

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	
2	ORAL ARGUMENT OF	PAGE
3	LISA S. BLATT, ESQ.	
4	On behalf of the Petitioners	3
5	ORAL ARGUMENT OF	
6	GINGER D. ANDERS, ESQ.	
7	On behalf of the United States, as	
8	amicus curiae, supporting Petitioners	19
9	ORAL ARGUMENT OF	
10	DAVID C. FREDERICK, ESQ.	
11	On behalf of the Respondent	29
12	REBUTTAL ARGUMENT OF	
13	LISA S. BLATT, ESQ.	
14	On behalf of the Petitioners	51
15		
16		
17		
18		
19		
20		
21		
22		
23		
24		
25		

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 action 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

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?

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

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 to 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

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.

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.

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

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

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

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

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

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.)

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A	actor 46:23	10:3,6 11:1,1	analogize 27:5	49:13 51:16
abide 20:11	Acts 15:24	11:14,15 12:3,4	analysis 9:22	arose 10:16
ability 24:7 41:3	addition 7:20	12:7 19:21	42:1 45:9 53:6	arrangement
able 5:24 25:19	address 45:3	20:10,13,19	analyzing 39:17	34:9
27:3 34:19 35:3	adjoining 44:12	21:16 22:8 23:2	Anders 1:17 2:6	arranging 17:1
35:11 37:20	44:13	23:3 30:4,15	19:15,16,19	arsenal 14:16
38:2	adjudicate 28:6	31:6,9,11,17	20:5,18 21:11	Arthur 44:3
above-entitled	administer 24:8	32:22 34:10	22:4 23:1,7,11	Article 5:6
1:11 53:23	27:21	35:18 37:10	24:4,20 25:8,13	asked 21:19
absence 43:14	administering	40:20,20,21	25:21 26:4,8,13	52:24
51:5	4:25	44:6 46:13 47:1	27:2,11 28:12	asking 10:10
absolutely 9:11	administrability	47:4 51:8	28:23 29:15	45:16,18 49:5
accepted 33:17	38:23	agreements 11:8	50:9	50:5
accepts 9:23	administrative	20:8 23:13,15	Andersen 44:4	assert 49:1
access 36:9	14:3,4,23 15:8	38:11 40:23	answer 4:16 5:7	asserts 4:7
accomplished	22:14 27:24	51:6	5:15 7:25 29:18	assess 10:6
9:1	28:15 29:2	agrees 20:10,11	30:3,17 33:8	assigned 16:7
account 28:19	administrator	31:8,9	44:3 50:16	assistant 1:17
achieved 46:4	18:23,24 19:9	ahead 27:1,7	APA 15:15,20	40:14
acknowledge	advance 44:24	28:24	22:15	associated 51:8
48:10	advanced 28:25	aim 46:4	App 19:7	Astra 1:3 3:4
acknowledged	adversary 6:19	Airlines 38:10	appeals 18:9	ation 3:12
48:18 49:7	adverse 44:12	43:11	APPEARANC...	attorney 26:10
act 4:6 5:6 8:12	advocates 6:4	airport 44:10	1:14	26:12,20
8:13 10:5,25	afford 34:25	AL 1:3	appendix 31:7	audit 10:24 14:15
13:9 15:22 16:5	Affordable 27:23	Alabama 52:10	40:22 53:3	author 45:6
18:16 24:10,24	AG 27:9 40:12	Alito 20:15 21:19	applied 6:4 42:15	authority 7:19
25:13,17,21	40:14	23:21 34:4,11	43:5	21:10,13 22:14
27:23 48:10,20	agencies 50:22	34:14,21,23	apply 30:9 42:10	26:25 28:6 29:7
48:23	agency 4:24	35:9,19	46:20 49:11	29:17 39:4
acting 22:12,13	15:12 18:23	allegation 18:15	51:1	42:24 44:10,14
action 3:17 4:9	20:19 22:8 28:5	allege 16:19	arbitration 44:6	average 24:2
4:13 5:10 6:2,8	28:23,24 29:3	allow 28:16,17	area 23:12,15,17	25:9 52:14,18
7:1 8:10 15:5	29:16 46:3	31:4 44:24	45:10	avoid 26:16
15:14,15,20,22	50:14	allowing 24:11	argue 32:21 42:8	awful 39:3
21:8 25:6 28:4	agency's 32:12	32:18 47:3	arguing 34:1	a.m 1:13 3:2
33:25 35:11	ago 32:23 43:12	allows 30:24	37:22	
37:3 39:16,20	agree 9:9 18:1	amended 10:5	argument 1:12	B
40:1,3 44:18	23:10,22 24:4	amendment	2:2,5,9,12 3:3,7	back 4:14 28:25
45:1,5,15,17	25:25 37:18	37:10	6:20,22,25 15:5	32:11 43:10
45:24 46:17,24	agreed 34:2	American 43:11	19:16 21:12	background
47:9 53:7	48:25	amicus 1:19 2:8	23:22 29:24	37:24 38:4
actions 24:1	agreeing 21:2	19:17 41:6	35:12,13 39:12	bad 7:3 16:11
43:25	agreement 3:13	amount 51:24,25	39:14 40:10	52:12,12,21
activity 13:8	5:19 8:1,4 10:2	AMP 28:18	41:2 44:2,17	bar 17:13

bargain 34:2,6 48:24	best 28:18 38:20 48:8 49:7 52:14	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	cases 8:3,6 15:7 43:10 46:17,22 47:9 48:6,10 51:2	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
based 49:1	better 13:4 50:11 52:2	bringing 4:13 16:4 26:8,18 33:19 41:25	cast 42:2	choose 46:14
basic 5:7	beyond 17:6	brings 26:15	cause 3:12 5:10 6:2 12:8 21:7 25:5	circuit 3:23 6:4
basically 6:11	big 27:8 43:18,18	brought 15:24 16:8,18 24:1 39:22 40:1,2 48:12	causes 4:8	citations 53:3
basis 41:22 42:14	bigger 7:12	bundling 49:21	caution 33:23	cites 13:10
bears 42:1	bilateral 5:19	business 47:19	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	citizens 50:3
begins 4:12	billions 12:15,15	busy 13:21,22	central 38:10 43:11 45:21 52:7	civil 10:21,24
begs 21:18	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	buy 6:7	certain 9:14 12:8 16:24	claim 13:25 16:7 33:13,16 34:1
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		C	certainly 34:23 35:4 36:6 45:9 51:9	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
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	Blatt's 30:3	calculate 48:3	cetera 14:23	Clara 1:6 3:5 12:23 27:7,10 38:19 40:3
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	blurring 42:4	California 1:6 25:19,24,24 26:19 40:5,15 52:7	CFR 52:4	class 39:15,20 40:1,3
beneficiary's 4:7 35:17 43:12 44:5	board 49:12	call 13:15 20:16 32:14 45:22	challenged 4:4	Clause 8:11 9:22 47:7
benefit 14:10 24:13 29:10 30:24 34:18 35:23 36:24 37:20 48:24 52:19	body 25:16	calls 13:23	challenging 6:17	clear 5:12 34:16 35:22 41:7,9 45:14 51:3 53:7
benefits 39:15 50:4	bound 12:2	canard 38:17	chance 26:16	clearly 29:6,18 31:3
	breach 3:16 9:7 10:6 15:2 23:17 28:4 33:13,16 43:13,16	canons 43:4	changed 39:9 44:19 50:8	clinic 18:2
	breached 43:16	care 7:11,12 8:13 10:20 20:8 23:16 27:23	changing 45:11	clinics 51:23 52:1
	breath 18:8	carries 51:6	channel 7:19	closed 29:3
	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	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	channeled 14:17	cluster 38:12 51:7
	brief 13:10 23:23 41:6,8 45:22		characterized 36:24	CMS 19:11
	briefs 16:1		charge 4:21 8:24 37:11 47:14,25 49:1	colleague 48:17
	bring 10:25		chargeable 38:21	collective 50:4
			charged 9:15 31:10 38:20 47:15	
			charging 49:3,4 49:19	

come 6:12,14 8:4 44:3,7	conferred 7:4	3:21,24 4:7,19	24:22 42:22	D 1:17 2:6 3:1
comes 26:20	confidential 14:14	4:23 5:3,9,11	43:8	19:16 23:22
comment 29:2 50:22	conflicts 7:1	5:17,19,22,25	coordinate 26:16	DAVID 1:21
comments 29:1	Congress 4:1,12 4:14,17 5:7,11	6:20 7:10,10	correct 9:11 35:25	2:10 29:24
common 3:15 18:10 36:1	6:9,15 7:15,21	8:22 9:2,5,6,14	counsel 19:14 20:25 29:22	Davis-Bacon 8:13
38:12 43:17	9:5 11:3,4,9	9:18 10:11,15	35:20 53:19,20	days 12:8
51:8,19 53:2,4	13:23 21:2	11:9,21,21,22	counties 25:19	deadline 50:19
companies 10:3	23:12 28:1,14	11:22 12:12,17	26:2 34:7 40:4	deal 3:21,22 4:1
11:8 17:25	30:7,14 31:3	12:17 14:10	40:5,11	16:25
33:25 48:5 49:9	34:17 37:5,25	16:22 17:5 18:3	country's 39:8	dealing 8:10
49:18 51:19,22	38:7,10 45:23	18:5,19,20,22	county 1:6 3:5	dealt 46:17
company 12:25 48:8 52:21	46:1,1 49:24	19:25 20:4,5,6	12:24 26:11,12	decide 29:8
compared 13:7	51:3,4,7	20:16,17,17,24	26:24 27:8 35:1	46:25 52:11
complete 16:10	congressional 7:2 17:21 18:10	21:4,7,21,25	40:3 44:8	decided 44:23
completely 17:24 21:13	18:17 53:11	22:7,19,24	county's 35:1	decides 52:7
complexities 49:17,17	Congress's 3:25	23:10,18 24:7	coupled 51:5	decision 7:4,9,9
complicated 48:3 48:5 49:8	consent 9:24	28:5 29:6,9,13	court 1:1,12 3:10	7:14 45:6 53:14
comply 46:18	consideration 12:13	30:8,8,10,12	3:23 6:5 18:8	53:17
component 53:1	considered 9:23	30:22,23 31:20	19:20 22:6	decisions 32:23
components 11:11,12 52:18	consistent 5:3 45:9	32:6,23,25	27:16 32:3,11	deep 51:21
comprehensive 23:24	consistently 45:12	33:13,14,14,16	38:9-42:7,11,15	deficiencies 38:24
computing 47:18	constitute 12:9	36:17,21 38:8	43:5 44:9 51:9	defined 40:19
conceded 8:16	construction 43:4	42:5,6,10,13	courts 5:6 14:5	DeKalb 44:8
concedes 3:18 30:7	construe 24:6 32:25	42:19 43:13	24:12 28:10	deliberate 7:14
concern 27:12	construed 19:22 29:19	44:10 45:18,25	32:25 53:5	delivered 17:3
concerns 28:2,13 44:21	consult 25:3	46:10,12 48:25	Court's 32:23	delivery 17:1
concur 35:15	consultation 24:12 26:13	contracting 22:13 31:21	43:10 44:15	delta 34:7 49:5
conduct 12:8 22:17	consumers 37:19	contractors 10:2	45:6 51:2	deny 43:15 44:10
confer 5:5 17:15 17:18 18:10	contains 22:8	contracts 5:13 5:18 8:14 11:4	covered 9:20 24:11 26:5,17	Department 1:18
29:8,19 30:5	contemplated 24:25	11:6,7 17:14	27:11,13 28:2	departure 38:7
33:6 35:24 37:6	context 24:21 27:12	18:4 30:20 33:4	28:16 31:13	designed 48:4
53:8	continued 11:9	37:8 38:11 42:3	37:7,11 38:18	49:22
	contract 3:16,20	42:9 43:5 51:10	co-counsel 21:1	despite 24:14
		contractual 4:4 5:18 9:8 11:2	create 28:3 32:4 33:12,19 38:3	50:13
		20:1 44:23	48:10	determine 28:18
		contribution 18:1	created 50:4	determines 52:15
		control 16:10 48:14,15	curiae 1:19 2:8 19:17	determining 17:21
		controlling 53:12	cut 39:3	develop 50:23
		controls 9:18		development 40:10
		cooperative	D	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	37:1 38:6 39:10	given 6:22 20:13	grounds 12:9	I
Federal 5:17	39:14,21 40:2	41:14 42:24	guess 16:25 23:6	idea 6:6,9
7:13 8:1,5,20	40:18 41:21	48:8 51:24,25	H	identical 9:12
9:23 24:22	42:25 43:3,19	gives 21:7 25:14	haec 4:5 9:6,12	identified 28:8
26:14 37:14	44:1 45:3,16,21	36:15,19	16:22 18:13	identifying 39:23
43:23 53:4	46:12,21 47:11	giving 41:24	53:10	ignoring 35:21
federalism 43:8	47:21 48:2,16	go 3:20 7:9 14:3	half 21:23,23	III 5:6
Federal-State	50:15 51:14	14:13 15:11	hands 39:4	II(a) 31:6,7
42:22	free 34:25 51:25	21:20,22 27:1,6	happened 10:20	illustrating 7:3
figure 21:4 49:9	front 4:14 26:14	40:11 44:23	21:14	imagined 7:5
file 13:25	full 38:12	53:1,5	happens 13:18	implement 10:20
filing 39:5	function 8:22	goes 12:17 52:18	25:20 49:16	21:4 28:22
find 25:15 31:5	9:17	52:20	happy 12:2 53:14	49:25
37:12	funding 9:23,24	going 7:13 14:10	hard 15:19	implementing
finding 31:1	funds 24:23	14:13 15:1 18:9	harmed 15:3	42:9 50:19
first 3:15 19:24	further 50:25	18:11 21:6 38:2	harms 7:3	implicit 9:23
22:5 28:17	51:11	45:14 49:1	health 7:11,12	implied 3:17 4:13
50:18	fuzzy 41:7	50:10,11,13,23	8:13 10:20 20:8	6:8,25 8:9 25:5
fisc 8:20	G	Gonzaga 15:2	23:15	33:24 44:18,25
flouts 6:25	G 3:1	good 6:6,9 12:7	hear 3:3 31:15	45:5 46:16 47:8
flow 5:18 9:8	gee 37:21	52:21 53:3	37:24	53:7
following 12:4	general 1:18	govern 23:20	heavily 24:10	imply 6:8 45:15
footnote 41:7	9:22 26:11,20	38:18	heightened	45:17
42:13	28:14 49:3	governing 22:17	16:18	important 12:5
forced 3:22	generally 42:21	government 8:2	held 32:24 43:13	24:21 27:22
46:18	52:20	8:5,14 9:11,11	HHS 19:10,11	impose 22:14
foreclosed 4:12	getting 13:4	10:6,10,23 11:2	24:12 25:3	imposes 16:24
formula 48:3,7	47:24 49:25	11:20,25 17:13	27:20,25 28:17	imposition 46:22
forth 20:12 22:9	gift 18:2	17:15 22:12,16	41:20 52:4	incidental 34:24
31:7 32:2 40:22	GINGER 1:17	23:25 24:23	high 17:13	35:4 36:5,6
41:9	2:6 19:16	26:14,15 32:20	higher 47:25	include 4:2
forward 29:4	Ginsburg 8:21	32:21 36:15,16	holiday 18:2	included 17:5
founding 38:14	16:2,12,16	37:21 38:24,25	honor 45:18	including 23:14
four 53:3	22:21 28:20	42:8 43:5,6	hospital 18:2	inconsistent
frames 36:3	32:8,10,17	44:23 48:19	HRSA 18:23	29:20
fraud 25:1,15	41:13,21 45:20	49:6 51:10	19:10	incorporate
26:8 27:3 43:24	46:19,21 47:16	government's	huge 5:8	38:11
43:25	47:22 48:6,13	11:18,19 24:7	hundred 39:6	incorporated
Frederick 1:21	48:18 49:14	24:13 25:4 41:8	43:11	9:13 38:1
2:10 29:23,24	50:7,16	41:16 42:2,12	hundreds 23:18	incorporates 4:5
30:1,17 31:5,16	give 14:2,13	42:16	hurdles 48:23	7:11 9:6
31:23 32:1,8,16	17:23 20:6 21:4	grafted 27:16	hypothetical	indicate 10:10
32:21 33:10	28:5 31:20	greater 43:9	52:24	indicated 28:10
34:6,20,22	50:16	gross 49:15		indirectly 34:22
35:13 36:2,9		ground 45:2		indistinguishable

3:16 individual 15:11 24:11 28:9 32:14 individuals 31:4 Industry 24:2 inference 11:4 informal 14:7 36:16 information 15:4 36:15 inherent 4:24 30:11 input 24:13 inside 48:22 insofar 34:24 Inspectorate 49:3 instances 15:13 institute 36:16 insurance 35:3 intend 7:6 17:18 30:22 31:21 33:5,19 34:17 34:19 35:16 37:19 intended 6:10,21 21:24 32:4,4 33:15 34:15,16 34:17 35:24 36:5 37:12,19 38:7 49:24 51:7 intends 17:15 38:11 intensively 25:3 intent 3:24,25 7:2 17:21 18:11 18:12,17 30:25 31:1,3,4,6 32:22,24 33:6 33:21 35:6,17 36:13 50:25 51:4 53:8,11 interested 13:12 interfere 24:7	Internet 51:23 interpreted 21:15 intervene 48:19 intricate 47:18 introduced 49:18 intrusion 48:11 49:14 inventory 17:4 invoke 44:5 involve 46:22 involved 25:9 involving 24:1 25:12 51:10 Island 27:8,9 issue 3:23 23:8 36:12 43:21 47:8 issued 28:24 52:3 issuing 50:19 J Jackson 9:4 38:9 January 1:9 28:21 joint 40:22 judge 14:3 41:22 judicial 14:23 jurisprudence 7:1 8:10 17:20 44:19 45:1,10 45:14 Justice 1:18 3:3 3:9,19 4:16 5:2 6:19 7:16,24 8:8,21 10:4,9 10:15 11:16,23 12:11,23 13:12 13:16,21,24 14:8,18,22 15:7 15:10,17,21 16:2,12,16,21 17:9 18:19 19:1 19:4,14,19 20:3	20:15,25 21:18 21:19 22:20,21 23:5,8,21 24:16 25:5,11,18,23 26:6,9,19 27:5 28:8,20 29:5,22 30:2,16,19 31:5 31:14,18,24,25 32:8,9,10,17 33:1,2,3,9,11 34:4,11,12,14 34:21,23 35:9 35:19,20 36:8 36:11 37:2,15 39:2,11,18,19 39:25 40:8 41:13,21 42:12 43:1,3,18 44:1 44:16 45:4,4,8 45:17,20 46:19 46:21 47:5,12 47:16,22 48:6 48:13,18 49:14 50:7,15 51:13 53:19 K KENNEDY 10:4 10:9,15 33:1 key 16:25 37:1 47:12 kickbacks 49:21 kind 14:4 20:17 kinds 33:24 41:4 41:25 know 17:1 23:10 23:18 26:17,21 27:7,14 37:16 37:21 40:18 49:2 50:15,17 50:24 knowing 16:20 L land 44:12,13	language 5:12 16:22 44:22 large 18:11 larger 13:5 Laughter 53:18 launch 40:14 law 3:15 5:17 12:14 14:3,18 18:10 23:18 25:1,2,8,17,17 27:3 30:8 33:17 33:18 35:10,22 36:1,18 38:12 43:15,17,23 46:18 51:8,19 53:2,4 laws 43:20,22 lawsuit 37:20 40:12,15 lawsuits 6:8,17 lawyer 39:5 40:13 lead 24:14 leave 4:14 21:8 leaving 39:12 left 30:13 legislation 8:11 47:7 50:9 lens 6:13 level 28:14 light 23:24 limited 35:2 line 18:11 36:3 36:12 lines 42:4 Lipitor 38:19 39:6,9 51:19 52:6,8 LISA 1:15 2:3,13 3:7 51:16 litigation 23:25 24:3 49:8,16 local 44:10 logical 44:2 long 6:5 30:6	35:15 43:5 45:19 long-settled 5:24 look 6:13 22:10 29:2 36:13 39:6 52:3 looked 41:23 looking 28:1 lose 17:12 lot 8:9 9:10 10:13 11:17 15:24 17:2 18:8 39:3 44:17 lower 49:10 luck 44:15 M Madison 14:19 maintenance 37:17 major 37:23 making 32:14,18 mandate 5:22 manifestation 10:1 manufacturer 9:19 12:9,11,18 12:19,21 13:15 13:16 22:1 31:8 31:12 37:18 46:3,13,14 52:14,18 manufacturers 3:14,22 6:15,17 6:21 7:9,21 9:17 12:1,6 14:13,14 19:23 21:8,16 23:9 34:2 36:6,23 37:4 40:6 41:5 41:19 46:25 47:24 48:25 manufacturer's 4:5 36:14 Marbury 14:19
---	--	---	---	--

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	9:16 13:10	23:23 28:4 31:4	provider 20:2,8,9 23:14	R 3:1
pharmaceutical 3:13 9:19 10:2 11:15 17:25 19:21 24:2	practice 39:16	35:10 38:1	providers 23:16 23:20	raised 37:4
pharmaceuticals 17:2	precise 18:14	45:15,17,23	provides 20:22	raising 28:13
phone 13:14	precisely 32:6	46:2	providing 21:15 50:2	rarely 17:15,16
pick 13:14	premise 4:12	probably 52:2	provision 15:2 17:17 29:12	reacted 28:3,14
picked 11:4	prescribed 30:7	problem 16:11 26:21 28:9 39:17	provisions 16:24 17:2 23:19 47:3	read 46:1
piggybacks 11:5	presumably 15:3	procedurally 13:13	public 8:15	really 52:12
place 6:14 22:16 28:15 40:16 41:25	presumption 51:7	procedures 50:11,11,23	purchaser 48:9	reason 3:15 10:9 27:1 47:4 50:17
plain 34:9	pre-emption 27:15	proceed 16:16	purchasers 49:22	reasonable 14:9
plainest 50:16	price 4:6,22 8:25 9:14,18 12:16 19:23 24:2	process 29:3	purchases 50:5	reasonableness 14:5
plaintiffs 17:12	25:10 28:18	profits 48:4	pure 4:17	reasonably 21:15
plans 8:7 28:22	31:10 34:9,19	program 7:11,12 9:20 11:6,12,13	purported 34:16	reasons 3:11 6:12 19:24
play 43:25	36:23 37:2,12	13:6,7,8 19:11	purporting 42:14	rebate 11:1,5,8 11:13,14 13:6
pleading 16:19	37:17,18 38:18	20:1,9,12,14	purpose 20:20 39:22 40:14	18:16 24:10,19
please 3:10 19:20	38:19,20 47:18	23:9 24:19	put 24:9 27:16 28:15 39:3 50:22	27:17 37:8
point 4:17 24:21 27:22 37:5,22	47:20,23,25,25	32:19 34:9 35:6	puts 27:25	40:21 41:5,11
42:23 43:7	48:1,8 49:1,4,5	37:3,7,8 38:25	p.m 53:22	42:21 52:3,15
45:13,22	49:8,11,11,19	39:7,9 41:5,12		52:16,16
points 37:23	49:22 52:8,14	41:17,18 42:22		rebuttal 2:12 19:13 51:16
policy 42:9	52:14,16,17,18	43:24 44:24		receive 24:23
poorest 50:3	52:20	46:20 48:11		received 35:23
population 8:19	prices 24:15 37:3 39:17	49:25 50:1		receiving 29:10
position 5:4 9:10 11:18,19,22	pricing 3:13 6:18 11:11,12 16:25	51:24 52:15,16		recognized 32:3 38:14 43:12 44:4
21:9,22,23	18:16 19:21	52:17	Q	reflecting 9:2
23:24 24:17	24:9 27:18	programs 8:14 11:13	question 21:12 21:19 22:5	reflects 7:14
29:6,11 32:12	36:15 39:9	promise 12:5,12 12:13	27:15 29:17	reform 10:21
32:20 40:4	52:17 53:1	promised 47:14	30:4,13 31:15	refusal 15:13
41:16 50:7	primary 6:25	promises 5:21 12:4	31:18 33:4,11	regime 14:17
possibility 50:13	prime 13:15	proof 35:22,24	47:24 48:1,17	regimes 27:16 27:16
potentially 26:18	principles 5:3 30:12 38:8	proposed 28:25 50:21	questions 51:11	regulated 20:7 23:17 24:10
power 5:6 39:3 43:9,14	42:10 45:18	prosecute 25:16	qui 16:13 48:17	regulation 5:20 9:21 23:6,8 42:5
PPA 19:24 25:12 29:18 36:13,18	private 3:20,25 7:16,17,18,22	Protection 10:5	quickly 45:11	regulations 20:11 23:19
practical 5:15	7:23 8:2,14 15:3,4 16:4,6,7 16:25 21:7	provide 20:10 27:24 28:4 35:6 36:15 39:16	quote 42:21	
		provided 45:23	R	

50:19	requirements	23:1,4,6 24:18	38:19 40:3	36:19 39:13
regulator 22:13	16:19 18:17	26:1,19 27:9	Saris's 41:22	46:14 49:25
regulatory 4:18	19:24 20:23	28:4 31:20,22	save 19:12	50:18,22,24
10:12 14:17	27:17,19 28:19	32:5 35:8,10,25	saved 18:9	52:4
20:1,21,24	requires 36:23	36:16 38:3 40:9	saying 4:11	Secretary's 7:8
21:20 22:6,11	resale 37:16,18	43:12 44:5,11	14:24 18:8 23:9	section 3:11
22:19 23:14	resolution 36:17	44:18 45:1,15	25:6 26:11	see 18:3
25:11 29:4,6	resort 43:4	45:17,24 46:16	33:15 35:10	seeks 4:8
42:3,6,9	resources 21:6	47:2,8 53:7,16	39:5,6	seen 19:9
Rehabilitation	respect 25:3	rights 7:4 14:15	says 4:19 11:20	sees 11:25
8:12	35:14	17:15,19 20:6	11:21 12:3	sell 4:20 49:9
Rehnquist 45:4	respectfully	23:20 29:9,19	13:16 19:6,7	sense 11:24
reimbursement	49:14	30:5,11,20,21	21:5 23:10	sensible 6:7,9
7:22 12:20,21	respond 46:8	30:23 33:6,12	25:14,19 26:20	11:4
reject 41:2	Respondent 1:22	33:25 35:17	26:21 37:10	sentence 36:22
rejected 42:7,11	2:11 3:18 6:3	36:20 37:13	40:13 42:14	seriously 23:23
relationship	13:9 29:25	38:12,13 41:10	52:23	served 8:19
24:22	Respondent's	41:11 45:5 51:8	Scalia 7:16 11:16	serves 8:22
relator 16:14	27:25	53:8	11:23 12:11	service 50:2
release 52:3	response 38:5	rise 20:6	18:19 19:1,4	services 20:10
rely 42:13	52:3	road 15:1	30:16,19 31:5	set 3:21 20:12
remainder 19:12	responsibilities	ROBERTS 3:3	31:14,18,24,25	22:9 31:6,10
remaining 51:15	12:18 25:1	7:24 8:8 15:21	33:2,3,9 42:12	32:2 40:21 41:8
remedial 51:5	responsibility	16:21 17:9	43:1,3,18 44:1	settled 5:9,25
remedies 5:18	25:14	19:14 20:3 23:5	Scalia's 33:11	settlements 13:9
9:8 10:13 11:3	Restatement	23:8 28:8 29:22	scarce 35:7	15:25
14:14 47:15	32:2 33:4 36:2	39:2,11,19,25	scheme 20:1,21	SG 41:7
remedy 4:8 7:18	rests 35:13	44:16 45:8 47:5	22:10,11 23:14	shalt 8:24 37:11
7:22 10:11,12	result 44:8 45:20	51:13 53:19	23:24 24:8,9	shocked 52:5
10:16 14:4,11	46:4 50:8	role 41:14,17,19	25:12 27:19,21	show 51:23
14:20,22 15:8	return 13:22	43:25	28:1 29:2,21	side's 52:8
27:24 28:10,11	20:12	route 21:20 46:5	search 51:23	sign 47:1,7
28:15 47:11,13	reverse 5:23	rule 5:9,24,25	second 6:11 38:2	signature 19:8
repeated 23:2	reversed 53:15	rulemaking	Secretary 3:13	signed 6:15 10:1
repeats 22:24	53:17	28:25 50:21	5:20 6:15 7:5,8	10:3 12:17 19:9
reply 37:24	review 15:12	rules 22:17 30:8	7:19 10:1 12:3	significant 16:9
reporting 18:16	reviewable 14:5	50:20,23,25	12:4,5,6,19,20	17:11
19:23 20:23	reviewed 22:15	run 13:6 44:25	13:20 14:1,1,9	signs 20:10
reports 28:13	Rhode 27:8,9	runs 19:11 31:12	14:15 15:16	silence 35:14
49:2	right 3:17,17 4:8		16:3 18:3,12,20	similar 20:7
represent 25:4	4:9,13 5:1,4 6:1		18:21,25 19:3,5	simple 48:7
representing	6:8,25 8:10		19:8 21:5,9,13	50:16 52:5
43:2	10:18,24 13:2		21:14,16 22:1,2	simply 20:24
republic 38:15	14:6 15:4 16:15		23:2 29:7,12	21:17 22:7 23:2
required 4:18	16:17 21:2 22:4		30:9,15 31:2,2	28:5 50:22

situation 8:3 27:3 29:6 42:17,19 42:20 47:6	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	23:24 24:8 29:20 41:19 50:18	supposed 12:24 13:1,13 24:15 27:18,21	29:22 30:1 51:13 53:19
small 13:7	25:17,18 26:10	strange 46:1	Supreme 1:1,12	theory 41:24 42:3,6,6
society 46:23	26:11,14,15	strikes 39:11	sure 7:25 37:22 40:9,24	thing 41:18
sole 20:20 49:18	27:3,16,16 37:8	stronger 45:2	Surety 43:11	things 14:16
solicited 29:1	40:12,19,24	students 15:3	surprise 32:12	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
Solicitor 1:17	52:15	subject 9:18	system 36:17	
solve 38:24	stated 51:4	subjective 32:22		
somebody 17:14	statement 16:20 36:1 50:20	submissions 49:7	T	
sorry 34:13 35:20 37:10	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	submit 30:17 49:15 51:2,12	T 2:1,1 table 41:25	
sort 5:15 7:3 9:16 9:22,23 20:16 21:21 27:2	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	submitted 53:21 53:23	take 16:13 21:8 22:5 28:19 50:7 51:21	
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	statutes 20:11 50:1	substantial 12:22 24:14	taken 23:25	
Southern 52:9	statutory 5:9,13 5:22 9:6,12 10:23 15:2 22:10,17 23:19	substantially 41:3	talk 51:18,20 53:13	
sovereign 43:20		subverted 17:21	talking 9:13 18:13 35:2 38:17 44:21 46:24 47:13,17 48:24 52:14	
sovereigns 43:21		sue 5:12,24 29:13 30:25 31:4,21,22 32:19 34:19 35:8 43:16 44:11	tam 16:13 48:17	
specific 5:20 43:7,14 44:14 51:5		suggest 42:4	tell 21:21 22:6,18 23:21 32:9	thinking 37:16
specifically 30:6		suggestion 51:22	telling 20:25 29:13	thinks 12:19
specifics 7:20		suing 46:9,10	tends 42:2	third 6:11 17:19 22:2 31:19,20 33:6,15
specified 4:1 31:16		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	term 4:4	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
specifies 36:17		suits 10:25 23:23 24:6,12 25:2,2 25:4,6,9 32:13 33:25 48:15 52:13	terminate 10:25 12:7 47:3	
specify 9:5		supporting 1:20 2:8 19:18	termination 12:10 47:3	thou 8:24 37:10
Spending 8:10 9:22 47:6		suppose 25:18 25:23	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	thought 21:23 28:11 31:25
spent 37:14			test 6:3,4,7	
spoke 5:11			tested 41:1	
standard 31:24 32:1 41:9			Texas 52:9	
standing 40:25			Thank 3:9 19:14	
stands 40:3 46:6				
start 27:13 30:3				
started 45:11				

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