Nos. 20-15398, 20-15399, 20-16045 and 20-35044

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

CITY AND COUNTY OF SAN FRANCISCO, *Plaintiff-Appellee*,
v.
ALEX M. AZAR II, et al., *Defendants-Appellants*.

COUNTY OF SANTA CLARA, et al., *Plaintiffs-Appellees*,
v.
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al., *Defendants-Appellants*.

STATE OF CALIFORNIA, *Plaintiff-Appellee*,
v.
ALEX M. AZAR, et al., *Defendants-Appellants*.

STATE OF WASHINGTON, *Plaintiff-Appellee*,
v.
ALEX M. AZAR II, et al., *Defendants-Appellants*.

On Appeal from the United States District Courts for the
Northern District of California and the Eastern District of Washington

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SUPPLEMENTAL EXCERPTS OF RECORD
VOLUME VIII OF X

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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK
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STATE OF NEW YORK, et al.,

Plaintiffs,

v. 19-cv-4676 (PAE)
19-cv-5433 (PAE)
19-cv-5435 (PAE)

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al.,

Defendants. Argument

----------x

New York, N.Y.
October 18, 2019
9:32 a.m.

Before:

HON. PAUL A. ENGELMAYER

District Judge

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(In open court)

THE COURT: Good morning everyone.

I will have some words of introduction in a moment but before I do I want to just take the roll to make sure I understand who is who. Who do I have appearing for the provider plaintiffs?

MS. KOLBI-MOLINAS: Alexa Kolbi-Molinas for plaintiffs National Family Planning Reproductive Health Association and Public Health solutions.

THE COURT: Good morning, Ms. Kolbi-Molinas.

MR. ZIONTS: Good morning, your Honor.

David Zionts for the Planned Parenthood plaintiffs.

THE COURT: Good morning, Mr. Zionts.

Anyone else for the provider plaintiffs?

MS. SALGADO: Yes, your Honor. Diana Salgado on behalf of the Planned Parenthood plaintiffs.

THE COURT: Good morning, Ms. Salgado.

For the New York State and other state plaintiffs.

MS. SALGADO: Good morning, your Honor. Matthew Colangelo from the New York Attorney General's Office on behalf of the governmental plaintiffs.

There are a number of other plaintiffs' counsel in the courtroom but not near a microphone. They include Marie Soueid for the State of New Jersey, Jonathan Burke for Massachusetts, Cynthia Weaver for New York City, Lisa Landau for New York

State and Justin Deabler for New York State.

THE COURT: Good morning, Mr. Colangelo.

I appreciate your putting those names on the record. I take as a given that a number of the people who are here are lawyers who have worked in one way or the other on the case. Solely in the interest of economy, I'm taking appearance only from those in front of the bar but I very much value, as I'll say in a moment, the contributions by everybody here and behind the scenes.

MS. MEYER: Good morning, your Honor. Amanda Meyer on behalf of the governmental plaintiffs.

THE COURT: Good morning to you, Ms. Meyer.

Now for the defense, who do I have for HHS?

MR. BATES: Christopher Bates from the U.S. Department of Justice representing HHS but you're asking about counsel from HHS?

THE COURT: Yes. Well I was asking for the government. Thank you, Mr. Bates. Good morning.

MR. KEVENEY: Good morning, your Honor. Sean Keveney with HHS.

THE COURT: Very good. Good morning, Mr. Keveney. Anyone else for the government?

MR. VOLTAIRE: Jean-Michel Voltaire for HHS.

THE COURT: Very good, it's Mr. Voltaire?

MR. VOLTAIRE: Yes.

THE COURT: Very good. Good morning, Mr. Voltaire.

Anyone else for HHS?

MS. ANDRAPALLIYAL: Vinita Andrapalliyal from DOJ representing HHS.

THE COURT: Good morning, Ms. Andrapalliyal.

Anyone else for HHS?

MR. TAKEMOTO: And Benjamin Takemoto for the Department of the Justice.

THE COURT: Good. Very good. Good morning Mr. Takemoto. All right.

And for the intervenor defendants, who do I have?

MR. DUNN: Good morning, your Honor. Robert Dunn for the Christian Medical and Dental Association.

THE COURT: Good morning, Mr. Dunn.

MR. BLOMBERG: Daniel Blomberg for intervenor defendants.

THE COURT: Good morning, Mr. Blomberg.

You may all be seated.

Let me begin just by welcoming everyone in this courtroom and to the extent there is anybody following in the overflow courtroom, although at this point it doesn't appear necessary, welcome to you as well.

We're here today for argument on a rule promulgated earlier this year by the Department of Health and Human Services. The rule is entitled Protecting Statutory Conscience

Rights in Health Care Delegations of Authority. It is scheduled to take effect on November 22.

In the consolidated lawsuits before me several groups of plaintiffs challenged the rule on various grounds, including based on The Administrative Procedure Act and on several provisions of the Constitution.

Before argument begins I want to take a moment and thank and compliment counsel. I have received, it is safe to say, extensive briefing from the parties. The briefs have been absolutely first rate. Really absolutely first rate. They are as good as it gets. And I have benefited enormously from counsel's thoughtful and close attention to the many complex issues in the case.

I've also received a large number of amicus briefs. They too have been thoughtful and very valuable to me.

So thank you to all of those who worked on the briefs. And I'd ask the lead counsel here to please kindly, on my behalf, acknowledge all of the lawyers and staff on your teams who worked on these briefs and associated materials and please thank them for me for a job very, very, very well done.

In terms of argument, here is how we will proceed. And earlier this week I issued an order to this effect so this will not come as a surprise to the counsel in front.

First of all, I'm going to hear argument from the plaintiffs. I've allocated 75 minutes for that.

Plaintiffs have divided their time and topics according to a letter I received from them among four advocates. The first two are on behalf of the provider plaintiffs, which is to say Planned Parenthood and the National Family Planning and Reproductive Health Association, et al. The second two are on behalf of the governmental or state plaintiffs and are from the New York State Attorney General's office.

As I did in my order, I had asked plaintiffs' counsel to please watch the clock and be sure to leave sufficient time for the later of your four advocates because I expect I'll be active in asking questions that may get you off script. I need you, nevertheless, to be mindful of the time just so that important topics that happen to be batting third and fourth don't get squeezed for time.

After I hear from the plaintiffs, we'll then take a short comfort break and I will then hear from the defendants to whom I've also allocated 75 minutes. Specifically, I've allocated 65 minutes for HHS and ten minutes to the intervenor defendants, specifically counsel for Dr. Regina Frost and the Christian Medical and Dental Association.

I hope afterwards we will have time for rebuttal and follow-up. I certainly expect that I will have a lot of questions for all counsel throughout.

So with that preface, let's begin with the provider

plaintiffs and I understand that I'll hear first from Mr. Zionts.

MR. ZIONTS: Thank you, your Honor.

THE COURT: Go ahead.

MR. ZIONTS: Thank you, your Honor. And good morning. I'm mindful of your Honor's instruction in terms of time allocation. Just to let you know in advance my plan here is to speak for about 15 minutes and each of my colleagues plan to speak for about 20 minutes although, of course, we'll be in your hands in terms --

THE COURT: Thank you. That's helpful to know.

MR. ZIONTS: Your Honor, I'll be spoking about HHS's authority or rather lack of authority to issue this regulation. I'd like to start with a basic but fundamental point.

The heart of HHS's position is that the rule is just housekeeping. The agency says it is just letting everyone know how it interprets the refusal statutes and how it enforces them so it doesn't need any delegation of substantive rule-making authority.

Your Honor, the best answer to this argument is in the text of the rule itself. At every step it is clear from the face of the rule that it is legislative, imposing substantive requirements on regulated parties.

So with the Court's permission, I would like to very briefly walk through the rule's key provisions.

THE COURT: If I may. I know -- I know what the key provisions are. Let me see -- I understand your point that components of the rule are substantive and legislative and I understand those to involve the definitions of discriminate and assist in the procedure and the like.

But let's focus on the other side of the equation. Is there some part of the rule that you would acknowledge is housekeeping and that can properly be done under the housekeeping statute?

MR. ZIONTS: Your Honor, what I would say is there are parts of this rule that could have been done in a way that would be consistent with housekeeping.

For example, if the agency had simply said: Go look at the UAR; we are letting you know that we will follow to the letter the UAR and that is how we will enforce, I think that would indeed be housekeeping.

But the way this rule is structured at every step of the way it's hard to disassociate the pieces of this that impose substantive requirements from other provisions that might for example, if done differently, could be genuine housekeeping.

THE COURT: Well let me pushback on that. You say repeatedly in your briefs that you're not challenging the conscience provisions that are in the statutes, correct?

MR. ZIONTS: Correct, your Honor.

THE COURT: Let's assume for argument's sake, imagine whatever scenario you would concede would be a between-the-eyes blatant violation of those statutes. Right now I take it the law is silent as to remedy.

Imagine a violation of the statutes. Put aside any gloss on those statutes by rule. Just imagine a between-the-eyes violation.

MR. ZIONTS: Right.

THE COURT: What does HHS do without rule-making to explain how the process of adjudicating a violation is and what the consequences would be and is that something that HHS can properly rule-make on?

MR. ZIONTS: Well, your Honor, there was a 2011 rule, that we do not challenge its validity, that provided a complaints mechanism and we don't dispute the agency's power to do that.

THE COURT: Now let's suppose the complaints process results in a finding of a between-the-eyes violation or set of violations. Is there anything out there right now that would set out the consequences?

MR. ZIONTS: Your Honor, we also do not challenge the existing regulatory grant procedure.

So, for example, if OCR, through that 2011 complaint procedure, determined that there was a square violation of the statute -- not the rule, of the statute -- then the agency's

position, and we don't have any problem with this, is that they would go through the ordinary procedures under the UAR. Remedies would be limited to that. There would be notice and due process and there would be -- one key feature of the UAR is the remedy is generally limited to the specific source of funding at issue. And they could do that. We're not disputing that.

THE COURT: So if there were a violation, let's say, of any or all of the ACA, Medicaid, or the other three primary statutes that are our main focus here, you don't dispute that under existing authority the agency, if it crossed its Ts and dotted its Is, it could ultimately get to the place of retracting federal funding limited to the funding stream attributable to that statute?

MR. ZIONTS: Right, your Honor. It would be limited to the funding stream.

And one just additional crucial point would be that in terms of -- I think in this hypothetical we're talking about a square, everyone-would-agree violation. And just one key proviso I would put would be: HHS would have its view of what the statute means and it would go through this procedure and it would be free -- it would be upon the regulated party to potentially go to court and say it doesn't mean this. And there would be no deference at that point. The Court would decide.

THE COURT: Give me an example of something you would agree is a between-the-eyes violation of the conscience statutes.

MR. ZIONTS: Your Honor, I think Ms. Salgado may be able to speak to this a bit more when she addresses discrimination. If, for example, just turning to the Church Amendments, speaking of discrimination of employment because someone performed or refused to perform.

If you had someone who was -- who an employer demanded you must perform an abortion or you'll be fired, there is no hardship to the employer to find someone else to do it. There is really no reason for purposes of patient care. There is no emergency, etc. It's essentially: Person standing there. Do it or you're fired. No good reason, no hardship preventing that. I think we would all agree that that violates the statute.

THE COURT: Under the UAR suppose there's a singular violation, one violation to that effect. But it's absolutely adjudicated perfectly and there is no question that exactly that happened.

If the agency, crosses its Ts and dots its Is, at the end of that possess for that single violation does the existing statute and the existing regulations, do they permit the agency to pull the entity's entire funding under that statute?

MR. ZIONTS: The agency's entire funding, I don't

think so, your Honor.

THE COURT: Under that statutory -- under that one statute?

MR. ZIONTS: Well, your Honor, I think it's not just -- I distinguish between the statute itself.

So, for example, the Church Amendments which might impose obligations across a range of funding stream grants, etc. Generally the way the UAR works is that it speaks of the cost of the specific federal award or activity. So in general if there was -- we're speaking hypotheticals -- if there were to be an actual health care entity that committed this violation and committed a violation, of course, of a particular funding stream, I think what the UAR would say is you could lose that. Of course, there's voluntary remedies. The UAR is phrased a little differently from this rule in that it is intended to escalate and to give various offramps for voluntary remedies and cessation. But ultimately you could lose funding under the particular grant at issue. We don't think anything in the UAR provides for just wiping out all federal funds.

THE COURT: Go ahead.

Sorry. Just explain to me just a little more the meaning of funding stream, as you concede, it could be implicated by a violation. The Church Amendment covers a number of different funding streams. I want to be sure that I understand what you're acknowledging and what you're resisting.

How would HHS ultimately, if we got to the end of the series of enforcement events, how would they go about defining the funding stream that is jeopardized by such a brief?

MR. ZIONTS: Your Honor, I think just looking at the language of Church, and it applies based on receiving a grant contract, loan, or loan guarantee under the Public Health Service Act. So I think you would go grant-by-grant, contract-by-contract. And, again, you would have to see how this would play it, and it could vary depending upon the circumstances. I think you would look at the grant.

THE COURT: Let's look at a big one. Let's suppose it's Medicare or Medicaid. Let's use New York State as an example, although they'll have an opportunity to defend their own perspective on this. But imagine, again, a between-the-eyes violation of the sort that you hypothesize and assuming that no offramp applies or is activated, at the end of the day for one error like that, can New York State lose its entire let us say Medicaid funding?

MR. ZIONTS: Your Honor, I do not want to stand here and bind the State of New York.

THE COURT: Choose some other state.

MR. ZIONTS: Particularly when they are sitting right here.

What I would say, it's an interesting problem that the agency itself has not clarified. Their position here has been

this is all part of existing regulations. And they're fairly specific about the UAR, which is about grants in particular.

THE COURT: Why can't -- go ahead.

MR. ZIONTS: I was going to say with respect to Medicaid, we're actually not sure how the agency believes it would go about withdrawing federal funding; not in terms of the rule, in terms of if it believes it as the existing statute.

So in the part of the rule where it speaks to: For grants, see the UAR; for contracts, see this. For Medicaid, it just says in the rule: See the Social Security Act. They don't point to a provision. They don't point to a regulation. So we're not really sure how they think existing regulations would allow --

THE COURT: Well then that begs the question. It's the agency's existing regulations don't clarify the universe. What is it that prevents the agency, whether in the context of this rule or another, from sharpening up its guidance even if, perhaps, having a more muscular approach to these problems and saying at least in this area where we're talking about violations of religious or moral conscience rights recognized by statute, we're going to have a particularly strong penalty and deterrent. Why can't they do that?

MR. ZIONTS: Your Honor, we think -- well, first of all, the statute itself, just looking at the Church Amendment, Church B-- this may not be a good example because it doesn't

apply to Medicaid funds but Church D may. Church D is simply written as individuals have a right not to do acts. And it doesn't say anything about: Or else you lose X or Y or X, Y, and Z or everything under the sun.

So in our view -- we acknowledge there are things that HHS can do under its existing authorities in a careful step-by-step way, in a way that has been done for as long as these statutes have been on the books and, in particular, under the 2011 Rule.

But when Congress intends the Draconian remedy of you lose all your federal funding, a state loses Medicaid, it says so. Title VI says so. It says agencies have the authority to promulgate regulations, provide for the termination of funding, provide adaptors to process. There's even notice to congressional committees. And it doesn't say anything like this. So while -- we're happy to concede that there is some level in the administration of these grant programs that it can do, it would be quite anomalous if we're -- in Title VI Congress was very explicit in saying you can take money but only up to here and with these protections. Here, the Congress didn't say anything but HHS has free reign to say we can take it all.

THE COURT: Very helpful. I want to give you a chance in a moment just to turn to the more substantive dimensions of the regulation, but one final housekeeping-type question.

The rule has new assurance and certification requirements imposed on recipients. Are those compatible with the housekeeping statutes?

MR. ZIONTS: We don't think so, your Honor. And, again, if you look at the rule, here's how Section 88.6 is written. Parties shall, in quotes, shall. Excuse me. It's 88.4. Requires that the applicant or recipient to comply with applicable federal conscience and discrimination laws and this part, and this part is referring to this part of the CFR.

So, first of all, that certification does not just certify that you comply with the underlying statutes. It's saying what we just added to the CFR, which are substantive legislative requirements, you have to certify --

THE COURT: Fair. Fair point. Strip away the substantive components of the rule and focus just on the violations or not of the statute.

Could HHS under its housekeeping authority require the hospital, state, etc. to comply with assurance and certification if those -- if that's limited to compliance with the statute?

MR. ZIONTS: Your Honor, I think there are -- in the existing UAR there are much more general certifications. This is a bit different in that --

THE COURT: But the UAR is a measure of what the agency can do. It's one thing the agency has done but they may

or may not be able to do more.

MR. ZIONTS: Agreed, your Honor.

The main point I would make is that this is, in our view, a substantive requirement: You shall complete the certification. And that has legal consequences. A certification raises issues under the False Claims Act. You could potentially be sued if someone thinks that you have made a certification for compliance with these statutes and someone believes that that was false and that led to receiving federal funds. And so when an agency legislates and says you must do this -- and when you look at the enforcement provisions as well, 88.7, the enforcement provisions, they say they will take your money away if you violate this part, and that includes certification.

So even if you haven't done anything substantively wrong, if you just don't do the certification the way they say, they say you violated the regulation, we will enforce it, that's a substantive force of law rule.

THE COURT: All right. Let's turn to the substantive parts of the statute. And I think I understand from your briefs the definitions of all the various statutory terms are ones that you intend, and I understand why, are substantive.

MR. ZIONTS: Right. Your Honor, I think I'm about at fifteen minutes. I will just say one word. The -- we do think it is clear when you look at the way this rule is framed,

including with the definitions and the way they work with what the rule calls applicable requirements and prohibitions, this is a federal agency telling regulated third parties: Do this or you will be in trouble. Do this or we will enforce against you.

The one point, just because it's not in the briefing, I wanted to alert your Honor to a decision, fairly recent decision from the D.C. Circuit called Guedes v. ATF. The citation is 920 F.3d 1. It's somewhat similar in the sense that there you had an agency insisting that all it was doing was interpreting, telling people -- this had to do with the bump stocks regulation -- it was just telling people how it interprets this rule.

The agency said: No. It says shall. It's in this CFR. The agency was claiming Chevron deference. Everything about it said legislative substantive rule-making. And the Court said yes. And I think the Court, if you look at the opinion, you'll find a number of parallels. The one difference in that statute was the agency was actually delegated authority to issue a legislative rule. Here, we have all the indicia of a substantive legislative rule. We just don't have any source of authority to do that.

THE COURT: Final point on that. That appears to be so, at least explicitly with respect to Church and Coats-Snowe and Weldon. But under the Affordable Care Act and Medicare and

Medicaid there is some grant of substantive rule-making authority.

Suppose the rule had simply defined terms like discriminate or refer, etc., within the framework of the statutes that do have substantive rule-making authority delegated to the agency. Could the agency have done that, had it confined the definitions to the statutes that have the explicit delegation of rule-making provisions?

MR. ZIONTS: We may have other problems with that, but in terms of statutory authority, we absolutely agree. The ACA says you can regulate on this topic. It can't --

THE COURT: So while you're not happy with the definitions, as it relates to those statutes, the ACA, Medicare, Medicaid, you're not making a lack-of-authority challenge with respect to the definition of those statutory terms for those statutes.

MR. ZIONTS: That's right, your Honor.

THE COURT: Thank you.

MR. ZIONTS: In the interest of keeping everything moving, I'll turn things over to Ms. Salgado, unless your Honor has any other questions on the rule-making issue.

THE COURT: No. I think there will be an issue about remedy and severability that is very much implicated by our last exchange. But I think it's better to move on and we'll touch on that later. Very helpful. Thank you.

So next up I think is Ms. Salgado.

MS. SALGADO: May it please the Court, Diana Salgado on behalf of plaintiffs.

Your Honor I'm going to focus my time on two plaintiffs' claims: That the rule is contrary to law and, if time permits, that the final rule is not a logical outgrowth of the proposal.

There are several reasons that the rule is contrary to law but I'd like to start with conflict with the underlying statutes. In promulgating this challenge regulation, not only has the agency given the rule the force of law but it has also stretched the terms of the statutes beyond their limit and far exceed what Congress intended.

Starting with the term discrimination, which is found in nearly all of the underlying statutes, HHS has taken a general prohibition on nondiscrimination and promulgated a regulation that defines the term to mean that health care entities, such as the plaintiffs here, have an absolute duty to accommodate employees who have objections to performing or assisting in the performance of, and depending on the statute, abortion or sterilization and must do so regardless of the burden on employers and the patients they're seeking to serve.

THE COURT: So pause on that for a moment.

Let's focus on the part of the rule that affects employees and employers. I take it your view is that up to

this point the Title VII framework has governed that.

MS. SALGADO: That's correct, your Honor.

THE COURT: And Title VII requires that ultimately at the end of the sequence if there is an undue hardship essentially the employer is allowed to refuse to accommodate the religious objector.

MS. SALGADO: Yes.

Title VII requires that an employer provide a reasonable accommodation unless there is an undue hardship on that employer.

THE COURT: So is the point here then at least as to the employment dimension of the world covered by the rule, we've got a square conflict with a statute, Title VII.

MS. SALGADO: Well, your Honor, we haven't -- that's true. There is -- that the statutes or actually that the agency, in the way that they have interpreted the statutes in this rule, seeks to abrogate Title VII's application.

THE COURT: I have read with great interest your briefs that focus on the emergency care and Title X and whatnot. Why isn't the most explicit example or, as good an example you have, Title VII where since 1972 we have a statute that appears to encode the hardship exception and, therefore, it has much more of a carve-out than the rule does in allowing an employer that needs to exist to insist.

MS. SALGADO: I'm sorry, your Honor. Are you

asking --

THE COURT: It's a softball but it's an important question. But the reason I'm asking is from your briefs I did not get the impression you were pushing nearly as frontally on the conflict with the statute, and a familiar one at that, Title VII, as a basis for your contrary-to-law argument.

MS. SALGADO: Well it is true, your Honor, as you know, we have brought many claims in this case and one specific one is not that the rule itself conflicts with Title VII; rather, that the term discrimination and the way that the agency has interpreted that rule here is not a faithful application of the underlying statutes; that the agency has exceeded what Congress intended when it passed the refusal statutes.

THE COURT: Right. I'm just trying to understand why the argument isn't being made flat-out that at least as to the definition of discriminate it can't stand because that aspect of the rule is contrary to a separate law, not the law under which the agency purports to have but Title VII, which predates even the first of the conscience statutes, has given employers an opportunity -- a hardship basis for refusing to accommodate.

Why isn't the simple answer -- and I'll obviously be eager to hear the government's perspective -- why isn't the simple answer Title VII is law; the agency by regulation can't contravene that?

MS. SALGADO: That is our position. That's absolutely our position, your Honor, is that in interpreting this -- the statutes that the agency has promulgated a definition of discrimination that is in conflict with Title VII.

THE COURT: If I were to agree on that, what part of the rule would be unaffected by it? Would it be the parts that simply don't affect the employment context?

MS. SALGADO: Your Honor, absolutely those parts would be affected. I think that raises a fair question, which is: Are there other applications of the agency's definition of discrimination that are not a faithful application of the statute beyond the employer and employee context.

And as a whole, your Honor, we believe that the term discrimination is always sensitive to context and circumstance. It always considers whether there is a justification for the treatment that's being complained of.

So as a broader matter, the term discrimination that the agency has put forth here in this rule as a whole is not a faithful application of the statutes.

THE COURT: So let's get down to brass tacks. Your agency employs medical professionals, correct?

MS. SALGADO: That's correct.

THE COURT: Pre-rule, if you had a religious objector who didn't want to participate in an abortion, didn't want to hand the forceps over or something like that, how would --

within the Title VII framework and in the real world how does your agency deal with an objector like that?

MS. SALGADO: Well, your Honor, you're correct that we have health care professionals that would be subject to this rule in medical centers all across the country, in every state of this country. And how a religious objections are dealt with are through the Title VII framework.

THE COURT: So a nurse says: I've been on the job for a while. I've now developed a sincere religious view that prevents me from assisting in an abortion. Let's put the nurse in the operating room so we're not dealing with more distended ways of assisting. The nurses says: No can do.

What is it that the -- how does the agency -- how does your -- as an employer, how does your client deal with that problem now within the Title VII framework?

MS. SALGADO: Well, your Honor, it's a hard question to answer because the -- in terms of how a very specific objection would be dealt with, I think it would depend on a number of factors. It would depend on whether the agency or the plaintiffs in this case have a duty to try to reasonably accommodate the nurse.

So the question would be: Is there is a way to accommodate this particular individual's objections by, for example, if abortions were only performed on a certain day then that nurse -- there would be perhaps a conversation about

whether that nurse would be willing to work on the days when abortions are not provided.

THE COURT: You would reallocate responsibility so the nurse worked on non-abortion procedures?

MS. SALGADO: Exactly, yes.

Or there might be a question of whether instead of actually working in a room where abortions are being provided, whether the nurse would actually be -- whether be able to work in a different room.

But all of those decisions have to be balanced with whether accommodating that nurse would impose a hardship.

And if I may, your Honor, just add that the record evidence, what it shows is that the plaintiffs in this case operate several clinics where there is only one medical professional.

THE COURT: That's where I was going to go in the rural hypothetical or the short-staffed hypothetical that appear here. Maybe it hasn't, in fact, arisen in the real world, but how -- under the current framework what would your client do if in the end there wasn't an alternative person to fill in?

MS. SALGADO: Well, your Honor, I do think there is a question of whether -- what the individual has been hired to do as one of their primary or substantial duties to perform, then I think there is a question of whether that individual was

qualified for that position.

THE COURT: Right. And I'm using the hypothetical in which a sincere religious conviction develops after the point of hire. And so we're the actually -- you've got an employee -- is it your view ultimately that under the Title VII framework, in our hypothetical rural hospital, if the person cannot do an essential part of the job and there's nobody else, in the end that could be a basis for something up to discharge?

MS. SALGADO: Depending on the facts and circumstances, yes. I mean I guess I would say that many of Planned Parenthood's affiliates operate several health centers in a particular region. So perhaps there would be -- and not every one of those centers offers abortion so there would be a conversation of whether that person could be transferred to a different health center. And, yes, your Honor, if what the nurse was hired to do was to assist with -- assist in the performance of abortion services or in states that actually allow it provide abortion services and the individual developed a religious objection and was not able to perform the primary duties of their position and was not willing to work on other days or be transferred to another health center, then, yes, your Honor, I think the Title VII framework does allow for consideration of undue hardship.

THE COURT: And under the rule, same hypothetical, if the rule were to take effect, how does it work as you

understand the rule?

MS. SALGADO: I think the rule has no consideration or the term -- the rule's definition of discrimination has no consideration of a balancing of interests, the interests of the employer in seeking to provide care, or the interests of their patients. And it doesn't allow for any consideration of hardship. The only thing that the rule references is, quote, an effective accommodation, which is one that the employee must voluntarily accept. And isn't lost on anyone than an effective accommodation is different than a reasonable accommodation that allows for some consideration of the balancing of interests.

THE COURT: But in the end there is no hardship exception to the rule is your point.

MS. SALGADO: That's correct, your Honor.

I would say as an example of, a real world example, because we've been talking about hypothetical situations, a real world example of how the rule would work, if I may, a reference the Court to the Shelton case.

THE COURT: I was -- I've got that on my list for the defendants.

MS. SALGADO: And in that case the nurse refused to assist in emergency abortions. The second time the patient was standing in a pool of blood and the nurse still refused to perform an emergency abortion. It took the hospital 30 minutes to find another person to fill in. And even after that the

hospital offered the nurse an accommodation to the NICU department. She refused and the hospital had no other option but the terminate her. She brought a Title VII claim and the Court found against her because the hospital had offered a reasonable accommodation.

THE COURT: Your point is under the rule if the rule were law Shelton comes out the other way?

MS. SALGADO: That's right.

And certainly the agency has not said otherwise.

THE COURT: All right. Thank you. Very helpful. I realize I've taken you off topic. Focus on other ways, apart from the Title VII conflict, that the rule is contrary to law.

MS. SALGADO: Yes, your Honor.

So I think the -- as we were just discussing in the context of emergency abortions, the rule has no exception for cases where there is a need to provide emergency treatment. And the parties agree that under the Emergency Medical Treatment and Labor Act there is a duty for providers to provide stabilizing treatments or a transfer, if possible. And defendants don't dispute that in some cases patients need emergency abortions. But the rule doesn't have any exception for that. All the agency has said is that it will -- it will seek to harmonize the statutes to the extent possible. That isn't -- EMTALA doesn't say that it can be applied, quote, to the extent possible. There is no exception.

THE COURT: When was EMTALA enacted, if you know?

MS. SALGADO: I don't, your Honor. I know that it predates -- I am sure that it predates Weldon and I don't know -- I'm being told 1985 or 1986.

THE COURT: So it comes after Church. It comes after the first of the conscience provisions but not some of the later ones. I guess the question is whether there's anything in the legislative history of the later ones that suggested an intention to modify the state of play under EMTALA, emergency statute.

MS. SALGADO: Yes, your Honor. Each of the statutes there was discussion about -- well Weldon specifically Representative Weldon specifically noted that EMTALA forbid health care facilities to abandon patients with medical emergencies and particularly pregnant women. Senator Church also made clear: We're not permitted to shield a hospital from denying services in, quote, in emergency situations, life or death type. And Senator Coats also stressed in his amendment which was, as I've said in the briefing, the Coats amendment was actually focused on abortion training, so it was a little bit more removed, but Senator Coats did stress that the amendment wouldn't prevent physicians from being able to provide -- or being trained to provide emergency treatment.

THE COURT: One thing I'm couldn't quite figure out was the interplay between EMTALA and Title VII under current

law. In other words, in practice is the way EMTALA applied in the use of undue hardship notes from Title VII but in an emergency context the employer has a particular deference, or the hardship concern comes particularly before you can't have somebody, you know, stopping in a transverse on the way to the hospital because they realize they're driving somebody to an abortion.

MS. SALGADO: Absolutely, your Honor. I think the Sheldon case highlights this; is that the hospital, after having two serious incidents in which a nurse was not providing care to a patient that had life-threatening conditions, the hospital had to remove the nurse. I'm not -- honestly, I'm not quite sure whether that decision discusses EMTALA, but I think that is an example where the hospital -- that it would have been an undue hardship for the hospital if -- to keep that staff and not be able to comply with EMTALA.

THE COURT: So I have your points on Title VII and EMTALA. Just come back just for a moment to the ACA.

The ACA does have a substantive ruling provision and it specifically says that nothing in the Act shall be construed to have any effect on federal laws regarding conscience protection.

Given that, what's the contrary-to-law argument you have with respect to the ACA?

MS. SALGADO: Well in the ACA, in Section 1554 of the

ACA specifically, that statute prohibits HHS from promulgating regulations -- or shall not promulgate any regulation that creates any unreasonable barrier, impedes timely access to health services. And specifically Section 1554 of the ACA what it says is: Notwithstanding any other provisions of this Act the Secretary of Health shall not promulgate any regulation that does these six different things.

So, your Honor, I think that it was clear that Section 1554 was meant to trump any other provision of the Act including section -- I think you're referring to Section 1303, 42 U.S.C. 1823. So I think it's clear by the face of the statute that Section 1554 was meant to trump any other provisions of the Act including that provision.

I would also note that in Section 1303 --

THE COURT: In other words, the ACA leaves in place all the conscience provisions that were there by statute. Your issue is that if the agency substantively expands the reach of those provisions, then you're not only -- whatever other rule-making issues there may be, you're now encroaching into a space that the ACA limits the agency's room to run in.

MS. SALGADO: Yes, your Honor. Section 1554 has been on the books for nearly nine years, coexisting with refusal statutes. So our position isn't that 15 -- defense counsel has tried to argue this but our position isn't that 1554 conflicts with the statute. It conflicts with the rule or, better yet,

the rule conflicts with the statute because the rule itself does -- it does create unreasonable barriers to the ability of individuals to obtain appropriate medical care. It does impede timely access to health care services. And the most clear example of that is by not having exceptions for emergency services. But I think that there are other ways in which the rule also violates 1554, right, even outside of emergency care. The rule also restricts full -- requires full disclosure of all relevant information to patients. But through the expansive definition of assist in the performance, which includes referral. And the way in which they have defined referral means that just the mere provision of information if that person believes that it will assist someone in performing an abortion is a referral, that would lead individuals to be able to deny people basic information such as if a patient faced with an unplanned pregnancy asked about abortion --

THE COURT: The rule reaches back to events, days, weeks, months before the procedure, including a phonecall, a conversation -- a chat with a receptionist.

MS. SALGADO: Exactly, your Honor. We think in those ways, by allowing refusals or individuals to refuse to provide basic information is another way in which it violates the clear mandate of Section 1554.

THE COURT: Why don't you in the remaining time just deal with logical outgrowth briefly. Your argument is that the

agency in it's notes and rule-making didn't, among other things, telegraph the possibility that it will be repudiating the Title VII accommodation framework. I get the argument. Nevertheless, a lot of commentators clearly understood that that was in play because a lot of the comments on the rule are addressing just that.

Doesn't that suggest that while the agency could have been more precise it was understood that the accommodation framework was in play in the rule-making process?

MS. SALGADO: Well I have two responses to that, your Honor.

The first is that, as a legal matter, the agency cannot bootstrap notice from the comments; otherwise, that would turn notice into an elaborate treasure hunt of which interested parties would have to search the record for the sort of buried treasure.

But you are right, your Honor. There were several commenters that submitted comments imploring the agency to make clear that it was not taking away the reasonable accommodation undue hardship framework. Those comments came from the plaintiffs in this case but they also came from major medical organizations, American College of Emergency Physicians, The American Medical Association, The American Hospital Association.

But they were in response -- what they were in

response to was the fact that the proposed rule actually -- it only had -- I think it had four sections. But the proposed rule gave a definition of discrimination that just listed out certain types of actions that would be deemed discrimination like the withdrawal of a benefit or termination. And that's all it said.

THE COURT: In other words, the rule was silent about the other side of the equation?

MS. SALGADO: Exactly.

And in response to the comments, where the plaintiffs and other organizations and other medical providers weren't sure what the rule meant, in response to that they submitted comments asking for the reasonable accommodation undue hardship framework, explaining that it would --

THE COURT: But from an administrative law perspective, the fact that the agency is essentially talking about a bright line ban and not talking about an offset, a hardship, a carve-out, an exception, why isn't that notice enough that the agency's not talking about a hardship or an exception; i.e., that's it's rethinking the whole framework?

MS. SALGADO: You're right, your Honor in that the -- we were on notice that the agency was rethinking or might have been, I guess, really, right; that the agency might have been rethinking the framework because our position is that when -- is that the term discrimination in the employment context

inherently requires a balancing of interests; it inherently, certainly in the context of religious accommodation, for decades that term has meant to include the reasonable accommodation undue hardship framework.

So what I would say what the public was on notice of was that the agency may be thinking that it was going to strip away Title VII protections. But what they weren't on notice of was the unusual ground rules that the agency has put into the rule in subsections four through six; not only that, there is this, quote, effective accommodation, which is a term that the agency has made up; but also that you can only ask employees about their objections once perfect calendar year or you can't ask potential hires unless there is persuasive justification. You might be able to post notices but only unless it's adverse action.

The public had no notice of those unusual groundworks.

THE COURT: This shows up in the final rule and not before.

MS. SALGADO: Exactly.

And the reason why I think -- the agency tries to push these away as just details, but at every turn through its briefing it points to those subsections as the agency's -- the framework that it is created and the reason why the rule is justifiable and reasonable. And so we believe that the agency's failure to put the public on notice of this new

framework it created does violate the notice of common procedures and the APA.

THE COURT: Ms. Salgado, I want to come back to contrary law. There's an establishment clause challenge. For argument's sake assume that the Court were to conclude that there was not a facial establishment clause problem here but there are all sorts of imaginable hypotheticals that could give rise to as-applied challenges. Does that then become a basis to argue that the rule is contrary to law or does the fact that any establishment clause problem on my hypothetical conclusion could only be as applied, prior view to the ability to identify the establishment clause violation as contrary to law?

MS. SALGADO: If the Court -- I just want to follow your hypothetical. If the Court found --

THE COURT: There is no facial establishment clause problem but as applied you could have any number of such problems but on its face it's not a violation of the establishment clause, does that prevent you as a matter of Administrative Procedure Act Doctrine, does that prevent you from arguing that on that basis the law is contrary to law -- that the rule is contrary to law?

Do as-applied violations count?

MS. SALGADO: Well, we don't believe this is an as-applied violation. But I will confess that you have stumped me and if I may confer with my colleagues and get back to you.

THE COURT: There will be a chance for -- I expect a chance for rebuttal. That is of interest to me. Thank you, Ms. Salgado. Very helpful.

Next up is Mr. Colangelo.

MR. COLANGELO: Good morning, your Honor.

Matthew Colangelo from the New York Attorney General's Office on behalf of the plaintiffs. And I will argue the arbitrary and capricious claims for relief in these consolidated challenges.

Your Honor, to meet the standard for reasoned decision making the agency must examine relevant data and articulate a rational connection between the facts found and the choice made. The agency fails this test and its decision must be set aside as arbitrary where its explanation runs counter to the evidence before the agency, the agency entirely failed to consider important aspects of the problem, or the agency doesn't justify its reversible unsettled policy.

Here, HHS fails each of these tests of a rational agency's action, first, because the agency's explanation is counter to the evidence in the administrative record.

In multiple critical respects the agency relied on a factual claim of evidence that examination shows to be either mischaracterized or flatly untrue.

THE COURT: I'm eager to have you get into it in just a moment. One threshold question. It looks as if it has been

ping pong ball between administrations here. You have the 2008 rule, which prefigures part of the current rule. It's retracted to say that at some point the administrative component in 2009 is substituted by a 2011 rule that, again, is more housekeeping and now there's a change of administration and there's a new policy.

To what degree does the agency have to -- let me put it this way. You're arguing that there's a change in effect from the 2011 rule and I appreciate that, but there is some harmony, some extension, but some harmony with the 2008 rule. Why isn't that also a relevant point of comparison here? Why is the only test here how this compares with what the agency had done and thought at the previous chapter which you go back to two administrations ago they're more in sync?

MR. COLANGELO: It doesn't inform the Court's analysis for two reasons, your Honor. First, if we're looking at the chapters in the story, I think the story most reasonably told is that for nearly the entire 46-year history, starting with the enactment of the first Church Amendment in 1973, there was no need at all for any regulatory implementation for any of these statutes. The 2008 rule, published in December of 2008, was the first effort to regulate these statutes at any point and never took effect. So as a practical matter I don't think the 2008 rule is --

THE COURT: Why did it never take effect? It was that

the implementation date was into the next administration and it was tabled or was there an injunction?

MR. COLANGELO: There was an implementation date that was to take effect I believe the day before the inauguration of the new president. The incoming administration suspended effective dates. There was litigation in the District of Connecticut. But then the agency said that it was not -- both not enforcing the regulation and was not completing the paperwork production act process to implement the certification requirement in the 2008 rule. So as a practical matter that rule was never enforced and didn't inform the state of play.

So I think the more realistic assessment of the state of play is that for nearly five decades no regulations had been necessary and, in fact, that's what the agency said in 2011 when it completed the rescission of the 2008 rule.

Your Honor to go to the many ways that this rule is counter to the evidence, there is no specific example where this error is more egregious than with respect to HHS's claim that it relied upon a, quote, significant increase in complaints filed with OCR alleging violations of the laws that were the subject of the 2011 rule. The administrative record makes clear, after we moved to compel its completion, that those assertions are factually false. And a factually false evidentiary claim can't be the basis for reasoned agency decision making. Now for context, your Honor --

THE COURT: There are a lot of complaints but they deal with extraneous matters like vaccinations, right.

MR. COLANGELO: Yes, your Honor.

Nearly 80 percent of the 343 complaints the agency said it relied on deal with vaccinations which the defendants now concede have nothing to do with the underlying statutes. Another 15 percent of the complaints are irrelevant because they either oppose the rule-making. They don't allege prohibitive conduct like the complaint that the state attorney was failing to prosecute a voyeur. They don't cover a protected entity like the complainant who said that the FDA was acting like the Mafia because it required the removal of social media ads for divine cancer care. That leaves just 21 complaints, only six percent of what the agency said in the final rule that they were relying on, that even potentially allege a violation.

Now we quarrel with some of those complaints. But even if you accept them all, to say that you've relied on 343 complaints of discrimination when the record -- the uncontested record shows you relied on at most 20 in a two-year period.

THE COURT: Is there any indication of how many complaints had been there before just by way of comparison?

MR. COLANGELO: So the administrative record shows that the agency received, I believe it was either nine or ten complaints from 2010 to 2016. So the figure that I believe the

agency cites is one or two each year for the years before 2016 and then they claim 343 in fiscal year 2018. In point of fact they received only 20 in a merely two-year period from the November 2016 election until the end of fiscal year 2018.

It's the definition of arbitrary to rest a decision so consequential on claims that are factually untrue or can be so readily disproved. The Second Circuit reached that conclusion three-and-a-half decades ago in the Mizerak v. Adams case. An agency's decision is arbitrary and must be set aside when it rests on a crucial factual premise shown by the agency's records to be indisputably incorrect.

Your Honor, to emphasize, this mismatch between what the agency says they relied on and what the record shows is only known because we sued and only known because after suing we moved to compel completion of the record. It should go without saying that it's not a rational basis for agency decision making to fail to disclose the true facts.

THE COURT: Put another way, the administrative record shows that this is a solution in search of a problem.

MR. COLANGELO: Yes, your Honor. I think that's exactly right.

There are a number of other ways in particular that the record shows that the rule is a solution in search of a problem. So, for example, the harms that the agency identifies, and by their own analysis HHS estimates that this

is a billion-dollar rule, costs more than nine hundred million dollars to implement over the first five years, so nearly a billion-dollar rule in quantifiable costs.

THE COURT: What would make it so costly?

MR. COLANGELO: The most significant component of those costs, your Honor, are the assurance and certification requirements. I believe they estimate about $150 million a year to implement the certification and assurance requirements. And then the additional costs that they quantify are other costs regarding familiarization with the rule and other compliance procedures.

One of the harms that they fail entirely to examine in any adequate way is the overwhelming showing of harm to specific patient populations in particular vulnerable communities like immigrants, poor people, women, people of ill health, the LGBT community. The administrative record includes overwhelming evidence from not only advocacy organizations but the nation's leading medical associations and health care providers that access to care would be undermined by this rule and the agency does not quantify those costs.

THE COURT: Come back for a moment though to your first point which had to do with the falsity in the stated number of complaints.

What should I take away from the fact of not just the falsity but the number of complaints? Why so few complaints?

What does that mean about the world as it's working?

MR. COLANGELO: So, your Honor, I think that the fact that there is so few complaints shows that the fundamental justifications for this rule are not well founded.

Now the agency says that they needed greater enforcement authority and they needed to clear up confusion. And they also make the assertion that the relative absence of complaints before 2016 was really only a function of the prior administration sending the signals that they weren't open for business. They didn't want to hear from complainants regarding violations of conscience rights.

Now, two-and-a-half years after the agency has attempted to send the opposite signal, to receive only ten complaints a year when, remember, your Honor, OCR receives in the last fiscal year for which we have records 30,000 complaints of the other statutes that they --

THE COURT: OCR is Office of Civil rights within HHS?

MR. COLANGELO: Yes, your Honor.

THE COURT: So what would be the paradigm complaint that that office gets?

MR. COLANGELO: So OCR investigates HIPAA complaints for violations of health care privacy. They investigate Title VI complaints for discrimination on the basis of race, color, or national origin which can include complaints regarding a denial of language access. OCR also investigates Title IX

complaints as well as, I believe, Section 504 which relates to disability.

So when the evidence here shows that less than three one-hundredths of a percent of their annual complaint volume relates to the statutes that they are enforce here, your Honor, I think to answer your question directly, I think it shows, again, that this is a solution in search of a problem.

THE COURT: I take your point about the number of complaints. A separate justification which I guess applies more to the enforcement architecture that the rule sets up as opposed to the substantive standard, but focus on that for a moment. Agency says essentially it's opaque. Where do you go and how do you get this enforced?

Does the record reflect any instance in which the agency did an investigation leading to enforcement action of the sort that we see from other federal agencies, whether DOJ, SEC, FCC, FTC. All sorts of agencies have enforcement apparatuses which result in notices of potential violations, evidence gathering, often a pre-allegation of what the charges would be and then ultimately a charge either brought administrative or either in litigation. I'm having difficulty in the record figuring out whether any such complaint ever reached the end line of that.

What have you found?

MR. COLANGELO: Your Honor, the final rule mentions

agency action with regard to a Hawaii state statute that the agency believe violated the Church Amendments. And the Hawaii Attorney General said she would not enforce the statute.

I believe my next example would not be in the record because it's more recent but within the last several months OCR, the Office for Civil Rights, issued a notice of violation regarding employment practices at the University of Vermont Medical Center.

THE COURT: That's based on the complaint at tab 130, right?

MR. COLANGELO: Yes, your Honor.

And then a third example I believe is the instance -- and the agency cites this in connection with litigation by affected employees, but the instance of the nurse at Mount Sinai Hospital here in New York. That nurse's complaint was ultimately resolved by a successful OCR investigation.

THE COURT: I guess the question is I'm trying to figure out whether there has been enough of a developed enforcement process to conclude -- to allow us to conclude whether there is clarity as to how it works and what the rules are so as to bear on the need for enforcement clarification.

MR. COLANGELO: Well I think, your Honor, we don't need to -- we don't necessarily need to look at some significant extant body of investigations and resolutions regarding the conscience protection because the question, as it

pertains to arbitrary and capricious review of the rule, is whether the agency has sufficiently connected the facts they found to the procedures and substantive prohibitions that they're implementing here. And the record does not show anything close to a need for the enforcement procedures and the intrusive mechanisms that they're implementing in this rule.

THE COURT: Even if the number of complaints investigated doesn't get you there, is there any place a person would go pre-rule to explain, for example, what the consequences or the outer bound consequences could be of a violation of one of the conscience statutes.

MR. COLANGELO: Yes, your Honor. I think the 2011 rule which delegates the authority to enforce these statutes to the HHS Office for Civil Rights sets out the assignment and delegation of that authority and someone could go to the Office for Civil Rights with a complaint or an inquiry --

THE COURT: Where would you go if you are a entity that is covered and, therefore, whose conduct could subject somebody to the loss of a funding stream, where would you go that spells out pre-rule what the consequences are of having on your watch an employee of yours or a subrecipient of a grant or whatnot violate a conscience statutory provision.

MR. COLANGELO: I think, your Honor, there are two answers to that question.

The first is that you would go to OCR, which has been

assigned authority to enforce these statutes, and one could request technical assistance. I should say three answers.

Second is that the statutes themselves setout what the contours of the prohibitions are.

THE COURT: Sorry. But that's the contours of the prohibitions. I'm asking about the consequences.

Assume a violation of the statute. Let's use the hypo from the first discussion I had. Is it clear right now to a provider or to a state that receives funding what is in jeopardy, concretely what funding stream is in jeopardy from a violation in a particular area or is that something where clarity could be enhanced by a rule.

MR. COLANGELO: I think -- there are two answers to that question. The first is that OCR has provided guidance regarding what funds are in jeopardy, including through the 2011 rule; but the second and more import answer, your Honor, is that even if it is true that the agency had reason to believe that greater clarity was needed in terms of what funds are at risk, for which violations of which statutes, the agency still has to connect this final rule to that concern. And they haven't done that. The focus of the rule, including on the complaints that they purport are at risk, and as implemented through these Draconian enforcement provisions, the expansion of liability to sub-recipients, the assurance and certification requirements, the recordkeeping obligations and the expanded

definitions of terms like health care entity, assist in the performance of discrimination, none of those mechanisms are necessary or at least not rationally connected in this record to any interest in clarifying what the consequences are of a violation of the statutes that the agency says here that they're implementing.

So I guess a different way to put it, your Honor, is that the agency --

THE COURT: Does the existing rule -- pre-rule, is it clear what the liability would be, for example, for New York State -- for a violation by a subrecipient, some -- you use your Medicare funds or whatnot fund, a hospital and somebody on their watch -- I may have a bad hypothetical, but essentially a subrecipient's violation, does the rule clarify the consequences, for example, to New York State if a subrecipient breaches one of the conscience statutes?

MR. COLANGELO: The 2019 rule does assign responsibility to every recipient for the activity of its subrecipients.

THE COURT: Does anything beforehand clearly speak to that? I'm trying to figure out if there are gaps or lacunas here that could properly be clarified by rule.

MR. COLANGELO: I don't believe the 2011 rule speaks to subrecipient conduct and a recipient's vicarious liability at all, your Honor.

There are, of course, preexisting mechanisms under the general grant-making and acquisition regulations and frameworks where recipients do have some obligation to ensure, for example, anti fraud protections in how a subrecipient uses the funds.

I will say, your Honor, there is no evidence in this administrative record, certainly not that the agency has pointed to, that either recipients or subrecipients or complainants were asking: What are we going to do about a subrecipient violating the conscience statutes?

Your Honor, I think the best way to think about this is that even if one believes that there are other aspects of the implementation of the refusal statutes that could fruitfully be clarified, the agency has articulated a justification that is based on specific claims of evidence that are untrue. And it has implemented specific provisions to enforce particular statutes that prohibit particular kinds of conduct in connection with particular funding with no record that there is any underlying justification for those -- for those prohibitions as to that particular conduct.

THE COURT: One of the points you make in your brief is that the agency didn't properly consider what you call reliance interest.

MR. COLANGELO: Yes.

THE COURT: I couldn't quite tell concretely what you

meant. What reliance interests should the agency have considered that it didn't?

MR. COLANGELO: So, your Honor, and I think the Court touched on this a moment ago with a question to my colleague regarding Title VII. But the regulated entities, which include the states and cities and providers that are plaintiffs in your courtroom this morning, your Honor, regulated entities have conformed their operations around the way HHS has implemented these statutes for nearly five decades in a number of ways. And this is evident both from the administrative record --

THE COURT: Pause on that. You said that HHS has implemented these statutes. The overall portrait I get is that the statutes have existed but that this is an area of relative inactivity. Has HHS done much to enforce these statutes over these decades or have plaintiffs essentially treated Title VII, for example, as applicable but not because HHS has done something but because Title VII is on the books.

MR. COLANGELO: Your Honor, the administrative record shows that the plaintiffs have aligned their policies to the refusal statutes consistent with how HHS has interpreted those refusal statutes.

So, for example, the governmental plaintiffs discuss this in our briefs in connection with how we have organized our personnel practices, the typical requirements for advanced notice of objections, the staffing procedures in terms of what

to do when somebody raises an objection that was unanticipated.

THE COURT: Sure. But I mean that's a matter of changing your procedures. Reliance interest I would think would be more: We've hired a bunch of people whom we thought we had the flexibility to move around and we're now stuck with them as parts that will prevent effective delivery of medicine in particular areas. Is there a reliance interest along those lines that hasn't been considered?

MR. COLANGELO: Yes, your Honor.

There certainly is reliance interest on exactly what the Court just articulated. And, in addition, if one thinks about the expansion of the definitions of health care entity to include nonmedical personnel, including plan sponsors, there is no plaintiff in the courtroom right now, your Honor, that has ever considered a clerk in the billing department, a receptionist at the check-in desk --

THE COURT: What about the ambulance drive?

MR. COLANGELO: The ambulance drivers are not typically considered in most employers' practices someone who assists in the performance, for example, of an abortion if the person they are transporting to the hospital may have a miscarriage that may result in an abortion.

THE COURT: I mean plaintiffs may have conceived of the rule a little differently but -- conceived of the statutes differently. But pre-rule, if you can generalize, how did the

providers and states treat the outer bound systems of performance? Was it in effect within the operating theater? Did it extend beyond that? How was it widely understood pre-rule?

MR. COLANGELO: What the administrative record shows is that, at least as to governmental plaintiffs, assist was widely understood within the rule as providing a typically medical aid in specific connection with and furtherance of a particular procedure. So the medical staff performing a procedure, the nurse assisting the medical stuff or performing procedures themselves, that would be considered assisting. The billing clerk at the insurance company after the fact who sends the bill, that's not -- no plaintiff --

THE COURT: And somebody who is giving patient guidance in the days or weeks beforehand that may inform the decision whether undertake the procedure, was that considered pre-rule assisting the performance?

MR. COLANGELO: Not typically, your Honor, no, it has not been.

THE COURT: And the scheduling -- not the scheduler, no?

MR. COLANGELO: Certainly not, your Honor.

For these reasons the rule is arbitrary and capricious. We're happy to address anymore questions on rebuttal.

THE COURT: Just one moment.

MR. COLANGELO: Yes.

THE COURT: Just explain to me you mentioned disadvantaged populations. What's the reason to infer that this rule would disproportionately affect particular populations?

MR. COLANGELO: So there are two reasons, your Honor. First, there is a documented existing pervasive disparities in health care as to discrete and identifiable populations including people of color, low-income families, the LGBT community, and immigrants.

So the first reason is that any rule that affects the delivery of health care will necessarily bear more heavily on disadvantaged populations. And the administrative record includes a number of examples. Both because those populations are already subject to discrimination in health care, but because in many instances they are also located in areas where the provision of health care is strained by other factors, whether it's rural communities or whether because of lack of financial resources their most common vehicles for delivery of care are in the emergency setting which is also stressed by this rule. So that's one reason why the vulnerable populations are likely to be particularly affected.

And the second reason, as a number of the administrative record comments point out, is that as a

historical matter many of the religious refusals to provide care have arisen in the context of circumstances that distinctly affect vulnerable populations like the LGBT community. So, for example, an objection to gender reassignment surgery or hormone therapy that would likely apply to only a transgender individual --

THE COURT: But your point as to that, and I thought this was in the context I think of one of the complaints, I think it's the Washington State complaint, I thought your point was that procedure is not implicated by these statutes at all.

MR. COLANGELO: Yes, your Honor. In connection with the Washington Department of Corrections complaint, it's pretty clear from the record that there is no connection between that complaint and that complainant's concerns and what the statutes are prohibiting. I'm trying to make a broader point that the record is full of evidence that transgender individuals face significant and extreme discrimination in health care.

THE COURT: Right. But the particular procedures that are implicated by these statutes are primarily abortion and sterilization, right?

MR. COLANGELO: Yes, your Honor.

THE COURT: To what extent do the statutes include, for example, what you're talking about now which is change of gender, procedures, that sort of thing?

MR. COLANGELO: Well, your Honor, there has been

religious objections to that kind of procedure on the ground that it would functionally result in sterilization.

THE COURT: So that's how it becomes within the scope of these statutes?

MR. COLANGELO: Yes, your Honor.

THE COURT: Final question. HHS, as to the issue of denial of access of care, says: No, we did respond to your concerns, you just don't agree with us. Their statement is that by making the health care world a more receptive one to people with strong religious views you'll actually increase the population of people who choose to participate in an area who are right now deterred by the possibility of being in effect stuck performing a procedure to which they object.

Is your objection to that simply that that's unpersuasive or that the agency didn't consider the issue?

MR. COLANGELO: Your Honor, the plaintiffs' objection to that is that its counter to the evidence and that they've failed adequately to consider the issue and although -- although your Honor is correct that the defendants do say, particularly in litigation, that this is simply a policy disagreement and that they have reached a contrary view that we disagree with, I think the fairest reading of what the agency actually said in the final rule was that after considering the overwhelming record evidence regarding access to care, including the agency's own determination just eight years ago

that expansion of the conscience protection rights would affect detrimentally access to care, the agency said, quote, that they should finalize the rule without regard to whether it exists on the effect of access to care.

So although your Honor is correct that the rule purports to walk through some of these analyses, I do think the fairest reading is that they ultimately concluded that the effect on access to care was immaterial.

I think the other reason why that conclusion is irrational is that they discount the record evidence regarding the effect on access to care for the same reasons that they credit record evidence that supports the conclusions that they -- we believe that they have predetermined that they wanted to reach.

So, in other words, they dismiss some of the concerns that your Honor and I have just been discussing regarding risks to the LGBT community, they dismiss those concerns as anecdotal and qualitative but they credit Kellyanne Conway's survey conducted on behalf of the Prison Medical Association as a qualitative survey because they thought it was informative. It's irrational to be internally inconsistent. If you believe qualitative evidence has some persuasive force, you can't dismiss qualitative evidence when it cuts against your --

THE COURT: Thank you, Mr. Colangelo. Very helpful. Finally, I'll hear from Ms. Meyer.

MS. MEYER: Good morning again, your Honor.

THE COURT: Good morning.

MS. MEYER: I want to first address both the ripeness and merits of the governmental plaintiffs --

THE COURT: The last thing you said?

MS. MEYER: Discuss the scope of relief of the plaintiffs.

Plaintiffs' spending clause claim is ripe for judicial review. On November 22 if the rule takes effect plaintiffs will need to adjust their conduct immediately and significantly or face risk -- or risk losing billions of dollars of funds that the rule authorizes HHS to withhold or suspend.

THE COURT: So let's assume the rule takes effect November 22. Right away what are the most primary, most significant transformative things you would need to do to meet the rule?

MS. MEYER: So if the rule takes effect the compliance requirements go into effect immediately because the threat of funding termination springs into effect immediately. So specifically the plaintiffs have submitted over 48 declarations containing hundreds of patients' sworn testimony from preeminent leaders across the country in the health care sector. And these leaders have testified that the harm stemming from the final rule is real and immediate.

For example, plaintiffs' institutions have various

policies and procedures in place that have balanced conscience objections with patient care for decades. For example, many of the institutions require that employees with conscience objections provide their employer with advanced notice in writing so that they can make accommodations in advance based on objections to care.

An employee may not object in real time or abandon a patient in need of care and an employee could face consequences for failing to abide by these critical notice requirements.

THE COURT: The employer could?

MS. MEYER: The employee under plaintiffs' policies exist -- that currently exist, if they do not provide advanced notice of an objection, they could face consequences.

THE COURT: Explain that. In other words, I thought your primary concern was really on the employer, that the employer suddenly has to scramble to meet a new framework and if it doesn't ask questions, for example, of employees to smoke out potential objections, the employer then could be stuck in a situation where it has somebody with a bona fide right to object who the employer has to accommodate in a situation which could affect care. I thought that was the primary argument. I didn't perceive a separate impact on the employee. Can you explain that?

MS. MEYER: Correct, your Honor. That is our primary argument. The only point with respect to the fact that an

employee could be disciplined for not giving an advanced notice requirement is that is a provision that allows employers to enforce these particular notice requirements that are now implicated by the final rule. When the final rule does take effect or if it does take effect on November 22, plaintiffs to comply with this are going to have to overhaul those policies and procedures in significant ways.

THE COURT: Give me a scenario of something that could happen in the first week after the rule takes effect that could affect let's say a funding stream but for the employer's quick adaptation to the rule.

MS. MEYER: Many of our declarants have testified, for example, in the emergency context that a women presenting with an obstetrics problem would face -- would encounter anywhere from 12 to 16 hospital employees. So our declarants have testified that if the final rule goes into effect, they need to be prepared to deal with objections on the spot from those various 12 to 16 employees. And this is because of, for example, the expansion of the definition of discrimination and the expansion of the definition of assisting performance.

THE COURT: Let's focus on the employers' ability under the rule to smoke out, if you will, from employees or applicants what they object. Under the rule what can the employer do in the hiring process to determine, if anything, whether an employee is going to be off limits for certain

procedures?

MS. MEYER: So in the hiring process the employer cannot ask the hire whether there's any objection.

THE COURT: And that's true even in our rural hypothetical even in the situation where accommodating may be impractical.

MS. MEYER: Correct.

Once the employee is hired, the employer may ask once per calendar year or with persuasive justification.

THE COURT: Let's suppose we don't know what persuasive justification is. I take it that's undefined.

MS. MEYER: Correct.

THE COURT: Let's assume that the process of adapting to the rule itself is a persuasive justification; that the fact that there's a new regulatory framework in place almost necessarily allows the employer right out of the gate to ask employees who's eligible for what, on a conscience perspective, for what areas of work.

Assume that the employer is allowed, at least, to ask that and that would clear a persuasive justification bar, what happens next? How is -- how is your primary conduct affected?

MS. MEYER: So assuming that that is a persuasive justification which, frankly, our declarants cannot rely on because they have not received that clarification from HHS so they have to proceed under this regime of one calendar per

year. But assuming that is a persuasive justification, there's still the extreme financial burdens that are imposed on institutions for needing to basically double or triple staff certain departments or going to an employer and asking if they will accept an accommodation like a transfer to a different department. If that employee says no, then our institutions have to have backup or shadows.

THE COURT: Is there anything out there in the world that would guide me in the record as to the number of employees, in fact, who work appertinent to procedures at issue who actually would object in them?

In other words, there are a lot of hypotheticals that have populated everybody's briefs. One thing that's a little less clear is, assuming a widespread regulatory right to object, assuming even a statute that said that, any information out there about in practice what that would mean?

MS. MEYER: The exact number of people who holds religious objections?

THE COURT: Right. Or number of people who both hold those religious objections and are let us say presently in jobs where those objections might be triggered.

MS. MEYER: We don't have those exact numbers in the record, your Honor, but the objections to procedures do exist and this is exactly why these policies and procedures are in place, to make sure that employers can accommodate those

conscience objections while protecting patient care.

THE COURT: Does the rule have any safe harbor, any unramped period in effect where an employer gets some period of time to adapt its procedures without being subject to loss of funding because the procedures have not been fully developed or implemented?

MS. MEYER: No, your Honor. HHS explicitly rejected comments requesting that it allow for compliance in one year after the effective date of the rule or for a one-year safe harbor. So HHS explicitly made this choice. And, in fact, one of the key reasons that HHS issued this final rule was to affect compliance with --

THE COURT: So going back to the hypothetical earlier, in the hypothetical situation in which a subrecipient of a New York Medicaid grant, let us say, breaches the rule by following a Title VII accommodation approach that's now been eclipsed by the rule, if that happens on November 23 subject to how the enforcement process plays out, at the end of that process New York's failure to adapt its subrecipient's policies to the new rule could cost New York its Medicaid funding?

MS. MEYER: Correct, your Honor.

THE COURT: Which is billions of dollars a year.

MS. MEYER: Yes. Yes, it is.

THE COURT: So I take -- I think I take the argument as to ripeness. Let's focus on the merits of the spending

clause point.

MS. MEYER: With respect to the final -- the merits, the final rule violates each of the four limitations placed on the federal government's use of funds in violation of this spending clause. Critically the rule conditions plaintiffs' compliance with HHS's new federal conscience reviews on 192 billion in federal health care funding. Specifically the rule gives the department the authority to withhold funding in the whole or part to deny use of federal financial assistance or funds from the department in whole or part, to wholly or partly suspend award activities, to terminate federal financial assistance or other federal funds from the department in whole or part, or to deny in whole or part new federal funds from the department. This all includes based on any indication that a recipient has failed to comply with the rule and during pendency of good faith compliance efforts or for failure to comply with the new assurance and certification requirements in the rule.

THE COURT: May I ask you. One of the situations that can give rise to a spending clause problem involves a situation where the rule would violate another constitutional provision. I'm going to come back to a question I asked one of your colleagues earlier. Focus on -- one thing that you argue is that the rule would violate the establishment clause. Indulge the hypothetical that it might in some applications but it

doesn't on its face and that that was the Court's determination.

Is the spending clause implicated by that problem in which one can imagine scenarios where you have an establishment clause problem but that on its face the rule doesn't?

MS. MEYER: It is, your Honor, especially in the context of this rule where if liability is imposed on the states for the activity of their staff recipient. So, for example, as a practical matter our declarants have testified that they will have to review their contractual arrangements with various subrecipients to ensure compliance with the final rule because they are now subject to vicarious liability. And in doing so, in reviewing those contracts and imposing conditions if necessary on subrecipients, if those conditions present a constitutional problem, what defendants are subjecting plaintiffs to is imposing those unconstitutional conditions on its recipients.

THE COURT: OK. Another dimension of spending clause analysis involves retroactively. Articulate for me why the rule has a retroactive effect. Right now are you able to hire people -- are you able to ask the conscience question in hiring?

MS. MEYER: We are, your Honor.

THE COURT: And is the retroactive point that you're now stuck with people -- so if -- that doesn't work. In other

words, if you were able to fence out people who simply couldn't do core parts of the job by virtue of asking that in hiring, how is there a retroactive application of the rule, meaning you are getting punished for past conduct or decisions?

MS. MEYER: So one of the prohibitions of the spending clause is retroactivity in the fact that plaintiffs need to knowingly and voluntarily accept the conditions of the funding streams. And when plaintiffs accepted these particular funds they had no idea that HHS would expand their substantive requirements to, for example, broaden definition of discrimination in such a way that it would severely curtail plaintiffs' current policies and procedures.

THE COURT: But you accept funding typically on a year-to-year basis.

MS. MEYER: That's correct.

THE COURT: So we're in right the middle or early part of the fiscal year right now. Suppose on November 23 comes the violation. Suppose it's adjudicated in full on January 1. Presumably the image -- I'm telescoping the process here just for purposes of a hypothetical, I know the world doesn't work that fast, but assuming that it did. If the agency were to cut off your funding from January 1 through the end of the fiscal year, why is that retroactive? Yes. You took the money not knowing that the regulatory world would change, although the notice was out there, but you would only be cutoff

prospectively unless the agency is threatening to clawback the money going back to the beginning of the fiscal year, how is that retroactive?

MS. MEYER: A couple of responses, your Honor.

First, let me clarify that various contracts and grants govern the administration of all of these underlying funds. And so I don't think that it is accurate to say that we renew, for instance, on a yearly basis. I think the underlying funds are governed by various provisions of the grants and contracts.

With respect to why this particular provision is, in fact, retroactive is the obligations that are imposed on day one go into effect on day one. And so the funding streams that are threatened are the funding streams that we currently operate under now and the policies and procedures that we have to change are policies --

THE COURT: You have hired people and engaged subcontractors and the like on the premises that the funding stream is intact at least through the end of that grant or installment whether it's yearly or whatnot. The point is there's an architecture that develops around the expectation that your Medicare grant isn't going to be yanked in the fiscal year.

MS. MEYER: Yes, your Honor. And, in fact, we have declarants that testified as to the expectation of the spending

streams the governs had budgeted for them in 2019 and 2020 and 2021 and so you have those reliance interests as well.

In addition, the written assurances and certifications of compliance with the final rule are new and retroactive conditions that plaintiffs may be subject to immediately. The final rule authorizes HHS to require certification if OCR suspects a violation and it makes that certification an explicit condition of continued receipt. So that's another way in which this rule is retroactive.

THE COURT: I realize there are multiple ways in which the spending clause could be violated but one of the things you say is that -- one of the concerns implicated is that retraction of spending is unrelated to the federal interests at issue.

Assume for argument's sake a small dose of conscience statutory violations. Just put aside the issue whether the rule faithfully implements the statute and just let's take our hypothetical of the no-doubt-about-it violation.

How would one go about narrowing the scope of the financial penalty to get rid of your concern about the penalty being Draconian or unrelated?

Is it literally just the salary of that employee? Is it real -- does the fit have to be that tight as to what the hospital or state uses or is there some broader retraction of funds that it would still be considered in effect related to

the violation?

MS. MEYER: So we think that under current procedures for any type of funding with withholding or suspending or termination that those procedures are tied to specific funding streams. So if a violation came up HHS would look to the specific funding stream that was implicated.

THE COURT: So right now assuming a violation of a conscience statute which is litigated to completion and procedurally sound, you would not contend there's a spending clause problem with the retraction of the entirety of the funds from that funding stream even if you only had one bad act or one bad apple in the hospital?

MS. MEYER: We would -- we would rely on the regulations and provisions that are already in place. So we do not take issue in the underlying statutes that say certain funding --

THE COURT: No. I appreciate that. But I'm trying to understand your constitutional argument based on the spending clause and I understand that you've argued ambiguity, coerciveness, violation of other constitutional provisions.

I'm just focusing now on the problem which you say also exists here of the penalty in effect, the spending clause -- spending retraction being unrelated to the problem.

I think what you're saying to me is that you don't have a problem with that as long as if -- even if the entire

funding stream is taken away on the basis of a single violation of the conscience statutes. Am I hearing you right?

MS. MEYER: So we're not quibbling with the fact that HHS has options through provisions like the UAR at its disposal. But here the amount of funding on which HHS conditions compliance in the final rule is a much larger pool.

THE COURT: Right. Let's suppose there's a Medicaid funding stream. I have the numbers handy somewhere. One moment.

New York received -- well it's not clear. I don't have it broken out by Medicaid. New York received many billions of dollars in health care funding, but certainly billions in Medicare. Let's just take Medicare for a moment.

Is it really your position that all of that could properly be taken away based on a violation of the conscience statutory provision applicable to Medicare by a single violation by a single person? Is that the way we define funding stream? And is that really your view that the spending clause concept of unrelatedness is not offended by that?

MS. MEYER: Your Honor, our view is not that -- that a small violation would jeopardize all of our Medicare funding, which is exactly what the final rule says here.

THE COURT: So, is there a case that helps define the relatedness concept?

If you're saying that there's a separate problem here

that the funding -- that the threat to the funding stream implicated by a singular violation, if what you're saying to me is that presents a spending clause problem of an unrelated penalty, what's the case that helps me with that?

MS. MEYER: So I think that there is a distinction between our relatedness argument which we are saying that the termination scheme plainly violates that requirement because the rule conditions funds on things that have nothing to do with health care like the Department of Labor and Education.

THE COURT: Right. That's your point which is that we're going outside the scope of HHS or going to funding streams not implicated by a particular violation.

MS. MEYER: Yes, your Honor.

THE COURT: But you're not making that argument even if it costs you an entire funding stream that that is a spending clause problem?

MS. MEYER: No, your Honor.

We are arguing separately that this scheme here is coercive; it has combined funding streams. And it also puts the final rule's new provisions and conditions those compliance with new provisions on that funding stream.

THE COURT: Final couple questions just on remedy.

Hypothetically assume that portions of the rule are problematic for one reason or another, including the ones that have been articulated today, but that portions are not,

including ones that sound in a more housekeeping nature, or where the application of a certain term is authorized by a rule-making grant as in ACA or Medicare or Medicaid.

Why shouldn't, given the severability provision in the rule itself, the definitions that are statutorily authorized, assume that we don't have the other APA problems that Mr. Colangelo addressed, why shouldn't those definitions be permitted to stand and why shouldn't the portions of the regulatory administrative structure that I conclude are fair and housekeeping, why shouldn't those stand?

MS. MEYER: The rule's provisions, your Honor, are codependent. So, for example, several sections rely on one another and cross-reference one another. For example, the posting of notices in 88.5 is evidence of compliance for purposes of enforcement in 88.7.

We don't believe that severability is appropriate. So, for example, as to the definitions this rule is already incredibly ambiguous, as we argued in our papers. And the little explanation that HHS gives as to various situations in the preamble is predicated on their understanding of multiple interpretations and definitions in this rule working together. And so where this rule provides very little clarity for plaintiffs on how to comply in the first instance, if the Court were to sever certain definitions but leave others, we would be left with even less clarity.

In terms of the severability clause itself, there are several cases that say -- and we've cited them in our papers -- that the severability clause is not an indication by itself that the rule should not be vacated in its entirety. Instead, we look to the intent of the agency. And the agency made clear here that it was trying to address confusion created by the 2011 rule. The confusion created by the 2011 rule, it claims, stem from the 2011 rule's interpretation of Weldon, Coats-Snowe and the Church Amendments. And so if the Court were to, for instance, strike certain provisions with respect to those statutory provisions, it's not clear at all that HHS would have made the same decision to promulgate this rule absent those core statutes.

THE COURT: Thank you very much.

In a moment we'll take a break. Let me just ask counsel for defendants who will be arguing for each side and who will be arguing first.

MR. BATES: Your Honor, I will be arguing for HHS. Christopher Bates.

THE COURT: That's Mr. Bates. And you'll be going first, I take it?

MR. BATES: Yes your Honor.

THE COURT: Who will be arguing for the intervenor?

MR. DUNN: I will, your Honor.

THE COURT: That's Mister?

MR. DUNN: Dunn.

THE COURT: OK. Very good. We'll take a fifteen-minute comfort break. I'll see you in fifteen minutes. Thank you counsel.

(Recess)

THE COURT: Welcome back. Be seated.

I'll hear now from counsel for the government. That's Mr. Bates.

MR. BATES: Thank you your Honor. Would you like me to speak from here?

THE COURT: Podium, kindly, please.

MR. BATES: Good morning, your Honor.

THE COURT: Good morning.

MR. BATES: HHS promulgated a conference rule, a law that exercises at its core, in order to provide clarity and ensure robust protections for rights of conscience that are protected under federal statute. I'd like to begin with the agency's authority for this rule.

There are expressed delegations of authority to the agency in a number of statutes to ensure compliance with grant conditions, other conditions, and to insure clients under applicable law. There's been some discussion about today there are some limiting authority with regard to Medicare and Medicaid and CHIP, which we have cite in our briefs, 42 U.S.C. 1302. There is limiting authority with regard to the ACA that

applies to implementation of the ACA's conscience provisions which we've cited in our briefs as well. It's in 42 U.S.C. 18 -- these are expressed delegations of authority for the agency promulgated or related to --

THE COURT: But I take it with respect to Church, Weldon and Coats-Snowe it's not disputed that there is no express delegation.

There is not express delegation, you said, for those three?

MR. BATES: That's correct.

THE COURT: The question just to take -- just to focus our discussion. In total, there are about 30 or so statutes that contain conscience provisions. Having looked at the others, each is really targeted to a rather narrow scope type of activity. Can I assume that for the purposes of discussion we're really talking about the several you just mentioned that have express delegation provisions and the three that I just mentioned that do not, that the others are really targeted to small corners of the world?

MR. BATES: So the intersections that do have expressed limiting authority are -- do apply to a more discrete subject.

THE COURT: So for the purpose of this discussion am I safe to really treat us as talking about the ones you identified a moment ago and the three that I identified in my

statement to you?

MR. BATES: So in terms of rule-making as it pertains to those three conscience statutes that you mentioned.

THE COURT: The heart -- the rule covers a broad set of conduct. It, to be justified, would have to be justified saving those discrete areas' conduct by one of either the statutes you mentioned, Medicare, Medicaid, ACA, or the ones that I identified to you as lacking express rule-making authority. We're not for the most part relying on any of the other three.

MR. BATES: For the other three conscience statutes, that's correct, your Honor. There's also the other housekeeping statute which we point to as authority for the rule here. I would note for the Court's information that the general housekeeping statute is the authority for the UAR; it is, in fact, the only statute that the agency cites as authority for the UAR. UAR is a comprehensive regulatory scheme. It governs the agency's administration of grants and processing the AG uses for ensuring compliance with grants. It is a comprehensive scheme set for the UAR. The statute ability for the UAR is solely general housekeeping statutes. That doesn't indicate that the housekeeping statute does provide broad authority in terms of assuring compliance.

THE COURT: Has HHS ever taken away anybody's funding for violation of a conscience statute?

MR. BATES: Agency counsel informed me no.

THE COURT: Has HHS ever threatened to do that?

MR. BATES: HHS has issued notice. It has issued warning letters, notices of enforcement, has taken enforcement actions under the conscience statutes. In terms of the --

THE COURT: What actions has it taken that are -- if it's never taken away somebody's funding, what enforcement action has it taken?

MR. BATES: So, your Honor, I'm looking over here at agency counsel now for specifics.

THE COURT: Rather than your looking, agency counsel, if there's an answer to the question that you want to furnish, Mr. Bates, would write it out rather than our going --

MR. BATES: Certainly in the vast majority of instances, conscience statutes, civil rights statutes as well, the resolution that is reached is a voluntary resolution that's worked out throughout informal processing, informal means between the agency and the -- its only in instances where those informal processes do not result in voluntary compliance that further enforcement action is taken. As to the specifics of -- I'll wait for --

THE COURT: I'm eager to come back to get a quantification as to the number of full enforcement actions in this area. If it's not something you're immediately facile with it, we'll come back to it, but it is of interest to me.

Go ahead.

MR. BATES: So the general housekeeping statute is as well exclusive authority for HHS's actions here. And then there is also, as HHS explained in the rule, there is inherent in Congress's adoption of the conscience statutes to require recipients of federal funds from the department to comply with statutes, the authority of the department to take measures to ensure compliance with those statutes. The Supreme Court has been clear that delegations of authority to --

THE COURT: Let me ask you this. The very last page of your regulation -- and I take it this must be justified with your housekeeping statute -- states that as a remedy for a violation the agency can -- the remedies include, quote, terminating federal financial assistance or other federal funds from the department in whole or in part.

Putting aside what you say in the briefs, that appears to be stating that for a singular violation of a conscience statute, as interpreted in the rule, an entity such as New York could lose all of its federal funding from HHS and perhaps from other agencies.

Is there -- does the housekeeping statute UAR authorize a rule like that, a consequence like that?

(Continued on next page)

MR. BATES: So in terms of the last point about funds from HHS for other entities, HHS has been clear in the rule that the funding streams that are impacted by the rule are only funds that are administered through HHS. So it would not subject funding through other agencies for violations.

THE COURT: Does the rule say that?

MR. BATES: So, it says -- let me just turn to my notes here. There are a number of places where it says that the funds that are at issue in the rule are tied to specific funding streams.

So I can provide a couple of quotes here for the court's information. Page 23223: "The only funding streams threatened by a violation of the conscience statutes are the funding streams that such statutes directly implicate."

On page 23192: "The prohibition discrimination is always conditioned on and applied in the context of violating a specific right of protection, and each protected right is typically associated with the particular federal funding stream or streams."

THE COURT: Those are comments. The actual reg itself on the last page, on its face, it has no limitation as to funding stream. I appreciate that it can be read not to implicate policies of the Department of Education or of Labor. But on the face of it, what I just read to you seems to say that, for a singular violation by New York State, it could lose

the entirety of, let's say, the $46.9 billion it got from HHS in healthcare funding in fiscal year 2018. In the face of the reg itself, where does it limit the threatened consequence to a particular funding stream?

MR. BATES: So this is not a way in which the regulation is different from the UAR, your Honor. The UAR also uses somewhat broad language here, as well. HHS --

THE COURT: Does the UAR use the language that I quoted to you from the last page?

MR. BATES: So the UAR does not use identical language, but the UAR speaks about terminating funding in whole or in part.

THE COURT: It says here "other federal funds from the department." It's hard to read the words "other federal funds from the department" as, given that it is unlimited, as unlimited.

MR. BATES: So, again, your Honor, the agency made clear in the preamble to the rule.

THE COURT: Preamble is not the rule. The text of the rule appears, on an unlimited basis, to leave open the possibility that, in an extreme case, the -- the agency could seek to terminate all federal funds from the department. It doesn't have any limitation in there. Would the UAR permit that? Would the UAR permit as a matter of housekeeping the agency to enforce the conscience statute so as to, without

limitation to a particular funding stream, deprive a recipient of the entirety of HHS funding for a singular violation?

MR. BATES: So, your Honor, I'm going to look to agency counsel now to answer --

THE COURT: You have to stop looking at HHS counsel. In baseball we call that sign stealing. You have to give me the answer. This is a fundamental question. It is all over the briefs. Yes or no: Do the funding statutes authorize you to adopt a rule that on its face threatens the entirety of HHS funding for a single violation? I take it the answer might be different for a particular funding stream, but I'm reading the text of the regulation now.

MR. BATES: So first point, your Honor, is that the regulation would not do that. For the purposes -- for the terms of the UAR, my understanding is that the UAR would not do that either. The rule is similar to the UAR here in the sense that it is tied to the specific funds that are at issue with regard to the specific statute that the agency has found a potential violation.

THE COURT: All right. So if I am understanding you right, so we can proceed with the balance of the discussion, your position, at least in this litigation, is that "all" that is in jeopardy -- quote/unquote around "all" -- is the specific funding stream implicated, right?

MR. BATES: That's correct, your Honor.

THE COURT: So if, hypothetically, within the scope of activity under Medicaid, there was a singular violation, you would reserve the right or HHS would reserve the right to withdraw the entirety of the Medicaid funding scheme, but that wouldn't extend to, let's say, Medicare.

MR. BATES: That's correct, your Honor. And in practice, HHS's practice is to tie or limit those enforcement mechanisms to the specific grant report or funding stream that's at issue.

THE COURT: But that's never happened in the context of the conscience statute. It's happened in other contexts, right?

MR. BATES: Yes.

THE COURT: How often does HHS terminate funding midstream for a violation, civil rights violation?

MR. BATES: So my understanding, your Honor, is that it is not common. My understanding is that there are approximately 12 to 13 enforcement actions that are taken each year, that this is under the civil rights statutes as well as under the conscience statutes and HIPAA as well, which OCR also administers. And agency counsel just confirmed that they have never -- that they have never terminated funding for a violation.

THE COURT: For a violation of this statute or anything else?

MR. BATES: Of any of them.

THE COURT: So HHS has never terminated funding of any recipient for any civil rights violation?

MR. BATES: That's correct, your Honor.

THE COURT: So this would be a first if that were -- if what is threatened here, whatever the scope, were to transpire?

MR. BATES: If HHS took an enforcement action under the rule that resulted in the termination of funds, that would be the first time that the agency had done that. But the agency has authority, under other statutes, to do it in other instances as well. So that is not unique to the rule or to the conscience statutes.

THE COURT: May I ask you, do any of the conscience statutes say anything about a remedy?

MR. BATES: I'm sorry. Say that again.

THE COURT: Do any of the conscience statutes say anything about the remedy for a violation?

MR. BATES: So the conscience statutes provide that -- that none of the funds made available in the funding streams that are specified in the various conscience statutes may be used or made available to an entity that engages in discrimination or other prohibited acts under the statute in terms of what the -- a specific remedy for such violations are. The conscience statutes themselves, or at least the three

statutes that you identified, setting aside other conscience statutes that you have more detailed -- the three that you have identified do not specify those remedies. And so, again, for purposes of that aspect of this, we would look to the housekeeping statute and to other statutes that provide authority for ensuring compliance with applicable laws.

THE COURT: Why is it that -- and I am now going -- I have a question beyond conscience statute violations, but to other civil rights violations that are within the ambit of OCR, why is it that none of them ever reached a point by way of a remedy of retraction of funding? What are the lesser remedies that tend to be deployed?

MR. BATES: The funding component in HHS?

THE COURT: Right. In other words, I am now asking you, beyond conscience statutes, you have told me that for no violation has the department ever retracted or cut off funding. What do they do to a violater?

MR. BATES: So under the UAR, there are various remedies that are set off. The first point, again, your Honor, I think, would be that it is uncommon for there to be a formal enforcement remedy actually imposed. The vast majority of these are worked out between the agency and the regulated entity. And so at least in terms of the context of the UAR, so the UAR sets out various penalties or enforcement mechanisms that could come into play, such as temporarily withholding

payments --

THE COURT: Has that ever happened?

MR. BATES: -- disallowing matching funds.

THE COURT: Sorry. I took you to be saying essentially that there hasn't been a financial hit for violations. Maybe I misread you. Has there been some lesser financial consequence to violaters of any of these conscience statutes?

MR. BATES: So agency counsel informed me no.

THE COURT: Let's deal with the enforcement part of our argument now, and we will get back to the authorization.

To what degree has HHS ever investigated complaints of violations of the conscience statute? How often does that happen?

MR. BATES: So there are obviously more investigations per year than there are, you know, further action or further enforcement actions taken. I know that in this most recent year there were three enforcement actions that were brought. I believe that those were mentioned earlier.

In terms of the number of investigations beyond that, obviously the answer is higher. HHS does review complaints when they come in, institutes investigations of those complaints.

And in terms of a discrete number, with your Honor's indulgence, I'm going to wait for if agency's counsel has a

specific number to give me on that. I do know that the number --

THE COURT: Would it be useful just to take a moment and have agency counsel at the podium? Because I am interested in, in practice, how enforcement works and how it has worked. That's an important backdrop here. You tell me, but at some point I want to have that discussion about the history of enforcement of these statutes within HHS. If that's not something that you are familiar with, but agency counsel is, would that make sense?

MR. BATES: Yes, your Honor.

THE COURT: Let's just take a moment. I will come back to you, because I realize there are many categories and topics for us to discuss, but I would welcome briefly to hear from agency counsel.

MR. TAKEMOTO: Can we pause for a moment so that we can converse with --

THE COURT: No. No. You have prepared for months. Let's get agency counsel. Come on.

MR. KEVENEY: Sean Keveny, your Honor, with HHS.

THE COURT: Sorry, that is Mr.?

MR. KEVENEY: Keveney, your Honor.

THE COURT: Mr. Keveney.

Just tell me about the history of the actual enforcement of these statutes. How often does HHS investigate

a complaint for a violation of these statutes?

MR. KEVENEY: With the caveat that I have only been at HHS for about eight months, your Honor --

THE COURT: But you were the counsel assigned to this important case.

MR. KEVENEY: Correct, your Honor, and I have asked these questions within the agency.

There are approximately 35,000 complaints per year that come into OCR. Those cover the full range of areas for which OCR has enforcement authority, traditional civil rights cases, Title VI, Title IX, 504 of the Rehabilitation Act, HIPAA, and the conscience statutes.

THE COURT: Focusing on the conscience statutes, how many investigations have been undertaken, if you know, of the violations -- alleged violations of the conscience statutes?

MR. KEVENEY: It is my understanding, your Honor, that there are approximately 20 open investigations. It is my understanding that in the last three years there have been four formal or informal notices of violation issued in connection with the conscience statutes, including in Hawaii, Mt. Sinai Hospital here in New York, Vanderbilt University, and most recently the University of Vermont Medical Center.

THE COURT: That's the one that trips off of the complaint that I referenced earlier, the UVM one.

MR. KEVENEY: That's correct, your Honor.

THE COURT: How often has a violation been found by OCR of a conscience statute?

MR. KEVENEY: A formal finding has only occurred in the University of Vermont Medical Center.

THE COURT: Over the course of what period of time?

MR. KEVENEY: Over, to my knowledge, the last three years. But it is important to distinguish, too, your Honor, the difference between formal findings of violation and informal communication of concerns or potential violations to a covered entity -- and, by way of analogy, to put this in helpful light, I will point the court to the Justice Department's enforcement of Title VI the 1964 Civil Rights Act. That's been on the books for years, it covers a wide range of federal funding, and the Justice Department has never pulled federal funding for a violation of the '64 Act.

THE COURT: Tell me, with respect to the investigations of conscience violations, how many times has the agency determined that there was a violation even if it is not in an informal way?

MR. KEVENEY: To my knowledge, there are the four that I referenced, your Honor.

THE COURT: Over what period of time?

MR. KEVENEY: Over the last three years.

THE COURT: All right. And was there, in the course of that work, was there -- did the agency encounter problems

presented by limited enforcement authority or ambiguous enforcement authority, did the agency have any hiccups in doing its work.

MR. KEVENEY: Yes. I can point the court specifically, and I hesitate because we are in ongoing negotiations with the University of Vermont, so to the extent some of those negotiations may had been covered by the rules of evidence, but the University of Vermont specifically --

THE COURT: As of the date the rule had been promulgated here --

MR. KEVENEY: Yes.

THE COURT: -- what, if any, problems had the agency encountered in the enforcement of the conscience provisions?

MR. KEVENEY: I can tell your Honor the University of Vermont particularly challenged the agency's authority to enforce any of these statutes, and that is an issue over which we are engaged in ongoing discussions.

THE COURT: Was the University of Vermont experience or your experience with the University of Vermont a reason for this regulation? Does the rule say that; and, if not, is there a basis on which to represent that that was a reason for this rule?

MR. KEVENEY: Yes and no. So the rule, again, obviously wouldn't specifically refer to the situation with the University of Vermont, because it hadn't come up yet; but the

concerns that arose in dealing with the University of Vermont were very much on the agency's mind.

So, specifically, your Honor, the university, understandably, has questioned what the procedures are, what the procedures are for withdrawing funds, which portion -- which component of HHS would be ultimately responsible for withdrawing any particular grant funds that the university receives. Those are questions that this rule answers.

THE COURT: Prior to the University of Vermont issue, and I'm not eager to get into anything that's confidential in that case, but had the agency experienced any practical problems investigating or enforcing allegations of violations of conscience statutes?

MR. KEVENEY: Without knowing the details of the Mt. Sinai investigation, your Honor, I can't answer that definitively.

THE COURT: Can you answer it nondefinitively? I'm trying to understand whether any part of this rule has its anchor in learned experience from enforcing the statutes.

MR. KEVENEY: So I can tell you, your Honor, that much of this rule is anchored in OCR and the federal government's experience enforcing civil rights protections generally. Obviously the rule draws upon the Title VI enforcement framework and the federal government has -- and across the federal government, including at HHS, has long experience

enforcing Title VI. And it obviously has been useful over the years to make sure the covered entities are aware of the procedures the agencies will follow. The Justice Department has its Title VI manual available online for covered entities to see, so they are aware of what the potential consequences of violations are. So in that sense, the agency's long experience of enforcement does inform the architecture of this rule.

THE COURT: All right. In a moment I will let Mr. Bates get back, but this question, you mentioned that there are currently four notices of violation pending. How does that compare to the previous three-year period or the three-year period before that? Is the number four greater, lesser, or about the same?

MR. KEVENEY: Greater.

THE COURT: It grew to four from what?

MR. KEVENEY: There was approximately, as is set forth in the preamble of the rule, one complaint per year prior to the issuance of the MPRM that is increased by a thousand percent. There are approximately ten complaints per year.

THE COURT: That has happened since the notice of rule-making in this case.

MR. KEVENEY: That's correct.

THE COURT: And without going out on a limb, is it safe to assume that it was the notice of rule-making by the agency itself that may have been causative in the increase in

complaint.

MR. KEVENEY: That is certainly the agency's view, setting aside difficulties --

THE COURT: All right.

MR. KEVENEY: -- in cause and effect generally.

THE COURT: So prior to the notice of rule-making was there any empirical data that suggested an increase in complaints actually made to the agency in this area?

MR. KEVENEY: Not that I am aware of.

THE COURT: I think if --

MR. KEVENEY: I think the answer is no.

THE COURT: If there is no one else in the room who would be more aware of it, is the answer to that no?

MR. KEVENEY: I think the answer is no, your Honor. I hesitate because there very may well have been statements from the agency that it intended to start enforcing these statutes. The Office of Civil Rights stood up a new unit, and I think that predated the issuance of the MPRM.

THE COURT: All right. Mr. Keveney, I appreciate your help. Is there anything else responsive to what I have asked so far that you, given your familiarity as agency counsel, wish to clarify?

MR. KEVENEY: No, your Honor.

THE COURT: Thanks very much. I appreciate you didn't come here today expecting to argue, and I appreciate the

helpful answers under fire.

MR. KEVENEY: Absolutely. You're welcome, your Honor.

MR. TAKEMOTO: Your Honor, may I say one thing? I just want to formally object to the record just on the basis of APA case are limited to the record and not based off of agency testimony.

THE COURT: I appreciate that, so why don't we turn to the record?

Mr. Bates, let's go to what Mr. Colangelo was saying about the number of complaints. The record that Mr. Colangelo recites suggests that the number of complaints that were presented to the agency was not nearly the quote/unquote significant increase that the agency represented. Factually, over the course of your briefs, the number has gotten smaller and smaller and smaller.

How many complaints does the agency say it received in the ramp-up to this rule?

MR. BATES: So the agency stated in the rule that it received 343 alleging violations.

THE COURT: That's what it said, but once we strip away things like vaccinations, what are we left with that actually implicate this rule?

MR. BATES: So it is a smaller number, your Honor. We have cited a number of them in our reply brief. I believe that we cited about ten in the reply brief, and I know that

plaintiffs have stated that they believe that there are about 20 or 21. In terms of the exact number of complaints, there are -- we didn't cite all the ones in our reply that we would say fall in here, but it would be something probably relatively similar to the number that the plaintiffs provided.

THE COURT: So you are not directionally disagreeing with Mr. Colangelo's numeric representations.

MR. BATES: Not to the extent that plaintiffs have identified that a number of the complaints of those 343 did not allege violations that were relevant to the --

THE COURT: I'm sorry. Let's go back to the 343. The agency at the time it proposed the rule represented that there had been a significant increase in the number of complaints that it used the 343 as a measure of that. If I am hearing you right, that 343, once we strip away complaints that deal with extraneous problems like vaccination, we are down to something like 20, correct?

MR. BATES: In terms of the complaints that would have dealt more directly with rights that were protected under the conscience section.

THE COURT: I going to drill down a little more until I get a direct answer. Yes or no: Are we down to about 20 that actually implicate these statutes as opposed to other problems?

MR. BATES: Yes. In that ballpark, your Honor.

THE COURT: Now, your brief, your brief ultimately, I think it is your reply, identifies actually three at one point that you say are responsive. I took a look at the three and, unless I am missing something, two of the three aren't even responsive.

There is a complaint from a law firm on behalf of an adequacy group -- this is at tab 129 -- that doesn't cite any specific instance of discrimination. There is a complaint at tab 27 from the doctor at the Washington State Department of Corrections that deals with the sex transformation procedure, but there's no HHS funding that appears to be implicated. And the third one seems actually to fit the paradigm here, and that's the nurse at the University of Vermont who says she was coerced into participating in an abortion. Am I misreading you as to those three?

MR. BATES: So we also cited some additional complaints in our reply brief, your Honor. That's at page 26, note 5.

THE COURT: I have got that. But at one point you highlighted those three. Am I right that two of the three actually drop away?

MR. BATES: Two of the three would not implicate violations of the conscience statutes. Those complaints I believe would have alleged violation of the conscience statute; and, in part, the rule here, as the agency explained in the

preamble, was to help to increased understanding and awareness of the rights that are protected under the conscience statute. So the fact that there may have been complaints filed did not actually implicate is still relevant here, because it shows some confusion about what the statutes do cover.

THE COURT: All right. I took you off script. I know you wanted to talk initially about authority and rule-making authority. Thank you. Go ahead.

MR. BATES: So turning back to my notes here, so I think that I also, as we explain in our briefs, in addition to the express delegations of authority, there are also implicit delegations that are relevant. The Supreme Court has made clear that delegations of authority can be both explicit and implicit, and in the process of enacting the conscience statutes and imposing obligations on regulated entities, placing obligation on the agency to ensure compliance with those statutes, there was implicit delegation to the agency to ensure that the agency complies with requirements of those statutes. And so that is relevant --

THE COURT: What is the basis for arguing implicit delegation for the three statutes I mentioned earlier that would substantively define, for example, a term like "assist in the performance" to capture, for example, the range of services or acts that are covered? That seems substantive. That deals with the range of people whose primary conduct implicates the

rule. What's the basis for arguing that implicitly Congress meant HHS to fill that gap and define that?

MR. BATES: So HHS is the agency that's tasked with ensuring compliance with the statutes. So in the process of ensuring compliance, HHS has authority to set forth definitions for what those terms are in the statute.

THE COURT: But, so you say. I mean, isn't the other way to look at it that if Congress was able to affirmatively give you substantive rule-making authority for Medicare, Medicaid, ACA for terms like "discrimination" or "aid and assist in the performance," as the case may be, its silence on that, as to the Church and Weldon and Coates-Snowe amendments, implies that it wasn't intended to give, other than housekeeping, rule-making authority to the agency.

MR. BATES: So, again, delegations can be both explicit and implicit. The various statutes you have discussed here, they were passed at different times by different Congresses as parts of different public laws. So attempting to engage in some sort of intertextual comparison among the different statutes passed at different times doesn't necessarily show that --

THE COURT: Be that as it may, what's your affirmative evidence that when Frank Church put forward the Church amendment, after *Roe*, he intended HHS to rule-make? 1972, the year before Title VII adopts the accommodation framework with

the hardship exception, allowing the employer to insist on somebody's performance of the task. Frank Church was presumably well aware of that, as was Congress. They passed the Church amendment. There was not word one about Title VII and there is not one word about delegating to the agency the ability to rule-make in this area, let alone to supervene Title VII. What's the basis for implying that intention on Congress's part? It's the very next year.

MR. BATES: Well, that's, I think, the nature of an implicit delegation, your Honor. That there is not --

THE COURT: No, but that is circular. Give me something that suggests that HHS, in Congress's eyes, was free to roam around and define those terms, including in a way that would supervene a statute that Congress passed the previous year. I mean, you keep saying it is implied, but implied from what? Otherwise it is just a say-so. What's the evidence?

MR. BATES: Well, in terms of the question of supervening Title VII, your Honor, again, conscience statute, Church amendment was passed after Title VII. Congress chose not to include certain aspects of Title VII in the Church amendment. So that doesn't necessarily --

THE COURT: That doesn't mean that they disagree with it. Maybe they liked what they had previously done. I mean, in Title VII, as of 1972, you have an amendment that, at least in the context of the religion protection in Title VII, as

opposed to morality-based conscience objections, explicitly deals with this problem at a level of greater specificity than does Church or Coates-Snowe or Weldon. What is the basis for inferring in those very short conscience provisions that post date the 1972 amendment of Title VII that Congress was *sub silentio* saying, you know, be done with this hardship exception?

MR. BATES: So there is a difference in the statutory text there, your Honor. And I apologize, I have lost my train of thought here for a moment.

THE COURT: I'm focusing -- look, I want to engage with you on the basis for implying that -- for implying an intent on Congress's part to allow the agency to substantively rule-make here, let alone substantively rule-make in a way that would cover what were a different outcome and a different test, what Congress itself had dealt with the previous year in Title VII.

MR. BATES: I think that what you are speaking to here, your Honor, may be a statutory gap. So this question of how Congress set forth the scene in Title VII, how that's going to interact here with the conscience statute, that may be an example of a statutory gap that then is left for the agency to fill.

THE COURT: But it's not -- it would be perhaps a gap if there weren't conflict. But let's engage, then, with the

issue of how the rule intersects with the area of conduct covered by Title VII. So let's focus just on the employment context as opposed to, for example, benefits situations. In the context of employment, do you disagree with the way that plaintiffs portrayed, pre-rule, the operation of the hardship exception?

MR. BATES: In terms of?

THE COURT: How it worked.

MR. BATES: In terms of its application here?

THE COURT: How an employer, presented with an employee who asserted an objection to, let's say, assisting in an abortion. Do you disagree with the portrait, given by plaintiffs, as to how the dynamic worked under Title VII, that there would be an attempted accommodation, but in the end, if there was a -- forgive me, I'm forgetting the adjective modifying hardship. Undue hardship. Thank you. Do you agree that that was the standard that applied in terms of an employer's latitude to insist on an employee's performance of a task under Title VII?

MR. BATES: So that may have been the standard that the -- that employers of the plaintiffs were applying. That exception does not apply in the text of the conscience statutes.

THE COURT: No, no, no, no. Do you disagree that under Title VII the employer was able to overcome in effect a

religious-based objection to a procedure based on undue hardship?

MR. BATES: Under Title VII, yes.

THE COURT: Okay. So had any court ever held that the conscience statutes in the context of employment overcame that framework, the Title VII framework?

MR. BATES: I am not sure that that issue ever had been presented, your Honor.

THE COURT: Except in the *Shelton* case, which goes the other way, Third Circuit, right? That's exactly the Third Circuit. The Third Circuit in *Shelton* is an employment context involving the nurse who refuses to participate in the abortion and declines the accommodation, gets fired, sues, and loses, essentially based on the Title VII hardship framework, right?

MR. BATES: So, that question would then depend, your Honor, on if the plaintiff in that case raised the conscience statutes and what the court decided about the interplay of the conscience statute for Title VII in that case.

THE COURT: In other words, *Shelton*, you think, would have come out differently if the lawyer in that case had had the wisdom to invoke the conscience statute as having *sub silentio* overcome the Title VII framework.

MR. BATES: That the conscience statutes are more specific and address a more discrete instance, which is conscience protections in the healthcare arena, and that

therefore they apply there in that instance.

THE COURT: But the conscience statutes don't get to this level of granularity. They use words like "discriminate," which, by the way, is also used in Title VII. But beyond the words like "discriminate," they don't get granular as to the operation of the statute as applied to workplace context. They don't say there is or isn't an undue hardship. They just say "don't discriminate," right?

MR. BATES: Yes, that's correct.

THE COURT: So what is the basis for inferring in that that they meant discriminate in some way other than by then the very familiar Title VII framework? I understand that might have been preferred by some, but the statute itself just doesn't say that.

MR. BATES: Congress chose not to include an undue hardship exception in the conscience statutes.

THE COURT: When did they choose that? They use a general term, but they don't -- they simply don't spell out the details. But on what basis can you say that Congress affirmatively chose Frank Church and all the others to not afford an undue hardship exception? Was it a choice or was it simply silence?

MR. BATES: I mean, they knew that that provision was in Title VII. They could have included that provision in the conscience statutes if they chose to --

THE COURT: And they could have indicated in some way in the legislative history or a committee report or the text a disagreement with the existing framework and didn't do that either.

The point is, it seems like it's an *ipse dixit* to say that their silence means that they chose to quietly overcome this very familiar framework. I am looking for some dollop of evidence beyond your say-so that that's what Congress intended. Do you have anything?

(Pause)

MR. BATES: I am just turning to my notes here, your Honor.

THE COURT: Go ahead.

MR. BATES: So the absence in the text is a point, your Honor. As I also mentioned, there are also differences between what Title VII covers and what the conscience statutes cover. And Congress may have determined based on difference in scope not to include the exception there.

THE COURT: They might have done a lot of things. The issue is what they actually did. To a large degree, the conscience statutes cover the employment world, *i.e.*, the world covered by Title VII. I'm asking you, last time, if there is any reason to think, anything specific you can point to that indicates that anybody at Congress intended to overcome the Title VII framework with the conscience statutes in the area

the Title VII framework otherwise applies to.

MR. BATES: Just in the statutory text, your Honor.

THE COURT: May I ask you, up until this rule, I know that the Bush era 2008 rule doesn't define "discrimination," so it didn't seek to overcome the Title VII framework, correct?

MR. BATES: So I have here the rule in front of me, your Honor, the 2008 rule. I would need to review that specific provision of the rule. I will take your Honor's --

THE COURT: Well, it doesn't define "discriminate." It defines other terms, but it doesn't do that, right?

MR. BATES: I -- I'll -- I'll take your Honor's correct on that.

THE COURT: As you understand here now, can you think of any time prior to the promulgation of this rule when HHS, either in the context of a rule-making or in the context of the application of the conscience statutes to a particular scenario, ever took the position prior to this rule-making that the Title VII framework didn't apply to conscience objectors covered in the employment setting?

MR. BATES: I'm not aware of HHS having previously taken that position, your Honor.

THE COURT: So if Congress intended *sub silentio* to overcome Title VII, it was first discovered in or about 2019? Is that the point?

MR. BATES: That?

THE COURT: All those people have been dead for a while who passed -- it's the early parts of the statutes. What's the basis in 2019 for saying that archeology discovers that the framers of these statutes going back to 1973 intended to override Title VII?

MR. BATES: I mean, I, I, I, I apologize. It seems to be the same back-and-forth here, your Honor. It is based on the statutory text. There is a difference in the statutory text. Title VII explicitly has the exception that is not present in the statutory text in any of the conscience amendments which were passed at various times across various Congresses and various public laws. There were multiple times that Congress considered rights of conscience and in none of those instances did they incorporate an undue hardship exception.

THE COURT: Congress was surely aware with the second and third and fourth and all of those up to the 30 conscience statutes that there was apparently no authority out there that read the conscience statutes as intentioned with Title VII or as overcoming it. Given that Congress is presumed to be aware of the facts on the ground, wouldn't one have expected in conscience statutes 2 through 30 to then circle back and say, hey, wait a minute, you know nothing of our work, you don't know what we -- we obviously meant the first of these statutes to override Title VII. You have misread us, so we are going to

be clearer in each of the ensuing statutes.

Isn't there some mileage we can get out of the fact that they didn't do that?

MR. BATES: I mean, it would depend on the extent to which the issue had been brought to Congress's attention, your Honor. I mean, the fact that Congress, time after time, has enacted conscience statutes without this protection -- I suppose one could draw the inference both ways. Here in the text, we would say that the absence in the text, you compare Title VII -- and I apologize if we are just going round and round here, your Honor, but it is a difference in the statutory text, and the question is, what is the inference that you draw from the absence in the statutory text?

THE COURT: What inference do you draw from the fact that the ACA, Affordable Care Act, 2010 says that it doesn't conflict with Title VII?

MR. BATES: What do you mean, your Honor?

THE COURT: Doesn't the ACA, isn't the ACA, doesn't it contain the explicit language harmonizing itself with Title VII?

MR. BATES: It also says that nothing in the act -- let me just turn to. . .

THE COURT: That's one of your examples of substantive rule-making authority. But the ACA, it is hard to read that as, given its reference to Title VII, overcoming Title VII.

MR. BATES: The ACA also says that nothing in the act shall be construed to have any effect on federal laws regarding conscience protection.

THE COURT: Sure. But that assumes the conclusion. If you assume the conscience provisions overcame Title VII, I suppose that's right. If you start with the opposite conclusion, that Congress, in referencing Title VII, presumably, if it intended to override Title VII, would have said something different than it said, you come up to a very different place.

All right. Let's go back to other issues of authorization, unless there is something else you want to tell me about Title VII.

MR. BATES: Just one point. To the extent there is an issue you have identified here, your Honor, I think that it would apply to that specific aspect of the definition of "discrimination." And so to the extent that you find an issue here, that is not a basis to sort of go beyond that specific issue in terms of the scope of relief with regard to plaintiffs' challenge.

THE COURT: As to that, do you agree that the rule adopts a different framework with respect to discrimination and then Title VII?

MR. BATES: The rule does not include the undue hardship.

THE COURT: Give me a concrete example in which that difference would result in a different outcome.

MR. BATES: So the Title VII framework says that the employer has to provide a reasonable accommodation unless doing so would result in undue hardship. And so some of the examples we have talked about, where an employee raises an objection to a procedure and the employer offers an accommodation or the employee seeks an accommodation and the employer determines that the accommodation would be, you know, problematic, would result in the employer having to spend some more money or complicate their staffing decisions --

THE COURT: Let's be concrete. Suppose an employee now says she has been a nurse or he has been a nurse assisting in abortions and does not want to do so anymore, develops that objection, and the employer says, fine, you are now going to no longer be working in OB-GYN, but you can work in orthopedics, you can work in pediatrics, you can work in neonatal; and the employee says -- and same pay, same title, same perks -- and the employee says, no, I insist on staying in OB-GYN. Under the statute, under the rule, who wins?

MR. BATES: Under the conscience rule, your Honor?

THE COURT: Yes.

MR. BATES: So that will depend on whether that reassignment constitutes discrimination.

THE COURT: But doesn't discrimination -- if the

employee rejects the accommodation and the employee is being transferred because of the religious objection to performing a particular procedure in his or her department, doesn't that, under the rule, constitute discrimination?

MR. BATES: So the rule says that the acceptance of the accommodation, that that does not itself -- so it creates a safe harbor. It says the accommodation is not itself discrimination. It doesn't necessarily -- they will set in place the converse or --

THE COURT: Right.

MR. BATES: -- that's going to be a fact-dependent scenario depending on what the assignment entails that's going to be a question for the agency in the first instance to determine what the difference is between the responsibilities and --

THE COURT: In my scenario, here, though, the OB-GYN nurse is transferred to neonatal work, and every other mete and bound of the employment is the same, and the only reason for the transfer is, from the employer's perspective, it is functionally a challenge to have somebody there who is saying on a procedure-by-procedure basis, yes, I can, no, I can't. You would rather have somebody who is available for all procedures that come through the department. You can understand the functional reasons for that.

But if the employee refuses to get out of that

department than be transferred to another equally estimable reputable department, isn't that, under the rule, in terms of discrimination, there is nothing in the rule that gives the employer comfort that in doing so they are not jeopardizing their federal funds, correct?

MR. BATES: So again, your Honor, it is fact specific, and it is going to be a determination by the agency based on the facts of the scenario what the outcome is.

THE COURT: In the hypothetical I gave, though, does that mean that the employer could be, depending on how the agency views that problem, the employer could have violated the conscience statutes as interpreted by the agency under my scenario?

MR. BATES: Yes, your Honor.

THE COURT: Whereas, if, under the Title VII framework, there was an undue hardship determination, the employer would be free to do what it did, right? Undue hardship is no longer something the employer can trot out under this rule as a defense.

MR. BATES: That's correct, your Honor.

THE COURT: All right. So what defense does the employer have if it's being candid in saying, yeah, of course it is your objection to this procedure that is causing you to be moved, it is nothing else, but we have a job to do and it is much more functional to have somebody who is reporting for duty

for all aspects of the job to be in that department, we honor your work, we honor your religious conviction, but you are a better fit for pediatrics and neonatal than for handling an ectopic pregnancy. What defense does the employer have under the rule?

MR. BATES: What do you mean by defense, your Honor?

THE COURT: Well, if you claim that it was a violation and the employer admitted that the reason for the transfer was because of the conscience objection and what it -- the complications it presented for the workplace, under Title VII the complications in the workplace have a doctrinal home. It's called undue hardship. Maybe you meet it, maybe you don't. But under the rule, is there anything that the employer can point to to avoid liability for that behavior, for that transfer?

MR. BATES: Not in terms of the possibility of an undue hardship. The question would come down to what the nature of the reassignment is and whether the nature of the reassignment falls within the definition of the --

THE COURT: Right, but doesn't the rule essentially say that in the event -- the rule doesn't say that only a diminution of responsibility or a diminution of salary, or something like that, constitutes discrimination. It is the transfer itself, the accommodation itself, if it isn't accepted by the employee, that is the discrimination. I'm asking you,

can you point to something in the rule that you would, if you were the general counsel or the employer, point to and say, ah-ha, we have comfort. We can move this valued employee to an area in which he can do equally valued and equally paid work and not complicate our mission. Is there anything in the rule that gives the employer a legal hook to hold on to?

MR. BATES: So the rule sets forth what constitutes discrimination. The rule does not say *per se* that reassignment is discrimination. It talks about adverse impact and those sorts of things. I think that in the scenario that you posit, the best practice might be to contact the agency and discuss the situation with the agency and seek the agency's guidance.

THE COURT: I see. How long does that take?

MR. BATES: It could vary, your Honor. I mean, there is information on the agency's website about how to get in contact with the agency. I would presume it would vary depending upon the complexity of the question and those sort of things.

THE COURT: Would *Shelton* come out the other way under your reading if the rule were determinative?

MR. BATES: So in terms -- so if you had a scenario where you had a nurse who objected to performing an abortion and did not accept a reassignment to another unit, the question is --

THE COURT: And got fired.

MR. BATES: So it would depend on, your Honor, whether that reassignment constitutes discrimination.

THE COURT: No, it would be whether the termination constitutes discrimination. Remember in *Shelton* she gets fired and she sues for being fired after refusing the accommodation. And I am asking you, under the rule, isn't it clear that *Shelton* would come out the other way as long as providing the employee made the right argument under the rule.

MR. BATES: Well, it does depend on whether the reassignment is discrimination. Because if the employee were terminated for refusing to accept something that is not discrimination, then that wouldn't come within the ambit. There has to be discrimination in order for the rule to be --

THE COURT: Maybe this is circular, but I'm trying to figure out, it is HHS that has defined "discrimination." I'm trying to figure out what in the definition of "discrimination" gives the employer some latitude in dealing with this type of problem.

MR. BATES: So the definition sets forth what can constitute discrimination. It talks about -- let's see here. It talks about withholding, reducing, excluding, terminating employment, title, position, utilizing criterion, method of administration.

THE COURT: So there is terminating employment. *Shelton* nurse terminated employment. It is checkmate, isn't

it, under the rule?

MR. BATES: Not if the reassignment itself was not discrimination. So if the employer --

THE COURT: If the employee doesn't like being in pediatrics or neonatal and says no, under the rule, isn't it discrimination?

MR. BATES: Only if -- the reassignment. So the termination in this hypothetical is triggered by the rejection of the reassignment.

THE COURT: Right.

MR. BATES: So if the reassignment is discrimination, the consequence that follows from that would also be discrimination.

THE COURT: And under the rule, isn't the fact that the reassignment is triggered by the refusal to accommodate a -- it's triggered by the refusal to allow the morally objecting or religiously objecting nurse to stay in his or her job, isn't that itself an act of discrimination?

MR. BATES: I'm sorry. Can you repeat that, your Honor?

THE COURT: Let me put it this way. You are, I take it, at this point unprepared to give an answer to the question under the *Shelton* scenario, which is the case and the case law that is the most clear, how it would come out under the rule. You certainly can't assure me to come out the same way.

MR. BATES: No, your Honor.

THE COURT: Throughout your brief, you repeatedly tell the court that this is just about housekeeping. Is it really the agency's position that there is no substantive component to any part of this rule?

MR. BATES: No, your Honor. The agency does take the position that the rule is substantive, that it does impose obligations on regulated entities.

THE COURT: Is that a change from what was said in the brief? I think we collected about ten sound bites that say the opposite. I'm not going to waste your time reading them to you, but it was housekeeping, housekeeping, housekeeping throughout the brief. I think this dialogue explores and demonstrates that, for better or worse, there are substantive changes in the sense that the law applies different or potentially different consequences to the same primary conduct.

MR. BATES: And there are different elements at play here, your Honor, so I think with regard to the definitions, there are some substantive elements there. With regard to compliance and enforcement of grant conditions and those sorts of things, which, like the UAR, the agency has taken pursuant to the housekeeping statute, those are housekeeping matters.

THE COURT: Okay. There certainly are some housekeeping matters in here, but the brief depicted the rule as entirely housekeeping.

Let me continue to understand how this rule would apply in some workplace context.

Let's take a clinic that unwittingly hires a receptionist who objects to abortions. The clinic largely does work that includes a lot of abortions. The receptionist refuses to schedule abortions and refuses to switch jobs. Business slows to a halt. Can the clinic fire the receptionist without potentially breaching the rule?

MR. BATES: So in the rule, the agency said that scheduling an abortion can constitute assistance in the performance, so that would then bring this action within the ambit of the rule.

THE COURT: Right.

MR. BATES: So that therefore the agency could not -- I'm sorry, not the agency -- the employer could not discriminate on the basis of that which would include termination.

THE COURT: Meaning that the termination, then, would appear to be a violation of the rule.

MR. BATES: That's correct, your Honor.

THE COURT: All right. A pregnant woman takes an ambulance across Central Park to Mt. Sinai Hospital and, midway through, from conversation with the ambulance driver, it becomes clear that she is headed there to terminate an ectopic pregnancy. The driver tells her to get out in the middle of

the park, and the employer fires the ambulance driver for that. Is the ambulance driver assisting in the performance of the procedure if the ambulance driver takes her to the hospital?

MR. BATES: So the agency did say in the rule that transporting an individual to a hospital for the purpose of having a procedure that falls within the ambit of the rule, that that would constitute performance.

THE COURT: So the --

MR. BATES: I think that that might implicate other issues as how the ambulance driver dealt with that situation.

THE COURT: Right. It's certainly not a best practice. But the issue is, is the conduct of the ambulance driver, in refusing to drive any further because of the ambulance driver's sincere religious objection to the procedure, is that protected by the rule?

MR. BATES: The rule protects an ambulance driver's ability not to assist in the performance of a procedure to which the driver has an objection.

THE COURT: So play out for me what is supposed to happen in that scenario under the rule, if the ambulance driver simply says, I'm breaching my convictions to get to the other end of Central Park.

MR. BATES: So employers have an obligation, under EMTALA, to provide sufficient staffing and recourse in the event of emergencies that are implicated so the agency -- or,

sorry, I keep saying "agency" when I mean to say "employer" -- so the employer, under EMTALA, should already have in place procedures to handle that situation, and so therefore would put into place whatever --

THE COURT: Right now --

MR. BATES: -- ambulance procedures were and would have had the ability to ask the ambulance driver about his objections, so that they would then be aware to know what the proper way would be to deal with that situation.

THE COURT: So the employer, you are saying, would have known before the ambulance mission began -- the employer is allowed to ask the ambulance driver in the driver's employment whether or not he objects to any particular procedures, such as abortion, on religious grounds --

MR. BATES: Yes.

THE COURT: -- or other moral grounds.

And if the driver has said yes, then the employer is allowed to task the driver with nonabortion ambulance drives? I'm trying to understand just how this works.

MR. BATES: The employer would need to have in place a procedure to handle a situation just as your Honor has posited.

THE COURT: And now, look, we are talking about emergencies. It is a bleeding ectopic pregnancy, and the driver realizes in the middle of the park what the nature of this is. It's not, by the nature of emergency, something which

calm deliberation or all facts are brought to bear at the outset. So in the middle of the transverse in the park, the driver realizes what is going to happen when the ambulance hits the hospital, and the driver then says "no can do" and refuses to drive any further. Can the employer take action against the ambulance driver under this rule or is the employer risking its federal funding by taking action against the driver?

MR. BATES: So, again, the employer should have had in place procedures to deal with this, whether it be another driver in place or something in place to deal with this situation, and then to the question of what then happens to the driver, the driver would be protected under the rule because it would have had a right, under the conscience statutes, not to assist in the performance of a procedure as to which the driver has objection.

THE COURT: And in my scenario in which the -- we have an emergency situation that pops up in the middle of the drive that we have this problem, in other words, it can't be anticipated at the outset, the employer cannot say to the driver: We have somebody who is bleeding. You have to get to the hospital. Sorry. The employer can't do that, you are saying. The employer has to, quote, accommodate in the crucible.

MR. BATES: So the employer has to accommodate, that's correct, under the rule. HHS also made clear that if it

intends to read EMTALA harmoniously with the requirements under the rule, so that if it came to questions of enforcement by the agency, working out sort of what to do in the scenario, that's not necessarily to say, then, that the most extreme measures are necessarily going to come into play because the agency has said it intends to read them as harmoniously as possible.

THE COURT: Right. What that means is the agency may, in its grace, choose not to cut off billions of dollars of funding, but it also might, it still reserves the right to do so, correct?

MR. BATES: The rule would not prohibit that, but the agency is clear that it intends to read them harmoniously wherever possible, that it will begin -- it says it will begin with informal enforcement, informal communications, and only take further action when voluntary compliance cannot be reached. So there is a long series of events that has to take place before any of these more extreme eventualities come into play, and --

THE COURT: When, under the new rule, can the employer even ask about these matters? I gather once a year or if there is a persuasive justification, but not on a more regular basis, right?

MR. BATES: Yes. After hiring, and once a year, unless there is a more -- absent a persuasive justification.

THE COURT: What about the rural hypothetical? That's

the classic example that's given for undue hardship, where you have got a very limited number of personnel. You really need to have somebody there who is a full spectrum, you know, nurse, scheduler or whatnot. It is not realistic to have a substitute in the wings or something like that. How does the rule apply in that setting?

MR. BATES: It applies the same as it applies in other settings, your Honor. It sets forth the various responsibilities for employers. It doesn't create an exception or other conditions that apply in rural instances.

THE COURT: Okay. So meaning that essentially if there is an employee there who asserts religious objections to a range of procedures and it is economically impractical, you know, to have a platoon situation for objectionable and non-objectionable procedures, where you have different employees filling that role, the employer is -- simply has to find a way to pay for a second job there, even if it is impractical, right? The employer intends to continue performing that service and the one person who works there, the one scheduler, the one operating room nurse, that sort of thing, the employer is stuck.

MR. BATES: So with regard to the specific discrete service or discrete procedure that the employee may have an objection to, yes, the employer would in that instance not be able to force the employee to perform the procedure; and so if

the employer wished to continue providing that service, it would need to find an alternative way to do so.

THE COURT: Let's pivot now from discrimination, which has been largely the focus of this line of hypotheticals and questions, to "assist in the performance."

From your perspective, substantively, how does the rules definition of "assist in the performance," insofar as it spells out the range of people who are assisting in some sense with a medical -- with an abortion, just to be direct, how does it change, in your view, from prior definitions or understandings? There really wasn't a definition of "assist in the performance," but I take it the agency had never acted so as to apply the term to people, for example, who did something the day before a procedure. Is that correct?

MR. BATES: I believe so, your Honor.

THE COURT: So in what ways does "assist in the performance" expand the scope of that term from what was previously applied or understood?

MR. BATES: So in terms of the relationship between the term and the statute, we have argued in our briefs that the term is consistent, claiming in the statute, in terms of how HHS has applied that term in the past. I think that is a question that goes to prior enforcement actions.

THE COURT: So in any prior enforcement action, has HHS ever even investigated somebody for -- where the objection

was made by somebody who had a role in a procedure that didn't involve the same day?

MR. BATES: So, your Honor, I don't want to ask to bring agency counsel back up here, so I am going to say --

THE COURT: I'm sure agency counsel doesn't want to come back up either, but --

MR. BATES: So I'm going to say no, with the caveat that I would ask agency counsel to correct me if that's incorrect.

THE COURT: You would say what?

MR. BATES: I would say no with the caveat that agency counsel would correct me.

THE COURT: Agency counsel, if you have got an example in mind where there was a -- an enforcement action or interpretation taken where the conscience objection was to something on a day other than the date of the procedure, I would welcome your letting me know.

MR. BATES: No, your Honor.

THE COURT: I will construe silence that at least offhand you don't have such an example.

That is a not inconsequential change. Whether or not it is linguistically supportable by the text of the conscience statutes, you will agree that that is a consequential change in the way going forward these statutes would be applied, would you not?

MR. BATES: So your question is would that be -- to the extent that HHS has not brought an enforcement action in that scenario previously --

THE COURT: Or to the extent it is not announced that people who perform previous-day or post-day support roles are covered by the conscience statute, yeah, I mean, in other words, whether or not it can be linguistically supported by the text of the conscience statutes and the words "assist in the performance of," it is a newly articulated interpretation that doesn't have its anchor in anything that's been articulated or acted upon before. Is that much correct?

MR. BATES: Not previously by the agency.

THE COURT: Well, by anybody else? Who else?

MR. BATES: Well, there is the text of the statute which sets forth the term "assisted performance." HHS administers that statute. So insofar as HHS has not taken enforcement action pursuant to that scenario then --

THE COURT: Do you know if HHS has even been presented with the scenario before in all the years of these statutes, where somebody who was distressed about the possibility of non-same day steps or assistance towards an abortion felt that that religious objection, that conscience objection wasn't being respected, has the agency even been presented with that as a problem in any of the complaints presented?

MR. BATES: Not to my knowledge, your Honor, and we

would be happy to submit briefing to the court about these sort of specifics.

THE COURT: Let me ask you, you were relying on all these vaccination complaints. Did any one of those complaints even involve somebody who was scheduling a vaccination or doing something as to even a vaccination other than on the day of the vaccination?

MR. BATES: I don't know the answer to that, your Honor, not to my knowledge.

THE COURT: In terms of the rule-making process here and the factual basis, you heard me engage with Mr. Colangelo about the number of complaints. Can you point to a single complaint that the agency has ever gotten in connection with a failure to accommodate somebody whose connection to the abortion or sterilization procedure was other than on the day in question? Is there a single example of that?

MR. BATES: In terms of the complaints, not that I am aware of, your Honor.

THE COURT: So how can the agency be said to have a factual basis for that dimension of its work?

MR. BATES: Because "assistance in the performance," that term --

THE COURT: No, no, no, no. I understand that if we are playing the textual game that one can use -- one can construe "assist" in a variety of ways, and I understand the

linguistic basis for saying that assistance goes all the way back to, you know, a person who paid for the nursing school of the nurse, I get all that, you can do that. I am asking you factually why the rule was enacted? The agency said we have got the significant number of complaints. Well, that's all fine and good, but how does that sync up to the broadened definition of "assist in the performance"? Even if you had a lot of complaints, that might justify rule-making in the area of the ambit of the complaints, but if there literally wasn't anybody who complained that their conscience rights were being offended by participating in some non-same day way, I'm trying to understand if there is any factual way to prompt for that, for engaging in this space? Why rule-make on that point?

MR. BATES: So an agency does have authority and ability to use its expertise to engage in rule-making and set forth definitions, and I don't believe it is the case your Honor that, in setting forth the definition in this context or in another context, an agency must sync up every single individual piece of a definition that sets out with some complaint or a piece of evidence that was brought. It doesn't have to rate some massive chart where it is linking up all of the definitions with all of the complaints or evidence that was brought forward to the agency.

THE COURT: But arbitrary and capricious review turns, as Mr. Colangelo pointed out, on a factual basis. I am trying

to test the factual basis for this consequential part of the rule. That's all. And I take it the answer is that although there is a textual justification, there is not a factual basis for rule-making on that point.

MR. BATES: On the point that action taken a day before a procedure can constitute assistance in the performance of the procedure, so on that discrete point, there is not, to my knowledge, a complaint that addresses that issue.

THE COURT: Is the agency aware of any receptionist, ambulance driver, elevator repairman, anybody, who ever complained that their ancillary work, other than on the day of the procedure, was violating their conscience rights?

MR. BATES: Not that I'm aware of, your Honor.

THE COURT: All right. Is this statute consistent with EMTALA or not?

MR. BATES: May I add one point, your Honor?

THE COURT: Please go ahead.

MR. BATES: Getting back to that hypothetical you have identified a specific scenario, that doesn't necessarily then mean the definition itself as a whole is invalid. You have identified sort of one application that, to the extent it raises issues, may be a potential issue, but that would go to the application as to that specific factual scenario, like an as-applied challenge as opposed to a facial challenge, which is what we face here.

THE COURT: It would be facial as to parts of the definition but not to, perhaps, parts of the definition that involve the nurse handing over the forceps, right? In other words, it is not that -- it is not that the distant, remote assistance is in any scenario justified by an empirical basis before the agency, it is that there are parts of the definition that are not made problematic by that failure of evidence, *i.e.*, the nurse who is immediately in the operating theater.

MR. BATES: That's correct.

THE COURT: Just briefly, counsel for the plaintiffs says that, on the contrary to law point, the statute is inconsistent with EMTALA, the Emergency Medical Act.

Putting aside the agency's promise to do its best to harmonize them, on the face of the rule how is the rule -- is the rule, on its face, consistent with EMTALA?

MR. BATES: On this question, the rule is, like the conscience statutes themselves, the conscience statutes themselves do not discuss the interaction of those statutes with EMTALA. So this question applies equally to the conscience statutes themselves. And the agency said it intends to read them harmoniously. It applies both to the rule and to the conscience statutes.

THE COURT: Isn't there all sorts of legislative history, including Weldon and Church, that, if we consider it, makes clear they had no intention of compromising the execution

of emergency medicine? I recognize there are issues about the extent to which one can consider legislative history, but put that aside for a moment, doesn't the legislative history to the extent that it exists make clear that emergency medicine was intended to be cordoned off from the impact of the conscience statute.

MR. BATES: So there is legislative history indicating that the individuals who made those statements did not -- were not expecting for the conscience statutes to impact the requirements to provide emergency services under EMTALA.

THE COURT: Like Frank Church.

MR. BATES: That's correct.

THE COURT: All right.

MR. BATES: And the rule implements those statutes, and so the interaction between the statutes and EMTALA is going to be the same as the interaction between the rule and EMTALA.

THE COURT: It depends how one construes the statute. Has the agency -- prior to the rule, had the agency been presented by any complaint from anybody practicing emergency medicine?

MR. BATES: So there were complaints. There were complaints by various nurses. I don't know that those complaints specified whether the nurse participated in emergency services or not.

THE COURT: Why -- what was the agency's basis for

interpreting the rule so as not to carve out the emergency situation? Given that EMTALA is out there as a federal statute, what was the agency's reasoning in not correspondingly carving out the emergency space in terms of the ambit of the rule?

MR. BATES: I think it was consistent with the conscience statutes, which don't explicitly do that either. It was implementing the conscience statutes. Conscience statutes don't have that explicit carveout. So, again, it is a question of the interaction between the rule and EMTALA is going to be the same as the interaction between the statutes and EMTALA. So I don't think the agency found it necessary to carve that out because it wasn't in the statutes either, and the interaction is going to be the same between the two of those.

THE COURT: *Shelton*, of course, applies in the emergency context. It is at once a Title VII case and an emergency medical case. Did the agency consider *Shelton* explicitly in its rule-making as a federal appellate court application of these concepts in the Title VII context? Did it engage with that? What was its reasoning for, in effect, coming up with a different framework?

MR. BATES: So I believe that the agency did cite *Shelton* at some point in the footnotes. I don't know the exact footnote that that was at, your Honor.

But getting to your question about, again, the

interaction between the rule and EMTALA, again, I apologize if I am repeating myself, I think the agency determined reasonably that the interaction between the rule and EMTALA would be the same between the interaction between the conscience statutes and EMTALA, and so that it wasn't necessary, then, to provide an explicit carveout because the extent that there is tension there, it is the tension with the conscience statutes as well, so that resolving that tension is the same between the statutes and the rule, and so it wasn't necessary to provide a carveout that wasn't in the statutes that was implementing itself.

THE COURT: All right. Go ahead. I have taken you off. I think we have covered a lot of what I am sure you intended to cover, but I want to make sure that you have enough air time for the points you wanted to make to me.

MR. BATES: Thank you, your Honor. How much time do I have remaining?

THE COURT: I have taken you off script. You have got what you need.

MR. BATES: So let me just go through my notes here, your Honor.

So we talked about the evidence that the agency can serve. We talked about the complaints. I noted that, as we did cite in our reply, that a number of the complaints did implicate violations of the conscience statutes. So there was, before the agency, evidence of the complaints, as agency

counsel mentioned, that there was an increase in complaints, even setting aside the vaccination complaints, they went from, like, one year to around ten or so a year, so there was a substantial increase.

THE COURT: But that was after the notice of rule-making. Prior to the notice of rule-making, which presumably was prompted by -- I mean it is a Heisenberg principle you have here, right? Where you -- once you throw out the notice of rule-making, you are stirring the pot. Prior to the notice of rule-making, was there any increase in complaints?

MR. BATES: So not prior to the notice of the rule-making, but the rule-making, to the extent it did increase its knowledge or awareness of these rights --

THE COURT: But it's not laboratory conditions. In other words, if you say, We are open season for new complaints, you can't then treat the new complaints as reflecting that concern over an area as growing. You are responding to the invitation.

MR. BATES: Well, it could also be an indication that when individuals are made aware of these issues, that they will then respond by filing complaints. So, yes, there may have been a causal relationship between the MPRM and the complaints, but the fact that complaints were then filed and people were made aware may indicate that there had been problems going on

for a while, but just folks weren't aware of their rights. So once they were made aware of their rights by the MPRM that they then sought to bring them to the attention of the agency.

THE COURT: You said there were ten complaints after the notice of rule-making. With as much specificity as possible, what scenarios did they implicate?

MR. BATES: So among the ones that we cite in our reply, it depends on the level of specificity that is included in the complaints themselves. There was a nurse who was placed on administrative leave by a hospital on the ground -- she alleges this -- that she was placed on administrative leave by a hospital on the ground that she sought a religious accommodation for having to perform abortions.

THE COURT: The actual performance, in other words, operating theater apparently.

MR. BATES: She had not gone to that level of granular detail, but performance of abortions.

Complaint by a nurse alleging that she was terminated from a hospital for her unwillingness to participate in the provision of abortion-related services.

Complaint by a nurse alleging she was --

THE COURT: Do we know what that means, what services those were?

MR. BATES: She does not spell that out in the complaint.

Complaint by a nurse alleging that she was coerced into performing an abortion after previously notifying her employer of religious objections to performing abortions.

Complaint by a nursing professor alleging that she was not hired for a full-time faculty position because of her views on abortion.

So these are just a few examples, your Honor, that do show that there are instances where employers are not abiding by their obligations under the conscience statutes, and so this is evidence before the agency that there were problems and --

THE COURT: What would the reason be, if any, for an uptick if one was to credit that in disrespect for conscience-based -- sincere conscience-based objections? In other words, if the premise is this is a growing problem in our country, can you theorize why that would be? We are dealing with a quite small numbers here, so I am not blind to that. But if one accepts the premise that there had been a consequential increase not generated by the notice of rule-making, any idea why?

MR. BATES: So the fact that -- it is not necessarily going to be the case that there was an uptick in the actual violations of rights under the statute, although that might be the case, it may have been the case that there were -- even if the amount was consistent, going back 20 or 30 years, the folks were not aware of their obligations under the statute so that

they were not aware of their rights under the statutes, then that would be equally a problem as if there was a change in how employers dealt with requests --

THE COURT: So why not just have a public awareness campaign? Why not if you see something say something? Why isn't that the answer if people don't understand their rights? Why do we need this whole apparatus of the rule?

MR. BATES: That could have been one way that the agency could have addressed the problem, your Honor. The agency, in the exercise of its expertise, in the exercise of its authority, after having reviewed the situation, decided that, in addition to the notice requirements under the rules that would advise individuals of their rights, that the best way to address the problem was through the policy as implemented in the rule. The agency has the authority and the ability to, in the exercise of its expertise, to decide what the best way is to address a policy, and the court, upon review, need not agree with the agency that it was the best policy or even that it was better than the alternative policies, but merely that the agency gave a -- considered the relevant data and gave an explanation -- rational explanation for -- in connection between the data and the decisions that it made.

THE COURT: Can I come back "to assisting in the performance," that definition. Am I right that that is

actually only in the Church amendment or is that somewhere else?

MR. BATES: So I'm just comparing here Church, Coates-Snowe, and Weldon, because I know those are the ones we have been talking most about. So in those three, that is the only -- that is the only --

THE COURT: And that has no substantive rule-making delegation explicit.

MR. BATES: Church does not.

THE COURT: All right. I want to make sure I give a little time to our intervenors. Is there anything further you wanted to say to me? If not, I have got one or two more questions.

MR. BATES: I think I might just note, there was not a great deal of discussion today about the establishment clause. I would just point to -- point your Honor to our argument about the state or forum is distinguishable here.

And in terms of the scope of relief --

THE COURT: Yes. That's what I was going to get to.

MR. BATES: Okay. Just real quickly there, your Honor, plaintiffs have asserted that sort of a standard procedure when a court finds a rule invalid is vacatur of the rule in its entirety in nationwide application. I believe they cited some D.C. Circuit cases to that effect. We cited the California case, *California v. ASR*, out of the Ninth Circuit,

that vacated the nationwide scope of an injunction under a facial challenge under the APA.

Just for your Honor's information, in that *California v. ASR* case, that cites another Ninth Circuit case, *Havens Hospice*, which is relevant here and there is also a Fourth Circuit case, *Virginia Society for Human Life*, that I think has some very helpful language about in a similar instance where a plaintiff made an argument that, under the EPA, the standard remedy is vacatur in the entirety, nationwide relief, and the Fourth Circuit rejected that argument there.

So to the extent plaintiffs are saying that the normal -- the usual practice, there is authority out of both the Ninth and Fourth Circuits saying that is not in fact --

THE COURT: So there are two questions. One is severability and one is if there were an injunction, whether it applies on a more limited basis. Let's just take the second one. What is your view as to the proper geographic scope of any injunction or any relief in this case?

MR. BATES: So it would be the scope necessary to afford relief to the parties in this case, so there are various state and various municipal plaintiffs in this case. So it would be --

THE COURT: There are 23 states, right?

MR. BATES: 23 states and municipalities. I don't know that all of the government plaintiffs are states.

THE COURT: All right. But, in other words, by your lights, if the court were to rule against the government in whole or in part, and let's move out of the world of injunctions and focus on the merits, the summary judgment dimension, is it your view that that should be -- invalidation should only be as to those 23 states and as to the activities of the named plaintiffs in other states?

MR. BATES: That's correct, your Honor.

THE COURT: So the rule would still stand in 27 states, plus territories, less -- but not as applied to, for example, Planned Parenthood to the extent that it has a presence in those 27 states. Is that what you are saying?

MR. BATES: So it depends on who the plaintiffs are. So -- and that depends on sort of the relationship between Planned Parenthood writ large and its -- I don't know the exact terminology to use here, your Honor, but the sub-entities that it contracts with and sort of who are plaintiffs in the case and who are not, but our position would be that the remedy should be limited to the plaintiffs in this case. So it would be --

THE COURT: So other people in New York State who haven't joined the lawsuit could still have the rule enforced against them. Even if I found that it was arbitrary and capricious, contrary to law, all of that stuff, other people in New York State could still have the rule applied because they

didn't join this lawsuit.

MR. BATES: Other --

THE COURT: I thought what you were saying was 23 states it is invalid, 27 states somebody has got to sue in those states. I think you are now actually saying that unless this turned into a class action or an opt-in class involving every medical entity in the United States, you haven't actually sued in this case, you can't get the benefit of relief. Is that what the United States is telling me?

MR. BATES: That the relief should be limited to the plaintiffs as the regulated parties here.

THE COURT: So.

MR. BATES: To the extent New York is a regulated entity --

THE COURT: Right. You are telling me that to get relief, let's suppose, just indulge the hypothetical, that the rule is found by the court to be for one reason or another invalid. Is what you are really telling me is to get the benefit of that rule there now have to be follow-on lawsuits by every hospital and doctor and clinic and, you know, farmhouse, you know, to get relief as opposed to the invalidation of the rule having operation of law across the board? Is that really what the United States thinks is the right approach here? I get the problems with nationwide injunctions, but you are going way beyond that. You are telling me that you actually have to

be a party to the case to get relief. Was there thought given to that position before this argument began?

MR. BATES: So, your Honor, we have cited to the court the *Gill* case of the Supreme Court that instructed that the remedy should be limited to the inadequacy that produced the injury, tailored to redress the plaintiffs' particular injury. The remedy here should be tied to the injury that the plaintiffs have alleged. And my understanding is that the states and municipalities have brought this suit in their capacity as regulated entities.

THE COURT: Is there any reason why the arguments that have been made today and in the briefs apply any differently to the other 27 states or to medical providers in -- to covered entities by the rule in any -- in the 23 states who haven't filed suit or anywhere in the 27? The rule -- the infirmities that have been alleged about the rule rise or fall without respect to the identity of the plaintiff who sues, no?

MR. BATES: In terms of the arguments about why the rule is legally invalid in terms -- the harms that are alleged against the rule, those do relate to what services regulated entities provide, what policies those regulated entities have in place in terms of the alleged harms that are --

THE COURT: But that's more of a preliminary injunction notion, and I get that. That's a little different. But in the context of the relief that the parties reciprocally

seek on summary judgment, it is a unitary calculation. Regardless of whether you are affected a little or a lot, the rule either is valid or it is not, correct?

MR. BATES: Yes.

THE COURT: Okay. All right. Thank you very much. Appreciate the helpful argument under substantial fire. Thank you.

All right. I will hear now from Mr. Dunn.

MR. DUNN: Thank you, your Honor. Robert Dunn for defendant intervenors. Thank you for granting us intervention and the chance to present argument today.

THE COURT: As you know, the reason I granted intervention was substantially on the basis that the case might need to be resolved as a preliminary injunction and, as such, I wanted to make sure there was a voice given to parties who could be harmed by an injunction stopping the rule. I don't know whether or not we will go in that direction, but the unique value that the intervenors add is in bringing to bear in a real world sense the experiences of the people whose rights are affected by the rule.

MR. DUNN: Understood, and appreciate that. Hopefully our briefing contributed to that.

THE COURT: It did very much.

MR. DUNN: So a couple of points on that and then we can pivot to discussing the definition of discrimination which

might be helpful as well.

But the two quick points I want to make and advance, with respect to CNDA and its members, they treat patients of every religion, every race, every gender, sexual orientation, etc. There have been some insinuations in the brief that the rule is essentially a cloak or a cover for the expression of animus and bigotry, and I hope that plaintiffs' counsel will confirm that that's not the case, but the briefing suggests that --

THE COURT: I don't think plaintiffs' counsel said anything like that, and I take the conscience statutes as directed at protecting very valid interests, which is the legitimate desire of people, in good faith, for moral or religious reasons, not to participate in various procedures. I don't think that's at issue, and I appreciate as well your point that renaming the statutes, the refusal statutes may be seen by some as not fully respecting the legitimate conscience interests. I read that. I understood what you were saying.

MR. DUNN: So we are all agreed this is about protecting folks who have objections to specific procedures, not patients. With that in mind, our position is that the rule is important. I think there has been some discussion of is it a solution in search of a problem? In the rule-making, on pages 23175 to 179, I think the agency does a good job of looking back at some of the prior comments that were submitted

both in the 2008 and the 2011 and the current rule-making. Beyond complaints filed at OCR, these are comments from healthcare providers -- doctors, nurses in the profession -- who have personally experienced discrimination or pressure. There was some of discussion in the briefing about the 2008 CMDA survey. In that survey, the respondents -- we are talking about doctors and nurses primarily -- 40 percent of them said I have experienced personal pressure or some form of discrimination.

THE COURT: And I read that with interest. What was less clear to me was what their experiences had been in front of HHS.

MR. DUNN: And from what I gather, most do not proceed in front of HHS.

THE COURT: Is that because they are unaware of their legal right to do so?

MR. DUNN: I think it is probably because HHS cannot do much for them. There is no private right of action. HHS cannot get them reinstated, cannot provide them damages.

THE COURT: But your co-counsel, counsel for HHS, says that to the degree that there have been cases, in effect, some solution, some accommodation has often been worked out, whether in this or other civil rights areas, short of an ultimate adjudication in which simply reporting to the agency gets the mighty HHS on the side of the objector and often results, in

practice, in getting relief. And what was striking to me from what you submitted was not the number of people who say that they have had discomfort in the workplace because their conscience objections haven't been treated seriously, but any argument that the regulatory apparatus is not up to the task or that they have had bad experiences with it. Can you help me with that?

MR. DUNN: Yeah. I think that from the comments submitted to the agency, the uniform theme of those comments are there are no teeth in the actual existing regulation.

THE COURT: Has any member of CMDA -- there are 20,000 -- brought a complaint before the agency?

MR. DUNN: Not to my knowledge.

THE COURT: So maybe they should try. In other words, how can they say the agency is not up to the task if they haven't given it a whirl.

MR. DUNN: If you uphold the rule, I am sure they will.

THE COURT: But with respect, the justification for the rule is a greater number of complaints. I have heard about that. But that somehow or other there is a -- the agency has proven toothless or incapable of action. If this is a concern of your membership and none of them has ever gone to the agency, how do we know if that is true?

MR. DUNN: Well, I mean, you look at the existing

rule, the 2008 rule that was, you know, a blip in time, and the 2011 rule, which essentially, you know, wiped out all of the substantive provision of the 2008 rule --

THE COURT: But, sorry, it is your co-counsel who says the statutes are the source of all this authority and that the application by the agency is merely explaining what Congress meant by the rule, by the statutes. If you buy that, if you believe that, all along the statutes have had meaning consistent with what is being articulated today. That was an invitation for somebody to go before the agency and say, I shouldn't have had to hand over that forceps, I should have been respected when I said I didn't want to do it, or even other ways of assisting. I'm having difficulty with the premise that there is an enforcement gap here that is demonstrated other than stated. Is there anything you can point to?

MR. DUNN: Yeah. I think what it comes down to is if you are a physician or a nurse and you have been discriminated against or terminated or transferred, you have to put your career a little bit on the line to run to HHS and sort of flag yourself as a thorn in the side of a hospital that wants to provide these types of services. You are kind of putting your career in jeopardy. Once you have done that, you basically can be blacklisted essentially from the profession, and it is unclear what HHS can do for you, you know, absent the rule. So

you can run to HHS and say, hey, the Church amendment says they can't do this if they receive federal funds, and my understanding is my employer received federal funds, do something for me.

THE COURT: But HHS says that in the limited number of cases it has done something for people, just as it says it has done so with respect to other civil rights violations. Is the problem a public education problem? Do your clients know of either the conscience statutes or the existence of HHS or that there is a remedial place, procedure and a place to go? Do the members of the organization, Dr. Frost and the other 20,000, do they know about all this?

MR. DUNN: I'm quite certain that there is an information problem and that this is not something that is well known both for the employers and the employees. I think there were comments submitted to the effect that even in the enforcement proceedings some of the hospitals were made aware of the statutes and said, We didn't even know about these statutes. So I think there is a lack of awareness of the statutes themselves and certainly lack of awareness of HHS's role in them.

THE COURT: Am I correct to assume that most of your members probably fit into the employment box?

MR. DUNN: Almost all of them.

THE COURT: So what has their experience been with the

Title VII framework? How does that work for them?

MR. DUNN: Unclear. I think an employer who is fired probably has -- there have been undoubtedly Title VII claims in that context, you know, less clear when we are talking about transfers or other types of hiring, you know, I didn't get hired, difficult to --

THE COURT: Are they finding that the undue hardship exception, if you will, under Title VII has been applied to capaciously so as to, in effect, unneedlessly override legitimate conscience objections? Is that what they are saying?

MR. DUNN: I think that's a concern that's been expressed. It puts the burden quite heavily on them to prove that it wasn't an undue hardship. Because the employer can invoke the undue hardship standard and it is difficult for an employee to combat that.

I think the bigger concern is that many of these instances sort of evade Title VII, where people are feeling like they are pressured to do something, they do it, don't feel like they have a recourse under Title VII when they have sort of done it, and part of the thing that the rule provides is it gives them a recourse with the agency.

THE COURT: But they haven't -- but the -- they have had recourse, even the 2011 rule which you are not pleased with gave the recourse and presumably it was there before, but it

certainly is clear who you call, right? The rule is consequential here because of its interpretation of discrimination, aid in the performance, and referral and the like, but can it really be said that, after the 2011 rule, members of your organization didn't know where to go if they were concerned that their statutory conscience rights were being infringed?

MR. DUNN: Well, there are sort of two answers to that. The first is, I think there was probably a lack of confidence in the agency administering the rule at that point, and that's an issue of sort of, as you mentioned, the political ping-ponging, how serious is the administration and the agency taking conscience protections. You know, we had litigation all over the country regarding the contraception mandate and the agency was taking positions there that indicated it was not terribly sympathetic to, you know, sort of rights of conscience and religious freedom. So that I think probably plays a role. And I think the other part is just you go to the agency for what? And it is a big step for someone to sort of invoke the power of the federal government if you don't know what you are going to get or what the agency can do for you.

THE COURT: But isn't that exactly what the rule does? It just gives the agency -- it broadens, perhaps, the scope of the prohibitions beyond certainly what was previously understood and it may give the agency more muscle if you accept

the face of the rule that said all HHS funding is in play, but in the end there is still no private right of action. The statute still doesn't allow you to go to court if you are the ambulance driver or the nurse in *Shelton*. You have to bring your lawsuit under something else, like Title VII. The rule still directs you to the agency. So to the extent that that is a deterrent, what's changed?

MR. DUNN: Well, the specific power that HHS has invoked to step in and address funding streams, you know, regardless of how broadly you construe that, there is an extreme. You can cut off funds that the Labor Department supposedly administers. That would be an extreme version. But even if it was just a narrow funding stream to the specific offending employer, that's muscle.

THE COURT: It's because the agency is putting at risk, at least -- depending on how we construe this, at least the funding stream that the rule has teeth you were saying.

MR. DUNN: Yes. I think that's more or less it.

THE COURT: Doesn't that help plaintiffs on their spending clause argument?

MR. DUNN: They have to still prove all of the retroactivity and the unexpected nature of it, and we have addressed that in our briefing. But there is a spending element here. The agency specifically invoked its spending power, so I think the fact that it is putting spending at

risk --

THE COURT: The agency says that essentially under the UAR it had the same authority with or without the statute to implicate the spending stream.

MR. DUNN: But nobody knew that.

THE COURT: That's public education, right? There is a remedy other than a statute for that, than a rule.

MR. DUNN: If that's true, then the challenge to HHS's authority to strip funding under this rule is also irrelevant, because if they had that power all along, what are we talking about?

THE COURT: Understood. I get that.

From your perspective as an advocate for the religious or moral objector, what do we do with the *Shelton* scenario? What's the right answer to that?

MR. DUNN: I think that's a great question. I think I read the rule slightly differently than plaintiffs' counsel. Possibly I read the rule differently than DOJ. I don't think so. The way I look at it, if you take a look at the definition of discrimination in 88.2, you have to prove some sort of adverse treatment or some sort of penalty to even say this is discrimination. But paragraph 4, the point of paragraph 4, notwithstanding paragraphs 1 through 3, is to basically incentivize employers to provide reasonable or effective accommodations to provide them. Now there is a safe harbor if

it is accepted, so that's one thing. Provided it is accepted, there is no issue here.

THE COURT: But in *Shelton*, the nurse refuses to be transferred.

MR. DUNN: Yes. And I take the next sentence to basically say "in determining whether any entity has engaged in discriminatory action with respect to any complaint or compliance review under this part, OCR will take into account the degree to which an entity had implemented policies to provide effective accommodations for the exercise of protected conduct," etc., etc.

THE COURT: But it doesn't say we will take into account the impact on the entity of continuing the employee in the present job. In other words, it removes the Title VII undue hardship. It focuses on something else.

MR. DUNN: It does. But to the extent that, in *Shelton*, the accommodation offered appeared to be in effect an accommodation that appeared to be offered in good faith.

THE COURT: And was rejected.

MR. DUNN: And was rejected. I take the rule to say OCR will take that into consideration when even deciding if there was discrimination, and it might well decide in that particular situation that there was no discrimination.

THE COURT: Well, we don't know.

MR. DUNN: We don't know.

THE COURT: We can't.

Final question for you, and I realize this is a hypothetical, but the rural hypothetical and the ambulance in Central Park hypothetical, how does your client base view those?

MR. BATES: Sorry, say --

THE COURT: How would your client base view those scenarios where, in a very real world sense, there are adverse health consequences to patients from the Central Park driver refusing to bring the bleeding ectopic patient to the hospital because of an objection or in the rural scenario where the person refuses an accommodation and is essentially occupying a singular position.

You know, it is easy in the real world to understand adverse medical or treatment availability consequences. I welcome your view as an advocate for the people with religious objections, how you view those scenarios? I appreciate they are extreme, but they are out there in the briefing.

MR. DUNN: So with the ambulance hypothetical, that one strikes me as about as extreme as you can get, because nobody calls 911 and says, I am having an ectopic pregnancy. They say, I am having abdominal pain with bleeding. So the driver isn't going to ascertain what's going on, what the treatment is on the back end and make the decision to kick the person out. It's hard to deal with something quite that

extreme.

But the rural situation, that, I think, is a real issue, because you could have a doctor, the only physician in a hospital that itself permits abortions to be provided, and he or she objects and says --

THE COURT: And Title VII framework would presumably permit the person to be screened to allow the hiring of somebody who is able to do the full job or the termination of somebody who refuses to do a good portion of it in those circumstances. Just from a human perspective, how does your client -- do you object to the Title VII framework application to that scenario? Is there something problematic about that?

MR. DUNN: I don't object to the Title VII application, but with respect to the rule, I mean, I think the consequence of that is to say, well, you know, Christian doctors or religious doctors can never serve in those positions. So I think that would have some real world effects, too, if you are going -- and nurses, like no nurse can serve in a rural hospital if she has a religious objection to abortion. And I recognize this is a balancing, and there are winners and losers on both sides, but clinics closing down, nurses leaving their profession, doctors leaving the profession, that has an adverse impact on patients as well, and I think the agency tried to balance that.

THE COURT: All right. Thank you. Very helpful. I

appreciate the very thoughtful briefing as well.

Is there any rebuttal from plaintiffs?

MR. ZIONTS: Your Honor, we are very conscience of the time, and I think a couple of us have very, very few points to make, subject to any questions that you have.

THE COURT: Go ahead.

MR. ZIONTS: In terms of regulatory authority, really just two points, your Honor.

One, we have heard a lot of assurances this morning. We really aren't going to do that. The agency is not going to go that far. It's not going to take every last dime of New York's $45 billion in Medicaid. The rule says what it says. It says "terminating federal financial assistance from the department in whole or in part" and our clients can't say, well, in open court a lawyer from the Department of Justice did say they are probably not really going to do it. Our clients have to adjust their conduct based on what it says in the C.F.R.

The only other point I would make, your Honor, in terms of where the agency gets this implicit authority that it believes it has to issue substantive rules with authoritative interpretations, I think the closest we heard to something was essentially inferring it from their enforcement role, you know, they have to enforce these statutes so that, by implication, they bootstrap onto that the idea that they need to issue

substantive rules and authoritative interpretations.

Respectfully, your Honor, that is just flat out inconsistent with how Title VII and the EEOC have operated for half a century. It's been very clear, the Supreme Court has said it multiple times, EEOC obviously has a role to play in the enforcement of Title VII. But Congress did not delegate a substantive rule-making authority. It can issue binding force-of-law interpretations. that doesn't mean that agency is toothless. It issues guidance. It issues interpretive opinions. It tells -- you know, your Honor mentioned public awareness campaigns. The EEOC has no shortage of ways to let it be known how it views Title VII.

The exact same thing could be said of HHS here. HHS and other agencies, all the time they issue guidance documents. They have a big box at the front that says: This is not binding, a court may interpret this differently, but this is how we see the world, this is how we see is the statutes, this is how we are going to interpret it. There is nothing preventing HHS from doing that. It just didn't do it.

THE COURT: All right. Thank you. Anything else from plaintiffs?

MS. SALGADO: Yes, your Honor.

THE COURT: Go ahead.

MS. SALGADO: Your Honor, I wanted to get back to the question that you asked me, the last question you asked me.

There was some confusion about what the court was concerned about, but the question is whether, here, if the court believes that there is a constitutional violation, but that it is as applied to the plaintiffs --

THE COURT: It was that one could imagine constitutional applications that would be unconstitutional but that the rule was not facially invalid under the establishment clause. That was the hypothetical.

MS. SALGADO: Right. And I think here plaintiffs have shown that the rule is unconstitutional as to plaintiffs here because it does require plaintiffs to put above all other interests the day the rule takes effect those of religious beliefs that were put into this rule. So just take as a concrete example, on the day the rule takes effect, plaintiffs are required to change their hiring practices. The record shows they have open positions, they are hiring, and the record shows that through that process they ask questions. The rule prohibits that from doing so because it -- because -- well, I'm not really sure why the rule does that, but it prohibits covered entities from asking prospective employees whether they have religious objectives to performing the services that they are being hired to do. So in that example, your Honor, we believe that the rule is putting above all other interests those of religious beliefs and does violate the establishment clause. So the question about whether there is an as

applied -- the question about as applied versus facial --

THE COURT: Your premise is not that it is in fact an as-applied violation as to your client. That was not what I was -- I was not so finding but, rather, just positing that there are possible applications that could be unconstitutional. That was the question. If that's all we have got, is it contrary to law?

MS. SALGADO: The relief under the APA is under its nature the relief must be set aside.

THE COURT: Thank you.

MS. SALGADO: The only other question I wanted to -- oh, and just one last point about the question about as applied versus facial is that, even setting that aside, your Honor, I just wanted to say that the canon, the constitutional avoidance would still prohibit the agency from defining the term "discrimination" in the way that it has here.

THE COURT: All right. Thank you.

MS. SALGADO: Thank you.

THE COURT: Anything else from plaintiffs?

(Continued on next page)

MR. COLANGELO: Thank you, your Honor.

The justice department made a number of arguments attempting to pare back the Draconian scope of the enforcement provisions here and in particular mentioned the intent to pursue voluntary compliance efforts.

I want to point out that the rule itself expressly disclaims any need to wait for the resolution of voluntary compliance efforts before funds can be terminated. That's at 88.7(i)(2).

Attempts to resolve matters informally shall not preclude OCR from simultaneously pursuing any action described in the other paragraphs.

Your Honor, my second point. There has been considerable discussion regarding Title VII and the import for the Court's analysis of the rule's departure from the Title VII framework.

One argument that we just wanted to point out, your Honor, is the particularly on-point case that we've cited in our papers is Chamber of Commerce v. United States Department of Labor. This is a Fifth Circuit case from 2018 where the Court held that it was arbitrary for the Labor Department to interpret a long extant statute, in that case ERISA which was enacted in 1974, more or less contemporaneously with the amendments we're talking about here.

It was arbitrary for the Department of Labor to

interpret ERISA to regulate in a new way the thousands of people and organizations working in that market or to discover in a long extant statute an unheralded power to regulate a significant portion of the economy.

So for all the reasons the Court has been discussing, the concerns about Title VII bear directly on the arbitrary and capricious analysis.

Finally, your Honor, the agency has conceded in this courtroom that the complaint -- the volume of complaint evidence it was looking at was ten complaints a year, not 343. And of those ten complaints a year the agency has deemed only three or four complaints worthy of investigation.

That alone is fatal to the final rule. It is unsupportable for the agency to claim that this rule is necessary to enforce in a context where they've only pursued three or four a year and where it's not the explanation that they gave.

Thank you.

THE COURT: Thank you.

Ladies and gentlemen, we're going to adjourn now but before we do I just want to say something for the benefit of all the people out here which is you have all had the privilege of seeing some truly excellent lawyers all around and I think we judges don't often give shout-outs, not often enough. But the quality of the briefs I got in this case was extraordinary

and the quality of the advocacy I've gotten here was extraordinary and invaluable to me in making sense of what is really a series of complicated problems.

So thank you very much for the excellence of the advocacy and all the hard work.

We stand adjourned.

(Adjourned)

Pages 1 - 147

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

BEFORE THE HONORABLE WILLIAM H. ALSUP

CITY AND COUNTY OF SAN FRANCISCO Plaintiff, vs. ALEX M. AZAR II, et al, Defendants.	No. C 19-2405 WHA
STATE OF CALIFORNIA, BY AND THROUGH ATTORNEY GENERAL XAVIER BECERRA Plaintiff, vs. ALEX M. AZAR II, et al, Defendants.	No. C 19-2796 WHA
COUNTY OF SANTA CLARA, ET AL Plaintiffs, vs. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al, Defendants.	No. C 19-2916 San Francisco, California Wednesday October 30, 2019 8:00 a.m.

TRANSCRIPT OF PROCEEDINGS

(APPEARANCES CONTINUED ON FOLLOWING PAGE)

Reported By: ***Debra L. Pas, CSR 11916, CRR, RMR, RPR***
Official Reporter - US District Court
Computerized Transcription By Eclipse

Congressional intent, it should strike and not adopt that interpretation.

THE COURT: All right. You're not answering my question. Thank you. Please have a seat.

I'm going to let the other side start. I'll come back to the plaintiffs later in the morning.

All right.

MS. HULING DELAYE: Thank you, Your Honor.

THE COURT: Your name is what?

MR. TAKEMOTO: Benjamin Takemoto.

THE COURT: All right. Mr. Takemoto, I'm going to tell you, this is an interpretive regulation at most. It's not a legislative history rule. It has no substantive effect. Do you disagree with that?

MR. TAKEMOTO: Yes, Your Honor.

THE COURT: All right. Tell me why. Because I think you're totally wrong, and I can't believe the U.S. Justice Department would take such a position.

However, you know, go ahead. Explain to me why this is anything more than just an interpretation. If it is, then you may be in a lot of trouble with me.

All right. Go ahead.

MR. TAKEMOTO: Your Honor, to begin -- and I will answer your question. I just want to say that in the alternative, we do have arguments if the Court finds that this

is an interpretive rule in --

THE COURT: Where is the authority under any statute for you to issue a -- this agency to issue a legislative history rule? Here. Maybe you could find it. I just missed it. But where is it?

MR. TAKAMOTO: The rule points to three sources of authority for the rule. The first is explicit authorities for the rule. And it's important to note --

THE COURT: Where is that? Maybe I missed it. I've got the rule right here.

MR. TAKEMOTO: One moment.

THE COURT: We're going to look at each one of these statutes, because I don't believe that you have any authority to issue something that enlarges on the Church amendment, Snowe amendment or the Weldon amendment.

MR. TAKEMOTO: No, Your Honor. With respect to those statutes, the Department relied on the implicit authority in those statutes.

THE COURT: Oh, yeah.

MR. TAKEMOTO: And it's worth pointing out --

THE COURT: Where is the implicit -- what do you mean? There is no such thing.

The Church amendment has zero words that gives you the authority to issue a legislative rule. Let's just stick with that one. I read it several times.

Where is the authority there for you, your agency, to issue a legislative rule?

MR. TAKEMOTO: Your Honor is absolutely correct, that there is no language in the statute itself that explicitly delegates authority.

THE COURT: Right. Then it has to be an interpretive rule; right?

MR. TAKEMOTO: No, your Honor. The Supreme Court has said on numerous occasions and we -- in *Chevron* itself, that agencies can have implicit authority, and the Court looks to --

THE COURT: Implicit authority to do what?

MR. TAKEMOTO: To make rules.

THE COURT: Yes. Interpretive rules.

MR. TAKEMOTO: To make legislative rules as well.

THE COURT: Oh, hand up -- give me your best authority on that. I would like to read that.

MR. TAKEMOTO: Your Honor, the best authority would be *Chevron* itself where the Court said:

> "Sometimes the legislative delegation to an agency on a particular question is implicit rather than explicit. In such a case the Court may not substitute its own construction of a statutory provision for a reasonable interpretation made by the administer of an agency."

The Court said the same thing in *Meade* --

CERTIFICATE OF OFFICIAL REPORTER

I certify that the foregoing is a correct transcript from the record of proceedings in the above-entitled matter.

Debra L. Pas, CSR 11916, CRR, RMR, RPR

Wednesday, November 6, 2019

But this is so clearly an interpretive rule, I can't imagine that the law has changed so much in ten or 15 years.

So let's stick with the idea that it's an interpretation. I'm going to go look at these things you cited, but help me on -- why -- if this is an interpretation, then is it really true that you think an ambulance driver could go through Central Park and find out that the passenger is on the way for an emergency procedure at the hospital connected with an abortion and say: Sorry, get out of my ambulance.

MR. TAKEMOTO: Your Honor, I have two responses to that question.

THE COURT: That's a pretty bad situation.

Go ahead. What are your responses?

MR. TAKEMOTO: First response is that this is a facial challenge to the rule. And as Your Honor has pointed out on numerous occasions, in order to invalidate the rule plaintiffs have an obligation to show that it's invalid in all circumstances.

So to the extent that they can point to some speculative example that's not in the record, that's not sufficient under the Administrative Procedure Act to invalidate the rule.

The second --

THE COURT: What is the remedy, though, there? What does -- I'll just tell you. I can't imagine that that's what Congress intended. None of these statutes, to my mind, would

go that far.

So I would rule against you if that case came before me, and it was an ambulance driver who did that, and I would say: The hospital was totally right to fire that person and make sure they never got a job in the industry again for endangering the life of somebody like that.

So that would be, to me, topsy-turvy to even think for a second that anybody in Congress intended that.

So now that's the way I feel. However, you say: Oh, well, the issue hasn't come up yet and it may never come up and so don't decide that now. In any event, it's just one scenario. We've got a thousand scenarios. So how can you invalidate the whole thing over one hypothetical?

Well, that part, that last point I -- I may be sympathetic to your position on.

All right. Help me on the -- give me cases on point that help me understand the framework here of what -- what do you do for an interpretive rule when one interpretation or two interpretations are not in accordance with the statute? Does the judge just throw those out? Does the judge invalidate the whole thing?

MR. TAKEMOTO: Yes, Your Honor.

THE COURT: What is the right answer here?

MR. TAKEMOTO: The right answer is if this Court determines that this is an interpretive rule, then the Court,

of course, has *de novo* review and actually looks at the statute itself, sees if the regulation comports with the statute, and then determines whether to uphold or invalidate the rule.

THE COURT: But can two examples undo the entire interpretation?

MR. TAKEMOTO: Not at all, Your Honor. And I would point the Court to the Supreme Court's decision in *Reno versus Flores*.

THE COURT: *Reno* what?

MR. TAKEMOTO: *Versus Flores*. I can give you the Reporter cite if you would like.

THE COURT: Give me the cite, please.

MR. TAKEMOTO: 507 United States Reporter 292 at Page 309 is the relevant portion of this case.

So in that case the plaintiff was an undocumented minor who was in the administrative immigration judge system, and there was a provision that permitted the waiver of the right to an immigration judge.

And the Supreme Court held that although there might be some circumstances where an underage undocumented individual may not be able to constitutionally or lawfully waive their right to an immigration judge, that it was the plaintiff's burden in that case to show that that regulation was unlawful in all applications. And, therefore, it did not allow that one, albeit serious hypothetical, to invalidate the entire

thing.

THE COURT: Okay. Thank you. That's worth looking at.

Help me understand why you think an ambulance driver would be covered by any of these three amendments or -- you know, these days it's more than a driver. There is an EMT person sitting in there. So it's not driving at all. I understand that.

So, but their purpose is to stabilize the passenger until they can get to the hospital. They don't actually do an abortion in the ambulance. Their role is to keep the passenger stabilized as best they can until the hospital can perform the abortion, let's say, in an emergency.

So why -- how does that even come close to what Frank Church had in mind?

MR. TAKEMOTO: Your Honor, of course, the Court turns first to the language of the statute. And the Weldon, Coats-Snowe and Affordable Care Act use the term "healthcare entity" and they provide definitions of that term through non-exhaustive lists.

And when HHS developed the definitions of healthcare entity in this case, it looked to those terms. It looked to the dictionary definition and that's how it developed the definitions that it did.

I will say, Your Honor, that -- Your Honor, I would also

point to Page 23188 of the regulation, which explains HHS's response to this particular question; that EMTs and paramedics are just like any other healthcare entity that's listed in that statute. In other words, they provide healthcare in some circumstances.

I will note at the bottom of the first column on that page HHS made perfectly clear that it's not saying that all ambulance drivers or all EMTs are healthcare entities under the rule. It said explicitly that the Department believes it would depend on the facts and circumstances of each case.

So the rule doesn't go as far as plaintiffs say here.

THE COURT: That's true, but why should it ever cover any ambulance driver or EMT aboard an ambulance? I have trouble thinking of any -- there could be any scenario where we would let an ambulance driver or EMT refuse service in an emergency, period.

And I just can't believe that Coats-Snowe or anybody else -- show me the language in Coats-Snowe. None of them refer to ambulance driver, by the way. I bet that's something that your agency came up with. But show me the language that gets as close as possible to that concept.

I think there is something about a technician; right? Is that what you mean?

MR. TAKEMOTO: I mean, I refer the Court to the Coats-Snowe amendment Subsection (c) where it defines the term

"healthcare entity."

THE COURT: All right. I've got it right here.

"The term healthcare entity includes" --

MR. TAKEMOTO: "Includes."

THE COURT: Yeah, "includes."

"...includes an individual physician, a post-graduate physician training program and a participant in a program of training in the health profession."

That's it; right? So there is nothing there that comes close to ambulance driver.

MR. TAKEMOTO: Your Honor, it may be that under the explicit terms of the statute, that an EMT is a participant in a program of training in the health provision. They, of course, undergo training.

THE COURT: Well, "a participant in a program of training in the health profession."

See, this whole thing is -- this particular amendment was directed at training. Really, isn't that it? Training.

MR. TAKEMOTO: Yes.

THE COURT: So this is like education; true? It's like med schools.

MR. TAKEMOTO: Yes.

THE COURT: So if you're in the medical school as a student and you don't want to be taught how to do an abortion

because you find it offensive, then this amendment protects you and says: Okay, you have the right, as a student, not to learn how to do an abortion.

So I get that. That's what the -- but the -- how does that kind of training relate to an EMT who is actually on the job in the ambulance and suddenly decides that he or she doesn't want to stabilize a woman on the way to get abortion?

MR. TAKAMOTO: Your Honor, that -- that may be the case with respect to Coats-Snowe. The rule nowhere says in this particular section that it's referring to Coats-Snowe.

I would also point Your Honor to --

THE COURT: I want to stick with these statutes. All right? So Coats-Snowe is out.

So how about Weldon? How does Weldon fit into the ambulance driver and the EMT?

MR. TAKEMOTO: Well, just with one respect to Coats-Snowe. I don't agree that it's out, as I said.

THE COURT: You use the word "include."

MR. TAKEMOTO: Yes, exactly.

THE COURT: Well, that could include -- that could include anybody under your definition. Maybe it's a taxi driver who is -- so the word "include" opens up the possibility that it has -- there is more people in there than just the ones that are mentioned there.

But, all right. With that possibility, that's all you've

got going for you on Coats-Snowe is the word "include;" right? There is nothing else. This whole thing is about training.

MR. TAKEMOTO: Exactly.

THE COURT: Med schools.

MR. TAKEMOTO: It does not say medical schools. It says --

THE COURT: Training.

MR. TAKEMOTO: (As read)

"The federal government may not subject any healthcare entity to discrimination on the basis that that entity refuses to undergo training in the performance of induced abortions..."

And it goes on and on.

THE COURT: All right. You're right. It's about training, learning how to do abortions.

MR. TAKEMOTO: Yes. And without stepping in front of OCR in any particular adjudication, I think it's a fair reading of the statute to say that an EMT might fall under the statute, might be protected by Coats-Snowe.

THE COURT: Let's say somebody who is an EMT, who is learning how to be an EMT, and you get to the course on abortions they say: I don't want to do that one. Okay. Let's say they are protected in that.

That's a far cry from once they become an EMT, that they will not assist -- they will not stabilize a patient who is on

the way to get an abortion in the ambulance.

To me, they are worlds apart. I just can't see how you can shoehorn that.

All right. So that's Coats-Snowe.

Let's go to Weldon now.

MR. TAKEMOTO: Yes.

THE COURT: How would Weldon cover ambulance drivers or EMTs aboard an ambulance?

MR. TAKEMOTO: So Weldon, Subsection (d)(2) defines the term "healthcare entity," and it --

THE COURT: (d)(2), as in delta.

MR. TAKEMOTO: Delta, yes. And it says it includes. Once again, we have that term "includes."

THE COURT: Right.

MR. TAKEMOTO: (As read)

"...an individual physician or other healthcare professional."

"Other healthcare professional." And it's HHS's's view that that term, "other healthcare professional "may include, depending on the circumstances, an EMT.

THE COURT: Let's say it does. Let's say "other healthcare professional" includes an EMT. Let's assume that for a second.

MR. TAKEMOTO: Okay.

THE COURT: But still, there is a specific purpose

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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

CITY AND COUNTY OF SAN FRANCISCO, Plaintiff, vs. ALEX M. AZAR II, Secretary of U.S. Department of Health and Human Services; ROGER SEVERINO, Director, Office for Civil Rights, Department of Health and Human Services; U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; and DOES 1-25, Defendants.	Case No. 3:19-cv-2405 **COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF**

INTRODUCTION

1. For decades, the Office of Civil Rights ("OCR") in the United States Department of Health and Human Services ("HHS") worked to reduce discrimination in health care. It took bold steps to end practices such as segregation in health care facilities, categorical insurance coverage denials of care for transition related services, and insurance benefit designs that discriminate against people who are HIV positive. Over the past two years, however, OCR has turned this legacy on its head.

2. Most recently, on May 2, 2019, OCR submitted regulations entitled, "Protecting Statutory Conscience Rights in Health Care; Delegations of Authority" for publication in the Federal Register (hereafter, the "Final Rule").[1] In the Final Rule, OCR appropriates language from civil rights statutes and regulations that were intended to remedy discrimination, and applies it in a manner that will, in fact, *increase* discrimination and disparities in healthcare.

3. The Final Rule requires the City and County of San Francisco ("City" or "San Francisco")—in any and all circumstances—to prioritize providers' religious beliefs over the health and lives of women, lesbian, gay, bisexual, or transgender people, and other medically and socially vulnerable populations. If San Francisco refuses to comply, it risks losing nearly $1 billion in federal funds that support critical health care services and other vital functions.

4. This is a perversion of OCR's mission, it is unlawful, and San Francisco will not abide it.

5. San Francisco recognizes and respects that an individual's religious beliefs, cultural values and ethics may make that person reluctant to participate in an aspect of patient care. It does so by providing accommodations to those providing direct care where possible. But while the City supports the legitimate conscience rights of individual health care professionals, the exercise of these rights must be balanced against the fundamental obligations of the medical profession and the right of *all* patients to receive quality health care. Worse, the Final Rule would define San Francisco's policy

[1] A copy of the HHS-approved document that was submitted to the Office of the Federal Register for publication is attached to this Complaint as Exhibit A.

that seeks to accommodate individual's religious freedoms—in accordance with Title VII—as a violation.

6. San Francisco thoughtfully engages in this balancing and reflects a deep commitment to basic civil rights and patient care, while complying with existing federal law. OCR's Final Rule does not. The Final Rule is unconscionable and unlawful. It should be struck down in full.

JURISDICTION AND VENUE

7. The Court has jurisdiction under 5 U.S.C. Sections 703-706 (Administrative Procedure Act) and 28 U.S.C. Sections 1331 (action arising under the laws of the United States) and 1346 (United States as a defendant). This Court has further remedial authority under the Declaratory Judgment Act, 28 U.S.C. Sections 2201(a) and 2202 *et seq*.

8. San Francisco timely submitted detailed comments on the proposed rule.

9. The Final Rule constitutes final agency action and is therefore judicially reviewable within the meaning of the Administrative Procedure Act. 5 U.S.C. §§ 704, 706.

10. Venue properly lies within the Northern District of California because Plaintiff, San Francisco, resides in this judicial district and a substantial part of the events or omissions giving rise to this action occurred in this District. 28 U.S.C. § 1391(e)(1).

INTRADISTRICT ASSIGNMENT

11. Assignment to the San Francisco or Oakland Division of this District is proper pursuant to Civil Local Rule 3-2(c)-(d) because a substantial part of the acts or omissions that give rise to this action occurred in the City and County of San Francisco.

PARTIES

12. Plaintiff San Francisco is a municipal corporation organized and existing under and by virtue of the laws of the State of California, and is a charter city and county.

13. Defendant Alex M. Azar II is the Secretary of the United States Department of Health and Human Services ("HHS"). He is sued in his official capacity. Secretary Azar is responsible for implementing and fulfilling HHS's duties under the United States Constitution and the Administrative Procedure Act ("APA").

14. Defendant Roger Severino is the Director of the Office for Civil Rights ("OCR") at HHS. He is sued in his official capacity.

15. Defendant HHS is an agency of the United States government and bears responsibility, in whole or in part, for the acts complained of in this Complaint. OCR is an entity within HHS.

16. Does 1 through 25 are sued under fictitious names. Plaintiff San Francisco does not now know the true names or capacities of said Defendants, who were responsible for the alleged violations, but pray that the same may be alleged in this Complaint when ascertained.

FACTUAL ALLEGATIONS

I. San Francisco's Public Health System

17. The mission of the San Francisco Department of Public Health ("SFDPH") is to protect and promote health and well-being for all in San Francisco. SFDPH is dedicated to reducing health disparities and providing inclusive care to *all* patients, operating facilities, clinics, and programs committed to this mission.

18. For example, SFDPH established Gender Health SF to provide access to transgender surgeries and related education and preparation services to eligible transgender adult residents. Currently, SFDPH also provides a range of health services to transgender residents such as primary care, prevention, behavioral health, hormone therapy, specialty and inpatient care.

19. SFDPH strives to achieve its mission through the work of two main branches—the Population Health Division and the San Francisco Health Network.

A. The San Francisco Health Network

20. Through the San Francisco Health Network ("SFHN"), SFDPH administers a complete heath care system including primary care for all ages, dental care, emergency and trauma treatment, medical and surgical specialties, diagnostic testing, skilled nursing and rehabilitation, and behavioral health to residents of, and visitors to, San Francisco, and within the county jail system.

21. SFHN includes two hospitals:

a) Zuckerberg San Francisco General Hospital ("ZSFG") is a licensed general acute care hospital and trauma center owned and operated by the City and County of San Francisco. ZSFG delivers over one thousand babies a year, has been at the forefront of HIV/AIDS care from the

beginning of the AIDS crisis, and provides inpatient medical and psychiatric treatment. ZSFG also routinely provides both first- and second-trimester abortion care, including medication abortion, and has on-site ultrasound and interpretation services.

The hospital provides care for approximately one in eight San Franciscans a year, regardless of their ability to pay. As the City's safety net hospital, ZSFG provides the highest-quality services, including to many patients covered through Medi-Cal (California's Medicare program). As the only level one trauma center serving a region of more than 1.5 million people, it provides life-saving emergency care to individuals and victims of mass tragedies like airplane crashes and natural disasters. With the busiest emergency room in San Francisco, ZSFG receives one-third of all ambulances in the City, and treats nearly four thousand patients with traumatic injuries, annually. Many of ZSFG's programs focus on providing life-saving care in emergency situations.

ZSFG is one of University of California San Francisco's ("UCSF") primary teaching hospitals, where medical residents train under UCSF faculty and City staff. ZSFG also trains nurses, including in undergraduate and graduate RN, Advanced Practice Nursing, Vocational Nursing, Psychiatric Tech, Medical Assistant, Certified Nursing Assistant, Sterile Processing Technician, Scrub Technician, clerical and phlebotomy programs.

b) Laguna Honda Hospital provides a full range of skilled nursing services to adult residents of San Francisco who are disabled or chronically ill, including specialized care for those with chronic wounds, head trauma, stroke, spinal cord and orthopedic injuries, HIV/AIDS, and dementia.

22. In addition to these two hospitals, SFHN includes over fifteen clinics throughout the community where patients can access health care services, including primary care, pediatric care, vaccinations, phlebotomy, asthma care, cardiology, HIV prevention and treatment services, dermatology, physicals, dental care, cancer care, family planning, and prenatal care.

23. The Maternal, Child and Adolescent Health ("MCAH") Section of SFDPH also offers a wide range of services to patients through SFHN. MCAH focuses on the most vulnerable children and families, filling what would otherwise be a serious public health gap. Its aim is to reduce health

disparities and improve health outcomes by strengthening the public health systems and services that address the root causes of poor health.

24. For example, the Family Planning and Preconception Health Program ("FPPHP") offers a wide range of services to patients through SFHN, including: reproductive life planning; reproductive health exams; birth control counseling and prescriptions; emergency contraception; preconception health screening and education; pregnancy tests, counseling, and referral; testing and treatment for sexually transmitted infections; testing and counseling for HIV; and sexual health education and counseling. FPPHP offers these services at no or low cost to women, men, and adolescents in the City and County of San Francisco.

25. MCAH also supports young women during pregnancy and families during the early years of childrearing with an evidence-based home visiting program—the Nurse Family Partnership—and through a revamped group-centered model for young women who may not have had consistent linkages with health care services.

26. Behavioral Health Services ("BHS") is also part of the comprehensive SFHN. BHS operates the County Mental Health Plan and provides San Franciscans with a robust array of services to address mental health and substance use disorder treatment needs. Treatment services include: early intervention/prevention; outpatient treatment (including integrated medical and behavioral health services); residential treatment; and crisis programs.

27. The Transitions Division of SFHN serves severely mentally ill individuals who have multiple complex characteristics—including mental health issues, being medically compromised, and those with cognitive impairments.

28. The Managed Care Section oversees the contracts under which the SFHN provides medical and mental health care to members of managed care programs including those operated by the San Francisco Health Plan, which is the government entity that administers the Medi-Cal managed care plan for the City and County of San Francisco, and by private insurance plans.

29. SFHN is also the lead entity in the Whole Person Care Pilot designed by the State of California to serve the multiple medical and mental health care needs of adults experiencing homelessness and of high users of multiple systems.

B. Population Health Division

30. SFDPH also includes a Population Health Division ("PHD"). This division addresses public health concerns, including consumer safety, health promotion and disease prevention, and the monitoring of threats to the public's health.

31. PHD consists of ten integrated branches that work together to assess and monitor the health status of San Francisco and implement traditional and innovative public health interventions. For example:

- Applied Research, Community Health Epidemiology, and Surveillance coordinates data collection, processing, management, analysis and interpretation related to health and morbidity in San Francisco.
- Bridge HIV is a global leader in HIV prevention, research, and education. Operating as a clinical trials unit within SFDPH, Bridge HIV conducts innovative research that guides global approaches in HIV prevention. Its heritage in the early fight against HIV/AIDS has made it a trusted and renowned resource for understanding HIV infection and disease.
- Community Health Equity and Promotion includes the core public health functions of informing, educating and empowering communities. Through the use of comprehensive approaches across the spectrum of prevention, the Branch plans, implements, and evaluates prioritized community initiatives, including promoting active living, decreasing HIV, sexually transmitted infections, viral hepatitis, and the effects of trauma.
- Disease Prevention and Control integrates core public health communicable disease functions, along with specialty care and treatment, and laboratory diagnostics. It is responsible for interacting with SFDPH Health Delivery Systems in order to coordinate and maximize disease screening and other prevention activities in primary care and the hospitals.
- And Emergency Medical Services Agency ("EMS") manages and prepares for all types of medical emergencies in San Francisco. Among other things, they direct, plan, monitor, evaluate, and regulate the San Francisco EMS System in collaboration with system and community providers.

II. Congress's Regulation of Religious Refusals In Health Care

32. Over the years, Congress has enacted numerous federal statutes concerning refusals to provide healthcare services due to religious objections. OCR references several of these statutes as being the subject and basis of the Final Rule. The statutes relied upon by OCR are collectively referred to as the "Federal Health Care Conscience Laws." As summarized below, these laws focus largely on abortion, but some also include sterilization procedures, assisted suicide, and advance directives, among other types of medical care.[2] San Francisco fully complies with all of these laws.

A. The Church Amendments

33. Under the Church Amendments—a series of laws passed in the 1970s—government entities are prohibited from using certain federal funds as a basis to require that individuals "perform or assist in the performance" of any sterilization procedure or abortion if doing so would be contrary to religious beliefs or moral convictions. 42 U.S. § 300a-7. Similarly, receipt of federal funds cannot be used to require entities to make their facilities or personnel available for any sterilization procedure or abortion if the procedure is otherwise prohibited by the entity based on religious beliefs or moral convictions. And entities that receive certain federal funds cannot "discriminate" in employment, promotion, termination, or the extension of staff or other privileges because a provider "performed or assisted in the performance" of a lawful sterilization procedure or abortion or refused to do so based on religious beliefs or moral convictions. *See id.*

B. The Weldon Amendments

34. The Weldon Amendment is an appropriations rider that was first passed in 2004 and has been included in the Labor, Health and Human Services, Education, and Related Agencies Appropriations Act every year since. It states that none of the funds appropriated in the Act may be made available to government entities that discriminate against any "institutional or individual health care entity" because the entity "does not provide, pay for, provide coverage of, or refer for abortions." *See, e.g.*, Consolidated Appropriations Act of 2009, Pub. L. No. 111-117, 123 Stat 3034, § 508(d)(1).

[2] In addition to the statutes summarized below, OCR also relies upon a handful of other statutes. *See* 45 CFR § 88.3.

35. The Weldon Amendment defines "health care entity" to mean "an individual physician or health care professional, a hospital, a provider-sponsored organization, a health maintenance organization, a health insurance plan, or any other kind of health care facility, organization, or plan." *Id.* § 508(d)(2).

C. The Coats-Snowe Amendment

36. The Coats-Snowe Amendment prohibits government entities that receive federal financial assistance from discriminating against "health care entities" (including physicians and those in health professional training programs) that refuse to undergo training to perform abortions, refuse to provide referrals for abortions or abortion training, or refuse to make arrangements for those activities. 42 U.S.C. § 238n(a).

37. The Amendment defines "health care entity" to include "an individual physician, a postgraduate physician training program, and a participant in a program of training in the health professions." *Id*. § 238n(c)(2).

D. The Affordable Care Act

38. The Patient Protection and Affordable Care Act ("ACA") included a number of health care conscience provisions.

39. Section 1303 of the ACA affirms that health plans are not required to cover abortion services as part of the essential health benefits package, and that qualified health plans cannot discriminate against providers or facilities because of their unwillingness to provide, pay for, provide coverage of, or refer for abortions. 42 U.S.C. § 18023.

40. The individual mandate includes a religious conscience exemption that covers organizations or individuals that adhere to established tenets or teachings in opposition to acceptance of the benefits of any private or public insurance. 26 U.S.C. § 5000A.

41. Finally, Section 1553 prohibits government entities that receive federal financial assistance under the ACA from discriminating against a health care entity because of an objection to providing items or service related to assisted suicide. 42 U.S.C. § 18113.

E. Medicaid Or Medicare Statutes

42. Under a statutory provision related to state-administered Medicaid programs, Medicaid managed care organizations cannot be compelled to provide, reimburse for, or cover counseling or referrals that they object to on moral or religious grounds (as long as the organization makes its policy clear to prospective enrollees). 42 U.S.C. § 1396u-2(b)(3)(B).

43. And although 42 U.S.C. § 1396a(w) generally imposes advanced directive requirements on state-administered Medicaid programs, it also makes clear that this does not override any state law that "allows for an objection on the basis of conscience for any health care provider." *Id.* § 1396a(w)(3). And 42 U.S.C. § 14406 clarifies that the advanced directives requirements do not require a provider "to inform or counsel any individual regarding any right to obtain an item or service furnished for the purpose of causing, or the purpose of assisting in causing, the death of the individual, such as by assisted suicide, euthanasia, or mercy killing [or] to apply to or to affect any requirement with respect to a portion of an advance directive that directs the purposeful causing of, or the purposeful assisting in causing, the death of any individual, such as by assisted suicide, euthanasia, or mercy killing."

III. OCR's Discriminatory And Unlawful New Rule

44. The Final Rule was originally proposed in a Notice of Proposed Rulemaking ("NPRM") on January 26, 2018. 83 Fed. Reg. 3880, RIN 0945-ZA03.

45. In attempting to explain the need for the proposed rule, OCR noted that it had received 10 complaints alleging violations of federal religious refusal laws between 2008 and November 2016, and an additional 34 similar complaints between November 2016 and January 2018. By comparison, however, during a similar time period from fall 2016 to fall 2017, OCR received *more than 30,000 complaints* alleging either civil rights or HIPAA violations. These numbers demonstrate that rulemaking to enhance enforcement authority over religious refusal laws is, in fact, manifestly *unwarranted* and a misappropriation of OCR's resources.

46. In response to the proposed rule, Defendants received more than 70,000 comments. A wide range of commenters—including the American Medical Association, the California Medical Association, the National Health Law Program, the Leadership Conference on Civil and Human

Rights, the American Nurses Association, and the American Academy of Nursing—all urged OCR to rescind or significantly alter the proposed rule. SFDPH also submitted a comment expressing significant concerns about the rule and urging HHS to withdraw it from consideration.

47. On May 2, 2019, Defendants took final agency action when they submitted the Final Rule for publication in the Federal Register.

A. Substantive Scope Of The New Rule

48. Ostensibly, the Final Rule simply implements the underlying federal statutes discussed in Part II, above. Upon closer inspection, however, it becomes apparent that the Final Rule vastly expands the statutes' scope—far beyond their plain language and Congress's intent. It expands the range of health care institutions and individuals who may refuse to provide services, and broadens the scope of what qualifies as a refusal under the applicable law beyond the actual provision of health care services to information and counseling about health services.

49. The Final Rule accomplishes this by adopting excessively broad definitions of certain terms used in the statutory text of the Federal Health Care Conscience Laws.

50. For example, the Final Rule defines "*health care entity*" so broadly as to encompass any entity, program, or activity in the health care, education, research, or insurance fields, even those that do not provide treatment to patients. *See* 45 C.F.R. 88.2. Similarly, the definition of "*health service program*" includes any employer who provides health benefits and receives any HHS funds. *See id.*

51. The Final Rule defines "*assist in the performance*" to include not only assistance in the performance of those actual procedures—the ordinary meaning of the phrase—but also participation in any other activity with "an articulable connection to furthering a procedure." *Id.* This means, for example, that simply admitting patients to a health care facility, filing their charts, transporting them from one part of the facility to another, or even scheduling the appointment or processing an insurance claim could conceivably be considered "assist[ing] in the performance" of an abortion or sterilization, as any of those activities could have an "articulable connection" to the procedure.

52. Indeed, OCR expressly acknowledges that it "believes [such] examples are properly considered as within the scope of the protections enacted by Congress for those who choose to assist

and those who choose not to assist in the performance of an abortion." Final Rule at 74 ("Scheduling an abortion or preparing a room and the instruments for an abortion are necessary parts of the process of providing an abortion, and it is reasonable to consider performing these actions as constituting 'assistance.'").

53. The Final Rule thus allows any entity involved in a patient's care—from a hospital board of directors to the receptionist that schedules procedures—to use their personal beliefs to determine a patient's access to care.

54. This goes well beyond what was intended by Congress. The Church Amendments prohibit federal funding recipients from discriminating against those who refuse to perform or "assist in the performance" of sterilizations or abortions. And during debate on the legislation, Senator Church expressly stated that, "the amendment is meant to give protection to the physicians, to the nurses, to the hospitals themselves, if they are religious affiliated institutions. There is no intention here to permit a frivolous objection from someone unconnected with the procedure to be the basis for a refusal to perform what would otherwise be a legal operation." 119 Cong. Rec. S9597 (Mar. 23, 1973) (statement of Sen. Church).

55. The Final Rule's definition of "referral or refer for" similarly goes far beyond the statutory language and Congress's intent. The Final Rule states that "referral or refer for" "includes the provision of information in oral, written, or electronic form (including names, addresses, phone numbers, email or web addresses, directions, instructions, descriptions, or other information resources), where the purpose or reasonably foreseeable outcome of provision of the information is to assist a person in receiving funding or financing for, training in, obtaining, or performing a particular health care service, program, activity, or procedure." 45 C.F.R. 88.2.

56. But the term "referral" has a far more limited meaning in the health care context—for a doctor to direct a patient to another care provider for care. *See, e.g.*, Medicare.gov, *Glossary-R*, https://www.medicare.gov/glossary/r.html (last visited Apr. 30, 2019) (defining referral as "[a] written order from your primary care doctor for you to see a specialist or get certain medical services"); Ctrs. for Medicare & Medicaid Services, *Glossary*, https://www.cms.gov/apps/glossary/default.asp?Letter=R&Language (last visited Apr. 30, 2019)

("Generally, a referral is defined as an actual document obtained from a provider in order for the beneficiary to receive additional services."); *id*. (a referral is a "written OK from your primary care doctor for you to see a specialist or get certain services").

57. OCR brushed aside critiques that this definition was overly broad, stating that it believes "[t]he definition is a reasonable interpretation of these terms and faithfully effectuates the text and structure of Congress's protection of health care professionals and entities from being coerced or compelled to facilitate conduct . . . that may violate their legally protected rights through the forced provision of referrals." Final Rule at 131.

58. Meanwhile, although OCR states that it amended the definition of "discrimination" to "narrow[] the scope of possible bases of a violation under the rule" (Final Rule at 132), it still purports to provide virtually unfettered immunity for employees who refuse to perform critical health care. *See* 45 C.F.R. 88.2. It does not take into consideration whether the provision of such an accommodation would cause an "undue hardship" for the employer, and would compel employers to categorically conform their business practices to the particular religious practices of employees, regardless of the impact on the business, other employees, and most importantly, patients. Indeed, discrimination is defined so broadly as to include the provision of reasonable accommodations for religious practices which are required to *avoid* discrimination under Title VII, such as changing an employee's employment, title, or other similar status so that they can be moved into a role in which they would not encounter a religious conflict with their job duties.

59. This expansion of "discrimination" would appear to treat virtually any action—including government enforcement of a patient non-discrimination or access-to-care law—against a health care facility or individual as per se discrimination. But "discrimination" does not mean any action, and instead requires an assessment of context and justification, with the claimant showing unequal treatment on prohibited grounds under the operative circumstances.

60. As discussed further below (*see* Part IV, *infra*), in light of the breadth of these definitions, the various requirements and prohibitions imposed on San Francisco by the Final Rule have sweeping implications for the City's ability to continue to provide the highest quality patient care, comply with federal law, and operate as a functioning, non-discriminatory employer.

61. For example, Section 88.3(a)(2)(vi) would prohibit San Francisco from "requir[ing] any individual to perform or assist in the performance of any part of a health service program or research activity . . . if the individual's performance or assistance in the performance of such part of such program or activity would be contrary to his religious beliefs or moral convictions." In light of the nearly all-encompassing definitions of "assist in the performance" and "health service program," this provision of the Final Rule would prohibit San Francisco from requiring nearly any worker whose job is even tangentially related to health care from performing their job duties if they held religious belief somehow in conflict with those duties. It provides no consideration for whether a reasonable accommodation for such beliefs could be reasonably provided. If an individual were to believe that transgender people should not transition, it would empower them to refuse to provide any health-related service to a transgender patient, such as medical bill processing or scheduling an x-ray for a broken leg. If a nurse were to oppose a same-sex couple's marriage, the Final Rule would allow the nurse to refuse to let one spouse see the other in the hospital. If an individual claims that their moral convictions do not allow them to assist LGBTQ persons, the individual could refuse to even set up a room where an LGBTQ patient would be receiving services.

62. Section 88.3(b)(2)(i)(A) prohibits "discrimination" against an individual who "refuses to undergo training in the performance of induced abortions, to require or provide such training, to perform such abortions, or to provide referrals for such training or such abortions." This would allow nurse trainees and resident doctors who work at SFDPH hospitals and clinics to refuse to provide information to patients about the availability of abortions within its own system.

B. Enforcement Mechanism Created By The New Rule

63. The Final Rule requires applicants for HHS funds to submit an assurance and certification of full compliance with the Final Rule as "a condition of continued receipt of Federal financial assistance or other Federal funds from the Department." 45 C.F.R. 88.4(a), (b). Failure to submit this assurance and certification in connection with any application for funding could result not only in the loss of those specific funds, but of all HHS funds for that applicant. 45 C.F.R. 88.4(b)(8), 88.7.

64. The Final Rule also allows anyone to file a complaint against an entity alleging noncompliance with the rule, even if the complaint-filer's rights are not alleged to have been violated. 45 C.F.R. 88.7(b). OCR is vested with the authority to investigate such complaints—and to initiate investigations on its own initiative, even in the absence of any complaint. 45 C.F.R. 88.7(c), (d).

65. In the course of an investigation, either related to a complaint or not, if a party fails to respond to a request for information or data from OCR within 45 days, that in itself shall constitute a violation of the Final Rule. 45 C.F.R. 88.7(e).

66. Moreover, the Final Rule purports to require San Francisco to waive all rights of privacy and confidentiality of doctors and patients should OCR decide to investigate. 45 C.F.R 88.6(c), 88.3(b)(1)(ii).

67. And if OCR concludes that there is a failure to comply with the Final Rule, the consequences are harsh. HHS may, among other sanctions, terminate all funds, withhold new HHS funds, and refer the matter to the Attorney General. 45 C.F.R. 88.7(i)(3).

68. In other words, San Francisco will have to submit documentation to HHS certifying that it is in full compliance with the Final Rule, or risk losing *all* of its HHS funding. Similarly, even if not one single individual complains or alleges that their rights have been violated by SFDPH, OCR can initiate an investigation, and terminate *all* of San Francisco's HHS funds based on its determination of a failure to comply with the Final Rule.

IV. San Francisco Faces Immediate Injury From The Final Rule

69. While San Francisco complies with the laws passed by Congress, the Final Rule would result in immediate injury to San Francisco. San Francisco has two options: comply with the Final Rule in full or risk losing all HHS funds. Neither option is an actual option for San Francisco as both would cripple the ability of SFDPH to continue to operate as San Francisco's safety-net healthcare provider for all its residents.

A. Complying With The Final Rule Would Be Operationally Devastating And Put Patients' Health At Risk

70. San Francisco recognizes and respects that an individual's religious beliefs, cultural values, and ethics may make that person reluctant to participate in an aspect of patient care. But while

the City supports the legitimate conscience rights of individual health care professionals, the exercise of these rights must be balanced against the fundamental obligations of the medical profession and the right of patients to receive quality patient care.

71. San Francisco has carefully considered these competing values and has established policies and procedures that strike a thoughtful and appropriate balance between personnel's religious beliefs and SFDPH's mission—indeed, obligation—to provide high quality inclusive care to all patients.

72. For example, the City's Memorandums of Understanding with its nurses and supervising nurses contain conscientious objection clauses, which state:

> The rights of patients to receive quality nursing care are to be respected.
>
> It is recognized that Registered Nurses hold certain moral, ethical and religious beliefs and in good conscience may be compelled to refuse involvement with abortions and other procedures involving ethical causes.
>
> Situations will arise where the immediate nature of the patient's needs will not allow for personnel substitutions. In such circumstances the patient's right to receive the necessary nursing care will take precedence over exercise of the nurse's individual beliefs and rights until other personnel can be provided.

73. Similarly, ZSFG Administrative Policy 5.15 ("Policy") "establish[es] guidelines for processing [a] staff member's requests not to participate in patient care in a manner which ensures continuity of quality patient care." It states:

> In the event that a staff member feels reluctant to participate in an aspect of patient care because the patient's condition, treatment plan, or physician's orders are in conflict with the staff member's religious beliefs, cultural values or ethics, the staff member's written request for accommodation will be considered if the request does not negatively affect the quality of patient's care.
>
> In situations where the immediate nature of the patient's needs do not allow for the substitution of personnel, the patient's right to receive the necessary quality patient care will take precedence over the staff member's individual beliefs and rights until other competent personnel can be provided.

74. The Policy explains that "[a]n accommodation may include personnel substitutions through a change in patient assignment or transfer of the staff member to a different patient care area in accordance with organizational standards."

75. It is also clear in the Policy that the individual's "manager and/or supervisor must determine if the staff member's request for accommodation negatively affects the quality of the

patient's care," and "[i]f the patient's needs do not allow for the substitution of personnel, the manager and/or supervisor must inform the staff member to stay at their post until other competent personnel can be provided."

76. Pursuant to these provisions and policies, San Francisco medical personnel including nurses may be required to participate in medical procedures despite a moral, religious, or ethical objection if a patient's needs require it and a staffing change cannot be made.

77. If possible, however, accommodations will be made, which may include transferring individuals to another area where they will not be called on to perform the task they find objectionable.

78. These policies reflect SFDPH's respect for the religious and moral beliefs of its staff, as well as its paramount responsibility and commitment to serve the needs of its patients. They represent a careful balancing of the important interests at issue in this area. But these policies put San Francisco in violation of the Final Rule.

79. Requiring personnel to participate in a procedure as necessary to protect a patient's health unless and until other competent personnel can be assigned is contrary to the categorical right to refuse to provide essential services enshrined in the Final Rule. Transferring staff members to a different department to accommodate their request not to perform responsibilities of their current position could run afoul of the broadly defined prohibition on "discrimination" based on religious objection.

80. But strict adherence to the requirements of the Final Rule would be operationally devastating and put patient care at risk.

81. If nurses refuse to assist with a critical procedure when no alternate staff is available, patients could die. This is neither hyperbole nor hypothetical. At a hospital in New Jersey, a pregnant patient was diagnosed with placenta previa that was deemed life-threatening by the attending Labor and Delivery physician. The doctor ordered an emergency cesarean-section delivery. Because the procedure would terminate the pregnancy, the Labor and Delivery nurse refused to participate. Although another nurse eventually took her place, the emergency life-saving procedure was delayed

by thirty minutes, putting the patient's health at significant risk. *See Shelton v. Univ. of Med. & Dentistry of New Jersey*, 223 F.3d 220, 222-23 (3d Cir. 2000).

82. If SFDPH cannot involuntarily transfer receptionists or schedulers who refuse to schedule patients for medically necessary services, San Francisco's hospitals and clinics will not be able to function efficiently, significantly compromising patient care for everyone.

83. If providers refuse to give patients information to help them obtain time-sensitive healthcare services like emergency contraception or abortion (45 C.F.R. 88.2), those patients will lose time crucial to the decision whether to terminate a pregnancy. Under these circumstances, a woman may lose the option to choose a particular procedure, or to terminate the pregnancy at all.

84. And if health care systems prioritize providers' religious beliefs over patients' care, vulnerable communities will not access critical medical care. A recent study from the Center for American Progress showed that "LGBTQ people experience discrimination in health care settings; that discrimination discourages them from seeking care; and that LGBTQ people may have trouble finding alternative services if they are turned away."[3] Indeed, 8% of LGBTQ respondents reported that they had delayed or foregone medical care because of concerns of discrimination in healthcare settings.[4] And a recent study by the National Center for Transgender Equality revealed that nearly one-quarter (23%) of transgender respondents did not seek the health care they needed—including routine and non-transition related care—in the year prior to completing the survey due to fear of being mistreated as a transgender person.[5] Rather than addressing this pressing concern, the Final Rule provides *greater* opportunity for LGBTQ people to be denied necessary access to health care, which not only imposes immediate life-threatening consequences, but future deadly consequences for those who fear being denied the care they need.

[3] Shabab Ahmed Mirza & Caitlin Rooney, *Discrimination Prevents LGBTQ People from Accessing Health Care*, Center for American Progress (Jan. 18, 2018), https://www.americanprogress.org/issues/lgbt/news/2018/01/18/445130/discrimination-prevents-lgbtq-people-accessing-health-care/.

[4] *Id.*

[5] Sandy E. James et al., *Executive Summary of the Report of the 2015 U.S. Transgender Survey*, National Center for Transgender Equality at 8 (2016), https://transequality.org/sites/default/files/docs/usts/USTS-Executive-Summary-Dec17.pdf

85. For all these reasons, San Francisco cannot and will not commit to full compliance with the Final Rule.

B. Losing HHS Funds Would Devastate San Francisco's Health Care System

86. As described above (*see* Part III(B), *supra*), San Francisco will be required to provide an assurance and certification that it will comply with the Final Rule "as a condition of the approval, renewal, or extension of any Federal financial assistance or Federal funds from the Department." 45 CFR 88.4(a)(1). If it fails to do so, OCR may "[t]erminate Federal financial assistance or other Federal funds from [HHS], in whole or in part." 45 CFR 88.7(i)(3)(iv).

87. Termination or withdrawal of these funds from San Francisco would be devastating.

88. In Fiscal Year 2018 alone, San Francisco expended over $61 million in HHS grant funds. This money was used to fund a wide array of critical health care services and public health research.

89. For example, the SFDPH Population Health Division receives approximately $2.5 million in federal funding for public health research including randomized clinical trials focused on HIV and substance use.

90. The Division's HIV research unit, Bridge HIV, has been at the vanguard of HIV prevention science since the beginning of the HIV epidemic and is a recognized global leader in HIV prevention research. It is 100% grant funded, primarily through the HHS National Institutes of Health ("NIH"). Bridge HIV's work touches HIV prevention efforts at the highest levels; national health entities, such as the Centers for Disease Control and Prevention ("CDC") draw upon the data that comes from its trials to create guidelines to stop the spread of HIV. Bridge HIV provides evidence that directly informs public health practice decisions. For example, Bridge HIV participated in the landmark trial that demonstrated the safety and efficacy of using antiretroviral medicine for HIV prevention in healthy people who are at risk of HIV infections. This prevention strategy is known as pre-exposure prophylaxis (PrEP). PrEP has changed the landscape of HIV prevention. In fact, the Getting to Zero San Francisco Consortium has adopted PrEP as one of the key strategies to achieve its immediate goal of reducing both HIV infections and HIV deaths by 90% from their 2013 levels by the year 2020.

91. None of this would have been possible without funding from HHS—and future life-saving breakthroughs will be jeopardized if these funds are terminated.

92. Similarly, SFDPH's Disease Prevention and Control Branch ("DPC") oversees public health clinical, laboratory and disease intervention services. It performs many of the legally mandated activities intended to protect public health and therefore serves everyone in San Francisco. This Branch is also responsible for informing and guiding San Francisco clinicians in best practices for communicable and chronic disease prevention and is a resource for expert clinical and laboratory consultation, including control and treatment of communicable diseases during outbreaks. Within SFDPH, DPC staff work closely with the San Francisco Health Network to optimize clinical policies and care in the DPC core areas. In addition, DPC staff work with clinical providers and systems throughout San Francisco to improve prevention, diagnosis, and treatment of communicable diseases using a public health detailing model of engagement.

93. DPC currently receives over $15 million in funding from the CDC. Losing these funds would impact all aspects of the Branch's work and threaten San Francisco's ability to detect, treat, and prevent diseases such as HIV, STDs, TB, Hepatitis C and other communicable diseases—putting hundreds of thousands of people at higher risk for illness.

94. As another example, SFDPH uses HHS Title X grant money to fund family-planning projects for 6,623 patients at 10 sites/clinics. Approximately 40% of the patients served by SFDPH's Title X-funded clinics are Latinx, approximately 35% are Asian or Pacific Islander, approximately 20% are African-American, and the remainder are white or Middle Eastern. Almost 100% of SFDPH's Title X patients are at 250% of the federal poverty level ("FPL") or below. Only 1% of SFDPH's Title X patients have private health insurance, while 47% are on Medi-Cal (California's Medicaid program), and the remainder are either uninsured or enrolled in California's Family Planning, Access, Care, and Treatment ("Family PACT") program.

95. Among other things, SFDPH uses Title X funding to develop training programs that have greatly improved the quality and effectiveness of care offered at SFDPH's Title X clinics. Using Title X funds, SFDPH trains approximately 20–30 clinical staff members every year with respect to key aspects of their services, including contraceptive counseling and prescriptions, STI testing and

treatment, harm reduction approaches, and pregnancy testing and counseling. SFDPH also provides smaller training to specific clinics upon request. Without Title X funding, SFDPH's ability to provide these trainings will be greatly inhibited.

96. SFDPH also uses Title X funds to develop protocols for registered nurses ("RNs") to dispense oral emergency contraceptives. One such protocol that is currently pending will enable registered nurses to dispense pills, patches, and contraceptive rings. These protocols will significantly expand patient access to important contraceptive methods.

97. SFDPH uses Title X funds to educate the public on important topics relating to family planning and reproductive health. For example, SFDPH uses Title X funds to support its "Go Folic" project to increase community awareness of the importance of folic acid supplementation, which prevents birth defects. SFDPH uses Title X funds to support a public education campaign to combat chlamydia, whose rates have increased in San Francisco and across California. And with Title X funds, SFDPH has partnered with the San Francisco Unified School District, Planned Parenthood, and other youth-serving health agencies to make San Francisco a leader in developing evidence-based sex education curricula and outreach. Indeed, thanks to those public education and outreach efforts, we now frequently see adolescents visiting Title X clinics seeking birth control before they become sexually active—a major public-health accomplishment.

98. Without HHS funds, SFDPH will have to substantially curtail all of the projects discussed above.[6]

99. These are just some of the myriad ways that termination of HHS grant funding will impact SFDPH, leading to a lower quality of care and significantly worse health outcomes for patients, and for the public as a whole.

100. But it is not just grant funds that are at risk under the Final Rule. To the contrary, in the absence of San Francisco's full compliance with the Final Rule, the City stands to lose *all* "Federal

[6] Notably, the U.S. District Court for the Northern District of California recently granted a preliminary injunction against new HHS regulations concerning the implementation of Title X based, in part, on the Court's conclusion that the loss of Title X funds in jurisdictions across California would significantly impact the availability of important medical services. California v. Azar, No. 19-CV-01184-EMC, 2019 WL 1877392, at *8-10 (N.D. Cal. Apr. 26, 2019).

financial assistance or other Federal funds from the Department" (45 C.F.R. 88.7(i)(3)(iv)), including funds San Francisco receives for entitlement programs for its residents including Medicaid and Medicare, Temporary Assistance for Needy Families ("TANF"), Foster Care, and Child Support Services.

101. In the Fiscal Year ending June 2017, San Francisco expended over $58 million in TANF funds, nearly $35 million in Foster Care—Title IV-E funds, $10 million in adoption assistance funds, $8 million is child support enforcement funds, $642 million in Medicaid, and $128 million in Medicare funds—all of which are administered by HHS.

102. Taking all of HHS grants and HHS administered entitlements into account, San Francisco stands to lose close to $1 billion in funding.

103. These HHS funds make up approximately a third of SFDPH's total budget, approximately 40% of Zuckerberg San Francisco General's budget, and well over half the budget for Laguna Honda Hospital.

104. If HHS terminated these funds, the result would be catastrophic. SFDPH would have to restructure the entire public health system with a drastic reduction in services. Hospital beds, behavioral health clinics, primary care clinics, and emergency services would all have to be significantly reduced. Hundreds of employees would likely lose their jobs. People in need of urgent and emergent health care may not be able to receive timely services. In short, termination of all HHS funds would cause a loss of critical health care capacity for San Francisco and the region.

105. In short, San Francisco faces an impossible—and unlawful—choice: forgo critical funds or agree to unlawful rules that prioritize providers' religious beliefs over patients' care. Either way, SFDPH's ability to continue providing critical high-quality safety-net healthcare to all of its residents will be impacted and patient care will be compromised.

COUNT ONE

Violation of APA (5 U.S.C. § 706(2)(C))—Exceeds Statutory Authority

106. Plaintiff repeats and incorporates by reference each allegation of the prior paragraphs as if fully set forth herein.

107. The APA requires courts to "hold unlawful and set aside" agency action that is "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706(2)(C).

108. The Final Rule violates Section 706(2)(C) because the underlying laws do not delegate authority to Defendants to promulgate legislative regulations with the force of law.

109. In addition, the Final Rule exceeds Defendants' authority under the enabling statutes because it impermissibly adopts excessively broad definitions of statutory text, including but not limited to the terms: "assist in the performance," "health care entity," "referral," "refer for," and "discrimination."

110. The Final Rule also exceeds Defendants' authority under the enabling statutes because nothing within the statutes cited by Defendants gives HHS the authority to (a) require healthcare entities to provide assurances or certifications, (b) post the extensive notice included as Appendix A of the Final Rule, (c) keep and make records available for review, and (d) conduct periodic compliance reviews or to subject healthcare entities to the full investigative process described in Section 88.7 of the Final Rule.

111. For all of these reasons, Defendants acted in excess of their statutory authority by promulgating the Final Rule, rendering it invalid.

COUNT TWO

Violation of APA (5 U.S.C. § 706(2)(A))—Contrary To Law

112. Plaintiff repeats and incorporates by reference each allegation of the prior paragraphs as if fully set forth herein.

113. The APA requires courts to "hold unlawful and set aside" agency action that is "not in accordance with law." 5 U.S.C. § 706(2)(A).

114. The Final Rule violates Section 706(2)(A) because it conflicts with at least three federal laws.

115. First, the Final Rule conflicts with Section 1554 of the Affordable Care Act, which forbids the HHS Secretary from promulgating "any regulation" that:

> (1) creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care; (2) impedes timely access to health care services; (3) interferes with communications regarding a full range of treatment options between the patient and provider; (4) restricts the ability of health care providers to provide full disclosure of all relevant information to patients making health care decisions; [or] (5) violates the principles of informed consent and the ethical standards of health care professionals.

42 U.S.C. § 18114.

116. Second, the Final Rule conflicts with the Emergency Medical Treatment and Labor Act ("EMTALA"), which requires hospitals to provide emergency care. 42 U.S.C. § 1395dd. The Final Rule contains no protections to ensure that patients have adequate access to necessary health care in emergencies, placing it in direct conflict with EMTALA.

117. Third, the Final Rule conflicts with Title VII of the Civil Rights Act of 1964. Title VII prohibits discrimination in employment on the basis of religious or ethical beliefs, but also states that employers are not obligated to accommodate an employee's religious belief if doing so would cause an "undue hardship." The Final Rule ignores the "undue hardship" test in favor of a blanket rule against "discrimination."

118. For all of these reasons, the Final Rule is "not in accordance with" federal law, and is therefore invalid.

COUNT THREE

Violation of APA (5 U.S.C. § 706(2)(A))—Arbitrary and Capricious

119. Plaintiff repeats and incorporates by reference each allegation of the prior paragraphs as if fully set forth herein.

120. The APA requires courts to "hold unlawful and set aside" agency action that is "arbitrary" or "capricious." 5 U.S.C. § 706(2)(A). Agency action should be overturned when, among other things, the agency: (i) relied on factors Congress did not intend for it to consider; (ii) failed to consider important aspects of the problem it is addressing, including issues raised in multiple comments submitted on the proposed rule; or (iii) explained its decision counter to the evidence before it. *Motor Veh. Mfrs. Ass'n v. State Farm Ins.*, 463 U.S. 29, 43 (1983).

121. In issuing the Final Rule, Defendants ignored important aspects of the problem, including impacts of the Final Rule on vulnerable populations that were raised by San Francisco and

others in public comments. Moreover, Defendants reversed course on current policy without offering an adequate explanation. Indeed, Defendants have offered an explanation for their decision that "runs counter to the evidence before the agency" and is "so implausible that it could not be ascribed to a difference of view or the product of agency expertise." *Id.*

122. Accordingly, Defendants' actions were arbitrary and capricious and the Final Rule is invalid.

COUNT FOUR

Violation of the Establishment Clause

123. Plaintiff repeats and incorporates by reference each allegation of the prior paragraphs as if fully set forth herein.

124. Laws that compel employers to categorically "conform their business practices to the particular religious practices of . . . employees"—regardless of the impact on the business, other employees and patients/customers—violate the Establishment Clause. *Estate of Thorton v. Caldor*, 472 U.S. 703, 709 (1995).

125. The Final Rule does not include any provision for balancing or accounting for a patient's right to care or an employer's commitment to deliver that care against an employee's religious objection to providing health care services.

126. Accordingly, the Final Rule is unconstitutional under the Establishment Clause of the First Amendment of the Constitution.

COUNT FIVE

Violation of Separation of Powers

127. Plaintiff repeats and incorporates by reference each allegation of the prior paragraphs as if fully set forth herein.

128. The Constitution vests Congress with legislative powers, *see* U.S. Const. art. 1, § 1, and the spending power, *see* U.S. Const. art. 1, § 8, cl. 1. Absent a statutory provision or an express delegation, only Congress is entitled to attach conditions to federal funds. The Executive Branch cannot "amend[] parts of duly enacted statutes" to impose additional conditions on such funds. *Clinton v. City of New York*, 524 U.S. 417, 439 (1998).

129. By adopting excessively broad definitions of statutory text and conditioning receipt of federal funds on compliance with the resulting conditions, Defendants unconstitutionally intrude upon and usurp powers that have been assigned to Congress, violating principles of separation of powers.

COUNT SIX

Violation of Spending Clause

130. Plaintiff repeats and incorporates by reference each allegation of the prior paragraphs as if fully set forth herein.

131. The Final Rule also violates the Spending Clause of the Constitution because it:

a. coerces state and local governments to adhere to the Final Rule or lose millions of dollars in federal funds (*see Nat'l Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 581 (2012));

b. is vague and ambiguous and does not provide adequate notice of what specific action or conduct, if engaged in, will result in the withholding of federal funds (*see Pennhurst State Sch. & Hosp. v. Halderman*, 451 U.S. 1, 17 (1981));

c. constitutes unlawful post-acceptance conditions on federal funds (*see id.*); and

d. is not rationally related to the federal interest in the program that receives the federal funds (*see South Dakota v. Dole*, 483 U.S. 203, 207 (1987)).

132. For all of these reasons, the Final Rule is unconstitutional under the Spending Clause.

COUNT SEVEN

Violation of Due Process

133. Plaintiff repeats and incorporates by reference each allegation of the prior paragraphs as if fully set forth herein.

134. To satisfy due process, a law must (1) "give the person of ordinary intelligence a reasonable opportunity to know what is prohibited, so that he may act accordingly," and (2) "provide explicit standards for those who apply them." *Grayned v. City of Rockford*, 408 U.S. 104, 108 (1972).

135. The Final Rule's enforcement provisions do not meet either of these requirements.

PRAYER FOR RELIEF

Wherefore, San Francisco prays that the Court grant the following relief:

1. Declare the Final Rule as published in the Federal Register unconstitutional;

2. Postpone the effective date of the Final Rule as published in the Federal Register, pending judicial review, pursuant to 5 U.S.C. § 705;
3. Hold unlawful and set aside the Final Rule as published in the Federal Register, pursuant to 5 U.S.C. § 706(2);
4. Issue a preliminary injunction against implementation and enforcement of the Final Rule as published in the Federal Register;
5. Issue a permanent injunction against implementation and enforcement of the Final Rule as published in the Federal Register;
6. Award San Francisco reasonable costs and attorneys' fees; and
7. Grant any other further relief that the Court deems fit and proper.

Dated: May 2, 2019

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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

CITY AND COUNTY OF SAN FRANCISCO,

Plaintiff,

vs.

ALEX M. AZAR II et al.,

Defendants.

STATE OF CALIFORNIA, *by and through* ATTORNEY GENERAL XAVIER BECERRA,

Plaintiff,

vs.

ALEX M. AZAR II et al.,

Defendants.

COUNTY OF SANTA CLARA et al.,

Plaintiffs,

vs.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES et al.,

Defendants.

No. C 19-02405 WHA
Related to
No. C 19-02769 WHA
No. C 19-02916 WHA

DEFENDANTS' NOTICE OF MOTION; MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT; AND MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF THEIR MOTION

Hon. William Alsup
Hearing: October 30, 2019, 8:00 a.m.

Phillip Burton Federal Building & United States Courthouse, Courtroom 12, 19th Fl., 450 Golden Gate Ave., San Francisco, CA 94102

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NOTICE OF MOTION AND MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT

Please take notice that on August 21, 2019, at 12:00 p.m., before the Honorable William Alsup, Phillip Burton Federal Building & United States Courthouse, Courtroom 12, 19th Fl., 450 Golden Gate Avenue, San Francisco, California 94102, Defendants will and hereby do move to dismiss or, in the alternative, for summary judgment pursuant to Rules 12(b)(1), 12(b)(6), and 56 of the Federal Rules of Civil Procedure in the three above captioned cases: *City and County of San Francisco v. Azar*, No. 19-2405; *California v. Azar*, No. 19-2769; and *County of Santa Clara v. U.S. Department of Health & Human Services*, No. 19-2916. Defendants' motion is based on this notice, the accompanying memorandum of points and authorities, the administrative record, the Court's files and records in this action, any matter that may be judicially noticed, and any other matter that the Court may consider at any oral argument that may be presented in support of this motion. Pursuant to the Court's July 1, 2019 order, ECF No. 66, Plaintiffs' opposition and cross-motion for summary judgment must be filed by September 12, 2019 at 12:00 p.m., Defendants' reply and opposition must be filed by September 26, 2019 at 12:00 p.m., and Plaintiffs' reply must be filed by October 10, 2019 at 12:00 p.m. The Court has scheduled oral argument on October 30, 2019 at 8:00 a.m.

INTRODUCTION

Since the beginning of this nation, the United States has recognized the importance of and provided accommodations to protect rights of conscience. This case concerns a number of conscience protections that Congress has enacted in the health care arena. Collectively, these Federal Conscience Statutes[1] protect individuals and entities with religious, moral, or other objection to providing (or, in some cases, providing coverage for) certain services in government-provided or government-funded health care programs.

The Federal Conscience Statutes work by placing conditions on federal funding: those who accept the funds voluntarily accept the anti-discrimination provisions. Plaintiffs in this case are government and private entities that have accepted and plan to continue accepting federal funds subject to the Federal Conscience Statutes. But Plaintiffs apparently now object to the accompanying federal conditions. Of course, it is completely routine and unobjectionable for the federal government to encourage favored conduct through conditions on federal funding. Indeed, it is so routine and unobjectionable that Plaintiffs do not challenge any of the Federal Conscience Statutes. Instead, Plaintiffs bring a collateral challenge to a Department of Health and Human Services (HHS) regulation that describes HHS's process for enforcing the Federal Conscience Statutes as to federal funds that HHS administers. The Rule provides clarifying definitions and explains how HHS will take enforcement action, but the Rule is not the source of HHS's enforcement authority; the Federal Conscience Statutes themselves obligate and compel HHS to meet the Statutes' conditions in disbursing HHS funding. Plaintiffs' challenge to the Rule is therefore misplaced. It is Congress—not HHS—that has made the determination to protect health care entities against government or government-funded discrimination.

Even if that were not the case, Plaintiffs' challenge fails on the merits.

First, Plaintiffs' cataclysmic predictions about the potential loss of all of their federal health care funding are not ripe. Before Plaintiffs' fears could come to pass, multiple events would have to occur: Plaintiffs would need to discriminate against a health care entity in violation of a Federal Conscience Statute as implemented by the Rule; HHS would need to take enforcement action against Plaintiffs

[1] The Federal Conscience Statutes are listed in the challenged rule. *See* Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, 84 Fed. Reg. 23,170, 23,264–69 (May 21, 2019) (to be codified at 45 C.F.R. § 88.3) [hereinafter Rule].

pursuant to the mechanisms laid out in the Rule; Plaintiffs' attempts to resolve the dispute through formal or informal means, including any procedures provided for by HHS's grants and contracts regulations, must fail; HHS would then need to withhold at least some funding from Plaintiffs; and Plaintiffs would then have to exhaust their administrative appeals. This highly speculative chain of events has not occurred. The Court thus lacks a concrete setting and important factual information to resolve Plaintiffs' claims, such as the amount of federal funding that Plaintiffs stand to lose and the interaction between any applicable state statutes, the Rule, and the Federal Conscience Statutes.

Second, the Rule is entirely consistent with the Administrative Procedure Act (APA). The Rule does not change any of the Federal Conscience Statutes' substantive requirements, but rather clarifies HHS's enforcement process. This is squarely within HHS's statutory authority. The definitions in the Rule, moreover, are consistent with the Federal Conscience Statutes. And the Rule is neither arbitrary nor capricious because HHS thoroughly considered all of the concerns presented in comments.

Third, the Rule comports with the Constitution. Because Plaintiffs' constitutional claims are facial, they must show that the Rule is invalid in all of its applications. However, Plaintiffs rely on a series of outlandish hypotheticals about the results of specific violations of certain Federal Conscience Statutes, as well as speculative enforcement actions by HHS. Those Statutes offer recipients a clear and simple deal: federal funding in exchange for non-discrimination. This offer is well within the bounds of the Spending Clause. If the Statutes themselves do not violate the Spending Clause, then a rule faithfully implementing them also does not. Furthermore, it is well established that when the government acts to preserve neutrality in the face of religious differences, it does not "establish" or prefer religion. Here, the Federal Conscience Statutes, and the Rule that implements them, simply ensure that the targeted federal funds are not used to disadvantage individuals or entities on the basis of objections to certain health care activities, some of which may be rooted in religion. The Rule is also far from unconstitutionally vague; its requirements are clear, and—in practice—any funding recipient can seek additional information from HHS if there is any uncertainty. Nor does the Rule interfere with patients' ability to access abortion services in any way.

Plaintiffs are welcome to structure their own health care systems in the lawful manner of their choice—the Federal Conscience Statutes and the Rule are not universal requirements binding on the world. But the Statutes and Rule do require that, if Plaintiffs accept federal funds, they must extend the

accompanying protections to objecting health care entities. These conditions are longstanding. If Plaintiffs are unwilling to afford such protections, or have become unwilling, then they have the straightforward remedy of no longer accepting the conditioned federal funds. What Plaintiffs may *not* do is accept the benefit of their bargain and then balk at fulfilling their anti-discrimination obligations.

The Court should dismiss this case or, in the alternative, grant summary judgment to Defendants.

BACKGROUND

I. Statutory History of Relevant Conscience Protections

Congress has long acted to protect the rights of individuals and entities to maintain the free exercise of their religious, moral, and ethical convictions in providing government-funded health care. The Rule gives effect to various conscience protection provisions put in place by Congress—known collectively as the Federal Conscience Statutes. The four key laws addressed by the Rule, 84 Fed. Reg. 23,170, and discussed below, are (1) the Church Amendments (42 U.S.C. § 300a-7); (2) the Coats-Snowe Amendment (42 U.S.C. § 238n(a)); (3) the Weldon Amendment (*see, e.g.*, Departments of Defense and Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2019, Div. B., sec. 507(d), Pub. L. No. 115-245, 132 Stat. 2981, 3118 (Sept. 28, 2018)); and (4) the conscience protection provisions in the Patient Protection and Affordable Care Act (i.e., 42 U.S.C. § 18113; 42 U.S.C. § 14406(1); 26 U.S.C. § 5000A; 42 U.S.C. § 18081; 42 U.S.C. § 18023(b)(1)(A) and (b)(4)).[2]

A. The Church Amendments

The Church Amendments, which were enacted beginning in the 1970s, apply to entities that

[2] Other statutes implemented by the Rule include conscience protections for Medicare Advantage organizations and Medicaid managed care organizations with moral or religious objections to counseling or referral for certain services (42 U.S.C. §§ 1395w-22(j)(3)(B) and 1396u-2(b)(3)(B)); Medicare and Medicaid conscience protections related to the performance of advanced directives (42 U.S.C. §§ 1395cc(f), 1396a(w)(3), and 14406(2)); conscience and nondiscrimination protections for organizations related to Global Health Programs, to the extent such funds are administered by the Secretary of Health and Human Services (Secretary) (22 U.S.C. § 7631(d)); conscience protections, attached to federal funding, regarding abortion and involuntarily sterilization, to the extent such funding is administered by the Secretary, (22 U.S.C. § 2151b(f), *see, e.g.*, the Consolidated Appropriations Act, 2019, Pub. L. No. 116-6, Div. F, sec. 7018, 133 Stat. 13, 307); conscience protections from compulsory health care or services generally (42 U.S.C.§§ 1396f and 5106i(a)), and under specific programs for hearing screening (42 U.S.C. § 280g-1(d)), occupational illness testing (29 U.S.C. § 669(a)(5)), vaccination (42 U.S.C. § 1396s(c)(2)(B)(ii)), and mental health treatment (42 U.S.C. § 290bb-36(f)); and protections for religious, nonmedical health care providers and their patients from certain requirements under Medicare and Medicaid that may burden their exercise of their religious beliefs regarding medical treatment (*e.g.*, 42 U.S.C. §§ 1320a-1(h), 1320c-11, 1395i-5, 1395x(e), 1395x(y)(1), 1396a(a), and 1397j-1(b)).

receive certain federal funds and to health service programs and research activities funded by HHS. 42 U.S.C. § 300a–7. The Church Amendments require those entities not to discriminate based on religious beliefs or moral convictions regarding "a lawful sterilization procedure or abortion," or, more generally, "any lawful health service or research activity." *Id*. Such discrimination includes threatening an individual's job and threatening to condition government funding on providing abortions. *See generally id.* Although § 300a–7 does not define its terms, it applies explicitly to both the "performance" of certain procedures or activities and "assist[ing] in the performance of" such procedures or activities. *See id.* § 300a-7(b)(1), (b)(2), (c)(1)(B), (c)(2)(B), (d), (e).

B. The Coats-Snowe Amendment

The Coats-Snowe Amendment, 42 U.S.C. § 238n, was enacted with bi-partisan support in 1996. A sponsor of the statute, Senator Olympia Snowe, described her goal as to "protect those institutions and those individuals who do not want to get involved in the performance or training of abortion" while still maintaining adequate medical training standards for women's gynecological care. Balanced Budget Downpayment Act, II, 142 Cong. Rec. S2268. (Statement of Sen. Snowe) (Mar. 19, 1996). Specifically, the Coats-Snowe Amendment prohibits the federal government and any state or local government that receives federal financial assistance from discriminating against a health care entity that, among other things, refuses to perform induced abortions; to provide, receive, or require training on performing induced abortions; or to provide referrals or make arrangements for such activities. 42 U.S.C. § 238n(a)(1). The statute defines "health care entity" as including an "individual physician, a postgraduate physician training program, and a participant in a program of training in the health professions." *Id.* § 238n(c)(2). The statute also applies to accreditation of postgraduate physician training programs. *Id.* § 238n(b)(1).

C. The Weldon Amendment

Since 2004, Congress has also included nondiscrimination protections, referred to as the Weldon Amendment, in every appropriations bill for the Departments of Labor, Health and Human Services, and Education. *See, e.g.*, Consolidated Appropriations Act, 2005, Pub. L. No. 108-447, Title V, § 508(d)(1)–(2), 118 Stat. 2809, 3163 (2004); Pub. L. No. 115-245, Div. B., sec. 507(d), 132 Stat. at 3118. The Weldon Amendment provides, in pertinent part, that "[n]one of the funds made available in this Act may be made available to a federal agency or program, or to a State or local government, if such agency, program, or

government subjects any institutional or individual health care entity to discrimination on the basis that the health care entity does not provide, pay for, provide coverage of, or refer for abortions." *Id*. The Weldon Amendment's scope and definitions are broad, defining the term "health care entity" as "includ[ing] an individual physician or other health care professional, a hospital, a provider-sponsored organization, a health maintenance organization, a health insurance plan, or any other kind of health care facility, organization, or plan." *Id*. HHS must abide by the Weldon Amendment in its use and distribution of funds, through grant programs or otherwise.

D. Conscience Protections in the ACA

Congress has also included several conscience protections in the Patient Protection and Affordable Care Act (ACA):

Section 1553 provides that the federal government, and any state or local government or health care provider that receives federal financial assistance under the ACA, or any health plan created under the ACA

> may not subject an individual or institutional health care entity to discrimination on the basis that the entity does not provide any health care item or service furnished for the purpose of causing, or for the purpose of assisting in causing, the death of any individual, such as by assisted suicide, euthanasia, or mercy killing.

42 U.S.C. § 18113. In § 1553, Congress again defined "health care entity" broadly to "include [] an individual physician or other health care professional, a hospital, a provider-sponsored organization, a health maintenance organization, a health insurance plan, or any other kind of health care facility, organization, or plan." *Id.* Section 1553 also designates HHS's Office for Civil Rights (OCR) to receive such complaints of discrimination relating to participation in assisted suicide. *Id*.

Section 1303 declares that the ACA does not require health plans to provide coverage of abortion services as part of "essential health benefits." 42 U.S.C. § 18023(b)(1)(A)(i). Furthermore, no qualified health plan offered through an ACA exchange may discriminate against any individual health care provider or health care facility because of its unwillingness to provide, pay for, provide coverage for, or refer for, abortions. *See id.* § 18023(b)(4). The ACA also clarified that nothing in the act is to be construed to "have any effect on federal laws regarding—(i) conscience protection; (ii) willingness or refusal to provide abortion; and (iii) discrimination on the basis of the willingness or refusal to provide, pay for,

cover, or refer for abortion or to provide or participate in training to provide abortion." *Id.* § 18023(c)(2)(A)(i)–(iii).

Section 1411 designates HHS as the agency responsible for issuing certifications to individuals who are entitled to an exemption from the individual responsibility requirement imposed under section 5000A of the Internal Revenue Code, including when such individuals are exempt based on a hardship (such as the inability to secure affordable coverage without abortion), are members of an exempt religious organization or division, or participate in a "health care sharing ministry[.]" 42 U.S.C. § 18081(b)(5)(A); *see also* 26 U.S.C. § 5000A(d)(2).

II. Unchallenged Rules that Require Compliance with the Federal Conscience Statutes

HHS has issued several rules, in addition to the challenged Rule, that require recipients of federal funds to comply with federal law, including the Federal Conscience Statutes. Notably, one of these requirements is that "Federal funding is expended and associated programs are implemented *in full accordance with U.S. statutory and public policy requirements*: Including, but not limited to, those . . . prohibiting discrimination." 45 C.F.R. § 75.300(a) (emphasis added). If a non–Federal entity fails to comply with *Federal statutes, regulations, or the terms and conditions of a Federal award*, the HHS awarding agency or pass-through entity may impose additional conditions, as described in 45 C.F.R. § 75.207. And if the HHS awarding agency or pass-through entity determines that noncompliance cannot be remedied by imposing additional conditions, the HHS awarding agency or pass-through entity may take one or more of the following actions, as appropriate in the circumstances:

(a) Temporarily withhold cash payments pending correction of the deficiency by the non–Federal entity or more severe enforcement action by the HHS awarding agency or pass-through entity.

(b) Disallow (that is, deny both use of funds and any applicable matching credit for) all or part of the cost of the activity or action not in compliance.

(c) Wholly or partly suspend (suspension of award activities) or terminate the Federal award.

(d) Initiate suspension or debarment proceedings as authorized under 2 CFR part 180 and HHS awarding agency regulations at 2 CFR part 376 (or in the case of a pass-through entity, recommend such a proceeding be initiated by a HHS awarding agency).

(e) Withhold further Federal awards for the project or program.

(f) Take other remedies that may be legally available.

45 C.F.R. § 75.371 (emphasis added); *see also* 45 C.F.R. §§ 75.372–75.375 (describing how HHS may terminate a federal award); 45 C.F.R. §§ 75.501–75.520 (describing auditing process for federal awards).

III. HHS Conscience Protection Regulations

A. 2008 and 2011 HHS Conscience Protection Regulations

In 2008, HHS issued regulations clarifying the applicability of the Church, Coats-Snowe, and Weldon Amendments and designating OCR to receive complaints and coordinate with the applicable HHS funding component to enforce certain statutes. *See* 45 C.F.R. § 88 *et seq.* (2008 Rule); Ensuring That Department of Health and Human Services Funds Do Not Support Coercive or Discriminatory Policies or Practices in Violation of Federal Law, 73 Fed. Reg. 78,072 (Dec. 19, 2008). The 2008 Rule recognized (1) the inconsistent awareness of these statutory protections among federally funded recipients and protected persons and entities, and (2) the need for greater enforcement mechanisms to ensure that HHS funds do not support morally coercive or discriminatory policies or practices in violation of the Federal Conscience Statutes. 73 Fed. Reg. at 78,078–81.

In 2011, however, HHS rescinded the 2008 Rule in part and issued a new rule with a more limited scope and poorly defined enforcement mechanism after noting concerns about whether the 2008 Rule was consistent with the new administration's priorities. *See* Regulation for the Enforcement of Federal Health Care Provider Conscience Protection Laws76 Fed. Reg. 9968 (2011 Rule); *see also* Rescission of the Regulation Entitled "Ensuring That Department of Health and Human Services Funds Do Not Support Coercive or Discriminatory Policies or Practices in Violation of Federal Law"; Proposal, 74 Fed. Reg. 10,207 (Mar. 10, 2009). The preamble to the 2011 Rule expressed HHS's support for conscience protections for health care providers and indicated the need for enforcement of the Federal Conscience Statutes. *See, e.g.*, *id.* at 9968–69. Nevertheless, the 2011 Rule created ambiguity regarding OCR's enforcement tools and processes, and removed the definitions of key statutory terms. *Id.*

B. Notice of Proposed Rulemaking

On January 26, 2018, HHS published a Notice of Proposed Rulemaking (NPRM) to revise and expand earlier regulations to implement properly the Federal Conscience Statutes in programs funded by HHS. *See* Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, 83 Fed. Reg.

3,880 (proposed Jan. 26, 2018) [hereinafter 2018 NPRM]. HHS's stated goals were to (1) "effectively and comprehensively enforce Federal health care conscience and associated anti-discrimination laws"; (2) establish OCR's overall enforcement responsibility to ensure compliance with these federal laws; and (3) clear up confusion caused by certain OCR sub-regulatory guidance. *Id.* at 3,881, 3,890. In particular, "there [wa]s a significant need to amend the 2011 Rule to ensure knowledge, compliance, and enforcement of the Federal health care conscience and associated anti-discrimination laws." *Id*. at 3,887. For example, the 2011 Rule was inadequate because it covered only three of the Federal Conscience Statutes.

C. Final Rule

Following a sixty-day comment period, HHS analyzed and carefully considered all comments on the NPRM and made appropriate modifications before finalizing the Rule. *See* 84 Fed. Reg. at 23,180. The Rule implements the Federal Conscience Statutes' nondiscrimination protections for individuals, health care providers, and health care entities with objections to providing, participating in, paying for, or referring for, certain health care services. In addition, the Rule provides procedures for the effective enforcement of those protections. To do this, the Rule clarifies Federal Conscience Statutes' requirements, addresses the inadequate enforcement of conscience rights under existing federal laws, and educates those who lack knowledge of their statutory and civil rights or obligations under HHS-funded or administered programs. 84 Fed. Reg. at 23,175–79. The Rule does not change the substantive law of the Federal Conscience Statutes. *See* 84 Fed. Reg. 23,256.

The Rule has five principal provisions. First, the Rule collects the various statutory conscience protections that apply to certain HHS-funded health programs. 84 Fed. Reg. at 23,264–69 (to be codified at 45 C.F.R. § 88.3). Second, the Rule defines certain terms that appear in the Rule, including "assist in the performance," "discriminate or discrimination," "health care entity," and "referral or refer for." *Id.* at 23,263–64 (to be codified at 45 C.F.R. § 88.2). Third, the Rule requires recipients of federal funds to provide assurances and certifications of compliance with these conscience requirements. *Id.* at 23,269–70 (to be codified at 45 C.F.R. § 88.4). Written assurances and certifications of compliance with the Federal Conscience Statutes must be submitted during the application and reapplication processes associated with receiving federal financial assistance or federal assistance. *Id.* Entities that are already receiving such assistance as of the effective date of the Rule are not required to submit an assurance or certification until

they reapply for such assistance, alter the terms of existing assistance, or apply for new lines of federal assistance. *Id.* OCR may require additional assurances and certifications if it or HHS has reason to suspect noncompliance with the Federal Conscience Statutes. *Id.* Fourth, the Rule explains HHS's enforcement authority. *See id.* at 23,271–72 (to be codified at 45 C.F.R. § 88.7). This authority, which HHS has already set forth in the unchallenged regulations referenced *supra*, includes conducting outreach, providing technical assistance, initiating compliance reviews, conducting investigations, and seeking voluntary resolutions, to more effectively address violations and resolve complaints. *Id.* Where voluntary resolutions are not possible, the Rule provides that HHS may supervise and coordinate compliance using existing and longstanding procedures to enforce conditions on grants, contracts, and other funding instruments. *Id.* (citing, *e.g.*, the Federal Acquisition Regulation and 45 C.F.R. Part 75).[3] To ensure that recipients of HHS funds comply with their legal obligations, as HHS does with other civil rights laws within its purview, the Rule requires certain funding recipients (and sub-recipients) to maintain records and cooperate with OCR's investigations, reviews, or enforcement actions. *Id.* Fifth, the Rule states that HHS will favorably consider a notice summarizing the Federal Conscience Statutes as evidence of compliance. *See* 84 Fed. Reg. at 23,270–71 (to be codified at 45 C.F.R. § 88.5).

The Rule also includes a severability provision. 84 Fed. Reg. at 23,272 (to be codified at 45 C.F.R. § 88.10).

IV. This Litigation

Plaintiffs filed suit challenging the Rule and moved for a preliminary injunction. Subsequently, the Court granted the parties' stipulated request to postpone the effective date of the Rule until November 22, 2019 and held Plaintiffs' motions for preliminary injunction in abeyance. The Court then set a briefing

[3] Involuntary remedies—such as withholding of funds, termination, suspension, or debarment—will not occur under the Rule itself, but rather, under HHS's separate regulations governing grants and contracts. 84 Fed. Reg. 23,222; *see also* 45 C.F.R. 75.374 (addressing HHS's process when a non-federal entity fails to comply with conditions on a federal award, and requiring that "[u]pon taking any remedy for non-compliance, the HHS awarding agency must provide the non-Federal entity an opportunity to object and provide information and documentation challenging the suspension or termination action, in accordance with written processes and procedures published by the HHS awarding agency" and "must comply with any requirements for hearings, appeals or other administrative proceedings to which the non-Federal entity is entitled under any statute or regulation applicable to the action involved"); 45 C.F.R. pt. 16 (describing the procedures of the Departmental Grant Appeals Board, which reviews certain grants disputes as specified in Appendix A to Part 16).

schedule for cross-motions for summary judgment. Defendants now move to dismiss or, in the alternative, for summary judgment.

ARGUMENT

I. Legal Standard

Defendants move to dismiss the complaint under Rules 12(b)(1) and (6) of the Federal Rules of Civil Procedure. Plaintiffs bear the burden to show subject matter jurisdiction, and courts must determine if they have jurisdiction before addressing the merits. *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 94–95, 104 (1998). If this burden is not met, dismissal under Rule 12(b)(1) is proper. Courts should grant a motion to dismiss under Rule 12(b)(6) if the complaint does not contain "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp.*, 550 U.S. at 570).

In the alternative, Defendants move for summary judgment under Rule 56. Summary judgment is appropriate if "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). For APA claims, "the district judge sits as an appellate tribunal" to resolve issues at summary judgment. *McCrary v. Gutierrez*, No. C-08-015292, 2010 WL 520762, at *2 (N.D. Cal. Feb. 8, 2010) (quoting *Am. Bioscience v. Thompson*, 269 F.3d 1077, 1083 (D.C. Cir. 2001)).

II. Plaintiffs' Spending Clause and Establishment Clause Claims Are Not Ripe.

As a threshold matter, Plaintiffs' Spending Clause and Establishment Clause claims are not ripe for review because Plaintiffs have identified no specific enforcement action against them under the Rule—as indeed, they cannot, given that Defendants have postponed the effective date of the Rule. *See Yahoo! Inc. v. La Ligue Contre le Racisme et l'Antisemitisme*, 433 F.3d 1199, 1211 (9th Cir. 2006). Both claims rely on hypotheses about HHS's enforcement of the Rule that are not yet clearly factually defined. At least two courts have declined to decide similarly premature challenges to the underlying Federal Conscience Statutes on standing and ripeness grounds. *See, e.g.*, *Nat'l Family Planning & Reprod. Health Ass'n, Inc. v. Gonzales* (*NFPRHA*), 468 F.3d 826, 827 (D.C. Cir. 2006) (dismissing plaintiff's Spending Clause and vagueness challenges to the Weldon Amendment for lack of ripeness and standing, because plaintiff could not show that it would ever be injured); *California v. United States*, No. C 05-00328 JSW, 2008 WL

744840, at *3 (N.D. Cal. Mar. 18, 2008) (dismissing plaintiff's Spending Clause challenges to the Weldon Amendment for lack of standing and ripeness because enforcement against the plaintiff was speculative).

Plaintiffs' claims rest on "contingent future events that may not occur as anticipated, or indeed may not occur at all." *Texas v. United States*, 523 U.S. 296, 300 (1998) (quoting *Thomas v. Union Carbide Agric. Prods. Co.*, 473 U.S. 568, 580–81 (1985)). If Plaintiffs are concerned that, for example, hypothetically a nurse might object to assisting in an abortion, multiple steps would have to occur before this speculative scenario would implicate the Spending Clause or Establishment Clause. First, a nurse would have to object to assisting in an abortion in a way protected by the Statutes and Rule. Next, a healthcare entity would have to take action against that nurse in violation of the Federal Conscience Statutes. Then, HHS would have to become aware of the situation, find the healthcare entity's actions to be discriminatory, and take enforcement action under the Rule that would endanger Plaintiffs' funding. Finally, that enforcement action would have to be upheld after exhaustion of all available administrative remedies. *See supra* note 3. The occurrence of any of these steps is uncertain, much less all of them. Thus, judicial resolution of Plaintiffs' Spending Clause and Establishment Clause claims "may turn out to [be] unnecessary," and they should be dismissed. *See Ohio Forestry Ass'n, Inc. v. Sierra Club*, 523 U.S. 726, 736 (1998).

In addition, this case also presents no concrete factual situation in which to evaluate Plaintiffs' Spending Clause and Establishment Clause claims. Courts "should not be forced to decide constitutional questions in a vacuum." *San Diego Cty. Gun Rights Comm. v. Reno*, 98 F.3d 1121, 1132 (9th Cir. 1996) (quoting *W.E.B. DuBois Clubs of Am. v. Clark*, 389 U.S. 309, 312 (1967)). Because the Rule has never been enforced, and indeed, no funding has ever been withheld under the Federal Conscience Statutes, the contours of any such enforcement action and the scope of funding that may be at risk is unknown. To exercise jurisdiction before any such enforcement action runs the risk of "entangl[ing]" this Court "in an abstract disagreement" over the Rule's validity before "it [is] clear that [Plaintiff's conduct is] covered by the [Rule]," and before any decision has been made that "affect[s] [Plaintiff] in any concrete way." *See Am.-Arab Anti-Discrimination Comm. v. Thornburgh*, 970 F.2d 501, 511 (9th Cir. 1991).

These claims are also unripe because Plaintiffs would suffer no hardship as to their Spending Clause and Establishment Clause claims if judicial review were postponed. A party suffers no hardship

warranting review unless governmental action "now inflicts significant practical harm upon the interests that the [plaintiff] advances," *Ohio Forestry Ass'n*, 523 U.S. at 733. *See Nat'l Park Hosp. Ass'n v. DOI*, 538 U.S. 803, 810 (2003) (noting that a case is not ripe unless "the impact" of the challenged law is "felt immediately by those subject to it in conducting their day-to-day affairs" (quoting *Toilet Goods Ass'n v. Gardner*, 387 U.S. 158, 164 (1967))). Plaintiffs cannot claim hardship based on the mere existence of the Rule. *Western Oil & Gas Ass'n v. Sonoma Cty.*, 905 F.2d 1287, 1291 (9th Cir. 1990); *see also San Diego Gun Rights Comm.*, 98 F.3d at 1132–33 (case not ripe where plaintiffs faced no credible threat of enforcement); *Am.-Arab Anti-Discrimination Comm.*, 970 F.2d at 511 (same). Here, Plaintiffs' many hypothetical enforcement scenarios (*see, e.g.*, Santa Clara's Compl. ¶ 79) illustrate the difficulty of undertaking an unnecessary quest now to resolve Plaintiffs' imagined Spending and Establishment Clause challenges in the absence of any factual context.

Nor are Plaintiffs in any immediate danger. The false choice Plaintiffs present—between abandoning state health care policy or losing billions of dollars in federal funds—is not an "immediate" one justifying review of their premature claims. Should Plaintiffs discriminate in a fashion barred by the Federal Conscience Statutes, and should HHS take enforcement action under the Rule, and should Plaintiffs decide not to comply through informal means, Plaintiffs will then have the opportunity, if necessary, to present their challenges to a court. *Am.-Arab Anti-Discrimination Comm.*, 970 F.2d at 511. Because no "irremediable adverse consequences [will] flow from requiring [Plaintiffs to bring] a later challenge," *Toilet Goods Ass'n*, 387 U.S. at 164, there is no present need to decide Plaintiffs' Spending Clause and Establishment Clause claims. *See Lee v. Waters*, 433 F.3d 672, 677 (9th Cir. 2005); *Poe v. Ullman*, 367 U.S. 497, 503 (1961).

III. Plaintiffs' Claims Lack Merit.

A. HHS Has Statutory Authority to Issue the Rule.

HHS's statutory authority is fully set forth in the Rule. *See* 84 Fed. Reg. at 23,183–86. In brief, this authority comes from the Federal Conscience Statutes themselves, 5 U.S.C. § 301, 40 U.S.C. § 121(c), and from more specific provisions in various other statutes.

First, the Federal Conscience Statutes implicitly grant HHS the authority to condition its funds on compliance with those statutes and to ensure that recipients comply with their requirements. *See United*

States v. Mead Corp., 533 U.S. 218, 229 (2001) (observing that delegated authority may be explicit or implicit). Congress has granted HHS the authority to disburse funds and has also instructed HHS to condition such funds on the terms of the Federal Conscience Statutes. It follows from these authorizations that HHS may ensure that recipients of its funds comply with the Federal Conscience Statutes and explain its interpretation of those statutes. The converse proposition illustrates its own absurdity. Courts have held that some of the Federal Conscience Statutes do not provide a private right of action. *See, e.g.*, *Cenzon-DeCarlo v. Mount Sinai Hosp.*, 626 F. 3d 695, 698–99 (2d Cir. 2010). If HHS could not require funding recipients to comply with federal law, the corresponding lack of a private right of action would leave victims of unlawful discrimination without a remedy. It would be this resultant stripping of conscience protections—not the enforcement of conditions on federal funds—that would truly contravene congressional intent.

Second, 5 U.S.C. § 301 and 40 U.S.C. § 121(c) grant HHS the authority to administer its funding instruments. HHS has issued several regulations under these statutes that grant it the same authority as does the Rule. Chief among these are the UAR and HHSAR. The UAR requires "that Federal funding is expended and associated programs are implemented *in full accordance with U.S. statutory* and public policy *requirements*: Including, but not limited to, those protecting public welfare, the environment, and *prohibiting discrimination*." 45 C.F.R. § 75.300(a) (emphasis added). Similarly, the HHSAR permits HHS to include "requirements of law" and "HHS-wide policies" in its contracts. *See* 48 C.F.R. § 301.101(b)(1). Of course, some of the federal statutes with which recipients of federal funds must comply are the Federal Conscience Statutes, which prohibit the government and recipients of federal funds from discriminating against entities that decline to engage in certain activities. The Rule does not alter or amend the obligations of the respective statutes, 84 Fed. Reg. at 23,185, but rather ensures that recipients of federal funds do not violate those statutes through the ordinary grant and contract issuing process.

The authority to ensure compliance with grant conditions is consistent with the well-established power of the United States "to fix the terms and conditions upon which its money allotments to state and other governmental entities should be disbursed." *See United States v. Marion Cty. Sch. Dist.*, 625 F.2d 607, 609 (5th Cir. 1980) (collecting Supreme Court cases). Inherent in the authority to fix such terms and conditions is the authority to sue for specific performance of the recipient's obligations under the grants

that it accepts. *See id.*; *United States v. Mattson*, 600 F.2d 1295, 1298 (9th Cir. 1979). Nowhere is this authority exercised with greater prominence than to enforce civil rights. *See Marion Cty. Sch. Dist.*, 625 F.2d at 609. In light of this inherent authority to sue for specific performance, it must be the case that HHS can rely on § 301, the UAR, and the HHSAR to take more modest steps to assure compliance, such as investigating a complaint.

In addition to HHS's authority to enforce the conditions of the grants and contracts that it awards, certain statutes explicitly authorize HHS to promulgate regulations implementing conscience protections. For instance, the ACA authorizes the Secretary to issue regulations setting standards for meeting certain of the statute's requirements, including the prohibition against discrimination on the basis of provision of abortion, 42 U.S.C. § 18023(b)(4), and assisted suicide, *id.* § 18113. *See id.* § 18041(a)(1). The latter statutory provision explicitly authorizes OCR to receive complaints of discrimination regarding assisted suicide. *Id.* § 18113(d). The Secretary is also authorized to promulgate regulations "as may be necessary to the efficient administration of the functions with which" he is charged under Medicare, Medicaid, and the Children's Health Insurance Program. *See* 42 U.S.C. § 1302; *see also id.* (granting rulemaking authority regarding small rural hospitals); 42 U.S.C. 263a(f)(1)(E) (granting rulemaking authority regarding certification of laboratories). And, the Secretary has authority to promulgate regulations related to certain Centers for Medicare & Medicaid Services funding instruments. *See, e.g.*, 42 U.S.C. § 1315a; *see generally* 84 Fed. Reg. at 23,185 (listing statutes).

B. The Challenged Definitions Are Reasonable Exercises of HHS's Authority and Are Not Arbitrary or Capricious.

The definitions section of the Rule is plainly within HHS's statutory authority and is not arbitrary or capricious. In their complaints, Plaintiffs attack four definitions: (1) *assist in the performance*, (2) *discriminate* or *discrimination*, (3) *health care entity*, and (4) *referral* or *refer for*. As California acknowledges, *see* Cal.'s Mem. Points & Auth. in Support of Mot. Prelim. Inj. 12–13, ECF No. 11 [hereinafter Cal.'s PI Mem.], these claims are governed by *Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 842–43 (1984). Under this standard, a court first asks "whether Congress has directly spoken to the precise question at issue." *Id.* at 842. If the answer is yes, the court must give effect to Congress's intent. If the answer is no—that is, the statute is ambiguous—"the question for the court is

whether the agency's answer is based on a permissible construction of the statute."[4] *Id.* at 843. For the reasons set forth below, Plaintiffs' challenge to each definition fails at step one or, in the alternative, at step two of *Chevron*.

1. "Assist in the Performance"

HHS's definition of "assist in the performance" is entirely consistent with the Church Amendments, 42 U.S.C. § 300a-7, the only Federal Conscience Statute that contains the term. Although the term is used in the Church Amendments, it is not explicitly defined. The Rule defines the term "assist in the performance" as follows:

> to take an action that has a specific, reasonable, and articulable connection to furthering a procedure or a part of a health service program or research activity undertaken by or with another person or entity. This may include counseling, referral, training, or otherwise making arrangements for the procedure or a part of a health service program or research activity, depending on whether aid is provided by such actions.

84 Fed. Reg. at 23,263 (to be codified at 45 C.F.R. § 88.2).

1. Plaintiffs' challenge fails at *Chevron* step one because Congress has directly spoken to the precise question at issue. The Court need only open the dictionary, *see Mayo Found. for Med. Educ. & Research v. United States*, 562 U.S. 44, 52 (2011) (applying a dictionary definition at step one) which contains the same commonsense definition as the Rule: *Merriam-Webster* defines *assist* as "to give usually supplementary support or aid to," https://www.merriam-webster.com/dictionary/assist (last visited Aug. 20, 2019), and *performance* as "the execution of an action," https://www.merriam-webster.com/dictionary/performance (last visited Aug. 12, 2019). The Rule's definition is as close to the dictionary definition of these terms as can be without repeating them verbatim: *assist in the performance* is limited to "specific, reasonable, and articulable" connections between the conscientious objector's action and the medical procedure. 84 Fed. Reg. at 23,263 (to be codified at 45 C.F.R. § 88.2). "If the connection between an action and a procedure is irrational, there is no actual connection by which the action specifically furthers the procedure." *Id.* at 23,187.

2. Even if the Court determines that the term "assist in the performance" is ambiguous, the Court should still uphold HHS's definition because it is eminently reasonable. "At step two of *Chevron*, [courts]

[4] This same standard applies to whether the definitions are arbitrary and capricious. *See Judulang v. Holder*, 565 U.S. 42, 52 n.7 (2011).

must 'accept the agency's construction of the statute' so long as that reading is reasonable, 'even if the agency's reading differs from what the court believes is the best statutory interpretation.'" *Perez-Guzman v. Lynch*, 835 F.3d 1066, 1079 (9th Cir. 2016) (quoting *Nat'l Cable and Telecomms. Ass'n v. Brand-X Internet Servs.*, 545 U.S. 967, 980 (2005)).

HHS's definition is reasonable in light of the dictionary definitions of "assist" and "performance" and the Rule's requirement that "a specific, reasonable, and articulable connection" exist between the conscientious objector's action and the medical procedure, 84 Fed. Reg. at 23,263 (to be codified at 45 C.F.R. § 88.2); *id.* at 23,187 (prohibiting irrational or excessively attenuated connections). In addition, the Rule furthers the statute's purpose to protect individuals and health care entities from discrimination on the basis of their religious or moral convictions by recipients of federal funds; for example, an individual who schedules a patient's abortion is not outside the scope of the Church Amendments merely because they did not perform the abortion themselves. The Rule recognizes that such individuals are also protected because they provide necessary assistance in the performance of an abortion. *See id.* at 23,188.

2. "Discrimination"

Plaintiffs' challenge to HHS's definition of "discriminate or discrimination" is also meritless. The definition, which consists of a three-point list of examples that apply *only to the extent permitted by the Federal Conscience Statutes*, is by definition reasonable. Virtually all of the Statutes covered by the Rule employ the term "discriminate" and, as with "assist in the performance," do not define it. For example, the Coats-Snowe Amendment provides that government recipients of federal funds "may not subject any health care entity to discrimination" on certain bases, such as the "refus[al] to undergo training in the performance of induced abortions." 42 U.S.C. § 238n(a)(1). But the Coats-Snowe Amendment does not explicitly define "discrimination." Consistent with the varying types of discrimination that the Federal Conscience Statutes prohibit, the Rule provides a non-exhaustive list of actions that may constitute discrimination "as applicable to, and to the extent permitted by the applicable statute." *See* 84 Fed. Reg. at 23,263 (to be codified at 45 C.F.R. § 88.2). The definition then provides several safe harbors, consisting of actions that, if taken by a regulated entity, would not constitute discrimination. *See id.*

1. Plaintiffs' challenge to this definition fails at *Chevron* step one. By its terms, the definition does not extend beyond the Statutes to which it applies. *See* 45 C.F.R. § 88.2 (defining the term to include

actions "as applicable to, and to the extent permitted by, the applicable statute"). Therefore, the definition does not exceed Congress's intent because it explicitly *cannot* exceed Congress's intent. Moreover, the common definition of "discrimination" is "to make a difference in treatment or favor on a basis other than individual merit," *Discriminate*, Merriam-Webster, https://www.merriam-webster.com/dictionary/discriminate (last visited Aug. 20, 2019), and the Rule merely makes explicit the various manifestations of that broad definition.

2. Even if the term is ambiguous, the Court should uphold HHS's definition at *Chevron* step two. As discussed above, the definition by its terms does not extend beyond the meaning of the Statutes, but rather "must be read in the context of each underlying statute at issue, any other related provisions of the Rule, and the facts and circumstances." 84 Fed. Reg. at 23,192. To provide guidance on the meaning of discrimination without being under-inclusive, HHS used the word "includes" to establish a non-exhaustive list of examples that could, in the context of the particular underlying Federal Conscience Statute, constitute discrimination. *See id.* at 23,190. And, to ensure that the Rule was not over-inclusive, HHS included three provisions to protect entities that seek to accommodate those with religious or moral objections. *See id.* at 23,263 (to be codified at 45 C.F.R. § 88.2).

3. "Health Care Entity"

Plaintiffs' challenge to HHS's definition of "health care entity," which appears in the Weldon Amendment, the Coats-Snowe Amendment, and the ACA, also fails. The Rule defines "health care entity" in two parts:

> (1) For purposes of the Coats-Snowe Amendment (42 U.S.C. 238n) and the subsections of this part implementing that law (§ 88.3(b)), an individual physician or other health care professional, including a pharmacist; health care personnel; a participant in a program of training in the health professions; an applicant for training or study in the health professions; a post-graduate physician training program; a hospital; a medical laboratory; an entity engaging in biomedical or behavioral research; a pharmacy; or any other health care provider or health care facility. As applicable, components of State or local governments may be health care entities under the Coats-Snowe Amendment; and
>
> (2) For purposes of the Weldon Amendment (e.g., Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019, and Continuing Appropriations Act, 2019, Pub. L. 115-245, Div. B., sec. 507(d), 132 Stat. 2981, 3118 (Sept. 28, 2018)), Patient Protection and Affordable Care Act section 1553 (42 U.S.C. 18113), and to sections of this part implementing those laws (§ 88.3(c) and (e)), an individual physician or other health care professional, including a pharmacist; health care personnel; a participant in a program of training in the health professions; an applicant for training or study in the health professions; a post-graduate physician training program; a hospital; a medical laboratory; an entity engaging in biomedical or behavioral research; a

> pharmacy; a provider-sponsored organization; a health maintenance organization; a health insurance issuer; a health insurance plan (including group or individual plans); a plan sponsor or third-party administrator; or any other kind of health care organization, facility, or plan. As applicable, components of State or local governments may be health care entities under the Weldon Amendment and Patient Protection and Affordable Care Act section 1553.

84 Fed. Reg. at 23,264 (to be codified at 45 C.F.R. § 88.2).

1. Beginning with the text, each of these statutes defines the term through a non-exhaustive list of constituent entities. The Coats-Snowe Amendment provides that the term "*includes* an individual physician, a postgraduate physician training program, and a participant in a program of training in the health professions." 42 U.S.C. § 238n(c)(2) (emphasis added). The Weldon Amendment and the ACA provide that the term "*includes* an individual physician or other health care professional, a hospital, a provider-sponsored organization, a health maintenance organization, a health insurance plan, or any other kind of health care facility, organization, or plan." 42 U.S.C. § 18113(b) (emphasis added); § 507(d)(2), 132 Stat. at 3118. The term "'include' can signal that the list that follows is meant to be illustrative rather than exhaustive." *Samantar v. Yousuf*, 560 U.S. 305, 317 (2010). Furthermore, the statutes contain catch-all phrases: "a participant in a program of training in the health professions" in the Coats-Snowe Amendment and "other health care professional" and "any other kind of health care facility, organization, or plan" in the Weldon Amendment and ACA. Given these features, the statutes plainly contemplate a broader group of health care entities than merely those explicitly listed.

2. Even if the term "health care entity" in these statutes were ambiguous, the Rule's definition is reasonable for the reasons stated above: the statutes explicitly contemplate the inclusion of entities beyond those explicitly listed in the statutes, and Plaintiffs have not identified any entity in the Rule's definition that would not meet the ordinary dictionary definition of "health care entity" or the statutes' catch-all provisions. Furthermore, the Rule recognizes that the definition of "health care entity" is a flexible one that depends on "the context of the factual and legal issues applicable to the situation." 84 Fed. Reg. at 23,196. None of the Rule's definitions applies in all circumstances. *See id.*

4. "Referral or Refer For"

Last, Plaintiffs' challenge to "referral or refer for" is misplaced. As with many of the other definitions in the Rule, "referral or refer for" is not defined in the Weldon Amendment, the Coats-Snowe

Amendment, or the ACA, the only statutes in which they appear. The Rule defines "referral or refer for" through a list of items that qualify as "referral or refer for": the term

> includes the provision of information in oral, written, or electronic form (including names, addresses, phone numbers, email or web addresses, directions, instructions, descriptions, or other information resources), where the purpose or reasonably foreseeable outcome of provision of the information is to assist a person in receiving funding or financing for, training in, obtaining, or performing a particular health care service, program, activity, or procedure.

84 Fed. Reg. at 23,264 (to be codified at 45 C.F.R. § 88.2).

1. Congress has directly spoken to the question of what constitutes a referral, and the Rule's definition is consistent with Congress's intent. Although the statutes do not include a definition of "referral or refer for" and the legislative history is silent on the matter, the ordinary dictionary definition of the term indicates Congress's intent. *See Mayo Found. for Med. Educ. & Research*, 562 U.S. at 52. As HHS explained, "The rule's definition of 'referral' or 'refer for' . . . comports with dictionary definitions of the word 'refer,' such as the Merriam-Webster's definition of 'to send or direct for treatment, aid, information, or decision.'" 84 Fed. Reg. at 23,200 (quoting *Refer*, Merriam-Webster.com, https://www.merriam-webster.com/dictionary/refer) (citing *Refer*, Dictionary.com, available at https://www.dictionary.com/browse/refer). The statutes' structure also makes Congress's intent clear. The addition of the term "for" following "refer" indicates that Congress did not intend the statutes to be limited to a referral document, but rather to include any referral for abortion (or other health services) in a more general sense. For example, the Coats-Snowe Amendment protects not only a health care entity that declines to refer a patient to an abortion provider, but also a health care entity that decline to refer "for" abortions generally. *See, e.g.*, 42 U.S.C. § 238n(a)(1).

2. In the alternative, the Rule's definition should be upheld at *Chevron* step two. In addition to being consistent with dictionary definitions and the statutes' structure, the Rule's definition is faithful to the statutes' remedial purposes. As HHS explained, defining the term "referral or refer for" more narrowly would exclude forms of coercion that the statutes protect against. For example, the Supreme Court recently held that a law requiring health care providers to post notices regarding the availability of state-subsidized abortion likely violated the First Amendment. *See Nat'l Inst. of Family & Life Advocates v. Becerra*, 138 S. Ct. 2361, 2378–79 (2018). A narrower definition would not include referrals of this sort, even though

they constitute unconstitutional coercion of a health care entity that has a conscientious objection to abortion. The Weldon Amendment, Coats-Snowe Amendments, and the ACA are not this narrow, and HHS acted reasonably when it interpreted the term accordingly.

The definition is reasonable for another reason: it uses a non-exhaustive list that "guide[s] the scope of the definition," recognizing that the terms "take many forms and occur in many contexts." 84 Fed. Reg. at 23,201. This flexibility means that "the applicability of the rule would turn on the individual facts and circumstances of each case" (i.e., "the relationship between the treatment subject to a referral request and the underlying service or procedure giving rise to the request"). *Id.*

C. The Rule Is Consistent with Other Provisions of Law.

Plaintiffs also claim that the Rule conflicts with certain statutes. No such conflict exists.

Section 1554 of the ACA. Plaintiffs claim that the Rule conflicts with Section 1554 of the ACA. *See* Cal.'s Compl. ¶ 132, ECF No. 1; S.F.'s Compl. ¶ 115, ECF No. 1; Santa Clara's Compl. ¶ 215. That provision provides as follows:

> Notwithstanding any other provision of [the ACA], the Secretary of Health and Human Services shall not promulgate any regulation that—
>
> (1) creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care;
>
> (2) impedes timely access to health care services;
>
> (3) interferes with communications regarding a full range of treatment options between the patient and the provider;
>
> (4) restricts the ability of health care providers to provide full disclosure of all relevant information to patients making health care decisions;
>
> (5) violates the principles of informed consent and the ethical standards of health care professionals; or
>
> (6) limits the availability of health care treatment for the full duration of a patient's medical needs.

42 U.S.C. § 18114. Plaintiffs' claim is meritless. All six subjects of Section 1554's sub-sections involve the *denial* of information or services to patients. The Rule, however, denies nothing. It merely revises the 2011 Rule to ensure knowledge of, compliance with, and enforcement of, the longstanding Federal Conscience Statutes. At bottom, Plaintiffs' objection is not so much to the Rule as to the Federal Conscience Statutes that the Rule interprets. Under Plaintiffs' theory, any time a health care entity declines

to provide a service to which it objects, HHS would violate Section 1554. Plaintiffs' argument, then, is that Congress essentially abrogated the Federal Conscience Statutes through Section 1554. Plaintiffs take this position even as to the Weldon Amendment, which Congress has readopted every year since the ACA's passage.

The Court should reject Plaintiffs' untenable position. First, Section 1554 expressly applies "[n]otwithstanding any other provision *of this Act*," 42 U.S.C. § 18114 (emphasis added)—that is, the ACA. The great majority of the Federal Conscience Statutes that the Rule implements, of course, are not part of the ACA. Nor are the statutes that give the Secretary authority to award funding grants part of the ACA. Had Congress intended Section 1554 to extend beyond the ACA, it could have simply specified that it applies "[n]otwithstanding any other provision of law[.]" 42 U.S.C. § 18032(d)(3)(D)(i). By its own terms, Section 1554 does not apply to conscience protection provisions outside of the ACA, and therefore does not undermine the Rule's validity.[5]

It is a basic principle of statutory interpretation, moreover, that Congress "does not alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions—it does not, one might say, hide elephants in mouseholes." *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 468 (2001). Plaintiffs would have this Court believe that Congress effectively gutted the Federal Conscience Statutes, without any meaningful legislative history so indicating, when it passed Section 1554. That proposition is implausible on its face. To the contrary, Congress went out of its way to clarify that nothing in the ACA undermines the Federal Conscience Statutes:

> Nothing in [the ACA] shall be construed to have *any effect* on Federal laws regarding (i) conscience protection; (ii) willingness or refusal to provide abortion; and (iii) discrimination on the basis of the willingness or refusal to provide, pay for, cover, or refer for abortion or to provide or participate in training to provide abortion.

42 U.S.C. § 18023(c)(2) (emphasis added). This clear expression of congressional intent undercuts Plaintiffs' argument that Section 1554 somehow prevents HHS from giving effect to the Federal Conscience Statutes. And, even if that somehow were not enough, Congress added *additional* conscience

[5] Another reason that Section 1554 is of no moment is that the Rule does not create, impede, interfere with, restrict, or violate anything. Instead, it simply limits what the government chooses to fund (i.e., providers that do not engage in discrimination).

protections in the ACA. *See, e.g.*, 42 U.S.C. § 18113. The ACA adds to and underscores the importance of the Federal Conscience Statutes, contrary to Plaintiffs' claim.

Defendants' interpretation of Section 1554 also comports with common sense. Section 1554's subsections are open-ended. Nothing in the statute specifies, for example, what constitutes an "unreasonable barrier[]," "appropriate medical care[,]" "all relevant information[,]" or "the ethical standards of health care professionals[,]" 42 U.S.C. § 18114. And there is nothing in the ACA's legislative history that sheds light on this provision. Under these circumstances, it is a substantial question whether Section 1554 claims are reviewable under the APA at all. *See Citizens to Pres. Overton Park*, 401 U.S. at 410 (explaining that the APA bars judicial review of agency decision where "statutes are drawn in such broad terms that in a given case there is no law to apply" (citation omitted)).[6] But even if Section 1554 claims are reviewable, it is inconceivable that Congress intended to subject the entire U.S. Code to these general and wholly undefined concepts and that it did so without leaving any meaningful legislative history.

Other principles point in the same direction. "[I]t is a commonplace of statutory construction that the specific governs the general," *Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 384 (1992). "[T]he specific provision is construed as an exception to the general one." *RadLAX Gateway Hotel, LLC v.Amalgamated Bank*, 566 U.S. 639, 645 (2012) (citation omitted). Thus, even if Section 1554 applied to regulations implementing the Federal Conscience Statutes (it does not), and even if Section 1554 and those Statutes were in conflict (they are not), the Federal Conscience Statutes would prevail over Section 1554. Section 1554 is at best a general prohibition of certain types of regulations (very broadly described) and does not speak to conscience objections at all. The Federal Conscience Statutes, by contrast, contain specific protections with respect to specific activities in the context of federally funded health programs and research activities. Section 1554, therefore, must give way to the more specific Federal Conscience Statutes and the Rule interpreting them.

[6] Even within the ACA, HHS routinely issues regulations placing criteria and limits on what the government will fund, and on what will be covered in ACA programs. Under Plaintiffs' standardless interpretation of Section 1554, it is far from clear that the government could ever impose any limit on any parameter of a health program—even if the program's own statute requires it. Nor is it evident how a court could possibly evaluate challenges brought under Section 1554 if that provision sweeps as broadly as Plaintiffs claim.

Section 1557 of the ACA. California and Santa Clara further claim that the Rule conflicts with Section 1557 of the ACA, 42 U.S.C. § 18116. *See* Cal.'s Compl. ¶ 132; Santa Clara's Compl. ¶ 215(d). Plaintiffs' claim is meritless. Section 1557 provides that, subject to certain exceptions, "an individual shall not," on the grounds of race, color, national origin, sex, disability, or age, "be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance, ..." 42 U.S.C. § 18116(a). Nothing in the Rule runs afoul of this prohibition, and Plaintiffs' argument with respect to Section 1557 fails for essentially the same reasons above.

HHS has explained that it intends "to read every law passed by Congress in harmony to the fullest extent possible so there is maximum compliance with each law," including both the Federal Conscience Statutes and Section 1557. 84 Fed. Reg. at 23,183. Plaintiff's speculation that there could be some situation in which the Rule conflicts with Section 1557 is therefore just that—speculation—and cannot support a facial challenge. Even assuming there could be some conflict, however, Congress expressly stated that nothing in the ACA should be construed to have "*any effect*" on federal conscience protection. 42 U.S.C. § 18023(c)(2) (emphasis added). Plaintiffs' claim under Section 1557 (i.e., that the Rule, which implements the Federal Conscience States is inconsistent with Section 1557) cannot survive such clear contrary instruction from Congress.

Emergency Medical Treatment and Active Labor Act (EMTALA). Plaintiffs also argue that the Rule conflicts with EMTALA, which requires hospitals with emergency departments to either provide emergency care "within the staff and facilities available at the hospital" or transfer the patient to another medical facility in circumstances permitted by the statute. 42 U.S.C. § 1395dd(b)(1)(A). *See* Cal.'s Compl. ¶ 131; S.F.'s Compl. ¶ 116; Santa Clara's Compl. ¶ 215. There is no conflict, however. Once again, HHS "intends to read every law passed by Congress in harmony to the fullest extent possible so that there is maximum compliance with the terms of each law." 84 Fed. Reg. at 23,183. With respect to EMTALA specifically, HHS indicated that it generally agrees with the explanation in the preamble to the 2008 Rule that fulfilling the requirements of EMTALA would *not* conflict with the Federal Conscience Statutes that the Rule interprets. *See id.*

Plaintiffs point to the possibility that emergency medical personnel may refuse to provide care, as well as the possibility of consequences for non-compliance. *See, e.g.*, Cal.'s PI Mem. 16–17. In considering Plaintiffs' facial challenge to the Rule, however, the Court should not assume that some future, hypothetical conflict between EMTALA and the Rule will come to pass. *See Reno v. Flores*, 507 U.S. 292, 309 (1993). Indeed, HHS has explained that it is "not aware of any instance where a facility required to provide emergency care under EMTALA was unable to do so because its entire staff objected to the service on religious or moral grounds." 73 Fed. Reg. 78,087. Regardless, HHS has stated that "where EMTALA might apply in a particular case, the Department would apply both EMTALA and the relevant law under this rule harmoniously to the extent possible." 84 Fed. Reg. 23,188.

Title X. California and Santa Clara also argue that the Rule somehow conflicts with Title X of the Public Health Services Act, *see* Pub. L. No. 91-572, 84 Stat. 1504 (1970), which provides federal subsidies for certain types of family planning services. *See* Cal.'s Compl. ¶ 131; Santa Clara's Compl. ¶ 215(f). They suggest that the Rule may be inconsistent with the requirement that Title X family planning services be "voluntary." *See* Cal.'s Compl. ¶ 76; Santa Clara's Compl. ¶ 215(f). However, nothing in the Rule—which merely facilitates health care entities' exercise of their federal conscience rights—makes anyone accept Title X family planning services against their will. *See, e.g.*, Pam Belluck, *Planned Parenthood Refuses Federal Funds over Abortion Restrictions*, N.Y. TIMES (Aug. 19, 2019), https://nyti.ms/2NfgJQc, (quoting the acting president of Planned Parenthood: "When you have an unethical rule that will limit what providers can tell our patients, it becomes really important that we not agree to be in the program").

Title VII of the Civil Rights Act of 1964. Plaintiffs also argue that because the Rule does not include the same "undue hardship" exception that Congress included in Title VII, there is a conflict between that statute and the Rule. *See* Cal.'s Compl. ¶ 131; S.F.'s Compl. ¶ 117; Santa Clara's Compl. ¶ 215(e). Once again, however, the Rule merely implements the substantive requirements of the Federal Conscience Statutes. These statutes, unlike Title VII, do not contain an undue hardship exception. Indeed, that Congress included an "undue hardship" exception in Title VII but declined to do so in the Federal Conscience Statutes is strong evidence that Congress did not intend for such an exception to apply. *See, e.g.*, *Franklin Nat'l Bank of Franklin Square v. New York*, 347 U.S. 373, 378 (1954) (finding "no indication that Congress intended to make [an issue] subject to local restrictions, as it has done by express

language in several other instances"). In addition, the Federal Conscience Statutes apply in more specific contexts than does Title VII. Therefore, it is reasonable to infer—given the absence of the "undue hardship" limitation in the Federal Conscience Statutes—that Congress did not intend for that limitation to apply. *See* 84 Fed. Reg. at 23,191; *see also Morales*, 504 U.S. at 384 ("[I]t is a commonplace of statutory construction that the specific governs the general[.]").

"Non-Directive" Appropriations Rider. California and Santa Clara also argue that the Rule somehow conflicts with HHS appropriations language requiring that all pregnancy counseling be non-directive. Cal.'s Compl. ¶ 131 (citing 132 Stat. at 2981); Santa Clara's Compl. ¶ 215(f). Their claim fails. The rider applies only to the Title X appropriation, and the Rule does not require Title X funding recipients to engage in pregnancy counseling at all—much less counseling that directs women to any particular outcome with respect to their pregnancy. The Rule implements the Federal Conscience Statutes. Accepting Plaintiffs' argument that the Rule unlawfully requires withholding information from patients would require the Court to believe that—despite Congress's explicit provisions in the Federal Conscience Statutes—Congress, through an appropriations rider, repealed those protections and compelled health care entities to counsel on all pregnancy options, including abortion, even if they have religious or moral objections to providing such counseling—especially given that the Congress that first adopted the appropriations rider also adopted the Coates-Snowe Amendment. That proposition is wholly implausible and should be rejected. *See Tenn. Valley Auth. v. Hill*, 437 U.S. 153, 190 (1978).

D. The Rule Is Not Arbitrary and Capricious.

The Rule easily satisfies the deferential review afforded to agency action under the APA. Such action is not arbitrary and capricious if the agency "examined the relevant data and articulated a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made.'" *Motor Vehicle Mfrs. Ass'n of the United States v. State Farm Mut. Auto. Ins.*, 463 U.S. 29, 43 (1983) (quoting *Burlington Truck Lines, Inc. v. United States*, 371 U.S. 156, 168 (1962)). Courts' "review is 'narrow;' [they] may not 'substitute [their] judgment for that of the agency.'" *Gill v. DOJ*, 913 F.3d 1179, 1187 (9th Cir. 2019) (quoting *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 513–14 (2009)). "And, [they] will 'uphold a decision of less than ideal clarity if the agency's path may reasonably be discerned.'" *Id.* at 1187–88 (quoting *State Farm*, 463 U.S. at 43).

1. HHS Adequately Explained Why It Changed Course.

The Rule undeniably revises HHS's approach to enforcing the Federal Conscience Statutes. But HHS is permitted to "'consider varying interpretations and the wisdom of its policy on a continuing basis,' for example, in response to changed factual circumstances, or a change in administrations." *Nat'l Cable & Telecomm. Ass'n v. Brand X Internet Servs.*, 545 U.S. 967, 981 (2005) (quoting *Chevron*, 467 U.S. at 863–64). There is no heightened standard when an agency changes its policy so long as the agency shows that "the new policy is permissible under the statute, that there are good reasons for it, and that the agency believes it to be better, which the conscious change of course adequately indicates." *Fox Television*, 556 U.S. at 515. HHS has met that standard here.

Contrary to California's position, Cal.'s PI Mem. 18–20, HHS did acknowledge that it was changing its policy, including its policy with respect to the Rule's assurance and certification requirements. HHS determined that the preexisting regulatory structure was insufficient to protect the statutory rights and liberty interests of health care entities. *See* 84 Fed. Reg. at 23,228. And it reasonably judged that the 2011 Rule lacked adequate measures to ensure compliance with the Federal Conscience Statutes and promoted confusion, not clarity, about the scope of those statutory protections. The 2011 Rule referenced to just three of the many Federal Conscience Statutes and did not provide adequate incentives for covered entities to "institute proactive measures to protect conscience, prohibit coercion, and promote nondiscrimination." *Id.* at 23,228. Moreover, the 2011 Rule failed to provide sufficient information concerning the scope of the various Federal Conscience Statutes, especially regarding their interaction with state laws, including state laws adopted since the promulgation of the 2011 Rule. *Id.*; *see also* NPRM, 83 Fed. Reg. at 3,889.

In the same breath that it claims that HHS did not give reasons for the change, California also criticizes one of HHS's stated reasons—the increase in complaints of alleged violations of the Federal Conscience Statutes. Cal.'s PI Mem. 18–19. The increase in complaints is, of course, just "one of the many metrics used to demonstrate the importance of this rule." 84 Fed. Reg. at 23,229. In addition, the Rule is based on HHS's determination (as explained above) that the existing rule provided inadequate mechanisms for HHS to ensure compliance with the Federal Conscience Statutes, and caused confusion about the scope of conscience protections. In any event, the increase in complaints was both real and

significant. *See* NPRM, 83 Fed. Reg. at 3886; Final Rule, 84 Fed. Reg. at 23,229. Many of these complaints allege violations of religious and conscience-based beliefs in the medical setting, and while a large subset of them complain of conduct that is outside the scope of the Federal Conscience Statutes and the Rule,[7] some do implicate the relevant statutes, *see*, *e.g.*, A.R. 544,188–207, 544,516, 544,612–23. Further, the complaints overall illustrate the need for HHS to clarify the scope and effect of the Federal Conscience Statutes.

2. HHS Reasonably Weighed the Rule's Costs and Benefits.

In addition to HHS's purpose of improving knowledge about and enforcement of the Federal Conscience Statutes, HHS identified four primary benefits of the Rule in its cost-benefit analysis: (1) increasing the number of health care providers; (2) improving the doctor-patient relationship; (3) eliminating the harm from requiring health care entities to violate their conscience; and (4) reducing unlawful discrimination in the health care industry and promoting personal freedom. 84 Fed. Reg. at 23,246. Plaintiffs criticize HHS's conclusion that the Rule will have the benefit of increasing the number of health care providers. *See* S.F.'s Mem. Points & Auth. in Support of Mot. Prelim. Inj. 14–15, ECF No. 14 [hereinafter S.F.'s PI Mem.]; Cal.'s Compl ¶ 149. That Plaintiffs might give the 2009 poll cited by HHS less weight than HHS did is insufficient to show that the agency acted unreasonably in considering it. *See San Luis & Delta-Mendota Water Auth. v. Locke*, 776 F.3d 971, 995 (9th Cir. 2014) (Even "if the only available data is "'weak,' and thus not dispositive," an agency's reliance on such data "does not render the agency's determination 'arbitrary and capricious.'" (quoting *Greenpeace Action v. Franklin*, 14 F.3d 1324, 1336 (9th Cir. 1992)). HHS's policy determination relied on its own analysis, the comments it received in response to the NPRM, anecdotal evidence, and the 2009 poll. 84 Fed. Reg. at 23,247. There was nothing unreasonable, arbitrary, or capricious in HHS considering the poll among other non-empirical evidence. *See Fox Television*, 556 U.S. at 521 ("[E]ven in the absence of evidence, the agency's predictive judgment (which merits deference) makes entire sense. To predict that complete immunity for fleeting expletives, ardently desired by broadcasters, will lead to a substantial increase in fleeting expletives seems to us an exercise in logic rather than clairvoyance."). Plaintiffs criticize HHS for not having run studies

[7] For example, many complaints were from patients and/or parents who criticized the vaccination policies at schools and medical offices, *see, e.g.*, AR 542,458.

after the 2011 Rule, but the arbitrary-and-capricious standard does not permit outsiders to compel the agency to investigate an issue in a particular way. *See Chamber of Commerce of U.S. v. SEC*, 412 F.3d 133, 142 (D.C. Cir. 2005).

Moreover, HHS scarcely assigned controlling weight to either the 2009 survey or the ramifications of that survey: HHS ultimately concluded merely that it lacked sufficient data to quantify the theoretical effect but that the available data was adequate "to conclude that the rule will increase, or at least not decrease, access to health care providers and services." 84 Fed. Reg. at 23,247; *The Lands Council v. McNair*, 537 F.3d 981, 993 (9th Cir. 2008). ("[W]e are to conduct a 'particularly deferential review'" of an "'agency's predictive judgments about areas that are within the agency's field of discretion and expertise . . . .'" (citation omitted)).[8] Plaintiffs also criticize HHS for not including "evidence" that the Rule will increase the number of health care providers and entities. *See* S.F.'s PI Mem. 14–15. But an agency need not perform an impossible study to determine the specific effects of a rule that does not yet exist, *see BellSouth Corp. v. FCC*, 162 F.3d 1215, 1221 (D.C. Cir. 1999).

Whether the Rule would increase or decrease the number of providers is a difficult policy assessment that should be left to the entity with responsibility for making those assessments—HHS. Indeed, "[w]hether [the Court] would have done what the agency did is immaterial," so long as the agency engages in an appropriate decisionmaking process. *Mingo Logan Coal Co. v. EPA*, 829 F.3d 710, 718 (D.C. Cir. 2016). The court asks only whether the decision "was based on a consideration of the relevant factors and whether there has been a clear error of judgment." *Citizens to Pres. Overton Park*, 401 U.S. at 416. Here, HHS assessed the available evidence and reasonably concluded that the Rule would "increase, or at least not decrease" the number of providers. 84 Fed. Reg. at 23,247.

California suggests that HHS did not adequately account for the existing effects of Title VII, which Plaintiffs cast as a panacea that has adequately protected the consciences of all health care employees. Cal.'s PI Mem. 21–23. But Title VII's protections are distinct from the Federal Conscience Statutes that Congress separately enacted. *See* 84 Fed Reg. 23,191. What is more, HHS reasonably concluded that the

[8] HHS also considered other potential benefits of the rule for health care entities, such as the reduction in "harm that providers suffer when they are forced to violate their consciences." 84 Fed. Reg. 23,246 (citing, among other sources, Kevin Theriot & Ken Connelly, *Free to Do No Harm: Conscience Protections for Healthcare Professionals*, 49 Ariz. Stat. L.J. 549, 565 (2017)).

status quo was not adequately protecting at least some health care entities who object to participating in certain care, in part due to the increasing number of complaints it was receiving. *See* 84 Fed. Reg. 23,254 (rejecting the option of maintaining the status quo because that would "perpetuate the current circumstances necessitating Federal regulation, which include (1) inadequate to non-existent Federal government frameworks to enforce Federal conscience and antidiscrimination laws and (2) inadequate information and understanding about the obligations of regulated persons and entities and the rights of persons, entities, and health care entities . . . under the Federal conscience and antidiscrimination laws"). And while the Rule adopts the Title VII reasonable-accommodation-of-religion framework in part by recognizing that "when appropriate accommodations are made for objections protected by Federal conscience and antidiscrimination laws, those accommodations do not themselves constitute discrimination[,]" HHS sensibly declined to adopt Title VII's "undue hardship" exception because "Congress chose not to place that limitation on the protections set forth in the [later-in-time] Federal conscience and antidiscrimination laws." 84 Fed. Reg. at 23,191.

Plaintiffs also argue that HHS inadequately considered the effect of the Rule on health-care access, Santa Clara Compl. ¶ 205, Cal.'s Compl. ¶ 147, S.F.'s Compl. ¶ 121, but HHS received no data that would "enable[] a reliable quantification of the effect of the rule on access to providers and to care[,]" 84 Fed. Reg. at 23,250. Absent reliable data from which to quantify the effects, HHS was scarcely arbitrary in relying on the data it did have—and that data indicated that, if anything, the Rule would increase the number of available providers, which can reasonably be predicted to improve patient care. *See id.* at 23,180; *see also Fox Television*, 556 U.S. at 521.

Further, HHS explicitly sought comments on "whether this final rule would result in unjustified limitations on access to health care." 84 Fed. Reg. at 23,250; NPRM, 83 Fed. Reg. at 3,900 (request for comment). Ultimately, and as HHS explained, the majority of the comments it received in response to that request focused on preexisting discrimination in health care and did not attempt to answer the question of how the Rule itself would affect access to health care. 84 Fed. Reg. at 23,250; *see also* Cal.'s PI Mem. 24–26 (similarly focusing on preexisting discrimination and making conjectural statements regarding the actual impact of the Rule). HHS studied academic literature relating to preexisting statutes, but found "insufficient evidence to conclude that conscience protections have negative effects on access to health

care." *See id.* at 23,251 & n.345. HHS also considered a report with anecdotal data on discrimination against LGBT patients in states with religious freedom laws. 84. Fed. Reg. at 23,252. But, as HHS explained, that report contained only anecdotal accounts—thus making it unfit for extrapolation—and made no attempt to establish a causal mechanism between the religious freedom laws and the discrimination it reported. *Id.*

Many of these questions—the precise effect of the Rule on patient care, the effort that will be required to comply with a new policy—are difficult to answer. Plaintiffs' view seems to be that an agency cannot take an action until it has commissioned or executed studies on every potential repercussion of that action. While that might be a technocrat's dream, it is not what the APA requires. Instead, the APA commits these decisions to the agency's expertise. "Whether [the Court] would have done what the agency did is immaterial[,]" so long as the agency engages in an appropriate decisionmaking process. *Mingo Logan*, 829 F.3d at 718. Where, as here, HHS assessed the available evidence on a subject, and reached a reasonable conclusion, this Court should not accept Plaintiffs' invitation to second-guess the agency's policy conclusions.

Finally, Santa Clara claims that the Rule provides "little guidance" on how health care entities can provide health care while respecting the conscience rights of their employees. Santa Clara's Mem. Points & Auth. in Support of Mot. Prelim. Inj. 17–18, ECF No. 36 [hereinafter Santa Clara's PI Mem.]. Santa Clara essentially claims confusion about when and how the Rule might apply in certain hypothetical situations. *See id.* But again, Plaintiffs mount a facial challenge, and Santa Clara's uncertainty about the correct outcome in a hypothetical set of facts does not render the entire Rule arbitrary and capricious in all applications. *See Am. Hosp. Ass'n v. NLRB*, 499 U.S. 606, 619 (1991). Further, a health care entity can easily request HHS's technical assistance to resolve any questions about a specific set of facts. *See* 84 Fed. Reg. at 23,180.

E. The Rule Complies with the Spending Clause.

The governmental plaintiffs allege that the Rule violates the Spending Clause for several reasons, Cal.'s Compl. ¶¶ 142-80, S.F.'s Compl. ¶¶ 130-32, Santa Clara's Compl. ¶¶ 253–54, but all of their contentions are wrong. First, although Plaintiffs purport to object to the *Rule*, their true objection is to the Federal Conscience Statutes, the source of the conditions on the government's offer of funds. The Rule

does not alter those substantive conscience requirements. *See* 84 Fed. Reg. at 23,256. Nor can Plaintiffs show that the Rule deviates from the Federal Conscience Statutes in an unconstitutional way; many of their arguments—for example, that the amount of funding at stake is coercively large—apply equally to the Rule and the Federal Conscience Statutes. In other instances, the Rule is clearly *less* susceptible to attack than the statutes—for example, Plaintiffs argue that the conditions on federal grants are ambiguous, but the Rule provides greater clarity. Plaintiffs' requested relief against the Rules would therefore not redress their objections to the Statutes.

Furthermore, Plaintiffs' objections under the Spending Clause fail on their merits:

Coercion. A conditional offer of federal funds will be found to be unduly coercive only in the unusual case—"[i]n the typical case we look to the States to defend their prerogatives by adopting 'the simple expedient of not yielding' to federal blandishments." *NFIB*, 567 U.S. at 579 (Roberts, C.J.) (quoting *Massachusetts v. Mellon*, 262 U. S. 447, 482 (1923)). Comparing this case to *NFIB* shows that no unconstitutional coercion has occurred.

First, unlike in *NFIB*, where the states were provided with a binary choice—either expand their Medicaid programs or lose their Medicaid funding—here, it is far from clear that noncompliance with the Federal Conscience Statues and the Rule would impact all of the funding sources identified by Plaintiffs. HHS has a variety of enforcement options when the conditions for its grants are not met, and the Rule clarifies that HHS will always begin by trying to resolve a potential violation through informal means. 84 Fed. Reg. at 23,271 (explaining that a failure to comply with the Statutes "*will be resolved by informal means whenever possible*" (emphasis added)); *see also supra* note 3 (discussing HHS's enforcement procedures). Far from the "gun to the head" at issue in *NFIB*, 567 U.S. at 581, this possibility of informal enforcement proceedings is not unduly coercive. Plaintiffs' apocalyptic and hypothetical scenarios of complete funding loss—scenarios that have not remotely come to pass in the decades that many of the Federal Conscience Statutes have existed—are of no help. Plaintiffs cannot succeed on their facial challenge by identifying a handful of implausible and speculative circumstances in which the Federal Conscience Statutes and the Rule *might* have a coercive effect; instead, they must show that the Rule has *no* constitutional applications. *See United States v. Sineneng-Smith*, 910 F.3d 461, 470 (9th Cir. 2018). And, the further factual context that would be available if such a scenario did occur would be helpful to

the Court in evaluating the Spending Clause claims, thus highlighting the lack of ripeness at this time.

Second, unlike in *NFIB*, Plaintiffs cannot plead surprise because the Federal Conscience Statutes and their conditions have existed for decades. *See, e.g.*, 42 U.S.C. § 300a-7 (first Church Amendments enacted in 1973). The ACA provisions at issue in *NFIB*, by contrast, required the states to adopt an entirely new Medicaid expansion. *Cf. NFIB*, 567 U.S. at 584 (Roberts, C.J.) (criticizing the Medicaid expansion as an attempt to "enlist[] the States in a new health care program"). If anything, the Rule should be an improvement from Plaintiffs' perspective because the Rule provides additional transparency, notice, and insight into HHS's enforcement processes.

Ambiguity. Plaintiffs make no attempt to argue that the Federal Conscience Statutes are ambiguous, likely because each clearly provides unambiguous notice to funding recipients of the anti-discrimination provisions. The Rule—which adds additional clarification and interpretation on top of that provided in the Statutes—is necessarily clearer and less ambiguous than the Statutes. Either passes the ambiguity analysis, which focuses on whether potential recipients are aware that the government has placed conditions on federal funds, rather than on whether every detail of the conditions has been set forth. *See, e.g.*, *Mayweathers v. Newland*, 314 F.3d 1062, 1067 (9th Cir. 2002) (observing that "conditions may be 'largely indeterminate,' so long as the statute 'provid[es] clear notice to the States that they, by accepting funds under the Act, would indeed be obligated to comply with the conditions.' Congress is not required to list every factual instance in which a state will fail to comply with a condition. . . . Congress must, however, make the existence of the condition itself . . . explicitly obvious." (quoting *Pennhurst State Sch. & Hosp. v. Halderman*, 451 U.S. 1, 24–25 (1981))). In addition, Plaintiffs' concern that they will be penalized for misconduct by sub-recipients, even if they had no knowledge of any violations or attempted to stop them, is rank speculation about hypothetical enforcement actions, and was addressed by HHS in making changes to the Rule based on comments received on the NPRM. 84 Fed. Reg. at 23,220. Plaintiffs' Spending Clause claims are unripe for resolution.

Retroactivity. According to Plaintiffs, the Rule retroactively changes the conditions that apply to Plaintiffs. But this is merely a retread of Plaintiffs' statutory authority arguments, which fail for the reasons described above. In any event, there is no Spending Clause barrier to clarifying the terms on which an entity may receive federal funding. *Cf. NFIB*, 567 U.S. at 582–83 (holding that the Medicaid statute

authorized Congress to modify its terms without creating Spending Clause problems, so long as the modifications did not rise to the level of creating a new program).

Nexus. Plaintiffs' allegation that the Rule is not adequately related to the purpose of the targeted funding fails because it is the Federal Conscience Statutes that establish the linkage between conscience protections and federal funding. The purpose of the Statutes is to ensure that federal funds do not subsidize discrimination against individual and institutional health care entities on the basis of their moral, religious, or other beliefs about certain care (or coverage), in service of the government's interests in protecting the free exercise of religion and in encouraging and overseeing a robust health care system. *See Mayweathers*, 314 F.3d at 1066–67 (upholding RLUIPA against a Spending Clause challenge because "by fostering non-discrimination, RLUIPA follows a long tradition of federal legislation designed to guard against unfair bias and infringement on fundamental freedoms"). Plaintiffs object that the funding for their "labor and educational programs" might also be at risk, Cal.'s PI Mem. 31, but offer no supporting evidence. The Rule applies only to funds administered or programs conducted by HHS. Plaintiffs should not succeed on their *facial* challenge on the speculative theory that the Rule would somehow affect funds provided by the Departments of Labor or Education.

F. The Rule Does Not Violate the Separation of Powers.

Plaintiffs assert that the Rule violates the separation of powers because an agency "cannot amend or cancel appropriations that Congress has duly enacted." Santa Clara's Compl. ¶ 257. But the Rule does not "usurp powers that have been assigned to Congress," S.F.'s Compl. ¶ 129—rather the Rule *complies* with congressional dictates. As explained above, the Rule does not change the substantive law at all. 84 Fed. Reg. 23,256. Agencies commonly enact such regulations implementing Congress's funding conditions. *See, e.g.*, Final Rule, 68 Fed. Reg. 51,334-01 (Aug. 26, 2003) (a regulation by twenty-two agencies implementing Title VI, the Rehabilitation Act, and the Age Discrimination Act). Once again, Plaintiffs' arguments to the contrary are a retread of their erroneous statutory authority arguments.

G. The Rule Complies with the Establishment Clause.

Plaintiffs' Establishment Clause claims fail for several reasons. First, under their theory, it would be the preexisting Federal Conscience Statutes that violate the Establishment Clause by placing anti-discrimination conditions on federal funding that (in Plaintiffs' view) unduly prioritize provider's

conscience rights over the preferences of others.[9] Yet Plaintiffs do not challenge the Statutes. *See* Santa Clara's PI Mem. 3–5 (describing several of the Statutes with approval). As explained above, the Rule does not change the substantive law that Congress established in the Federal Conscience Statutes. *See* 84 Fed. Reg. at 23,256.

Furthermore, several of the Federal Conscience Statutes have already been upheld against Establishment Clause challenges, and that reasoning is instructive as to the Rule. *See Chrisman v. Sisters of St. Joseph of Peace*, 506 F.2d 308, 311 (9th Cir. 1974) (upholding a provision of the Church Amendments—Pub. L. No. 93-45, 87 Stat. 95 § 401—because Congress was seeking to "preserve the government's neutrality in the face of religious differences" rather than to "affirmatively prefer[] one religion over another"); *see also Kong v. Scully*, 341 F.3d 1132 (9th Cir. 2003), *op. am. on denial of reh'g*, 357 F.3d 895 (9th Cir. 2004) (upholding several Federal Conscience Statutes concerning payments for nonmedical care of objectors). Like the Statutes, the Rule serves the legitimate secular purpose of alleviating potential burdens of conscience on individual and institutional health care entities. Like the Statutes, the Rule neither promotes nor subsidizes any religious message or belief; rather, it explains the enforcement processes for existing federal statutes. And, like many of the Statutes, the Rule is generally neutral between various religions and between religion and non-religion. *Cf., e.g.*, 42 U.S.C. § 238n (Coats-Snowe Amendment, the applicability of which does not turn on a religious belief); Pub. L. No. 115-245, Div. B., sec. 507(d) (Weldon Amendment, the applicability of which does not turn on religious belief); 42 U.S.C. § 300a-7 (Church Amendments, which equally protect health care providers from discrimination based on religious beliefs or moral convictions); *contra* S.F.'s PI Mem. 19–21 (arguing that the definition of "discrimination," which does not involve religion, improperly advances religion). The Rule, like the Statutes, fits well within the mantra that "there is ample room for accommodation of religion under the Establishment Clause." *Corp. of Presiding Bishop of Church v. Amos*, 483 U.S. 327, 338 (1987).

Burden on third parties. Contrary to Plaintiffs' position, the Establishment Clause does not bar

[9] The *Santa Clara* Plaintiffs briefly refer to a "strict scrutiny" test, Santa Clara's Mem. 23 (citing *Larson v. Valente*, 456 U.S. 228 (1982)), that applies only to *denominational* preferences. *Larson*, 456 U.S. at 246. Because they cannot show that the Rule prefers religion to non-religion, they certainly cannot show any such sectarian preference.

all religious accommodations that could have an adverse effect on others. For example, in *Amos*, the Supreme Court held that Title VII's religious exemption to the prohibition against religious discrimination in employment was consistent with the Establishment Clause even though it allowed an employer to terminate the plaintiff's employment. *Id.* While the plaintiff was "[u]ndoubtedly" adversely affected, "it was the Church[,] . . . not the Government" that caused that result. *Id.* at 337 n.15. Similarly, in *Doe v. Bolton*, the Supreme Court characterized a state statute allowing hospitals, physicians, and other employees to refrain from participating in abortions as "appropriate protection [for] the individual and [ ] the denominational hospital." 410 U.S. 179, 197–98 (1973). Here, the Federal Conscience Statutes (and, therefore, the Rule) do not directly burden anyone; instead, they simply encourage entities not to discriminate. If any adverse effects occur, they result from the conscience decisions of health care entities, not the government. *See Amos*, 483 U.S. at 337 n.15 (noting plaintiff employee "was not legally obligated" to take the steps necessary to save his job, and that his discharge "was not required by statute"). To the extent that it is appropriate to consider the burdens on third parties and determine if they "override other significant interests," *Cutter v. Wilkinson*, 544 U.S. 709, 720, 722 (2005), Congress has already struck this balance by conditioning federal health care funds on compliance with the Federal Conscience Statutes.

Coercion. Nor does the Rule coerce any religious exercise. Quite the opposite: it allows providers to act in accordance with their consciences due to better understanding and enforcement of the Statutes. And, the Federal Conscience Statutes and the Rule do not "dictate" to anyone, *id.*; rather they offer or provide information about conditioned federal funds for recipients to accept or reject. If Plaintiffs do not wish to avoid discriminating as required by Congress, then they are free to decline HHS funds and make their own unfettered decisions. *See* Belluck, *supra*.

H. The Rule Complies with the Free Speech Clause.

The right to freedom of speech "prohibits the government from telling people what they must say." *Rumsfeld v. Forum for Acad. & Inst. Rights, Inc.*, 547 U.S. 47, 61 (2006); *see Agency for Int'l Dev. v. All. for Open Soc'y Int'l, Inc.*, 133 S. Ct. 2321, 2327 (2013). But contrary to the certain plaintiffs' far-fetched claim, Santa Clara's Compl. ¶¶ 232–240,[10] the Rule does not "compel speech"—by Plaintiffs, LGBTQ

[10] The plaintiffs in the Santa Clara action, with the exception of the County of Santa Clara itself, bring this particular claim. *See* Santa Clara's Compl. at 67. None describe themselves in their Complaint

individuals, or any other persons—in violation of the Free Speech Clause. As a threshold matter, the plaintiffs attempt to raise this claim on behalf of third-party LGBTQ and other patients. Santa Clara's Compl. ¶¶ 235–39. But as a general rule, a plaintiff "must assert his own legal rights and interests, and cannot rest his claim to relief on the legal rights or interests of third parties." *Warth v. Seldin*, 422 U.S. 490, 499 (1975). The allegations in the Santa Clara Complaint fail to overcome this general rule, *see generally* Santa Clara's Compl., and therefore lack standing to bring this claim. *See Mills v. United States*, 742 F.3d 400, 407 (9th Cir. 2014); *Kowalski v. Tesmer*, 543 U.S. 125, 129–130 (2004). But even if they had established standing, the Rule's enforcement of statutorily-protected conscience rights through federal funding conditions does not place any restrictions, speech-related or otherwise, on patients.

Indeed, this claim runs headlong into the Supreme Court's decision in *Rust v. Sullivan*, 500 U.S. 173, 193 (1991). There, the Court confirmed that the Constitution clearly permits the Government to "selectively fund a program to encourage certain activities it believes to be in the public interest," *id.*, and upheld Title X funding restrictions "prohibiting counseling, referral, and the provision of information regarding abortion as a method of family planning" under the Free Speech clause. *Id.* at 194. Here, the Rule administers much less restrictive funding restrictions: it places no independent restrictions on anyone and merely implements the Federal Conscience Statutes' requirements that health care entities receiving federal funds adhere to the Statute's anti-discrimination provisions. *See* 84 Fed. Reg. at 23,179. As such, plaintiffs' Free Speech claim fails.

I. The Rule Complies with the Due Process Clause and Equal Protection.

The *Santa Clara* Plaintiffs also claim that the Rule "violates the rights of Plaintiffs' patients to privacy, liberty, dignity, and autonomy," Santa Clara's Compl. ¶ 229, and that the Rule's "purpose and effect . . . are to discriminate against Plaintiffs' patients based on their sex, gender identity, transgender status, gender nonconformity, and exercise of fundamental rights, including the rights to bodily integrity and autonomous medical decisionmaking, the rights of access to abortion and contraceptives, and the rights to live and express oneself consistent with one's gender identity," *id.* ¶ 245. These claims fall because these plaintiffs lack standing to raise claims on behalf of patients. *See Warth*, 422 U.S. at 499;

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as impacted by the Rule as patients. *See id.* ¶¶ 13 –46.

Mills, 742 F.3d at 407; *Kowalski*, 543 U.S. at 129–130. They also fail on the merits:

Due process. Courts have "always been reluctant to expand the concept of substantive due process because guideposts for responsible decisionmaking in this unchartered area are scarce and openended," *Collins v. City of Harker Heights, Tex.*, 503 U.S. 115, 125 (1992). Accordingly, plaintiffs must provide "a 'careful description' of the asserted fundamental liberty interest" when raising such a claim. *Chavez v. Martinez*, 538 U.S. 760, 775–76 (2003); *see also Fields v. Palmdale Sch. Dist.*, 271 F. Supp. 2d 1217, 1222 (C.D. Cal. 2003), *aff'd*, 427 F.3d 1197 (9th Cir. 2005), *opinion amended on denial of reh'g sub nom.*, 447 F.3d 1187 (9th Cir. 2006). "Where a fundamental right is not implicated . . . governmental action need only have a rational basis to be upheld against a substantive due process attack." *Kim v. United States*, 121 F.3d 1269, 1273 (9th Cir. 1997). Here, the plaintiffs provide only broad and conclusory descriptions of any fundamental rights potentially at issue, Santa Clara Compl. ¶¶ 226–31, which is not sufficient to state a claim.

Regardless, the Rule does not infringe on any fundamental rights that could possibly be at issue. As with the plaintiffs' Free Speech claim, *Rust* disposes of their Due Process claim. "The Government has no constitutional duty to subsidize an activity merely because the activity is constitutionally protected," and funding restrictions "'place[] no governmental obstacle in the path of a woman who chooses to terminate her pregnancy.'" *Rust*, 500 U.S. at 201 (quoting *Harris v. McRae*, 448 U.S. 297, 315 (1980)). Similarly, here, the Rule merely ensures that, consistent with the Federal Conscience Statutes, federal funds do not subsidize discrimination against health care entities that object to performing certain health care activities. The Rule, thus, places no governmental obstacles in the path of patients' rights to "privacy, liberty, dignity, and autonomy," Santa Clara's Compl. ¶ 229.

Equal protection. Plaintiffs' equal protection claim also fails. "A denial of equal protection entails, at a minimum, a classification that treats individuals unequally." *Coal. for Econ. Equity v. Wilson*, 122 F.3d 692, 707 (9th Cir. 1997), *as amended on denial of reh'g and reh'g en banc* (Aug. 21, 1997), *as amended* (Aug. 26, 1997). Here, however, the Rule does *not* create classifications of patients based on "sex, gender identity, transgender status, gender nonconformity," Santa Clara's Compl. ¶ 245, or any other kind of classification; nor does it infringe on a fundamental right, as explained *supra*. The Rule, again, merely administers the Federal Conscience Statutes' prohibition of discrimination against those who

object to performing certain health care services. *See* 84 Fed. Reg. 23,179. Thus, the Rule is facially neutral regarding any of the groups that Plaintiffs identify.

Even if the Rule were to have a disparate impact on certain groups—which Plaintiffs do not establish—the "mere fact that a facially neutral policy has a 'foreseeably disproportionate impact' on a protected group, without more, does not rise to the level of an equal protection violation." *McDaniels v. Stewart*, No. 3:15-CV-05943-BHS-DWC, 2016 WL 499316, at *7 (W.D. Wash. Feb. 8, 2016) (quoting *Lee v. City of Los Angeles*, 250 F.3d 668, 687 (9th Cir. 2001)); *see also Snoqualmie Indian Tribe v. City of Snoqualmie*, 186 F. Supp. 3d 1155, 1164 (W.D. Wash. 2016) ("[D]isparate impact alone cannot show intentional discrimination absent a 'stark' and 'clear' pattern, 'unexplainable on grounds other than [suspect class].'" (citation omitted)). That is because the Supreme Court has long recognized that "*purposeful discrimination* is the condition that offends the Constitution," *Washington v. Seattle Sch. Dist. No. 1*, 458 U.S. 457, 484 (1982) (emphasis added) (quoting *Pers. Adm'r of Mass. v. Feeney*, 442 U.S. 256, 274 (1979)); *see also Crawford v. Marion Cnty. Election Bd.*, 553 U.S. 181, 207 (2008) ("[W]ithout proof of discriminatory intent, a generally applicable law with disparate impact is not unconstitutional."). Plaintiffs have not shown any discriminatory purpose. The Rule aims to reduce "confusion over what is and is not required under" the Federal Conscience Statutes and to expand "OCR's enforcement processes." 84 Fed. Reg. at 23,175. These aims are not only plainly legitimate, they are supported by HHS's own experiences with enforcement under the 2011. *See id.* Because the Rule is facially neutral and rationally related to several legitimate governmental purposes, and because the plaintiffs fail demonstrate any purposeful or intentional discrimination in issuing the Rule, the plaintiffs' Equal Protection claim has no basis and should be dismissed.

IV. Any Relief Should Be Limited.

For the reasons discussed above, the Court should dismiss these cases or grant summary judgment to Defendants and deny Plaintiffs' forthcoming motion for summary judgment. But even if the Court were to disagree, under the Court's constitutionally prescribed role, any relief should be limited to redressing the injuries of the parties before this Court. *See Gill v. Whitford*, 138 S. Ct. 1916, 1921, 1933–34 (2018). Equitable principles likewise require that any relief "be no more burdensome to the defendant than necessary to provide complete relief to the plaintiffs." *Madsen v. Women's Health Ctr., Inc.*, 512 U.S.

753, 765 (1994) (quoting *Califano v. Yamasaki*, 442 U.S. 682, 702 (1979)).

Here, Plaintiffs fail to show that nationwide relief is necessary to redress their alleged injuries. To start, Plaintiffs' choice to bring a facial challenge does not justify nationwide relief. *See City & Cty. of San Francisco v. Trump*, 897 F.3d 1225, 1244–45 (9th Cir. 2018) (vacating nationwide scope of injunction in facial constitutional challenge to executive order). Nor does Plaintiffs' decision to bring APA claims necessitate a nationwide remedy. *See, e.g.*, *California v. Azar*, 911 F.3d 558, 582–84 (9th Cir. 2018) (vacating nationwide scope of injunction in facial challenge under the APA). A court "do[es] not lightly assume that Congress has intended to depart from established principles" regarding equitable discretion, *Weinberger v. Romero-Barcelo*, 456 U.S. 305, 313 (1982), and the APA's general instruction that unlawful agency action "shall" be "set aside," 5 U.S.C. § 706(2), is insufficient to mandate such a departure. The Supreme Court therefore has confirmed that, even in an APA case, "equitable defenses may be interposed." *Abbott Labs. v. Gardner*, 387 U.S. 136, 155 (1967). Accordingly, the Court should construe the "set aside" language in Section 706(2) as applying only to the named Plaintiffs, especially as no federal court had issued a nationwide injunction before Congress's enactment of the APA in 1946, nor would do so for more than fifteen years thereafter, *see Trump v. Hawaii*, 138 S. Ct. 2392, 2426 (2018) (Thomas, J., concurring). Nationwide relief would be particularly harmful here given that three other district courts in Washington, New York, and Maryland are currently considering similar challenges. If the government prevails in all three other jurisdictions, nationwide relief here would render those victories meaningless as a practical matter. It would also preclude appellate courts from testing Plaintiffs' factual assertions against the Rule's operation in other jurisdictions.

Similarly, should the Court decide to set aside or enjoin any portion of the Rule, the Court should allow the remainder to go into effect. In determining whether severance is appropriate, courts look to both the agency's intent and whether the regulation can function sensibly without the excised provision(s). *MD/DC/DE Broadcasters Ass'n v. FCC*, 236 F.3d 13, 22 (D.C. Cir. 2001).

Here, the intent of the agency is clear: Section 88.10 of the Rule provides that, if a provision of the Rule is held to be invalid or unenforceable, "such provision shall be severable[,]" and "[a] severed provision shall not affect the remainder of this part . . . ." 84 Fed. Reg. at 23,272; *see also id.* at 23,226. Nor is there any functional reason why the entire Rule must fall if the Court agrees with Plaintiffs' attacks

on particular provisions. The Rule implements a variety of statutory provisions protecting conscience, but Plaintiffs have not alleged harms stemming from compliance with the Rule with respect to each and every one of those statutes. Moreover, the various definitions in Section 88.2 that Plaintiffs challenge can operate independently, as can the other provisions in the Rule. And there is certainly no logical basis for setting aside or enjoining the entire Rule if the Court disagrees with some of Plaintiffs' challenges.

Finally, if the Court does set aside the Rule or enter an injunction, the Court should make clear that this relief does not prevent HHS from continuing to investigate violations of, and to enforce, federal conscience and anti-discrimination laws under the prior 2011 Rule or the Federal Conscience Statutes themselves. Such investigations are independent of the Rule that is the subject of this lawsuit and require the investment of significant resources, and therefore HHS should not be prevented from continuing to pursue them, or from acting under its existing statutory or regulatory enforcement authority, even if the Court were to otherwise set aside or enjoin the Rule.

CONCLUSION

For the foregoing reasons, the Court should grant Defendants' motion.

Dated: August 21, 2019

Respectfully Submitted,

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[PROPOSED] ORDER

Having considered Defendants' motion to dismiss or, in the alternative, for summary judgment and any opposition, reply, and oral argument presented, it is HEREBY ORDERED that the Defendants' motion is GRANTED.

IT IS SO ORDERED.

Dated: _____

_____
WILLIAM ALSUP
UNITED STATES DISTRICT JUDGE

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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

CITY AND COUNTY OF SAN FRANCISCO,

Plaintiff,

vs.

ALEX M. AZAR II et al.,

Defendants.

STATE OF CALIFORNIA, *by and through* ATTORNEY GENERAL XAVIER BECERRA,

Plaintiff,

vs.

ALEX M. AZAR II et al.,

Defendants.

COUNTY OF SANTA CLARA et al.,

Plaintiffs,

vs.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES et al.,

Defendants.

No. C 19-02405 WHA
Related to
No. C 19-02769 WHA
No. C 19-02916 WHA

DEFENDANTS' REPLY IN SUPPORT OF THEIR MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT AND OPPOSITION TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

Hon. William Alsup
Hearing: October 30, 2019, 8:00 a.m.

Phillip Burton Federal Building & United States Courthouse, Courtroom 12, 19th Fl., 450 Golden Gate Ave., San Francisco, CA 94102

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INTRODUCTION

Defendants respectfully ask that the Court grant their motion to dismiss or, in the alternative, for summary judgment. Plaintiffs' brief is long on hyperbole, but Plaintiffs at no point articulate how the challenged regulation, Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, 84 Fed. Reg. 23,170 (May 21, 2019) [hereinafter Rule], meaningfully differs from the statutes that it administers (Federal Conscience Statutes), *see generally id.* at 23,264–69 (to be codified at 45 C.F.R. § 88.3). That is because, far from being a sea change, the Rule merely implements and clarifies important preexisting conscience protections enacted by Congress. Remarkably, Plaintiffs do not challenge the underlying Federal Conscience Statutes. Nor do they challenge the authority of the Department of Health and Human Services (HHS) to condition federal funds on compliance with federal law, including the Federal Conscience Statues. Together, these omissions are fatal to Plaintiffs' challenge to the Rule.

Plaintiffs' specific arguments fail for other reasons, too. The main thrust of Plaintiffs' Administrative Procedure Act (APA) challenge is that the Rule exceeds Defendants' statutory authority. But Plaintiffs' argument is belied by the delegations of authority in certain of the Federal Conscience Statutes and other statutes identified in the Rule. Plaintiffs' attack on several of the Rule's definitions fares no better because those definitions are consistent with the plain text of the Statutes and the dictionary meanings of the relevant terms. At the very least, the Rule's definitions are entitled to *Chevron* deference and are reasonable. Contrary to Plaintiffs' claim, the Rule is also entirely consistent with the provisions scattered throughout the United States Code that Plaintiffs cite. And, in promulgating the Rule, Defendants made reasonable decisions, thoroughly considering the issues raised in the comments and providing thoughtful explanations in response.

Plaintiffs' constitutional claims likewise fail. At the threshold, Plaintiffs' Spending and Establishment Clause claims are not ripe. Plaintiffs insist that the loss of "billions of dollars in federal funding" is imminent, *see* Pls.' Mem. P. & A. & Opp'n Defs.' Mot. Dismiss or Summ. J. 2, ECF No. 113 [hereinafter Pls.' Opp'n], even though several speculative events would need to occur before Plaintiffs could lose federal funding for failure to comply with the Federal Conscience Statutes. Furthermore, Plaintiffs' Spending and Establishment Clause claims fail on the merits. The funding conditions that Plaintiffs challenge flow from the Federal Conscience Statutes, which is fatal to Plaintiffs' Spending

Clause claim because Plaintiffs do not challenge those Statutes. The Rule also does not "establish" religion in any way; it protects religious beliefs only where the Federal Conscience Statutes protect religious beliefs, not to mention that most of the Federal Conscience Statutes address objections regardless of their religious or secular nature. In addition, Plaintiffs lack standing to claim violations of equal protection, due process, or free speech, and those claims are meritless besides. Nor does the Rule create separation of powers concerns.

Last, even if the Court held some aspect of the Rule unlawful—which it should not—the Rule's severability clause instructs the Court to sever the offending portion from the Rule rather than vacate the Rule entirely. Any relief, moreover, should be limited to the parties before the Court and should not extend nationwide.

I. The Rule Fits Comfortably within HHS's Authority.

As Defendants explained in their opening brief, the Federal Conscience Statutes, the housekeeping statutes, and various other statutes support the Rule. *See See* Defs.' Mot. Dismiss or Summ. J. 12–14, ECF No. 54 [hereinafter Defs.' Mem.]; *see also* 84 Fed. Reg. at 23,183–86, 23,263 (describing the various authorities). Plaintiffs respond that certain Federal Conscience Statutes lack an explicit delegation provision and that the housekeeping statutes do not support the Rule. *See* Pls.' Opp'n 27–30. As discussed below, Plaintiffs are wrong on these points. Crucially, however, Plaintiffs *do not respond* to one of Defendants' central arguments: to wit, the Rule is no different than HHS's longstanding regulatory regime of monitoring and enforcing the condition in federal awards that recipients must comply with federal law. *See* Defs.' Mem. 13–14; *see also* 84 Fed. Reg. at 23,183–84 (describing HHS's authority under federal award regulations). Accordingly, Plaintiffs have abandoned argument on this point and the Court should grant Defendants' motion with respect to this claim. *See Ramirez v. City of Buena Park*, 560 F.3d 1012, 1026 (9th Cir. 2009).

Even if the Court considers Defendants' unrebutted statutory authority argument, it should still dismiss Plaintiffs' claim. As Defendants explained in their opening brief, *see* Defs.' Mem. 13–14, pursuant to various housekeeping and other statutes, *see* 5 U.S.C. § 301, 40 U.S.C. § 121(c), 10 U.S.C. ch. 137, and 51 U.S.C. § 20113, HHS has promulgated grants and contracts regulations that correspond to or supplement the Uniform Administrative Requirements (UAR) and Federal Acquisition Regulation (FAR)

(known as the HHS UAR and HHSAR), which among other things govern the enforcement of conditions in federal awards. Under these regulations, recipients of HHS's federal awards are required to comply "with U.S. statutory and public policy requirements," 45 C.F.R. § 75.300(a), which include the Federal Conscience Statutes. HHS may, and in some cases must, audit recipients for compliance with this and other conditions. *See* 45 C.F.R. §§ 75.500–75.520. And if a recipient does not comply with a federal award's requirements, HHS may impose additional conditions or take further action, including to "[w]holly or partly suspend . . . or terminate the Federal award." 45 C.F.R. § 75.371. Furthermore, under the 2011 Rule, HHS explicitly states that it enforces the Church, Coats-Snowe, and Weldon Amendments using these procedures. *See* 45 C.F.R. § 88.2 ("OCR will coordinate the handling of complaints [based on the Church, Coats-Snowe, and Weldon Amendments] with the Departmental funding component(s) from which the entity, to which a complaint has been filed, receives funding."). The 2019 Rule simply makes explicit that under existing (and unchallenged) HHS UAR and HHSAR procedures, recipients of HHS funds must comply with the Federal Conscience Statutes and may face certain consequences if they do not.[1]

In addition to this longstanding authority, several statutory provisions explicitly grant HHS sufficient regulatory authority to promulgate the Rule. *See* 84 Fed. Reg. 23, 184–85, 23,263 (citing, *inter alia*, 42 U.S.C. §§ 1302, 18023, 18041, 18113, 263a, 1315a). And, as discussed in the definitions section *infra*, the Federal Conscience Statutes implicitly grant HHS the authority to administer them.

Plaintiffs' response—that the presence of explicit rulemaking authority in some contexts indicates the lack of delegation in others, *see* Pls.' Opp'n 29–30—is unsupported and incorrect. Although Congress has explicitly delegated enforcement authority in some contexts, the existence of explicit delegations in other statutes has no bearing on HHS's authority to ensure compliance with the Federal Conscience Statutes and this Rule under the provisions of the HHS UAR or HHSAR or the other statutes cited in the Rule. Plaintiffs have not shown that the statutes that contain explicit delegations, which were enacted in

[1] Plaintiffs incorrectly suggest that the housekeeping statutes cannot support regulations that relate to later-enacted statutes. *See* Pls.' Opp'n 29. First, such a rule would absurdly restrict HHS's ability to enforce all statutes enacted after the housekeeping statutes under the HHS UAR and HHSAR. Second, it is inconsistent with the forward-thinking purpose of the housekeeping statutes to permit an "agency to regulate its own affairs." *Chrystler Corp. v. Brown*, 441 U.S. 281, 309 (1979).

different sessions of Congress and as different public laws, are subject to inter-textual comparison as Plaintiffs would like. *See Erlenbaugh v. United States*, 409 U.S. 239, 243–44 (1972) (describing the standard for comparing different statutes). Furthermore, Plaintiffs' theory cannot be squared with longstanding precedent that "[s]ometimes the legislative delegation to an agency on a particular question is implicit." *Chevron U.S.A. Inc. v. Natural Resources Def. Council, Inc.*, 467 U.S. 837, 844 (1984).

Plaintiffs' other response—that *United States v. Marion County School District*, 625 F.2d 607 (5th Cir. 1980), and *United States v. Mattson*, 600 F.2d 1295 (9th Cir. 1979), do not support the government's inherent authority to impose contractual assurances—is not a response to Defendants' argument at all. Defendants cited those cases for the proposition that when the government issues funds on certain conditions, it has the inherent authority to sue for a breach of those conditions. *See Marion Cty. Sch. Dist.*, 625 F.2d at 609 ("As the Supreme Court has long recognized, the United States may attach conditions to a grant of federal assistance, the recipient of the grant is obligated to perform the conditions, and the United States has an inherent right to sue for enforcement of the recipient's obligation in court."); *Mattson*, 600 F.2d at 1299 (recognizing that the government wielded "the threat of withholding funds should the states not comply with all procedural requirements").[2] The Rule does not establish or seek to establish HHS's authority to impose those conditions in the first place; rather, it explains *how* HHS enforces those conditions using existing authority.[3]

II. The Challenged Definitions Are within HHS's Statutory Authority.

The challenged definitions in the Rule reflect the unambiguous meaning of the terms in the Federal Conscience Statutes. At a minimum, they are reasonable interpretations entitled to *Chevron* deference.

A. The Highly Deferential Standard Described in *Chevron* Applies.

Plaintiffs contend that the Rule's definitions are not entitled to *Chevron* deference because

[2] Plaintiffs also overgeneralize *Mattson*'s holding. The court rejected the government's inherent authority to sue for *injunctive* relief, *see* 600 F.2d at 1297, not to withhold federal funds for failure to comply with conditions in federal awards, *see id.* at 1299, which is the dispute in this case.

[3] The Court has asked "what specific denial of abortion or sterilization scenarios are covered by the new rule, but were not covered under the federal conscience statutes." Notice re Briefing, ECF No. 135. The answer is straightforward: there are no such scenarios. As Defendants have explained, the Rule simply employs existing procedures to administer the Federal Conscience Statutes among recipients of HHS's funds; it does not add any conditions to those Statutes. And the Rule certainly does not define the term "sterilization," as the *Santa Clara* Plaintiffs suggest, *see* Santa Clara's Compl. ¶ 101, ECF No. 1.

Congress has not delegated authority to HHS to interpret the Federal Conscience Statutes. *See* Pls.' Opp'n 31. But, as explained in Defendants' opening brief and below, Congress has delegated such authority both explicitly and implicitly. *See* Defs.' Mem. 12–14. The Court thus should review Plaintiffs' challenges to the Rule's definitions under the highly deferential framework set forth in *Chevron*.

To begin with, several statutes explicitly authorize HHS to issue the Rule, which merely provides public notice of HHS's process for implementing the requirements of the Federal Conscience Statutes and the interpretations of those Statutes that HHS will employ in that process. A number of statutory provisions provide authority for HHS to promulgate the Rule, including 42 U.S.C. §§ 1302, 18023, 18041, 18113, 263a, and 1315a. *See* Defs.' Mem. 14; 84 Fed. Reg. at 23,185 (listing statutes). And other statutes that support HHS's enforcement of federal awards, 5 U.S.C. § 301; 40 U.S.C. § 121(c) (procurement contracts); 42 U.S.C. § 216 (grants), also explicitly delegate such authority. *See* Defs.' Mem. 13–14.

Yet another source of authority is the implicit delegation from the Federal Conscience Statutes themselves. Just as Congress may delegate authority to the agency explicitly, "[s]ometimes the legislative delegation to an agency on a particular question is implicit." *Chevron*, 467 U.S. at 844. Although Plaintiffs focus on whether the Rule is supported by explicit delegation provisions (and it is), implicit delegations are also common: "The power of an administrative agency to administer a congressionally created and funded program necessarily requires the formulation of policy and the making of rules to fill any gap left, implicitly or explicitly, by Congress." *Morton v. Ruiz*, 415 U.S. 199, 231 (1974). "[I]t can still be apparent from the agency's generally conferred authority and other statutory circumstances that Congress would expect the agency to be able to speak with the force of law when it addresses ambiguity in the statute or fills a space in the enacted law, even one about which 'Congress did not actually have an intent' as to a particular result." *United States v. Mead Corp.*, 533 U.S. 218, 229 (2001) (quoting *Chevron*, 467 U.S. at 845). To determine whether Congress has implicitly delegated authority, courts consider "the interstitial nature of the legal question, the related expertise of the Agency, the importance of the question to administration of the statute, the complexity of that administration, and the careful consideration the Agency has given the question over a long period of time." *See Barnhart v. Walton*, 535 U.S. 212, 222 (2002). All of these factors weigh in HHS's favor.

First, the subject of the Rule is interstitial in nature and necessary to the administration of the

Federal Conscience Statutes. In general, the Federal Consciences Statutes direct HHS to issue federal funds contingent on recipients complying with the Statutes' conditions. *See, e.g.*, 42 U.S.C. § 300a-7(c) (prohibiting recipients of certain federal funds from discriminating on certain bases). But the Statutes do not define the key terms listed in the Rule's definitions section. And even when definitions are provided, they are explicitly non-exhaustive. *See, e.g.*, 42 U.S.C. § 238n(c) (defining "health care entity" through a non-exhaustive list of examples). Furthermore, the Statutes do not explicitly detail the mechanisms to ensure that recipients comply with the Statutes' conditions. In view of the lack of private rights of action. *see* Defs.' Mem. 28, surely Congress did not intend to impose significant conditions on federal funds without also authorizing HHS to employ longstanding procedures to enforce those conditions with respect to the funds that HHS disburses and administers and, to the extent a term is ambiguous, to interpret such ambiguity. These are quintessentially interstitial questions; they are important for the administration of the Statutes, but the Statutes themselves do not answer them.

In addition, the administration of federal awards connected to the Federal Conscience Statutes is complex. "The HHS Office of the Secretary and its 11 Operating Divisions (OpDivs) administer more than 300 programs covering a wide spectrum of activities." HHS, FY 2018 *Agency Financial Report* 7 (Nov. 14, 2018), https://www.hhs.gov/sites/default/files/fy-2018-hhs-agency-financial-report.pdf. In total, "HHS is responsible for more than a quarter of all federal outlays and administers more grant dollars than all other federal agencies combined." *Id.* And the Rule, which addresses a variety of statutes that apply in different contexts, is estimated to cover 502,899 entities. *See* 84 Fed. Reg. at 23,235.

Last, HHS has significant expertise developed over years of enforcing civil rights laws in the health care context, including the Federal Conscience Statutes. HHS has promulgated regulations regarding the Federal Conscience Statutes several times. OCR has also investigated complaints of discrimination, issued notices of violations, and negotiated settlements with entities found to have violated the Federal Conscience Statutes and implementing regulations. Its staff has experience overseeing and ensuring the protection of civil rights, including protection from discrimination, such as religious discrimination. Based on this experience, HHS determined there was a need to provide more concrete and detailed guidance on how the agency intends to enforce conscience protections with respect to recipients of its federal funds.

B. The Rule's Definitions Are Consistent with the Federal Conscience Statutes

1. "Assist in the Performance"

Plaintiffs' only objection to HHS's definition of "assist in the performance" is that it is allegedly inconsistent with the Church Amendments' legislative history. However, this meager objection ignores the plain text of the statute and overstates the legislative history. First, Plaintiffs fail to respond to any of Defendants' points regarding the standard dictionary definition of "assist," *see* Defs.' Mem. 15. Instead, Plaintiffs suggest that a medical dictionary must be consulted rather than a standard dictionary. The Ninth Circuit, however, regularly consults *Merriam-Webster* at *Chevron* step one. *See, e.g.*, *Lagandaon v. Ashcroft*, 383 F.3d 983, 988 (9th Cir. 2004). Plaintiffs offer no statutory basis to deviate from this practice here.[4] Nor do they identify a contradictory definition in a medical dictionary. *See* Pls.' Opp'n 33 n.52. In addition, and as Defendants have also explained, *see* Defs.' Mem. 16, the text of the Church Amendments is not limited to individuals who *perform* certain procedures, but rather extends to individuals who *assist* in the performance: "No individual shall be required to *perform* or *assist in the performance* of any part of a health service program or research activity funded in whole or in part under a program administered by the Secretary of Health and Human Services if his *performance* or *assistance in the performance* of such part of such program or activity would be contrary to his religious beliefs or moral convictions." *See* 42 U.S.C. § 300a-7(d) (emphasis added).

The legislative history that Plaintiffs cite does not contradict the Rule's definition for several reasons. First, courts "cannot ignore clear statutory text because of legislative floor statements," *see United States v. Hall*, 617 F.3d 1161, 1167 (9th Cir. 2010), and for the reasons above, the text supports the Rule's definition. Second, Plaintiffs cite only a single comment that the Church Amendments' sponsor made on the floor of the Senate. "Floor statements are not given the same weight as some other types of legislative history, such as committee reports, because they generally represent only the view of the speaker and not necessarily that of the entire body." *See Kenna v. U.S. Dist. Ct. for the Central Dist. of Cal.*, 435 F.3d

[4] Plaintiffs' citation to extra-record declarations, *see* Pls.' Opp'n 33 n.52, is inappropriate *See infra* sec. X. In APA cases, courts cannot consult extra-record documents outside of limited circumstances, which are not present here. *See Sw. Ctr. for Biological Diversity v. U.S. Forest Serv.*, 100 F.3d 1443, 1450–51 (9th Cir. 1996). Furthermore, it is unclear why Plaintiffs seek to use a medical dictionary with respect to only "assist in performance." That this is their only response to the commonsense meaning of "assist in the performance" suggests the weakness of their argument.

1011, 1015 (9th Cir. 2006). Although sponsors' floor statements may be given more weight than non-sponsors' floor statements, Senator Church's statement is entitled to little or no weight because the relevant House committee issued a report on the statute, which did not endorse his statement. *See* H.R. Rep. No. 93-227, at 11 (1973). At any rate, the substance of Senator Church's statement does not conflict with the Rule. Just as Senator Church did not intend, when voting for the bill, "to permit a frivolous objection from someone unconnected with the procedure," 119 Cong. Rec. 9,597 (Mar. 27, 1973), so too does the Rule exclude such unconnected persons from its definition. Rather, there must be "a specific, reasonable, and articulable connection to furthering a procedure or a part of a health service program or research activity undertaken by or with another person or entity." 84 Fed. Reg. at 23,263 (to be codified at 45 C.F.R. § 88.2).

2. "Discriminate or Discrimination"

Plaintiffs' response to the definition of "discriminate or discrimination" is remarkably bereft of legal citations or response to the *Chevron* arguments in Defendants' opening brief. Instead, Plaintiffs assert—without any acknowledgement of what the Rule actually says—that the Rule "encompasses almost any adverse employment action toward religious objectors without considering what may be legally justifiable." *See* Pls.' Opp'n 34. This is *not* what the Rule says. As explained in Defendants' opening brief, *see* Defs.' Mem. 16–17, the definition is quite clear that it provides a non-exhaustive list of what *may* constitute discrimination "as applicable to, and to the extent permitted by, the applicable statute," *see* 84 Fed. Reg. at 23,263 (to be codified at 45 C.F.R. § 88.2). Furthermore, the Rule identifies certain actions that definitively do not constitute discrimination. *See id.* (subsections (4)–(6)).

Plaintiffs also suggest that the Rule should permit additional rationales to justify adverse employment actions, pointing to Title VII. *See* Pls.' Opp'n 34. However, Plaintiffs do not identify a statutory basis to import their desired provisions of Title VII into the Federal Conscience Statutes. And again, to the extent such provisions are incorporated in the Federal Conscience Statutes, HHS recognizes them. *See* 84 Fed. Reg. at 23,263 (stating that the Rule applies the Federal Conscience Statutes).

3. "Health Care Entity"

Plaintiffs' threadbare arguments regarding HHS's definition of "health care entity" likewise do not pass muster. As Defendants explained in their opening brief, the Coats-Snowe and Weldon

Amendments as well as § 1553 identify examples of health care entities in non-exhaustive lists. *See* Defs.' Mem. 17–18. Plaintiffs suggest that these lists are exhaustive, arguing that the term "include," which proceeds each statutory list, is limiting. Although the term "include" *can* be limiting, the Supreme Court has quoted approvingly that "the word 'includes' is *usually* a term of enlargement, and not of limitation." *Samatar v. Yousuf*, 560 U.S. 305, 317 n.10 (2010) (emphasis added) (quoting 2A N. Singer & J. Singer, Sutherland on Statutory Construction § 47.7, p. 305 (7th ed.2007)); *see also Include*, MERRIAM-WEBSTER, https://www.merriam-webster.com/dictionary/include (defining "include" as "to take in or comprise as a part of a whole or group"). Plaintiffs offer no reason why the usual definition of "includes" should not apply other than their own preference.

Furthermore, Plaintiffs have yet to explain why any of the examples of a health care entity in the definition are not, in fact, health care entities. Instead, they hyperbolically assert that the Rule's definition includes "all members of the workforce of a healthcare entity." Pls.' Opp'n 32. This assertion is not supported by the text of the Rule, which identifies specific positions covered by the Coats-Snowe and Weldon Amendments. *See* 84 Fed. Reg. at 23,264 (to be codified at 45 C.F.R. § 88.2). In fact, each item in the Rule's definition is a dictionary example of a healthcare entity.

4. "Referral or Refer For"

Finally, Plaintiffs argue that the Rule's definition of "referral" or "refer for" is inconsistent with the Federal Conscience Statutes because it is contrary to the text of the Coats-Snowe and Weldon Amendments and could have negative consequences. *See* Pls.' Opp'n 33–34. Both points can be dismissed out of hand. Plaintiffs' statutory argument is circular; they quote the Coats-Snowe and Weldon Amendments and state—without explanation—that the definition "strains the plain language of both statutes." *See* Pls.' Opp'n 33. Such a perfunctory argument leaves the Court and Defendants guessing. At a minimum, this is no response to Defendants' argument that the dictionary definition of "refer" and an intra-textual analysis of the statutes supports the Rule's definition. *See* Defs.' Mem. 19.

Plaintiffs' other argument—that the definition would deprive patients of information—is not only incorrect, it also is untethered from any statutory analysis. First, the Rule "do[es] not prohibit any doctor or health care entity from providing information to their patients—or referring for a medical service or treatment—if they feel they have a medical, legal, ethical, or other duty to do so." 84 Fed. Reg. at 23,200.

Rather, the Rule protects certain individuals from "being coerced by entities receiving Federal funds to violate their moral or religious convictions." *Id.* And at any rate, the meaning of the term "referral or refer for" is *legal* in nature. To the extent that Plaintiffs would like to require a health care entity to issue referrals or refer for procedures in violation of that entity's moral or religious convictions, Plaintiffs' objection is to the Federal Conscience Statutes themselves (the source of such protections), not the Rule.

III. The Rule Is Consistent with Other Provisions of Law.

A. Section 1554 of the Affordable Care Act (ACA)

Plaintiffs press on with their extraordinary claim that § 1554 of the ACA prohibits HHS from promulgating any regulation that, *inter alia,* "creates [a] barrier," "impedes [] access," or "limits the availability of health care treatment," including by allowing a health care entity with an objection to providing, for instance, an abortion, to abstain from doing so. *See* Pls.' Opp'n at 35. It is worth pausing to consider the incredible breadth of Plaintiffs' argument: if they were correct, § 1554 would render meaningless (if not completely abrogate) many Federal Conscience Statutes that touch on health care because—by respecting the conscience rights of health care entities—the Statutes allegedly "impede access" to care. And § 1554 would do this without mentioning any of the Federal Conscience Statutes and without otherwise indicating that Congress intended to limit in some cases decades-old conditions. Plaintiffs' reading of § 1554 would also mean that HHS could not condition Medicare or Medicaid funding through regulations. To suggest that Congress intended any of this is absurd.

As Defendants explained in their opening brief, there is no plausible reason to accept Plaintiffs' sweeping interpretation of § 1554. *See* Defs.' Mem. 21–22. In § 1303(c)(2) of the ACA, Congress was absolutely clear that nothing in the ACA (including § 1554) "shall be construed to have *any effect* on Federal laws regarding (i) conscience protection; (ii) willingness or refusal to provide abortion; and (iii) discrimination on the basis of willingness or refusal to provide, pay for, cover, or refer for abortion or to provide or participate in training to provide abortion." 42 U.S.C. § 18023(c)(2). That provision is fatal to Plaintiffs' argument that § 1554 somehow interferes with implementation of the Federal Conscience Statutes through the Rule. Plaintiffs' rebuttal—that § 1303(c)(2) "works together" with § 1554 because § 1303(c)(2) "does not 'create[],' 'impede[],' 'interfere[] with,' 'restrict,' or 'violate[],' healthcare rights or access," Pls.' Opp'n 36 (alterations in original)—misses the point. Congress was clear that the ACA,

including § 1554, should not have "any effect" on federal conscience protections. *See* 42 U.S.C. § 18023(c)(2).

B. Section 1557 of the ACA

Plaintiffs' § 1557 argument should also be rejected out of hand. Plaintiffs barely attempt to defend it in their brief. *See* Pls.' Opp'n 37. Putting aside that Plaintiffs can point to no actual conflict between the Rule and § 1557 in their facial challenge, Congress stated explicitly in § 1303(c)(2) of the ACA that nothing in that act (e.g., § 1557) should have "any effect" on federal conscience protections. *See* 42 U.S.C. § 18023(c)(2). Plaintiffs offer no reason to ignore Congress's clear instruction.

C. Emergency Medical Treatment and Active Labor Act

Plaintiffs claim that the Rule violates the Emergency Medical Treatment and Active Labor Act (EMTALA) because it "fails to provide for any balancing" in cases of emergency care. Pls.' Opp'n 36–37. The case that Plaintiffs cite for that proposition, however, offers no such support. In *California v. United States*, No. C 05-00328 JSW, 2008 WL 744840, (N.D. Cal. Mar. 18, 2008), the district court *rejected* the plaintiff's challenge to the Weldon Amendment. Much like Plaintiffs here, the plaintiff claimed that there was a conflict between EMTALA and the Weldon Amendment. But the district court held that there was no clear indication of a conflict, relying on the Ninth Circuit's instruction that "to the extent that statutes can be harmonized, they should be." *Id.* at *4 (citing *United States v. Trident Seafoods Corp.*, 92 F.3d 855, 862 (9th Cir. 1996)). The Court should hold no differently here.

As Defendants explained in the preamble to the Rule and in their opening brief, HHS believes the Rule can be read harmoniously with EMTALA and does not foresee any circumstance in which fulfilling the requirements of EMTALA would violate the Federal Conscience Statutes. *See* 84 Fed. Reg. at 23,183; Defs.' Mem. 23–24. OCR, moreover, "intends to read every law passed by Congress in harmony to the fullest extent possible so that there is maximum compliance with the terms of each law." 84 Fed. Reg. at 23,183. Plaintiffs may continue to abide by EMTALA's requirements without any reasonable fear that doing so would run afoul of the Federal Conscience Statutes.

D. Title X

Plaintiffs also continue to press their argument that the Rule somehow conflicts with Title X. Pls,' Opp'n 37–38. This claim fails for multiple reasons. First, Plaintiffs do not identify any portion of Title X with which the Rule allegedly conflicts. And, indeed, there is nothing in Title X that could plausibly prevent HHS from implementing the Federal Conscience Statutes. *See* Pub. L. No. 91-572, 84 Stat. 1504 (1970). Plaintiffs' argument appears to be that, because Title X grantees *may* (though are not required to) counsel women regarding pregnancy options, including abortion, those grantees will somehow violate Title X when one of their individual employees declines to provide such counseling. *See* Pls.' Opp'n 37. But that is not correct. Title X does not *require* pregnancy counseling at all, much less that every single one of a Title X grantee's employees do so, even against their conscience. There is no conflict between the Rule and Title X, and the Court should reject Plaintiffs' attempt to manufacture one.

IV. The Rule Is the Product of Reasoned Decision-making.

As Defendants explained in their opening brief, the Rule is neither arbitrary nor capricious under 5 U.S.C. § 706(1) because HHS provided "a rational connection between the facts found and the choice made." *Motor Vehicle Mfrs. Ass'n, of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (citation omitted); *see also* Defs.' Mem. 25–30. Plaintiffs' arguments to the contrary are meritless. HHS supported each challenged aspect of the Rule with sound and detailed reasoning, and Plaintiffs' attempt to couch their policy disagreements as an APA challenge must fail. *Pub. Citizen, Inc. v. Nat'l Highway Traffic Safety Admin.*, 374 F.3d 1251, 1263 (D.C. Cir. 2004) (rejecting an "arbitrary-and-capricious challenge [that] boils down to a policy disagreement").

A. HHS Adequately Explained Its Reasons for the Rule.

First, HHS offered a reasoned explanation for changing course from the 2011 Rule. Here, the agency proposed a new rule because "[a]fter reviewing the previous rulemakings, comments from the public, and OCR's enforcement activities," it concluded that the 2011 Rule "created confusion over what is and is not required under Federal health care conscience laws and narrowed OCR's enforcement authority." 83 Fed. Reg. at 3,887. In promulgating the Rule, HHS considered (1) recent, documented instances of alleged and demonstrated conscience discrimination, such as litigation regarding new,

potentially discriminatory laws passed by various States, (2) complaints that OCR has received in recent years, (3) comments received during the 2018–19 rulemaking,[5] (4) a survey conducted in 2009, (5) comments received in the 2008 and 2011 rulemakings, and (6) various studies and articles. *See* 84 Fed. Reg. 23175–79; *see also* Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, 83 Fed. Reg. 3,880, 3,887–891 (proposed Jan. 26, 2018).

Plaintiffs assail HHS's reliance on recent complaints that OCR received to argue that the agency failed to acknowledge record evidence allegedly contradicting its assertions. *See* Pls.' Opp'n 24–25. But again, HHS considered the complaints in conjunction with all of the factors discussed above and noted that the complaints *alleged* violations of the Federal Conscience Statutes. *See* 84 Fed. Reg. at 23,245. The presence or absence of complaints does not, by itself, paint a full picture of whether individuals and entities understand their rights and obligations under the Federal Conscience Statutes; as HHS indicated elsewhere, the agency is concerned that "segments of the public have been dissuaded from complaining about religious discrimination in the health care setting to OCR as the result, at least in part, of [the agency's previous,] unduly narrow interpretations of the Weldon Amendment." 84 Fed. Reg. at 23,179.

Furthermore, although Defendants have acknowledged that many of the complaints that OCR received related to matters that are outside the scope of the Federal Conscience Statutes, a sizeable number of complaints *did* implicate the relevant Statutes and underscore the need to both clarify the scope of, and more robustly safeguard, the conscience rights protected by the Statutes.[6] While the complaints in the

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[5] *See, e.g.*, Administrative Record (AR) 135,736–746, Ex. 4 (comment from a "diverse group of faith-based ministries" stating that "[f]or the wellbeing of patients and the integrity of the [health care] profession, . . . healthcare professionals must be free to practice medicine in accordance with their professional judgment and ethical beliefs" and noting "examples of violations against conscience rights in healthcare, indicating that the threat to conscience rights is rising"); AR 134,132–136, Ex. 3 (comment from Ascension, a faith-based healthcare organization, applauding HHS "for taking steps to protect the religious freedoms of all Americans, especially when it comes to healthcare workers and organizations that are called by their faith to serve *all* persons, especially those who are poor and vulnerable"); AR 139,527–529, Ex. 5 (comment from Catholic Health Association noting that "[t]he lack of implementing regulations and of clarity concerning enforcement mechanisms for [the Federal Conscience Statues] has stymied their effectiveness"); AR 133,746–758, Ex. 2 (comment from Alliance Defending Freedom supporting the proposed Rule because it seeks "to not only raise awareness of conscience rights but to put . . . teeth into federal protections for those rights"); AR 28,049–053, Ex. 1 (comment from various religious organizations stating that the proposed Rule would "help guarantee that health care institutions and professionals are not pushed into [a] Hobson's choice"). Although the AR has been filed with the Court, Defendants have attached citations to the AR to this brief for the Court's convenience.

[6] Defendants cited some complaints in their opening brief as examples, *see* Defs.' Mem. 53, and

record are not the sole reason for HHS's decision to promulgate the Rule, they represent one factor that HHS considered in determining that "there is a significant need to amend the 2011 Rule to ensure knowledge of, compliance with, and enforcement of" the Federal Conscience Statutes. 84 Fed. Reg. at 23,175.

HHS's recent investigations into complaints alleging conscience discrimination, meanwhile, do not undercut HHS's reasons for promulgating the Rule, as Plaintiffs argue, *see* Pls.' Opp'n 25 (claiming that HHS is "engaging in 'robust' enforcement of the federal conscience statutes" under its current authority (citation omitted)). A central objective of the Rule is to dispel "confusion" created in part by the 2011 Rule "over what is and is not required" under the Federal Conscience Statutes. 84 Fed. Reg. at 23,175. The Rule also clarifies for recipients of HHS funds the procedures that HHS uses to enforce the Federal Conscience Statutes. *See id.* The fact that HHS can also enforce the Statutes under the 2011 Rule does not undermine these purposes; indeed, it reveals as unfounded Plaintiffs' objections to HHS's authority to promulgate the Rule, which is based in part on the same authority as the 2011 Rule.

B. HHS Considered All Important Aspects of the Problem.

Plaintiffs also complain that HHS failed to consider the Rule's purported impact on a host of matters such as patients, providers, and the Title VII reasonable-accommodation framework, Pls.' Opp'n 16–24, 25–27. For the following reasons, these arguments fail.[7]

Impact on Patient Populations. As Defendants explained in their opening brief, HHS considered whether the Rule would harm access to care and reasonably concluded that it would not. Defs.' Mem. 27–

include others here, *see, e.g.*, AR 542,017–26, Ex. 6 (complaint that California's health insurance abortion coverage mandate violates the Weldon Amendment); AR 542,151, Ex. 7 (nursing student alleges discrimination due to request for an exemption from assisting in abortions); AR 542,229–60, Ex. 13 (complaint against Illinois statute mandating that healthcare providers exercising conscience rights to engage in compelled speech and referrals); AR 542,285, Ex. 8 (complaint against Hawaii's statutory mandate that religious-based alternative pregnancy centers must advertise for state-funded abortions); AR 542,316–24, Ex. 9 (complaint against Pennsylvania's involvement in contraception mandate litigation); AR 545,932, Ex. 12 (nurse alleges that university hospital refused to hire her for full-time faculty position because of her views regarding abortion); AR 542,337, Ex. 10 (pediatric nurse complains that hospital informed her that she could no longer work in the health department clinics if she was unwilling to participate in the provision of abortion-related services) AR 544,612–23, Ex. 11 (complaint against the University of Vermont Medical Center for deceptively coercing nurse to participate in elective abortion); AR 544,945–52, Ex. 14 (complaint by pharmacist who objects to filling birth control prescriptions).

[7] Plaintiffs improperly rely on declarations in support of their argument that the Rule violates the APA. *See infra* sec. X.

28. HHS reached this conclusion for several reasons. First, implementation and enforcement of the Federal Conscience Statutes "would help alleviate the country's shortage of health care providers," 84 Fed. Reg. at 23,180, as the Statutes make it easier for health care professionals to perform their jobs while staying true to their religious beliefs or moral convictions. Second, the agency was unaware of any data or persuasive reasoning, presented by commenters or otherwise, demonstrating that the Rule could negatively impact access to care. *See id.* at 23,180–82. As noted in the Rule, "[a]ccess to care is a critical concern" of HHS, 84 Fed. Reg. at 23,180, and HHS examined the commenters' concerns closely. *Id.* at 23,180–82, 23,253–55. The agency probed commenters' illogical assumption that "there are health care providers in underserved communities who are protected by these laws but are offering services to which they object anyway," *id.* at 23,181, and explained why it believed that the Rule would improve access to care by (1) encouraging individuals who had previously "anticipated they would be pressured to violate their consciences" to enter the health care field, *id.*; (2) preventing some health care entities from leaving the field in light of data indicating that some entities currently felt pressure to do so, *id.*; and (3) allowing an increase in the provision of health care by religious institutions, *id.*

Plaintiffs speculate about a series of far-fetched harms and claim that the agency "brushed those concerns aside." *See* Pls.' Opp'n 16–17. But they conflate the receipt of certain federal funds conditioned on protecting the conscience rights of individual and institutional health care entities with the absolute denial of care for entire swaths of the patient population. Further, neither Plaintiffs nor the comments on which they rely explain why the Rule, which does not require any entity to refuse to care for patients and which for the most part protects conscience objections to specified services such as abortion, sterilization, and assisted suicide, *see* 84 Fed. Reg. at 23,170–74, would deny treatment to the children of LGBT individuals or "curtail or eliminate reproductive healthcare and training," Pls.' Opp'n 17. *See* 84 Fed. Reg. at 23,252. Plaintiffs' objections boil down to a policy disagreement with Congress over its decision to protect health care entities that have conscience objections to performing certain services and do not warrant invalidation of the Rule.[8] *See Owner-Operator Indep. Drivers Ass'n v. Fed. Motor Carrier Safety*

[8] Plaintiffs claim that "none of the purported authorizing [Federal Conscience] statutes require" or allow HHS to conclude that certain conscience rights are "'worth protecting even if they impact [overall or individual] access to a particular service, such as abortion.'" Pls.' Opp'n 18–19 (quoting 84 Fed. Reg. at 23,182). But none of the Statutes make protection of the applicable conscience rights conditional. *See,*

Admin., 494 F.3d 188, 210–11 (D.C. Cir. 2007).

Contrary to Plaintiffs' assertions, HHS's conclusion that the benefits of the Rule outweigh its burdens is not "pure conjecture," Pls.' Opp'n 22. The agency thoroughly analyzed the Rule's benefits by considering the available evidence and identified several benefits beyond the probable increase in overall access to medical care, including an increase in the quality of care that patients receive and a decrease in unlawful discrimination. *See* 84 Fed. Reg. at 23,246–54. Regarding access to care, HHS explained that it expects the Rule "to remove barriers to the entry of certain health professionals, and to delay the exit [of others] from the field, by reducing discrimination or coercion that health professionals anticipate or experience," and supported that conclusion by relying on public comments received, academic literature, and historical support for conscience protections. *Id.* Defendants have already explained why the agency's reliance on 2009 and 2011 polls in conjunction with other evidence was not unreasonable, especially in light of a lack of "data that allows for an estimate of the effect of this rule on access to services," 84 Fed. Reg. at 23,247. *See* Defs.' Mem. It stands to reason that the Rule's clarification of the protections in the Federal Conscience Statutes would allow more health care entities with conscience objections to certain medical procedures or services to enter, or stay, in the field, thereby allowing them to provide more care to patients overall, and it is logical that "[t]he burden of not being able to receive any health care clearly outweighs the burden of not being able to receive a particular treatment" from a particular provider. 84 Fed. Reg. at 23,252.

Nor was it arbitrary or capricious for HHS to reach this conclusion in the absence of empirical data (one way or the other) on the Rule's potential impact on access to care. "[P]redictive calculations are a murky science in the best of circumstances, and the [agency] naturally has no access to infallible data." *Cablevision Sys. Corp. v. F.C.C.*, 597 F.3d 1306, 1314 (D.C. Cir. 2010). Here, HHS considered studies that "specifically found that there is insufficient evidence to conclude that conscience protections have negative effects on access to care," and Plaintiffs offer no contrary studies, in the record or elsewhere. 84

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e.g., 42 U.S.C. § 300a-7 (Church Amendments); 42 U.S.C. § 238n(a) (Coats-Snowe Amendment); Pub. L. No. 115-245, 132 Stat. 2981, 3118 (most recent iteration of the Weldon Amendment); 42 U.S.C. §§ 18081, 18023(b)(1)(A). (b)(4), 18113, 14406(1) (certain conscience protection provisions in the Patient Protection and Affordable Care Act). And while Plaintiffs point to the emergency treatment requirements in EMTALA, the Rule makes clear that HHS believes that EMTALA does not conflict with the Federal Conscience Statutes or the Rule. 84 Fed. Reg. at 23,183; *see also* 73 Fed. Reg. at 78087–88.

Fed. Reg. 23,810. Plaintiffs fail to explain why the agency should be required to perform an unworkable study in these circumstances on the specific effects of the Rule before it went into effect. *See BellSouth Corp. v. FCC*, 162 F.3d 1215, 1221 (D.C. Cir. 1999).

Impact on Providers. HHS also extensively considered the Rule's impact on providers and other affected entities. 84 Fed. Reg. 23,239–46. The agency identified several categories of potential burdens, attempted to quantify them with the available data, and considered comments suggesting that the proposed rule's notice, assurance, and certification requirements were too burdensome. *Id.*; *see also id.* at 23,217, 23241. In response to comments, the agency modified its notice provision "from a requirement to a voluntary action and to accept self-drafting of notices to provide greater tailoring to individual circumstances." *Id.* at 23,217. HHS also "exempted certain classes of recipients from" the assurance and certification requirements in § 88.4 of the Rule. *Id.* at 23,241. "The impact of the exemption means that . . . approximately 70 percent of recipients do not have to comply with the assurance and certification requirement." *Id.* As to the recipients that remain subject to the assurance and certification requirements, HHS explained that the requirements provide "important protections to persons and entities under these laws and would be consistent with requirements under other civil rights laws" because entities would be more likely to understand their obligations upon application for federal funding and be more vigilant about complying with the Federal Conscience Statutes. *Id.* at 23,213–14. HHS therefore acknowledged and factored in the reasonable burdens associated with the Rule and ultimately concluded that "the benefits . . . justify the burdens of the regulatory action." *Id.* at 23,277. Contrary to Plaintiffs' assertions, *see* Pls.' Opp'n 21–22, HHS did not disregard commenters' concerns when data was unavailable; rather, while it noted that certain burdens "cannot be fully monetized," 84 Fed. Reg. at 23,239, it considered them to the extent it could, *see id.* at 23,239–46. Plaintiffs' attacks on HHS's burden analysis attempt to elevate Plaintiffs' judgment over that of the agency and, accordingly, must fail.

Title VII. Plaintiffs also claim that HHS "substitutes Title VII's established religious-accommodation process with a process that would be fundamentally unworkable," Pls.' Opp'n 25–26, and failed to explain why it departed from Title VII's framework, *id.* at 27. Plaintiffs' complaint, however, is nothing more than a policy disagreement with the path HHS took in promulgating the Rule. As is evident from the preamble to the Rule, HHS clearly explained why it did not adopt the Title VII framework to

implement the Federal Conscience Statutes. *See* 84 Fed. Reg. at 23,190–91. For one, Title VII contains distinct protections from the Federal Conscience Statutes, and therefore HHS was not required to incorporate standards from that separate statute. HHS explained that Congress's decision to

> take a different approach in Title VII as compared to [the Federal Conscience Statutes] is consistent with the fact that Title VII's comprehensive regulation of American employers applies in far more contexts, and is more vast, variable, and potentially burdensome (and, therefore, warranting of greater exceptions) than the more targeted conscience statutes that are the subject of this rule, which are health care specific, and often procedure specific, and which are specific to the exercise of Congress's Spending Clause authority.

Id. at 23,191. HHS did, however, consider the reasonable-accommodation standard set forth under Title VII and adopted components of that standard when modifying the definition of "discrimination" in response to comments on the proposed Rule. *See id*. Thus, it can hardly be said that HHS failed to adequately consider or explain its choices vis-a-vis Title VII. Plaintiffs would simply prefer that HHS had made a different choice.

V. Plaintiffs' Spending Clause and Establishment Clause Claims Are Not Ripe.

Plaintiffs' Spending Clause and Establishment Clause claims are not ripe. The ripeness analysis turns on whether the Court would benefit from awaiting a concrete enforcement action applying the Rule before assessing the merits of Plaintiffs' constitutional claims and whether there would be any harm to Plaintiffs in the interim. Plaintiffs cannot dispute that they have not been the subject of any enforcement action, or that multiple steps would have to occur before any loss of federal funds could come to pass. And of course if Plaintiffs did violate the Rule, and the agency's informal resolution attempts failed, and the agency took enforcement action against Plaintiffs, and all other applicable procedures were exhausted, Plaintiffs offer no reason why they could not seek judicial relief *then*.

Plaintiffs are also unsuccessful in distinguishing *NFPRHA v. Gonzales*, 468 F.3d 826, 827 (D.C. Cir. 2006), and *California v. United States*, No. C 05-00328 JSW, 2008 WL 744840, at *3 (N.D. Cal. Mar. 18, 2008). Plaintiffs argue that the definition of "discrimination" and other terms in the Rule present an "immediate regulatory burden[]" that was lacking in *NFPRHA,* Pls.' Opp'n 14, but *NFPRHA* involved a challenge to the entire Weldon Amendment, which originated various conscience-based restrictions on federal funds in the first place. To distinguish *California*, Plaintiffs suggest that there is an ongoing enforcement action against them, but the letter they cite discusses an investigation occurring directly under

the Statutes, not under the Rule. Pls.' Opp'n 5 & n.3, 15. Plaintiffs argue that they must decide now on their future course of action, but that was equally true when the Weldon Amendment was enacted prior to *NFPRHA* and *California*. And, to the extent that Defendants do not challenge the ripeness of Plaintiffs' non-constitutional claims, those claims will still be adjudicated.

VI. The Rule Does Not Violate the Spending Clause.

In their Spending Clause arguments, Pls.' Opp'n 38–42, Plaintiffs reaffirm that they do not object to the Federal Conscience Statutes and double-down on their insistence that the Rule is an unconstitutional departure from the Statutes. But Plaintiffs do not even attempt to identify an unconstitutional difference between the two. For example, Plaintiffs argue the Rule is coercive because it potentially affects a large pot of money, *id.* at 38–39, but precisely the same is true of the Federal Conscience Statutes. The Rule does not expand the Statutes—for example, it does not "bootstrap[]" the consequences of a violation of the Weldon Amendment into a violation of other provisions, *contra id.* at 39. As Defendants have explained elsewhere, the Rule is a clarifying regulation that does not alter the Statutes' substantive requirements. 84 Fed. Reg. at 23,256.

HHS's previous comments concerning the interaction of the Spending Clause and the Weldon Amendment are not relevant here, where Plaintiffs do not challenge the constitutionality of the Weldon Amendment. *Cf.* Pls.' Opp'n 39 (citing App'x 396). Indeed, HHS's sensitivity to the Spending Clause provides no reason to rush to judgment on the Rule given that it is not yet in effect and thus has never been applied in a specific factual circumstance.

The Rule, like the Federal Conscience Statutes, is unambiguous, and Plaintiffs had ample notice of the conditions attached to federal funds. As Defendants have previously explained, Defs.' Mem. 32, the standard for conditions on federal funds is not perfect clarity or perfect notice. When a condition is present but "largely indeterminate," the Spending Clause is satisfied if a state nonetheless chooses to accept the federal funds. *Mayweathers v. Newland*, 314 F.3d 1062, 1067 (9th Cir. 2002); *see also id.* ("Congress is not required to list every factual instance in which a state will fail to comply with a condition."). The question is whether the state knew the funds were conditioned. Plaintiffs do not substantively dispute this contention or assert that they did not understand that the Federal Conscience Statutes included non-discrimination requirements. It is thus irrelevant if Plaintiffs believe there is some

uncertainty concerning specific definitions or subrecipients.[9] Indeed, it is ironic that Plaintiffs object to the lack of clarity and specificity in the Rule, when the Rule provides additional clarity for funding recipients as compared to the Statutes.

Likewise, Plaintiffs argue that the funds at issue are allegedly unrelated to the conscience protections' purpose of alleviating potential conscience burdens on individual and institutional health care entities. Pls.' Opp'n at 42. If any such nexus problem existed, however, it would apply equally to the Statutes, since it is the Statutes that determine which sources of federal funds are subject to conditions. Plaintiffs do not explain how the Rule, which applies only to HHS administered, conducted, or funded programs, would somehow affect Plaintiffs' funds from the Departments of Labor and Education. *See* 84 Fed. Reg. at 23,170 (stating that the rule addresses enforcement of "Federal conscience and anti-discrimination laws applicable to the Department, its programs, and recipients of HHS funds"). To the extent that remedies under other regulations, such as the UAR, may affect other funds, those other regulations are not altered by the Rule or challenged by Plaintiffs.

Nor are the conditions on federal funds retroactive—Plaintiffs admit that they have long been aware of the funding conditions set by the Federal Conscience Statutes. This is not a case where, as in *NFIB*, the programs are being changed so dramatically that they constitute entirely new programs. *Cf. Nat'l Fed'n of Indep. Bus.* (*NFIB*) *v. Sebelius*, 567 U.S. 519, 582–83 (2012) (holding that the Medicaid statute authorized Congress to modify the statute's terms without creating Spending Clause problems, so long as the modifications did not rise to the level of creating a new program). Instead, as discussed previously, the Rule merely implements the Statutes, and Plaintiffs are incorrect that this is a shift in kind rather than degree, for the reasons previously discussed.

And of course, the Spending Clause does not bar *all* adjustments to the terms on which the federal government offers funds—if that were the case, the Supreme Court's opinion in *NFIB* would likely have been much shorter. *See NFIB*, 567 U.S. at 575, 583, 585 (noting that "[t]here is no doubt that the Act dramatically increases state obligations under Medicaid" before engaging in multiple pages of Spending Clause analysis to determine the extent of the changes).

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[9] Plaintiffs do not rebut that the Rule addresses concerns about liability for sub-recipients' actions. *Compare* Defs.' Mem. at 32 (citing 84 Fed. Reg. at 23,220), *with* Pls.' Opp'n at 40 n.61.

VII. The Rule Does Not Violate the Establishment Clause.

Plaintiffs fail to reconcile the essential tension of their Establishment Clause argument: their insistence that the Rule somehow violates the Establishment Clause and their apparent concession that the Federal Conscience Statutes do not. Other than Plaintiffs' unsupported assertion that the Rule "wildly expands" the Statutes, Pls.' Opp'n 42, (which is incorrect, for the reasons stated *supra*), Plaintiffs fail to explain why the Statutes do not likewise burden third parties, elevate religion over non-religion, or entangle the government with religion.

Plaintiffs boldly argue that the Rule improperly advances certain religious beliefs, even though the Rule (and Statutes) do not endorse any religion, much less a specific religion. Both the Rule and Statutes are generally neutral between religion and non-religion.[10] *See, e.g.*, 42 U.S.C. § 238n (Coats-Snowe Amendment); Pub. L. No. 115-245, Div. B., sec. 507(d), 132 Stat. 2981 (Weldon Amendment); 42 U.S.C. § 300a-7 (Church Amendments). The fact that the government accommodates both religious and non-religious objections has long been a factor indicating that there is no Establishment Clause violation, *Bd. of Educ. of Kiryas Joel Vill. Sch. Dist. v. Grumet*, 512 U.S. 687, 704 (1994) (collecting cases), and Plaintiffs cite no contrary case finding an Establishment Clause violation as to a statute or regulation that accommodates objections whether based on religion or not.

Plaintiffs misstate the law by asserting that the government can protect religious liberty through religious accommodations "only to alleviate substantial government-imposed burdens on religious practice." Pls.' Opp'n 45. Title VII, which Plaintiffs cite with approval elsewhere in their brief, is a clear counterexample where the government has required private entities not to discriminate based on their employee's religious beliefs. *See* Cal. Gov. Code § 12940 (likewise prohibiting employers from discriminating against employees based on religious creed). Plaintiffs cite cases discussing RFRA, Pls.' Opp'n 46, but RFRA is not a ceiling on the government's power to accommodate religious freedom.

Plaintiffs assert—without support—that the Rule "protects certain denominations' religious

[10] And the handful of Federal Conscience Statutes that are limited to religious objectors, *see, e.g.*, 42 U.S.C. §§ 1320a-1(h) (referring to religious nonmedical health care institutions), are not challenged by Plaintiffs. In any event, the Establishment Clause does not prevent the government from accommodating religion. *See, e.g.*, *Corp. of Presiding Bishop of Church of Jesus Christ of Latter-day Saints v. Amos*, 483 U.S. 327, 335 (1987).

beliefs in opposition to religious freedom and LGBT rights," Pls.' Opp'n 46, and suggest—again, baselessly—that the Rule is HHS's attempt to "favor[]" the Jewish faith over other traditions, Pls.' Opp'n 46. This is an astonishingly wrong argument. On its face, the Rule explains its purpose to protect the conscience rights, both religious and non-religious, of entities covered by the Federal Conscience Statutes. Under Plaintiffs' flawed logic, a federal requirement that school lunch include fruits and vegetables would violate the Establishment Clause by "favoring" Seventh-day Adventism, Jainism, or other faith groups that encourage vegetarianism. Finally, the Church Amendments, and thus the Rule in implementing them, equally protect entities from discrimination based on choosing to *perform* abortions and choosing *not* to perform abortions, *see, e.g.*, 42 U.S.C. § 300a-7(c)(1), further demonstrating that the Rule does not, as Plaintiffs suggest, favor particular religious beliefs.

And of course if any of these contentions were correct (and they are not), they would apply equally to the Statutes, which originate the conditions on federal funds and control which services are affected. For the same reasons, the Rule does not coerce anyone to adhere to purportedly favored religious practices, or entangle the government with religion. Pls.' Opp'n 46–47.

Plaintiffs continue to argue that the Establishment Clause bars *any* burdens on a third party, but Supreme Court precedent forecloses this extreme view. "[In *Gillette*,] the Court upheld a military draft exemption, even though the burden on those without religious objection to war (the increased chance of being drafted . . .) was substantial. And in *Corporation of Presiding Bishop*, the Court upheld the Title VII exemption even though it permitted employment discrimination against nonpractitioners of the religious organization's faith." *Bd. of Educ. of Kiryas Joel Vill. Sch. Dist.*, 512 U.S. at 725. Instead, potential burden is one factor that the court may consider to determine if an accommodation strays into the unlawful fostering of religion. *See Amos*, 483 U.S. at 334–35. Here, as previously discussed, the Rule does not improperly foster religion because it also protects non-religious objections, and because it merely encourages entities not to discriminate against health care providers based on the providers' conscience decisions. *Cf. Chrisman*, 506 F.2d at 311 (concluding that a provision of the Church Amendments satisfied the Establishment Clause without analyzing the burden on third parties).

Contrary to Plaintiffs' view, the problem that the Supreme Court identified in *Estate of Thornton v. Caldor*, 472 U.S. 703 (1985), was not the burden on third parties, but rather that the statute offered a

benefit only to the religiously inclined. In *Texas Monthly, Inc. v. Bullock*, 489 U.S. 1 (1989), the Supreme Court discussed tax exemptions for religious and nonreligious organizations that had been upheld and explained, citing *Thornton*, that "were [the] benefits confined to religious organizations . . . we would not have hesitated to strike them down for lacking a secular purpose and effect." *Id*. at 11, s*ee also Hobbie v. Unemployment Appeals Comm'n of Fla.*, 480 U.S. 136, 144–46 & n.11 (1987) (citing *Thornton* as an example of an impermissible religious preference and upholding an award of unemployment benefits to a religious objector when the benefits were available to the religious and non-religious alike because "the provision of unemployment benefits generally available within the State to religious observers . . . neutrally accommodate[s] religious beliefs and practices, without endorsement"). Here, the Establishment Clause is not violated because the Statutes and Rule address both religious and non-religious objections. Nor does the Rule "require[] Plaintiffs to accede to all religious objections." Pls.' Opp'n 43. Many conceivable religious objections would not be covered by any of the Federal Conscience Statutes, and, thus, would not be covered by the Rule.

VIII. The Rule Does Not Violate Equal Protection or Due Process.

Plaintiffs lack third-party standing to bring facial equal protection and due process challenges to the Rule, and in any event fail to state a claim.

Plaintiffs now assert that they bring their Equal Protection, Due Process, and Free Speech claims through the Santa Clara physician-plaintiffs, and claim an unequivocal right to do so. Pls.' Opp'n 11. Plaintiffs rely on *Singleton v. Wulff*, 428 U.S. 106, 117 (1976), which concerned the rights of "physicians who perform nonmedically indicated abortions," *id.* at 108, to assert rights on behalf of pregnant "women patients as against governmental interference with the abortion decision," *id.* at 106. But Plaintiffs attempt to extend that case to circumstances well beyond its ken.[11] None of the Santa Clara physician-plaintiffs appear to be "physicians who perform nonmedically indicated abortions," *id.* at 108; *Santa Clara v. HHS,* 19-cv-2916, Compl. ("Santa Clara Mem.") ¶¶ 29–46, ECF No. 1; *see also Santa Clara v. HHS,* 19-cv-

[11] As the *Singleton* court emphasized, "[u]nless the 'provider of services' that he has in mind enjoys with his 'client' a confidential relationship such as that of the doctor and patient, unless the 'client's' claim is imminently moot, as the pregnant woman's technically is, the standing issue in such a future case will not be definitively controlled by this one." *Singleton*, 428 U.S. at 118 n.6 (plurality op.).

2916; *see also* Decl. of Colleen McNicholas ¶ 6, ECF No. 36-14 at 3–4, and none of them plead that their specific patients' claims may be "imminently moot" in the way that pregnant, abortion-seeking women's claims can be, thus potentially necessitating the physicians' assertion of their patients' rights.[12] *Singleton*, 428 U.S. at 115–16; *see also* Santa Clara Compl. ¶¶ 29–46. Thus, *Singleton* and its progeny do not control, nor do Plaintiffs identify any other binding precedent that would allow them to raise claims on behalf of third-party patients in this case. *See* Pls.' Opp'n 11–12.

Even if the Santa Clara Plaintiffs had standing, their claims, which would essentially require this Court to treat the Federal Conscience Statutes themselves as invalid, fail. Plaintiffs narrow their previously sweeping Equal Protection claim to challenge only the Rule's purported "targeting [of] transgender patients' transition-related health care needs for religious and moral objection," Pls.' Opp'n 47; *compare with* Santa Clara Compl. ¶ 245. But the Rule's provisions apply regardless of whether a patient is transgender, and thus, they do not treat individuals unequally. Indeed, in their opening brief, Defendants explained that Plaintiffs' Equal Protection claim fails because the Rule does not create suspect classes, facially infringe on any fundamental right, or evince purposeful discrimination. Defs.' Mem. 37–38. Plaintiffs offer no response to these arguments in their opposition.

Plaintiffs do suggest that the Rule targets transgender patients by characterizing "medically-necessary healthcare procedures sought by transgender patients to treat gender dysphoria as 'sterilization,'" Pls.' Opp'n 47, but the Rule does no such thing. The Rule does not define the term "sterilization"—for purposes of the Church Amendments or otherwise. *See generally* 45 C.F.R. § 88.1–88.10. Instead, the agency explained that it would consider the issue of whether the Federal Conscience Statutes "apply to sterilizations performed in the context of gender dysphoria," if necessary, "on a case-

[12] Regarding transgender patients, on whose behalf Plaintiffs appear to raise their Equal Protection and Free Speech claims, Plaintiffs attempt to extend the imminent-mootness prong described in *Singleton* to cases in which transgender patients seek gender-transition treatments. They do so by improperly relying on facts asserted in a declaration submitted by a putative expert attached to their opposition brief. *See infra* sec. X. The declaration, moreover, generally predicts that some "[g]ender dysmorphic patients who are assigned a male sex at birth but identify as female and lack access to appropriate care are often so desperate for relief that they may resort to life-threatening attempts at auto-castration . . . ." Decl. of Randi Ettner ¶ 22, ECF No. 75. This generalized statement about decisions that *some* gender dysmorphic patients *may* take is insufficient to show that any claims that the Santa Clara physician-plaintiffs' specific patients have are "imminently moot,.L." *Cf. Kowalski v. Tesmer*, 543 U.S. 125, 131 (2004).

by-case basis." 84 Fed. Reg. 23,205. Plaintiffs' claim based on a non-existent definition is meritless.[13]

Finally, contrary to Plaintiffs' assertions, Pls.' Opp'n 47–48, the Rule clearly bears a rational relationship to the government's interest in preventing conscience discrimination as set forth in the Federal Conscience Statutes. *See* 84 Fed. Reg. 23,175; *see also Erotic Serv. Provider Legal Educ. & Research Project v. Gascon*, 880 F.3d 450, 457 (9th Cir. 2018), *amended,* 881 F.3d 792 (9th Cir. 2018) ("Rational basis review is highly deferential to the government, allowing any conceivable rational basis to suffice.").

As for their Due Process challenge, Plaintiffs attempt to escape the Supreme Court's decision in *Rust v. Sullivan*, 500 U.S. 173, 193 (1991), with no more than a cursory sentence claiming that they have made a "specific showing" of undue burden and a level of harm "failing any level of scrutiny." Pls.' Opp'n 50–51. But contrary to Plaintiffs' assertions, they have not shown that the Rule facially violates any fundamental right,[14] *see* Pls.' Opp'n 49–50; even if the Court could consider Plaintiffs' declarations (and it cannot, *see infra* sec. X), those declarations at most speculate about the Rule's potential downstream effects.[15] That is not enough to sustain a facial, substantive due process challenge. *Lopez-Valenzuela v. Arpaio*, 770 F.3d 772, 780 (9th Cir. 2014) ("To succeed on their facial challenge, the plaintiffs must show that the [challenged rule is] unconstitutional in all . . . applications."); *United States v. Salerno*, 481 U.S. 739, 745 (1987). And *Rust* makes cleal#ed00 U.S. at 201, let alone a duty to fund health care entities that discriminate against those who object to abortion or other similar services or procedures on conscience grounds. That such regulations "do not impermissibly burden a woman's Fifth Amendment rights is

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[13] The Court has asked "whether the word 'sterilization' as used in the Church Amendments was intended to cover transgender medical operations and/or gender reassignment surgery." ECF No. 135. As noted above, HHS did not address that question in the Rule and has not otherwise taken a position on whether the Church Amendments intended to cover such procedures. The Court thus need not resolve the issue here, on this facial challenge, since Plaintiffs challenge only the Rule itself.

[14] Nor do Plaintiffs establish that "gender identity[] and self-definition" are fundamental rights for the purposes of Due Process analysis. *But see Karnoski v. Trump*, 926 F.3d 1180, 1201 (9th Cir. 2019) (applying intermediate scrutiny to a government policy that excluded transgender individuals).

[15] *See, e.g.*, Second Decl. of Colleen McNicholas ¶ 27, ECF No. 87 ("To the extent that [the Rule] discourages entities like Trust Women from offering any services to which our employees, volunteers, or contractors may possibly object and threatens to remove or even claw back funding from entities that do not comply with such broad requirements, it is unworkable and could force Trust Women and other providers across the country to drastically alter the care we offer to patient or close entirely."); Decl. of Elizabeth Barnes ¶ 20, ECF No. 60 ("The Rule creates an opening for anti-wwwws to infiltrate and incapacitate our clinic by . . . creating threats to security as well as the basic right of the patient to non-judgmental supportive care . . . .").

evident" from a whole line of cases predating *Rust*, and Plaintiffs offer no meaningful reason to stray from this established jurisprudence. *Id.*

I. The Rule Does Not Violate the Free Speech Clause.

Even assuming that the Santa Clara physician-plaintiffs have standing to raise a Free Speech challenge to the Rule on behalf of their patients—which they do not—the Rule does not unconstitutionally burden their patients' speech. As Defendants explained in their opening brief, the Rule imposes *no* burdens or other restrictions on patients' speech and merely ensures health care entities' compliance with the funding restrictions in the Federal Conscience Statutes.[16] Defs.' Mem. 35–36. Here again, Plaintiffs fail to grapple with the Supreme Court's decision in *Rust*, dismissing the case because it purportedly did not involve patient rights and instead weaving together inapposite case law to make their point. Pls.' Opp'n 51–52. But the plaintiffs in *Rust* did claim that the regulations at issue "violate[d] the 'free speech rights of private health care organizations that receive Title X funds, of their staff, *and of their patients*' by impermissibly imposing 'viewpoint-discriminatory conditions on government subsidies,'" *Rust*, 500 U.S. at 192 (emphasis added), and the Court in turn explained that there was "no question" that the regulations were constitutional, *id.* "To hold that the Government unconstitutionally discriminates on the basis of viewpoint when it chooses to fund a program dedicated to advance certain permissible goals, because the program in advancing those goals necessarily discourages alternative goals, would render numerous Government programs constitutionally suspect." *Id.* at 194.

IX. The Rule Creates No Separation of Powers Concerns.

Plaintiffs' arguments concerning the separation of powers, Pls.' Mem. at 52–54, continue to misapprehend the Rule by suggesting that the Rule changes the amount of money or funding sources that the Federal Conscience Statutes could affect. As previously explained, the Rule does not change the Statutes' substantive requirements and thus does not newly link funds tied by statute to the Church Amendments (for example) to violations of the Weldon Amendment (for example) or *vice versa*.

[16] Nor do Plaintiffs plead that "deterrence [of protected speech] was a substantial or motivating factor in the [agency's] conduct." *Mendocino Envtl. Ctr. v. Mendocino Cnty.*, 192 F.3d 1283, 1300 (9th Cir. 1999).

X. The Court May Not Consider Plaintiffs' Extra-Record Materials.

The Court should reject Plaintiffs' improper attempt to create a new record for the purposes of this litigation by submitting declarations and other materials to bolster their merits arguments. The APA provides that, "[i]n making the [] determinations [regarding the lawfulness of agency action], the court shall review the whole record," 5 U.S.C. § 706, and the Supreme Court has long held that the whole record is limited to "the full administrative record that was before the Secretary at the time he made his decision," *Citizens to Pres. Overton Park Inc. v. Volpe*, 401 U.S. 402, 420 (1971). *See also Camp v. Pitts*, 411 U.S. 138, 142 (1973) (holding that "the focal point for judicial review should be the administrative record already in existence, not some new record made initially in the reviewing court"); *Florida Power & Light Co. v. Lorion*, 470 U.S. 729, 743–44 (1985) ("The task of the reviewing court is to apply the appropriate APA standard . . . to the agency decision based on the record the agency presents to the reviewing court.").

Ninth Circuit decisions reflect these same principles that the court should ordinarily not consider extra-record evidence when evaluating the merits of claims brought under the APA. *See, e.g.*, *Jet Inv., Inc. v. Dep't of Army*, 84 F.3d 1137, 1139 (9th Cir. 1996). The Ninth Circuit "allows for a court to review material outside of the administrative record" in only "four narrow circumstances." *Cachil Dehe Band of Wintun Indians of Colusa Indian Cmty. v. Zinke*, 889 F.3d 584, 600 (9th Cir. 2018). Those narrow exceptions are as follows: (1) where the extra record-evidence is necessary to determine whether the agency has considered all relevant factors and has explained its decision; (2) where the agency has relied on documents not in the record; (3) where supplementing the record is necessary to explain technical terms or complex subject matter; or (4) where plaintiffs make a showing of agency bad faith. *Id.* The scope of these exceptions is "constrained, so that the exception does not undermine the general rule." *Lands Council v. Powell*, 395 F.3d 1019, 1039 (9th Cir. 2005). Otherwise, "[w]ere the federal courts routinely or liberally to admit new evidence when reviewing agency decisions, it would be obvious that the federal courts would be proceeding, in effect, *de novo* rather than with the proper deference to agency processes, expertise, and decisionmaking." *Id.* Plaintiffs bear the burden of demonstrating that the administrative record is inadequate. *Animal Def. Council v. Hodel*, 840 F.2d 1432, 1437 (9th Cir. 1988).

None of the Ninth Circuit's recognized exceptions applies here, nor have Plaintiffs claimed that any exception applies. Defendants provided the administrative record to Plaintiffs on July 22, 2019, and

then supplemented it—mostly with materials that were already publicly available—on August 19, 2019. Plaintiffs therefore had ample opportunity to seek to supplement the administrative record or to identify any deficiencies if they believed it to be incomplete. But Plaintiffs have not done so.

Instead, Plaintiffs baldly flout the longstanding rule limiting review to the administrative record. For example, Plaintiffs rely in several instances on declarations to attempt to support their arguments that the Rule is arbitrary and capricious. *See* Pls.' Opp'n 17; *id.*at 19 & n.36. Plaintiffs cite to the declarations of Darrel Cummings and Sarah Henn to describe certain emergency experiences among their patients. *See* Pls.' Opp'n 17. Dr. Cummings or Dr. Henn could have described those circumstances by submitting comments during the rulemaking, but because they did not, the Court cannot consider their statements now. Plaintiffs also submit the declaration of Randie Chance for his description of complaints contained in the administrative record. *See* Pls.' Opp'n 24. But the complaints in the record speak for themselves, and Dr. Chance's analysis was not before the Secretary when he made his decision. It is therefore not properly part of the Court's merits analysis. Plaintiff also include a declaration from Dr. Wendy Chavkin for her perspective on HHS's citation in the Rule to an article she authored. *Id.* 13, 19, 24. But Dr. Chavkin's article also speaks for itself, and to the extent Dr. Chavkin identifies other potentially relevant articles to consider, she or other commenters could have identified the same articles in comments submitted to the agency during the rulemaking process.

The Court should also limit its review to the administrative record on Plaintiffs' constitutional claims. As Plaintiffs acknowledge, the APA provides the private right of action necessary for Plaintiffs to assert constitutional claims for equitable relief with respect to final agency action. *See* Pls.' Opp'n 13 n.21 ("[T]he APA provides a single cause of action challenging final agency action."); *see also* 5 U.S.C. § 706(2)(B) (permitting judicial review of agency action "contrary to constitutional right, power, privilege, or immunity"). Section 706 of the APA, by its plain language, restricts the review of constitutional claims to the administrative record. A contrary rule—one of admitting exception for constitutional claims—would "incentivize every unsuccessful party to agency action to allege . . . constitutional violations to trade in the APA's restrictive procedures" for the Federal Rules of Civil Procedure. *Jarita Mesa Livestock Grazing Ass'n v. U.S. Forest Serv.*, 58 F. Supp. 3d 1191, 1238 (D.N.M. 2014). Defendants, moreover, are aware of no Ninth Circuit decision recognizing an exception to the

record review rule for constitutional claims. And many district courts have rejected requests to create any such exception. *See, e.g.*, *Jiahao Kuang v. U.S. Dep't of Defense*, 2019 WL 293379, at *2-3 (N.D. Cal. Jan 23, 2019); *Moralez v. Perdue*, 2017 WL 2265855, at *3 (E.D. Cal. May 24, 2017). The Court should therefore reject Plaintiffs' improper attempt to support their constitutional claims with extra-record material. *See, e.g.*, Pls.' Opp'n 41 & nn. 63–65 (citing declarations for Plaintiffs' Spending Clause claim); *id.* at 43 (citing declarations for Plaintiffs' Establishment Clause claim).

The Ninth Circuit confirmed this principle in *Fence Creek Cattle Co. v. U.S. Forest Service*, in which it affirmed the judgment of the district court to limit review to the administrative record even though the plaintiff had alleged violations of "constitutional due process guarantees." 602 F.3d 1125, 1131 (9th Cir. 2010). The court of appeals reiterated that "expansion of the administrative record" is permitted only in "four narrowly construed circumstances," discussed above. *See id*. Accordingly, and as a district court helpfully summarized, "when a constitutional challenge to agency action requires evaluating the substance of an agency's decision made on an administrative record, that challenge must be judged on the record before the agency." *Bellion Spirits, LLC v. United States*, 335 F. Supp. 3d 32, 43 (D.D.C. 2018). No matter how Plaintiffs frame this case, this Court will ultimately "evaluat[e] the substance of an agency's decision," *id.* That evaluation should rest on the administrative record alone, as the APA requires.

Because none of the Ninth Circuit's exceptions applies, the Court should not consider extra-record material when evaluating the merits of Plaintiffs' claims. Defendants acknowledge, of course, that Plaintiffs have flooded the docket with declarations purporting to establish alleged harm that will result from the Rule. Defendants disagree fervently with those allegations for the reasons explained in the preamble to the Rule, among others. However, because review in this case is properly limited to the administrative record, and because the appropriate time for Plaintiffs to comment on the alleged impact of HHS's proposals was during the rulemaking process, Defendants do not address the factual allegations in Plaintiffs' declarations. Nor is it necessary for the Court to address those allegations in order to resolve the legal questions at issue in the parties' cross motions for summary judgment. *See, e.g.*, *Am. Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1083 (D.C. Cir. 2001) ("As we have repeatedly recognized [ ], when a party seeks review of agency action under the APA, the district judge sits as an appellate tribunal. The entire case on review is a question of law." (internal quotation omitted)).

XI. Any Relief Accorded to Plaintiffs Should Be Limited.

For all the reasons described above, and in Defendants' opening brief, the Rule is lawful and therefore should not be vacated. Plaintiffs insist, however, that, if the Court finds that any part of the Rule is invalid, it must strike down the Rule in its entirety, rather than respect the agency's clear intent that portions of the Rule found to be invalid should be severed from the remainder. *See* Pl.'s Opp'n 40; *see also* 84 Fed. Reg. at 23,272. Plaintiffs fault Defendants for providing only a "conclusory severance argument." Pl.'s Opp'n 40. But Plaintiffs ignore that it is *Plaintiffs'* burden—not Defendants'—to explain why any portion of a lawfully promulgated regulation should not be allowed to go into effect. *Cf. Alaska Airlines v. Donovan*, 766 F.2d 1550, 1560 (D.C. Cir. 1985) ("[T]he burden is placed squarely on the party arguing against severability to demonstrate that Congress would not have enacted the provision without the severed portion."). It is therefore Plaintiffs whose severability analysis is lacking. In any event, portions of the Rule can clearly operate independently from each other. For example, if the Court were to strike down any particular definition in the Rule (which it should not, for the reasons explained above), the remaining definitions and other provisions of the Rule could continue to operate independently.

Finally, although the Rule is lawful for the reasons Defendants have explained, if the Court were to disagree, any relief must be limited to the specific Plaintiffs before the Court. Plaintiffs insist that nationwide relief is the "usual" remedy under the APA. But Plaintiffs ignore the Supreme Court's recent instruction to the contrary. In *Gill v. Whitford*, 138 S. Ct. 1916 (2018), the Court explained that any remedy "must be tailored to redress the plaintiff's particular injury." *Id.* at 1934. Vacating the Rule on a nationwide basis would go far beyond what is necessary to address Plaintiffs' particular alleged injury, and nationwide relief would effectively stop courts in other jurisdictions assessing similar challenges from evaluating those separate claims. *See* Defs.' Mem. 38–39.[17]

CONCLUSION

For the foregoing reasons, the Court should grant Defendants' motion and deny Plaintiffs' motion.

Dated: September 26, 2019 Respectfully Submitted,

[17] Defendants previously explained that, even if the Court were to set aside any or all of the Rule, the Court should make clear in its order that the relief does not prevent HHS from continuing to investigate violations of, and to enforce, federal conscience and anti-discrimination laws under the existing 2011 Rule or the Federal Conscience Statutes themselves. *See* Defs.' Mem. 40. Plaintiffs did not respond and therefore have conceded the point.

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