological evidence is currently insufficient to provide an accurate assessment of the effectiveness of condoms in preventing the spread of Chlamydial infection, syphilis, chancroid, trichomoniasis, genital herpes and genital human Papillomavirus (HPV) infection."

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"At the request of former Rep. Tom Coburn of Oklahoma, the National Institutes of Health, the Centers for Disease Control and Prevention, the Food and Drug Josh McDowell Research Condoms

Administration, and the U.S. Agency for International Development organized the workshop held in June 2000. Twenty-eight expert panel members analyzed more than 138 peer-reviewed, published studies on the properties and user patterns of the male latex condom during penile-vaginal intercourse."

("Scientific Review Panel Confirms: No Evidence Condoms Are Highly Effective Against STDs," www.abstinence.net/library/index.php?entryid=391)

#### "EDITORIAL: TO TELL THE TRUTH ABOUT CONDOMS"

"The studies reviewed consistently reported that condoms had no impact on the risk of sexual transmission of human papillomavirus (HPV) infection in women, which is responsible for more than 98 percent of cervical cancers. Finally, they learned that there is no clear evidence that condoms reduce the risk of any other STD, including gonorrhea and chlamydia in women and HPV infection in men."

"The other truth is that America is experiencing an epidemic of STDs. Sixty percent of co-eds at Rutgers University, for example, were found to be infected with HPV at some time during a three-year study. A study of herpes infection showed that 45.9 percent of all African-Americans over the age of 11 in this country is infected. And there has been a 500 percent increase in the prevalence of genital herpes in white adolescents over the past 25 years."

(Joseph S. McIlhaney, Jr., M.D., "To Tell the Truth About Condoms," <a href="https://www.medinstitute.org/media/Condoms.htm">www.medinstitute.org/media/Condoms.htm</a>)

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"NIH REPORT ON THE SCIENTIFIC EVIDENCE ON CONDOM EFFECTIVENESS FOR SEXUALLY TRANSMITTED DISEASE (STD) PREVENTION:"

"Frequently Asked Questions"

"What is the 'NIH Condom Report'?"

"In June 2000, the National Institutes for Health co-sponsored a meeting of scientists, researchers and clinicians to examine, review and summarize the available scientific evidence for condom effectiveness in reducing the risk of transmission (or acquisition) of sexually transmitted diseases. Twenty-eight experts were charged with identifying and

reviewing published articles that contained data about the risk reduction effect of condoms and summarizing those published findings in a scientific report."

## "Who participated in the meeting? Who was on the expert panel?"

"NIH staff invited experts on condom effectiveness and STD prevention to participate as panel members. Others with specific expertise (knowledge of specific STDs, knowledge of the physical properties of latex, knowledge of condom testing procedures etc.) presented and summarized the current scientific data to the panel. Of the 28 expert panelists, four were nominated by The Medical Institute: Joe S. McIlhaney, Jr., M.D., President of the Medical Institute for Sexual Health; J. Thomas Fitch, M.D. Pediatrician and Chairman of the Board of The Medical Institute; David Hager, M.D., Obstetrician with specialization in infectious diseases; and, Mary Adam, M.D., Pediatrician."

"The conference coordinators extended additional invitations to non-panel researchers, practitioners and policy makers with a special interest in STD prevention and allowed a limited number of others from the general public to attend."

## "What were the findings?"

- "Consistent condom use reduces the yearly risk of contracting HIV from an infected sexual partner via vaginal sex by approximately 87percent."
- "Consistent condom use also reduces the risk of gonorrhea transmission from women to men."
- "Consistent condom use may or may not reduce the risk of chlamydia transmission from women to men."
- "Consistent condom use does not appear to reduce the risk of transmission of human papillomavirus (HPV) infection from men to women. Some evidence exists that condoms may reduce the risk of genital warts, but the results of studies to determine whether condoms reduce the risk of cervical dysplasia ('pre-cancer') and cervical cancer in women are equivocal (some show protection while others do not)."
- "There was insufficient evidence to make statements about condom effectiveness for any other STDs, including gonorrhea or chlamydia transmission from men to women and transmission of genital herpes, trichomoniasis, chancroid or syphilis."

# "What do the findings mean?"

"The available scientific evidence shows that condoms appear to reduce one's risk of contracting or transmitting only two STDs: HIV and gonorrhea (in men). While the panel stopped short of concluding that condoms do not reduce HPV infection risk, the report states that **all** the articles reviewed indicated that condoms did **not** reduce the risk of HPV infection. And for the other STDs—there simply was not enough evidence to make any conclusions about condom effectiveness."

("Nih Report On The Scientific Evidence On Condom Effectiveness For Sexually Transmitted Disease (Std) Prevention," www.medinstitue.org/media/NIH%20Answers.htm)

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## NIH CONDOM REPORT PRESS RELEASE"

"Federal Panel on Condoms Offers Crucial Warnings to Sexually Active Americans, Says The Medical Institute for Sexual Health"

"We are in the midst of an epidemic of sexually transmitted diseases,' continued Dr. McIlhaney. 'Approximately 15 million Americans acquire STDs each year. 25 percent are younger than 20. Some STDs are deadly. Others contribute to infertility and cancer."

"What this report tells us about the effectiveness of condoms and about our public health approach to STDs must be widely and loudly communicated to our young people. Ultimately, they must understand that there is only way to avoid the risk of contracting one of the approximately 25 STDs in existence today – that is sex within the context of marriage."

("NIH Condom Report Press Release – Fereal Panel on Condoms Offers Crucial Warnings to Sexually Active Americans, says The Medical Institute for Sexual Health," July 19, 2001; <a href="https://www.medinstitue.org/media/NIH%20Report.htm">www.medinstitue.org/media/NIH%20Report.htm</a>)

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#### "BIRTH CONTROL- CONDOM EFFECTIVENESS"

"These holes are 700 times larger than the HIV-1 virus. There are pores in latex, and some of the pores are large enough to pass sperm-sized particles. Carey, et al., observed leakage of HIV-sized particles through 33%+ of the latex condoms tested. In addition, as Gordon

points out in his review, the testing procedures for condoms are less than desirable. United States condom manufacturers are allowed 0.4% leaky condoms (AQL). Gordon states, "The fluctuations in sampling permits many batches not meeting AQL to be sold." In the United States, 12% of domestic and 21% of imported batches of condoms have failed to meet the 0.4% AQL." (10)

"In addition Steiner, et al., observed newer lots of condoms had actual breakage rates of 3.5-8.8%, while actual breakage rates for older lots ranged from 9.8-18.6%. In a study conducted by Ahmed, et al., 29%-42% of those who had used condoms experienced at least one breakage. In a survey conducted by the University of Manchester, 52% of those who had obtained condoms from their family planning clinic had one or more either burst or slip off in the 3 months before the survey. In studies by Albert, et al., and by Wright, et al., 36% and 38% of their respondents reported condom failures respectively." (12)

"Cohen, et al., (25) conducted a study in which patients who had contracted an STD were given a condom education course. Within nine months '19.9% of the men and 12.6% of the women returned with new STD,' some multiple times. The STD re-infection rate actually increased for women. Frosner states the U.S. government has withdrawn a \$2.6 million grant to study condoms because 'an unacceptably high number of condom users probably would have been infected in such a study.' He adds that the only safe sex is mutually monogamous and between two non-infected persons." (26)

10. "Collart, David G., M.D., loc. cit.

12. Collart, David G., M.D., op. cit.

25. Cohen, D.A.; Dent, C.; MacKinnon, D.; and Hahn, G.; Sexually Transmitted Diseases, Vol. 19, pp. 245-251, 1992.

26. Frösner, G.G., loc. cit."

(Dr. David G. Collart, "Birth Control- Condom Effectiveness" <a href="http://www.all.org/issues/se04.htm">http://www.all.org/issues/se04.htm</a>)

"SEXUAL HEALTH UPDATE"

"(FALL 2000, Volume 8 • Number 3)"

# "Condom Quiz: Frequently Asked Questions About Condoms"

1. "Natural pores present in latex cause condoms to be ineffective in preventing HIV and other sexually transmitted diseases."

☐ True ☐ False
2. "How often do condoms break or slip off during vaginal intercourse?"
A. "0 to 1%"
B. "2 to 4%"
C. "5 to 10%"
D. "11 to 15%"
E. "15 to 20%"
3. "What proportion of sexually active individuals use condoms consistently and correctly?"
A. "75 to 100%"
B. "50 to 75%"
C. "25 to 50%"
D. "It depends on the population"
4. "What is the risk of acquiring HIV from a single episode of vaginal intercourse with an infected person if a condom is not used?"
A. "Approximately .01% (1/10,000)"
B. "Approximately .1% (1/1,000)"
C. "Approximately 10% (1/10)"
D. "Approximately 25% (1/4)"
E. "Approximately 50% (1/2)"
5. "How effective are condoms for prevention of human papilloma virus (HPV)?"

Condoms

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Josh McDowell Research

A. "Highly effective (prevent 98 to 100 percent of infections)"
B. "Not effective at all (do not reduce the risk of infection any)"
C. "We do not know exactly, but in theory they should be very effective"
D. "We do not know exactly, but in theory they should not be very effective"
6. "Which of the following sexually transmitted diseases is most likely to be contracted from sexual intercourse with an infected person if a condom is used?"
A. "HIV"
B. "Hepatitis B"
C. "Gonorrhea"
D. "Chlamydia"
E. "HPV"
7. "There is good data to show that condoms are effective at reducing the risk of most sexually transmitted diseases."
□ True □ False
8. "If two different sexually transmitted diseases are transmitted by the same mechanism (by infected body fluids, for example), condoms should provide equal protection from both of them."
□ True □ False
9. "With typical use, what proportion of women relying on condoms for contraception will become pregnant in the first year?"
A. "Approximately 5%"
B. "Approximately 10%"
C. "Approximately 15%"

- D. "Approximately 25%"
- E. "Approximately 40%"
- 10. "If the relative risk of STD infection with condom use is .10, there is a 10 percent chance a condom user will get a STD."
- ☐ True ☐ False

#### "ANSWERS"

1. "Natural pores in latex cause condoms to be ineffective in preventing HIV and other sexually transmitted diseases."

"Answer: False"

"Despite a few studies that demonstrate some leakage of virus-sized particles through latex, infection due to leakage is highly unlikely, (1) particularly when the STD requires a large infectious dose to cause infection. (Infectious dose is the number of organisms required to produce infection). This does not mean that infection due to condom leakage never occurs. For STDs with low infectious doses, infection resulting from condom leakage is more likely, but still not probable."(2)

"The fact that the bacteria and viruses do not ordinarily leak through latex does not mean that condoms offer complete disease protection. Condoms can and do fail to prevent the transmission of infection, particularly with infections transmitted by skin-to-skin contact, because the condom fails to cover an area of infected genital skin."

"Infection due to condom leakage is the least likely cause of infection during condom use, and is most likely due to occasional and random manufacturing defects."

"When discussing condom failure, The Medical Institute suggests focusing on these facts: Even when used consistently and correctly, condoms do fail. Contracting (or transmitting) a sexually transmitted disease is one potential consequence of condom failure. Contracting a STD despite correct condom use is most likely to occur when: (a) the STD in question is transmitted by skin-to-skin contact and the condom does not cover an infected area; or (b) the condom breaks or slips. Infection due to condom leakage probably accounts for a very small portion of all sexually transmitted diseases. Note that these 'condom failures' can occur even when the condom is used correctly."

2. "How often do condoms break or slip off during vaginal intercourse?"

"Answer: B—2 to 4 percent of the time."

"Studies show that condom breakage and complete slippage rates range from 2-4 percent for most users. (3) Partial slippage (where the condom slips but does not come completely off the penis) also occurs, but is not included in the 2-4 percent figures."

"Although the condom breakage and slippage rate for one act of intercourse is low, after 100 episodes of intercourse with a 3 percent breakage and slippage rate, 95 percent of individuals will have experienced at least one condom break or slip. Condom breakage and slippage probably account for most condom failures (and subsequent infection) that occurs when condoms are used consistently and correctly."

"The cumulative effect of condom breakage and slippage means that sexually active condom users—even those who use condoms consistently and correctly—face substantial and increasing risk of pregnancy and/or STD when condoms are used for extended periods of time."

3. "What proportion of sexually active individuals use condoms consistently and correctly?"

"Answer: D—It depends on the population."

"In 1996, 40 percent of unmarried American adults reported using condoms the last time they had intercourse. (4) It is difficult to estimate rates of consistent use based on reported use at last intercourse. In 1995, 45 percent of adolescent males reported that they always used a condom during the prior year."(5)

"Unfortunately, the number of episodes of intercourse during the year was not reported, because the actual number of sexual acts (episodes or exposures) is important to determine one's risk of infection. For example, someone who had two episodes of intercourse during the year and used a condom both times would have been classified as an 'always' user in the 1995 study. Additionally, the individual who is reporting makes a difference, since adolescent girls report less frequent condom use than do adolescent boys. Given this gender-based disparity in reporting boys may regularly overestimate the frequency of their condom use. This potential reporting bias means that estimates of condom use reported by boys are somewhat suspect."

"Finally, even though reported condom use was higher, rates of consistent condom use declined with increasing age, so that, among 19 year olds only 39 percent reported always using a condom. This decline in use among older adolescents is important, because older adolescents are often more sexually experienced and more likely to be infected with a STD."

"Even among consistent condom users, incorrect condom use is common. A study of male college students who used condoms consistently found that one in three were exposed to pregnancy or STD risk in the prior month due to either incorrect use or condom failure. The majority of these experiences were due to incorrect use. (6) Examples of incorrect use include putting the condom on inside—out then flipping it over and putting it back on, putting the condom on after intercourse begins or completely unrolling the condom before putting it on."

"Even if condoms were 100 percent effective when used correctly, the existing high rates of inconsistent and incorrect use would place unmarried sexually active individuals at significant risk. This inconsistent and incorrect use, despite efforts to vigorously promote condoms and despite increases that have been reported in condom use rates at last intercourse, is one reason STD rates among sexually active unmarried adolescents remain high."

4. "What is the risk of acquiring HIV from a single episode of vaginal intercourse with an infected person if a condom is not used?"

"Answer: B—Approximately 0.1 percent."

"HIV is one of the least infectious sexually transmitted diseases transmitted by heterosexual vaginal intercourse. Though the risk of contracting HIV from an infected partner varies with the length of time infected and whether individuals are receiving HIV treatment, the risk of HIV infection is approximately 1 in 1,000, or 0.1 percent. (7) In fact, an individual who participates in vaginal intercourse without a condom with an HIV positive sexual partner for an entire year probably faces less than a 10 percent probability of infection. (8) Other factors that seem to alter the transmission of HIV are the presence of another STD (especially, ulcerative STDs) and whether the participating males are circumcised. In contrast to the low transmission rates of HIV, a single episode of vaginal intercourse with someone who has gonorrhea confers a 20 to 50 percent risk of infection if a condom is not used." (9)(10)

"When discussing condom effectiveness for STD prevention, it is important to keep in mind these differences in disease-specific infectivities (per episode infection risks). Further, generalizing condom effectiveness from diseases with low infectivities (for example, HIV) and using these results to predict condom effectiveness in diseases with higher infectivities (for example, gonorrhea, chlamydia) is not an honest or valid generalization. Neither is attempting to predict condom effectiveness based on pregnancy prevention data, since pregnancy can occur only during three days a month, but an STD can be transmitted every day of the month. Most STDs are much more infectious than HIV. In fact, the very low infectivity of HIV—even when condoms are not used—partially explains why condoms seem to prevent HIV infection. In this situation, at least a portion of the reported condom 'effectiveness' is due to the small chance of contracting HIV

during a single act of vaginal intercourse with an infected partner even if condoms are not used."

5. "How effective are condoms for prevention of human papilloma virus (HPV)?" "Answer: D—We do not know exactly, but in theory they should not be very effective."

"We do not know exactly what effect condom use has on HPV infection risk, but in theory condoms should not be very effective. HPV infection is spread by skin-to-skin contact and the virus is frequently present throughout the genital region of infected people—including those areas not covered by the condom. (11) Since a condom only covers the penis itself and the virus often resides in the pubic area or on the scrotum, infection may be transmitted or contracted even when condoms are used consistently and correctly—100 percent of the time. In fact, published studies have failed to demonstrate that the male latex condom protects women from HPV infection."

"There are studies that suggest condoms may offer some protection from genital warts and cervical cancer in women, but definitive conclusions about condom effectiveness for HPV cannot be concluded from these studies. Similarly, condom use may lower the risk of genital warts in men, but the protection is incomplete."

"HPV is common and very infectious, and condoms are of limited value (if any) for reducing the risk of infection. Even couples that use condoms perfectly are at risk of HPV infection when one partner is infected."

6. "Which of the following sexually transmitted diseases is most likely to be transmitted from sexual intercourse with an infected person even if a condom is used?"

"Answer: E—HPV."

"As discussed above, condoms offer limited (if any) protection from HPV because the infection is spread by skin-to-skin contact. The other infections listed as possible answers are spread primarily by exposure to infected body fluids. When condoms 'work,' they reduce the exposure of one sexual partner to the sexual bodily fluids of the other. Barring condom failure, the infections transmitted by infected bodily fluids are theoretically more likely to be prevented by consistent condom use."

7. "There is good data to show that condoms effectively reduce the risk of most sexually transmitted diseases."

"Answer: A—False."

"Studies show that condoms reduce the risk of HIV if they are used 'consistently and correctly.' (12) A few studies with very short follow-up periods show that condoms

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effectively reduce the short-term risk for gonorrhea. (13)(14) Even though latex condoms have been vigorously promoted to prevent non-HIV STDs, proof that condoms prevent transmission of non-HIV STDs is lacking."

"Although condoms may have some ability to reduce the risk of cervical cancer and risk of developing genital warts, condoms have not been proven effective in reducing the risk of contracting human papilloma virus (HPV) for females. The available data about transmission of genital herpes, syphilis, chancroid, Hepatitis B and trichomonas vaginalis is insufficient to draw conclusions about condom effectiveness."

"The effectiveness of the condom in decreasing the transmission of chlamydia is questionable. Condoms may provide some protection, but the research is unclear."

"Theoretically, condoms should reduce the risk of diseases that are transmitted by infected body fluids, but in the absence of good data from appropriate studies, risk reduction cannot be assumed. Genital herpes and syphilis, like HPV, are transmitted by exposure to organisms living on the skin or from skin lesions. Therefore, any reduction in transmission risk provided by condom use is likely to be substantially less for these skin-transmitted infections than for those that are transmitted by infected body fluids."

"Despite the absence of reliable data, many continue to promote condom use as an effective way to prevent all sexually transmitted diseases. Common reasons given to justify this 'leap of faith' are: 1) a personal belief that condoms should be effective; 2) a personal belief that condoms will eventually be proven effective; 3) a personal belief that, 'condoms may not be perfect, but they are all we have;' and, 4) a fear that people will stop using condoms if they believe that condoms do not fully protect them from all STDs."

"Condoms, if used consistently and correctly, do decrease the transmission of HIV to an uninfected partner. Condoms also seem to protect users from contracting gonorrhea when the exposure to gonorrhea is limited to a few sex acts. Condoms may offer some risk reduction for chlamydia, but the data is unclear. For other STDs, we lack adequate proof that condoms are effective in decreasing one's risk of contracting them. Until condoms can be proven to protect from other STDs, we must continue to be forthright and honest with patients about the lack of available evidence."

8. "If two different sexually transmitted diseases are transmitted by the same mechanism (by infected body fluids, for example), condoms should provide equal protection from both of them."

"Answer: A—False."

"If all STDs had the same infectivity (risk of infection with one exposure), the same infectious dose (number of organisms required to produce infection), and were transmitted

by the same mechanism, this statement would be true. However, some STDs (for example, gonorrhea and chancroid) are highly contagious (have high infectivities) while others (like HIV) are not. These differences mean that the risk of contracting or transmitting infection will be quite different for the two infections, even when condoms are used. And real risk of infection does exist because condoms—even when used consistently— do fail. Highly infectious STDs (infections with high infectivities) are less 'forgiving' of condom failure. Therefore, even one episode of condom breakage or slippage may expose one to a significant risk of contracting a highly infectious STD, like gonorrhea."

"The mechanism of transmission of infection is also an important factor. Infections spread by skin-to-skin contact (like genital herpes and HPV) can be transmitted during many forms of sexual contact, even if a condom is used and does not break, slip or otherwise fail. Again, this transmission is possible because the condom may not cover all the infected areas on the genitalia."

"The lack of data about condom effectiveness for preventing non-HIV STDs is often ignored or minimized by condom advocates because they 'believe' that condoms should be effective in reducing the risks of STD transmission. You will hear terms like, 'biologically plausible' or 'reasonable' to justify their stated 'belief' that condoms should be equally effective for diseases spread by the same mechanism. This rationale is inaccurate, however. Differences in per-episode infection risk for different STDs must be considered. These differing risks probably account for the observed differences in condom effectiveness for different STDs."

9. "With typical use, what proportion of women relying on condoms for contraception will become pregnant in the first year?"

"Answer: C—Approximately 15%"

"With typical use, a woman experiences a 14 percent probability of becoming pregnant during the first year of condom use. (15) This failure rate includes both the failure of the condom itself (primarily breakage and slippage) and the failure to use condoms consistently and correctly—100 percent of the time. The theoretical pregnancy rate if condoms are used perfectly is approximately 2-3 percent." (16)

"A 15 year-old girl who is sexually active and uses condoms with 'typical' effectiveness has a very high risk of becoming pregnant before she is 20. After five years of condom use with a yearly pregnancy rate of 15 percent, an adolescent would face a greater than 50 percent chance of having become pregnant. Even if this young woman were able to use condoms 'perfectly' with every sex act for five years, she would face greater than a 10 percent risk of pregnancy."

10. "If the relative risk of STD infection with condom use is .10, there is a 10 percent chance a condom user will get a STD."

"A: False"

"A relative risk of 0.10 means that condom users are 10 percent as likely to be infected as condom non-users. It does not mean the risk of infection is 10 percent. In this case, if the risk of infection in condom non-users is 20 percent, the risk in condom users would be 2 percent (10 percent of the risk in non-users)."

# "Why is this Sexual Health Update about condoms?"

"Over 50 percent of American high school students have never had sexual intercourse. This means that nearly 50 percent of high school students have participated in sexual intercourse. The primary strategy promoted today for STD prevention in unmarried sexually active individuals of any age is condom use."

"Those who promote condoms regularly make inaccurate statements claiming that, 'condoms reduce the risk of STDs by 98 percent.' Even more incorrect is the common statement, 'condoms are 98 percent effective.' No scientifically credible data published to date supports these assertions."

"Unfortunately, the use of condoms as a long-term STD prevention strategy has been advocated for years based on assumptions about condom effectiveness that are not supported by good data. When the lack of supporting data is mentioned, many express fears that telling young people and single adults about these uncertainties or quoting published condom failure rates will cause people to stop using condoms. There is no anecdotal or scientific evidence to suggest that telling people the truth would result in fewer people using condoms."

"In contrast, The Medical Institute believes individuals must know all the facts about condoms, including condom failure rates (when known) and the lack of supporting data regarding risk reduction for most non-HIV STDs. This information is needed so that individuals can make educated and informed decisions. The messages provided to young people and unmarried adults about sexual activity and condoms need to stress that abstinence from sexual activity and sex while using a condom are not equally safe behaviors."

"Sexual abstinence, that is, 'the calculated decision and deliberate action to refrain from sexual activity,' eliminates the risks of both pregnancy and STD making it clearly the healthiest and preferred sexual behavior for unmarried adolescents and young adults."

"In keeping with efforts to present all the facts about condoms, The Medical Institute also believes it is important to avoid exaggerating condom failure rates or making inaccurate

statements about STD and pregnancy risks. The scientific facts speak for themselves. There is no need to exaggerate or misstate the evidence about condoms and the risk of either STD or pregnancy. Such inaccuracies ultimately hurt our young people and the credibility of the abstinence message."

"As mentioned earlier, the questions asked in this Sexual Health Update are typical of the questions The Medical Institute's research department receives on a weekly basis. Too often, by the time people call us with a question, incorrect information has already been given and cannot be corrected. Misinformation frequently results in harsh criticism of abstinence supporters by opponents of the abstinence message. Abstinence supporters may be labeled 'fear-based,' 'medically inaccurate,' 'religiously-based' or just plain 'ignorant.'"

"The truth about condoms is that, if used consistently and correctly—100 percent of the time—they do reduce the risk of HIV and for a short period of time gonorrhea. They may reduce the risk for chlamydia, but the research is unclear. For other STDs, there is simply not enough information to make any statements of protection or non-protection. Most unmarried sexually active individuals do not use condoms consistently and correctly. (According to the Centers for Disease Control, in order for condoms to be effective, they must be used consistently and correctly—which means 100 percent of the time.)"

"These non-monogamous sexual partners are therefore at high risk of non-marital pregnancy and STDs. Even the most careful unmarried sexually active condom users are at consider able risk for STDs and some risk for a non-marital pregnancy if they continue to participate in sexual activity."

"Sexual abstinence is, and will remain, the only way unmarried individuals can eliminate and not just reduce the risk of sexually transmitted disease and non-marital pregnancy. Condoms do not make sex safe enough to preserve the future health, hope and happiness for unmarried individuals."

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#### "A NEW GENERATION OF PROBLEMS"

"With 'typical use', 13.9 percent of condom-using couples become pregnant within the year (Fu et al 1999)."

"Preventing a sexually transmitted infection is most often represented by the calculation of relative risk (RR). Relative risk is the probability that an individual using a condom would contract the disease compared to the probability he/she will contract that same disease when a condom is not used."

"The risk to an HIV-negative male using a condom of contracting HIV from intercourse with an HIV-positive female is reduced to 1 in 100 (1%). Then the risk of infection while using a condom is about 10 percent of what it would be without a condom. Therefore, the relative risk of contracting HIV when condoms are used is 10 percent."

(Joshua Mann, M.D., M.P.H., Joe S. McIllhaney, Jr., M.D. and Curtis C. Stine, M.D., "A New Generation of Problems", from Building Healthy Futures: Tools for helping adolescents avoid or delay the onset of sexual activity, The Medical Institute for Sexual Health, Austin TX. 2000, pp9-10)

#### "LATEX CONDOMS AND SEXUALLY TRANSMITTED DISEASES"

"Latex condoms, when used consistently and correctly, are highly effective in preventing the transmission of HIV, the virus that causes AIDS." (p. 1)

"Latex condoms, when used consistently and correctly, are highly effective in preventing transmission of HIV." (p. 2)

"Latex condoms, when used consistently and correctly, can reduce the risk of transmission of gonorrhea, chlamydia, and trichomoniasis." (P. 2)

"Latex condoms when used consistently and correctly, can reduce the risk of genital herpes, syphilis, chancroid. And HPV infection, only when the infected areas are covered or protected by the condom." (p. 3)

("Latex Condoms and Sexually Transmitted Diseases Prevention Messages," Centers for Disease Control and Prevention)

"CDC-HIV/AIDS PREVENTION- FACTS ABOUT CONDOMS AND THEIR USE IN PREVENTING HIV INFECTION AND OTHER STDS"

"As these studies indicate, condoms must be used consistently and correctly to provide maximum protection. Consistent use means using a condom from start to finish with each act of intercourse. Correct condom use should include the following steps:"

- "Use a new condom for each act of intercourse."
- "Put on the condom as soon as erection occurs and before any sexual contact (vaginal, anal, or oral)."
- "Hold the tip of the condom and unroll it onto the erect penis, leaving space at the tip of the condom, yet ensuring that no air is trapped in the condom's tip."
- "Adequate lubrication is important, but use only water-based lubricants, such as glycerine or lubrication jellies (which can be purchased at any pharmacy). Oil-based lubricants, such as petroleum jelly, cold cream, hand lotion, or baby oil, can weaken the condom"
- "Withdraw from the partner immediately after ejaculation, holding the condom firmly to keep it from slipping off."

(CDC-HIV/AIDS "Prevention- facts about Condoms and their Use in Preventing HIV Infection and other STDs", July 30, 1993)

"HOW EFFECTIVE ARE CONDOMS IN PREVENTING PREGNANCY AND

# "HOW EFFECTIVE ARE CONDOMS IN PREVENTING PREGNANCY AND STDS IN ADOLESCENTS?"

"Are We Using The Best Primary Strategy?"

"(September 1996, J.Thomas Fitch, M.D.)"

#### A. "Introduction"

1) "The Problem: A unprecedented epidemic of out-of-wedlock pregnancy "

"and STDs in adolescents: (Webster defines adolescents as ages 12 years to approximately 20 years of age. By definition a teenager includes the years from 13 to 19. For the purpose of this paper the terms are interchangeable realizing in some studies of teenagers less than 13 years of age is included and some studies of adolescents really stop at 18 to 19.)"

- a) "Though they make up less than 10% of the population, teens contract" "approximately 25% of the STDs in America."
- b) "Teens are 10 times more susceptible to Pelvic Inflammatory Disease (PID) than adults and thus are at greater risk for later infertility."
- c) "25% of all new HIV infections are found in people under the age of 22. (peri-natal transmission accounts for a small part of the 25% figure.)"
- d) "The prevalence of chlamydia is higher in the adolescent age group than in any other age group."
- e) "A recent study in the AJDC found that in the population they studied, 38% of sexually active females, ages 13-21 years of age, were infected with the human papillomavirus. (the virus which causes 90-95% of all cases of cancer of the cervix.)"
- f) "The incidence of gonorrhea is increasing among adolescents while it is decreasing in all other age groups."
- g) "77% of unmarried teen mothers go on welfare within 5 years of giving birth. A recent study out of Washington D.C. estimated that taxpayers will spend nearly \$7 billion dollars in 1996 to deal with social problems resulting from recent birth to girls under age 18."

# **2.** "The Current Strategy:"

- a) "Clearly, what we are doing is not working. Are we better off now than we were ten years ago? Will we be better off ten years from now in terms of teen STDs and out of wedlock pregnancy?"
- b) "Although most medical groups, including the AAP, acknowledge that abstaining from intercourse is the surest way to prevent STDs and pregnancy, and encourage those teenagers who choose to be abstinent, the greatest effort and attention seems to be directed toward increasing consistent and correct condom use, the assumption being that most teenagers will not choose abstinence."
- 3. "Strategies for the Future:"

- a) "Clearly a change in behavior is needed to stem the current epidemic. The question before us today is, 'where should the <u>primary</u> emphasis be placed?' Should we teach teens to postpone sexual intercourse and other activities that lead to pregnancy and STDs (until they can commit to a lifelong, faithful, mutually monogamous relationship, most commonly found in marriage) as our primary strategy or should we teach and encourage teens to use condoms correctly and 100% of the time as our primary strategy?"
- b) "If the main strategy is to increased condom use then the basic question of condom effectiveness for preventing STDs and pregnancy must be answered."
- c) "The AAP, in their recent statement on 'Condom Availability for Youth,' make the statement that the 'correct use of condoms during each coital encounter is a well-established prevention measure.' The committee later says that 'The consensus of expert opinion concludes that the proper use of latex condoms can considerably reduce the risk of transmission of STD agents, including HIV.' How correct are these statements? Does the medical literature substantiate 'the consensus of expert opinion'?"
- d) "Clearly the literature must be reviewed to answer the following questions about the effectiveness of condoms."

# B. "What Questions Should Be Asked When Evaluating the Effectiveness of Condoms?"

- 1. "What factors are responsible for method failure and what is the accepted method failure rate?"
- 2. "What is the first year failure rate for condoms in preventing pregnancy?"
- 3. "Are condoms equally effective against all STDs?"
- 4. "Are males and females equally protected?"
- 5. "What level of consistent condom use is needed to give good protection? Stated another way, how protective is intermittent condom use?"

- 6. "At present what percent of sexually active youths use a condom consistently every time?"
- 7. "At present what percent of sexually active youths who use condoms use one correctly every time?"
- 8. "Given perfect and consistent condom use what levels of relative risk reduction for pregnancy and STDs are acceptable to public health officials, physicians, patients, and parents? Are the levels of acceptable risk reduction equal for each group?"
- 9. "Does the public know the actual risk for pregnancy and the various STDs? Does the medical profession know? Several years ago a poll of the second year medical students at the University of Arizona revealed that 89% percent of the class believed the efficacy of the condom to be 98% or higher? The rest of this paper will address these questions."

## C. "Method Failure"

- 1. "What is the definition of condom method failure?"
  - a. "Method failure includes 1) the rupture or breakage of a condom during intercourse or withdrawal, 2) slippage either completely off the penis or partial slippage down the shaft of the penis during intercourse and 3) relatively rare manufacturing defects. (3-4 holes/thousand condoms are allowed by the FDA)."
  - b. "User failure is the failure to use a condom properly (such as failing to put on a condom prior to penetration, not holding a condom in place during withdrawal, not withdrawing while penis is still erect, poking holes in condom with fingernails, improper positioning of condom, etc.) The ultimate user failure of course is no use at all."
- 2. "What is the reported range of condom breakage or rupture for vaginal intercourse?"
  - a. "You will find studies in the literature that report a 0-12% condom breakage rate for vaginal intercourse. Most tend to be in the 1.5-5% range."
  - b. "A zero percent breakage rate was reported in the AJPH, Nov. 1995. It was a study of 41 licensed prostitutes in Nevada from three brothels with 353 acts of vaginal intercourse with clients. No condoms broke, 0.6% fell off completely during withdrawal, 3.4% partially slipped down during intercourse and 4.3%

slipped down but not off in withdrawal. In retrospective questionnaires from the same group during the previous month approximately 0.19% broke and 0.91% fell off during intercourse. The authors acknowledge that licensed sex workers in Nevada enjoy a work environment that fosters consistent and correct condom use (state law) and that their results would not likely apply to the entire universe of sex workers. The authors also acknowledge that the 8% refusal rate to participate in the study may bias that results in that women who had had problems using condoms in the past may have chosen not to participate in the study."

- c. "1994 Contraceptive Technology', 16th Edition uses an average 1.5% condom breakage statistic."
- 3. "What is the accepted method failure rate? About 2-3%."
  - a) "Probably the most widely accepted authors and study are Trussell and Hatcher as published in 'Contraception,' January 1992, vol. 45, No. 1."
  - b) "The above authors found a 1.3% breakage rate and a 0.6% rate of condoms that completely fell off during intercourse."
    - 1) "Of concern however is the additional finding of incomplete slippage. (In other words, the condom did not fall off completely but slipped down the shaft of the penis.) 9.4% slipped during intercourse (Method failure) and 16.5% slipped during withdrawal. (user failure)."
    - 2) "The authors had this comment about slippage without completely falling off. 'Given the frequency of such occurrences, research is needed to determine whether slippage places the woman at greater risk of pregnancy (due to possible semen leakage from the open end of the condom) or either partner at greater risk of acquiring a sexually transmitted disease (either due to semen leakage or due to contact of the penile shaft and the female genitalia)."
- 4. "Summary of Method Failure:"
  - a. "The generally accepted method failure rate is 2-3%."

- b. "A 2% failure rate means 2 failures in 100 acts of intercourse. If a couple has sex twice a week they could expect two failures per year. In five years 10 failures, in ten years 20 failures. Sex four times per week would double the figures."
- c. "For licensed prostitutes in Nevada, professionals whose jobs and lives are on the line some 105 times per month, method failure may be 1% or less. For adolescents just beginning sex there are no studies but one would assume that the rate would be greater than 2-3%."

### D. "Condom Use"

- 1. "What percent of sexually active individuals report condom use at last intercourse?"
- a) "In the 1988 National Study of Adolescent Males (NSAM), 57% of sexually active teenage males aged 15-19 reported use of a condom at last intercourse. In contrast, only 31% of teenage females reported condom use at last intercourse in the 1988 NSFG. 'Either males over report use of condoms because they know that it is the socially responsible answer or females under report condom use when a condom is used as and adjunct to another method."
  - b) "23% of 15-19 year olds reported condom use at last intercourse in a study by Orr & Langefeld, <u>Pediatrics</u>, 91:5, May 1993."
- 2. "What percent of sexually active individuals use condoms consistently every time?"
  - a) "The highest rate of consistent condom use I could find is in two studies (Saracco, 1993 and de Vincenzi, 1994) of serodiscordant heterosexual couples. (i.e. in which one partner is HIV positive and the other HIV negative). In these studies, despite the fact that the uninfected partner knew their partner had HIV infection and despite frequent counseling, only 50% used a condom every time. (de Vincenzi 48.4% & Saracco 56%)."
  - b) "8-9% of adolescents used a condom always for STD prevention and 17% used a condom always for contraception according to authors Orr & Langefeld, 'Pediatrics' 91:5, May 1993. The same authors reported intermittent use 54% for contraception and 50-60% for STD

prevention."

- c) "In an article on 'Adolescents and Condom Use' in <u>AJDC</u>, Vol. 147, 1993 author Joffee quotes one study which showed that 90% use was achieved by only 17% of adolescents. Another study quoted was that 29.5% of males in the National Survey of Adolescent Males reported using a condom all the time with their last or next to last partner."
- d)"A study in 'Pediatrics', Vol. 93, April 1994 reported on a national 5 year Swiss STOP-AIDS Campaign to modify sexual behavior among adolescents. The authors were happy that in males the regular use of condoms increased from 22% to 34% and in females the regular use of condoms increased from 10% to 27%. This still leaves 66% not using condoms regularly."
- 3. "What percent of sexually active individuals use a condom correctly?"
  - a) "The adolescent committee of ACOG in their report of April 1995, Number 154 on 'Condom Availability for Adolescents' presented in table 1 four factors in good condom use: 1) Put on Condom prior to penetration 2) Hold condom in place during withdrawal 3) Withdraw while penis is still erect and 4) Use a condom during every act of intercourse. Out of a perfect score of 4.0 the average score was about 2.0."
  - b) "'Quality of Condom Use as Reported by Female Clients of a Family Planning Clinic', Oakley, et. Al, AJPH, 1993, Vol. 85, No. 11."
    - 1) "In a study of 360 female family planning clients who reported using condoms as their primary method of contraception for at least one month 1% always engaged in all five use behaviors studied: 1) using a condom for each sexual intercourse, 2) putting the condom on before first entry, 3) withdrawal after intercourse while there is still an erection, 4) holding on to the condom's rim during withdrawal, and 5) using foam."
    - 2) "12% consistently engaged in four criteria, 24% in three criteria, 28% in two, and 21% in one. Almost 13% did not consistently engage in any of the use behaviors."
    - 3) "The authors report that 'in national surveys and other large-scale studies, only 5% to 17% of individuals have reported using

condoms for each episode of intercourse. In smaller, less representative studies, from 29% to 41% have reported use of condoms for every sexual contact during the time period studied.' The authors did not say what time period studied was the average, but their study was for a month."

- 4) "In the current reported study 37% of all of the condom users reported using a condom every time they had sex during a condom study month."
- c) "A recent 1996 article (Arch Pediatr Adolesc Med/Vol. 150, Jan 1996) reported on the combined contraceptive practices among urban African-American early adolescents. Authors Stanton (et.al) conclude that many youth are using condoms and prescription birth control simultaneously and these use rates can be increased through AIDS education interventions. A question which the authors did not address was what percent used a condom correctly and consistently and was there any clinical difference in regard to rates of STD infection or pregnancy. A review of this study shows that it is a poorly reported study and based on table 3 on page 21 the best consistent condom use one can interpolate after the AIDS intervention program was 35% or less."
- 4. "Does increase in the number of partners increase condom use? No!"
  - a) "Joffe in the previously mentioned 1993 article in AJDC says that 'studies by DiClemente et al, Bowie and Ford, and Sonenstein (et.al) demonstrated that condom use is inversely related to the number of lifetime partners.""
  - b) "Joffe further says 'of considerable concern is that condom use by adolescents who may be at highest risk for HIV and STDs is quite low.""
- 5. "Summary of Condom Use:"
  - a) "Condom use at last intercourse by adolescents ranges from approximately 30-50%."
  - b) "Consistent condom use by adolescents ranges from approximately 5% to 40%."

- c) "Correct condom use by adolescents is approximately 50% or less."
- d) "Consistent condom in two studies of adults where the sero-negative person knew their partner was infected by HIV was achieved by only 50% of the couples."
- e) "Condom use is less in those individuals at high risk and those with higher numbers of lifetime partners."

## E. "Effectiveness of Condoms Preventing Pregnancy:"

1. "What is the average 1st year failure rate for pregnancy for all ages, both married and unmarried, corrected for abortion underreporting and standardized? Based on 1982 NSFG statistic 15.7% and 1988 NSFG statistics: 5.8%."

("Family Planning Perspectives," Volume 21, Number 3, May/June 1989 and Volume 24, Number 1, January/February 1992.)

- 2. "What is the lowest reported 1st year failure rate for pregnancy in the world literature for a large study? 4.2%"
  - a) "This was a large study in 1974 from Great Britain of 2,057 highly motivated married couples 25-39 years of age."

(Glass, et. At., "Contraception," November 1974, Vol. 10, No. 6, Pages 591-598.)

- 3. "While a 10-15% yearly failure rate for condoms is regularly quoted, various authors will mentions that a 1% or 2% failure rate is reported or is theoretically possible."
  - a) "For example both the CDC (in their MNWR report August 6, 1993/Vol. 42/No 30) and the AAP Committee on Adolescence, ('Condom Availability for Youth', Pediatrics, Vol. 95, No. 2), report that consistent male condom users will have a 2% failure rate. When the reference ('Studies in Family Planning,' Vol. 21, No. 1) is looked up you find on Page 52, Table 1, Footnote 'c' under the lowest expected column: 'the <u>author's best guess</u> of the percentage expected to experience an accidental pregnancy during the first year if they do not stop use for any other reason.""
  - b) "Other authors will refer to several small studies in Great Britain that achieved a 1% failure rate. One such study was reported in 1969 in the 'Practitioner,' 202:677-681. It was a study of 53 couples and the

criteria for recruitment into the study were that the "woman should have had at least four pregnancies in the previous six years, including a live birth in the last twelve months, and the couple should be known to be in need of advice and assistance." Nineteen of the 53 couples had 6 or more children and one was 43 years old with 19 children."

c) "Others will quote small studies in women over 35 years of age that have low failure rates. For example a study in Great Britain studied women ages 35-39, parity 0-2, that used condoms for 49+ weeks and found a yearly failure rate of 1.2%.

(Vessey, et. At, 'British Journal of Family Planning' 14 (2): 40-43, July 1988.)

- d) "Pediatric and Adolescent Gynecology,' 1992, Editors Sue Carpenter, M.D., and John Rock, M.D., Raven Press, New York. On page 344 under the male condom section the authors say the following: 'The first year failure rate for condoms can be as low as 1 to 4%. Among typical users, failure rates are 10-20%.' The referenced article for the 1-4% failure rate is 'Family Planning Perspective, 1982; 14:68. On Page 72, Table 2 you find 'estimated' percentage of currently married women who have an unplanned pregnancy with the first year of contraceptive use. The 'estimated' first year failure rate for women over 30 years of age varied from 0.9 to 4.2 depending on age and pregnancy intention. It should be pointed out that the quoted 1-4% failure rates are calculation based on data collected from the 1973 and 1976 National Survey of Family Growth and thus are estimates. In addition these figures were not adjusted for abortion underreporting. In summary we have a 1992 textbook on adolescent gynecology quoting figures on married women over 30 years of age in a publication from 1982 using data from 1973 to 1976."
- e) "Pediatric & Adolescent Gynecology,' Third Edition 1990, Editors S. Emans, M.D. and Donald Golstein, M.D. The authors quote a failure rate of 2-20% and use the about 1982 issue of 'Family Planning Perspectives' as one of three references."
- 4. "Summary of Condom Failure Rates for Pregnancy:"
  - a) "The average first year failure rate for condoms for prevention of pregnancy for all ages, both married and unmarried, is approximately 15%."

b) "The lowest reported first year failure rate in a large diverse group for condoms in the prevention of pregnancy is 4.2%."

# F. "Effectiveness of Condoms to Prevent non AIDS STD's as Referenced by the CDC. (Cates and Stone article 'Family Planning Perspectives,' 1992)"

- 1. "General information on statistical data and reporting:"
  - a) "The statistical term most used in the following articles is relative risk, often abbreviated as RR. It can be defined as the proportion of risk that a group is still exposed to compared to a reference group."
  - b) "In the following studies for the most part the authors are comparing the relative risk of 'always condom use' (Experimental group) to 'no condom use' (control group). At times the 'always condom users' will be compared to the sum of the intermittent condom users and the no condom users."
  - c) "In the area of STDs it is important to remember that the condom is used to prevent exposure to disease. In studies on STDs we are interested in the proportion of time a condom fails to prevent disease. The proportion of time a condom fails to prevent disease is also the percent that the condom is failing to its job."
  - d) "When evaluation condom effectiveness it is important to know the likelihood of infection given exposure to disease. For example many experts estimate the chance of acquiring HIV from one episode of vaginal intercourse (with no condom use) to be 1 in 500 versus 1 in 2 with the HPV virus."
  - e) "At time the amount of relative risk reduction (=RRR) is reported which is 1 minus the relative risk."
  - f) "If the RR is greater than 1.0 then there is no risk reduction."
  - g) "In the HIV sero-conversion studies it is important to distinguish between rate of sero-conversion and relative risk. For example in the Saracco study 2% of always condom users sero-converted compared to 10% of the individuals who did not use a condom. The relative risk for condom users is not 2% but 20% (0.20) as you compare the 2% to the 10%. In the Brazil study 23% of the condom users sero-converted compared to 53% of non condom users. The relative risk is 43%. In

the Weller meta-analysis of eleven studies the average relative risk was 31% or stated another way 31% of the time condoms failed to prevent HIV infection."

- 2. "General Information on mechanism of STD spread"
  - a) "STD's such as Chlamydia trachomatis, Neisseria gonorrhoeae, HIV, are spread by fluids such as semen and vaginal secretions. STD's such as Syphilis, Human papillomavirus (HPV), and Herpes Simplex (HSV) are spread by skin to skin contact."
  - b) "The CDC in their MNWR of March 11, 1988, Vol. 37, No. 9 report that 'For infectious agents spread from lesions rather than fluids, condoms may offer less protection because area of skin not covered by the condom may be infectious or vulnerable to infection."
- 3. "The CDC in their MNWR report of August 6, 1993, Vol. 42, No. 30 report the following: 'Condom use reduces the risk for gonorrhea, herpes simplex virus (HSV) infection, genital ulcers, and pelvic inflammatory disease. In addition, intact latex condoms provide a continuous mechanical barrier to HIV, HSV, hepatitis B virus (HBV), Chlamydia trachomatis, and Neisseria gonorrhoeae.' Please note that HPV (human papillomavirus) was not mentioned.

(The referenced article for the CDC quote was an article by Cates & Stone, Family Planning Perspective, 1992;24:75-84. Items #4 & 5 below are taken from Table 1, page 78 of the 1992 Cates & Stone article).

- 4. "Studies on condom efficacy for prevention of STD's on Males, Table 1, Page 78 before 1980.' The majority studied only gonorrhea but several include (NSU) non-specific urethritis (Chlamydia for the most part) and one study mentioned syphilis. There were no studies on efficacy for Herpes Simplex, Hepatitis B, or Human papillomavirus."
  - a) "Cates & Stone reference only six articles for males and four of the six are before 1980. The majority studied only gonorrhea but several include (NSU) non-specific urethritis (Chlamydia for the most part) and one study mentioned syphilis. There were no studies on efficacy for Herpes simplex, Hepatitis B, or Human papillomavirus."
  - b) "Pemberton, 'British Journal Veneral disease,' 1972, Vol. 48: Page 391 showed a relative risk even with condoms of 33% for syphilis

- (due to the small numbers this may not be significant), 51% for gonorrhea, and 100% for non-specific urethritis (for the most part probably Chlamydia)."
- c) "Barlow, 1977, 'Lancet,' October 15, 1977, Page 811, showed a relative risk of 25% for gonorrhea when condoms were always used but 90% with incorrect users. Only 7-8% of the total clinic group used condoms at all. They also reported the following: 'A totally unexpected finding was that non-specific urethritis was diagnosed as often in the group of condom users (both correct and incorrect) as in the rest of the clinic users...The organism implicated in most cases of N.S.U. is Chlamydia trachomatis."
- d) "Hart, 'British Journal Veneral Disease, 1974,' 50, Page 68 reports zero risk of an STD (the type of STD was not reported in the article) for Australian soldiers returning from Vietnam after 12 months. Of 55 soldiers who had always used a condom none developed a STD. Of interest is that approximately half of the 55 had had only one episode of sex. 78% of this group had three or fewer episodes of sex. Another interesting fact seen in this study is that 27% of non condom users developed an STD but 42% of sometime users developed an STD. Few will argue that for most STDs a condom will reduce risk for a single act of sex but over the long haul there is little risk protection form inconsistent condom use. Interestingly, in this study and many others in this report, the 'sometime condom users' have greater rates of infection than 'non condom users.' A possible explanation is that 'sometime condom users' as a group may have riskier sex with more partners than 'non condom users.'"
- e) "Hooper, 'American Journal of Epidemiology,' Vol. 108, No. 2, studied volunteer crew members of a large naval vessel after a four day liberty. The volunteers were tested before and after liberty. No crew member who used a condom developed gonorrhea but due to the small number of sailors who used condoms (5.5%) and the low transmission rate (only 10% of non condom users developed gonorrhea) the results were not statistically significant. It is also important to note that the number of episodes of sexual intercourse in the condom group averaged 2.3."
- f) "Darrow, 'Sexually Transmitted Diseases,' July/September 1989 (for some reason the study was done in 1971 but published in 1989) showed a relative risk of 34% (0.34) for acquiring gonorrhea but the results were not statistically significant. Apparently the authors either experienced a 'typo' or made a bad calculation as the correct RR

- should have been (0.73) 73%. The results are not statistically significant as the 95% C.I. varies from 10% to 113%. (0.10 to 1/13)."
- g) "In summary the literature reviewed by the Cates & Stone article and referenced by the CDC shows that there is an relative risk in males of acquiring gonorrhea, even with consistent condom use, varying from approximately 25-50%. (excluding the non statistically significant studies and the one Vietnam study by Hart) There appeared to be no risk reduction from acquiring N.S.U. or Chlamydia. One study showed some risk reduction from syphilis but the study size was very small. There were no studies reported that studied the efficacy of condoms for Hepatitis B, Herpes Simplex or Human papillomavirus."
- 5. "Studies on condom efficacy to prevent STD's in Females: (Table 1, Page 78, Cates & Stone article, 'Family Planning Perspective,' 1992, Vol. 24."
  - a) "Oberle et. Al., 'American Journal Tropical Medicine Hygiene,' 41 (2), 1989, Page 224, showed that women who had used condoms for two years had a 60% relative risk of having Herpes 2 seropositivity.
  - b) "Syrjaned, et. Al. reported in the 'British Journal Veneral Disease,' 1984, 60: Page 243, that condoms in a Finish study had no protective effect against cervical human papillomavirus infections. (Relative Risk was 135%)."
  - c) "Rosenberg et. Al., May 1992, Vol. 82, No. 5, Page 669 of the 'American Journal of Public Health; reported that women whose partners had used condoms during the previous month had a 66% relative risk for cervical gonorrhea, 70% risk for vaginal trichomoniasis, 97% risk for cervical Chlamydia and 111% risk for bacterial vaginosis compared to non condom users."
  - d) "Cramer, (et.al), JAMA, May 8, 1987, Vol. 257, No. 18, Page 2446 report on 'The Relationship of Tubal Infertility to Barrier Method and Oral Contraceptive Use.' Condom use showed a relative risk of 70% but it was not statistically significant. Condoms with spermicides showed a relative risk of 50%."
  - e) "In summary the Cates & Stone article which was referenced by the CDC showed at least to this author that in the articles they reviewed there is significant risk for females, even if the male partner uses a condom, of acquiring an STD. The relative risks of condom use to

compared to no condom use are as follows: Herpes 2 seropositivity 60%, Human Papillomavirus 135%, Gonorrhea 66%, Trichomoniasis 70%, Chlamydia 97%, and Bacterial Vaginosis 111%."

6. "What do Cates & Stone say about their finding (Pages 77-78, 'Family"

"Planning Perspectives,' Vol. 24, Number 2, March/April 1992)?"

- a) "On page 77 under the topic 'Effects of Contraceptive Use on STD's' the authors say the following: 'The recent scientific literature includes numerous reviews concerning the effects of different contraceptives on the risk of STD transmission. In general, they come to the same conclusion—condoms alone, spermicides alone, and combinations of mechanical and chemical methods all provide good protection against most STD's."
- b) "On page 78, under Table 1, the authors summarize the table 1 in regard to the effectiveness of the condom for males in their six referenced studies: 'These data, taken together, a consistent with an increasing body of knowledge indicating that condoms are protective against sexually transmitted infection.' (See summary bottom of page 7)."
- c) "In the next paragraph on the same page 78, the authors begin their commentary on the six studies for females in table 1. 'Condoms may also protect women against some STDs, although the data are equivocal (Table 1).' (See summary page 8)."
- d) "Do public Health officials use a different level of effectiveness than parents, patients and physicians? Should they? What do you think?"

# G. "Non CDC Referenced Articles Dealing With Effectiveness of Condoms Against Non HIV Infection."

- 1. "A study of Four STD's" (Chlamydia, Syphilis, Gonorrhea, Trichomoniasis)"
  - a) "Zenilman, (et.al), 'Sexually Transmitted Diseases,' Vol. 2 January/February 1995. Men and women who report use of condoms with every sexual encounter (over a four month period) did not have a lower incidence of STD's in a study conducted at the Johns Hopkins Medical School of Preventative Medicine. Organisms studied were

gonorrhea, chlamydia, syphilis, and vaginal trichomonaiasis but the statistics reported considered them as a group. The authors suggested that incorrect usage of condoms or inaccurate recall on how frequently condoms were used might have made the results less accurate. (Another distinct possibility which the authors did not mention is that condoms may not be nearly as effective for preventing STDs as previously thought.)"

## 2. "A Review Study From Europe:"

- a) "d'Oro (et.al), reported in 1994 in Genitourinary Medicine; 70:410-417. The authors reviewed 22 papers that examined the impermeability of BMC (barrier methods of contraception) in vitro against STD agents or the effect of spermicides, and 60 papers reporting results of epidemiological studies on the risk of STD in users of BMC."
- b) "There was in vitro evidence that both BMC and spermicides were effective against most sexually transmissible agents."
- c) "Doubts remain on the effectiveness of BMC and spermicides in normal conditions of use, particularly against human papillomavirus."
- d) "Epidemiological studies show a consistent reduction in the risk for use of condoms against gonococcal (most studies giving relative risk RR, estimates around 0.4 to 0.6) and HIV infection (RRs between 0.3 and 0.6 in most studies)." (The d'Oro study was submitted for publication prior to the Saracco and de Vincenzi studies reported in item "F" below)."
- e) "The author's conclusions: 'A large amount of evidence indicates that BMC reduce the risk of gonorrhea and HIV transmission, but the results are—at least in quantitative terms—less consistent for other diseases."

## 3. "A Review Study From Canada:"

- a) "Brian Morris, M.D. reports in the Canadian Family Physician, Vol. 39: April 1993, Page 819, 'How Safe are Safes? Efficacy and Effectiveness of Condoms in Preventing STDs.'"
- b) "The author searched MEDLINE, for the years 1986-1991. The

author in his summary says 'Condoms are widely promoted for preventing sexually transmitted diseases, with an implicit message that a properly used condom will ensure that you are safe from STDs. A literature review shows that little solid evidence supports this belief '"

- 4. "Studies that mention condom effectiveness for preventing the transmission of the human papillomavirus in females."
  - a) "Jamison, et. al., 'Spectrum of Genital Human Papillomavirus Infection in a Female Adolescent Population,' Sexually Transmitted Diseases, July/August 1995, Pages 236-243. The authors found no difference in the percent of persons infected with HPV between the >75% condom use, the 25-75% condom use over 6 months."
  - b) "Kreiss, M.D. (et.al), 'STDs', Vol. 19, No. 1, Pages 54-59, found no condom effectiveness for preventing genital warts, human papillomavirus, or cervical intraepithelial neoplasia in females."
- 5. "Studies that mention condom effectiveness for preventing the transmission of the human papillomavirus in males."
  - a) "The only study in a MEDLINE search was a Finnish study by Hippelainen, (et.al.) in 1994 ('STDs', Vol. 21, No. 5, Page 272). In the abstract the authors say that condom use had a protective effect if P=0.04 against the HPV but the text of the article give no data or tables to tell how the authors derived this figure. There is also no data or tables to tell how the authors derived this figure. There is also no data to tell what percent of risk reduction was present."
  - b) "In the 1994 article by Hippelainen et. Al. The authors mention a previous study of theirs in the same journal, 'STDs', Vol. 20, No. 6, in 1993. This was a study on Finnish conscripts and was a retrospective case control study. From the data there appears to be an association between condom usage and prevalence of HPV infection but from the data it is impossible to tell how strong an association there is."
- 6. "Summary of non-CDC referenced articles showing effectiveness of condoms against non HIV STDs:"
  - a) "Several review articles clearly show that there are relatively few

- research articles in the literature in regard to studies about condom efficacy against STDs and most of those are more than ten years old."
- b) "The condom gives the most protection to gonorrhea with a relative risk of 40% to 60% (d'Oro review), less protection for other STDs and little if any for the human papillomavirus (HPV)."

### H. "Effectiveness of Condoms to Prevent HIV Infection"

- 1. "General Statements:"
  - a) "Four articles were chosen to review that studied discordant sexual couples. The first is a Meta-Analysis by Weller in 1993 that summarized the results from all 11 studies published prior to July 1990 in scientific journals worldwide that examined how effectively condoms prevented the spread of HIV from one person infected with the virus to another uninfected partner. The second is a 1993 longitudinal study from Italy that followed 343 steady partners of HIV infected men. The third is a 1994 European longitudinal study group of HIV transmission by heterosexual partners. The fourth is a 1995 study of HIV infection among female partners of seropositive men in Brazil. The results vary from zero (0%) transmission in one study to 23% with always vaginal condom use and up to 53% with no condom use in the Brazil study. In terms of relative risk (=failure rate) for consistent condom use the results varied from zero in European stud to 20% in the Italian study to an average of 31% in an eleven study metaanalysis to 43% in the Brazil study."
  - c) "The first three studies were referenced in the MNWR report of August 6, 1993. The 1995 Brazil study was published after the 1993 CDC report."
- 2. "Weller, 'A Meta-Analysis of Condom Effectiveness in Reducing Sexually Transmitted HIV', Social Science Medicine 36:1635-1644. Dr. Weller found that in 11 studies published in scientific journals prior to 1990 there was an average failure rate of 31% among heterosexual couples who used condoms. Dr. Weller cautioned that these results should be viewed tentatively because of the limitation in the 11 original studies. For example she said 'an obvious limitation in many of these studies is in the definition of condom use."
- 3. "Saracco, et. at., "Man-to Woman Sexual Transmission of HIV:

Longitudinal Study of 343 Steady Partners of Infected Men", <u>Journal of Acquired Immune Deficiency Syndromes</u>, 6:497-502, 1993. The authors found that 2% of consistent condom users sero-converted, compared with 10% of non condom users and 15% of inconsistent condom users. In terms of relative risk, consistent condom users had a 20% risk compared to those who never used a condom. Interestingly the "not always users" had a 70% greater risk than did the "never used a condom" group. Also of interest is that despite the fact the women knew their sexual partner had HIV infection and were counseled and tested regularly, only slightly more than half of the study group (56%) uses a condom consistently.

- 4. de Vincenzi, et. al., 'A Longitudinal Study of Human Immunodeficiency Virus Transmission by Heterosexual Partners,' NEJM, Vol. 331, No. 6. Page 341, 1994. In this study none (0%) of the 122 seronegative partners who used condoms consistently seroconverted; in comparison 12 (10%) of 122 seronegative partners who used condoms inconsistently became infected. Again of interest is that despite having the strong motivational factor of knowing that your partner had HIV infection and that you also would die if you became infected, only 48.4% of the couples used a condom consistently."
- 5. "Guimaraes, et. al., 'HIV infection among Female Partners of Seropositive Men in Brazil', American Journal of Epidemiology, Vol. 142, No. 5, the authors from the John Hopkins University found that the overall prevalence of HIV infection was 45% among the 204 female partners in the study. 23% of the women who always used a condom were HIV positive versus 53% who never used condoms. This was not a longitudinal study compared to the Sarraco and de Vincenzi study. Most of the couples were in long-term and steady relationships (25+ months) but only recently (within 6 months prior to the interview) had learned that their sexual partner was HIV infected. Most of the index cases were in advanced stages of HIV infection. The authors felt that the high rate of anal sex (31%) in the past year (83% of those participating in anal sex did not use a condom) probably was a reason for the high rate of sero-conversion."
- 6. "In summary it would seem that with consistent condom use it might be possible to achieve a 2% or less sero-conversion rate (with consistent and correct use of condoms) for the transmission of HIV in cases where the sero-negative partner knows the HIV status of their partner. Motivation can be no higher than knowing that your partner is HIV infected and even then only 50% used condoms consistently. The longitudinal studies were

for an average 20 months in the de Vincenzi study to about 4 years in the Saaracco study. A statistic often overlooked in the Saracco study is that even with consistent condom use versus no condom use the relative risk was 20% (2% of condom users sero-converted compared to 10% of non condom users). In the Weller eleven study meta-analysis the average relative risk was 31% and the recent Brazil study showed a 43% relative risk for condoms. What happens out in the real world where you do not know the HIV status of your partner and consistent condom use is less, especially in the adolescent population who tend to be risk takers? This author's guess is that the percent of time a condom fails to prevent disease will be significantly higher than the Italian and European study, probably matching or exceeding the 31% and 43% figures for the Weller and Brazil studies respectively."

## I. "Answers to Questions About Condom Effectiveness:"

- 1. "What factors are responsible for method failure and what is the accepted method failure rate? Answer: The accepted failure rate is about 2% (2 failures in 100 acts of intercourse). For some licensed sex workers and some experienced married couples it may be closer to 1% but for inexperienced unmarried adolescents the figure is probably higher."
- 2. "What is the first year failure rate for condoms in preventing pregnancy? Answer: The average for all age ranges, both married and unmarried, is about 15%."
- 3. "Are condoms equally effective against all STDs? Answer: No—The condom, especially for females, offers very little to no protection from the human papillomavirus. Risk reduction for chlamydia is not much better and risk for tubal infertility is limited unless a spermicide is used in addition to a condom. Few studies on risk reduction for herpes and syphilis are found but in those few studies the risk reduction is approximately 40%. Risk reduction for gonorrhea varies from 40% to 75% with males having the better risk reduction. Risk reduction is best for HIV infection and with the exception of one study with no seroconversion the risk reduction varies from 60% to 80% (=20% relative risk) in the Saracco study. Thus the effectiveness of condoms seems to be related to the ease of transmission of the organism. The condom is most effective against HIV infection where the risk of unprotected sex with an infected person is estimated to be 1 in 500 to the opposite end of the spectrum where the risk or acquiring HPV infection is about 1 in 2 exposures and chlamydia is not far behind."

- 4. "Are males and females equally protected? Answer: No—females are at greater risk for almost all STDs including infertility. HIV is about the only STD where there is close parity between the sexes."
- 5. "What level of consistent condom use is needed to give good protection? Stated another way, how protective is intermittent condom use? Answer: The studies reviewed and even the commentary from the CDC (AJPH, Vol. 83, No. 4, Page 501) agreed that there is little or no protection from intermittent condom use."
- 6. "At present what percent of sexually active youths use a condom consistently every time? Answer: The range varies from 5-40% but the average is probably close to 20%."
- 7. "At present what percent of sexually active youths use a condom consistently every time? Answer: The data is limited but based on a report from ACOG it is probably 50% at best."
- 8. "Given perfect and consistent condom use what levels of relative risk reduction for pregnancy and STDs are acceptable to public health officials, physicians, patients, and parents? Are the levels of acceptable risk reduction equal for each group? Answer: Each adult will have to decide what risk he or she is willing to accept. However adults who influence children and youth must be very careful about the guidance they provide." (See commentary below # 5 & 8)
- 9. "Does the public know the actual risk for pregnancy and the various STDs? Does the medical profession know? Answer: In the opinion of this author the answer is no. I doubt most women know that most cancer of the cervix is caused by a sexually transmitted disease with little or no protection from condoms. (I found no articles in the world literature that show condoms are protective in females against the HPV virus). I doubt most teenage girls know that having sex at an early age puts them at greater risk for STD infection and later for cancer of the cervix and infertility."

# J. "Commentary:"

1. "This author believes it is important to know the facts so that we, as physicians, can make an intelligent decision as how to proceed. Is the glass half full or is it half empty. Is a glass half full acceptable in certain

circumstances but not others?"

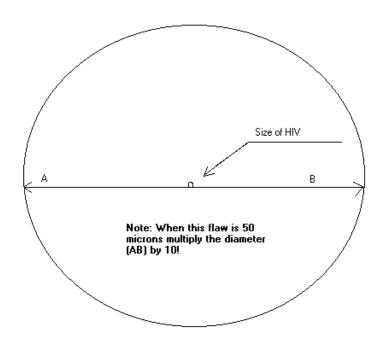
- 2. "All would agree that STD Infection and Out-of Wedlock Pregnancy in adolescents is out of control. The question is what do we do about it...More of the same or a different approach?"
- 3. "Roper, et al report in the <u>AJPH</u>, April 1993, Vol. 83, No. 4, 'Commentary: Condoms and HIV/STD Prevention—Clarifying the Message.' The authors from the CDC say 'Studies show that correct and consistent use of latex condoms is highly effective in preventing sexually transmitted HIV infection and other sexually transmitted diseases.' The authors then say further studies are needed to maximize the use and effectiveness of condoms for those who choose to be sexually active and then conclude: 'In the interim, our prevention message should be clear: When used correctly and consistently, condoms are highly effective; when used otherwise, they are not."'
- 4. "Only after reviewing, studying and pondering the literature can each physician answer the following questions. Is Roper, et al in the above commentary totally accurate?, partially accurate?, are his qualifications realistically achievable? If not, what are the alternatives?"
- 5. "How realistic is it to expect immature adolescents, most of whom still functioning cognitively in the concrete mode rather than the adult formal operator mode, to achieve method failure results when even mature adults cannot reach these goals? How realistic it is to expect all adolescents to use a condom consistently when in two studies from Europe only half the partners of known HIV infected individuals consistently used a condom every time. This author believes that realistically speaking we have a better chance of changing behavior so that adolescents postpone sexual activity than we do of having adolescents use a condom consistently and correctly 100% of the time. In the process we would eliminate the pregnancies the STDs, the infertility and the cancers that would result from method failure."
- 6. "The father of modern day obstetrics and gynecology, a Hungarian physician by the name of Ignaz Semmelweis recognized in 1838 that many European hospitals had an enormously high maternal mortality rate. He noticed that physicians, especially medical students, were coming straight from cadavers without washing their hands and then examining women in the labor and delivery areas. By introducing simple hand washing techniques. Dr. Semmelweis reduced the maternal

mortality rate in his hospital from 31.4% to 1.3% over a period of six years. Although Dr. Semmelweis documented his findings carefully the medical years. Although Dr. Semmelweis documented his findings carefully the medical community was slow to abandon their outdated theories and practices and to accept his discovery. 'In contrast to the lethargic response in Semmelweis' era, it is vitally important that the dilemma of adolescent sexuality which we face today be acknowledge, carefully analyzed from a health perspective, and that the role of physicians in effecting a solution be explored.' The story of Dr. Semmelweis was abstracted from a four-part series by Stephen Genuis, M.D. and Shelagh Genuis, BScOT entitled 'The Dilemma of Adolescent Sexuality--Part 1: The Onslaught of Sexually Transmitted Diseases.'"

(Journal of the Society of Obstetricians and Gynecologist of Canada, Vol. 15, Number 5, June 1993, Page 552.)

- 7. "So the debate continues. Clearly a change of behavior is needed. Both the behavior of improved and consistent condom use for the sexually active youth and the behavior of postponing sex until marriage (even for those who have already had sex) need to improve. The question is, 'which strategy is the best for our youth and society in general and which strategy do you think is most achievable?' Only when we can come to grips with this question will change occur. This is why, especially among physicians, we need to examine without bias what the literature and research have to tell us."
- 8. "This author believes that emotionally and physically it is in the best interest of teen to postpone sexual activity until marriage...that condoms are at best a poor second choice for those teens whom we as a society have failed...and finally that adolescents should be openly and honestly taught about contraceptives but they must not leave the classroom or the physician's office thinking, 'I'm being responsible and safe if I use a condom.' The message by society, schools, parents and physicians must be unmistakably clear: 'There is no responsible sex for unmarried teenagers."
- 9. "What do you think? Have you been objective in your evaluation about condoms, STDs, and pregnancy? Hopefully this review of the literature will be of help."

# "The Nature and Significance of Defects in Condoms and HIV Prevention"



Scale: HIV (.1 Microns)=1/8" Flaw (5 microns) = 61/4" (50 x size of HIV)

"C. Michael Roland, Ph.D., Editor, Rubber chemistry and Technology who is also Head of the Polymer Properties Section, Naval Research Laboratory."

"While HIV is only .1 microns in size, sensitive laboratory tests revealed naturally occurring defects in latex in a range of 5-50 microns which is 50-500 times the size of HIV! The largest flaw sizes found were 70 microns (700 times larger than HIV.) The FDA admits that their testing procedures could not detect defects in the range of 1-10 microns which is 10-100 times larger than HIV."

"In consideration of these realities, do you believe that the advocacy, promotion and/or distribution of condoms for HIV prevention should be called, 'safe', 'protected' or 'safer sex'? Attorneys who litigate personal injury and wrongful death actions view these as, 'Make my day!' "

(NO. DOC)

### "IS THE CONDOM REALLY SAFE SEX? A TESTIMONIAL STATEMENT"

"I am a public health professional with more than twenty combined years experience in the epidemiology of Sexually Transmitted Diseases and HIV/AIDS prevention and control. As a matter of conscience I offer this information to you as a citizen, taxpayer and parent. Consequently, I do not represent any official agency nor do I hold myself out as a spokesman for any such agency."

"From 1964-1977 I was a Venereal Disease Investigator (Disease Intervention Specialist) charged with the responsibility of case management of patients infected with syphilis which also included clinic duties four days each week. During that time I never distributed condoms nor was I requested to do so. They were regarded only as marginal information in our prevention message and left to personal choice and private purchase. I left public service in 1977 returning in 1985 and was assigned to the emerging AIDS crisis. I was astounded to learn that whereas condoms previously regarded as marginal against treatable syphilis were now purported to be 'safe' against a insidious, incurable and prolonged death by a lethal virus."

"At first, I thought that perhaps the condom had been so improved as to correct its celebrated failure rate. I quickly learned that no such technological improvement existed. I did experience, however, retaliation, harassment and threats in an unsuccessful attempt to suppress my professional dissent. It became necessary to invoke my First Amendment rights and speak as a citizen only to still endure personal attacks that have now given rise to formal remedies. This in itself begs the question: If condoms are so reliable why attempt to suppress the dissent? For the last five years my research has revealed the following information:"

- 1) "Incurably fatal, HIV is three times smaller than Herpes Simplex Virus (HSV), 60 times smaller than Treponema pallidum, the bacterial spirochete that causes syphilis, and 450 times smaller than sperm. (1) However, the 'fertile window' is generally only one week per month, whereas disease can occur any moment of any day. Therefore, with four weeks in a month and an organism (HIV) which is 450 times smaller than sperm, the chances of transmitting an incurably lethal disease dramatically increases by a factor of at <u>least</u> four!"
- 2) "While HIV is only .1 microns in size, sensitive laboratory tests revealed naturally occurring defects in latex in a range of 5-50 microns which is 50-500 times the size of HIV. The largest flaw sizes found were 70 microns (700 times larger than HIV.)(2) The FDA admitted to Dr. Roland that their testing procedures could not detect defects in the range of 1-10 microns which is 10-100 times larger than HIV."

- 3) "Futhermore, FDA testing procedures of filling the condom with water to determine leakage through these voids (defects) are woefully inadequate. 'Condoms are currently tested in a completely non-biological manner, using water as the filling fluid.'(3) This example of an in vitro laboratory test fails to account for the dynamic variables of a vital system. Yet it is commonly known that 'biological environments encountered upon actual use are likely to promote leakage.' Id. This study demonstrated that the FDA water test was a 75% failure in detecting defects."
- 4) "Not only is the above referenced water leakage test inadequate, but it is only performed on 144 condoms randomly selected from each lot of 1000!(4)"
- 5) "Common sense and the facts of biology tell us that the conditions most favorable for transmission of disease occur at the moment of ejaculation. It is then that each partner has increased tissue vascularization, the condom membrane is most fatigued from the frictional act of intercourse, and the force of ejaculatory fluid tests the compromised membrane the most. Yet, the condom has <u>never</u> been tested and observed against HIV <u>in vivo</u> at this lethally critical moment. Medical ethics and legal liabilities precluded such a test between discordant couples (one partner HIV + the other HIV-). The federal government cancelled the study because it feared that 'condoms may be incapable of providing protection to study participants.'(5) Yet, there are promoted as safe sex to the general public including students!"
- 6) "Virtually all of the studies alleging impressive effectiveness of the condom were either done in the laboratory (<u>in vitro</u>) under ideal but static (non-vital) conditions devoid of the dynamic physiological variables and realities of actual sexual intercourse, or they were done by gathering subjective information (epidemiological studies) from select samples of individuals for relatively short durations leading to even more subjective and interpretive results."
- 7) "Latex may cause lethally allergic reactions prompting the FDA to caution 'doctors and manufacturers about potential allergic reactions to latex products-including gloves and condoms after receiving reports of deaths and life-threatening shock." (6)
- 8) "Published efficacy/failure rates are inaccurately and irresponsibly assessed and, therefore, are lethally misleading in application to HIV prevention. For example, failure rates are confined to so called 'user failure' and/or 'breakage' (rupture of the membrane). No mention, allowance or particularly warning is provided regarding inherent voids (defects) in latex (50-700 times

- larger than HIV) which under <u>in vivo</u> conditions afford wide passage through an intact latex condom. Furthermore, these failure rates are frequently derived from epidemiological data on birth prevention."
- 9) "Yet, the government states this contradiction, 'No scientific data on the frequency or causes of condom breakage are available." (7)
- 10) "Latex is heat, cold, light and pressure sensitive and adversely affected by humidity, ozone and air pollution as well as the mere passage of time-deterioration. For these reasons of fact the FDA states, 'You should store condoms in a cool, dry place out of direct sunlight, perhaps in a drawer or closet." (8)
- 11) "Yet, condoms are rarely, if ever, stored/transported from moment of manufacture to point of distribution, in compliance with FDA recommendations. Oven thermometers were needed to record temperatures of 185° in trailers transporting condoms. In fact, eggs were fried just sitting in a skillet next to the condoms. (9) Futhermore, I have personally seen documented proof that it takes a mean of 25 days for condoms to go only 30-70 miles from drug manufacturer to retailers! (9) During that time they are stored in aluminum trailers that are microwaves in the summer and freezers in the winter."
- 12) "Lethal Presumption: The government instructs health care workers to wear latex gloves when around blood and body fluids. Yet they instruct children to remove a used condom with no mention that HIV might have been deposited on the <u>outside</u> of the condom depending on <u>which partner</u> was infected!"
- 13) "Whatever benefit condoms may offer their effectiveness is only possible 'provided there is no preliminary sex play, the condom is intact before use, the condom is put on correctly and the condom is taken off correctly. However, the male population has never been able to fulfill the very first requirement.'(10) In other words, condom advocates presume the absence of foreplay which at the height of emotional excitation is far more unrealistic than abstinence!"

### "Lethal Result"

"In consideration of the above realities I conclude that it is morally, professionally and ethically inconceivable and unconscionable that condoms for HIV prevention be promoted as 'safe' or 'protected sex.' For example each of the above events statistically detracts from an already unsubstantiated proclaimed efficacy. In fact, many of these realities do not act

independently of each other but tragically in lethal concert. Therefore, under such circumstances they <u>cumulatively</u> reduce the statistical efficacy leaving the condom very risky risk reduction against a lethal virus. Its celebrated compliance failures also demonstrate that its use is unrealistic."

"Therefore, I submit that because of the deadly realities and legal consequences the use of the condom as a method of HIV/AIDS prevention should be left to a matter of <u>personal choice</u> and <u>private commercial purchase</u> pursuant to an accurate, adequate and <u>complete</u> disclosure of <u>lethal risk!</u> As a result, its place in the prevention message should reflect this justifiable deprioritization."

"Consider this very realistic scenario:"

"From the moment that condoms are made they begin with inherent (naturally) occurring defects 50-500 times the size of HIV. Then testing procedures fail to reveal defects 10-100 times the size of HIV for those condoms that are tested. Remember, the inadequate water test is only applied to a random sample."

"Furthermore, the condom is <u>not</u> tested for the moment of ejaculation and latex can be lethally allergic. Latex is heat, cold, light and pressure sensitive and yet are not stored/transported under temperature-controlled conditions. Proclaimed efficacy rates are not disease specific and grossly misleading as well as interpretive."

"You are then told that the use of this device against an insidious, lethal virus 450 times smaller than sperm is 'safe' or 'protected sex' from a prolonged, insidious, incurable death! Do you believe it?"

"Thank you for allowing me to contribute to this life-saving effort to address a lethally defective public policy."

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(Dr. Richard W. Smith, "Is The Condom Really Safe Sex? A Testimonial Statement	.")
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### "MEDICAL INSTITUTE"

"One infection does not confer immunity. A woman, therefore, can have an infection cured and become infected again. Each time she has a new infection, she has even more risk of infertility and of tubal pregnancy. (one infection—8.1% chance of sterility, two infections—21% chance of infertility, more than two infections—40% risk of infertility)."

"Some studies have shown that if a couple uses condoms for sexual intercourse, the transmission of the chlamydia organism is less than if they were not using condoms. An equal or greater number of studies show just the opposite—that among unmarried people having sexual intercourse, the same rate of clamydial infection occurs in those who use condoms and those who do not."

"Excellent studies suggest that condoms do not protect a woman's fertility. A study by Cramer, et al, stated, 'Table V examines risks by the specific type of barrier method used for the longest period. Spermicide use alone had no significant effect on risk for tubal infertility, whereas condom use along decreased the risk, but not to a significant extent.' 'Significant' is a scientific term which essentially means that in this study the researchers could not say that condoms definitely protected these women's fertility. Another study with similar results was done by Westrom, et al, which evaluated women who had pelvic inflammatory disease. Patients were asked if they used contraceptives techniques. It was found that if a woman used no contraceptive techniques, she had a 35.2 percent risk of having mild PID and a 25.9 percent risk of having severe PID. The woman who used barrier methods of contraception, which would include condoms, had a 21.1 percent risk of having mild PID (which was lower than the risk associated with using no contraceptive),

but a 22.4 percent chance of having severe PID (Which was almost the same as using no contraceptive technique)."

"The only hope of avoiding the risk of chlamydia is for single people to avoid sexual contact until they are involved with a life-long mutually monogamous uninfected partner. If a person has been sexually active, but has avoided chlamydial infection so far, he/she still has the opportunity of avoiding future infection by limiting sexual activity to one lifetime partner. This may be a hard choice today, but the benefits for future health including better fertility, less chance of pain, and fewer medical problems will be well worth the effort."

(Joe S. McIhaney, Jr., MD, Medial Institute for Sexual Health-slides)

"A RESPONSE TO MORBIDITY AND MORTALITY WEEKLY REPORT, 'UPDATE: BARRIER PROTECTION AGAINST HIV AND OTHER SEXUALLY TRANSMITTED DISEASES,"

"A more complete review of the scientific data shows condom failure to range between 0% and 31%."

"Condoms only reduced HIV transmission by 69%. The CDC may consider 69% 'substantial,' but the resultant 31% failure in prevention means many HIV infections, all resulting in premature death."

"Furthermore, the CDC Report states 'intact latex condoms provide a continuous mechanical barrier to HIV, HSV (herpes), hepatitis B virus (HBV), Chalmydia trachomatis and Neiserria gonorrhoeae.' This statement is partially true, but misleading. Bacterial STDs cannot penetrate an intact condom, but these diseases as well as many viral diseases are often regional—the infectious agent is not just located at one place on the body—and may infect the entire genital area."

"Medial studies confirm that condoms do not offer much, if any, protection in the transmission of chlamydia and human papillomavirus, two serious STDs with prevalence as high as 40% among sexually active teenagers. The epidemic rise in the rate of these two as well as many other STDs may well be a side effect of the encouragement of condom use."

"Further evidence of the failure of the condom to act as a mechanical barrier is found in a study by Dr. Carey at the FDA. The CDC's reference to the Carey study, 'A recent laboratory study indicated that latex condoms are an effective mechanical barrier to fluid containing HIV-sized particles,' contrasts with the findings of the study. Actually 32% of normal intact condoms leaked enough HIV sized particles to cause concern. The other 68% of the condoms only leaked a few viral sized particles. A 32% leakage rate of HIV cannot be considered an 'effective mechanical barrier.' Dr. Carey has responded that even though the condoms do leak HIV-sized particles, the concentration of the virus is so low that it is unlikely to cause infection. Exposure to any HIV particles puts an individual at risk, as it has not been determined how few particles are necessary to cause infection."

"The CDC, using 'one study' by Dr. Trussel reports an 0.8% slippage/breakage rate of condoms when used during vaginal intercourse. This extremely low rate conflicts with another study published at the same time by the same author. The second Trussel study states '7.9% (of condoms) either broke during intercourse or withdrawl or slipped off during intercourse; none of these events were related to condom brand, past condom use or use of additional lubricant. OF the remaining condoms, 7.2% slipped off during withdrawal; slippage was not related to condom brand or past use of condoms, but was significantly higher when additional lubricant (such as spermicide) was used.' Contrast 0.8% to 15.1% slippage/breakage rate, and it is easy to understand the importance of using more than one study when making policies to protect people's lives. It would be more complete to consider the findings of both studies in making this important point."

"The female condom has a pregnancy failure rate between 11% and 26%, indicating it is possibly an even less effective contraceptive than the male condom."

("A Response To Morbidity And Mortality Weekly Report, 'Update: Barrier Protection Against Hiv And Other Sexually Transmitted Diseases," August 6, 1993.Medical Institute for sexual Health, Sexual Health Update December 1993, Volume 2, Number 1)

## "THE CDC STATES:"

"For the wearer, condoms provide a mechanical barrier that should reduce the risk of infections acquired through penile exposure to infectious cervical, vaginal, vulvar, or rectal secretions or lesions. For the wearer's partner, proper use of condoms should prevent semen deposition, contact with urethral discharge, and exposure to lesions on the head or shaft of the penis. For infectious agents spread from lesions rather than fluids, condoms may offer less protection because areas of skin not covered by the condom may be infectious or vulnerable to infection."(1)

"(Centers for Disease Control and Prevention, "Condoms for Prevention of Sexually Transmitted Disease," Morbidity and Mortality Weekly Report, March 11, 1988; 37(9): 133-137.)"

"...Proper use of condoms with each act of sexual intercourse can reduce, but not eliminate, risk of STD. Individuals likely to become infected or known to be infected with human immunodeficiency virus (HIV) should be aware that condom use cannot completely eliminate the risk of transmission to themselves or to others."

(The Medical Institute for Sexual Health, Slide 15, p22)
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## "CONDOMS INEFFECTIVE AGAINST HUMAN PAPILLOMA VIRUS"

"The spread of human papilloma virus, the organism which causes venereal warts and 90% of the cancers of the cervix, vagina, vulva and penis which are seen in Americans." (3)

"Human papilloma virus infection has become the number one reason American women visit a gynecologist according to the Centers for Disease Control and Prevention.' (4) Dr Stephen Curry of the New England Medical Center in Boston was quoted in Time. 'This virus is rampant. If it were not for AIDS, stories about it would be on the front page of every newspaper.' (5) Why is this virus causing so many patients to see physicians? Why would it be on the front page of every newspaper except for HIV? There are several reasons, but the first is that it is an extremely common sexually transmitted infection. Bauer, et.al., reported from as study of sexually active coeds seen at the Student Health Center, University of California at Berkeley, that 46 percent were infected with human papilloma virus. (6) Other studies show similar infection rates. Therefore, HPV is probably the most common sexually transmitted disease in America."

"The greatest danger of this organism is that it is the probable cause of almost all cervical cancer. Alex M. Gerenczy, M.D., Professor of Pathology, Obstetrics and Gynecology, McGill University Faculty of Medicine, states that of all STD's HPV is the greatest cancer killer and that nearly 500,000 women each year world wide develop cancer of the cervix." (7)

"HPV also causes warts of both women's and men's genital organs. These warts can range from the size of a small tick to the size of a cauliflower. They can be very difficult to cure, often requiring multiple treatments by a physician. At times they even require anesthesia and surgical therapy."

"Most gynecologists are seeing more and more patients with vulvar discomfort. This discomfort is called 'vulvar vestibulitis.' Many patients have developed this problem as a result of human papilloma virus infections of their vulvar tissues. It can be very difficult to treat, even requiring a series of twelve vulvar injections with Interferon. Even then, it frequently does not respond. We are, therefore, dealing with a very dangerous sexually transmitted infection."

" Dr. Kenneth Noller is quoted in the newsletter of the American College of Obstetricians and Gynecologists: 'We have no treatment that will eliminate the virus. We can treat the warts, but the virus is still present after the warts are gone.'(9) There has never been such an epidemic of human papilloma virus in the U.S."

"The Following quotations are from medical exerts who are giving their unbiased view of the effectiveness of condoms in preventing sexual transmission of the human papilloma virus."

• "Kenneth L. Noller, M.D.: 'Indeed several studies have shown that condoms do not protect against this virus (HPV)." (10)

"(Dr. Noller is Professor and Chairman, Department of OB/GYN, University of Massachusetts School of Medicine, past Chairman of the American College of Obstetricians and Gynecologists Committee on Gynecologic Practice and past President of the American Society for Colposcopy and Cervical Pathology.)"

• "Thomas V. Sedlacek, M.D.: 'Condom use is of little or no value in protecting patients from papilloma infection." (11)

"(Dr. Sedlacek is Chairman, Department of Gynecology, Graduate Hospital, Philadelphia.)"

• "Robert Reid, M.D.: 'Because HPV is a disease of the entire genital area, condoms probably do not prevent transmission." (12)

"(Dr. Reid is Director of Gynecologic Laser Services, Sinai Hospital of Detroit, and Assistant Professor, Wayne State University School of Medicine.)"

• "Michael Campion, M.D.: 'Condoms are useless in preventing HPV transmission, because the virus is spread by cells that are shed onto the scrotum, which then comes into contact with vulvar skin."" (13)

- "(Dr. Campion is Director of Gynecologic Endoscopy at Graduate Hospital, Philadelphia.)"
- "Mitchell Greenberg, M.D.: 'Even condoms don't block transmission because the virus can be transmitted from the scrotum and vaginal secretions.'" (14)
- "(Dr. Greenberg is Director of Clinical Research and Education, Graduate Hospital, Philadelphia.)"
- "John V. Dervin, M.D.: 'Human papillomavirus, thought of as the 'seed' of cervical cancer, is a regional rather than localized disease, and its infectivity is not contained by condoms..." (15)
- "(Dr. Dervin is Associate Specialist in Radiology and Assistant Clinical Professor, University of California, San Francisco.)"
- "The CDC is clearly dishonest in its public service announcements. It is evident from a number of national experts that condoms give no protection against this sexually transmitted disease, even though CDC in its nationally aired television ad says that they do. There is also evidence that condoms do not protect against chlamydia which is increasingly a cause of sterility among young people."
- "Remember, 46 percent of sexually active coeds at the University of California at Berkeley already were infected with this organism."
- "References:"
- "(3) Jenson, A.B. "Historical Perspectives and Current Perception of Human Papillomavirus Infections: Part 1, Focus on Human Papillomavirus," 1:1, Winter, 1989.
- (4) OB/GYN News, 28:15, 1993.
- (5) Time, April 6, 1988
- (6) Bauer, H.M., et. Al. "Genital Human Papillomavirus Infection in Female University Students as Determined by a PCR-Based Method," JAMA, 265:472,1991.
- (7) Symposium. "HPV DNA: Quicker Ways to Discern Viral Types," Contemporary OB/GYN, 33:4, April 1989.
- (9) American College of Obstetricians and Gynecologists, Newsletter, February, 1990.
- (10) Noller, Kenneth L. OB/GYN Clinical Alert, September, 1992.
- (11)Sedlacek, Thomas V. "Clinical Options in Dealing with Minor Cytologic Abnormalities," The Colposcopist, XXIV: 4, Fall, 1992.

- (12) American College of Obstetricians and Gynecologists, Newsletter, August, 1989.
- (13)OB/GYN News, 26:12, 1991.
- (14)OB/GYN News, 28:15, 1993.
- (15) "Condom Won't Prevent Transmission of Human Papillomavirus," Family Planning News, 22:12, June, 1992."

("Condoms Ineffective Against Human Papilloma Virus," Sexual Health Update, Medical Institute for Sexual Health, April 1994, Volume 2, No. 2)

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## "POWELL'S 'CONDOM'NATION"

"Taking heat from some of President Bush's supporters on the political right, Secretary of State Colin Powell is standing his ground in counseling the sexually active to use condoms as a health measure. First, though, Powell advocates abstinence, as he has advised young people for years. Taping a program sponsored by MTV, Powell advised, 'Forget about taboos, forget about conservative ideas with respect to what you tell young people about. It's the lives of young people that are put at risk by unsafe sex, and therefore, protect yourself... In my own judgment, condoms are a way to prevent infection, and therefore, I not only support their use, I encourage their use among people who are sexually active.' Ken Connor, president of the Family Research Council, said Powell's remarks were 'reckless and irresponsible' and a 'slap in the face' for the President's supporters. Gary Bauer, president of Family Values said, 'On public health issues he should follow the lead of the Bush administration which he serves.'"

("Powell's 'Condom' Nation," AP News Service, February 19/Youthworker, May/June 2002, pg12)