

# different TAKES

A Publication of the Population and Development Program at Hampshire College • No. 30 • Spring 2005

## Reproductive Health and the FDA: Buffeted by Political Battles

By Amy Allina

Since its inception, the Food and Drug Administration (FDA), the U.S. government's main watchdog agency over the pharmaceutical industry, has been subject to political pressures that undermine its mission to ensure drug safety and protect consumer health. In the last several years, these pressures have intensified as the FDA is buffeted by the Bush administration's right-wing agenda and an ever more powerful pharmaceutical industry. More often than not, women's reproductive health and safety are caught in the crossfire of these political and economic agendas.

### The Religious Right and the Battle over Emergency Contraception

In 2002, the Bush administration set off a powerful reaction when it tried to install W. David Hager as chair of the reproductive health drugs advisory committee responsible for advising the FDA on questions relating to contraception and abortion. The outrage of women around the country — expressed by more than 10,000 protest email messages to the FDA — led to a close public scrutiny of Hager's record. Hager had been the lead spokesperson for the Christian Medical Association's petition for a ban on mifepristone,<sup>1</sup> the drug approved by the FDA for abortion. He had spoken publicly of his reluctance to prescribe contraception to patients who are not married.<sup>2</sup> And as headlines across the country proclaimed, he was co-author of a book recommending prayer as treatment for PMS.<sup>3</sup>

In the face of this storm of public opposition, the Bush administration backed off from the original plan of putting Hager in charge of the committee, but they did make him a member. And they provided him with like-minded colleagues, appointing Joseph Stanford (who has written that he is unwilling to prescribe contraception even to married patients because of his belief that any

interference between sexuality and fertility is detrimental to marriage<sup>4</sup>) and Susan Crockett (a board member of the American Association of Pro-Life Obstetricians and Gynecologists) to the committee as well.

Reproductive rights advocates and FDA watchers saw these appointments as a sign of the Bush administration's allegiance to the religious right and pointed out that they set the stage for a fight over the pending FDA decision on whether to make emergency contraception (EC) available over-the-counter. Following that discouraging development, feminist activists and reproductive health advocates cheered the triumph of science a year later when the committee voted unanimously that emergency contraception was safe for use in an over-the-counter setting. In the face of overwhelming scientific evidence, even the three staunch opponents of reproductive rights on the committee had to acknowledge that this after-the-fact contraceptive method could be used safely without a prescription requirement. Among the doctors, scientists and activists who had been working for years to expand women's access to EC, most had expected far worse from the committee.

The victory was short-lived, however. Despite the overwhelming recommendation from FDA's science advisors, opponents of contraception prevailed and the FDA denied the EC over-the-counter application.\*

Scientists and medical experts joined reproductive rights advocates in criticizing that decision, pointing out that by bowing to anti-choice political pressure, the FDA has denied women access to a safe and effective contraceptive and has undermined its own credibility as a scientific agency around the world. An editorial in the *New England Journal of Medicine* lamented the loss of FDA's "enviable

international reputation” and pointed out that the decision was “likely to mean that both physicians and patients will wonder whether future drug-approval decisions are based on the evidence with regard to efficacy and safety or, rather, on political considerations.”<sup>5</sup>

## Mission in Flux

The EC controversy was not a typical, everyday occurrence at FDA. The FDA usually operates behind-the-scenes, unnoticed by most people — even those concerned about health. Yet, despite being out of the public eye, the FDA is still under constant pressure from political forces of a different kind than the very public battles that take place over reproductive rights. The standard battle at the agency is between the interests of the companies that make the drugs and devices it regulates and consumer advocates concerned about the safety of those products.

Since the FDA was first created early in the twentieth century, there have been struggles between businesses, determined to fight off government interference, and consumers and their advocates, working to establish a role for the federal government in protecting the public health.<sup>6</sup> At its start the FDA was made up of a handful of scientists who worked in an obscure bureau of the Department of Agriculture; as the scope of drugs and medical devices in the world has expanded, the FDA has grown as well, now responsible for regulating over a trillion dollars worth of food, drugs and medical devices, more than a fifth of the U.S. economy.

This growth has taken place in spite of industry resistance. It has taken fierce fights between consumer advocates and industry, and all too often, national and international tragedies to expand the

scope of FDA regulation. Sadly, many of the events that have persuaded Congress of the need for better regulation of drugs and medical devices have specifically involved damage to the life and health of women. Only after thalidomide, given to pregnant women to reduce morning sickness, was found to have caused nerve damage in the women who took it and sometimes fatal birth defects in their children, did Congress mandate that FDA must review evidence of a drug’s safety and efficacy before a company could begin to sell it. And pre-market review of medical devices came even later. In the United States alone, 17 women died and thousands more had emergency hysterectomies to save their lives as a result of using the unsafe Dalkon Shield IUD before the FDA was given the authority to require those reviews.

In the last decade, however, the trend has gone in the opposite direction. When conservative lawmakers won control of Congress in 1994, they went to work on a broad reform agenda that reflected the wish lists of industries from financial services to pharmaceuticals. The FDA Modernization Act of 1997 reshaped the agency in response to the drug industry’s long-held desires. The new law speeded up drug approvals, scaling back safety requirements, and even redefined the agency’s mission statement to commit it to working in consultation with “manufacturers, importers, packers, distributors, and retailers of regulated products.”<sup>7</sup>

Recent news about drug safety problems with widely prescribed pain relievers, however, has led to a growing public understanding that FDA’s ability to protect the public has been eroded. Public outrage has already translated into Congressional interest, and these developments may lead to drug safety reform legislation to restore some of FDA’s capacity to ensure drug safety.

## The False Choice Between Speed and Safety

Over the years as these trends have evolved, drug companies have not always been alone in criticizing FDA for its slow approval process. Patient activists have sometimes made common cause with industry, pushing for faster drug approvals even at the expense of rigorous safety testing. Early AIDS activists, in particular, urged FDA to dispense with stringent safety requirements to give dying patients access to new treatment drugs. Later, as more AIDS



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drugs became available, many of these same activists responded to the changed circumstances and urged the FDA to reprioritize the need for evidence of long-term effectiveness and safety in its consideration of AIDS drugs.

Women's health advocates similarly urged faster approval for the female condom and other barrier methods of contraception that hold the potential to protect women from HIV infection and other sexually transmitted diseases. The question of how to balance safety concerns with the urgent need for a product will again be at center stage when FDA eventually considers approval of microbicides now in development — topically applied products that help prevent the transmission of HIV and other infections.

Drug companies and device manufacturers have watched these developments carefully and learned from them. Industry-funded patient groups now often play a very public role in companies' plans for obtaining FDA approval; in some cases these patient groups have been found to be wholly created by the companies whose products they are demanding access to. But activists who are accountable to real-life patients suffering from illness are learning as well. They have learned to reject the false choice between faster approval and safer products. The demand for efficient consideration of urgently needed products does not have to result in the elimination of safeguards for the public health.

## Addressing Safety Concerns and Overcoming Division

When it comes to contraception, the political battles sometimes converge, subjecting these critical women's health products to the complicated tensions of the safety/access balance as well as the bruising assaults of the anti-choice, anti-family planning right-wing. In the past, this convergence has created division within the reproductive health community, as was seen with Depo Provera, the contraceptive injection, and Norplant, the contraceptive implant. Women's health advocates who asked the FDA not to approve a contraceptive because of safety concerns have been seen by family planning advocates as unwitting accomplices to anti-choice efforts to block access to products that improve women's ability to control fertility. Family planning advocates who have urged approval of new contraceptive products in spite of unanswered questions about safety have been seen by consumer health advocates as unwitting accomplices to an

industry agenda that promotes fast approval without adequate safeguards for women's health.

These controversies (as well as the fact that the Baby Boomers, who drive so many marketing choices in the United States, need less and less contraception as they age) have sometimes led major companies to shy away from contraceptive products, except in cases where they expect very high levels of profitability to counterbalance their concerns about political controversy. Both mifepristone and EC fell into this category, failing to attract the interest of the big pharmaceutical companies and only advancing to FDA approval with the support of smaller companies committed to providing women access to these products.



It is interesting to note that in the case of both mifepristone and EC, the companies involved worked closely with the reproductive rights and women's health communities to make sure that women's

safety concerns were seriously addressed. This cooperative approach headed off the potential for internal controversy and created a united front of women's advocates to face the anti-choice opposition which was thus effectively marginalized.

## Lack of Credibility Undermines FDA's Ability to Protect Women's Health

Last fall, a new development in the regulation of Depo Provera proved the truth of the *New England Journal of Medicine* editorial warning that FDA's motivation for future decisions would be called into question.

Women's health advocates have raised concerns about the safety of Depo Provera for decades. Over time, research has laid to rest some but not all of the questions about the effects of this drug. One uncertainty that had remained was about Depo's effect on the strength of the bones of women using it; some preliminary research indicated that women using Depo experienced a loss of bone.<sup>8</sup> Health advocates have continually called for better information on this and other possible risks of long-term use of the method. The kind of cooperative approach that created unity among women's advocates on EC and mifepristone has not yet

evolved with respect to Depo Provera. Meanwhile, the FDA — its credibility weakened by the Bush administration’s appointment of unqualified candidates like David Hager and by denying women improved access to safe and effective EC — announced labeling changes for Depo Provera that revealed the fault lines in the women’s community.

Based on new data, submitted by the company that makes Depo, the FDA has instructed the company to add information to the drug label about bone loss and to recommend that clinicians limit use of Depo to two consecutive years. This new information is being conveyed in the form of a black box warning on the label — FDA’s most severe label warning, commonly although not exclusively, used for life-threatening conditions. Many women’s health

advocates have been pleased to see the FDA requiring that the bone loss information be provided to women.<sup>9</sup> But at the same time, the agency’s recent history of manipulating and suppressing scientific data for political ends and the Bush administration’s track record of attacks on family planning cannot help but raise questions about what is really behind this label change. Is it a genuine effort to protect women’s health by sharing new scientific evidence? Or is it a politically motivated attack on contraception, using science as a smokescreen for an anti-choice agenda? Just as the editorial warned, FDA’s distorted decision on EC has undermined the agency’s credibility and led even those who support its role as a protector of the public health to question the motivations behind these actions.

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## References

\* While this is being written, a revised application to make EC available over-the-counter is still pending and may eventually be approved, but it’s been seriously weakened by a plan to restrict over-the-counter access to women 16 and older, setting up a two-tiered system of access based on age and denying improved access to younger women.

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