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SHOULD THE HHS DECISION TO OVERRULE
FDA ON PLAN B BE REVERSED?

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Should the HHS Decision to Overrule FDA on Plan B Be Reversed?

Peter J. Pitts, President, Center for Medicine in the Public Interest, Former FDA Associate Commissioner

I. INTRODUCTION

On December 7, 2011, Secretary of Health and Human Services Kathleen Sebelius overruled a decision of the Food and Drug Administration (FDA) on the over-the-counter (OTC) status of emergency contraception.

What will be the repercussions of Secretary Sebelius's action? Why is the act itself of far greater long-term significance than the transitory regulatory action it impacts?

By reversing an FDA decision, the Secretary has set a dangerous precedent for all-comers to lobby Congress, the Department of Health and Human Services (HHS) and the White House on any and all FDA decisions—directly inserting politics into what must be a scientifically driven process.

II. BACKGROUND

Secretary Sebelius's overruling of FDA's decision to permit OTC sales of emergency contraception without any age restrictions marked the first time that an HHS Secretary has ever usurped FDA's authority over a regulatory decision.

Despite the high-velocity nature of reproductive rights and their potential political repercussions during a presidential election cycle, the more important issues relate to the erosion of faith in FDA's authority by both the communities the agency regulates as well as the public at large.

This decision directly and unambiguously injects politics into the FDA regulatory process. Even if this specific decision was made with the most altruistic of intentions, the precedent is clear—FDA is not the master of its own regulatory decisions. If this decision stands, the obvious next question is, do we even need to have an FDA? And that's a dangerous proposition.

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POLICY RECOMMENDATIONS

- The Secretary's reversal of this specific FDA decision must be reversed by direct order of the President in order to maintain trust and respect for FDA's regulatory authority.
- The ability for the Secretary of Health and Human Services to reverse FDA decisions must be removed via federal statute.
- The FDA Commissioner should serve a congressionally mandated six-year term in order to ensure the position is "above" the political fray.

III. MAJOR ISSUES IN DISPUTE

A. What are the unintended consequences of a Health and Human Services Secretary overruling an FDA regulatory decision?

Secretary Sebelius's unprecedented overruling of FDA's decision makes one thing clear—the door is now wide open to anyone to lobby Congress and HHS regarding any FDA decision not to their liking.

When asked directly if the White House had weighed in on this matter, the HHS press office refused to comment. This refusal to comment is surprising, considering the high-profile nature of this particular product and that this is the first time that a politically appointed official at HHS has overruled an administrative decision by FDA.

As the *New York Times* opined in a December 7 editorial:

After a careful review, the F.D.A. was about to approve the drug for all females of childbearing age, based on evidence that it is very safe and effective and that adolescent girls can understand how to use it and what it does (prevent pregnancy) and doesn't do (protect against sexually transmitted diseases). That was the considered judgment of agency scientists. The agency's commissioner, Dr. Margaret Hamburg, concurred after conducting her own review.

Kathleen Sebelius, the Secretary of Health and Human Services, reversed the decision, arguing that younger girls, those 11 or 12 years old, have different cognitive and behavioral skills than older girls. She offered no evidence to challenge her agency's in-depth analysis. And it is hard not to see this as anything but an effort to blunt Republican criticism in the presidential campaign or shield the F.D.A. budget from retaliation. Unfortunately, the losers will be young girls who need easy access to the pill.¹

Having served as Associate Commissioner at the FDA during the first round of Plan B hysteria, I can personally attest to the heat and scrutiny it generated—and, appropriately so. The significant difference about the last time is that it was a debate internal to the agency. There were differences of opinion to be sure—and you can argue whether or not there was political pressure brought to bear—but the decisions (whether you agreed with them or not) were FDA decisions.

B. Why don't the arguments in support of the Secretary's decision pass either scientific or political muster?

Two studies, described by FDA Commissioner Margaret Hamburg as "designed specifically to address the regulatory standards for nonprescription drugs," clearly "hit their endpoints."² In other words, both studies (of girls aged 12 to 17 and 11 to 16) demonstrated sufficient understanding of the package by those age cohorts to take the medication without a doctor's supervision.

Here's the regulatory logic as explained by Commissioner Hamburg:

The Center for Drug Evaluation and Research (CDER) completed its review of the Plan B One-Step application and laid out its scientific determination. CDER carefully considered whether younger females were able to understand how to use Plan B One-Step. Based on the information submitted to the agency, CDER determined that the product was safe and effective in adolescent females, that adolescent females understood the product was not for routine use, and that the product would not protect them against sexually transmitted diseases. Additionally, the data supported a finding that adolescent females could use Plan B One-Step properly without the intervention of a healthcare provider.³

That's a key OTC question—can the patient understand how to use the product without the supervision of a physician? Asked and answered. Yes. Efficacy was never an issue and safety is always (it is important to understand) a relative concept. Perhaps it's better, in the context of Plan B, to refer instead to benefit and risk.

The benefit is a reduction in unwanted pregnancies. The *risk* is a medical/scientific question. And the risks are minimal enough for this product to already be available OTC to older teenagers.

Then Commissioner Hamburg put the issue into its proper perspective:

It is our responsibility at FDA to approve drugs that are safe and effective for their intended use based on the scientific evidence. The review process used by CDER to analyze the data applied a risk/benefit assessment consistent with its standard drug review process. Our decision-making reflects a body of scientific findings, input from external scientific advisory committees, and data contained in the application that included studies designed specifically to address the regulatory standards for nonprescription drugs. CDER experts, including obstetrician/gynecologists and pediatricians, reviewed the totality of the data and agreed that it met the regulatory standard for a nonprescription drug and that Plan B One-Step should be approved for all females of child-bearing potential.⁴

And then Dr. Hamburg reminded us of her personal responsibility, "I reviewed and thoughtfully considered the data, clinical information, and analysis provided by CDER, and I agree with the Center that there is adequate and reasonable, well-supported, and science-based evidence that Plan B One-Step is safe and effective and should be approved for nonprescription use for all females of child-bearing potential."⁵

The regulatory science experts at FDA were satisfied. The FDA Commissioner was satisfied. Both were satisfied as to the sound *scientific* basis of the agency's decision. From a nuts-and-bolts perspective, this decision was not of the overly nuanced variety. But, what of the *moral* implications? Well, not to put too fine a point on it, who cares? The first thing we need to stipulate is that FDA does not (and should not) render its decisions based on morality. Morality is important, but it is not science. That's why FDA doesn't do death panels.

(Speaking of which, you may ask, what about expanded access programs for oncology medicines? What about the desire for conditional approvals as called for in the pending TREAT legislation? I believe there is a fundamental difference between access to potentially *life saving medicines* and every other category of FDA regulated products. That is why, in PDUFA V, there is general consensus that the patient voice must be taken into more careful consideration during product reviews and factored into the still nascent FDA concept of a more formalized mechanism for risk/benefit analysis.⁶)

So, was the decision to override FDA based on a different view of benefit and risk? Here is the explanation the Secretary gave for her decision:

Today's action reflects my conclusion that the data provided as part of the actual use study and the label comprehension study are not sufficient to support making Plan B One-Step available to all girls 16 and younger, without talking to a health care professional.⁷

In other words, Secretary Sebelius—a lawyer—studied the Teva data and decided they were not robust enough to meet the standard for approval.

That's right, the Secretary *studied the data* and *reached a difference conclusion* from the experts at FDA.

And maybe she did. In fact, let's give her the benefit of the doubt and *stipulate* that she did. This raises two important questions: 1) why did she study the data in the first place and 2) what are her qualifications to do so? Does she regularly study data on FDA decisions?

If so, did she study the data on Avandia? Did she study the meta analysis on the potential for cardiac risk for children taking medications for ADHD? And if not, why not? What about Avastin? (Even before FDA announced its recent decision to remove that drug's breast cancer indication, the Centers for Medicare & Medicaid Services announced they would continue reimbursement for this use—regardless of the FDA's decision.⁸)

Why intercede on the Plan B decision when, from a risk/benefit proposition, so little is at stake? (Another issue at play here is some sort of official BTC (Behind-the-Counter) designation—but that's another discussion for another time.)

Then there's another, more troubling, question: *how* is this happening? I don't think the Secretary would ever claim to be an expert in regulatory data analysis, so to whom is she turning for advice on these matters? Is there some double secret shadow-FDA deep within the bowels of the Humphrey Building? And, if there is, who is standing it?

According to the December 7 statement by Secretary Sebelius, "I have directed FDA to issue a complete response letter (CR) denying the supplemental new drug application (SNDA) by Teva Women's Health, Inc."⁹ She added in a subsequent interview, "There are always opportunities for the company to come back with additional data."¹⁰

If Teva decides, based on the contents of the CR, to resubmit their application, should they also send a copy to Secretary Sebelius? Perhaps they should bypass FDA altogether? After all, the agency has already signaled that they already approve—based on data already submitted—of broader OTC availability. And how closely will Secretary Sebelius and her secret FDA monitor the drafting of this CR? Will the CR be drafted in White Oak or at 200 Independence Avenue?

Senator Patty Murray has asked the Secretary to testify in front of a Senate committee to explain her scientific views on the matter. Senator Murray stated, "I want to know what the scientific evidence is that the secretary made this decision on in overriding the FDA ... Pharmaceutical companies here in this country make some very expensive decisions, and they need to know that the FDA is going to base a decision based on science."¹¹

In fact, 13 senators (Kirsten Gillibrand, Barbara Boxer, Richard Blumenthal, Daniel Akaka, Carl Levin, John Kerry, Tom Harkin, Al Franken, Frank Lautenberg, Bernie Sanders, Ron Wyden, Maria Cantwell and Jeff Merkley) joined Senator Murray in a rather terse letter to the Secretary asking, "*that you share with us your specific rationale and the scientific data you relied on for the decision to overrule the FDA recommendation. On behalf of the millions of women we represent, we want to be assured that this and future decisions affecting women's health will be based on medical and scientific evidence.*"¹²

All this to say that it's pretty tough to believe that Secretary Sebelius made this decision minus any consultation with the White House. And if she did, well, she's got a lot of explaining to do. *Qui bono?* Certainly not Secretary Sebelius.

Now let's address some relevant *social* science to add some spice and context to this historic decision.

According to the Guttmacher Institute, a nonpartisan research institute that studies sexual health, less than 1 percent of 11-year-olds are sexually active, but almost half of teenage girls are having sex by age 17. Importantly, there's no evidence to suggest that making Plan B available OTC without respect to age will somehow cause *younger* teenagers to start having sex in greater numbers. Looking north to Canada, where Plan B is sold over the counter and without age restrictions, there has been no increase in teen pregnancy, no outbreak of promiscuity in junior high school, no uptick in any drug-related adverse events. From a public health perspective, it's important to note that the United States has a teen birth rate three times that of Canada.¹³

Secretary Sebelius's claim that she's standing up for better science instead of pandering to American fears about teenage sexuality becomes more and more suspect the more and more you consider the facts.

C. What has the President done to either mitigate or enflame the issue?

Whether or not the President will receive any political benefit from this is certainly open to debate. Consider his statement on the issue. First he said, “as the father of two daughters,” he supported the Secretary’s decision.¹⁴

Really? If he had been the father of two sons, would he have felt differently? As the Feminist Majority Foundation commented, “Who needs lengthy scientific review, when apparently father knows best?”¹⁵

The President believes that 10- and 11-year-olds should not be able to buy Plan B “alongside bubble gum or batteries.”¹⁶

Such a nonserious statement should generally go without comment, but let me make just one: how many more adverse events are caused by a plethora of other OTC products? Should they all be withdrawn beyond the proximity of bubble gum and batteries? In fact, there are likely more adverse events related to bubble gum than for Plan B. (In December 2009, Ukrainian media reported that a chemistry student from the northern city of Konotop was killed when a stick of chewing gum exploded in his mouth. You can never be too careful.¹⁷)

Finally the President commented, “I think it is important for us to make sure that we apply some common sense to various rules when it comes to over-the-counter medicine.”

Whatever that means. Does it mean that “common sense” should overrule, um, *science*? Is “common sense” a wink-and-a-nod placeholder for “politics?”

According to a December 8 article in the *Washington Post*, “One former White House official familiar with decision-making on such issues said the scientific evidence clearly supported the FDA’s findings that it was safe for girls younger than 17 to use Plan B without a prescription—adding that this was a higher standard than that applied to any number of potentially lethal medications offered over the counter. *One of the President’s first executive orders was that we will use science to guide decisions and not politics*, said the official. *And I don’t understand how this can possibly square with science.*”¹⁸

Qui bono? President Obama? Well, intelligent minds can differ.

IV. RESEARCH AND RESPONSE

A. The Secretary’s reversal of this specific FDA decision must be reversed by direct order of the President in order to maintain trust and respect for FDA’s regulatory authority.

Leaving aside the peculiar politics of reproductive health, this reversal by the Secretary of an FDA decision must itself be reversed by direct order of the President in order to maintain trust and respect for FDA’s regulatory authority. Left standing it will severely undermine the authority of the FDA and embolden those who think that political arm-twisting should be used to influence agency decisions. Unless this action is undone, there will be a continued diminishment of faith in the FDA as the expert and ultimate arbiter of issues put before the agency.

B. The ability for the Secretary of Health and Human Services to reverse FDA decisions must be removed via federal statute.

So that this can never happen again, and to signal the importance of FDA’s integrity and authority, Congress must act to remove the ability of the Secretary of Health and Human Services to reverse FDA decisions.

C. The FDA Commissioner should serve a congressionally mandated six-year term in order to ensure the position is “above” the political fray.

When one considers the mission of FDA—to independently protect and advance the public health—it is not at all clear whether the Commissioner should be a Senate-confirmed political appointee “serving at the pleasure of the President.” I think that the American people would prefer he or she be nominated by the President for a fixed 6-year term—similar to that of the Director of the FBI—and then approved by the Senate. Think about it—why should the safety of food additives, the integrity of the blood and vaccine supply, and decisions on drug labeling indications (to name only a few FDA responsibilities) be considered Democratic or Republican issues? The boss of the FDA Commissioner is and should continue to be the Secretary of Health and Human Services—a politically appointed, Senate-confirmed cabinet officer.

Let the person chosen as FDA Commissioner serve as free of the political current as possible. Selection of career officials should not be dismissed out of hand. Such selections have led to excellent choices at, for example, the Centers for Disease Control and Prevention and the Food Safety and Inspection Service, two complex, important, and large organizations with critical public health missions—and both overseen by cabinet secretaries.

V. CONCLUSION

As a veteran of the regulatory wars, my argument is that the rocky seas began to roil when the position of FDA Commissioner was converted from a career position to a political position in the late 1960s. Prior to that time, the FDA chieftain was generally someone who had advanced through the ranks of the agency gaining experience and seasoning along the way. When the Commissioner's position became Senate confirmable in the late 1980s, some believe an adverse change took place. Others believe that politics is just more contentious than ever before. Both of these notions are correct.

Having had the honor to serve our country and our President as an FDA Associate Commissioner, I can unequivocally state that the unwelcome infusion of politics into science makes an already difficult job virtually impossible. To have the job of Commissioner open and only partially filled for extended lengths of time grinds progress to a halt. Low morale, lengthy delays, and even postponements often characterize an open Commissionership. This is not acceptable. Unless and until we address this and the other issues discussed in this paper, December 7, 2011, will be a day that lives in regulatory infamy.

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CITIZENS PETITION DENIED BY FDA; RENDERED “MOOT” BY JUDGE

In a related matter, FDA has denied a citizen's petition from the Center for Reproductive Rights to allow broader access to generic versions of the Plan B contraceptive for girls under 17. At issue was whether the Teva product should be taken out from behind the pharmacists' counter, making it available outside pharmacy hours—and without a prescription for girls younger than 17 for the first time.

In a letter explaining its actions to the center, FDA points out that the application to approve access to girls 16 and younger without a prescription was denied because Teva provided data for Plan B One-Step, a single-dose tablet, not Plan B. (Plan B One-Step is an OTC pill for women ages 17 and older and is available by prescription for those under the age of 17. Plan B, on the other hand, uses a two-dose regimen, as per the FDA.) According to the FDA, “In particular, because Plan B One-Step consists of a single tablet, the dosing data for Plan B One-Step could not provide support for an OTC switch of Plan B as that data would not adequately address the ability of subjects to correctly follow the directions related to the timing of a second dose that is required for proper use of Plan B.”

U.S. District Judge Edward Korman said that FDA's response rendered moot a complaint to hold the agency in contempt of court. But, the court is willing to hear arguments on whether FDA should stop requiring prescriptions for girls younger than 17 to buy morning-after pills. Judge Korman invited the Center for Reproductive Rights to file appropriate legal motions in the case, and said that Secretary Sebelius could be added as a defendant.¹⁹

Which raises an interesting question—will FDA experts testify against the Secretary? Will Commissioner Hamburg? *Qui bono?*

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