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# POLITICS AND SCIENCE: REPRODUCTIVE HEALTH

### Representative Henry A. Waxman, U.S. Congress

# INTRODUCTION

A key to the creation of effective health policy is access to the best available scientific research. When scientific research and the scientific method conflict with political priorities, the science should be honestly presented, and the work of scientists respected and encouraged. The public is ill-served when science is abused to support political or ideological ends.

Under the Bush Administration, however, the boundaries between politics and science have frequently been breached. The Administration has censored accurate scientific information that it does not want disseminated to the public. It has gagged scientists conducting research perceived as threatening its priorities. And, it has manipulated scientific advisory committees to replace objective expert advice with echoes of what it wants to hear. In some cases, these actions have taken place to support business interests that are politically allied with the Administration or the Republican Party. But in many others, the motivation is ideological.

Nowhere is the ideologically motivated manipulation of science more evident than in the area of reproductive health. One of President Bush's first actions after his inauguration was to reinstate the "Mexico City policy," blocking any foreign groups that receive U.S. funding from speaking out about the harms of illegal abortion.<sup>1</sup> Since that time, the Administration has repeatedly relied on gross distortions of scientific information to bolster its policies on a range of crucial reproductive health issues, including sex education, breast cancer, condoms, HIV/AIDS, emergency contraception, and stem cells. This article describes some of the most egregious cases of this political interference.

<sup>&</sup>lt;sup>1</sup> Laurie Goodstein, Personal and Political, *Bush's Faith Blurs Lines*, N.Y. TIMES, Oct. 26, 2004, at 21 (stating "On his first working day in office, President Bush issued an executive order reinstating a Reagan-era policy that anti-abortion groups call the Mexico City policy but family planning groups refer to as the gag rule.").

# I. ABSTINENCE-ONLY-UNTIL-MARRIAGE EDUCATION

President Bush has consistently supported the view that sex education should teach "abstinence only" and omit information on other ways to avoid sexually transmitted diseases and pregnancy.<sup>2</sup> In 2003, White House Spokesperson Ari Fleischer stated that "abstinence is more than sound science, it's a sound practice . . . abstinence has a proven track record of working."<sup>3</sup>

The Bush Administration's "abstinence only" agenda often rests upon scientific distortions and inaccuracies. Administration officials have never acknowledged that abstinence-only programs have not been proven to reduce sexual activity, teen pregnancy, or sexually transmitted disease.<sup>4</sup> Instead, the Administration has defended abstinence-only curricula that contain serious factual errors, loosened standards to measure abstinence-only programs, and censored information on effective sex education programs.

#### A. Abstinence-Only Curricula

In December 2004, I released a report finding serious factual errors and omissions in federally funded curricula that exclusively promote abstinence to youth.<sup>5</sup> The Administration's response has been to deny that there are any problems at all.

The report found that over 80 percent of the abstinence-only curricula, funded directly by the Department of Health and Human Ser-

<sup>&</sup>lt;sup>2</sup> See, e.g., Press Release, Pres. George W. Bush, President Discusses Welfare Reform and Job Training (Feb. 27, 2002), *available at* http://www.whitehouse. gov/news/releases/2002/02/print/20020227-5.html.

<sup>&</sup>lt;sup>3</sup> Press Release, Ari Fleischer, Press Briefing by Ari Fleischer (Jan. 27, 2003), available at http://www.whitehouse.gov/news/releases/2003/01/20030127-2. html.

<sup>&</sup>lt;sup>4</sup> DOUGLAS KIRBY, NAT'L CAMPAIGN TO PREVENT TEEN PREGNANCY, DO ABSTINENCE-ONLY PROGRAMS DELAY THE INITIATION OF SEX AMONG YOUNG PEOPLE AND REDUCE TEEN PREGNANCY? 1 (2002), *available at* http://www.teenpregnancy. org/resources/data/pdf/abstinence\_eval.pdf ("[T]here do not currently exist any abstinence-only programs with reasonably strong evidence that they actually delay the initiation of sex or reduce its frequency.") (quoting DOUGLAS KIRBY, NAT'L CAMPAIGN TO PREVENT TEEN PREGNANCY, EMERGING ANSWERS: RESEARCH FINDINGS ON PROGRAMS TO REDUCE TEEN PREGNANCY 88 (2001)).

<sup>&</sup>lt;sup>5</sup> U.S. HOUSE OF REPRESENTATIVES COMM. ON GOV'T REFORM - MINORITY STAFF, THE CONTENT OF FEDERALLY FUNDED ABSTINENCE-ONLY EDUCATION PROGRAMS I (2004), *available at* http://www.democrats.reform.house.gov/ Documents/20041201102153-50247.pdf (report prepared for Rep. Henry A. Waxman).

vices (HHS) in 2003, contained false, misleading, or distorted information about reproductive health.<sup>6</sup> Specifically, the report found:<sup>7</sup>

• Abstinence-only curricula contain false information about the effectiveness of contraception. Many of the curricula misrepresent the effectiveness of condoms in preventing sexually transmitted diseases and pregnancy. For example, one curriculum states that "[i]n heterosexual sex, condoms fail to prevent HIV approximately 31 [percent] of the time."<sup>8</sup>

• Abstinence-only curricula contain false information about the risks of abortion. One curriculum states that 5 percent to 10 percent of women who have legal abortions will become sterile; that "[p]remature birth, a major cause of mental retardation, is increased following the abortion of the first pregnancy;" and that "[t]ubal and cervical pregnancies are increased following abortions."<sup>9</sup> In fact, these risks do not rise after the procedure used in most abortions in the United States.<sup>10</sup>

• Abstinence-only curricula blur religion and science. Many of the curricula present as scientific fact the religious view that life begins at conception. For example, one lesson states, "Conception, also known as fertilization, occurs when one sperm unites with one egg in the upper third of the fallopian tube. This is when life begins."<sup>11</sup> Another curriculum calls a

<sup>10</sup> F. GARY CUNNINGHAM ET AL., WILLIAMS OBSTETRICS 877 (Andrea Seils et al. eds., McGraw-Hill, 2001). The book notes that "[a] possible exception is the small risk from pelvic infection." *Id.* Another book states that "[c]oncerns about infertility as a result of induced abortion seem largely unfounded, except for the rare severe complication managed by hysterectomy." STEVEN G. GABBE ET AL., OBSTETRICS: NORMAL AND PROBLEM PREGNANCIES 643 (4<sup>th</sup> ed. 2002). In addition, vacuum aspiration, the method used in most abortions in the United States, "results in no increased incidence of midtrimester spontaneous abortions, preterm deliveries, or lowbirthweight infants in subsequent pregnancies;" and "[s]ubsequent ectopic pregnancies are not increased if the first termination is done by vacuum aspiration." CUNNINGHAM ET AL., *supra*, at 877.

<sup>11</sup> ROSE FULLER ET AL., I'M IN CHARGE OF THE FACTS: MIDDLE SCHOOL CURRICULUM, 23 (7th ed. 2000), *available at* http://www.democrats.reform.house. gov/features/abstinence\_report/index.htm (follow "Middleschool Facts page 23 (pdf)" hyperlink). See also Lawmaker: Abstinence Programs Misleading, ABC NEWS, Dec.

<sup>&</sup>lt;sup>6</sup> Id.

<sup>&</sup>lt;sup>7</sup> *Id.* at i-ii.

<sup>&</sup>lt;sup>8</sup> WHY KNOW ABSTINENCE EDUCATION, INC., WHY KNOW 91 (2004), *available at* http://www.democrats.reform.house.gov/features/abstinence\_report/index.htm (follow "Why kNOw page 91 (pdf)" hyperlink).

<sup>&</sup>lt;sup>9</sup> TEEN-AID, INC., ME, MY WORLD, MY FUTURE 157 (Nancy Roach & LeAnna Benn eds., 1998).

forty-three-day-old fetus a "thinking person."<sup>12</sup>

• Abstinence-only curricula treat stereotypes about girls and boys as scientific fact. One curriculum teaches that women need "financial support," while men need "admiration."<sup>13</sup> Another instructs: "Women gauge their happiness and judge their success by their relationships. Men's happiness and success hinge on their accomplishments."<sup>14</sup>

• Abstinence-only curricula contain scientific errors. In numerous instances, the curricula teach erroneous scientific information. One curriculum incorrectly lists exposure to sweat and tears as risk factors for HIV transmission.<sup>15</sup> Another curriculum states that "[t]wenty-four chromosomes from the mother and twenty-four chromosomes from the father join to create this new individual;" the correct number is twentythree.<sup>16</sup>

In response to the report, Administration officials have denied that these curricula had any problems at all. Deputy Assistant Secretary for Population Affairs Alma Golden asserted, "[t]his report misses the boat. These issues have been raised before and discredited."<sup>17</sup> The Administration proposed a more than 50 percent increase in federal abstinence-only funding—to \$270 million—for Fiscal Year 2005.

<sup>2, 2004,</sup> http://www.abcnews.go.com/Politics/wireStory?id=296614.

<sup>&</sup>lt;sup>12</sup> TEEN-AID, INC., ME, MY WORLD, MY FUTURE: TEACHER MANUAL 77 (Nancy Roach & LeAnna Benn eds., 1998), available at http://www.democrats. reform.house.gov/features/abstinence\_report/index.htm (follow "Me, My World, My Future page 77 (pdf)" hyperlink). See also Ceci Connolly, Some Abstinence Programs Mislead Teens, Report Says, WASH. POST, Dec. 2, 2004, at A1.

<sup>&</sup>lt;sup>13</sup> FRIENDS FIRST, WAIT (WHY AM I TEMPTED) TRAINING 199 (1998), available at http://www.democrats.reform.house.gov/features/abstinence\_report/index.htm (follow "Wait Training page 199 (pdf)" hyperlink). See also Connolly, supra note 12, at A1.

<sup>&</sup>lt;sup>14</sup> WHY KNOW ABSTINENCE EDUCATION, INC., *supra* note 8, at 122 (follow "Why kNOw page 122 (pdf)" hyperlink).

 <sup>&</sup>lt;sup>15</sup> FRIENDS FIRST, supra note 13, at 219 (follow "Wait Training page 219 (pdf)" hyperlink). See also Connolly, supra note 12, at A1.
 <sup>16</sup> WHY KNOW ABSTINENCE EDUCATION, INC., supra note 8, at 166 (follow

<sup>&</sup>lt;sup>10</sup> WHY KNOW ABSTINENCE EDUCATION, INC., *supra* note 8, at 166 (follow "Why kNOw page 166 (pdf)" hyperlink).

<sup>&</sup>lt;sup>17</sup> News Release, U.S. Dep't of Health & Human Servs., Statement by Alma Golden, M.D., Deputy Assistant Secretary for Population Affairs, Office of Public Health & Science Regarding Abstinence Education Report of the House Committee on Government Reform (Dec. 1, 2004), http://www.dhhs.gov/news/press/2004pres/ 20041201.html.

#### B. Sex Education Performance Measures

In November 2000, under the Clinton Administration, HHS developed four meaningful outcome measures to assess whether newly community-based abstinence-only education created programs achieved their intended purposes. These measures included the "proportion of program participants who have engaged in sexual intercourse" and the birth rate among female program participants.<sup>18</sup> Fund recipients were required to report on these four measures annually.<sup>19</sup>

In late 2001, however, the Bush Administration dropped these measures and replaced them with a set of standards that does not include any real outcomes. Rather than tracking pregnancy or sexual activity, these measures assess attendance and the attitudes of teens at the end of the education program, including the "proportion of participants who indicate understanding of the social, psychological, and health gains to be realized by abstaining from premarital sexual activity."20

- [1] Proportion of program participants who successfully complete or remain enrolled in an abstinence-only education program.
- [2] Proportion of program participants who have engaged in sexual intercourse.
- [3] Proportion of program participants who report a reduction in risk behaviors, such as tobacco, alcohol, and drug use.
- [4] The rate of births to female program participants.  $^{19}$  Id.

  - <sup>20</sup> The new measures are:
- Proportion of program participants who successfully complete or remain enrolled in an abstinence-only education program.
- Proportion of adolescents who understand that abstinence from sexual activity is the only certain way [sic] to avoid out-of-wedlock pregnancy and sexually transmitted disease.
- Proportion of adolescents who indicate understanding of the social, psychological, and health gains to be realized by abstaining from premarital sexual activity.
- Proportion of participants who report they have refusal or assertiveness skills necessary to resist sexual urges and advances.
- Proportion of youth who commit to abstain from sexual activity until marriage.
- Proportion of participants who intend to avoid situations and risk, such ٠ as drug use and alcohol consumption, which make them more vulnerable to sexual advances and urges.

U.S. Dep't of Health and Human Servs., SPRANS Community-Based Abstinence Education Program, Pre-Application Workshop, Application Narrative (Dec. 2002), http://web.archive.org/web/20030324065935/http://www.mchb.hrsa.gov/programs/ad

<sup>&</sup>lt;sup>18</sup> Maternal and Child Health Federal Set-Aside Program; Community-Based Abstinence Education Project Grants, 65 Fed. Reg. 69564 (Nov. 17, 2000). The four national performance measures were:

Such standards are not scientifically valid. A 2001 review of scientific evidence concluded that "adolescents' sexual beliefs, attitudes, and even intentions are . . . weak proxies for actual behaviors."<sup>21</sup> According to a major HHS-funded report, two "hallmarks of good evaluation" in programs designed to reduce teen pregnancy rates are evaluations that "[m]easure behavior[s], not just attitudes and beliefs" and "[c]onduct long-term follow-up (of at least one year)."<sup>22</sup> However, the Bush Administration's standards for measuring the success of abstinence-only programs contain no reports or assessments of actual behavior or health outcomes and do not require any minimum follow-up period. The result is that the performance measures appear constructed to produce the appearance that scientific evidence supports abstinence-only programs when, in fact, the best evidence does not.

In April 2004, White House Science Adviser Dr. John Marburger responded that performance measures had not been altered to "obscure the lack of efficacy of such programs."<sup>23</sup> He stated that "[t]he program was never designed as a scientific study, and so even if the original performance measures had been kept, little or no scientifically usable data would be obtained. However, other independent evaluation efforts are underway that *are* intended to address questions of the effectiveness of abstinence only programs."<sup>24</sup>

Dr. Marburger did not address the fact that the point of outcome measurement is not rigorous scientific assessment, but rather basic oversight.<sup>25</sup> Subsequently, the Administration announced that the results of its planned independent evaluation of abstinence-only programs would be delayed for two years.<sup>26</sup>

olescents/abedguidetext.htm.

<sup>23</sup> JOHN H. MARBURGER, III, STATEMENT OF THE HONORABLE JOHN H. MARBURGER, III ON SCIENTIFIC INTEGRITY IN THE BUSH ADMINISTRATION: RESPONSE TO UNION OF CONCERNED SCIENTISTS DOCUMENT 8 (2004), http://ostp.gov/html/ucs/ ResponsetoCongressonUCSDocumentApril2004.pdf.

<sup>&</sup>lt;sup>21</sup> Gov't Reform Minority Office, Politics & Science: The Effectiveness of Abstinence-Only Education, http://democrats.reform.house.gov/features/politics\_and\_ science/example\_abstinence.htm (last visited Nov. 12, 2005) (quoting DOUGLAS KIRBY, NAT'L CAMPAIGN TO PREVENT TEEN PREGNANCY, EMERGING ANSWERS: RESEARCH FINDINGS ON PROGRAMS TO REDUCE TEEN PREGNANCY 78 (2001)).

<sup>&</sup>lt;sup>22</sup> Susan Philliber, *Building Evaluation into Your Work, in* GET ORGANIZED: A GUIDE TO PREVENTING TEEN PREGNANCY 135, 136 (1999), *available at* http://www. teenpregnancy.org/resources/reading/getorgan.asp (follow "Building Evaluation into Your Work" hyperlink).

<sup>&</sup>lt;sup>24</sup> Id.

<sup>&</sup>lt;sup>25</sup> *Id.* 

<sup>&</sup>lt;sup>26</sup> Bush Seeks Money for Abstinence Education, ABC NEWS, Nov. 25, 2004, http://abcnews.go.com/Politics/wireStory?id=283153.

When the evaluation was finally released in summer 2005, it contained only information about participant attitudes and intentions.<sup>27</sup> Information on behavior is to be released in a later report.

#### C. Programs That Work

Until recently, a CDC initiative called Programs That Work identified sex education programs that have been found to be effective in scientific studies and provided this information through its website to interested communities.<sup>28</sup> In 2002, all five Programs That Work related to HIV prevention provided comprehensive sex education to teenagers and none were "abstinence-only."29

In 2002, CDC ended this initiative and erased information about these proven sex education programs from its website.<sup>30</sup> In defending this action, White House Science Adviser Dr. John Marburger asserted that the website was "removed because the programs it listed were limited."<sup>31</sup> But he declined to provide any further explanation about why a successful program had been canceled.

#### II. ABORTION AND BREAST CANCER

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.<sup>32</sup> 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 a scientific consensus that it is not.

Until the summer of 2002, the National Cancer Institute (NCI) posted an analysis on its website concluding that the current body of

<sup>&</sup>lt;sup>27</sup> REBECCA A. MAYNARD ET AL., FIRST-YEAR IMPACTS OF FOUR TITLE V, SECTION 510 ABSTINENCE EDUCATION PROGRAMS (2005), available at http://aspe.hhs. gov/hsp/05/abstinence/report.pdf.

<sup>&</sup>lt;sup>28</sup> CDC, Adolescent and School Health, Programs That Work, http://web. archive.org/web/20010606142729/www.cdc.gov/nccdphp/dash/rtc/index.htm (last visited Feb. 6, 2006). <sup>29</sup> Id.

<sup>&</sup>lt;sup>30</sup> CDC, Adolescent and School Health, Programs That Work, http://web. archive.org/web/20021201081613/www.cdc.gov/nccdphp/dash/rtc (last visited Feb. 6, 2006) ("Thank you for your interest in Programs that Work (PTW). The CDC has discontinued PTW and is considering a new process that is more responsive to changing needs and concerns of state and local education and health agencies and community organizations.").

<sup>&</sup>lt;sup>31</sup> MARBURGER, supra note 23, at 8.

<sup>&</sup>lt;sup>32</sup> Scott Gold, Texas OKs Disputed Abortion Legislation, L.A. TIMES, May 22, 2003, at A1.

scientific evidence does not support the claim that abortions increase a woman's risk of breast cancer.<sup>33</sup> The analysis explained that after some uncertainty before the mid-1990s, this issue had been resolved by several well-designed studies, the largest of which, published in the *New England Journal of Medicine* in 1997,<sup>34</sup> found no link between abortion and breast cancer risk.

In November 2002, however, the Bush Administration removed this analysis and posted new information about abortion and breast cancer on the NCI web site. The new fact sheet stated:

[T]he possible relationship between abortion and breast cancer has been examined in over thirty published studies since 1957. Some studies have reported statistically significant evidence of an increased risk of breast cancer in women who have had abortions, while others have merely suggested an increased risk. Other studies have found no increase in risk among women who had an interrupted pregnancy.<sup>35</sup>

This new fact sheet erroneously suggested that whether abortion caused breast cancer was an open question with studies of equal weight supporting both sides. *The New York Times* called the NCI's new statement "an egregious distortion of the evidence."<sup>36</sup> According to the director of epidemiology research for the American Cancer Society, "[t]his issue has been resolved scientifically... This is essentially a political debate."<sup>37</sup>

After members of Congress protested the change,<sup>38</sup> NCI convened a three-day conference of experts on abortion and breast cancer. Participants reviewed all existing population-based, clinical, and animal data available, and concluded that "[i]nduced abortion is not associated with an increase in breast cancer risk," ranking this conclusion as

<sup>36</sup> Abortion and Breast Cancer, supra note 33, at A20.

<sup>37</sup> Stephanie Simon, Abortion Foes Seize on Reports of Cancer Link in Ad Campaign, L.A. TIMES, Mar. 24, 2002, at 26 (quoting Dr. Michael Thun).
 <sup>38</sup> Letter from Rep. Henry A. Waxman et al. to Tommy G. Thompson, Sec'y,

<sup>&</sup>lt;sup>33</sup> See Editorial, Abortion and Breast Cancer, N. Y. TIMES, Jan. 6, 2003, at A20.

<sup>&</sup>lt;sup>34</sup> Mads Melbye et al., *Induced Abortion and the Risk of Breast Cancer*, 336 New Eng. J. Med. 81, 84 (1997).

<sup>&</sup>lt;sup>35</sup> National Cancer Inst., Early Reproductive Events and Breast Cancer (Nov. 25, 2002), http://www.cancer.gov/cancer\_information/doc.aspx?viewid=8cf78b34-fc6a-4fc7-9a63-6b16590af277.

<sup>&</sup>lt;sup>38</sup> Letter from Rep. Henry A. Waxman et al. to Tommy G. Thompson, Sec'y, U.S. Dep't of Health & Human Servs. (Dec. 18, 2002), *available at* http://www. democrats.reform.house.gov/Documents/20040817143143-53989.pdf.

"[w]ell-established."<sup>39</sup> On March 21, 2003, the NCI web site was updated to reflect this conclusion.<sup>40</sup>

In response to concerns about these events, the President's science adviser, Dr. John Marburger, has denied that the Administration did anything wrong. After the Union of Concerned Scientists report also criticized the removal of the original fact sheet,<sup>41</sup> Dr. Marburger wrote that HHS removed the fact sheet "when it became clear" that "conflicting information" existed.<sup>42</sup> Dr. Marburger neglected to mention that the "conflicting information" was a set of inconclusive studies that were conducted years before the original fact sheet was posted, were specifically acknowledged and discussed by NCI in the original fact sheet, and were rejected because a subsequent, more rigorous study had confirmed that there is no causal link.

# **III. CONDOM EFFECTIVENESS**

Social conservatives have long opposed government efforts to support birth control. In recent years, some have claimed that condoms are not very effective in protecting against sexually transmitted diseases and have pressed federal agencies to adopt this viewpoint.<sup>43</sup> Under the Bush Administration, scientific evidence on condoms has been suppressed or distorted to reflect this conclusion.

A. Government Web Sites on Condoms

In October 2002, CDC replaced a comprehensive online fact sheet about condoms with one lacking crucial information on condom use and efficacy. The original information, entitled *Condoms and Their Use in Preventing HIV Infection and Other STDs,* included sections on the proper use of condoms, the effectiveness of different types of

<sup>&</sup>lt;sup>39</sup> National Cancer Inst., Summary Report: Early Reproductive Events and Breast Cancer (Mar. 4, 2003), http://www.cancer.gov/cancerinfo/ere-workshopreport.

<sup>&</sup>lt;sup>40</sup> National Cancer Inst., Abortion, Miscarriage, and Breast Cancer Risk (Mar. 21, 2003), http://www.cancer.gov/cancertopics/factsheet/Risk/abortion-miscar riage.

<sup>&</sup>lt;sup>41</sup> UNION OF CONCERNED SCIENTISTS, SCIENTIFIC INTEGRITY IN POLICYMAKING: AN INVESTIGATION INTO THE BUSH ADMINISTRATION'S MISUSE OF SCIENCE 12 (2004), *available at* http://www.ucsusa.org/assets/documents/scientific\_in tegrity/RSI\_final\_fullreport\_1.pdf.

<sup>&</sup>lt;sup>42</sup> MARBURGER, *supra* note 23, at 8.

<sup>&</sup>lt;sup>43</sup> See, e.g., Letter from John R. Diggs, Jr., Advisory Board Member, Family Research Council, to Hon. Michael Bilirakis, Chair, Health Subcomm., H. Energy & Commerce Comm. (Apr. 23, 2002), *available at* http://www.frc.org/get.cfm?i= PD02D3.

condoms, and the studies showing that condom education does not promote sexual activity.<sup>44</sup> It noted that "a World Health Organization (WHO) review . . . found no evidence that sex education leads to earlier or increased sexual activity in young people."<sup>45</sup>

A revised fact sheet entitled *Male Latex Condoms and Sexually Transmitted Diseases* was subsequently posted.<sup>46</sup> The new fact sheet lacks instruction on condom use and specific information on the effectiveness of different types of condoms.<sup>47</sup> It begins by emphasizing condom failure rates and the effectiveness of abstinence.<sup>48</sup> It also drops the discussion of the evidence that sex education does not lead to increased sexual activity.<sup>49</sup>

Like the CDC, the State Department's Agency for International Development (USAID) has censored its website to remove information on the effectiveness of condoms. As recently as February 2003, USAID's website included two detailed documents on condom effectiveness.<sup>50</sup> The document *The Effectiveness of Condoms in Preventing Sexually Transmitted Infections* stated, "Latex condoms are <u>highly</u> <u>effective</u> in prevention of HIV/AIDS"<sup>51</sup> and "[p]ublic and government support for latex condoms is essential for disease prevention."<sup>52</sup> The document *HIV/AIDS and Condoms* stated that condoms are "<u>highly</u>

<sup>45</sup> Id.

<sup>46</sup> CDC, Fact Sheet for Public Health Personnel: Male Latex Condoms and Sexually Transmitted Diseases, http://www.cdc.gov/nchstp/od/latex.htm (last visited Feb. 6, 2006).

<sup>47</sup> See id.

<sup>50</sup> USAID, Global Health: HIV/AIDS, The Effectiveness of Condoms in Preventing Sexually Transmitted Infections, http://web.archive.org/web/20021226022 539/http://www.usaid.gov/pop\_health/aids/TechAreas/condoms/codom\_effect.html (last visited Jan. 25, 2006) (this fact sheet was previously available on the USAID website at http://www.usaid.gov/pop\_health/aids/TechAreas/condoms/condom\_ef fect.html and was last visited on Jan. 28, 2003) *and* USAID, Global Health: USAID: HIV/AIDS and Condoms, http://web.archive.org/web/ 20030224192153/http://www. usaid.gov/pop\_health/aids/TechAreas/condoms/condomfactsheet.html (last visited Jan. 25, 2006) (this fact sheet was previously available on the USAID website at http://www.usaid.gov/pop\_health/aids/TechAreas/condoms/condomfactsheet.html and was last visited on Feb. 10, 2003).

<sup>51</sup> USAID, Global Health: HIV/AIDS, The Effectiveness of Condoms in Preventing Sexually Transmitted Infections, *supra* note 50 (emphasis added).

<sup>52</sup> Id.

<sup>&</sup>lt;sup>44</sup> CDC, Condoms and Their Use in Preventing HIV Infection and Other STDs (Sept. 1999), http://web.archive.org/web/20040401170231/http://www.house.gov/reform/min/pdfs/pdf\_inves/pdf\_admin\_hhs\_info\_condoms\_fact\_sheet\_orig.pdf (last visited Jan. 25, 2006) (this fact sheet was previously available on the CDC website at http://www.house.gov/reform/min/pdfs/pdf\_inves/pdf\_admin\_hhs\_info\_con doms\_fact\_sheet\_orig.pdf).

<sup>&</sup>lt;sup>48</sup> *Id*.

<sup>&</sup>lt;sup>49</sup> *Id.* 

<u>effective</u> for preventing HIV infection.<sup>53</sup> It called condom distribution a "cornerstone of USAID's HIV prevention strategy.<sup>54</sup>

USAID then substantially altered its website. The document *The Effectiveness of Condoms in Preventing Sexually Transmitted Infec-tions* was removed. A new version of the document *HIV/AIDS and Condoms* was made available.<sup>55</sup> This new version stated only that "condom use can reduce the risk of HIV infection" and "[w]hile no barrier method is 100 percent effective, correct and consistent use of latex condoms can reduce the risk of transmission of HIV and some other STIs."<sup>56</sup>

The President's science adviser, Dr. John Marburger, categorically denied that the Administration had removed truthful information about condoms from its websites for political reasons. After the Union of Concerned Scientists expressed concern about the changes,<sup>57</sup> Dr. Marburger responded that they were just part of the "routine" process of updating information.<sup>58</sup>

Dr. Marburger offered no supporting evidence for his assertion. He also did not dispute the allegation of a CDC staffer, cited by the Union of Concerned Scientists, who stated that the changes were demanded by Administration officials at HHS. Dr. Marburger then failed to respond to a congressional request for more information about his answer.<sup>59</sup>

At some date after November 2004, the document HIV/AIDS and Condoms was revised to read: "condom use can reduce <u>significantly</u> the risk of HIV infection."<sup>60</sup>

<sup>54</sup> Id.

- <sup>57</sup> UNION OF CONCERNED SCIENTISTS, *supra* note 41, at 11.
- <sup>58</sup> MARBURGER, *supra* note 23, at 8.

<sup>59</sup> See Letter from Rep. Henry A. Waxman, Ranking Minority Member, Comm. on Gov't Reform, to John H. Marburger, III, Dir., Office of Sci. & Tech. Policy, Executive Office of the President (Apr. 13, 2004), *available at* http://www.house.gov/reform/min/pdfs\_108\_2/pdfs\_inves/pdf\_science\_marburger\_ap ril\_13\_let.pdf, for a congressional request for additional information on Dr. Marburger's response to a report released by the Union of Concerned Scientists (UCS).

<sup>60</sup> USAID, USAID: HIV/STI Prevention and Condoms (May 2005), http:// www.usaid.gov/our\_work/global\_health/aids/TechAreas/prevention/condomfactsheet. html (emphasis added).

<sup>&</sup>lt;sup>53</sup> USAID, Global Health: USAID: HIV/AIDS and Condoms, *supra* note 50 (emphasis added).

<sup>&</sup>lt;sup>55</sup> USAID, USAID: HIV/AIDS and Condoms, http://web.archive.org/web/ 20041123051117/http://www.usaid.gov/our\_work/global\_health/aids/TechAreas/ prevention/condomfactsheet.html (last visited Jan. 30, 2006) (this fact sheet was previously available on the USAID website at http://www.usaid.gov/our\_work/ global health/aids/TechAreas/prevention/condomfactsheet.html).

<sup>&</sup>lt;sup>56</sup> USAID, USAID: HIV/AIDS and Condoms, supra note 55.

#### **B.** International Negotiations

The Bush Administration has also promoted unscientific positions on condom use internationally. In December 2002, the U.S. delegation at the Asian and Pacific Population Conference, sponsored by the United Nations, attempted to delete endorsement of "consistent condom use" as a means of preventing HIV infection.<sup>61</sup> U.S. delegates took this position on the grounds that recommending condom use would promote underage sex.<sup>62</sup> "Contrary to these U.S. claims, scientific studies have shown that comprehensive sex education does not encourage and can in fact delay the onset of sexual activity."<sup>63</sup> The U.S. opposition to "consistent condom use" was rejected, 32–1.<sup>64</sup>

#### C. The President's AIDS Initiative

The Administration has continued to misrepresent the effectiveness of condoms in preventing the transmission of HIV around the world. Randall Tobias, the White House's Global AIDS Coordinator, told the House Appropriations Committee in March 2004: "[W]hat we know from a number of studies that have been done increasingly in recent times is that we put lots, and lots and lots of money into condom distribution over the years, in environments where the disease is in a generalized population, with very disappointing results."<sup>65</sup> To support this claim, Tobias cited one study from the London School of Hygiene and Tropical Medicine.<sup>66</sup> Subsequently, the Dean of the London School wrote to Mr. Tobias and stated that the school had never

<sup>62</sup> *Id.* 

<sup>&</sup>lt;sup>61</sup> The Body: Complete HIV/AIDS Resource, U.S. Stance on Abortion and Condom Use Rejected at Population Conference (Dec. 18, 2002), http://www. thebody.com/cdc/news\_updates\_archive/dec18\_02/population\_conference.html (citing Vijay Joshi, U.S. Stance on Abortion and Condom Use Rejected at Population Conference, ASSOCIATED PRESS, Dec. 17, 2002).

<sup>&</sup>lt;sup>63</sup> Gov't Reform Minority Office, Politics & Science: Investigating the State of Science under the Bush Administration: Condom Effectiveness, http://democrats. reform.house.gov/features/politics\_and\_science/example\_condoms.htm (last visited Nov. 12, 2005) (quoting DOUGLAS KIRBY, NAT'L CAMPAIGN TO PREVENT TEEN PREGNANCY, EMERGING ANSWERS: RESEARCH FINDINGS ON PROGRAMS TO REDUCE TEEN PREGNANCY 88 (2001) ("a number of programs that discussed condoms or other forms of contraception and encouraged their use among sexually active youth also delayed or reduced the frequency of sexual intercourse")).

<sup>&</sup>lt;sup>64</sup> The Body: Complete HIV/AIDS Resource, supra note 61.

<sup>&</sup>lt;sup>65</sup> U.S. Representative Jim Kolbe (R-Az) Holds Hearing on International HIV/AIDS: Hearing Before the Subcomm. on Foreign Operations, Export Financing and Related Programs, Comm. on Appropriations, 108th Cong. (2004) (testimony of Randall Tobias, Global Aids Coordinator).

produced the supposed report and that its research in fact demonstrated the effectiveness of condoms.<sup>67</sup>

# **IV. HIV/AIDS**

The Administration has interfered with scientific research on the AIDS epidemic among gays and lesbians, backing down only after these efforts led to a major backlash in the scientific community. The Administration also appointed an unqualified individual with a history of bigoted comments to a leading AIDS advisory panel.

#### A. The NIH "Hit List"

At the National Institutes of Health (NIH), officials have told scientists who study HIV and AIDS to prepare for political interference with their research. In May 2003, The New York Times reported that HHS may be applying "unusual scrutiny" to grants that used key words such as "men who sleep with men," "gay," and "homosexual."68 Experts responded that such scrutiny undermines effective science to combat AIDS.<sup>69</sup> Dr. Alfred Sommer, Dean of the Bloomberg School of Public Health at Johns Hopkins University, commented, "If people feel intimidated and start clouding the language they use, then your mind starts to get cloudy and the science gets cloudy."<sup>70</sup>

In the fall of 2003, scientists reported hearing from NIH officials that certain grants related to HIV and sexuality would undergo extra review in response to congressional pressure.<sup>71</sup> It was then revealed that a right-wing group, the Traditional Values Coalition, had taken credit for compiling a "hit list" of more than 150 scientists and 250 grants.<sup>72</sup> NIH inquiries to scientists on the list created a climate of fear and intimidation. One researcher wrote, "[w]e are seriously concerned that extra-scientific criteria are being introduced into the NIH grant making process that until now has been based solely on the scientific merit and public health importance of proposed research."<sup>73</sup>

<sup>&</sup>lt;sup>67</sup> Editorial, Opposition to Condoms, N.Y. TIMES, May 18, 2004, at 22.

<sup>&</sup>lt;sup>68</sup> Erica Goode, Certain Words Can Trip up AIDS Grants, Scientists Say, N.Y. TIMES, Apr. 18, 2003, at A10.

<sup>&</sup>lt;sup>69</sup> *Id.* <sup>70</sup> Id.

<sup>&</sup>lt;sup>71</sup> Planned Parenthood Fed'n of Am., Inc., NIH Defends Studies of Human Sexuality Against Anti-Choice Criticism, http://www.plannedparenthood.org/pp2/ portal/webzine/eyeonextremism/eoe-040223-NIH.xml (last visited Nov. 12, 2005).

<sup>72</sup> Id.

More than thirty scientific organizations and universities issued statements of objection.<sup>74</sup> An editorial in the *New England Journal of Medicine* stated, "[t]he gem of worldwide biomedical research should not be rubbed in political dirt."<sup>75</sup> Dr. Alan Leshner, chief executive officer of the American Academy for the Advancement of Science, wrote in *Science*: "The recent assaults on science were . . . aimed at imposing ideology and religious doctrine on the awarding of individual research grants, intervening in and thereby subverting the scientific peer review system that has served both science and national needs so well."<sup>76</sup>

In the wake of this response from the scientific community, NIH Director Elias Zerhouni reported to Congress in February 2004 that an extra review of the grants had found them all to be justified.<sup>77</sup> HHS refused to comply with repeated requests for information about contacts between the agency and the Traditional Values Coalition.<sup>78</sup>

#### B. Presidential Advisory Council on HIV/AIDS

In January 2003, President Bush appointed marketing consultant Jerry Thacker to the Presidential Advisory Council on HIV/AIDS. Mr. Thacker has described homosexuality as a "deathstyle" and referred to AIDS as "the gay plague."<sup>79</sup> Mr. Thacker has also promoted "reparative therapy," a process by which homosexuals are reformed through religion.<sup>80</sup> According to the American Psychological Association,

<sup>&</sup>lt;sup>74</sup> Gov't Reform Minority Office, Politics & Science: Investigating the State of Science under the Bush Administration: Scientific Organization Defend Peer-Reviewed Research, http://democrats.reform.house.gov/features/politics\_and\_science/ nih\_support.htm (last visited Nov. 19, 2005).

 <sup>&</sup>lt;sup>75</sup> Jeffrey M. Drazen & Julie R. Ingelfinger, Editorial, Grants, Politics, and the NIH, 349 NEW ENG. J. MED. 2259, 2261 (2003).
 <sup>76</sup> Alan I. Leshner, Editorial, Don't Let Ideology Trump Science, 302

<sup>&</sup>lt;sup>10</sup> Alan I. Leshner, Editorial, *Don't Let Ideology Trump Science*, 302 SCIENCE<sub>2</sub>1479, 1479 (2003).

<sup>&</sup>lt;sup>77</sup> Letter from Elias A. Zerhouni, M.D., Dir., Nat'l Inst. of Health, to Rep. Henry Waxman, House of Representatives (Feb. 5, 2004) (on file with author).

<sup>&</sup>lt;sup>78</sup> Letter from Rep. Henry A. Waxman, Ranking Minority Member, Comm. on Gov't Reform, to Tommy G. Thompson, Sec'y of Health & Human Servs., U.S. Dep't of Health & Human Servs. (Oct. 28, 2003), available at http://www.democrats.reform.house.gov/Documents/20040901163959-12989.pdf; Letter from Rep. Henry A. Waxman, Ranking Minority Member, Comm. on Gov't Reform, to Tommy G. Thompson, Sec'y of Health & Human Servs., U.S. Dep't of Health & Human Servs. (Nov. 13, 2003), available at http://www.democrats.reform. house.gov/Documents/20040901164051-66997.pdf.

<sup>&</sup>lt;sup>79</sup> Ceci Connolly, *AIDS Panel Choice Wrote of a 'Gay Plague'*, WASH. POST, Jan. 23, 2003, at A1.

<sup>&</sup>lt;sup>80</sup> Gays Shocked at Bush Choice for AIDS Panel: Appointee Calls Homosexuality a "Deathstyle," S.F. CHRON., Jan. 23, 2003, at A1.

such therapy lacks an evidence base and attracts patients because of social pressure and ignorance.<sup>81</sup> Shortly after the appointment was made public, Mr. Thacker withdrew from the Council.<sup>82</sup>

# V. EMERGENCY CONTRACEPTION

The agenda of social conservatives includes limiting access to the morning-after pill. In this area, the Administration has again disregarded science to make appointments and important regulatory decisions that further this agenda.

#### A. The FDA Decision on Plan B

In May 2004, the Food and Drug Administration rejected the over-the-counter sale of the morning-after pill, or "Plan B." <sup>83</sup> This decision defied the overwhelming vote of the scientific advisory committee that had considered this application, the professional judgment of FDA scientists, and the consensus of scientific experts.

The scientific standards for approval of over-the-counter sales are straightforward. A company must demonstrate that consumers can use the drug safely and effectively without professional supervision.<sup>84</sup> Advisory review panels must consider evidence on safety, effective-ness, and labeling and make a recommendation to the Commissioner regarding the switch.<sup>85</sup>

In the case of Plan B, an overwhelming majority of the experts found that the standards for approval of OTC status have been met.<sup>86</sup> Twenty-three of twenty-seven members voted to recommend the switch.<sup>87</sup>

<sup>85</sup> 21 C.F.R. § 330.10 (2005).

<sup>86</sup> FDA, Ctr. for Drug Evaluation & Research, Nonprescription Drugs Advisory Comm. (NDAC) in Joint Session with the Advisory Comm. for Reproductive Health Drugs (ACRHD), Meeting (Dec. 16, 2003), http://www.fda.gov/ohrms/dockets/ac/03/transcripts/4015T1.DOC [hereinafter NDAC Meeting].

<sup>87</sup> The full set of advisory committee questions and votes were:
1. Does the actual use study demonstrate that consumers used the product as

recommended in the proposed labeling? 27 Yes; 1 No

<sup>&</sup>lt;sup>81</sup> Am. Psychological Ass'n, Resolution on Appropriate Therapeutic Responses to Sexual Orientation (Aug. 14, 1997), http://www.apa.org/pi/sexual.html.

<sup>&</sup>lt;sup>82</sup> Ceci Connolly, Choice for AIDS Panel Withdraws After Criticism, WASH. POST, Jan. 24, 2003, at A2.

<sup>&</sup>lt;sup>83</sup> Gardiner Harris, U.S. Rules Morning-After Pill Can't Be Sold Over the Counter, N.Y. TIMES, May 7, 2004, at A1.

<sup>&</sup>lt;sup>84</sup> FDA, Ctr. for Drug Evaluation & Research, Questions and Answers: Overthe-Counter Drug Products Public Hearing June 28 and 29, 2000, http://www.fda. gov/cder/meeting/otcqa-600.htm (last visited Feb. 8, 2006).

The advisory committee's decision was also supported by senior scientists at the FDA in charge of reviewing the product's application.<sup>88</sup> In late April, Dr. John K. Jenkins, the director of the Office of New Drugs at the FDA, wrote that "both divisions and offices responsible for review of this application have recommended approval."<sup>89</sup> He added that "the data from the studies submitted by the sponsor are sufficient and adequate on which to base a regulatory approval."<sup>90</sup>

Yet despite the clear view of the advisory committee and agency experts, the FDA did not approve over-the-counter-sale. In an unprecedented step, the acting director of the Center for Drug Evaluation and Research signed the agency's action, apparently because the senior scientists who had reviewed the application had refused to do so. In explaining this decision, the acting director said that there was not enough evidence to be sure that the product could be used safely by the youngest teenagers.<sup>91</sup> The FDA asked Barr Laboratories to provide additional data on this question.<sup>92</sup>

According to FDA staff and scientific experts, however, this reasoning is not credible. The logic of the argument—that young teenagers might forgo contraception in order to use the morning-after

27 Yes; 1 No

0 Yes; 28 No

4. Do the data demonstrate that Plan B is safe for use in the nonprescription setting?

28 Yes; 0 No

5. Are the plans for introduction of Plan B into the non-Rx setting adequate with respect to consumer access and safe use?

22 Yes; 5 No; 1 Abstain

6. Do you recommend Plan B be switched from Rx to non-Rx status?

23 Yes; 4 No

Id.

<sup>88</sup> See Rita Rubin, Plan B Decision Called Political, USA TODAY, May 10, 2004, at 7D.

<sup>89</sup> MINORITY STAFF, COMM. ON GOV'T REFORM, U.S. HOUSE OF REPRESENTATIVES, FACT SHEET: THE POLITICIZATION OF EMERGENCY CONTRACEPTION, PREPARED FOR REP. HENRY A. WAXMAN AND REP. LOUISE MCINTOSH SLAUGHTER 3 (2005), *available at* http://www.democrats.reform.house. gov/Documents/20051013155450-84328.pdf (quoting John K. Jenkins from his April 22, 2004 memorandum titled "Review of NDA for Rx to OTC Switch for Plan B").

<sup>90</sup> Id.

<sup>91</sup> See Marc Kaufman, FDA: Plan B Sales Rejected Against Advice, WASH. POST, May 8, 2004, at A2.

<sup>92</sup> Id.

<sup>2.</sup> Are the actual use study data generalizable to the overall population of potential non-Rx users of Plan B?

<sup>3.</sup> Based on the actual use study and literature review, is there evidence that non-Rx availability of Plan B leads to substitution of emergency contraceptive for the regular use of other methods of contraception?

pill—was rejected by the advisory committee. Moreover, over-thecounter availability of Plan B has been endorsed by both the American Academy of Pediatrics and the Society for Adolescent Medicine. They conclude in a joint letter that "[i]t is important to provide easily accessible and affordable emergency contraception for adolescents whose contraception fails or is not used during the most recent sexual encounter."<sup>93</sup>

The medical community recognized that the FDA's actions were based on politics, not science. As the *New England Journal of Medicine* editorialized, "[i]n this case there is no medical dispute."<sup>94</sup> Dr. David Grimes wrote in *Obstetrics and Gynecology* that "the agency caved in to political pressure."<sup>95</sup> The President of the American College of Obstetricians and Gynecologists, Dr. Vivian M. Dickerson, said that the FDA's "action is a tragedy for American women, and a dark stain on the reputation of an evidence-based agency like the FDA."<sup>96</sup>

The nonpartisan Government Accountability Office has determined that the FDA's treatment of the Plan B application involved multiple "unusual" departures from agency practice.<sup>97</sup> In August 2005, the FDA indefinitely delayed a decision on an amended Plan B application, claiming that new age restrictions—which the agency itself had suggested—present regulatory questions too "novel" to answer in the near future.<sup>98</sup>

#### B. Reproductive Health Drugs Advisory Committee

In 2002, HHS impeded its ability to obtain objective scientific advice in women's health by nominating Dr. W. David Hager, a conser-

<sup>&</sup>lt;sup>93</sup> Letter from Carden Johnston, President, Am. Acad. of Pediatrics, & Vaughn I. Rickert, President, Soc'y for Adolescent Med., to Food and Drug Admin. (Dec. 5, 2003) (on file with author).

<sup>&</sup>lt;sup>94</sup> Jeffrey M. Drazen et al., Editorial, *The FDA, Politics, and Plan B*, 350 New ENG. J. MED. 1561, 1562 (2004).

<sup>&</sup>lt;sup>95</sup> David A. Grimes, Emergency Contraception: Politics Trumps Science at the U.S. Food and Drug Administration, 104 OBSTETRICS & GYNECOLOGY 220, 220 (2004).

<sup>&</sup>lt;sup>96</sup> Kaufman, *supra* note 91, at A2.

<sup>&</sup>lt;sup>97</sup> U.S. Gov't Accountability Office, Food and Drug Administration: Decision Process to Deny Initial Application for Over-the-Counter Marketing of the Emergency Contraceptive Drug Plan B Was Unusual, GAO-06-109 (2005).

<sup>&</sup>lt;sup>98</sup> Letter from Lester M. Crawford, Commissioner, FDA, to Joseph A. Carrado, Senior Director, Regulatory Affairs, Duramed Research, Inc. (Aug. 26, 2005), *available at* http://www.fda.gov/cder/drug/infopage/planB/Plan\_B\_letter20050826. pdf.

vative religious activist, to chair the FDA's Reproductive Health Drugs Advisory Committee. The committee is charged with evaluating the safety and effectiveness of drugs for obstetrics, gynecology, and related specialties.<sup>99</sup> In the past, the FDA has chosen for this important position highly respected members of the scientific community with strong credentials in the field of reproductive health.

Dr. Hager's principal experience for the position appeared to be his lobbying for a renewed safety review of the approved drug RU-486, an abortifacient, even though no significant new evidence called its safety into question. The Lancet described his "track record" as a researcher as "sparse."<sup>100</sup> Dr. Hager's major publications are medical books imbued with religious themes, such as offering advice that women who suffer from premenstrual syndrome should pray and read the Bible.<sup>101</sup> Although ultimately not appointed chair, Dr. Hager was named a member of the committee.<sup>102</sup>

In the two years following his appointment, the Administration has continued to defend Dr. Hager. In April 2004, the President's science adviser, Dr. John Marburger, said any concern about the appointment was "offensive and wrong." He stated that Dr. Hager is "in fact well qualified," noting that his CV is "widely available."<sup>103</sup>

Dr. Marburger neither provided evidence establishing Dr. Hager's qualification for a leading advisory role on reproductive drugs nor addressed the concern that Dr. Hager's extreme views make him an unfit appointee.<sup>104</sup> Dr. Hager continued to serve on the Reproductive Health Drugs Advisory Committee until June 2005, taking part in the Committee's December 2003 deliberations on the morning-after pill.<sup>105</sup>

<sup>&</sup>lt;sup>99</sup> FDA, Committee Charter: Advisory Committee for Reproductive Health, http://www.fda.gov/cder/audiences/acspage/reproductivecharter1.htm (last updated Mar. 24, 2004).

<sup>&</sup>lt;sup>100</sup> Editorial, Keeping Scientific Advice Non-partisan, 360 LANCET 1525

<sup>(2002).</sup> <sup>101</sup> Karen Tumulty, Jesus and the FDA, TIME, Oct. 14, 2002, at 26 (citing a book written by Dr. Hager and his wife).

<sup>&</sup>lt;sup>102</sup> See FDA. Advisory Committee for Reproductive Health Drugs (Dec. 11, 2003), http://www.fda.gov/ohrms/dockets/ac/03/roster/4015R1 02 Committee-RE PRO.pdf.

MARBURGER, supra note 23, at 18.

<sup>&</sup>lt;sup>104</sup> Id. See also Letter from Rep. Henry A. Waxman, Ranking Minority Member, Comm. on Gov't Reform, to John H. Marburger, III, Dir., Office of Sci. & Tech. Policy, Executive Office of the President (Apr. 13, 2004) (on file with author) (asking Dr. Marburger for further evidence regarding Dr. Hager's fitness and qualification).

<sup>&</sup>lt;sup>105</sup> NDAC Meeting, supra note 86. Frank Lockwood, Gynecologist Expects to Be Off Panel: Nation Article Puts Hager on Defensive, LEXINGTON HERALD-LEADER (Kentucky), May 13, 2005, at A1.

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#### VI. STEM CELLS

The ramifications of ideological pressures related to abortion extend beyond reproductive and sexual health. According to the NIH, research on human embryonic stem cells offers great promise for those suffering from Parkinson's Disease, heart disease, Alzheimer's Disease, spinal cord injury, and diabetes.<sup>106</sup> Many social conservatives, however, see stem cell research as related to abortion.<sup>107</sup> In August 2001, President Bush banned federal funding for research on new stem cell lines.<sup>108</sup>

In pursuing this policy, the President and senior Administration officials have consistently provided misleading information to the public. When a senior cell biologist on the President's Council on Bioethics raised questions about the scientific accuracy of a draft report on stem cells, she was dropped from the Council.

#### A. Number of Cell Lines Available

In a nationwide address on August 9, 2001, President Bush argued that his decision to ban research on new stem cell lines would not adversely affect patients.<sup>109</sup> He claimed that "more than [sixty] genetically diverse stem cell lines already exist[ed]" and that research on these lines "could lead to breakthrough therapies and cures.<sup>110</sup> Senior White House officials, including the former head of domestic policy, subsequently stated that as many as seventy-eight cell lines could be available.<sup>111</sup>

These claims were untrue. Shortly after the President's announcement, stem cell researchers expressed skepticism about the number and quality of available cell lines.<sup>112</sup> This skepticism, while disregarded by the Administration, has proven to be justified. Some of the institutions that had stem cell lines did not have the resources to

<sup>&</sup>lt;sup>106</sup> NAT'L INST. OF HEALTH, STEM CELLS: SCIENTIFIC PROGRESS AND FUTURE RESEARCH DIRECTIONS 97-99 (2001).

<sup>&</sup>lt;sup>107</sup> See, e.g., Stem-Cell Research and the Catholic Church, http://www. americancatholic.org/News/StemCell (last visited Oct. 25, 2005).

<sup>&</sup>lt;sup>108</sup> Press Release, Pres. George W. Bush, Remarks by the President on Stem Cell Research (Aug. 9, 2001), *available at* http://www.whitehouse.gov/news/ re-leases/2001/08/20010809-2.html.

<sup>&</sup>lt;sup>109</sup> Id.

<sup>&</sup>lt;sup>110</sup> Id.

<sup>&</sup>lt;sup>111</sup> See Jay Lefkowitz, Editorial, *The Facts on Stem Cells*, WASH. POST, Oct. 30, 2003, at A23 for former head of domestic policy Jay Lefkowitz's view on the status of stem cells.

<sup>&</sup>lt;sup>112</sup> Anthony Shadid, Cell Lines Are Listed; Not All Can Be Used, BOSTON GLOBE, Aug. 28, 2001, at A1.

ship them safely to other labs; others had not developed the lines to the stage necessary for research.<sup>113</sup> Still other lines may have genetic problems.<sup>114</sup> In February 2004, Dr. James Battey, the head of stem cell research at NIH, wrote that the "best case scenario" today is that just twenty-three of these cell lines will ever be available to the research community.<sup>115</sup> The Administration never released Dr. Battey's assessment to the public.

Despite the public position of the President and his senior political advisers, a scientific consensus has emerged that research on additional lines is needed. Dr. George Daley wrote in the *New England Journal of Medicine* that 128 new cell lines have been created that are ineligible for federal funding, and as a result, "[m]any opportunities are being missed. . . .<sup>n116</sup> In a May 2004 letter to Congress, NIH Director Dr. Elias Zerhouni acknowledged that "from a purely scientific perspective more cell lines may well speed some areas' of research.<sup>n117</sup>

#### B. The President's Council on Bioethics

In February 2004, Dr. Elizabeth Blackburn, a distinguished cell biologist, and Dr. William May, a prominent medical ethicist, were dismissed from the President's Council on Bioethics. Both disagreed with the President's stem cell policy. Refusing to acknowledge an ideological motive in the dismissals, a White House spokesperson stated that "[w]e've decided to go ahead and appoint other individuals with different expertise and experience."<sup>118</sup>

In Dr. Blackburn's case, she was fired after she informed the Council Chair, Dr. Leon Kass, of problems with a January report by the Council entitled *Monitoring Stem Cell Research*. The report pro-

<sup>&</sup>lt;sup>113</sup> Raja Mishra, *Stem Cell Research Runs into Roadblocks*, BOSTON GLOBE, May 12, 2002, at A1 (discussing the logistical roadblocks to stem cell research).

<sup>&</sup>lt;sup>114</sup> Carl T. Hall, Scientists Worry How Policy Affects Them; Few Cell Lines, Limited Funds for Studies, S.F. CHRON., Aug. 10, 2001, at A1.

<sup>&</sup>lt;sup>115</sup> Justin Gillis & Rick Weiss, *NIH: Few Stem Cell Colonies Likely Available* for Research; Of Approved Lines, Many Are Failing, WASH. POST, March 3, 2004, at A3 (quoting James Battey, Adm'r NIH, in an unpublished NIH Report to Congress); See also Dan Vergano, New Stem Cell Lines Available, USA TODAY, March 4, 2004, at 2D (providing that the "best-case scenario" quote was in a February NIH summary).

<sup>&</sup>lt;sup>116</sup> George Q. Daley, *Missed Opportunities in Embryonic Stem-Cell Research*, 351 New Eng. J. Med. 627, 627 (2004).

<sup>&</sup>lt;sup>117</sup> Sheryl Gay Stolberg, *Advocates See Hope in Letter on Stem Cells*, N.Y. TIMES, May 16, 2004, at 24.

<sup>&</sup>lt;sup>118</sup> Rick Weiss, Bush Ejects Two From Bioethics Council, WASH. POST, Feb. 28, 2004, at A6.

vided a generally sunny assessment of the promise of research using adult stem cells, which some consider an alternative to research using embryonic stem cells for a variety of diseases.<sup>119</sup> Dr. Blackburn, a past President of the American Society for Cell Biology and a member of the National Academy of Sciences, found the report to be misleading.<sup>120</sup> She took the position that the report could benefit from additional discussion of the technical barriers to research on adult stem cells.<sup>121</sup> Dr. Blackburn subsequently wrote, "[t]he public is done a disservice when science is presented incompletely; myths are then perpetuated."<sup>122</sup>

#### CONCLUSION

Policy decisions about health, particularly reproductive health, are rarely uncontroversial. An Administration is justified in applying its values and priorities to those decisions—and its critics are justified in disagreeing. But the process is irrevocably harmed when the Administration abuses science and scientists to justify its choice. Modern science should be respected as a vital source of information for sound policy decisions, not as just another tool to be manipulated in the service of ideological and political ends.

<sup>121</sup> Id.

<sup>&</sup>lt;sup>119</sup> President's Council on Bioethics, Monitoring Stem Cell Research 10-11 (2004).

<sup>&</sup>lt;sup>120</sup> Letter from Rep. Henry A. Waxman, Ranking Minority Member, Comm. on Gov't Reform, & Rep. Louise M. Slaughter, Member of Cong., to Pres. George W. Bush (Mar. 2, 2004) (on file with author).

<sup>&</sup>lt;sup>122</sup> Elizabeth Blackburn & Janet Rowley, *Reason as Our Guide*, 2 PLoS BIOLOGY 420, 422 (2004), *available at* http://biology.plosjournals.org/archive/1545-7885/2/4/pdf/10.1371\_journal.pbio.0020116-S.pdf.