1   IN THE SUPREME COURT OF THE UNITED STATES

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3   ASTRA USA, INC., ET AL.,   :

4   Petitioners   :   No. 09-1273

5   v.   :

6   SANTA CLARA COUNTY, CALIFORNIA   :

7   - - - - - - - - - - - - - - - - - - x

8   Washington, D.C.

9   Wednesday, January 19, 2011

10

11   The above-entitled matter came on for oral

12   argument before the Supreme Court of the United States

13   at 11:08 a.m.

14   APPEARANCES:

15   LISA S. BLATT, ESQ., Washington, D.C.; on behalf of

16   Petitioners.

17   GINGER D. ANDERS, ESQ., Assistant to the Solicitor

18   General, Department of Justice, Washington, D.C.; on

19   behalf of the United States, as amicus curiae,

20   supporting Petitioners.

21   DAVID C. FREDERICK, ESQ., Washington, D.C.; on behalf of

22   Respondent.

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1   C O N T E N T S

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1   P R O C E E D I N G S

2   (11:08 a.m.)

3   CHIEF JUSTICE ROBERTS: We'll hear argument

4   next this morning in Case 09-1273, Astra USA v. Santa

5   Clara County.

6   Ms. Blatt.

7   ORAL ARGUMENT OF LISA S. BLATT

8   ON BEHALF OF THE PETITIONERS

9   MS. BLATT: Thank you, Mr. Chief Justice,

10   and may it please the Court:

11   There are three reasons why section 340B

12   entities do not have a cause of ation to enforce the

13   pharmaceutical pricing agreement between the Secretary

14   and manufacturers.

15   The first reason is that this common law

16   breach of contract suit is indistinguishable from an

17   implied right of action to enforce the statute, a right

18   Respondent concedes it does not have.

19   JUSTICE SOTOMAYOR: I don't understand that.

20   A private contract is just that. Two parties go into

21   the contract. They set the terms of their deal. No one

22   forced the manufacturers to enter into this deal. So

23   why isn't the issue exactly what the circuit court said:

24   What was the intent of the parties to the contract? You

25   want to make it Congress's intent, but this is a private

                                3

1 deal between you. And Congress may have specified some

2 terms to include, but --

3   MS. BLATT: Yes. And the -- what is being

4 challenged here is the contractual term that

5 incorporates in haec verba the manufacturer's ceiling

6 price obligations under the Act, and a third-party

7 beneficiary's suit to enforce the contract asserts the

8 same right, seeks the same remedy, and causes all the

9 same disruptions as a right of action to enforce the

10 statute.

11   And another way of saying that is, if the

12 case begins with the premise that Congress foreclosed

13 340B entities from bringing an implied right of action

14 through the front door, Congress did not leave the back

15 door open to essentially the same suit.

16   JUSTICE SOTOMAYOR: How do you answer the

17 point that, if Congress wanted to make this a pure

18 regulatory statute, it wouldn't have even required a

19 contract? It would have just passed a statute that says

20 anyone who wants to -- to sell to the -- to the States

21 or to the 340B entities -- you can't charge more than

22 this price.

23   Why do we even need a contract, unless

24 inherent with it is some discretion in the agency who's

25 administering it?

4

1   MS. BLATT: Right. Well --

2   JUSTICE SOTOMAYOR: Discretion that is

3   consistent with normal contract principles.

4   MS. BLATT: Right. Well, our position is

5   obviously that the parties had no discretion to confer

6   Article III power on courts to enforce an Act of

7   Congress, and this is. But the -- the basic answer is

8   that there has always been a huge difference between the

9   settled rule that parties to a statutory contract are

10 enforceable -- they have a cause of action to enforce

11 the contract, because Congress spoke with unambiguously

12 clear language that the parties could sue. That's the

13 way statutory contracts must work. They must be

14 enforceable.

15   But your answer, sort of as a practical

16 matter, what's the difference, is this is a -- this is a

17 contract, and we do think that the Federal law of

18 contracts and contractual remedies flow between the

19 parties to the contract. It's a bilateral agreement,

20 it's not a regulation, and the Secretary made specific

21 enforceable promises. And there's obviously no even

22 operation of the statutory mandate without the contract.

23   But the reverse, in terms of the -- the

24 long-settled rule that parties must be able to sue to

25 enforce a contract, there's an equally settled rule that

1   beneficiaries under a statute do not have the right to

2   enforce it unless there's a cause of action.

3   Now, the test that I think Respondent

4   advocates and that the Ninth Circuit applied is a test

5   this Court has long since discarded, which is: Well,

6   I'm a beneficiary, and this is a good idea, and this is

7   sensible. Even if you don't buy our test of you have to

8   imply the implied right of action, these lawsuits are

9   neither sensible nor a good idea and not what Congress

10 intended. And here's why.

11   And it is basically the second and third

12 reasons. So no matter how you come at this case and the

13 lens through which you look at this, I think everyone

14 should come out to the same place, which is that neither

15 Congress nor the Secretary nor the manufacturers signed

16 up to what is in essence -- would be over 14,000

17 lawsuits against 500 manufacturers challenging the

18 pricing for over 35,000 medications under Medicaid.

19   JUSTICE SOTOMAYOR: Your adversary claims

20 you gave up your argument that the contract doesn't make

21 the manufacturers a third-party intended beneficiary.

22 Have you given up that argument?

23   MS. BLATT: No. I think that the -- that

24 the whole thrust of the petition -- and obviously the

25 primary argument is that this flouts the implied right

1   of action jurisprudence and it -- it conflicts with

2   congressional intent in all events. But one of the

3   harms, and sort of illustrating just how bad the

4   decision was, is this conferred rights that the parties

5   never imagined and that the Secretary did not -- did not

6   intend.

7   But I -- I think that, in our view, even if

8   the Secretary had wanted to, it's not the Secretary's

9   decision nor was it the manufacturers' decision to go

10   contract by contract and say this multi-billion dollar

11   health care program that incorporates another, even

12   bigger multi-billion dollar health care program -- we're

13   going to turn this over to Federal enforcement, when on

14   the face of the statute reflects a deliberate decision

15   by Congress to withhold --

16   JUSTICE SCALIA: Private enforcement.

17   MS. BLATT: Private enforcement -- to

18   withhold a private remedy in favor of 340B entities and,

19   instead, channel exclusive authority to the Secretary to

20   enforce it. And those three specifics, in addition to

21   the disruption, are that Congress gave manufacturers,

22   but not 340B entities, a private reimbursement remedy

23   and a private --

24   CHIEF JUSTICE ROBERTS: Is it -- I'm not

25   sure of the answer, but is it different in this case or

7

1   unusual that the agreement is between the Federal

2   Government and private entities, as opposed to what I

3   think is the more typical situation in which these cases

4   come up, where it's, say, an agreement between the

5   Federal Government and a State?

6   MS. BLATT: Well, all your Medicaid cases,

7   obviously, under State plans --

8   CHIEF JUSTICE ROBERTS: Yes.

9   MS. BLATT: -- and a lot of your implied

10   right of action jurisprudence is dealing with Spending

11   Clause legislation as to State entities. But there are

12   a number, a number -- the Rehabilitation Act, the

13   Davis-Bacon Act, and a fair number of health care

14   programs -- where the government contracts with private

15   parties as a public welfare mechanism to get to what I

16   think are conceded are beneficiaries.

17   Here, there's a number of beneficiaries.

18   It's not just the 340B entities. It's the patient

19   population that's being served and, obviously, the

20   Federal fisc. So --

21   JUSTICE GINSBURG: Ms. Blatt, would you

22   explain the function that the contract mechanism serves?

23   I mean, you could just have this -- you could just have

24   the statute say: Thou shalt not charge more than the

25   ceiling price. Period.

1   What -- what is accomplished by having the

2   contract reflecting the terms of the statute?

3   MS. BLATT: Well, I don't think it's any

4   different than Mobil Oil or Jackson Transit, where

5   Congress wants to specify the terms of the contract, and

6   the contract incorporates in haec verba the statutory

7   terms. And if there's a breach of that, there are

8   contractual remedies that flow.

9   But I agree with you that there's not a

10   whole lot difference between our position and the

11   Government, because the Government is absolutely correct

12   that it's in haec verba and identical, and the statutory

13   obligation that we're talking about that's incorporated

14   into the contract is that a certain ceiling price must

15   be charged.

16   But the -- the other sort of practical

17   function is only manufacturers who enter into this

18   contract are subject to these price controls. So if

19   they -- a pharmaceutical manufacturer doesn't want to

20   participate in the program, they're not covered.

21   And in a typical regulation and I think

22   general sort of Spending Clause analysis, someone who

23   accepts Federal funding has considered sort of implicit

24   consent to the funding obligations because they're

25   taking the money. But here's there's an express

1   manifestation both by the Secretary who signed the

2   agreement and the contractors, the pharmaceutical

3   companies who signed the agreement.

4   JUSTICE KENNEDY: Before the statute was

5   amended by I think the Patient Protection Act and there

6   was a breach of the agreement, did the government assess

7   penalties?

8   MS. BLATT: Well --

9   JUSTICE KENNEDY: Because -- and the reason

10 I'm asking this is that you indicate that the government

11 had a contract remedy. It seemed to me it had a

12 regulatory remedy.

13   MS. BLATT: It has got a lot of remedies.

14 It has -- but it --

15   JUSTICE KENNEDY: What was the contract

16 remedy that it had at the time this case arose, which

17 was before the -- these mechanisms.

18   MS. BLATT: Yes. They're -- right. We are

19 still -- today is no different than yesterday, because

20 nothing has happened to implement the 2010 health care

21 reform except that there are now more civil monetary

22 penalties than there were.

23   But the government has statutory penalties,

24 civil monetary penalties, a right of audit. It can

25 bring suits under the False Claims Act and can terminate

1   both this agreement and the Medicaid rebate agreement.

2   But as a -- the government has contractual

3   remedies, too. I mean, why Congress, I think -- a

4   sensible inference for why Congress picked contracts is

5   that this is -- this piggybacks off the Medicaid rebate

6   program, and that uses contracts. And that instead --

7   that in turn, rather, used contracts because the States

8   had negotiated rebate agreements with drug companies way

9   before 1990. And so Congress continued the contract

10   feature.

11   And then, since the pricing components under

12   this program are the same pricing components under the

13   Medicaid rebate program, both programs are parallel and

14   that both use agreement, one is the Medicaid rebate

15   agreement. In this case, it's the pharmaceutical --

16   JUSTICE SCALIA: Ms. Blatt, you said that

17   there's not a whole lot of difference between your

18   position and the Government's. What is the difference

19   between your position and the Government's?

20   MS. BLATT: Well, the Government says a

21   contract is not a contract even though it says it's a

22   contract. Our position is this a contract.

23   JUSTICE SCALIA: That doesn't make much

24   sense, does it?

25   MS. BLATT: The -- the Government sees this,

 1   I think, as just a unilateral -- that the manufacturers

 2   walked in and said we're here and happy to be bound.

 3   But the agreement on its face says the Secretary makes

 4   the following agreement; the Secretary promises this.

 5   The most important promise the Secretary

 6   made to manufacturers is that the Secretary said that

 7   she would not terminate the agreement without good

 8   cause, 60 days' notice, and certain conduct that the

 9   manufacturer did would not constitute grounds for

10   termination.

11   JUSTICE SCALIA: What did the manufacturer

12   promise in exchange for a contract? You do need

13   consideration. What did they promise that they weren't

14   already obliged to do by law?

15   MS. BLATT: Well, the billions and billions

16   in price discounts they were not obliged to do unless

17   they -- they signed the contract. But the contract goes

18   through a ton of manufacturer responsibilities. The

19   manufacturer -- if the Secretary thinks that there is

20   reimbursement that's owed, the Secretary can order

21   reimbursement, and the manufacturer has -- it's a --

22   it's a pretty substantial --

23   JUSTICE BREYER: So what is Santa Clara

24   County supposed do? They -- they think they're being

25   overcharged. And in your opinion, they -- the company

1   doesn't, but they do. So what are they supposed to do

2   if they're right? How do they get the money?

3   MS. BLATT: Well, the way they have been

4   getting the money, and for better or worse until 2010,

5   they have been at the mercy of the vastly larger

6   Medicaid rebate program, which is run on behalf of the

7   States. And because this program is so small compared

8   to that program, all the enforcement activity, which is

9   all the False Claims Act settlements that Respondent

10   cites in his brief, that's how, as a practical matter,

11   it's been enforced.

12   JUSTICE BREYER: I'm interested in

13   procedurally what are they supposed to do?

14   MS. BLATT: Oh, pick up the phone and either

15   call the manufacturer, the prime vendor --

16   JUSTICE BREYER: The manufacturer says:

17   Okay, you're wrong. I'm not; I'm undercharging you.

18   Now what happens.

19   MS. BLATT: Ultimately, if they can't get

20   the Secretary to --

21   JUSTICE BREYER: He's busy.

22   MS. BLATT: If she's busy and won't return

23   the calls, Congress said you can't enforce it --

24   JUSTICE BREYER: Well, Why can't they -- can

25   they, for example, file a claim with the -- with the

1   Secretary and say we would like the Secretary to order

2   them to give us the money; they're violating this? They

3   go to an administrative law judge. Is there an

4   administrative remedy of some kind that would be

5   reviewable in the courts for reasonableness?

6   MS. BLATT: There's just -- right now,

7   there's just an informal, non-mandatory --

8   JUSTICE BREYER: Okay. So why is it

9   reasonable, then, to think that the Secretary would have

10   entered into a contract which is going to benefit them

11   and there's no remedy?

12   MS. BLATT: Because the statute itself said:

13   We're going to go out of our way to give manufacturers

14   remedies, make this confidential; manufacturers have

15   rights of audit, but 340B entities don't. The Secretary

16   -- here's a vast arsenal of things at your disposal, and

17   it's channeled through that regulatory regime.

18   JUSTICE BREYER: But normally under the law

19   from Marbury v. Madison onward, where there's a wrong,

20   there's a remedy.

21   MS. BLATT: But --

22   JUSTICE BREYER: And the remedy could be

23   administrative, could be judicial, et cetera. But

24   you're saying there's none?

25   MS. BLATT: No. I think 30 years have said

1   that we're not going down that road. I mean, in

2   Gonzaga, there was a breach of the statutory provision,

3   and students presumably are harmed when private

4   information gets disclosed. But every private right of

5   action case where you've said no, the argument has

6   been --

7   JUSTICE BREYER: But in such cases, there

8   very often is an administrative remedy --

9   MS. BLATT: That's true.

10   JUSTICE BREYER: -- and the person always --

11   any individual in the United States can go ask any

12   agency to do anything, and there is even review in

13   instances of a refusal to withhold -- a withholding of

14   action.

15   MS. BLATT: There's always an APA action

16   against the Secretary. I just think --

17   JUSTICE BREYER: Is there here? You said

18   there was.

19   MS. BLATT: Well, I think it would be hard

20   to bring an APA action.

21   CHIEF JUSTICE ROBERTS: What about a False

22   Claims Act action?

23   MS. BLATT: Yes. Yes. And False Claims

24   Acts are brought. There's a lot of them, and there's a

25   multitude of settlements that are outlined in the

1   briefs.

2   JUSTICE GINSBURG: Well, to the extent that

3   you're objecting to the disruption of the Secretary,

4   there is disruption when it's a private party bringing a

5   False Claims Act.

6   MS. BLATT: Well, it's not a private party.

7   It's the private party who's assigned the claim. I

8   mean, the case is brought in the name of, and it is a

9   case by the United States. And that's significant

10   because the United States has complete and total control

11   over that case. Here, the problem -- it's bad enough --

12   JUSTICE GINSBURG: Even if the United States

13   doesn't take over the case, just lets the qui tam

14   relator --

15   MS. BLATT: Right.

16   JUSTICE GINSBURG: -- proceed?

17   MS. BLATT: Yes, that's right. It's still

18   brought in the name of the United States with heightened

19   pleading requirements, and they actually have to allege

20   a knowing false statement.

21   CHIEF JUSTICE ROBERTS: You -- you emphasize

22   that the contract has the language in haec verba of the

23   statute. What if -- what if it doesn't?

24   The statute imposes certain provisions. The

25   pricing I guess is the key one. But in a private deal,

1   when you're arranging for the delivery of, you know,

2   pharmaceuticals, you could have a lot of provisions.

3   It's got to be delivered by this much. You've got to

4   have this much inventory. You've got to -- whatever.

5   I mean, what if the contract here included

6   terms beyond those in the statute? Could those be

7   enforced by the third-party beneficiaries?

8   MS. BLATT: Yes. And there is --

9   CHIEF JUSTICE ROBERTS: Yes?

10   MS. BLATT: If it's not enforced in the

11   statute -- only if -- and I think it's significant that

12   plaintiffs always lose under a third-party beneficiary

13   because the bar is so high. The government always

14   enters into contracts on behalf of somebody, and the

15   government rarely intends to confer enforceable rights,

16   and the parties rarely do it.

17   But if you had an express provision outside

18   the statute that said we intend to confer enforceable

19   rights on third parties, and it's not an enforcement of

20   the statute at all, then all your jurisprudence for

21   determining congressional intent aren't being subverted

22   and aren't being undermined.

23   I could give you an example. I mean, it

24   could be anywhere from something just completely outside

25   the statute. Together, the pharmaceutical companies

1   could say we hereby agree to make a contribution every

2   year to the clinic or hospital for a holiday gift. That

3   would be an odd contract. I don't see the Secretary

4   entering into third-party beneficiary contracts. A much

5   more efficient way would just be to contract with the

6   entity itself.

7   But I think this is just another way of

8   saying that a lot of the energy and breath in the court

9   of appeals would be saved in going through why the

10   common law doesn't confer it because congressional

11   intent, by and large, is going to line up with the

12   Secretary, the party's intent.

13   But when you're talking in haec verba, and

14   this could not be more precise because it's the exact --

15   it's actually not even 340B. The allegation is it's a

16   violation of the Medicaid Rebate Act pricing reporting

17   requirements. It's -- congressional intent is all that

18   matters.

19   JUSTICE SCALIA: Is this a contract with the

20   Secretary or a contract with the United States executed

21   on behalf of the United States by the Secretary?

22   MS. BLATT: It is a contract executed by

23   HRSA, the administrator of -- an agency within, and he

24   or she, whoever the administrator is at the time, enters

25   it on behalf of the Secretary. So the --

 1   JUSTICE SCALIA: On behalf of the --

 2   MS. BLATT: So it's in the name of the

 3   Secretary.

 4   JUSTICE SCALIA: It's in the name of the

 5   Secretary?

 6   MS. BLATT: It says -- I mean, it's in the

 7   Pet. App. starting at around 169. It says the

 8   Secretary. And you don't have the signature page, but

 9   I've seen them. They're all signed by the administrator

10   of HRSA, which is the -- the organization within HHS,

11   not CMS but HHS, that runs the 340B program. But if I

12   could -- actually, I'll just save the remainder for

13   rebuttal.

14   CHIEF JUSTICE ROBERTS: Thank you, counsel.

15   Ms. Anders.

16   ORAL ARGUMENT OF GINGER D. ANDERS

17   ON BEHALF OF THE UNITED STATES, AS AMICUS CURIAE,

18   SUPPORTING THE PETITIONERS

19   MS. ANDERS: Mr. Chief Justice, and may it

20   please the Court:

21   The pharmaceutical pricing agreement should

22   not be construed to permit 340B entities to bring suit

23   to enforce drug manufacturers' price reporting

24   requirements for two reasons: First, the PPA is not an

25   ordinary contract, and it does not transform the 340B

 1   program from a regulatory scheme into a contractual one.

 2   Like a Medicare provider --

 3   CHIEF JUSTICE ROBERTS: Is it -- is it a

 4   contract at all?

 5   MS. ANDERS: It's not an ordinary contract

 6   in that it doesn't give rise to contract rights in

 7   the -- in the regulated entities. This is very similar

 8   to Medicare provider agreements, in which a health care

 9   provider who wants to enter into the Medicare program

10   and provide services agrees -- signs an agreement in

11   which he agrees to abide by the statutes and regulations

12   set forth in the Medicare program and, in return for

13   that agreement, is given the opportunity to participate

14   in the Medicaid -- in the Medicare program.

15   JUSTICE ALITO: Well, how do we distinguish

16   between what you call an ordinary contract and this sort

17   of a contract, if it's any kind of contract?

18   MS. ANDERS: Well, I think when the statute

19   directs an agency to enter into an agreement for the

20   sole purpose of memorializing the parties' opt-in to the

21   regulatory scheme and directs -- directs what the terms

22   shall be, so here provides statutorily what the

23   reporting requirements will be, that's when the

24   contract is simply a regulatory mechanism.

25   JUSTICE SOTOMAYOR: Counsel, are you telling

1   me you're taking -- then your -- then your co-counsel is

2   right; you're agreeing with her totally. If Congress

3   wrote the statute, said these are the terms we want to

4   give you in a contract, you figure out how to implement

5   and enforce this, and the Secretary says I don't have

6   the resources to enforce this, I'm going to write a

7   contract that gives the 340B entities a private cause of

8   action, the manufacturers can take it or leave it --

9   you're taking the position that the Secretary is without

10   authority to do this?

11   MS. ANDERS: I think it would be a difficult

12   question. I think it would be a difficult argument to

13   say that the Secretary was completely without authority.

14   I think what has happened here is the Secretary has

15   reasonably interpreted the statute in providing for an

16   agreement between the Secretary and the manufacturers to

17   simply mark the opt-in.

18   JUSTICE SOTOMAYOR: Well, that begs the

19   question that Justice Alito asked you, which is: If we

20   go your route, which is, is this a regulatory or some

21   sort of other contract, how do we tell the difference,

22   and do we need to go that far? Isn't your position -- I

23   thought half of your -- other half of your position was

24   that this is not a third-party intended beneficiary.

25   All the terms of the contract are between

1   the manufacturer and the Secretary and the obligations

2   to the Secretary, not the obligations to the third

3   parties.

4   MS. ANDERS: That's exactly right. I

5   think -- to take the first part of your question, I

6   think the Court can tell when this is a regulatory

7   contract when the statute itself simply directs the

8   agency to enter into an agreement that -- that contains

9   the terms that are set forth in the statute. And when

10   you look at the statutory scheme as a whole, it is a

11   regulatory scheme.

12   The government is not acting as a

13   contracting party here. It's acting as a regulator. It

14   has the authority to impose administrative penalties

15   which would be reviewed under the APA. There's no

16   transaction that's taking place with the government.

17   The only rules governing the conduct are statutory. So

18   that's why we think you can tell that this is not an

19   ordinary contract. It's a regulatory one.

20   JUSTICE SOTOMAYOR: Is there a different --

21   JUSTICE GINSBURG: You mean -- you mean

22   there's no negotiated element to it? It's what the

23   statute -- it's the same as Ms. Blatt said? It's -- the

24   contract repeats the words, the terms of the statute,

25   and that's it; is that what you mean?

1   MS. ANDERS: That's right. This isn't a

2   negotiated agreement. The Secretary has simply repeated

3   the terms of the statute in the agreement. That's

4   exactly right.

5   CHIEF JUSTICE ROBERTS: You could do this, I

6   guess, by regulation, right?

7   MS. ANDERS: I think that would be one way.

8   CHIEF JUSTICE ROBERTS: Issue a regulation

9   saying manufacturers who participate in this program

10   agree to do, you know, whatever your contract says.

11   MS. ANDERS: I think that would be one way

12   to do it, yes. Throughout this area, though, Congress

13   has often used agreements to mark entry into the

14   regulatory scheme, including in the Medicare provider

15   area, where you do have these agreements with health

16   care providers. But it would be very odd, then, to say

17   that the -- the entire area is regulated by breach of

18   contract law rather than by the, you know, hundreds of

19   pages of regulations and statutory provisions that

20   govern the providers' rights there.

21   JUSTICE ALITO: Could you tell us whether

22   you agree with the Petitioner's argument in part D of

23   its brief that private suits would seriously disrupt the

24   comprehensive statutory scheme, in light of the position

25   that the Government has taken in other litigation

1   involving actions brought by States, In re

2   Pharmaceutical Industry Average Wholesale Price

3   Litigation in the District of Massachusetts?

4   MS. ANDERS: We do agree with the

5   Petitioners that -- that permitting third-party

6   beneficiary suits here, if you construe this as a

7   contract, would interfere with the government's ability

8   to administer the statutory scheme. This is a national

9   pricing scheme that's put together by the Medicaid

10 Rebate Act, which has -- which is heavily regulated.

11 Allowing 14,000 covered entities to bring individual

12 suits in different courts without HHS consultation,

13 without the benefit of the government's input, could

14 lead to substantial dis-uniformity despite the fact that

15 these are supposed to be national prices.

16   JUSTICE SOTOMAYOR: You're walking away from

17 your position in the District of Massachusetts? The

18 States do not have, according to you, the right to

19 enforce the rebate program?

20   MS. ANDERS: No. That's actually an

21 important point. I think in the Medicaid context the

22 States have a cooperative relationship with the Federal

23 Government. And so they receive some of these funds

24 directly, and they have -- in fact, in the Medicaid Act,

25 it is contemplated that they have their own enforcement

24

1   responsibilities. So when States bring State law fraud

2   suits, State law FCA suits, they actually -- they

3   consult intensively with HHS. And so, in that respect,

4   those suits represent the government's --

5   JUSTICE SOTOMAYOR: An implied cause of

6   action? Is that what you're saying those State suits

7   are?

8   MS. ANDERS: Those are actually State law

9   suits that were involved in the Average Wholesale

10   Price --

11   JUSTICE SOTOMAYOR: How is that regulatory

12   scheme any different than the one involving the PPA?

13   MS. ANDERS: Well, the Medicaid Act itself

14   gives States an enforcement responsibility and says that

15   they are to use their efforts to find fraud and the

16   prosecute it. And so States actually have a whole body

17   of State law, State law false claims act --

18   JUSTICE BREYER: Suppose that the State of

19   California says we'd like our counties to be able to

20   enforce this. Then what happens?

21   MS. ANDERS: Under the Medicaid Act, there

22   would be --

23   JUSTICE BREYER: Well, suppose that

24   California -- if California wants to say we could bring

25   this suit like Massachusetts did, you agree they could.

1   And then they say, all right, but we don't have the

2   time; we want the counties to do it. Couldn't they do

3   that?

4   MS. ANDERS: Well, we think it's very

5   different when you have covered entities --

6   JUSTICE BREYER: Well, what's the difference

7   between --

8   MS. ANDERS: -- bringing even a fraud suit.

9   JUSTICE BREYER: What's the difference

10 between a State doing it itself through its attorney

11 general and the State saying we'd like the county to do

12 it through its county attorney?

13   MS. ANDERS: Well, there's consultation with

14 the Federal Government at the front end when the State

15 -- when the State brings a suit. And so the government

16 has a chance to coordinate, to avoid dis-uniformity.

17 But when you have covered entities, you know, thousands

18 of them, potentially bringing suit in different --

19   JUSTICE BREYER: All right. California

20 comes to you tomorrow and says the attorney general

21 says: You know, this is a problem. You don't have time

22 to enforce this. There should be some enforcement, and

23 we want to enforce it. And, moreover, we'd like each

24 county affected to enforce it.

25   Do you have the authority? Is there any

 1   reason you wouldn't say go ahead?

 2   MS. ANDERS: Well, in that sort of

 3   situation, you might be able to have a State law fraud

 4   suit --

 5   JUSTICE BREYER: I'm trying to analogize it

 6   to the Massachusetts one. You say they can just go

 7   ahead and do it, and they say, you know, Santa Clara

 8   County is just as big as Rhode Island. And you say the

 9   AG of Rhode Island can bring the suit; am I right? And

10   so why can't the -- why can't Santa Clara do it?

11   MS. ANDERS: Well, in the covered entity

12   context, the concern is that, because you have so many

13   of them, if you -- if you start permitting covered

14   entities to bring suit, you know, this is essentially a

15   pre-emption question, but you then have 50 different

16   State regimes, State court regimes, put onto -- grafted

17   onto, the Medicaid rebate requirements.

18   This is supposed to be a uniform pricing

19   scheme. And so once the requirements become

20   dis-uniform, it becomes very difficult for HHS to

21   administer the scheme in the way that it's supposed to.

22   I think it's also important to point out

23   that the recently enacted Affordable Care Act will

24   provide the exclusive administrative remedy for claims

25   exactly like Respondent's once HHS puts that into

1   effect. So Congress, in looking at the scheme, to the

2   extent it had concerns about enforcement by covered

3   entities -- the way it reacted was not to create a

4   private right of action or provide for breach of

5   contract enforcement but was simply to give the agency

6   enhanced authority in order to adjudicate the claims

7   itself.

8   CHIEF JUSTICE ROBERTS: It identified the

9   problem that the individual beneficiaries did not have a

10   remedy? They -- or that courts had indicated that they

11   didn't and they thought there should be a remedy?

12   MS. ANDERS: There were -- there were OIG

13   reports raising concerns with oversight and enforcement

14   at a general level, and the way Congress reacted to that

15   was to put in place this administrative remedy which

16   will allow covered entities to bring these claims and

17   will allow HHS to have the first opportunity to

18   determine the meaning of the AMP and best price

19   requirements, and to take into account --

20   JUSTICE GINSBURG: Ms. Blatt said nothing

21   has been done. It just went into effect on January 1st,

22   but are there -- are there plans to implement it?

23   MS. ANDERS: Yes. The agency is moving

24   ahead with that. The agency has already issued an

25   advanced notice of proposed rulemaking back in the fall.

28

1   And it has solicited comments about how the -- the

2   administrative scheme should look. That comment period

3   has closed, and so now the agency is in the process

4   of -- of moving forward with the regulatory --

5   JUSTICE SOTOMAYOR: So I understand your

6   position clearly, in a regulatory contract situation

7   like this one the Secretary is without authority to

8   decide he or she can't enforce the statute and to confer

9   expressly by contract third-party beneficiary rights to

10 the -- to the people receiving the benefit? That's the

11 position you're taking?

12   If the Secretary had written a provision

13 into this contract telling 340B entities you can sue,

14 that would have been, according to you, ultra vires?

15   MS. ANDERS: I think it would be difficult

16 to say that the agency would have been totally without

17 authority to do that. It's not a question you have to

18 answer here, because I think the PPA clearly shouldn't

19 be construed to confer third-party beneficiary rights

20 because that would be inconsistent with the statutory

21 scheme.

22   CHIEF JUSTICE ROBERTS: Thank you, counsel.

23   Mr. Frederick.

24   ORAL ARGUMENT OF DAVID C. FREDERICK

25   ON BEHALF OF THE RESPONDENT

 1   MR. FREDERICK: Thank you, Mr. Chief

 2   Justice.

 3   I'd like to start with Ms. Blatt's answer to

 4   your question about whether a provision of the agreement

 5   here could confer third-party beneficiary rights. She

 6   said yes, so long as the wording wasn't specifically

 7   prescribed by Congress. In so doing, she concedes that

 8   this is a contract, that normal rules of contract law

 9   apply, that the fact that the Secretary has entered into

10   the contract is of no moment, and that third-party

11   beneficiary rights are an inherent part of normal

12   contract principles.

13   So now we're left with the question, does it

14   matter that Congress wrote the particular words that the

15   Secretary used in the agreement?

16   JUSTICE SCALIA: Well, wait. Is the --

17   MR. FREDERICK: We submit that the answer is

18   no.

19   JUSTICE SCALIA: Third-party beneficiary

20   rights are part of normal contracts, but the third-party

21   beneficiary has rights under -- under the normal

22   contract only when the parties intend him to have

23   rights. It's not that every -- every contract which --

24   which has a benefit for some person allows that person

25   to sue. There has to be an intent. And I -- I have

1   trouble finding that intent here, either on the -- on

2   the part of the Secretary -- would the Secretary have

3   had that intent when -- when Congress clearly did -- did

4   not have the intent to allow private individuals to sue?

5   MR. FREDERICK: Justice Scalia, you find the

6   intent in part II(a) of the agreement, which is set

7   forth in the petition appendix. And in part II(a), the

8   manufacturer who agrees voluntarily to enter into this

9   agreement agrees that the entity -- that the entity will

10   be charged only a set ceiling price.

11   That is a voluntary agreement of a duty by

12   the manufacturer that runs to the third-party

13   beneficiary covered entities --

14   JUSTICE SCALIA: Yes, you didn't -- you

15   didn't hear my question.

16   MR. FREDERICK: -- who are specified in the

17   agreement.

18   JUSTICE SCALIA: My question was the mere

19   fact that there's a duty to a third party in the normal

20   contract does not give that third party the right to

21   sue, only if the contracting parties intend the

22   third-party beneficiary to have a right to sue.

23   MR. FREDERICK: Well, that's not the

24   standard, Justice Scalia.

25   JUSTICE SCALIA: Well, I thought the --

1   MR. FREDERICK: The standard for a

2 third-party beneficiary, as set forth in the Restatement

3 and as recognized by this Court, is whether or not the

4 parties objectively intended to create intended

5 third-party beneficiaries whose right to bring the suit

6 would enforce the contract. And that's precisely what

7 we have here.

8   JUSTICE GINSBURG: Mr. Frederick --

9   JUSTICE SOTOMAYOR: Can you tell me where --

10   JUSTICE GINSBURG: -- I thought when this

11 case went back to the -- to the district court, the --

12 the agency's position was this is a total surprise to

13 us, 14,000 suits or whatever it is. No, we never -- we

14 never envisioned making the individual whatever you call

15 them -- the 430B --

16   MR. FREDERICK: The 340B entities.

17   JUSTICE GINSBURG: We never envisioned

18 making them the beneficiaries and -- and allowing them

19 to sue. That would be quite disruptive of our program.

20 That, I thought, was the position the Government took.

21   MR. FREDERICK: The Government cannot argue

22 for subjective intent of an agreement written 18 years

23 ago. This Court's decisions in contract have always

24 held that the objective intent as expressed by the words

25 of the contract are what courts are to construe.

32

1   JUSTICE KENNEDY: Well, I -- I don't

2   understand why what Justice Scalia said isn't the same

3   as what you said. You said no, Justice Scalia,

4   Restatement of Contracts. But what he said the question

5   is whether or not did the parties intend -- and it's an

6   objective intent -- to confer these rights on a third

7   person. And -- and you said no, no, that's not it. But

8   then it seems to me that your answer that you gave was

9   just what Justice Scalia said. I -- I missed something.

10   MR. FREDERICK: Okay. Here's what I think I

11   misunderstood perhaps from Justice Scalia's question.

12   For third-party beneficiary rights to create an

13   enforceable breach of contract claim, the parties to the

14   contract do not have to have a provision in the contract

15   saying "and therefore the intended third parties get to

16   bring a breach of contract claim." That's never been

17   the accepted law.

18   The law has always said if the parties

19   intend to create third-party beneficiaries and bringing

20   of that suit to enforce the contract would be within the

21   objective intent of the parties, such a suit is

22   permissible.

23   Now, I want to caution that what is

24   different about this suit from the kinds of implied

25   rights of action suits that the drug companies here

1   claim to be so disruptive is that all we're arguing for

2   is the bargain that the manufacturers agreed to

3   undertake.

4   JUSTICE ALITO: Could that be -- could there

5   be --

6   MR. FREDERICK: That bargain was -- was the

7   discount. It's the delta between what the counties paid

8   and what they should have paid under the discount

9   program ceiling price arrangement in the plain terms of

10   the agreement.

11   JUSTICE ALITO: Well, could there be --

12   JUSTICE SOTOMAYOR: Third-party -- I'm

13   sorry.

14   JUSTICE ALITO: Could there be a

15   third-party -- a suit by an intended beneficiary and a

16   purported intended beneficiary, if it is clear that

17   Congress intended, to the extent it can intend

18   something, for those beneficiaries to get the benefit of

19   the price but did not intend for them to be able to sue?

20   MR. FREDERICK: Yes.

21   JUSTICE ALITO: So if there were --

22   MR. FREDERICK: I think indirectly here,

23   Justice Alito, that the patients here certainly are

24   incidental beneficiaries, insofar as those who can't

25   afford to pay for the drugs get them for free at the

1   county's expense. This is county money that we're

2   talking about here. Or if they have some limited

3   insurance, they're able to get the drugs at a discount.

4   So they are certainly incidental

5   beneficiaries, but because they are not named and

6   because the intent of the program is to provide the 340B

7   entities with discounted drugs so they can extend scarce

8   dollars farther, they have no right to sue.

9   JUSTICE ALITO: If there were a provision in

10   the law saying expressly there is no private right of

11   action under this statute, would you be able to make the

12   same argument?

13   MR. FREDERICK: No. Our argument rests on

14   the silence of contract with respect to how enforcement

15   would concur. It has long been the case, though, that

16   where the parties intend to displace a third-party

17   beneficiary's rights, the objective intent of the -- of

18   the agreement is what is understood.

19   JUSTICE ALITO: There's --

20   JUSTICE SOTOMAYOR: Counsel -- I'm sorry. I

21   don't understand the distinction that you're ignoring in

22   the law. I thought it was very clear that proof that

23   you merely received the benefit in a -- by a contract is

24   not proof that the parties intended to confer on you an

25   enforceable right; is that correct? Is that the

1   statement of the common law?

2   MR. FREDERICK: That is how the Restatement

3   frames it. It's a -- it is a difficult line I think

4   sometimes to understand the difference between an

5   intended beneficiary and an incidental beneficiary.

6   Certainly, the manufacturers here are incidental

7   beneficiaries --

8   JUSTICE SOTOMAYOR: No matter how --

9   MR. FREDERICK: -- because they have access

10   to this market.

11   JUSTICE SOTOMAYOR: No matter how you want

12   to draw this line, if the issue is what's the objective

13   intent about enforceability, if I look at the PPA, it

14   makes the manufacturer's obligation one-way to the

15   government to provide the pricing information. It gives

16   only the government the right to institute the informal

17   dispute resolution system that the contract specifies.

18   This is not the new law. This is the PPA as it existed

19   at the time. It gives only the Secretary other

20   enforcement rights.

21   What am I missing? Where in the contract is

22   there one provision, one sentence, one anything that

23   requires the manufacturers, other than the price

24   benefit, to do something that could be characterized as

25   enforcement?

1   MR. FREDERICK: But that is the key,

2   Justice Sotomayor. The price discount is where all the

3   action is in this program. These prices, between 1990

4   and 1992, were being raised by the drug manufacturers as

5   against these entities, and the whole point of Congress

6   enacting this statute was to confer the same discounted

7   drug program to the covered entities as had been done

8   through contracts to the State Medicaid rebate program.

9   And that's why the provision in the

10   amendment -- sorry, in the agreement that says thou

11   shalt not charge the covered entities more than the

12   ceiling price is exactly where you find the intended

13   third-party beneficiary rights, because that's their

14   money that's being spent. It's not Federal --

15   JUSTICE BREYER: Well, that's true -- that's

16   true, you know, of -- I was thinking maximum resale

17   price maintenance. You could -- the distributor and the

18   manufacturer agree on the maximum resale price. Pretty

19   unlikely that they intend the consumers who are intended

20   to benefit to be able to have a lawsuit. And I think,

21   well, gee, I don't know. And what the Government is

22   arguing is, sure, the point you make favors you, but

23   they say there are two major points here that favor them

24   about background. I want to hear what your reply is.

25   One of them is Congress, in the statute that

37

1   it incorporated here, didn't want a private person to be

2   able to enforce it. And the second one is it's going to

3   create a mess. All right? So they say those are two

4   background features here that favor them.

5   So what's your response?

6   MR. FREDERICK: Number one, there's no

7   evidence that Congress intended there to be a departure

8   from normal operating contract principles, and this

9   Court, in Winstar, in Mobil Oil, in Jackson Transit, in

10   Central Airlines -- all said that when Congress uses

11   contracts or agreements, it intends to incorporate the

12   full cluster of the common law rights as they've

13   existed. And third-party beneficiary rights have been

14   recognized for 350 years, even before the founding of

15   this republic.

16   Now, as to the disruption, I think it's a

17   canard, because what we're talking about here is one

18   price that would govern all 14,500 covered entities. So

19   if Santa Clara gets the discount price for Lipitor, say,

20   that is the best price, and it will be charged and

21   chargeable to all of the 340B entities across the

22   nation.

23   So in terms of administrability, one suit

24   actually can solve the deficiencies in the government

25   enforcement program, and the government can participate

1 in this suit.

2   CHIEF JUSTICE ROBERTS: Well, which way does

3 that cut? That seems to me to put an awful lot of power

4 and authority in the hands of one beneficiary and one

5 lawyer saying -- all they have to do is filing a suit

6 saying, look, we get a hundred doses of Lipitor from

7 this program; we think we should get less.

8   And if they win, the whole country's -- the

9 pricing of Lipitor under this program has changed.

10   MR. FREDERICK: Well --

11   CHIEF JUSTICE ROBERTS: That strikes me as

12 an argument in favor of leaving the enforcement with the

13 Secretary.

14   MR. FREDERICK: No, I think it's an argument

15 that may misunderstand some of the benefits that class

16 action practice can provide, where there is a uniform

17 way of analyzing the problem, because these prices,

18 Mr. Chief Justice --

19   CHIEF JUSTICE ROBERTS: It doesn't have to

20 be a class action, does it?

21   MR. FREDERICK: Well, it doesn't. This was

22 brought as one for the efficiency purpose of obtaining

23 exactly the effect that you are identifying, which

24 is that if it is more efficient --

25   CHIEF JUSTICE ROBERTS: That's why it was

 1 brought as a class action?

 2   MR. FREDERICK: Well, it was brought as a

 3 class action because the County of Santa Clara stands in

 4 exactly the same position as the other 57 counties of

 5 California and the other counties in the United States

 6 who are overpaying for drugs that the manufacturers

 7 are --

 8   JUSTICE BREYER: What do you think

 9 about -- is the -- I'm not sure I'm right at all here,

10 but as I understand the development of this argument

11 today, it's open to you and the other 57 counties to go

12 to the State AG, and you say you bring the lawsuit,

13 okay? Or make us -- make me -- the lawyer says make me

14 an assistant AG for this purpose. And I launch the

15 lawsuit in the name of California, and then I can get to

16 the same place.

17   What do you think of that?

18   MR. FREDERICK: I don't know that the

19 State -- because these are entities that are not defined

20 in the agreement. The -- this is a different agreement

21 than under the Medicaid rebate agreement, which is set

22 forth in the joint appendix, where the States are the

23 third-party beneficiaries of those agreements.

24   I'm not sure that the State actually has

25 standing to bring these particular claims. That is not

1   something that has been tested. But what I would say is

2   that if you reject our argument here, you are

3   substantially undercutting the ability of the States to

4   bring the same kinds of overcharging claims against drug

5   manufacturers under the Medicaid rebate program.

6   That's what the States' amicus brief here

7   makes clear. The SG has a very fuzzy footnote at the

8   very end of the Government's brief that does not set

9   forth a clear standard that differentiates why 340B

10   entities' third-party beneficiary rights are any

11   different from States' rights under the Medicaid rebate

12   program.

13   JUSTICE GINSBURG: I thought it was because

14   the States have been given a role in the statute itself,

15   where the 340B entities have not. I thought that was

16   the -- the Government's position, that the States have a

17   role in the Medicaid program, and that's an entirely

18   different thing than this program, where these entities

19   have no statutory role, say the drug manufacturers and

20   then HHS.

21   MR. FREDERICK: Justice Ginsburg, I don't

22   think that was the basis for Judge Saris's opinion in

23   the District of Massachusetts, which looked at the

24   third-party beneficiary theory of the States in giving

25   them a place at the table in bringing these kinds of

1   claims. And to the extent that that analysis bears out

2   anything, it tends to cast doubt on the Government's

3   theory that these are somehow regulatory contracts that

4   suggest a blurring of the normal lines between

5   regulation and contract.

6   That theory, the regulatory contract theory,

7   has been rejected by this Court in Winstar and in Mobil

8   Oil, where the Government tried to argue that because it

9   was implementing regulatory policy through contracts,

10   somehow normal contract principles don't apply, and this

11   Court rejected that.

12   JUSTICE SCALIA: But the Government's

13   footnote doesn't -- doesn't rely on the contract. It

14   says that -- and it wasn't purporting to say the basis

15   that the court applied in the District of Massachusetts

16   case, but it was explaining why, in the Government's

17   view, it's a different situation.

18   And what it said, it's a different

19   situation, not because of a different contract, but

20   because in that other situation, Medicaid -- the

21   Medicaid rebate -- Medicaid generally is, quote, "a

22   cooperative Federal-State program."

23   I mean, their point is that the States are

24   explicitly given authority for enforcement in that.

25   MR. FREDERICK: Well, the --

1   JUSTICE SCALIA: And here the entities

2   you're representing are not.

3   MR. FREDERICK: Justice Scalia, and that is

4   why resort to the normal canons of construction that

5   this Court has long applied to government contracts is

6   what is most pertinent here. The Government, I don't

7   think, can point to a specific provision of the

8   cooperative federalism that empowers States to engage in

9   any greater enforcement power than a normal third-party

10   beneficiary under this Court's normal cases, and back to

11   Central Airlines and American Surety, which, a hundred

12   years ago, recognized a third-party beneficiary's right

13   to bring suit on a breach of contract and held that the

14   absence of a specific enforcement power in the statute

15   was not enough to deny the normal operation of law for

16   the breached party to sue for that breach.

17   That's common in the law.

18   JUSTICE SCALIA: The big -- the big

19   difference, it seems to me, Mr. Frederick, is that the

20   States are sovereign. They can enforce their own laws.

21   The entities at issue here are not sovereigns. They're

22   not enforcing their own laws. They are trying to

23   enforce Federal law. But under the -- under the

24   Medicaid program, the States, using their own fraud --

25   fraud actions, whatever else, have a role to play.

1   MR. FREDERICK: Well, Justice Scalia, I

2   think if you took that argument to its logical extreme,

3   you would have come to a different answer in the Arthur

4   Andersen case, where, there, you recognized a

5   third-party beneficiary's right to invoke a statute to

6   get an arbitration agreement upheld.

7   And I think you would have come to a

8   different result in the Miree v. DeKalb County case, in

9   which the Court said that just because there is an FAA

10   contract with a local airport authority does not deny a

11   third-party beneficiary right to sue if there is an

12   adverse effect on adjoining land because you would have

13   said that, because the adjoining land owner had no

14   specific enforcement authority, that person or entity

15   would be out of luck. I think the -- this Court's --

16   CHIEF JUSTICE ROBERTS: That's Miree.

17   That's 1977. And a lot of your argument, it seems to

18   me, is in the earlier world of implied right of action

19   jurisprudence that has changed dramatically in the last

20   30 years.

21   And what concerns me is when you are talking

22   about the same language, the mere fact that the

23   government has decided to go through a contractual

24   mechanism to advance this program doesn't allow you to

25   use that to get an end run around all of the implied

44

1   right of action jurisprudence of the last 30 years.

2   You're on stronger ground before that.

3   MR. FREDERICK: Well, let me address that

4   directly, Mr. Chief Justice, because Justice Rehnquist,

5   who was not any fan of implied rights of action, was the

6   author for the Court's opinion in the Miree decision.

7   And --

8   CHIEF JUSTICE ROBERTS: Well, but that was

9   pretty well -- that analysis was certainly consistent

10   with the established jurisprudence in this area then.

11   But it started changing very quickly thereafter -- I

12   think about 1980 -- and then consistently went in the

13   other direction, to the point now where I think the

14   jurisprudence is pretty clear that we're not going to

15   imply a private right of action at all.

16   MR. FREDERICK: We're not asking you to

17   imply a private right of action, Mr. Chief Justice.

18   We're asking you to honor contract principles that have

19   long --

20   JUSTICE GINSBURG: The result is the same,

21   Mr. Frederick. And that's -- I mean, it was a central

22   point in this last brief. You can call it whatever you

23   want. It's -- Congress has not provided for a private

24   right of action to enforce the terms of the statute.

25   The contract embodies the terms of statute. So it would

1 be passing strange if Congress, as we now read Congress,

2 said we want private parties out of this; this is to be

3 between the agency and the manufacturer to say. The

4 same exact result. The same aim can be achieved through

5 this third-party beneficiary route. And I think that

6 said, that is the -- I mean, that is what stands out

7 about this case.

8   And so how do you respond to that? What's

9 the difference between suing because the statute has

10 been violated and suing because the contract has been

11 violated?

12   MR. FREDERICK: A contract is a voluntary

13 agreement entered into between the drug manufacturer and

14 the Secretary. The manufacturer can choose not to

15 participate.

16   So in every one of the implied right of

17 action cases that you have dealt with, a -- an outside

18 entity has been forced to comply with a statute or law.

19   JUSTICE GINSBURG: But the statute wouldn't

20 apply to someone who doesn't want to be in the program.

21   MR. FREDERICK: But the -- Justice Ginsburg,

22 those cases all involve the imposition of duties on the

23 part of an entity or actor out in society.

24   Here we're talking about voluntary action.

25 The drug manufacturers can decide not to participate and

46

1   not sign the agreement.

2   And they have the right, under the

3   provisions allowing termination, to terminate the

4   agreement at will with no reason whatsoever. But --

5   CHIEF JUSTICE ROBERTS: But so do the --

6   it's the same situation with the States under Spending

7   Clause legislation. They don't have to sign up, but if

8   they do, then the issue is, is there an implied right of

9   action on the beneficiaries? And our cases for the last

10   25, 30 years have said no.

11   MR. FREDERICK: But the remedy is different,

12   Mr. Chief Justice. And that is a key difference. All

13   we're talking about here as a remedy is the difference

14   between what they promised to charge and what they

15   actually charged. The remedies --

16   JUSTICE GINSBURG: But we're told that

17   whatever you say -- that's all we're talking about. We

18   are told that computing the price is a very intricate

19   business and that many of these disputes have been about

20   what is -- what should the ceiling price be.

21   MR. FREDERICK: There --

22   JUSTICE GINSBURG: There would not -- the

23   ceiling price is out there, and there's no dispute about

24   it. It's just a question of getting the manufacturers

25   to charge that price and not a higher price. The

47

1   question is: What is the ceiling price?

2   MR. FREDERICK: And there are two ways to

3   calculate it. Under the more complicated formula that

4   is designed to enhance the profits of the drug

5   companies, it is a more complicated endeavor.

6   All of these cases, Justice Ginsburg, all of

7   them, have been with the simple formula, which is has

8   the drug company given its best price to some other

9   purchaser in the market. That's where the False Claims

10   Act cases that they acknowledge do not create such an

11   intrusion into the program that somehow they can't be

12   brought --

13   JUSTICE GINSBURG: But that's -- and then

14   they have control over them. And they don't have

15   control over these suits.

16   MR. FREDERICK: Well, no, the difference in

17   a qui tam case, as your question earlier to my colleague

18   earlier acknowledged, Justice Ginsburg, is the

19   government doesn't have to intervene in a False Claims

20   Act case.

21   What's different there is that there has to

22   be some inside whistleblower who can pass through the

23   very difficult hurdles of a False Claims Act case;

24   whereas here we're talking about benefit of the bargain.

25   The manufacturers agreed by contract they were only

48

1   going to charge a ceiling price, and we assert, based

2   on, you know, quite extensive reports by officers of

3   Inspectorate General that they have not been charging

4   that price. They've been charging in excess of that

5   price, and all we're asking for is the delta.

6   And the Government in its Massachusetts

7   submissions has acknowledged that this type of best

8   price litigation is not so complicated because all one

9   needs to do is figure out did the drug companies sell

10   the particular drug to some other entity for a lower

11   price; and if that's so, that's the price you apply

12   across the board to all the 340B entities.

13   The argument about distraction and

14   intrusion, Justice Ginsburg, I would respectfully

15   submit, is a gross overstatement of what actually

16   happens in this type of litigation. And to the extent

17   that there are complexities, the complexities are

18   introduced by the drug companies for the sole purpose of

19   masking what price they are charging to the 340B

20   entities. Because all these various mechanisms, the

21   bundling of drugs, the use of kickbacks and payments to

22   purchasers are all designed to mask what the true price

23   of the drug is.

24   And if Congress intended anything in the

25   program, and in getting the Secretary to implement this

1   program through statutes, it was that the 340B entities

2   who are providing drugs and medical service to the

3   poorest of our citizens should be entitled to the

4   benefits of the collective market created by these 340B

5   drug purchases. And that's all that we're asking for

6   here.

7   JUSTICE GINSBURG: Do you take the position

8   that nothing has changed as a result of the new

9   legislation? That is, Ms. Anders told us that this

10   statute is going into -- to become effective. There's

11   going to be procedures, better procedures than there

12   were before. Is there still this third-party

13   beneficiary suit, despite the possibility of going to

14   the agency?

15   MR. FREDERICK: We don't know, Justice

16   Ginsburg, is the simple and plainest answer I can give

17   you. And the reason we don't know is because the

18   Secretary has already missed the first statutory

19   deadline for issuing implementing regulations.

20   There was no statement of rules in the

21   notice of proposed rulemaking, as is ordinarily the case

22   for agencies. The Secretary simply put out for comment

23   that we are going to develop procedures and rules. So

24   we don't know whether or not the Secretary will express

25   some further intent as to how these new rules are to

1   apply.

2   But I would submit that this Court's cases

3   are very clear, that a later enactment of Congress is

4   not intent of what an earlier Congress has stated, and

5   the absence of any specific remedial provision coupled

6   with the use of agreements carries with it the ordinary

7   presumption that Congress intended for that cluster of

8   common law rights to be associated with the agreement.

9   And that's certainly been the way this Court

10   has enforced contracts involving the government itself.

11   If there are no further questions, we'll

12   submit.

13   CHIEF JUSTICE ROBERTS: Thank you, Mr.

14   Frederick.

15   Ms. Blatt, you have 3 minutes remaining.

16   REBUTTAL ARGUMENT OF LISA S. BLATT

17   ON BEHALF OF THE PETITIONERS

18   MS. BLATT: Yes. If I could just talk about

19   the drug companies, Lipitor, and the common law. And if

20   you want, I can also talk about States.

21   We take, obviously, deep umbrage at the

22   suggestion that the drug companies are somehow against

23   these clinics. Any Internet search will show you that

24   the amount of discounts given under this program equals

25   the amount of free drugs that are given to these same

1   clinics.

2   And I'd also -- probably even a better

3   response is you can look at any rebate release issued by

4   the Secretary of HHS or any page of their CFR, and if

5   you think it's simple, I would be shocked.

6   On Lipitor, it's not the case that the

7   Central District of California decides nationwide what

8   the price of Lipitor is. The -- under the other side's

9   view, the Southern District of Texas, the Northern

10   District of New York, and the District in Alabama would

11   all decide.

12   And what's really bad -- it is bad enough to

13   have 14,000 suits over 35,000 drugs, but what he's

14   talking about, best price and average manufacturer price

15   that determines the State rebate program -- because the

16   rebate program is a rebate, and the ceiling price

17   program is a ceiling price, when one of the pricing

18   components goes up, such as average manufacturer price,

19   the States benefit. They get more money. But,

20   generally, 340B entities -- their ceiling price goes up.

21   So what's good for the 340B company -- or entity is bad

22   for the States.

23   And that's not disputed. He just says it's

24   hypothetical. But he's asked for millions and millions

25   and millions and millions and more millions of

1 transactions that go to that very pricing component.

2   Common law. On pages 9 to 11a of the

3 petition appendix is a good three or four citations to

4 the third-party beneficiary Federal common law. And the

5 courts go out of their way to say it's not enough to be

6 a direct beneficiary. The analysis is exactly the same

7 under implied right of action. Is there clear and

8 unambiguous intent to confer enforceable rights? It's

9 the same.

10   We just think because it's in haec verba

11 with the statute, it's congressional intent that's

12 controlling, not the parties.

13   I could talk about States if you want.

14 Otherwise, I'm happy to just ask for the decision to be

15 reversed.

16   All right. Then we would ask that the

17 decision be reversed.

18   (Laughter.)

19   CHIEF JUSTICE ROBERTS: Thank you, counsel.

20 Counsel.

21   The case is submitted.

22   (Whereupon, at 12:05 p.m., the case in the

23 above-entitled matter was submitted.)

24

25

A

abide 20:11
ability 24:7 41:3
able 5:24 25:19
  27:3 34:19 35:3
  35:11 37:20
  38:2
above-entitled
  1:11 53:23
absence 43:14
  51:5
absolutely 9:11
accepted 33:17
accepts 9:23
access 36:9
accomplished
  9:1
account 28:19
achieved 46:4
acknowledge
  48:10
acknowledged
  48:18 49:7
act 4:6 5:6 8:12
  8:13 10:5,25
  13:9 15:22 16:5
  18:16 24:10,24
  25:13,17,21
  27:23 48:10,20
  48:23
acting 22:12,13
action 3:17 4:9
  4:13 5:10 6:2,8
  7:1 8:10 15:5
  15:14,15,20,22
  21:8 25:6 28:4
  33:25 35:11
  37:3 39:16,20
  40:1,3 44:18
  45:1,5,15,17
  45:24 46:17,24
  47:9 53:7
actions 24:1
  43:25
activity 13:8

actor 46:23
Acts 15:24
addition 7:20
address 45:3
adjoining 44:12
  44:13
adjudicate 28:6
administer 24:8
  27:21
administering
  4:25
administrability
  38:23
administrative
  14:3,4,23 15:8
  22:14 27:24
  28:15 29:2
administrator
  18:23,24 19:9
advance 44:24
advanced 28:25
adversary 6:19
adverse 44:12
advocates 6:4
afford 34:25
Affordable 27:23
AG 27:9 40:12
  40:14
agencies 50:22
agency 4:24
  15:12 18:23
  20:19 22:8 28:5
  28:23,24 29:3
  29:16 46:3
  50:14
agency's 32:12
ago 32:23 43:12
agree 9:9 18:1
  23:10,22 24:4
  25:25 37:18
agreed 34:2
  48:25
agreeing 21:2
agreement 3:13
  5:19 8:1,4 10:2

10:3,6 11:1,1
  11:14,15 12:3,4
  12:7 19:21
  20:10,13,19
  21:16 22:8 23:2
  23:3 30:4,15
  31:6,9,11,17
  32:22 34:10
  35:18 37:10
  40:20,20,21
  44:6 46:13 47:1
  47:4 51:8
agreements 11:8
  20:8 23:13,15
  38:11 40:23
  51:6
agrees 20:10,11
  31:8,9
ahead 27:1,7
  28:24
aim 46:4
Airlines 38:10
  43:11
airport 44:10
AL 1:3
Alabama 52:10
Alito 20:15 21:19
  23:21 34:4,11
  34:14,21,23
  35:9,19
allegation 18:15
allege 16:19
allow 28:16,17
  31:4 44:24
allowing 24:11
  32:18 47:3
allows 30:24
amended 10:5
amendment
  37:10
American 43:11
amicus 1:19 2:8
  19:17 41:6
amount 51:24,25
AMP 28:18

analogize 27:5
analysis 9:22
  42:1 45:9 53:6
analyzing 39:17
Anders 1:17 2:6
  19:15,16,19
  20:5,18 21:11
  22:4 23:1,7,11
  24:4,20 25:8,13
  25:21 26:4,8,13
  27:2,11 28:12
  28:23 29:15
  50:9
Andersen 44:4
answer 4:16 5:7
  5:15 7:25 29:18
  30:3,17 33:8
  44:3 50:16
APA 15:15,20
  22:15
App 19:7
appeals 18:9
APPEARANC...
  1:14
appendix 31:7
  40:22 53:3
applied 6:4 42:15
  43:5
apply 30:9 42:10
  46:20 49:11
  51:1
arbitration 44:6
area 23:12,15,17
  45:10
argue 32:21 42:8
arguing 34:1
  37:22
argument 1:12
  2:2,5,9,12 3:3,7
  6:20,22,25 15:5
  19:16 21:12
  23:22 29:24
  35:12,13 39:12
  39:14 40:10
  41:2 44:2,17

49:13 51:16
arose 10:16
arrangement
  34:9
arranging 17:1
arsenal 14:16
Arthur 44:3
Article 5:6
asked 21:19
  52:24
asking 10:10
  45:16,18 49:5
  50:5
assert 49:1
asserts 4:7
assess 10:6
assigned 16:7
assistant 1:17
  40:14
associated 51:8
Astra 1:3 3:4
ation 3:12
attorney 26:10
  26:12,20
audit 10:24 14:15
author 45:6
authority 7:19
  21:10,13 22:14
  26:25 28:6 29:7
  29:17 39:4
  42:24 44:10,14
average 24:2
  25:9 52:14,18
avoid 26:16
awful 39:3
a.m 1:13 3:2

B

back 4:14 28:25
  32:11 43:10
background
  37:24 38:4
bad 7:3 16:11
  52:12,12,21
bar 17:13

bargain 34:2,6 48:24
based 49:1
basic 5:7
basically 6:11
basis 41:22 42:14
bears 42:1
begins 4:12
begs 21:18
behalf 1:15,19 1:21 2:4,7,11 2:14 3:8 13:6 17:14 18:21,25 19:1,17 29:25 51:17
beneficiaries 6:1 8:16,17 17:7 28:9 32:5,18 33:19 34:18,24 35:5 36:7 40:23 47:9
beneficiary 6:6 6:21 17:12 18:4 21:24 24:6 29:9 29:19 30:5,11 30:19,21 31:13 31:22 32:2 33:12 34:15,16 36:5,5 37:13 38:13 39:4 41:10,24 43:10 44:11 46:5 50:13 53:4,6
beneficiary's 4:7 35:17 43:12 44:5
benefit 14:10 24:13 29:10 30:24 34:18 35:23 36:24 37:20 48:24 52:19
benefits 39:15 50:4

best 28:18 38:20 48:8 49:7 52:14
better 13:4 50:11 52:2
beyond 17:6
big 27:8 43:18,18
bigger 7:12
bilateral 5:19
billions 12:15,15
Blatt 1:15 2:3,13 3:6,7,9 4:3 5:1 5:4 6:23 7:17 8:6,9,21 9:3 10:8,13,18 11:16,20,25 12:15 13:3,14 13:19,22 14:6 14:12,21,25 15:9,15,19,23 16:6,15,17 17:8 17:10 18:22 19:2,6 22:23 28:20 51:15,16 51:18
Blatt's 30:3
blurring 42:4
board 49:12
body 25:16
bound 12:2
breach 3:16 9:7 10:6 15:2 23:17 28:4 33:13,16 43:13,16
breached 43:16
breath 18:8
BREYER 12:23 13:12,16,21,24 14:8,18,22 15:7 15:10,17 25:18 25:23 26:6,9,19 27:5 37:15 40:8
brief 13:10 23:23 41:6,8 45:22
briefs 16:1
bring 10:25

15:20 19:22 24:11 25:1,24 27:9,14 28:16 32:5 33:16 40:12,25 41:4 43:13
bringing 4:13 16:4 26:8,18 33:19 41:25
brings 26:15
brought 15:24 16:8,18 24:1 39:22 40:1,2 48:12
bundling 49:21
business 47:19
busy 13:21,22
buy 6:7

C

C 1:21 2:1,10 3:1 29:24
calculate 48:3
California 1:6 25:19,24,24 26:19 40:5,15 52:7
call 13:15 20:16 32:14 45:22
calls 13:23
canard 38:17
canons 43:4
care 7:11,12 8:13 10:20 20:8 23:16 27:23
carries 51:6
case 3:4 4:12 6:12 7:25 10:16 11:15 15:5 16:8 16:9,11,13 32:11 35:15 42:16 44:4,8 46:7 48:17,20 48:23 50:21 52:6 53:21,22

cases 8:3,6 15:7 43:10 46:17,22 47:9 48:6,10 51:2
cast 42:2
cause 3:12 5:10 6:2 12:8 21:7 25:5
causes 4:8
caution 33:23
ceiling 4:5 8:25 9:14 31:10 34:9 37:12 47:20,23 48:1 49:1 52:16 52:17,20
central 38:10 43:11 45:21 52:7
certain 9:14 12:8 16:24
certainly 34:23 35:4 36:6 45:9 51:9·
cetera 14:23
CFR 52:4
challenged 4:4
challenging 6:17
chance 26:16
changed 39:9 44:19 50:8
changing 45:11
channel 7:19
channeled 14:17
characterized 36:24
charge 4:21 8:24 37:11 47:14,25 49:1
chargeable 38:21
charged 9:15 31:10 38:20 47:15
charging 49:3,4 49:19

Chief 3:3,9 7:24 8:8 15:21 16:21 17:9 19:14,19 20:3 23:5,8 28:8 29:22 30:1 39:2,11,18,19 39:25 44:16 45:4,8,17 47:5 47:12 51:13 53:19
choose 46:14
circuit 3:23 6:4
citations 53:3
cites 13:10
citizens 50:3
civil 10:21,24
claim 13:25 16:7 33:13,16 34:1
claims 6:19 10:25 13:9 15:22,23 16:5 25:17 27:24 28:6,16 40:25 41:4 42:1 48:9 48:19,23
Clara 1:6 3:5 12:23 27:7,10 38:19 40:3
class 39:15,20 40:1,3
Clause 8:11 9:22 47:7
clear 5:12 34:16 35:22 41:7,9 45:14 51:3 53:7
clearly 29:6,18 31:3
clinic 18:2
clinics 51:23 52:1
closed 29:3
cluster 38:12 51:7
CMS 19:11
colleague 48:17
collective 50:4

come 6:12,14 8:4
  44:3,7
comes 26:20
comment 29:2
  50:22
comments 29:1
common 3:15
  18:10 36:1
  38:12 43:17
  51:8,19 53:2,4
companies 10:3
  11:8 17:25
  33:25 48:5 49:9
  49:18 51:19,22
company 12:25
  48:8 52:21
compared 13:7
complete 16:10
completely 17:24
  21:13
complexities
  49:17,17
complicated 48:3
  48:5 49:8
comply 46:18
component 53:1
components
  11:11,12 52:18
comprehensive
  23:24
computing 47:18
conceded 8:16
concedes 3:18
  30:7
concern 27:12
concerns 28:2,13
  44:21
concur 35:15
conduct 12:8
  22:17
confer 5:5 17:15
  17:18 18:10
  29:8,19 30:5
  33:6 35:24 37:6
  53:8

conferred 7:4
confidential
  14:14
conflicts 7:1
Congress 4:1,12
  4:14,17 5:7,11
  6:9,15 7:15,21
  9:5 11:3,4,9
  13:23 21:2
  23:12 28:1,14
  30:7,14 31:3
  34:17 37:5,25
  38:7,10 45:23
  46:1,1 49:24
  51:3,4,7
congressional
  7:2 17:21 18:10
  18:17 53:11
Congress's 3:25
consent 9:24
consideration
  12:13
considered 9:23
consistent 5:3
  45:9
consistently
  45:12
constitute 12:9
construction
  43:4
construe 24:6
  32:25
construed 19:22
  29:19
consult 25:3
consultation
  24:12 26:13
consumers 37:19
contains 22:8
contemplated
  24:25
context 24:21
  27:12
continued 11:9
contract 3:16,20

3:21,24 4:7,19
4:23 5:3,9,11
5:17,19,22,25
6:20 7:10,10
8:22 9:2,5,6,14
9:18 10:11,15
11:9,21,21,22
11:22 12:12,17
12:17 14:10
16:22 17:5 18:3
18:5,19,20,22
19:25 20:4,5,6
20:16,17,17,24
21:4,7,21,25
22:7,19,24
23:10,18 24:7
28:5 29:6,9,13
30:8,8,10,12
30:22,23 31:20
32:6,23,25
33:13,14,14,16
33:20 35:14,23
36:17,21 38:8
42:5,6,10,13
42:19 43:13
44:10 45:18,25
46:10,12 48:25
contracting
  22:13 31:21
contractors 10:2
contracts 5:13
  5:18 8:14 11:4
  11:6,7 17:14
  18:4 30:20 33:4
  37:8 38:11 42:3
  42:9 43:5 51:10
contractual 4:4
  5:18 9:8 11:2
  20:1 44:23
contribution 18:1
control 16:10
  48:14,15
controlling 53:12
controls 9:18
cooperative

24:22 42:22
43:8
coordinate 26:16
correct 9:11
35:25
counsel 19:14
20:25 29:22
35:20 53:19,20
counties 25:19
26:2 34:7 40:4
40:5,11
country's 39:8
county 1:6 3:5
12:24 26:11,12
26:24 27:8 35:1
40:3 44:8
county's 35:1
coupled 51:5
court 1:1,12 3:10
3:23 6:5 18:8
19:20 22:6
27:16 32:3,11
38:9·42:7,11,15
43:5 44:9 51:9
courts 5:6 14:5
24:12 28:10
32:25 53:5
Court's 32:23
43:10 44:15
45:6 51:2
covered 9:20
24:11 26:5,17
27:11,13 28:2
28:16 31:13
37:7,11 38:18
co-counsel 21:1
create 28:3 32:4
33:12,19 38:3
48:10
created 50:4
curiae 1:19 2:8
19:17
cut 39:3

——— D ———

D 1:17 2:6 3:1
19:16 23:22
DAVID 1:21
2:10 29:24
Davis-Bacon
8:13
days 12:8
deadline 50:19
deal 3:21,22 4:1
16:25
dealing 8:10
dealt 46:17
decide 29:8
46:25 52:11
decided 44:23
decides 52:7
decision 7:4,9,9
7:14 45:6 53:14
53:17
decisions 32:23
deep 51:21
deficiencies
38:24
defined 40:19
DeKalb 44:8
deliberate 7:14
delivered 17:3
delivery 17:1
delta 34:7 49:5
deny 43:15 44:10
Department 1:18
departure 38:7
designed 48:4
49:22
despite 24:14
50:13
determine 28:18
determines
52:15
determining
17:21
develop 50:23
development
40:10
difference 5:8,16

9:10 11:17,18
21:21 26:6,9
36:4 43:19 46:9
47:12,13 48:16
different 7:25 9:4
10:19 22:20
24:12 25:12
26:5,18 27:15
33:24 40:20
41:11,18 42:17
42:18,19 44:3,8
47:11 48:21
differentiates
41:9
difficult 21:11,12
27:20 29:15
36:3 48:23
direct 53:6
direction 45:13
directly 24:24
45:4
directs 20:19,21
20:21 22:7
discarded 6:5
disclosed 15:4
discount 34:7,8
35:3 37:2 38:19
discounted 35:7
37:6
discounts 12:16
51:24
discretion 4:24
5:2,5
displace 35:16
disposal 14:16
dispute 36:17
47:23
disputed 52:23
disputes 47:19
disrupt 23:23
disruption 7:21
16:3,4 38:16
disruptions 4:9
disruptive 32:19
34:1

distinction 35:21
distinguish 20:15
distraction 49:13
distributor 37:17
district 24:3,17
32:11 41:23
42:15 52:7,9,10
52:10
dis-uniform
27:20
dis-uniformity
24:14 26:16
doing 26:10 30:7
dollar 7:10,12
dollars 35:8
door 4:14,15
doses 39:6
doubt 42:2
dramatically
44:19
draw 36:12
drug 11:8 19:23
33:25 37:4,7
41:4,19 46:13
46:25 48:4,8
49:9,10,18,23
50:5 51:19,22
drugs 34:25 35:3
35:7 40:6 49:21
50:2 51:25
52:13
duties 46:22
duty 31:11,19
D.C 1:8,15,18,21

E

E 2:1 3:1,1
earlier 44:18
48:17,18 51:4
effect 28:1,21
39:23 44:12
effective 50:10
efficiency 39:22
efficient 18:5
39:24

efforts 25:15
either 13:14 31:1
element 22:22
embodies 45:25
emphasize 16:21
empowers 43:8
enacted 27:23
enacting 37:6
enactment 51:3
endeavor 48:5
energy 18:8
enforce 3:12,17
4:7,9 5:6,10,25
6:2 7:20 13:23
19:23 21:5,6
24:19 25:20
26:22,23,24
29:8 32:6 33:20
38:2 43:20,23
45:24
enforceability
36:13
enforceable 5:10
5:14,21 17:15
17:18 33:13
35:25 53:8
enforced 13:11
17:7,10 51:10
enforcement
7:13,16,17 13:8
17:19 24:25
25:14 26:22
28:2,5,13 35:14
36:20,25 38:25
39:12 42:24
43:9,14 44:14
enforcing 43:22
engage 43:8
enhance 48:4
enhanced 28:6
enter 3:22 9:17
20:9,19 22:8
31:8
entered 14:10
30:9 46:13

entering 18:4
enters 17:14
18:24
entire 23:17
entirely 41:17
entities 3:12 4:13
4:21 7:18,22
8:2,11,18 14:15
19:22 20:7 21:7
24:11 26:5,17
27:14 28:3,16
29:13 31:13
32:16 35:7 37:5
37:7,11 38:18
38:21 40:19
41:10,15,18
43:1,21 49:12
49:20 50:1
52:20
entitled 50:3
entity 18:6 27:11
31:9,9 44:14
46:18,23 49:10
52:21
entry 23:13
envisioned 32:14
32:17
equally 5:25
equals 51:24
ESQ 1:15,17,21
2:3,6,10,13
essence 6:16
essentially 4:15
27:14
established
45:10
et 1:3 14:23
events 7:2
evidence 38:7
exact 18:14 46:4
exactly 3:23 22:4
23:4 27:25
37:12 39:23
40:4 53:6
example 13:25

17:23
excess 49:4
exchange 12:12
exclusive 7:19
27:24
executed 18:20
18:22
existed 36:18
38:13
expense 35:1
explain 8:22
explaining 42:16
explicitly 42:24
express 9:25
17:17 50:24
expressed 32:24
expressly 29:9
35:10
extend 35:7
extensive 49:2
extent 16:2 28:2
34:17 42:1
49:16
extreme 44:2

F

FAA 44:9
face 7:14 12:3
fact 24:14,24
30:9 31:19
44:22
fair 8:13
fall 28:25
false 10:25 13:9
15:21,23 16:5
16:20 25:17
48:9,19,23
fan 45:5
far 21:22
farther 35:8
favor 7:18 37:23
38:4 39:12
favors 37:22
FCA 25:2
feature 11:10

features 38:4
Federal 5:17
  7:13 8:1,5,20
  9:23 24:22
  26:14 37:14
  43:23 53:4
federalism 43:8
Federal-State
  42:22
figure 21:4 49:9
file 13:25
filing 39:5
find 25:15 31:5
  37:12
finding 31:1
first 3:15 19:24
  22:5 28:17
  50:18
fisc 8:20
flouts 6:25
flow 5:18 9:8
following 12:4
footnote 41:7
  42:13
forced 3:22
  46:18
foreclosed 4:12
formula 48:3,7
forth 20:12 22:9
  31:7 32:2 40:22
  41:9
forward 29:4
founding 38:14
four 53:3
frames 36:3
fraud 25:1,15
  26:8 27:3 43:24
  43:25
Frederick 1:21
  2:10 29:23,24
  30:1,17 31:5,16
  31:23 32:1,8,16
  32:21 33:10
  34:6,20,22
  35:13 36:2,9

  37:1 38:6 39:10
  39:14,21 40:2
  40:18 41:21
  42:25 43:3,19
  44:1 45:3,16,21
  46:12,21 47:11
  47:21 48:2,16
  50:15 51:14
free 34:25 51:25
front 4:14 26:14
full 38:12
function 8:22
  9:17
funding 9:23,24
funds 24:23
further 50:25
  51:11
fuzzy 41:7

G

G 3:1
gee 37:21
general 1:18
  9:22 26:11,20
  28:14 49:3
generally 42:21
  52:20
getting 13:4
  47:24 49:25
gift 18:2
GINGER 1:17
  2:6 19:16
Ginsburg 8:21
  16:2,12,16
  22:21 28:20
  32:8,10,17
  41:13,21 45:20
  46:19,21 47:16
  47:22 48:6,13
  48:18 49:14
  50:7,16
give 14:2,13
  17:23 20:6 21:4
  28:5 31:20
  50:16

given 6:22 20:13
  41:14 42:24
  48:8 51:24,25
gives 21:7 25:14
  36:15,19
giving 41:24
go 3:20 7:9 14:3
  14:13 15:11
  21:20,22 27:1,6
  40:11 44:23
  53:1,5
goes 12:17 52:18
  52:20
going 7:13 14:10
  14:13 15:1 18:9
  18:11 21:6 38:2
  45:14 49:1
  50:10,11,13,23
Gonzaga 15:2
good 6:6,9 12:7
  52:21 53:3
govern 23:20
  38:18
governing 22:17
government 8:2
  8:5,14 9:11,11
  10:6,10,23 11:2
  11:20,25 17:13
  17:15 22:12,16
  23:25 24:23
  26:14,15 32:20
  32:21 36:15,16
  37:21 38:24,25
  42:8 43:5,6
  44:23 48:19
  49:6 51:10
government's
  11:18,19 24:7
  24:13 25:4 41:8
  41:16 42:2,12
  42:16
grafted 27:16
greater 43:9
gross 49:15
ground 45:2

grounds 12:9
guess 16:25 23:6

H

haec 4:5 9:6,12
  16:22 18:13
  53:10
half 21:23,23
hands 39:4
happened 10:20
  21:14
happens 13:18
  25:20 49:16
happy 12:2 53:14
hard 15:19
harmed 15:3
harms 7:3
health 7:11,12
  8:13 10:20 20:8
  23:15
hear 3:3 31:15
  37:24
heavily 24:10
heightened
  16:18
held 32:24 43:13
HHS 19:10,11
  24:12 25:3
  27:20,25 28:17
  41:20 52:4
high 17:13
higher 47:25
holiday 18:2
honor 45:18
hospital 18:2
HRSA 18:23
  19:10
huge 5:8
hundred 39:6
  43:11
hundreds 23:18
hurdles 48:23
hypothetical
  52:24

I

idea 6:6,9
identical 9:12
identified 28:8
identifying 39:23
ignoring 35:21
III 5:6
II(a) 31:6,7
illustrating 7:3
imagined 7:5
implement 10:20
  21:4 28:22
  49:25
implementing
  42:9 50:19
implicit 9:23
implied 3:17 4:13
  6:8,25 8:9 25:5
  33:24 44:18,25
  45:5 46:16 47:8
  53:7
imply 6:8 45:15
  45:17
important 12:5
  24:21 27:22
impose 22:14
imposes 16:24
imposition 46:22
incidental 34:24
  35:4 36:5,6
include 4:2
included 17:5
including 23:14
inconsistent
  29:20
incorporate
  38:11
incorporated
  9:13 38:1
incorporates 4:5
  7:11 9:6
indicate 10:10
indicated 28:10
indirectly 34:22
indistinguisha...

23:13
market 36:10
  48:9 50:4
mask 49:22
masking 49:19
Massachusetts
  24:3,17 25:25
  27:6 41:23
  42:15 49:6
matter 1:11 5:16
  6:12 13:10
  30:14 36:8,11
  53:23
matters 18:18
maximum 37:16
  37:18
mean 8:23 11:3
  15:1 16:8 17:5
  17:23 19:6
  22:21,21,25
  42:23 45:21
  46:6
meaning 28:18
mechanism 8:15
  8:22 20:24
  44:24
mechanisms
  10:17 49:20
Medicaid 6:18
  8:6 11:1,5,13
  11:14 13:6
  18:16 20:14
  24:9,21,24
  25:13,21 27:17
  37:8 40:21 41:5
  41:11,17 42:20
  42:21,21 43:24
medical 50:2
Medicare 20:2,8
  20:9,12,14
  23:14
medications 6:18
memorializing
  20:20
mercy 13:5

mere 31:18
  44:22
merely 35:23
mess 38:3
millions 52:24,24
  52:25,25,25
minutes 51:15
Miree 44:8,16
  45:6
missed 33:9
  50:18
missing 36:21
misunderstand
  39:15
misunderstood
  33:11
Mobil 9:4 38:9
  42:7
moment 30:10
monetary 10:21
  10:24
money 9:25 13:2
  13:4 14:2 35:1
  37:14 52:19
morning 3:4
moving 28:23
  29:4
multitude 15:25
multi-billion 7:10
  7:12

N

N 2:1,1 3:1
name 16:8,18
  19:2,4 40:15
named 35:5
nation 38:22
national 24:8,15
nationwide 52:7
need 4:23 12:12
  21:22
needs 49:9
negotiated 11:8
  22:22 23:2
neither 6:9,14

never 7:5 32:13
  32:14,17 33:16
new 36:18 50:8
  50:25 52:10
Ninth 6:4
non-mandatory
  14:7
normal 5:3 30:8
  30:11,20,21
  31:19 38:8 42:4
  42:10 43:4,9,10
  43:15
normally 14:18
Northern 52:9
notice 12:8 28:25
  50:21
number 8:12,12
  8:13,17 38:6

O

O 2:1 3:1
objecting 16:3
objective 32:24
  33:6,21 35:17
  36:12
objectively 32:4
obligation 9:13
  36:14
obligations 4:6
  9:24 22:1,2
obliged 12:14,16
obtaining 39:22
obviously 5:5,21
  6:24 8:7,19
  51:21
odd 18:3 23:16
officers 49:2
Oh 13:14
OIG 28:12
Oil 9:4 38:9 42:8
okay 13:17 14:8
  33:10 40:13
once 27:19,25
one-way 36:14
onward 14:19

open 4:15 40:11
operating 38:8
operation 5:22
  43:15
opinion 12:25
  41:22 45:6
opportunity
  20:13 28:17
opposed 8:2
opt-in 20:20
  21:17
oral 1:11 2:2,5,9
  3:7 19:16 29:24
order 12:20 14:1
  28:6
ordinarily 50:21
ordinary 19:25
  20:5,16 22:19
  51:6
organization
  19:10
outlined 15:25
outside 17:17,24
  46:17
overcharged
  12:25
overcharging
  41:4
overpaying 40:6
oversight 28:13
overstatement
  49:15
owed 12:20
owner 44:13

P

P 3:1
page 2:2 19:8
  52:4
pages 23:19 53:2
paid 34:7,8
parallel 11:13
part 22:5 23:22
  30:11,20 31:2,6
  31:7 46:23

participate 9:20
  20:13 23:9
  38:25 46:15,25
particular 30:14
  40:25 49:10
parties 3:20,24
  5:5,9,12,19,24
  7:4 8:15 17:16
  17:19 20:20
  22:3 30:22
  31:21 32:4 33:5
  33:13,15,18,21
  35:16,24 46:2
  53:12
party 16:4,6,7
  22:13 31:19,20
  43:16
party's 18:12
pass 48:22
passed 4:19
passing 46:1
patient 8:18 10:5
patients 34:23
pay 34:25
payments 49:21
penalties 10:7,22
  10:23,24 22:14
people 29:10
period 8:25 29:2
permissible
  33:22
permit 19:22
permitting 24:5
  27:13
person 15:10
  30:24,24 33:7
  38:1 44:14
pertinent 43:6
Pet 19:7
petition 6:24
  31:7 53:3
Petitioners 1:4
  1:16,20 2:4,8
  2:14 3:8 19:18
  24:5 51:17

Petitioner's 23:22

pharmaceutical 3:13 9:19 10:2 11:15 17:25 19:21 24:2

pharmaceuticals 17:2

phone 13:14

pick 13:14

picked 11:4

piggybacks 11:5

place 6:14 22:16 28:15 40:16 41:25

plain 34:9

plainest 50:16

plaintiffs 17:12

plans 8:7 28:22

play 43:25

pleading 16:19

please 3:10 19:20

point 4:17 24:21 27:22 37:5,22 42:23 43:7 45:13,22

points 37:23

policy 42:9

poorest 50:3

population 8:19

position 5:4 9:10 11:18,19,22 21:9,22,23 23:24 24:17 29:6,11 32:12 32:20 40:4 41:16 50:7

possibility 50:13

potentially 26:18

power 5:6 39:3 43:9,14

PPA 19:24 25:12 29:18 36:13,18

practical 5:15

9:16 13:10

practice 39:16

precise 18:14

precisely 32:6

premise 4:12

prescribed 30:7

presumably 15:3

presumption 51:7

pretty 12:22 37:18 45:9,14

pre-emption 27:15

price 4:6,22 8:25 9:14,18 12:16 19:23 24:2 25:10 28:18 31:10 34:9,19 36:23 37:2,12 37:17,18 38:18 38:19,20 47:18 47:20,23,25,25 48:1,8 49:1,4,5 49:8,11,11,19 49:22 52:8,14 52:14,16,17,18 52:20

prices 24:15 37:3 39:17

pricing 3:13 6:18 11:11,12 16:25 18:16 19:21 24:9 27:18 36:15 39:9 52:17 53:1

primary 6:25

prime 13:15

principles 5:3 30:12 38:8 42:10 45:18

private 3:20,25 7:16,17,18,22 7:23 8:2,14 15:3,4 16:4,6,7 16:25 21:7

23:23 28:4 31:4 35:10 38:1 45:15,17,23 46:2

probably 52:2

problem 16:11 26:21 28:9 39:17

procedurally 13:13

procedures 50:11,11,23

proceed 16:16

process 29:3

profits 48:4

program 7:11,12 9:20 11:6,12,13 13:6,7,8 19:11 20:1,9,12,14 23:9 24:19 32:19 34:9 35:6 37:3,7,8 38:25 39:7,9 41:5,12 41:17,18 42:22 43:24 44:24 46:20 48:11 49:25 50:1 51:24 52:15,16 52:17

programs 8:14 11:13

promise 12:5,12 12:13

promised 47:14

promises 5:21 12:4

proof 35:22,24

proposed 28:25 50:21

prosecute 25:16

Protection 10:5

provide 20:10 27:24 28:4 35:6 36:15 39:16

provided 45:23

provider 20:2,8,9 23:14

providers 23:16 23:20

provides 20:22

providing 21:15 50:2

provision 15:2 17:17 29:12 30:4 33:14 35:9 36:22 37:9 43:7 51:5

provisions 16:24 17:2 23:19 47:3

public 8:15

purchaser 48:9

purchasers 49:22

purchases 50:5

pure 4:17

purported 34:16

purporting 42:14

purpose 20:20 39:22 40:14 49:18

put 24:9 27:16 28:15 39:3 50:22

puts 27:25

p.m 53:22

Q

question 21:12 21:19 22:5 27:15 29:17 30:4,13 31:15 31:18 33:4,11 47:24 48:1,17

questions 51:11

qui 16:13 48:17

quickly 45:11

quite 32:19 49:2

quote 42:21

R

R 3:1

raised 37:4

raising 28:13

rarely 17:15,16

reacted 28:3,14

read 46:1

really 52:12

reason 3:15 10:9 27:1 47:4 50:17

reasonable 14:9

reasonableness 14:5

reasonably 21:15

reasons 3:11 6:12 19:24

rebate 11:1,5,8 11:13,14 13:6 18:16 24:10,19 27:17 37:8 40:21 41:5,11 42:21 52:3,15 52:16,16

rebuttal 2:12 19:13 51:16

receive 24:23

received 35:23

receiving 29:10

recognized 32:3 38:14 43:12 44:4

reflecting 9:2

reflects 7:14

reform 10:21

refusal 15:13

regime 14:17

regimes 27:16 27:16

regulated 20:7 23:17 24:10

regulation 5:20 9:21 23:6,8 42:5

regulations 20:11 23:19

50:19
regulator 22:13
regulatory 4:18
  10:12 14:17
  20:1,21,24
  21:20 22:6,11
  22:19 23:14
  25:11 29:4,6
  42:3,6,9
Rehabilitation
  8:12
Rehnquist 45:4
reimbursement
  7:22 12:20,21
reject 41:2
rejected 42:7,11
relationship
  24:22
relator 16:14
release 52:3
rely 42:13
remainder 19:12
remaining 51:15
remedial 51:5
remedies 5:18
  9:8 10:13 11:3
  14:14 47:15
remedy 4:8 7:18
  7:22 10:11,12
  10:16 14:4,11
  14:20,22 15:8
  27:24 28:10,11
  28:15 47:11,13
repeated 23:2
repeats 22:24
reply 37:24
reporting 18:16
  19:23 20:23
reports 28:13
  49:2
represent 25:4
representing
  43:2
republic 38:15
required 4:18

requirements
  16:19 18:17
  19:24 20:23
  27:17,19 28:19
requires 36:23
resale 37:16,18
resolution 36:17
resort 43:4
resources 21:6
respect 25:3
  35:14
respectfully
  49:14
respond 46:8
Respondent 1:22
  2:11 3:18 6:3
  13:9 29:25
Respondent's
  27:25
response 38:5
  52:3
responsibilities
  12:18 25:1
responsibility
  25:14
Restatement
  32:2 33:4 36:2
rests 35:13
result 44:8 45:20
  46:4 50:8
return 13:22
  20:12
reverse 5:23
reversed 53:15
  53:17
review 15:12
reviewable 14:5
reviewed 22:15
Rhode 27:8,9
right 3:17,17 4:8
  4:9,13 5:1,4 6:1
  6:8,25 8:10
  10:18,24 13:2
  14:6 15:4 16:15
  16:17 21:2 22:4

23:1,4,6 24:18
  26:1,19 27:9
  28:4 31:20,22
  32:5 35:8,10,25
  36:16 38:3 40:9
  43:12 44:5,11
  44:18 45:1,15
  45:17,24 46:16
  47:2,8 53:7,16
rights 7:4 14:15
  17:15,19 20:6
  23:20 29:9,19
  30:5,11,20,21
  30:23 33:6,12
  33:25 35:17
  36:20 37:13
  38:12,13 41:10
  41:11 45:5 51:8
  53:8
rise 20:6
road 15:1
ROBERTS 3:3
  7:24 8:8 15:21
  16:21 17:9
  19:14 20:3 23:5
  23:8 28:8 29:22
  39:2,11,19,25
  44:16 45:8 47:5
  51:13 53:19
role 41:14,17,19
  43:25
route 21:20 46:5
rule 5:9,24,25
rulemaking
  28:25 50:21
rules 22:17 30:8
  50:20,23,25
run 13:6 44:25
runs 19:11 31:12

——————
S
——————
S 1:15 2:1,3,13
  3:1,7 51:16
Santa 1:6 3:4
  12:23 27:7,10

38:19 40:3
Saris's 41:22
save 19:12
saved 18:9
saying 4:11
  14:24 18:8 23:9
  25:6 26:11
  33:15 35:10
  39:5,6
says 4:19 11:20
  11:21 12:3
  13:16 19:6,7
  21:5 23:10
  25:14,19 26:20
  26:21 37:10
  40:13 42:14
  52:23
Scalia 7:16 11:16
  11:23 12:11
  18:19 19:1,4
  30:16,19 31:5
  31:14,18,24,25
  33:2,3,9 42:12
  43:1,3,18 44:1
Scalia's 33:11
scarce 35:7
scheme 20:1,21
  22:10,11 23:14
  23:24 24:8,9
  25:12 27:19,21
  28:1 29:2,21
search 51:23
second 6:11 38:2
Secretary 3:13
  5:20 6:15 7:5,8
  7:19 10:1 12:3
  12:4,5,6,19,20
  13:20 14:1,1,9
  14:15 15:16
  16:3 18:3,12,20
  18:21,25 19:3,5
  19:8 21:5,9,13
  21:14,16 22:1,2
  23:2 29:7,12
  30:9,15 31:2,2

36:19 39:13
  46:14 49:25
  50:18,22,24
  52:4
Secretary's 7:8
section 3:11
see 18:3
seeks 4:8
seen 19:9
sees 11:25
sell 4:20 49:9
sense 11:24
sensible 6:7,9
  11:4
sentence 36:22
seriously 23:23
served 8:19
serves 8:22
service 50:2
services 20:10
set 3:21 20:12
  22:9 31:6,10
  32:2 40:21 41:8
settled 5:9,25
settlements 13:9
  15:25
SG 41:7
shalt 8:24 37:11
shocked 52:5
show 51:23
side's 52:8
sign 47:1,7
signature 19:8
signed 6:15 10:1
  10:3 12:17 19:9
significant 16:9
  17:11
signs 20:10
silence 35:14
similar 20:7
simple 48:7
  50:16 52:5
simply 20:24
  21:17 22:7 23:2
  28:5 50:22

situation 8:3 27:3
29:6 42:17,19
42:20 47:6
small 13:7
society 46:23
sole 20:20 49:18
solicited 29:1
Solicitor 1:17
solve 38:24
somebody 17:14
sorry 34:13
35:20 37:10
sort 5:15 7:3 9:16
9:22,23 20:16
21:21 27:2
Sotomayor 3:19
4:16 5:2 6:19
20:25 21:18
22:20 24:16
25:5,11 29:5
32:9 34:12
35:20 36:8,11
37:2
Southern 52:9
sovereign 43:20
sovereigns 43:21
specific 5:20
43:7,14 44:14
51:5
specifically 30:6
specifics 7:20
specified 4:1
31:16
specifies 36:17
specify 9:5
Spending 8:10
9:22 47:6
spent 37:14
spoke 5:11
standard 31:24
32:1 41:9
standing 40:25
stands 40:3 46:6
start 27:13 30:3
started 45:11

starting 19:7
State 8:5,7,11
25:1,2,6,8,17
25:17,18 26:10
26:11,14,15
27:3,16,16 37:8
40:12,19,24
52:15
stated 51:4
statement 16:20
36:1 50:20
States 1:1,12,19
2:7 4:20 11:7
13:7 15:11 16:9
16:10,12,18
18:20,21 19:17
24:1,18,22 25:1
25:14,16 40:5
40:22 41:3,6,11
41:14,16,24
42:23 43:8,20
43:24 47:6
51:20 52:19,22
53:13
statute 3:17 4:10
4:18,19 6:1
7:14 8:24 9:2
10:4 14:12
16:23,24 17:6
17:11,18,20,25
20:18 21:3,15
22:7,9,23,24
23:3 29:8 35:11
37:6,25 41:14
43:14 44:5
45:24,25 46:9
46:18,19 50:10
53:11
statutes 20:11
50:1
statutorily 20:22
statutory 5:9,13
5:22 9:6,12
10:23 15:2
22:10,17 23:19

23:24 24:8
29:20 41:19
50:18
strange 46:1
strikes 39:11
stronger 45:2
students 15:3
subject 9:18
subjective 32:22
submissions 49:7
submit 30:17
49:15 51:2,12
submitted 53:21
53:23
substantial 12:22
24:14
substantially
41:3
subverted 17:21
sue 5:12,24
29:13 30:25
31:4,21,22
32:19 34:19
35:8 43:16
44:11
suggest 42:4
suggestion 51:22
suing 46:9,10
suit 3:16 4:7,15
19:22 25:25
26:8,15,18 27:4
27:9,14 32:5
33:20,21,24
34:15 38:23
39:1,5 43:13
50:13
suits 10:25 23:23
24:6,12 25:2,2
25:4,6,9 32:13
33:25 48:15
52:13
supporting 1:20
2:8 19:18
suppose 25:18
25:23

supposed 12:24
13:1,13 24:15
27:18,21
Supreme 1:1,12
sure 7:25 37:22
40:9,24
Surety 43:11
surprise 32:12
system 36:17

———————
T
———————
T 2:1,1
table 41:25
take 16:13 21:8
22:5 28:19 50:7
51:21
taken 23:25
talk 51:18,20
53:13
talking 9:13
18:13 35:2
38:17 44:21
46:24 47:13,17
48:24 52:14
tam 16:13 48:17
tell 21:21 22:6,18
23:21 32:9
telling 20:25
29:13
tends 42:2
term 4:4
terminate 10:25
12:7 47:3
termination
12:10 47:3
terms 3:21 4:2
5:23 9:2,5,7
17:6 20:21 21:3
21:25 22:9,24
23:3 34:9 38:23
45:24,25
test 6:3,4,7
tested 41:1
Texas 52:9
Thank 3:9 19:14

29:22 30:1
51:13 53:19
theory 41:24
42:3,6,6
thing 41:18
things 14:16
think 5:17 6:3,13
6:23 7:7 8:3,16
9:3,21 10:5
11:3 12:1,24
14:9,25 15:16
15:19 17:11
18:7 20:18
21:11,12,14
22:5,6,18 23:7
23:11 24:21
26:4 27:22
29:15,18 33:10
34:22 36:3
37:20 38:16
39:7,14 40:8,17
41:22 43:7 44:2
44:7,15 45:12
45:13 46:5 52:5
53:10
thinking 37:16
thinks 12:19
third 6:11 17:19
22:2 31:19,20
33:6,15
third-party 4:6
6:21 17:7,12
18:4 21:24 24:5
29:9,19 30:5,10
30:19,20 31:12
31:22 32:2,5
33:12,19 34:12
34:15 35:16
37:13 38:13
40:23 41:10,24
43:9,12 44:5,11
46:5 50:12 53:4
thou 8:24 37:10
thought 21:23
28:11 31:25

32:10,20 35:22
41:13,15
thousands 26:17
three 3:11 7:20
53:3
thrust 6:24
time 10:16 18:24
26:2,21 36:19
today 10:19
40:11
told 47:16,18
50:9
tomorrow 26:20
ton 12:18
total 16:10 32:12
totally 21:2
29:16
transaction
22:16
transactions
53:1
transform 19:25
Transit 9:4 38:9
tried 42:8
trouble 31:1
true 15:9 37:15
37:16 49:22
trying 27:5 43:22
turn 7:13 11:7
two 3:20 19:24
37:23 38:3 48:2
type 49:7,16
typical 8:3 9:21

U

Ultimately 13:19
ultra 29:14
umbrage 51:21
unambiguous
53:8
unambiguously
5:11
undercharging
13:17
undercutting

41:3
undermined
17:22
understand 3:19
29:5 33:2 35:21
36:4 40:10
understood
35:18
undertake 34:3
uniform 27:18
39:16
unilateral 12:1
United 1:1,12,19
2:7 15:11 16:9
16:10,12,18
18:20,21 19:17
40:5
unusual 8:1
upheld 44:6
USA 1:3 3:4
use 11:14 25:15
44:25 49:21
51:6
uses 11:6 38:10

V
---

v 1:5 3:4 14:19
44:8
various 49:20
vast 14:16
vastly 13:5
vendor 13:15
verba 4:5 9:6,12
16:22 18:13
53:10
view 7:7 42:17
52:9
violated 46:10
46:11
violating 14:2
violation 18:16
vires 29:14
voluntarily 31:8
voluntary 31:11
46:12,24

W
---

wait 30:16
walked 12:2
walking 24:16
want 3:25 9:19
21:3 26:2,23
33:23 36:11
37:24 38:1
45:23 46:2,20
51:20 53:13
wanted 4:17 7:8
wants 4:20 9:5
20:9 25:24
Washington 1:8
1:15,18,21
wasn't 30:6
42:14
way 4:11 5:13
11:8 13:3 14:13
18:5,7 23:7,11
27:21 28:3,14
39:2,17 51:9
53:5
ways 48:2
Wednesday 1:9
welfare 8:15
went 28:21 32:11
45:12
weren't 12:13
we'll 3:3 51:11
we're 7:12 9:13
12:2 14:13 15:1
30:13 34:1 35:1
38:17 45:14,16
45:18 46:24
47:13,16,17
48:24 49:5 50:5
whatsoever 47:4
whistleblower
48:22
Wholesale 24:2
25:9
win 39:8
Winstar 38:9
42:7

withhold 7:15,18
15:13
withholding
15:13
wording 30:6
words 22:24
30:14 32:24
work 5:13
world 44:18
worse 13:4
wouldn't 4:18
27:1 46:19
write 21:6
written 29:12
32:22
wrong 13:17
14:19
wrote 21:3 30:14

X
---

x 1:2,7

Y
---

year 18:2
years 14:25
32:22 38:14
43:12 44:20
45:1 47:10
yesterday 10:19
York 52:10

0

09-1273 1:4 3:4

1

1st 28:21
11a 53:2
11:08 1:13 3:2
12:05 53:22
14,000 6:16
24:11 32:13
52:13
14,500 38:18
169 19:7
18 32:22
19 1:9 2:8

1977 44:17
1980 45:12
1990 11:9 37:3
1992 37:4

2

2010 10:20 13:4
2011 1:9
25 47:10
29 2:11

3
---

3 2:4 51:15
30 14:25 44:20
45:1 47:10
340B 3:11 4:13
4:21 7:18,22
8:18 14:15
18:15 19:11,22
19:25 21:7
29:13 32:16
35:6 38:21 41:9
41:15 49:12,19
50:1,4 52:20,21
35,000 6:18
52:13
350 38:14

4

430B 32:15

5
---

50 27:15
500 6:17
51 2:14
57 40:4,11

6
---

60 12:8

9
---

9 53:2