IN THE SUPREME COURT OF THE UNITED STATES

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TOMMY G. THOMPSON, :

SECRETARY OF HEALTH AND HUMAN :

SERVICES, ET AL., :

Petitioners :

v. : No. 01-344

WESTERN STATES MEDICAL CENTER, :

ET AL. :

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Washington, D.C.

Tuesday, February 26, 2002

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

APPEARANCES:

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

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

C O N T E N T S

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

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

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

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

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

QUESTION: Well, I could tell that.

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

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

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

MR. KNEEDLER: Yes.

QUESTION: They're not a corner --

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

QUESTION: Exactly.

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

pharmacist, the physician, and the patient.

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

MR. KNEEDLER: Well --

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

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

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

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

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

MR. KNEEDLER: Yes, but --

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

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

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

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

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

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

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

diluted, pharmacist-diluted, is that manufacturing?

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

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

doctor in compounding a particular drug.

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

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

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

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

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

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

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

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

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

MR. KNEEDLER: Yes.

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

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

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

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

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

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

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

MR. KNEEDLER: That's exactly right.

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

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

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

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

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

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

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

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

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

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

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

MR. KNEEDLER: Well --

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

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

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

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

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

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

MR. KNEEDLER: That's correct.

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

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

absolutely prohibited.

QUESTION: Right.

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

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

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

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

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

MR. KNEEDLER: This case --

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

MR. KNEEDLER: Well --

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

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

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

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

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

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

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

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

make any sense?

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

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

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

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

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

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

QUESTION: Then have a narrower volume restriction.

MR. KNEEDLER: But a drug that --

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

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

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

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

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

MR. KNEEDLER: Well, under --

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

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

If I could reserve the balance of my time.

QUESTION: Very well, Mr. Kneedler.

MR. KNEEDLER: Thank you.

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

ORAL ARGUMENT OF HOWARD M. HOFFMAN

ON BEHALF OF THE RESPONDENTS

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

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

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

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

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

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

QUESTION: May I ask -- you have large companies

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

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

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

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

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

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

MR. HOFFMAN: No, Your Honor.

QUESTION: Why not?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

QUESTION: Is it --

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

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

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

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

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

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

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

QUESTION: 85a, thank you.

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

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

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

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

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

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

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

MR. HOFFMAN: But the Government keeps asserting

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

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

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

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

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

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

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

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

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

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

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

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

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

MR. HOFFMAN: Correct.

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

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

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

MR. HOFFMAN: Correct.

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

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

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

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

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

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

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

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

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

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

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

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

MR. HOFFMAN: Correct.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

QUESTION: Well, but --

MR. HOFFMAN: I --

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

MR. HOFFMAN: We do.

QUESTION: Well, then, your portrait of the

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

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

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

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

MR. HOFFMAN: Yes, Your Honor.

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

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

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

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

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

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

QUESTION: And compounding, yes.

MR. HOFFMAN: I'm sorry.

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

MR. HOFFMAN: Then I may have --
QUESTION: It describes them in the same definition.
MR. HOFFMAN: I may have mis-cited. Then it's 368, but it talks about manufacturing, and I apologize that I don't have that number.
QUESTION: Oh, this talks about manufacturing, but it also -- what it says is, manufacturing as well as compounding shall include repackaging or otherwise changing the container in furtherance of the distribution.
MR. HOFFMAN: Correct.
QUESTION: It has nothing to do with what we're talking about here. What's the other section you wanted --
MR. HOFFMAN: And the other section will be section 374(a)(2).
QUESTION: 374(a)(2).
MR. HOFFMAN: 374 -- actually, it's 374(2), or 360(g)(2). They're identical.
QUESTION: Where do we find these?
MR. HOFFMAN: Your Honor, I'm sorry, I don't have the reference cites here.
QUESTION: Well, I -- you know, I found --
QUESTION: 106(a).
MR. HOFFMAN: I'm sorry.

QUESTION: 106(a).
QUESTION: Well, can I turn to 321(p), which is the other section --
MR. HOFFMAN: Yes, Your Honor.
QUESTION: -- you cited earlier, and you said that that section makes clear that compounding --
QUESTION: What page are you on?
QUESTION: That's 85a of the Government's petition. You said that 321(p) makes clear that compounding is not manufacture of a new drug?
MR. HOFFMAN: No. What I said was, it defines new drugs, and under a new drug, it has to be capable of being submitted to the FDA's new drug process. The Government --
QUESTION: You said more than it just defines new drug. You said that that definition makes it clear that compounding isn't included.
MR. HOFFMAN: No, but by --
QUESTION: And that that's why it's no problem to you if we invalidate the whole statute and you go back to the status quo ante, because you say compounding is not a new drug anyway, right?
MR. HOFFMAN: That's correct.
QUESTION: That was the context in which it came up.

MR. HOFFMAN: It is not a problem.
QUESTION: Okay.
MR. HOFFMAN: We would be delighted --
QUESTION: Now, what is it in that definition that you think exempts compounding?
MR. HOFFMAN: Because it talks about drugs that are capable of being submitted, and the Government itself acknowledges that we cannot submit compounds for new drug approval --
QUESTION: I don't see anything in the definition that says -- I mean, we went through this in the tobacco case. I thought that a new drug was any drug, except grass.
MR. HOFFMAN: But how can it be a new drug that cannot be tested?
QUESTION: I don't know. That's why I'm just saying --
MR. HOFFMAN: Right.
QUESTION: -- that's what it says here, so if there is some exception for some of these things --
MR. HOFFMAN: No.
QUESTION: I don't see it --
MR. HOFFMAN: I really think --
QUESTION: Where does it say capable of being submitted? I -- where does it say capable of -- that's

not --

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

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

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

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

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

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

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

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

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

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

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

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

Also, for example, positron emissions

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

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

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

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

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

If there are no further questions, I shall conclude.

QUESTION: Thank you, Mr. Hoffman.

Mr. Kneedler, you have 3 minutes remaining.

REBUTTAL ARGUMENT OF EDWIN S. KNEEDLER

ON BEHALF OF THE PETITIONERS

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

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

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

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

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

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

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

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

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

QUESTION: How does he find that out?

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

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

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

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

MR. KNEEDLER: He has to ask.

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

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

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