

Public Health in the Shadow of the First Amendment

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Collected Readings

The attached sources were chosen to inform the conference discussions and to put in one place key materials that illustrate the emerging tension between First Amendment case law and the public's health.

The sources are all heavily excerpted. Most internal citations have also been removed, except when necessary to show context.

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HEALTH BEHAVIORS PANEL

Today, the First Amendment comes into potential conflict with any public health campaign that is designed to highlight particular information or risks to individuals, or to influence an individual's perception of legal products. Such programs are, however, an increasingly prominent aspect of public health efforts, for example to combat obesity and smoking. Prominent campaigns have been recently launched in the U.S. to require the disclosure of nutritional/caloric information at restaurants, to mandate graphic warnings on cigarette cartons, and to discourage the marketing of junk food to children. All have been subject to First Amendment challenge. Even disclosure of plainly factual information, such as caloric content, is not immune from constitutional challenge (although such challenges have so far not succeeded). More risky are strategies that seek to condense information into simple heuristics, or that deliberately invoke emotion in order to persuade the public. A prominent federal appeals court recently concluded, for example, that the FDA's proposed graphic warnings on cigarettes were unconstitutional because they strayed from the presentation of factual information and instead attempted to use emotion to persuade. Children as well as adults are the targets of sophisticated food and cigarette marketing, and evidence clearly shows that such marketing has significant effects on their experience and choices. But it is unclear whether or how government can counteract these messages and their influence on health, without running afoul of the First Amendment. Finally, cases about marketing of food and tobacco must be considered alongside recent precedents about information disclosure in the abortion context. Can the government require clinics or doctors to transmit certain information or images to women seeks abortions, or might these interventions – like graphic warnings on cigarettes – be rejected as too emotive, or otherwise as improperly compelled speech? These questions will be revisited in the next section on intersections between the First Amendment and the regulation of professional conduct.

Important questions that are raised by this series of cases, and that will be addressed in this panel include: How important are information campaigns to reducing the ill-health effects of obesity and smoking? How important is emotion to such campaigns, and should the use of emotion in social marketing raise constitutional concerns? Should courts consider evidence from behavioral psychology when assessing the validity of social marketing campaigns? Should government be allowed to use the same tools that advertisers use to garner attention and convey information in simplified fashion – and if they are not, what will the resulting “market” in speech about products look like? What leeway does government have to constrain marketing to children in particular, especially given that it may be difficult to regulate marketing to children without also affecting marketing that reaches adults? And in general, what are the implications of constitutionalizing this area of commercial regulation, and allocating more authority to courts to adjudicate complex issues of science and public health?

Food Marketing to Children and Youth: Threat or Opportunity?

National Research Council¹ (2006), pp. 342-351

[This report provides evidence of the influence of food marketing on the dietary patterns and health behaviors of children and youth, as well as a set of policy proposals. The excerpted section, which analyzes the legal regulation of the food industry's marketing to children, provides a useful summary of some trends in the commercial speech case law up to that point.]

Legal Regulation of Advertising and Marketing

The legal regulation of food is frequently directed not merely at defects or dangers in the food itself, but also at the ways in which food is marketed. Common law and related statutory causes of actions have traditionally provided redress for harms caused by the fraudulent selling of food such as misbranded meat (*United States v. Jorgensen*, 1998), misleading or deceptive advertising related to food (*National Bakers Services, Inc. v. FTC*, 1964), and failure to warn with regard to dangerous food. The precise legal standards vary in the 50 states, and also change over time.

The regulation of consumer advertising is a central task of the Federal Trade Commission (FTC). The FTC is authorized to regulate “unfair or deceptive acts or practices in or affecting commerce” (15 U.S.C. § 45(a)(1), 2002), and in particular, any “false advertisement . . . in or having an effect upon commerce, by any means, for the purpose of inducing, or which is likely to induce, directly or indirectly the purchase of food . . .” (15 U.S.C. § 52(a)(1), 2002). “[A]n advertisement is deceptive under the Act if it is likely to mislead consumers, acting reasonably under the circumstances, in a material respect. . . .” In implementing this standard, the FTC examines the overall net impression of an advertisement and engages in a 3-part inquiry: (1) What claims are conveyed in an advertisement? (2) Are the claims false or misleading? (3) Are the claims material to prospective consumers?”. . . In determining the acceptability of advertising to children, the law—in both its judicial and administrative manifestations—recognizes the special status and cognitive limitations of children. Advertisements that are acceptable if addressed to an adult, might be deceptive, unfair, or misleading when directed to a child. When an act or a practice is targeted to a specific audience such as children, the FTC will determine whether it is unfair or deceptive by reference to its effect on a reasonable member of that group. The FTC thus evaluates the legality of advertisements or sales practices directed to children in terms of how they are perceived by an ordinary child. The FTC has required those who sought to use television commercials containing characters such as Santa Clause or the Easter Bunny to promote 1-900 telephone numbers allowing children to speak with the fictional characters and to win prizes, to disclose a range of relevant information “in a manner understandable to children.” Congress

¹ The National Institute of Medicine's Committee on Food Marketing and the Diets of Children and Youth prepared the report. Members of this committee included: J. Michael McGinnis (chair); Daniel Anderson; J. Beales, III; David Britt; Sandra Calvert; Keith Darcy; Aimee Dorr; Lloyd Kolbe; Dale Kunkel; Paul Kurnit; Robert Post; Richard Scheines; Frances Seligson; Mary Story; Ellen Wartella; and Jerome Williams.

followed up on the FTC's efforts in this area by enacting the Telephone Disclosure and Dispute Resolution Act (15 U.S.C. § 5701 et seq., 2004), which, among other requirements, mandated that the FTC promulgate rules which prohibited marketers from directing advertisements for pay-per-call services at children under the age of 12 years, unless the service was for a bona fide educational service.

In 1978 the FTC sought commentary on a proposed rule that would ban television advertisements addressed to children too young to understand the selling purpose of advertising and also ban television advertisements for food products posing the most serious dental health risks which are directed to, or seen by, audiences with a significant proportion of older children. The proposed rulemaking, known as "kid-vid," proved intensely controversial, evoking criticism from Congress, and resulted in a 1981 FTC staff recommendation that the FTC terminate the proposed rulemaking.

There is an important legal distinction between regulations of food and regulations of advertising for food. The former poses few constitutional questions, whereas the latter directly raises issues of freedom of expression. Although the Supreme Court had held in 1942 that "the Constitution imposes no . . . restraint on government" regulation of "purely commercial advertising," (*Valentine v. Chrestensen*, 1942), it reversed course in 1976 (*Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 1976) and created what is now known as "commercial speech doctrine," a complex web of rules restricting government regulations of private advertising. The precise nature of these rules remains contested and complex, but the doctrine which the Court uses most frequently to resolve constitutional issues of commercial speech is the Central Hudson test:

In commercial speech cases, then, a four-part analysis has developed. At the outset, we must determine whether the expression is protected by the First Amendment. For commercial speech to come within that provision, it at least must concern lawful activity and not be misleading. Next, we ask whether the asserted governmental interest is substantial. If both inquiries yield positive answers, we must determine whether the regulation directly advances the governmental interest asserted, and whether it is not more extensive than is necessary to serve that interest (*Central Hudson Gas & Electric Corporation v. Public Service Commission*, 1980).

Under the Central Hudson test, government can regulate advertisements which are misleading. There is some suggestion in the case law that advertisements that are merely potentially misleading, as distinct from inherently misleading, may not be prohibited altogether, but must instead be subject to milder correctives, such as mandatory disclosure requirements designed to ameliorate potential deception (*Peel v. Attorney Registration and Disciplinary Commission*, 1990). Because "[t]he determination whether an advertisement is misleading requires consideration of the legal sophistication of its audience" (*Bates v. State Bar of Arizona*, 1977), it is likely that advertisements addressed to children may be deemed misleading even if they would not be if addressed to adults (*FTC v. R. F. Keppel & Brothers, Inc.*, 1934).

The Central Hudson test imposes constitutional restraints on government efforts to restrict truthful, non-misleading advertisements in order to achieve desirable policy objectives like preventing smoking by children (*Lorillard Tobacco Company v. Reilly*, 2001) or promoting energy conservation (*Central Hudson Gas & Electric Corporation v. Public Service Commission*, 1980). Government regulations must directly advance a substantial state interest in a manner that is not more “extensive than is necessary.” It is typically not difficult to demonstrate that well-designed regulation directly advances the interests it is designed to serve. Although the government ““must demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree,”” (*Greater New Orleans Broadcasting Association v. United States*, 1999), the Supreme Court has generally proved receptive to the practical “theory that product advertising stimulates demand for products, while suppressed advertising may have the opposite effect” (*Lorillard Tobacco Company v. Reilly*, 2001).

In recent years, however, the Supreme Court has tended to interpret the final prong of the Central Hudson test with increasing severity. It has used the “no more extensive than is necessary” requirement to strike down many government efforts to regulate truthful, non-misleading advertising (*Lorillard Tobacco Company v. Reilly*, 2001; *Thompson v. Western States Medical Center*, 2002). The Court has not been entirely consistent in its interpretation of this requirement. Although, on the one hand, the Court has “made it clear that ‘the least restrictive means’ is not the standard” and that case law instead requires merely “a reasonable ‘fit between the legislature’s ends and the means chosen to accomplish those ends’” (*Lorillard Tobacco Company v. Reilly*, 2001), the Court has also, on the other hand, held “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” (*Thompson v. Western States Medical Center*, 2002). What is clear is that a majority of the Court has grown decidedly unreceptive to the idea that the state can prohibit “the dissemination of truthful commercial information in order to prevent members of the public from making bad decisions with the information” (*Thompson v. Western States Medical Center*, 2002, at 374–375). . . .

The extent to which Central Hudson will govern restrictions on marketing as well as restrictions on advertising is not clear. In *Hoffman Estates v. Flipside*, the Court considered a village ordinance that made it illegal for any person to “sell any items, effect, paraphernalia, accessory or thing which is designed or marketed for use with illegal cannabis or drugs” without first obtaining a license from the government (*Hoffman Estates v. Flipside, Hoffman Estates, Inc.*, 1982). Despite the fact that the restrictions of the ordinance were triggered because of “the presence of drug-related designs, logos, or slogans on paraphernalia,” the Court ruled that “the village does not restrict speech as such, but simply regulates the commercial marketing of items that the labels reveal may be used for an illicit purpose.” The Court added that “insofar as any commercial speech interest is implicated here, it is only the attenuated interest in displaying and marketing merchandise in the manner that the retailer desires. We doubt that the village’s restriction on the manner of marketing appreciably limits Flipside’s communication of information.”

In *Lorillard Tobacco Company v. Reilly* (2001) the Court upheld against the First Amendment challenge a Massachusetts law that required retailers to place all tobacco products behind a counter and that prohibited retailers from permitting customers to handle tobacco products before they had contact with a salesperson. The Court held that even “[a]ssuming that petitioners have a cognizable speech interest in a particular means of displaying their products,” the statute survived First Amendment scrutiny because it sought “to regulate the placement of tobacco products for reasons unrelated to the communication of ideas.”

These decisions suggest that the line between regulating advertising and regulating the marketing of products is quite unclear. The Court has intimated that the latter may be subject to different and more lenient forms of constitutional scrutiny than the former, even if marketing regulations are triggered by communicative content. Yet lower courts have applied the Central Hudson test to restrictions on marketing that include telemarketing (*Mainstream Marketing Services, Inc. v. FTC*, 2004), “winback” marketing (*Southwestern Bell Telephone, L.P. v. Moline*, 2004), and the use of consumer information in marketing (*Trans Union, LLC v. FTC*, 2002).

The Central Hudson test governs regulations of advertising that apply to the general public. It is probable that the test will not pertain if government wishes to regulate advertising within specific and limited institutional contexts, like prisons or schools, in which the state exercises more comprehensive managerial control. The Court has held that in such environments state regulations of speech should be treated with special and considerable deference (*Burbridge v. Sampson*, 1999; *Hazelwood School District v. Kuhlmeier*, 1988; *Jones v. N.C. Prisoners’ Labor Union, Inc.*, 1977; *Thornburgh v. Abbott*, 1988; *Turner v. Safley*, 1987; *Williams v. Spencer*, 1980).

Because “there is a compelling interest in protecting the physical and psychological well-being of minors” (*Sable Communications, Inc. v. FCC*, 1989) special constitutional rules may also apply to the regulation of advertising addressed to children. Although children retain First Amendment rights, it is also clear that in “at least . . . some precisely delineated areas, a child . . . is not possessed of that full capacity for individual choice which is the presupposition of First Amendment guarantees” (*Ginsberg v. New York*, 1968). For this reason “material which is protected for distribution to adults is not necessarily constitutionally protected from restriction upon its dissemination to children.” Specific constitutional concerns may be raised if state regulations substantially interfere with the ability of parents to communicate information to their children (*Bolger v. Youngs Drug Products Corporation*, 1983), but even if “the supervision of children’s reading may best be left to their parents, the knowledge that parental control or guidance cannot always be provided and society’s transcendent interest in protecting the welfare of children justify reasonable regulation of the sale of material to them”(Ginsberg v. New York, 1968). Schools have broad discretion in restricting speech if that speech poses a material and substantial disruption (*Tinker v. Des Moines Independent School District*, 1969), bears the imprimatur of the school (*Hazelwood School District v. Kuhlmeier*, 1988), or is inconsistent with its basic educational mission (*Bethel School District v. Fraser*, 1986).

The primary constitutional constraint which the Court has imposed on the regulation of children's advertising flows from the idea that "the governmental interest in protecting children from harmful materials . . . does not justify an unnecessarily broad suppression of speech addressed to adults" (*Reno v. American Civil Liberties Union*, 1997). Thus the Court ruled in a recent case that even if a state has an important interest in regulating the advertising of tobacco to children, it must nevertheless respect the fact that "tobacco manufacturers and retailers and their adult consumers still have a protected interest in communication" (*Lorillard Tobacco Company v. Reilly*, 2001). Regulation of children's advertising must not only satisfy the final prong of the Central Hudson test, but it must also respect the integrity of communications between an advertiser and adults. It may not "reduce the adult population . . . to reading only what is fit for children" (*Butler v. Michigan*, 1957). As the Court recently said in the context of striking down restrictions on commercial mail designed, in part, to limit children's access to certain information: "The level of discourse reaching a mailbox simply cannot be limited to that which would be suitable for a sandbox" (*Bolger v. Youngs Drug Products Corp.*, 1983; *Lorillard Tobacco Company v. Reilly*, 2001).

There are also distinct constitutional rules that apply to federal regulation of the broadcast media. Although "broadcasting is clearly a medium affected by a First Amendment interest" (*Red Lion Broadcasting Company v. FCC*, 1969), it is accorded "special treatment" (*Action for Children's Television v. FCC*, 1995; *FCC v. Pacifica Foundation*, 1978). This is because broadcast frequencies are said to constitute "a scarce resource" that broadcasters hold in trust for the general public (*Columbia Broadcasting System, Inc. v. Democratic National Committee*, 1973; *Red Lion Broadcasting Company v. FCC*, 1969) and because the broadcast media are said to constitute "a uniquely pervasive presence in the lives of all Americans" that reach into "the privacy of the home," where they become "uniquely accessible to children, even those too young to read" (*FCC v. Pacifica Foundation*, 1978). The Court has concluded that "the government's interest in the 'well-being of its youth' and in supporting 'parents' claim to authority in their own household' . . . amply justifies special treatment of indecent broadcasting." In the special case of broadcast media, government regulation can infringe on adult communicative rights in order to ensure the protection of children.

Congress has largely entrusted the regulation of broadcast media to the Federal Communications Commission (FCC), which possesses a "broad" and "expansive" power "to assure that broadcasters operate in the public interest" (*McConnell v. FEC*, 2003; *Red Lion Broadcasting Company v. FCC*, 1969). The FCC has promulgated rules to protect the interests of children. Of particular pertinence are the FCC's rules enforcing the Children's Television Act, P.L. No. 101-437, 104 Stat. 996 (1990), which sets advertising limits for children's programming. The Act requires television broadcasters to "limit the duration of advertising in children's television programming to not more than 10.5 minutes per hour on weekends and not more than 12 minutes per hour on weekdays" (47 U.S.C. § 303a(b), 2002). The FCC interpreted children's programming to refer to "programs originally produced and broadcast primarily for an audience of children 12 years of age and under," and it crafted rules specifically designed to protect such

children, who “constitute the audience primarily affected by overcommercialization because they are the persons who have the most difficulty distinguishing between commercial and programming material.” The FCC also regulates television stations’ broadcast of “program-length commercials,” which it defines as “a program associated with a product, in which commercials for that product are aired” (16 C.F.R. § 308.3(a)(6), 2005). The FCC has applied these rules to prevent integrated cross-promotion. In one instance, it fined a television station which broadcast an advertisement for “Disney on Ice” during an episode of “Chip and Dale’s Rescue Rangers.” In holding the station responsible for violating the rule, the FCC noted that the policy was motivated by “a fundamental regulatory concern, that children who have difficulty enough distinguishing program content from unrelated commercial matter, not be all the more confused by a show that inter-weaves program content and commercial matter” (UTV of San Francisco [KBHK-TV], 10 FCC Record 10,986 [Oct. 4, 1995]). The FCC has held various other stations liable for violating this marketing restriction as well (North Carolina Broadcasting Partners [WCCB-TV], 16 FCC Record 5,627 [Mar. 7, 2001]; Gary M. Cocola [KXVO-TV], 15 FCC Record 9,192 [May 26, 2000]; Peak Media of Pennsylvania [WWCP-TV], 14 FCC Record 13,937 [Aug 27, 1999]).

Because of the special constitutional status of the broadcast media, there is little doubt that these FCC regulations meet First Amendment standards, even though they substantially interfere with the ability of advertisers to reach adults, who often view children’s programs. The committee agreed that there was potential benefit from children’s advertising closely aligned with healthful diets, and if an emphasis on the advertising of healthful foods and beverages could not be accomplished voluntarily, Congress should consider and, most felt, enact legislation mandating the shift on both broadcast and cable television. The customary deliberations of the legislative process would afford the opportunity for further assessment of the execution and implications of such a shift.

Government regulation of the Internet, by contrast, has been held subject to ordinary First Amendment principles (*Reno v. American Civil Liberties Union*, 1997). At the present time, the FTC is the lead federal agency in regulating commercial practices on the Internet. As of 2004, the FTC had pursued approximately 300 cases that challenged Internet practices involving substantial harms to consumers (North Carolina Broadcasting Partners [WCCB-TV], 16 FCC Record 5,627 [Mar. 7, 2001]; Gary M. Cocola [KXVO-TV], 15 FCC Record 9,192 [May 26, 2000]; Peak Media of Pennsylvania [WWCP-TV], 14 FCC Record 13,937 [Aug. 27, 1999]). Some of these cases involved deceptive or unfair marketing practices deployed in other media as well as the Internet, such as deceptive weight loss practices. Other cases have involved advertising or marketing practices that are unique to the Internet, such as the use of spyware (*FTC v. D Squared Solutions, LLC*, 2003). The FTC has also issued rules regulating websites’ collection of personal information from children pursuant to its authority under the Children’s Online Privacy Protection Act (COPPA) (15 U.S.C. §§ 6501–6506, 2002). The regulations apply to operators of any websites or online services directed at children and to operators who knowingly collect or maintain personal information from a child.

The rules impose various requirements on operators, including that they post a clear and prominent link to a notice of their privacy policies with regard to children on the home pages of their websites or online service as well as in each additional area where personal information is collected from children. These notices must include information about the identity of the operator, the types of personal information that is being collected from children, how the operator uses that information, and whether that information is disclosed to third parties. In addition, the regulations require that the operators obtain parental permission before they collect, use, or disclose the personal information of children. Operators must provide parents with a reasonable means to review the personal information collected from their children and to stop its maintenance or continued collection if they desire. The regulations prohibit an operator from conditioning a child's "participation in a game, the offering of a prize, or another activity on the child's disclosing more personal information than is reasonably necessary to participate in such activity." Finally, the regulations require operators to establish and continue reasonable procedures to protect the confidentiality, security, and integrity of personal information collected from children (16 C.F.R. 312.8).

It is likely that restrictions on Internet speech will be subject to the same kind of First Amendment scrutiny as would be deployed were the restrictions applicable to speech in movies or in newspapers. The nature of this scrutiny will depend upon whether the communication at issue is categorized as "public discourse" (*Hustler Magazine v. Falwell*, 1988), in which case constitutional review will be quite strict, or instead as "commercial speech," in which case it will be subject to the more lenient standard of the Central Hudson test. Regulation of the Internet poses unresolved constitutional issues because the constitutional status of much speech on the Internet is at this time highly uncertain.

Increasingly prominent are "advergames," which contain branded products built directly into a game through video games or Internet-based games with the intent to sell products (Chapter 4). Courts are just now beginning to rule that video games, if they are sufficiently artistic and complex, can be "analytically indistinguishable from other protected media, such as motion pictures or books, which convey information or evoke emotions by imagery, and are protected under the First Amendment" (*American Amusement Machine Association v. Kendrick*, 2001; *Interactive Digital Software Association v. St. Louis County*, 2003; *Video Software Dealers Association v. Maleng*, 2004; *Wilson v. Midway Games*, 2002). If advergames seem to have the primary purpose and effect of selling products, however, they might be categorized as advertisements rather than motion pictures or books, and hence subject to the standards of the Central Hudson test. There is also the question of how courts will categorize entire websites, such as *Postopia.com*, hosted by Viacom International (compare *Ford Motor Company v. Texas Department of Transportation*, 2001 with *Fred Wehrenberg Circuit of Theatres, Inc. v. Moviefone, Inc.*, 1999). This website features Kraft Foods' food and beverage brands that contain both advergames and other types of commercial informational content (Viacom International, 2005).

Finding: Regulations for those who advertise and market food and beverage products to

children will need to evolve as the food industry develops new techniques for promoting its products. How current law will be applied to rapidly changing areas like the Internet cannot currently be predicted with confidence. However, future regulatory interventions should certainly be taken on the basis of reliable data concerning the impacts on children of the marketing and advertising of food and beverage products. Currently, neither the Federal Trade Commission, nor any other responsible federal agency, collects or maintains such data.

Lorillard Tobacco Co. v. Reilly
United States Supreme Court
533 U.S. 525 (2001)

[The Attorney General of Massachusetts promulgated regulations governing the advertising and sale of cigarette and other tobacco products. A group of cigarette manufacturers filed suit, arguing that the regulations were preempted by a federal statute, and violated the First Amendment. The First Circuit upheld most of the regulations. The Supreme Court affirmed in part and reversed in part, holding that most of the regulations invalid. Most relevant, the Court held *inter alia* that regulations prohibiting outdoor advertising of smokeless tobacco or cigars within 1,000 feet of school or playground violated the First Amendment; regulations prohibiting indoor, point-of-sale advertising of smokeless tobacco and cigars lower than 5 feet from floor of retail establishment located within 1,000 feet of school or playground violated the First Amendment; but regulations requiring retailers to place tobacco products behind counters and requiring customers to have contact with salesperson before they are able to handle such products did not violate the First Amendment.]

Justice O'CONNOR delivered the opinion of the Court.

For over 25 years, the Court has recognized that commercial speech does not fall outside the purview of the First Amendment. Instead, the Court has afforded commercial speech a measure of First Amendment protection “ ‘commensurate’ ” with its position in relation to other constitutionally guaranteed expression. The analysis contains four elements:

At the outset, we must determine whether the expression is protected by the First Amendment. For commercial speech to come within that provision, it at least must concern lawful activity and not be misleading. Next, we ask whether the asserted governmental interest is substantial. If both inquiries yield positive answers, we must determine whether the regulation directly advances the governmental interest asserted, and whether it is not more extensive than is necessary to serve that interest.” *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm’n of New York*, 447 U.S. 557, 566 (1980). . . .

Only the last two steps of *Central Hudson*’s four-part analysis are at issue here. The Attorney General has assumed for purposes of summary judgment that petitioners’ speech is entitled to First Amendment protection. With respect to the second step, none

of the petitioners contests the importance of the State's interest in preventing the use of tobacco products by minors.

The third step of *Central Hudson* concerns the relationship between the harm that underlies the State's interest and the means identified by the State to advance that interest. . . . We do not, however, require that "empirical data come . . . accompanied by a surfeit of background information. . . . [W]e have permitted litigants to justify speech restrictions by reference to studies and anecdotes pertaining to different locales altogether, or even, in a case applying strict scrutiny, to justify restrictions based solely on history, consensus, and 'simple common sense.'"

The last step of the *Central Hudson* analysis "complements" the third step, "asking whether the speech restriction is not more extensive than necessary to serve the interests that support it." We have made it clear that "the least restrictive means" is not the standard; instead, the case law requires a reasonable "'fit between the legislature's ends and the means chosen to accomplish those ends, . . . a means narrowly tailored to achieve the desired objective.'" Focusing on the third and fourth steps of the *Central Hudson* analysis, we first address the outdoor advertising and point-of-sale advertising regulations for smokeless tobacco and cigars. We then address the sales practices regulations for all tobacco products. . . .

Our review of the record reveals that the Attorney General has provided ample documentation of the problem with underage use of smokeless tobacco and cigars. In addition, we disagree with petitioners' claim that there is no evidence that preventing targeted campaigns and limiting youth exposure to advertising will decrease underage use of smokeless tobacco and cigars. On this record and in the posture of summary judgment, we are unable to conclude that the Attorney General's decision to regulate advertising of smokeless tobacco and cigars in an effort to combat the use of tobacco products by minors was based on mere "speculation [and] conjecture."

Whatever the strength of the Attorney General's evidence to justify the outdoor advertising regulations, however, we conclude that the regulations do not satisfy the fourth step of *Central Hudson* analysis. . . . The substantial geographical reach of the Attorney General's outdoor advertising regulations is compounded by other factors. "Outdoor" advertising includes not only advertising located outside an establishment, but also advertising inside a store if that advertising is visible from outside the store. The regulations restrict advertisements of any size and the term advertisement also includes oral statements.

In some geographical areas, these regulations would constitute nearly a complete ban on the communication of truthful information about smokeless tobacco and cigars to adult consumers. The breadth and scope of the regulations, and the process by which the Attorney General adopted the regulations, do not demonstrate a careful calculation of the speech interests involved. . . . The uniformly broad sweep of the geographical limitation demonstrates a lack of tailoring.

In addition, the range of communications restricted seems unduly broad. For instance, it is not clear from the regulatory scheme why a ban on oral communications is necessary to further the State's interest. Apparently that restriction means that a retailer is unable to answer inquiries about its tobacco products if that communication occurs outdoors. Similarly, a ban on all signs of any size seems ill suited to target the problem of highly visible billboards, as opposed to smaller signs. To the extent that studies have identified particular advertising and promotion practices that appeal to youth, tailoring would involve targeting those practices while permitting others. As crafted, the regulations make no distinction among practices on this basis.

The Court of Appeals recognized that the smokeless tobacco and cigar petitioners' concern about the amount of speech restricted was "valid," but reasoned that there was an "obvious connection to the state's interest in protecting minors." Even on the premise that Massachusetts has demonstrated a connection between the outdoor advertising regulations and its substantial interest in preventing underage tobacco use, the question of tailoring remains. The Court of Appeals failed to follow through with an analysis of the countervailing First Amendment interests. . . .

A careful calculation of the costs of a speech regulation does not mean that a State must demonstrate that there is no incursion on legitimate speech interests, but a speech regulation cannot unduly impinge on the speaker's ability to propose a commercial transaction and the adult listener's opportunity to obtain information about products. After reviewing the outdoor advertising regulations, we find the calculation in these cases insufficient for purposes of the First Amendment. . . .

We conclude that the point-of-sale advertising regulations fail both the third and fourth steps of the *Central Hudson* analysis. A regulation cannot be sustained if it "provides only ineffective or remote support for the government's purpose," or if there is "little chance" that the restriction will advance the State's goal. As outlined above, the State's goal is to prevent minors from using tobacco products and to curb demand for that activity by limiting youth exposure to advertising. The 5-foot rule does not seem to advance that goal. Not all children are less than 5 feet tall, and those who are certainly have the ability to look up and take in their surroundings. . . .

[The Court then turned to the regulations requiring retailers to place tobacco products behind counters and requiring customers to have contact with salesperson before they are able to handle such products.] We conclude that the sales practices regulations withstand First Amendment scrutiny. The means chosen by the State are narrowly tailored to prevent access to tobacco products by minors, are unrelated to expression, and leave open alternative avenues for vendors to convey information about products and for would-be customers to inspect products before purchase.

We have observed that "tobacco use, particularly among children and adolescents, poses perhaps the single most significant threat to public health in the United States." From a policy perspective, it is understandable for the States to attempt to prevent minors from using tobacco products before they reach an age where they are capable of weighing for

themselves the risks and potential benefits of tobacco use, and other adult activities. Federal law, however, places limits on policy choices available to the States. . . .

To the extent that federal law and the First Amendment do not prohibit state action, States and localities remain free to combat the problem of underage tobacco use by appropriate means. The judgment of the United States Court of Appeals for the First Circuit is therefore affirmed in part and reversed in part, and the cases are remanded for further proceedings consistent with this opinion.

United States v. United Foods, Inc.

United States Supreme Court

533 U.S. 405 (2001)

[The Mushroom Promotion, Research, and Consumer Information Act empowered the Secretary of Agriculture to impose mandatory assessments upon handlers of fresh mushrooms. The funds were generally spent on generic advertising to promote mushroom sales. A large agricultural company filed suit, arguing that the assessments violated the First Amendment by forcing companies to subsidize generic advertising that benefited rival mushroom producers. The Sixth Circuit held that the assessments violated the First Amendment and the Supreme Court affirmed.]

Justice KENNEDY delivered the opinion of the Court.

A quarter of a century ago, the Court held that commercial speech, usually defined as speech that does no more than propose a commercial transaction, is protected by the First Amendment. “The commercial marketplace, like other spheres of our social and cultural life, provides a forum where ideas and information flourish.” *Edenfield v. Fane*, 507 U.S. 761, 767 (1993). . . .

Just as the First Amendment may prevent the government from prohibiting speech, the Amendment may prevent the government from compelling individuals to express certain views or from compelling certain individuals to pay subsidies for speech to which they object. Our precedents concerning compelled contributions to speech provide the beginning point for our analysis. The subject matter of the speech may be of interest to but a small segment of the population; yet those whose business and livelihood depend in some way upon the product involved no doubt deem First Amendment protection to be just as important for them as it is for other discrete, little noticed groups in a society which values the freedom resulting from speech in all its diverse parts. First Amendment concerns apply here because of the requirement that producers subsidize speech with which they disagree.

“[T]he general rule is that the speaker and the audience, not the government, assess the value of the information presented.” There are some instances in which compelled subsidies for speech contradict that constitutional principle. Here the disagreement could be seen as minor: Respondent wants to convey the message that its brand of mushrooms is superior to those grown by other producers. It objects to being charged for a message

which seems to be favored by a majority of producers. The message is that mushrooms are worth consuming whether or not they are branded. First Amendment values are at serious risk if the government can compel a particular citizen, or a discrete group of citizens, to pay special subsidies for speech on the side that it favors; and there is no apparent principle which distinguishes out of hand minor debates about whether a branded mushroom is better than just any mushroom. As a consequence, the compelled funding for the advertising must pass First Amendment scrutiny. . . .

It is true that the party who protests the assessment here is required simply to support speech by others, not to utter the speech itself. We conclude, however, that the mandated support is contrary to the First Amendment principles set forth in cases involving expression by groups which include persons who object to the speech, but who, nevertheless, must remain members of the group by law or necessity. . . .

The statutory mechanism as it relates to handlers of mushrooms is concededly different from the scheme in *Glickman*; here the statute does not require group action, save to generate the very speech to which some handlers object. In contrast to the program upheld in *Glickman*, where the Government argued the compelled contributions for advertising were “part of a far broader regulatory system that does not principally concern speech,” there is no broader regulatory system in place here. We have not upheld compelled subsidies for speech in the context of a program where the principal object is speech itself. Although greater regulation of the mushroom market might have been implemented under the Agricultural Marketing Agreement Act of 1937, 50 Stat. 246, 7 U.S.C. § 601 et seq., the compelled contributions for advertising are not part of some broader regulatory scheme. The only program the Government contends the compelled contributions serve is the very advertising scheme in question. . . . [T]he expression respondent is required to support is not germane to a purpose related to an association independent from the speech itself. . . . For these and other reasons we have set forth, the assessments are not permitted under the First Amendment. . . .

R.J. Reynolds Tobacco Co. v. Food and Drug Administration
United States Court of Appeals for the District of Columbia Circuit
696 F.3d 1205 (2012)

[Pursuant to the Family Smoking Prevention and Tobacco Control Act, the Food and Drug Administration issued regulations requiring cigarette packages to include text and graphic images designed to highlight the dangers of smoking. Five tobacco companies challenged the rule, arguing that it compelled speech in violation of the First Amendment. The District Court granted the companies’ motion for summary judgment. The D.C. Circuit affirmed, holding that an intermediate standard of review applied and that the FDA failed to provide substantial evidence that graphic warnings on cigarette advertising would directly advance its interest in reducing smoking rates.]

BROWN, Circuit Judge:

. . . . Both the right to speak and the right to refrain from speaking are “complementary components of the broader concept of individual freedom of mind” protected by the First Amendment. . . . This case contains elements of compulsion and forced subsidization. The Companies contend that, to the extent the graphic warnings go beyond the textual warnings to shame and repulse smokers and denigrate smoking as an antisocial act, the message is ideological and not informational. “[B]y effectively shouting well-understood information to consumers,” they explain, “FDA is communicating an ideological message, a point of view on how people should live their lives: that the risks from smoking outweigh the pleasure that smokers derive from it, and that smokers make bad personal decisions, and should stop smoking.” In effect, the graphic images are not warnings, but admonitions: “[D]on’t buy or use this product.” No one doubts the government can promote smoking cessation programs; can use shock, shame, and moral opprobrium to discourage people from becoming smokers; and can use its taxing and regulatory authority to make smoking economically prohibitive and socially onerous. And the government can certainly require that consumers be fully informed about the dangers of hazardous products. But this case raises novel questions about the scope of the government’s authority to force the manufacturer of a product to go beyond making purely factual and accurate commercial disclosures and undermine its own economic interest—in this case, by making “every single pack of cigarettes in the country [a] mini billboard” for the government’s anti-smoking message.

Even assuming the Companies’ marketing efforts (packaging, branding, and other advertisements) can be properly classified as commercial speech, and thus subject to less robust First Amendment protections, a thorny question remains: how much leeway should this Court grant the government when it seeks to compel a product’s manufacturer to convey the state’s subjective—and perhaps even ideological—view that consumers should reject this otherwise legal, but disfavored, product? Neither the Act nor the agency’s regulation squarely addresses this question. However, for present purposes, we can assume, without deciding, that *if* such compulsion is constitutionally permissible, the state’s actions must still withstand the applicable level of scrutiny.

Courts have recognized a handful of “narrow and well-understood exceptions” to the general rule that content-based speech regulations—including compelled speech—are subject to strict scrutiny. There are two primary exceptions in the commercial speech context. First, “purely factual and uncontroversial” disclosures are permissible if they are “reasonably related to the State’s interest in preventing deception of consumers,” provided the requirements are not “unjustified or unduly burdensome.” *Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio*, 471 U.S. 626, 651 (1985). Second, restrictions on commercial speech are subject to less stringent review than restrictions on other types of speech. For a statute burdening commercial speech to survive, the government must affirmatively prove that (1) its asserted interest is substantial, (2) the restriction directly and materially advances that interest, and (3) the restriction is narrowly tailored. *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm’n of New York*, 447 U.S. 557, 566 (1980). While this text is not quite as demanding as strict scrutiny, it is significantly more stringent than *Zauderer*’s standard, which is akin to rational-basis review. . . .

[The Court first considered the applicability *Zauderer*.] . . . FDA does not frame *this* rule as a remedial measure designed to counteract specific deceptive claims made by the Companies, nor did it offer a remedial justification for the graphic warnings during the rulemaking proceeding. While the Companies' representations about "light" or "low tar" cigarettes might have been misleading, the Act now prohibits such statements. Unlike in *Warner-Lambert*, FDA has not shown that the graphic warnings were designed to correct any false or misleading claims made by cigarette manufacturers in the past. Nor did it show that absent disclosure, consumers would likely be deceived by the Companies' packaging in the future. Rather, FDA framed the warnings as general disclosures about the negative health effects of smoking. The warnings thus represent an ongoing effort to discourage consumers from buying the Companies' products, rather than, as in *Warner-Lambert*, a measure designed to combat specific deceptive claims.

Moreover, the graphic warnings do not constitute the type of "purely factual and uncontroversial" information or "accurate statement[s]," to which the *Zauderer* standard may be applied. The disclosures approved in *Zauderer* [] were clear statements that were both indisputably accurate and not subject to misinterpretation by consumers.

The FDA's images are a much different animal. FDA concedes that the images are not meant to be interpreted literally, but rather to symbolize the textual warning statements, which provide "additional context for what is shown." But many of the images chosen by FDA could be misinterpreted by consumers. For example, the image of a man smoking through a tracheotomy hole might be misinterpreted as suggesting that such a procedure is a common consequence of smoking—a more logical interpretation than FDA's contention that it symbolizes "the addictive nature of cigarettes," which requires significant extrapolation on the part of the consumers. Moreover, the graphic warnings are not "purely" factual because—as FDA tacitly admits—they are primarily intended to evoke an emotional response, or, at most, shock the viewer into retaining the information in the text warning.

In fact, many of the images do not convey *any* warning information at all, much less make an "accurate statement" about cigarettes. For example, the images of a woman crying, a small child, and the man wearing a T-shirt emblazoned with the words "I QUIT" do not offer any information about the health effects of smoking. And the "1-800-QUIT-NOW" number, when presented without any explanation about the services provided on the hotline, hardly sounds like an unbiased source of information. These inflammatory images and the provocatively-named hotline cannot rationally be viewed as pure attempts to convey information to consumers. They are unabashed attempts to evoke emotion (and perhaps embarrassment) and browbeat consumers into quitting. While none of these images are patently false, they certainly do not impart purely factual, accurate, or uncontroversial information to consumers. Consequently, the images fall outside the ambit of *Zauderer*. . . .

Because this case also involves a compelled commercial disclosure, we follow the lead of *Philip Morris* and apply the intermediate standard set forth in *Central Hudson*. . . . Under

Central Hudson, the government must first show that its asserted interest is “substantial.” If so, the Court must determine “whether the regulation directly advances the governmental interest asserted, and whether it is not more extensive than is necessary to serve that interest.” The party seeking to uphold a restriction on commercial speech bears the burden of justifying it. Because this case involves a challenge to final agency action, the Administrative Procedure Act governs our review of the record.

Unlike rational-basis review, the *Central Hudson* standard does not permit this Court to “supplant the precise interests put forward by [FDA] with other suppositions.” We thus begin by identifying FDA’s asserted interests.

A review of the statute and the administrative record makes clear that the graphic warnings are intended to encourage current smokers to quit and dissuade other consumers from ever buying cigarettes. One of the Act’s many stated purposes is “promot[ing] cessation to reduce disease risk and the social costs associated with tobacco-related diseases.” The *only* explicitly asserted interest in either the Proposed or Final Rule is an interest in reducing smoking rates. The Proposed Rule states in its preamble that the government has a “substantial interest in reducing the number of Americans, particularly children and adolescents, who use cigarettes and other tobacco products.” And the preamble to the Final Rule reiterates the same interest. Although counsel attempted to disclaim this interest at oral argument, the administrative record shows otherwise: the primary objective of the Rule was “both to discourage nonsmokers from initiating cigarette use and to encourage current smokers to consider quitting.”

Assuming FDA’s interest in reducing smoking rates is substantial, we next evaluate whether FDA has offered substantial evidence showing that the graphic warning requirements “directly advance[] the governmental interest asserted” to a “material degree.” The government bears the burden of justifying its attempt to restrict commercial speech and its burden is not light. A restriction that “provides only ineffective or remote support for the government’s purposes” is not sufficient, and the government cannot satisfy its burden “by mere speculation or conjecture.” The requirement that a restriction directly advance the asserted interest is “critical,” because without it, the government “could [interfere with] commercial speech in the service of other objectives that could not themselves justify a burden on commercial expression.”

FDA has not provided a shred of evidence—much less the “substantial evidence” required by the APA—showing that the graphic warnings will “directly advance” its interest in reducing the number of Americans who smoke. FDA makes much of the “international consensus” surrounding the effectiveness of large graphic warnings, but offers no evidence showing that such warnings have *directly caused* a material decrease in smoking rates in any of the countries that now require them. While studies of Canadian and Australian youth smokers showed that the warnings on cigarette packs caused a substantial number of survey participants to think—or think more—about quitting smoking, and FDA might be correct that intentions are a “necessary precursor” to behavior change, it is mere speculation to suggest that respondents who report increased *thoughts* about quitting smoking will actually follow through on their intentions. And at

no point did these studies attempt to evaluate whether the increased thoughts about smoking cessation led participants to actually quit. Another Australian study reported increased quit *attempts* by survey participants after that country enacted large graphic warnings, but found “no association with short-term quit success.” Some Canadian and Australian studies indicated that large graphic warnings *might* induce individual smokers to reduce consumption, or to help persons who have already quit smoking remain abstinent. But again, the study did not purport to show that the implementation of large graphic warnings has *actually* led to a reduction in smoking rates.

FDA’s reliance on this questionable social science is unsurprising when we consider the raw data regarding smoking rates in countries that have enacted graphic warnings. . . .

The First Amendment requires the government not only to state a substantial interest justifying a regulation on commercial speech, but also to show that its regulation directly advances that goal. FDA failed to present any data—much less the substantial evidence required under the APA—showing that enacting their proposed graphic warnings will accomplish the agency’s stated objective of reducing smoking rates. The Rule thus cannot pass muster under *Central Hudson*. . . .

Comments Of Viacom Inc. Before The Federal Trade Commission

In the Matter of Interagency Working Group on Food Marketed to Children: General
Comments and Proposed Market Definitions
FTC Project No. P094513

[In 2011, the FTC released a set of preliminary proposed principles to guide industries that market food to children, and a request for comments. The proposed guidelines were voluntary, and designed to refocus food industry advertising towards ensuring that children make healthy eating choices, in order to combat childhood obesity. Several corporations opposed the proposed guidelines, including Viacom. The excerpt below is Viacom’s First Amendment argument against the proposed guidelines.]

While the Interagency Report labels its proposals as voluntary, the fact that the principles were drafted by government, will be shared with Congress, and have been accompanied by explicit threats of more onerous government intervention gives the Federal Working Group’s action the distinct imprimatur of government coercion. When viewed, as they must be, through the lens of a government speech restriction, the purportedly voluntary guidelines trigger the same First Amendment concerns – and constitutional scrutiny – that unquestionably would invalidate mandatory restrictions on truthful advertising. If these types of marketing restrictions were imposed pursuant to direct regulations or legislation, they plainly would be unconstitutional. In short, the notion that proposed restrictions issued by a group of regulatory agencies are intended only to guide “voluntary” conduct is an exercise in sophistry that no court would view as anything other than government action, subject to full First Amendment analysis.

In a long line of decisions, the Supreme Court has struck down restrictions on “commercial speech” that, like the Federal Working Group proposals here, are not narrowly tailored to serve a substantial governmental interest. Viacom has retained a constitutional law expert, Professor Kathleen Sullivan, to evaluate the constitutional implications of the Federal Working Group’s efforts to restrict food marketing; her report is attached as Appendix A hereto. In Professor Sullivan’s expert opinion, “government may not regulate truthful commercial speech unless its means are narrowly tailored to such objectives, a test that any effort to stop childhood obesity by regulating speech must fail.”

Notwithstanding the attempts in the Interagency Report to cloak the marketing restrictions in comforting prose through words such as “voluntary” and “guidelines,” the Federal Working Group quite clearly is attempting to address its professed concern with childhood obesity through restricting lawful speech. Rather than using its considerable direct powers to address the causes of childhood obesity, which are in the proper ambit of regulation, the government instead attempts to address the issue only by limiting speech – a “violation of the basic First Amendment principle that regulation of speech, including commercial speech, should be a last, not a first, resort for government action.” Indeed, as Professor Sullivan explains, the “Supreme Court has long made clear that the government should not be in the business of approving or disapproving truthful commercial speech based on its content in order to protect consumers from making choices that the government views as bad for them. The Court has likewise made clear that this analysis does not change where the government aims at protecting children.” Professor Sullivan concludes that “[t]he government’s food marketing proposal departs from all of these basic First Amendment premises.”

Professor Sullivan puts it succinctly: “A set of ‘guidelines’ issued by a group of regulatory agencies with enormous regulatory and investigatory power over the food and media industries that are subject to those guidelines is the functional equivalent of government action, and companies may not be required to surrender free speech protections in exchange for the ‘benefit’ that government refrains from regulating them directly.”

Under an appropriate First Amendment analysis, restrictions on commercial speech – truthful speech that proposes the sale of lawful goods or services – are subject to heightened scrutiny. The Federal Working Group’s proposals cannot withstand such scrutiny. First, the proposals would have a harmful impact on far more speech than is related to the government’s goals. The Federal Working Group would sweep within its purview a tremendous volume of programming that is accessible to and of interest to adults as well as children. The Supreme Court repeatedly has admonished that speech restrictions cannot reduce general discourse to only that which is fit for children’s consumption. Second, any causal connection between advertising and childhood obesity is far too attenuated to satisfy the strong empirical showing required for restrictions on commercial speech. Third, the government has numerous alternative, less restrictive means to achieve its objectives, rather than resorting to a ban on free speech. For these

reasons, Professor Sullivan concludes, the restrictions set out in the Interagency Report must fail.

Under the governing four-part test set forth by the Supreme Court in *Central Hudson Gas v. Public Service Comm'n*, commercial speech that (1) promotes a lawful transaction and is not misleading may not be restricted unless the government can show that its regulation (2) serves a substantial government interest, (3) directly advances the governmental interest asserted, and (4) is no more extensive than necessary to serve that interest. In *Board of Trustees, SUNY v. Fox*, the Court clarified step (4), holding that “no more extensive than is necessary” means that a regulation must be narrowly tailored to its goal, but need not be the least restrictive means of achieving it (as would be the case for a content-based regulation of noncommercial speech). The Court has invalidated virtually every commercial speech regulation challenged before it in recent decades, most often for failing either or both of steps (3) and (4).

It goes without saying that the food advertising in the crosshairs of the Interagency Report is truthful and not misleading; not even the Federal Working Group claims otherwise. Even conceding that the government has a substantial interest in addressing childhood obesity, “such an interest may not be pursued through excessively sweeping or paternalistic means of limiting access to truthful speech, as the government attempts to do by promulgating” so-called “voluntary” guidelines.⁴² Thus, the Federal Working Group cannot demonstrate that its proposed marketing restrictions meet the narrow tailoring required by steps (3) and (4).

As Professor Sullivan details, the Federal Working Group proposals fail to directly advance the government’s goals. *Central Hudson*’s “narrow tailoring” analysis requires a strong empirical showing that a speech restriction “will truly and effectively advance its goal; it cannot be satisfied based merely on a conceivable or hypothetical relationship between the government’s asserted end and the means of suppressing commercial speech.” Thus, the Federal Working Group “bears a heavy burden to demonstrate empirical support for its contentions that changes in advertising will cause changes in consumption.” Yet the Interagency Report is bereft of any attempt to draw the necessary connection. If anything, the report is all the more troubling because the government persists in focusing on speech limitations even in the face of its own studies (both the Interagency Report itself as well as the National Institute of Medicine) refuting a connection between advertising or obesity or, at a minimum, showing any possible connection to be highly attenuated.

Greater Baltimore Center For Pregnancy Concerns, Inc. v. Baltimore
United States Court of Appeals for the Fourth Circuit
721 F.3d 264 (2013)

[Baltimore passed an ordinance requiring “limited-service pregnancy centers” to disclose that they do not provide abortion and contraceptive services. The District Court enjoined the ordinance for compelling speech in violation of the First Amendment. In this en banc

proceeding, the Fourth Circuit vacated and remanded the judgment, finding that strict scrutiny may not have been the appropriate standard but that the trial record was insufficiently developed to determine the appropriate level of scrutiny.]

KING, Circuit Judge:

. . . The plaintiffs insisted that the strict scrutiny standard applies and cannot be satisfied, because the Ordinance fosters viewpoint discrimination against what they termed “pro-life pregnancy centers” and unjustifiably compels only those centers to engage in government-mandated speech. The plaintiffs portrayed the Ordinance-mandated sign as ensuring that every conversation at a limited-service pregnancy center begins with the subject of abortion, and conveying the morally offensive message that abortion is available elsewhere and might be considered a good option. . . .

The City characterized the Ordinance as a consumer protection regulation, referring to evidence in the Ordinance’s legislative record showing that limited-service pregnancy centers often engage in deceptive advertising to attract women seeking abortion and comprehensive birth-control services, and then use delay tactics to impede the women from accessing those services. According to the City, limited-service pregnancy centers thereby pose a threat to public health, in that the risks and costs of abortion increase as a woman advances through her pregnancy, and that delays in access to the birth control of a woman’s choice can leave the woman vulnerable to unintended pregnancy and sexually transmitted diseases. . . .

The court explained that “[t]he dialogue between a limited-service pregnancy center and an expectant mother begins when the client or prospective client enters the waiting room of the center,” and that the presence of an Ordinance-mandated sign (as “a stark and immediate statement about abortion and birth-control”) would alter the course of the center’s communications with its clients and prospective clients. “At the very least,” according to the court, “a disclaimer conspicuous to anyone visiting the CENTER regarding the lack of abortion and birth-control services, mandates the inclusion of a government message concurrent, and intertwined with, [the CENTER’s] delivery of fully protected speech.”

As an additional reason to apply strict scrutiny, the district court declared that the City “enacted the Ordinance out of disagreement with Plaintiffs’ viewpoints on abortion and birth-control,” thereby engaging in “a particularly offensive form of content-based discrimination.”

The court reasoned that, because “the Ordinance is applicable only to those who will *never* provide or refer for abortion or [certain] birth-control services,” it must have been discriminatorily aimed at “those with strict moral or religious qualms regarding abortion and birth-control.” . . .

There were two grounds for the district court’s ruling on the narrow tailoring issue. First, “the Ordinance does not provide a ‘carve-out’ provision for those limited-service

pregnancy centers which do not engage in any deceptive practices”; rather, “[t]he disclaimer requirement is imposed irrespective of how forthcoming and transparent a pregnancy center presents itself.” Second, “[i]n lieu of the disclaimer mandate of the Ordinance, [the City] could use or modify existing regulations governing fraudulent advertising to combat deceptive advertising practices by limited-service pregnancy centers,” or it “could enact a new content-neutral advertising ordinance applicable to noncommercial entities that directly ameliorate [its] concerns regarding deceptive advertising.” . . .

Although it may not ultimately prove meritorious, the City’s commercial speech theory should not have been so easily dismissed by the district court. Under that theory, a limited-service pregnancy center

proposes a commercial transaction every time it offers to provide commercially valuable goods and services, such as pregnancy testing, sonograms, or options counseling, to a consumer. Such an offer may take the form of an advertisement in the phone book, on the internet, or on a sign above the [center’s] door. It may also take the form of an oral solicitation from a [center] staff member to a consumer. The City Council received evidence that many [centers] intentionally mislead consumers about the scope of services they offer to obtain the patronage of those seeking abortion and comprehensive birth control services. The Ordinance regulates a [center’s] offer to provide services to consumers by making clear that the offer does not include abortion and comprehensive birth control services.

The threshold question presented is whether the speech regulated by the Ordinance is actually commercial. That analysis is fact-driven, due to the inherent “difficulty of drawing bright lines that will clearly cabin commercial speech in a distinct category.” . . .

From *Bolger*, courts of appeals have gleaned “three factors to consider in deciding whether speech is commercial: (1) is the speech an advertisement; (2) does the speech refer to a specific product or service; and (3) does the speaker have an economic motivation for the speech.” . . . In any event, the potential commercial nature of speech does not hinge solely on whether the Center has an economic motive, as even *Bolger* does not preclude classification of speech as commercial in the absence of the speaker’s economic motivation. . . .

[C]ontext matters. From a First Amendment free speech perspective, that context includes the viewpoint of the listener, for “[c]ommercial expression not only serves the economic interest of the speaker, but also assists consumers and furthers the societal interest in the fullest possible dissemination of information.” . . .

[O]ur review today is of a permanent injunction entered in the absence of a fully developed record. Without all the pertinent evidence—including evidence concerning the Center’s economic motivation (or lack thereof) and the scope and content of its advertisements—we cannot properly analyze the speech regulated by the Ordinance. Put succinctly, the district court should have likewise refrained from immediately deciding

the commercial speech issue. . . . [O]ur ruling today is simply this: the district court improperly denied the City essential discovery. . . . Consequently, we vacate the judgment and remand for further proceedings.

New York State Restaurant Association v. New York City Board Of Health
United States Court of Appeals for the Second Circuit
556 F.3d 114 (2009)

[New York City Health Code § 81.50 requires large chain restaurants to post calorie content information on their menus and menu boards. The New York City Restaurant Association challenged this provision on both First Amendment and preemption grounds. The District Court denied the plaintiff’s motion for preliminary injunction. The Second Circuit affirmed, holding inter alia that the calorie content information requirement does not violate the First Amendment.]

POOLER, Circuit Judge:

. . . . [New York State Restaurant Association (NYSRA)] argues that Regulation 81.50 should be subjected to heightened scrutiny, and not, as the district court concluded, “rationality.” However, the district court’s conclusion was compelled by this Circuit’s law, which rested on our interpretation of Supreme Court precedent. The Supreme Court has stated that there are “material differences between [purely factual and uncontroversial] disclosure requirements and outright prohibitions on speech,” and that regulations that compel “purely factual and uncontroversial” commercial speech are subject to more lenient review than regulations that restrict accurate commercial speech. In light of *Zauderer*, this Circuit thus held that rules “mandating that commercial actors disclose commercial information” are subject to the rational basis test. *Nat’l Elec. Mfrs. Ass’n v. Sorrell*, 272 F.3d 104, 114-15 (2d Cir. 2001), We explained that:

Commercial disclosure requirements are treated differently from restrictions on commercial speech because mandated disclosure of accurate, factual, commercial information does not offend the core First Amendment values of promoting efficient exchange of information or protecting individual liberty interests. Such disclosure furthers, rather than hinders, the First Amendment goal of the discovery of truth and contributes to the efficiency of the “marketplace of ideas.” Protection of the robust and free flow of accurate information is the principal First Amendment justification for protecting commercial speech, and requiring disclosure of truthful information promotes that goal. In such a case, then, less exacting scrutiny is required than where truthful, nonmisleading commercial speech is restricted. *Id.* at 113–14.

In arguing both that *Sorrell* was incorrectly decided and that it does not govern this case, NYSRA makes the following three arguments. First, *United States v. United Foods, Inc.*, issued three months before *Sorrell* and which *Sorrell* does not discuss, limited the rational basis test described in *Zauderer* to those situations in which the law at issue furthers the State’s interest in preventing deception of consumers. Second, *International*

Dairy Foods Association v. Amestoy (IDFA), in which we applied intermediate scrutiny pursuant to *Central Hudson*, is more akin to this case. Third, the parties in *Sorrell* did not dispute the significance of the facts that they were being asked to disclose. In contrast, NYSRA’s member restaurants, which do not believe that disclosing calorie information would reduce obesity, and would prefer to provide complete nutrition information, are instead forced, as counsel informed us during oral argument, to “cram” calorie information “down the throats” of their customers.

We think NYSRA reads too much into *United Foods*. The paragraph on which NYSRA relies simply distinguishes *Zauderer* on the basis that the compelled speech in *Zauderer* was necessary to prevent deception of consumers; it does not provide that all other disclosure requirements are subject to heightened scrutiny. Of course, there is no error in this distinction as *Zauderer* addressed deceptive advertising. Nor was this distinction lost on us in *Sorrell*, when we held that *Zauderer*’s holding was broad enough to encompass nonmisleading disclosure requirements. . . .

NYSRA’s final objection is also resolved by *Sorrell*, which clearly held that laws that compel the reporting of “factual and uncontroversial” information by commercial entities are scrutinized for rationality. Thus, “[t]he question that we must answer is whether [Regulation 81.50’s] labeling ... requirements are compelled speech in violation of the Constitution or simply requirements of purely factual disclosures.”. . .

Accordingly, rational basis applies and NYSRA concedes that it will not prevail if we apply that test. Our review reveals the concession to be warranted; New York City has plainly demonstrated a reasonable relationship between the purpose of Regulation 81.50’s disclosure requirements and the means employed to achieve that purpose. . . .

Stuart v. Huff

United States District Court for the Middle District of North Carolina
834 F. Supp. 2d 424 (2011)

[North Carolina’s “Women’s Right to Know Act” created a set of “informed consent” requirements for abortion procedures. Most controversially, the statute’s “speech-and-display requirement” established that providers must perform an ultrasound at least four hours in advance of the abortion procedure, make the images produced from the ultrasound visible to the patient, and describe the images to the patient. Several North Carolina physicians challenged the law on First Amendment, vagueness, and substantive due process grounds. The District Court issued a preliminary injunction, excerpted below, holding inter alia that the statute plaintiffs were likely to succeed on the merits in their First Amendment challenge. In 2014, Judge Eagles issued a permanent injunction striking down the provision.]

EAGLES, District Judge:

. . . . Section 90–21.85 of the Act setting forth the “speech-and-display requirements”

first requires that a woman undergo an ultrasound at least four hours before an abortion. The statute also mandates that the physician or qualified technician working with the physician shall display the images produced from the ultrasound “so that the [patient] may view them.” It further requires the providers to give “a simultaneous explanation of what the display is depicting, which shall include the presence, location, and dimensions of the unborn child within the uterus,” and “a medical description of the images, which shall include the dimensions of the embryo or fetus and the presence of external members and internal organs, if present and viewable.”

The Plaintiffs contend these speech-and-display requirements violate the First Amendment by compelling unwilling speakers to deliver the state's message discouraging abortion. The Plaintiffs argue that the compelled speech required by the Act should be viewed under a strict scrutiny standard. The Defendants argue that strict scrutiny is the wrong standard to apply; they contend in the alternative that even applying strict scrutiny, the state has three compelling state interests: protecting the psychological health of the patient, preventing coercive abortions, and expressing its preference for the life of the unborn.

The First Amendment generally includes the right to refuse to engage in speech compelled by the government. “[T]he First Amendment guarantees ‘freedom of speech,’ a term necessarily comprising the decision of both what to say and what not to say.” Both compelled statements of opinions and compelled statements of fact burden protected speech.

The Supreme Court has historically taken a dim view of content-based speech compelled by the government, finding it to violate the First Amendment in the absence of a compelling state interest in a wide variety of circumstances. “Mandating speech that a speaker would not otherwise make necessarily alters the content of the speech,” and laws which mandate speech are generally considered content-based regulations of speech.

“[C]ontent-based regulations of speech are presumptively invalid.” Even when the state has a compelling interest, “any restriction based on the content of the speech must satisfy strict scrutiny, that is, the restriction must be narrowly tailored to serve a compelling government interest.”

It is undisputed that the Act compels content-based speech by providers; it requires providers to orally and visually convey specified material about the fetus to their patients. The message is compelled regardless of a patient's individual circumstances or condition and regardless of the provider's medical opinion. The message is required even when the provider does not want to deliver the message and even when the patients affirmatively do not wish to see it or hear it. It is further undisputed that this implicates the First Amendment rights of providers such as the Plaintiffs. *See Planned Parenthood of Se. Penn. v. Casey*, 505 U.S. 833, 884, (1992) (plurality opinion) (applying strict scrutiny to compelled ideological speech). Thus, strict scrutiny would ordinarily apply.

The Defendants contend that the compelled speech here should instead be evaluated under an undue burden standard, relying on the Supreme Court's decision in *Casey*. *Casey* concerned a Pennsylvania law that required, among other things, that providers give a woman seeking an abortion certain written materials concerning her decision. In ruling on a claim that the provision violated the liberty interests of women protected by *Roe v. Wade*, the Court held that a state could require physicians to provide patients with information that is “truthful and non-misleading” and related to a woman's decision to have an abortion. In determining which regulations may be permitted, the Court adopted the undue burden standard.

What is at stake is the woman's right to make the ultimate decision, not a right to be insulated from all others in doing so. Regulations which do no more than create a structural mechanism by which the State, or the parent or guardian of a minor, may express profound respect for the life of the unborn are permitted, if they are not a substantial obstacle to the woman's exercise of the right to choose. Unless it has that effect on her right of choice, a state measure designed to persuade her to choose childbirth over abortion will be upheld if reasonably related to that goal. Regulations designed to foster the health of a woman seeking an abortion are valid if they do not constitute an undue burden. The Defendants argue that the North Carolina statute does not create an undue burden on a woman's right to get an abortion, and as such the compelled speech mandated by the Act is permitted.

The Court in *Casey* did not, however, combine the due process/liberty interest analysis with the First Amendment analysis. Rather, the Supreme Court applied the undue burden standard only in evaluating the Pennsylvania statute's limits on a woman's liberty interest under the Due Process Clause.

The Supreme Court's brief discussion of the First Amendment challenges to the Pennsylvania statute was undertaken separately and without substantial detail. It seems unlikely that the Supreme Court decided by implication that long-established First Amendment law was irrelevant when speech about abortion is at issue, and this Court declines to so find.

In the alternative, the Defendants contend that the speech at issue is “professional” or “commercial” and thus “the Act's regulation of physicians' speech is not subject to strict scrutiny.” The Defendants do not clearly state what a non-strict-scrutiny standard would be or explain how it would apply here.

Commercial speech is “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). When regulated speech is purely commercial, it is often entitled to less protection under the First Amendment, though the degree of that protection is not always easy to discern. Just what “professional speech” means and the degree of protection it receives is even less clear; the phrase has been used by Supreme Court justices only in passing.

The Defendants' contention that this speech is “commercial” and thus subject to a lower degree of scrutiny is not persuasive. Where the speech at issue blends commercial with noncommercial elements, strict scrutiny ordinarily applies. To the extent there is some commercial or professional speech involved here, it is intertwined with non-commercial speech and thus entitled to the full protection of the First Amendment.

It is unlikely that a rational basis standard would be found to apply here, given the Supreme Court's deeply entrenched precedent that “[t]he law is not free to interfere with speech for no better reason than promoting an approved message or discouraging a disfavored one, however enlightened either purpose may strike the government.” *Hurley v. Irish American Gay, Lesbian, and Bisexual Group of Boston*, 515 U.S. 557, 579 (1995). As the Court stated in *Hurley*, outside the context of commercial speech, the government “may not compel affirmance of a belief with which the speaker disagrees.”

It is possible that the Supreme Court would apply some intermediate standard to compelled speech in the ordinary informed-consent context, given the historical interest the state has in regulating certain aspects of medical care. That is not, however, this case. The Act goes well beyond requiring disclosure of those items traditionally a part of the informed consent process, which include in this context the nature and risks of the procedure and the gestational age of the fetus. The Act also goes well beyond the provision approved in *Casey*, which only required providers to “make available” state-generated written materials which contained a viewpoint. In this case, the state compels the provider to physically speak and show the state's non-medical message to patients unwilling to hear or see. Other courts have applied strict scrutiny in similar circumstances.

The Court finds that the speech-and-display requirements of the Act are subject to strict scrutiny under traditional and longstanding First Amendment principles. Thus, the Defendants must establish that the compelled speech required of the providers furthers a compelling state interest and that the requirements are narrowly tailored to achieve that interest. The Defendants have not established either element.

The Defendants first assert that the state has an interest in protecting abortion patients from psychological and emotional distress and that this interest justifies the speech-and-display requirements. Even if this is a compelling interest, there is no evidence in the record supporting the state's claim that the speech-and-display requirements further this interest. Indeed, the undisputed evidence offered by the Plaintiffs establishes that these provisions are likely to harm the psychological health of the very group the state purports to protect.

The Defendants next put forth the state's interest in preventing women from being coerced into having abortions. Assuming without deciding that this is a compelling interest, the Defendants have not articulated how the speech-and-display requirements address the stated concern in reducing compelled abortions, and none is immediately apparent.

At oral argument, the Defendants added the state's interest in promoting life and discouraging abortion as a compelling interest justifying the compelled speech. This interest might well be present after viability, but nowhere does *Casey* characterize the state's interest in potential life as “compelling” during the entire term of a woman's pregnancy.

In any event, even if the state has a compelling interest, the state has provided no evidence that alternatives more in proportion to the resulting burdens placed on speech would not suffice. These alternatives might include making the information at issue available to the patient in written form, as in *Casey*, or possibly offering to provide the verbal or visual information to the patient but respecting the patient's rejection of hearing or seeing the information.

The speech-and-display requirements in section 90–21.85 thus do not survive strict scrutiny. The Court concludes that the Plaintiffs are likely to prevail on their First Amendment claim as to the compelled speech required by section 90–21.85.

Texas Medical Providers Performing Abortion Services v. Lakey
United States Court of Appeals for the Fifth Circuit
667 F.3d 570 (2012)

[Texas statute H.B. 15 amended Texas’s “informed consent” requirements for women who seek abortion services. The law requires physicians to display a sonogram of the fetus, play heart auscultation of the fetus for the patient to hear, and explain the sonogram images to the patient. The patient must generally wait 24 hours after these procedures before the abortion can be performed. A patient may opt out of the viewing the sonogram images and hearing the heart auscultation, but may decline to hear the explanation of the images only on certification that her pregnancy falls into one of several statutory exceptions. Any woman who chooses to go forward with the abortion procedure must also complete a form certifying that the informed consent requirements have all been abided by. A group of physician challenged the law on First Amendment and vagueness grounds. While the District Court enjoined several of the statute’s provisions, the Fourth Circuit’s opinion, excerpted below, vacated the judgment. On remand, the district court granted summary judgment for the defendant.]

JONES, Chief Judge:

. . . Appellees contend that H.B. 15 abridges their First Amendment rights by compelling the physician to take and display to the woman sonogram images of her fetus, make audible its heartbeat, and explain to her the results of both exams. This information, they contend, is the state's “ideological message” concerning the fetal life that serves no medical purpose, and indeed no other purpose than to discourage the abortion. Requiring the woman to certify the physician's compliance with these procedures also allegedly violates her right “not to speak.” In fashioning their First Amendment compelled speech arguments, which the district court largely accepted, Appellees must confront the

Supreme Court's holding in *Planned Parenthood of Southeastern Pennsylvania v. Casey*, that reaffirmed a woman's substantive due process right to terminate a pregnancy but also upheld an informed-consent statute over precisely the same “compelled speech” challenges made here. . . . We begin this analysis with *Casey*.

The law at issue in *Casey* required an abortion provider to inform the mother of the relevant health risks to her and the “probable gestational age of the unborn child.” The woman also had to certify in writing that she had received this information and had been informed by the doctor of the availability of various printed materials “describing the fetus and providing information about medical assistance for childbirth, information about child support from the father, and a list of agencies which provide adoption and other services as alternatives to abortion.” Planned Parenthood contended that all of these disclosures operate to discourage abortion and, by compelling the doctor to deliver them, violated the physician's First Amendment free-speech rights. Planned Parenthood urged application of the strict scrutiny test governing certain First Amendment speech rights.

The *Casey* plurality's opinion concluded that such provisions, entailing “the giving of truthful, nonmisleading information” which is “relevant. . . to the decision,” did not impose an undue burden on the woman's right to an abortion and were thus permitted by the Fourteenth Amendment. . . .

The plurality then turned to the petitioners' asserted First Amendment right of a physician not to provide information about the risks of abortion, and childbirth, in a manner mandated by the state. To be sure, the physician's First Amendment rights not to speak are implicated, but only as part of the practice of medicine, subject to reasonable licensing and regulation by the State. We see no constitutional infirmity in the requirement that the physician provide the information mandated by the state here.

The plurality response to the compelled speech claim is clearly not a strict scrutiny analysis. It inquires into neither compelling interests nor narrow tailoring. The three sentences with which the Court disposed of the First Amendment claims are, if anything, the antithesis of strict scrutiny. . . . The only reasonable reading of *Casey*'s passage is that physicians' rights not to speak are, when “part of the practice of medicine, subject to reasonable licensing and regulation by the State[.]” This applies to information that is “truthful,” “nonmisleading,” and “relevant. . . to the decision” to undergo an abortion.

The Court's decision in *Gonzales v. Carhart*, reaffirmed *Casey*, as it upheld a state's “significant role. . . in regulating the medical profession” and added that “[t]he government may use its voice and regulatory authority to show its profound respect for the life within the woman.” . . .

The import of these cases is clear. First, informed consent laws that do not impose an undue burden on the woman's right to have an abortion are permissible if they require truthful, nonmisleading, and relevant disclosures. Second, such laws are part of the state's reasonable regulation of medical practice and do not fall under the rubric of compelling “ideological” speech that triggers First Amendment strict scrutiny. Third, “relevant”

informed consent may entail not only the physical and psychological risks to the expectant mother facing this “difficult moral decision,” but also the state's legitimate interests in “protecting the potential life within her.” Finally, the possibility that such information “might cause the woman to choose childbirth over abortion” does not render the provisions unconstitutional.

Fortifying this reading, the Eighth Circuit sitting en banc construed *Casey* and *Gonzales* in the same way: . . . [W]hile the State cannot compel an individual simply to speak the State's ideological message, it can use its regulatory authority to require a physician to provide truthful, non-misleading information relevant to a patient's decision to have an abortion, *even if that information might also encourage the patient to choose childbirth over abortion*. *Planned Parenthood Minn. v. Rounds*, 530 F.3d 724, 735 (8th Cir. 2008) (en banc) (emphasis added). Significantly, the *Rounds* dissent agreed that the state's reasonable medical regulation of abortion includes its assertion of “ ‘legitimate interests in the health of the mother and in protecting the potential life within her.’ ” *Rounds* upheld, against compelled speech challenges, an informed consent provision, and associated compliance certifications by both the physician and pregnant woman, requiring, inter alia, a disclosure that the abortion “will terminate the life of a whole, separate, unique, living human being” with whom the woman “has an existing relationship” entitled to legal protection.

In contrast to the disclosures discussed in *Rounds*, H.B. 15 requires the taking and displaying of a sonogram, the heart auscultation of the pregnant woman's fetus, and a description by the doctor of the exams' results. That these medically accurate depictions are inherently truthful and non-misleading is not disputed by Appellees, nor by any reasoned analysis by the district court. (We consider later the Appellees' argument that the disclosures are not medically necessary, and are therefore “irrelevant” to procuring the woman's informed consent under *Casey*). Unlike the plaintiffs in *Casey* and *Rounds*, the Appellees here do not contend that the H.B. 15 disclosures inflict an unconstitutional undue burden on a woman's substantive due process right to obtain an abortion. These omissions, together, are significant. If the disclosures are truthful and non-misleading, and if they would not violate the woman's privacy right under the *Casey* plurality opinion, then Appellees would, by means of their First Amendment claim, essentially trump the balance *Casey* struck between women's rights and the states' prerogatives. *Casey*, however, rejected any such clash of rights in the informed consent context.

Applying to H.B. 15 the principles of *Casey*'s plurality, the most reasonable conclusion is to uphold the provisions declared as unconstitutional compelled speech by the district court. To belabor the obvious and conceded point, the required disclosures of a sonogram, the fetal heartbeat, and their medical descriptions are the epitome of truthful, non-misleading information. They are not different in kind, although more graphic and scientifically up-to-date, than the disclosures discussed in *Casey*—probable gestational age of the fetus and printed material showing a baby's general prenatal development stages. Likewise, the relevance of these disclosures to securing informed consent is sustained by *Casey* and *Gonzales*, because both cases allow the state to regulate medical

practice by deciding that information about fetal development is “relevant” to a woman's decision-making.

As for the woman's consent form, that, too, is governed by *Casey*, which approves the practice of obtaining written consent “as with any medical procedure.” H.B. 15, § 171.012(a)(5), requires that a pregnant woman certify in writing her understanding that (1) Texas law requires an ultrasound prior to obtaining an abortion, (2) she has the option to view the sonogram images, (3) she has the option to hear the fetal heartbeat, and (4) she is required to hear the medical explanation of the sonogram unless she falls under the narrow exceptions to this requirement.⁶

To invalidate the written consent form as compelled speech would potentially subject to strict scrutiny a host of other medical informed-consent requirements. Appellees have offered no theory how the H.B. 15 informed-consent certification differs constitutionally from informed-consent certifications in general. Nevertheless, the district court was especially troubled by the requirement that, to avoid the description of the sonogram images, a victim of rape or incest might have to certify her status as a victim, despite fearing (by the very terms of the certification) physical reprisal if she makes her status known. This system of certified exceptions may be a debatable choice of policy, but it does not transgress the First Amendment. If the State could properly decline to grant any exceptions to the informed-consent requirement, it cannot create an inappropriate burden on free speech rights where it simply conditions an exception on a woman's admission that she falls within it. Indeed, such an infirmity could just as well be cured by striking down the exceptions alone as by striking down the requirement of written certification. Because the general requirement is valid, we see no constitutional objection to the certification required for an exception.

Notwithstanding the facial application of *Casey* to H.B. 15, Appellees characterize its disclosure requirements as “qualitatively different” in two ways. First, the disclosure of the sonogram and fetal heartbeat are “medically unnecessary” to the woman and therefore beyond the standard practice of medicine within the state's regulatory powers. Appellees refer to currently required disclosures of health risks to the mother alone and apparently would limit information about the fetus in these circumstances to its “probable gestational age,” as specifically approved in *Casey*. Requiring any more information about the fetus amounts to advocacy by the state. Second, whereas *Casey* only required the physician to make certain materials about childbirth and the fetus “available” to the woman, the physician here is required to explain the results of sonogram and fetal heart auscultation, and the woman is required to listen to the sonogram results. This interchange makes the physician the “mouthpiece” of the state, again for medically unnecessary reasons. Appellees' position seems to assume that the facts of *Casey* represent a constitutional ceiling for regulation of informed consent to abortion, not a set of principles to be applied to the states' legislative decisions. On this broad level, however, the Court has admonished that federal courts are not the repository for regulation of the practice of medicine.

Turning to Appellees' specific objections, the provision of sonograms and the fetal heartbeat are routine measures in pregnancy medicine today. They are viewed as "medically necessary" for the mother and fetus. Only if one assumes the conclusion of Appellees' argument, that pregnancy is a condition to be terminated, can one assume that such information about the fetus is medically irrelevant. The point of informed consent laws is to allow the patient to evaluate her condition and render her best decision under difficult circumstances. Denying her up to date medical information is more of an abuse to her ability to decide than providing the information. In any event, the Appellees' argument ignores that *Casey* and *Gonzales*, as noted above, emphasize that the gravity of the decision may be the subject of informed consent through factual, medical detail, that the condition of the fetus is relevant, and that discouraging abortion is an acceptable effect of mandated disclosures.

More to the point, perhaps, is Appellees' concern that H.B. 15 requires a doctor, at a minimum, to converse with the patient about the sonogram as a predicate to securing informed consent, rather than show her the way to obtain a brochure or similar written information. Certainly, the statute's method of delivering this information is direct and powerful, but the mode of delivery does not make a constitutionally significant difference from the "availability" provision in *Casey*. The *Casey* plurality opinion places this issue squarely in the context of the regulation of medical practice. . . . *Casey* did not analyze the doctor's status based on how he provided "specific information." . . . The mode of compelled expression is not by itself constitutionally relevant, although the context is. Here, the context is the regulation of informed consent to a medical procedure. The constitutional irrelevance of the verbal nature of this description is even clearer given the facts of *Casey*; the law upheld there required doctors to describe verbally the fetus's gestational age, a description which the *Casey* plurality acknowledged was relevant to "informed consent" only in a sense broad enough to include the potential impact on the fetus.

For all these reasons, we conclude that the enumerated provisions of H.B. 15 requiring disclosures and written consent are sustainable under *Casey*, are within the State's power to regulate the practice of medicine, and therefore do not violate the First Amendment. Appellees have not demonstrated a likelihood of success on the merits justifying the preliminary injunction.

FOOD AND DRUG REGULATION PANEL

The basic architecture of our food and drug regulation regime is decades old. Recent Supreme Court cases, however, have brought the First Amendment into tension with this regime. We include here a key Supreme Court case, *Sorrell v. IMS Health Inc.*, which invalidated a Vermont law restricting the disclosure of pharmaceutical records, in the process suggesting that the Court's traditional and more permissive scrutiny of commercial speech was not appropriate where restrictions on commercial speech were "content based." Following *Sorrell*, the Second Circuit's decision in *United States v. Caronia* concluded that the government is not permitted to criminalize the off-label promotion of drugs, a decision that cuts at the heart of the FDA's ability to require drug companies to produce evidence of the safety and efficacy of their drugs. The court in *Caronia* noted that the government could still prosecute pharmaceutical speech as false and misleading, which raises the question: when is speech in this context false or misleading? The POM Wonderful case illustrates the challenges of applying such a standard, and how the First Amendment might be used to give courts rather than regulators substantial power to evaluate scientific claims. *United States v. Alvarez*, another recent Supreme Court case, has opened the door for new claims that the First Amendment protects false speech. And in *Harkonen v. United States*, a drug company executive convicted of fraud for misrepresenting a clinical trial claims that the First Amendment protects his expression of scientific "opinion." When is a scientific matter one of fact, and when of opinion? Can the government regulate in ways that seek to generate evidence, as the FDA seeks to do, and if not, how will we ensure that we have a sound evidence base about the food and drugs that we prescribe and ingest?

Sorrell v. IMS Health Inc.
United States Supreme Court
131 S. Ct. 2653 (2011)

[Vermont’s Prescription Confidentiality Law restricted the sale, disclosure, and use of pharmacy records that reveal the prescribing practices of individual doctors. A group of data miners and drug manufacturers challenged the law on First Amendment grounds. The district court ruled in favor of Vermont but the Second Circuit reversed, holding that the law unconstitutionally burdened speech. The Supreme Court affirmed.]

Justice KENNEDY delivered the opinion of the Court.

. . . . On its face, Vermont's law enacts content-and speaker-based restrictions on the sale, disclosure, and use of prescriber-identifying information. The provision first forbids sale subject to exceptions based in large part on the content of a purchaser's speech. For example, those who wish to engage in certain “educational communications,” may purchase the information. The measure then bars any disclosure when recipient speakers will use the information for marketing. Finally, the provision's second sentence prohibits pharmaceutical manufacturers from using the information for marketing. The statute thus disfavors marketing, that is, speech with a particular content. More than that, the statute disfavors specific speakers, namely pharmaceutical manufacturers. As a result of these content- and speaker-based rules, detailers cannot obtain prescriber-identifying information, even though the information may be purchased or acquired by other speakers with diverse purposes and viewpoints. Detailers are likewise barred from using the information for marketing, even though the information may be used by a wide range of other speakers. . . .The law on its face burdens disfavored speech by disfavored speakers. . . .

Act 80 is designed to impose a specific, content-based burden on protected expression. It follows that heightened judicial scrutiny is warranted. . . . The First Amendment requires heightened scrutiny whenever the government creates “a regulation of speech because of disagreement with the message it conveys.” . . . Commercial speech is no exception. A “consumer’s concern for the free flow of commercial speech often may be far keener than his concern for urgent political dialogue.” *Bates v. State Bar of Ariz.*, 433 U. S. 350, 364 (1977). That reality has great relevance in the fields of medicine and public health, where information can save lives.

The State argues that heightened judicial scrutiny is unwarranted because its law is a mere commercial regulation. It is true that restrictions on protected expression are distinct from restrictions on economic activity or, more generally, on nonexpressive conduct. It is also true that the First Amendment does not prevent restrictions directed at commerce or conduct from imposing incidental burdens on speech. That is why a ban on race-based hiring may require employers to remove “ ‘White Applicants Only’ ” signs, why “an ordinance against outdoor fires” might forbid “burning a flag”; and why antitrust laws can prohibit “agreements in restraint of trade.”

But § 4631(d) imposes more than an incidental burden on protected expression. Both on its face and in its practical operation, Vermont's law imposes a burden based on the content of speech and the identity of the speaker. While the burdened speech results from an economic motive, so too does a great deal of vital expression. Vermont's law does not simply have an effect on speech, but is directed at certain content and is aimed at particular speakers. . . .

Vermont further argues that § 4631(d) regulates not speech but simply access to information. Prescriber-identifying information was generated in compliance with a legal mandate, the State argues, and so could be considered a kind of governmental information. . . . [But] Vermont has imposed a restriction on access to information in private hands. . . . An individual's right to speak is implicated when information he or she possesses is subjected to “restraints on the way in which the information might be used” or disseminated. *Seattle Times Co. v. Rhinehart*, 467 U.S. 20, 32 (1984). . . .

The State also contends that heightened judicial scrutiny is unwarranted in this case because sales, transfer, and use of prescriber-identifying information are conduct, not speech. Consistent with that submission, the United States Court of Appeals for the First Circuit has characterized prescriber-identifying information as a mere “commodity” with no greater entitlement to First Amendment protection than “beef jerky.” In contrast the courts below concluded that a prohibition on the sale of prescriber-identifying information is a content-based rule akin to a ban on the sale of cookbooks, laboratory results, or train schedules.

This Court has held that the creation and dissemination of information are speech within the meaning of the First Amendment. Facts, after all, are the beginning point for much of the speech that is most essential to advance human knowledge and to conduct human affairs. There is thus a strong argument that prescriber-identifying information is speech for First Amendment purposes.

The State asks for an exception to the rule that information is speech, but there is no need to consider that request in this case. The State has imposed content- and speaker-based restrictions on the availability and use of prescriber-identifying information. So long as they do not engage in marketing, many speakers can obtain and use the information. But detailers cannot. Vermont's statute could be compared with a law prohibiting trade magazines from purchasing or using ink. Like that hypothetical law, § 4631(d) imposes a speaker- and content-based burden on protected expression, and that circumstance is sufficient to justify application of heightened scrutiny. As a consequence, this case can be resolved even assuming, as the State argues, that prescriber-identifying information is a mere commodity.

In the ordinary case it is all but dispositive to conclude that a law is content-based and, in practice, viewpoint-discriminatory. The State argues that a different analysis applies here because, assuming § 4631(d) burdens speech at all, it at most burdens only commercial speech. As in previous cases, however, the outcome is the same whether a special commercial speech inquiry or a stricter form of judicial scrutiny is applied. For the same

reason there is no need to determine whether all speech hampered by § 4631(d) is commercial, as our cases have used that term.

Under a commercial speech inquiry, it is the State's burden to justify its content-based law as consistent with the First Amendment. To sustain the targeted, content-based burden § 4631(d) imposes on protected expression, the State must show at least that the statute directly advances a substantial governmental interest and that the measure is drawn to achieve that interest. There must be a “fit between the legislature's ends and the means chosen to accomplish those ends.” As in other contexts, these standards ensure not only that the State's interests are proportional to the resulting burdens placed on speech but also that the law does not seek to suppress a disfavored message.

The State's asserted justifications for § 4631(d) come under two general headings. First, the State contends that its law is necessary to protect medical privacy, including physician confidentiality, avoidance of harassment, and the integrity of the doctor-patient relationship. Second, the State argues that § 4631(d) is integral to the achievement of policy objectives—namely, improved public health and reduced healthcare costs. Neither justification withstands scrutiny.

Vermont argues that its physicians have a “reasonable expectation” that their prescriber-identifying information “will not be used for purposes other than ... filling and processing” prescriptions. It may be assumed that, for many reasons, physicians have an interest in keeping their prescription decisions confidential. But § 4631(d) is not drawn to serve that interest. Under Vermont's law, pharmacies may share prescriber-identifying information with anyone for any reason save one: They must not allow the information to be used for marketing. Exceptions further allow pharmacies to sell prescriber-identifying information for certain purposes, including “health care research.” And the measure permits insurers, researchers, journalists, the State itself, and others to use the information. All but conceding that § 4631(d) does not in itself advance confidentiality interests, the State suggests that other laws might impose separate bars on the disclosure of prescriber-identifying information. But the potential effectiveness of other measures cannot justify the distinctive set of prohibitions and sanctions imposed by § 4631(d).

Perhaps the State could have addressed physician confidentiality through “a more coherent policy.” For instance, the State might have advanced its asserted privacy interest by allowing the information's sale or disclosure in only a few narrow and well-justified circumstances. A statute of that type would present quite a different case than the one presented here. But the State did not enact a statute with that purpose or design. Instead, Vermont made prescriber-identifying information available to an almost limitless audience. The explicit structure of the statute allows the information to be studied and used by all but a narrow class of disfavored speakers. Given the information's widespread availability and many permissible uses, the State's asserted interest in physician confidentiality does not justify the burden that § 4631(d) places on protected expression.

The State points out that it allows doctors to forgo the advantages of § 4631(d) by consenting to the sale, disclosure, and use of their prescriber-identifying information. It is

true that private decisionmaking can avoid governmental partiality and thus insulate privacy measures from First Amendment challenge. But that principle is inapposite here. Vermont has given its doctors a contrived choice: Either consent, which will allow your prescriber-identifying information to be disseminated and used without constraint; or, withhold consent, which will allow your information to be used by those speakers whose message the State supports. Section 4631(d) may offer a limited degree of privacy, but only on terms favorable to the speech the State prefers. This is not to say that all privacy measures must avoid content-based rules. Here, however, the State has conditioned privacy on acceptance of a content-based rule that is not drawn to serve the State's asserted interest. To obtain the limited privacy allowed by § 4631(d), Vermont physicians are forced to acquiesce in the State's goal of burdening disfavored speech by disfavored speakers.

Respondents suggest that a further defect of § 4631(d) lies in its presumption of applicability absent a physician's election to the contrary. Vermont's law might burden less speech if it came into operation only after an individual choice, but a revision to that effect would not necessarily save § 4631(d). Even reliance on a prior election would not suffice, for instance, if available categories of coverage by design favored speakers of one political persuasion over another. Rules that burden protected expression may not be sustained when the options provided by the State are too narrow to advance legitimate interests or too broad to protect speech. As already explained, § 4631(d) permits extensive use of prescriber-identifying information and so does not advance the State's asserted interest in physician confidentiality. The limited range of available privacy options instead reflects the State's impermissible purpose to burden disfavored speech. Vermont's argument accordingly fails, even if the availability and scope of private election might be relevant in other contexts, as when the statute's design is unrelated to any purpose to advance a preferred message.

The State also contends that § 4631(d) protects doctors from “harassing sales behaviors.” “Some doctors in Vermont are experiencing an undesired increase in the aggressiveness of pharmaceutical sales representatives,” the Vermont Legislature found, “and a few have reported that they felt coerced and harassed.” It is doubtful that concern for “a few” physicians who may have “felt coerced and harassed” by pharmaceutical marketers can sustain a broad content-based rule like § 4631(d). Many are those who must endure speech they do not like, but that is a necessary cost of freedom. In any event the State offers no explanation why remedies other than content-based rules would be inadequate. Physicians can, and often do, simply decline to meet with detailers, including detailers who use prescriber-identifying information. Doctors who wish to forgo detailing altogether are free to give “No Solicitation” or “No Detailing” instructions to their office managers or to receptionists at their places of work. Personal privacy even in one's own home receives “ample protection” from the “resident's unquestioned right to refuse to engage in conversation with unwelcome visitors.”

Vermont argues that detailers' use of prescriber-identifying information undermines the doctor-patient relationship by allowing detailers to influence treatment decisions. According to the State, “unwanted pressure occurs” when doctors learn that their

prescription decisions are being “monitored” by detailers. Some physicians accuse detailers of “spying” or of engaging in “underhanded” conduct in order to “subvert” prescription decisions. And Vermont claims that detailing makes people “anxious” about whether doctors have their patients' best interests at heart. But the State does not explain why detailers' use of prescriber-identifying information is more likely to prompt these objections than many other uses permitted by § 4631(d). In any event, this asserted interest is contrary to basic First Amendment principles. Speech remains protected even when it may “stir people to action,” “move them to tears,” or “inflict great pain.” *Snyder v. Phelps*, 131 S.Ct. 1207, 1220 (2011). The more benign and, many would say, beneficial speech of pharmaceutical marketing is also entitled to the protection of the First Amendment. If pharmaceutical marketing affects treatment decisions, it does so because doctors find it persuasive. Absent circumstances far from those presented here, the fear that speech might persuade provides no lawful basis for quieting it.

The State contends that § 4631(d) advances important public policy goals by lowering the costs of medical services and promoting public health. If prescriber-identifying information were available for use by detailers, the State contends, then detailing would be effective in promoting brand-name drugs that are more expensive and less safe than generic alternatives. This logic is set out at length in the legislative findings accompanying § 4631(d). Yet at oral argument here, the State declined to acknowledge that § 4631(d)'s objective purpose and practical effect were to inhibit detailing and alter doctors' prescription decisions. The State's reluctance to embrace its own legislature's rationale reflects the vulnerability of its position.

While Vermont's stated policy goals may be proper, § 4631(d) does not advance them in a permissible way. As the Court of Appeals noted, the “state's own explanation of how” § 4631(d) “advances its interests cannot be said to be direct.” The State seeks to achieve its policy objectives through the indirect means of restraining certain speech by certain speakers—that is, by diminishing detailers' ability to influence prescription decisions. Those who seek to censor or burden free expression often assert that disfavored speech has adverse effects. But the “fear that people would make bad decisions if given truthful information” cannot justify content-based burdens on speech. “The First Amendment directs us to be especially skeptical of regulations that seek to keep people in the dark for what the government perceives to be their own good.” These precepts apply with full force when the audience, in this case prescribing physicians, consists of “sophisticated and experienced” consumers.

As Vermont's legislative findings acknowledge, the premise of § 4631(d) is that the force of speech can justify the government's attempts to stifle it. Indeed the State defends the law by insisting that “pharmaceutical marketing has a strong influence on doctors' prescribing practices.” This reasoning is incompatible with the First Amendment. In an attempt to reverse a disfavored trend in public opinion, a State could not ban campaigning with slogans, picketing with signs, or marching during the daytime. Likewise the State may not seek to remove a popular but disfavored product from the marketplace by prohibiting truthful, nonmisleading advertisements that contain

impressive endorsements or catchy jingles. That the State finds expression too persuasive does not permit it to quiet the speech or to burden its messengers.

The defect in Vermont's law is made clear by the fact that many listeners find detailing instructive. Indeed the record demonstrates that some Vermont doctors view targeted detailing based on prescriber-identifying information as "very helpful" because it allows detailers to shape their messages to each doctor's practice. Even the United States, which appeared here in support of Vermont, took care to dispute the State's "unwarranted view that the dangers of [n]ew drugs outweigh their benefits to patients." There are divergent views regarding detailing and the prescription of brand-name drugs. Under the Constitution, resolution of that debate must result from free and uninhibited speech. As one Vermont physician put it: "We have a saying in medicine, information is power. And the more you know, or anyone knows, the better decisions can be made." There are similar sayings in law, including that "information is not in itself harmful, that people will perceive their own best interests if only they are well enough informed, and that the best means to that end is to open the channels of communication rather than to close them." The choice "between the dangers of suppressing information, and the dangers of its misuse if it is freely available" is one that "the First Amendment makes for us."

Vermont may be displeased that detailers who use prescriber-identifying information are effective in promoting brand-name drugs. The State can express that view through its own speech. But a State's failure to persuade does not allow it to hamstring the opposition. The State may not burden the speech of others in order to tilt public debate in a preferred direction. "The commercial marketplace, like other spheres of our social and cultural life, provides a forum where ideas and information flourish. Some of the ideas and information are vital, some of slight worth. But the general rule is that the speaker and the audience, not the government, assess the value of the information presented."

It is true that content-based restrictions on protected expression are sometimes permissible, and that principle applies to commercial speech. Indeed the government's legitimate interest in protecting consumers from "commercial harms" explains "why commercial speech can be subject to greater governmental regulation than noncommercial speech." The Court has noted, for example, that "a State may choose to regulate price advertising in one industry but not in others, because the risk of fraud. . . is in its view greater there." Here, however, Vermont has not shown that its law has a neutral justification. . . .

The capacity of technology to find and publish personal information, including records required by the government, presents serious and unresolved issues with respect to personal privacy and the dignity it seeks to secure. In considering how to protect those interests, however, the State cannot engage in content-based discrimination to advance its own side of a debate.

If Vermont's statute provided that prescriber-identifying information could not be sold or disclosed except in narrow circumstances then the State might have a stronger position. Here, however, the State gives possessors of the information broad discretion and wide

latitude in disclosing the information, while at the same time restricting the information's use by some speakers and for some purposes, even while the State itself can use the information to counter the speech it seeks to suppress. Privacy is a concept too integral to the person and a right too essential to freedom to allow its manipulation to support just those ideas the government prefers.

When it enacted § 4631(d), the Vermont Legislature found that the “marketplace for ideas on medicine safety and effectiveness is frequently one-sided in that brand-name companies invest in expensive pharmaceutical marketing campaigns to doctors.” “The goals of marketing programs,” the legislature said, “are often in conflict with the goals of the state.” The text of § 4631(d), associated legislative findings, and the record developed in the District Court establish that Vermont enacted its law for this end. The State has burdened a form of protected expression that it found too persuasive. At the same time, the State has left unburdened those speakers whose messages are in accord with its own views. This the State cannot do.

The judgment of the Court of Appeals is affirmed.

JUSTICE BREYER, with whom JUSTICE GINSBURG and JUSTICE KAGAN join, dissenting.

. . . . Because many, perhaps most, activities of human beings living together in communities take place through speech, and because speech-related risks and offsetting justifications differ depending upon context, this Court has distinguished for First Amendment purposes among different contexts in which speech takes place. Thus, the First Amendment imposes tight constraints upon government efforts to restrict, e.g., “core” political speech, while imposing looser constraints when the government seeks to restrict, e.g., commercial speech, the speech of its own employees, or the regulation-related speech of a firm subject to a traditional regulatory program.

These test-related distinctions reflect the constitutional importance of maintaining a free marketplace of ideas, a marketplace that provides access to “social, political, esthetic, moral, and other ideas and experiences.” At the same time, our cases make clear that the First Amendment offers considerably less protection to the maintenance of a free marketplace for goods and services. . . . applied a less than strict, “intermediate” First Amendment test when the government directly restricts commercial speech.

Under that test, government laws and regulations may significantly restrict speech, as long as they also “directly advance” a “substantial” government interest that could not “be served as well by a more limited restriction.” Moreover, the Court has found that “sales practices” that are “misleading, deceptive, or aggressive” lack the protection of even this “intermediate” standard. *Liquormart, Inc. v. Rhode Island*, 517 U. S. 484, 501 (1996). . . .

To apply a strict First Amendment standard virtually as a matter of course when a court reviews ordinary economic regulatory programs (even if that program has a modest

impact upon a firm's ability to shape a commercial message) would work at cross-purposes with this more basic constitutional approach. Since ordinary regulatory programs can affect speech, particularly commercial speech, in myriad ways, to apply a "heightened" First Amendment standard of review whenever such a program burdens speech would transfer from legislatures to judges the primary power to weigh ends and to choose means, threatening to distort or undermine legitimate legislative objectives. To apply a "heightened" standard of review in such cases as a matter of course would risk what then-Justice Rehnquist, dissenting in *Central Hudson*, described as a "retur[n] to the bygone era of *Lochner v. New York*, in which it was common practice for this Court to strike down economic regulations adopted by a State based on the Court's own notions of the most appropriate means for the State to implement its considered policies." 447 U. S., at 589. . . .

The Court (suggesting a standard yet stricter than *Central Hudson*) says that we must give content-based restrictions that burden speech "heightened" scrutiny. It adds that "[c]ommercial speech is no exception." [But [r]egulatory programs necessarily draw distinctions on the basis of content. Electricity regulators, for example, oversee company statements, pronouncements, and proposals, but only about electricity. The Federal Reserve Board regulates the content of statements, advertising, loan proposals, and interest rate disclosures, but only when made by financial institutions. And the FDA oversees the form and content of labeling, advertising, and sales proposals of drugs, but not of furniture. Given the ubiquity of content-based regulatory categories, why should the "content-based" nature of typical regulation require courts (other things being equal) to grant legislators and regulators less deference?

Nor, in the context of a regulatory program, is it unusual for particular rules to be "speaker-based," affecting only a class of entities, namely, the regulated firms. An energy regulator, for example, might require the manufacturers of home appliances to publicize ways to reduce energy consumption, while exempting producers of industrial equipment. Or a trade regulator might forbid a particular firm to make the true claim that its cosmetic product contains "cleansing grains that scrub away dirt and excess oil" unless it substantiates that claim with detailed backup testing, even though opponents of cosmetics use need not substantiate their claims. Or the FDA might control in detail just what a pharmaceutical firm can, and cannot, tell potential purchasers about its products. Such a firm, for example, could not suggest to a potential purchaser (say, a doctor) that he or she might put a pharmaceutical drug to an "off label" use, even if the manufacturer, in good faith and with considerable evidence, believes the drug will help. All the while, a third party (say, a researcher) is free to tell the doctor not to use the drug for that purpose.

If the Court means to create constitutional barriers to regulatory rules that might affect the content of a commercial message, it has embarked upon an unprecedented task—a task that threatens significant judicial interference with widely accepted regulatory activity. . . .

United States v. Caronia

United States Court of Appeals for the Second Circuit
703 F.3d 149 (2012)

[Under the Federal Food, Drug, and Cosmetic Act, companies wishing to sell new drugs must first prove to the FDA that the drug is safe and efficacious. When a drug is approved, it is given a certain “label” that corresponds to the evidence provided by the company. The FDA prohibits companies from marketing the drug “off-label,” for indications that were not supported by the evidence submitted to the FDA. Such marketing is considered prohibited “misbranding” under the FDCA. Marketers can earn the legal right to market for new indications by submitting supporting evidence in a supplemental application. Doctors, however, may (and commonly do) prescribe drugs off-label, especially in certain fields, such as pediatrics, where clinical trials are relatively rare. Alfred Caronia promoted the promoted the drug Xyrem, approved for narcolepsy, for unapproved uses including restless leg syndrome and insomnia. He was convicted of conspiracy to introduce a misbranded drug into interstate commerce. Caronia appealed, arguing that the he was convicted for his speech in violation of the First Amendment. The Second Circuit agreed and vacated the conviction. The US did not appeal.]

CHIN, Circuit Judge:

. . . . Caronia argues that the First Amendment does not permit the government to prohibit and criminalize a pharmaceutical manufacturer's truthful and non-misleading promotion of an FDA-approved drug to physicians for off-label use where such use is not itself illegal and others are permitted to engage in such speech.

We review Caronia's First Amendment challenge to his conspiracy conviction *de novo*. We agree that Caronia's conviction must be vacated, but for narrower reasons than he urges.

While the FDCA makes it a crime to misbrand or conspire to misbrand a drug, the statute and its accompanying regulations do not expressly prohibit or criminalize off-label promotion. Rather, the FDCA and FDA regulations reference “promotion” only as evidence of a drug's intended use. Thus, under the principle of constitutional avoidance, explained *infra*, we construe the FDCA as not criminalizing the simple promotion of a drug's off-label use because such a construction would raise First Amendment concerns. Because we conclude from the record in this case that the government prosecuted Caronia for mere off-label promotion and the district court instructed the jury that it could convict on that theory, we vacate the judgment of conviction. . . .

As the Supreme Court has held: “Speech in aid of pharmaceutical marketing ... is a form of expression protected by the Free Speech Clause of the First Amendment.” *Sorrell v. IMS Health, Inc.*, 131 S.Ct. 2653, 2659, (2011). Here, the proscribed conduct for which Caronia was prosecuted was precisely his speech in aid of pharmaceutical marketing. Accordingly, we conclude that the government did prosecute Caronia for his speech, and we turn to whether the prosecution was permissible. . . .

The FDCA defines misbranding in terms of whether a drug's labeling is adequate for its intended use, and permits the government to prove intended use by reference to promotional statements made by drug manufacturers or their representatives. . . .

We review the government's theory of prosecution under the *Sorrell* Court's two-step analysis to determine whether it runs afoul of the First Amendment. First, we conclude that the government's construction of the FDCA's misbranding provisions imposes content- and speaker-based restrictions on speech subject to heightened scrutiny. Second, we conclude the government cannot justify a criminal prohibition of off-label promotion even under *Central Hudson's* less rigorous intermediate test.

The government's construction of the FDCA's misbranding provisions to prohibit and criminalize the promotion of off-label drug use by pharmaceutical manufacturers is content- and speaker-based, and, therefore, subject to heightened scrutiny.

First, the government's interpretation of the FDCA's misbranding provisions to prohibit off-label promotion is content-based because it distinguishes between “favored speech” and “disfavored speech on the basis of the ideas or views expressed.” Under this construction, speech about the government-approved use of drugs is permitted, while certain speech about the off-label use of drugs—that is, uses not approved by the government—is prohibited, even though the off-label use itself is not. . . .

Second, this construction is speaker-based because it targets one kind of speaker—pharmaceutical manufacturers—while allowing others to speak without restriction. . . .

Additionally, a claim to First Amendment protection here is more compelling than in *Sorrell* because this case involves a criminal regulatory scheme subject to more careful scrutiny. Accordingly, the government's construction of the FDCA's misbranding provisions to prohibit and criminalize off-label promotion is content- and speaker-based, and subject to heightened scrutiny under *Sorrell*. . . .

The first two prongs of *Central Hudson* are easily satisfied here. . . . The third and fourth prongs of *Central Hudson* require that the regulation directly advance the government's interests and be narrowly drawn. . . .

First, off-label drug usage is not unlawful, and the FDA's drug approval process generally contemplates that approved drugs will be used in off-label ways. In effect, even if pharmaceutical manufacturers are barred from off-label promotion, physicians can prescribe, and patients can use, drugs for off-label purposes. . . .

Second, prohibiting off-label promotion by a pharmaceutical manufacturer while simultaneously allowing off-label use “paternalistically” interferes with the ability of physicians and patients to receive potentially relevant treatment information; such barriers to information about off-label use could inhibit, to the public's detriment, informed and intelligent treatment decisions. In fact, in granting safe harbor to manufacturers by permitting the dissemination of off-label information through scientific

journals, the FDA itself “recognizes that public health can be served when health care professionals receive truthful and non-misleading scientific and medical information on unapproved uses” of approved drugs. . . .

While some off-label information could certainly be misleading or unhelpful, this case does not involve false or misleading promotion. Moreover, in the fields of medicine and public health, “where information can save lives,” it only furthers the public interest to ensure that decisions about the use of prescription drugs, including off-label usage, are intelligent and well-informed.

The government's construction of the FDCA essentially legalizes the outcome—off-label use—but prohibits the free flow of information that would inform that outcome. . . . Thus, the government's construction of the FDCA's misbranding provisions does not directly advance its interest in reducing patient exposure to off-label drugs or in preserving the efficacy of the FDA drug approval process because the off-label use of such drugs continues to be generally lawful. Accordingly, the government's prohibition of off-label promotion by pharmaceutical manufacturers “provides only ineffective or remote support for the government's purpose.”

The last prong of *Central Hudson* requires the government's regulation to be narrowly drawn to further the interests served. Here, the government's construction of the FDCA to impose a complete and criminal ban on off-label promotion by pharmaceutical manufacturers is more extensive than necessary to achieve the government's substantial interests. . . .

To advance the integrity of the FDA's drug approval process and increase the safety of off-label drug use, the government could pursue several alternatives without excessive First Amendment restrictions. For example, if the government is concerned about the use of drugs off-label, it could more directly address the issue. If the government is concerned that off-label promotion may mislead physicians, it could guide physicians and patients in differentiating between misleading and false promotion, exaggerations and embellishments, and truthful or non-misleading information. The government could develop its warning or disclaimer systems, or develop safety tiers within the off-label market, to distinguish between drugs. The government could require pharmaceutical manufacturers to list all applicable or intended indications when they first apply for FDA approval, enabling physicians, the government, and patients to track a drug's development. To minimize off-label use, or manufacturer evasion of the approval process for such use, the government could create other limits, including ceilings or caps on off-label prescriptions. The FDA could further remind physicians and manufacturers of, and even perhaps further regulate, the legal liability surrounding off-label promotion and treatment decisions. Finally, where off-label drug use is exceptionally concerning, the government could prohibit the off-label use altogether. The possibilities are numerous indeed.

“If the First Amendment means anything, it means that regulating speech must be a last—not first—resort.” The government has not established a “reasonable fit” among its

interests in drug safety and public health, the lawfulness of off-label use, and its construction of the FDCA to prohibit off-label promotion. The government's interests could be served equally well by more limited and targeted restrictions on speech. . . .

Accordingly, even if speech can be used as evidence of a drug's intended use, we decline to adopt the government's construction of the FDCA's misbranding provisions to prohibit manufacturer promotion alone as it would unconstitutionally restrict free speech. We construe the misbranding provisions of the FDCA as not prohibiting and criminalizing the truthful off-label promotion of FDA-approved prescription drugs. Our conclusion is limited to FDA-approved drugs for which off-label use is not prohibited, and we do not hold, of course, that the FDA cannot regulate the marketing of prescription drugs. We conclude simply that the government cannot prosecute pharmaceutical manufacturers and their representatives under the FDCA for speech promoting the lawful, off-label use of an FDA-approved drug.

Brief for Petitioners POM Wonderful LLC et al.
POM Wonderful LLC v. FTC
United States Court of Appeals for the D.C. Circuit
August 16, 2013

[The FTC recently decided that POM Wonderful, a pomegranate juice and vitamin supplement producer, had deceptively advertised that its products are capable of treating or preventing various health conditions. While POM had offered some evidence to support its health claims, the FTC ruled that experts in the field would require two randomized controlled trials (RCTs) to support claims of treatment or preventative effect. Because POM provided no such trials, the FTC concluded that its treatment and prevention claims were misleading. The case is now pending before the D.C. Circuit, where POM's challenge is based on First Amendment and overbreadth grounds. The Selections from POM's brief to the D.C. Circuit – where the case is pending as of this writing – are included below.]

Summary of the Argument

The Commission's Order violates the First Amendment. The Order bans constitutionally protected statements about healthy foods. Part I, *infra*. Because that prohibition seeks to prevent *potentially* misleading speech rather than *actually* misleading speech, it is subject to constitutional scrutiny. Part II, *infra*. The Commission did not assert that its Order could survive First Amendment scrutiny, and it cannot for two reasons: (i) it does not directly advance the government's asserted interest in preventing consumer confusion (Part III.A, *infra*); and (ii) it is broader than necessary to achieve that interest (Part III.B, *infra*).

POM's advertisements advance accurate, truthful, and carefully qualified claims about the health benefits of consuming pomegranate juice. Those claims are based on the best science that is reasonably available. Although there are claims in POM's ads that are not based on statistically significant, randomized, and placebo-controlled human clinical

trials (“RCTs”), the fact is that there will never be statistically significant RCTs to substantiate most of the health benefits of foods and nutrients because of overwhelming scientific, economic, and ethical barriers to conducting such studies on food products. . . . The Commission’s Order, however, withdraws from consumers a significant source of truthful information: speech that is supported by competent and reliable scientific evidence other than statistically significant RCTs. . . .

Even if some consumers inferred that POM products are causally linked to specific health benefits, the Commission did not doubt that many others will not infer that claim and thus will not be misled. Also, the Commission did not find that the POM products fail to produce the positive health effects that the Commission inferred were claimed by the advertisements. Instead, it concluded that because POM did not substantiate its claims with RCTs, it lacked sufficient proof to justify its claims.

POM’s advertisements cannot be labeled “actually misleading” on the theory that RCTs have not yet proven with scientific certainty that POM’s products are causally linked to health benefits. . . . In any event, the Commission did not find, or even assert, that *consumers* would be misled into reading POM’s qualified advertisements to imply that POM’s claims were backed by statistically significant RCTs.

Of note, the Commission did not produce the proof it has regularly used in past cases to establish that consumers interpret advertisements as the Commission alleges: extrinsic evidence documenting the effects of advertising, such as consumer surveys. Traditionally, that evidence has ensured that the Commission’s regulatory impulses are based upon the actual effect of advertising on consumers, rather than an aggressive policy agenda. Here, however, the Commission asserted that the burden was on POM to produce evidence that would disprove the Commission’s assertion that the advertising would mislead consumers. That the Commission has absolved itself in prior cases from producing such evidence cannot rescue the Order: the First Amendment does not permit the government to presume that protected speech is misleading and require the speaker to produce the evidence invalidating that assumption.

Assuming that POM’s advertising was potentially misleading, under *Central Hudson Gas & Electric Corp. v. Public Service Commission of New York*, 447 U.S. 557, 566 (1980), the Order can be upheld only if (1) the prohibition seeks to further a substantial interest, and its rule both (2) directly advances that interest and (3) is not broader than necessary to achieve that interest. . . .

Importantly, the FTC’s asserted interest in this case was to prevent consumer confusion, *not* to protect public health. . . .

[T]he Commission failed to produce “substantial evidence” that its regulation “directly advances” its asserted interest. . . . Consumers will not be better informed if the Commission suppresses advertising that accurately reports the results of *in vitro* or animal studies, or if they are permitted to learn about a clinical trial involving human subjects only if that study satisfies the government’s definition of statistical significance.

Further, the aim of the Order is to deprive consumers of information. . . . [T]he First Amendment does not allow the government to command a speaker to include all details and all sides of a debate on a matter of public concern simply to avoid the possibility of creating misleading “implications.” The Order pursues the forbidden objective of “prohibit[ing] certain kinds of speech on the premise that consumers need government to protect them from accurate information.”

If anything, the Order augments consumer confusion by creating different standards of proof that turn entirely on the identity of the speaker. It prohibits advertisers from making claims to promote their products based on competent and reliable scientific evidence other than RCTs. By contrast, regulatory agencies remain free to rely on such evidence as the basis for promoting, regulating, or even prohibiting products in the marketplace. For similar reasons, the Commission’s rule also amounts to prohibited viewpoint discrimination: it bans speech only when the speaker asserts that its food products improve health; contrary claims of opponents and the government calling into question the benefits of POM products are freely permitted even if they are based on the same scientific basis.

B. The Commission’s newfound RCT requirement also fails the third *Central Hudson* requirement because it is broader than necessary to achieve the government’s interest. . . . For certain kinds of claims – such as an unqualified claim that a drug has been proven to be an effective treatment of heart disease or prostate cancer – an RCT might be required. Here, however, the Commission as a practical matter deemed irrelevant critical *Pfizer* factors – such as the type of product at issue, and the complete infeasibility of an RCT standard.

At no point has the Commission explained why it could not achieve its interest in preventing consumer confusion by faithfully adhering to its competent and reliable scientific evidence standard. . . . At a minimum, the FTC had narrower remedies available, such as requiring claim qualification under *Pearson*, to protect consumers short of prohibiting categories of speech outright. The First Amendment compels the Commission at least to consider, if not to adopt, such remedies.

IV. If this Court were nonetheless to affirm the Commission’s finding of liability, it should vacate the Commission’s remedy requiring that all health claims in POM’s advertising be supported by two RCTs. Such a broad “fencing in” remedy is inappropriate where far less intrusive remedies were available to prevent consumer deception, and where the Commission applied its newfound liability standard – the RCT requirement – for the first time in this case.

United States v. Alvarez
United States Supreme Court
132 S. Ct. 2537 (2012)

[The Stolen Valor Act criminalized false claims about winning a military decoration or medal, and added enhanced penalties for falsely claiming to have won the Congressional

Medal of Honor. Xavier Alvarez was prosecuted under the Act for claiming to have won the Congressional Medal of Honor and entered a conditional guilty plea. The Ninth Circuit held that the Act was invalid under the First Amendment. The Supreme Court affirmed.]

Justice KENNEDY announced the judgment of the Court and delivered an opinion, in which THE CHIEF JUSTICE, Justice GINSBURG, and Justice SOTOMAYOR join.

Respondent challenges the statute as a content-based suppression of pure speech, speech not falling within any of the few categories of expression where content-based regulation is permissible. The Government defends the statute as necessary to preserve the integrity and purpose of the Medal, an integrity and purpose it contends are compromised and frustrated by the false statements the statute prohibits. It argues that false statements “have no First Amendment value in themselves,” and thus “are protected only to the extent needed to avoid chilling fully protected speech.” Although the statute covers respondent’s speech, the Government argues that it leaves breathing room for protected speech, for example speech which might criticize the idea of the Medal or the importance of the military. The Government’s arguments cannot suffice to save the statute. . . .

. . . [C]ontent-based restrictions on speech have been permitted, as a general matter, only when confined to the few “historic and traditional categories [of expression] long familiar to the bar.” . . . Absent from those few categories where the law allows content-based regulation of speech is any general exception to the First Amendment for false statements. This comports with the common understanding that some false statements are inevitable if there is to be an open and vigorous expression of views in public and private conversation, expression the First Amendment seeks to guarantee.

The Government disagrees with this proposition. It cites language from some of this Court’s precedents to support its contention that false statements have no value and hence no First Amendment protection. . . . These quotations all derive from cases discussing defamation, fraud, or some other legally cognizable harm associated with a false statement, such as an invasion of privacy or the costs of vexatious litigation. In those decisions the falsity of the speech at issue was not irrelevant to our analysis, but neither was it determinative. The Court has never endorsed the categorical rule the Government advances: that false statements receive no First Amendment protection. Our prior decisions have not confronted a measure, like the Stolen Valor Act, that targets falsity and nothing more.

Even when considering some instances of defamation and fraud, moreover, the Court has been careful to instruct that falsity alone may not suffice to bring the speech outside the First Amendment. The statement must be a knowing or reckless falsehood. . . .

The Government thus seeks to use this principle for a new purpose. It seeks to convert a rule that limits liability even in defamation cases where the law permits recovery for tortious wrongs into a rule that expands liability in a different, far greater realm of discourse and expression. That inverts the rationale for the exception. The requirements of a knowing falsehood or reckless disregard for the truth as the condition for recovery in

certain defamation cases exists to allow more speech, not less. A rule designed to tolerate certain speech ought not blossom to become a rationale for a rule restricting it. . . .

Section 1001's prohibition on false statements made to Government officials, in communications concerning official matters, does not lead to the broader proposition that false statements are unprotected when made to any person, at any time, in any context. . . .

It is not simply because perjured statements are false that they lack First Amendment protection. Perjured testimony "is at war with justice" because it can cause a court to render a "judgment not resting on truth." Perjury undermines the function and province of the law and threatens the integrity of judgments that are the basis of the legal system. . . .

Statutes that prohibit falsely representing that one is speaking on behalf of the Government, or that prohibit impersonating a Government officer, also protect the integrity of Government processes, quite apart from merely restricting false speech. . . .

As our law and tradition show, then, there are instances in which the falsity of speech bears upon whether it is protected. Some false speech may be prohibited even if analogous true speech could not be. This opinion does not imply that any of these targeted prohibitions are somehow vulnerable. But it also rejects the notion that false speech should be in a general category that is presumptively unprotected. . . .

Before exempting a category of speech from the normal prohibition on content-based restrictions, however, the Court must be presented with "persuasive evidence that a novel restriction on content is part of a long (if heretofore unrecognized) tradition of proscription." The Government has not demonstrated that false statements generally should constitute a new category of unprotected speech on this basis. . . .

The Act by its plain terms applies to a false statement made at any time, in any place, to any person. It can be assumed that it would not apply to, say, a theatrical performance. . . . Here the lie was made in a public meeting, but the statute would apply with equal force to personal, whispered conversations within a home. The statute seeks to control and suppress all false statements on this one subject in almost limitless times and settings. And it does so entirely without regard to whether the lie was made for the purpose of material gain. . . .

Permitting the government to decree this speech to be a criminal offense, whether shouted from the rooftops or made in a barely audible whisper, would endorse government authority to compile a list of subjects about which false statements are punishable. That governmental power has no clear limiting principle. Our constitutional tradition stands against the idea that we need Oceania's Ministry of Truth. . . . Where false claims are made to effect a fraud or secure moneys or other valuable considerations, say offers of employment, it is well established that the Government may restrict speech without affronting the First Amendment. But the Stolen Valor Act is not so limited in its reach. Were the Court to hold that the interest in truthful discourse alone is sufficient to sustain a ban on speech, absent any evidence that the speech was used to gain a material

advantage, it would give government a broad censorial power unprecedented in this Court's cases or in our constitutional tradition. . . .

Although the objectives the Government seeks to further by the statute are not without significance, the Court must, and now does, find the Act does not satisfy exacting scrutiny. . . . The First Amendment requires that the Government's chosen restriction on the speech at issue be "actually necessary" to achieve its interest. . . . The link between the Government's interest in protecting the integrity of the military honors system and the Act's restriction on the false claims of liars like respondent has not been shown. . . . The Government points to no evidence to support its claim that the public's general perception of military awards is diluted by false claims such as those made by Alvarez. . . . The Government has not shown, and cannot show, why counterspeech would not suffice to achieve its interest. The facts of this case indicate that the dynamics of free speech, of counterspeech, of refutation, can overcome the lie. . . .

The remedy for speech that is false is speech that is true. . . . And in any event, in order to show that public refutation is not an adequate alternative, the Government must demonstrate that unchallenged claims undermine the public's perception of the military and the integrity of its awards system. . . .

In addition, when the Government seeks to regulate protected speech, the restriction must be the "least restrictive means among available, effective alternatives." . . . A Government-created database could list Congressional Medal of Honor winners. Were a database accessible through the Internet, it would be easy to verify and expose false claims. . . .

Petition for Writ of Certiorari, Harkonen v. United States

United States Supreme Court

August 5, 2013

[Here we provide excerpts from a petition for certiorari to the U.S. Supreme Court, on behalf of a pharmaceutical executive convicted of wire fraud. The basis of the conviction was the government's claim that he misrepresented the results of a clinical trial and had sufficient knowledge to know that the presentation of these results, in a press release, was false. He objected, arguing that the case involved a difference of opinion, rather than fact. Cert was denied in the case.]

Questions Presented

The Ninth Circuit upheld a wire fraud conviction for the issuance of a press release about a pharmaceutical clinical study. The only statements charged as false expressed a conclusion, *i.e.*, that the data demonstrated that the drug benefitted patients. The government conceded that the data in the press release, which showed that far more patients survived on the drug than on placebo, were accurate. The government challenged as false only the inference that the drug (and not random chance) caused that beneficial

outcome.

The questions presented are:

1. Whether a conclusion about the meaning of scientific data, one on which scientists may reasonably disagree, satisfies the element of a “false or fraudulent” statement under the wire fraud statute, 18 U.S.C. § 1343?
2. Whether applying 18 U.S.C. § 1343 to scientific conclusions drawn from accurate data violates the First Amendment’s proscription against viewpoint discrimination, or renders the statute, as applied, unconstitutionally vague.

Statement of the Case

This case has drawn national attention because the government has criminalized the expression of a reasonable scientific opinion. Harkonen, a physician, researcher, and former CEO of InterMune, Inc., was convicted on one count of wire fraud. His conviction stemmed solely from the issuance of a single press release. The press release reported the preliminary results of a randomized, double-blind, placebo-controlled clinical trial, “the ‘gold standard’” for clinical trials. The press release stated that study results demonstrated that a prescription medication, Actimmune, provided a survival benefit to patients with idiopathic pulmonary fibrosis (“IPF”).

Harkonen’s conviction is extraordinary because the “Government has always agreed that there was *no falsification of data here, so that fact is not in dispute.*” . . . The government contended, however, that because the study failed to meet its primary endpoint, the study itself was a failure, and the remarkable survival data “at best only ‘suggested’” a survival benefit, but did not *demonstrate* one. It is this alleged “*falsification of the conclusions that could be drawn* from the data, that was what the trial was all about.” . . .

No federal fraud prosecution should ever be “all about” the conclusions drawn from concededly accurate data, at least where, as here, no law mandates adherence to the government’s viewpoint, and no scientific consensus exists on the issue. The fraud laws do not apply to such scientific conclusions, and any prosecution of them violates the First Amendment and the Due Process Clause. . . . In this country, “the conclusions that one ought to draw from . . . data” are for scientists to debate, not for the government to prosecute as wire fraud. This Court established that principle over a century ago in *American School of Magnetic Healing v. McAnnulty*, 187 U.S. 94 (1902). There, the Court limited the materially identical language of the civil mail fraud statute to “cases of actual fraud in fact, in regard to which opinion formed no basis.” . . .

This Court established long ago that the expression of a scientific conclusion about which reasonable minds can differ is not “false and fraudulent” within the meaning of the civil postal mail fraud statute. . . .

Review is warranted immediately, because pharmaceutical companies routinely do and must issue press releases announcing material clinical trial results. Chilling such speech—forcing it to conform to the opinions of FDA staff—was the avowed intent of

this prosecution. Government officials are now empowered to say, in the investigations that pervade the pharmaceutical industry, that those who publicly disagree with the scientific views of government employees do so at their criminal peril. They may send the same message to the many scientists whose research depends on government grants or public funding. The chilling effect of this message is immediate and extraordinary, and fully warrants this Court's review. . . .

The petition also should be granted because the Ninth Circuit's construction of the wire fraud statute squarely presents the "grave questions of constitutional law". . .

The first such question implicates the First Amendment. Construing the criminal mail and wire fraud statutes to permit the government to prosecute scientific conclusions with which the government disagrees raises a question of exceptional importance about the role of independent judicial review to prevent the government from prosecuting as "fraud" scientific viewpoints that the First Amendment protects.

Viewpoint discrimination lies at the core of the First Amendment: the government may not proscribe speech "because of disagreement with the message it conveys." . . . But here the government prosecuted Harkonen because the press release expressed a conclusion about accurate data—that they demonstrated a survival benefit—with which two individuals at FDA—"FDA medical review staff"—disagreed.

The freedom to disagree with other scientists, and especially with government staff, is fundamental to the First Amendment. . . . First Amendment protections cannot rest solely on labels; they require fair scrutiny of the defendant's statement in the context of legitimate scientific disagreement.

The Ninth Circuit's decision thus raises an important question that this Court has resolved for other categories of unprotected speech, but not yet for fraud, about an appellate court's "constitutional duty to conduct an independent examination of the record as a whole" and to decide "whether a given course of conduct falls on the near or far side of the line of constitutional protection." . . .

Therefore, this Court has required independent judicial review in cases involving speech that allegedly falls into many unprotected categories, including not only "fighting words," but also obscenity, child pornography, incitement to imminent lawless action, and libel. . . . Just as independent review was necessary in *Snyder* and *Peel* to ensure that the factfinders did not punish protected speech, so it is necessary here, where prosecutors have attacked the expression of a protected scientific opinion that government officials condemned. . . .

The Ninth Circuit's alternate tact—observing that "nearly all" government witnesses stated that the press release "misrepresented" the study results—is equally indefensible because those who so testified did so based on a single viewpoint about the proper interpretation of data: that a clinical study lacking statistically significant p-values on pre-specified end- points cannot "demonstrate" anything. Yet the government made no attempt to establish the universality of its p-value restriction on truthful scientific

inference. No such showing could be made. . . .

It stated that courts “frequently permit expert testimony on causation based on evidence other than statistical significance,” and medical professionals and researchers do not limit the data they consider to “statistically significant evidence.” . . .

Some of science’s greatest leaps forward defied conventional thinking and were roundly and publicly condemned. Leaving juries to decide whether a scientific conclusion drawn from accurate facts is false or misleading, without the check of independent judicial review, is a recipe for viewpoint discrimination and chilling extraordinarily important speech. This Court should grant the petition to clarify that the First Amendment mandates independent judicial review of falsity where, as here, the government prosecutes speech about the meaning of scientific research results, to ensure that a fraud prosecution does not transgress “acceptably narrow limits” and impermissibly regulate protected scientific opinion. . . .

The public interest in the free flow of information has particular relevance “in the fields of medicine and public health, where information can save lives.” *Sorrell*, 131 S. Ct. at 2664. Press releases expressing opinions about the import of the latest clinical studies are integral to this communication. . . .

Two criticisms have been and always can be levied against such press releases. One is that they omitted important information; that is unavoidable, because no release can contain the same details as could a full report to FDA, a journal article, or a conference presentation, and scientists will disagree on what is most important. The other is that the conclusions overstate the importance of the results; such disagreement again is inevitable, because drawing conclusions from data involves exercising judgment. . . .

Pharmaceutical companies sponsor important research. Their scientists should enjoy the same freedoms that government and academic scientists have to express conclusions about the meaning of data. . . . By allowing fraud prosecutions to target scientific conclusions, the Ninth Circuit let the government cross a line into criminalizing scientific opinion that no court before let it cross. . . .

Whether the government may convict scientists of fraud for the inferences they draw from accurate data is a question of exceptional importance to which this Court should promptly provide a uniform national answer.

PROFESSIONAL CONDUCT PANEL

Speech is integral to the professional practice of medicine. How, then, may professional speech be regulated consistent with the First Amendment? The Supreme Court has long considered doctors to have First Amendment rights, but the extent of those rights is far from clear. Doctors clearly can be legally sanctioned for their speech. They may, for example, lose their license if they engage in speech that constitutes malpractice.

But legislatures also sometimes seek, independently of medical licensing boards, to regulate what physicians must or may not say to patients. In recent years, this has occurred with some regularity, particularly in the highly charged contexts of abortion, gun violence, and sexual orientation. Doctors have invoked First Amendment rights against such statutes, arguing that they either (1) prevent healthcare professionals from communicating truthful disciplinary knowledge to clients, or (2) compel healthcare professionals to communicate statements that they know to be false according to the professional consensus of medical science. Judges then must decide whether the regulation in question blocks or encourages the flow of accurate and non-misleading information to patients in the name of patient health, safety, and well-being. But what standard should they use, and how well are courts situated to resolve such questions? In the sphere of public discourse, all opinions are created equal; this is not true in the sphere of professional knowledge, where some opinions are harmful. The difficulty is determining when legislation aims to supplant expert knowledge with mere political opinion, thus triggering First Amendment protection, and when regulation protects the integrity of disciplinary knowledge and the patients who receive it from harmful or untested professional advice, consistent with First Amendment values.

This panel will address the implications of the First Amendment for the regulation of the speech and workflow of health professionals. Issues for discussion include: (1) how First Amendment doctrine should approach government regulation that mandates or forbids certain statements or disclosures to patients; (2) how and whether the First Amendment protects health professionals' duties of loyalty and advocacy, (3) the implications, for the First Amendment, of the fact that medicine frequently intersects with controversial social issues, and that medical evidence can be misconstrued or inadequate in the face of such social conflict; and (4) the First Amendment implications of moving from a health care system governed by professional self-regulation (e.g., of advertising) and individual care delivery to a system more governed by direct government regulation and corporate care delivery.

Conant v. Walters
United States Court of Appeals for the Ninth Circuit
309 F.3d 629 (2002)

[In response to California and Arizona initiatives decriminalizing the use of marijuana for some medical purposes, the federal government began investigating doctors for “recommending” the use of marijuana to their patients. A group of patients and physicians challenged this policy. The District Court granted a permanent injunction and the Ninth Circuit affirmed, holding inter alia that the policy violated doctors’ First Amendment rights.]

SCHROEDER, Chief Judge:

The government policy [] strike[s] at core First Amendment interests of doctors and patients. An integral component of the practice of medicine is the communication between a doctor and a patient. Physicians must be able to speak frankly and openly to patients. That need has been recognized by the courts through the application of the common law doctor-patient privilege.

The doctor-patient privilege reflects “the imperative need for confidence and trust” inherent in the doctor-patient relationship and recognizes that “a physician must know all that a patient can articulate in order to identify and to treat disease; barriers to full disclosure would impair diagnosis and treatment.” The Supreme Court has recognized that physician speech is entitled to First Amendment protection because of the significance of the doctor-patient relationship. *See Planned Parenthood of Southeastern Pennsylvania v. Casey*, 505 U.S. 833 (recognizing physician's First Amendment right not to speak).

This Court has also recognized the core First Amendment values of the doctor-patient relationship. In *Nat'l Ass'n for the Advancement of Psychoanalysis v. California Bd. of Psychology*, 228 F.3d 1043 (9th Cir. 2000), we recognized that communication that occurs during psychoanalysis is entitled to First Amendment protection. We upheld California's mental health licensing laws that determined when individuals qualified as mental health professionals against a First Amendment challenge. Finding the laws content-neutral, we noted that California did not attempt to “dictate the content of what is said in therapy” and did not prevent licensed therapists from utilizing particular “psycho-analytical methods.”

Being a member of a regulated profession does not, as the government suggests, result in a surrender of First Amendment rights. To the contrary, professional speech may be entitled to “the strongest protection our Constitution has to offer.” Even commercial speech by professionals is entitled to First Amendment protection. Attorneys have rights to speak freely subject only to the government regulating with “narrow specificity.”

In its most recent pronouncement on regulating speech about controlled substances, *Thompson v. Western States Medical Ctr.*, 535 U.S. 357 (2002), the Supreme Court found that provisions in the Food and Drug Modernization Act of 1997 that restricted physicians and pharmacists from advertising compounding drugs violated the First Amendment. The Court refused to make the “questionable assumption that doctors would prescribe unnecessary medications” and rejected the government's argument that “people would make bad decisions if given truthful information about compounded drugs.” The federal government argues in this case that a doctor-patient discussion about marijuana might lead the patient to make a bad decision, essentially asking us to accept the same assumption rejected by the Court in *Thompson*. We will not do so. Instead, we take note of the Supreme Court's admonition in *Thompson*: “If the First Amendment means anything, it means that regulating speech must be a last—not first—resort. Yet here it seems to have been the first strategy the Government thought to try.”

The government's policy in this case seeks to punish physicians on the basis of the content of doctor-patient communications. Only doctor-patient conversations that include discussions of the medical use of marijuana trigger the policy. Moreover, the policy does not merely prohibit the discussion of marijuana; it condemns expression of a particular viewpoint, i.e., that medical marijuana would likely help a specific patient. Such condemnation of particular views is especially troubling in the First Amendment context. “When the government targets not subject matter but particular views taken by speakers on a subject, the violation of the First Amendment is all the more blatant.” Indeed, even content-based restrictions on speech are “presumptively invalid.”

The government's policy is materially similar to the limitation struck down in *Legal Services Corp. v. Velazquez*, 531 U.S. 533 (2001), that prevented attorneys from “present[ing] all the reasonable and well-grounded arguments necessary for proper resolution of the case.” In *Velazquez*, a government restriction prevented legal assistance organizations receiving federal funds from challenging existing welfare laws. Like the limitation in *Velazquez*, the government's policy here “alter[s] the traditional role” of medical professionals by “prohibit[ing] speech necessary to the proper functioning of those systems.”

The government relies upon *Rust* and *Casey* to support its position in this case. However, those cases did not uphold restrictions on speech itself. *Rust* upheld restrictions on federal funding for certain types of activity, including abortion counseling, referral, or advocacy. In *Casey*, a plurality of the Court upheld Pennsylvania's requirement that physicians' advice to patients include information about the health risks associated with an abortion and that physicians provide information about alternatives to abortion. The plurality noted that physicians did not have to comply if they had a reasonable belief that the information would have a “severely adverse effect on the physical or mental health of the patient,” and thus the statute did not “prevent the physician from exercising his or her medical judgment.” The government's policy in this case does precisely that.

The government seeks to justify its policy by claiming that a doctor's “recommendation”

of marijuana may encourage illegal conduct by the patient, which is not unlike the argument made before, and rejected by, the Supreme Court in a recent First Amendment case. In *Free Speech Coalition*, the government defended the Child Pornography Prosecution Act of 1996 by arguing that, although virtual child pornography does not harm children in the production process, it threatens them in “other, less direct, ways.” For example, the government argued pedophiles might use such virtual images to encourage children to participate in sexual activity. The Supreme Court rejected such justifications, holding that the potential harms were too attenuated from the proscribed speech. “Without a significantly stronger, more direct connection, the Government may not prohibit speech on the ground that it may encourage . . . illegal conduct.” The government’s argument in this case mirrors the argument rejected in *Free Speech Coalition*.

The government also relies on a case in which a district court refused to order an injunction against this federal drug policy. The court did so, however, because the plaintiffs in that case did not factually support their claim that the policy chilled their speech. In this case, the record is replete with examples of doctors who claim a right to explain the medical benefits of marijuana to patients and whose exercise of that right has been chilled by the threat of federal investigation. The government even stipulated in the district court that a “reasonable physician would have a genuine fear of losing his or her DEA registration to dispense controlled substances if that physician were to recommend marijuana to his or her patients.”

To survive First Amendment scrutiny, the government’s policy must have the requisite “narrow specificity.” Throughout this litigation, the government has been unable to articulate exactly what speech is proscribed, describing it only in terms of speech the patient believes to be a recommendation of marijuana. Thus, whether a doctor-patient discussion of medical marijuana constitutes a “recommendation” depends largely on the meaning the patient attributes to the doctor’s words. This is not permissible under the First Amendment. In *Thomas*, the court struck down a state statute that failed to make a clear distinction between union membership, solicitation, and mere “discussion, laudation, [or] general advocacy.” The distinction rested instead on the meaning the listeners attributed to spoken words. The government’s policy, like the statute in *Thomas*, leaves doctors and patients “no security for free discussion.” As Judge Smith appropriately noted in granting the preliminary injunction, “when faced with the fickle iterations of the government’s policy, physicians have been forced to suppress speech that would not rise to the level of that which the government constitutionally may prohibit.”

Our decision is consistent with principles of federalism that have left states as the primary regulators of professional conduct. We must “show [] respect for the sovereign States that comprise our Federal Union. That respect imposes a duty on federal courts, whenever possible, to avoid or minimize conflict between federal and state law, particularly in situations in which the citizens of a State have chosen to serve as a laboratory in the trial of novel social and economic experiments without risk to the rest of the country.”

For all of the foregoing reasons, we affirm the district court's order entering a permanent injunction.

Pickup v. Brown

United States Court of Appeals for the Ninth Circuit
740 F.3d 1208 (2014)

[California's Senate Bill 1172 (SB 1172) prohibits licensed therapists from engaging in "sexual orientation change efforts" (SOCE)—also called conversion therapy or reparative therapy—with minors. That statute defines sexual orientation change efforts as "any practices. . .that seek to change an individual's sexual orientation."

Two separate district court judges heard preliminary injunction challenges brought by SOCE practitioners and the parents of children undergoing SOCE therapy. In *Pickup v. Brown*, the court denied a request for preliminary injunction, holding *inter alia* that that statute does not violate doctors' or patients' First Amendment rights. Judge Kimberly Mueller based her decision on the finding "that SOCE therapy is subject to the state's legitimate control over the professions [and] SB 1172's restrictions on therapy do not implicate fundamental rights and are not properly evaluated under strict scrutiny review, but rather under the rational basis test." She further found that SB 1172's stated purpose of protecting the health of minors more than meets this burden.

In *Welch v. Brown*, Judge William Shubb disagreed and issued a preliminary injunction. He found *inter alia* that SB 1172 ran afoul of the First Amendment: "When a mental health provider's pursuit of SOCE is guided by the provider's or patient's views of homosexuality, it is difficult, if not impossible, to view the conduct of performing SOCE as anything but integrally intertwined with viewpoints, messages, and expression about homosexuality." As a restriction on speech content and viewpoint neutral, the court held that SB 1172 must be subjected to strict scrutiny. Judge Welch further found that "in light of the heavy burden strict scrutiny imposes on defendants, the lack of evidence demonstrating 'actual harm' and a causal relationship between SOCE and harm to minors, and the underinclusiveness of SB 1172" the bill was unlikely to withstand strict scrutiny.

In the opinion excerpted below, the Ninth Circuit resolved the conflicting district court opinions on SB 1172's constitutionality, holding *inter alia* that the statute does not violate the First Amendment. Certiorari was recently denied by the Supreme Court.]

GRABER, Circuit Judge:

The first step in our analysis is to determine whether SB 1172 is a regulation of conduct or speech. "[W]ords can in some circumstances violate laws directed not against speech but against conduct. . . ." *R.A. V. v. City of St. Paul*, 505 U.S. 377, 389 (1992). "Congress,

for example, can prohibit employers from discriminating in hiring on the basis of race. The fact that this will require an employer to take down a sign reading ‘White Applicants Only’ hardly means that the law should be analyzed as one regulating the employer’s speech rather than conduct.” The Supreme Court has made clear that First Amendment protection does not apply to conduct that is not “inherently expressive.” In identifying whether SB 1172 regulates conduct or speech, two of our cases guide our decision: *National Association for the Advancement of Psychoanalysis v. California Board of Psychology* (“*NAAP*”), 228 F.3d 1043 (9th Cir. 2000), and *Conant v. Walters*, 309 F.3d 629 (9th Cir. 2002). . . .

We distill the following relevant principles from *NAAP* and *Conant*: (1) doctor-patient communications *about* medical treatment receive substantial First Amendment protection, but the government has more leeway to regulate the conduct necessary to administering treatment itself; (2) psychotherapists are not entitled to special First Amendment protection merely because the mechanism used to deliver mental health treatment is the spoken word; and (3) nevertheless, communication that occurs during psychotherapy does receive *some* constitutional protection, but it is not immune from regulation.

Because those principles, standing alone, do not tell us whether or how the First Amendment applies to the regulation of specific mental health treatments, we must go on to consider more generally the First Amendment rights of professionals, such as doctors and mental health providers. In determining whether SB 1172 is a regulation of speech or conduct, we find it helpful to view this issue along a continuum.

At one end of the continuum, where a professional is engaged in a public dialogue, First Amendment protection is at its greatest. Thus, for example, a doctor who publicly advocates a treatment that the medical establishment considers outside the mainstream, or even dangerous, is entitled to robust protection under the First Amendment—just as any person is—even though the state has the power to regulate medicine. That principle makes sense because communicating to the *public* on matters of *public concern* lies at the core of First Amendment values. Thus, outside the doctor-patient relationship, doctors are constitutionally equivalent to soapbox orators and pamphleteers, and their speech receives robust protection under the First Amendment.

At the midpoint of the continuum, within the confines of a professional relationship, First Amendment protection of a professional’s speech is somewhat diminished. For example, in *Planned Parenthood of Southeastern Pennsylvania v. Casey*, 505 U.S. 833, 884 (1992), the plurality upheld a requirement that doctors disclose truthful, nonmisleading information to patients about certain risks of abortion:

All that is left of petitioners’ argument is an asserted First Amendment right of a physician not to provide information about the risks of abortion, and childbirth, in a manner mandated by the State. To be sure, the physician’s First Amendment rights not to speak are implicated, but only as part of the practice of medicine, *subject to reasonable licensing and*

regulation by the State. We see no constitutional infirmity in the requirement that the physician provide the information mandated by the State here.

Outside the professional relationship, such a requirement would almost certainly be considered impermissible compelled speech.

Moreover, doctors are routinely held liable for giving negligent medical advice to their patients, without serious suggestion that the First Amendment protects their right to give advice that is not consistent with the accepted standard of care. A doctor “may not counsel a patient to rely on quack medicine. The First Amendment would not prohibit the doctor's loss of license for doing so.” And a lawyer may be disciplined for divulging confidences of his client, even though such disclosure is pure speech. Thus, the First Amendment tolerates a substantial amount of speech regulation within the professional-client relationship that it would not tolerate outside of it. And that toleration makes sense: When professionals, by means of their state-issued licenses, form relationships with clients, the purpose of those relationships is to advance the welfare of the clients, rather than to contribute to public debate.

At the other end of the continuum, and where we conclude that SB 1172 lands, is the regulation of professional *conduct*, where the state's power is great, even though such regulation may have an incidental effect on speech. Most, if not all, medical and mental health treatments require speech, but that fact does not give rise to a First Amendment claim when the state bans a particular treatment. When a drug is banned, for example, a doctor who treats patients with that drug does not have a First Amendment right to speak the words necessary to provide or administer the banned drug. Were it otherwise, then any prohibition of a particular medical treatment would raise First Amendment concerns because of its incidental effect on speech. Such an application of the First Amendment would restrict unduly the states' power to regulate licensed professions and would be inconsistent with the principle that “it has never been deemed an abridgement of freedom of speech or press to make a course of conduct illegal merely because the conduct was in part initiated, evidenced, or carried out by means of language, either spoken, written, or printed.”

Senate Bill 1172 regulates conduct. It bans a form of treatment for minors; it does nothing to prevent licensed therapists from discussing the pros and cons of SOCE with their patients. Senate Bill 1172 merely prohibits licensed mental health providers from engaging in SOCE with minors. It is the limited reach of SB 1172 that distinguishes the present cases from *Conant*, in which the government's policy prohibited speech *wholly apart* from the actual provision of treatment. Pursuant to its police power, California has authority to regulate licensed mental health providers' administration of therapies that the legislature has deemed harmful. Under *Giboney*, the fact that speech may be used to carry out those therapies does not turn the regulation of conduct into a regulation of speech. In fact, the *Welch* Plaintiffs concede that the state has the power to ban aversive types of SOCE. And we reject the position of the *Pickup* Plaintiffs—asserted during oral argument—that even a ban on aversive types of SOCE requires heightened scrutiny

because of the incidental effect on speech. Here, unlike in *Conant*, the law *allows* discussions about treatment, recommendations to obtain treatment, and expressions of opinions about SOCE and homosexuality. . . .

We further conclude that the First Amendment does not prevent a state from regulating treatment even when that treatment is performed through speech alone. As we have already held in *NAAP*, talk therapy does not receive special First Amendment protection merely because it is administered through speech. That holding rested on the understanding of talk therapy as “the *treatment* of emotional suffering and depression, *not* speech.” Thus, under *NAAP*, to the extent that talk therapy implicates speech, it stands on the same First Amendment footing as other forms of medical or mental health treatment. Senate Bill 1172 is subject to deferential review just as are other regulations of the practice of medicine. . . .

Because SB 1172 regulates only treatment, while leaving mental health providers free to discuss and recommend, or recommend against, SOCE, we conclude that any effect it may have on free speech interests is merely incidental. Therefore, we hold that SB 1172 is subject to only rational basis review and must be upheld if it bears a rational relationship to a legitimate state interest.

According to the statute, SB 1172 advances California's interest in “protecting the physical and psychological well-being of minors, including lesbian, gay, bisexual and transgender youth, and in protecting its minors against exposure to serious harms caused by sexual orientation change efforts.” Without a doubt, protecting the well-being of minors is a legitimate state interest. And we need not decide whether SOCE actually causes “serious harms”; it is enough that it could “reasonably be conceived to be true by the governmental decisionmaker.”

The record demonstrates that the legislature acted rationally when it decided to protect the well-being of minors by prohibiting mental health providers from using SOCE on persons under 18. The legislature relied on the report of the Task Force of the American Psychological Association, which concluded that SOCE has not been demonstrated to be effective and that there have been anecdotal reports of harm, including depression, suicidal thoughts or actions, and substance abuse. The legislature also relied on the opinions of many other professional organizations. Each of those organizations opposed the use of SOCE, concluding, among other things, that homosexuality is not an illness and does not require treatment (American School Counselor Association), SOCE therapy can provoke guilt and anxiety (American Academy of Pediatrics), it may be harmful (National Association of Social Workers), and it may contribute to an enduring sense of stigma and self-criticism (American Psychoanalytic Association). Although the legislature also had before it some evidence that SOCE is safe and effective, the overwhelming consensus was that SOCE was harmful and ineffective. On this record, we have no trouble concluding that the legislature acted rationally by relying on that consensus.

Plaintiffs argue that the legislature acted irrationally when it banned SOCE for minors

because there is a lack of scientifically credible proof of harm. But, under rational basis review, “[w]e ask only whether there are plausible reasons for [the legislature's] action, and if there are, our inquiry is at an end.”

Therefore, we hold that SB 1172 is rationally related to the legitimate government interest of protecting the well-being of minors.

Pickup v. Brown, Dissent from Denial for Rehearing En Banc
United States Court of Appeals for the Ninth Circuit
740 F.3d 1208, 1214-21 (2014)

[The Ninth Circuit denied a motion for rehearing en banc by the plaintiffs in *Pickup*. In a dissent from this denial, Judge O’Scannlain questioned the *Pickup* panel’s First Amendment reasoning.]

O'SCANNLAIN, Circuit Judge, joined by BEA and IKUTA, Circuit Judges, dissenting from the denial of rehearing en banc:

May the legislature avoid First Amendment judicial scrutiny by defining disfavored talk as “conduct”? That is what these cases are really about.

The State of California, in the statute at issue here, has prohibited licensed professionals from saying certain words to their clients. By labeling such speech as “conduct,” the panel's opinion has entirely exempted such regulation from the First Amendment. In so doing, the panel contravenes recent Supreme Court precedent, ignores established free speech doctrine, misreads our cases, and thus insulates from First Amendment scrutiny California's prohibition—in the guise of a professional regulation—of politically unpopular expression. . . .

According to the panel the words proscribed by SB 1172 consist entirely of medical “treatment,” which although effected by verbal communication nevertheless constitutes “professional *conduct* ” entirely unprotected by the First Amendment. Unlike a professional's opinions, theories, recommendations, or advocacy, such “conduct” effected through speech would receive no constitutional safeguards against state suppression. *Id.* The panel provides no principled doctrinal basis for its dichotomy: by what criteria do we distinguish between utterances that are truly “speech,” on the one hand, and those that are, on the other hand, somehow “treatment” or “conduct”? The panel, contrary to common sense and without legal authority, simply asserts that some spoken words—those prohibited by SB 1172—are not speech.

Empowered by this ruling of our court, government will have a new and powerful tool to silence expression based on a political or moral judgment about the content and purpose of the communications. The First Amendment precisely forbids government from punishing speech on such grounds.

Our precedents do not suggest that laws prohibiting “conduct” effected exclusively by means of speech escape First Amendment scrutiny. In fact, the Supreme Court, in its most recent relevant case, flatly refused to countenance the government's purported distinction between “conduct” and “speech” for constitutional purposes when the activity at issue consisted of talking and writing.

The plaintiffs in *Holder v. Humanitarian Law Project*, 561 U.S. 1, 130 (2010), had challenged a Federal statute forbidding “material support” to terrorist organizations for criminalizing protected verbal communications. The Supreme Court upheld the statute, but only after applying First Amendment scrutiny. Specifically, the Court rejected the government's argument that the statute only punished “conduct”: for, in this situation, the “conduct triggering coverage under the statute consists of communicating a message.” In other words, the government's *ipse dixit* cannot transform “speech” into “conduct” that it may more freely regulate. . . .

The reasoning of *Humanitarian Law Project* specifically forecloses courts from approving a statutory restriction on speech simply because it still permits various and extensive political expression.

The cases here present an analogous situation: professionals—including but not limited to doctors and psychologists—desire to “communicate a message” that the law in question does not permit. This court accordingly should subject SB 1172 to *some level of scrutiny* under the First Amendment.

It bears noting, further, that the Court in *Humanitarian Law Project* did not examine the content or purpose of the “message” the plaintiffs desired to communicate. Thus the panel's attempt to validate SB 1172, on the basis that the speech—the communicated “message”—it proscribes is not “expressive” or “symbolic,” finds no support in *Humanitarian Law Project* itself. Whether the prohibited communications in any given situation qualify as pure political speech or, for example, commercial speech will affect only the level of scrutiny, not whether the First Amendment applies at all. The Supreme Court has not required that speech, as a threshold matter, be “expressive” or “symbolic” before deigning to extend to it constitutional protection. . . .

The regulation at issue may very well constitute a valid exercise of California's police power: I take no view as to the merits of SB 1172, either as a matter of policy or on the question whether it would withstand strict or some intermediate level of scrutiny. But as to the threshold issue—may California remove from the First Amendment's ambit the speech of certain professionals when the State disfavors its content or its purpose?—the Supreme Court has definitively and unquestionably said “No.” It is no longer within our discretion to disagree.

For the foregoing reasons I respectfully dissent from the court's decision not to rehear these cases en banc.

Wollschlaeger v. Farmer

United States District Court for the Southern District of Florida
814 F. Supp. 2d 1367 (2011)

[A 2011 Florida law, the “Firearm Owners’ Privacy Act,” forbade doctors from including information about a patient’s firearm ownership in medical records, asking a patient whether they own a firearm unless relevant to the patient’s medical care, or discriminating against a patient because they own a firearm. A group of physicians challenged the law on First and Fourteenth Amendment grounds. The district court opinion excerpted below, held *inter alia* that the statute was a content-based speech restriction subject to strict scrutiny under the First Amendment. A later district court opinion, not included here, also *held inter alia* that the state’s interests in protecting the Second Amendment right to bear arms, protecting the privacy rights of patients, and regulating the professions were also insufficient to justify the legislation.]

COOKE, District Judge:

At issue in this litigation is a law directed at maintaining patients' privacy rights regarding firearm ownership within the context of the doctor-patient relationship. In effect, however, the law curtails practitioners' ability to inquire about whether patients own firearms and burdens their ability to deliver a firearm safety message to patients, under certain circumstances. The Firearm Owners' Privacy Act thus implicates practitioners' First Amendment rights of free speech. The Act also implicates patients' freedom to receive information about firearm safety, which the First Amendment protects.

“The First Amendment presupposes that the freedom to speak one's mind is not only an aspect of individual liberty—and thus a good unto itself—but also is essential to the common quest for truth and the vitality of society as a whole.” *Bose Corp. v. Consumers Union of United States, Inc.*, 466 U.S. 485, 503–04 (1984). This case concerns one of our Constitution's most precious rights—the freedom of speech. “Open speech by a private citizen on a matter of public importance lies at the heart of expression subject to protection by the First Amendment.” . . .

“The First Amendment generally prevents government from proscribing speech . . . because of disapproval of the ideas expressed.” *R.A.V. v. City of St. Paul*, 505 U.S. 377, 382 (1992). A content-based statute by its terms distinguishes favored speech from disfavored speech based on the ideas or views expressed. *Turner Broad. Sys., Inc. v. FCC*, 512 U.S. 622 (1994). “Regulation of the subject matter of messages, . . . is . . . an objectionable form of content-based regulation.” A content-neutral statute, on the other hand, “places no restrictions on . . . either a particular viewpoint or any subject matter that may be discussed.”

Content-based statutes that ban or burden constitutionally protected speech are subject to strict scrutiny, i.e., “it is constitutional only if it constitutes the least restrictive means of advancing a compelling government interest.” “It is rare that a regulation restricting

speech because of its content will ever be permissible.” Content-based statutes, therefore, “are presumptively invalid.”

On its face, the Firearms Owners' Privacy Act places restrictions on a practitioner's freedom to inquire about or discuss a particular subject matter. The law bans inquiries regarding firearms unless the practitioner has a good faith belief that the information is relevant to the medical care or safety of the patient or others. Under the law, practitioners may not record such information in the patient's medical record unless she knows the information is relevant. Under this law, for example, physicians may ask a new patient complaining of a stomachache to fill out an initial intake questionnaire that includes questions regarding household chemicals, risky recreational activities, sexual conduct, or drugs and alcohol kept in the home, but not whether the patient owns a firearm. Additionally, although the law does not prevent practitioners from providing unsolicited information regarding firearm safety to any patient, the law arguably burdens practitioners' speech. Physicians concerned that a patient may interpret unsolicited counseling as “unnecessarily harassing” have stopped or curtailed their practice of counseling patients on firearm safety.

Review of legislative history reinforces the conclusion that the law places restrictions on a particular subject matter. The “current situation” that the State legislature intended to change through this law's passage was practitioners' practice of asking about firearm ownership. . . .

The Florida legislature specifically identified policies encouraging and recommending that physicians ask about firearms as an aspect of the problem that the law would rectify. The title of the bill—“An Act relating to the privacy of firearm owners”—and the title of § 790.338—“Medical privacy concerning firearms”—both suggest that the focus of the law is directed at only one subject matter—firearm ownership.

Statements by certain members of the Florida legislature similarly evidence concern or disagreement with health practitioners' firearm safety message. The Florida legislature also heard testimony from the NRA, which stated, “Every single day in Florida physicians are violating patients' privacy rights and people are furious. Questioning patients about gun ownership to satisfy a political agenda and withholding medical care when patients are most vulnerable needs to stop.”

The plain language of the law, with reference to its legislative history, leads me to conclude that the Firearms Owners' Privacy Act is content-based. Having so determined, I must analyze whether the law will likely survive strict scrutiny. . . .

To survive strict scrutiny, a law must constitute the least restrictive means of advancing a compelling government interest. A court's determination of whether an interest is compelling, “is not to be made in the abstract, by asking whether fairness, privacy, etc., are highly significant values; but rather by asking whether the *aspect* of fairness, privacy, etc., addressed by the law at issue is highly significant.”

The State's asserted justification for the Firearm Owners' Privacy Act is to prohibit practitioners from forcing patients to disclose information about firearm ownership during the course of the provision of medical care, as well as to prevent health practitioners from harassing and discriminating against patients based on their ownership of firearms. The State does not cite any case law to support the proposition that protecting patients from inquiries regarding firearm ownership constitutes a compelling government interest. In fact, “[w]here the designed benefit of a content-based speech restriction is to shield the sensibilities of listeners, the general rule is that the right of expression prevails, even where no less restrictive alternative exists.”

The State's interest in assuring the privacy of this piece of information from practitioners does not appear to be a compelling one. Information regarding firearm ownership is not sacrosanct; federal and state statutes heavily regulate firearm ownership, possession, and sale, and require firearm owners to provide personal information in certain circumstances as a condition for obtaining a firearm or certain licenses. For example, to purchase a firearm, Florida residents must provide personal information and identification and subject themselves to a criminal background check. To carry a concealed firearm in Florida, a person must obtain a license.

The State also provides no case law indicating that preventing practitioners from harassing or discriminating against a patient based on firearm ownership constitutes a compelling government interest. The State also fails to provide any specific evidence, beyond anecdotal information, that such “harassment” and “discrimination” is widespread or pervasive. It is unlikely that a concern for some patients who may be offended or uncomfortable by questions regarding firearm ownership could justify this law. “Many are those who must endure speech they do not like, but that is a necessary cost of freedom.”

Additionally, the State's interest in preventing discrimination is dubious, as the State itself acknowledges that the law does not prevent a physician from terminating the doctor-patient relationship if a patient refuses to answer questions regarding firearm ownership. The antidiscrimination provision therefore provides only remote, if any, support for the State's asserted purpose.

Even assuming, however, that the State's asserted interests are compelling, the law likely cannot withstand strict scrutiny because it is not the least restrictive means to accomplish that end. . . .

Plaintiffs contend that a least restrictive alternative to the recordkeeping and inquiry restriction provisions would be a law permitting patients to decline to answer any inquiries regarding firearm ownership. Plaintiffs' proposed alternative would also prohibit a practitioner from entering any information regarding firearm ownership into the medical records of a patient who declined to provide such information.

The State does not provide any argument or evidence to suggest that Plaintiffs' proposed least restrictive alternative would be less effective in protecting patients from forced

disclosure of information regarding firearm ownership. Section 790.338(4) already provides that a patient may decline to answer questions about firearm ownership. This provision likely provides an effective means to protect patients' privacy. Placing the decision-making authority in the hands of the patient is likely to be a less restrictive alternative to prohibiting practitioners' speech. . . .

Further, the State does not explain why existing laws are insufficient to achieve the government's asserted interests in protecting patient privacy. State and federal laws protect as confidential patients' medical records.

As to the anti-harassment and anti-discrimination provisions, Plaintiffs contend that a least restrictive alternative would be a law that targets only offensive behavior or the manner of delivery of speech without regard to subject matter. A law not limited to a particular subject matter would have the same beneficial effect as the State hopes to achieve with the anti-harassment and antidiscrimination provisions. The State does not provide any argument or evidence to suggest that Plaintiffs' proposed alternative would be less effective in protecting patients from harassment or discrimination.

In *R.A.V. v. St. Paul*, the Supreme Court struck down an ordinance that prohibited “fighting words” that insulted or provoked violence on the basis of race, color, creed, religion, or gender. The Court noted that, through this ordinance, the city had not “singled out an especially offensive mode of expression,” such as fighting words that communicate ideas in a threatening manner; rather, it “proscribed fighting words of whatever manner that communicate messages of racial, gender, or religious intolerance.”

Here, the State has proscribed harassment and discrimination with respect to the subject of firearm ownership only. For example, a practitioner would remain in compliance with § 790.338 if she harassed or discriminated against a patient because of her use of alcohol or tobacco, or her sexual behavior. The State has singled out only harassing or discriminating words and conduct that communicate messages regarding firearm safety. In *R.A.V.*, the Court made clear that “[s]electivity of this sort creates the possibility that the city is seeking to handicap the expression of particular ideas.” However, “[w]here the government does not target conduct on the basis of its expressive content, acts are not shielded from regulation merely because they express a discriminatory idea or philosophy.” Thus, a less restrictive alternative would be a law proscribing harassment and discrimination in a content-neutral manner.

I will not speak to the wisdom of the legislation now before me. Questions of a law's constitutionality do not create “a license for courts to judge the wisdom, fairness, or logic of legislative choices.” *FCC v. Beach Commc'ns, Inc.*, 508 U.S. 307, 313 (1993). The First Amendment, however, “was not designed to facilitate legislation,” whether wise or not. *FEC v. Wis. Right to Life, Inc.*, 551 U.S. 449 (2007) (Scalia, J., concurring). Based on the foregoing, I find that Plaintiffs have a substantial likelihood of succeeding on the merits of their constitutional challenge.

Planned Parenthood of Minnesota v. Rounds (Rounds I)
United States Court of Appeals for the Eighth Circuit
653 F.3d 662 (2011)

[In 2005 South Dakota enacted House Bill 1166, expanding the requirements for informed consent to abortion. Under §7, any woman contemplating abortion must be given oral advisories twenty-four hours in advance of the procedure by the doctor scheduled to perform the abortion or by the doctor's designee. The doctor must give other written advisories at least two hours before the procedure. The written advisories required by §7(1) are to inform the patient: “(b) That the abortion will terminate the life of a whole, separate, unique, living human being” (the human being advisory); (c) “That [the patient] has an existing relationship with that unborn human being and that the relationship enjoys protection under the United States Constitution and under the laws of South Dakota”; and (d) “That by having an abortion, her existing relationship and her existing constitutional rights with regards to that relationship will be terminated” (the relationship advisories). The advisory must further contain “[a] description of all known medical risks of the procedure” (the risk advisory). That description must include “[i]ncreased risk of suicide ideation and suicide” as a known risk of abortion (the suicide advisory).

Several abortion service providers brought suit, challenging the constitutionality of these various disclosure requirements. As relevant here, the district court granted the plaintiffs’ summary judgment motions in part. The Eighth Circuit found *inter alia* that most of the advisories were constitutional, but that the suicide advisory violated the First Amendment.]

MURPHY, Circuit Judge:

. . . . Another portion of § 7 challenged by Planned Parenthood requires that doctors describe “all known medical risks” of abortion, including “[i]ncreased risk of suicide ideation and suicide” (collectively suicide). The district court granted summary judgment in Planned Parenthood's favor in respect to it, holding that this provision would unduly burden a woman's right to voluntary abortion and would violate doctors' First Amendment right to be free from compelled speech. South Dakota and the intervenors appeal, arguing that the suicide advisory presents no undue burden and requires only a truthful and nonmisleading statement. The question on appeal is whether this advisory is “untruthful, misleading or not relevant to the patient's decision to have an abortion.”

We begin by examining what this part of the statute requires doctors to tell patients who have come for abortions. They must describe to the patient “all known medical risks of abortion.” Since the word “known” is not defined in the statute, we consider its ordinary meaning. In ordinary use “known” means “generally recognized,” “proved,” or “familiar to all.” Thus, the inclusive statement that “increased risk of suicide and suicide ideation are *known* medical risks of abortion” must be understood as opining that those conditions are generally recognized, proven, or familiar risks of abortion.

The statute also does not define “risk,” but medical dictionaries generally agree on that term's several possible meanings. “Absolute risk” is the “[p]robability that a specified event will occur in a specified population.” *Stedman's Medical Dictionary* 1701 (28th ed. 2006). “Attributable risk” means “the rate of a disease ... in exposed individuals that can be attributed to the exposure.” In respect to the statute's suicide advisory, attributable risk would refer to the rate of suicide attributable to a woman's having had an abortion. “Relative risk” refers to “the ratio of the risk of disease among those exposed to a risk factor to the risk among those not exposed.” The other definitions are of unlikely relevance here, as they refer to family related risk or to issues of research design. Of special significance in this case is the reality that risk has varying meanings and that its usage is not clarified in the statute.

The dissent assumes without explanation that the legislature must have intended “increased risk” to refer specifically to “relative risk.” The legislature's usage of “increased risk” does not support the dissent's theory, however. Attributable risk, absolute risk, and other types of medical risk can also be increased or decreased. Nothing in the advisory forecloses a patient from understanding it to mean that abortion would increase her absolute risk of suicide, for example from two to five percent.

Moreover, in the context of this statute a court cannot assume that the legislature had any one of several competing definitions of medical risk clearly in mind. The suicide advisory appears in the same subsection of § 7 that requires doctors to “descri[be]. . . [all] statistically significant risk factors to which the pregnant woman would be subjected” by abortion. The statute does not define “risk factor.” After reviewing expert testimony, however, the district court concluded that “a ‘risk factor’ refers to a predisposing condition that a patient has *before* a procedure” rather than a risk resulting *from* a procedure. The statute thus used “risk factor” in a manner inconsistent with its medical meaning, leaving doctors “to guess as to the meaning the legislature intended to give to the phrase.” The district court therefore enjoined enforcement of the “risk factor” provision, a ruling neither South Dakota nor the intervenors have attacked. The district court concluded that the legislative drafters “may not have fully understood the meaning of this phrase as used in the medical profession.” It does not appear from the record that the word “risk” was used with the technical precision that the dissent would attribute to it.

Even if we were entitled to incorporate the term “relative risk” into the suicide advisory, rather than to “confine [ourselves] to the language used” in the statute as South Dakota rules of interpretation require, *see Langdeau v. Langdeau*, 751 N.W.2d 722, 727 (S.D. 2008), the advisory would not be made truthful, nonmisleading, and relevant. “Relative risk” incorporates the concept of a “risk factor,” which may or may not denote causation of an increased risk. Nothing in the advisory would prevent the unproven inference that the “increased risk” mentioned in § 7 is increased *by* abortion.

The record does not demonstrate a generally recognized causal connection between abortion and suicide. In fact, it reveals vigorous debate over whether an apparent statistical correlation results from common cofactors rather than a showing that one causes the other. In the course of evaluating relevant peer reviewed literature, the

American Psychological Association concluded that there is no evidence that risk of mental health problems among women who abort unwanted pregnancies is any greater than that of women who miscarry or deliver such pregnancies. Brenda Major et al., American Psychological Association, *Report of the APA Task Force on Mental Health and Abortion* 68 (2008).

Section 7 as written could mislead women who have unwanted pregnancies into believing that choosing abortion would increase their risk of suicide. The American Psychological Association report illustrates the fallacy of the dissent's proposed rewording of the suicide advisory which would assert that the "relative risk of suicide and suicide ideation is higher for women who abort their pregnancies compared to women in other relevant groups." The critical point is that data are lacking on the most relevant other group—that being women who carry unwanted pregnancies to term. Without that data it is not possible to talk about any effect of abortion on suicide risk.

Before granting summary judgment to Planned Parenthood on this issue, the district court considered a report by South Dakota expert Dr. Elizabeth M. Shadigian, who referenced reports by the American College of Obstetricians and Gynecologists, "the leading professional association of physicians who specialize in the health care of women." According to Dr. Shadigian, this specialized group of experts has rejected any connection between suicide risk and abortion as did the American Psychological Association. Also relevant to its position that suicide is not generally recognized as a danger of abortion is the labeling for the abortion inducing drug mifepristone. Although the FDA requires prescription drug labels to warn of all "clinically significant adverse reactions" and "other potential. . . hazards," it approved a label for mifepristone which did not mention suicide or suicide ideation.

South Dakota and the intervenors cite numerous peer reviewed articles, a portion of which concluded there is a causal relationship between suicide and abortion. The American Psychological Association report found several of these studies methodologically flawed because they failed to distinguish women with wanted pregnancies from women with unwanted pregnancies in evaluating the mental health effects of various pregnancy outcomes. Testimony by individual women reporting emotional problems after abortion has also been offered by South Dakota and the intervenors; all of these women had abortions either outside of South Dakota or before passage of the state's earlier informed consent provisions.

While the dissent objects that "nothing in the record . . . suggest[s] that abortion as a cause [of suicide] has been ruled out with certainty," it overlooks the fact that "medical risks" is modified in the statute by the word "known." Although the statute requires doctors to warn of all "known medical risks" of abortion, the dissent would read the word "known" out of the statute. Legislatures have "wide discretion to pass legislation in areas where there is medical and scientific uncertainty," but the suicide advisory asserts certainty on the issue of medical and scientific knowledge where none exists. The advisory thus "very likely . . . require[s] physicians to disclose information that is false." Robert Post, *Informed Consent to Abortion: A First Amendment Analysis of Compelled*

Physician Speech, 2007 U. Ill. L. Rev. 939, 961 (2007). The district court did not err in concluding that the suicide advisory's warning of “known” risks compels untruthful speech by doctors. An untruthful, misleading, or irrelevant advisory violates both a patient's due process rights to voluntary abortion and a doctor's First Amendment rights.

The required suicide advisory would significantly constrain doctors' exercise of their professional judgment. South Dakota common law already requires doctors to inform patients of all the known material or significant risks of a medical procedure. Thus, if a doctor considers suicide a known material risk of abortion, there is a common law duty to warn patients. Unlike the statutory suicide advisory, this common law rule has an exception for risks that are extremely remote. It also affords a physician the discretion not to issue a warning which would cause severe emotional distress. The requirements of the suicide advisory would thus be redundant if a doctor were to believe that abortion posed a material risk of suicide to a patient and that advising her of it was unlikely to cause harm. The common law rule would compel a warning in these cases. In other cases the suicide advisory would have the effect of overriding doctors' professional judgment by compelling a statement that a doctor believes immaterial or even dangerous.

Informed consent requirements in the abortion context “must be calculated to inform [a] woman's free choice, not hinder it,” facilitating “wise” and “informed” decisions. *Casey*, 505 U.S. at 877, 887. A compelled medical statement that contradicts in unequivocal terms the leading associations of experts in relevant fields does not serve that end. We conclude that the suicide advisory places a “substantial obstacle in the path of [women] seeking abortion,” *id.* at 878, and thus violates due process. By compelling untruthful and misleading speech, the advisory also violates doctors' First Amendment right to be free from compelled speech that is untruthful, misleading, or irrelevant. We conclude that the district court did not err in granting Planned Parenthood summary judgment as to the suicide advisory.

Planned Parenthood Minnesota v. Rounds (Rounds II)
United States Court of Appeals for the Eighth Circuit
686 F.3d 889 (2012)

[A rehearing en banc was granted to review the suicide advisory issue decided in *Rounds I*. The court reversed the *Rounds I* panel, finding the suicide advisory constitutional.]

GRUENDER, Circuit Judge:

[T]he disclosure actually required by the suicide advisory depends upon the accepted usage of the term “increased risk” in the relevant medical field. We turn to the medical literature and expert evidence in the record to discern the accepted usage of the term “increased risk” in the applicable medical context, with an eye towards whether that accepted usage necessarily implies proof of causation.

The peer-reviewed medical literature in the record on the topic of suicide and abortion

consistently uses the term “increased risk” to refer to a relatively higher probability of an adverse outcome in one group compared to other groups—that is, to “relative risk.” For example, one study compared the rate of suicide for women who had received an induced abortion with the rates of suicide for two other groups, women who had given birth and women who had miscarried. That study characterized its finding of a vastly higher suicide rate for women who received an induced abortion as “an increased risk of suicide.” Another study compared the rate of, *inter alia*, suicide ideation in women who had received an induced abortion with the rates for women who had given birth and for women who had not become pregnant. That study concluded, “Certainly in this study, those young women who had abortions appeared to be at moderately *increased risk* of both concurrent and subsequent mental health problems when compared with equivalent groups of pregnant or non-pregnant peers.

The discussion of risk in the medical context provided by Intervenor's expert also supports the conclusion that the term “increased risk” refers to the comparison of two groups, or relative risk:

Assessment of degree of risk is often expressed in terms of absolute risk, which relates to the chance of developing a disease over a time-period (e.g., a 10% lifetime risk of suicide) or in terms of relative risk, which is a comparison of the probability of an adverse outcome in two groups. For example, abortion would be considered an *increased risk* for suicide *if the relative risk is significantly higher* for women who abort compared to women who give birth or never have children.

Based on the “accepted usage” of the term in the relevant field, *Peters*, 567 N.W.2d at 885, the term “increased risk” in subsection (ii) indicates that the “relative risk” definition is the one intended by the legislature for the suicide advisory.

Noticeably absent from the contextual definition of “increased risk” is a requirement for conclusive proof of causation. This stands to reason, because, as explained by the Intervenor's expert:

When examining complex human psychological and physical health outcomes, such as depression and suicidal behavior, identification of a single, precise causal mechanism applicable to all situations is not possible.... Given this inherent complexity, sound epidemiological evidence is nevertheless derived by identifying those variables which are most strongly linked with adverse mental or physical health outcomes for large groups of individuals.

While such evidence of relative risk eventually may prove direct causation as further experiments rule out plausible competing explanations, conclusive proof of causation is not required in order for the identification of a medical risk.

Even the evidence upon which Planned Parenthood heavily relies is consistent with the

“relative risk” definition of “increased risk,” with no requirement for proof of causation. For example, the report of the American Psychological Association's (“APA”) Task Force on Mental Health and Abortion decries the “tendency to confuse a risk and a cause” as a “logical fallacy.” As another example, Planned Parenthood submitted into the record a letter to a medical journal from one of the researchers mentioned above. While the researcher emphasized that his studies linking suicide and abortion did not prove causation, he resolutely reiterated his finding of “increased risk.” It would be nonsensical for those in the field to distinguish a relationship of “increased risk” from one of causation if the term “risk” itself was equivalent to causation. . . .

We certainly agree that the amendments to the medical-risks provision are “evidential of an intent that the words shall have a different construction,” but in this case that different construction does not hinge on the removal of one word. Instead, the Act effects essentially a complete rewriting of the former § 34–23A–10.1(1)(b) (2004), removing thirteen of the original twenty-eight words and adding seventy new words, including an entirely new introduction requiring a description of “all known medical risks” and a listing of three new specific areas of concern in subsections (i)-(iii). Taken as a whole, these sweeping changes to the language of the provision express the legislature's intent to address a much broader range of specific medical risks in the required disclosure, not to implicitly sever the term “increased risk” from its accepted usage in the medical field. Indeed, where only fifteen words of original language remain in an amended provision of eighty-five words, ascribing such an effect to the removal of a single word would go far beyond any use of the cited rule of statutory construction of which we are aware.

Finally, even if the language of the suicide advisory also reasonably could be construed to require a disclosure of a causal link, we would be faced with “varying constructions of the South Dakota statute, ‘by [one] of which grave and doubtful constitutional questions arise and by [the other] of which such questions are avoided.’” In such a situation, our “duty is to adopt the latter,” and “[t]his is especially so since ‘[i]n evaluating a facial challenge to a state law, a federal court must. . . consider any limiting construction that a state . . . enforcement agency has proffered.’” As a result, we would be called to apply the “relative risk” construction of increased risk over a construction that required disclosure of a causal link.

To summarize, in subsection (ii), the legislature expressly required the disclosure of an “increased risk,” not a causal link. Based on the accepted usage of the term “increased risk” in the relevant medical field, the usage of that term in the context of § 34–23A–10.1(1)(e)(ii) does not imply a disclosure of a causal relationship. Instead, subsection (ii) requires a disclosure simply that the risk of suicide and suicide ideation is higher among women who abort compared to women in other relevant groups, such as women who give birth or do not become pregnant. . . .

As a result, we hold that the disclosure facially mandated by the suicide advisory is truthful. . . .

Thus, the truthful disclosure regarding increased risk cannot be unconstitutionally

misleading or irrelevant simply because of some degree of “medical and scientific uncertainty,” *Gonzales*, 550 U.S. at 163, as to whether abortion plays a causal role in the observed correlation between abortion and suicide. Instead, Planned Parenthood would have to show that any “medical and scientific uncertainty” has been resolved into a certainty *against* a causal role for abortion. In other words, in order to render the suicide advisory unconstitutionally misleading or irrelevant, Planned Parenthood would have to show that abortion has been ruled out, to a degree of scientifically accepted certainty, as a statistically significant causal factor in post-abortion suicides. An examination of Planned Parenthood's evidence reveals that it has not met this burden.

First, Planned Parenthood points out that the label approved by the Food and Drug Administration (“FDA”) for the abortion-inducing drug Mifeprex (mifepristone, also known as RU-486) does not list suicide or suicide ideation as a risk of using the drug, despite FDA labeling regulations requiring the listing of, *inter alia*, all “clinically significant adverse reactions” and “other potential safety hazards.” However, an FDA-approved label does not represent the definitive or exclusive list of risks associated with a drug. The record before us does not show whether any evidence of the link between abortion and suicide was submitted to the FDA, nor does it provide details of the FDA's analysis, if any, of the link. Thus, the FDA-approved label for Mifeprex yields no information as to whether abortion has been ruled out as a statistically significant causal factor in post-abortion suicides.

Second, Planned Parenthood argues, and the district court found, that the American College of Obstetricians and Gynecologists (“ACOG”), a well-known professional medical organization, “rejects any suggestion that increased risk of suicide and suicide ideation are known risks of abortion.” Unfortunately, there was no evidence from ACOG in the record for the district court to consider. The only evidence in the record pertaining to ACOG's position is a second-hand reference in a 2005 report by the State's expert, Dr. Elizabeth M. Shadigian, that quoted two sentences from a single ACOG Practice Bulletin: “Long-term risks sometimes attributed to surgical abortion include potential effects on . . . psychological sequelae. However, the medical literature, when carefully evaluated, clearly demonstrates no significant negative impact on any of these factors with surgical abortion.” Dr. Shadigian further reported her opinion that ACOG's statement was erroneous and that “ACOG seems to claim that they have adequately evaluated the medical literature, but they do not consider our study or the many other studies we evaluated.” There is no other evidence in the record as to what “medical literature” ACOG considered, in what fashion it was “carefully evaluated,” whether suicide was one of the “psychological sequelae” considered, whether ACOG's analysis received any independent peer review, or indeed whether a “Practice Bulletin” purports to be grounded in any sort of reliable scientific method at all. The two unsupported sentences from an ACOG Practice Bulletin lend no credence to the argument that abortion has been ruled out as a statistically significant causal factor in post-abortion suicides.

Third, Planned Parenthood cites the previously mentioned APA Report. The six-person Task Force on Mental Health and Abortion that authored the APA Report reviewed “50

papers published in peer-reviewed journals between 1990 and 2007 that analyzed empirical data of a quantitative nature on psychological experiences associated with induced abortion, compared to an alternative.” For some of the studies that found increased mental health risks associated with abortion, the APA Report identifies perceived methodological deficiencies, including an inability to limit the comparison group to women who carried unplanned or unwanted pregnancies to term. Based on one study that attempted to account for that variable, the report states that “the *best* scientific evidence indicates that the relative risk of mental health problems among adult women who have an *unplanned pregnancy* is no greater if they have an elective first-trimester abortion than if they deliver that pregnancy.” In the very same sentence, however, the report states that the published literature could not provide “unequivocal evidence regarding the relative mental health risks associated with abortion per se compared to its alternatives (childbirth of an unplanned pregnancy).”

The State and Intervenor argue that the APA Report is deficient in several respects. While the APA Report alleges methodological flaws in all of the studies that found a strong link between abortion and adverse mental health outcomes, it does not systematically list or analyze those flaws for each study considered. Instead, the report uses a handful of studies as illustrative examples. The State and Intervenor contend that this lack of rigor allowed the APA Report to analyze studies that found abortion to be “a benign experience for most women” less stringently than studies that found abortion to cause adverse effects. For example, while the APA Report suggests that the studies showing increased risk did not compare women receiving abortions to women who carried *unplanned* pregnancies to term, at least three studies purportedly considered by the task force did use such a control group, and each of those studies still “definitively indicated that abortion was associated with more mental health problems.” The APA Report also does not acknowledge that some of the studies showing increased risk did statistically control for other potential causal factors such as history of depression, anxiety, suicide ideation, childhood sexual abuse, physical abuse, child neuroticism, and low self-esteem. As another example, although a high rate of attrition (i.e., the loss of subjects from a long-term study before the study is complete) is typically regarded as a methodological weakness, the APA Report downplays the significance of attrition, possibly because “the studies with the highest attrition rates. . . are also the ones that provide little evidence of negative effects” of abortion. A number of published authors in the field contacted the APA to point out these problems and ask that the APA Report be retracted.

At a minimum, it appears that many published authors in the field do not accept the opinion of the APA's six-person task force that the “best evidence” suggests that there is no real significance to the link between abortion and suicide. Even if one accepts the findings in the APA Report at face value, however, the crux of the matter is that while the APA Report states that the evidence available at the time of its review is not “sufficient to support the claim that an observed association between abortion history and mental health was *caused* by the abortion,” it also concludes that the published literature is inconclusive and more research is needed “to disentangle confounding factors and establish relative risks of abortion compared to its alternatives,” (admitting that the published literature

could not provide “unequivocal evidence regarding the relative mental health risks associated with abortion per se compared to its alternatives, i.e. childbirth of an unplanned pregnancy”). In other words, while the APA Report finds that studies to date have not established with certainty that abortion is a causal factor in post-abortion suicide, it also acknowledges that abortion has not been ruled out as a causal factor and that currently available studies are inadequate for that purpose. Thus, the APA Report provides no support for the proposition that abortion has been ruled out as a statistically significant causal factor in post-abortion suicides. . . .

In summary, although the record reflects “medical and scientific uncertainty,” *Gonzales*, 550 U.S. at 163, as to whether abortion itself is a causal factor in the observed correlation between abortion and suicide, there is nothing in the record to suggest that abortion as a cause *per se* has been ruled out with certainty. As a result, the disclosure of the observed correlation as an “increased risk” is not unconstitutionally misleading or irrelevant under *Casey* and *Gonzales*. Indeed, physicians who provide abortions should be capable of reviewing the research in the field, understanding the difference between relative risk and proof of causation, and explaining it correctly to their patients. In the end, “[t]he point of informed consent laws is to allow the patient to evaluate her condition and render her best decision under difficult circumstances. Denying her up to date medical information is more of an abuse to her ability to decide than providing the information.”

Accordingly, we hold that the suicide advisory is non-misleading and relevant to the patient's decision to have an abortion.

In conclusion, we hold that the requirements of S.D.C.L. § 34–23A–10.1(1)(e)(ii) are satisfied by a disclosure that the relative risk of suicide and suicide ideation is higher for women who abort compared to women in other relevant groups, as described in the relevant medical research. The statute does not require the physician to disclose that a causal link between abortion and suicide has been proved. The disclosure is truthful, as evidenced by a multitude of studies published in peer-reviewed medical journals that found an increased risk of suicide for women who had received abortions compared to women who gave birth, miscarried, or never became pregnant. Various studies found this correlation to hold even when controlling for the effects of other potential causal factors for suicide, including pre-existing depression, anxiety, suicide ideation, childhood sexual abuse, physical abuse, child neuroticism, and low self-esteem.

Moreover, the suicide advisory is non-misleading and relevant to the patient's decision to have an abortion, as required by *Casey*. It is a typical medical practice to inform patients of statistically significant risks that have been associated with a procedure through medical research, even if causation has not been proved definitively. While Planned Parenthood points to uncertainty as to whether abortion itself is a causal factor in the observed correlation to suicide, as opposed to other underlying factors that tend to be associated independently with both abortion and suicide, the Supreme Court “has given state and federal legislatures wide discretion to pass legislation in areas where there is medical and scientific uncertainty,” including “in the abortion context.” Thus, a truthful disclosure cannot be unconstitutionally misleading or irrelevant simply because some

degree of medical and scientific uncertainty persists. To be sure, informed consent requirements “must be calculated to inform [a] woman's free choice, not hinder it,” *Casey*, 505 U.S. at 877, but there is no unconstitutional hindrance of the woman's choice where, as here, the State merely is using “its regulatory authority to require a physician to provide truthful, non-misleading information relevant to a patient's decision to have an abortion, even if that information might also encourage the patient to choose childbirth over abortion.”

On its face, the suicide advisory presents neither an undue burden on abortion rights nor a violation of physicians' free speech rights. Accordingly, we reverse the district court's grant of summary judgment to Planned Parenthood with respect to S.D.C.L. § 34–23A–10.1(1)(e)(ii), direct the entry of summary judgment for the State as to that provision, and vacate the permanent injunction against the enforcement of that provision.

Stuart v. Loomis

United States District Court for the Middle District of North Carolina
2014 WL 186310 (Jan. 17, 2014)

[In 2011, North Carolina imposed new requirements on doctors who treat patients seeking abortions. The new law's “speech-and-display provision” required that the doctor perform an ultrasound at least four hours in advance of an abortion, during which he or she must display ultrasound images so that the patient may view them and must describe the images to the patient. A group of doctors challenged this provision on First Amendment grounds. The district court opinion, excerpted below, held that the provision unconstitutionally infringes doctors' free speech rights. The Attorney General of North Carolina has indicated that he intends to appeal the decision to the Fourth Circuit.]

EAGLES, District Judge:

Plaintiffs contend that the speech-and-display provision violates their First Amendment rights because it compels them to deliver the state's content-based message to their patients, a message they do not want to deliver in the absence of a request from or consent of their patients. Plaintiffs contend that the Court should apply strict scrutiny to this compelled, content-based speech, and that the provision does not survive this review.

The First Amendment generally prohibits the government from requiring people to speak its messages. Because “[m]andating speech that a speaker would not otherwise make necessarily alters the content of the speech,” speech compelled by the government is typically considered content-based regulation. Content-based speech compelled by the government is generally subject to strict scrutiny, even where the compelled speech is limited to factually accurate or non-ideological statements.

Despite the apparent absolute nature of these rules, courts have recognized certain areas of compelled speech to which strict scrutiny does not apply. One common area exempt from strict scrutiny is compelled commercial speech, which is “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). Such speech is still entitled to First Amendment protection, though the government has more leeway to impose restrictions. Typically, laws restricting or prohibiting non-misleading commercial speech are subject to intermediate scrutiny, under which the government must prove that the restriction directly advances and is narrowly tailored to serve a substantial government interest. If, however, the government compels people to disclose “purely factual and uncontroversial information about the terms under which [their] services will be available” in order to avoid misleading advertisements, the regulation is scrutinized less heavily, and the government need only show a reasonable connection between its interest in preventing deception and the regulation. *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 651 (1985). The Court has upheld disclosure rules in the bankruptcy context under this same standard when the compelled disclosures at issue were needed to prevent deception in advertising.

The Supreme Court does not necessarily apply rational basis review every time the government compels speech in the context of professional advertising. “Unjustified or unduly burdensome disclosure requirements,” for example, “offend the First Amendment.” The Court has evaluated some restrictions and prohibitions on professional advertising under intermediate scrutiny, and others under strict scrutiny.

Moreover, the commercial speech doctrine is less likely to apply when the speech regulation at issue is content-based. For example, in *Riley*, the Supreme Court considered a First Amendment challenge to a statute requiring professional fundraisers to disclose to potential donors the percentage of charitable contributions collected during the previous twelve months that were actually turned over to charity. In deciding to apply strict scrutiny, the Court noted only that the Act was a content-based regulation of speech because it was compelled speech and that the speech could not be labeled commercial when examined as a whole.

Similarly, in *Sorrell v. IMS Health Inc.*, the Supreme Court held that a state statute that prohibited pharmaceutical manufacturers from using prescriber-identifying information for marketing was First Amendment-protected expression that must be subject to “heightened judicial scrutiny.” Even though the statute regulated commercial speech, the Court applied heightened scrutiny in striking it down because it was content-based; its express purpose was “to diminish the effectiveness of marketing by manufacturers of brand-name drugs.” Heightened scrutiny requires at a minimum that the provision at issue must directly advance a substantial state interest and be drawn to achieve that interest. It also requires that the harms the provision prevents must be “real, not merely conjectural,” and that the provision at issue “in fact alleviate[s] these harms in a direct and material way.”

Outside of the advertising context, it has long been recognized that the state can require licenses and impose reasonable regulations on professions which require “a certain degree of skill and learning upon which the community may confidently rely.” *Dent v. West Virginia*, 129 U.S. 114, 122 (1889). In *Dent*, the Supreme Court upheld a state law

prohibiting the practice of medicine without a license, holding that a state may require a license so long as it is “appropriate to the calling or profession, and attainable by reasonable study or application.” Similarly, in *Keller v. State Bar of California*, the Supreme Court held that the state may require lawyers to belong to an organized bar that expended dues to fund activities germane to the profession because of its interests in regulating the profession and improving the quality of legal services.

In a variety of contexts, the Supreme Court has acknowledged the government's “interest in protecting the integrity and ethics of the medical profession” specifically. *Washington v. Glucksberg*, 521 U.S. 702, 731 (1997). States have routinely required that health care providers conform to professional standards within the field and provide competent medical advice. See *Pickup v. Brown*, 728 F.3d 1042, 1054–55 (9th Cir. 2013) (collecting cases, noting that a doctor “may not counsel a patient to rely on quack medicine” (quotation marks omitted)).

States have also long required health care providers to give patients information they need to make informed decisions about medical treatment. Thus, courts have routinely imposed civil liability on physicians who have failed to provide enough information to patients in advance of treatment. In doing so, courts have linked informed consent and competent advice requirements to standards of the profession and to well-established negligence standards.

Beyond generally applicable licensing systems and enforcement of professional norms, just what “professional speech” means and whether it receives a different degree of protection under the First Amendment is not particularly clear. Nonetheless, it is clear that individuals do not surrender their First Amendment rights entirely when they speak as professionals. In *Casey*, the Court explicitly recognized a physician's First Amendment rights and cited *Wooley v. Maynard*, 430 U.S. 705 (1977), which held that the state cannot compel a person to speak the state's ideological message. The Supreme Court also has noted in dicta that “[s]peech by professionals obviously has many dimensions. There are circumstances in which we will accord speech by [professionals]. . . the strongest protection our Constitution has to offer.” *Fla. Bar v. Went For It, Inc.*, 515 U.S. 618, 634 (1995).

In fact, the Fourth Circuit recently intimated that where professionals are accredited and licensed, the state has a lower interest in compelling their speech. See *Moore–King v. Cnty. of Chesterfield*, 708 F.3d 560, 570 (4th Cir. 2013). In *Moore–King*, the Fourth Circuit upheld a regulation requiring professional fortune tellers to obtain and pay for licenses, finding no First Amendment violation. The court noted that “[w]ith respect to an occupation such as fortune telling where no accrediting institution like a board of law examiners or medical practitioners exists, a legislature may reasonably determine that additional regulatory requirements are necessary.”

In the health care context specifically, the Ninth Circuit recently reiterated that “doctor-patient communications about medical treatment receive substantial First Amendment protection.” *Pickup*, 728 F.3d at 1053 (emphasis omitted). In *Pickup*, the court

characterized a statute that prohibited a certain kind of psychotherapy for use with minors as a regulation of conduct with only an incidental effect on speech. The court found rational basis review was appropriate because the statute “regulates only treatment, while leaving mental health providers free to discuss and recommend, or recommend against.” Because the “overwhelming consensus” of opinion within the profession was that the recommended therapy was harmful and ineffective, the Court found the legislature acted rationally in relying on that consensus.

The Ninth Circuit in *Pickup* was guided by two of its earlier speech cases. In *NAAP*, the Court held that California's psychology licensing scheme did not violate the First Amendment, as it was content- and viewpoint-neutral and did not “dictate what can be said between psychologists and patients during treatment.” The *Pickup* court contrasted *NAAP* with *Conant v. Walters*, in which the Ninth Circuit applied strict scrutiny to a federal policy declaration that a doctor's recommendation or prescription of medical marijuana would lead to revocation of the doctor's registration to prescribe controlled substances. The court recognized that “[b]eing a member of a regulated profession does not, as the government suggests, result in a surrender of First Amendment rights,” and concluded that the content- and viewpoint-based policy was not sufficiently narrowly tailored. The court in *Pickup* characterized *Conant* as holding that “content-or viewpoint-based regulation of communication *about* treatment must be closely scrutinized.”

It is also clear that a state's regulation of professional speech must be consistent with the goals and duties of the profession. In *Legal Services Corp. v. Velazquez*, for example, the Supreme Court expressed concern about a statute that interfered with traditional professional relationships by restricting the kind of professional advice a lawyer could give. The Court found that regulations which prohibited federally-funded legal aid attorneys from advising clients about potential constitutional claims violated the First Amendment, noting that “[r]estricting . . . attorneys in advising their clients and in presenting arguments and analyses to the courts distorts the legal system by altering the traditional role of the attorneys.” Likewise, in *Milavetz*, the Court narrowly construed the statute at issue so as to avoid any concerns that the statute would inhibit “frank discussion” between attorney and client. Courts have been careful to insure that the regulation at issue was in fact directed at the state's purported interest in the profession.

As a review of these authorities makes clear, whether, when, and to what extent the government can compel speech by a professional cannot be established with hard and fast rules. The use of labels and categories is of limited utility. Rather, compelled professional speech is more appropriately viewed on a continuum, taking into account the regulatory context, the nature of the professional relationship, the degree of intrusion into the relationship, the reasons and evidentiary support for the intrusion, and the connection between the compelled speech and the government's interests.

To the extent the speech-and-display provision requires providers to deliver a message designed to persuade women not to terminate a pregnancy, which the state forthrightly acknowledges is one of its purposes, it “imposes burdens that are based on the content of speech and that are aimed at a particular viewpoint.” See *Sorrell*, 131 S.Ct. at 2663–64.

Requiring a physician or other health care provider to deliver the state's content-based, non-medical message in his or her own voice as if the message was his or her own constitutes compelled ideological speech and warrants the highest degree of First Amendment protection. 1428. This is so even if the disclosure is limited to factual information.

The state contends that the speech-and-display provision is related to medical care so that, consistent with the state's traditional authority to regulate medical care, a lower standard of scrutiny should apply. Plaintiffs appear to dismiss this argument completely, contending that strict scrutiny always applies when the state compels content-based speech. Yet Plaintiffs' approach overlooks the state's historic interest in the health and safety of its citizens, which the state may protect through reasonable regulation of the medical profession, including compelled speech consistent with professional norms.

Nonetheless, the talismanic recitation that the state has the authority to license and regulate health care providers does not mean much merely by being invoked. The Court cannot disregard the state's express ideological interest in determining what level of scrutiny to apply, even if it is only one of several interests at play. Therefore, it is appropriate to evaluate the speech-and-display provision with heightened scrutiny. It is also appropriate to apply heightened scrutiny because the state is seeking to compel "doctor-patient communications *about* medical treatment," *see Pickup*, 728 F.3d at 1053, and to create a new professional norm in a highly regulated field where providers are educated specialists with significant training and expertise and who are already licensed by the state. There may be minimal First Amendment concerns when the state compels compliance with "standards of acceptable and prevailing medical practice," but when the state seeks to compel speech outside those prevailing practices, the issue is quite different.

Even though the speech at issue is obviously not commercial, the heightened scrutiny applicable to commercial speech restrictions provides a good model for evaluating restrictions on professional speech. This is particularly so here, where "the outcome is the same whether a special commercial speech inquiry or a stricter form of judicial scrutiny is applied." *See Sorrell*, 131 S.Ct. at 2667. As stated earlier, heightened scrutiny requires at a minimum that the provision directly advances a substantial state interest and is drawn to achieve that interest. It also requires that the harms the provision prevents are "real, not merely conjectural," and that the provision at issue "in fact alleviate[s] these harms in a direct and material way." This evaluation must take into account the regulatory context, the nature of the professional relationship, the degree of intrusion into it, the reasons for the intrusion and evidentiary support for the intrusion, and the connection between the compelled speech and the government's interests.

The state has offered no real defense of this one-size-fits-all requirement, and the only evidence the state presents about psychological harm does not contradict Plaintiffs' evidence. The state's expert information "simply because it might cause temporary stress or anxiety," and further testified that he is "not aware of any evidence that patients will

be harmed by the provision of information.” He does not address or even mention those patients who have individual risk factors for more profound psychological problems.

Plaintiffs have presented undisputed evidence that compelled delivery of the state's message in these situations would raise serious ethical issues and be inconsistent with the purposes of the informed consent rule.

Consistent with rules of medical ethics summarized above, even the state's expert emphasizes that “there can obviously be no rigid prescription” as to what a patient medically and ethically should be told, and that an individual approach to patients is generally required. Further, he agrees that informed consent procedures “must be free of coercion,” should be “designed to facilitate the capacity of rational beings to make judgments of what they consider best, rather than what the physician or any other person might consider best for them,” and should be free of paternalism. These ethical rules honoring medical judgment and discretion and patient autonomy support accepting the patient's decision not to receive the information and do not support forcing providers to give this information to women who do not want it, who are not required to receive it, and who take steps to avoid receiving it.

The state attempts to justify the compelled speech with the contention that showing a woman her own fetus and describing it to her is the best way for the state to express its interest in promoting life, as it has the effect of encouraging the woman “to engage in a moment of reflection about her decision whether to terminate her pregnancy—and the gravity of that decision.” But the speech-and-display provision is *not* the state's expression of its own message promoting childbirth and discouraging abortion. Rather, it compels a health care provider to act as the state's courier and to disseminate the state's message discouraging abortion, in the provider's own voice, in the middle of a medical procedure, and under circumstances where it would seem the message is the provider's and not the state's. This is not allowed under the First Amendment. While “[t]he government may use *its* voice and its regulatory authority to show its profound respect for the life within the woman,” *Gonzales*, 550 U.S. at 128, the Supreme Court has never held that the government may use a professional's voice to do the same. The state “does not have a compelling interest in each marginal percentage point by which its goals are advanced.”

Defendants also contend that the speech-and-display requirement furthers the state's interest in promoting voluntary and informed consent by making women aware of the extent of fetal development, by protecting women's psychological health by ensuring that women are fully informed before making an irreversible decision that they may come to regret, and by reducing coerced abortions. Here, the state relies on its traditional power to regulate the practice of medicine so as to promote and protect patient health.

This argument is undermined by the very structure of the Act, which does not require women to receive the information about fetal development. Because the Act explicitly allows a woman to “refuse to hear” the information, she can give voluntary and informed consent even if she refuses to receive the state's message. Indeed, the speech-and-display

provision is in an entirely different section of the Act, from the section dealing with informed consent. It is also undermined by the state's expert, who agrees that requiring the provider to deliver information to women who refuse to listen does nothing to advance the state's goals, and by the state's willingness to require providers to inflict psychological harm on some of their patients in order to insure delivery of its message.

Further, the state has not shown that the speech-and-display provision is necessary to alleviate a real harm. The state offers no evidence that psychological harm caused by learning of the fetus's physical characteristics after an abortion is substantial either in numbers or degree, nor is there evidence that the compelled disclosures ameliorate any such harm, especially when they are not received. In the face of Plaintiffs' evidence that the provision will cause serious psychological harm to some women, the state has not shown that its interest "would be achieved less effectively absent the regulation."

Even assuming provider-coerced abortion is a real and not theoretical harm, the state has not shown that the speech-and-display provision is directed at alleviating this harm. If a provider is already in the habit of unethically and illegally coercing abortions, in violation of unquestionably valid informed consent law and ethical rules, the addition of the speech-and-display provision will not deter him or her from continuing to ignore the law. Rather than more regulations that compel speech from ethical providers, better enforcement of the existing rules is an obvious, more direct solution.

To the extent Defendants contend that third-parties, such as boyfriends, husbands, or parents, are coercing abortions, Defendants have not provided any evidence that the speech-and-display provision is directed at preventing such coercion. Even under intermediate scrutiny, the government's burden is heavy.

Even assuming the speech-and-display provision actually reduces the risk of psychological harm or of coercive abortion, it burdens substantially more speech than necessary. There are many other ways to provide the necessary information to patients without hijacking the provider's voice in the middle of a medical procedure. The Act, generally applicable informed consent law, and established medical practices in North Carolina ensure that women are informed several times in several ways of the availability of information about fetal development and that it is easily available to those women who believe it will be helpful to their decision-making. The Act requires that its informed consent disclosures be provided to the woman "individually," and in a manner that ensures that "the woman is not the victim of a coerced abortion." It further requires the provider to inform the patient that she has other alternatives to abortion and that she is "free to withhold or withdraw her consent to the abortion at any time." The uncontradicted evidence is that providers in the state consider it to be part of the standard of care to offer women the opportunity to view the ultrasound and to ensure that women are not being coerced before they perform an abortion.

In short, the state's arguments do nothing to avoid the First Amendment issues raised by compelling providers to speak the state's message to women who refuse to hear it or who would be harmed by it. Indeed, those arguments increase the First Amendment concerns,

given the lack of empirical evidence for the supposed health interests put forth, the conflicts with established rules of medical ethics, and the admitted non-medical and value-based motives behind the Act. With no provision for a therapeutic exception or for a different method of delivery to women at serious risk of harm and with no evidence of any benefit from delivering the message to women who refuse to listen to it, the Act does not directly or indirectly advance any of the proffered state interests and is not drawn to achieve a substantial state interest. It undermines well-established professional norms in the medical field, without empirical justification. It does not survive heightened scrutiny.

Casey does not compel a different analysis. The state contends that *Casey* stands for the proposition that if a statute compels physicians to convey truthful, non-misleading, and relevant information to patients, then it does not constitute an undue burden on the woman's right to choose and, *ipso facto*, it passes First Amendment muster. The state also points to two federal courts of appeals cases which employed the undue burden test to uphold compelled disclosure laws in the abortion context against First Amendment challenges.

In the due process context, *Casey* provides an exhaustive and detailed analysis of the reasons the state may regulate abortion providers and the ways in which such regulation is permissible under the Fourteenth Amendment. *Casey* does not provide a similarly detailed analysis on the way to evaluate such laws under the First Amendment. Rather, *Casey* refers to the state's ability to license and regulate the practice of medicine, contrasts it to the state's inability to compel ideological speech, and concludes there is no “constitutional infirmity in the requirement that the physician provide the information mandated by the State *here*.”

Despite its brevity, the First Amendment analysis is clearly a traditional one, couched by its reference to *Wooley* in terms of compelled speech and by its reference to the state's ability to regulate the practice of medicine in terms of professional speech. *Casey* did not purport to carve out a new First Amendment exception or create a new standard of review for all abortion-related speech cases.

Nowhere else in First Amendment law is the state's effort to compel speech evaluated by determining whether the compelled speech violates a different constitutional right, much less a different constitutional right belonging to a different person. Such an interpretation of *Casey* would be inconsistent with decades of First Amendment case law and would ignore the values memorialized in the First Amendment.

With due respect, *Lakey* and *Rounds* are wrongly decided. They are not grounded in traditional First Amendment principles, from which *Casey* did not diverge. They read *Casey* as creating, in two sentences, an entirely new category of abortion-related compelled speech to which a unique standard of review applies. The application of a due process standard to a First Amendment issue improperly conflates two separate constitutional doctrines in a way that gives short shrift to the First Amendment. Even if the Court credited this standard of review, the speech-and-display provision would not

pass First Amendment muster. It goes significantly further than the statute at issue in *Casey*, and it would not survive even under Defendants' proposed test.

Under Defendants' test, the state can compel providers to speak so long as the information is truthful, not misleading, and relevant. As discussed above, the Act by its terms says that the information is not necessary or relevant to every woman's decision, and other provisions make sure that women are aware of the availability of the information if she wants to receive it. It is standard medical practice in North Carolina to provide the information upon request. Yet if a woman permissibly decides the information is not relevant to her, or indeed would be harmful to her, she must still be physically present, undressed or half-undressed on an examining table, while the provider is compelled to deliver the state's message, a message which, by the Act's own terms, is not necessary for informed consent. Indeed, the state would have a physician attempt to persuade a woman not to have an abortion by showing and describing any physical characteristics against the woman's will, even if she will die if she continues her pregnancy and even if she has a mental health history that makes forced and graphic delivery of this information in the middle of a medical procedure a risky proposition for her.

Instead of a “reasonable framework” within which a woman makes the decision about terminating a pregnancy, the speech-and-display provision is more like an unyielding straightjacket. It goes well beyond “encourag[ing the pregnant woman] to know that there are philosophic and social arguments of great weight that can be brought to bear in favor of continuing the pregnancy to full term” and “taking steps to ensure that [her] choice is thoughtful and informed.” By requiring providers to deliver this information to a woman who takes steps not to hear it or would be harmed by hearing it, the state has erected an obstacle and has moved from “encouraging” to lecturing, using health care providers as its mouthpiece. As discussed above, there is no health reason for requiring the disclosure to women who take steps not to hear it or would be harmed by hearing it, making this an “unnecessary health regulation[]” which is not allowed under *Casey*.