

Mr. SOUDER. Let me start with the questioning. And first, if we are going to have any kind of reasonable discussion, let's cut out this cardiologist stuff and so on. There is a major difference between the exceptions in fraud that we see in the scientific community in fields of research where we have had research for decades and decades, and fraud in the sole big case touted in journals and touted by all sorts of researchers in a field that has no history of such research, and the question of whether the fraud involved was endemic to the process. Don't treat us like little children and try to BS us. It is not going to work.

Now, one of the things that Mr. Waxman, Mr. Cummings, and I have had a question about baseball and steroids is whether or not you can trust an institution to patrol itself when they have a financial stake in the matter that is being investigated.

And Mr. Pascal, you went through this detail, but you said the first, basic, where you get your information whether there is fraud is whether the grantee discovers there is fraud, who clearly has a conflict of interest. Could you elaborate on this and how you would—how we find out, if the institution chooses to cover up? Because South Korea had tougher laws than we have in the United States, and they weren't followed.

Mr. PASCAL. Well, it is true that an institution can have a natural preference for not finding research misconduct. It can lead to embarrassment, it may lose—loss of funds from NIH or whoever the funding source is, or whatever.

But based on ORI's many years of experiences with institutions, we think most of them want to do a good job in finding out what actually happened, and make findings when it is appropriate. In fact, some institutions make findings of research misconduct that ORI does not pursue because we don't think the evidence is substantial enough to support a finding that we could uphold in an administrative hearing.

Also, part of this is in the structure of the regulatory process. Our new regulation has followed the policy established by the Office of Science and Technology Policy which was adopted in 2000, which states that research institutions bear primary responsibility for prevention and detection of research misconduct, and for the inquiry and investigation and adjudication of research misconduct alleged to have occurred in association with the institution.

There are also a number of checks and balances in the ORI regulation. ORI has oversight review over the institution's findings. The institution sometimes will make minimal findings or weak findings, and ORI will come in and do additional analysis and investigation with its scientists, and we make additional findings.

There is a regulatory requirement that the institution must utilize experts in the relative scientific field, and must ensure objectivity in the investigation. That is a regulatory—

Mr. SOUDER. Let me ask a followup question and we will submit your full answer for the record.

Mr. PASCAL. OK.

Mr. SOUDER. Because that is basically the procedure that Korea had.

In ORI, you have given a major grant to University of Pittsburgh researcher Gerald Schatten, who is the co-author of these studies,

who withdrew after the fraud became public, but who was co-author. And I am going to have some detailed questions that we submitted before and we are trying to get the answers to.

But given that he cited this Korean research multiple times in his grant application, are you in the process of reviewing that grant? And do you have a process—because in effect, what you were just giving me is a whole process that, if the review was weak, if you had questions about it, then you could step in. Are you reviewing this grant?

Mr. PASCAL. Due to ORI confidentiality constraints, we cannot admit nor deny any specific—

Mr. SOUDER. OK. Let me re-ask. Do you have the authority to review this grant based on the information that came out that he had been a co-author of the fraudulent study in Korea?

Mr. PASCAL. If there is a matter that involves PHS funds and alleged research misconduct, yes, ORI would have authority to review the results of the investigation by the institution.

Mr. SOUDER. And Dr. Battey, I am going to read a number of questions here. You have been—we sent these over 2 years ago. Your response to some of the questions was—not these particular questions, but you responded slowly to some of the others. But we are trying to make a policy. And I am going to read a couple of these. If you can kind of give a general feeling, and then submit back in the record regarding Pittsburgh researcher Schatten's question.

One is, how much money was spent on human embryonic stem cell research in 2005, and how much of that went to University of Pittsburgh researcher Gerald Schatten?

Also, is his research on the Bush-approved stem lines as well as on primate embryos, and could you separate that funding for us?

Also, of his \$16.1 million, how does this compare to other people who have embryonic stem cell grants? If you could give us his rank in terms of grants for the research on monkeys and approved stem lines, and how many grants he has been awarded. And is he your top single grantee? Because his grant makes reference several times to this Korean research, which he was co-author of till he withdrew after the fraud became public.

And also, will you give us the 2005 figures for ESCR grant awards? How many grants, total dollar amount, smallest grant award, and largest grant award? Because quite frankly, and your agency is doing oversight, this is just basic data, and it shouldn't take 2 years to get to this oversight committee to get basic data.

Now, if you don't have it today, although we did submit these in advance.

Dr. BATTEY. Let me do the best I can to answer your questions immediately.

In fiscal year 2005, NIH supported about \$40 million in research involving human embryonic stem cells. In fiscal year 2005, Dr. Schatten's NIH-supported research involving human embryonic stem cells was approximately \$1.1 million.

Getting to your issue about size of grants, Dr. Schatten is not the champion in terms of garnering NIH support for human embryonic stem cell research. Larger awards have been made, and in fact, an award of a little over \$4 million was made to WiCell, which is a

biotechnology firm associated with the University of Wisconsin, to form the National Stem Cell Bank, which is an effort to make the stem cell lines that are eligible for Federal funding more readily available to the research community.

In fiscal year 2005, NIH supported 154 individual research projects involving human embryonic stem cells at the total amount of about \$40 million. Of these, the smallest grant was \$2,000 awarded to NGRl Intramural Scientists to conduct genome instability in cancer development research. The largest human embryonic stem cell project was the \$4.2 million that I mentioned earlier awarded to the WiCell Research Institute.

Mr. SOUDER. Thank you very much. That was helpful. Can you submit a full list of the grants for the record?

Dr. BATTEY. The full list of the 154 individual research projects? Yes.

Mr. SOUDER. In 2005?

Dr. BATTEY. Yes.

Mr. SOUDER. OK. Thank you very much.

Yield to Mr. Cummings.

Mr. CUMMINGS. Thank you very much.

Dr. Battey, I think it was you that said that one of the best ways to discover fraud in these instances is when you have to duplicate the research in another lab. Is that correct?

Dr. BATTEY. Yes. If I can elaborate on that for just a moment.

Mr. CUMMINGS. Please do.

Dr. BATTEY. When a major scientific breakthrough takes place, it generally has implications for research going on in a number of other independent laboratories. And one of the first things they will try to do to take the next step and build on that research is to take the protocol that was reported in the published literature to have given a specific result and reproduce that result.

Now, when multiple laboratories around the world or in the United States cannot reproduce a major scientific finding, it rapidly falls into disrepute.

Mr. CUMMINGS. Now, you stated in your testimony that while the stem cell research fraud in South Korea is unacceptable, it doesn't reflect on the potential of human embryonic stem cell research one way or the other. Is that what you said?

Dr. BATTEY. I am saying that the arguments for or against doing human embryonic stem cell research are not directly implicated by the—or directly influenced by the fraud that everybody agrees was inappropriate that took place in South Korea.

Mr. CUMMINGS. You know, the thing that has—I think you listened to the opening statements, and you heard Ms. Norton. And I think one of the major concerns here is, do you—I mean, are you a scientist?

Dr. BATTEY. I am reported to be a scientist, yes.

Mr. CUMMINGS. OK. Well, I will take your word for it.

Dr. BATTEY. My mother thinks I am a scientist.

Mr. CUMMINGS. I am sorry. Say that again?

Dr. BATTEY. My mother thinks I am a scientist.

Mr. CUMMINGS. Your mother?

Dr. BATTEY. Yeah.

Mr. CUMMINGS. OK. That is good. [Laughter.]

Dr. BATTEY. She also thinks I am a doctor.

Mr. CUMMINGS. I guess the question becomes—I think at least two of you, and I know Mr. Waxman, referred to it, and others—this whole thing of fraud and whether the fraud in an area like this should then cause us not to go into that area. And then the chairman got very upset when we talked about—you all talked about the cardiology piece.

But I guess the point is that you can have these problems. You are going to have problems as long as you have human beings doing things. The question becomes, do you stop going in the direction because of that research. Is that what you all are saying?

Dr. BATTEY. My comment was that there is an enormous potential to improve the human condition through research that involves all types of stem cells. And it is my belief, and the belief of the National Institutes of Health, that we need to move forward and explore all avenues that are reasonable and ethically sound that have the potential to alleviate human suffering.

Mr. CUMMINGS. And when you see instances like California and Maryland moving toward funding this research, how does that affect the people in you all's shops? In other words, if you see States now moving toward that and you are, I guess, kind of standing on the sideline and watching, does that create concern for you all at all?

Dr. BATTEY. My job as the Chair of the NIH Stem Cell Task Force, which is a role that I was asked to assume by the NIH Director, Dr. Zerhouni, in the summer of 2002, is to try to find areas within the President's policy where we can accelerate the pace of research using stem cells.

And I think it is fair to say that there has been very significant progress made by support provided by the National Institutes of Health. As I mentioned, in the last fiscal year we have 154 research projects. We invested \$40 million. And much has been learned about the fundamental events that drive cells to become specialized adult cell types.

This is the information that will ultimately allow us to potentially generate cells for cell replacement third party in the laboratory; to potential mobilize endogenous populations of stem cells within patients to become these interesting cell types; or, ultimately, to understand the molecular mechanisms that determine this magical process of nuclear reprogramming whereby an adult nucleus in a specialized cell can turn back the clock and become a pluripotent cell nucleus, and in so doing, allow us the opportunity to generate pluripotent cells without the destruction of human embryos.

Mr. CUMMINGS. We have a tough time situation, but I have to ask you this one last question. You know, so you—based upon what you just said and your testimony, you don't see this area of research as some pie in the sky. And it has been implied that some of this research is just giving people false hope. You don't see that based upon your knowledge and expertise? Do you understand the question?

Dr. BATTEY. I understand the question very well, I believe. I will say freely that the comments that have been made about therapies using adult stem cells and the therapies using embryonic stem cells

at this time are 100 percent true. There are no therapies using human embryonic stem cell lines at the current point in time.

Adult stem cells, in particular hematopoietic stem cells, stem cells of the blood-forming organ, the bone marrow, have been part of the research landscape for nearly 3½ decades. Human embryonic stem cells first became available to the research community in 1998, when James Thompson published his landscape paper.

I think it is premature at this point in time to evaluate exactly what type of stem cell and in what way knowledge gleaned from studying that type of stem cell in 10, 20, or 30 years is going to inform the medicine of the future and empower the next generation of physicians.

Mr. CUMMINGS. And I imagine if we had taken that position in a lot of our science, we wouldn't be where we are today in various areas of science.

Dr. BATTEY. It is unfortunate, but the progress of science is usually incremental. And we make slow steps forward, and it takes many, many of those slow steps over a long period of time, before we have even done the safety and efficacy testing in animal models that poise us to do the first experiments that involve human patients.

And I am delighted to be joined here by my colleagues from Office of Human Research Protection, who see to it that we do these studies in people in a responsible fashion. You know, we are absolutely bound to do that, as human beings and as physicians.

Mr. CUMMINGS. Thank you very much.

Mr. SOUDER. I really need to hold to the 5-minute rule because we have a lot of Members, and we are trying to reach a 5 p.m. deadline, and we have six witnesses on the second panel.

Ms. FOXX.

Ms. FOXX. Thank you very much.

I want to ask Dr. Battey: Did SCNT create Dolly the sheep?

Dr. BATTEY. Dolly the sheep was created by somatic cell nuclear transfer. That was in fact the time that we learned that an adult cell nucleus could be reprogrammed. That was the first demonstration that I am aware of in a mammal that was possible, although such experiments had been done in amphibians for decades.

Ms. FOXX. Then what is the difference between somatic cell nuclear transfer and cloning?

Dr. BATTEY. Somatic cell nuclear transfer is the process whereby the nucleus is removed from an oocyte and replaced by the nucleus from a somatic cell, a body cell. That is why it is called somatic cell nuclear transfer.

When this procedure is done with the goal of creating an embryonic stem cell line that is genetically matched to an individual or has a specific genetic background, that term that is used for that is therapeutic cloning. When it is done with the intent of creating a new life through—all the way through gestation and having, in this case, a baby sheep born, in the case of Dolly, that is reproductive cloning.

And, you know, the nomenclature—you mentioned that language can be very tricky. And the whole word "cloning" is a word that is a tricky word because it is used in many different ways. In my laboratory, we talk about cloning a cell line, which means basically

taking a culture of cells and growing up a new culture from a single cell.

We talk about cloning a recombinant DNA molecule, where we take a single recombinant DNA molecule and make 10 to the 8 copies of that molecule. And then here we talk about therapeutic cloning and reproductive cloning. And while they employ similar technologies at the beginning, they have different end points.

Ms. FOXX. Well, I am curious about the phrase that you use, "ethically sound." I wonder whose definition of ethically sound it is. And I will tell you what went through my mind when you said that, and I want to be very careful how I say this.

I heard a presentation a couple of weeks ago by a physician, and he raised the issue of the Tuskegee experiments that were done. If there is anybody here who doesn't know those, those were experiments done on African American men in Alabama, I believe, or—I am not sure what State it was in, 40 years ago, 40 or 50 years ago, where they were injected with syphilis, I believe, and then studied for it.

I wonder if those people said those studies were ethically sound. And would you feel that those were ethically sound studies?

Dr. BATTEY. No. I would not feel they are ethically sound. And they led, in fact, to the creation of human subjects protection rules as we know them today.

Ms. FOXX. OK. Then how would you define ethically sound if, in the process of doing embryonic stem cell research, you are destroying human life? How do you define ethically sound?

Dr. BATTEY. That is the subject of a national debate at this time. And there are many different opinions on that subject that cut to the very heart of when people believe that life begins. That is a subject where the major religions of the world are divided. And it will be a subject that I predict will be a contentious subject that will need to be debated for the foreseeable future.

Ms. FOXX. Mr. Chairman, that is the last question I had. But I would really like to go back to some of the testimony that might have been given around the Tuskegee experiments, and I will have a feeling that a lot of the scientists who were engaged in those used the very same language that you use.

Mr. SOUDER. Mr. Waxman.

Mr. WAXMAN. The Tuskegee experiments were reprehensible. They involved human subjects who were not informed of the nature of the experiments. As I understand it, they never were reviewed by any outside agency. And you indicated, Dr. Battey, that is why the whole protections for human subjects has been created, so that an institutional review board has to approve any kind of experiment to be sure that it is ethical and meets ethical standards. Is that correct?

Dr. BATTEY. That is correct.

Mr. WAXMAN. Now, a lot of people worry that embryonic stem cell research is going to be conducted. It is going to be conducted by private companies.

If embryonic stem cell research is conducted by the Government, is there a greater chance that ethical standards will be met, that there are going to be—there will be greater scrutiny of all the procedures that go into that research?

Dr. BATTEY. I think it is fair to say that there will be the same scrutiny that we have applied to other areas of biomedical research, with doubling scrutiny because of the respect that one has to have for the sensitive area of research where there is an enormous divide in our country.

Mr. WAXMAN. Well, the American Society for Cell Biology emphasized the importance of public funding. And they at one point said that without Federal funding, the Nation's top academic researchers at universities, medical schools, and teaching hospitals cannot join in the search for cures, which means slower progress, and that the Government oversight will ensure that research complies with ethical guidelines.

Do you agree with that statement, that last point, and how does it guarantee or ensure that research complies with ethical guidelines?

Dr. BATTEY. We can insist that before Federal funds are expended, that proper oversight has taken place. And that in fact is done with all the research that involves human subjects, where the experiment must be reviewed by an institutional review board in the institution in question before such an experiment goes forward.

Mr. WAXMAN. In your view, does the Korean scandal establish or suggest that the field of embryonic stem cell research is unique in being susceptible to scientific fraud and/or patient exploitation?

Dr. BATTEY. Unfortunately, I am afraid that scientific fraud has been found in many areas of science, as I mentioned earlier. It is rare, but it happens in many different areas. And scientists need to be vigilant to try to prevent it.

But I would emphasize that it is my sincere belief in my 23 years of experience as a scientist has taught me that the overwhelming majority of individuals engaged in biomedical research are sincere, hardworking, and would like nothing better than to see what they do in their laboratories lead to better cures and better health of the Nation.

Mr. WAXMAN. Should women be allowed to donate eggs for purely research purposes under any condition? And if so, what should those conditions be? Maybe you want to—

Dr. BATTEY. I think that might be a better question for Mr. Schwetz to try to answer, if he would like to, or I will answer to the best of my ability if he would prefer.

Mr. SCHWETZ. All we can say is that if in fact there is going to be research that involved eggs from donors, and this is research that is funded by HHS and doesn't involve the cell lines—it doesn't get outside of the cell lines that are acceptable for HHS-funded research, then all we can say is that we have a network in place through the institutional review board system that determines that these protocols must be reviewed, and they need to meet the standards that are set in our regulation.

Mr. WAXMAN. Well, what if we changed the ban on this research through NIH and broadened it to further investigations using embryonic stem cells, does a—exploitation of women is a major and disturbing theme in the story of the Korean scandal. Would this be something that we could make sure is done appropriately, if a woman wishes to participate in donating an egg for research beyond stem cells that are available now?

Mr. SCHWETZ. It is hard to know what is going to come up in the future. But based on what we know today, these—we are faced—this is an enterprise that is faced with a number of risks in research, and the possibility that there would be a problem with harvesting eggs from females is one of a number of risks that would be handled by the institutional review board system on a regular basis.

So I don't think there are limitations in the regulations that would suggest we shouldn't go into this kind of research because we don't know how to handle it.

Mr. WAXMAN. We don't know how to handle it until it is reviewed? Until some proposal is reviewed?

Mr. SCHWETZ. That is correct.

Mr. WAXMAN. OK. Thank you. Thank you, Mr. Chairman.

Mr. SOUDER. I have a feeling that though Mr. Waxman and I may disagree fundamentally on where life begins and in embryonic research, if this were to go forward with congressional standards, I have a feeling that we would want more than an institutional review because that is partly what happened here. In other words, just trusting the university isn't going to cut it in something this controversial ethically. Is that—

Mr. WAXMAN. Well, I don't think an institutional review board is trusting the university, and maybe we can have the experts inform us on the subject. But I think an institutional review board is to oversee the work of the universities and their proposals when they evaluate the ethics of any experiment.

Mr. SOUDER. This is important to clarify because we had it in the testimony in response to several questions. My understanding is that unless you feel there has been abuse, the research on whether there has been fraud, and the guidelines are standard, they submit. Then they do an internal review, and unless you feel something is wrong, you don't review it. Is that correct?

Mr. WAXMAN. I think they have to review it in advance to prevent an abuse, not wait till—

Mr. SOUDER. They set the guidelines, but to make sure that the guidelines are being followed, it is self-reported unless somebody blows a whistle or you suspect something. Is that correct, Mr. Pascal?

Mr. PASCAL. Is your question to me?

Mr. SOUDER. Yes.

Mr. PASCAL. I am sorry. Yes. We normally get complaints of allegations from individual scientists. Also, the institution is required to report to us when they get to the investigation stage.

Mr. SOUDER. Thank you. Is that clarified?

Mr. WAXMAN. Well, I think it is an answer, and I appreciate the answer. Thank you.

Mr. SOUDER. OK. Ms. Schmidt.

Ms. SCHMIDT. Thank you. I have a question. But before I ask my question, Ms. Foxx said that language is important. And Dr. Battey, this goes to you as well as the question. Language is important, and I don't think we should discuss the term "religion" when we are discussing when life begins because I have a very dear friend that is an atheist, and he believes the same as I do as to

when life begins. And he doesn't believe in any God or in any religion.

But having said that, I have been concerned about the issue of appropriate stem cell research for some time. In my days when I was in the Ohio Legislature, I actually went to the University of Cincinnati to find out exactly how they were handling this. And so I know that extrapolating information is important. And when I got here, I did some research, and I found out that this committee in its past has had a difficult time getting information from you.

As you know, and as I found out, this subcommittee requested information from you in October 2002 seeking a detailed report providing comprehensive information on the medical applications of adult and embryonic stem cells, as well as cells from cloned embryos and aborted fetuses. The subcommittee received a response from you in June 2004, 20 months after its initial request, during which time the subcommittee staff continuously inquired about the status of this report, and subsequent chairmen's letters were sent seeking this material. And I have copies of them.

Your reply to this oversight request, 20 months in the making, was completely insufficient and unresponsive to the plain meaning of the committee's request. Ultimately, you acknowledged this and apologized for the inadequacy of the response.

But throughout this entire period, when Congress was seeking critical information about these very issues we are discussing today in 2006, information that would have been useful for complex policy decisions being faced by the Congress and our President, members and their staffs were unable to obtain the kind of accurate, timely, and up-to-date information from NIH necessary to do, quite frankly, the people's work.

This happened on your watch. It seems only appropriate that while we are examining the problems in this research area, that you explain to this body why such critical information was withheld from Congress for so long. And the second part of that is: Will you be forthcoming when we ask for additional information in a timely manner and a comprehensive format in the future? Because I believe the public has a right to know.

Dr. BATEY. It is a fair question. I am very sorry that response was delayed the length of time that it was. But I must inform the committee that the NIH had developed its response within a few weeks of when the request was initially received. Once we develop a response, it is then subject to a clearance process in the Department of Health and Human Services over which I have no control.

So yes, it was done on my watch, and I take responsibility for it. But aspects of that delay were beyond my control. And what I will tell you is that I will do what I can to get information to this subcommittee or any other subcommittee, factual scientific information, in as timely and accurate a fashion as the resources I have at my disposal allow me to do.

But again, I say I am sorry you were without that information for a 2-year period.

Ms. SCHMIDT. Well, I have a followup, sir. And again, I am new to this process. But information is key—

Mr. SOUDER. Mr. Schmidt, will the gentlelady yield a second?

Ms. SCHMIDT. I would be honored, yes.

Mr. SOUDER. And I will put your time back on. And if Ms. Norton and Ms. Watson will let me make a brief comment, that I appreciate your apology. Ms. Schmidt will have a followup question.

But in the role of oversight in the U.S. Congress—and this is not directed at you—I am getting increasingly frustrated with this administration coming up with multiple excuses as to why they can't give us documents on this, on HHS, on the State Department, on the Office of Faith-Based, and other departments. We constantly hear, well, it has to be reviewed.

We represent the American people. Two-year review is not acceptable. And I am not sure who we have to call in, whether we have to do this at the full committee level. But other subcommittees are having the same problem, in that exactly what takes 2 years of review to figure out, when we ask data and the data is coming over to us, what kind of review has to happen for elected officials to see the fundamental data.

Then second, then we are told that the process of why it took 2 years is pre-decisional, as though there was some sort of a political discussion over what they were going to get us. And quite frankly, both at Department of HHS under this Secretary and at the State Department under multiple Secretaries, if it wasn't for individuals leaking us documents, we wouldn't know that when we get the documents, often, what has been taken out.

And different agencies are saying—because we will make a document request. Then we will be told that this is all the documents. Then we will show the department—this happened three times in one State Department request. This, I think, dealt with Afghanistan. And it is getting increasingly exasperating. Then you are sent up here having to defend that.

But the bottom line is: We need timely responses. The type of requests we made were basically factual requests. They shouldn't have had such a political screen. Even though we know this is a difficult subject, we are the same party. We know how difficult the subject is, but elected officials have a right to know what this data is.

And the extra-exasperating part of this is that by the time we get the data, then we don't have the trust in the data. And then we—in the example of the State Department—had to request 10,000 documents. And then they came back and said the great cost.

Well, we lost confidence in the trust of the Department. And HHS is headed this direction, too. If you can take this back. We will try to target our document requests if we get them in a timely fashion and get the documents that we requested. But if we don't get the documents requested in a timely fashion, we have to keep broadening the search because we are an oversight committee.

And quite frankly, this happened under the last administration until the last stretch, and then they started sending over like truckloads of documents and taking forever to go through. But at least they were more forthcoming. And I appreciate your willingness to cooperate, and that this administration, hopefully at higher levels than yourself, will start to respond. But the frustration is building, and it is going to boil over if we can't figure out how to do it.

So thank you for having the other data earlier. I yield to Ms. Schmidt. But sorry, I wanted to go on the record that this is far greater, even, than just his Department. We are having a tremendous problem in doing oversight right now for this very reason, getting 2 years and then not getting the—getting an incomplete amount, and not knowing what we are missing. That is because we don't know what has been taken out.

Do you have any insight as to what took 2 years to review?

Dr. BATTEY. No.

Ms. SCHMIDT. Thank you, Mr. Chairman. As a followup, since you had to put this through a review process, who are the people we have to call to stop the delay in the review? Who—give me the name, please, of the person that is accountable for the holdup in this document request because as the chairman said, it is not just Congress that has the right to know. It is the people that have the right to know.

We represent the people of the United States. And we have the right to know information in a timely fashion, sensitive information on this issue, and this is a very controversial issue. If we don't have that information, we can't make the appropriate policy decisions that the people expect us to make.

So who at your Department held this up for 2 years, so we can bring him in and ask why?

Dr. BATTEY. I don't know.

Ms. SCHMIDT. Can you find that out for us?

Dr. BATTEY. I can try to find it out for you.

Ms. SCHMIDT. Thank you, Mr. Chairman.

Mr. SOUDER. Thank you. Ms. Norton.

Ms. NORTON. Mr. Chairman, I have a couple of questions, but I want to just say a word because both gentleladies have mentioned the word—the care we must take in language. And I want to second what they said.

I want to say I appreciate that the gentlelady from North Carolina said she wanted to be careful about her language when she made analogies to the Tuskegee experiments involving living, Black men who were treated in a way that was emblematic of the way Black people were treated in the Southern States.

And I just want to say for the record, for those of you who want to use those analogies into the African American experience, you are right. You had best be careful. Because I believe I speak for African Americans when I say we do not want anybody comparing Black people to human embryos.

Mr. Chairman, I just want to say, because you have always been very remedy-oriented and I was a little surprised at what you said to the ranking member about BS'ing about analogies, we just heard some analogies that, frankly, I resented.

But I really don't think you meant that we are only interested in the past. I have never seen you approach an issue that way. And I know you don't—you are not holding the hearing for political reasons or to keep any information we get from these witnesses to ourselves.

And Mr. Chairman, if I can remind you, our own Chair, Mr. Davis, has said repeatedly that the Government Reform Committee, by the way, has the largest staff in the Congress of the United

States because its writ is to investigate anything involving the Government.

And I suppose the best indication of that, Mr. Chairman, for something that some would argue is totally outside our jurisdiction, is not only the hearings, not only the investigation, but the bill we passed on baseball. I mean, there is another committee that has primary jurisdiction over that matter, but the chairman brought forward his own bill on it.

And I think when we are talking about this matter, we would want to be remedy-oriented. And in light of my work with you on this committee and my respect for your work on this committee, I know that you would want us, if we could uncover some remedies for adult stem abuses or embryonic stem abuses, to let everybody know about it.

Let me have—let me ask a question to Mr.—Dr.—I think it is Battey. Am I pronouncing that Right?

Dr. BATTEY. Yes, ma'am.

Ms. NORTON. And your role is the chair, of course, of this important task force on stem cell research. And Mr. Pascal, who is a lawyer, who speaks from another angle.

First of all, I was relieved that both of you appear to have testified that we don't yet have this problem in this country, Dr. Battey, that the vast majority are honest, do not reflect on even the potential on the human embryonic cell research one way or another.

You refuse to draw conclusions in advance. By the way, everybody, that is how the scientific—how the scientific method works. You come in with a hypothesis and you say, prove it one way or the other. Prevent it if you can. Mr. Pascal says virtually the same thing. Serious consequences if you had any particular case of—great majority of scientists here are dedicated.

My question, and as far as you know have not been involved in anything like this kind of fraud and human rights violation. Let me ask you this. We talked about how fraud gets uncovered. Again, going back to scientists, who first uncovered this fraud?

Dr. BATTEY. The initial—

Ms. NORTON. In Korea?

Dr. BATTEY. The initial allegations of fraud involved members of the research team in Korea.

Ms. NORTON. Very important point to put on the record, that it is a primary obligation of scientists themselves, as any ethical scientist moves forward, to replicate, to investigate, and moves forward in the spirit of great skepticism and that. But very important, as we seek guidance—at least people like me seek guidance—from the Federal Government, I don't know what form it should take to indicate how most fraud is uncovered, how most matters of this kind are uncovered.

Are most of them brought forward by scientists, or was that unusual?

Dr. BATTEY. I will yield to my colleague, Mr. Pascal, who probably knows better than I do, but would comment that in my experience generally, they are brought forward by individuals familiar with the research in question.

Mr. PASCAL. I would agree with that, that it is usually somebody who is in the laboratory or the department and is familiar with the

research being done so they have enough knowledge to know that something is wrong.

Ms. NORTON. Whereas whistleblowers are uncommon in the Federal Government, that is the job of a scientist. And I am just pleased to hear that for the most part, it seems to be working in this country.

I have a question that bothers me very much, though, and this involves the testimony of Mr. Schwetz—yes, of Mr. Schwetz, who said that—in page 4 of your testimony that the guidance, the stem cell guidance, does not generally meet the—your definition, HHS definition, of human subjects research, and that is where you have offered guidance. Is that correct?

Mr. SCHWETZ. Let me clarify because there are circumstances where research involving stem cells would be human research that would have to be reviewed and approved by an institutional review board, and you would have to have—

Ms. NORTON. No. I am trying to establish—I am not trying to understand that. What I am trying to establish is that you have no guidance involving stem cell research.

Mr. SCHWETZ. Yes. We do have guidance to the IRB and investigator community on their responsibilities if they are doing research involving stem cells. We do have guidance on that.

Ms. NORTON. So the guidance you have—the guidance you have offered would keep—in your judgment, would alert the scientific community that the kind of abuses we find in South Korea are not—or violate, I guess, your regulations and U.S. law?

Mr. SCHWETZ. I am not sure I really understand your question. But there are some circumstances where fraud would represent risk to subjects. But there are other—to research subjects. There are other cases where fraud would not necessarily represent risk to subjects of research, but would have other implications for the quality of the data that are coming out of a laboratory.

Guidance that we have put out regarding research involving human subjects and stem cell research is meant to be taken in the context of our broader regulations that tell investigators and the IRB community how to ethically review the research.

Ms. NORTON. Dr. Battey, one last question. Are you aware of the research—they have been very careful in how they have described it. I have read it. I have seen some of it on television involving rats, where rats have been injected with human embryonic cells. These rats were totally paralyzed before, and you see that the rats now move, awkwardly but amazingly and astoundingly.

Without commenting on where this would lead because I don't think anybody knows where it would lead, and those who have been involved in this astounding, this startling, this amazing research are careful to say that these are rats only, but they were injected, were they not, with embryonic human stem cells?

Dr. BATTEY. I believe that is correct.

Ms. NORTON. Very important to note since we had all kinds of opinion from non-scientists on the other side that there is no progress whatsoever. And Congress, however, knows best.

Thank you very much, Mr. Chairman.

Dr. BATTEY. I am. Could I add just one comment, though? It is not clear in what way the embryonic stem cells are enabling the rats to move their hind legs again.

Ms. NORTON. That is precisely why this work is going on, Dr. Battey. And in fact, you know, I mention it only because of the implication on the other side that there is no evidence of any results from embryonic—not because—

Mr. SOUDER. He just said there was no evidence.

Ms. NORTON [continuing]. And to their credit—to their credit, I have to say not because even those who are responsible for this—

Mr. SOUDER. Ms. Norton.

Ms. NORTON [continuing]. Scientific feat have said, hey, right around the corner, guess what? Everybody who is paralyzed is going to walk. All they have said is, we have a moral obligation—

Mr. SOUDER. He said—

Ms. NORTON [continuing]. To proceed with this—

Mr. SOUDER. Ms. Norton, your time is well past.

Ms. NORTON [continuing]. With this kind of scientific research. And I agree they do.

Mr. SOUDER. There is no evidence. What he said is there is hope in that research. His opinion gives hope, among other potential research. But there is no evidence.

Ms. Watson.

Ms. WATSON. Thank you, Mr. Chairman. And thank you for this oversight hearing on the issue.

In listening to the questions my colleagues have asked, there was a mention of the challenges of when life begins and so on. And in reading through the materials that were prepared for this hearing, it comes to light that the Korean government had approved of Dr. Hwang's research.

Now, my question is: Do we have a bioethic commission similar within your Department, NIH or HHS? And do we run papers through it? When they have come up with a new piece of research, what do we do in response? Because in other countries, the ethics and morals and principles upon which they might do research can differ with the country, the culture, and tradition.

And what do we do when we receive something called research and, you know, the controversy is over the fact that he misrepresented how he got the ova. So our concern should be: How do we protect our research and not allow this to happen? So can you respond?

Dr. BATTEY. I will respond to the best of my ability. You are correct in pointing out that there are different national standards for providing Government funding or private funding for research in the area of human embryonic stem cells and human somatic cell nuclear transfer.

Right now, the Department of Health and Human Services is operating under the President's policy as well as legislative language that is on the DHHS appropriation. The legislative language prohibits the use of DHHS funds for human embryo research. This is often called the Dickey language.

The President's policy allows Federal funds to be used for human embryonic stem cell research so long as the embryo was created for reproductive purposes; was no longer needed for those purposes; in-

formed consent was obtained from the donors; and no fiduciary incentive was provided for the donation of the embryo, with the condition that the inner cell mass be removed from the 5-day-old blastocyst on or before 9 p.m. Eastern Daylight time, August 9, 2001.

So the policy under which DHHS currently operates is a policy that oversees the use of Federal funds for research. There is no national policy governing this research when the funds being used come from sources other than the Federal Government. And there is a patchwork of regulations in various States that provide different sets of guidelines for the legality or the provision of funds for this area of research.

Ms. WATSON. I think you make my point. And if we are results-oriented and remedy-oriented, and I too must agree with my colleague that our Chair seems to try to get to that point, and I appreciate that because that is the function of our committee, to have that kind of oversight.

I would hope that you and maybe HHS could come together and talk about what the standard would be for Federal funding. We cannot control what other countries do. We look at their results and we look at the 50 States, and I know I chaired a committee where we dealt with this issue.

We look at—as you say, they are a patchwork. But maybe we could develop some standards that would be guidelines. And when we read a piece of research that comes from another country, it has to go through a screening process before we make a big deal over it. You know, that is the way the Koreans dealt with this. The professor resigned. The doctor resigned, but he is going to go on with his research. So there is a cloud over whatever he produces.

But I think we ought to set some standards where anything that comes from abroad flows through. And we ought to have a bioethics unit through which they go so we can discuss, you know, all these different theories and all these different ethics, and separating church from State, and, you know, what I believe in my religion versus what you believe. You are the scientist, and all.

So I would like you to respond to that. I think I heard you mention that we needed something like that. Can you respond, please?

Dr. BATTEY. You raise a very interesting issue. My response is that the fraud that was perpetrated in South Korea is reprehensible to everybody in the scientific community, every physician that I know in this country, and in fact, every responsible citizen that I know.

It was wrong. It should never have happened. It was revealed because responsible individuals, subordinates within the laboratory, brought forward allegations. And in a very short amount of time, the problem was explored and revealed, and the fraud revealed to the entire world, and Dr. Hwang discredited.

Had this individual not come forward, when it became apparent that no one else could reproduce his results, his results would have fallen into discredit. So we have a process that sorts out the truth from fabrication. And the linchpin of that process is reproducibility in another laboratory. And it isn't science if it can't be reproduced in another laboratory.

Ms. WATSON. Did you want to mention my suggestion that we look at the bioethics and try to work that piece out so that when

you come forth with your empirical evidence that this can be duplicated, we have run it through these tests, including our discussion? Because I think there is a future for this research, and particularly here in this country. But we want to be sure that we can avoid the fraudulent practices up front.

Dr. BATTEY. I think that is an interesting suggestion that should be considered by those who are higher ranking than I am in the administration.

Ms. WATSON. Well, I throw that out for whoever is listening. Maybe it will get into the press and somebody will start considering it.

Thank you so very much, panel.

Mr. SOUDER. I want to also thank this panel. We will most likely have some written questions. Hopefully we can get a timely response. We will leave the record open longer than 3 days. But if we can't, my inclination will be to write that we could not get clearance of the Secretary of HHS, OMB, and the White House for the answers because we will try to keep the questions narrow enough. When this hearing book comes out, it should include a fair amount of data with that.

I also want to clarify two things that Ms. Norton said. She is correct that we do—in this committee, what I said is we look back on the past. We look in the past, at Katrina, at steroids, at whatever the issue is, to try to then develop and highlight what can be solutions that would then move to legislative committees. And so we have a future orientation by looking back on the past, and I didn't mean to imply we didn't have a future orientation.

The second thing, but I do think the record needs to reflect this: This committee does have jurisdiction over both the oversight on baseball, but also the legislation. There was a difference of opinion, which we have worked out, that if the steroid was overseen by the Office of National Drug Control Policy, it would be our legislative as well as oversight. If it is DEA, it is Judiciary. If it is FDA, it is Energy and Commerce.

The only question of where jurisdiction fell was on oversight, and that is really what we are battling over because we did have—in narcotics, we do have legislative as well as oversight. So I wanted the record to show that.

I once again thank this panel. Thank you for your time, and I look forward to continuing to work with you.

If the second panel could come forward.

Dr. BATTEY. Thank you, Mr. Chairman.

Mr. SOUDER. Thank you.

Our second panel is Dr. Richard Chole, Lindberg professor and chairman of the Department of Otolaryngology—the subcommittee stands in brief recess.

[Recess.]

Mr. SOUDER. The subcommittee will come to order.

Our second panel is Dr. Richard Chole, Lindberg professor and chairman, Department of Otolaryngology, Washington University School of Medicine, St. Louis; Judy Norsigian, executive director, Our Bodies Ourselves, co-author of "Our Bodies, Ourselves"; Dr. Diane Beeson, professor emerita, Department of Sociology and Social Services, California State University, East Bay; Mr. Richard