

## DECLARATION OF JOHN S. SANTELLI, M.D., M.P.H.

I, JOHN S. SANTELLI, M.D., M.P.H., declare and state the following:

1. I am Chairman of the Heilbrunn Department of Population and Family Health and Professor of Clinical Population and Family Health at Columbia University's Mailman School of Public Health. I am also Professor of Clinical Pediatrics at Columbia University's College of Physicians and Surgeons. My curriculum vitae is attached.

2. As Chairman of the Heilbrunn Department of Population and Family Health, I provide strategic direction to an academic department with major domestic and global initiatives in research, training, service, and human rights. I also conduct research on a variety of topics relating to adolescent reproductive health, including trends in adolescent pregnancy, teen contraceptive use, and prevention of sexually transmitted infections (STIs, also often referred to as sexually transmitted diseases or STDs), HIV, and unintended pregnancy. I have published more than seventy peer-reviewed articles regarding reproductive health care and/or adolescent health care issues, including teen pregnancy, adolescent contraceptive use and prevention of STIs, and sexuality education. I am also a frequent lecturer on these topics.

3. Prior to coming to Columbia University, I served for thirteen years in the United States Public Health Service. I spent the last nine of those years at the Centers for Disease Control and Prevention (CDC) in Atlanta, Georgia. At CDC, I held various positions, including Chief of the Applied Sciences Branch of the Division of Reproductive Health (DRH) and Assistant Director of Science at DRH. At CDC, I was extensively involved in conducting research on adolescent and reproductive health, and I had significant responsibility for scientific review of CDC-supported research. In 2000, I served on the panel of experts for the National Institutes of Health's (NIH) workshop entitled Scientific Evidence on Condom Effectiveness for Sexually Transmitted Disease (STD) Prevention. See ¶¶ 16-21, *infra* (discussing NIH panel's report on condom effectiveness).

4. I am currently also a Senior Fellow at the Guttmacher Institute. Guttmacher is a leading organization focused on sexual and reproductive health research, policy analysis, and public education. As a Senior Fellow, I conduct and review research on adolescent reproductive health.

5. From 2004-2007 I was on the Board of Directors of the Society for Adolescent Medicine. I am currently a member of the Science Board of the American Public Health Association, and I am a consultant member of the Adolescent Health Committee of the American College of Obstetricians & Gynecologists. I have also held leadership positions in the American School Health Association (Executive Committee) and the National Assembly on School-Based Health Care (Co-Chair of the Research Section), and I continue to be an active member of these organizations. I am also an active member of other professional organizations, including the American Academy of Pediatrics and the Population Association of America.

6. I have served on the editorial board of a number of academic journals, including *AIDS Education and Prevention*, the *Journal of Adolescent Health* (the official journal of the Society for Adolescent Medicine), *Perspectives on Sexual and Reproductive Health*, and the *American Journal of School Health*. I also serve as a peer-reviewer for numerous journals, including the *Journal of the American Medical Association*, *Pediatrics* (the official journal of the American Academy of Pediatrics), the *American Journal of Public Health* (the official journal of the American Public Health Association), the *Archives of Pediatrics and Adolescent Medicine*, and *Demography*.

7. I earned my medical degree from the State University of New York at Buffalo in 1982 and did my residency in pediatrics at the University of Maryland from 1982-1985. After completing my residency, I earned a Masters in Public Health from Johns Hopkins University. I subsequently completed a fellowship in Adolescent Medicine at the University of Maryland.

8. I have reviewed three curricula used by federal abstinence funding grantees to determine whether they present medically accurate information about the effectiveness of condoms in preventing various STIs. The information about condoms presented in these curricula does not represent complete, current, and accurate medical knowledge about the effectiveness of condoms in preventing STIs, including HIV. Instead, these curricula explicitly and/or implicitly convey the erroneous message that condoms fail to provide protection against STIs. They do so by misrepresenting studies on condom efficacy; relying on poorly designed studies and excluding or distorting the conclusions of better-designed studies; routinely taking information out of context; selectively reporting the data; and/or drawing unsupported conclusions that go beyond the scope of the medical literature. These issues are explained in detail below.

## **BACKGROUND ON CONDOMS AND STIs**

### **A. How Condoms Work**

9. The male condom covers the penis and acts as a physical barrier to both pre-ejaculate emissions and semen following ejaculation. NAT'L INST. OF ALLERGY & INFECTIOUS DISEASES, NAT'L INSTS. OF HEALTH, U.S. DEP'T OF HEALTH & HUMAN SERVS., WORKSHOP SUMMARY: SCIENTIFIC EVIDENCE ON CONDOM EFFECTIVENESS FOR SEXUALLY TRANSMITTED DISEASE (STD) PREVENTION 6 (2001) [hereinafter NIH REPORT].

10. The Food and Drug Administration (FDA) regulates condoms and requires that condom manufacturers employ various safeguards and quality assurance tests to ensure that condoms meet a high level of safety specifications. *Id.* at 6-8; Lee Warner et al., *Male Condoms*, in *CONTRACEPTIVE TECHNOLOGY* 331, 335 (Robert A. Hatcher et al. eds., 18th rev. ed. 2004). Laboratory tests have shown that latex condoms provide an essentially impermeable barrier to both sperm and organisms that are the size of even the smallest STIs. NIH REPORT, *supra* ¶ 9, at 7-8; Terri L. Walsh et al., *Effectiveness of the Male Latex Condom: Combined Results for Three Popular Condom Brands Used as*

*Controls in Randomized Clinical Trials*, 70 CONTRACEPTION 407, 408 (2004); CTRS. FOR DISEASE CONTROL AND PREVENTION, FACT SHEET FOR PUBLIC HEALTH PERSONNEL: MALE LATEX CONDOMS AND SEXUALLY TRANSMITTED DISEASES 2-5 (2003) [hereinafter CDC]. In other words, neither seminal fluids nor STI organisms will leak through an intact latex condom.

## **B. Condom Effectiveness in Preventing STIs**

11. Peer-reviewed studies show that condoms provide effective protection against STIs that are transmitted through genital secretions, including HIV, gonorrhea, and chlamydia. Warner, *Male Condoms*, *supra* ¶ 10, at 336-37; *see also* NIH REPORT, *supra* ¶ 9, at 14-15; Gabriela Paz-Bailey et al., *The Effect of Correct and Consistent Condom Use on Chlamydial and Gonococcal Infection Among Urban Adolescents*, 159 ARCH PEDIATRIC ADOLESCENT MED. 536, 539 (2005); King K. Holmes et al., *Effectiveness of Condoms in Preventing Sexually Transmitted Infections*, 82 BULL. WORLD HEALTH ORG. 454, 455-57 (2004); Lee Warner et al., *Condom Effectiveness for Reducing Transmission of Gonorrhea and Chlamydia: The Importance of Assessing Partner Infection Status*, 159 AM. J. EPIDEMIOLOGY 242, 247 (2004) [hereinafter Warner, *Condom Effectiveness*]. Condoms also provide some protection against STIs that are transmitted thorough skin-to-skin contact, including syphilis, herpes simplex virus-2, and human papilloma virus (“HPV”), when the lesions or ulcers that transmit these diseases are covered by the condom. Warner, *Male Condoms*, *supra* ¶ 10, at 336-37; Rachel L. Winer et al., *Condom Use and the Risk of Genital Human Papillomavirus Infection in Young Women*, 354 NEW ENG. J. MED. 2645, 2650-51 (2006); *see also* Holmes, *supra*, at 455-57.

12. Notwithstanding the fact that latex condoms are impermeable to STI-sized organisms, STIs vary in their rate of transmission. For example, gonorrhea is a highly infectious disease, while HIV is not. *Cf.* Roy M. Anderson, *Transmission Dynamics of Sexually Transmitted Infections*, in SEXUALLY TRANSMITTED DISEASES 25, 27 tbl. 3-1 (King K. Holmes et al. eds., 3d ed. 1999). A person could become infected with gonorrhea, for example, by exposure to an infected partner’s genital secretions before a condom is in place or after a condom has been removed. Such a scenario is much less likely to result in HIV infection.

13. Our knowledge of HIV in general, and the manner in which condom use reduces the risk of HIV transmission, has greatly improved since the 1980s, the early days of the HIV epidemic. As discussed in more detail below, well-designed studies conducted since the early 1990s, and particularly in the past ten years, have confirmed that condoms are highly effective in reducing the risk of HIV transmission, about fivefold. *See, e.g.*, S.C. Weller & K. Davis-Beatty, *Condom Effectiveness in Reducing Heterosexual HIV Transmission (Review)*, COCHRANE DATABASE OF SYSTEMATIC REV. at 1 (2002). And, while the public health community agrees that HIV is still an extremely serious disease, important advances in research have led to drug treatments that have made HIV a controllable condition and that significantly prolong the lives of individuals with the virus. *Cf.* NAT’L INST. OF ALLERGY & INFECTIOUS DISEASES, NAT’L INSTS. OF

HEALTH, U.S. DEP'T OF HEALTH & HUMAN SERVS., HOW HIV CAUSES AIDS (2004) [hereinafter NIAID], available at <http://www.niaid.nih.gov/factsheets/howhiv.htm>.

14. Rates of condom effectiveness for HIV are calculated by studying serodiscordant couples, *i.e.*, couples with one HIV-positive and one HIV-negative partner. These couples are divided into two groups – those who always use condoms, and those who never use condoms – and the rate of seroconversion (or the rate of infection among the partners who were HIV-negative at the start of the study) over time is recorded. Finally, the ratio of the rate of infection among the “always” condom users and the “never” condom users is calculated. This ratio represents the relative risk of contracting HIV among the “always” condom users versus the “never” condom users. For example, in a 2002 meta-analysis of existing studies on condoms and HIV transmission, Drs. Weller and Davis-Beatty found that among serodiscordant couples who engaged in multiple acts of intercourse over a one-year period, the rate of seroconversion was 1.14% per year for the “always” condom users versus 5.75% per year for the “never” condom users. See Weller & Davis-Beatty, *supra* ¶ 13, at 1; *cf.* ¶ 15, *infra* (discussing HIV infectivity rates in a single act of intercourse). The ratio of these two percentages leads to the conclusion that correct and consistent condom usage reduces the relative risk of contracting HIV by 80%. See Weller & Davis-Beatty, *supra* ¶ 13, at 1.

15. As is explained above in ¶ 14, condom effectiveness rates for protecting against HIV transmission represent the relative reduction of risk – over time and where one partner is HIV-positive – of contracting the virus when condoms are used consistently and correctly. Thus, using the data from the 2002 Weller and Davis-Beatty study, if your partner is HIV-positive and you are HIV-negative, your risk of contracting the virus is reduced by 80% if you correctly use a condom every time you have sex. The 80% figure does not mean that condoms “fail” to prevent HIV 20% of the time, nor does it mean that a random member of the general population has a 20% chance of contracting HIV every time they have sex while using a condom. A person’s risk of contracting HIV depends on a number of factors, the most important factor being that they must be having sex with a partner who is HIV-positive. Obviously, if your partner is HIV-negative, then your risk of sexually contracting HIV from them is zero, whether you use a condom or not. Factors, in addition to correct and consistent condom usage, that influence a person’s risk of contracting HIV include: the prevalence of HIV in the population; frequency of intercourse; and, if a partner is HIV-positive, the infected partner’s viral load, stage of infection, and use of medication. Among heterosexual couples in the United States, in a single act of vaginal intercourse without a condom, a person who has sex with an infected partner has about a 0.08% to 0.14% chance of contracting HIV. Anderson, *supra* ¶ 12, at 27 tbl. 3-3. Similarly, among gay men in the United States, without a condom the receptive partner has about a 0.5% to 3% chance of contracting HIV from an infected partner during anal sex. *Id.*

16. In 2000, I served on a panel of experts convened by the National Institutes of Health (NIH) to review the existing medical literature on the effectiveness of condoms in preventing STIs. The panel reviewed approximately 138 peer-reviewed papers on

condom efficacy published on or before June 2000. Based on this research, we concluded that “consistent condom use decreased the risk of HIV/AIDS transmission by approximately 85%. These data provide strong evidence for the effectiveness of condoms for reducing sexually transmitted HIV.” NIH REPORT, *supra* ¶ 9, at 14. Other recent, reliable reviews of studies on HIV and condoms, such as the Weller & Davis-Beaty meta-analysis discussed in ¶ 14, *supra*, have also concluded that condoms are highly effective – at least 80% effective – in reducing the risk of HIV transmission from an infected to an uninfected partner. *See, e.g.*, Weller & Davis-Beaty, *supra* ¶ 13, at 1; Karen R. Davis & Susan C. Weller, *The Effectiveness of Condoms in Reducing Heterosexual Transmission of HIV*, 31 FAM. PLAN. PERSP. 272 (1999) (finding that condoms reduce the rate of HIV infection by approximately 87%). (Although the exact percentage of risk reduction in these analyses is very similar, it is not identical because the analyses include different individual studies, which may vary in the length of time that study participants were followed.).

17. In addition to concluding that condoms dramatically reduce the risk of HIV transmission, the NIH panel concluded that “studies demonstrated that correct and consistent condom use would reduce the risk of gonorrhea for men.” NIH REPORT, *supra* ¶ 9, at 16. However, the panel was unable to draw any further definitive conclusions about the effectiveness of condoms for other STIs due to a lack of well-designed, reliable studies on the subject. The panel cautioned that its inability to make further conclusions “reflected inadequacies of the evidence available and should not be interpreted as proof of the adequacy or inadequacy of the condom to reduce the risk of STDs other than HIV transmission in men and women and gonorrhea in men. To definitively answer the remaining questions about condom effectiveness for preventing STD infections will require well-designed and ethically sound clinical studies.” *Id.* at ii.

18. Given the lack of reliable research on the effectiveness of condoms in preventing STIs other than HIV and gonorrhea in men, the NIH panel called for “better-designed studies to assess condom effectiveness for STD prevention.” *Id.* at 26. The panel noted that “it is important that robust research be pursued to ascertain the true benefits and limitations of an available risk reduction technology – latex male condoms – for preventing the transmission of STDs.” *Id.* at 27.

19. The few studies on STIs and condom effectiveness conducted prior to the NIH Report were retrospective studies, in which, for example, individuals visiting an STI clinic were surveyed about their past condom usage. Retrospective studies are less expensive and easier to conduct, and although they can provide useful information, prospective studies are better because they contemporaneously record study participants’ condom usage during the course of the study, producing better data. The NIH Report’s call for more and better-designed condom studies has led to increased interest among top researchers, as well as increased funding. With this increase in interest and funding, more recent studies have produced better data by employing a prospective design and following study participants over longer periods of time.

20. Since June 2000 – the cutoff date for studies included in the NIH Report – well-designed, peer-reviewed studies published in leading journals have shown that condoms provide protection against gonorrhea, chlamydia, syphilis, and herpes simplex virus-2 in men and women. See Holmes, *supra* ¶ 11, at 455-59; Willard Cates, Jr., *The NIH Condom Report: The Glass is 90% Full*, 33 FAM. PLAN. PERSP. 231, 232 (2001). For gonorrhea and chlamydia, numerous studies show that this level of protection is significant, although less than the level of protection provided by condoms against HIV, for the reasons discussed in ¶ 12, *supra*. See L. M. Niccolai et al., *Condom Effectiveness for Prevention of Chlamydia Trachomatis Infection*, 81 SEXUALLY TRANSMITTED INFECTIONS 323, 325 (2005); Paz-Bailey, *supra* ¶ 11, at 539; Lee Warner et al., *Application of the Case-Crossover Design to Reduce Unmeasured Confounding in Studies of Condom Effectiveness*, 161 AM. J. EPIDEMIOLOGY 765, 770 (2005); Warner, *Condom Effectiveness*, *supra* ¶ 11, at 247.

21. Studies conducted prior to June 2000 and discussed in the NIH report suggested that condom use was associated with a reduced risk of HPV-associated diseases, including genital warts in men and cervical neoplasia in women, but not a reduced risk of HPV infection. NIH REPORT, *supra* ¶ 9, at 26; see also CDC, *supra* ¶ 10, at 5 (“While the effect of condoms in preventing human papillomavirus infection is unknown, condom use has been associated with a lower rate of cervical cancer, an HPV-associated disease.”). A recent well-designed, peer-reviewed study found that consistent condom use in fact reduces the risk of HPV infection itself in newly sexually active women. See Winer, *supra* ¶ 11, at 2650-51.

### C. Condom Failure

22. Condoms are susceptible to slippage and breakage during intercourse and withdrawal, but numerous recent studies have shown that the rates of slippage and breakage are low. For example, reviewing the most up-to-date and reliable data, the NIH Report found that per condom used “[t]he combined method failure (slippage plus breakage) is estimated at 1.6% – 3.6%.” NIH REPORT, *supra* ¶ 9, at 9; see also Walsh, *supra* ¶ 10, at 411 (in study of 3677 condoms, 1.5% failed due to breakage or slippage during intercourse or withdrawal); Warner, *Male Condoms*, *supra* ¶ 10, at 343 (citing per condom used breakage and slippage rates of approximately 2%, respectively); Maurizio Macaluso et al., *Mechanical Failure of the Latex Condom in a Cohort of Women at High STD Risk*, 26 SEXUALLY TRANSMITTED DISEASES 450-58 (1999) (finding breakage rate of 2.3% and slippage rate of 1.3% in a study of 892 women using 21,852 condoms over a six-month period).

23. Given latex condoms’ impermeability to sperm and STI organisms, as well as their very low breakage and slippage rates, the biggest cause of condom failure is nonuse, not device failure. Warner, *Male Condoms*, *supra* ¶ 10, at 342; Cates, *supra* ¶ 20, at 232. This point is well-illustrated by comparing condom failure rates for pregnancy. Without using any form of birth control, 85 out of 100 women (85%) will become pregnant over a one-year period. However, when condoms are used consistently and correctly – *i.e.*, used for every act of intercourse, and used correctly – only two out of

100 women (2%) will experience an unintended pregnancy over a one-year period. Warner, *Male Condoms*, at 333-34. By contrast, with “typical use,” meaning when condoms are only used some of the time or are used incorrectly, approximately 15 out of 100 (15%) of women will experience an unintended pregnancy over a one-year period. *Id.* at 334. In other words, the typical use failure rate includes data for couples who identify as condom users, but who do not use condoms every time they have sex. It also includes couples who do not use condoms correctly, for example by failing to use a condom throughout intercourse; mistakenly putting a condom on inside-out and then flipping it over and using it for intercourse, which may expose the condom user’s partner to pre-ejaculatory fluid or penile secretions that can lead to STI infection; or using an improper oil-based lubricant that can damage the latex. *Id.* at 334, 342-44.

### **MEDICALLY INACCURATE INFORMATION ABOUT CONDOMS IN THREE CURRICULA USED BY ABSTINENCE FUNDING GRANTEEES**

24. Medically accurate information is information that is supported by the weight of scientific evidence and consistent with generally recognized scientific theories; supported by research conducted under accepted scientific methods and published in peer-reviewed journals; consistent with the consensus of leading, mainstream professional organizations such as the American Medical Association (AMA), the American Academy of Pediatrics (AAP), the American College of Obstetricians and Gynecologists (ACOG), and the American Public Health Association (APHA), and government scientific agencies such as CDC, NIH, and FDA; and does not deliberately withhold or omit information that is needed to protect life and health. (This definition applies to issues like condom effectiveness and other issues addressed in this declaration, which have been sufficiently researched and studied.).

25. I reviewed three curricula used by federal grantees: *Me, My World, My Future*, and *Sexuality, Commitment and Family* (collectively, “the Teen-Aid curricula”); and *Why kNOw*. See NANCY ROACH & LEANNA BENN, *ME, MY WORLD, MY FUTURE* (1998); STEVE POTTER & NANCY ROACH, *SEXUALITY, COMMITMENT & FAMILY* (1998); KRIS FRAINIE, *WHY KNOW ABSTINENCE EDUCATION PROGRAMS, CURRICULUM FOR SIXTH GRADE THROUGH HIGH SCHOOL, TEACHER’S MANUAL* (Marcia Swearingen & Pam Sulser eds., 2002). Each fails to meet the definition of medical accuracy in its presentation of information on the effectiveness of condoms in preventing HIV and other STIs, by citing out-of-date studies from the 1980s and early 1990s that have been superseded by more recent, better-designed studies; misrepresenting the literature and manipulating the data; selectively reporting study results; making plainly inaccurate and inappropriate statements; omitting key information; and presenting information that is directly at odds with the consensus of leading scientific and medical organizations and government scientific agencies.

## A. Condoms and HIV

26. For example, the Teen-Aid curricula compare relying on condoms to prevent STIs to playing “the insane game of Russian roulette.” *Me, My World, My Future* at 215, 258; *Sexuality, Commitment and Family* at 19. The curricula explain that in Russian roulette, “[a] cartridge is loaded into one of the six chambers of a revolver. The first ‘player’ spins the cylinder, points the gun at his/her head and pulls the trigger. He/she has only one in six chances of being killed. But if one continues to perform this act, the chamber with the bullet will ultimately fall into position under the hammer, and the game ends as one of the players dies.” *Me, My World, My Future* at 215, 258; *Sexuality, Commitment and Family* at 19. Similarly, they state that “[c]ondoms are like Russian roulette. Condoms do not prevent pregnancy, STI’s [sic] or AIDS; they only delay them. Theoretically, the longer one relies on them, they will fail and the ‘game’ is over.” *Me, My World, My Future* at 215, 258; *Sexuality, Commitment and Family* at 19. This analogy is absurd on four levels. First, it is wrong as a matter of statistics to imply that a person has an initial 1 in 6 chance of disaster each time they have sex while relying on a condom. As discussed in ¶ 15, *supra*, the risk of contracting HIV during a single sexual encounter depends upon a number of factors, the most important being whether one’s partner is HIV-positive. Among the teenage population, the prevalence of HIV is very low; a 2000 United Nations report estimated that between 0.16% and 0.30% of females and 0.25% and 0.75% of males ages fifteen to twenty-four were HIV-positive in the United States. Joint United Nations Programme on HIV/AIDS, *Estimated HIV Prevalence Rate (%) in Young People, 1999, in REPORT ON THE GLOBAL HIV/AIDS EPIDEMIC (2000)*; see also CTRS. FOR DISEASE CONTROL & PREVENTION, *HIV PREVALENCE TRENDS IN SELECTED POPULATIONS IN THE UNITED STATES 21, 22 (2001)* (reporting results from studies that found: an overall HIV prevalence rate of 0.4% among youth ages 13-24 visiting five adolescent medicine clinics in Baltimore, Houston, and New York City; and an overall HIV prevalence rate, depending on race, of 0.02% to 0.32% among youth ages 16-21 entering the Department of Labor’s Job Corps program). Second, as discussed in ¶ 15, *supra*, because the chance of contracting HIV during a single sexual encounter even without a condom is low, and because correct and consistent condom usage is highly effective in preventing HIV transmission, the likelihood of becoming infected with HIV during a single sexual encounter while correctly using a condom is extremely low. Third, although the Teen-Aid curricula claim that the possibility of condom failure increases the longer one relies on them, in fact, more experienced condom users have increased rates of efficacy and lower failure rates. See, e.g., Warner, *Contraceptive Technology, supra* ¶ 10, at 342; Nalini Ranjit et al., *Contraceptive Failure in the First Two Years of Use: Differences Across Socioeconomic Subgroups*, 33 *FAM. PLAN. PERSP.* 19, 26 (2001). Fourth, the analogy between Russian roulette and sex with a condom fails because it wrongly implies that HIV transmission is synonymous with a bullet wound to the head causing imminent death. Although HIV is and continues to be a serious disease, “the median time from infection with HIV to the development of AIDS-related symptoms has been approximately 10 to 12 years in the absence of antiretroviral therapy,” and with medical treatments available today it is largely a controllable condition. NIAID, *supra* ¶ 13.



27. The Teen-Aid curricula also claim that “[c]ondoms appear to reduce the risk of heterosexual HIV infection by only 69%,” relying on what is deemed to be a “meticulous review of condom effectiveness . . . reported by Dr. Susan Weller in 1993.” *Me, My World, My Future* at 214, 256 (citing Susan C. Weller, *A Meta-Analysis of Condom Effectiveness in Reducing Sexually Transmitted HIV*, 36 SOC. SCI. MED. 1635 (1993)); *Sexuality, Commitment and Family* at 19, 36 (citing same). The *Why kNOw* curriculum also cites Dr. Weller’s 1993 meta-analysis for the proposition that condoms fail to prevent HIV transmission 31% of the time during heterosexual sex. See *Why kNOw* at 90 (citing same). However, Dr. Weller has co-authored two more recent meta-analyses of condoms and HIV in 1999 and 2002, in which she concluded that condoms afford significantly greater protection from HIV than was originally reported in 1993. See Weller & Davis-Beaty, *supra* ¶ 13 (finding that condoms reduce the rate of HIV infection by 80%); Davis & Weller, *supra* ¶ 16 (finding that condoms reduce the rate of HIV infection by 87%). Additionally, Dr. Weller cautioned that the results of the 1993 meta-analysis “should be viewed tentatively due to design limitations in the original studies.” Weller, 36 SOC. SCI. MED. at 1635. Finally, leaving aside the fact that there are more recent and more reliable studies on condom effectiveness, *Why kNOw* misrepresents the findings of even the 1993 Weller study. Dr. Weller found in 1993 that condom use offers a 69% reduction in the risk of contracting HIV from an infected partner as compared to not using a condom. This is qualitatively different than *Why kNOw*’s claim that Weller found that condoms fail to prevent HIV transmission 31% of the time. Cf. ¶¶ 14-15, *supra*.

28. The Teen-Aid curricula further claim that “[i]n one study of heterosexual couples where one partner is HIV infected, over an average of two years of sexual exposure if latex condoms were relied upon there was still a 10 to 23% risk of transmission of HIV infection even with training and proper use.” *Me, My World, My Future* at 214, 256; *Sexuality, Commitment and Family* at 19, 36. This statement is problematic for several reasons. First, the Teen-Aid curricula incorrectly and misleadingly report the results of the cited study. The study – which was done in the early days of the AIDS epidemic and published in 1987, only two years after HIV testing became available – focused on only forty-five individuals infected with AIDS, their spouses, children, and other household contacts. See Margaret A. Fischl et al., *Evaluation of Heterosexual Partners, Children, and Household Contacts of Adults with AIDS*, 257 J. AM. MED. ASS’N 640 (1987). Ten of the forty-five study participants with a spouse who was HIV-negative at the start of the study continued to have sexual contact while using condoms. *Id.* at 641. Of these ten couples, only one of the HIV-negative spouses was infected with the virus during the course of the two-year study. *Id.* Therefore, the study data reflected that 10% of the condom users contracted HIV, not that a “10 to 23% risk” remained. Second, contrary to the Teen-Aid curricula’s claims, the cited study does not state that the couples who used condoms had training in how to use them, or that they used them properly. Third, the Teen-Aid curricula omit the fact that the study found twelve out of fourteen spouses – or 85% – who were HIV-negative at the start of the study, but who continued to have sexual intercourse over the next two years with their infected partner *without* using condoms, contracted the virus. *Id.* at 644; cf. ¶ 15 (discussing factors that influence HIV transmission from an infected partner, including

frequency of intercourse and infected partner's viral load, stage of infection, and treatment). Now, with the benefit of an additional twenty years of research, we know that condoms are highly effective in preventing HIV transmission. *See, e.g.*, NIH REPORT, *supra* ¶ 9, at 14; Weller & Davis-Beatty, *supra* ¶ 13, at 1; Davis & Weller, *supra* ¶ 16, at 276. And, finally, the Teen-Aid curricula's explanation of the study's statistics is inconsistent with the way that researchers understand condom effectiveness for HIV. As discussed in ¶¶ 14-15, *supra*, condom effectiveness rates for HIV represent the relative reduction in risk that correct and consistent condom use offers when one partner is HIV-positive. Assuming for the sake of argument that the couples identified as condom users in the study always used condoms, the study data yields a condom risk reduction rate of approximately 88% (ratio of 10% rate of infectivity among condom users versus 85% rate of infectivity among non-condom users).

29. The Teen-Aid curricula also make statements about condoms that either strongly imply or explicitly state that condoms are ineffective in preventing HIV. For example, the curricula ask whether one should "trust" condoms when they "have been shown to be ineffective in preventing pregnancy or disease, to break, and even with proper usage to allow the transmission of HIV." *Me, My World, My Future* at 214; *Sexuality, Commitment and Family* at 19, 36. While it is true that condoms are not 100% effective in preventing HIV transmission or pregnancy, with proper and consistent usage they are highly effective in reducing the risk of contracting HIV or becoming pregnant. *See, e.g.*, NIH REPORT, *supra* ¶ 9, at 14; Warner, *Male Condoms*, *supra* ¶ 10, at 333.

30. The Teen-Aid curricula also highlight extremely improbable scenarios for HIV infection, for example, noting that while HIV "has a low rate of infectivity with a single sexual contact, it may take only one contact with infected bodily fluids to contract the virus. In one artificial insemination clinic, the semen of a symptomless carrier of the AIDS virus was deposited, without trauma, into the healthy vaginas of eight women. Four of them became infected." *Me, My World, My Future* at 214-15, 257; *Sexuality, Commitment and Family* at 19, 37. First, while it is possible that this scenario occurred at some point in the past, under current assisted reproductive technology procedures sperm donors are carefully screened for HIV. Second, and more important, while the above statement is qualified by the recognition that HIV has a low rate of infectivity, the statement nonetheless confusingly implies that half of the women who have sex with a partner who is HIV-positive even once will become infected with the virus. As discussed in ¶ 15, *supra*, in the United States, the risk of contracting HIV from an infected partner without a condom during a single act of vaginal intercourse is approximately 0.08% to 0.14%. *See* Anderson, *supra* ¶ 12, at 27 tbl. 3-3.

31. The Teen-Aid curricula raise questions about the effectiveness of teaching about HIV and condoms as an HIV prevention strategy. *See Me, My World, My Future* at 215-16; *Sexuality, Commitment and Family* at 20-21. In support of this claim, the curricula cite materials that have been superseded by better-designed studies, are not peer reviewed, and/or do not support the Teen-Aid curricula's conclusion that promoting safer sex practices is futile. *See Me, My World, My Future* at 215-16 (citing Noni E. MacDonald et al., *High-Risk STD/HIV Behavior Among College Students*, 263 J. AM.

MED. ASS'N 3155, 3159 (1990) (concludes that study results demonstrate the need for STI/AIDS risk reduction education that focuses, in part, on training on how to increase and improve condom use); Steven E. Keller et al., Letter to the Editor, *The Sexual Behavior of Adolescents and Risk of AIDS*, 260 J. AM. MED. ASS'N 3586 (1988) (outdated, not peer reviewed); Marsha F. Goldsmith, *Stockholm Speakers on Adolescents and AIDS: Catch Them Before They Catch It*, 260 J. AM. MED. ASS'N 757 (1988) (outdated, not peer-reviewed article reporting on a medical conference)); *Sexuality, Commitment and Family* at 20-21 (citing same). Recent, extensive, and well-designed research on sexuality education programs confirms that effective HIV/AIDS prevention programs that change adolescent behavior are those that include discussions of condom use, including how to obtain and use them. See DOUGLAS KIRBY ET AL., THE IMPACT OF SEX AND HIV EDUCATION PROGRAMS IN SCHOOLS AND COMMUNITIES ON SEXUAL BEHAVIORS AMONG YOUNG ADULTS 32-33 (2006). Additionally, research shows that teens who are comfortable using condoms, confident in their ability to refuse to have sex without a condom, and able to discuss sexual matters with their partners are more likely to use condoms and, consequently, have lower rates of STIs. See R.J. DiClemente et al., *Prevention and Control of Sexually Transmitted Infections Among Adolescents: the Importance of a Socio-Ecological Perspective – A Commentary*, 119 PUB. HEALTH 825, 827 (2005).

## **B. Condoms and Other STIs**

32. The Teen-Aid curricula inaccurately imply that condoms are ineffective at preventing chlamydia. The curricula cite a 1989 study “that found barrier contraceptives apparently do not afford adequate protection against chlamydia. User infection rates were: diaphragm – 44%, condom – 36%, oral contraceptives – 37%, and no contraception – 44%.” *Me, My World, My Future* at 214; *Sexuality, Commitment and Family* at 19. There are several problems with this statement. First, the information concerning condoms in the cited study is the result of a retrospective, cross-sectional survey of patients at a health clinic, and is extremely outdated. Several recent, well-designed, prospective studies published in the past few years have found that correct and consistent condom use decreases the risk of contracting chlamydia from an infected partner. See, e.g., Niccolai, *supra* ¶ 20, at 325; Paz-Bailey, *supra* ¶ 11, at 539; Warner, *Application of the Case-Crossover Design*, *supra* ¶ 20, at 770; Warner, *Effectiveness for Reducing Transmission of Gonorrhea and Chlamydia*, *supra* ¶ 11, at 247; see also Lee Warner et al., *Condom Effectiveness for Prevention of C trachomatis Infection*, 82 SEXUALLY TRANSMITTED INFECTIONS 265 (2006); Holmes, *supra* ¶ 11, at 455-59; Cates, *supra* ¶ 20, at 232. Second, while the cited study noted the percentage of patients who reported using various contraceptive methods, it was not per se a study of condom effectiveness in reducing the risk of chlamydia; rather, the study merely noted a number of characteristics of clinic patients who tested positive for chlamydia, including the use of contraceptives. See Sandra Samuels, *Chlamydia: Epidemic Among America's Young*, MED. ASPECTS HUMAN SEXUALITY 16, 16-18 (Dec. 1989). Furthermore, these patients self-selected their contraceptive methods. Women using different contraceptive methods are also likely to have different behavioral risks for getting chlamydia – for example, different numbers of sexual partners – a factor the survey did not control for.

33. Apart from discussing condoms in relation to HIV and chlamydia, the Teen-Aid curricula fail to give information on the effectiveness of condoms as a means of preventing other STIs, despite the fact that the curricula discuss the symptoms, treatment, and possible long-term effects of a number of other diseases, including gonorrhea, syphilis, herpes simplex virus, and HPV. *See Me, My World, My Future* at 222-30; *Sexuality, Commitment and Family* at 241-49. Similarly, in addition to HIV, *Why kNOw* discusses syphilis, gonorrhea, chlamydia, herpes simplex virus 2, HPV, and hepatitis B, yet the curriculum does not give information on condom efficacy that is specific to these diseases. *See Why kNOw* at 90-95. By failing to even mention condoms, the curricula leave the erroneous impression that condoms provide no protection for these STIs. Yet the medical literature shows that condoms, when used consistently and correctly, provide some protection against all of these diseases. *See, e.g., Paz-Bailey, supra* ¶ 11, at 539 (finding that “consistent and correct use of condoms provided significant protection against both chlamydia and gonorrhea”); Warner, *Condom Effectiveness, supra* ¶ 11, at 247 (finding that “self-reported, consistent condom use is associated with a reduced risk of gonorrhea and chlamydia”); Winer, *supra* ¶ 13, at 2650-51 (results of study “suggest that male condoms effectively reduce the risk of male-to-female genital HPV transmission”); Holmes et al., *supra* ¶ 11, at 455-57 (discussing studies conducted since 2000 that have found condoms provide protection against chlamydia, gonorrhea, herpes simplex virus 2, trichomoniasis, and syphilis); Warner, *Male Condoms, supra* ¶ 10, at 336-37 (condoms should effectively prevent gonorrhea, chlamydia, trichomoniasis, and hepatitis B infection, as well as herpes simplex virus 2, HPV, and syphilis where the lesions or ulcers that transmit these diseases are covered by the condom); CDC, *supra* ¶ 10, at 4-5 (correct and consistent condom use reduces the risk of gonorrhea, chlamydia, and trichomoniasis; reduces the risk of genital herpes and syphilis when the site of infection is covered by the condom; and is associated with a lowered rate of cervical cancer, an HPV-associated disease).

### C. Condom Failure

34. The Teen-Aid curricula imply that condoms are not effective because they break or slip. The curricula consistently cite old sources that report significantly higher condom failure rates than more recent and more accurate literature, and selectively report the highest rates of breakage and slippage from those old studies. Although condoms have not changed over time, research on condoms has gotten better and more recent data on slippage and breakage is therefore more reliable. Additionally, the Teen-Aid curricula do not explain the different implications for incidents of breakage and slippage. The curricula fail to explain, for example, that breakage is often discovered before intercourse, and that when the condom is discarded before intercourse the breakage poses no risk. *See Warner, Male Condoms, supra* ¶ 10, at 343. Moreover, the curricula fail to explain that slippage, particularly slippage during withdrawal, often results from user error, not method failure. Proper condom use involves grasping the open end of the condom at the base of the penis during withdrawal, soon after ejaculation. *Id.* Slippage during withdrawal can occur when condom users fail to follow these instructions. *Id.*

35. The Teen-Aid curricula claim that “[d]uring vaginal intercourse condoms have been reported to break or slip off 14.6% of the time.” *Me, My World, My Future* at 214 (citing James Trussell et al., *Condom Slippage and Breakage Rates*, 24 FAM. PLAN. PERSP. 20 (1992)); *Sexuality, Commitment and Family* at 19 (citing same). However, more recent studies based on better data – including the NIH Report and materials authored and edited by the authors of the 1992 study cited by Teen-Aid – report a significantly lower range of condom slippage and breakage. See NIH REPORT, *supra* ¶ 9, at 9 (reporting a combined method failure of 1.6%-3.6%); Macaluso, *supra* ¶ 22, at 450-58 (finding breakage rate of 2.3% and slippage rate of 1.3%); Walsh, *supra* ¶ 10, at 411 (reporting 1.5% breakage or slippage rate during intercourse or withdrawal); Warner, *Male Condoms*, *supra* ¶ 10, at 343 (citing breakage and slippage rates of approximately 2%, respectively). Additionally, in the 1992 study cited by Teen-Aid, the authors specifically noted that “the frequent occurrence of problems with condom use found in our study” may have been attributable to the fact that study participants “were required not to be at risk for STDs or pregnancy, [and] they may not have used condoms as carefully as they would have if they had depended on them for protection.” Trussell, *supra*, at 23; see also *id.* (recording errors in condom usage by study participants, including failing to follow instructions for condom use during withdrawal and using oil-based lubricants despite explicit warnings not to do so).

36. The Teen-Aid curricula also give misleading statistics on condom breakage and slippage among gay men. The curricula state that “[b]etween male homosexuals, condoms have been shown to fail 7.3%, 8% and 25.5% of the time.” *Me, My World, My Future* at 214; *Sexuality, Commitment and Family* at 19. All three of these statistics are outdated and/or taken out of context. For example, the 8% failure rate is from a 1988 study that involved several different types of experimental condoms, including vaginal condoms and different varieties of anal condoms, a fact that the Teen-Aid curricula omit. See G.J.P. van Griensven et al., *Failure Rate of Condoms During Anogenital Intercourse in Homosexual Men*, 64 GENITOURIN MED. 344 (1988). Similarly, the very high 25.5% failure rate comes from a 1987 study involving a small sample of seventeen gay male couples who were recruited by a magazine article to sample a number of condoms that were not yet on the market or available to the public, all facts that the Teen-Aid curricula fail to mention. See Lode Wigersma & Ron Oud, *Safety and Acceptability of Condoms for Use By Homosexual Men as a Prophylactic Against Transmission of HIV During Anogenital Sexual Intercourse*, 295 BRITISH MED. J. 94 (1987). Although the rates of condom breakage slippage and breakage during anal intercourse are slightly higher than the rates during vaginal intercourse, they are significantly lower than the Teen-Aid curricula suggest. See Susan Golombok et al., *An Evaluation of a Thicker Versus a Standard Condom With Gay Men*, 15 AIDS 245-50, tbl. 2 (2001) (reporting total breakage rate of 4.8% – 3.3% of which was attributable to user error – and slippage rate of 3% for men using a standard latex condom for anal intercourse); see also Warner, *Male Condoms*, *supra* ¶ 10, at 343 (“Breakage rates during anal intercourse are similar [to rates during vaginal intercourse],” but “Data on rates of complete slippage during anal intercourse, although very limited, appear to range more widely”).

37. Compounding the exaggerated breakage and slippage rates, one Teen-Aid curriculum also give a wide range of additional statistics on condom failure – a total of fourteen different percentages ranging from 0.6% to 15.1% – that serve to misleadingly suggest both that condoms are unreliable and that the public health community cannot establish, within a narrow range of percentage points, the actual rate of method failure. *See Me, My World, My Future* at 257. However, the public health and medical communities agree that condoms are reliable; and, recent, reliable resources cite rates of condom slippage and breakage ranging from 1.5% to 3.6% per condom used. *See, e.g.*, NIH REPORT, *supra* ¶ 9, at 9 (breakage and slippage rate ranges from 1.6% to 3.6%); Walsh, *supra* ¶ 10, at 411 (reporting breakage and slippage rate of 1.5%); Warner, *Male Condoms*, *supra* ¶ 10, at 343 (reporting breakage and slippage rate of approximately 2%, respectively); Macaluso, *supra* ¶ 22, at 450-58 (reporting breakage rate of 2.3% and slippage rate of 1.3%). Furthermore, some of the studies cited in the curriculum, for example, studies specific to commercial sex workers, are of questionable relevance in the context of a sexuality education curriculum targeting junior high school students. *See Me, My World, My Future* at 257.

38. Many of the statements in the Teen-Aid curricula imply that teens are less able than adults to use condoms consistently and correctly. Other statements cite condom failure rates that are dependent on couples' experience with using condoms or cohabitation. Embedded in these statements is the implicit idea that teens are not effective condom users. For example, the curricula claim that "unmarried adolescents consistently experience higher contraceptive failure rates for pregnancy" than married adults, citing a 1986 study (based on data from 1982) that purports to show that married adults have a 14.1% condom failure rate while unmarried adolescents have a failure rate of 18.4%. *Me, My World, My Future* at 215; *Sexuality, Commitment and Family* at 20 (citing William R. Grady et al., *Contraceptive Failure in the United States: Estimates from the 1982 National Survey of Family Growth*, 18 FAM. PLAN. PERSP. 200, 204-05 (1986)). However, more recent research demonstrates that method specific contraceptive failure rates for teenagers are similar to, and in some cases may be lower than, the failure rate for women in their twenties. *See, e.g.*, Ranjit, *supra* ¶ 26, at 25-26 (finding that in the first year of condom use, women under eighteen had a 14.5% typical use pregnancy failure rate, while women ages twenty to twenty-four had a typical use failure rate of 17.8%; during second year of condom use, typical use failure rate for women under eighteen dropped to 11.2%, and for women age twenty to twenty-four dropped to 11.9%).

#### **D. Condoms, Pregnancy, and STIs**

39. The Teen-Aid curricula also make inaccurate statements about condom failure rates and pregnancy, which are, in turn, used to inappropriately bolster the message that condoms are less than effective in preventing HIV and STIs. The curricula claim that the "standardized failure rate" for condoms in preventing pregnancy over the course of a year is 15.7%. *Me, My World, My Future* at 257; *Sexuality, Commitment and Family* at 37. This statement, standing alone, is misleading because it fails to explain that 15.7% is a typical use failure rate that includes couples who identify as condom users, but who failed to use a condom every time they had sex and/or failed to correctly use a

condom for every act of intercourse. It is not, as the curricula suggest, a reflection of condom method failure. The Teen-Aid curricula also claim that notwithstanding the “standardized” 15.7% failure rate, “among some women it has gone as high as 36.3 percent and 44.5 percent. This means that at the least, the chances of getting pregnant with a condom are 1 out of 6.” *Me, My World, My Future* at 257; *Sexuality, Commitment and Family* at 37. These claims are also extremely misleading. First, the curricula selectively report the two highest typical use failure rates from the cited literature; in fact, the nearly twenty-year-old cited study reported a wide range of condom failure rates depending on factors such as age, race, marital status, and income, with failure rates ranging from as low as 3.3% (for white, married women aged 35-44) up to 44.5% (for unmarried Hispanic women). See Elise F. Jones & Jacqueline Darroch Forrest, *Contraceptive Failure in the United States: Revised Estimates from the 1982 National Survey of Family Growth*, 21 FAM. PLAN. PERSP. 103, 105 tbl. 2, 106 tbl. 3 (1989). Second, the claim that the chance of getting pregnant while using condoms is “at least” one in six is simply wrong. Used correctly for every act of sexual intercourse, a couple’s chance of experiencing an unintended pregnancy over the course of a year is 2%. Warner, *Male Condoms*, *supra* ¶ 10, at 333.

40. *Why kNOw* stacks misleading statistic on misleading statistic to impart the message that condoms are unreliable in preventing pregnancy. The curriculum states that “the condom has a 22.5% failure rate in preventing pregnancy in unmarried women under the age of 20 during the first 12 months of use” and that “[c]ohabiting women under the age of 20 had a condom failure rate of 53.4 percent in preventing pregnancy during the first 12 months of use.” *Why kNOw* at 90. As support for these statistics, the curriculum cites “*Family Planning Perspectives*, March/April 1999.” *Id.* Although this citation is somewhat unclear, it appears to refer to an article that analyzed data from the 1995 National Survey of Family Growth. See Haishan Fu et al., *Contraceptive Failure Rates: New Estimates From the 1995 National Survey of Family Growth*, 31 FAM. PLAN. PERSP. 56 (1999). *Why kNOw*’s citation of this article is misleading in at least two respects. First, the curriculum selectively reports the highest failure rates in the article, leaving out the study’s finding that unmarried, not cohabiting women under the age of twenty and living at or above 200% of the poverty level had a typical use failure rate of 13.3%. *Id.* at 61. Second, and more important, *Why kNOw* fails to explain that these failure rates do not reflect condom failure for correct and consistent use; rather, the data reflect failure rates for women in certain demographic subsets who generally identified as condom users, but who did not use condoms for every act of sexual intercourse. It fails to place this data in context and explain the difference between typical use – which includes nonuse – and consistent, correct use. Its attempt to use this data to suggest that condoms are ineffective in preventing pregnancy is thus extremely misleading.

41. After giving misleading data on condom efficacy for preventing pregnancy, the Teen-Aid curricula state that “[c]ontracting HIV is easier than getting pregnant because you can only get pregnant several days a month.” *Me, My World, My Future* at 257; *Sexuality, Commitment and Family* at 37. *Why kNOw* similarly asks students to “consider” that a woman is only fertile approximately six days during her menstrual cycle, yet “[y]ou can acquire an STI any day of the month.” *Why kNOw* at 90;

*see also id.* at 96 (concluding that “the failure rate of the condom to prevent AIDS is logically much worse than its failure rate to prevent pregnancy”). However, the comparison between acquiring an STI and becoming pregnant is not valid because the risk of acquiring an STI depends on completely different factors than the risk of pregnancy. To acquire an STI, one must engage in sexual activity with a partner who is infected with the STI; therefore, the risk of contracting an STI depends on the prevalence of the virus in the population and is affected by condom use and efficacy in preventing that particular disease. *See, e.g.,* discussion, ¶ 15, *supra*. The risk of pregnancy depends on a women’s fertility during intercourse and is affected by contraceptive use (including condom use) and the efficacy of the contraceptive method used in preventing pregnancy. Thus, the comparison of these two risks as presented in *Why kNOw* and the Teen-Aid curricula is not scientifically accurate.

42. *Why kNOw* builds on its misleading statistics about condoms and pregnancy by inviting students to “consider” that a human sperm is 450 times larger than the HIV virus. *Why kNOw* at 90. The curriculum includes directions for an in-class illustration of this size difference, using an 18.75 ft. model of a sperm (named “Speedy”) and a penny, which is supposed to demonstrate the size of the HIV virus. This demonstration culminates in the instructor’s asking the class, “If the condom has a failure rate of 14% in preventing ‘Speedy’ from getting through to create a new life, what happens if this guy (the penny) gets through? You have a death: your own.” *Id.* at 96; *see also id.* (stating that the 14% failure rate for condoms and pregnancy is equivalent to the percent of time that a condom “keep[s] sperm from entering the women’s body”). This demonstration and corresponding statements suffer from a host of inaccuracies. First, the difference in size between a sperm and the HIV virus is completely irrelevant, because latex condoms are impermeable to both sperm and HIV-sized organisms. *See* NIH REPORT, *supra* ¶ 9, at 7-8; Walsh, *supra* ¶ 10, at 408. When a condom fails to prevent pregnancy, it is not because sperm “get[] through” the latex. In nearly all cases, it is because a condom is not in fact being used; the latex is actually punctured or otherwise damaged; and/or the condom is used improperly. *See, e.g.,* Warner, *Male Condoms*, *supra* ¶ 10, at 334, 342-44. *Why kNOw*’s suggestion that sperm “get[] through” a condom 14% of the time is therefore completely false. Second, the “Speedy the Sperm” demonstration improperly conflates the typical use and perfect use failure rates for condoms in preventing pregnancy by suggesting that condoms have a method failure rate of 14%. As explained in ¶ 23, *supra*, the 14% typical use failure rate – which is based on the notion that out of 100 couples relying on condoms during the course of a year, fourteen will experience an unintended pregnancy – includes data for couples who are not using condoms consistently and correctly for every act of intercourse. Therefore, condoms do not fail to prevent pregnancy 14% of the time; rather, among couples that rely on condoms for birth control but do not use them consistently and correctly for every act of sexual intercourse, approximately 14% will experience an unintended pregnancy over the course of a year. Third, as discussed in ¶ 41, *supra*, comparing “failure” rates of condoms for pregnancy and HIV/STIs is inherently misleading.

43. The Teen-Aid curricula also undermine the fact that condoms are effective in preventing STIs and pregnancy by quoting an individual physician’s opinion that



“Condoms don’t hack it. Passing them out is futile.” *Me, My World, My Future* at 215; *Sexuality, Commitment and Family* at 20. This statement is inaccurate. The medical literature overwhelmingly demonstrates that condoms *do* protect against STIs and pregnancy. See, e.g., NIH REPORT, *supra* ¶ 9, at 14, 16; Warner, *Male Condoms*, *supra* ¶ 10, at 333-34, 336-37; Holmes, *supra* ¶ 11, at 457; Paz-Bailey, *supra* ¶ 11, at 539; Warner, *Condom Effectiveness*, *supra* ¶ 11, at 247; Winer, *supra* ¶ 11, at 2650-51. Additionally, the prevailing medical opinion, as expressed by leading professional organizations such as the AMA, AAP, and ACOG, is that adolescents should have access to condoms through comprehensive school health programs. See AM. MED. ASS’N, POLICY H-170.968 SEXUALITY EDUCATION, ABSTINENCE, AND DISTRIBUTION OF CONDOMS IN SCHOOLS, available at [http://www.ama-assn.org/apps/pf\\_new/pf\\_online?f\\_n=browse&doc=policyfiles/HnE/H-170.968.HTM](http://www.ama-assn.org/apps/pf_new/pf_online?f_n=browse&doc=policyfiles/HnE/H-170.968.HTM) [hereinafter AMA]; Am. Academy of Pediatrics, Comm. on Adolescence, *Condom Use By Adolescents*, 107 PEDIATRICS 1463, 1467 (2001) [hereinafter AAP]; Am. Coll. of Obstetricians & Gynecologists, *Condom Availability for Adolescents*, in HEALTH CARE FOR ADOLESCENTS (2003) [hereinafter ACOG]; see also Holmes, *supra* ¶ 11, at 459 (“Condom promotion represents an important component of comprehensive HIV-prevention and STI-prevention strategies.”); CTRS. FOR DISEASE CONTROL AND PREVENTION, CDC HIV/AIDS FACT SHEET, HIV/AIDS AMONG YOUTH 3 (2006) (“Adolescents need accurate, age-appropriate information about HIV infection and AIDS, including . . . how to use a condom correctly.”).

#### E. Misleading, Directed Questioning

44. Both the Teen-Aid curricula and *Why kNOw* present directed, unscientific questions in relation to condoms’ purpose, reliability, and utility in protecting students. See, e.g., *Me, My World, My Future* at 214, 259 (“If you knew someone was infectious with the AIDS virus (HIV), would you have sex with that person? Would you recommend that your son, or your daughter, or your students place their trust in condoms? Would you trust a condom when condoms have been shown to be ineffective in preventing pregnancy or disease, to break, and even with proper usage, to allow the transmission of HIV?”); *Sexuality, Commitment and Family* at 19, 36 (same); *Why kNOw* at 89-90 (describing a condom as “a small piece of latex that, up to [the start of the AIDS epidemic] had been relegated to the back of drug store counters and sleazy hotels. Suddenly, the condom became ‘Super Condom,’ able to leap all obstacles, *if* properly used. But can it really?”). These questions often sequentially lead the reader to doubt condom effectiveness. Because the curricula selectively present condom failure rates without accurately discussing the benefits and protective nature of condoms, these value judgments inherent in the questions are one-sided and misleading. Research shows that increased condom use by sexually active adolescents leads to lower rates of STIs and teen pregnancy. See, e.g., DiClemente, *supra* ¶ 31, at 827 (adolescents who are confident in their ability to use condoms, refuse to have sex without a condom, and discuss sexual matters with their partners are more likely to use condoms and to have lower rates of STIs); John S. Santelli et al., *Explaining Recent Declines in Adolescent Pregnancy in the United States: The Contribution of Abstinence and Improved Contraceptive Use*, 97 AM. J. PUB. HEALTH 150, 153 tbl. 2, 154 (2007) (“Our data suggest that declining adolescent

pregnancy rates in the United States between 1995 and 2002 were primarily attributable to improved contraceptive use,” including significantly increased condom use). Additionally, one factor influencing adolescents’ use of condoms is the belief that condoms can prevent STIs and HIV infection. See AAP, *supra* ¶ 43, at 1464. Thus, value-laden statements that undermine confidence in condom effectiveness could discourage sexually active teens from using condoms, potentially leading to higher rates of STIs and teen pregnancy.

45. The Teen-Aid curricula and *Why kNOw* also use directed policy questions to imply that teaching students about the effectiveness of condoms will cause them to engage in early sexual activity, with, in turn, adverse mental health consequences. For example, one Teen-Aid curriculum asks, “Should physical safety from HIV, other STDs, or pregnancy be our paramount concern? Or are there other very important long-term considerations? What effect does condom instruction have on young people spiritually, emotionally and socially? Does condom instruction result in positive or negative effects on future family stability and economic success? Could it not actually be harmful to young people, or to the rest of us, to follow this course?” *Me, My World, My Future* at 259. Similarly, *Why kNOw* notes that “[c]urrently there is not a condom made that can protect a person’s emotions.” *Why kNOw* at 90. In actuality, there is *no* evidence that teaching students about condoms is damaging to their spiritual, emotional, or social health and/or development. Indeed, as discussed in ¶ 43, *supra*, the leading medical groups in the United States recommend that young people receive instruction about condoms. See, e.g., AMA, *supra* ¶ 43; AAP, *supra* ¶ 43, at 1467; ACOG, *supra* ¶ 43; CDC HIV/AIDS FACT SHEET, *supra* ¶ 43, at 3. Nor is there evidence that teaching students about condoms encourages them to engage in early sexual activity. To the contrary, research demonstrates that comprehensive sexuality education programs that include information about condoms do not lead to early sexual activity, and in many cases such programs have the opposite effect, causing youth to delay sexual activity. See Kirby, *supra* ¶ 31, at 20 (studies “strongly demonstrate that in general [comprehensive programs] did not increase sexual behavior as some people have feared, but that a majority of them actually reduced sexual behavior, either by significantly delaying the initiation of sex, reducing the frequency of sex, or reducing the number of sexual partners”); accord Douglas B. Kirby et al., *Sex and HIV Education Programs: Their Impact on Sexual Behaviors of Young People Throughout the World*, 40 J. ADOLESCENT HEALTH 206, 209 (2007). There is also very little evidence to support the assertion that early sex causes negative mental health consequences. Rather, research suggests that early sexual experience and mental health problems are both consequences of social deprivation and abuse. See John S. Santelli et al., *Abstinence-Only Education Policies and Programs: A Position Paper of the Society of Adolescent Medicine*, 38 J. ADOLESCENT HEALTH 83, 84 (2006) (“Mental health problems are associated with early sexual activity, but these studies suggest that sexual activity is a consequence not a cause of these mental health problems.”) (citing Michael A. Koenig et al., *Coerced First Intercourse and Reproductive Health Among Adolescent Women in Rakai, Uganda*, 30 INT’L FAM. PLAN. PERSP. 156 (2004); Robert F. Anda et al., *Adverse Childhood Experiences and Risk of Paternity in Teen Pregnancy*, 100 OBSTETRICS & GYNECOLOGY 37 (2002); Lianne J. Woodward & David M. Fergusson, *Early Conduct Problems and*

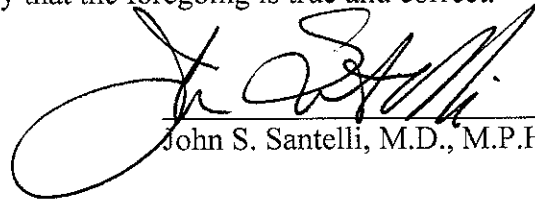
*Later Risk of Teenage Pregnancy in Girls*, 11 DEV. PSYCHOPATHOLOGY 127 (1999); Yu-Wen Chen et al., *Mental Health, Social Environment, and Sexual Risk Behaviors of Adolescent Service Users: A Gender Comparison*, 6 J. CHILD & FAM. STUD. 9 (1997)); see also John S. Santelli, *Abstinence-Only Education: Politics, Science, and Ethics*, 73 SOC. RES. 835, 843-44 (2006) (“[R]esearch shows that early sexual activity and pregnancy are associated with adverse childhood experiences, including unwanted sexual intercourse, sexual abuse, unsupportive social environments, and individual mental health problems such as conduct disorder and substance abuse. Thus, certain mental health problems are associated with early sexual activity, but these peer-reviewed studies suggest that sexual activity is a consequence of pre-existing mental health problems.”).

## CONCLUSION

46. In sum, the Teen-Aid curricula and *Why kNOW* each present information about the effectiveness of condoms in preventing STIs that is misleading, incomplete, incorrect, and, ultimately, medically and scientifically inaccurate.

I declare under penalty of perjury that the foregoing is true and correct.

Dated: 4/18/07

  
\_\_\_\_\_  
John S. Santelli, M.D., M.P.H.