NOTE

Sales Versus Safety: The Loss of Balance in the Commercial Speech Standard in *Thompson v. Western States Medical Center*

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INTRODUCTION

Your child is sick with asthma. She dislikes the taste of the Ventolin that the pediatrician prescribed for her, so it is a struggle to get her to use it. One day at the drugstore, you see an advertisement proclaiming, "Fruit-Flavored Inhalers Custom-Made for Kids!" This seems like the perfect solution for your daughter. The pharmacist assures you that kids with asthma just love the new inhalers. To purchase one, all you need is a prescription.

When you call for a prescription, your doctor tries to dissuade you. She points out that Ventolin is effective and safe. Your daughter does not need a custom, compounded drug like the inhaler, she says. Pharmacists make compounded drugs manually by combining ingredients to create a medication specifically tailored to an individual patient.[1] Untested for safety or efficacy, compounded drugs offer an alternative to mass-produced medications for those few patients who are allergic to an ingredient or need a liquid instead of a pill.[2]

By now, however, you are convinced that life would be much easier with a fruit-flavored inhaler. You insist your daughter needs it. Your doctor reluctantly agrees to fax the prescription to the drugstore.

The inhaler ad and pharmacist's sales pitch seduced you into selecting a drug that could do more harm to your daughter than good.[3] You rejected the Ventolin, which the government tested for effectiveness and safety, and instead chose an untested inhaler.[4] The inhaler's flavoring may seem harmless, but it can weaken a drug's effectiveness.[5] At worst, the inhaler could injure your child because of ingredient contamination or interactions.[6] People have died from ingesting compounded drugs.[7]

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[1] Thompson v. W. States Med. Ctr., 535 U.S. 357, 360 (2002); Brief for Petitioners at 30, Thompson v. W. States Med. Ctr., 533 U.S. 357 (2002) (No. 01-344).

[2] *Thompson*, 535 U.S. at 360.

[3] *See* Tamar Nordenberg, *Pharmacy Compounding: Customizing Prescription Drugs*, FDA CONSUMER MAG., July-Aug. 2000 (explaining that people are better served taking commercially manufactured drugs that have been scientifically tested and manufactured under controlled conditions rather than compounded drugs, which carry greater risks), *available at* http://www.fda.gov/fdac/features/2000/400_compound.html (last visited Apr. 7, 2004).

[4] *See* Brief for Petitioners at 2, *Thompson* (No. 01-344) (outlining Federal Food, Drug, and Cosmetic Act's comprehensive scheme for determining safety and effectiveness of new drugs before their release into interstate commerce); *id.* at 5 (stating that newly created, customized compounded drugs are not subjected to controlled clinical trials that establish drug safety and effectiveness).

[5] Nordenberg, *supra* note 3.

[6] *Id.*

[7] *Id.* (recounting deaths of infants who received incorrectly prepared intravenous

Two years ago, you would not have succumbed to the inhaler ad because the Food and Drug Administration Modernization Act (FDAMA) prohibited such advertising.[8] Now, however, advertisements for potentially unsafe, untested compounded drugs are legal, following the Supreme Court's decision in *Thompson v. Western States Medical Center*.[9] The Court found FDAMA's restrictions unconstitutional after applying the *Central Hudson* test for commercial speech regulations using strict scrutiny review.[10]

This Note argues that the Court erred in applying the *Central Hudson* test in *Thompson*. Such application resulted in greater freedom of speech for commercial purposes while sacrificing public safety standards. Part I describes the evolution of commercial speech standards, from the Court's view that such speech merited no constitutional protection to the balancing of government and free speech interests developed in the *Central Hudson* test. Part II discusses the facts, holding and law of *Thompson*, a case in which the Court ostensibly applied the *Central Hudson* test, but in actuality compromised that standard's even-handed balancing of public and commercial interests. Part III maintains that the *Central Hudson* test is inapplicable to *Thompson* because it has evolved into a strict scrutiny review. It also argues that the use of strict scrutiny compromised important governmental interests in protecting public safety in favor of unrestricted commercial speech. Finally, Part III proposes that intermediate scrutiny is the appropriate level of review for laws safeguarding public health.

I. BACKGROUND

The legal status of commercial speech has been in flux for over twenty-five years.[11] While the Court's definition of commercial speech has

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solutions and patient who became blind in one eye from pharmacy-prepared eye drops that were contaminated).

[8] 21 U.S.C. § 353a(c) (2003); *Thompson*, 535 U.S. at 362. Instead of a sign specifically advertising the fruit-flavored inhalers, the pharmacist could only advertise that custom compounding of drugs was available, or that he or she was an expert in compounding drugs. *Id.*; *see also* Brief for Petitioners at 6, *Thompson* (No. 01-344) (explaining that health benefits outweighed risks of compounding, if performed in response to valid prescription to meet medical needs of individual patient for whom commercially available drugs were inadequate); Nordenberg, *supra* note 3 (suggesting doctor might determine that benefits of compounded drug over alternative commercial prescription justified risk for particular patient).

[9] *Thompson*, 535 U.S. at 368.

[10] *Id.* at 360.

[11] After 30 years of no substantive change in its views on commercial speech, the

remained fairly consistent, if vague, what has changed is the value that the Court accords commercial speech.[12] This Part explores the evolution of commercial speech, from the minimal constitutional protection granted it during the mid-twentieth century to the highly protected status it enjoys today.[13] As commercial speech has become more important, the Court has deferred less to government restrictions on that speech.[14] Yet, the government's reasons for restricting commercial speech are often persuasive, as is evident in the history of commercial speech and FDAMA.[15]

Court's holding in *Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748 (1976) initiated a series of often conflicting commercial speech decisions by the Court. *See* Susan Dente Ross, *Reconstructing First Amendment Doctrine: The 1990s [R]evolution of the Central Hudson and O'Brien Tests*, 23 HASTINGS COMM. & ENT. L.J. 723, 724 (2001) (tracing history of Court's treatment of commercial speech from no constitutional protection in 1942, to limited First Amendment protection in 1970s, to increased constitutional protection throughout 1990s).

[12] ERWIN CHEMERINSKY, CONSTITUTIONAL LAW: PRINCIPLES AND POLICIES, 1047 (2d ed. 2002) (declaring that there is no clear definition of what is meant by commercial speech.) The Court has said commercial speech "propose[s] a commercial transaction." *Va. State Bd. of Pharmacy*, 425 U.S. at 762. It has also defined commercial speech as "an expression related solely to the economic interests of the speaker and its audience." Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y., 447 U.S. 557, 561 (1980). The Court has referred to three characteristics of commercial speech: it is an advertisement of some form; it refers to a specific product; and the speaker has an economic motivation for the speech. Bolger v. Youngs Drug Prods. Corp., 463 U.S. 60, 67 (1983). Thus, commercial speech can include messages as diverse as advertising product prices, political speech, or information about using a service. CHEMERINSKY, *supra*, at 1047-48; *see also id.* at 901, 953 (explaining that, historically, Court afforded commercial speech less protection than speech concerning politics or ideas, placing it in category receiving intermediate-level scrutiny); Ross, *supra* note 11, at 724. Although in general the Court has increased its protection of commercial speech over the years, the Court has long held that the Constitution does not protect false and deceptive speech. *Cent. Hudson*, 447 U.S. at 566; *see also* CHEMERINSKY, *supra*, at 1055-57 (discussing restrictions on advertising that may be deceptive, such as trade names and in-person solicitation of prospective clients by attorneys).

[13] Most commercial speech today is protected by the First Amendment, which states that "Congress shall make no law . . . abridging the freedom of speech . . . ." U.S. CONST. amend. I. As a fundamental right, freedom of speech is applicable to the states through the Due Process Clause of the Fourteenth Amendment. CHEMERINSKY, *supra* note 12, at 480-82 (citing Gitlow v. New York, 268 U.S. 652 (1925)).

[14] *See* Ross, *supra* note 11, at 738 (noting that as Supreme Court rulings lowered standards against regulations infringing on media's First Amendment rights, Court raised standards against regulation of commercial speech).

[15] *See* discussion *infra* Parts I.A-B.

A. The Evolution of the Commercial Speech Standard

Although the Court now protects commercial speech under the Constitution, this has not always been true.[16] The Court's changing position on commercial speech falls roughly into three phases: pre-*Central Hudson*, the development of *Central Hudson*'s four-pronged test, and post-*Central Hudson*.[17]

1. Commercial Speech Before *Central Hudson*

In early cases, the Supreme Court did not grant constitutional protection to most commercial speech.[18] The Court protected commercial speech only if it contained political or other valued elements.[19] For instance, religious content could transform a purely commercial message into an expression of protected free speech.[20] Thirty years later, the Court expanded constitutional protection to include speech that advertised matters of clear public interest, such as legal abortion services.[21]

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[16] CHEMERINSKY, *supra* note 12, at 1045.

[17] *Cf.* Ross, *supra* note 11, at 724 (dividing analysis of commercial speech into three phases: 1942 to mid-1970s, mid-1970s to *Central Hudson*, Post *Central Hudson).*

[18] *See* Valentine v. Chrestensen, 316 U.S. 52, 54 (1942) (stating that "the Constitution imposes no such restraint on government as respects purely commercial advertising"); *see also* Metromedia, Inc. v. City of San Diego, 453 U.S. 490, 505 (1981) (acknowledging that prior to 1975, purely commercial advertisements of services or goods were considered to be outside protection of First Amendment). The Court declined to protect commercial speech because of its purpose, not its medium. *Valentine*, 316 U.S. at 54 (holding that city of New York could prohibit distribution of handbill advertising public viewing of submarine but not handbill describing political protest). In *Valentine*, respondent attempted to circumvent a New York ordinance prohibiting advertisements but allowing protests against political action. *Id.* at 53. Both the Circuit Court of Appeals and lower court granted respondent an injunction preventing the interference of the police commissioner in distributing the handbill. *Id.* at 54. The Supreme Court reversed, not on commercial speech grounds but in support of New York's authority to regulate the conducting of business on public streets. *Id.* at 55.

[19] *Valentine*, 316 U.S. at 54.

[20] ROY L. MOORE ET AL., ADVERTISING AND PUBLIC RELATIONS LAW 26 (1998); *see* Martin v. Struthers, 319 U.S. 141, 144 (1943) (reversing conviction for door-to-door distribution of leaflets because they were religious in content); Murdock v. Pennsylvania, 319 U.S. 105, 111 (1943) (protecting door-to-door distribution of religious books by Jehovah's Witnesses). *But see* Breard v. Alexandria, 341 U.S. 622, 644-45 (1951) (upholding conviction prohibiting door-to-door sales of magazine subscriptions).

[21] Bigelow v. Virginia, 421 U.S. 809, 822 (1975). *Bigelow* involved criminal charges filed against a Virginia newspaper publisher who printed ads announcing legal abortions in New York. *Id.* at 815. The Court rejected the state of Virginia's argument that First Amendment protections did not apply to paid advertisements. *Id.* at 825; *see also* MOORE ET AL., *supra* note 20, at 26 (arguing that Virginia's motive was not to regulate commercial

In 1976, the Court broke from precedent to extend First Amendment protection to advertising that reflected purely economic interests.[22] In *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council,* consumers challenged a statute that prohibited pharmacists from advertising prescription drug prices.[23] The law stated that pharmacists who advertised were guilty of unprofessional conduct.[24] The consumers, however, claimed that they would benefit greatly from knowing drug prices.[25] The Supreme Court agreed and declared the statute void.[26] The Court defended price advertising as a matter of general public interest.[27] Because of this benefit to the public, the Court reasoned that the commercial purpose of price ads should not disqualify them from First Amendment protection.[28]

Following *Virginia Board of Pharmacy,* the Court extended protection of commercial speech further to include some professional services advertising.[29] In *Bates v. State Bar of Arizona,* two attorneys ran a simple newspaper ad announcing their legal aid services and fees.[30] The Arizona State Bar charged the attorneys with violating State Bar rules prohibiting advertising.[31] The Arizona Supreme Court affirmed the State Bar's ruling, but the U.S. Supreme Court reversed on the case's First Amendment issue.[32] The Court held that there was nothing inherently

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speech but to restrict woman's right to choose, and Court's realization of this motive influenced its holding).

[22] Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc., 425 U.S. 748 (1976); *see* MOORE ET AL., *supra* note 20, at 26 (characterizing this case as "highwater mark in the development of First Amendment protection for purely commercial speech").

[23] *Va. State Bd. of Pharmacy,* 425 U.S. at 748.

[24] *Id.* at 750 n.2.

[25] *Id.* at 753.

[26] *Id.* at 773. The district court found for the plaintiffs and declared the statute void. *Id.* at 750. The Supreme Court affirmed. *Id.* at 773.

[27] *Id.* at 764.

[28] *Id.* at 762. The Court criticized its early commercial speech decisions as simplistic, arguing that speech did not lose its First Amendment protection because an advertiser paid to publish it. *Id.* at 759, 761. Furthermore, the Court contended that a free flow of commercial information was indispensable to the United States' free enterprise system. *Id.* at 765.

[29] Bates v. State Bar of Ariz., 433 U.S. 350, 354-55 (1977).

[30] *Id.* at 354. The attorneys had started a legal aid clinic and priced their services to attract clients of moderate income who did not qualify for government aid. *Id.* In their first two years of practice, the attorneys had not attracted enough clients to be profitable. *Id.* They resorted to advertising to attract more clients and income, so they would not go out of business. *Id.*

[31] *Id.* at 350.

[32] *Id.* at 350, 384. The Court affirmed the Arizona Supreme Court's holding that appellants' Sherman Act claim was barred. *Id.* at 363.

misleading in advertising routine legal services and that the practice did not undermine professionalism.[33]

Despite expanding protection of commercial speech during the 1970s, the Court also acknowledged that some speech restrictions were appropriate.[34] For instance, regulation was constitutional if it served a significant government purpose and if alternative methods of communication were available.[35] The Court also declined to protect professional services advertising directed at individual clients.[36]

2. *Central Hudson* and Its Four Prongs

In 1980, the Court seized the opportunity in *Central Hudson* to establish a formal test for determining when commercial speech regulations violated the First Amendment.[37] The case concerned a ban on advertising electric utilities in New York City.[38] The city issued the prohibition in the winter of 1973, seeking to blunt public appetite for an ever-dwindling supply of fuel.[39] The fuel shortage eased three years later, but the city continued to enforce the ban on promotional advertising.[40] The city reasoned that the ban would result in residents consuming less energy, which in turn would prevent inequities in utility rates.[41] The Central Hudson Gas & Electric Company challenged the continuation of the ban, arguing that it violated its freedom of speech.[42] The trial court upheld the regulation and the New York Court of

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[33] *Id.* at 368-75.

[34] Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc., 425 U.S. 748, 771 (1976); *see also id.* at 773 n.25. The Court expressly exempted physicians and lawyers from its decision because they did not dispense standardized products but professional services "of almost infinite variety." *Id.* Justice Burger also clarified in his concurrence that the drug pricing receiving First Amendment protection was that of prepackaged, or mass-produced, drugs. *Id.* at 774.

[35] *Id.* at 771.

[36] Ohralik v. Ohio State Bar Ass'n, 436 U.S. 447, 456 (1978) (upholding suspension of attorney Ohralik from bar because he solicited clients following their traffic accident). *But cf.* MOORE ET AL., *supra* note 20, at 30 (arguing that *Bates*, which focused on rights of speaker, was retreat from Court's position in *Va. State Bd. of Pharmacy*, which focused on rights of audience).

[37] Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y., 447 U.S. 557, 566 (1980).

[38] *Id.* at 558-59.

[39] *Id.* at 559.

[40] *Id.*

[41] *Id.*

[42] *Id.* at 560.

Appeals affirmed.[43] The Supreme Court reversed, holding that the regulation infringed on the utility's First Amendment rights.[44]

In *Central Hudson*, the Court announced a four-step analysis for determining the constitutionality of commercial speech regulations.[45] First, the speech must concern lawful activities, and must not be false, inaccurate or misleading.[46] Second, the government must prove that its regulation advances a substantial interest.[47] Third, the government's restrictions must directly advance its interests.[48] Fourth, any speech restrictions beyond those necessary to achieve the government's interests are unconstitutional.[49]

In applying the four-pronged test, the Court concluded that the city's advertising ban met the first three criteria.[50] The utility company's ads satisfied the test's first prong because they were neither false nor related to an unlawful activity.[51] To meet the test's second prong, the city cited two regulatory goals: to conserve energy and to avoid inequitable utility rates.[52] Upon verifying the city's interests in energy conservation and fair rates, the Court concluded that the goals were clear and substantial.[53] The Court argued that concern over rate inequities alone did not satisfy the third prong of directly advancing the government's interest.[54] However, the Court conceded that the connection between the advertising ban and overall demand for electricity justified a regulation and, hence, satisfied the third prong.[55]

The fourth prong, that the regulation must restrict no more speech than necessary, proved the stumbling block for the city's ban.[56] The Court concluded that even an interest as substantive as energy conservation could not justify banning all promotional advertising for electrical services.[57] The city had failed to prove that its goals could not

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[43] *Id.* at 561.

[44] *Id.*

[45] *Id.* at 566.

[46] *Id.* at 564.

[47] *Id.*

[48] *Id.*

[49] *Id.*

[50] *Id.* at 566-70.

[51] *Id.*

[52] *Id.*

[53] *Id.* at 568-69.

[54] *Id.* at 569.

[55] *Id.*

[56] *Id.* at 566, 570.

[57] *Id.* at 570. The Court pointed out that the ban suppressed information on electric

be met through less stringent restrictions.[58]

Although the Court struck down the advertising ban, it also noted the "common-sense" distinction between commercial and noncommercial speech.[59] The Court pointed out that speech proposing a commercial transaction occurred in areas traditionally subject to government regulation.[60] Thus, the Court said, protection for commercial speech depended on both the nature of the speech and the government interests served by regulating the speech.[61]

3. *Central Hudson* Applied

When applying its new commercial speech test, the Court occasionally deferred to government rationales for restricting commercial speech.[62] In these cases, meeting the conditions of Central Hudson's third prong was key to the Court's upholding of advertising regulations.[63] So long as the government's interest reasonably related to the commercial speech restriction, the Court concluded that the regulation directly advanced the interest.[64]

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devices and services that did not cause a net increase in total energy use. *Id.* In fact, the Central Hudson Company argued that, but for the ban, they would promote products that used energy more efficiently and thus reduce overall energy use. *Id.*

[58] *Id.* As an alternative to a complete advertising ban, the Court suggested that the Commission restrict the format and content of Central Hudson's ads. *Id.* at 571. The Commission could also require Central Hudson to include information in their ads about the efficiency and expense of energy-saving products. *Id.*

[59] *Id.* at 562.

[60] *Id.*

[61] *Id.* at 562-63.

[62] *See* United States v. Edge Broad. Co., 509 U.S. 418, 435 (1993) (upholding ban on lottery broadcast advertising to states that opposed lotteries); Bd. of Trs. of the State Univ. of N.Y. v. Fox, 492 U.S. 469, 485 (1989) (upholding university regulation prohibiting Tupperware parties and other commercial activities in dormitories); Posadas de P.R. Assocs. v. Tourism Co., 478 U.S. 328, 348 (1986) (upholding Puerto Rican legislature's ban on casino advertising to local citizens); Metromedia, Inc. v. City of San Diego, 453 U.S. 490, 521 (1981) (upholding San Diego's ordinance restricting commercial speech, although finding ban on noncommercial speech unconstitutional).

[63] *See Metromedia*, 453 U.S. at 508.

[64] *See id.* at 509 (agreeing with California Supreme Court that legislature's judgment that commercial billboards were traffic hazards was "common sense" and not "unreasonable"). The City of San Diego created a complex ordinance permitting onsite commercial advertising but prohibiting offsite commercial advertising and noncommercial advertising that did not fit one of twelve exceptions. *Id.* at 493-96. These exceptions included temporary political campaign signs, religious symbols, public service signs, and other noncommercial advertising. *Id.* at 496. A consortium of outdoor advertising firms challenged the ordinance, complaining that the law would put them out of business. *Id.* The trial court declared the law an unconstitutional exercise of the city's police powers and

The Court's deference to government rationale became most pronounced in *Posadas de Puerto Rico Associates v. Tourism of Puerto Rico.*[65] There, the Puerto Rican legislature passed an act authorizing gambling for tourists but forbidding casino advertising to local residents.[66] Evaluating the ban under *Central Hudson's* third prong, the Court agreed with the legislature that the ban reasonably related to reducing citizen demand for gambling.[67] Under the fourth prong, the Court found the advertising ban no more extensive than necessary to serve the government's interest.[68] Thus, the Court found that the ban easily satisfied the *Central Hudson* test and upheld it.[69]

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a violation of plaintiffs' First Amendment rights. *Id.* at 497. The California Court of Appeal affirmed on the first ground, but the California Supreme Court reversed, holding that the ordinance was not facially valid. *Id.* The Court said local legislators' arguments that the billboards were traffic hazards and unattractive were not unreasonable and thus directly advanced government interests. *Id.* at 509, 512. Although the Court upheld the ban on commercial billboards, it found the city's restrictions on noncommercial billboards and signs to be facially unconstitutional. *Id.* at 521; *see also Edge Broad.*, 509 U.S. at 435 (upholding government restrictions on broadcast of lottery advertisements into states that banned lottery). The Federal Communications Act of 1934 permitted the broadcasting of lottery ads in states that sponsored a lottery but forbade them in nonlottery states. *Id.* at 421. Edge was a broadcaster that operated a radio station in North Carolina, a nonlottery state, right at the border of Virginia, a lottery state. *Id.* at 423. Ninety percent of Edge's listeners lived in Virginia. *Id.* Edge charged that the federal law violated its First Amendment rights. *Id.* at 424. The district court held that the federal statutes, as applied to Edge, did not directly advance the government's interest in assisting states to control gambling. *Id.* at 425. The Court of Appeals affirmed. *Id.* The Supreme Court, however, reversed. *Id.* at 436. The Court found that the statutes directly advanced the government's interest under *Central Hudson*'s third factor. *Id.* at 428. The Supreme Court also found the statutes valid as applied to Edge under the fourth *Central Hudson* prong. *Id.* at 431-35. The Court reasoned that to allow Edge to broadcast lottery advertisements to North Carolina listeners would weaken the government's goal of specifically assisting each state's decision to either support or oppose the lottery. *Id.* at 435.

[65] *Posadas*, 478 U.S. at 328.

[66] *Id.* at 331-32. The government had fined appellant casino operator, Posadas, twice for printing the word "casino" on innocuous business items, such as casino stationery and brochures. *Id.* at 333-34.

[67] *Id.* at 342.

[68] *Id.* at 343. The Court did not probe for less stringent alternatives to the advertising ban. *Id; see* Ross, *supra* note 11, at 740 (referring to Court's lenient application of intermediate scrutiny). Ross explores the Court's inconsistency in applying the *Central Hudson* test to "vice advertising" in cases such as *Posadas*. Ross, *supra* note 11, at 741. The Court in *Posadas* held that restrictions on vice activities were subject to lesser scrutiny than ads on other types of activities. *Posadas*, 478 U.S at 361.

[69] *Posadas*, 478 U.S at 340-48. The Superior Court had found the act unconstitutionally applied, but facially constitutional. *Id.* at 334-37. The Puerto Rican Supreme Court had dismissed the casino's appeal. *Id.* at 337. The Court accepted the legislature's argument that gambling would seriously harm the health, safety, and welfare of Puerto Rican residents. *Id.* at 341.

Ten years after deciding *Posadas*, the Court repudiated that decision and abandoned its deference to government rationales in two pivotal cases.[70] In *Edenfield v. Fane*, the Court refused to simply acknowledge a connection between the state of Florida's interests in protecting consumers and its ban on business solicitations by certified public accountants (CPAs).[71] The Court agreed that Florida's reasons for the ban — to ensure accurate commercial information, protect client privacy, and prevent CPA fraud — were substantial.[72]The Court said, however, that the state did not prove that the ban directly accomplished those goals to a material degree.[73] The Court declared the ban unconstitutional because it failed to satisfy completely *Central Hudson's* third prong.[74]

Likewise, in *44 Liquormart, Inc. v. Rhode Island*, the Court criticized Rhode Island for not providing statistics to justify its ban on liquor price advertising.[75] Rhode Island argued that its advertising ban helped to reduce residents' alcohol consumption.[76] The Court, however, said the state failed to prove that the ban *significantly* reduced consumption.[77] When Rhode Island cited *Posadas* in defending its ban, the Court announced that it had "erroneously performed the First Amendment analysis" in *Posadas*.[78] The Court held that Rhode Island's ban on advertising was unconstitutional because it failed both *Central Hudson's*

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[70] 44 Liquormart, Inc. v. Rhode Island, 517 U.S. 484, 513 (1996); Edenfield v. Fane, 507 U.S. 761, 777 (1993). In these cases, the Court attacked the rationales it had used in *Posadas* to justify regulation of commercial speech. Ross, *supra* note 11, at 741. Although all members of the Court concurred in rejecting *Posadas*, the justices were widely split in their rationale. *See* MOORE ET AL., *supra* note 20, at 45 (noting that Justice Thomas, on one extreme, felt that all government regulations that banned truthful, legal speech were illegitimate, whereas Justices O'Connor, Souter, Breyer, and Rehnquist seemed to believe Rhode Island's total ban could not survive even reasonable fit test under *Central Hudson's* fourth prong).

[71] *Edenfield*, 507 U.S. at 768.

[72] *Id.* at 769.

[73] *Id.* at 771. The Court said the state failed to present studies or anecdotal evidence proving that personal solicitations of business clients resulted in fraud, overreaching, or compromised independence. *Id.*

[74] *Id.* at 777. The Court's holding affirmed decisions by both the District Court and Eleventh Circuit Court of Appeals.

[75] *44 Liquormart*, 517 U.S. at 509-10.

[76] *Id.* at 504.

[77] *Id.* at 506. The Court did not define what it meant by "significantly," but implied it had to be more than "some" impact on purchasing. *Id.*

[78] *Id.* at 509. Justice Stevens stated, "As the entire Court apparently now agrees, the statements in the *Posadas* opinion on which Rhode Island relies are no longer persuasive." *Id.* The Court declared its *Posadas* decision irreconcilable with former cases where the Court had struck down similarly broad regulations on truthful advertising. *Id.* at 509-10.

third and fourth prongs.[79]

In summary, for over thirty years, the Court usually declined to protect commercial speech from regulation, distinguishing it from political speech.[80] Then the Court began to grant commercial speech greater protection if it dealt with matters of public interest.[81] Even after creating the *Central Hudson* test, the Court often deferred to government rationales for restricting commercial speech.[82] In 1993, however, the Court reversed its deferential stance and now tends to invalidate state regulations that prohibit commercial speech.[83] Although the Court states that it is still applying the *Central Hudson* intermediate scrutiny test, the Court has increasingly interpreted the third and fourth prong standards more strictly, thus granting commercial interests nearly unrestrained freedom of speech today.

B. *Drug Compounding and Limitations on Commercial Speech*

Congress has long prohibited new drugs from entering interstate commerce without prior approval by the Food and Drug Administration (FDA).[84] The FDA conducts rigorous scientific studies to test drugs.[85] The government also regulates drug labeling and advertising because these activities greatly impact drug safety for individual use.[86]

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[79] *Id.* at 489, 507. The district court had held the statutes to be invalid. *Id.* at 493. The First Circuit Court of Appeals reversed. *Id.* at 494. The Supreme Court reversed. *Id.* at 516. The Court also found that the Rhode Island statutes failed the fourth *Central Hudson* prong because they were more extensive than necessary. *Id.* at 507-08. The Court suggested that alternatives such as higher prices, higher taxes, or educational campaigns would more effectively reduce alcohol consumption and not violate freedom of speech. *Id.* at 507.

[80] *See* discussion *supra* Part I.A.1.

[81] *Id.*

[82] *See* discussion *supra* Part I.A.3.

[83] *Id; see, e.g.,* Lorillard Tobacco Co. v. Reilly, 533 U.S. 525 (2001) (invalidating Massachusetts regulations that banned outdoor advertising for tobacco products and point-of-sale regulations requiring indoor advertising to be placed no lower than five feet from floor); United States v. United Foods, 533 U.S. 405 (2001) (striking down assessment on mushroom growers to fund generic advertisements promoting mushroom sales); Greater New Orleans Broad. Ass'n v. United States, 527 U.S. 173 (1999) (striking down prohibitions to advertisements of private casino gambling in states where gambling was legal).

[84] 21 U.S.C. §§ 301-397 (2002), also known as the Federal Food, Drug and Cosmetic Act of 1938; Brief for Petitioners at 20, Thompson v. W. States Med. Ctr., 535 U.S. 357 (2002) (No. 01-344).

[85] Brief for Petitioners at 14, *Thompson* (No. 01-344). Historical experience convinced Congress and the FDA that premarket approval was necessary to ensure that pharmacies and manufacturers sold safe and effective drugs. *Id.*

[86] *Id.*

Historically, the FDA refrained from enforcing drug approval requirements against compounded drugs.[87] Although compounding is a traditional pharmacy service, it comprises only a small percentage of prescriptions sold to the public.[88] Congress was concerned that the high costs of obtaining new drug approval would discourage pharmacies from compounding drugs.[89] Congress therefore directed the FDA to exempt compounds from the drug approval process so long as pharmacies compounded drugs in response to individual prescriptions.[90]

In 1992, the FDA became aware that some pharmacists were manufacturing and selling new, unapproved drugs under the guise of compounding.[91] In response, Congress passed FDAMA.[92] FDAMA continued to exempt compounded drugs from new drug testing, but only if pharmacists did not engage in business activities normally associated with mass manufacture.[93] One of those activities was advertising the compounding of a specific drug or type of drug.[94] Congress and the FDA reasoned that advertising specific drugs was an activity indicative of mass manufacture, not of drug compounding for individual patients.[95]

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[87] *Id.* at 6.

[88] Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc., 425 U.S. 748, 773-74 (1976). Chief Justice Burger notes that approximately 95% of a pharmacy's prescriptions are prepackaged rather than compounded by hand. *Id.* at 773.

[89] Brief for Petitioners at 31, *Thompson* (No. 01-344) (explaining that cost of developing and obtaining approval of new drug that is not similar to already approved drug is estimated to exceed $200 million dollars, and cost of developing drugs that closely resemble approved products ranges from $300,000 to $500,000); *see also* Reply Brief for Petitioners at 7, *Thompson* (No. 01-344) (rebutting respondents' assertion that compounded drugs are not subject to approval process in first place and thus may be legally introduced into interstate commerce or held for sale without FDA approval).

[90] Thompson v. W. States Med. Ctr, 535 U.S. 357, 360-64 (2002); *see also* Brief for Petitioners at 28, *Thompson* (No. 01-344) (referring to repeated references in legislative history of 1938 Act and 1962 amendments that Congress did not want FDA to interfere with physician's ability to prescribe legally approved products for unapproved uses).

[91] *Thompson*, 535 U.S at 362.

[92] Federal Food, Drug, and Cosmetic Act of 1938, 21 U.S.C. §§ 301-397 (2002) (hereinafter FDAMA).

[93] FDAMA, 111 Stat. 2328, 21 U.S.C. §§ 353a, 503A; *Thompson*, 535 U.S. at 360-64. For instance, a compounded drug had to be made from approved ingredients and only in limited quantities. *Thompson*, 535 U.S. at 360-64. The compound could not copy the formula of a commercially available drug. *Id.*

[94] *Thompson*, 535 U.S. at 360-64. However, pharmacists could advertise their compounding services in general. *Id.*

[95] *See* Reply Brief for Petitioners at 3, *Thompson* (No. 01-344) (arguing that traditional compounding responds to idiosyncratic medical needs of specific individuals, for which advertising is not necessary or common. In contrast, mass manufacture of drugs requires advertising to effectively reach larger market, resulting in sales that justify drug

II. *THOMPSON V. WESTERN STATES MEDICAL CENTER*

Shortly before FDAMA took effect, a group of pharmacies sued the government, alleging that FDAMA's advertising restrictions for compounded drugs were unconstitutional.[96] The district court granted respondents' motion for summary judgment and invalidated the relevant provisions.[97] The Ninth Circuit agreed that the provisions were unconstitutional, as did the Supreme Court.[98] However, the Supreme Court was split 5-4 in its decision.[99] The Court evaluated the government's interests in restricting compounded drug advertising using the *Central Hudson* test.[100]

The Court had little difficulty in finding that FDAMA met the criteria for prongs one and two of the test.[101] The first prong was not at issue because the drug advertising was not misleading, inaccurate, or unlawful.[102] In considering the second *Central Hudson* factor, the Court agreed that the government's three primary interests in regulating advertising were substantial.[103] The first interest was to preserve the integrity of the new drug approval process.[104] The second interest was to ensure the availability of compounded drugs for individuals who could not use mass-produced drugs.[105] These two interests conflict because it is generally not feasible to subject a compounded drug to the lengthy and expensive new drug approval process.[106] Therefore, the government's

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development and approval costs).

[96] *Thompson*, 535 U.S. at 365. Specifically, respondents challenged provision 21 U.S.C. § 353a(a), which required that pharmacists not solicit prescriptions for compounded drugs from patients or doctors, and 21 U.S.C. § 353a(c), which required that pharmacists "not advertise or promote the compounding of any particular drug, class of drug, or type of drug." 21 U.S.C. §§ 353a(a), (c) (1998); *see also* Brief for Petitioners at 9, *Thompson* (No. 01-344).

[97] *Thompson*, 535 U.S. at 365. The district court severed the provisions from the rest of section 503A. *Id.*

[98] *Id.* at 365, 377. The Ninth Circuit Court of Appeals affirmed the district court's holding that the provisions were unconstitutional, but also reversed in part, holding that the provisions were not severable from section 503A. *Id.* at 365. The government agreed with the Court of Appeals that the speech-related provisions were not severable. *Id.* Therefore, the government challenged only the Court of Appeals' constitutional holding in its petition for certiorari. *Id.*

[99] *Id.*

[100] *Id.* at 367.

[101] *Id.* at 367-68.

[102] *Id.*

[103] *Id.* at 368.

[104] *Id.*; Brief for Petitioners at 14, *Thompson* (No. 01-344).

[105] *Thompson*, 535 U.S. at 368.

[106] *Id.*; Reply Brief for Petitioners at 2, *Thompson* (No. 01-344).

third goal in enacting FDAMA's advertising restrictions was to balance the two competing interests.[107]

The Court was skeptical, however, as to whether FDAMA satisfied *Central Hudson*'s third prong.[108] Although acceding to the need to distinguish between small- and large-scale drug manufacture to enforce new drug approval regulations,[109] the Court questioned FDAMA's use of advertising as "the trigger" for making that distinction.[110] The Court considered the government's reasons for why advertising was appropriate for mass manufacture but not for compounded drugs.[111] Concluding its third-prong analysis, the Court agreed that if advertising were essential to large-scale manufacture, then FDAMA's restrictions might directly advance the government's interests.[112]

Despite this concession, upon applying *Central Hudson*'s fourth prong, the Court held that the government had failed to demonstrate that FDAMA's restrictions were not more extensive than necessary.[113] The Court noted that it had made clear in previous cases that the government had to achieve its interests in a manner that restricted little or no speech.[114] The Court posited several alternatives to restricting speech that it found equally effective in regulating compounded drugs.[115] In addition, the Court argued that the restrictions prevented physicians and

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[107] *Thompson*, 535 U.S. at 368-69; Reply Brief for Petitioners at 2, *Thompson* (No. 01-344).

[108] *See Thompson*, 535 U.S. at 371 (implying that what government called "traditional compounding," in that it responded to physician's prescription, was actually government's desired approach to compounding). In recounting the government's defense of FDAMA, the Court repeatedly uses phrases such as "seems to believe" and "assuming it is true" to qualify the validity of the government's point of view. *Id.*

[109] *Id.* at 370-71.

[110] *Id.*

[111] *See supra* note 95 and accompanying text.

[112] *Thompson*, 535 U.S. at 369-71.

[113] *Id.* at 371.

[114] *Id.* The Court cited *Rubin v. Coors Brewing Co.* and the Colorado law prohibiting the listing of alcohol content on beer labels. *Id.* In *Rubin*, the Court found the speech ban to be unconstitutional because other alternatives such as directly limiting alcohol content on beers were available and less restrictive of commercial speech. Rubin v. Coors Brewing Co., 514 U.S. 476, 490-91 (1995). The Court also cited *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484 (1996), where it had struck down the ban on liquor price advertising because alternatives to speech restrictions would more effectively achieve the government's temperance goals. *Thompson*, 535 U.S. at 372.

[115] *Thompson*, 535 U.S. at 372. The Court suggested banning the use of commercial scale equipment for compounding drugs as a way of limiting drug quantities. *Id.* The government could also prohibit pharmacists from compounding more drugs than what were needed to fulfill prescriptions already received. *Id.* The amount of any particular compounded drug could be capped by volume, number of prescriptions, or revenue produced to prevent large quantities from being manufactured and sold. *Id.*

hospitals from learning about important developments in compounded drugs that would benefit their patients.[116]

The *Thompson* Court also evaluated an argument from the dissenting justices regarding a fourth governmental interest for restricting compounded drug advertising.[117] The dissent suggested that the government wanted to prevent the sale of compounded drugs to consumers who did not need them.[118] The majority was critical that FDAMA did not directly forbid such sales.[119] The Court also found it unlikely that physicians would prescribe unnecessary medications for patients who wanted compounded drugs that they saw advertised.[120] A five-member majority concluded that FDAMA's advertising restrictions failed to directly advance the goal of preventing people who did not need compounded drugs from obtaining them.[121]

III. ANALYSIS

The evolution of the commercial speech standard shows that the Court is now applying the *Central Hudson* test in a manner approaching strict scrutiny review.[122] This level of scrutiny has run roughshod over the FDA's new drug approval process.[123] The use of strict scrutiny has sacrificed drug safety standards in favor of free speech for pharmaceutical interests.[124] The Court's reasoning in several commercial speech cases supports the use of true intermediate scrutiny for

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[116] *Id.* at 373-74.

[117] *Id.* The majority Court rejected this additional interest on the grounds that the government in its briefs or during the trial had not argued it. *Id.* at 373.

[118] *Id.*

[119] *Id.* at 373-74.

[120] *Id.*

[121] *Id.*

[122] *See* Ross, *supra* note 11, at 748 (arguing that Court has determined that most commercial speech regulations could be reviewed "to something close to strict scrutiny"); *see also* Nicholas P. Consula, Note, *The First Amendment, Gaming Advertisements, and Congressional Inconsistency: The Future of the Commercial Speech Doctrine After* Greater New Orleans Broad. Ass'n v. United States, 28 PEPP. L. REV. 353, 360 (2001) (characterizing *Central Hudson* test as lying in "constitutional abyss, somewhere between the deferential rational basis test the Court uses for regulating health, safety, welfare, and morals and the restrictive strict scrutiny test used for, inter alia, assessing pure First Amendment speech interests").

[123] *See* discussion *infra* Part III.C. *See generally* Brief for Petitioners at 32-36, *Thompson* (No. 01-344) (discussing necessity of preventing compounding that is tantamount to manufacturing because it undermines new drug approval process and weakens core mission of FDA).

[124] *See* discussion *infra* Part III.B-C.

regulations that protect the public.[125] The need for safe and effective prescription drugs requires the Court to balance First Amendment rights with public safety interests.[126]

A. The Judicial Standard for Evaluating Commercial Speech Has Evolved Into Strict Scrutiny Review

The Court's use of the *Central Hudson* test has evolved into nearly strict scrutiny review.[127] The level of scrutiny matters because it determines whether the Court finds a regulation constitutional or not.[128] In general, under intermediate scrutiny, the Court upholds laws that are substantially related to an important government interest.[129] Under strict scrutiny, the Court strikes down laws that fail to achieve a compelling government purpose or are not narrowly tailored to meet that purpose.[130]

When the Court created the *Central Hudson* test for commercial speech, it intended the test to be intermediate scrutiny review.[131] In fact, the majority in *Central Hudson* argued against strict scrutiny.[132] To explain its decision to use intermediate scrutiny, the Court stated that the Constitution protected commercial speech less than other constitutionally guaranteed expressions.[133] Under intermediate scrutiny, the Court balances the value of the speech against the interests that the regulation serves.[134] Hence, the Court intended *Central Hudson* to be a balancing test.[135]

Over the ensuing years, that balance has swung back and forth as the Court has placed sometimes lesser, sometimes greater weight on *Central*

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[125] *See* discussion *infra* Part III.B.

[126] *See* discussion *infra* Part III.B.

[127] Ross, *supra* note 11, at 748.

[128] *See* CHEMERINSKY, *supra* note 12, at 520 (explaining that levels of scrutiny are extremely important in determining constitutionality of laws involving individual rights).

[129] *Id.*

[130] *Id.* at 519-20.

[131] Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y., 447 U.S. 557, 563-66 (1980); *see also id.* at 573 (Blackmun, J., concurring) (agreeing with Court that "this level of intermediate scrutiny" is appropriate for restraining commercial speech that misleads consumers or regulates time, place, or manner of speech); MOORE ET AL., *supra* note 20, at 31 (noting Supreme Court's need to resolve conflicting rulings on commercial speech regulations in lower federal and state courts); Ross, *supra* note 11, at 739-40.

[132] *Cent. Hudson*, 447 U.S. at 566.

[133] *Id.* at 563. Ross, *supra* note 11, at 740.

[134] *Cent. Hudson*, 447 U.S. at 563 (noting protection available for commercial speech turns both on nature of speech and on governmental interests served by regulation).

[135] *Id.*

Hudson's third and fourth prongs.[136] This shifting of emphasis has resulted in widely divergent levels of scrutiny and outcomes in commercial speech cases.[137] Since the 1990s, the Court has made it increasingly more difficult for government restrictions on commercial speech to satisfy *Central Hudson*'s third and fourth prongs.[138] Thus, the *Central Hudson* test has moved from being intermediate scrutiny review to strict scrutiny review.[139]

This shift is evident when comparing the Court's third-prong analysis in 1980s commercial speech cases to its third-prong analysis in 1990s cases.[140] In the earlier cases, the Court required that the relationship between the government's interest and its regulation be reasonable, not substantial.[141] During this period, the Court decided *Posadas*, applying the *Central Hudson* test to the Puerto Rican advertising ban using lenient intermediate scrutiny.[142] In *Posadas*, the Court simply accepted the legislature's reasons for the ban.[143] The Court did not require any proof of the need for the ban beyond the government's argument that it was necessary for the public's welfare.[144] In the 1990s, however, the Court ceased to defer to government rationales for speech-restrictive regulations and applied a test akin to strict scrutiny.[145] In *Edenfield*, for example, the Court referred to *Central Hudson*'s third provision as the "penultimate prong," as though it were a threat.[146] The Court insisted the government prove that harms from commercial speech were real, and that the challenged regulation would alleviate those harms to a

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[136] Ross, *supra* note 11, at 741.

[137] *See id.* at 740 (referring to Court's inconsistent rulings in area of commercial speech).

[138] *See* Consula, *supra* note 122, at 373-74 (noting Court has strengthened third and fourth prongs of *Central Hudson* test).

[139] Ross, *supra* note 11, at 748.

[140] *See* discussion *infra* Part III.A.

[141] *See* Metromedia, Inc. v. City of San Diego, 453 U.S. 490, 509 (1981) (agreeing with California Supreme Court and other courts that legislature's judgment that commercial billboards were traffic hazards was "common sense" and not "unreasonable").

[142] *See* Ross, *supra* note 11, at 741 (noting that critics have called decision in *Posadas*, "the Court's most lenient application of intermediate scrutiny"). *But cf.* Consula, *supra* note 122, at 361 (arguing that Court's deferential stance under third and fourth prong of *Central Hudson* in *Posadas* relegated test from one of intermediate scrutiny to rational basis test).

[143] Ross, *supra* note 11, at 741.

[144] *See* Posadas de P. R. Assoc. v. Tourism Co., 478 U.S. 328, 341-42 (1986) (asserting that answer to whether ban on commercial speech directly advanced government's interests was "clearly 'yes'").

[145] *See* discussion *supra* Part I.A.3.

[146] Edenfield v. Fane, 507 U.S. 761, 770 (1993).

material degree.[147] Thus, in *Edenfield*, the Court's demands for conclusive evidence that the regulation advanced state interests resembled strict scrutiny review.[148]

Another 1990s case, *44 Liquormart*, also illustrates how the Court moved from intermediate to strict scrutiny in its third-prong analysis.[149] In *44 Liquormart*, the Court demanded that the state prove that its total ban on liquor price advertising significantly reduced consumption.[150] By "significantly," the Court meant that the state had to produce evidentiary support that the ban had more than just some impact on alcohol purchases.[151] Rhode Island's records only proved a small impact on purchasing, so the Court found the ban unconstitutional.[152] The Court also announced that total bans on commercial speech merited "the rigorous review that the First Amendment generally demands."[153] The Court thus seemed to declare that it would use strict rather than intermediate scrutiny when evaluating total bans on commercial speech.[154]

The Court has vacillated in how strictly to apply *Central Hudson*'s fourth prong, but used strict scrutiny most recently in *Thompson*.[155] *Central Hudson*'s fourth factor states that a regulation must be no more extensive than necessary to achieve the government's purpose.[156] In a 1989 case involving college Tupperware parties, the Court discussed at length what it meant by the word "necessary."[157] The Court stated that a

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[147] *Id.* at 771.

[148] *Id.* at 777. Yet, in her dissent, Justice O'Connor points out the inconsistency of this rationale in light of the Court's earlier decision in *Ohralik v. Ohio State Bar Ass'n*, 435 U.S. 447 (1978).

[149] *See* discussion *infra* Part III.A and notes 150-54.

[150] 44 Liquormart, Inc. v. Rhode Island, 517 U.S. 484, 505 (1996). Previously in *Edenfield*, the Court had said the state must provide evidence that its regulation of commercial speech would prevent the speech's harms to "a material degree." *Edenfield*, 507 U.S. at 771.

[151] *44 Liquormart*, 517 U.S. at 506.

[152] *Id.* at 516.

[153] *Id.* at 501. The Court distinguished regulations that protected consumers from misleading, deceptive, or inaccurate ads from regulations that entirely prohibited advertising for reasons not related to consumer protection. *Id.* The Court said the former warranted less strict review. *Id.*

[154] *See* CHEMERINSKY, *supra* note 12, at 520 (explaining that, in general, Supreme Court uses strict scrutiny when evaluating interference with freedom of speech).

[155] *Id.* at 1050.

[156] Cent. Hudson Gas & Elec. Corp. v. Public Serv. Comm'n of N.Y., 477 U.S. 557, 566 (1980).

[157] Bd. of Trs. of the State Univ. of N.Y. v. Fox, 492 U.S. 469, 478 (1989). The Court discussed what it meant in *Central Hudson* when it said that government restrictions on commercial speech could be no more broad or extensive than "necessary" to serve its

loose rather than strict interpretation of "necessary" was appropriate for the subordinate position of commercial speech under the First Amendment.[158] The Court held that the state need not use the least restrictive alternative when regulating commercial solicitations on campuses.[159] Thus, the Court defined the intermediate level of scrutiny for *Central Hudson*'s fourth prong.[160] In contrast, in *44 Liquormart*, the Court declared a prohibition on liquor price advertisements unconstitutional because it was more extensive than necessary.[161] The Court stated there were alternative means to achieve the state's goal of reducing alcohol consumption.[162] Similarly in *Thompson*, the Court stated that the government must choose alternatives that advanced its interests in a manner less intrusive of free speech than FDAMA.[163] The fact that such alternatives exist, the Court reasoned, proved that FDAMA was more extensive than necessary.[164]

Some critics agree that the Court has abandoned intermediate scrutiny for strict scrutiny in commercial speech cases; however *Thompson* argues otherwise.[165] In *Thompson*, the Court implied that it was still using intermediate scrutiny when applying the *Central Hudson* test.[166] One

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interests. *Id.* at 476. The Court admitted that, when interpreted strictly, the word "necessary" would translate into the "least-restrictive-means" test, which the Court had approved in dicta. *Id.* But the Court also said that it had sometimes used the term "necessary" more loosely. *Id.* at 477. The Court concluded by declaring that the subordinate position of commercial speech made it incompatible to apply the more rigid interpretation of "necessary" to commercial speech. *Id.* at 478.

[158] *Id.* at 476-77.

[159] *Id.* at 478.

[160] *Id.* at 476-78.

[161] 44 Liquormart, Inc. v. Rhode Island, 517 U.S. 484, 507 (1996).

[162] *Id.*; *see* discussion *supra* Part I.A.3.

[163] Thompson v. W. States Med. Ctr, 535 U.S. at 357, 371 (2002).

[164] *Id.* *See* Steven G. Brody & Jeanette M. Viggiano, *Summary of Major 2002 Commercial Speech Developments*, 726 PLI/PAT 381 (arguing that *Thompson* Court's fourth-prong analysis made clear new bright-line rule that government must use alternative means to impose less or no burden on speech). Brody and Viggiano also pointed out that the Court shifted the burden of proof in *Thompson*, from requiring that the plaintiff prove the viability of alternatives to speech bans to requiring that the government prove that alternatives are not viable. *Id.* at 382-83.

[165] *See* discussion *infra* Part III.A.

[166] The Court referred to some of the justices not wanting to use the *Central Hudson* test because it was not strict enough. *Thompson*, 535 U.S. at 367; *see also* Lorillard Tobacco Co. v. Reilly, 533 U.S. 525, 554-55 (2001); Greater New Orleans Broad. Ass'n v. United States, 527 U.S. 173, 197 (1999); *44 Liquormart*, 517 U.S. at 32; Ross, *supra* note 11, at 746-48. Ross analyzes the shift in the Court's thinking from the inception of the *Central Hudson* test to its application in *Greater New Orleans*. Ross, *supra* note 11, at 746-48. She notes that Justice Blackmun expressed the minority view in *Central Hudson* when he stated his preference for a strict rather than intermediate review standard. *Id.* Ross discusses how this minority

reason for this ambiguity is that some of the justices are ready to protect commercial speech as rigorously as they would noncommercial speech.[167] Other justices are not willing to abandon intermediate scrutiny for commercial speech.[168] Critics also point out inconsistencies in the meaning and use of the phrase "intermediate scrutiny."[169] At times the phrase refers to review that defers to government rationales, but at other times it signals a more rigorous review of government regulations.[170]

By continuing to use the *Central Hudson* test, the Court implies that it is still using intermediate scrutiny for commercial speech regulations.[171] However, critics argue that the Court has made it increasingly difficult for government restrictions to satisfy the *Central Hudson* test.[172] In actuality, the Court is applying strict scrutiny review in commercial speech cases.[173]

B. *Intermediate Scrutiny Is the Appropriate Level of Judicial Review for Advertising Compounded Drugs*

Legal precedent argues in favor of retaining intermediate scrutiny review for regulations safeguarding the public.[174] By according greater weight to freedom of speech than to ensuring public safety, the Court

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view had come to dominate commercial speech jurisprudence over the previous five years. *Id.* She also comments on Justice Thomas' steadfast insistence that most commercial speech bans are per se unconstitutional. *Id.* She concludes that "the Court has determined that most advertising regulation should be subjected to something close to strict scrutiny." *Id.*

[167] *See* Ross, *supra* note 11, at 726 (noting elevation of First Amendment protection for commercial speech suggests Court views advertising as vital source of information).

[168] *See Thompson*, 535 U.S. at 389 (Breyer, J., dissenting) (protesting that majority Court applied *Central Hudson* too strictly). Justice Breyer, joined in dissent by Chief Justice Rehnquist, Justice Stevens, and Justice Ginsburg, argued that commercial speech warranted a more lenient application of First Amendment rights than political speech. *Id.*

[169] CHEMERINSKY, *supra* note 12, at 520.

[170] *Id.*; *see also Thompson*, 535 U.S. at 374 (stating that "the *Central Hudson* test is significantly stricter than the rational basis test").

[171] CHEMERINSKY, *supra* note 12, at 520.

[172] *See* discussion *supra* Part III.A.

[173] *Id.*; *see* Consula, *supra* note 122, at 379-80 (arguing that practical result of *Central Hudson* test is to give "de facto full First Amendment protection" to commercial speech, even though overt overturning of *Central Hudson* will not occur with present Court).

[174] Lorillard Tobacco Co. v. Reilly, 533 U.S. 525 (2001); Florida Bar v. Went For It, Inc., 515 U.S. 618 (1995); Bates v. State Bar of Arizona, 433 U.S. 350, 388 (1977); Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, 425 U.S. 748 (1976). Most major commercial speech cases make a sharp distinction in the level of judicial review for commercial speech versus noncommercial speech restrictions. *See* 44 Liquormart, Inc. v. Rhode Island, 517 U.S. 484, 498-99 (1996); Edenfield v. Fane, 507 U.S. 761, 767 (1993); Bd. of Trs. of State Univ. of N.Y. v. Fox, 492 U.S. 469, 480 (1989); Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y., 447 U.S. 557, 564 (1980).

has upset the balance between these competing interests.[175] The Court should either restore equilibrium to the *Central Hudson* test or develop another intermediate standard for reviewing health and safety regulations in which commercial advertising is at issue.

Previous Supreme Court cases support the argument that the Court should defer to Congress when evaluating advertising regulations for customized services such as drug compounding.[176] In *Virginia Board of Pharmacy*, the Court declared that a ban on price advertising for prepackaged drugs was unconstitutional.[177] The Court approved of prepackaged drug advertising because dispensing mass-produced drugs is simple and standardized whereas drug compounding is complex.[178] The Court underscored this distinction when noting that advertising would not be acceptable for nonstandard professional services such as medical and legal services.[179] A similar argument prevailed in *Bates v. State Bar of Arizona*.[180] There, the Court agreed to attorney advertising only if it was confined to "specifically defined" standard services.[181] By approving the advertising of standard but not complex services, the Court balanced the interests of commercial speech and public safety.[182]

Legal precedent also argues that the Court should refrain from applying strict scrutiny under *Central Hudson*'s fourth prong and instead use intermediate review.[183] In two recent cases, the Court averred that the government could justify advertising restrictions based solely on "history, consensus, and simple common sense."[184] That is exactly what the government attempted to do in *Thompson*, but the Court dismissed

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[175] *See* Margaret Gilhooley, *Constitutionalizing Food and Drug Law*, 74 TUL. L. REV. 815, 871 (2000) (claiming that "reasonable fit" test for commercial speech is unduly rigorous if it precludes Congress from requiring agency testing of drugs).

[176] *See Bates*, 433 U.S. at 391 (Powell, J., concurring); *Va. Bd. of Pharmacy*, 425 U.S. at 773-74 (Burger, J., concurring).

[177] *Va. Bd. of Pharmacy*, 425 U.S. at 773.

[178] *Id.* at 766, 773 n.25. In his concurrence, Justice Burger also stated, "Our decision today, therefore, deals largely with the State's power to prohibit pharmacists from advertising the retail price of *prepackaged drugs*." *Id.* at 774.

[179] *Id.* at 773 n.25.

[180] *Bates*, 433 U.S. at 372.

[181] *Id.*; *see also* Edenfield v. Fane, 507 U.S. 761, 778 (1993) (O'Connor, J., dissenting) (arguing that State may prohibit certain profit-seeking practices such as advertising because they are inadequately justified in terms of consumer welfare).

[182] *Bates*, 433 U.S. at 383.

[183] *See* discussion *infra* Part III.B.

[184] Lorillard Tobacco Co. v. Reilly, 533 U.S. 525, 559-60 (2001) (quoting Florida Bar v. Went For It, Inc., 515 U.S. 618, 628 (1995)).

the government's arguments.[185] In earlier cases, the Court did not require states to adopt speech regulations that were the least restrictive in achieving the government's interests.[186] The Court characterized such a requirement as a "burden."[187] The Court emphasized that regulations should be narrowly tailored to achieve their objective, but within those bounds, Congress was free to set a regulation's parameters.[188] Yet, in *Thompson*, the Court used strict scrutiny to reject the fit between FDAMA's advertising regulations and the government's goals, rendering the regulations unconstitutional.[189] The Court should adhere to its previous reasoning and permit government regulations more latitude in meeting *Central Hudson*'s fourth prong.[190]

Finally, the Court should defer more readily to Congress when examining public safety laws.[191] Intermediate level scrutiny traditionally grants greater deference to legislative intent.[192] It is the role of Congress to pass legislation on matters that affect public welfare.[193] Because such issues are often controversial, government assures citizens that it will consider divergent views when enacting laws that restrict freedoms.[194] The Court should respect Congress' role in speaking for the people when enacting such laws.[195] FDAMA's advertising restrictions are a case in

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[185] *See* Brief for Petitioners at 35, *Thompson* (No. 01-344) (describing history of congressional regulation of drug manufacturing, FDA's experience regulating compounded drugs, and common sense of restricting advertising to achieve government's substantial interests).

[186] Bd. of Trs. of the State Univ. of N.Y. v. Fox, 492 U.S. 469, 480 (1989).

[187] *Id.*

[188] *Id.*

[189] *See* discussion *infra* Part III.C.

[190] *See* Ross, *supra* note 11, at 750 (arguing that intermediate scrutiny standards have been misapplied in recent decisions, blurring bright-line rules that delineated commerce from free expression). Ross claims that the Court has failed to provide clear jurisprudence in commercial speech cases and instead offers "little beyond biting rhetoric." *Id.*

[191] *See* discussion *infra* Part III.B.

[192] Gilhooley, *supra* note 175, at 871 (agreeing with critics that because commercial speech is not political speech, it need not receive highest level of protection in order to ensure democracy).

[193] *See id.* at 871-72 (pointing out that invalidation of legislation on constitutional grounds overturns decision of elected representatives, especially when statutes concern balance of burdens and harm).

[194] *See id.* at 872 (arguing that courts need to respect approaches of compromise that lie at heart of legislative process).

[195] *Id.* Gilhooley argues that Congress should be able to address issues affecting prescription drugs as broadly as necessary and not be handicapped by the courts. *Id.* She strongly advocates that the courts avoid having to reach constitutional questions when they review consumer protection laws and regulations. *Id.* at 821. Instead, she suggests that courts use administrative law and its "hard look" standard when reviewing federal

point. Congress decided that protecting the drug approval process and making compounded drugs accessible were interests that warranted advertising restrictions.[196] The use of true intermediate scrutiny in *Thompson* would have led the Court to defer to government rationales on FDAMA's advertising limits.

Critics have argued that commercial speech merits the same First Amendment protection as noncommercial speech.[197] They insist that the standard for commercial speech, like noncommercial speech, should be the content-neutral analysis called the *O'Brien* test.[198] They reason that under *O'Brien*, government regulations that currently impinge on commercial speech would be struck down.[199]

However, if the Court were to apply the *O'Brien* test to FDAMA's compounded drug regulations, it is likely that the regulations would satisfy *O'Brien*.[200] The Court in *Thompson* held that the compounded drug regulations met criteria that correspond to the *O'Brien* test's first three requirements.[201] *O'Brien*'s fourth requirement is that the regulation's restriction on expression must be incidental and no greater than necessary to further the government's interest.[202] Although it resembles the *Central Hudson* test's fourth prong, *O'Brien*'s fourth requirement lacks *Central Hudson*'s recent strict scrutiny bite.[203] Recently,

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regulations. *Id.* at 822. She likens the hard look standard to an intermediate level of scrutiny in commercial speech cases. *Id.*

[196] Brief for Petitioners at 17-28, *Thompson* (No. 01-344).

[197] *See* Richard T. Kaplar, *The FDA and the First Amendment*, *in* BAD PRESCRIPTION FOR THE FIRST AMENDMENT 56-58 (Richard T. Kaplar ed., 1993) (concluding that commercial speech of drug manufacturers merits full First Amendment protection due to its utilitarian value to listeners as economic decisionmakers); Alex Kozinski & Stuart Banner, *Who's Afraid of Commercial Speech*, 76 VA. L. REV. 627, 651-53 (1990) (arguing that in free market economy, it is important to grant commercial speech full First Amendment protection).

[198] Kaplar, *supra* note 197, at 57-58; Kozinski & Banner, *supra* note 197, at 651-52.

[199] *See* Kaplar, *supra* note 197, at 58 (noting that FDA regulations meeting *O'Brien* test could still regulate drug information, but meeting test would be insurmountable challenge).

[200] *See* Kozinski & Banner, *supra* note 197, at 651 (noting that under *O'Brien* test, consumer fraud and securities regulations might survive Court's scrutiny).

[201] Thompson v. W. States Med. Ctr., 535 U.S. 357, 367-68 (2002); United States v. O'Brien, 391 U.S. 367, 377 (1968). *O'Brien*'s first requirement is that the regulation must be within the constitutional power of the government. *Id.* The second requirement is that the regulation must further an important governmental interest. *Id.* The third factor is that the governmental interests must be unrelated to the suppression of information. *Id.* The fourth factor is that incidental restrictions on speech must be no greater than is essential to the furtherance of that interest. *Id.*

[202] *O'Brien*, 391 U.S. at 377.

[203] *See* Ross, *supra* note 11, at 734 (noting that, since 1989, Court has not required least restrictive or least intrusive means of advancing government's interest for content-neutral

when applying *O'Brien*, the Court required only that the government prove that without speech restrictions, it would achieve its interests less effectively.[204] Without FDAMA's restrictions on compounded drug advertising, the government will not achieve its goals as effectively as it did with the restrictions.[205] Thus, it seems likely that FDAMA's regulations would pass the test the Court uses to evaluate noncommercial speech regulations.

Legal scholars and the Court consider the *O'Brien* test to be intermediate scrutiny.[206] In advocating that the Court treat commercial speech similarly to noncommercial speech, the critics seem to be arguing, then, for intermediate scrutiny review. Under intermediate scrutiny, public safety regulations like FDAMA's can satisfy First Amendment requirements if they are drawn narrowly to fit the government's interests.

C. *The Court's Faulty Reasoning in* Thompson *Resulted in a Holding That Compromises Public Safety*

The Court based its holding in *Thompson* on faulty premises and on insufficient consideration of important governmental interests.[207] The Court misinterpreted the extent of FDAMA's restrictions.[208] It also underestimated the influence of advertising on drug use, prescribing habits, and drug industry growth.[209] Furthermore, the Court suggested

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regulations).

[204] *See id.* (citing Court's comment in *Ward v. Rock Against Racism*, 491 U.S. 781, 799 (1989)).

[205] *See Thompson*, 535 U.S. at 384.

[206] Turner Broad. Sys. v. F.C.C., 520 U.S. 180, 185 (1997); CHEMERINSKY, *supra* note 12, at 1028; George W. Evans and Arnold I. Friede, *The Food and Drug Administration's Regulation of Prescription Drug Manufacturer Speech: A First Amendment Analysis*, 58 FOOD & DRUG L.J. 365, 394 (2003); R. Randall Kelso, *Standards of Review Under the Equal Protection Clause and Related Constitutional Doctrines Protecting Individual Rights: the "Base Plus Six" Model and Modern Supreme Court Practice*, 4 U. PA. J. CONST. L. 225, 253 (2002).

[207] *See Thompson*, 535 U.S. at 388 (Breyer, J. dissenting) (arguing that Court majority undervalued government's reasons for FDAMA's advertising restrictions and too easily assumed that there were viable alternatives).

[208] *Compare id.* at 371-72 (comparing FDAMA's speech restrictions to total speech prohibitions in *Rubin* and *44 Liquormart* that Court found unconstitutional), *with* Brief for Petitioners at 49-52, *Thompson* (No. 01-344) (rebutting similar argument made earlier by Ninth Circuit that FDAMA absolutely prohibited speech), *and* Reply Brief for Petitioners at 19, *Thompson* (No. 01-344) (arguing FDAMA's provisions were significantly less onerous than absolute prohibitions of speech involved in *44 Liquormart* and cited by Ninth Circuit in *W. States Med. Ctr. v. Shalala*, 238 F.3d 1090, 1096 (9th Cir. 2001)).

[209] *Thompson*, 535 U.S. at 382 (Breyer, J., dissenting) (citing evidence that consumer-oriented advertising creates strong demand for particular drugs).

alternatives to FDAMA's restrictions that fail to meet all three important government interests.[210] These shortcomings produced a decision that denies the government adequate means to protect the public from unsafe prescriptions, while still keeping compounded drugs accessible.

The Court misinterpreted the extent of FDAMA's restrictions on advertising by treating them as though they were a total ban.[211] However, FDAMA's provisions only partially restricted advertising.[212] FDAMA permitted pharmacists to advertise that they offered compounding services and that they were experts in compounding.[213] Pharmacies could also advertise the price mark-up they charged for compounding.[214] Thus, the public could easily learn about available compounding services and costs.[215] In *Thompson*, the Court also failed to acknowledge that pharmacists could advertise compounded drugs if they submitted them to the FDA for approval.[216] This was the same rule that federal courts upheld for years for mass manufacturers of drugs.[217]

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[210] *Thompson*, 535 U.S. at 371-88.

[211] *Id.* at 371 (citing *Rubin*, concerning ban on advertising alcohol content on beer labels, and *44 Liquormart*, concerning prohibition on price advertising, as examples of speech restrictions that were more extensive than necessary). In both cases, however, the restrictions were total bans on advertising. 44 Liquormart, Inc. v. Rhode Island, 517 U.S. 484, 489-90 (1996); Rubin v. Coors Brewing Co., 514 U.S. 376, 480-81 (1995).

[212] *Thompson*, 535 U.S. at 363-64; Brief for Petitioners at 9, *Thompson* (No. 01-344).

[213] *Thompson*, 535 U.S. at 363-64; Brief for Petitioners at 9, 50, *Thompson* (No. 01-344).

[214] Brief for Petitioners at 50, *Thompson* (No. 01-344).

[215] *Id.*

[216] Reply Brief for Petitioners at 18-19, *Thompson* (No. 01-344). FDAMA's restrictions on advertising compounded drugs only affected enterprises that did not submit the customized drugs for FDA testing. *Id.*

[217] Weinberger v. Hynson, Westcott & Dunning, Inc., 412 U.S. 609, 613 (1973) (upholding necessity for manufacturer or distributor to demonstrate that drug is both safe and effective for each intended use). Before FDAMA was enacted in 1997, circuit courts agreed with the government that compounded drugs were new drugs that were subject to the new drug approval process. *See* Prof'ls & Patients for Customized Care v. Shalala, 56 F.3d 592, 593 n.3 (5th Cir. 1995); United States v. Baxter Healthcare Corp., 901 F.2d 1401, 1410-11 (7th Cir. 1990); United States v. Algon Chem. Inc., 879 F.2d 1154, 1158 (3d Cir. 1989); United States v. 9/1 Kg. Containers, 854 F.2d 173, 179 (7th Cir. 1988). The Supreme Court affirmed that unapproved new drugs should be prohibited, except for those exempted by Congress. *See* Brief for Petitioners at 3, *Thompson* (No. 01-344); *see also* United States v. Generix Drug Corp, 460 U.S. 453, 460-61 (1983) (holding that drug that differs in material way from approved drug is new drug that must be established through FDA testing process that it is safe and effective). Congress specifically asked the FDA to exempt compounded drugs from the new approval process because of its prohibitive cost. *Thompson*, 535 U.S. at 360-61; Brief for Petitioners at 28, *Thompson* (No. 01-344). Federal courts supported the FDA when it cracked down on pharmacies that were mass-manufacturing drugs under the guise of compounding. United States v. Sene X. Eleemosynary Corp., 479 F. Supp. 970, 978 (S.D. Fla. 1979); Cedars N. Towers Pharmacy, Inc. v. United States [1978-1979 Transfer Binder] Food Drug Cosm. L. Rep. (CCH) ¶ 38,200

FDAMA offered two alternatives to pharmacies: either submit compounded drugs for testing and advertise freely, or do not submit compounds for testing and limit advertising.[218] FDAMA's solution struck a balance between public safety and commercial speech. The Court's holding in *Thompson* destroyed that balance.[219]

Furthermore, the Court's assertion that FDAMA's restrictions prevented doctors from learning about alternative drugs was faulty.[220] The Court stated that FDAMA prevented pharmacists from telling doctors about alternative drugs available through compounding.[221] This was not true.[222] The FDA did permit pharmacists to recommend compounds to physicians for specific patients and permitted doctors to consult pharmacists about alternative drug compounds or forms.[223] Doctors could also obtain information on alternative drugs from scientific books and journals, drug vendor literature, and medical conferences and continuing education programs.[224]

In finding that FDAMA's restrictions were too extensive, the Court erroneously dismissed the influence of advertising on drug use and industry growth.[225] Secondary sources and sales statistics, however,

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(S.D. Fla. Aug. 28, 1978). Thus, based on the correlation between advertising and the mass manufacture of drugs and receiving federal court support for its new drug approval process, it was logical for the FDA and Congress to include advertising restrictions in FDAMA in 1997. Brief for Petitioners at 34, *Thompson* (No. 01-344).

[218] Reply Brief for Petitioners at 18-19, *Thompson* (No. 01-344).

[219] *Thompson*, 535 U.S. at 377-90 (Breyer, J., dissenting).

[220] *Id.* at 374-77.

[221] *Id.* at 377.

[222] *See* Brief for Petitioners at 51-52, *Thompson* (No. 01-344).

[223] *Id.* The government argues that the FDA permitted a pharmacist to initiate such a call to a physician in the context of an existing practitioner-patient-pharmacist relationship. *Id.* Such a practice fits squarely within the traditional scope of drug compounding in which a pharmacist, based on previous knowledge of the patient, his or her medications, and the pharmacist's relationship with the physician, responds to the patient's unique needs by suggesting a compound to better meet those needs. *Id.* This is very different from the pharmacist advertising a specific drug compound to generate sales to new, unknown customers, with no knowledge of their medication history. *Id.* at 51.

[224] *See Thompson*, 535 U.S. at 389 (pointing out that doctors can obtain information about individual drugs through many channels other than directly from pharmacists); J. Howard Beales, III, *FDA Regulation of Pharmaceutical Advertising: Economic Analysis and the Regulation of Pharmaceutical Advertising*, 24 SETON HALL L. REV. 1370, 1394-95 (1994) (explaining that, when manufacturers are unable to directly inform physicians about drug uses, they can diffuse that knowledge through symposia and other continuing education programs).

[225] *See Thompson*, 535 U.S. at 371-73 (expressing doubt that manufacturers could not market drugs on large scale without advertising or that physicians would prescribe unnecessary medications if pressured by patients). The Court's skepticism about the link between advertising and drugs might have arisen from the scarcity of case documentation

verify the strong connection between advertising and drugs.[226] The purpose of direct-to-consumer (DTC) drug advertising is to persuade consumers to request prescriptions for advertised drugs from their doctor.[227] Pharmaceutical companies have been successful in accomplishing that purpose, as seen in the 6 percent growth in the number of prescriptions dispensed annually, totaling three billion for the year 2000.[228] Over a similar period, the pharmaceutical industry increased DTC advertising spending 32.9 percent per year on average, from $791 million in 1996 to $2.467 billion in 2000.[229] Most of these sales and advertising increases occurred after 1997, when the FDA loosened advertising restrictions for commercial prescription drugs.[230] The timing of the increases substantiates the causal effect of advertising on drug

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for that link. *See* Lars Noah, *Advertising Prescription Drugs to Consumers: Assessing the Regulatory and Liability Issues*, 32 GA. L. REV. 141, 146 n.21 (1997) (noting that FDA has preferred to issue nonbonding policy statements and guidelines or pursue individual enforcement actions rather than litigate violations of its advertising regulations); Beales, *supra* note 224, at 1381-82 (explaining that although detailed set of advertising regulations for prescription drugs is in place, there are no cases interpreting rules or statute itself).

[226] *See* Beales, *supra* note 224, at 1377 (noting that importance of advertising has been demonstrated in pharmaceutical market by significant increase in prescription drug's market share after being advertised as compared to its market share before advertising).

[227] Noah, *supra* note 225, at 150; *see also* Nicole Endejann, Comment, *Is the FDA's Nose Growing?: The FDA Does Not "Exaggerate Its Overall Place in the Universe" When Regulating Speech Incident to "Off-Label" Prescription Drug Labeling and Advertising*, 35 AKRON L. REV. 491, 502 (2002) (commenting on criticism that direct-to-consumer advertising will adversely affect physician-patient relationship). *See generally* Fred Gebhart, *Rx Scoreboard*, 144 DRGTOPICS 31, Apr. 3, 2000, *available at* 2000 WL 9185056. Gebhart analyzes how direct-to-consumer advertising suggests to consumers that they may need to purchase a drug for a medical condition they would not otherwise know they had. This can lead to a fundamental alteration in the roles of doctor and patient, with the worst scenario resulting in "a world of aggressive, distrustful, and only partially informed patients and cowed physicians." *Id.* (quoting Michael Wilkes, M.D., associate professor of medicine at University of California Los Angeles Medical Center).

[228] Larry Levitt, The Henry J. Kaiser Family Foundation, *Prescription Drug Trends* (Nov. 2001) (documenting annual percent increases in the United States of 7.5% in 1993, 3.4% in 1994, 6.1% in 1995, 4.5% in 1996, 4.6% in 1997, 6.8% in 1998, 9.1% in 1999, and 5.6% in 2000). For 2000, the Foundation records the average number of prescriptions per person in the United States as 10.8. *Id.*

[229] Levitt, *supra* note 228, at Chart 9. Statistics cited for 1996 to 2000. Another indirect indicator of the efficacy of prescription drug advertising can be seen in the retail cost of prescription drugs, which averaged $27.16 per prescription in 1990 as compared to $65.29 per prescription in 2000. *Id.* at Chart 5. Even discounting the gain for inflation, the dramatic increase suggests that prescription drug advertising does not lower the prices of drugs, but instead raises them. *Id.* Also, during eight out of nine years from 1991 to 2000, retail pharmacies were most responsible for drug price increases, not the manufacturers. *Id.*

[230] Gebhart, *supra* note 227.

sales.[231]

Advertising produces such phenomenal sales because patients who see the ads successfully pressure their doctors to write prescriptions, whether they actually need the drug or not.[232] Prescribing a drug that may not be obviously harmful is a way to pacify a patient, especially one suffering from chronic or annoying symptoms.[233] DTC advertising also persuades patients to ask for specific drug brands and leads to patients' resisting the prescribing advice of their doctors.[234] Combine this predilection for choosing drugs based on advertising with the lack of testing for compounded drugs, and the result is an increased potential for unsafe drug use.

Lastly, the Court offered alternatives that were neither as practical nor as effective in meeting the government's interests as FDAMA's ad restrictions.[235] The Court suggested that the government use the factors from its 1992 Compliance Guide to curtail illegal mass manufacture.[236] Yet, the Guide explicitly rebutted these alternatives by warning that they insufficiently distinguished legal compounding from illegal manufacturing.[237] The Court's suggestion to limit overall quantities of compounded drugs would make compounds less available for people who really need them.[238] Advertising could exacerbate this problem, depleting limited quantity drugs through sales to customers who merely want the drugs but do not need them.[239]

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[231] *See id.* (discussing enormous influence of direct-to-consumer (DTC) advertising on drug sales after FDA relaxed advertising guidelines in 1997).

[232] Thompson v. W. States Med. Ctr., 122 S. Ct. 1497, 1512 (2002); *see also* Gebhart, *supra* note 227. Gebhart discusses the pros and cons of DTC advertising in the drug industry with the vice president of marketing for Express Scripts, the nation's largest independent pharmacy benefit manager. Noting the significant tension created when patients ask their physician for a prescription they don't need, the vice president comments, "The physician can be put in the position of having to unsell the patient on a completely inappropriate product. That's what physicians hate about DTC." *Id.*

[233] Gebhart, *supra* note 227.

[234] *See* Noah, *supra* note 225, at 150.

[235] *Thompson*, 535 U.S. at 371-73.

[236] *Id.* For instance, the government could ban the use of commercial scale manufacturing equipment in compounding drugs, or restrict compounding to fill only those prescriptions already received. The Court also suggested that the government limit the amount of a compounded drug by volume, number of prescriptions, gross revenue or profits. *Id.*

[237] *Id.* at 386.

[238] *Id.*

[239] *Id.*

In summary, FDAMA carefully tailored its restrictions on advertising compounded drugs to achieve substantial government goals.[240] The Court agreed that preserving the integrity of the drug approval process and the availability of compounded drugs were clearly important interests.[241] Yet, by discounting advertising's effect on drug sales, misinterpreting the extent of FDAMA's restrictions, and embracing ineffective alternatives, the Court compromised those interests.[242] Allowing pharmacies to advertise specific compounded drugs subverts the government's new drug approval process.[243] It permits pharmacies to achieve significant sales without undergoing FDA drug testing.[244] Furthermore, that practice releases a greater number of potentially unsafe and ineffective drugs into the market.[245] It also undermines the willingness of manufacturers who currently pay for FDA drug testing to undergo that testing in the future.[246] By striking down FDAMA's advertising restrictions, the Court handed pharmacists the sales increases they sought and dealt a blow to public safety.

CONCLUSION

By applying the *Central Hudson* test to FDAMA's advertising regulations using strict scrutiny review, the Court in *Thompson* found the regulations to be unconstitutional.[247] The Court formulated the *Central Hudson* test to be an intermediate level of review for laws restricting commercial free speech.[248] Over the years, however, the Court has widely varied its level of scrutiny, often leading to divergent outcomes in commercial speech cases.[249] The outcome in *Thompson* is alarming. The Court paid lip-service to the importance of protecting the drug approval process, ensuring the availability of compounded drugs, and balancing these values against competing interests.[250] However, instead,

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[240] *See* discussion *supra* Parts II, III.C.

[241] *Thompson*, 535 U.S. at 369.

[242] *See* discussion *supra* Part III.C.

[243] Brief for Petitioners at 33, *Thompson* (No. 01-344); *Thompson*, 535 U.S. at 387 (Breyer, J., dissenting) (2002).

[244] Brief for Petitioners at 33, *Thompson* (No. 01-344).

[245] *Id.*; *see also Thompson*, 535 U.S. at 382-83.

[246] Brief for Petitioners at 33, *Thompson* (No. 01-344).

[247] *Thompson*, 535 U.S. at 378-80.

[248] Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y., 447 U.S. 557, 566 (1980).

[249] *See* discussion *supra* Part III.A.

[250] *Thompson*, 535 U.S. at 368-69.

the Court compromised all three goals by striking down FDAMA's advertising limits. The result was to award full First Amendment protection to pharmacists' commercial speech rights while jeopardizing public safety through the proliferation of untested drugs.

The time has come for the Court to resolve its inconsistent approach to commercial speech and the *Central Hudson* test. Several members of the Court want to abandon *Central Hudson* because they say it does not sufficiently protect commercial speech.[251] Yet, in cases like *Thompson* that involve public safety, the Court's near strict scrutiny review has become too protective of free speech rights.[252]

In *Thompson*, the Court should have used intermediate scrutiny to uphold FDAMA's limited advertising regulations. Legal precedent and appropriate judicial deference to legislative decision-making support intermediate review. The need for safe prescription drugs required the Court to adopt a balancing approach between commercial speech rights and public safety.

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[251] *Id.* at 368; *see also* David L. Hudson, Jr., *Justice Clarence Thomas: The Emergence of a Commercial Speech Protection*, 35 CREIGHTON L. REV. 485, 497 (2002) (discussing Justice Thomas's now familiar condemnation of *Central Hudson* test for commercial speech).

[252] *See* Gilhooley, *supra* note 175, at 876 (arguing that autonomy rationale for commercial free speech is at odds with Congress' ability to limit access of untested drugs).

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