THOMPSON V. WESTERN STATES MEDICAL CENTER

Supreme Court of the United States, 2002
535 U.S. 357, 122 S.Ct. 1497, 152 L.Ed.2d 563
http://laws.findlaw.com/us/000/01-344.html

FACTS Drug compounding is a process by which a pharmacist or doctor combines, mixes, or alters ingredients to create a medication tailored to the needs of an individual patient. Compounding is typically used to prepare medications that are not commercially available, such as medication for a patient who is allergic to an ingredient in a mass-produced product.

The Federal Food, Drug, and Cosmetic Act of 1938 (FDCA) regulates drug manufacturing, marketing, and distribution, providing that no person may sell any new drug unless approved by the Food and Drug Administration (FDA). The Food and Drug Administration Modernization Act of 1997 (FDAMA), which amends the FDCA, exempts compounded drugs from the FDCA's requirements provided the drugs satisfy a number of restrictions, including that the prescription must be "unsolicited," and the provider compounding the drug may "not advertise or promote the compounding of any particular drug, class of drug, or type of drug." The provider may, however, "advertise and promote the compounding service."

The plaintiffs are a group of licensed pharmacies that specialize in drug compounding. They filed a complaint in the United States District Court for the District of Nevada, arguing that the Act's requirement that they refrain from advertising and promoting their products if they wish to continue compounding violates the Free Speech Clause of the First Amendment. The District Court agreed with the plaintiffs and granted their motion for summary judgment, holding that the provisions do not meet the test for acceptable government regulation of commercial speech set forth in *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n of N. Y.* The Court of Appeals for the Ninth Circuit affirmed in relevant part agreeing that the provisions regarding advertisement and promotion are unconstitutional.

DECISION Judgment affirmed.

OPINION The parties agree that the advertising and soliciting prohibited by the FDAMA constitute commercial speech. Commercial speech receives First Amendment protection, because "It is a matter of public interest that [economic] decisions, in the aggregate, be intelligent and well-informed. To this end, the free flow of commercial information is indispensable." Although the First Amendment protects commercial speech, not all regulation of such speech is unconstitutional.

Central Hudson articulated a test for determining whether a particular commercial speech regulation is constitutionally permissible. Under that test a threshold matter is whether the commercial speech concerns unlawful activity or is misleading. If so, then the speech is not protected by the First Amendment. If the speech concerns lawful activity and is not misleading, however, the next question is "whether the asserted governmental interest is substantial." If it is, then the courts "determine whether the regulation directly advances the governmental interest asserted," and, finally, "whether it is not more extensive than is necessary to serve that interest." Each of these latter three inquiries must be answered in the affirmative for the regulation to be found constitutional.

The Government asserted that three substantial interests underlie the FDAMA. The first is an interest in "preserving the effectiveness and integrity of the FDCA's new drug approval process and the protection of the public health that it provides." The second is an interest in "preserving the availability of compounded drugs for those individual patients who, for particularized medical reasons, cannot use commercially available products that have been approved by the FDA." Finally, the Government argued that "achieving the proper balance between those two independently compelling but competing interests is itself a substantial governmental interest."

The Government needs to be able to draw a line between small-scale compounding and large-scale drug manufacturing. That line must distinguish compounded drugs produced on such a small scale that they could not undergo safety and efficacy testing from drugs produced and sold on a large enough scale that they could undergo such testing and therefore must do so. The Government argued that the FDAMA's speech-related provisions "directly advance the governmental interests asserted." Those provisions use advertising as the trigger for requiring FDA approval—essentially, as long as pharmacists do not advertise particular compounded drugs, they may sell compounded drugs without first undergoing safety and efficacy testing and obtaining FDA approval. If they advertise their compounded drugs, however, FDA approval is required.

Assuming it is true that drugs cannot be marketed on a large scale without advertising, the FDAMA's prohibition on advertising compounded drugs might indeed "directly advance" the Government's interests. Even assuming that it does, however, the Government has failed to demonstrate that the speech restrictions are "not more extensive than is necessary to serve [those] interests." In addressing this final prong of the *Central Hudson* test, previous cases have made clear that if the Government could achieve its interests in a manner that does not restrict speech, or that restricts less speech, the Government must do so.

Several non-speech-related means of drawing a line between compounding and large-scale manufacturing might be possible here. First, it seems that the Government could use the very factors the FDA relied on to distinguish compounding from manufacturing. For example, the Government could ban the use of "commercial scale manufacturing or testing equipment for compounding drug products." It could prohibit pharmacists from compounding more drugs in anticipation of receiving prescriptions than in response to prescriptions already received. It could prohibit pharmacists from "offering compounded drugs at wholesale to other state licensed persons or commercial entities for resale." Alternately, it could limit the amount of compounded drugs, either by volume or by numbers of prescriptions, that a given pharmacist or pharmacy sells out of state.

Even if the Government had argued that the FDAMA's speech-related restrictions were motivated by a fear that advertising compounded drugs would put people who do not need such drugs at risk by causing them to convince their doctors to prescribe the drugs anyway, that fear would fail to justify the restrictions. The Supreme Court has previously rejected the notion that the Government has an interest in preventing the dissemination of truthful commercial information in order to prevent members of the public from making bad decisions with the information. In *Virginia Bd. of Pharmacy*, the state feared that if people received price advertising from pharmacists, they would "choose the low-cost, low-quality service and drive the 'professional' pharmacist out of business" and would "destroy the pharmacist-customer relationship" by going from one pharmacist to another. The Court found these fears insufficient to justify a ban on such advertising.

INTERPRETATION A governmental restriction on non-misleading commercial speech concerning lawful activity is invalid under the First Amendment if the regulation is more extensive than necessary to directly advance a substantial governmental interest.

CRITICAL THINKING QUESTION Do you agree that the Court's suggested non–speech-related means of drawing a line between compounding and large-scale manufacturing would be effective? Explain.

Defamation injury of a person's reputation by publication of false statements

Defamation

Defamation is a civil wrong or tort that consists of disgracing or diminishing a person's reputation through the communication of a false statement. An example would be the publication of a statement that a person had committed a crime or had a loathsome disease. (Defamation is also discussed in Chapter 7.)

Because defamation involves a communication, it receives the protection extended to speech by the First Amendment. Moreover, the Supreme Court has ruled that a public official who is defamed in regard to his conduct, fitness, or role as public official may not recover in a defamation action unless the statement was made with *actual malice*, which requires clear and convincing proof that the defendant had knowledge of the falsity of the communication or acted in reckless disregard of its truth or falsity. This restriction on the right to recover for defamation is based on "a profound national commitment to the principle that debate on public issues should be uninhibited, robust and wide-open, and that it may well include vehement, caustic, and sometimes unpleasantly sharp attacks on government and public officials." The communication may deal with the official's qualifications for and performance in office, which would likely include most aspects of character and public conduct. In addition, the Supreme Court has extended the same rule to public figures and candidates for public office. (The Court, however, has not precisely defined the term *public figure*.)

In a defamation suit brought by a private person (one who is neither a public official nor a public figure), the plaintiff must prove that the defendant published the defamatory and false comment with malice *or* negligence.

Due Process

The Fifth and Fourteenth Amendments prohibit the federal and state governments, respectively, from depriving any person of life, liberty, or property without **due process** of law. Due process has two different aspects: substantive and procedural. As we discussed in Chapter 1, substantive law creates, defines, or regulates legal rights, whereas procedural law establishes the rules for enforcing those rights. Accordingly, substantive due process concerns the compatibility of a law or governmental action with fundamental constitutional rights such as free speech. In contrast, procedural due process involves the review of the decision-making process that enforces substantive laws and results in depriving a person of life, liberty, or property.

Due process Fifth and Fourteenth Amendments prohibit the federal and state governments from depriving any person of life, liberty, or property without due process of law

Substantive Due Process

Substantive due process, which involves a court's determination of whether a particular governmental action is compatible with individual liberties, addresses the constitutionality of a legal rule, not the fairness of the process by which the rule is applied. Legislation affecting economic and social interests satisfies substantive due process so long as the legislation is rationally related to legitimate governmental objectives. Where a rule affects individuals' fundamental rights under the Constitution, however, the Court will carefully scrutinize the legislation to determine if it is necessary to promote a compelling or overriding state interest.

Substantive due process requirement that governmental action be compatible with individual liberties

Procedural Due Process

Procedural due process pertains to the governmental decision-making process that results in depriving a person of life, liberty, or property. As the Supreme Court has interpreted procedural due process, the government is required to provide an individual with a fair procedure if, but only if, the person faces deprivation of life, liberty, or property. When governmental action adversely affects an individual but does not deny life, liberty, or property, the government is not required to give the person any hearing at all.

Procedural due process requirement that governmental action depriving a person of life, liberty, or property be done through a fair procedure

For the purposes of procedural due process, **liberty** generally includes the ability of individuals to engage in freedom of action and choice regarding their personal lives. **Property** includes not only all forms of real and personal property but also certain benefits (entitlements) conferred by the government, such as social security payments and food stamps.

When applicable, procedural due process requires that a court use a fair and impartial procedure in resolving the factual and legal basis for a governmental action that results in a deprivation of life, liberty, or property.

Liberty ability of individuals to engage in freedom of action and choice regarding their personal lives

Property includes real property, personal property, and certain benefits conferred by government

Equal Protection

The Fourteenth Amendment provides that "nor shall any State . . . deny to any person within its jurisdiction the equal protection of the laws." Although this amendment applies only to the actions of state governments, the Supreme Court has interpreted the Due Process clause of the Fifth Amendment to subject federal actions to the same standards of review. The most important constitutional concept protecting individual rights, the guarantee of **equal protection** basically requires that similarly situated persons be treated similarly by governmental actions.

Equal protection requirement that similarly situated persons be treated similarly by government action

When governmental action involves classification of people, the equal protection guarantee comes into play. In determining whether governmental action satisfies the equal protection guarantee, the Supreme Court uses one of three standards of review, depending on the nature of the right involved. The three standards are (1) the rational relationship test, (2) the strict scrutiny test, and (3) the intermediate test.

Rational relationship test a standard of review used to determine whether economic regulation satisfies the equal protection guarantee

Rational Relationship Test The rational relationship test, which applies to economic regulation, simply requires that the classification *conceivably* bear some rational relationship to a legitimate governmental interest the classification seeks to further. Under this standard of review, the governmental action is permitted to attack part of the evil to which the action is addressed. Moreover, there is a strong presumption that the action is constitutional. Therefore, the courts will overturn the governmental action *only* if clear and convincing evidence shows that there is *no* reasonable basis justifying the action.

Strict scrutiny test exacting standard of review applicable to regulation affecting a fundamental right or involving a suspect classification

Strict Scrutiny Test The strict scrutiny test is far more exacting than the rational relationship test. Under this test, the courts do not defer to the government; rather, they independently determine whether a classification of persons is constitutionally permissible. This determination requires that the classification be necessary to promote a compelling or overriding governmental interest.

The strict scrutiny test is applied when governmental action affects fundamental rights or involves suspect classifications. Fundamental rights include most of the provisions of the Bill of Rights and certain other rights, such as interstate travel, voting, and access to criminal justice. Suspect classifications include those made on the basis of race or national origin. A classic and important example of strict scrutiny applied to classifications based upon race is found in the 1954 school desegregation case of *Brown v. Board of Education of Topeka*, in which the Supreme Court ruled that segregated public school systems violated the equal protection guarantee. Subsequently, the Court has invalidated segregation in public beaches, municipal golf courses, buses, parks, public golf courses, and courtroom seating.