

**SCIENTIFIC INTEGRITY  
IN POLICY MAKING**

**Further Investigation  
of the Bush Administration's  
Misuse of Science**

**By  
The Union of Concerned Scientists**

**July 2004**

© 2004 Union of Concerned Scientists  
All rights reserved

The Union of Concerned Scientists is a nonprofit partnership of scientists and citizens combining rigorous scientific analysis, innovative policy development, and effective citizen advocacy to achieve practical environmental solutions.

More information about UCS and the full text of this report are available at [www.ucsusa.org](http://www.ucsusa.org).

Union of Concerned Scientists  
Two Brattle Square  
Cambridge, MA 02238-9105

Phone: 617-547-5552  
Fax: 617-864-9405  
Email: [ucs@ucsusa.org](mailto:ucs@ucsusa.org)

## **Contents**

<b>Introduction</b>	5
<b>Section I: Undermining the Integrity of Scientific Analysis at Federal Agencies</b>	7
Leveling a Mountain of Research on Mountaintop Removal Strip Mining	7
Science Overruled on Emergency Contraception	11
Deleting Scientific Advice on Endangered Salmon	15
Science Undermined at the U.S. Fish and Wildlife Service	18
Distorting Scientific Knowledge on Florida Panthers	18
Suppressing Analyses on Bull Trout Habitat	20
Misrepresenting Scientific Knowledge on Rare Swans	22
<b>Section II: Undermining the Integrity of Science Advisory Councils</b>	25
Political Litmus Tests	25
NIH Councils	25
<i>National Advisory Council for Human Genome Research</i>	26
<i>National Institute on Drug Abuse</i>	28
<i>Fogarty International Center Advisory Board</i>	29
President's Council on Bioethics	30
<b>Section III: Finding Solutions</b>	32

## **Acknowledgments**

Seth Shulman was the lead investigator and primary author of this report. Boyce Thorne-Miller provided research assistance. Suzanne Shaw edited this report with assistance from Heather Tuttle. UCS would like to thank the following individuals for their helpful comments: Michael Bean, Morrow Cater, Nancy Cole, Peter Frumhoff, Kurt Gottfried, Arielle Lutwick, Alden Meyer, Kirsten Moore, Joan Mulhern, Lexi Shultz, and James Trussell.

Major support for this report was provided by the Beldon Fund, The William and Flora Hewlett Foundation, The David and Lucile Packard Foundation, and The Streisand Foundation.

The findings and opinions expressed in this report do not necessarily reflect the opinions of the foundations that supported the work, nor the reviewers who provided comment on its content. Both the opinions and information contained herein are the sole responsibility of the Union of Concerned Scientists.

## Introduction

On February 18, 2004, 62 preeminent scientists including Nobel laureates, National Medal of Science recipients, former senior advisers to administrations of both parties, numerous members of the National Academy of Sciences, and other well-known researchers released a statement titled *Restoring Scientific Integrity in Policy Making*. In this statement, the scientists charged the Bush administration with widespread and unprecedented “manipulation of the process through which science enters into its decisions.” The scientists’ statement made brief reference to specific cases that illustrate this pattern of behavior. In conjunction with the statement, the Union of Concerned Scientists (UCS) released detailed documentation backing up the scientists’ charges in its report, *Scientific Integrity in Policy Making*.<sup>1</sup>

On April 2, the White House Office of Science and Technology Policy issued a statement by Director John H. Marburger III that dismissed the scientists’ concerns and attempted to debunk the specific charges. In a detailed analysis released April 19, UCS reviewed each charge again, and directly addressed the administration’s responses, concluding, “UCS stands by the findings and conclusions of our report.” The UCS analysis found that the White House response failed to offer substantive evidence to support its claims. Instead, the White House document was filled with largely irrelevant information and arguments unrelated to the scientists’ charges.

“The administration is dismissive of the concerns of leading scientists across the country,” said Kurt Gottfried, UCS board chair and emeritus professor of physics at Cornell University. “The absence of a candid and constructive response from the White House is troubling, as these issues—from childhood lead poisoning and mercury emissions to climate change and nuclear weapons—have serious consequences for public health, well-being, and national security.”

Since the release of the UCS report in February, the administration has continued to undermine the integrity of science in policy making seemingly unchecked. Many scientists have spoken out about their frustration with an administration that has undermined the quality of the science that informs policy making by suppressing, distorting, or manipulating the work done by scientists at federal agencies and on scientific advisory panels. For instance, Michael Kelly, a biologist who had served at the National Oceanic and Atmospheric Administration’s National Marine Fisheries Service for nine years, recently resigned his position and issued an indictment of Bush administration practices. As Kelly wrote, “I speak for many of my fellow biologists who are embarrassed and disgusted by the agency’s apparent misuse of science.”<sup>2</sup>

This document investigates several new incidents that have surfaced since the February 2004 UCS report. These new incidents have been corroborated through in-depth interviews and internal government documents, including some documents released through the Freedom of Information Act. The cases that follow include:

---

<sup>1</sup> Both documents are available online at <http://www.ucsusa.org/rsi>. An updated report with supplemental information was posted on the UCS website on March 31, 2004.

<sup>2</sup> Michael Kelly’s resignation letter is available online at <http://www.peer.org/california/kellyresignation.html>.

- egregious disregard of scientific study, across several agencies, regarding the environmental impacts of mountaintop removal mining;
- censorship and distortion of scientific analysis, and manipulation of the scientific process, across several issues and agencies in regard to the Endangered Species Act;
- distortion of scientific knowledge in decisions about emergency contraception;
- new evidence about the use of political litmus tests for scientific advisory panel appointees. These new revelations put to rest any arguments offered by the administration that the cases to date have been isolated incidents involving a few bad actors.

Concern in the scientific community has continued to grow. In the months since the original UCS report, more than 4,000 scientists have signed onto the scientists' statement. Signers include 48 Nobel laureates, 62 National Medal of Science recipients, and 127 members of the National Academy of Sciences. A number of these scientists have served in multiple administrations, both Democratic and Republican, underscoring the unprecedented nature of this administration's practices and demonstrating that the issues of scientific integrity transcend partisan politics.

The United States has an impressive history of investing in and reaping the benefits of scientific research. The actions by the Bush administration threaten to undermine the morale and compromise the integrity of scientists working for and advising America's world-class governmental research institutions and agencies. Not only does the public expect and deserve government to provide it with accurate information, the government has a responsibility to ensure that policy decisions are not based on intentionally or knowingly flawed science. To do so carries serious implications for the health, safety, and environment of all Americans.

Given the lack of serious consideration and response by the administration to concerns raised by scores of prominent scientists, UCS is committed to continuing to investigate and publicize cases—corroborated by witnesses and documentation—in which politics is allowed to stifle or distort the integrity of the scientific process in governmental policy making. UCS—working with scientists across many disciplines, other organizations, and elected officials—will also seek to develop and implement solutions that will protect government scientists from retribution when they bring scientific abuse to light, provide better scientific advice to Congress, strengthen the role of the Office of Science and Technology Policy, strengthen and ensure adherence to conflict of interest guidelines for federal advisory panels, and ensure full access to government scientific analysis that has not been legitimately classified for national security reasons.

## **Section I: Undermining the Integrity of Scientific Analysis at Federal Agencies**

Numerous cases of suppression and distortion of scientific analysis at federal agencies have already been documented in the press and in *Scientific Integrity in Policy Making*, a report released by the Union of Concerned Scientists in February 2004. As illustrated below, this continuing misconduct not only compromises the integrity of the scientists involved in these analyses, it undermines the mission and credibility of the agencies who are charged with protecting Americans' health, environment, and natural resources.

### **Leveling a Mountain of Research on Mountaintop Removal Strip Mining**

Internal government documents initially obtained under the Freedom of Information Act reveal that senior Bush administration officials at the U.S. Department of the Interior intentionally disregarded extensive scientific studies conducted by five separate federal and state agencies over four years in preparation of an environmental impact statement (EIS) on mountaintop removal mining in Appalachia. The agencies had agreed to conduct the EIS as part of a settlement of an environmental lawsuit by residents of coalfield communities.<sup>3</sup>

According to the National Environmental Policy Act (NEPA) of 1969, an explicit purpose of an EIS is to list alternative possibilities, with a specific technical assessment of their environmental implications, for practices being reviewed.<sup>4</sup> The stated purpose of the mountaintop removal EIS was even more specific; the federal agencies agreed that the EIS would recommend policies and procedures to “minimize, to the maximum extent practicable, the adverse environmental effects to waters of the United States and to fish and wildlife resources from mountaintop [removal] mining operations, and to environmental resources that could be affected by the size and location of fill material in valley fill sites.”<sup>5</sup>

However, government documents and UCS interviews confirm that J. Stephen Griles, deputy secretary of the Department of the Interior and a former lobbyist for the National Mining Association,<sup>6</sup> instructed agency scientists and staff to change the focus

---

<sup>3</sup> Documents relating to this lawsuit were released through a series of Freedom of Information Act requests by the nonprofit Trial Lawyers for Public Justice. Available online at <http://www.tlpj.org>.

<sup>4</sup> The National Environmental Policy Act of 1969, as amended (Pub. L. 91-190, 42 U.S.C. 4321-4347, January 1, 1970, as amended by Pub. L. 94-52, July 3, 1975, Pub. L. 94-83, August 9, 1975, and Pub. L. 97-258, § 4(b), Sept. 13, 1982). Available at <http://ceq.eh.doe.gov/nepa/regs/nepa/nepaeqia.htm>.

<sup>5</sup> Environmental Protection Agency (EPA) et al. 1999. “Intent To Prepare an Environmental Impact Statement To Consider Policies, Guidance, and Processes to Minimize the Environmental Impacts of Mountaintop Mining and Valley Fills in the Appalachian Coalfields.” *Federal Register* 64(24):5830. February 9.

<sup>6</sup> James Stephen Griles' biographical information is available at <http://www.doi.gov/bio/griles.html>.

of the EIS. A memo from Griles to the White House Council on Environmental Quality and other federal agencies involved in the EIS states that a new draft EIS should “focus on centralizing and streamlining coal-mining permitting.”<sup>7</sup>

Under Griles’ direction, agencies were directed to drop consideration of any options for more environmentally benign alternatives to current practices despite overwhelming scientific evidence of environmental destruction from the technique.<sup>8</sup>

During the past decade, the practice of mountaintop removal strip mining has been widely used to extract coal in central Appalachia. In the technique, huge machines known as “draglines”<sup>9</sup> remove mountain ridges to expose coal seams. In the process, coal companies dump millions of tons of waste rock and dirt into nearby hollows, burying mountain headwater streams under enormous “valley fills.” As part of a 1998 court settlement,<sup>10</sup> the federal government agreed to produce an EIS analyzing the effects of this practice and finding ways to limit the environmental damage it causes, especially to streams in the region.<sup>11</sup>

Scientists working for various federal agencies have documented a wide range of enormously destructive environmental impacts from this mining technique. More than 7 percent of Appalachian forests have been cut down and more than 1,200 miles of streams across the region have been buried or polluted between 1985 and 2001.<sup>12</sup> According to the federal government’s scientific analysis, mountaintop removal mining, if it continues unabated, will cause a projected loss of more than 1.4 million acres by the end of the next decade<sup>13</sup>—an area the size of Delaware—with a concomitant, severe impact on fish,

---

<sup>7</sup> Griles, J.S. 2001. Memo to James L. Connaughton, Chairman Council on Environmental Quality, Marcus Peacock, Associate Director Office of Management and Budget, et al. FOIA request by Trial Lawyers for Public Justice. October 5. Online at [http://www.tlpj.org/briefs/mtm\\_vf\\_deis\\_comments.pdf](http://www.tlpj.org/briefs/mtm_vf_deis_comments.pdf).

<sup>8</sup> See FOIA documents available online at <http://www.tlpj.org>. See also Shogren, E. 2004. “Federal Coal-Mining Policy Comes Under Fire: Fish and Wildlife Service says the administration ignored its protection plan,” *Los Angeles Times*. January 7. See also Ward, K. 2003. “Mountaintop removal damage proved: Bush proposes no concrete limits on new mining permits,” *Charleston Gazette*. May 30. Available online at <http://www.wvgazette.com/static/series/mining/>.

<sup>9</sup> Draglines are \$100 million machines that weigh about eight million pounds and are the size of a city block. The dragline’s bucket can take a bite of earth equal to the size of about 26 Ford Escorts in one scoop. See Loeb, P. 1997. “Shear Madness,” *U.S. News and World Report*, August 11.

<sup>10</sup> See U.S. District Court, West Virginia. 1998. *Bragg v. Robertson*. Settlement agreement. Case history available online at [http://www.tlpj.org/key\\_current\\_cases.htm](http://www.tlpj.org/key_current_cases.htm).

<sup>11</sup> *Ibid.*

<sup>12</sup> EPA. 2003. *Draft Programmatic Environmental Impact Statement (EIS) on Mountaintop Mining*. May. Available online at <http://www.epa.gov/region3/mtntop/index.htm>. See also Ward, K. 2003. “Mountaintop removal damage proved: Bush proposes no concrete limits on new mining permits,” *Charleston Gazette*. May 30.

<sup>13</sup> EPA. 2003. *Draft Programmatic Environmental Impact Statement (EIS) on Mountaintop Mining*. May. Available online at <http://www.epa.gov/region3/mtntop/index.htm>.



wildlife, and bird species, not to mention a devastating effect on many neighboring communities.<sup>14</sup>

While the EIS produced by the Bush administration included some 5,000 pages of analysis documenting this destruction, there are instances where administration officials sought to soften the overwhelmingly negative findings. For example, a U.S. Fish and Wildlife Service (FWS) scientist says the Bush administration team ordered technical language rating the environmental impacts as “significant” or “severe” be stripped away in the editing process.<sup>15</sup> In addition, a Bush administration “steering committee” of the interagency EIS process initially removed an economic analysis prepared by an independent contractor that showed that limits on the size of individual valley fills would not have negative economic impacts on the region’s electric costs. The steering committee discredited the analysis for what it called a “fatally flawed” methodology.<sup>16</sup> A revised analysis, which took into account the comments and concerns of dozens of coal industry officials, was included in the draft EIS. However, this analysis still found that the economic costs of limiting the size of valley fills would have a negligible effect on the price of coal.<sup>17</sup>

While administration officials included extensive scientific documentation of the negative consequences of the mining practice in the EIS, they violated a central tenet of an EIS<sup>18</sup> by offering no proposed alternatives to mitigate the worst environmental consequences of mountaintop removal mining.

“We were flabbergasted and outraged,” says one high-ranking staff scientist at the FWS who had worked extensively on the preparation of the technical analysis for the EIS.<sup>19</sup> This official, whose name is withheld on request, explains that, in response to Griles’ directive, the Bush administration steering committee called a meeting in October 2001 at which agency scientists and administrators were told that the draft EIS “was going to be taken in a different direction.”<sup>20</sup>

Cindy Tibbot, an FWS biologist involved in the EIS process, was one of many agency scientists who expressed outrage about Griles’ directive, stating in an internal memo: “It’s hard to stay quiet about this when I really believe we’re doing the public and

---

<sup>14</sup> Ibid.

<sup>15</sup> Author interview with U.S. Fish and Wildlife Service scientist, name withheld on request, May 2004.

<sup>16</sup> Ibid.

<sup>17</sup> U.S. Environmental Protection Agency. 2003. *Draft Programmatic Environmental Impact Statement (EIS) on Mountaintop Mining*. May. Available online at <http://www.epa.gov/region3/mtntop/eis.htm>.

<sup>18</sup> The analysis of alternatives is “the heart of the environmental impact statement”; this analysis, based in large part upon the environmental consequences section of the EIS, should “[d]evote substantial treatment to each alternative considered in detail including the proposed action so that reviewers may evaluate their comparative merits.” See NEPA implementing regulations at 40 CFR 1502.14, available online at <http://ceq.eh.doe.gov/nepa/regs/ceq/1502.htm>.

<sup>19</sup> Author interview with U.S. Fish and Wildlife Service scientist, name withheld on request, May 2004.

<sup>20</sup> Ibid.

the heart of the Clean Water Act a great disservice.”<sup>21</sup> As Tibbot put it, the only alternatives offered in Griles’ proposed EIS would be “alternative locations to house the rubber stamp that issues the [mining] permits.”<sup>22</sup>

Tibbot was not alone. An internal memo from FWS staff reviewing the draft EIS prior to its release assessed the situation this way:

The EIS technical studies carried out by the agencies—at considerable taxpayer expense—have documented adverse impacts to aquatic and terrestrial ecosystems, yet the proposed alternatives presented offer no substantive means of addressing these impacts. The alternatives and actions, as currently written, belie four years of work and the accumulated evidence of environmental harms, and would substitute permit process tinkering for meaningful and measurable change. Publication of a draft EIS with this approach, especially when the public has seen earlier drafts, will further damage the credibility of the agencies involved.<sup>23</sup>

Recently obtained documents reveal that staff at other agencies involved in the EIS process were equally concerned with the administration’s approach to the EIS. Ray George, an Environmental Protection Agency (EPA) official from West Virginia’s Region 3, expressed concern that his agency’s “science findings are not reflected in [the draft EIS’s] conclusions/recommendations.”<sup>24</sup> Another EPA official, John Forren, underscored the severity of the problem. “It’s one thing,” Forren wrote, “to include such alternatives in the [draft] EIS and not choose one as a preferred alternative or not choose one as the selected action in the Record of Decision.” As Forren continued, however, it is quite another thing to offer no meaningful alternatives at all. Such a tactic, he warned, would “give the appearance we’re obscuring and de-emphasizing the [alternatives] that address directly environmental impacts,” leaving the entire EIS process open to legal challenge and public outcry.<sup>25</sup>

“In this case, the administration eliminated all environmental protective alternatives from consideration,” says Jim Hecker, environmental enforcement director at Trial Lawyers for Public Justice, who filed the Freedom of Information Act request for the internal documents in this case. As Hecker puts it, “The simple fact is, that is scientifically and intellectually dishonest.”<sup>26</sup>

The lack of scientific integrity in the preparation of the mountaintop removal mining EIS played out against the backdrop of an administration with close financial ties to the energy industry as well as an apparent conflict of interest presented by Griles’

---

<sup>21</sup> Tibbot, C., U.S. Fish and Wildlife Service. 2002. Email correspondence circulated internally. October 30. Part of FOIA request documents available online at <http://www.tlpj.org>.

<sup>22</sup> Ibid.

<sup>23</sup> Densmore, D., Supervisor, Pennsylvania Field Office, U.S. Fish and Wildlife Service. 2002. “FWS Comments on 9/20/02 Draft of Chapter IV (Alternatives).” Comments circulated internally. September 30. Part of FOIA request documents available online at <http://www.tlpj.org>.

<sup>24</sup> George, R., EPA Region 3. 2002. Email correspondence. December 30. Available online at <http://www.tlpj.org>.

<sup>25</sup> Forren, J., EPA Region 3. Memo. October 4, 2002. Available online at <http://www.tlpj.org>.

<sup>26</sup> Author interview with Jim Hecker, May 2004.

close involvement in the EIS process. Aware of Griles' longstanding association with the mining industry, the Senate requested that he sign a "statement of disqualification" on August 1, 2001, in which he made a commitment to avoid issues affecting his former clients. Documents obtained under the Freedom of Information Act show that Griles met no fewer than 12 times with top Bush administration officials and coal industry representatives on the EIS and mountaintop removal mining matters between September and December 2001, precisely the time the team issued its order to change direction on the EIS process.<sup>27</sup>

During the EIS official comment period, representatives from 50 environmental groups across the country wrote a letter charging that the draft EIS fails to comply with the NEPA, stating: "We find the draft EIS' failure to provide an alternative proposal that would provide better regulation of mountaintop removal mining to protect the environment unacceptable and inappropriate."<sup>28</sup> Former Maryland State Senator Gerald Winegrad, vice president of the American Bird Conservancy and co-author of the letter, contends the political process cannot function without an honest scientific assessment of the problem. "But in this case," he says, "the EIS process has been usurped and its scientific underpinnings destroyed."<sup>29</sup>

## **Science Overruled on Emergency Contraception**

An official at the Food and Drug Administration (FDA) overruled the advice of the agency's staff and two independent scientific advisory panels when he decided recently to deny women over-the-counter access to the emergency contraceptive levonorgestrel (sold under the brand name "Plan B"). Numerous FDA officials and medical advisers to FDA involved in and familiar with the approval process call the move an almost unprecedented repudiation of government scientific expertise. By law, the FDA is required to approve drugs that are found to be safe and effective.

In the case, Steven Galson, acting director of the FDA's Center for Drug Evaluation and Research, acknowledged to reporters recently that he overturned the recommendations of his own staff and two FDA advisory panels in declaring the drug "not approvable" for nonprescription status.<sup>30</sup> A joint meeting of two independent FDA scientific advisory committees voted 23 to 4 in December 2003 to recommend the emergency contraceptive as an over-the-counter drug. The panel also voted unanimously that the drug could be safely sold over the counter.<sup>31</sup>

---

<sup>27</sup> See list prepared by the Ohio Valley Environmental Coalition, available online at [http://www.ohvec.org/action\\_alerts/2002/09\\_28/GrilesMTRMeetings.pdf](http://www.ohvec.org/action_alerts/2002/09_28/GrilesMTRMeetings.pdf).

<sup>28</sup> Winegrad, G.W., Vice President for Policy, American Bird Conservancy, and 50 representatives from environmental organizations. 2004. Letters to President Bush and John Forren, EPA. January 2. Available online at [http://www.ohvec.org/issues/mountaintop\\_removal/articles/EIS\\_am\\_bird.pdf](http://www.ohvec.org/issues/mountaintop_removal/articles/EIS_am_bird.pdf).

<sup>29</sup> Author interview with Gerald Winegrad, March 2004.

<sup>30</sup> Galson, S. 2004. Comments presented at a U.S. Food and Drug Administration (FDA) press conference. May 7.

<sup>31</sup> FDA. 2003. "Transcript of the December 16, 2003 meeting of the FDA Nonprescription Drugs Advisory Committee in Joint Session with the Advisory Committee for Reproductive Health

Plan B, the drug in question, consists of two high-dose contraceptive pills that either interfere with ovulation or fertilization, or prevent implantation of a fertilized egg. Emergency contraception can be taken up to 72 hours after unprotected sexual intercourse to prevent pregnancy, but is more effective the sooner it is taken. Manufactured by New York-based Barr Pharmaceuticals, Inc., Plan B was approved as a prescription drug in 1999; another emergency contraceptive, Preven, was approved in 1998. Since then, millions of women in the United States have used such drugs to prevent pregnancy. Public health officials and researchers around the world widely agree that Plan B is a safe and effective means to prevent an unplanned pregnancy and to reduce the frequency of abortions. The drug is available without a prescription in 33 countries around the world. Its switch to nonprescription status in the United States was also endorsed by some 70 scientific organizations, including the American Medical Association, the American College of Obstetricians and Gynecologists, and the American Academy of Pediatrics.<sup>32</sup>

In the “not approvable” letter to Barr Pharmaceuticals, Galson notes that only 29 of the 585 women in the data submitted by the company about Plan B were 14 to 16 years of age and none was under 14 years of age. While Galson does not cite any particular safety concern for this age group, he writes “we have concluded that you have not provided adequate data to support a conclusion that Plan B can be used safely by young adolescent women for emergency contraception without the professional supervision of a practitioner licensed by law to administer the drug.”<sup>33</sup>

James Trussell, director of the Office of Population Research at Princeton University and a member of one of the FDA advisory committees that recommended the drug’s approval for over-the-counter sale, says that after hearing many hours of testimony and reviewing thousands of pages of medical literature, “[O]ur committee had absolutely no concern about the use of this drug by young girls.” Advisory committee member Dr. Julie Johnson, a professor of pharmacy in Gainesville, Florida, touted Plan B to be the safest product the committee had reviewed in several years.<sup>34</sup>

Advisory committee members also underscored the importance of making recommendations based on a risk-benefit analysis, particularly with regard to young people. Pediatrician Dr. Leslie Clapp from Buffalo, New York, spoke about her own clinical practice and acknowledged that, while abstinence is the best option for teens, “[I]f you are a sexually active teen...or eleven year old, it’s certainly a bad situation...I

---

Drugs.” December 16. Available online at

<http://www.fda.gov/ohrms/dockets/ac/03/transcripts/4015T1.DOC>.

<sup>32</sup> Barr Pharmaceuticals, Inc. 2004. “Barr Receives Not Approvable Letter for Over-the-Counter Emergency Contraceptive.” Press release. May 6. Available online at <http://www.barrlabs.com/pages/nprpr.html>.

<sup>33</sup> Galson, S., acting director of the FDA Center for Drug Evaluation. 2004. Letter to Barr Pharmaceuticals, Inc. NDA 21-045/S-011. May 6. Available online at [http://www.fda.gov/cder/drug/infopage/planB/planB\\_NALetter.pdf](http://www.fda.gov/cder/drug/infopage/planB/planB_NALetter.pdf).

<sup>34</sup> FDA. 2003. “Transcript of the December 16, 2003 meeting of the FDA Nonprescription Drugs Advisory Committee in Joint Session with the Advisory Committee for Reproductive Health Drugs.” December 16. Available online at <http://www.fda.gov/ohrms/dockets/ac/03/transcripts/4015T1.DOC>.

think their families and they would have far preferred this option than pregnancy, and it would have been safer.”<sup>35</sup> Dr. Abby Berenson, a gynecologist from Galveston, Texas, who treats adolescents, echoed the sentiment, arguing further that, “Barriers to use,” such as a prescription requirement for Plan B, “will ultimately...result in unintended pregnancies,”<sup>36</sup> which pose disproportionate health risks to adolescent women, including premature labor, anemia, and high blood pressure.<sup>37</sup>

Medical professionals, including several other prominent members of the advisory committees, take issue with Galson’s claim of lack of data on young women. The American Academy of Pediatrics and the Society of Adolescent Medicine noted in a May 27, 2004 statement that approximately one-fifth of the participants in the Barr trials were between the ages of 14 and 16, which represents ages below or consistent with the average age of first intercourse.<sup>38</sup> In a recent editorial letter to *The New England Journal of Medicine*, three physicians noted that the advisory panels considered data that showed adolescents understood 60 percent to 97 percent of the key communication objectives of the Plan B label without help from a health care professional. These results are comparable to those for the group as a whole and well within the standards for the approval of other over-the-counter drugs.<sup>39</sup> As Dr. Trussell puts it, “The objection the FDA is offering in denying the switch to a nonprescription status is nothing more than a made-up reason intended to sound plausible. From a scientific standpoint, it is complete and utter nonsense.”<sup>40</sup>

Dr. Trussell says that he has no doubt that politics trumped science in the FDA’s bureaucratic process in this case.<sup>41</sup> In an internal FDA memo obtained by the Associated Press, Galson apparently tried to quell similar questions from his own staff about the role political considerations may have played in the decision, noting that “Some staff have expressed the concern that this decision is based on non-medical implications of teen sexual behavior, or judgments about the propriety of this activity.”<sup>42</sup> Galson responded by claiming that politics did not influence his decision. In a press conference following his decision, Galson denied meeting personally with White House officials in the decision-

---

<sup>35</sup> Ibid.

<sup>36</sup> Ibid.

<sup>37</sup> March of Dimes. 2002. “Facts You Should Know About Teenage Pregnancy.” March. Available online at [www.marchofdimes.com/professionals/681\\_1159.asp](http://www.marchofdimes.com/professionals/681_1159.asp).

<sup>38</sup> American Academy of Pediatrics. 2004. “Plan B Should Be Over-the-Counter for Adolescents.” Press release. May 27. Available at [http://www.aap.org/advocacy/washing/Plan\\_B.htm](http://www.aap.org/advocacy/washing/Plan_B.htm).

<sup>39</sup> Drazen, J.M. et al. 2004. “The FDA, Politics, and Plan B,” *The New England Journal of Medicine* 350(23):2413-2414. Correspondence. June 3. Excerpt available online at <http://content.nejm.org/cgi/content/short/350/23/2413>.

<sup>40</sup> Author interview with James Trussell, May 2004.

<sup>41</sup> Ibid.

<sup>42</sup> As quoted in Neergaard, L. 2004. “FDA rejects OTC morning-after pill sales,” Associated Press. May 6.

making process and claimed to have “no knowledge” that any meetings between FDA and White House officials on the Plan B decision took place.<sup>43</sup>

Nonetheless, Dr. Galson broke with agency protocol by overruling FDA staff scientists who had concluded that this drug met FDA criteria for nonprescription status and overwhelmingly recommended the switch. In overruling his staff and the advisory committee, Galson offered no substantial new evidence, and took the unusual step of writing the official response to the drug company himself.<sup>44</sup>

FDA insiders also note that after the hearings on the matter late last year, conservative groups had mounted a political campaign to try to block the drug’s approval. Conservative lawmakers began efforts to undermine the application in December 2003 when members of the House of Representatives sent a letter to the FDA Commissioner decrying purported risks of nonprescription Plan B to teens. The advisory committees addressed these claims and implicitly rejected many—if not all—in their evaluation of the drug’s risk-benefit profile. After the overwhelmingly positive recommendation by the advisory committees, 49 members of Congress wrote to President Bush urging White House involvement, a move intended to supersede the FDA’s authority on this matter.<sup>45</sup> Shortly thereafter, on February 13, FDA officials notified Barr Pharmaceuticals that the agency would extend by 90 days its deadline for considering the switch to over-the-counter status.<sup>46</sup>

At this point in the process, three prominent doctors, including Alastair Wood, a professor of medicine and pharmacology at Vanderbilt University who also serves as an FDA advisory panel member, published an article in *The New England Journal of Medicine*, stating that, “FDA’s decision-making process is being influenced by political considerations.” As the authors noted, such political considerations have normally been kept out of the decision-making process at the FDA. Prior to this case, they write, approval has always been “based on scientific evidence from well-designed clinical trials with adequate power to establish efficacy and rule out toxicity at some reasonable level of confidence,” adding that the agency has an obligation under U.S. law “to approve drugs for sale once their efficacy and safety have been demonstrated.” In this case, they write, “there is no medical dispute” on these issues.<sup>47</sup>

Echoing these findings, Dr. Paul Blumenthal, a respected obstetrician-gynecologist at The Johns Hopkins Hospital in Baltimore, says Plan B meets all the scientific criteria for an over-the-counter drug: it is not toxic, there is no potential for

---

<sup>43</sup> Galson, S. 2004. Comments presented at a U.S. Food and Drug Administration (FDA) press conference. May 7.

<sup>44</sup> See Kaufman, M. 2004. “FDA rejects over-the-counter ‘Plan B’,” *The Washington Post*. May 7.

<sup>45</sup> See Kaufman, M. “Debate Intensifies Over ‘Morning After’ Pill,” *The Washington Post*. February 13.

<sup>46</sup> See Barr Laboratories, Inc. 2004. “Barr Says FDA Extends Plan B Emergency Contraceptive PDUFA Date.” Press release. February 13. Available online at <http://www.barrlabs.com/pages/nprpr.html>.

<sup>47</sup> Drazen, J.M. et al. 2004. “The FDA, Politics, and Plan B,” *New England Journal of Medicine* 350(15):1561-1562. Editorial. April 8. Excerpt available online at <http://content.nejm.org/cgi/content/short/350/15/1561>.

addiction or abuse, and there is no need for medical screening. Commenting on Galson's "not approvable" decision, Blumenthal says, "What the FDA has just done is deny access to an important pregnancy preventive agent to millions of women." As he puts it: "This is nothing but politics trumping science."<sup>48</sup>

Former FDA officials told *The New York Times* that they could not remember a single instance when someone in Dr. Galson's position had overruled both an advisory committee and staff recommendations. Dr. Robert R. Fenichel, who left the agency in 2000 after 12 years, for instance, called the action "simply unheard of."<sup>49</sup>

As FDA advisory panel member Trussell charges, "Unfortunately, for the first time in history, the FDA is not acting as an independent agency but rather as a tool of the White House." Trussell adds, it is "a very sad day when politicians start making medical decisions."<sup>50</sup>

## Deleting Scientific Advice on Endangered Salmon

Six leading ecologists who were appointed to a scientific advisory panel by the National Oceanic and Atmospheric Administration's (NOAA) National Marine Fisheries Service (NMFS) claim that they were asked to remove science-based recommendations from an official report.<sup>51</sup> Further, scientists contend that the Bush administration's new policy on endangered fish stocks put forth by the NMFS distorts the scientific evidence regarding the role of hatchery fish in maintaining viable populations of salmon in the Northwest. The new policy refers to old or discredited information in contradiction to current scientific information provided by the scientific advisory panel.

According to the advisory panel's lead scientist, Robert Paine, a world-renowned ecologist at the University of Washington,<sup>52</sup> the panel's science-based recommendations were suppressed by the NMFS. As Paine explains, "The members of the panel were told to either strip out our recommendations or see our report end up in a drawer."<sup>53</sup>

The controversy began in 2001 with a federal district court ruling about whether coastal Coho salmon in Oregon should be listed under the Endangered Species Act (ESA).<sup>54</sup> Prior to this ruling, the NMFS had determined protection policies based on the numbers of wild fish in salmon and steelhead trout populations, without counting

---

<sup>48</sup> As quoted in Graham, J. 2004. "'Morning after' pill restricted by FDA," *Chicago Tribune*. May 7.

<sup>49</sup> See Harris, G. "Morning-after-pill ruling defies norm," *The New York Times*. May 8.

<sup>50</sup> Author interview with James Trussell, May 2004. See also Kemper, V. 2004. "FDA: Doctor must still OK 'morning-after' pill," *Los Angeles Times*. May 7.

<sup>51</sup> See Weiss, K. 2004. "Action to Protect Salmon Urged: Scientists say their advice was dropped from a report to the U.S. fisheries service," *Los Angeles Times*. March 26.

<sup>52</sup> The panel also included Ransom Myers of Dalhousie University; Russell Lande of the University of California at San Diego; William Murdock of the University of California at Santa Barbara; Frances James of Florida State University; and Simon Levin of Princeton University (for profiles, see "members of the panel" online at [www.nwfsc.noaa.gov/trt/rsrp.htm](http://www.nwfsc.noaa.gov/trt/rsrp.htm)).

<sup>53</sup> Author interview with Robert Paine, April 2004.

<sup>54</sup> National Oceanic and Atmospheric Administration (NOAA). Alesha Valley Decision. Fact sheet. Available online at [http://www.nwr.noaa.gov/occd/110901\\_2.pdf](http://www.nwr.noaa.gov/occd/110901_2.pdf).

hatchery-bred fish.<sup>55</sup> The NMFS made this distinction even though they had included hatchery fish with wild fish in their designation of distinct salmon populations (described as evolutionarily significant units, or ESUs).

However, the court ruled that, under the Endangered Species Act, an ESU is a single unit that cannot be divided. As such, the court held that once NMFS made a decision to count wild and hatchery fish within a single ESU, it must count all fish within an ESU when determining protection policies. The court *did not* rule that hatchery fish should be included within an ESU with wild fish.

The Salmon Recovery Science Review Panel, with membership approved by the National Research Council, decided to study the situation. The panel found that there was a strong scientific basis for distinguishing between wild salmon and hatchery-raised fish of similar genetic stock. Providing extensive scientific documentation, the panel recommended that ESUs be specifically defined to include only wild, naturally spawning fish. This central recommendation was deleted from the final report by the NMFS on the grounds that it was policy, not science.

Panel member Ransom Myers, a marine biologist at Dalhousie University in Halifax, Nova Scotia, explains that the panel reviewed what he calls “a massive amount of research that shows that domestication occurs rapidly in hatchery fish. Within a few generations, these fish quickly evolve into something different, and lose their ability to survive in the wild.”<sup>56</sup> The protected status of some wild salmon and steelhead trout populations has been challenged by developers, farmers, ranchers, timber interests, and private property advocates who want to end government restrictions to protect wild fish habitat.

According to the NMFS, the review panel’s purpose is “to guide the scientific and technical aspects of recovery planning for listed salmon and steelhead species throughout the West Coast.” In particular, the panel was instructed to “ensure that well accepted and consistent ecological and evolutionary principles form the basis for all [salmon and steelhead trout] recovery efforts.”<sup>57</sup>

The development of a new Bush administration policy on hatchery fish was overseen by Mark Rutzick, who early in 2003 was appointed by President Bush as special adviser to the NOAA General Counsel. Previously, Rutzick served as a lawyer for the timber industry and was a strong opponent of fish and wildlife protections that logging companies viewed as overly restrictive. Rutzick first proposed the strategy of including hatchery fish in population counts for endangered salmon while he worked on behalf of timber interests.<sup>58</sup>

---

<sup>55</sup> Myers, R.A. et al. 2004. “Hatcheries and endangered salmon,” *Science* 303:1980. March 26.

<sup>56</sup> Author interview with Ransom Myers, April 2004.

<sup>57</sup> See National Marine Fisheries Service. 2003. “Salmon Recovery Science Review Panel.” Report for meeting held July 21–23 in Seattle, WA. Available online at [http://www.nwfsc.noaa.gov/trt/rsrp\\_docs/Hatchery\\_Experiments\\_Final\\_Report.pdf](http://www.nwfsc.noaa.gov/trt/rsrp_docs/Hatchery_Experiments_Final_Report.pdf).

<sup>58</sup> Egan, T. 2004. “Shift on Salmon Reignites Fight on Species Law,” *The New York Times*, p. A1. May 9.



This apparent conflict of interest was brought to light with a great deal of media attention in April and May 2004.<sup>59</sup> At that time, a copy of the draft policy leaked to *The Washington Post* suggested that all 26 listed populations of Northwest salmon and steelhead trout would be susceptible to delisting under the ESA once hatchery fish were included in their population assessments.<sup>60</sup> The negative media coverage and public outcry subsequently led NOAA Administrator Conrad Lautenbacher to send a letter to senators and representatives from the northwest region, assuring them that the new hatchery fish policy would not lead to delisting and would maintain protections for at least 25 of the 26 listed salmon and steelhead trout populations.<sup>61</sup>

On May 28, 2004, the Bush administration's proposed new hatchery policy for the NMFS was published in the Federal Register along with a proposal for redefining and relisting 27 ESUs<sup>62</sup> of salmon and steelhead trout in the Northwest.<sup>63</sup> The new policy continues to include many hatchery and wild fish within the same ESUs,<sup>64</sup> thus inflating the population counts of several endangered or threatened naturally spawning fish. While the policy acknowledges that some hatchery fish should be distinguished from wild populations, the new policy fails to provide measurable scientific criteria for distinguishing which hatchery fish may contribute to wild fish survival.<sup>65</sup> According to Jim Lichatowich, salmon expert and former chief of fisheries research for the Oregon Department of Fish and Wildlife, the policy is "not a new approach. It is a return to the past when hatcheries were exchanged for habitat and hatchery salmon were considered the same as wild. The vague criteria for separating hatchery and wild salmon will either cause mass confusion or send salmon recovery back to the failed practices of 100 years ago."<sup>66</sup>

---

<sup>59</sup> See for example, Harden, B. "Hatchery Salmon to Count as Wildlife," *The Washington Post*, p. A1. April 29. See also Egan, T. 2004 (cited above).

<sup>60</sup> Official statements from NOAA National Marine Fisheries Service (NMFS) claimed that the new policy is required by the 2001 Coho salmon court decision. Although the NOAA interpretation of this court decision leads to an across-the-board policy that hatchery fish be considered indistinguishable from wild fish in defining evolutionarily significant units (ESUs), other viable interpretations could lead to a policy of excluding all hatchery fish from ESU designation (as recommended by the scientific panel) or that hatcheries be closed or seriously modified to prevent deleterious effects on the protected ESUs (e.g., see Lichatowich, J. 1999. *Salmon Without Rivers*. Island Press).

<sup>61</sup> Rojas-Burke, J. 2004. "U.S. backs protecting wild runs of salmon," *Portland Oregonian*. May 15.

<sup>62</sup> The original 26 retained their listing and one new ESU was added.

<sup>63</sup> NOAA NMFS, Northwest Region. 2004. *Federal Register Notice Language*. May 28; and NOAA Fisheries' Response to the Alsea Valley Alliance v. Evans U.S. District Court Ruling. May 28. Available online at <http://www.nwr.noaa.gov/AlseaResponse/20040528/index.html>.

<sup>64</sup> Ibid.

<sup>65</sup> Ibid. See also Myers, R.A. et al. 2004. "Hatcheries and endangered salmon," *Science* 303:1980. March 26. The authors state that some conservation hatcheries may contribute to salmon recovery, but their effectiveness has never been shown. However, much evidence exists that hatcheries cannot maintain wild salmon populations indefinitely and that hatchery fish compete with naturally spawning fish.

<sup>66</sup> Author interview with James Lichatowich, June 2004.

While there appears to be scientific documentation in the new policy and there are a number of supporting documents included with the proposals, much of the science is out of date and disregards the extensive, up-to-date scientific record compiled by the Salmon Recovery Science Review Panel's report, which is not included among the background reports featured in the policy.<sup>67</sup> Thus, while the new policy and ESU proposals do not call for delistings, they provide little protection against legal challenges to delist populations that are currently threatened or endangered.

In response to the suppression of the advisory panel's recommendations, the scientists published their findings independently in the journal *Science*.<sup>68</sup> Describing the six scientists as "top-notch," Donald Kennedy, editor of *Science*, noted publicly that the article easily withstood review by scientific peers before publication. "Differences on scientific issues should be argued on the merits," Kennedy noted about this incident, "and censorship isn't the way to conduct an honest debate."<sup>69</sup>

## **Science Undermined at the U.S. Fish and Wildlife Service**

In several recent cases at the U.S. Fish and Wildlife Service (FWS), a branch of the Department of the Interior, Bush administration officials have demonstrated a serious disregard for scientific integrity by suppressing or distorting research by government scientists or contractors.

### ***Distorting Scientific Knowledge on Florida Panthers***<sup>70</sup>

According to an FWS biologist, officials at the agency have knowingly used flawed science in the agency's assessment of the endangered Florida panther's habitat and viability in order to facilitate proposed development in southwest Florida.

Andrew Eller, Jr., a biologist who has worked at the FWS for 17 years, charges that agency officials have knowingly inflated data about panther population viability and minimized assessments of the panthers' habitat needs<sup>71</sup> and, under the Bush administration, have been unwilling to correct inaccurate science that underlies habitat assessment practices. In frustration over the situation, Eller has recently filed a legal complaint against the government. Eller, who has worked for the past decade in Florida's Panther Recovery Program, stated recently, "I could no longer tolerate the scientific charade in which U.S. Fish and Wildlife Service officials are trying to pretend that the Florida panther is not in jeopardy."<sup>72</sup>

---

<sup>67</sup> NOAA NMFS, Northwest Region. 2004. *Federal Register Notice Language*. May 28.

Available online at <http://www.nwr.noaa.gov/AlseaResponse/20040528/index.html>.

<sup>68</sup> Myers, R.A. et al. 2004. "Hatcheries and endangered salmon," *Science* 303:1980. March 26.

<sup>69</sup> As quoted in Weiss, 2004. "Action to Protect Salmon Urged," *Los Angeles Times*.

<sup>70</sup> This section was updated after further consultation with Jane Comiskey on July 16, 2004.

Original text is available by request from [rsi@ucsusa.org](mailto:rsi@ucsusa.org).

<sup>71</sup> Public Employees for Environmental Responsibility (PEER). 2004. *Andrew J. Eller and Public Employees for Environmental Responsibility v. Department of Interior*. May 4. Available online at <http://www.peer.org/florida/pantherDQchallenge.htm>.

<sup>72</sup> Author interview with Andrew Eller, May 2004.

Among the charges in Eller's complaint is the fact that FWS assessments have inflated estimates of Florida panther populations by erroneously assuming that all known panthers are breeding adults, discounting juvenile, aged, and ill animals. In addition, Eller charges, the FWS has knowingly minimized assessments of the panther's habitat needs by equating daytime habitat use patterns (when the panther is at rest) with nighttime habitat use patterns (when the panther is most active).<sup>73</sup>

These serious errors in the science that guided agency actions were identified by members of a science advisory subteam impaneled by the FWS in 1999 to help develop a habitat conservation strategy for the panther. The 2002 Draft Landscape Conservation Strategy,<sup>74</sup> based on the subteam's work, contains contradictory material due to disagreements about the validity of existing panther literature.<sup>75</sup> Notably in this case, an independent four-member Scientific Review Team (SRT), convened by FWS in conjunction with the Florida Fish and Wildlife Conservation Commission, unanimously confirmed and documented these and other serious errors in panther literature used by the agency and urged that they be corrected.<sup>76</sup>

Jane Comiskey, a researcher at the University of Tennessee and one of eight outside experts on the subteam, is concerned that FWS has not yet allowed the subteam to incorporate peer-review and SRT comments that would resolve the contradictions in the Draft Landscape Conservation Strategy. "We were convened to deliver a peer-reviewed document to FWS, and until we are allowed to incorporate review comments," Comiskey contends, "we will not have done the job we were called upon to do by the federal government."<sup>77</sup>

Meanwhile, Eller asserts, the FWS has knowingly continued to disseminate the inaccurate information. As stated in Eller's legal complaint, "The U.S. Fish and Wildlife Service's policy contends that no development project in southwest Florida constitutes jeopardy for the panther; the agency is simply relying on science that they know has been discredited."<sup>78</sup>

As Comiskey notes, "An agency charged with using the best available science to protect panthers should not object to correcting known errors. Panther recovery is a well-funded program with a world-class capture team, dedicated field biologists, a wealth of accumulated data, and strong public support. There's no reason not to get the science right. There are legitimate interests that conflict with those of panthers, but policy channels are provided to resolve those conflicts, outside the context of science."<sup>79</sup>

---

<sup>73</sup> PEER 2004. Available online at <http://www.peer.org/florida/pantherDQchallenge.htm>.

<sup>74</sup> U.S. Fish and Wildlife Service, South Florida Ecosystem Office. 2002. "Draft Florida Panther Landscape Conservation Strategy." Vero Beach, Florida.

<sup>75</sup> Author communication with Jane Comiskey via email, July 2004.

<sup>76</sup> For review panel assessment, see Beier, P., M. R. Vaughan, M. J. Conroy, and H. Quigley. 2003. "An Analysis of Scientific Literature Related to the Florida Panther." Final Report. Florida Fish and Wildlife Conservation Commission, Tallahassee, Florida. Available online at <http://www.wildflorida.org/critters/panther/Beier-Panther-SRT.pdf>.

<sup>77</sup> Author communication with Jane Comiskey via email, July 2004.

<sup>78</sup> Author interview with Andrew Eller, May 2004. Also see PEER 2004. Available online at <http://www.peer.org/florida/pantherDQchallenge.htm>.

<sup>79</sup> Author communication with Jane Comiskey via email, July 2004.

### ***Suppressing Analyses on Bull Trout Habitat***

Officials at the U.S. Fish and Wildlife Service censored an analysis of the economics of protecting the bull trout, a threatened trout species in the Pacific Northwest, publishing only the costs associated with protecting the species and deleting the report's section analyzing the economic benefits. Furthermore, while the benefits of protecting the bull trout were deleted from the economic analysis, the costs associated with this species' protection were inflated.<sup>80</sup> An exaggerated cost analysis and a deleted benefits analysis essentially give the FWS the economic justification, under the ESA, to disregard scientific information when designating critical habitat for the endangered bull trout.<sup>81</sup>

As part of a 2003 court settlement, the FWS was ordered to develop a plan designating critical habitat in the Pacific Northwest for bull trout,<sup>82</sup> which has been listed as a threatened species under the ESA since 1998. In conjunction with this effort, the FWS contracted Bioeconomics Inc., a Missoula, Montana-based consulting firm, to conduct a cost-benefit analysis of bull trout recovery in Oregon, Washington, Idaho, and Montana.

The firm's peer-reviewed research determined that protecting bull trout and its habitat in the Columbia and Klamath river basins will cost \$230 million to \$300 million over the next decade, costs associated with adverse effects upon hydropower, logging, and highway construction. The study also reported \$215 million in economic benefits associated with a restored bull trout fishery.<sup>83</sup>

---

<sup>80</sup> Much of the cost analysis included money already spent in association with the Endangered Species Act (ESA) listing as well as money spent on critical habitat protection for other listed species that occur in the same habitats identified for the bull trout, as noted in the FWS press release, "Draft Economic Analysis of Critical Habitat Proposal for Bull Trout in the Columbia and Klamath River Basins Released for Public Comment," April 5, 2004. Available online at <http://news.fws.gov/newsreleases/r6/E6CD3A83-F8FD-484C-8523CF328EC43D93.html>. As the press release states, "The draft economic analysis does not separate costs associated with the designation of critical habitat from those already incurred by the listing of bull trout in the Columbia and Klamath basins in 1998." The press release also acknowledges, "Most of the estimated cost already is occurring due to the listing of bull trout and protective measures already in place for listed salmon and steelhead."

<sup>81</sup> The ESA permits the FWS to disregard scientific information in making critical habitat designation decisions under certain circumstances. Sec. 4(b)(2) of the ESA states: "The Secretary shall designate critical habitat, and make revisions therein...on the basis of the best scientific data available and after taking into consideration the economic impact, and any other relevant impact, of specifying any particular area as critical habitat. **The Secretary may exclude any area from critical habitat if he determines that the benefits of such exclusion outweigh the benefits of specifying such area as part of the critical habitat**, unless he determines, based on the best scientific and commercial data available, that the failure to designate such area as critical habitat will result in the extinction of the species concerned." [Emphasis ours.]

<sup>82</sup> See *Friends of the Wild Swan v. U.S. Fish and Wildlife Service*, 945 F. Supp 1388; 81 F. 3d 168; 12 F. Supp. 1121; 910 F. Supp 1500; 966 F. Supp. 1002.

<sup>83</sup> FWS. 2004. "Draft Economic Analysis of Critical Habitat Proposal for Bull Trout in the Columbia and Klamath River Basins Released for Public Comment." Press release. April 5.

When officials at the FWS released the report, however, they deleted 55 pages of the analysis outlining the economic benefits of bull trout recovery.<sup>84</sup> The censorship spurred an anonymous FWS employee to leak a copy of the deleted chapter to a Montana-based environmental group, which then released it to *The Missoulian*, a Montana daily newspaper. Upon questioning from the press, Diane Katzenberger, an information officer in the FWS regional office in Denver, told a reporter that the censorship did not occur in either the Denver or Portland regional FWS offices but rather “was a policy decision made at the Washington level.”<sup>85</sup>

Chris Nolin, chief of the division of conservation and classification in the Washington, DC FWS office, told the press that the benefits analysis was cut because its methodology was discouraged by the Office of Management and Budget (OMB).<sup>86</sup> However, similar benefits analyses have been released by the Bush administration. In February 2003, for instance, the Environmental Protection Agency used similar techniques that showed \$113 billion in economic benefits over 10 years would result from implementation of the Bush administration’s 2003 Clear Skies Act.<sup>87</sup>

Michael Garrity, executive director of the Alliance for the Wild Rockies, the group that helped bring the incident to light, stated that contrary to the contention of some Bush administration officials, the methodology of the benefits analysis is largely based on solid economic projections of income from sport fishing. Despite a public request, the full economic analysis has not been publicly released by the FWS.

The decision whether and where to designate critical bull trout habitat must be made by September 2004.<sup>88</sup> It is not yet clear whether the FWS will use the incomplete economic analysis to limit critical habitat below what is scientifically justified, but the stage is clearly set for such an outcome.<sup>89</sup>

---

Available online at <http://news.fws.gov/newsreleases/r6/E6CD3A83-F8FD-484C-8523CF328EC43D93.html>.

<sup>84</sup> The censored version of the report as released by FWS is available online at [http://pacific.fws.gov/bulltrout/colkla/documents/BT\\_finalDraftEconomicAnalysis\\_031804.pdf](http://pacific.fws.gov/bulltrout/colkla/documents/BT_finalDraftEconomicAnalysis_031804.pdf).

<sup>85</sup> As quoted in Devlin, S. 2004. “Economic benefits of recovery omitted from bull trout report,” *The Missoulian*. April 16. Available online at <http://www.missoulian.com/articles/2004/04/15/news/top/news01.txt>.

<sup>86</sup> As quoted in Harden, B. 2004. “Report condemned as one-sided: government cut out benefits of saving threatened trout,” *San Francisco Chronicle*. April 17.

<sup>87</sup> See EPA. 2003. “Clear Skies Act, 2003, Technical Support Package, Section B: Human Health and Environmental Benefits.” February. Available online at [http://www.epa.gov/air/clearskies/03technical\\_package\\_sectionb.pdf](http://www.epa.gov/air/clearskies/03technical_package_sectionb.pdf). See also Harden, B. 2004. “Report condemned as one-sided: government cut out benefits of saving threatened trout,” *San Francisco Chronicle*. April 17.

<sup>88</sup> The draft economic analysis and the FWS proposal to designate critical habitat in the Columbia and Klamath basins were open for public comment until May 5, 2004.

<sup>89</sup> The FWS has initiated other processes that could avoid protecting the bull trout. An April 13, 2004 press release announced that the agency would conduct a five-year review of the bull trout listing (it was first listed in 1998). While this review process cannot derail the court-dictated decision on critical habitat designations, it could lead to change of classification or delisting for the species, and puts the process to finalize Recovery Plans for bull trout populations on hold. The full text of the news release is available online at

### **Misrepresenting Scientific Knowledge on Rare Swans**

According to documents released through the Freedom of Information Act, as well as testimony from consulting scientists, the director of the FWS based decisions concerning the status of rare trumpeter swans (*Cygnus buccinator*)<sup>90</sup> on a scientifically flawed, report that lacked outside peer review<sup>91</sup> and seriously misrepresented another study.<sup>92</sup>

In response to a petition by conservationists to list the population of “tri-state” trumpeter swans (a distinct population that breeds in the Rocky Mountain states of Montana, Wyoming, and Idaho) as threatened or endangered under the ESA, Director Steve Williams, an appointee of President Bush, ruled in January 2003 that the swans did not constitute a “distinct population segment” and were therefore ineligible for ESA protection.

Tri-state Rocky Mountain trumpeter swans—North America’s largest waterfowl—constitute the only breeding population of trumpeter swans that survives in the lower 48 states, where this species was once ubiquitous. Some environmentalists and ornithologists have sought since 2000<sup>93</sup> to protect the tri-state trumpeter swans under the ESA. Migrating tri-state trumpeters, which resemble the smaller and more plentiful tundra swans, over-winter in Utah and are virtually always killed during the tundra swan hunt. If trumpeter swans were designated as a threatened species, the FWS would be forced to halt the popular swan hunting season in Utah. In response to these organizations’ efforts, the FWS produced a document, devoid of peer review and contrary to the preponderance of scientific analysis,<sup>94</sup> that argues that the tri-state Rocky Mountain trumpeter swans do not constitute a “distinct population segment” but are actually part of a much larger population of trumpeter swans in Canada and Alaska.<sup>95</sup> As a result, the FWS avoided an ESA listing, and tri-state trumpeter swans continue to be killed during the Utah hunt.

---

<http://news.fws.gov/NewsReleases/R1/2E1647DE-8244-4AD2-BA58835CFAB5DAD5.html>.

<sup>90</sup> See PEER. 2004. “Fish and Wildlife Director Overrules His Own Scientific Panel; Allows Continued Hunting of Rare Trumpeter Swans.” Press release. April 13. Available online at <http://www.peer.org/press/447.html>.

<sup>91</sup> See Dubovsky, J. and J. Cornely. 2003. “Trumpeter Swan Survey of the Rocky Mountain Population, U.S. Breeding Segment, Fall 2002,” Lakewood, CO: U.S. Fish and Wildlife Service Migratory Birds and State Programs, Mountain-Prairie Region. October. Available online at [http://grandjunctionfishandwildlife.fws.gov/species/birds/trumpeterswan/survey\\_fall2002.pdf](http://grandjunctionfishandwildlife.fws.gov/species/birds/trumpeterswan/survey_fall2002.pdf).

<sup>92</sup> Gale, R.S., E.O Garton, and I.J. Ball. 1987. “The History, Ecology and Management of the Rocky Mountain Population of Trumpeter Swans.” Unpublished report. Missoula, MT: U.S. Fish and Wildlife Service, Montana Cooperative Wildlife Research Unit.

<sup>93</sup> On August 25, 2000, The Biodiversity Legal Foundation, Fund for Animals, and others petitioned the FWS to designate the tri-state swan population a Distinct Population Segment and list it as threatened or endangered.

<sup>94</sup> Gale, R.S. et al. 1987. See also PEER. 2001. *Swan Dive: Trumpeter Swan Restoration Trumped by Politics*. White Paper. Washington, DC: PEER. August. See also Shea, R., executive director, Trumpeter Swan Society. 2003. Letter (with scientific citations) to Steve Williams, FWS director. March 23. Available online at

[www.trumpeterswansociety.org/news/letters/TTSS\\_resp\\_90day.pdf](http://www.trumpeterswansociety.org/news/letters/TTSS_resp_90day.pdf).

<sup>95</sup> Dubovsky and Cornely, 2002.

To support its ruling, the agency also cited an earlier study of the tri-state swan population completed for the agency in 1987.<sup>96</sup> However, the study's principal author, Ruth (Gale) Shea, stated in a March 2003 letter to the FWS that the agency seriously misinterpreted her study.<sup>97</sup> Shea, a wildlife biologist and expert on the Rocky Mountain trumpeters, explains that her research found the tri-state population of trumpeter swans was notable for its reproductive isolation. "To date," Shea notes, "there are no data indicating that pairing with Canadian trumpeters is likely or that Canadian trumpeters will abandon their natal areas and fill in vacant tri-state breeding habitat as the tri-state population declines."<sup>98</sup> Nonetheless, Shea says, the FWS used her study in part to argue the precise opposite in support of the agency's ruling that the tri-state trumpeters are not a distinct population segment.<sup>99</sup>

Following FWS Director Steve Williams' denial of protection to the tri-state trumpeter swans in January 2003, an organization named PEER (Public Employees for Environmental Responsibility) filed a formal complaint,<sup>100</sup> which requested that Williams review the agency's ruling and its use of scientific information in the listing determination. PEER's request was denied and they filed an appeal.

To reach his decision after PEER's appeal, Williams convened a scientific panel to review the matter. The panel's assessment, made available only after a Freedom of Information Act request, unanimously recommended that Williams grant the appeal, concurring with the complaint that the agency's policy ought not have been based upon a non-peer reviewed document. As the panel members put it, "[T]his panel concludes that the Dubovsky-Cornely paper lacks the objectivity demanded by the IQA [Information Quality Act] because it was not subjected to any clearly documented quality assurance process, such as independent peer review."<sup>101</sup>

In a March 2004 letter to PEER,<sup>102</sup> Williams agreed to allow the regional FWS office to peer review the controversial internal paper upon which the agency's trumpeter swan policy is based. But, at the same time, Williams overruled his panel's unanimous recommendation and denied the appeal, continuing to refuse protection to the tri-state

---

<sup>96</sup> Gale, R.S. et al. 1987. See also PEER. 2003. "Public Employees for Environmental Responsibility (PEER) v. Department of Interior." May 28. Available online at [www.peer.org/rocky\\_mountain/Trumpeter\\_DQA.pdf](http://www.peer.org/rocky_mountain/Trumpeter_DQA.pdf).

<sup>97</sup> Author interview with Ruth (Gale) Shea, May 2004.

<sup>98</sup> As quoted in Shea, R., executive director, Trumpeter Swan Society. 2003. Letter (with scientific citations) to Steve Williams, FWS director. March 23. Available online at [www.trumpeterswansociety.org/news/letters/TTSS\\_resp\\_90day.pdf](http://www.trumpeterswansociety.org/news/letters/TTSS_resp_90day.pdf).

<sup>99</sup> Ibid.

<sup>100</sup> PEER. 2003. "Public Employees for Environmental Responsibility (PEER) v. Department of Interior." May 28. Available online at [www.peer.org/rocky\\_mountain/Trumpeter\\_DQA.pdf](http://www.peer.org/rocky_mountain/Trumpeter_DQA.pdf).

<sup>101</sup> Ashe, D., S. Haseltine, R. Bennet, FWS. 2004. Undated memo to FWS Director Steve Williams regarding the PEER appeal of FWS ruling on the designation of the tri-state population of trumpeter swans as a distinct population segment. Released June 4, 2004.

<sup>102</sup> Williams, S., FWS. 2004. Correspondence to Eric Wingerter, PEER. In his verdict on the matter, Williams states that the agency's dissemination of information, including the Dubovsky-Cornely paper, "met the agency's standard for objectivity." March 26. Available online at [http://www.peer.org/ForestService/fwswilliams\\_letter.pdf](http://www.peer.org/ForestService/fwswilliams_letter.pdf).

trumpeter swan population in spite of the overwhelming evidence that the agency's policy had been based on inaccurate, misinterpreted, and highly questionable scientific information.<sup>103</sup>

---

<sup>103</sup> Notably, until the review panel's assessment was released in June 2004 under a Freedom of Information Act request, Williams even refused to make the names of the review panelists or their finding public. Williams claims that the appeal decision was his to make as director of the agency—a statement no one disputes. But it remains unclear whether Williams can claim any scientific basis for his decision as required by the ESA.



## Section II: Undermining the Integrity of Science Advisory Councils

### Political Litmus Tests

Released in February 2004, the UCS report, *Scientific Integrity in Policy Making*,<sup>104</sup> documented that political litmus tests have been applied by representatives of the Bush administration to candidates for scientific advisory positions. In an official response, Bush administration Science Adviser John H. Marburger III stated recently, “[T]he accusation of a litmus test that must be met before someone can serve on an advisory panel is preposterous.”<sup>105</sup> Since the initial publication of the UCS report, however, new information has surfaced that contradicts the Bush administration’s denial of these charges.

Since Dr. Marburger’s statement, more scientists have disclosed their personal experiences with political litmus tests applied by the Bush administration in the appointment process for a wide range of scientific advisory positions. For example, Sharon Smith, chair of the marine biology department at the Rosenstiel School of Marine and Atmospheric Science at the University of Miami, states that she was summarily rejected for a position on the U.S. Arctic Research Commission—a presidential appointment—after she gave a less-than-enthusiastic answer in response to a question from the White House personnel office about whether she supported President Bush.<sup>106</sup>

An investigation of the matter by UCS has determined that such political litmus tests have been widely applied by the Bush administration to nominees for science advisory positions, in a dramatic departure from the practices of other administrations. In particular, a number of such allegations have surfaced from scientists nominated for scientific advisory positions at the National Institutes of Health (NIH) “council level.” The following section reviews these specific allegations in detail.

### NIH Councils

The NIH is a large family of institutions that serves as a steward of medical and behavioral research in the United States. It is divided into some two dozen separate centers and institutes, most of which have a National Advisory Council or Board that serves as the oversight tier of the peer review process—a process upon which the NIH and the entire scientific community relies. Scientists asked to serve on these NIH councils

---

<sup>104</sup> Union of Concerned Scientists (UCS). 2004. *Scientific Integrity in Policy Making: An Investigation into the Bush Administration’s Misuse of Science*. Cambridge, MA: Union of Concerned Scientists. February 18. An updated edition of this report, published in March 2004, is available online at <http://www.ucsusa.org>.

<sup>105</sup> See Marburger III, J.H., 2004. “Statement of the Honorable John H. Marburger, III on Scientific Integrity in the Bush Administration.” April 2. p.3. Available online at <http://www.ostp.gov/html/ucs/SummaryResponsetoCongressonUCSDocumentApril2004.pdf>.

<sup>106</sup> The details derive from an email from Dr. Sharon Smith, March 2004, and an author interview with Dr. Smith’s office staff in June 2004 during her research trip in the Arctic.

are traditionally chosen based on their scientific credentials and technical expertise. Among their important functions, these council members oversee the process of allocating federal research funds. While NIH councils frequently make decisions that affect the direction of scientific research, they do not set or even recommend policy on behalf of the federal government. Because of their vital, independent role outside of the policy-making arena, committee heads at the NIH have traditionally received wide latitude in determining the scientific expertise needed in their committees' particular area of concern.

The law establishing these councils is very clear in its intention to create scientific bodies, not political or policy-making bodies. According to the guidelines published by the Office of Federal Advisory Committee Policy: "The basic criterion for [scientists chosen for] membership on NIH committees is excellence in biomedical and behavioral research... The Federal Advisory Committee Act (FACA), under which NIH committees operate, requires that membership must be fairly balanced in terms of points of view represented and the functions to be performed by the advisory committee."<sup>107</sup> As a result, council members' terms do not end with the inauguration of a new president, and members often overlap several administrations.

### **National Advisory Council for Human Genome Research**

Two of the most recently appointed members to the National Advisory Council for Human Genome Research, Richard Myers of Stanford University and George Weinstock of Baylor College of Medicine, report that they were each subjected to inappropriate questions about their political views by representatives of the White House during their confirmation process.

#### *Dr. Richard Myers*

Dr. Myers, a biochemist with a distinguished scientific record, currently serves as chair of the Department of Genetics at Stanford University and director of Stanford's Human Genome Center. A recognized expert in genome analysis and the study of DNA variation, his research has furthered worldwide scientific understanding of numerous genetic disorders, including Huntington's disease, progressive myoclonus epilepsy, and basal cell carcinoma.

In the spring of 2002, Dr. Myers was notified that he had been nominated to serve on the National Advisory Council for Human Genome Research, an NIH council-level position. Shortly thereafter, he says, he received a call from Secretary Tommy Thompson's office at the Department of Health and Human Services (HHS).<sup>108</sup> The Bush administration official began asking questions about Dr. Myers' background and scientific credentials that, he recounts, soon turned increasingly political in nature. First, he recalls, he was asked questions about his view of stem cell research. "I was a little

---

<sup>107</sup> See Office of Federal Advisory Committee Policy, National Institutes of Health (NIH). *Directory of NIH Federal Advisory Committees functions and members*. Online at <http://www1.od.nih.gov/cmo/committee/index.html>.

<sup>108</sup> Author interview with Richard Myers, March 2004.

surprised,” he says, “given what I know about the nature of the committee’s work.”<sup>109</sup> But Myers answered the question candidly. “I told the official that I was in favor of stem cell research. I said that my father has Parkinson’s disease and that I would very much like to see a cure. I believe I said it would be a crime in my view if we didn’t do that kind of research.”

“Then,” Dr. Myers recalls, “the staffer asked questions that really shocked me. She wanted to know what I thought about President Bush: did I like him, what did I think of the job he was doing.” Dr. Myers, who describes himself as normally “nonpolitical,” objected to the line of questioning. “I said that I thought it was inappropriate to be asked these kinds of questions which led, I think, to an awkward situation for both of us,” he says. “She said that she had been told that she needed to ask the questions and it appeared to me that she was reading from a prepared list. Because of her persistence, I tried to answer in the most nonspecific way possible. I talked about terrorism and the fact that it seemed that the attacks of September 11 had brought the country together. But there is no doubt that I felt the questions were an affront and highly inappropriate.”

Not long after this interview, Dr. Myers was notified that he had been denied the NIH council position. “I was very depressed,” he says. “I really wanted to serve in this capacity. I care deeply about the science and I’m an expert in this area.” Most notably, Dr. Myers knew that he had been selected by his NIH colleagues and so he determined that his rejection must have been due to the fact that his answers to the political questions posed had been deemed unsatisfactory. Alarmed, he appealed his case directly to Dr. Francis Collins, a senior NIH scientist who is chair of the National Advisory Council for Human Genome Research and director of a branch of the NIH called the National Human Genome Research Institute.

Dr. Collins declined to be interviewed about the matter. But, through his office, he confirmed the fact that, learning of the circumstances, he personally intervened on Dr. Myers’ behalf and successfully insisted that he be allowed to serve on the NIH council.<sup>110</sup>

#### *Dr. George Weinstock*

Dr. Weinstock, a microbiologist at Baylor College of Medicine, is a distinguished researcher, a professor in the departments of molecular and human genetics and molecular virology and microbiology as well as co-director of Baylor’s Human Genome Sequencing Center. Dr. Weinstock, who was appointed to the same NIH advisory panel in 2002, says that he too was subjected to questioning about his political views.

After learning of his nomination, he received a call from someone at the HHS. He too was asked a series of questions that he describes as “leading political questions that had nothing to do with my role on the NIH committee.”<sup>111</sup> Dr. Weinstock also reports that the interview included questions about his political views, whether he supported stem

---

<sup>109</sup> The National Advisory Council for Human Genome Research advises the NIH and the Department of Health and Human Services on genetics, genomic research, training, and programs related to the human genome initiative.

<sup>110</sup> Author interviews with two members of Dr. Collins’ policy staff, National Human Genome Research Institute, March 2004.

<sup>111</sup> This and the statements that follow come from an author interview with George Weinstock, March 2004.

cell research, and what he thought of President Bush. “There is no doubt in my mind that these questions represented a political litmus test,” he says. While he found the line of questioning disturbing, he chose not to confront the questioner but tried instead “to change the subject. I said things like: ‘we live in complicated times.’” Dr. Weinstock believes his answers must have been “innocuous enough to be palatable” because he was confirmed by the White House to serve on the NIH council.

### **National Institute on Drug Abuse**

#### *Dr. Claire Sterk*

During her confirmation process for the Council of the National Institute on Drug Abuse, Dr. Sterk reports she was subjected to repeated questioning about her political views in three separate calls from a White House staff member. Among the questions she was asked, and refused to answer, was whether she had voted for President Bush.

“I have nothing to hide,” Dr. Sterk commented. “But I told the questioner that I did not see the connection between his line of questioning and my work on a scientific advisory council. And I refused to answer unless the questioner could tell me that I would have some kind of particular political policy role, which I knew I would not.”<sup>112</sup>

Despite her refusal, however, Dr. Sterk states that the White House staffer continued trying to elicit an answer about her vote in the presidential election “for roughly 15 minutes.” Dr. Sterk was asked many other overtly political questions that she refused to answer, such as whether she supported “faith-based” drug treatment programs. While Dr. Sterk was confirmed for a position on the NIH council, she says she believes that a high-ranking NIH official may well have intervened on behalf of her nomination. Nonetheless, she says she finds it deeply disturbing that the Bush administration would subject its nominees for a scientific advisory position to such intrusive, partisan political questions.

Like Dr. Sterk, other scientists interviewed by UCS expressed dismay and discouragement about what they consider to be an overt politicization of the appointment process for scientific advisory positions. Scientists who have served Democratic and Republican administrations alike agree that questions of political affiliation have no place in the confirmation process for our highest echelon of science advisers and that the current administration’s practice is reprehensible.

As Donald Kennedy, editor of *Science* and former president of Stanford University, has noted, “I don’t think any administration has penetrated so deeply into the advisory committee structure as this one, and I think it matters. If you start picking people by their ideology instead of their scientific credentials you are inevitably reducing the quality of the advisory group.”<sup>113</sup>

As the following case indicates, however, the political questions asked of scientists in the confirmation process for high-level NIH advisory positions represent

---

<sup>112</sup> This and the statements that follow come from an author interview with Claire Sterk, March 2004.

<sup>113</sup> As quoted in Zitner, A. 2002. “Advisors Put Under a Microscope,” *The Los Angeles Times*, December 23.

only a small, albeit very important, aspect of the unprecedented politicization of the appointment process for NIH science advisers in the current administration.

### **Fogarty International Center Advisory Board**

As originally reported in *the New England Journal of Medicine*,<sup>114</sup> Gerald T. Keusch, who served from October 1998 to December 2003 as associate director for international research at the NIH and as a director of an NIH branch called the Fogarty International Center, recounts a dramatic change in the appointment process when the Bush administration took office. Now serving as assistant provost for global health at Boston University Medical Center, Dr. Keusch states that during three years under the Bush administration, he proposed 26 candidates to serve on the Fogarty Center's council-level advisory board. All the candidates he nominated were approved within a week by the NIH director but, after many months of delays in almost every case, only seven were approved by the Bush administration, while the remaining 19 candidates were rejected. Dr. Keusch contrasts this record with his personal experience during the previous administration, in which all seven of his nominations for the board were swiftly approved.

In response to in-depth questioning for this report, Dr. Keusch responded with specific information about the circumstances surrounding the repeated rejection of his nominees. Because the Fogarty Center gives research grants, Dr. Keusch says, "I knew what skills I needed on my board to review grants and help determine future scientific directions for the Center. I had 30 years of experience in science and developing countries and I knew who understood and had personal experience in developing countries and who could provide the scientific insight the Center, and I as director, desired."<sup>115</sup> Accordingly, he says, all his scientific nominees to the Fogarty Center's advisory board represented highly credentialed experts in their fields.

In his first set of nominations, Dr. Keusch proposed to empanel Torsten Wiesel, a Nobel laureate in medicine; Jane Menken, a highly respected demographer at the University of Colorado; and Geeta Rao Gupta, an internationally known expert on women's health and the president of the Washington, DC-based International Center for Research on Women. After more than seven months of delay in Secretary Thompson's office at the HHS, Dr. Keusch said he learned that all three of these initial candidates had been rejected without explanation.

"I was disappointed and puzzled," Dr. Keusch recalls. He went to Ruth Kirschstein, then acting director of the NIH, and requested that he be allowed to meet with Secretary Thompson's office. As Dr. Keusch puts it, "I had managed to get a Nobel laureate to agree to serve on my board and, if he was going to be rejected, I wanted to know why."

In response to detailed questions about the process, Dr. Keusch recounts that the meeting with Secretary Thompson's staff and another administration official was deeply

---

<sup>114</sup> Steinbrook, R. 2004. "Science, Politics, and Federal Advisory Committees," *The New England Journal of Medicine* 350(14):1454-1460. April 1.

<sup>115</sup> This and the statements that follow come from an author interview with Gerald T. Keusch, April 2004.

disturbing. “There is no written record, but I recall being told that Dr. Wiesel was rejected because he had signed too many full-page letters in *The New York Times* critical of President Bush. I was told Dr. Menken was unacceptable because she was on the board of the Alan Guttmacher Institute, a nonprofit reproductive health research organization. Dr. Rao Gupta, I was told, was deemed too political because she had publicly supported women’s right to abortion.”

Dr. Keusch reports that in one case even a sitting board member was rejected. When Dr. Keusch sought to renew the term of Cutberto Garza, associate provost at Cornell University and an expert on international nutrition, Secretary Thompson’s office rejected Dr. Keusch’s request. Eventually, Dr. Keusch said, the experience was so frustrating that he stopped even talking to candidates in advance of their confirmation. “It was too embarrassing to me to get these top people to agree to serve as board members only to have to tell them they were rejected by the Department of Health and Human Services.”

### **President’s Council on Bioethics**

In another clear case of political interference in the science advisory appointment process, on February 27, 2004, the Bush administration dismissed Dr. Elizabeth Blackburn, a leading cell biologist, and Dr. William May, a prominent medical ethicist, from the President’s Council on Bioethics. For three years, Dr. Blackburn had served on the panel, which is charged with advising the president on the ethical implications of advancements in biomedical research. Dr. Blackburn is best known as the co-discoverer of telomerase, an enzyme linked to cancer cell growth. This discovery launched a burgeoning cancer research field. According to Nobel laureate Thomas Cech, president of the Howard Hughes Medical Institute, Dr. Blackburn “is a very smart and successful scientist...one of the top biomedical researchers in the world.”<sup>116</sup> Dr. Blackburn states that she believes she was dismissed because she disapproved of the Bush administration’s restrictive position on stem cell research. According to Dr. Blackburn, she and Dr. May frequently disagreed with the administration’s positions on the ethics of biomedical research.<sup>117</sup> She was removed from the panel soon after she objected to a Council report on stem cell research. In an essay in the April 1, 2004 issue of *The New England Journal of Medicine*, Dr. Blackburn recounted how the dissenting opinion she submitted, which she believes reflects the scientific consensus in America, was not included in the council’s reports even though she had been told the reports would represent the views of all the council’s members.<sup>118</sup>

The removal of Drs. Blackburn and May—and the subsequent appointment of new panel members who are supportive of the administration’s stated positions, significantly limits the range of views now available to the president on bioethical issues.

---

<sup>116</sup> As quoted in Elias, P. 2004. “Scientist lauded after government fires her,” Associated Press. March 18.

<sup>117</sup> Author interview with Elizabeth Blackburn, March 2004.

<sup>118</sup> Blackburn, E. 2004. “Bioethics and the Political Distortion of Biomedical Science,” *The New England Journal of Medicine* 350(14):1379-1380. April 1. See also “Science and the Bush administration: Cheating nature?” *The Economist*, April 7, 2004.

This action violates the spirit, if not the letter, of the Federal Advisory Committee Act of 1972, which requires balance on such advisory bodies.<sup>119</sup> As Dr. Blackburn herself has pointed out, she was one of only three full-time biomedical scientists on the panel, which, even prior to her dismissal, was weighted heavily to nonscientists with strong ideological views. While no one disputes that nonscientists should play an important role on a bioethics panel, it is equally important that scientists, with strong biomedical expertise, provide the necessary scientific context for the panel.

The administration has claimed that politics played no role in Dr. Blackburn's dismissal,<sup>120</sup> but in the wake of Dr. Blackburn's firing, some 170 researchers signed an open letter to President Bush protesting the decision.<sup>121</sup> Dr. Janet Rowley,<sup>122</sup> Distinguished Service Professor of Medicine and Molecular Genetics at the University of Chicago and current member of the Bioethics Council, has characterized Dr. Blackburn's dismissal as "an important example of the absolutely destructive practices of the Bush administration."<sup>123</sup>

Among those expressing concerns about Dr. Blackburn's dismissal was the American Society for Cell Biology (ASCB), which represents 11,000 scientists worldwide. ASCB issued a public statement contending that Dr. Blackburn's dismissal reflected a pattern in the Bush administration in which politics trumps science. As ASCB President Harvey Lodish noted: "In his 2001 speech announcing the creation of the Council, President Bush said the Council would include strong representation from leading scientists. This action significantly undermines the ability of Councilors to base their considerations on the foundation of sound science."<sup>124</sup>

---

<sup>119</sup> See Federal Advisory Committee Act, 5 U.S.C. Appendix 2, Section 5(b) 2 and 3.

<sup>120</sup> See, for example, Kass, L. 2004. "We Don't Play Politics with Science," *The Washington Post*. Op-ed. March 3.

<sup>121</sup> See Holden, C. 2004. "Researchers blast U.S. bioethics panel shuffle," *Science* 303:1447. March 5.

<sup>122</sup> Among her many credentials, Janet D. Rowley M.D., D.Sc. is internationally renowned for her studies of chromosomal abnormalities in human leukemia and lymphoma. She is the recipient of the National Medal of Science (1999) and the Albert Lasker Clinical Medicine Research Prize (1998), the most distinguished American honor for clinical medical research.

<sup>123</sup> As quoted in Elias, P. 2004. "Scientist lauded after government fires her," Associated Press. March 18.

<sup>124</sup> American Society for Cell Biology. 2004. "Cell Biologists Oppose Removal of Top Scientist." Press release. March 2. Available online at <http://www.ascb.org/newsroom/blackburn.html>.

### Section III: Finding Solutions

This report provides additional evidence that when scientific knowledge has been found to be in conflict with its political goals, the Bush administration has manipulated the process through which science enters into its decisions.

The mountaintop removal strip mining case reveals a flagrant abuse of political power by the deputy secretary of the Interior, a former lobbyist for the National Mining Association, for the purpose of eliminating any and all plans not espoused by the mining industry. This action will have a severe impact on the environment of Appalachia. The decision of a senior FDA official to deny women over-the-counter access to emergency contraception, against the advice of both an expert advisory committee and his own scientific staff, will lead to more unplanned pregnancies and, ultimately, more abortions. The four cases regarding application of the Endangered Species Act demonstrate a disturbing pattern of administration officials suppressing or distorting the best available science when it conflicts with their policy objectives.

The report also provides further examples of political meddling with scientific advisory committees, showing how prominent scientists, in the course of being considered for important committees, have been asked inappropriate political questions, including whether they had voted for President Bush. This practice appears to be most prevalent in the HHS where, as we reported in our earlier study, Secretary Tommy Thompson has imposed previously unheard of political oversight on the selection of scientific advisors.

This report and its predecessor, *Restoring Scientific Integrity in Policy Making*, having established widespread and serious abuse, raise the issue of what reforms should be adopted to restore scientific integrity to the formation and implementation of federal public policy. This is a significant question, and will continue to be the subject of analysis, public education, and advocacy by the Union of Concerned Scientists. Since the first report was published, UCS has consulted with scientists who have served in government, experienced congressional staff, and other experts about reforms that might be pursued. The reforms suggested so far fall into several distinct categories:

- *Protecting Government Scientists.* The vulnerability of full-time scientific staff to actions by superiors that breach the ethical code of science can impede or prevent the transmission of objective scientific information and advice to policy makers. Such practices undermine the morale of scientific staff and make it more difficult to attract scientists to government service. Government scientists have minimal legal protection should they seek to resist orders or actions by their superiors that violate the ethical code of science. The Whistleblower Protection Act only offers protection against such abuse if the abuse violates laws or creates imminent danger to public health and safety. A handful of individual statutes, including the Clean Air and Clean Water Acts, protect disclosures of information that further implementation of those laws. Additional protection is needed for agency scientists who are pressured to distort or suppress scientific findings. One solution could be to create a corps of scientific ombudsmen who would, on a confidential basis, be responsible for resolving such problems in collaboration with the inspector general of the department and the Office of Science and Technology



Policy. Such a process, if properly designed, would conform to the culture of science and would reduce the likelihood that every such conflict becomes a public legal joust or political *cause celebre*.

- *Providing Better Scientific Advice to Congress.* The abolishment in 1995 of the Office of Technology Assessment left Congress with very little capacity to assess important science and technology issues independently of the executive branch. A bipartisan group of House members, including the chairman and ranking member of the Science Committee, is proposing creation of a Center for Scientific and Technical Assessment within the General Accounting Office, to restore some of this capability.<sup>125</sup> A Congress more fully informed about science and technology could play a stronger role in ensuring that federal policy making is informed by the best available science.
- *Strengthening the Office of Science and Technology Policy (OSTP).* The OSTP director, as the most senior scientific advisor in the U.S. government, should once again have the stature of assistant to the president for science and technology, and should report directly to the president. When a new administration comes to office, the OSTP director should be among the earliest appointments, so that he or she can be involved in the selection of the most senior appointees having scientific responsibilities in all departments. The staff of the OSTP should be expanded so that it can better provide the director with independent assessment of controversies involving science. OSTP staff should also have the ability and resources to receive and assess reports from the proposed ombudsman corps.
- *Ensuring the Independence of Scientific Advisory Committees.* The Federal Advisory Committee Act (FACA) stipulates that members of such committees are to be appointed as Special Government Employees (SGEs), with full disclosure of any conflicts of interest, when they are to serve in the role of experts, or as “representatives” when they are to represent various stakeholders. A number of departments, both in this administration and in past administrations, have appointed many experts as representatives, thereby avoiding the requirement for disclosure of conflicts of interest. Congress should see to it that the FACA is fully enforced, and that clear rules are established and applied to all departments. These rules should stipulate that committees that have a purely scientific or technical advisory mission, or that review research proposals, should be composed entirely of SGEs, and more generally, should require full transparency in the selection and activities of such committees. Furthermore, it should be forbidden to ask scientists and other experts being vetted for membership on scientific advisory committees about their political or policy positions, let alone how they have voted in past elections.

---

<sup>125</sup> The initial sponsors of this proposal are Representatives Rush Holt, Sherwood Boehlert, Amo Houghton, and Bart Gordon.

- *Providing for Increased Access to Information.* Full access to scientific information is critical for informed, transparent decision making. Unfortunately, such information is increasingly being withheld from the outside scientific community, the public, and even Congress. Among needed reforms are a top-to-bottom review of classification policy for all agencies, to ensure that only information that truly needs to be kept secret is withheld from disclosure, and a tightening of the “pre-decisional” exemption to the Freedom of Information Act that allows agency officials to suppress discordant or ill-timed release of scientific findings by indefinitely keeping reports in “draft” form.

Even if these and other reforms are adopted, scientists and scientific societies will still have an important role in monitoring the use of science in federal policy making and bringing any future abuses to the attention of the media, the public, and their elected representatives.

Finally, it should be acknowledged that in the American system of government, the chief executive inevitably sets the tone, and if science is to play the constructive role that citizens expect and deserve, the president must demonstrate a strong personal commitment to respecting objective scientific advice, even in situations where it is ultimately rejected because other factors carry greater weight. In his April 2 response to the scientists’ statement and original UCS report, OSTP Director Marburger stated that, “President Bush believes policies should be made with the best and most complete information possible, and expects his Administration to conduct its business with integrity and in a way that fulfills that belief.”<sup>126</sup> If this is indeed the case, this report demonstrates that there are many senior officials in the president’s administration who have yet to get the message.

---

<sup>126</sup> Statement of the Honorable John H Marburger, III on Scientific Integrity in the Bush Administration, April 2, 2004, online at <http://www.ostp.gov/html/ucs/ResponsetoCongressonUCSDocumentApril2004.pdf>