UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

JAMES L. SHERLEY, DR., ET AL., NIGHT-LIGHT CHRISTIAN ADOPTIONS, INDIVIDUALLY AND AS NEXT FRIEND FOR PLAINTIFF EMBRYOS, ET AL.,

Appellants,

v.

KATHLEEN SEBELIUS, IN HER OFFICIAL CAPACITY AS SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES, ET AL.,

Appellees.

No. 11-5241

Monday, April 23, 2012
Washington, D.C.

The above-entitled matter came on for oral argument pursuant to notice.

BEFORE:

CHIEF JUDGE SENTELLE AND CIRCUIT JUDGES HENDERSON AND BROWN

APPEARANCES:

ON BEHALF OF THE APPELLANTS:

RYAN J. WATSON, ESQ.

ON BEHALF OF THE APPELLEES:

BETH S. BRINKMANN, ESQ.

C O N T E N T S

P R O C E E D I N G S

THE CLERK: Case number 11-5241, James L. Sherley, Dr., et al, Appellants; Night-Light Christian Adoptions, individually and as next friend for Plaintiff Embryos, et al. v. Kathleen Sebelius, in her official capacity as Secretary of the Department of Health and Human Services, et al. Mr. Watson for the Appellants; Ms. Brinkmann for the Appellees.

ORAL ARGUMENT OF RYAN J. WATSON, ESQ.

ON BEHALF OF THE APPELLANTS

MR. WATSON: Good morning, Your Honors.

JUDGE SENTELLE: Good morning, Counsel.

MR. WATSON: May it please the Court. My name is Ryan Watson, and I represent the appellants. I would like to reserve three minutes for rebuttal.

NIH's guidelines are invalid for three reasons. First, by admittedly disregarding 30,000 comments addressing the scientific and ethical merits of human embryonic stem cell research, NIH blatantly violated the APA by ignoring important issues in failing to use an adequate notice and comment process.

Second, NIH's guidelines violate Dickey-Wicker's prohibition on funding research in which a human embryo is knowingly subjected to risk of injury or death which is an issue that was not before this court in Sherley II.

And finally, NIH's guidelines violate Dickey-

Wicker's prohibition on funding research in which a human embryo is destroyed.

JUDGE SENTELLE: Could you talk early on about whether the law of the case is binding and is against you on this?

MR. WATSON: Absolutely.

JUDGE SENTELLE: Before you get to those issues, we have to get to those issues.

MR. WATSON: Certainly, Your Honor. As an initial manner, at most of all, the case doctrine is relevant to one out of the three claims that we're making here which is the first prong of Dickey-Wicker. But, even with respect to that claim, we believe that the law of the case does not bind us penal at this stage of the case.

As you know, the Sherley II decision concluded that we have raised a serious legal question on the merits but we're not likely to succeed on the first prong of Dickey-Wicker. But, the Supreme Court's decision in University of Texas v. Camenisch held that findings of fact in conclusions of law made by a court granting a preliminary injunction are not binding at the later stages on the merits. In this court's decisions in the Berrien and the Val Botcha case, apply that principle and we believe that those three cases which are binding on this court indicate that the decisions made at the PI stage are not binding on the merits.

JUDGE SENTELLE: The opposing -- excuse me. Go ahead.

JUDGE BROWN: It may be true that there's no precedent saying that we're bound by that earlier case, but there have been a number of circuits who have looked at this as if not binding, persuasive, authority if we're looking at the same issue and if we have the same facts before us. So, why shouldn't we find this persuasive?

MR. WATSON: Both the Berrien and Belbacha decisions indicate that the touch tone is persuasiveness and that both the Sherley, through majority and descent, should be evaluated for their persuasiveness, and in the Berrien case specifically, it was a pure legal issue. It was a due process issue involving a parole board's restrictions on a parolee's international travel, and the subsequent panel in that case held that even if the record was substantially the same as it had been in the prior appeal and even though it was a legal issue in that case, the prior ruling was not law of the case, and also in the Belbacha case there was a denial of preliminary relief in the first ruling and the subsequent panel held that the denial of preliminary relief is not law of the case.

But again, for those reasons, we believe that the law of the case doctrine does not preclude this court from evaluating both the Sherley II majority and dissent in

considering whether they're persuasive. In our view, the Sherley II descent had the more persuasive evaluation of the plain text of Dickey-Wicker's first prong which prohibits funding research in which an embryo is destroyed.

With respect to the APA issues, virtually all of the issues in that aspect of the case are undisputed. Specifically, it's undisputed that the NIH did have a duty to respond to scientific and ethical issues in the record unless the executive order somehow excused it from doing so. It's also undisputed, and this is at Joint Appendix, pages 464 and page 480, that the government, that NIH, did not respond to the categorical opposition of human embryonic stem cell research on scientific and ethical grounds, and it's also undisputed in this court that if NIH violated the APA, then vacatur is the appropriate remedy.

Accordingly, the government has resisted its entire APA case on the theory that the executive order compelled NIH to fund human embryonic stem cell research and somehow excused it from its duty under the APA.

JUDGE SENTELLE: Not somehow but therefore, they didn't have to respond to comments that went 180 degrees the other way. I mean, it's not some back at you. You understand what they're saying. Don't --

MR. WATSON: Yes. I certainly understand the government's argument. Yes.

JUDGE SENTELLE: Okay.

MR. WATSON: But the text and the purpose of the executive order make clear that the President was intending to put science and ethics directly at the center of this rule making.

Section 2 of the executive order states that NIH may fund stem cell research to the extent that it's scientifically worthy and ethically responsible. Not that it must do so. Not that is shall do so. And, the notice of proposed rule making echoed those same criteria, and it stated at page 495 of the Joint Appendix that it's aim was to ensure that NIH funded research in this area was scientifically worthy and ethically responsible. NIH then welcomed all public comments without any sort of caveat and, in fact, NIH's approach in proposing the draft guidelines indicates that ethics were, indeed, on the table because NIH proposed some very modest restrictions on funding embryonic stem cell research based, apparently, on ethical considerations thus confirming that they were at issue.

In this court's decision in the Petroleum Communications case v. FCC, makes clear that when an agency establishes criteria in the notice of proposed rule making, it may not then when promulgating the final rule indicate that comments going to those very criteria are outside the scope of the record. That's a case in which this court held that the

agency had acted arbitrarily and capriciously by doing so and it vacated the relevant part of the rule.

In addition to the text of the executive order, the purpose of the executive order is consistent with plaintiff's position here. The President's purpose in signing this executive order was to ensure that politics were out of the equation and to remove the President's thumb off of the scales and to allow the agency to address these complicated and controversial issues, free of political interference, and that's what the purpose of the executive order was and that's clear based on Section 1 of the executive order in which he removes the prior Presidential restrictions electing the artificial, in his view, political restrictions off of the map and delegating these issues in Section 2 of the executive order to the NIH to decide pursuant to the criteria that he had established, and in this case, there are 30,000 comments in the record that particularly direct this court's attention to Joint Appendix, page 50 through 162, that show that there are a number of scientific problems with embryonic stem cell research as well as the obvious ethical draw backs and that there's a clear alternative here that was proposed in the record and that alternative is to fund only adult stem cell research and induced pluripotent stem cell research.

JUDGE SENTELLE: What did you understand the executive order to be directing them to do?

MR. WATSON: The only affirmative mandatory command in the executive order is to promulgate guidelines addressing stem cell research. Section 1 of the executive order removes President Bush's bright line temporal limitation on embryonic stem cell research. Section 2 says that the NIH must go promulgate guidelines and that it may fund stem cell research including embryonic stem cell research to the extent that it satisfies the President's criteria. So, the only thing it was commanding the agency to do was to address these issues and to address them pursuant to those criteria, and indeed, that is what the agency purported to do when it issued its notice of proposed rule making in echo of those very criteria. But, then after the fact, it declared that those issues were outside the scope of its rule making, and it conceded that it had not addressed them because it deemed them irrelevant.

Even if the executive order did do what the government suggests that it did here, it would not be enforceable because it would be directing the agency to act in violation of the APA.

The government's view is essentially that the President's executive order established the relevant criteria for stem cell research and that it commanded the agency to ignore those criteria with respect to a particular subset of research that the President apparently favored. That sort of arbitrary cherry picking of which criteria to apply and which

comments to address is the epitome of arbitrary and capricious action, and this court made clear in Chamber of Commerce v. Reich that courts have the power to compel subordinate executive officials to disobey illegal Presidential commands. And even if the President's executive order purported to do that, these were issues that were so fundamental to the rule making that it would have been arbitrary and capricious for NIH not to address them. It's arbitrary to decide which types of scientific research to fund without considering the scientific worthiness, and the President cannot simply sign an executive order that grants the APA a coupon good for one APA violation.

In addition to our APA arguments, there are two separate grounds under Dickey-Wicker under which the NIH guidelines are invalid. Specifically, the third prong of Dickey-Wicker which was not addressed in Sherley II prohibits funding research in which a human embryo or embryos are knowingly subjected to more than a minimal risk of injury and death.

In this case, it's very clear that embryos are being submitted to more than a minimal risk of injury or death by these guidelines. There's undisputed evidence in the record, including at Joint Appendix 543 through 547, showing that existing embryonic stem cell lines are often subject to narrow use restrictions, they're often specific to certain disease

which means that they have limited research value, and there is undisputed evidence that there's a demand for additional embryonic stem cell lines that contain additional diseases or that reflect ethnic diversity. And in fact, we know that that is what is happening.

NIH has approved at least four embryonic stem cell lines in which the embryo was destroyed after July 2009 which is when the guidelines were promulgated. And the purpose and the effect of the guidelines is clear. At Joint Appendix, page 46, they state that their purpose it to ensure that the greatest number of ethically derived human embryonic stem cell lines are available for NIH funded research, and they articulate requirements for "future embryo donations". So, the evidence in the record is clear that more than a minimal risk to embryos is being created by the NIH funded research.

And there's a knowledge requirement on the third prong of Dickey-Wicker as well that's very easily satisfied here because it's the natural foreseeable consequence of this NIH funded research that additional embryonic stem cell lines will be demanded and therefore embryos will be destroyed.

Then on the first prong of Dickey-Wicker which is the one that we believe is knocked down by law of the case, the structure of Dickey-Wicker and its text is very clear. Subparagraph (a)(1) of Dickey-Wicker is specifically targeted at the creation of human embryos for research purposes, and

Congress clearly did not want that to receive NIH funding.

JUDGE SENTELLE: What do you say to the argument that Congress has repeatedly re-adopted without amendment the Dickey-Wicker language after its interpretation by the government?

MR. WATSON: The Supreme Court's 1994 decision in Brown v. Gardner made clear that when the text of a statute is plain, the Congressional ratification theory is inapplicable. For that reason, we believe that it's inapplicable to both prongs of Dickey-Wicker.

JUDGE SENTELLE: So, your whole argument rests on plain language?

MR. WATSON: No. Not our whole argument. That's --

JUDGE SENTELLE: And if we understand the language to be ambiguous, what is your then response?

MR. WATSON: Our whole argument does not rest on that. With respect to the ratification theory specifically, even if the text was not deemed to be plain, under the third prong of Dickey-Wicker there's not a long standing interpretation that would trigger the ratification theory. One thing that's very clear since up until 2009 is that the government would not fund research that incentives embryo destruction. And, indeed, in 2009, it did not even interpret the phrase knowingly subjected to risk. So, there's nothing that would trigger the ratification theory under the third

prong.

JUDGE BROWN: But your argument would, I think, also say that Bush temporal limitation was a violation of Dickey-Wicker. Correct?

MR. WATSON: Your Honor, I see that I'm in to my rebuttal time. May I answer?

JUDGE SENTELLE: We don't worry about that, and you know that.

MR. WATSON: Yes.

JUDGE SENTELLE: This is not your first time in this court room, Counsel.

MR. WATSON: Thank you, Your Honor. Yes. Yes. It's an academic question with the Bush policy, how it would stand up to our analysis. But, we did concede in the previous appeal that the Bush policy would fail under the first prong of Dickey-Wicker. But, that's different than the third prong because as we noted, HHS took the position in 2002 that Dickey-Wicker cannot violate, Dickey-Wicker would be violated if funding research created an incentive for embryos. The third prong of Dickey-Wicker was not violated by President Bush's policy.

If there are no further questions, I'll reserve my remaining time for rebuttal.

JUDGE SENTELLE: Thank you, Counsel.

MR. WATSON: Thank you.

JUDGE SENTELLE: We'll hear from the respondent, appellee. Excuse me.

ORAL ARGUMENT OF BETH S. BRINKMANN, ESQ.

ON BEHALF OF THE APPELLEES

MS. BRINKMANN: May it please the Court, Beth Brinkmann on behalf of the government.

We urge the Court to affirm the judgment below on both points. This court's earlier opinion provided an authoritative construction of the statutory question here, a question of pure law, and plaintiff's have not presented anything new to challenge the reasoning of that opinion.

JUDGE SENTELLE: What do you do with Berrigan?

MS. BRINKMANN: We believe, Your Honor, that looking at this particular case is distinguishable in the sense that this was certainly a situation in which there was full and ample consideration of all of the issues on this question of law of the statutory interpretation. It was a matter that was briefed and fully argued, a well-reasoned opinion after four months of consideration by the Court, and we think in that situation, the statutory question of the interpretation of the text is appropriately authoritative construction that this court should adhere to.

JUDGE SENTELLE: The variant language is rather absolute, isn't it?

MS. BRINKMANN: Your Honor, I think other cases of

this court, certainly the Lashon case has recognized that in a case like this where there's law of the case and law of the circuit interacting, that's a particular situation in which the principles underlying those doctrines weigh in favor of applying it.

JUDGE SENTELLE: Was Lashon a preliminary injunction and then the second appeal or --

MS. BRINKMANN: No. That was a very complex --

JUDGE SENTELLE: Yes.

MS. BRINKMANN: -- up and down case. I understand that.

JUDGE SENTELLE: That's what I'm thinking.

MS. BRINKMANN: Yes, Your Honor.

JUDGE SENTELLE: So, Lashon is not really authoritative on the question of whether there is a fully litigated exception, whether this circuit recognizes a fully litigated exception to the doctrine announced in Berrigan and other cases.

MS. BRINKMANN: I think it's in this case where it's a pure question of law. It's a matter of statutory interpretation, and the plaintiffs have not introduced anything new to challenge that interpretation. It is consistent with those principles to adhere to that interpretation in this particular situation.

We also would suggest that the Court of Appeals

earlier opinion was correct in relying on the text of the statute. The research in which the present tense and in addition the ratification by Congress, and indeed the ratification by Congress has been bolstered since then because the rider was, again, re-enacted after the Court's earlier opinion in this case.

Also, as the Court has already pointed out, this has been the consistent interpretation of this statute over three Presidential administrations. It's the agency's interpretation, and it's also supported by the history against, the backdrop against which this provision was enacted, the type of research on embryos that the rider was intended to prohibit funding of. And as we pointed out before, this type of research is research that uses cells as a research tool and differentiates them for different types of research projects that are looking forward. That's what NIH is looking at when they get the application for the funding. They're looking at that research, what they will be funding going forward.

We recognize that plaintiffs here have urged a second prong of the statutory interpretation which we believe also is controlled by the prior opinion of this court interpreting a language research in which, and the present tense there, this prong that applies to research in which embryos are knowingly subjected to a risk of injury or death

is also based on that same present tense of research in which talking about the research which is at issue in the grant application, and it's in that research where there has to be that kind of risk posed. I think it would very extraordinary for the Court to construe that same statutory language differently for two different provisions of the same clause.

JUDGE BROWN: But aren't, I mean, isn't the present decision construing research differently? In other words, the word research is being used in a different way in the same statute.

MS. BRINKMANN: In this clause, actually, in the rider itself, in that sentence, it's in the same sentence, Your Honor. It's talking about research in which and then it describes two different things. Research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death. So, it's all in one clause, and we would submit that the research in which language should be construed consistently whenever the Court is reading that same clause as is the present tense.

Two other points I would make, Your Honor, about this argument where they create this incentive type argument. The statute also talks about knowingly subjecting an embryo to risk or death in that research, and of course, even if the plaintiffs are correct that somehow you could remove it from in that research and look to other kind of future research,

the knowingly requirement would be quite a hurdle there because the knowingly could not be met because of the safeguards that are required by the guidelines themselves having to do with the informed consent only using cells that have been derived following a donation that is related to in vitro fertilization.

The other point I would make about that interpretation also, it references a regulatory degree of risk. It references a regulation involving research on fetuses in utero and refers to that for the risk of harm, and looking at that regulation again bolsters the statutory interpretation that this language applies to the research in which an embryo is subject to a risk. That regulation talks about research on fetuses in utero and talks about procedures being performed on that fetus or on that woman, and again, talking about that research which is being conducted there. It doesn't talk about whether or not that type of research in the regulation could possibly create some kind of suggestion or encourage other research in the future.

JUDGE BROWN: If this interpretation is right then, it seems as if the discussion, the debate, that was going on in Congress, you know, even back in the 70s and 80s and in the 90s about the way in which that rider prohibited embryonic stem cell research was never correct.

MS. BRINKMANN: I guess two things I would respond,

Your Honor. It was certainly correct when you're looking at the type of research that is what triggered the enactment of the Dickey-Wicker Amendment. It was pre-implantation genetic diagnosis, and it was research on embryos to determine whether or not to use these embryos for in vitro fertilization. That is clearly, that research is clearly prohibited by Dickey-Wicker, and so it does make sense in that context.

The other thing I would make, I think, in a broader point, Your Honor, is plaintiffs have pointed to no evidence, even assuming every point of this incentive argument which we reject textually, grammatically, historically, the Congressional ratification, but there's no evidence to suggest that federal funding is any kind of driver for derivation of stem cells. As President Bush pointed out, one of the important things about federal funding for this kind of research is that it makes it most publicly available. That was the benefit of this. The funding by states, private companies, and foreign countries actually over shadows the federal funding that's on publicly available websites that the Court could take judicial notice of.

JUDGE SENTELLE: That would seem to make it strange that you're bothering to litigate here if it's not anymore important than that.

MS. BRINKMANN: Well, I think what President Bush made clear, and I think President Obama repeated this in the

executive order, was to ensure that this kind of research is made publicly available and accessible to all, to the benefit of the country and to the benefit of researchers everywhere. So, in that sense, I think, Your Honor, that it does --

JUDGE SENTELLE: I'm not sure that I didn't hear a contradiction. I mean, you seem to be saying it isn't important because there's so much other funding but it is important because there's not enough other funding. Is that--

MS. BRINKMANN: No, Your Honor. The point is that--

JUDGE SENTELLE: We don't have to decide that anyway. So, I probably shouldn't pick at you about it.

MS. BRINKMANN: Well, the difference that federal funding makes is that there's certain restrictions that NIH places on research that it funds that it cannot be privatized. There's certain requirements that the results of that research being provided publicly as opposed to research that's privately funded. So, that would be an important -- but that has nothing to do with encouraging or, you know, leading to the creation of additional stem cell lines. In fact, what is in the record is to the contrary because during the eight years of President Bush's administration where there was a ban on any federal funding for use of cells that came from lines that were derived during that time period, there were dozens and dozens of stem cell lines that were created. That's in the Landis Declaration of the record where Dr. Landis speaks

about those lines being what then needed to be considered under the new guidelines to see whether or not they would be allowed.

I'd like to turn to the APA issue, Your Honor.

JUDGE SENTELLE: Can I just back you up just another minute --

MS. BRINKMANN: Certainly.

JUDGE SENTELLE: -- on the law of the case question. The language out of Berrigan says the decision of a trial or appellate court, whether to granted or deny a preliminary injunction, does not constitute the law of the case for the purposes of further proceeding and does not limit or preclude the parties from litigating the merits unless there's been an order of consolidation pursuant to rule cited. Not the case here. Given the absolute language of that statement and given that it does provide a dicta exception, but only one, can we consistent with circuit law hold that it isn't binding on us?

MS. BRINKMANN: Well, I think, Your Honor, the language that you just read explains that it doesn't limit the litigation of the issue.

JUDGE SENTELLE: Yes.

MS. BRINKMANN: But, as we point out, plaintiffs introduce nothing new to challenge that statutory language and deem much--

JUDGE SENTELLE: Well, that would seem to be a so

what?

MS. BRINKMANN: I don't think so, Your Honor.

JUDGE SENTELLE: I mean the case says that it's not law of the case. It doesn't say it's not law of the case except for plaintiff introduced, only where plaintiff introduced as further evidence or makes the argument.

MS. BRINKMANN: No. But, I think it makes clear --

JUDGE SENTELLE: It just says it's not law of the case.

MS. BRINKMANN: Right. And I think even law of the case, itself, is actually not binding. It's a persuasive principle.

JUDGE SENTELLE: Yes.

MS. BRINKMANN: It's a doctrine for internal consistency among judicial decision making, and I think here, also, the law of the circuit comes into play in the Lashon case.

JUDGE SENTELLE: Yes. In the law of the circuit, that would be Berrigan, wouldn't it?

MS. BRINKMANN: I think that the Lashon also is certainly law of this circuit looking at the principles underlying it. But, I think whether or not technically it's a ruling that it is a binding determination, I think that in this situation, it wasn't a preliminary injunction or some back of the envelope or whatever and I think that the Court,

regardless of a legal determination, the exact weight to be given to it is --

JUDGE SENTELLE: You may be stating something that ought to be an exception, and some circuits have recognized as an exception. Berrigan doesn't sound like we have that exception.

MS. BRINKMANN: Well, Your Honor, I don't think that this court has recognized, other circuits have, but it certainly is recognized that at minimum, it's persuasive, and we think that the well-reasoned opinion is persuasive and should be treated as that.

JUDGE SENTELLE: You understand it was a divided panel.

MS. BRINKMANN: Yes.

JUDGE SENTELLE: Okay. Thank you.

MS. BRINKMANN: Certainly, Your Honor. But, we think that goes all the more to the robust debate --

JUDGE SENTELLE: Okay.

MS. BRINKMANN: -- and conclusion that was reached. It ensures that there were not arguments overlooked because of the divided nature of the panel, that it was a question that was definitively decided.

On the APA issue, Your Honor, we would urge the Court to affirm Judge Lamberth's ruling there. The notice here was to implement the guidelines that were the directive

of the executive order. The executive order did not compel funding on human embryonic stem cells. It allowed funding, and that determination is made in the peer review process by NIH. These guidelines were to address the issue of how such research could be considered for funding not whether to be.

Plaintiff's suggestion would re-open issues that had long been determined. If that was the type of issue that they wanted to raise to question the very funding of human embryonic stem cell research itself, contrary to more than a decade, over three Presidential administrations, they could petition for a rule making for example or a change in a rule. But, they can't do it within the limits of these guidelines and the notice that the agency put out. Indeed, if the agency would have expanded and considered these, they would have had to re-open the whole proceeding to give notice to everyone else that they could go back and challenge and raise these issues that were outside the scope of the notice that was provided.

We think that, on that ground, Judge Lamberth looked at the issues and recognized the scope of the guidelines and should be affirmed on that.

We would also say, Your Honor, there were several things that plaintiff suggested were undisputed and as I just pointed out, we don't agree with several of their characterizations of what is and is not in dispute, and I

would also say if there were any question about the APA, we also would not necessarily agree that it should be, could be remanded without vacatur. We understand there's disagreement on the Court about whether or not that is an appropriate remedy, but we believe it is. We believe that Judge Lamberth should be affirmed on both issues here.

JUDGE BROWN: I just have a sort of different question. I think in every case here, we have decided that this is a Chevron case and Chevron is applicable. But, I just wonder why we automatically assume that? I mean, normally, when we're talking about Chevron, it's because authority has been delegated to an agency that this amendment, this rider, was an attempt to actually restrict the authority of the agency. So, why would we defer to their interpretation?

MS. BRINKMANN: I think here, Your Honor, it's an appropriation rider that's going to an issue about issuing money. I see my time is up. May I continue?

JUDGE SENTELLE: As long as you're answering our questions.

MS. BRINKMANN: Thank you.

JUDGE SENTELLE: I've often cited our late colleague, Spottswood Robinson, who said those lights only control the bar, only God controls this bench.

MS. BRINKMANN: Thank you, Your Honor.

JUDGE SENTELLE: You may proceed as long as you're

interchanging with the Court.

MS. BRINKMANN: Thank you. It is an appropriations rider, Your Honor, but it's one that has been re-enacted for more than a decade and it goes directly -- it applies to other agencies but those other agencies, educationally, do not engage in stem cell research. It was directed at NIH. The context makes that quite clear. And if you look at the re-enactment, particularly subsequent to the guidelines in 2009 for the 2010 appropriations rider, it does two specific things. Now, these are committee reports and house reports but they are then embraced by the conference report which is the heaviest area, the weightiest legislative indication that accompanies the attacks, and there they specifically reinforce that, this is on page 17 of our brief, that this language was not to restrict the ongoing research involving human, and this is a quote, involving human embryonic stem cells carried out in accordance with policy outlined by the President and also another report welcomed the guidelines noting the congressional intent to expedite this important area of research.

So, in this situation, where you have text, which is at most ambiguous, we think, actually, a plain reading could support the NIH's determination but to the extent that there is ambiguity, the Court looks to other indications for statutory construction. Whether it's determined deference --

JUDGE SENTELLE: Should we look to anything other than the enacted language for delegation? If we are looking to see if Congress delegated to the agency, the law finding power implied in Chevron? Shouldn't that have to be in the statute rather than in reports not adopted by Congress?

MS. BRINKMANN: And I would say to that extent, if you're talking about delegation, in this unique situation where it's an appropriation rider to provide grants, clearly the statute is directing the agency to make these determinations within the context of its grant making authority, and that's the peer review process, and it is directing the agency on how to expend those funds. So, it is, in that sense, Your Honor, delegating, directing, the agency what to do specifically with money with the obvious result that it is the agency who will be making that determination, in particularly, in the scientific context. So, we do think that it provides adequate authority to give Chevron deference. But, moreover, we think that Congressional ratification, the Presidential administration's determinations, the text, the research in which the present tense and the history that the research against which this was initially enacted all bolster and support the interpretation that this court's early opinion reached of the statutory text.

JUDGE SENTELLE: Thank you, Counsel.

MS. BRINKMANN: Thank you, Your Honor.

JUDGE SENTELLE: Round the appellant up to two minutes for rebuttal.

MR. WATSON: Thank you, Your Honor.

ORAL ARGUMENT OF RYAN J. WATSON, ESQ.

ON BEHALF OF THE APPELLANTS

MR. WATSON: Thank you, Your Honor. Just a few brief points on rebuttal. I'd like to start with the APA. The government made one point about the APA and that was that the peer review process that NIH uses to evaluate grant proposals somehow affects the APA analysis here, and that's incorrect for three reasons.

First, there's nothing inconsistent with establishing categorical eligibility criteria up-front as to which types of research are eligible for funding and then using a case by case process to apply those criteria and to prioritize particular research grants.

Second, NIH cannot credibly dispute that here. At Joint Appendix, page 45, a comment was made when these guidelines were being proposed, suggesting that a case by case process should be used, and the NIH rejected that on the ground that it would create an undesirable patchwork of standards. So, for that reason as well, NIH cannot now switch gears and argue that it has to resolve everything through peer review.

And then also, the third reason is to the extent

that the government tries to tie that point in with the executive order, their citing just a boiler plate phrase in the executive order that says that it does not affect pre-existing statutory authority. That doesn't prove their point in any way.

With respect to the law of the case, the government did not distinguish Berrigan in any way but merely offered a certain pragmatic considerations as to why the Sherley II decision should be followed. But, there again, is the law of the circuit. It involved a pure legal issue. It involved a situation where the panel in the first appeal issued a reported decision and the subsequent panel said even if it was substantially the same record, that prior decision was not law of the case.

JUDGE SENTELLE: Well, I don't know that the second panel explicitly said that.

MR. WATSON: The second panel did explicitly say that on the assumption that it was the same record, substantially the same record, it would reach that result and that's at 499 F.2nd 517-518. They said that even assuming it is substantially the same record --

JUDGE SENTELLE: Okay.

MR. WATSON: -- that would reach them. Thank you, Your Honor.

JUDGE SENTELLE: Thank you, Counsel. Case is

submitted.

(Recess.)

DIGITALLY SIGNED CERTIFICATE

I certify that the foregoing is a correct transcription of the electronic sound recording of the proceedings in the above-entitled matter.

Dawn M. Bahnmiller May 1, 2012

DEPOSITION SERVICES, INC.