YANKEE DOODLING **Douglas Kamerow**

Science trumps politics on emergency contraception

US federal court overrules Obama administration policy

When President Obama was first elected in 2008, his supporters hoped that many things would change. One of them was the previous administration's contemptuous disregard for and subversion of scientific integrity throughout the government to serve political ends. Examples ranged from misrepresenting research on the effectiveness of abstinence-only sex to censoring testimony on climate change by government scientists to posting erroneous data linking abortions and breast cancer. Many people, including me, wrote about this and hoped things would improve with the new administration.2

One of the most egregious examples of politics and ideology trumping science was the case of emergency contraception—the "morning after" pill taken to prevent pregnancy after unprotected intercourse has occurred. It was available in the US as "Plan B" (great ironic brand name), but only with a doctor's prescription. The pills had been shown in studies and in the experience of other countries to be safe and effective—and, of course, much more widely used—when made available "over the counter" (OTC) in pharmacies without a prescription.

In 2001, a citizen's petition to the Food and Drug Administration (FDA) requested that the manufacturer be permitted to sell an OTC version. The Bush administration first refused approval, asking for more research. It then delayed the decision for more than three years after the relevant FDA advisory committee overwhelmingly voted to approve OTC use. The issue became a political struggle between the administration and several US senators, including Hillary Rodham Clinton, and it stood in the way of senate confirmation of two FDA commissioners. Finally, in 2006, the FDA allowed OTC salesbut only to women aged 18 years or above. Two senior staff at the FDA resigned in protest.

When his administration took office in 2009, President Obama said he would not interfere with scientific evidence and government deliberations. It was hoped that the long wait for OTC emergency contraception access for younger women was over. Such unrestricted use was supported by all major medical organizations and women's health groups. It did not go smoothly or quickly, however. The FDA under Obama took almost three more years to evaluate the issue. In early 2011, the manufacturer filed for permission to sell a one-pill version of Plan B to women without age restrictions. Finally, in December 2011, the FDA recommended that the drug be made available over the counter to all purchasers, finding it was safe and effective for such use.

In a widely publicized and largely unprecedented action, however, Obama's health and human services secretary, Kathleen Sebelius, overruled her FDA commissioner and continued the limitation of the OTC morning after pill to women aged 17 and over. Thus, younger women would still need a prescription to obtain emergency contraception. This policy was unsupported scientifically but unimpeachable politically, as the country was about to enter an election year. Obama himself denied a role in the decision but stated his support for it, "as the father of two daughters."3

Unsurprisingly, this decision unleashed a firestorm of criticism, from women's groups, medical associations, and others. 4 One group, the Center for Reproductive Rights, which had led the original citizen's petition, re-opened its lawsuit appealing the restrictions in February 2012. Fourteen months later, on 12 April 2013, a federal judge has just ordered that the morning after pill be made available without a prescription for all ages. In his ruling, Judge Edward Korman excoriated the administration,



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saying that Secretary Sebelius's action in reversing the FDA recommendation was "politically motivated, scientifically unjustified, and contrary to agency precedent." He gave the administration 30 days to implement OTC access to the morning after pill.

It has taken about 12 years from the time of first petition to achieve unfettered access to Plan B in the US, a sad and telling story. What can we learn from all this?

Firstly, it illustrates the power of scientific misinformation. A major objection to the morning after pill was that it caused abortions, because it supposedly interfered with implantation of the fertilized egg in the uterus. In fact, "the ability of Plan B to interfere with implantation remains speculative, since virtually no evidence supports that mechanism and some evidence contradicts it."6 Plan B is a contraceptive, not an abortifacient. Another major objection was that its unrestricted availability would increase sexual activity in young women. There is no evidence that this is true.

Secondly, we learnt yet again that politics can interfere with supposedly scientific governmental deliberations. It was outrageous when it occurred in the Bush administration and deeply disappointing when Obama appointees continued the outrage for crass political reasons.

Finally, the story concludes with a happy ending. Thanks to persistence (and funding) from women's groups, it looks like emergency contraception will finally be available to all in the US by the summer. A victory, even if a hugely delayed one.

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References are in the version on bmj.com.

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