FOR PUBLICATION

UNITED STATES COURT OF APPEALS

FOR THE NINTH CIRCUIT

WESTERN STATES MEDICAL CENTER, a Nevada corporation; WOMEN'S INTERNATIONAL PHARMACY, a Wisconsin corporation; HEALTH PHARMACY, a Wisconsin corporation; APOTHECURE, a Texas corporation; COLLEGE PHARMACY, a Colorado corporation; LAKESIDE PHARMACY, a Tennessee

corporation; WEDGEWOOD VILLAGE

PHARMACY, a New Jersey

corporation,

Plaintiffs-Appellees,

v.

DONNA E. SHALALA, in her official capacity as Secretary, United States Department of Health and Human Services; JANE E. HENNEY, M.D., in her official capacity as Commissioner,
Defendants-Appellants.

No. 99-17424

D.C. No.

CV-98-01650-

DAE(RLH)

OPINION

Appeal from the United States District Court

for the District of Nevada

David A. Ezra, District Judge, Presiding

Argued and Submitted
December 12, 2000--San Francisco, California

Filed February 6, 2001

Before: Mary M. Schroeder, Chief Judge,
Cynthia Holcomb Hall, and William A. Fletcher,
Circuit Judges.

Opinion by Judge Hall

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COUNSEL

Peter J. Smith, Civil Division, Department of Justice, Washington, D.C., for the defendants-appellants.

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Michael S. Labson, Covington & Burling, Washington, D.C., for the amicus.

OPINION

HALL, Circuit Judge:

This appeal requires us to assess the constitutionality of two subsections of the Food and Drug Administration Modernization Act of 1997 ("FDAMA"), 21 U.S.C.§ 353a. Subsections §§ 353a(a) and (c) of FDAMA prohibit drug providers from promoting or advertising particular compounded drugs. In return, the providers are exempted from the standard drug approval requirements imposed by the Food and Drug Administration. Plaintiffs seek to enjoin the enforcement of these subsections, contending that they violate the First Amendment's guarantee of free speech. The district court agreed with Plaintiffs and granted their motion for summary judgment in a published opinion. See Western States Medical Ctr. v. Shalala, 69 F. Supp.2d 1288 (D. Nev. 1999).

The district court exercised jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1361. We have jurisdiction over this appeal pursuant to 28 U.S.C. § 1291.

I

Plaintiffs are a group of licensed pharmacies. They have prepared written promotional materials that they distribute by mail and at medical conferences to inform patients and physicians of the uses and effectiveness of specific compounded drugs. "Compounding" is a process in which a pharmacist mixes ingredients to create a medication for an individual patient. Compounding is typically used to prepare medica-

tions that are not commercially available, such as a medication for a patient who is allergic to an ingredient in a mass-produced product. Pharmacists can provide compounded drugs to individual patients only upon receipt of a valid prescription. See 21 U.S.C. § 353a(a).

The Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301-397, regulates drug manufacturing, marketing, and distribution. It invests the Food and Drug Administration ("FDA") with enforcement powers to make sure that the regulations are followed. In 1997, Congress amended the FDCA to exempt compounding from certain requirements of the FDCA, but only if the compounding pharmacies followed several conditions, including refraining from promoting particular compounded drugs. The new legislation sets out several restrictions on compounding including prohibitions on advertisements, like those of the Plaintiffs, that promote particular compounded drugs. See 21 U.S.C.§§ 353a(a) and (c).**1** Pharmacists may, however, inform the public that they offer general compounding services. See 21 U.S.C.§ 353a(c).

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1 The statutes provide:

> [Some FDCA requirements do not] apply to a drug product if the drug product is compounded for an identified individual patient based on the unsolicited receipt of a valid prescription order or a notation, approved by the prescribing practitioner, on the prescription order that a compounded product is necessary for the identified patient . . . .

21 U.S.C. § 353a(a).

> A drug may be compounded under subsection (a) of this section only if the pharmacy, licensed pharmacist, or licensed physician does not advertise or promote the compounding of any particular drug, class of drug, or type of drug. The pharmacy, licensed pharmacist, or licensed physician may advertise and promote the compounding service provided by the licensed pharmacist or licensed physician.

21 U.S.C. 353a(c).

Plaintiffs challenged FDAMA's advertising and solicitation restrictions in district court. They contended that the restrictions violate the Free Speech Clause of the First Amendment. In a well-reasoned opinion, the district court granted Plaintiff's motion for summary judgment, holding that the restrictions do not meet the test for acceptable government regulation of commercial speech set forth in Central Hudson Gas & Electric Corp. v. Public Service Commission , 447 U.S. 557, 566 (1980). The district court also held that the unconstitutional provisions were severable from the rest of FDAMA. This Court reviews the district court's grant of summary judgment de novo. See Gutowsky v. County of Placer , 108 F.3d 256, 259 (9th Cir. 1997). "The evidence must be viewed in the light most favorable to the nonmoving party to determine whether there are any genuine issues of material fact for trial, and whether the district court correctly applied the relevant substantive law." Federal Deposit Ins. Corp. v. O'Melveny & Meyers, 969 F.2d 744, 747 (9th Cir. 1992).

II

In Central Hudson, the Supreme Court set out a four-part test for determining the constitutionality of a government restriction on commercial speech. The court must determine whether: 1) the regulated speech is misleading or concerns unlawful activity; 2) the government has asserted a"substantial" interest in restricting the speech; 3) the government has demonstrated that the regulation "directly advances" the asserted interest; and 4) the restriction is not more extensive than necessary to achieve the asserted governmental interest. See Central Hudson, 447 U.S. at 566. Although the government has asserted substantial interests, they have failed to demonstrate that the speech restrictions directly advance those interests or that they are narrowly tailored to those interests.

A

The First Amendment does not protect commercial speech that is "inherently misleading" or concerns unlawful

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activity. See id. at 563-64. On appeal, the government does not contend that the prohibited speech is unlawful or misleading, and there is no indication in the record that Plaintiffs' advertisements are untruthful. Therefore, the restricted speech must be evaluated according to the other three Central Hudson factors.

B

Under the second part of the Central Hudson test, the speech restriction must serve a "substantial" government interest. In the district court, the government argued that the challenged restrictions served three substantial interests: 1) protecting the public health and safety; 2) preserving the integrity of the drug approval process; and 3) balancing the need to preserve drug compounding for individual patients with particularized needs while preventing widespread distribution of compounded drugs. The district court determined that the first two interests were substantial and satisfied the second prong of the Central Hudson test. Because "the Government has a significant interest in protecting the health, safety, and welfare of its citizens," we agree that the first two interests are substantial. Rubin v. Coors Brewing Co., 514 U.S. 476, 485 (1995).

The third asserted interest was "insufficiently clear" to the district court. Western States, 69 F. Supp.2d at 1303. The court reasoned that for an interest in balancing competing goals to be substantial, the goals themselves must be substantial. See id. at 1302. The court agreed that the goal of ensuring the continued availability of compounded drugs to individual patients was a substantial concern, but was not convinced that the government had a substantial interest in preventing widespread compounding. It held that if the government could not offer an adequate rationale for its goal of preventing widespread distribution of compounded drugs, then the government did not have a substantial interest in balancing this

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concern with the need for continued access to such drugs. See

id. at 1302-03.

The government's effort to balance competing goals can be a substantial interest worthy of government protection. See United States v. Edge Broadcasting Co., 509 U.S. 418, 428 (1993) (holding that the "congressional policy of balancing the interests of lottery and nonlottery States is the substantial government interest that satisfies Central Hudson"). But the government must supply a compelling argument or convincing evidence that it has a substantial interest in achieving both goals. The government cannot carry its burden by"mere speculation or conjecture." Edenfield v. Fane, 507 U.S. 761, 770-71 (1993); cf. Florida Bar v. Went For It, Inc. , 515 U.S. 618, 624 (1995) (crediting the state's interest as substantial on the basis of a two-year study containing statistical and anecdotal evidence).

We agree with the district court that the government has not met its burden. There is insufficient evidence in the record to conclude that the government has a substantial interest in preventing widespread compounding. The government asserts that increased distribution of compounded drugs is dangerous because of the health risks associated with large numbers of patients taking such drugs. The government neither explains nor supports this contention. In fact, most of the evidence runs to the contrary. Compounding is not only legal under state law, but most states require their pharmacists to know how to compound. See Sen. Rep. No. 105-43, at 64 (1997). The government has failed to show that its interest in striking a balance between ensuring compounding availability and limiting widespread compounding is substantial. The only substantial interests asserted by the government are protecting the public's health and preserving the integrity of the drug approval process.

C

Under the third Central Hudson factor, the speech regulation must "directly advance" the government interest. In

essence, the government argues that the speech restrictions are necessary to prevent an increase in the demand for compounded drugs that would be injurious to the public health. But the government's argument falls short of what is required to show that the speech restrictions will protect the public.

The government has not offered evidence or arguments to explain sufficiently why such restrictions will reduce the type of consumption of compounded drugs that is harmful, and even admits that it has a substantial interest in ensuring the availability of compounded drugs.

The government bears the burden of showing that its regulation will advance its interest "to a material degree." See 44 Liquormart, Inc. v. Rhode Island, 517 U.S. 484, 505 (1996). In 44 Liquormart, the Supreme Court held that a state statute prohibiting advertisement of liquor prices violated the First Amendment. The Court agreed with the State that "common sense supports the conclusion that a prohibition against price advertising . . . will tend to mitigate competition and maintain prices at a higher level than would prevail in a completely free market." Id. at 505. But the Court disagreed with the State's argument that the prohibition would advance the State's interest in promoting temperance and reducing demand "to a material degree." The Court explained that it required evidentiary support for such an argument, not mere speculation. See id. "Such speculation certainly does not suffice when the State takes aim at accurate commercial information for paternalistic ends." Id. at 507. Similarly, the government in this case contends that § 353a's speech restrictions will keep the demand for particular compounded drugs artificially low, and thereby protect unwary consumers. The government offers no evidence demonstrating that its restrictions would succeed in striking the balance it claims is a substantial interest, or even would protect the public health.

Without the advertising restrictions, other safeguards exist to protect the public. No compounded drug may be dispensed without a valid prescription from a licensed physician

to an individual patient. See § 353a(a). FDAMA sets out specific requirements for the substances that can be used by the pharmacist to fashion a compounded drug. See§ 353a(b)(1). A pharmacist cannot regularly compound drugs that are essentially copies of a commercially available drug product. See § 353a(b)(1)(D).

In addition, FDAMA is so riddled with exceptions that it is unlikely that the speech restrictions would actually succeed in depressing the volume of compounded drugs. The exceptions also demonstrate that the restrictions do not

directly advance the government's interest in maintaining the integrity of the drug approval process. Under the statute, pharmacists can advertise their compounding services and promote their skills at medical trade events so long as they do not promote the compounding of any particular drug. It seems obvious that advertising that informs physicians that a pharmacy is available to compound drugs is likely to increase demand for compounding. Moreover, even with the ban on specific advertising, FDAMA provides significant incentives for pharmacies to increase their drug compounding business. The statute allows compounded drugs to constitute up to five percent of a pharmacy's interstate drug distributions and 100 percent of its intrastate drug distributions. If a pharmacy has a Memorandum of Understanding with the Secretary of Health and Human Services, up to twenty percent of its interstate drug distributions can be in the form of compounded drugs. See § 353a(b)(3). Under FDAMA, a pharmacist can call a physician and recommend a drug compound when a patient comes in with a prescription for a commercial drug and provides information to the pharmacist that indicates that the patient might require a compounded product. When exemptions and inconsistencies counteract the alleged purpose of a speech restriction, the restriction fails the direct advancement test. See Greater New Orleans Broadcasting Ass'n, 527 U.S. 173, 190 (1999); Rubin, 514 U.S. at 488-89 (1995).

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D

Finally, the speech restrictions fail the fourth Central Hudson factor; they are more extensive than necessary to achieve the asserted government interest. If clear alternatives exist that can advance the government's asserted interest in a manner far less intrusive to the pharmacists' free speech rights, then the restrictions are invalid. See Coors Brewing, 514 U.S. at 490-91; Project 80's, Inc. v. City of Pocatello, 942 F.2d 635, 637 (9th Cir. 1991). The district court proposed either disclaimers on compounded drugs explaining that they had not been subject to FDA approval or a full-blown safety review like that imposed on manufactured drugs as alternatives that would be far less intrusive to free speech. See Western States, 69 F. Supp.2d at 1308-09. Disclaimers would satisfy the government's substantial interest in preventing consumers from being misled into taking unsafe drugs. Full-scale FDA review of compounded drugs would satisfy the

government's interest in protecting the public health and serve as a much more precise way of preserving the integrity of the drug approval process. See Project 80's, 942 F.2d at 638 (stating that where there are "far less restrictive and more precise means" to achieve the desired end, the speech restriction is more extensive than necessary and fails the fourth Central Hudson factor.)

The government contends that the district court's suggested alternatives are useless since they do not address the government's substantial interest in balancing the availability of compounded drugs with the need to limit their widespread "manufacture." But the district court's alternatives are viable because the government's interest in balancing two competing goals failed to meet the second prong of Central Hudson. The alternatives do offer credible solutions for the government's substantial interests in safeguarding the public health and maintaining the integrity of the drug approval process.

Even if the district court had not proposed compelling alternatives and the government had marshaled sufficient evidence

to show that compounded drugs are dangerous and their volume should be limited, prohibitions on truthful speech are still strongly disfavored. "We have never held that commercial speech may be suppressed in order to further the State's interest in discouraging purchases of the underlying product that is advertised." Central Hudson, 447 U.S. at 574 (Blackmun, J., concurring). In 44 Liquormart, the Court explained:

> Precisely because bans against truthful, nonmisleading commercial speech rarely seek to protect consumers from deception or overreaching, they usually rest solely on the offensive assumption that the public will respond "irrationally" to the truth. The First Amendment directs us to be especially skeptical of regulations that seek to keep people in the dark for what the government perceives to be their own good.

517 U.S. at 503. Government prohibitions of truthful commercial messages are "particularly dangerous" and deserve "rigorous review." Id. at 501. The government has failed to support adequately its assertion that lower demand for compounded drugs will protect the public. Workable alternatives

to the speech restrictions exist. Therefore, FDAMA's speech restrictions are more extensive than necessary.

III

Sections 353a(a) and (c) cannot be severed from the rest of FDAMA unless Congress would have enacted the constitutional provisions of FDAMA absent the unconstitutional provisions. See Alaska Airlines v. Brock, 480 U.S. 678, 685 (1987); Board of Natural Resources v. Brown, 992 F.2d 937, 948 (9th Cir. 1993). A statute's unconstitutional provisions are not severable if the entire statute is designed to strike a balance between competing interests. See United States v. Spokane Tribe of Indians, 139 F.3d 1297, 1301 (9th Cir. 1998). FDAMA's legislative history demonstrates that Con-

gress intended to provide access to compounded drugs while preventing pharmacies from making an end run around the FDA's drug manufacturing requirements.

The first legislative proposal to address pharmacy compounding appeared in the House of Representatives in 1996. That bill would have exempted pharmacy compounding from FDCA requirements without restrictions on advertising specific compounded products. See H.R. 3199, 104th Cong. § 18 (Apr. 30, 1996). FDA Commissioner David Kessler expressed concern with the bill's lack of safeguards, and the possibility of a massive increase in the number of drugs available that did not meet FDA standards:

> The [bill] has no constraints on the volume of compounding. It is likely to encourage large-scale manufacturing under the guise of pharmacy compounding. It would allow bulk drug suppliers or drug manufacturers to circumvent the approval requirements of the Act by shipping bulk drug substances to pharmacies for reconstituting or other processing. A shadow industry of unapproved generic drugs is likely to develop. Moreover, the exemptions would allow potentially dangerous compounding.

FDA Reform Legislation: Hearings Before the Subcomm. on Health and Environ. of the House Comm. on Commerce , 104th Cong. 31, 125 (May 1 and 2, 1996) (statement of Hon. David A. Kessler).

Subsequent versions of the legislation responded to the FDA Commissioner's concerns. The new House bill provided that the compounded products would be exempt from FDCA requirements only if the compounding pharmacist"does no more than advertise or otherwise promote the compounding service and does not advertise or otherwise promote the compounding of a particular drug or device." H.R. 1411, 105th Cong. § 17 (Apr. 23, 1997). A similar Senate bill tied exemp-

tion from FDCA requirements to a prohibition on advertising particular compounded drugs. See S. 830, 105th Cong., § 809 (July 1, 1997).

Evidence in the legislative record interpreting the final legislation demonstrates that Congress meant to exempt compounding pharmacists from FDCA requirements only in return for a prohibition on the promotion of specific compounded drugs. A House report explained that FDAMA was designed to "ensure continued availability of compounded drug products as a component of individualized drug therapy, while limiting the scope of compounding so as to prevent manufacturing under the guise of compounding." H.R. Conf. Rep. No. 105-399. Senator Kennedy noted that "some of [FDAMA's] conditions are intended to ensure that the volume of compounding does not approach that ordinarily associated with drug manufacturing." 143 Cong. Rec. S9840 (Daily ed. Sept. 24, 1997). The President's comments upon signing FDAMA into law reflect a concern with striking a balance between compounding and manufacturing: "The Act will also resolve the issue of pharmacy compounding--the process of making customized medicines--so that legitimate pharmacy compounding is allowed, while the manufacture of unapproved drugs is not." Statement on Signing the Food and Drug Administration Modernization Act of 1997, 33 Weekly Comp. Pres. Doc. 1885 (Nov. 21, 1997). Given these statements and the decision by both houses of Congress to add specific provisions to address the advertising or promotion of compounded products, we believe that Congress would not have passed FDAMA absent the restrictions on commercial speech.

The existence of a severability clause at § 1391 of the FDCA does not change our interpretation of the legislative history.**2** It is true that the presence of a severability clause

2 The clause reads:

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creates a presumption that Congress did not intend for the validity of a statute to depend on the survival of its constitutionally offensive provisions. See Alaska Airlines v. Brock, 480 U.S. 678, 686 (1987). But that presumption is not conclusive. See id. Because Congress approved this severability clause before FDAMA's passage, it is less compelling evidence of legislative intent than a clause enacted simultaneously with FDAMA. Congress may have intended the original provisions of the FDCA to be severable, but meant for FDAMA's provisions to stand or fall together. Given the evidence in the legislative history of Congress's desire to facilitate drug compounding while not allowing for widespread creation of drugs that have not been FDA approved, the FDCA's severability clause is not persuasive.

IV

Thus, we hold that § 353a(a) and § 353a(c)'s restrictions on commercial speech violate the First Amendment. These provisions may not be severed from the rest of the provisions in § 353a. Accordingly, § 353a is invalid in its entirety.

AFFIRMED IN PART, REVERSED IN PART.

> If any provision of this Act is declared unconstitutional, or the applicability thereof to any person or circumstance is held invalid, the constitutionality of the remainder of the Act and the applicability thereof to other persons and circumstances shall not be affected thereby.

21 U.S.C. § 391.

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