

1                   IN THE SUPREME COURT OF THE UNITED STATES

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3   TOMMY G. THOMPSON,                   :

4       SECRETARY OF HEALTH AND HUMAN   :

5       SERVICES, ET AL.,               :

6                   Petitioners               :

7           v.                               :   No. 01-344

8   WESTERN STATES MEDICAL CENTER,   :

9       ET AL.                               :

10   - - - - -X

11   Washington, D.C.

12   Tuesday, February 26, 2002

13               The above-entitled matter came on for oral  
14   argument before the Supreme Court of the United States at  
15   10:11 a.m.

16   APPEARANCES:

17   EDWIN S. KNEEDLER, ESQ., Deputy Solicitor General,  
18       Department of Justice, Washington, D.C.; on behalf of  
19       the Petitioners.

20   HOWARD M. HOFFMAN, ESQ., Chicago, Illinois; on behalf of  
21       the Respondents.

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P R O C E E D I N G S

(10:11 a.m.)

CHIEF JUSTICE REHNQUIST: We'll hear argument now in Number 01-344, Tommy G. Thompson v. The Western States Medical Center.

Mr. Kneedler.

ORAL ARGUMENT OF EDWIN S. KNEEDLER

ON BEHALF OF THE PETITIONERS

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

It has long been a fundamental requirement of the Federal Food, Drug and Cosmetic Act that a new drug may not be marketed unless it has first been found by the Food and Drug Administration to be safe and effective for its intended use.

Congress concluded that the protection of the public health requires that safety and effectiveness be rigorously established by scientifically valid studies rather than the impressions of individual doctors, and also that persons who promote and distribute new drugs should be the ones to undertake the studies necessary to establish their safety effectiveness.

In 1997, Congress carved out a narrow exception to the new drug approval and certain other requirements of the Food and Drug Act for certain compounding by

1 pharmacists. The exemption is addressed to what is often  
2 referred to as extemporaneous compounding. That is,  
3 compounding undertaken in response to a physician's  
4 prescription based on the idiosyncratic needs of a  
5 particular patient. Such compounding is typically based  
6 on an existing relationship among the pharmacist,  
7 physician, and patient.

8 Congress provided in section 353(a), which it  
9 enacted in 1997, that the exemptions from the new drug  
10 approval and other requirements of the act would be  
11 limited, and available only in circumstances that  
12 conformed to extemporaneous compounding by pharmacists.

13 QUESTION: Mr. Kneedler, a moment ago you say  
14 this is based on an existing relationship between the  
15 physician, the druggist, and the patient. What is meant  
16 by that term?

17 MR. KNEEDLER: Well, I -- it's based on the  
18 relationship.

19 QUESTION: Well, I could tell that.

20 MR. KNEEDLER: Typically an existing  
21 relationship in the sense that the need for compounding  
22 often arises where there may be a commercially available  
23 product that maybe the physician has prescribed, but it  
24 might -- or would have otherwise prescribed, but it might  
25 contain an ingredient to which the patient is allergic, or

1 it may come in a dosage that would be inappropriate for a  
2 child or an older person, and therefore the physician and  
3 the pharmacist would consult and say, the pharmacist would  
4 be asked, could you modify this in some way, or develop  
5 the same drug without the ingredient, so --

6 QUESTION: The plaintiffs here seem to be  
7 engaged in a Nation-wide business.

8 MR. KNEEDLER: Yes.

9 QUESTION: They're not a corner --

10 MR. KNEEDLER: No, it is -- and the record in  
11 the case, the materials submitted in the district court,  
12 confirm exactly what you say. This is far different from  
13 that sort of situation. They're engaging in conduct that  
14 is essentially indistinguishable from that of any  
15 manufacturer or producer of drug products that is governed  
16 by the manufacturing --

17 QUESTION: Well, can't Congress limit the  
18 compounding to the ordinary prescription service that we  
19 expect pharmacists to be doing?

20 MR. KNEEDLER: And that's exactly what Congress  
21 has done. If I --

22 QUESTION: Well, but they added this ban on  
23 advertising.

24 MR. KNEEDLER: Well, if I could explain, the ban  
25 on advertising is one of the conditions that confine the

1 exemption to traditional extemporaneous compounding. The  
2 others are, for example, that it has to be on the basis of  
3 an unsolicited prescription, that the drug can't be  
4 prepared in advance of the prescription except in --

5 QUESTION: Well, don't all those things take  
6 care of the Government's interest in problems? What  
7 justifies the additional ban on promotion and advertising?

8 MR. KNEEDLER: That condition is essential to  
9 protecting the integrity of the new drug approval process,  
10 for this reason. The general rule under this act is that  
11 the introduction of any new drug in interstate commerce  
12 must conform with the prior approval requirements of the  
13 Food and Drug Act. This is a narrow exception from that,  
14 but what Congress had to do was draw the line between what  
15 is extemporaneous compounding and what is not.

16 QUESTION: Yes, but what I don't understand is,  
17 if Congress can limit in all these other ways the use of  
18 compounding of drugs, then why does it need this  
19 additional ban? The court below seemed to think that it  
20 was not necessary, and I think I have the same problem.

21 MR. KNEEDLER: Well, I -- first of all, we think  
22 that the court of appeals really misunderstood what the  
23 governmental interest here -- the -- is here. The  
24 governmental interest, again, is maintaining the integrity  
25 of the Government approval process and making sure that

1 those who hold themselves out as marketers and  
2 distributors of new drugs comply with those requirements  
3 in the same way that any other manufacturer must do. The  
4 mixing together of ingredients --

5 QUESTION: Well, is there any allegation here  
6 that the ads are false or fraudulent, misleading,  
7 deceptive? I mean, you could always attack that.

8 MR. KNEEDLER: But that's not really the basic  
9 point behind this. Again, no one, whether he holds a  
10 pharmacist's license, a physician's license, or not, may  
11 manufacture and market drugs in this economy without going  
12 through the prior approval requirement, and --

13 QUESTION: And what does manufacture mean? I  
14 mean, that's a problem I have with this case, they  
15 manufacture it. The manufacturer does exactly the same  
16 thing that the compounder does, puts together two or more  
17 other ingredients into a new drug.

18 MR. KNEEDLER: I think that's a very important  
19 point. There is nothing distinctive about a pharmacist  
20 putting together ingredients to produce a new drug as  
21 compared with a traditional manufacturer.

22 QUESTION: Exactly.

23 MR. KNEEDLER: But what distinguishes it is that  
24 Congress carved out a narrow exception, is the existence  
25 of this relationship between the pharmacist, among the

1 pharmacist, the physician, and the patient.

2 QUESTION: But why does that -- why does  
3 advert -- you see, I don't mind -- don't mind. I mean,  
4 surely Congress can constitutionally limit it to try to  
5 prevent evasion of the normal approval process, but there  
6 are other ways of limiting it, like saying, as you  
7 observed, this particular druggist operates Nation-wide  
8 and sells, you know, thousands and thousands of dollars.  
9 Fine, put a dollar limit on the amount that any single  
10 druggist can do. Wouldn't that achieve -- the problem is  
11 that the Government has sought to achieve its limitation  
12 by placing a limitation on speech.

13 MR. KNEEDLER: Well --

14 QUESTION: Why did it have to do that? Why does  
15 advertising equate with manufacturing?

16 MR. KNEEDLER: It -- what it equates with is the  
17 marketing of products in the economy, and this is not the  
18 only situation under the Food and Drug Act where the  
19 advertising that someone does is what triggers regulation.

20 This Court last term in the Buckman decision  
21 addressed a very analogous situation, and if I could  
22 explain why it's analogous, I think it would be  
23 instructive here. There, the Court pointed out that the  
24 FDA is faced with competing considerations. On the one  
25 hand there is a rigorous premarket approval process for,



1 in that case, devices, which is very analogous to the  
2 rigorous new drug approval process for drugs, but the  
3 Court at the same time recognized that it is permissible  
4 for physicians to prescribe for off-label uses,  
5 physicians, but if a manufacturer of the drug advertises  
6 the product for a use that is not on the label, that is  
7 prohibited. What someone cannot do is market in the  
8 economy a drug for an intended use that is not on the  
9 label, because in that situation, as here, Congress was  
10 trying to draw the line between marketing of drugs and  
11 protection of profession --

12 QUESTION: No, but it wasn't a distinction  
13 between manufacturers. I mean, the problem there is, if  
14 you're saying it is good for this, that is one of the  
15 intended uses, and you have to have gotten approval for  
16 that intended use. I mean, that's what did the trick  
17 there.

18 MR. KNEEDLER: Yes, but --

19 QUESTION: It wasn't an equation of advertising  
20 with manufacturing.

21 MR. KNEEDLER: Well, what it is, it's an  
22 equation of advertising with what triggers the, in that  
23 case the prior approval process and in this case the prior  
24 approval process. When someone holds himself out as  
25 producing and distributing drugs, then it is fair to make

1 that person, like every other manufacturer that  
2 distributes drugs in the national economy comply.

3 QUESTION: Mr. Kneedler, would you explain  
4 something to me? Going back before the point where --  
5 everybody seems to agree that compounding and  
6 manufacturing is no different, but there once was a world  
7 when there were mostly corner pharmacists, and there was  
8 something called compounding which surely was discrete  
9 from manufacturing, and it seems to me that what you  
10 described as an exemption for the compounding was the  
11 first time that compounding is put together with new  
12 manufactured new drugs.

13 Before the 1997 alteration, how was compounding  
14 dealt with by the FDA?

15 MR. KNEEDLER: The FDA had taken the position  
16 for quite a while before the 1997 amendments of at least  
17 two decades that pharmacy compounding, at least if it  
18 included such an indicia of manufacturing as advertising,  
19 or large volumes, a number of things that take it out of  
20 traditional pharmacy compounding, extemporaneous, and put  
21 it into the basically predetermined or planned marketing  
22 of a product, that's the line Congress is trying to draw.

23 QUESTION: But I mean, there's two kinds of  
24 compounding. Let's just say, it's the physician who's  
25 prescribing this medication for a child, so it needs to be

1 diluted, pharmacist-diluted, is that manufacturing?

2 MR. KNEEDLER: It would be producing a new drug  
3 within the meaning of the new drug provisions of the act,  
4 it would have been prior to 1997. The position that  
5 FDA -- FDA formalized its enforcement policy in 1992 to  
6 say that compounding that occurs in the normal course, the  
7 ordinary course of the practice of pharmacy,  
8 extemporaneous compounding that you've described to dilute  
9 a commercially available product, or to extract an  
10 ingredient from it, that would be all right, but when the  
11 pharmacist stepped out of that role and behaved in ways  
12 that a regular producer of drugs subject to the act  
13 behaves, then the person is subject to the prior approval,  
14 good manufacturing practices requirements of the act,  
15 because again, in terms of function, putting together  
16 different ingredients to produce a product, whether it's a  
17 manufacturer, or whether it is someone with a pharmacy  
18 license doing it, that doesn't matter, and the important  
19 public health considerations --

20 QUESTION: What you're doing -- tell me if I'm  
21 incorrect. You're equating the size of the market with  
22 whether there's manufacturing or compounding, and it seems  
23 to me that advertising is not necessarily a good proxy for  
24 that. Suppose you had a pharmacy that's near a home for  
25 senior citizens, and they have particular success with one

1 doctor in compounding a particular drug.

2 I take it if they advertise to the other doctors  
3 they take care of these people, now we can compound this  
4 drug for you, that that's a violation of the law. I don't  
5 think that that's a proxy for being a manufacturer. We  
6 have the other paradigm of this huge, Nation-wide chain  
7 that advertise and they look more like a manufacturer. I  
8 just don't know that that's an adequate proxy.

9 MR. KNEEDLER: Several things in response to  
10 that. First of all, the new drug provisions of the act  
11 are directed at single incidents of introducing a new drug  
12 into interstate commerce, or a single incident of  
13 receiving this branded drug in interstate commerce, so the  
14 act applies irrespective of the volume. Now, obviously  
15 the magnitude of the public health problem expands as more  
16 and more people are affected, but advertising, along with  
17 the other conditions Congress put in the act, were a  
18 pretty good indication of trying to draw a distinction  
19 between traditional pharmacy and what the FDA

20 QUESTION: No, but that's based on the size of  
21 the market, I take it.

22 MR. KNEEDLER: No, it's based on the undertaking  
23 by the person who is producing, who is trying to put the  
24 drug out on the market. It's really a difference between  
25 offering services and offering drugs.

1           QUESTION: I'll look at your brief again, but I  
2   thought that your whole theory was that advertising is a  
3   proxy for market, which is a proxy for manufacturing,  
4   versus the compounding. I thought that was the heart of  
5   your case.

6           MR. KNEEDLER: Well, it would certainly lead to  
7   those consequences. My point is, though, that the line  
8   Congress drew is not at a particular volume. It looked at  
9   the traditional operation of the act, which prohibits  
10  individual instances of introducing drugs --

11          QUESTION: Which is why advertising is such an  
12  imprecise proxy.

13          MR. KNEEDLER: No, I -- well, with all respect,  
14  what the pharmacist can do is advertise his services, his  
15  professional services, and what the act does -- this  
16  exemption in the act does is, respect that professional  
17  service and the relationship that grows out of that  
18  professional service.

19          QUESTION: Which can produce an enormous volume.  
20  Under the act, it's perfectly okay to advertise, you know,  
21  XYZ pharmacy. We compound whatever you want, best prices  
22  in the country, guaranteed lowest prices for all  
23  compounded drugs. That advertising's perfectly okay, so  
24  long as you don't name one particular compound that you're  
25  offering, right?

1 MR. KNEEDLER: Yes.

2 QUESTION: And that's going to lead to certainly  
3 very, very much increased volume.

4 MR. KNEEDLER: But what that does is conform to  
5 the line Congress was trying to draw. It allows the  
6 advertising of the services, but it does not allow the  
7 advertising and therefore the attempt to develop a market  
8 for a particular product, or drug.

9 Again, the Federal act is concerned with  
10 promoting drugs, not services, so when you hold yourself  
11 out as someone who says, I will sell drugs -- and if you  
12 look at the record in this case, the plaintiffs have  
13 advertising that lists a whole variety of drugs available  
14 for infertility, for cancer, for things like that. They  
15 are behaving just like any manufacturer, any -- just like  
16 exactly the sorts of persons that the new drug approval  
17 and the good manufacturing practice provisions of the act  
18 were designed to reach.

19 I want to go back to Justice Kennedy, because I  
20 would like to extrapolate a little bit on your answer to  
21 him. I thought, is this the -- what the Congress is after  
22 is, it's simply a matter of volume, and you said no, so I  
23 said, well, what is it?

24 Now, in my own mind what I thought is, it's the  
25 direction where the demand comes from. There might be

1 children, and there are, who find it very difficult to  
2 swallow pills and who are undergoing chemotherapy, and  
3 therefore there must be a way of adjusting that pill.

4 Now, with some medicines, maybe there's one  
5 child out of a million. With others, maybe there's one  
6 out of 10. Both cases you want the demands for the  
7 special drug to flow from the doctor, through the patient,  
8 to the pharmacist, and what you don't want is it to flow  
9 from the pharmacist to the patient to the doctor back to  
10 the pharmacist.

11 MR. KNEEDLER: That's exactly right.

12 QUESTION: The one is promotion and soliciting.  
13 The other is the doctor determining there's a genuine need  
14 for a special medicine.

15 MR. KNEEDLER: That's exactly right, and that's  
16 exactly what the FDA was referring to and others have  
17 referred to as extemporaneous compounding. It arises out  
18 of the relationship, so Congress -- in carving out this  
19 exemption, Congress was doing a number of things. It was  
20 looking at the --

21 QUESTION: But you have prohibited, or the  
22 Government prohibits the pharmacy from advertising to the  
23 doctor the availability of this remedy.

24 MR. KNEEDLER: The -- it doesn't prohibit the  
25 availability of the advertising services, which can

1 include, we can prepare a product to remove something to  
2 which a patient may be allergic. We can compound a  
3 product --

4 QUESTION: No, no. Suppose, in Justice Breyer's  
5 example, that doctors didn't know that this could be done  
6 with this pill, and -- but under the statute you're  
7 defending, the pharmacy could not advertise to doctors  
8 that it can prepare this drug in that way.

9 MR. KNEEDLER: Well, but it -- what it can do,  
10 though, is advertise in general terms that it can remove,  
11 or it can produce a product that is like a commercial one,  
12 but while removing ingredients to which the person may be  
13 allergic, or dilute a dosage. That is enough to get the  
14 critical information --

15 QUESTION: Well, how do we know that, because  
16 undoubtedly I think what Justice Kennedy said must be  
17 right. One of the negative effects of the statute is, it  
18 does prevent the pharmacist from, through advertising,  
19 telling the doctor that we have this special way of making  
20 drug X. That is a negative impact. On the other hand,  
21 there are counterbalancing positive impacts in preventing  
22 the general solicitation of the public, which will produce  
23 a demand you don't want.

24 Now, is there anything that tells us how that  
25 comparison breaks down?



1           MR. KNEEDLER: Yes, and I think the most  
2 critical thing that tells us that is the new drug approval  
3 provisions of the Food and Drug Act itself, which Congress  
4 enacted in 1938 and strengthened in 1962 precisely to  
5 reach the conduct of people developing new drugs and  
6 advertising and promoting drugs that have not been shown  
7 to be safe and effective to individuals or to the public  
8 at large. It is the act of --

9           QUESTION: Yes, but when you have the basic  
10 provision that compounding can only be conducted in  
11 response to a prescription by a physician, it's hard to  
12 understand why it has to be accompanied by a ban on  
13 truthful speech about it.

14          MR. KNEEDLER: Well --

15          QUESTION: I mean, we've had a long history in  
16 this very Court of giving voice to the notion that  
17 truthful advertising is acceptable in this country.

18          MR. KNEEDLER: But the new drug approval  
19 provisions of the Food and Drug Act rest on the premise  
20 that the judgment of the individual physician is not  
21 sufficient. That is the very purpose of requiring prior  
22 approval and requiring the person who wants to --

23          QUESTION: Yes, but presumably compounding  
24 cannot be done without resorting to approve -- the use of  
25 approved drugs. It's diluting it, it's mixing it some way

1 for children, it's adding some kind of sweetener so they  
2 can swallow it.

3 MR. KNEEDLER: That's one variation, but again,  
4 if you look at the record in this case, there are products  
5 that have been compounded that don't resemble that at all.  
6 What they are, are people holding themselves out as  
7 pharmacists who really see themselves as developing new  
8 cures, not just tinkering with an existing product, but  
9 putting --

10 QUESTION: Mr. Kneedler, isn't it true that --  
11 we haven't talked about the severability issue, but as I  
12 understand it, the whole statute has been held  
13 unconstitutional, because they disagreed with the district  
14 court on the severability point.

15 MR. KNEEDLER: That's correct.

16 QUESTION: It seems to me that you still can  
17 enforce -- I would have thought the parties to be arguing  
18 the opposite sides of this case, to tell you the truth.  
19 It seemed to me the statute actually helps the  
20 compounders, because it makes legal something that is  
21 otherwise illegal, and if the statute's knocked out, you  
22 have all your enforcement mechanisms to prevent them from  
23 doing the mass marketing, don't you?

24 MR. KNEEDLER: Yes. Well, not -- it would  
25 revert to the situation before, in which this would be

1 absolutely prohibited.

2 QUESTION: Right.

3 MR. KNEEDLER: And FDA would have the  
4 discretion, and again it's not just mass marketing, it is  
5 the situation, as Justice Breyer described, of where the  
6 demand comes from, and -- but more fundamentally, the act  
7 rests on the notion that it is fair to require people who  
8 hold themselves out and who attempt to develop and exploit  
9 a market to go through the new drug approval requirements.

10 QUESTION: I understand that, but it seems to me  
11 that the -- your opponents would be better off if the  
12 statute were held to be constitutional than having it held  
13 unconstitutional, because you now may prevent them from  
14 doing what you're basically saying is the wrong -- is  
15 marketing new drugs.

16 MR. KNEEDLER: Well, you make an important  
17 point, because Congress looked at this problem in 1997  
18 and, as the committee reports we quote show, it consulted  
19 broadly about this and arrived at a consensus about  
20 exactly where this dividing line should be between  
21 extemporaneous traditional compounding and the traditional  
22 kind of promotion of new drugs that the act was directed  
23 to.

24 QUESTION: Well, maybe you can't do it that way.  
25 I mean, maybe the Government is just trying to ride two

1 horses at the same time, the one horse being that all  
2 drugs must be approved by the FDA and the other one being,  
3 well, we're going to let, you know, drugs that are  
4 prescribed, special drugs prescribed by doctors are okay,  
5 and we're going to ride both of these horses at the same  
6 time by imposing a restriction on truthful advertising. I  
7 mean, just maybe you can't do that. I mean --

8 MR. KNEEDLER: This case --

9 QUESTION: -- it seems to me that the ultimate  
10 problem with the case is that the Government is trying to  
11 have it both ways. --

12 MR. KNEEDLER: Well --

13 QUESTION: It's trying to say, it's not enough  
14 to have the doctor approve this drug. We don't trust  
15 doctors. We want FDA approval. But then on the other  
16 hand it's saying, well, on the other hand, if it's a  
17 doctor and an individual druggist, it's okay. I don't  
18 understand why that makes any sense.

19 MR. KNEEDLER: The Central Hudson doctrine that  
20 this Court has developed for evaluating restrictions on  
21 commercial speech, its virtue is that it allows the  
22 recognition of these very real problems that regulatory  
23 agencies face.

24 Again, it's exactly the sort of balance the  
25 Court was addressing in Buckman last term between

1     respecting the integrity and creating incentives for  
2     producers to go through the new drug approval process on  
3     the one hand, but respecting professional services,  
4     existing relationships on the other, and under the Central  
5     Hudson analysis, as we explain in our brief, we think this  
6     statute easily passes muster, maintaining the integrity of  
7     the new drug approval process, and maintaining incentives  
8     for manufacturers to go through it is clearly, in our  
9     view, a substantial governmental interest.

10            QUESTION:  They're talking about Central Hudson  
11     and the narrow tailoring notion, or whether it's  
12     sufficiently tailored.  I forget the exact language.

13            I take it you'd have a much stronger case if the  
14     prohibition was limited to prohibition of advertising  
15     directed at consumers, as opposed to advertising directed  
16     at doctors.

17            MR. KNEEDLER:  No, I -- again, the new drug  
18     approval process of the act rests on the premises that  
19     doctors themselves cannot make independent judgments about  
20     the safety and effectiveness of products, and that is --  
21     that was a very firm understanding of Congress when it  
22     passed the new drug approval process.

23            QUESTION:  Unless they're druggists.  Unless  
24     they're druggists who don't sell too much.  Unless they do  
25     it with druggists who truthfully advertise.  Why does that

1 make any sense?

2 MR. KNEEDLER: But the paradigm that the act was  
3 directed to is where there is an approved new drug  
4 product, or an approved product on the market, and what  
5 the pharmacist is being asked to do is tinker with it a  
6 little bit by diluting it, by something on that order, to  
7 make it -- to adjust it but not be in the business of  
8 developing new cures, or advertising new cures for  
9 existing diseases.

10 QUESTION: No, but I thought just as Justice  
11 Scalia did, that you've really got two paradigms in it.  
12 One paradigm is, yes, you can't on a broad global scale  
13 depend upon the prescriptions of doctors to guarantee that  
14 the drugs the patients are going to get are safe. That's  
15 number 1.

16 Number 2 seems to be that so long as you can be  
17 sure that the doctor is focusing on what you earlier  
18 called sort of the idiosyncracies of a particular patient,  
19 so long as we know the doctor is really paying attention  
20 to detail, we can tolerate it up to a point, and the  
21 problem that the Congress I thought was addressing is, how  
22 do we draw the line so that we don't get a situation in  
23 which the doctor seems to be addressing idiosyncracies,  
24 i.e., he writes a prescription, but the volume gets so  
25 great that you know that that is not going on, and the act

1 seems to have two different answers. One answer is, don't  
2 advertise, because we know what that may lead to, and the  
3 other answer is, a restriction on volume that pharmacies  
4 can write, or can produce.

5 The question, I guess, that's bothering all of  
6 us is, why do you need the advertising in addition to the  
7 volume restriction. You can have it both ways, and you  
8 can have it both ways by enforcing the volume restriction.

9 MR. KNEEDLER: The volume restriction is on the  
10 aggregate number of compounded drugs.

11 QUESTION: Then have a narrower volume  
12 restriction.

13 MR. KNEEDLER: But a drug that --

14 QUESTION: Why can't a narrow volume restriction  
15 work?

16 MR. KNEEDLER: A drug-by-drug volume restriction  
17 would be extraordinarily difficult to administer, with  
18 thousands and thousands of pharmacies across the country,  
19 and having to keep track of particular patient's names --

20 QUESTION: Then have a lower -- then why not  
21 have a lower aggregate?

22 MR. KNEEDLER: Again, Congress, we think, was  
23 entitled to look at the conduct of the pharmacist and take  
24 the pharmacist at his word. If he stops being a  
25 pharmacist --

1 QUESTION: No, but that begs the question,  
2 because you know, the question is, under Central Hudson,  
3 is the pharmacist entitled to have his word, and --

4 MR. KNEEDLER: Well, under --

5 QUESTION: And why can the object not be  
6 accomplished by restrictions in volume rather than  
7 restrictions on speech?

8 MR. KNEEDLER: Because the restrictions on  
9 volume is directed at the overall character of the  
10 pharmacist. The restriction on the solicitation and  
11 advertising of a particular product is exactly what the  
12 Food and Drug Act is directed at, which is the promotion  
13 of a new drug, not just a volume, but a new drug, and  
14 Congress was specifically concerned about that as well.

15 If I could reserve the balance of my time.

16 QUESTION: Very well, Mr. Kneedler.

17 MR. KNEEDLER: Thank you.

18 QUESTION: Mr. Hoffman, we'll hear from you.

19 ORAL ARGUMENT OF HOWARD M. HOFFMAN

20 ON BEHALF OF THE RESPONDENTS

21 MR. HOFFMAN: Mr. Chief Justice, may it please  
22 the Court:

23 I think in response to some of the Court's  
24 questions I would like to give our position, the  
25 respondents position and a couple of key points on which



1     there may yet be some confusion, and I start with the  
2     proposition of why a compounding pharmacist is not a  
3     manufacturer, which seems to be a key point before this  
4     Court this morning, and I can understand why.

5             Let me address what it is the manufacturer does,  
6     how he does it, and what a compounding pharmacist does,  
7     and I will also say that there are in these respondents  
8     specialty compounding entities so that when the court was  
9     concerned about, they sell their compounds Nation-wide,  
10    they dispense them Nation-wide, indeed, some of them do,  
11    and that's because they happen to specialize in  
12    compounding, and do that as a special service,  
13    specializing in the interaction, as part of their triad,  
14    where they work with patients, they work with the  
15    specialist physician to, for example, treat cancers, treat  
16    tumors --

17            QUESTION: Mr. Hoffman, I take it all of this is  
18    in the record somewhere.

19            MR. HOFFMAN: Yes, Your Honor. It is -- in  
20    fact, it's in the affidavits in the lower court and the  
21    verified complaints. They work as part of this triad,  
22    they are specialists, and they work with infertility  
23    specialists, for example, for the purpose of helping  
24    childless couples be able to have children.

25            QUESTION: May I ask -- you have large companies

1 as clients. Is it lawful, or is it part of the practice  
2 to compound a large volume, have an inventory available  
3 that you then can advertise to the doctors, consumers that  
4 if you prescribe it, we will sell it to you?

5 MR. HOFFMAN: All that is lawful, and all --

6 QUESTION: And is that part of the practice that  
7 they follow?

8 MR. HOFFMAN: That is not what they do, except  
9 to this limited extent, and I don't want to mislead the  
10 Court. Yes, these compounding pharmacists do not compound  
11 in advance before getting prescription orders vast  
12 inventories. If that was the Court's question, the answer  
13 is yes, they do not.

14 However, do they not at all pre-compound some  
15 inventory, and the answer is yes, they do, because under  
16 State laws and under the practice of pharmacy as it is  
17 developed, if they know that there is, for a certain  
18 compound, a historical ordering pattern, a week --

19 QUESTION: Under your view of the case, it would  
20 be perfectly permissible for them, if they can anticipate  
21 a large volume of sales of a particularly tailor-made  
22 compound, they could store up a huge inventory and then  
23 market it later?

24 MR. HOFFMAN: No, Your Honor.

25 QUESTION: Why not?

1 MR. HOFFMAN: My concern is with the word, huge  
2 inventory. If the inventory is merely based upon a week,  
3 or --

4 QUESTION: It's based on a prediction of what  
5 the doctors will prescribe.

6 MR. HOFFMAN: Over the next week or two, yes.

7 QUESTION: Why is it limited to the next week or  
8 two?

9 MR. HOFFMAN: Mostly shelf life, and we don't  
10 know how long in advance this particular compound --

11 QUESTION: The shelf life of some of these drugs  
12 is only a week?

13 MR. HOFFMAN: No, we don't know that, but we  
14 don't want to go further than a week or 2 weeks for the  
15 sake of erring on the side of safety. We don't need to do  
16 that, we don't want to do that, and that's not what we do.  
17 I don't want to leave the impression we stockpile huge  
18 inventory amounts, because we don't. We just do enough  
19 where there's a series of patients that are now under that  
20 treatment to once compound it for that 1 or 2-week period  
21 if we know those kinds of refill orders are going to be  
22 coming back in again.

23 QUESTION: Let me ask you what's going to  
24 happen -- the Government for some reason did not raise on  
25 certiorari the issue of the severability of the

1 advertising provision, so if it is determined here that we  
2 should affirm the judgment below, and the cause is not  
3 severable, then do we go back to the old regime, which  
4 would allow no leeway for compounding?

5 MR. HOFFMAN: I'm sorry, it would allow what?

6 QUESTION: No leeway for compounding. Do we go  
7 back to a more limited regime for your clients, I assume?

8 MR. HOFFMAN: First, we will revert back to the  
9 pre-FDAMA area, whatever that was. The Government now  
10 maintains that this compounding practice, under all  
11 circumstances, as they say at page 18 of their opening  
12 brief, was always illegal. We strongly disagree with  
13 that. We also believe that it's not an issue before this  
14 case because it wasn't preserved, but to the extent the  
15 Court wants to know about it, there are innumerable  
16 provisions in both title 21, which clearly indicate that  
17 compounds are not new drugs. The Government itself  
18 acknowledges, even under FDAMA, it would not, and it is  
19 not able to submit compounds for pre-market approval,  
20 because of the extemporaneous numbers in which the need  
21 for them arises.

22 I really want to go back, if I may, to  
23 manufacturing versus compounding, and that we somehow  
24 confuse the fact that once a volume reaches a certain  
25 level, it's suddenly manufacturing and not compounding,

1 and that isn't the case at all, and let me explain why,  
2 and by the way, these are distinctions that are both  
3 covered in section 360(a)(1) -- at least one of them is --  
4 in title 21 of the United States Code, and also in the  
5 State statutes governing pharmacy, and regulating pharmacy  
6 of each of the several States.

7 QUESTION: Mr. Hoffman, in doing that, would you  
8 take into account what Mr. Kneedler told us this morning,  
9 because I put the question to him, what is the difference,  
10 and he said, the Government's position is, compounding is  
11 a form of making a new drug, that everything fits under  
12 the new drug, and that this section is designed to allow a  
13 limited kind of new drug-making. In other words, you are  
14 telling us that there are two categories, compounding and  
15 manufacturing. The Government is saying, there are new  
16 drugs and, by the grace of Congress, we're allowing some  
17 of those new drugs to escape the full process.

18 Now, you have told us in your brief that there's  
19 a bright line between compounding and manufacturing. In  
20 telling us what that bright line is, will you also say how  
21 you respond to the Government that says, we define  
22 everything as a new drug?

23 MR. HOFFMAN: And to address that, Your Honor,  
24 we turn to 21 United States Code, section 321(p)(1), which  
25 defines a new drug, and the Government talks about --

1 QUESTION: Where is that? Is that in the  
2 briefs?

3 MR. HOFFMAN: It's cited in the briefs.

4 QUESTION: Is it --

5 MR. HOFFMAN: It's referenced in the briefs.  
6 It's in Roman II of our response brief, 321(p)(1).

7 QUESTION: Is the text there, or just the  
8 citation?

9 MR. HOFFMAN: Just the reference. It's the  
10 citation. The text is not in the brief.

11 Mr. Kneedler has it. Where is it from? It's in  
12 section 5(a) of the petition. Thank you.

13 And Your Honor, on that, under that it says that  
14 new drugs need to be submitted for testing to be generally  
15 recognized for safety and efficacy. The Government  
16 acknowledges throughout, in all the pleadings in this  
17 case, in all the --

18 QUESTION: I'm sorry, it's not 5a of the  
19 petition. 5a of the --

20 MR. HOFFMAN: It's on page 5 -- I'm sorry, 85a.

21 QUESTION: 85a, thank you.

22 MR. HOFFMAN: And in that section it talks about  
23 submitting to the FDA for pre-market approval testing to  
24 determine safety and efficacy. Throughout, in the  
25 Government's briefs, the Government's briefs acknowledge

1     that that is not possible for compounds.  Compounds are  
2     incapable of being treated as new drugs, and that is  
3     because they appear so infrequently that you can't get a  
4     statistical data base to determine to the scientific  
5     certainty --

6             QUESTION:  I have difficulty with saying it's so  
7     infrequent, on the one hand, and you want to engage in  
8     national advertising on the other hand.

9             MR. HOFFMAN:  I'm sorry, Your Honor.

10            QUESTION:  You say it's so infrequently used,  
11     but then you say you want the right to advertise  
12     nationally.

13            MR. HOFFMAN:  Let us also talk about the  
14     national advertising that we allegedly do, and I don't --  
15     I think I will come back to respond to the Court's  
16     question.  I hope I do.

17            QUESTION:  You know, you say the national  
18     advertising that you allegedly do, well, there's an  
19     allegation in your complaint which I presume you don't  
20     really want to abandon, that advertising and promotion  
21     essential to do business in a market national in scope,  
22     and to inform physicians and patients of availability and  
23     benefits of the special class, specific classes and types  
24     of drugs the plaintiff compounds.

25            MR. HOFFMAN:  But the Government keeps asserting

1     that what we are advertising is finished products, and  
2     they try to impress upon the Court, which is absolutely  
3     untrue, that the finished product sits on shelves waiting  
4     to be shipped out in bulk to individuals or to middle  
5     people. That's just not what we do.

6             The advertising we do is to tell mostly the  
7     scientific community, nurses, medical care providers,  
8     mostly physicians, and at that special physicians --

9             QUESTION: Well, you say in your complaint, you  
10    add patients, too.

11            MR. HOFFMAN: And to patients, yes, that there  
12    are ingredients that are capable of being compounded, and  
13    then in working with the physician, a mixture of  
14    ingredients, together with the inactive ingredients, will  
15    be compounded into a delivery format that's best suitable  
16    for a patient, be it a suppository form, an injectable  
17    form, an oral form, a pill, a patch form, et cetera.

18            QUESTION: Mr. Hoffman, what you're telling us  
19    is something any doctor would know. Of course they know  
20    that things can be compounded and put in various forms.  
21    Doesn't your advertising get down to something pretty  
22    specific?

23            MR. HOFFMAN: It is specific in the ingredients  
24    that we list as being capable of being put into a compound  
25    suitable for a particular patient.



1           QUESTION: And don't you key it to a particular  
2 compound for a particular condition, or a particular kind  
3 of patient?

4           MR. HOFFMAN: It will lead to a particular  
5 compound in a particular dosage, worked out together  
6 between the pharmacist, the patient, and the physician --

7           QUESTION: All right. Isn't that, therefore,  
8 where your argument is weakest? You're arguing that  
9 there -- that compounding cannot be manufacturing, because  
10 compounding is essentially patient-specific. It is  
11 idiosyncratic in the sense that Mr. Kneedler used the term  
12 and yet, for your advertising to be of any value and,  
13 indeed, as you have just described the advertising, you're  
14 getting beyond specific patients. You're getting into  
15 classes of patients, and when you get into classes of  
16 patients, this neat distinction that you draw dissolves.

17          MR. HOFFMAN: We're getting into classes of  
18 drugs, and we're getting --

19          QUESTION: All right, classes of drugs and  
20 classes of drug-takers. It's the same point.

21          MR. HOFFMAN: And if there are classes of  
22 patients that require those classes of drugs, physicians  
23 do not know, always, what is available for their  
24 particular patient, and they have to --

25          QUESTION: That's -- I'm sure that's true --

1 MR. HOFFMAN: Correct.

2 QUESTION: -- and that's a different point, but  
3 I mean, this neat distinction between the, in effect, the  
4 mass manufacturer and purely idiosyncratic compounding  
5 just isn't a neat distinction.

6 MR. HOFFMAN: And we do not mass manufacture,  
7 and for some reason -- I apologize terribly that I'm not  
8 making that point, because let me explain what we do do.

9 QUESTION: Let me just say, my concern here is  
10 that you're telling us what the general practice of your  
11 particular client is. I thought what we were hearing was  
12 the legal question whether or not the Government may  
13 forbid you from advertising that you compound a specific  
14 drug, and it may be that that's not what you usually do.

15 MR. HOFFMAN: Correct.

16 QUESTION: But that's the question that we have  
17 before us, and if we affirm the judgment in your favor,  
18 you are going to be allowed to do advertising in a lot  
19 more specific ways than you now describe, and that's the  
20 legal issue we have to decide.

21 MR. HOFFMAN: That's correct, and given what the  
22 Government-asserted interests are, that is to protect  
23 public safety, through theoretically ineffective and  
24 unsafe drugs, then the ban on advertising doesn't do that  
25 at all. In fact, FDAMA had in it the laudable sections

1     which would have, in fact, been specifically addressed,  
2     which until the Ninth Circuit were still a part of FDAMA,  
3     only the advertising ban until then hadn't been held  
4     unconstitutional.

5             QUESTION: Well, but the advertising ban is  
6     surely devoted to keeping demand down, is it not?

7             MR. HOFFMAN: Well, it seems to be, that is  
8     correct, and that is a most inappropriate way to address  
9     demand, by withholding truthful information from patients  
10    and physicians who might benefit from that.

11            QUESTION: Well, why doesn't it specifically  
12    just -- what they say, I gather, it's one thing for a  
13    doctor, together with his patient, to understand the  
14    patient's allergy, or the hesitancy to swallow a pill, and  
15    say to the druggist, will you adjust this. They want to  
16    permit that.

17            What they don't want to permit is the kind of  
18    advertising which is a form of soliciting, which leads  
19    lots of patients, as I might -- or you might. Suppose  
20    they found something good for baldness, and suppose you  
21    could only do it through compounding, and I read that in  
22    the newspaper, I go to my doctor and I say, you know, the  
23    druggist over here, I saw it on the Internet, is there  
24    anything -- he says, is it safe? I guess so, I say,  
25    that's what it said on the Internet. He looks it up

1     there, and he prescribes that in reaction to what I want,  
2     rather than his thinking of it because of my special need.

3             Now, once that happens, they say, you will see  
4     widespread demand for certain drugs where there has been  
5     no double-blind study, there has been no normal testing,  
6     there's nothing here but the word of the pharmacist, and  
7     that is not sufficient to protect the public health and  
8     safety.

9             Now, you say that that advertising ban serves no  
10    purpose, they say, that's the purpose, so what's wrong  
11    with that argument?

12            MR. HOFFMAN:  There are many wrongs with that,  
13    and let me explain.  First of all, it denigrates the role  
14    of the pharmacist.  It assumes that there's not a dialogue  
15    that commences, for example, with the pharmacist.

16            QUESTION:  There's a dialogue, but what they  
17    haven't had is the double-blind test.

18            MR. HOFFMAN:  Correct.

19            QUESTION:  And Congress in this act says, we  
20    don't want dialogue.  We want double-blind studies before  
21    we let something go out into the marketplace, that's what  
22    they say, and that isn't here.

23            MR. HOFFMAN:  And the Government won't even  
24    change that, their intent of reducing volume theoretically  
25    is to protect widespread --

1           QUESTION: Oh, it's not quite reducing volume.  
2     It might be that there are 10 million children who have a  
3     hard time taking pills. It's to make certain that the  
4     demand initiates with the doctor and the patient, and the  
5     doctor recognizes the need of the patient, rather than a  
6     response to solicitation. That's the purpose, and it's  
7     not quite volume.

8           MR. HOFFMAN: Right, and at the end of the day,  
9     before any drug can be dispensed, the physician has to  
10    write a prescription, he has to approve it, and it makes  
11    no difference at which end of the spectrum it commences,  
12    because it always ends up with the physician.

13          QUESTION: It makes no difference. If that's  
14    true, why when I turn on the television set do I see  
15    advertisement after advertisement asking me to ask my  
16    doctor for -- and now, you fill in the blank -- if it  
17    makes no difference?

18          MR. HOFFMAN: What's the harm in the patient  
19    going to the physician?

20          QUESTION: The harm is that there are no double-  
21    blind studies for this particular test, and therefore,  
22    while we'll make an exception where the doctor initiates  
23    this together with the patient, we don't want Breyer and  
24    his friends seeing this on television and putting pressure  
25    on their doctors.

1           Now, that may sound a little vague, but what the  
2 Congress says, and what the FDA says, is that's necessary  
3 to protect the public health, and what they say is not  
4 without plausibility.

5           MR. HOFFMAN: There are innumerable  
6 opportunities to preserve and protect the public safety  
7 without resorting to First Amendment restriction.

8           QUESTION: Of course, the advertising man  
9 doesn't just apply that advertising to the general public.  
10 You cannot advertise to doctors, either.

11          MR. HOFFMAN: I did not hear, I'm sorry.

12          QUESTION: Does the advertising ban apply only  
13 to advertising to the general public? My understanding  
14 is, it applies to all advertising.

15          MR. HOFFMAN: And it's not just --

16          QUESTION: My understanding also is that most of  
17 your advertising does not go to the general public, but  
18 goes to the doctors and medical professionals.

19          MR. HOFFMAN: That is correct. First of all --

20          QUESTION: So it is not a matter of getting John  
21 Q. Public to put pressure on his doctor.

22          MR. HOFFMAN: And it is not just advertising.  
23 It is even the promotion and solicitation. As the lower  
24 court pointed out -- I think it was the Ninth Circuit, I  
25 forget which, where it did not find or understand the

1     rationale for why the patient or the doctor would have to  
2     ask the critical question, what's the best thing for this  
3     patient, or what's the best thing for me, because they  
4     would first have to ask the question.

5             And the whole concept of promotion and  
6     solicitation -- forget about just advertising.  
7     Advertising conjures up a specific type of sales provoking  
8     television ad, billboard ads, but pharmacists, as part of  
9     the canon of their ethics, is required as a professional,  
10    as part of the triad, who is not just a passive order-  
11    taker, who doesn't just count out and push pills, but a  
12    person who plays a scientific role in the context, he has  
13    to be able to on his own speak out and say, consistent  
14    with the canons of his professions, this is better for  
15    you. This is what the doctor brought in.

16            QUESTION: Well, but --

17            MR. HOFFMAN: I --

18            QUESTION: -- it's a little less chummy than you  
19    make it sound, I think, judging from your complaint. You  
20    have seven clients. They dispense in interstate commerce  
21    5 percent of their total sales, which amounts to 60 or 95  
22    percent of their total sales in another capacity, and you  
23    sell all over the country, do you not?

24            MR. HOFFMAN: We do.

25            QUESTION: Well, then, your portrait of the

1 intimate relationship between the pharmacist and the  
2 doctor I think is a little, perhaps, overblown.

3 MR. HOFFMAN: It is -- with all due respect,  
4 Your Honor, it is not, and let me explain why. We have  
5 the same patient profiles in our records, notwithstanding  
6 that there may be a half-a-country separating patient and  
7 pharmacist. We have 800 numbers that the patients call in  
8 on, just as you would call to a local pharmacist.

9 The only thing that is different is, there's a  
10 little bit more distance. It may take an extra day or  
11 half-day to get the prescription out there, but that  
12 intimacy in the relationship via the patient profiles, via  
13 the ability to consult, is the same with these pharmacists  
14 as it is with the corner druggist, if you will.

15 QUESTION: Mr. Hoffman, perhaps I've deflected  
16 you before, but you were going to tell us something about  
17 this bright line between what's a manufactured drug and  
18 what's a compounded drug.

19 MR. HOFFMAN: Yes, Your Honor.

20 QUESTION: So how do we tell whether one is a  
21 compound and whether it's a new drug?

22 MR. HOFFMAN: Under Federal statute, for  
23 example, manufacturing is defined as distribution to  
24 someone other than the ultimate consumer, and that's found  
25 in 21 United States Code, section 360(a)(1). 360(a)(1)



1 defines manufacturing as distribution to a middle man, or  
2 a distributor, or a wholesale -- wholesaler, so right  
3 away, the first distinction is the pharmacist only  
4 dispenses directly to the patient in the context of the  
5 triad. He's available for consultation, he gives  
6 directions on use, he has the patient profile on his  
7 records. He knows what drug interactions there may or may  
8 not be with this particular drug and this particular  
9 patient.

10 Second of all -- and, of course, the  
11 manufacturer doesn't do that, having no relationship with  
12 the physician, having no relationship with the patient.

13 In addition to that, they do, manufacturers do a  
14 one-size-fits-all type of product. They have determined  
15 that there is this vast, multimillion person individual  
16 need for a particular drug, and they fit that niche, and  
17 they play to it, and they market to it, and they  
18 manufacture for it, unlike --

19 QUESTION: The definition in 360(a)(1) applies  
20 equally to manufacturing and compounding.

21 QUESTION: And compounding, yes.

22 MR. HOFFMAN: I'm sorry.

23 QUESTION: The definition in 360(a)(1) is a  
24 definition of the term, manufacturing, preparation,  
25 propagation, compounding or processing.

1 MR. HOFFMAN: Then I may have --

2 QUESTION: It describes them in the same

3 definition.

4 MR. HOFFMAN: I may have mis-cited. Then it's

5 368, but it talks about manufacturing, and I apologize

6 that I don't have that number.

7 QUESTION: Oh, this talks about manufacturing,

8 but it also -- what it says is, manufacturing as well as

9 compounding shall include repackaging or otherwise

10 changing the container in furtherance of the distribution.

11 MR. HOFFMAN: Correct.

12 QUESTION: It has nothing to do with what we're

13 talking about here. What's the other section you

14 wanted --

15 MR. HOFFMAN: And the other section will be

16 section 374(a)(2).

17 QUESTION: 374(a)(2).

18 MR. HOFFMAN: 374 -- actually, it's 374(2), or

19 360(g)(2). They're identical.

20 QUESTION: Where do we find these?

21 MR. HOFFMAN: Your Honor, I'm sorry, I don't

22 have the reference cites here.

23 QUESTION: Well, I -- you know, I found --

24 QUESTION: 106(a).

25 MR. HOFFMAN: I'm sorry.

1 QUESTION: 106(a).

2 QUESTION: Well, can I turn to 321(p), which is

3 the other section --

4 MR. HOFFMAN: Yes, Your Honor.

5 QUESTION: -- you cited earlier, and you said

6 that that section makes clear that compounding --

7 QUESTION: What page are you on?

8 QUESTION: That's 85a of the Government's

9 petition. You said that 321(p) makes clear that

10 compounding is not manufacture of a new drug?

11 MR. HOFFMAN: No. What I said was, it defines

12 new drugs, and under a new drug, it has to be capable of

13 being submitted to the FDA's new drug process. The

14 Government --

15 QUESTION: You said more than it just defines

16 new drug. You said that that definition makes it clear

17 that compounding isn't included.

18 MR. HOFFMAN: No, but by --

19 QUESTION: And that that's why it's no problem

20 to you if we invalidate the whole statute and you go back

21 to the status quo ante, because you say compounding is not

22 a new drug anyway, right?

23 MR. HOFFMAN: That's correct.

24 QUESTION: That was the context in which it came

25 up.

1 MR. HOFFMAN: It is not a problem.

2 QUESTION: Okay.

3 MR. HOFFMAN: We would be delighted --

4 QUESTION: Now, what is it in that definition

5 that you think exempts compounding?

6 MR. HOFFMAN: Because it talks about drugs that

7 are capable of being submitted, and the Government itself

8 acknowledges that we cannot submit compounds for new drug

9 approval --

10 QUESTION: I don't see anything in the

11 definition that says -- I mean, we went through this in

12 the tobacco case. I thought that a new drug was any drug,

13 except grass.

14 MR. HOFFMAN: But how can it be a new drug that

15 cannot be tested?

16 QUESTION: I don't know. That's why I'm just

17 saying --

18 MR. HOFFMAN: Right.

19 QUESTION: -- that's what it says here, so if

20 there is some exception for some of these things --

21 MR. HOFFMAN: No.

22 QUESTION: I don't see it --

23 MR. HOFFMAN: I really think --

24 QUESTION: Where does it say capable of being

25 submitted? I -- where does it say capable of -- that's

1 not --

2 MR. HOFFMAN: But you have to read it into --  
3 the word -- it does not use the words, capable of. It  
4 says -- it says, has to be --

5 QUESTION: Will you read it verbatim, please,  
6 instead of just trying to conjure it up?

7 MR. HOFFMAN: It -- what I was referring to is,  
8 any drug which is not generally recognized among experts,  
9 qualified by science as safe and effective, the case law  
10 under that determines that in order to determine safety  
11 and efficacy, the drug has to be submitted to this  
12 exhaustive FDA free market approval process. The  
13 Government acknowledges that that costs hundreds of  
14 millions of dollars. It also requires, as case law  
15 identifies, a huge data base from which to be able to draw  
16 and determine the safety and effect -- efficacy, none of  
17 which can be done for --

18 QUESTION: That's why they want the exception.  
19 Of course you're right about that. They want the  
20 exception, but the issue before us concerns one part of  
21 the definition of the exception, and so I don't really see  
22 what you're talking about now has to do with that.

23 I mean the real issue, it seemed to me, was what  
24 we've been trying to get, which is the pros and cons of  
25 defining this exception a particular way.

1           MR. HOFFMAN:   Okay, because there would have  
2   been ways to make compounds safe and effective, and these  
3   ways would have been -- and they were in FDAMA until they  
4   were held not severable by the Ninth Circuits, and this  
5   was the use of ingredients that appear in the  
6   pharmacopeia. We took no quarrel with that. That seemed  
7   to be something that addressed the safety of the public.

8           It also required that the Secretary prepare some  
9   lists. One of them was, if there was an ingredient that  
10   was necessary for compounding, the Secretary could be  
11   petitioned -- I'm sorry, if there was an ingredient  
12   necessary that didn't appear in the pharmacopeia, the  
13   Secretary could be petitioned to put onto that list  
14   something that the Secretary would determine was safe and  
15   effective.

16           If there was something that was established that  
17   was not safe and effective for compounding, FDAMA included  
18   a list to be prepared by the Secretary to forbid these  
19   kinds of products to be used as ingredients in  
20   compounding. Compounding would have to be done by  
21   licensed physicians. It would have to be done by licensed  
22   pharmacists. These were all the conduct-specific related  
23   regulations that one would applaud, that Congress has a  
24   right to do.

25           But to try to reduce the demand, and try to keep

1 truthful information by restrictions on First Amendment  
2 is, this is what's offensive about that part of FDAMA. We  
3 didn't seek to have the conduct-related provisions  
4 stricken, and in fact it was the Government that it,  
5 itself put it in, then went to the Ninth Circuit and said,  
6 well, we can't have the First Amendment restriction, we  
7 don't want the others, either.

8 I also want to point out that when it comes to  
9 manufacturing, manufacturing, going back to Justice  
10 Ginsburg's question, we sell it retail, they sell it  
11 wholesale. We sell pursuant to a prescription. They sell  
12 just to a middle man distributor. We provide  
13 consultation. There is no consultation when it comes to a  
14 manufacturer.

15 There's also, on this issue of widespreadness,  
16 the degree, or the volume concern. First of all, we can  
17 only dispense, and we routinely only prepare upon receipt  
18 of a pharmacist's -- of a physician's prescription, but in  
19 addition to that, if volume were such a concern, there was  
20 unlimited intrastate transportation allowed, dispensing of  
21 pharmaceuticals, so I seriously question, for example,  
22 whether or not they even -- FDAMA even addressed  
23 adequately the volumes, the volume restrictions it was  
24 trying to impose.

25 Also, for example, positron emissions

1     compounding, and radiopharmaceutical compounding were  
2     exempted from the operation of FDAMA, so that potentially  
3     the most lethal, most dangerous of all the compounds could  
4     be advertised, promoted, solicited, and no pharmacopeia  
5     ingredients could have been used for them.

6             They also provided for industry transportation  
7     in the event of a memorandum of understanding. Up to 20  
8     percent of the total pharmaceutical sales by that pharmacy  
9     could be shipped intrastate, so that if, for example,  
10    there were five compounding pharmacists in a State, they  
11    could fill 100 percent of the outside -- of the out-of-  
12    State demand, so at the end of the day, as in Greater New  
13    Orleans, this case -- I'm sorry, this statute was so  
14    riddled with exemptions -- with exceptions that undermined  
15    the Government's own very purpose, that it would fail just  
16    because it was simply irrational.

17            As the Court pointed out already, it is  
18    irrational to suggest that only speech that's provoked by  
19    the physician can be unregulated, whereas the same speech  
20    in the context of a professional relationship as provoked  
21    by the pharmacist, then somehow it becomes  
22    unconstitutional.

23            In the lower court we pointed out the following.  
24    That means under this statute a pharmacist would have to  
25    have a little sign on his counter. On this little sign it



1 would say, please ask me to tell you what I think you  
2 should know, but because of FDAMA, I, under restrictions  
3 on advertising, promotion, solicitation, am forbidden from  
4 telling you.

5 If there are no further questions, I shall  
6 conclude.

7 QUESTION: Thank you, Mr. Hoffman.

8 Mr. Kneedler, you have 3 minutes remaining.

9 REBUTTAL ARGUMENT OF EDWIN S. KNEEDLER

10 ON BEHALF OF THE PETITIONERS

11 MR. KNEEDLER: Mr. Chief Justice, what Congress  
12 was trying to do here was to make sure that the narrow  
13 exemption that it intended did not swallow the critical  
14 general rule that new drugs have to be submitted to prior  
15 approval.

16 The question of volume limitations has been  
17 raised. The act contains an aggregate volume limitation  
18 but, as I mentioned, individual drug-by-drug volume  
19 limitations would be very difficult to administer, and  
20 Congress was not required to go down that path, but an  
21 additional point about that is that if you look -- if you  
22 add up a couple of prescriptions by each pharmacy, Nation-  
23 wide you will be talking about a pretty large volume of a  
24 new drug, which is precisely the sort of thing that should  
25 be submitted to the FDA for prior approval.

1           The act does not just prohibit manufacturing new  
2 drugs, it prohibits the introduction in interstate  
3 commerce of new drugs. It isn't just focused on large  
4 volumes, it's focused on individual instances. So are the  
5 misbranding and adulteration provisions of the act.

6           The line Congress drew here that includes  
7 solicitation and advertising among the conditions was not  
8 invented in 1997. In case law it goes all the way back to  
9 1978 in the Cedars case we mentioned in the brief, where  
10 the Court there was trying to define the scope of the  
11 express exemption for pharmacy in registration and  
12 inspections, and among the factors it says when someone  
13 steps out of the traditional pharmacy role was, do they  
14 engage in promotion of the product.

15           The definition also appears in the Model Rules  
16 of Good Pharmacy Practice of the State of the National  
17 Association of State Boards of Pharmacy, which says that  
18 pharmacists should not solicit or advertise compounded  
19 drugs.

20           All of this represents a general understanding  
21 that compounding by pharmacists has to be contemporaneous  
22 and responsive --

23           QUESTION: How does the doctor find out -- how  
24 does the doctor find out that -- he knows that Joe Smith  
25 the pharmacist deals with compounding generally. He

1 thinks that this patient might use the compounded drug.  
2 How does he know that this particular drug can be  
3 compounded?

4 MR. KNEEDLER: That's what he is supposed --

5 QUESTION: How does he find that out?

6 MR. KNEEDLER: The pharmacist holds himself out  
7 as having pharmacy services and expertise, and that's  
8 where the promotion of the consultation and the  
9 professional relationship --

10 QUESTION: No, no, but does he have to call the  
11 pharmacy --

12 MR. KNEEDLER: No. The pharmacist can advertise  
13 that he engages in the pharmacy services.

14 QUESTION: Take my question. My question is not  
15 whether this pharmacist engages in compounding. We know  
16 it. How does the doctor know that the pharmacist can  
17 compound this drug?

18 MR. KNEEDLER: He has to ask.

19 Under respondent's theory, a pharmacist, someone  
20 holding a pharmacist license presumably could promote  
21 Laetrile, or could promote Prozac and advertise it to the  
22 market at large, and Congress certainly did not expect  
23 that sort of thing.

24 CHIEF JUSTICE REHNQUIST: Thank you, Mr.  
25 Kneedler. The case is submitted.

1                   (Whereupon, at 11:10 a.m., the case in the  
2 above-entitled matter was submitted.)  
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