

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.                    :

10 - - - - -X

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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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. Kneeder --

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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