

1 IN THE SUPREME COURT OF THE UNITED STATES

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3 PHARMACEUTICAL RESEARCH AND :

4 MANUFACTURERS OF AMERICA :

5 Petitioner :

6 v. : No. 01-188

7 KEVIN CONCANNON, COMMISSIONER, :

8 MAINE DEPARTMENT OF HUMAN :

9 SERVICES, ET AL. :

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11 Washington, D.C.

12 Wednesday, January 22, 2003

13 The above-entitled matter came on for oral
14 argument before the Supreme Court of the United States at
15 11:07 a.m.

16 APPEARANCES:

17 CARTER G. PHILLIPS, ESQ., Washington, D.C.; on behalf of
18 the Petitioner.

19 EDWIN S. KNEEDLER, ESQ., Deputy Solicitor General,
20 Department of Justice, Washington, D.C.; on behalf of
21 the United States, as amicus curiae.

22 ANDREW S. HAGLER, ESQ., Assistant Attorney General,
23 Augusta, Maine; on behalf of the Respondents.

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

2 (11:07 a.m.)

3 CHIEF JUSTICE REHNQUIST: We'll hear argument
4 next in Number 01-188, The Pharmaceutical Research and
5 Manufacturers of America v. Kevin Concannon, et al.

6 Mr. Phillips.

7 ORAL ARGUMENT OF CARTER G. PHILLIPS

8 ON BEHALF OF PETITIONER

9 MR. PHILLIPS: Thank you, Mr. Chief Justice, and
10 may it please the Court:

11 Under 42 U.S.C. section 1396a, in subsection
12 (a)(19), which is found on page 244 of the joint appendix,
13 Congress made absolutely clear, as a singular precondition
14 of all Medicaid plans, that they must assure that care and
15 services will be provided in a manner consistent with
16 simplicity of administration and the best interests of the
17 recipients. This statute does not allow Maine to use
18 Medicaid recipients as pawns in its effort to reduce
19 health care costs for those individuals who are not
20 eligible for Medicaid.

21 QUESTION: Was this statute -- was the statute
22 discussed in the First Circuit opinion?

23 MR. PHILLIPS: The Medicaid statute?

24 QUESTION: The -- the provision you just read.

25 MR. PHILLIPS: Oh, absolutely, Mr. Chief

1 Justice.

2 QUESTION: Mr. Phillips, that -- that provision
3 is -- is in the portion of the statute dealing with the
4 approval of the State plan, a State plan has to have that
5 consequence. It has to serve the interest of the Medicaid
6 recipients.

7 MR. PHILLIPS: That's true, Justice Scalia.

8 QUESTION: It doesn't say that each -- each --
9 each feature enacted by a State has to be judged
10 individually under that standard. It seems to me, why
11 isn't it the case that if -- if a State adopts some
12 provision which does not comply with that provision, its
13 plan is no longer a conforming plan, and the Secretary has
14 explicit authority under the statute to -- to repeal the
15 Secretary's prior approval of the plan. Why isn't that
16 the way this thing should work?

17 MR. PHILLIPS: Well, the way this operates is
18 that this is not adopted as a part of the State's plan
19 that's subjected to review by the Secretary of HHS. What
20 this is, is a completely separate program that's been
21 adopted independently, and all it does is reach out and
22 hold the recipients of Medicaid as hostages in order to
23 extract money from out-of-state manufacturers --

24 QUESTION: Yes, but do you --

25 MR. PHILLIPS: -- but it's not a part of the

1 plan.

2 QUESTION: -- but is it -- is it the case, if we
3 were to, let's suppose, affirm here, that the Health &
4 Human Services head could nonetheless call a halt to it
5 and say, you no longer conform with our understanding of
6 what's required, you're holding hostage our Medicaid
7 recipients and it's having a negative effect on them
8 because of the prior approval requirements of drugs that
9 otherwise wouldn't be required? Is -- would -- would the
10 Secretary have that power?

11 MR. PHILLIPS: I believe the Secretary might
12 have that power, although I would ask you to ask
13 Mr. Kneedler when -- when he's arguing.

14 QUESTION: Well, I probably will.

15 (Laughter.)

16 MR. PHILLIPS: But over and above that, that
17 doesn't -- but that's not an exclusive remedy, that's all.

18 QUESTION: But how can the authorization
19 provision and the requirements attached to the
20 authorization provision, how can that conceivably not be
21 part of the State plan, as you say? I mean, it seems to
22 me it's central to the --

23 MR. PHILLIPS: Well, I mean --

24 QUESTION: -- there's an authorization --

25 MR. PHILLIPS: -- there's a -- there's a

1 formalistic way of looking at it, which is that they have
2 a State plan, and this is not incorporated as part of the
3 State plan. What this has been -- what has been done here
4 is to adopt a completely separate program which simply
5 reaches out, as I said before, and seeks to hold hostage
6 certain elements of it.

7 QUESTION: But if you take that position, the
8 State plan could be rendered meaningless. I mean, the
9 State plan simply becomes a kind of formal Open Sesame.

10 The -- there's got to be power to look, as
11 Justice Scalia suggests, or the State plan means nothing.

12 MR. PHILLIPS: Well, no, there has to be a State
13 plan. The question is whether or not (a)(19) reflects
14 congressional intent that the State has to act in a
15 particular way. If it acts contrary to that way, the only
16 question then is, are there multiple remedies available to
17 respond to it?

18 I think, Justice O'Connor, the answer to your
19 question is yes. I think the Secretary does have that
20 authority to go forward, although I would ask
21 Mr. Kneedler --

22 QUESTION: Can I ask this question: Could the
23 State, if it just -- without adopting a Maine Rx program,
24 just decide, we want to take a good, hard look at every
25 sale of drugs that comes into our State, so we're going to

1 subject every drug manufacturer to prior approval pursuant
2 to 1396r-8(d), could they do that?

3 MR. PHILLIPS: I -- there's an open question as
4 to whether they could do that. Certainly, if you take the
5 most expansive reading of 1396r-8(d) you could make that
6 argument. The alternative argument would be to what
7 extent that that violates or interferes with the formulary
8 formulations that are embedded in the statute.

9 QUESTION: But if they do have that authority,
10 and you say that's an open question, doesn't it follow, a
11 fortiori, that they can do what they're doing here?

12 MR. PHILLIPS: No, it doesn't follow a fortiori,
13 because what they're doing here is imposing the prior
14 authorization with respect to, you know, to serve purposes
15 that are completely unrelated to the Medicaid program.

16 QUESTION: Well, maybe my hypothetical was
17 completely unrelated. They just want to be sure you can
18 open the caps on the drug containers, or whatever it might
19 be, some idiocentric -- I don't think that the -- as I
20 read it, I don't see anything in that provision that says
21 it must serve a Medicaid purpose.

22 MR. PHILLIPS: Well, I think you'd have to read
23 that provision in the context of the entirety of the
24 provision providing for coverage of drugs, and I think you
25 have to do it in that context, and I think there are

1 broader issues there, but the singular problem here,
2 obviously, is that if you interpret the statute as broadly
3 as the State of Maine does to say that we can impose prior
4 authorization requirements, then what they can say is, we
5 want to extract money from manufacturers solely for the
6 purpose of building schools or roads or anything else that
7 we want to, and there's no restriction on that, and it
8 seems to me that if what you're saying is you want to have
9 prior authorization as a mechanism to deal within
10 Medicaid, to provide generally for a balance of interest
11 between Medicaid recipients, that's one thing.

12 But what -- what -- what Maine is doing is using
13 Medicaid recipients to further completely unrelated
14 purposes of the State, then it seems to me what you've
15 done is essentially ask the Federal Government to
16 subsidize a program that -- that's not an appropriate one
17 to subsidize.

18 QUESTION: Okay, what about the halfway measure,
19 and the halfway measure has been described by the
20 Government as -- as some instances of prior approval that,
21 that it would authorize that go beyond what the -- the --
22 the -- the very strict enforcement of Medicaid in a
23 limited sense would require. Do you think what the
24 Government has -- excuse me. Do you think what the
25 Government has suggested is also beyond the authorization

1 of the statute?

2 MR. PHILLIPS: I think it is. I think the
3 better way to read the statute is to recognize that this
4 is designed to benefit Medicaid recipients, and the
5 problem is, once you get past programs that are designed
6 to benefit recipients themselves, it's very difficult to
7 see where you draw the line after that in terms of where
8 it goes.

9 QUESTION: Well, is it correct that the
10 Secretary has approved a few plans in other States that do
11 go beyond, technically, the direct Medicaid recipients,
12 for instance, the people who are very close to the line
13 and might well become eligible soon?

14 MR. PHILLIPS: Justice O'Connor, that is
15 correct. They have approved those programs.

16 QUESTION: Yes.

17 MR. PHILLIPS: Those programs are in litigation
18 as we stand here --

19 QUESTION: Uh-huh.

20 MR. PHILLIPS: -- as I stand here today, and --

21 QUESTION: Is that possible -- I mean, as I'm
22 seeing this at the moment, if the State uses the
23 authorization program for any purpose at all, we know that
24 some -- that some Medicaid recipients will be hurt.

25 MR. PHILLIPS: Yes.

1 QUESTION: If a Medicaid recipient walks into a
2 drugstore and asks for drug X, that recipient can get it
3 more easily if it's not on this prior approval list than
4 if it is, and that being so, it must be impermissible
5 under Federal law, unless the object of the program
6 achieves a Medicaid-related purpose, so the question in
7 front of us is, does it?

8 Now, what's bothering me about that is that the
9 Secretary thinks some programs like Maine's are okay, and
10 others maybe not.

11 MR. PHILLIPS: Well --

12 QUESTION: So in my mind the words, primary
13 jurisdiction, suddenly flash red. How can I decide this
14 case without knowing what the Secretary thinks, and how
15 can -- I mean, after all, if the Secretary says this one
16 is okay, that would have a big leg up under Chevron, and
17 if the Secretary says no, it wouldn't, so why isn't the
18 correct principle primary jurisdiction, which we can apply
19 whether the parties like it or not, and why isn't the
20 correct result here to send it back to the district court
21 and say, district court, Maine cannot put this into effect
22 until they ask the Secretary about it?

23 MR. PHILLIPS: Well, I don't have any particular
24 problem with sending it back to the district court
25 enjoined subject to approval by the Secretary of HHS, I

1 mean, if that's the way the Court wanted to resolve this
2 case.

3 QUESTION: Well, I'm really -- that's not what I
4 want. I want to have --

5 QUESTION: Is that the way primary jurisdiction
6 works? I thought there has to be in place some mechanism
7 for getting the agency to pass upon the question, a
8 mechanism that the person who is dismissed from Federal
9 court is entitled to use, and I'm not sure that exists
10 here.

11 MR. PHILLIPS: I don't know, Justice Scalia,
12 that you need to be dismissing it from Federal court. I
13 think it's quite possible for the --

14 QUESTION: Well, even if you sit on it until
15 it's done --

16 MR. PHILLIPS: Right, stay your hand pending --

17 QUESTION: -- you still have to assure that
18 there's some -- some mechanism. I mean, all the primary
19 jurisdiction cases I know of, there -- there was a means
20 to file a case before the agency.

21 MR. PHILLIPS: Well, I don't disagree with that,
22 Justice Scalia.

23 QUESTION: Well, I disagree with it, so we'll
24 have to work it out.

25 QUESTION: You can't just send them off and say,

1 you know, ask the Secretary, by the way, and have the
2 Secretary write us a letter. I don't know that we've ever
3 done that.

4 MR. PHILLIPS: Well, I'm not sure that there
5 isn't a mechanism for asking the -- to petition the
6 Secretary for review. I think if Maine wanted to get
7 approval of this particular program, it certainly had it
8 available to do that. It didn't seek that particular
9 course.

10 And Justice Breyer, I think it's important, in
11 the context of trying to figure out primary jurisdiction,
12 we know the views of the United States with respect to
13 this particular program. There may be other programs, as
14 Justice O'Connor identified, that come close to the line
15 where the Secretary would have a different view, and I
16 think it's appropriate in --

17 QUESTION: Is their views the Secretary's view?

18 QUESTION: That's what I --

19 QUESTION: I'll -- fine, I'll ask them.

20 MR. PHILLIPS: I believe it is the Secretary's
21 view, but --

22 QUESTION: Mr. Phillips, as I understand your
23 position, so long as it benefits Medicaid recipients, any
24 -- any authorization scheme is okay? I mean, a State can
25 say, we'll authorize your drug if you pay \$5 to each

1 Medicaid recipient?

2 MR. PHILLIPS: That is not my position. My
3 basic position is that the Court doesn't need to figure
4 out precisely what prior authorizations are permissible in
5 order to decide this case, because the one thing that
6 should be absolutely clear is, you cannot use this
7 mechanism in a Federal program in order to disadvantage
8 the primary recipients of that program without serving any
9 Medicaid, sort of, related purpose.

10 QUESTION: You -- you -- you may be up in a --
11 in a later case arguing that the -- that the reasonable
12 reading of the authorization requirement is -- is to
13 assure the safety of the drug, or the necessity of the
14 drug for the particular illness?

15 MR. PHILLIPS: That -- that's absolutely
16 correct, Justice Scalia. We'd -- we -- I mean, I think we
17 would take that position, and that we -- that you cannot
18 read (d)(1) completely in isolation, and -- and to the
19 fullest extent of the language of that, without regard to
20 the rest of the provisions of (d)(1) through (d)(6), and
21 you -- and for sure, you cannot read them without regard
22 to the more fundamental requirement in subsection (a) and
23 (a)(19), that the primary consideration must be the
24 beneficiaries of this program.

25 They are the most needy people in our country,

1 and the notion that you use them as a mechanism for trying
2 to simply lower health care costs for the Steven Kings of
3 the world strikes me as -- as an outrageous position for
4 the State of Maine to take.

5 QUESTION: No, but they may not be doing that.
6 They may think that the object of this is to lower the
7 health care costs for the moderately poor not yet on
8 Medicaid, and thereby prevent people from falling into the
9 Medicaid category.

10 MR. PHILLIPS: Justice Breyer, that would be a
11 persuasive argument if this statute had any kind of a
12 tailoring mechanism to it whatsoever. It is open to all
13 residents who are otherwise not covered by --

14 QUESTION: Maine says those are never caught --

15 QUESTION: Administrative regulations, one of
16 the things that Maine said was, you've stopped us at the
17 threshold. We could have regulations that say, for
18 example, people who are covered by insurance will not have
19 access to this benefit, but on the question -- you said
20 would -- you would be content if the Court said, the
21 Secretary has to look at it, until then it's no good.

22 Would you have -- this is the -- your lawsuit.
23 Could you have gone to the Secretary and say, said,
24 Secretary, we want you to look at this, the Secretary
25 says, I'm busy with a dozen other things and I don't want

1 to look at it?

2 MR. PHILLIPS: I don't know of any statutory
3 mechanism for a third party to come in and ask the
4 Secretary to review a State plan. I don't know that -- I
5 don't know that there's anything that prevents anyone from
6 sending a letter to the Secretary to ask him to take, to
7 undertake that. That said, the Secretary obviously knows
8 about this particular scheme.

9 QUESTION: Yes, and the Secretary, you said that
10 the -- at least the SG supports your view that this --
11 that this program of Maine's is impermissible, but the SG
12 also told us, essentially, that this case wasn't ripe, so
13 we shouldn't have granted cert. I mean, that was the SG's
14 first position, that this is a -- we don't know what, in
15 fact, the Maine scheme is, because it was never -- it
16 never went into effect, because you got an injunction.

17 MR. PHILLIPS: But the one thing that we
18 absolutely know about the Maine scheme, and it -- Justice
19 Breyer described it, is that every Medicaid recipient is
20 placed at risk by the prior authorization scheme.

21 QUESTION: Yes, but Mr. Phillips, are there any
22 findings that any Medicaid recipient has actually been
23 harmed by this program? I -- this is a --

24 MR. PHILLIPS: Well, because there was a
25 joinder --

1 QUESTION: -- one of the things that bothers me,
2 I don't know that we have any findings by the district
3 court as to what the real impact will be. I know your --
4 your -- the Government says this is going to happen --

5 MR. PHILLIPS: Well, if --

6 QUESTION: -- but if everybody agreed, for
7 example, to join the Maine program, maybe it may work out
8 fine.

9 MR. PHILLIPS: The -- I don't have to go to the
10 United States. The State of Maine concedes in its brief
11 at page 25, Maine Rx can be expected to trigger prior
12 authorization more often than previously.

13 QUESTION: Yes, but it may well be that prior
14 authorization would, in turn, lead to some solution
15 between the drug companies and the State as to how this
16 will all be handled. I don't think the fact they agreed
17 that it would trigger prior authorization necessarily
18 proves the conclusion that the Medicaid recipients will be
19 harmed. It may well be true, but I'm just not sure --

20 MR. PHILLIPS: Well, but --

21 QUESTION: -- the record supports that --

22 MR. PHILLIPS: Well --

23 QUESTION: -- as of this stage of the case.

24 MR. PHILLIPS: Well, but there'd be no way to
25 enjoin the program before going into effect, which means

1 that you essentially have to wait until actual Medicaid
2 recipients are deprived of drugs in order to be able to
3 implement -- to stop a program that on its face does
4 nothing to benefit Medicaid beneficiaries, and clearly
5 poses a serious threat to them.

6 I -- if we go back to *Hines v. Davidowitz*
7 language, it talks about the full achievement of Congress'
8 objectives.

9 QUESTION: But it only opposes the very threat
10 that the statute by its own terms authorizes. That's the
11 threat.

12 MR. PHILLIPS: Well, but it only authorizes --

13 QUESTION: The threat of prior approval which
14 the statute authorizes.

15 MR. PHILLIPS: Sure. It -- to serve Medicaid-
16 related purposes.

17 QUESTION: But the statute doesn't say that.

18 MR. PHILLIPS: I -- I understand that, Justice
19 Stevens, but the point is that if you read the statute,
20 and it's essentially six, those six words, to say that the
21 State has unlimited authority to do that, it strikes me as
22 inconceivable that Congress would have allowed this entire
23 mechanism to be available for the State to come in and
24 simply to raise revenue from out-of-State manufacturers.
25 There is no rational basis for that kind of a conclusion.

1 The much more sensible way to narrow the statute
2 is to say, if it serves other Medicaid purposes, then
3 that's an appropriate way to proceed. If it doesn't, then
4 it seems to me the -- the Court has to conclude that the
5 best interests of the beneficiaries ultimately has to
6 trump here under these circumstances.

7 QUESTION: Mr. Phillips, do you also rely on the
8 Commerce Clause as somehow prohibiting what Maine has
9 done --

10 MR. PHILLIPS: I --

11 QUESTION: -- and if so, how do you make that
12 argument?

13 MR. PHILLIPS: Well, Justice O'Connor, we have
14 three components to that argument. The thing that is -- I
15 concede at the outset that there is no case at this Court
16 that directly controls in either direction. This is a
17 unique scheme that's been adopted here, and -- and --

18 QUESTION: Is there anything in the Commerce
19 Clause that prevents a State from addressing within its
20 State boundaries requirements for dispensing prescription
21 drugs?

22 MR. PHILLIPS: Well, when the entire burden of
23 the program falls out of State, it seems to us that this
24 creates at least a serious question about what's going on
25 here. The --

1 QUESTION: Well, any State regulation, a State
2 wants to have a special rule for a bicycle, you could say,
3 well, that increases the cost to the manufacturer and the
4 other States have to pay for it, so I'm -- I'm not sure
5 that that reasoning, which was in your brief, carries the
6 day.

7 MR. PHILLIPS: Well, I --

8 QUESTION: Like a special fuel requirement for
9 automobiles? Do you think California can set certain
10 standards, that of course it affects the auto
11 manufacturers? They don't make them in California.

12 MR. PHILLIPS: Yes. There's no question that
13 States are free to create certain types of regulations
14 that are different from other States, and that's -- and
15 that's not the full sweep of the argument that we're
16 making here. What -- what --

17 QUESTION: That's not what happened here.

18 MR. PHILLIPS: No, that's --

19 QUESTION: I don't understand the Commerce
20 Clause argument.

21 MR. PHILLIPS: I wouldn't presume to try to
22 teach you about the Commerce Clause, Justice O'Connor, but
23 the reality of what's happening here is much more like the
24 West Lynn Creamery case, where what you're talking about
25 is the payment of a subsidy, all by out-of-state entities,

1 in order to benefit -- in that case it was to benefit in-
2 state competitors. There are no in-state competitors in
3 this case.

4 QUESTION: Oh, I've got quite --

5 QUESTION: Isn't that a --

6 QUESTION: -- a problem with the argument.

7 QUESTION: That was the problem.

8 MR. PHILLIPS: I'm sorry.

9 QUESTION: I'm sorry.

10 MR. PHILLIPS: I didn't hear --

11 QUESTION: Well -- no, let me yield to Justice
12 Kennedy.

13 QUESTION: I had thought you might make the
14 argument -- I didn't see it in your brief, maybe I missed
15 it -- that this is just so burdensome on manufacturers to
16 go from State to State to State that it's just an -- it's
17 an undue burden on an interstate transaction, period.

18 MR. PHILLIPS: Under Pike v. Bruce Church.

19 QUESTION: And -- and Southern Pacific v.
20 Arizona.

21 MR. PHILLIPS: Yeah. The reason we didn't raise
22 that argument is that we thought that we would require --
23 in order to make that argument we would require more
24 factual findings by the district court --

25 QUESTION: Right.

1 MR. PHILLIPS: -- in order to get into it,
2 because there's a balancing component to that --

3 QUESTION: The other thing I wondered about is,
4 if you've come over from Vermont or New York you can't
5 have the advantage of this. I suppose it's not
6 necessarily in your interest to argue that it has to be
7 expanded to other States, but I -- it seems to me that
8 also was a questionable part of the program.

9 MR. PHILLIPS: Well, I do think one of the real
10 problems with this program is that some States will adopt
11 this kind of a scheme and other States won't adopt this
12 kind of a scheme, which means that you're going to have
13 inherent discrimination with respect to consumers. Some
14 consumers will benefit to the detriment of other
15 consumers, and it does seem to me that -- that the theory
16 of West Lynn Creamery was designed to say that you don't
17 just look at the competitors and the relationships between
18 them, you have to look more broadly at the manufacturers,
19 the wholesalers, all the retailers, and all the way down
20 to the consumers, and if you have the kind of
21 discriminatory effects here where Maine seizes for itself
22 all the economic benefits and imposes on -- on everyone
23 else the economic burdens, that in that circumstance this
24 runs afoul of the core --

25 QUESTION: The -- wasn't this --

1 MR. PHILLIPS: -- command of the Commerce
2 Clause.

3 QUESTION: -- one of the reasons the First
4 Circuit vacated the injunction, the fact that there just
5 hadn't been any factual development here as to what was
6 happening?

7 MR. PHILLIPS: Well, that was part -- yes, to be
8 sure, Mr. Chief Justice, that's part of what they said.
9 On the other hand, if you accept our basic theory about
10 the clear discriminatory implication of the way the scheme
11 operates, that kind of an operation is per se invalid.
12 That's what the Court held in -- in West Lynn Creamery.

13 QUESTION: But isn't the West Lynn Creamery
14 difficulty in your argument that here, unlike West Lynn,
15 there are no entities within the same category,
16 manufacturers, e.g., producers, for example, some of whom
17 are being discriminated in favor of others? What's going
18 on here is not discrimination by the State within a given
19 class to benefit the members of the class within the
20 State. What is going on here is a scheme which happens to
21 fall on certain individuals in a manufacturing class who,
22 incidentally, are out of State, for the benefit of people
23 in a different class, that is, the consumers, who are in-
24 State, and West Lynn doesn't govern that.

25 MR. PHILLIPS: No, it doesn't directly cover

1 that, and I conceded that at the outset.

2 On the other hand, the point here is that there
3 are entities out there in the stream that are within
4 Maine, and on whom this burden is not imposed. It was
5 chosen to impose the burden strictly on the manufacturers,
6 and it is done in a way that will create disparate impacts
7 with respect to consumers in Maine versus consumers in
8 other -- in other States, but --

9 QUESTION: That is -- I mean, that's a -- that's
10 a necessary consequence of the prior approval scheme.
11 That -- you're going to have that argument no -- no matter
12 how -- no matter how prior approval --

13 MR. PHILLIPS: Well, and -- and if it operates
14 within Medicaid, it seems to me that there's no -- there's
15 no significant argument to be made there, because Congress
16 has basically taken it over.

17 QUESTION: Simply because you've got to have it.

18 MR. PHILLIPS: But otherwise -- and one last
19 point I'd like to make, which is simply that the Commerce
20 Clause issue does not need to be addressed in the event
21 the Court holds that the, that the Maine statute is
22 preempted.

23 If -- I'd like to reserve the balance of my
24 time.

25 QUESTION: Very well, Mr. Phillips.

1 Mr. Kneedler.

2 ORAL ARGUMENT OF EDWIN S. KNEEDLER

3 ON BEHALF OF THE UNITED STATES, AS AMICUS CURIAE

4 MR. KNEEDLER: Mr. Chief Justice, and may it
5 please the Court:

6 The Department of Health & Human Services has
7 articulated a position on two issues that are directly
8 relevant to this case, and those positions are set forth
9 in the letter to the State Medicaid directors that is set
10 forth in an appendix to our brief at page, I believe it's
11 page 45a it begins. The first of those --

12 QUESTION: Well, does that lead to a conclusion
13 as to its view as to this program that we're considering?
14 Is it valid, or isn't it?

15 MR. KNEEDLER: If I could -- there are two
16 problems --

17 QUESTION: As far as the Secretary is concerned.

18 MR. KNEEDLER: There are two problems with
19 the -- with the State program under this Medicaid
20 director's letter that the Secretary sent out. The first
21 is that it's the position of the department that a plan
22 such as this, which imposes a prior approval requirement
23 for Medicaid patients, if the drug manufacturer does not
24 pay rebates with respect to sales to non-Medicaid
25 patients, that sort of change is a material change in the

1 State's plan which requires the approval of a plan
2 amendment.

3 There is a regulation that we cite in our brief
4 at page 28, and quote, that requires that, and that, by
5 the way, I think could be the -- the mechanism effectively
6 for a prior jurisdiction sort of approach.

7 QUESTION: I see that, but I -- I mean, I'm a
8 little bit at sea. I absolutely wouldn't call it primary
9 jurisdiction. The label doesn't matter, but the -- the --
10 but -- now, where I'm -- where I'm -- where I'm at sea is
11 in figuring out whether it's possible to say, and you
12 don't say this in your brief, that -- that a program like
13 Maine's, which is arguably, arguably wrong, or arguably
14 right, that it can't go into effect without the prior
15 approval of HHS. Now, that's going to require me to look
16 up the approval statutes, a whole lot of things that
17 weren't briefed.

18 MR. KNEEDLER: Well, it's -- the -- the -- we
19 have cited this regulation in our brief, and the -- and
20 under Allens v. Robbins the Secretary's, or the -- the
21 Secretary's interpretation's set forth in the brief. It's
22 also set forth in the Medicaid director's letter.

23 QUESTION: After the Secretary acted under it,
24 then. What are you bothering us for? If the Secretary
25 has power under this -- under this regulation to stop this

1 plan from going forward because it amounts to an amendment
2 of the -- of the plan, and an amendment that hasn't been
3 approved, the -- the Secretary has the power to stop it.
4 Why -- you know, why --

5 MR. KNEEDLER: Well --

6 QUESTION: -- do we have to get involved?

7 MR. KNEEDLER: Well, if I could just answer that
8 and then move to the second question, because I think it's
9 related, the regulation identifies what -- that material
10 changes in the plan have to be submitted for an amendment.
11 The Secretary's enforcement authority comes from a
12 different source, which is in 42 U.S.C. 1396c, which
13 allows the Secretary to cut off funds in whole or in part
14 if a State is operating under a plan that requires an
15 amendment because of those changes, so -- but I --

16 QUESTION: Well then, why doesn't the Secretary
17 do it?

18 MR. KNEEDLER: I think it was -- it's entirely
19 reasonable -- first of all, that's a matter of enforcement
20 discretion under Heckler v. Cheney, and at least for the
21 time being, why this -- while this case is under -- is
22 under submission, the Secretary has not -- has not
23 proceeded.

24 QUESTION: Well, but I think the Secretary is
25 ignoring one serious problem, and I suspect it's behind

1 Justice Scalia's question. It's certainly in my mind.
2 It's one thing for the Secretary to act within enforcement
3 power. It's one thing for the Secretary to interpret the
4 regs by, the statute by regulations that are subject to
5 Chevron deference, but if the Secretary does neither one
6 of those things, and from one side of the Secretary's
7 mouth we hear, well, yes, some prior approval beyond what
8 is strictly necessary for the direct benefit of Medicaid
9 recipients is okay, but this goes a little bit too far,
10 courts are then placed in the position of saying, well,
11 can we read the statute so precisely as to say that the
12 Secretary's position of what is okay is okay and, by going
13 this step further, there's a violation of the statute?

14 We are placed in a very difficult position, in
15 effect by the Secretary, by you, in being asked to draw a
16 line with a very fine pencil, whereas if the Secretary
17 wants to act under administrative authority, presumably
18 that's the end of it.

19 MR. KNEEDLER: Well, in going forward, I mean,
20 the Secretary issued this Medicaid director's letter in
21 September, after the Court had granted review --

22 QUESTION: Ah.

23 MR. KNEEDLER: -- because this was an area that
24 required attention. Going forward, we -- we expect
25 that -- that States will submit their proposals to the

1 Secretary as plan amendments --

2 QUESTION: Well, is there some --

3 QUESTION: And --

4 QUESTION: Is there some mechanism by -- or
5 authority by which we could somehow refer this back to the
6 district court to seek some kind of information from the
7 Secretary?

8 MR. KNEEDLER: Well, here's the way I think that
9 it could proceed.

10 QUESTION: How -- how could we do it? I don't
11 know of a doctrine but --

12 MR. KNEEDLER: I -- I think the procedural
13 posture of this case would allow that, and let me explain
14 why. The Secretary's second position in this case, which
15 I wanted to also make sure I articulated, which was that
16 a -- that a proposed, or a plan such as this, which
17 provides for rebates for non-Medicaid patients, still must
18 serve some Medicaid purpose.

19 In the district court, when the district court
20 entered what is only a preliminary injunction at this
21 stage, at page 71 of the petition appendix, the district
22 court pointed out that the State had not argued that its
23 proposal served any Medicaid purpose. As the preliminary
24 injunction was entered, it was entered on that premise.
25 The court of appeals then speculated that perhaps it does

1 serve a Medicaid purpose, but looking back at when the
2 preliminary injunction was entered, it was entered on the
3 premise that it served none, and we think, and the
4 Secretary believes that a plan must at least serve some
5 Medicaid purpose.

6 QUESTION: But as I understand it, Mr. Kneedler,
7 it is -- it is at least theoretically possible that the
8 Secretary could approve this very plan.

9 MR. KNEEDLER: If -- on the proper showing. The
10 rationale --

11 QUESTION: Right, of course. It needs more
12 facts.

13 MR. KNEEDLER: Yes. The rationale adopted by
14 the district court was the rationale that some --

15 QUESTION: Yes. It may have now advanced a
16 Medicaid-related purpose that may or may not be
17 sufficient.

18 MR. KNEEDLER: That's -- but we believe that the
19 purpose that has been advanced does not save this statute.
20 The purpose that has been advanced and was identified by
21 the court of appeals was a purpose that some people who
22 were close to being Medicaid-eligible will be forced to
23 spend more on drugs, may become Medicaid-eligible, and
24 therefore cost the Medicaid program more money. That's a
25 Medicaid-related purpose. The problem is, the State

1 statute is not tailored to people who are close to the
2 poverty line.

3 QUESTION: So is the procedure --

4 QUESTION: Would you -- would you finish your
5 response to me --

6 MR. KNEEDLER: Yes. What --

7 QUESTION: -- to tell me --

8 MR. KNEEDLER: Yes.

9 QUESTION: -- what it is that you think we could
10 do?

11 MR. KNEEDLER: If the Court reversed the court
12 of appeals decision, in effect affirmed the district
13 court's injunction, which was entered on the basis that
14 the plan serves no Medicaid-related purpose, the State
15 program would be enjoined.

16 At that point the State of Maine could submit
17 the program to the Secretary of Health & Human Services
18 along with any justifications for the plan, such as
19 those -- there are two additional ones that have been
20 raised in its brief in this Court for the first time, and
21 we think that's how it should play out.

22 This is a -- right now, the case presents a very
23 narrow issue on a preliminary injunction.

24 QUESTION: Why couldn't that procedure be
25 followed by affirming, and saying there should be a

1 hearing in the district court on these very issues that
2 you're raising, and both sides would present the facts?

3 MR. KNEEDLER: We don't think it would be a
4 hearing in the district court. We believe it should be
5 submitted to the Secretary, because a plan amendment is
6 required, but we do believe that -- that the petitioner
7 has made a sufficient showing based on the, on what the
8 district court said, that this plan, that Maine had
9 offered no justification, no Medicaid justification for
10 the plan.

11 QUESTION: Do you read the statutory
12 authorization for prior approval to mean prior approval
13 only if there's a Medicaid-related benefit?

14 MR. KNEEDLER: We -- we do. The legislative
15 history of the prior approval position --

16 QUESTION: You rely entirely on legislative
17 history for that?

18 MR. KNEEDLER: No, and also there are two other
19 provisions of the act which we think are relevant, on the
20 one hand, a(19), which talks about the best interests of
21 the patients, but on the other hand, a(30) -- this is
22 1396a(30)(A), which says that a State plan must provide
23 for methods of payment that advance efficiency and economy
24 in the Medicaid program.

25 We think both of those speak to interests within

1 the Medicaid program and require in the prior approval
2 process, as well as in the administration of the plan
3 generally, weighing the interests of the Medicaid
4 beneficiaries against the broader institutional interests
5 of the Medicaid program. If there was no Medicaid-related
6 purpose requirement at all, then a State could impose a
7 prior approval requirement if the drug company contributes
8 money to the art museum or to the State highway program.
9 We think that under this Court's decision in *Dublino*, the
10 State must be pursuing a purpose in common with the
11 Federal Government, a Medicaid-related purpose. What --
12 what the scope --

13 QUESTION: Mr. Kneedler, it -- it was the
14 Government's first position that this Court ought to let
15 the case ripen, and now you -- you are necessarily taking
16 a position in this lawsuit because we granted cert, but
17 the Government made a pretty good argument essentially
18 that this case wasn't ripe.

19 MR. KNEEDLER: Well, ripe for this Court's
20 review, but we now -- we now believe that, given that the
21 director's letter that was sent out in September, that
22 there is a basis, there's an articulation of the
23 Secretary's position both on plan amendments and the
24 requirement of a Medicaid-related purpose that -- that
25 this Court could properly dispose of the case in the

1 narrow -- in the narrow way I suggested which, of course,
2 would also obviate any requirement to consider the
3 Commerce Clause question.

4 Things have evolved in the Secretary's
5 evaluation of this and, as Justice O'Connor, I think
6 pointed out, the Secretary has since approved a Michigan
7 plan amendment under this same general approach.

8 QUESTION: Thank you, Mr. Kneedler.

9 Mr. Hagler, we'll hear from you.

10 ORAL ARGUMENT OF ANDREW S. HAGLER

11 ON BEHALF OF THE RESPONDENTS

12 MR. HAGLER: Mr. Chief Justice and may it please
13 the Court:

14 People without insurance are charged more for
15 prescription drugs than any other purchaser in the market,
16 often much more. Patients who are forced to pay cash at
17 the pharmacy are those least able to absorb these high
18 prices. To ameliorate this hardship, Maine's legislature
19 will embrace a market-based approach used by other large
20 third party purchasers to leverage its purchasing power
21 under -- as a third party purchaser in Medicaid to obtain
22 price relief for the uninsured in Maine.

23 QUESTION: And you think that's one of the valid
24 uses of the authorization provision? You think that's why
25 it was included in the statute, so that a State could --

1 could shake down drug companies to lower prices to other
2 people?

3 MR. HAGLER: I concede that -- that Congress
4 never thought that Maine might use prior authorization in
5 the way that Maine Rx anticipates it. However, what
6 Congress said --

7 QUESTION: You can use it for anything at all?
8 Could -- could you use it to -- to say, we -- you know,
9 you -- you have to pay each member of the Maine
10 legislature \$100 a year? Could -- could you put that in
11 there?

12 MR. HAGLER: As you get further and further for
13 the purposes of -- of providing health care, you approach
14 uses a -- of prior authorization that might offend
15 Congress and this Court, but preemption is a question for
16 Congress.

17 QUESTION: Well, did Maine offer in the district
18 court, in the hearings on whether a preliminary injunction
19 should issue, a justification for how the Maine Rx program
20 benefits Medicaid patients?

21 MR. HAGLER: We did not so argue in the district
22 court.

23 QUESTION: Okay.

24 QUESTION: When you say -- who does it apply to?
25 That is, the statute says it applies to qualified

1 residents. They define that as people with a Maine Rx
2 enrollment card, and now I don't know who those people
3 are. Is it virtually everybody in the State? Is it a
4 small subclass, those who don't have insurance? Who is
5 it?

6 MR. HAGLER: Well, it's -- it's those without
7 insurance.

8 QUESTION: So that's a fairly small group. What
9 percentage of that -- it's 15 percent of the people of
10 Maine?

11 MR. HAGLER: If -- we estimate 22 percent. The
12 AARP had a different --

13 QUESTION: Okay, so 15, 22 percent. Now, if
14 that being so, it sounds to me like it could be like the
15 one that was approved, or maybe it's not like the one that
16 was approved.

17 MR. HAGLER: And you don't know --

18 QUESTION: It sounds like a case, to me, that
19 has to go to the Secretary, whose job it is to approve it,
20 rather than having us fly blind.

21 MR. HAGLER: Well, here's the difference between
22 what the Secretary approved and what the Maine -- and --
23 and what he's proposing with respect to Maine Rx and the
24 plan amendments. What the Secretary approved was a
25 program that's a demonstration project, a waiver program,

1 allowing more people into Medicaid notwithstanding the
2 fact that they're ineligible.

3 QUESTION: That has been approved for Maine?

4 MR. HAGLER: Approved and struck down by the
5 D.C. Circuit on Christmas Eve. The Secretary and the
6 Solicitor General, the Secretary and the Solicitor General
7 identified the fact that that program helped people up to
8 300 percent of poverty. Without the Healthy Maine
9 program, the demonstration project, Maine Rx is now the
10 only program that helps those people.

11 QUESTION: That isn't an answer to my question.
12 The answer to my -- my question was, it sounds to me like
13 a program that the Secretary might approve or might not
14 approve, and so why should we fly blind? Why isn't it the
15 case that you can't put this program into effect, given
16 Federal law, without the approval of the Secretary?

17 Now, when she approves it or disapproves it,
18 they can argue about whether that was legal.

19 MR. HAGLER: Well, the Secretary is suggesting
20 that the State of Maine seek a plan amendment, but by
21 definition, a plan amendment allows -- a plan amendment is
22 something that, if we sought a plan amendment to run Maine
23 Rx it would necessarily be allowed by the Medicaid
24 statute. 42 -- the Medicaid statute, 1396 section --

25 QUESTION: I'm not following you. Is your

1 argument that --

2 MR. HAGLER: We don't --

3 QUESTION: -- even if the Secretary disapproved
4 this, were it a plan, we still could do it? If that's
5 your argument, I'll answer that question. That's a legal
6 question. I think it's an easy one to answer. In my
7 mind, the answer's no.

8 MR. HAGLER: Well, if the Secretary were to --

9 QUESTION: Now, you can explain why it shouldn't
10 be no, but I want to know if that's what I'm supposed to
11 decide.

12 MR. HAGLER: It's not what you're supposed to
13 decide. The Secretary has not acted, other than speaking
14 to this Court through the brief of the Solicitor General.
15 The Medicaid statute provides a mechanism for the
16 Secretary to tell the State when it is running its
17 Medicaid program in a fashion which violates the
18 provisions of the Medicaid statute. That is --

19 QUESTION: Well, but is this actually a -- the -
20 - the State -- the State of Maine running its Medicaid
21 program, it --it's a freestanding statute, isn't it?

22 MR. HAGLER: It's an entirely different --
23 correct, it's an entirely different statute. We don't
24 believe we need a plan amendment to seek approval to run
25 the Maine Rx program.

1 QUESTION: That's fine. So then you want me to
2 decide the question of whether it would be possible to
3 have this statute even if the Secretary, were it an
4 amendment to the Medicaid plan, would say no, okay? I say
5 that's a legal question we can decide.

6 MR. HAGLER: But you should not decide that now.

7 QUESTION: Is that what you think we should
8 decide now? Are you following what I'm saying or not? Am
9 I not --

10 MR. HAGLER: Not precisely.

11 QUESTION: I can decide the question if the
12 Sec -- you're saying -- suppose the Secretary's approval
13 makes no difference. Let us assume the Secretary would
14 disapprove it.

15 MR. HAGLER: Okay.

16 QUESTION: There would -- a legal question, can
17 you have this statute anyway?

18 MR. HAGLER: Yes.

19 QUESTION: Okay. That's what you think we
20 should decide?

21 MR. HAGLER: I believe that's what I --

22 QUESTION: All right. If that's what you think
23 we should decide, fine, then why isn't the answer to that
24 question clearly no? You would have a Federal statute, it
25 uses the Federal program, the Secretary thinks it's

1 contrary to the Federal program, the Secretary's views are
2 within her authority, let's say, under the -- under the
3 Federal program, and so a State cannot put something into
4 effect --

5 MR. HAGLER: Well --

6 QUESTION: -- that is so clearly contrary to the
7 Medicaid program using the Medicaid device.

8 MR. HAGLER: The question that this -- the first
9 question that this Court certified was, as described in
10 the Secretary's brief, is whether the Federal Medicaid
11 statute allows the use of that authority under the statute
12 to compel -- the prior authorization authority --

13 QUESTION: And I assume it --

14 MR. HAGLER: And he says yes.

15 QUESTION: And it would be a waste of time and
16 money for us to send it back to the Secretary, at least if
17 we are convinced on the basis of the briefs submitted
18 here, that even if the Secretary did approve it, that
19 approval would be invalid. I mean, you would concede
20 that --

21 MR. HAGLER: If the --

22 QUESTION: -- that whatever primary jurisdiction
23 is involved here --

24 MR. HAGLER: If the --

25 QUESTION: -- it certainly makes no sense to

1 send it back to the Secretary if, when the Secretary
2 approves it, there is then a lawsuit and we say, oh, by
3 the way, he couldn't approve this.

4 MR. HAGLER: Right.

5 QUESTION: This goes too far. We might as well
6 decide that now, no?

7 MR. HAGLER: You can decide the preemption
8 question now, and I think that the Court should, and the
9 preemption question is whether Congress intended to
10 prohibit what Maine has here done.

11 When Congress legislates against the backdrop of
12 the preemption doctrine and it give -- gave to the State
13 the discretion to subject to prior authorization any
14 covered outpatient drug, it qualified that discretion
15 hardly at all. The only qualifications are the two
16 provisions, the procedural safeguards that require that if
17 prior authorization is sought --

18 QUESTION: Doesn't the Secretary have some
19 discretion in this area as to whether to say it's good or
20 bad, the -- the Maine plan, or are you saying it's simply
21 not his business?

22 MR. HAGLER: It's Congress' business --

23 QUESTION: Well, right.

24 MR. HAGLER: -- to set the line --

25 QUESTION: But did Congress in what it enacted

1 leave any room for the Secretary to have some discretion
2 here?

3 MR. HAGLER: What Congress enacted was the
4 opportunity for the Secretary to tell the State that when
5 it's begun a program or is operating its Medicaid program
6 out of compliance with the Medicaid statute, that it
7 believes that that's the case, and the provision provides
8 for a fair hearing for the State, we get together with the
9 Secretary, we try to work it out. If we can't, and if the
10 Secretary -- if Maine persists in wanting to run the
11 program, and the Secretary disapproves the program, then
12 his remedy is to withhold money from the State and --

13 QUESTION: But if-- if it's a freestanding
14 pro -- if it's a freestanding statute, not part of Maine's
15 Medicaid, how can the Secretary disapprove a freestanding
16 statute?

17 MR. HAGLER: What he can do is look to the
18 effect of what happens once Maine Rx is implemented, and
19 look to the effect on the Medicaid beneficiaries as to
20 whether or not they'll be harmed.

21 QUESTION: Well, the Secretary theoretically
22 could conclude already that to require prior approval for
23 every prescription drug will have negative effects on
24 Medicaid recipients who otherwise would not have to seek
25 prior approval, because there's quite a bit in the record

1 about the difficulty when prior approval must be obtained.

2 MR. HAGLER: Oh, I submit there -- that
3 there's -- I disagree with respect to the record. I
4 believe that there's very little in the record which
5 demonstrates that there will be any harm to Maine Rx
6 beneficiaries, harm to their health, once Maine Rx is
7 imposed, and should the State ultimately impose prior
8 authorizations under the Maine Rx statute.

9 You have lodging materials which are untested.
10 The fact of the matter is, if we were to return to the
11 district court we could demonstrate, based on a vigorous
12 use of prior authorization in the 2 years that have
13 intervened the granting of the injunction and today, that
14 we are imposing prior authorization and we are answering
15 the phone in less than 2 hours, and that Medicaid patients
16 are, in fact, not being harmed.

17 We -- our position is that to survive a facial
18 challenge the petitioner must demonstrate that any use of
19 prior authorization, as contemplated by the Maine Rx --

20 QUESTION: Well, I question whether this is
21 correctly described as a facial challenge. You think of a
22 facial challenge more in terms of somebody who has a --
23 First Amendment implications, or at least criminal law
24 applications. This -- as I read the First Circuit's
25 opinion, although they talked about a facial challenge, I

1 thought what they were saying was, we just don't know
2 enough, since the thing had never gone into effect to
3 uphold the injunction.

4 MR. HAGLER: No, and -- and what the First
5 Circuit didn't know was how the program would actually be
6 implemented, and there are many ways of implementing the
7 program that not only will not cause harm to Medicaid
8 beneficiaries, but which will affirmatively advance the
9 purposes of Medicaid.

10 QUESTION: Is the program now in a -- being
11 operated?

12 MR. HAGLER: It is not, and the reason that it's
13 not is because the --

14 QUESTION: The way you spoke, I thought you had
15 some current experience.

16 MR. HAGLER: We do have current experience with
17 the use of prior authorization to save Medicaid money.

18 QUESTION: For Medicaid, for Medicaid patients.

19 MR. HAGLER: For Medicaid, correct, and as a
20 result of that experience we know much more about our
21 abilities and would be able to describe to the district
22 court much more about our abilities should the First
23 Circuit --

24 QUESTION: Why wasn't the plan put into effect
25 if the injunction was lifted?

1 MR. HAGLER: The mandate was stayed pending --

2 QUESTION: Oh, I see.

3 MR. HAGLER: -- for a writ of certiorari, so
4 we've -- we've not had an opportunity to implement the
5 program.

6 QUESTION: But the Federal Government, with
7 reference to Medicaid, certainly thinks prior
8 authorization is an important enforcement mechanism and
9 now you're saying oh, don't worry about it, it doesn't
10 make much difference.

11 MR. HAGLER: Well --

12 QUESTION: That's hard for me to accept.

13 MR. HAGLER: Well, the Federal Government agrees
14 that prior authorization -- prior authorization is
15 undeniably a cost-saving measure. That's the primary
16 purpose why Congress permitted the States broad discretion
17 to impose prior authorization.

18 Under the Maine Rx program, what the State is
19 saying to manufacturers is, please negotiate with us, and
20 if you don't negotiate with us, we will review the drugs
21 that you manufacture to see and determine, on a drug-by-
22 drug basis, whether it would be appropriate to subject
23 those drugs to prior authorization.

24 QUESTION: But the very reason you put that on
25 the bargaining table is because you know it's going to --

1 it's going to slow down the sales of some of these drugs.
2 Incidentally, I -- and you can answer that. I take it
3 that if Company X has 10 different drugs, and it can't
4 agree with you on the rebate price for just one, that all
5 of those drugs must have prior authorization, or am I
6 wrong about that?

7 MR. HAGLER: I believe that you're wrong. I
8 believe that -- that the Secretary has the discretion --

9 QUESTION: I read the Government's brief to the
10 contrary, but I'll take a look at it.

11 MR. HAGLER: Yeah, I believe --

12 QUESTION: You're representing that it's drug-
13 by-drug, so a company can agree with you as to nine of the
14 drugs, and those will not be subject to prior
15 authorization, but only the tenth drug, as to which you
16 can't agree, will be subject to prior authorization?

17 MR. HAGLER: I believe --

18 QUESTION: That's your representation?

19 MR. HAGLER: As to the -- I believe that our
20 administrative rules demonstrate, proposed administrative
21 rules that the Department hasn't enacted because the
22 injunction has been imposed allow the Department of Human
23 Services of the State of Maine to look on a drug-by-drug
24 basis as to whether any particular drug ought to be
25 subjected to prior --

1 QUESTION: Does it allow it, if it uses, to look
2 on a company-by-company basis, as I'd first described? In
3 other words, does it subject --

4 MR. HAGLER: What will happen is, if --

5 QUESTION: -- to discretion of the State.

6 MR. HAGLER: In other words, if Pfizer were to
7 agree to provide a rebate for some of its drugs but not
8 all of its drugs, must we look to the other drugs --

9 QUESTION: Yes.

10 MR. HAGLER: -- and determine prior
11 authorization? The statute contemplates a negotiation.
12 The Commissioner is to use his best efforts to negotiate
13 with manufacturers in order to --

14 QUESTION: I take that to be a yes?

15 MR. HAGLER: The answer is yes.

16 QUESTION: You can keep all of their drugs off
17 unless they give you what you want for some of them?

18 MR. HAGLER: We could, but the statute also
19 allows us not to.

20 QUESTION: Yeah.

21 MR. HAGLER: The purpose of that --

22 QUESTION: You could, that's -- and -- and you
23 say it -- that the statute envisions using this
24 authorization as a cost-saving measure. Does this save
25 any costs -- does this statute save any cost to the

1 Medicare recipients?

2 MR. HAGLER: To the Medicare?

3 QUESTION: To -- to the Medicaid --

4 MR. HAGLER: Oh, the Medicaid recipients, the
5 Medicaid recipients themselves pay nothing, but it can
6 save money in, and it's probable that it will save money
7 in the Medicaid program, and the reason for that --

8 QUESTION: I understand, because some people
9 won't come into the program who otherwise would come in.

10 MR. HAGLER: Well, that's what the First Circuit
11 picked up on, but the other reason and the other method in
12 which it would save Medicaid money is, it would result in
13 shifting prescribing behavior from more expensive drugs to
14 less expensive drugs. The Commissioner, under
15 subsection --

16 QUESTION: But doesn't that depend on who you
17 make the deals with? Maybe the more expensive drug --
18 drugs we're willing to make this deal with you, and the
19 less expensive not willing.

20 MR. HAGLER: Subsection 13 of the Maine Rx
21 statute gives to the Commissioner the discretion to run
22 the Medicaid program and the Maine Rx program in a
23 coordinated manner so as to enhance efficiencies in both,
24 and so I believe that the Commissioner would never impose
25 prior authorization on the cheapest drug in a therapeutic

1 class even if that manufacturer didn't provide a Maine Rx
2 rebate, because it would be silly to do so. He's got a
3 budget to operate.

4 QUESTION: I've known some silly administrators.

5 (Laughter.)

6 QUESTION: The point is, he could do it. The
7 point is, he could -- you're - you're -- you're -- you're
8 troubled by a -- by a statute which would allow a denial
9 of authorization unless the drug company pays \$100 to each
10 member of the -- of the legislature. I -- I gather you -
11 - you acknowledge that -- that the authorization
12 requirement in the statute has some unstated limitation
13 upon it, or don't you acknowledge that?

14 MR. HAGLER: I believe that -- that under the
15 Court's preemption analysis we look to the primary
16 purposes of the Medicaid statute and you seek to determine
17 what Congress intended.

18 QUESTION: Does the authorization provision have
19 some unstated limitation upon it, a limitation that is not
20 in that sole provision alone?

21 MR. HAGLER: I believe that it doesn't, but even
22 if it does --

23 QUESTION: It doesn't, so \$100 to each
24 legislator is okay?

25 MR. HAGLER: And -- and -- and when that offends

1 Congress, Congress has the ability to act.

2 QUESTION: The real question is whether it has
3 an unstated limitation that's sufficiently clear that it
4 preempts the State law.

5 MR. HAGLER: I'm sorry.

6 QUESTION: The real question is whether the
7 unstated limitation is sufficiently clear to be preemptive
8 of a State statute to the contrary.

9 MR. HAGLER: That's -- that's correct.

10 QUESTION: Well, how is Congress --

11 MR. HAGLER: The language of the statute is, a
12 State may subject to prior authorization any covered
13 outpatient drug.

14 QUESTION: Well, how could Congress --

15 MR. HAGLER: Every --

16 QUESTION: Sorry. No, go ahead. Finish,
17 please.

18 MR. HAGLER: Indeed, every outpatient drug could
19 be subjected to prior authorization. That, too, would be
20 silly, but the power is that broad.

21 QUESTION: Now, that's what I want to know.
22 Why? I mean, how could Congress possibly want a statute
23 which would hurt the Medicaid patients at -- no argument
24 it wouldn't hurt some of them, and has nothing to be said
25 for helping anyone related to Medicaid?

1 MR. HAGLER: Well, we -- we disagree that --

2 QUESTION: I know you disagree about whether
3 that's the effect.

4 MR. HAGLER: -- that it will not hurt people.

5 QUESTION: I understand that.

6 MR. HAGLER: Right.

7 QUESTION: So how can I decide this case without
8 knowing whether the people in charge of the statute agree
9 with you about that, as they might, or you might negotiate
10 some implementation of how to have regulations that they
11 can agree to, or, or, or, the possibilities are endless.
12 How can I decide in your favor, in other words, without
13 knowing, the same question, what the Secretary thinks?

14 MR. HAGLER: Because the Secretary can act if
15 the injunction -- if the First Circuit's decision is
16 affirmed, the Secretary can act, and tell the State of
17 Maine we believe that you will harm Medicaid beneficiaries
18 and we will take your money away.

19 QUESTION: But suppose --

20 MR. HAGLER: But the Secretary hasn't acted.
21 The Secretary has asked this Court to approve his notions
22 of what Maine Rx might look like if it were more limited
23 in scope in terms of the number of beneficiaries, but he
24 hasn't defined for the Court how to set the line.

25 QUESTION: Suppose the State passes a law that

1 says that each Medicaid beneficiary shall pay an
2 additional tax of \$50 a year. You say that the only way
3 to get rid of that law, which would certainly contravene
4 the -- the whole purpose of Medicaid. The only way to get
5 rid of it is to go to the Secretary and say, since this
6 law is an amendment of the State's plan, you should
7 approve it, it requires your approval.

8 MR. HAGLER: Now, there --

9 QUESTION: They couldn't strike that down as
10 just being contrary to the --

11 MR. HAGLER: No, it's contrary to the statute.

12 QUESTION: Okay.

13 MR. HAGLER: Medicaid beneficiaries can't be
14 required to pay more than a nominal co-pay.

15 QUESTION: Okay, so --

16 MR. HAGLER: Congress thought --

17 QUESTION: So the only remedy for something that
18 is contrary to the statute is not going through the
19 Secretary, that some things that are contrary to the
20 statute can be attacked directly, as is being done here.

21 MR. HAGLER: But -- but I'm not convinced that
22 from the text of the statute you can find an intent --

23 QUESTION: Okay. That's a different question.

24 MR. HAGLER: -- on the part of Congress to
25 prohibit this, and even if it were to -- Congress were to

1 prohibit using Maine Rx like prior authorizations for some
2 purpose wholly unrelated to health care, when you get
3 closer and closer to something approaching what the
4 Secretary in fact does approve of, how can a court set the
5 line? The question really is --

6 QUESTION: That's the merits question, rather
7 than whether we have, you know, power to -- to move at
8 all, so long as the Secretary can handle the problem by
9 denying approval.

10 MR. HAGLER: The Secretary has indicated that
11 he'll handle the problem, or he's expressed his views
12 about what the program is. The Court should wait to see
13 whether the -- I mean, the Court should allow the
14 Secretary to --

15 QUESTION: Can I ask you this question: I
16 thought you would agree that, if it were clear as a matter
17 of fact that this program was going to harm Medicaid
18 recipients, that we would have power to enjoin the
19 program?

20 MR. HAGLER: Yes, but it's not -- I do agree
21 with that.

22 QUESTION: So your argument, as I understand it,
23 it's an unresolved factual question whether, in fact,
24 these adverse consequences would follow?

25 MR. HAGLER: That's correct. We have -- there's

1 no facts in the record, and -- and this -- this is a
2 facial challenge in which my colleague has to demonstrate
3 that they are in no way -- there's no possibility of
4 implementing the program in a way which doesn't cause harm
5 to --

6 QUESTION: Well, I may not agree with that
7 statement, but at least they have to make a showing there
8 in fact will be an adverse effect.

9 MR. HAGLER: Some showing.

10 QUESTION: Yes.

11 MR. HAGLER: And the only showing that the
12 district court seized upon is this notion that, by
13 definition, prior authorization imposes some sort of
14 procedural impediment to free access to all drugs on
15 behalf of Medicaid patients, but the --

16 QUESTION: I thought you -- I thought you had
17 acknowledged that the authorization requirement must not
18 merely not harm Medicaid recipients, but that the
19 authorization must serve the purpose of helping Medicaid
20 recipients. Don't -- don't -- don't you acknowledge that?

21 MR. HAGLER: Our --

22 QUESTION: You were saying it does help them,
23 you know, and you're mentioning the ways in which it helps
24 the Medicaid program.

25 MR. HAGLER: Under either test we think we win.

1 Under the first test, the question should be, did Congress
2 intend to prohibit what Maine has here done? If the
3 question is, does the Maine Rx program advance the
4 purposes of Medicaid --

5 QUESTION: Right.

6 MR. HAGLER: -- it assuredly does that.

7 QUESTION: But you don't think that's necessary?

8 MR. HAGLER: I'm -- I'm not convinced that
9 that's necessary.

10 QUESTION: Okay.

11 MR. HAGLER: But even if it were necessary,
12 there's -- the -- the facts in the record, and the
13 reasonable expectation of how the program will work will
14 yield Medicaid cost savings both by imposing prior
15 authorization on drugs that are more expensive than their
16 therapeutic equivalents, and also by making Maine --
17 allowing people without insurance in the State of Maine to
18 purchase their prescription drugs and become less likely
19 to become disabled and financially eligible for Medicaid.

20 QUESTION: Of the proposed regulations, is
21 anything published? There was nothing before either court
22 about how this would be implemented, was there?

23 MR. HAGLER: There were proposed regulations.
24 They are in the appendix. They have not been promulgated.
25 They were drafted, and they're --

1 QUESTION: Before the district court?

2 MR. HAGLER: Yes. They were handed up to the
3 district court, and they -- they should be in the court
4 file. They -- they are found on page 278 of the appendix,
5 and that provision describes how Maine will go about
6 reviewing the drugs for prior authorization. If a
7 manufacturer refuses to participate in -- in a Maine Rx
8 negotiation, then the Commissioner will hand a list of --
9 of that manufacturer's drugs to a committee of physicians
10 and pharmacists who will determine whether it's clinically
11 appropriate to subject those drugs to prior authorization,
12 guided constantly by the principle that the purpose of
13 Medicaid is to provide necessary medical assistance to
14 those in need.

15 QUESTION: Thank you, Mr. Hagler.

16 Mr. Phillips, you have 3 minutes remaining.

17 REBUTTAL ARGUMENT OF CARTER G. PHILLIPS

18 ON BEHALF OF THE PETITIONER

19 MR. PHILLIPS: Thank you, Mr. Chief Justice.

20 Justice Stevens, I want to focus on the
21 narrowest basis on which this case can be decided, which
22 is, we have a preliminary injunction that was issued by
23 the district court. A preliminary injunction was issued
24 on the basis of two bases, 1) the State has not put
25 forward any Medicaid-related purpose to be served by Maine

1 Rx, and 2) that no matter how you want to define it, there
2 is an obstacle to the full achievement of the recipient's
3 primary interest of receiving medicine.

4 As I said, there's a clear debate as to exactly
5 the extent of the obstacle, but that there could be no
6 question that there is an obstacle, and it seems to me
7 that what this Court can do is simply say, those two
8 findings are not an abuse of discretion on the record in
9 this particular case, therefore there is a basis for
10 affirming.

11 If the Court wants to go further from that and
12 say, on remand, some guidance might be useful from the
13 Secretary of HHS and propose some mechanism by which to
14 have primary jurisdiction or some other mechanism devised
15 by which to obtain the review by the Secretary, I think
16 there's probably no problem with that and, as I said
17 before, I can't imagine that we would have any complaint
18 about that, but the importance of this is to -- is to
19 retain the injunction in place so that the unquestioned
20 harms that are going to happen are not allowed to take
21 place, and then try to undo them after the fact, which was
22 the reason for issuing the injunction.

23 QUESTION: A brief question, I don't -- I'm
24 worried about your time, but is it inconceivable to say
25 that there was no showing at the time of the preliminary

1 injunction hearing but now they -- Maine says they can
2 make the showing that they should have made before.
3 Should the judge not listen to that?

4 MR. PHILLIPS: Well, I think when you get past
5 the preliminary injunction and you move on to the
6 permanent injunction, if they think that they can show no
7 burden whatsoever, or if they think they can show that
8 there are greater purposes to be served, that's certainly
9 available to them. But on an abuse of discretion standard
10 this Court ought to affirm that, and nothing that the
11 First Circuit said justifies taking any action in this
12 particular case.

13 If there are no other questions --

14 CHIEF JUSTICE REHNQUIST: Thank you, Mr.
15 Phillips. The case is submitted.

16 (Whereupon, at 12:07 p.m., the case in the
17 above-entitled matter was submitted.)

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