



May 20, 2004

Dear Member of Congress,

In recent months, numerous press reports have shed light on a disturbing trend with regard to the misuse of scientific data and processes in policy formulation under the Bush Administration.

The most recent transgression is a decision by the Bush Administration's Food and Drug Administration to reject Barr Laboratories' application to make the emergency contraceptive product, Plan B available over-the-counter. According to press reports, Dr. Steve Galson, Acting Director of the Center for Drug Evaluation and Research acted alone in this decision, going against an overwhelming vote by an independent expert advisory committee and his own staff at the FDA. Such an action is unprecedented and claims of no political interference or pressure simply ring false. By denying this application, the Bush Administration's FDA has denied women timely access to a second chance method to prevent unintended pregnancy, meaning that more women will face the prospect of an unwanted pregnancy, or potentially, an abortion.

Unfortunately, this is not the only example of scientists being forced to make their findings fit political objectives. A report by the nonpartisan organization, Union of Concerned Scientists documents the unprecedented manipulation, suppression, and misrepresentation of science across disciplines ranging from the environment and climate change, to military intelligence and public health. ("Scientific Integrity in Policymaking: An Investigation into the Bush Administration's Misuse of Science," Union of Concerned Scientists, February 2004, www.ucsusa.org/global_environment/rsi)

As a broad network of women's and public health advocates, we want to bring to your attention to this disturbing pattern and call on you to stand up for women's health. Congress must investigate these instances to ensure that our government agencies' scientific and medical decisions are made in the public interest, not for political reasons.

Sincerely,

Advocates for Youth
American Foundation for AIDS Research
Association of Reproductive Health Professionals
National Family Planning and Reproductive Health Association
National Partnership for Women & Families
National Women's Health Network

National Women's Law Center
Physicians for Social Responsibility
Reproductive Health Technologies Project
Sexuality Information & Education Council of the United States
Society for Women's Health Research

Abstinence Only: The Well-Funded, Unproven Approach

Currently, the federal government spends over \$140 million each year on abstinence-only-until-marriage programs. President Bush has proposed doubling the federal funding of unproven abstinence-only-until-marriage programs to \$273 million for FY 2005. If this request is fulfilled, total spending on these programs since 1996 will exceed one billion dollars. Yet there is still no peer-reviewed research that proves it is effective.

Evidence-Based Public Health Solution

- Research has shown that the most effective sexual health programs are comprehensive ones that focus on delaying sexual behavior and providing information on how sexually active young people can protect themselves.¹
- A report by one of the leading researchers in the field of sexuality education concluded that HIV-prevention and sexuality education programs that cover both abstinence and contraception can delay the onset of sexual intercourse, reduce the frequency of sexual intercourse, and reduce the number of sexual partners.²

The Bush Administration Distorts Sex Education Programs that Work

Despite the lack of published studies in the professional literature indicating that abstinence-only programs will result in young people delaying intercourse or reducing teenage pregnancy, the Bush Administration continues to let political conservatives dictate public health policies even if it conflicts with the research on programs.³

- According to a source working at the CDC, Bush Administration officials forced agency staff to discontinue and abandon a project called “Programs that Work,” which identified comprehensive sex education programs found to be effective in scientific studies.⁴ None of these programs were abstinence-only programs. In ending the project, the CDC removed all information about these programs from its website.⁵
- Virginity pledge programs, often incorporated in abstinence-only education, place some teenagers at higher risk of unintended pregnancy and sexually transmitted disease (STD) by deterring them from using contraceptives when they do become sexually active. A peer

¹ Science and Success: Sex Education and Other Programs That Work to Prevent Teen Pregnancy, HIV & Sexually Transmitted Infections. URL: <http://www.advocatesforyouth.org/publications/ScienceSuccessES.pdf>

² Sexual Health Education Does Lead to Safer Sexual Behavior—UNAIDS Review” Press Release, Joint United Nations Programme on HIV/AIDS, October 22, 1997

³ Baldo M *et al.* *Does Sex Education Lead to Earlier or Increased Sexual Activity in Youth*, presented at the IXth International Conference on AIDS, Berlin, June 6-10, 1993. Geneva: World Health Organization, 1993. Office of the Surgeon General. *The Surgeon General's Call to Action to Promote Sexual Health and Responsible Sexual Behavior*. Washington Office of the Surgeon General, 2001. “Education Now And Babies Later,” Federally funded study conducted in Minnesota.

⁴ “Scientific Integrity in Policymaking,” Union of Concerned Scientists, http://www.ucsusa.org/global_environment/rsi/page.cfm?pageID=1355 Author interview with current CDC staff member, name withheld on request, November 2003.

⁵ “The Effectiveness of Abstinence-Only Education” Investigating the State of Science. U.S. House Committee on Government Reform minority staff report, URL: http://www.house.gov/reform/min/politicsandscience/example_abstinence.htm CDC, *Programs That Work* (archived version online at <http://web.archive.org/web/20010606142729/www.cdc.gov/nccdphp/dash/rtc/index.htm>).

reviewed study on virginity pledges based on the National Longitudinal Study of Adolescent Health (*Add Health*) found that teens who break their pledge are one-third less likely than non-pledgers to use contraceptives once they do become sexually active. In a presentation at the 2004 National STD Prevention Conference, Dr. Peter Bearman, of Columbia University, and Dr. Hannah Brückner, of Yale University, concluded that, based on the *Add Health* data, young people who take virginity pledges have the same rates of STDs as young people who do not pledge, and fewer pledgers practice safe sex.⁶

- The Bush Administration abandoned meaningful, scientifically proven outcome measures such as charting the birth rate of female program participants to assess whether abstinence-only education programs achieved their intended purposes.⁷ These standards have been replaced by measures such as the “Proportion of program participants who successfully complete or remain enrolled in an abstinence-only education program” and the “Proportion of adolescents who indicate understanding of the social, psychological, and health gains to be realized by abstaining from premarital sexual activity which do not assess whether or not these programs have any real impact.”⁸

Public Health Consequence:

When it comes to protecting the public health, government agencies have a responsibility to use the best available science when making decisions. Federally mandated abstinence-only-until-marriage education jeopardizes the health and lives of young people by denying them information that can prevent unintended pregnancy and infection with sexually transmitted diseases (STDs), including HIV.⁹

⁶ “National Longitudinal Study of Adolescent Health”, National Institutes of Health, the Centers for Disease Control and Prevention, and the National Science Foundation, Analysis of data begun in 1994, URL: <http://www.mchb.hrsa.gov/programs/adolescents/abedguidetext.htm>, Accessed April 2004.

P. Bearman and H. Brückner, "Promising the Future: Virginity Pledges as They Affect Transition to First Intercourse," *American Journal of Sociology*, 2001.

⁷ Federal Register 65:69562-65, November 17, 2000. “The Effectiveness of Abstinence-Only Education” Investigating the State of Science. U.S. House Committee on Government Reform minority staff report, URL: http://www.house.gov/reform/min/politicsandscience/example_abstinence.htm, Accessed April 2004.

⁸ SPRANS Community-Based Abstinence Education Program, Pre-Application Workshop, Application Narrative, U.S. Dept Of Health And Human Services, Health Resources And Services Administration (HRSA), December 2002

⁹ National Institutes of Health. *Consensus Development Conference Statement*. Rockville, MD: The Institutes, 1997.

Distortion of Condom Effectiveness as a Prevention Strategy

Each year, nearly 9 million young people 15-24 acquire sexually transmitted diseases (STD) and it is estimated that about 20,000 new HIV infections occur each year among youth. In addition, 900,000 women younger than 20 become pregnant each year, 80% of these pregnancies are unintended, yet the Bush Administration has taken to discrediting effective prevention strategies including condoms.

Evidence-Based STD Prevention Strategies

- Studies employing rigorous scientific methods and measures have found some evidence that correct and consistent condom use can lower the incidence of HPV-associated diseases, such as cervical cancer and genital warts.¹⁰ For example, the CDC's recent report to Congress, a National Institute of Allergy and Infectious Disease workshop summary, and the CDC Division of STD Prevention (DSTDP)'s own external consultants' meeting state that correct condom use may reduce the quantity of HPV transmitted.¹¹
- Laboratory studies show that condoms present an impermeable barrier to particles the size of HPV, and studies of HPV infection in men show that condoms cover the parts of the penis where most infections occur.¹² Evidence from other studies corroborates this assertion.¹³

The Bush Administration Distorting the Evidence of Condom Effectiveness as a Prevention Strategy

- Prior to 2002, the website for the CDC included information on proper condom use, the effectiveness of different types of condoms, and studies showing that condom education does not promote sexual activity.¹⁴ In 2002, according to a source within the CDC, the

¹⁰ Centers for Disease Control & Prevention. *Male Latex Condoms and Sexually Transmitted Diseases*. Atlanta, GA: Author, 2002. [www.cdc.gov/hiv/pubs/facts/condoms.htm]; Centers for Disease Control & Prevention. *Condoms and Their Use in Preventing HIV Infection and Other STDs*. Atlanta, GA: Author, 1999; National Institutes of Health, report July 20, 2001; Manhart LE, Koutsky LA. Do condoms prevent genital HPV infection, external genital warts, or cervical neoplasia? A meta-analysis. *Sex Transm Dis* 29(11): 725-35, 2002.

¹¹ CDC 2004; National Institute of Allergy and Infectious Diseases. Workshop Summary: scientific evidence on condom effectiveness for sexually transmitted disease prevention. NIH Bethesda, MD 2001 and DSTDP. Prevention of genital HPV infection and sequelae: report of external consultants' meeting. CDC, Atlanta, December 1999.

¹² Lytle CD, Rouston LB, Seaborn GB, Dixon LG, Bushar HF, Cyr WH. An in vitro evaluation of condoms as barriers to a small virus. *Sex Transm Dis* 24(3):161-4, 1997. Weaver BA, Feng Q, Holmes KK, Kiviat N, Lee S, Meyer C. Evaluation of genital sites and sampling techniques for HPV DNA detection in men. *J of Infectious Dis*, In press.

¹³ DSTDP 1999; and Hodewoning C, Bleeker M, van den Brule A, Voorhorst F, Snijders P, Berkhof J, Westenberg P, Meijer C. Condom use promotes regression of cervical intraepithelial neoplasia and clearance of human papillomavirus: a randomized clinical trial. *Int J Cancer* 107:811-816, 2003.

¹⁴ *Scientific Integrity in Policymaking: An Investigation into the Bush Administration's Misuse of Science*. Interview conducted by the Union of Concerned Scientists. Author interview with current CDC staffer, name withheld on request, November 2003.

Bush Administration directed agency staff to replace this information with a document that emphasizes condom failure rates and the effectiveness of abstinence.¹⁵

Public Health Consequence

When we do not provide young people with balanced and accurate information about contraception as part of a basic sex education, we fail to help them protect themselves against unintended pregnancies and STDs. Making abstinence a priority while undermining the effectiveness of contraceptives in general, and condoms in particular, undermines the validity of “risk reduction” as a public health strategy. Further, promoting fear-based messages that question condom effectiveness and suggest that it is unsafe to use condoms jeopardizes the health of all Americans.

¹⁵ *Scientific Integrity in Policymaking: An Investigation into the Bush Administration’s Misuse of Science*. Interview conducted by the Union of Concerned Scientists. Author interview with current CDC staffer, name withheld on 15. by Congressman Henry Waxman. URL: http://www.house.gov/reform/min/politicsandscience/example_condoms.htm

Undermining Effective HIV/AIDS Programs Globally

A large share of unmarried adolescents in the priority countries cited in the *President's Emergency Plan for AIDS Relief: U.S. Five-Year Global AIDS Strategy* are already sexually active and therefore at immediate and high risk of infection. The Emergency Plan makes the critical but erroneous assumption that marriage is a protective factor against HIV infection.

Evidence-Based U.S. Strategy on Global HIV Prevention

- A review commissioned by the Joint United Nations Programme on HIV/AIDS (UNAIDS) looked at 22 HIV-prevention and comprehensive sexuality education programs and found that they delayed the onset of sexual activity, reduced the number of sexual partners among sexually active youth, and reduced the rates of unintended pregnancy and STDs.¹⁶
- Mounting evidence from throughout the world makes clear that married monogamous women are among the groups at greatest risk of infection today. The evidence also indicates that because they often have few rights within marriage, marriage itself may be a key risk factor for HIV among women.¹⁷ For example, an analysis by the United States Census Bureau shows that prevalence rates among women in sub-Saharan Africa peak at around 25 years of age, indicating that the majority of women and girls are contracting HIV within marriage.¹⁸
- Evidence indicates that in many countries HIV infection rates in the general population are extremely high, with one-fourth to one-third of the population already infected, meaning that virtually all those who are sexually active are at immediate risk of HIV infection. For example, in Botswana prevalence stands at almost 40% and in South Africa HIV prevalence rates among pregnant women rose from 1 percent to about 25 percent in the last decade.¹⁹ As a result promoting safer sex only among “high-risk” target groups in such settings when everyone is at risk, fails to address the urgent prevention needs of the millions of people at risk of infection throughout the world.

The Bush Administration Rejects Effective Global HIV Prevention

- The *President's Emergency Plan for AIDS Relief: U.S. Five-Year Global AIDS Strategy* released by the Office of Global AIDS at the State Department repeatedly states that efforts to prevent sexual transmission of infections among youth will focus on the promotion of abstinence-until-marriage, on secondary abstinence (for those who are already sexually active), and on messages about being faithful within marriage.²⁰
- There is no commitment in the Emergency Plan that U.S. programs will ensure that all individuals and groups at risk will have access to complete HIV prevention information, education, and training. Further, the Emergency Plan constantly underscores that condoms are only to be made available to, and in the vicinity of, so-called high-risk populations

¹⁶ UNAIDS, *Progress Report on the Global Response to the HIV/AIDS Epidemic 2003*, Annex 13.

¹⁷ Ibid

¹⁸ Stanecki, Karen. *The AIDS Pandemic in the 21st Century*. Draft Report. U.S. Census Bureau. July 2002.

¹⁹ UNAIDS/WHO. *AIDS Epidemic Update*. December 2003.

²⁰ Center for Health and Gender Equity. *Debunking the Myths in the U.S. Global Aids Strategy: An Evidence-Based Analysis*. March 2004.

defined as prostitutes, the military, sexually active sero-discordant couples, substance abusers, and others.²¹

Public Health Consequence

The Bush Administration is implementing the same ineffective approach to HIV prevention abroad as it has at home. The assumptions that underpin the U.S. Strategy document and the priorities on which programmatic decisions are made endanger the lives of the very women and children that the U.S. intends to reach. As a result, our nation will fall short on its promise to help millions avoid infection with HIV.

²¹ Center for Health and Gender Equity. *Debunking the Myths in the U.S. Global Aids Strategy: An Evidence-Based Analysis*. March 2004.

Insufficient Action on Mercury Endangers Health of Women and Children

Approximately one in twelve U.S. women have potentially hazardous blood levels of mercury -- possibly due to fish consumption -- which could harm the neurological development of fetuses and young children.

Evidence-Based Research Finds Mercury Endangers Public Health

- In 2000 the National Academy of Sciences (NAS) concluded that the children of women who eat fish and shellfish regularly during pregnancy are at risk of permanent neurological damage.²²
- The CDC has assembled statistics showing that 8% of American women of child-bearing age have levels of mercury in their bloodstreams that could harm their unborn children.²³
- The polluting industries admit they could achieve greater mercury reduction in a shorter timeframe than Environmental Protection Agency (EPA) has proposed. According to states, industry experts, and past EPA analyses, the technology to dramatically reduce mercury emissions -- and satisfy legal requirements -- is available and cost-effective.²⁴

The Bush Administration Ignores Mercury Toxicity Research

- Under the Bush Administration the EPA has proposed to delay any mercury controls at power plants for another decade or longer than the law provides under the federal Clean Air Act.
- The proposed mercury rule fails to take into account the abundant scientific evidence documenting the toxic levels of mercury emissions that can impair brain development in fetuses and children.

Public Health Consequence

The health of future generations of our nation's families and communities is increasingly being put at risk by toxic levels of mercury that is contaminating water supplies and food products. An EPA analysis released in 2004 has nearly doubled—to 630,000—the estimated number of newborn children at risk of irreversible harm from mercury exposure in the womb -- including learning disabilities and vision and hearing problems.²⁵ While the technology exists to eliminate 90 percent of mercury pollution from power plant emissions, the Bush Administration's lenient proposals ignore the scientific and legal realities that jeopardize our nation's health and way of life.

²² National Research Council, National Academy of Sciences (NAS), Toxicological Effects of Methyl Mercury 9 (2000), available at <http://books.nap.edu/openbook/0309071402/html/index.html>

²³ Centers for Disease Control (CDC), First National Report on Human Exposure to Environmental Chemicals 18 (2001)

²⁴ Natural Resources Defense Council. "Senators Say Mercury Rule 'Undermines' Pollution Control" Accessed April 12, 2004. URL: <http://www.nrdc.org/news/newsDetails.asp?nID=1336>

²⁵ Guy Gugliotta, Mercury Threat to Fetus Raised, EPA Revises Risk Estimates, Wash. Post, Feb. 6, 2004, at A3.

Misrepresentations about the Facts on Breast Cancer and Abortion Corrected by Public Pressure

In 2002, the Bush Administration removed information on NCI's web site which authoritatively stated there was no scientific evidence of a link between abortion and breast cancer. It was replaced with information describing the studies as inconsistent on this topic, despite the clear consensus of the scientific community that such a link does not exist. NCI subsequently held a meeting on this topic and as a result renewed credibility to an argument that has only the weakest scientific basis. While the correct information is currently available on the website, it is troubling that significant public pressure was necessary to halt this promotion of scientifically inaccurate information to the public and that considerable public resources were diverted to a topic which had already been solidly addressed.

Evidence-Based Consensus

- Until the summer of 2002, the National Cancer Institute (NCI)'s web site included an analysis concluding that the current body of scientific evidence does not support the claim that abortions increase a woman's risk of breast cancer.²⁶
- The analysis explained that this issue had been resolved by several well-designed studies, the largest of which was published in the *New England Journal of Medicine* in 1997, finding no link between abortion and breast cancer risk.²⁷
- Researchers at the National Cancer Institute, the American Cancer Society, the Royal College of Obstetricians and Gynecologists, the World Health Organization, and major universities say that the most reliable studies show no increased risk.²⁸

The Bush Administration Distorts of Accepted Scientific Conclusions

- Claiming that abortion can cause breast cancer, social conservatives have pushed for laws across the country that require doctors to provide "counseling" about this alleged risk to all women seeking abortions. As these efforts advanced, the Bush Administration distorted the science on this issue to misleadingly portray abortion as a risk factor in breast cancer when there is clear scientific consensus that it is not.
- Despite objections from CDC staff and several exhaustive scientific studies finding no tie between breast cancer and abortion, information on the NCI website was changed to read that the studies on the topic were inconsistent.

²⁶ National Breast Cancer Coalition. URL: <http://www.natlbcc.org/bin/index.asp?strid=588&depid=20>

²⁷ Melbye M, Wohlfahrt J, Olsen JH, et al. Induced abortion and the risk of breast cancer. *N Engl J Med* 1997;336(2):81-5.

²⁸ American Cancer Society. *Breast Cancer: Prevention and Risk Factors*, 1999, URL

http://www.cancer.org/docroot/CRI/content/CRI_2_2_2X_What_causes_breast_cancer_5.asp?sitearea=, Accessed April 2004. National Cancer Institute,). *Cancer Facts: Abortion and Breast Cancer*, March 6, 2002, URL:

http://cis.nci.nih.gov/fact/3_53.htm, Accessed April 2004. Royal College of Obstetricians and Gynecologists. *What You Need to Know About Abortion Care*, May 2001, URL:

<http://www.rcog.org.uk/print.asp?PageID=701&Type=main>, Accessed April 2004. World Health Organization. *Induced Abortion Does Not Increase the Risk of Breast Cancer*, June 2000, URL:

<http://www.who.int/mediacentre/factsheets/fs240/en/>, Accessed April 2004.

Reaffirming Science-Based Evidence

- After significant public pressure, in February 2003 the NCI convened a conference with over 100 experts to once again review the research and make conclusions about the relationship between reproductive factors and breast cancer risk.
- After reviewing the evidence, the workshop attendees issued a report stating that there is strong evidence that neither spontaneous nor induced abortion increases the risk of breast cancer. The report's findings were reviewed and unanimously approved by NCI's Board of Scientific Advisors and Board of Scientific Counselors.²⁹
- The NCI has again revised its website to state that "having an abortion or miscarriage does not increase a woman's subsequent risk of developing breast cancer."
- Months after the NCI conference, the *Lancet* reported on a analysis by Valerie Beral of Cancer Research UK in Oxford and her collaborators which reanalyzed the raw data from more than 80,000 women in 53 studies worldwide. They found no connection between abortion and breast cancer.³⁰

²⁹ Early Reproductive Events and Breast Cancer related materials URL: <http://www.cancer.gov/cancerinfo/ere>, Accessed April 2004. National Cancer Institute's (NCI) Board of Scientific Advisors and Board of Scientific Counselors URL: <http://www.cancer.gov/newscenter/pressreleases/BSCacceptERE>, Accessed April 2004.

³⁰ Collaborative Group on Hormonal Factors in Breast Cancer. *Lancet*, 363, 1007 - 1016, 2004.

Ignoring Racial and Ethnic Health Disparities

In a June 2003 draft report, the Department of Health and Human Services found that racial and ethnic disparities in health care are “national problems” that are “pervasive in our health care system” and carry a significant “personal and societal price.” After review by political appointees, however, the final version omitted these conclusions. When the difference in the two reports surfaced in the media, Secretary Thompson apologized and issued the draft report to the public – but only after significant public outcry.

June 2003 Evidence Based Findings (the Initial Draft Report)

- Scientists concluded that racial and ethnic minorities are more likely to be diagnosed with late-stage cancer, die of HIV, be subjected to physical restraints in nursing homes, and receive suboptimal cardiac care for heart attacks. Minorities are more likely to be diagnosed with late-stage breast cancer and colorectal cancer when compared with whites.
- Scientists concluded there is a personal and societal cost of disparities, including lost productivity, needless disability and early death.
- Scientists defined disparity as “the condition or fact of being unequal” and used the word over 30 times in the “key findings” section of the executive summary.

Bush Administration Manipulates Research Findings (the Original Final Report)

- An analysis comparing the final version of the report's executive summary with a draft completed in June 2003 showed that 28 mentions of the word "disparity" were removed from the final version; a conclusion stating that health care disparities "are national problems" was deleted; and a passage listing disparities relating to cancer, HIV and cardiac care was replaced with a reference to low use of cholesterol tests.³¹
- The January 2004 version of the report excluded findings on the social costs of disparities and replaced them with the finding that some “priority populations” do as well or better the general population in some areas of health care.
- The January 2004 version failed to define “disparity” and used the word only twice in the “key findings.”

Public Health Consequence

The Bush Administration’s January 2004 “final” version of the report failed to accurately document the science and research affecting the lives of the nation's racial and ethnic minorities. In doing so, the Administration set us on a course to exacerbate the health care disparities experienced by millions of minorities rather than confront the problems and provide real solutions.³² After public outcry, the division of HHS responsible for drafting the initial report released the original version of the report it had submitted to the Department for clearance.

³¹ “A Case Study in Politics and Science: Changes to the National Healthcare Disparities Report,” U.S. House Committee on Government Reform minority staff report, URL:

http://www.house.gov/reform/min/politicsandscience/example_disparities.htm

³² “The Right to Equal Treatment: Racial and Ethnic Disparities in the Quality of Care,” Harvard Health Policy Review, Fall 2003, in pdf (www.hcs.harvard.edu/~epihc/currentissue/borchelt.pdf)

Conservative Religious Agenda Impedes Advances in Stem Cell Research

Embryonic stem cells can develop into many different kinds of tissues, raising hopes that they might ultimately contribute to medical therapies for a number of chronic diseases. But the Bush Administration has dealt a serious blow to stem cell research in the U.S. by limiting federal funding for such research to only 11 existing stem cell lines – which are all contaminated by mouse “feeder” cells, which may make them unsuitable for use in the human therapeutic research.

Evidence-Based Information of the Promise of Stem Cell Research

- Scientists have long believed that stem cells – derived from blood, bone marrow or embryos – are capable of repairing damaged tissue by taking on the identity of that organ's cells.³³
- Leading scientists state that embryonic stem cells have significant potential to treat conditions like Parkinson's, Rett Syndrome, and autoimmune diseases, and federal funding is integral to finding the promise behind this potential for millions of Americans.

Bush Administration Distortion of Available Stem Cells Provides False Hope

- The Bush Administration has allowed politically conservative groups to drive our nation's policy on stem cell research, resulting in a ban on federal funding for research using new embryonic stem cell lines.
- When the President announced his embryonic stem cell research policy, there were thought to be at least 60 stem cell lines that qualified for federally funded research. The National Institutes of Health has since announced there are just 11 lines.³⁴
- Furthermore, all 11 lines are contaminated by mouse “feeder” cells, which may disqualify them for human therapeutic use. Science has progressed, and now we have the technology to develop stem cell lines free of mouse cells.³⁵ But under the Bush Administration's policy we cannot use federal funds to take advantage of these new technologies because to do so would mean the development of new stem cell lines.

Public Health Consequence

We now have the technology to develop stem cell lines to be used to treat and better understand deadly and disabling diseases that affect more than 100 million Americans, such as cancer, heart disease, diabetes, Parkinson's, Alzheimer's, multiple sclerosis, spinal cord injury, and many others. Yet the policy adopted by the Bush Administration is driving researchers overseas so that they will not be restricted by U.S. guidelines. As a result, it is difficult to attract new scientists to this field to pursue the groundbreaking research that will lead to new cures and treatments. Unless the Bush Administration reverses its restrictions on funding for embryo research, it will impede development of treatments that might save lives and improve health care for millions of people.

³³ Testimony of James Cordy on behalf of the Coalition for the Advancement of Medical Research (CAMR) before the Senate Appropriations Committee Subcommittee on Labor, Health and Human Services, and Education May 22, 2003

³⁴ Ibid

³⁵ Lemonick M. Stem cells in limbo: two years after President Bush said the U.S. had all the cell lines it needed, where did they go? *Time*. August 11, 2003: 51.

Moral Judgments Compromise Scientific Merit in Public Health Research

Biomedical and behavioral research across the federal government has been guided by visionary and knowledgeable scientists and policymakers who understand the value of long-term investments in research to improve health, and who have set up a system of the highest quality that allows good science to flourish. Diminishing the role of scientists in medical research decisions jeopardize the health and well-being of the American people and the rest of the world, by undermining the collective efforts of researchers and clinicians to improve health.

Relevant Public Health Studies

- NIH research has helped to save or improve the lives of millions of Americans for the past 125 years. This research has produced a body of evidence on how diseases develop and spread – and how they disappear when prevented or treated properly.
- The AIDS pandemic, the growth in sexually transmitted diseases, and the health risks associated with drugs, sex, and disease are significant public health issues affecting people that should and can be addressed by NIH sponsored research.

Bush Administration Distorts Scientific Research in Public Health

- Political and religious advocacy groups are pressuring Members of Congress and NIH staff to consider moral qualifications of the researchers and their studies in what has always been science based, peer reviewed decisions on research and public health policy.
- The Traditional Values Coalition (TVC), a coalition of conservative church groups, helped develop a list of grants funded by NIH that were identified as morally objectionable and a misuse of taxpayer dollars. The list was distributed to members of the Energy and Commerce Committee of the U.S. House of Representatives.
- The TVC asked the current Administration's Justice Department to investigate whether the NIH was wrong to fund certain projects because they were documenting the behavior of prostitutes, intravenous drug users and others at high risk of spreading sexually transmitted diseases.

Public Health Consequence

Sexual health and behavior research is essential to providing a scientific foundation for sound public health prevention and intervention programs. This research addresses unhealthy behaviors and is essential to producing outcomes that save lives and health care costs; enhance the quality of life of our families and children; and improve systems of health care delivery.³⁶ Yet under the Bush Administration, NIH is being pressured to include moral bias in its peer-review process in a way that threatens the funding and scientific merit of the very research that will help scientists, physicians and our nation's families and communities' battle against illness and disease.

³⁶ Elias Zerhouni, M.D., Director of the National Institutes of Health. Response to Congressional Inquiry from Congressman Henry Waxman. February 4, 2004. Accessed at URL: http://www.house.gov/reform/min/politicsandscience/pdfs/pdf_politics_and_science_nih_hit_list_jan_29_let.pdf

Using His Appointment Authority to Undermine the Quality and Integrity of Peer Review

In several cases, the Bush administration's candidates for advisory positions have so lacked qualifications or held such extreme views that they have caused a public outcry. The Administration's candidates have blatantly ignored the conclusions of peer reviewed research and the "best practices" adopted by health care professionals for approaching public health concerns.

FDA Reproductive Health Drug Advisory Committee

The U.S. Food and Drug Administration's (FDA) Reproductive Health Advisory Committee advises the agency on contraceptives, abortion, and other potentially controversial medical issues such as hormone replacement therapy.

The Bush Nominee: Part I

- In 2002 the Bush administration initially suggested that Dr. W. David Hager, an obstetrician-gynecologist with scant credentials and highly partisan political views, chair the FDA advisory committee.
- His nomination represents a dramatic departure from any past appointments to this committee. He is best known for co-authoring a book that recommends particular scripture readings as a treatment for premenstrual syndrome and, in his private practice, Hager has reportedly refused to prescribe contraceptives to unmarried women.³⁷

After widespread public outcry, HHS announced that Dr. Hager would sit on the committee, but would not serve as its chair.

The Bush Nominee: Part II

- In 2002 the Bush administration also nominated Dr. Joseph Stanford to serve on the Reproductive Health Advisory Committee. Dr. Stanford opposes all contraception except natural family planning methods.
- In a 1999 article in *First Things*, a religion journal, Stanford described natural family planning as part of a larger perspective on the role of religion in health. He wrote, "I have found that medicine is permeated with attitudes toward sexuality and fertility that are incompatible with Christian values of the sanctity of life, marriage, and procreation, attitudes that both reflect and perpetuate the recreational approach to sexuality found in our secular culture."

Dr. Joseph Stanford currently serves on the FDA's Reproductive Health Advisory Committee despite concerns that his opposition to contraception conflicts with the exact charge of the committee members – that is to evaluate the safety and effectiveness of contraceptive drugs.

³⁷ David W. Hager and Linda Carruth Hager, *Stress and the Woman's Body* (1996) as cited in *Jesus and the FDA*, *Time* (Oct. 5, 2002).

Presidential Advisory Council on HIV/AIDS

The Council provides the President and HHS Secretary with recommendations regarding programs and policies intended to promote the highest quality of research, prevention, care and treatment.

The Bush Nominee

- Dr. Joseph McIlhaney is a Texas-based doctor known for his published disdain for the use of condoms to prevent the spread of HIV and other sexually transmitted diseases and his continued advocacy of abstinence-only programs despite negligible evidence that they actually reduce pregnancy rates among young people. He is the founder of a pro-abstinence think tank called the Medical Institute for Sexual Health (MISH).
- In 1995, the Texas Department of Health wrote a letter to McIlhaney criticizing a slide presentation he had been showing throughout the state. The letter included a detailed critique, prepared by two doctors, a registered nurse and the director of the state's HIV/STD Epidemiology Division that pointed out a number of distorted, false and "ridiculous" statements in McIlhaney's presentation. According to accounts in the press, the letter stated that some of the data McIlhaney presented suffered from investigator bias, "Dr. McIlhaney's presentation tended to report the outlier data as 'proof' that condoms don't work rather than present those reports in the context of the entire data set. The only data that was reported in the presentation are those which supported his bias on the topics he addressed. Intellectual honesty demands that he present all the data."³⁸

Dr. McIlhaney was appointed by the Bush Administration to the Presidential Advisory Council on HIV/AIDS despite his dearth of published, peer-reviewed scientific research or endorsement by any established medical societies.

³⁸ Michelle Goldberg, "Bush's Sex Fantasy," Salon February 24, 2004, URL: http://www.salon.com/news/feature/2004/02/24/abstinence/index_np.html, Accessed April 2004.

Disregarding Scientific Data on Emergency Contraception: Placing Women at Risk for Unintended Pregnancies and Abortions

Approximately three million unintended pregnancies occur annually in the United States and more than half of these unintended pregnancies happen to women using a regular method of contraception. Unintended pregnancy is a major public health problem that can be effectively addressed by increasing the use of emergency contraception (EC). One of the most compelling facts about EC is that it is most effective in preventing pregnancy the sooner a woman can take it. Yet women have difficulty gaining access to physicians to obtain a prescription within the critical 72 hour window of time when EC works most effectively. Prescription-only status is a barrier that contributes to more negative outcomes, and more unintended pregnancies.

Evidence-Based Support for Making EC Available Over-the-Counter

- The Food and Drug Administration (FDA) staff reviewed more than 15,000 pages of clinical data from approximately 40 studies submitted with the Plan B® application for over-the-counter status which suggest that use of emergency contraception is *not* associated with increased risk for future STIs or pregnancy among adolescent girls.³⁹ The FDA staff found Plan B's safety risks were "very limited." An internal FDA agency memo suggests medical reviewers recommended nonprescription sales.⁴⁰
- One study considered by the FDA included women ages 15 to 20 which found no evidence to suggest that providing advance emergency contraception pills causes adolescents to have more unprotected intercourse or to stop using a regular contraceptive method. The findings, published in the April 2004 issue of the *Journal of Pediatric and Adolescent Gynecology*, adds to the growing body of literature that demonstrates there are no negative behavioral or health ramifications to making emergency contraceptives available outside the confines of a pediatric health care visit.⁴¹
- In December 2003, a joint hearing of the FDA Nonprescription Drugs and Reproductive Health Drugs Advisory Committees overwhelmingly recommended that the FDA make Plan B EC available over the counter by a 23 to 4 vote after reviewing the overwhelming evidence and hearing testimony from FDA staff and medical and public health experts.
 - The panels also voted 28-0 that the drug could be sold safely without a doctor's prescription.
 - On the question of whether Plan B was safe enough to be sold over-the-counter, the vote was a unanimous 28 to 0 in favor of Plan B.

³⁹ Raymond EG, et al. "Actual use" study of emergency contraceptive pills provided in a simulated over-the-counter manner. *Obstetrics & Gynecology* 2003; 102(1): 17-23; Glasier A, Baird D. The effects of self-administering emergency contraception. *The New England Journal of Medicine* 1993c; 339: 1-4; Jackson RA, et al. Advance supply of emergency contraception; effect on use and usual contraception – a randomized trial. *Obstetrics & Gynecology* 2003; 102(1): 8-16.

⁴⁰ FDA, Nonprescription Drugs Advisory Committee and the Advisory Committee for Reproductive Health Drugs, December 16, 2003, Transcript. <http://www.fda.gov/ohrms/dockets/ac/03/transcripts/4015T1.htm>; Neergaard, Laurant, Associated Press May 7, 2004

⁴¹ Gold, Melanie. *Journal of Pediatric and Adolescent Gynecology*. April 2004;

- The Committee agreed that Plan B® labeling is clear and comprehensible enough for women – regardless of age – to understand that Plan B® does not protect against sexually transmitted infections or HIV.
- These experts made clear that EC is safe and that it does not increase promiscuity or unprotected sex among teenaged women, nor does it cause women to abandon their regular birth control methods.⁴²
- In a letter to the FDA staff dated February 9, 2004, The American Academy of Pediatrics and the Society for Adolescent Medicine reaffirmed their support for making Plan B available over-the-counter, stating, “The only condition EC treats – contraception failure or failure to use contraception during intercourse – is one that is diagnosable by a young woman and has no contraindications that would pose a danger to the patient.”⁴³

The Bush Administration Interferes with FDA’s Decision Making Process on Emergency Contraception

- On May 6, 2004, the FDA rejected Barr Laboratories' application to sell the emergency contraceptive Plan B over the counter, citing concerns the company had not proved that teenagers could take the drug safely without doctor supervision.
- The FDA decision under the Bush Administration mirrors opposition from extreme social and religious conservatives, including some members of Congress who lobbied President Bush to deny approval of the application.⁴⁴
- Opposition to over-the-counter status has been limited to a very few but powerful, religiously based organizations – such as the Christian Medical Association and Concerned Women for America
- An internal FDA agency memo, obtained by The Associated Press, suggests the FDA medical reviewers supported nonprescription status but were overruled by senior officials. In issuing the decision, FDA acting drug chief Dr. Steven Galson stated he rejected the recommendations of his own reviewing staff at the agency and the FDA advisory committee. Ignoring a concurring assessment of the scientific evidence by staff and the advisory panel is extremely rare.⁴⁵

Public Health Consequence

Emergency contraception could prevent up to half of the 3 million unintended pregnancies that occur each year in the U.S. There is a public health imperative to increase access to emergency contraception to allow women to get it within the critical time period when it is most effective.

⁴² FDA, Nonprescription Drugs Advisory Committee and the Advisory Committee for Reproductive Health Drugs, December 16, 2003, Transcript. <http://www.fda.gov/ohrms/dockets/ac/03/transcripts/4015T1.htm>; Neergaard, Luran, Associated Press May 7, 2004

⁴³ American Academy of Pediatrics and Society for Adolescent Medicine. Letter to the FDA, February 9, 2004. See reference in letter: Zabin LS, Kanter JF, Zelnik, M. The risk of adolescent pregnancy in the first months of intercourse. *Fam Plann Perspect.* 1979;11:215-222.

⁴⁴ Congressman David Weldon, et al. Letter to the President Bush/FDA Commissioner McClellan February 2004. Christian Medical Association news release May 6, 2004 <http://www.cmdahome.org/index.cgi?BISKIT=3546977250&CONTEXT=art&art=2641> ; Chicago Tribune May 7, 2004;

⁴⁵ Gardiner Harris. “Morning-After-Pill Ruling Defies Norm” New York Times, May 8, 2004

Requiring a prescription is not only medically unjustified, it is also a known barrier to getting emergency contraception in time. Based on the scientific data and unprecedented consensus from medical and health care organizations – including the American College of Obstetricians and Gynecologist, the American Academy of Pediatricians and the American Academy of Family Physicians – it is absolutely clear that women would be best served by over-the-counter access to emergency contraception.

In rejecting the application to make Plan B available OTC, the Bush administration has disregarded the overwhelming scientific evidence and denied American women timely access to a safe, proven second chance to prevent pregnancy. The Bush Administration has also damaged the FDA's reputation as an evidence-based agency by interfering with the decision making process and elevating extreme social and religious priorities above the conclusions of scientific data. The concerns raised with the FDA decision making process have done irreparable harm to the trust the agency has earned from medical and health care organizations, practitioners, scientists, industry and the American public.