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SCHROEDER LECTURE

THE ROLE OF SCIENCE IN HEALTH POLICY DECISION-MAKING: THE CASE OF EMERGENCY CONTRACEPTION[†]

Susan F. Wood^{††}

Thank you, Professor Mehlman and Dean Simson, and thanks to Case Western Reserve for inviting me to provide this lecture and to be the Schroeder Scholar today. It is a real privilege and an honor. Contrary to remarks, being here with those who've spoken before, is rather humbling, and I'll try to live up to that, but you can be the judge of that.

It's also humbling to try to speak in front of a group of law students and law professors knowledgeable in legal and in policy issues far more than I am. I lived and learned by doing in terms of how to create health policy and being involved in health policy at the Food and Drug Administration, coming at it from the perspective of a scientist and a biologist, who then followed a rather zigzag career and immersed myself in public policy and health policy, specifically around women's health. But, I think, the connection is to areas much more broad than that, in terms of health across the spectrum and in, also, other areas of public policy that depend on good science and good decision-making that's based on that science.

So today, I'll talk about the case of emergency contraception. That's the most legalistic way I could think of saying it. It's, in part, a

[†] Edited from the 2006 Schroeder Scholar in Residence Lecture sponsored by the Law-Medicine Center at Case Western Reserve University School of Law on September 27, 2006. The Schroeder Lecture is conducted on an annual basis. This version has been edited for publishing purposes and does not contain the lecture in its entirety. The full transcript is on file at the Law-Medicine Center and at the offices of the Health Matrix: Journal of Law-Medicine (publisher's note).

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story about how FDA works, and it's in part a story about how science is used in this type of decision, normally, and then a story of what happened when science is, in fact, ignored. Things have been changing over the last few months, so we'll try to keep everyone up to date as to what the status is on this particular case. But, I think the issues of how an agency like the FDA, which we count on for so much, needs to make its decisions and how it has made its decisions in recent years, gives us pause, gives me pause as a scientist. I hope it gives you pause as a legal experts and scholars, and it certainly should give the public pause — and this includes all of us — when the public counts on the FDA for good decision-making. So I'll just go ahead and get started with that.

Now, I have been the assistant commissioner for women's health, and I want to talk about the fact that women's health is not just reproductive health. So my position within FDA included the role to ensure the appropriate focus on women's health across the FDA. When I talk about women's health, this is a definition by public health service that was actually created some years ago but serves as sort of a basis for what we mean by women's health. And so it is those things that are unique to women such as pregnancy, ovarian cancer, and conditions like that. It is things that are more prevalent in women like lupus and other auto-immune disorders. It is also things that might be more serious in women such as the consequences of sexually transmitted diseases. And, finally, it is those conditions for which the risk factors might be different in women — and that could be HIV-AIDS or heart disease — or where the intervention or care might be different, which would include all of the above because as we learn more about some of these distinctions, we learn when they exist and when they don't exist, where there are differences and where there are similarities, and that data helps then drive appropriate intervention or care. So that's what we meant by women's health and still mean by women's health, and it includes reproductive health, but it is not limited to reproductive health.

This gives an idea of the range of issues that we mean by women's health — from mental health to inclusion of women in clinical trials, analysis of sex and gender differences, menopause, heart disease, and so forth. It's not a limited view. But, unfortunately, it was on something around reproductive health, even though that's not something I spent much time on, that was what led to my resignation in August of 2005, and no one was more surprised than I was. This is the vision of women's health in terms the research that needs to be done, the knowledge that needs to be gained, and the application of that knowledge in the development of drugs and devices and so forth that are regulated by the FDA.

What FDA does and, in this case, we're talking about an intersection between law, science, and other factors. FDA was created under statute, and I'll talk a minute about that, but it depends on the data that is generated under certain required studies and evaluation by both internal and external experts and is driven towards the mission of promoting the public health by applying this knowledge in the constraints, the legal and regulatory constraints, that surround it.

I want bring you up to date on the latest decision on Plan B, then we'll drop back and figure out how we got there. Just a few weeks ago, FDA announced that we are, indeed, going to allow Plan B emergency contraception as an over-the-counter drug that does not require a prescription. It will be limited to those eighteen and older. Women under the age of eighteen will still require a prescription. Because of that status, it will be available only through pharmacies and health clinics, and the company has some other requirements in terms of marketing requirements and so forth. This was a dramatic change from where it was a year ago. It is not, still, a fully correct decision, in my view, but it is a movement in the right direction. So how did we get to this, and what does it really mean that we've now gotten to this sort of partial approval?

Now, I'm going to have to go back and, for those of you who are experts in FDA law, this will be very basic. For those of you who are not, I hope it's educational. FDA has a very broad mandate to ensure that products are safe and effective — that they are accurately represented in labeling and in any information that comes out about a product and that they comply with the numerous laws and regulations that exist around FDA. FDA is not just drugs. Food and Drug Administration gives you a clue as to one of the other major things that it regulates, but it does regulate drugs in terms of both brand name drugs and generic drugs, in terms of prescription and non-prescription drugs. It's not just approving new drugs but monitoring their safety after approval. It's also inspecting the manufacturing plants to assure quality control of production, both in the United States and around the world. It's also responsible for biologics, which includes the vaccine supply as well as the human blood supply, in terms of safety, animal drugs, as well. Medical devices and radiologic health, that includes medical devices such as what might be implanted in your hip or in your heart. It's also products such as breast implants. It's also any device that might be used in surgery, medical equipment, x-ray equipment, all mammography facilities, things that emit radiation like x-ray and mammography. It's also things like computer terminals and television screens and microwave ovens in terms of the radiation emission. So FDA has this huge mandate around all of these products.

FDA is responsible for ensuring the safety of much of the food supply, so, all of your reading about the spinach and E. coli at the moment is under FDA jurisdiction, and they're busily trying to sort that one out. They regulate food except meat and poultry, including fresh fruit, seafood, and processed food. They work to ensure that the manufacturing plants, the transportation, and the storage of these products are all maintained to standards to ensure safety from contamination from things that may come across international borders but also from terrorism, now. That has been added to the list of things to work on and be responsible for.

So there's this huge, very broad and very deep mandate for FDA and responsibility for FDA; and most people, unless you're involved in FDA law or science, should not have to really pay attention to that. Each one of these product groups has its own center within FDA. It has its own statutory authority, which differs one from another. Drugs and biologics probably have the most stringent requirements on demonstrating safety and efficacy of products, less so for medical devices, less so for foods, and less even so for cosmetics and dietary supplements. Each one these has its own statutory structure and infrastructure and regulations that flow from that.

So what I'm going to talk about has to do with the particular drug product but, because the action and the issues that are identified have to do with decisions made at the highest level of FDA, to whom all of these centers report, it reflects upon issues that are important across the agency.

Now, I'm going to tell you a little bit about Plan B emergency contraception to make sure we are all on board as to what this is about because I think many people rightfully think that this is a very controversial subject, and because of its controversy is perhaps unique and, therefore, it is more understandable in terms of how it was handled differently from other products. But in fact, I would argue that this is actually not a controversial subject. For the vast majority of the people in the United States, it is not a controversial subject, with regard to the science and medical evidence, and it's really not a controversial subject with regard to how it should be handled within FDA.

So what is emergency contraception? It is, in fact, just high dose birth control pills. It's the same hormone that's found in many birth control pills, progestin. It's a progestin-only birth control pill. It contains no estrogen. It acts the same way as regular birth control pills do, using the same biologic mechanisms. It's a method that's been around since the '60s when physicians and nurses and student-health clinics knew that if emergency contraception was needed, you just take two or four or six of your birth-control pill pack, and do that again in

twelve hours, and you would reduce the likelihood of pregnancy after unprotected sex.

However, it came as a special product in 1999 — before that, it was unapproved use; an off-label use of an approved product was how it was used in this country and around the world during the '60s, '70s and '80s and first part of the '90s. But in the middle of the '90s, the FDA put out a notice in the Federal Register asking companies to come in if they were interested in putting forward a product that would be an approved use, seek approval for this off-label use because it was so widespread, and there were a lot of studies and evidence available for it, and, therefore, companies should know that FDA was interested in looking at applications for these types of products.

Two products came in. One was an estrogen-progestin combination product called Preven. That product is now, largely off the market. A progestin-only product, which has fewer side effects in terms of immediate side effects, came on the market in 1999. And that was Plan B. The manufacturer then in 2003 sought over-the-counter status, sought to change it from prescription to non-prescription status. And that's a rather routine application when you're seeking a change, a labeling change and a status change through the FDA.

It is very important to point out that this product does not cause abortion, and its only connection to abortion is that it can prevent the need for one. This is why this is actually not controversial and should be common ground. It is very, very safe. There is no disagreement in the medical and scientific community about the risks of this. It has a very good safety profile. There are very limited risks associated with it. It's a very safe product in comparison with other over-the-counter products already on market. It is quite safe, and there is a very strong consensus about that.

An important factor is that this needs to be taken very soon, within hours, in order to be effective. It is labeled by the FDA for use up to seventy-two hours after unprotected sex. The World Health Organization indicates it can be taken up to five days after unprotected sex. However, everyone agrees that it loses efficacy over time. So it may have some minimal effectiveness at five days out, but, really, if you really want reduce chances of unintended pregnancy, sooner is better. Twelve hours is better than twenty-four hours, twenty-four hours is better than forty-eight hours, and so on. Sooner is better. Thus, there is a need for ready access; barriers that take time actually reduce the effectiveness of this particular product.

It's important that this provides a woman a second chance to prevent an unintended pregnancy. For whatever reason, a broken condom, missed pills, a rape, or just the case of unprotected sex, this is a second chance to actually prevent unintended pregnancy. This is not

RU-46; it does not cause an early abortion. It, in fact, acts the same way regular birth control pills do, and, therefore, if you're comfortable with birth control pills as a method of contraception, you can be equally comfortable with this. And, similarly, those who object to emergency contraception, for whatever their rationale happens to be, to be consistent one has to also object to all oral contraceptive methods and to the IUD. So this is squarely in the family of regular contraception and needs to be considered that way, not something different than regular birth control pills in terms of its mechanism of action.

So, now we're all up to speed on that. Now we get to go over FDA 101. And, again, my apologies to those who are more expert on this than I am. When FDA receives an application, it comes in from the company. The company has to initiate its application for a change. This is not something FDA can do or usually does in terms of changing the status without an application. The application comes in, and, in this case, it would have gone to the Center for Drug Evaluation and Research (CDER), and it will then be referred to the appropriate review divisions. In this case, these are teams of scientists and physicians who are looking at the chemistry, the physiology, the pharmacology, looking at the clinical aspects, looking at the manufacturing if it's a new product, and so forth.

So we have two divisions, actually, who are looking at an application to go over-the-counter. One, it goes to the division that reviews all over-the-counter drug products, the OTC group. It then goes to the home division for this type of product. So it goes to the reproductive health and urological drug products review team. So these two divisions receive the application for a product to go over the counter. They then begin the evaluation of the data that's submitted to them.

FDA has the option, and it is optional, to convene its outside advisory committee. Now each of the review divisions for all the different areas, in drugs and devices and so forth, has a standing advisory committee made up of outside experts. They can bring in additional experts for any additional advisory committee, but that advisory committee is convened at the call of the FDA, and it addresses questions that are posed by the FDA. They have presentations by the manufacturer, presentations by FDA staff, public comment and then discuss and vote on particular questions that are posed by the agency to the outside advisory committee. If such an advisory committee is called, it's after that that the reviews will be completed and recommendations would be generated by the reviewers. It then goes up a review chain through the Center for Drug Evaluation and Research. It goes to a chain of review from the review teams up the hierarchy until a final decision is reached and delivered.

FDA did convene a joint advisory committee between the OTC group and the reproductive health advisory group and convened a meeting in December to look at this, and then this chain of events occurred. Now there are a number of different places where decisions can change at FDA. The FDA does not have to take the advice of its advisory committee, and that's a prerogative held dear by the agency. There are identifiable cases where the FDA did not accept the recommendations of the advisory committee in terms of approval or disapproval. Sometimes it's because they had information that the advisory committee did not have. Sometimes it's because the advisory committee is making recommendations that went beyond the scope of the legal authority or regulatory authority of the agency. Sometimes it was just because there was a disagreement in the interpretation of the data, and they came to different conclusions.

So overruling the advisory committee is not something that, for folks inside FDA, gives people inside the FDA particular heartburn. It looks unusual from the outside, but it is not something that is inherently, by its nature, a problem. Not accepting recommendations usually happens at the reviewer level. The team of scientists and clinicians who know the data best have poured through the, usually, thousands of pages of data and studies that have come in. That's where, if there's going to be a disagreement, that's normally where it takes place.

Now after the review level, the reviewers then make their recommendations up, the two divisions to their division directors to approve or disapprove. Maybe there need to be further safety studies done. Maybe there are questions about the quality of the data, or maybe there's complete agreement. In any case, they report up to the division directors, then each division director reports to an office director, and there are about six or seven office directors in the Center for Drug Evaluation and Research and their attended divisions. Then the office directors all report to the Office of New Drugs who reports to the Center Director. And it's usually, if there's agreement, the decisions are made, the recommendations go up, and, if there's agreement at the reviewer level the division level and office director level — in this case we have two groups working on it, so we need the two office directors to agree with each other. If that's the case, if there is agreement, then that's normally where the decision is issued. It stops mid-level in FDA in the Center for Drug Evaluation and Research to issue a decision if there's agreement. If there's disagreement, and something has to be sorted out, it's sorted out throughout the hierarchy until it there's agreement. Occasionally, it might go up to the Office of New Drugs. Quite rarely it would go to up to the Center Director. It's quite extraordinary to get to the commissioner's office because usu-

ally, the disagreements have been sorted out one way or another before that.

But that's the hierarchy and the points of change that can occur within the Center for Drug Evaluation and Research. So what happened with Plan B? As I mentioned, the company came in with an application in the summer 2003 to bring it over-the-counter. The type of data you have to bring in for this type of application is not safety and efficacy data. That's the data that's been brought in for a new drug application to get it approved as a prescription drug. The type of data you have to bring in for this type of application is, primarily, label comprehension data and actual use data. So you have to show that the label is understandable and that people can use the product according to the label without the help of a learned intermediary, without the help of a doctor, a nurse-practitioner or other proscriber or a pharmacist. That's the type of data you have to show. And that's the data the company came in with. In December 2003, there was an advisory committee where this data was presented by the company. The data was also re-presented, re-analyzed, and presented by the FDA professional staff. It had the support of going over-the-counter from the American Medical Association, the American Academy of Pediatrics, and the American College OB/GYN. It also had strong public support, although there was this rather lively public comment session, but it was clear from the data and from the process, and it went that far that this was a very strong application. The data was quite clear, and it had a real possibility of public health benefits by being able to provide a method for women to prevent an unintended pregnancy. This is all to the good.

Everyone was quite optimistic at that point, except after that advisory committee meeting we began to hear a couple of different things inside the FDA. We began to hear that the answer was going to be no, and it was going to be about teens. We began to hear the decision was not going to be made at the office director level but would be made at a high level inside the FDA. So the reviewers heard all this, actually, before they had completed their reviews. This was rather disturbing, and they provided more data to answer questions that were being posed from above.

So they wrote up their reviews, and they all recommended approve, not approvable, which is the next step, but approve for all females of child-bearing potential. Both divisions recommended approve, the division directors concurred and recommended approve, the office directors concurred and recommended approve. They were then told no. This is — we normally would recommend a decision, but this will not happen this time. It went up to the head of the Office of New Drugs. He concurred quite strongly and recommended approve. He

was not allowed to issue that decision. And then it went up to the next level, when in May of 2004, when the Senator — well, that's some sort of Freudian slip. The Center Director sent a non-approvable letter. A non-approvable is significantly different from approve. It could have been an approvable — would have been the next level saying we're going to approve it, but you have to work something out. He actually went from a full-blown approval recommendation to a non-approvable and said that the company — that it was indeed about teens and that the company would have to submit further data on young teens in terms of their actual use and label comprehension studies, or they should come back in with a new application keeping it prescription status for those under the age of sixteen and non-prescription for those sixteen and older.

Now, some of the arguments here were public debate, and the public debate was around the concern that access to emergency contraception would promote risky sexual behavior, particularly among young teens. And that's a reasonably valid question. I understand the kind of worry that it evokes in parents, but, none-the-less, there's actually data to address that question. There have been studies done in the United States and in the United Kingdom looking at behavior change when there is access, ready access, to emergency contraception. And, as many of you probably know, it is very difficult to change people's behavior, particularly sexual behavior, and access to one more form of over-the-counter contraception does not change anybody's behavior in terms of the regular contraceptive use, in terms of risky sexual behavior. The only behavior it changed somewhat, and not as much as we'd like, is if a woman needed emergency contraception, she is more likely to reach for it and use it if it is readily available. She's not likely to need it more often, but when she needs it, she might actually use it, which might be a good thing.

That's what the data told us. That data was presented, but that's not the technical or legal or regulatory issue that was facing the agency at that time because that was not really, technically, what you're supposed to show in an over-the-counter application. You have to show actual use and label comprehension. Can you read the label and use it correctly based on this label? Those are the studies you have to present in order to demonstrate an appropriate movement to over-the-counter status. The letter from the Center Director said that the issue was there were not enough very young teens under age sixteen in the label comprehension and actual use studies that have been presented. And it's true. There were not many, there were some, but not many. Not enough to do a separate a sub-population analysis on that group of under-sixteens. It was a representative population of users, but it was not a large enough sample to do a statistical analysis.

And, so you say, well that seems a reasonable question. Maybe we should know if young teens, particularly, can read the label and understand it and use it correctly. Now it is a very simple label. It has about two or three steps. Take one now, take one in twelve hours. It's very simple. But, okay, that could be a fair question, except that FDA has never asked that question of any other over-the-counter medicine, ever. We don't ask if young teens can read the labels about pain medication, which they might be taking for menstrual cramps or migraines and might overdose on. We don't ask that question about cough medicine or cold medicine that's over-the-counter: can young teens understand the label correctly? We've never asked that. On the flip side, we have never asked — FDA has never asked — can people at the age of eighty read and understand and use the product correctly for any over-the-counter medication in combination with however many other medications they might be taking? We don't ask for sub-population analysis on different groups of those who might use the product based on a particular concern. Now, maybe we should. But we never have, but on this product at this time FDA insisted and denied approval of a product based on something that was unprecedented.

You have to remember that this is a very safe product. As I pointed out here it was a unanimous vote by the advisory committee that it was safe in an over-the-counter setting. So, there really is no question that even if they read it wrong and used it incorrectly, there's not a safety issue here. And that's, I think, critical when looking at when each drug is different and so forth, there really is no safety concern.

So in May of 2004, this decision was announced over the objections of everyone inside the professional staff at FDA below the Center Director. I'm not part of the review chain. I was part of the commissioner's office, but I disagreed with this decision. But I did not resign, because I think the Center Director did believe at that time that if this was done, for whatever reason he did this for whatever reason he felt the need to do this, that if he did this, in six months time he would be able to approve it, and that a partial approval was better than no approval. And that for if some reason he would not be allowed to approve it, in total, but he could get away with this limited approval. And so he made this decision to overturn the science and overturn all the recommendations and send a non-approvable letter and ask for a different status but laying out a path forward. So we all just went quiet and didn't ask any questions and hoped that the next round would be smoother.

So the company came back in that summer with an application asking, just as FDA had suggested in the letter, that the product only be approved over-the-counter for those sixteen and older. Six months

go by — that's normal FDA timeline for reaching a decision on a product like this — and it's now January of 2005. Now, I happened to be out of the country at this time. I was on a fellowship working with the FDA equivalent over in London, having a great time. But I was staying in touch with FDA, my colleagues back at the Office of Women's Health but also, various and sundry people in different parts of the agency on different issues I was working on. I know, quite conclusively, that in January of 2005, the Center for Drug Evaluation and Research had agreed that it would approve Plan B, emergency contraception over-the-counter.

Now at this point there had been a slight shift, now it was going to be seventeen and older. This was sort of a technical rationale based on the nature of the data that had been submitted, but it was also a rationale thinking we need to make sure we dot all our i's and cross all our t's in order to get this out. But we've now reached a conclusion. It is going to be approved. It's going to be approved for seventeen and older, and it's going to happen in a matter of days. It's going to be a straight approval letter, not an approvable. It will be a straight approval letter. It will go out within days, maybe a week, tops. We thought great, we will take it. We will take it. It's a compromise. It's ignoring young teens, and there's no rationale for doing that, but we'll take this for now. And then months go by, and the letter is not issued, the approval is not announced. Inside FDA we live behind a wall from which you cannot talk outside. So it wasn't unusual that people outside didn't know what was going on, but what was extraordinary was that no one inside knew what was going on.

This is a rather disturbing aspect of the whole story. So, during this period, all sorts of things began to happen outside of the agency. Months went by with no decision being announced. At that time, Dr. McClellan, the former Schroeder Scholar, had left the agency, just before the May of 2004 decision. He moved over to the Centers for Medicare and Medicaid Services, and he was replaced with an acting commissioner, Dr. Crawford. Dr. Crawford was still acting commissioner by the next spring and had become nominated to be permanent commissioner. However, Senators Murray of Washington state and Senator Clinton of New York put a hold on his nomination before his Senate confirmation, saying that there must be a decision, not what the decision should be, but that FDA had missed its statutory deadlines and, therefore, needed to issue a decision before they would confirm Dr. Crawford as permanent commissioner of the FDA.

This went on for several more months until a promise came from Dr. Crawford and Secretary Levitt, Secretary of Health and Human Services. They promised that, by September 1, FDA would take an action on the Plan B application. And so Dr. Crawford was confirmed.

I returned from the U.K. and, catching up on a whole host of things, but also asked what was going on with Plan B, and I asked at multiple levels — at the reviewer level, the division level, office director level, all up and down the chain into the highest levels of the commissioner's office to the professional staff. And the answer was sort of both surprising and disturbing, and also quite consistent. Throughout the agency within the review chain and into the commissioner's office the answer was we don't know. We have no idea. No one's asked us for any more data. No one's asked us any more questions. No one's asked us for any more memos. No one's told us what the decision is. No one's told us what's going to happen. We have no idea. And that was at every level inside the agency. When I got to the highest points in the commissioner's office, people who had been at the agency for years and who are extremely influential told me and, I believe quite honestly, that they didn't know what the answer was, but they were waiting on the answer.

This is now mid-August, and we're waiting on the answer. Now we're not waiting on it from the FDA review process. That decision had been made before January. It was ready to go and ready to be signed in early January. And here we are in August, and we are waiting on the answer, and we don't know what the answer is. And this is quite disturbing to me, not that I didn't know the answer. That's okay. But the fact that the people who knew the data best, who had been involved in the review process for the last, at that point, two years, did not know the answer.

So here we are on August 26, ironically, Women's Equality Day. It's the anniversary of the day that women got their right to vote. It was a Friday afternoon, and Dr. Crawford held a press conference alone without anyone from the Center for Drug Evaluation and Research there and announced that, yes, indeed, CDER is prepared to approve it for those seventeen and older. However, we need to open this for public comment and possible rulemaking on the issue of the two tier status, keeping a prescription for young teens and non-prescription for older teens and adults.

Now this is what FDA asked for nearly a year and a half earlier, and, yet, now we've decided we have to go into rulemaking. Being with an audience of law students and law professors and legal scholars, I assume you know how painful and long a process is of federal rulemaking. It takes years on a good day, and never if they don't really want it to come out. And, if you're involved in federal rulemaking, you want to be doing it for a very good reason. If there's a reason for developing a regulation, that you're doing it for a higher purpose and that you're going to have a concrete step forward when that rule is completed.

But there's no rationale for this rulemaking. The argument was this is such a novel and complex issue that had been proposed to keep it prescription status for one group and non-prescription status for another was so novel and complex that we needed a regulation on how to implement that situation. And so we were going to start the process of rulemaking. Now, we have to remember that the decision at this time was a very simple one. The question was do we allow access to a safe and effective contraception for women, essentially adults, seventeen and older, are we going to allow that to happen? And there was something so worrisome about that concept that it could not be allowed out. We've already cut out the young teens inappropriately, but we've cut them out of the equation. Now we're left only with, essentially, adult women with a safe and effective contraception that can prevent unintended pregnancy, prevent the need for abortion, and why is that so frightening?

I think when I heard this decision on the day, August 26, and I realized that it wasn't just me that had been left out of the loop, but I knew that the senior-most people in the Center for Drug Evaluation and Research — they weren't aware of this decision until right before was it announced, who did not recommend the need for rulemaking. There's no need for this process, but I knew, no matter what evidence came forward, no matter what rationale came forward, that this product was not going to be allowed out. And as head of Women's Health, I'm supposed to be able to — as part of my job — to explain what's happening with FDA and in particular, women's health issues, whether it's menopause, or inclusion of women in clinical trials, or diabetes and the products available for diabetes, this was not explainable. This was — there is no rationale. There is no justification. Either on a process basis or a scientific basis or a medical basis, this was not justified in any way. They were putting it into a bureaucratic black hole where it would disappear, and in their mind, it was a very strategic decision on their part.

So I resigned. And it was, in part, it was this issue of both scientific and personal credibility and was not, necessarily, to make a particular stand or a particular statement. But I was extraordinarily distressed by this decision because it was after years of working on the inside in a very collaborative and collegial way. It became clear that on this particular issue it didn't matter what rational discussion you brought to it, you were not going to succeed. So I resigned at that point, and an enormous amount of attention was generated. That attention, I think, led to, ultimately, why we have changed today, not that my resignation caused any change, but the fact that people became aware and energized and outraged at what was going on at FDA and began to ask the question. Whether they were folks involved in law

and policy or involved in reproductive health or women's health, or public health, or the research community or the clinical community began to say what is happening at FDA? This is a clear and obvious overturning of good science and good medical evidence for no good reason. This cannot be allowed to stand. And so, I think, the energy that came from around the country was what ultimately led to, at least, the partial success we had earlier this year.

And I think that when we are talking about decision-making for health policy we want it to be based on the best scientific and medical evidence, recognizing limitations to what we know, but we have to make judgments, and they also must promote the health of both the individuals and of the public health. And, unfortunately, this decision did neither. It left things in a rather dark and hopeless place, at that time, in terms of this particular issue but also in terms of what was happening at FDA in terms of the morale, in terms of the feeling amongst people not in that particular review chain, but throughout the agency in terms of were they valued as scientists? Were they valued as people who were doing their jobs, committed to the public health mission of the FDA? Was science going to be overturned in such a clear and obvious way in others cases? There are some serious issues here.

Meanwhile, there's a lawsuit that is pending, *Tummino v. Crawford*, and now it's *Tummino v. Von Eschenbach*, because — oh, I forgot to say that about a month after I resigned Dr. Crawford resigned. After the amazing amount of energy and effort it took to get him confirmed, he resigned about two months into the job as permanent commissioner. I have no idea why that occurred, but it led to a new acting commissioner Dr. Von Eschenbach. Dr. Von Eschenbach came over from the National Cancer Institute, and he became acting commissioner early on, not long after I resigned. It was a real opportunity for him to say that we're going to go back to doing things based on the evidence. I'll take a fresh look at it, and, with my evaluation, it looks to me that we should let the Center for Drug Evaluation and Research make its decision in a more routine fashion, and I don't need to be involved.

Unfortunately he did not say that. He continued to say for eleven months that this was such a novel and complex issue that having a dual status that we needed to go for this public comment period, and we now have all these thousands and tens of thousands of comments that needed to be evaluated. And it was still a very complex issue that need to be sorted out. So he, basically, took the same position as his predecessor until he didn't, in July. But, meanwhile, in January of 2005, after the delay, and we were having that second round of delay, the Center for Reproductive Rights filed a lawsuit against FDA on

behalf of organizations and individuals basing it on the Administrative Procedures Act and constitutional grounds of right to privacy and sex discrimination. They're seeking to force approval for Plan B, over-the-counter for all females of reproductive potential not limited by age. During the course of this, they were given the ability to depose government officials. And they have deposed Dr. McClellan and Dr. Crawford, the head of the Office of New Drugs, the head of CDER, a number of the reviewers and office directors involved in the decision. That served a very valuable purpose of getting us some more information about what happened, although we don't have any direct information about what happened at the commissioner level and above because they're not talking much about it. But it has been an opportunity to learn more, and this case still continues even though what happened with this past August with this partial approval.

So how the impact this legal case will play, I don't know. I've learned a lot as it's gone along, and I continue to try to understand because my position, upon my resignation, was that I didn't know if it was illegal what the commissioner had done. He does have the delegated authority, and he has authority to pull up decisions to his level rather than delegating it down the chain. But I certainly did know that the process was not usual and the process ignored both the evidence and ignored the normal way of reaching decisions in a place where there was actually no controversy over the actual data itself.

In November of 2005, after I resigned and after — while it's in the middle of rulemaking — the GAO issued a report talking about the first decision, the May of '04 decision. So it was the first decision that cut out the young teens. They had been asked to do an investigation of that first decision and came to the conclusion, which is summarized in this title, that “the decision process to deny the initial application for over-the-counter marketing of the emergency contraceptive drug, Plan B, was unusual.” It was very unusual. But the decision that was after that, the 2005 decision to put it into rulemaking was even more extraordinary and even more unusual and even more outrageous. So there's documentation now between both the lawsuit and the GAO investigation that documents these actions and how extraordinary the decision process was.

So now we're at July 31, 2006. So another year goes by or eleven months go by and all of a sudden Dr. Von Eschenbach announces that there is no need for rulemaking. Now, coincidentally, this was the day before his confirmation hearing in the Senate. And once again Senators Murray and Clinton had announced that they were putting a hold on his confirmation, and there was no way this hold was going to be lifted. And they did have the votes to keep this nomination from being voted on the floor of the Senate until the issue of Plan B was resolved

one way or the other. That hiding behind rulemaking was not acceptable. That no one believed that this, in fact, was a legitimate use of rulemaking and, in fact, was an abuse of the rulemaking process.

So he did announce that there's no need for rulemaking, and there was this new way to get possible approval for women eighteen and older. Now, notice the age has shifted once again. It's now up to age eighteen. Now he does not argue that there is any scientific rationale for changing between seventeen and eighteen. This is merely to improve convenience of implementation in pharmacies. There's no real reason for doing that either. But, nonetheless, he's put his own mark on this decision, his own input and raised the age to eighteen.

So he announced that that was possible and that he would like to meet with the Barr Pharmaceuticals, the company that owns Plan B, within the next week, and then the process would start up again. What was extraordinary was that within about three and a half weeks this process is complete. A process that has taken three years now can be done in three weeks. The company met with them. They submitted a supplemental application, which only changed the age. They had already said that they would only market to pharmacies. They had already said that they would carry on education and monitoring programs. They had already agreed and offered to do all of that in many earlier applications. And the only thing they did was shift up to age eighteen. And, low and behold, within about three weeks, it is, in fact, approved over-the-counter for those eighteen and older.

And, again, no one was more surprised that I was. But I give a lot of credit, again, to the voices of the public and the scientific community and those who care about FDA functioning as a strong scientific organization for keeping it visible. But FDA had strayed, quite clearly, off the path of good science and good decision-making. I put this up here. (Projected image.) This was a cartoon that came out right after the intelligent design case in Pennsylvania and was published by the Pittsburgh Post Gazette. And I put it up there, and I have to be very clear that I'm not criticizing those folks that work for FDA. I'm worried about the future of FDA. I'm worried about people looking and saying, "Is this a good career option for me? Is this somewhere I want to go to work as a scientist or anyone, a regulator, given this type of morale problem that this has generated within the agency?" As I mentioned earlier, Dr. Von Eschenbach is now nominated, and we now think his nomination will move forward. The hold has been lifted. But there is no evidence to continue this age restriction, and we still have FDA as a gold standard at risk. We still have damaged its reputation through this type of action, and it's not just this drug, but we now know it can happen anywhere across the agency if there's a small group of people with that much influence.

Here are places to get more information. (Projected image.) You can also get more information from the Center for Reproductive Rights, which is clrp.org, with regard to the lawsuit. These are other places for both scientists and the public to get information on what the status is on emergency contraception.

