

Journal of Contemporary Health Law & Policy (1985-2015)

Volume 19 | Issue 2

Article 6

2003

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Recommended Citation

Matthew N. Strawn, *Recent Developments in Direct Consumer Advertising of Attention Disorder Stimulants and Creating Limits to Withstand Constitutional Scrutiny.*, 19 J. Contemp. Health L. & Pol'y 495 (2003).

Available at: <https://scholarship.law.edu/jchlp/vol19/iss2/6>

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RECENT DEVELOPMENTS IN DIRECT CONSUMER ADVERTISING OF ATTENTION DISORDER STIMULANTS AND CREATING LIMITS TO WITHSTAND CONSTITUTIONAL SCRUTINY.

Matthew N. Strawn^{*}

INTRODUCTION

In recent years, pharmaceutical drug companies have been inundating consumers with advertising images for their products. Whether the ailment is a seasonal allergy, severe heartburn or even erectile dysfunction, television and print advertisements convey a sense that help is available. There has been one notable exception to the proliferation of prescription drug advertising directed at the consumer - advertisements marketing controlled drugs, such as stimulants. However, this too is changing.

As parents prepared their children for the start of the 2001 school year, they were greeted for the first time with advertisements pitching behavior control drugs for their children. One company used a blue-suited superhero to advertise in publications, such as Ladies' Home Journal, in an attempt to better reach parents.¹ This pushing of the advertising envelope for prescription stimulants, like Ritalin, is contrary to a thirty-year old international agreement prohibiting the advertisement of such controlled substances.²

The use of Ritalin, the most commonly known stimulant among those used to control the behavior of hyperactive and disruptive children, has been at the center of controversy in America's medical

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1. Karen Thomas, *Back to school for ADHD drugs*, USA TODAY, Aug. 28, 2001 at D1.

2. *Id.*

and educational communities for decades.³ Now that pharmaceutical manufacturers are directly advertising these controlled substances to the public, many public officials and law enforcement agencies have also taken notice.⁴

This Comment will explore the legal issues surrounding the emerging direct-to-consumer advertising of controlled pharmaceutical stimulants. In Part II, this Comment will discuss Schedule II prescription stimulants, recent actions in state legislatures and the trend by pharmaceutical companies to promote these controlled substances directly to consumers. Part III will explain direct-to-consumer advertising with regard to the federal statutes and regulations that control pharmaceutical advertising. Part IV will examine the Constitutional framework for regulating commercial speech. Finally Part V, applying the current Constitutional framework, the Comment will conclude with an analysis on how to construct a prohibition on psychotropic pharmaceutical product advertising that survives First Amendment scrutiny.

II. BACKGROUND ISSUES

A. The Current Treatment of Schedule II Stimulants

For nearly fifty years, parents have utilized prescription drugs, chiefly stimulants, to treat attention deficit/hyperactivity disorder (ADHD).⁵ The international non-proprietary name for these drugs is "methylphenidate."⁶ The most common of such behavior drugs is Ritalin, which first received approval from the Food and Drug Administration (FDA) in 1955.⁷

3. Pamela White, *High on Ritalin: A Nation of Dopes Numbs Its Kids with Drugs*, BOULDER WEEKLY, Oct. 4, 2001.

4. See Thomas, *supra* note 1. After seeing the Medadate CD ads in *Ladies Home Journal* and *Parade*, the U.S. Drug Enforcement Agency sent a cease-and-desist letter to Celltech, Medadate CD's manufacturer.

5. Melody Petersen & Kate Zernike, *Schools' Backing of Behavior Drugs Comes Under Fire*, N.Y. TIMES, Aug. 19, 2001, at A1.

6. See United Nations Conference on the Adoption of a Protocol on Psychotropic Substances, Official Records, Volume 1 (New York 1973) UN Doc. E/CONF.58/7; UN Publication Sales No.E.73XI.3 [hereinafter 1971 Agreement].

7. Petersen & Zernike, *supra* note 5, at A1; see also *Drugs of Abuse*, U.S. DRUG ENFORCEMENT ADMIN., U.S. DEP'T. OF JUSTICE, METHYLPHENIDATE, available at <http://www.usdoj.gov/dea/concern/methylphenidate.html> (last visited

The Controlled Substances Act of 1970 is the legal foundation that requires the classification of drugs.⁸ It also delegates authority to federal agencies to place all substances that are regulated under existing federal law into one of five schedules.⁹ Placement is based upon the substance's medicinal value, harmfulness and potential for abuse or addiction.¹⁰ The five schedule scheme operates as a sliding scale.¹¹ Schedule I regulates the most dangerous drugs that have no recognized medical use,¹² while Schedule V is reserved for the least dangerous drugs.¹³

Methylphenidate (hereinafter Ritalin) is classified as a Schedule II stimulant.¹⁴ Other drugs classified under Drug Enforcement Agency (DEA) Schedule II status include opium, cocaine and morphine.¹⁵ Since it is classified as a Schedule II stimulant, the abuse of Ritalin may produce the same effects as abusing cocaine or amphetamines.¹⁶ The addictive properties of Ritalin resulted in the DEA listing it as one of the top ten pharmaceutical drugs most likely to be stolen.¹⁷

B. Action in the States

There appear to be various political and policy goals behind the renewed interest for state actions related to Ritalin and its pharmaceutical progeny. While discussion on this topic alone could easily consume volumes, there are two major concerns. The first is the addictive nature of Ritalin and its abuse by children and young adults who are not diagnosed with ADHD. Second, is the explosive growth in

Feb. 10, 2003) (According to the United States Drug Enforcement Agency (DEA), the primary and legitimate use of methylphenidate is for the treatment of attention deficit disorders in children.).

8. 21 U.S.C. § 812 (2000).

9. *Id.*

10. U.S. DRUG ENFORCEMENT ADMIN., U.S. DEP'T. OF JUSTICE, CONTROLLED SUBSTANCES ACT, available at <http://www.usdoj.gov/dea/pubs/csa.html> (last visited Feb. 6, 2003).

11. *Id.*

12. DEA Schedules of Controlled Substances, 21 C.F.R. § 1308.11 (2002).

13. *Id.* § 1308.15.

14. *See id.* § 1308.12(d).

15. *See id.* § 1308.12

16. Drugs of Abuse, *supra* note 7.

17. Lisa Fine, *New Laws Leave Ritalin Decisions to Parents and Doctors*, EDUCATION WEEK, Aug. 8, 2001, available at 2001 WL 12046655.

the number of children taking stimulants to modify their behavior.¹⁸ It is against this backdrop that there has been significant action on Ritalin and psychotropic drugs throughout state legislatures.

In 2001, Minnesota approved legislation directly addressing the use of Ritalin in the state educational systems.¹⁹ Minnesota law now restrains school administrators from requiring parents to provide behavioral medication to their children before readmitting them to school after being suspended.²⁰ Minnesota also codified that a parent's refusal to provide his or her child with such medication does not constitute educational neglect.²¹ Finally, the Minnesota law provides resources to study the use of medications, like Ritalin, in the state and to report the number and overall incidence rate of its school children diagnosed with ADHD who are currently taking behavioral drugs.²² The law's chief sponsor in the Minnesota House of Representatives, Representative Barb Sykora, said that the legislation was necessary because recent studies linked Ritalin to later cocaine use as well as to the increase in the recreational abuse of children's behavioral drugs.²³

Connecticut took a step further in combating the rise of Ritalin use among the state's school children. Connecticut now requires its school boards to "adopt and implement policies prohibiting any school personnel from recommending the use of psychotropic drugs for any child."²⁴ Also, as in Minnesota, Connecticut provides that the refusal of a parent to medicate his or her child with psychotropic drugs does not constitute grounds for the state's child protection agency to take the child into custody.²⁵ Nor does it constitute grounds for a state court to order a child to be taken into custody by the Connecticut Department

18. Thomas, *supra* note 1, at D1 (The use of ADHD drugs is up thirty-seven percent over the past five years, and the prescriptions for one specific product, Adderall, has increased 1,017% since 1997).

19. *Id.*

20. 2001 Minn. Sess. Law Serv. ch. 6, art. 3, §8 (West).

21. *Id.* § 16.

22. *Id.* § 21.

23. Press Release, Rep. Sykora Introduces "Ritalin Relief Act": Bi-Partisan Legislation Gives Parents More Control of their Children's Health (Feb. 6, 2001) (on file with author).

24. Act of Oct. 1, 2001, No. 01-124, § 1, 2001 Conn. Acts 331, 331 (Reg. Sess.) (concerning the recommendations for and refusals of the use of psychotropic drugs by children).

25. *Id.* § 2.

of Children and Families.²⁶ The author of the legislation in the Connecticut House of Representatives, Representative Lenny Winkler, is an emergency room nurse who said she regularly witnesses the consequences of increased prescribing of psychotropic drugs and that there are “just too many far-reaching effects of these drugs.”²⁷ The Connecticut General Assembly also heard testimony regarding studies indicating Ritalin may cause children to smoke or abuse stimulants as adults.²⁸

Armed with similar evidence, other states are following suit. Texas²⁹ and Colorado³⁰ have approved non-binding resolutions that require educators to consider non-medical solutions to behavioral problems. Also, citing deep concern over the increased use of medication to control behavior in children, legislation is pending in the New Jersey State Assembly that would model Connecticut in prohibiting school personnel from “recommending, encouraging, or discussing medication” for school pupils.³¹ Similar legislation has also been introduced in Illinois,³² Iowa,³³ New York,³⁴ Oregon,³⁵ Utah,³⁶ Virginia³⁷ and Wisconsin.³⁸

26. *See id.*

27. Kelly Patricia O'Meara, *Hyper-Drugging of Active Kids*, INSIGHT ON THE NEWS, Aug. 27, 2001, at 18.

28. Schoolchildren and Medication: *Hearing on HB 5701 Before the Public Health Comm.*, 2001 Leg., Reg. Sess. 0315 (Conn. 2001) (statement of Ms. Sheila Matthews).

29. *See Thomas, supra* note 1, at D1.

30. *A New Prescription*, GAZETTER, Feb. 14, 2002, at Metro 2.

31. A. 2170, 209th Leg., Reg. Sess. (N.J. 2001).

32. *See Heath Hixson, Ritalin Proposal Rejected by Panel*, CHI. DAILY HERALD, Jan. 31, 2002, at 7. An Illinois House panel voted down an attempt to ban teachers from recommending students receive the prescription drug Ritalin.

33. H.F. 2318, 2002 State Assem., Reg. Sess. (Iowa 2002).

34. A. 9384, 2001 State Assem., Reg. Sess. (N.Y. 2001).

35. H.B. 3630, 71st Leg., Reg. Sess. (Or. 2001).

36. *House Approves Curb on Child-health Referrals*, DESERET NEWS, Mar. 1, 2002, at B4. *See also* James Thalman, *Mood-altering Drugs in Schools Targeted*, DESERET NEWS, Mar. 6, 2002, at B7 (discussing debate in the Oregon State Senate following passage of HB 123 in the Oregon State House).

37. Christina Nuckols, *Ritalin for Students: House Bill Says Schools Can't Recommend Drugs*, VIRGINIAN-PILOT AND THE LEDGER-STAR, Feb. 2, 2002, at B4.

38. *See Petersen & Zernike, supra* note 5, at A1.

The most extensive of these proposals is in Michigan, where five separate bills have been introduced as a "Ritalin reform" package.³⁹ One bill is modeled after the Connecticut law, while the others include: creation of an advisory council on psychiatric drug use among children; prohibition on excluding students from school or school functions for not taking such drugs; requiring creation of brochures for schools listing side effects of psychiatric drugs; and, amending the state's definition of child neglect so that the refusal of a parent to provide psychiatric drugs does not constitute criminal neglect.⁴⁰

C. *Celltech: Pushing the Consumer Advertising Envelope on Controlled Substances*

It is on the heels of this state legislative action that some pharmaceutical manufacturers are using television, radio, newspapers and magazines to promote Schedule II behavior drugs for children.

In August 2001, Celltech, makers of Metadate CD, a once-a-day pill made to rival Ritalin, launched the first salvo in the emerging Schedule II advertising battle. It placed direct-to-consumer print advertisements in a number of women's magazines.⁴¹ The advertisements, appearing in such periodicals as *Ladies' Home Journal* and *Parade*, introduce the drug by name and feature a smiling mother and son over a quote that reads, "One dose covers his ADHD for the whole school day."⁴²

By promoting Metadate CD by its name, Celltech became the first pharmaceutical company to break a thirty-year old United Nations agreement prohibiting direct-to-consumer advertising of Schedule II drugs.⁴³ In response to the Metadate CD advertisements, the DEA sent Celltech a cease-and-desist letter.⁴⁴ In addition to reminding Celltech of the long-standing international advertising agreement, the DEA's

39. Stacey Range, *Bills Encourages 'Ritalin Reform,'* LANSING STATE JOURNAL, Sept. 27, 2001, at 3B.

40. *Id.*

41. See Thomas, *supra* note 1, at D1; See also Kay Lazar, *School Daze – Kid-Drug Ads Spark Concern*, BOSTON HERALD, Sept. 2, 2001, at A1.

42. Lazar, *supra* note 41, at A1.

43. See *id.*

44. *Id.*

letter detailed the “significant risk to the national problem of controlled substance diversion” the ads may create.⁴⁵

Undaunted, Celltech maintains it is breaking no American laws and says the company “considers the communication of truthful information to consumers and the medical community essential in delivering quality patient care.”⁴⁶ As further evidence of Celltech’s intention to continue with its consumer-oriented marketing campaign for Metadate CD, the company is featuring, in promotional materials, a blue-suited cartoon superhero with the letters CD emblazoned across his chest.⁴⁷ Critics disagree with the company’s assertion that the cartoon superhero is not intended to grab the attention of children.⁴⁸

The lengths to which Celltech is going to promote Metadate CD, which was approved for distribution in April 2001,⁴⁹ underscore the competition in the billion-dollar behavioral drug market.⁵⁰ In 2001, physicians wrote over twenty million prescriptions for ADHD stimulants,⁵¹ which had sales of \$758 million in 2000.⁵² Given the financial stakes involved in this competitive market, there are indications that other manufacturers are following Celltech’s lead. The makers of two other Schedule II stimulants, Adderall and Concerta, advertise directly to consumers in print publications, but stop short of mentioning the product’s brand name and encourage the consumer to call a toll-free number for more information.⁵³ McNeil Consumer Healthcare, which manufactures Concerta, has broken new ground by airing direct-to-consumer advertisements on cable television.⁵⁴ The DEA claims such advertisements violate the spirit of the international agreement. McNeil, however, points out that the advertisements are not promoting a brand name, nor are they breaking any American law.⁵⁵

45. *Id.*

46. *Id.*

47. *See Thomas, supra* note 1, at D1.

48. *See id.*

49. Lazar, *supra* note 41, at A1.

50. *See Thomas, supra* note 1, at D1.

51. *Id.*

52. *Id.*

53. *See Thomas, supra* note 1, at D1.

54. *See Petersen & Zernike, supra* note 5, at A1.

55. *Id.*

III. DIRECT-TO-CONSUMER PRESCRIPTION DRUG ADVERTISING

The current state of the law on direct-to-consumer advertising of Schedule II stimulants is a mix of federal statutes, regulations and a long-standing international agreement. This section will survey relevant federal statutes and regulations, as well as the status of the 1971 international agreement that effectively prevented consumer advertising of controlled substances for over three decades.

A. The 1971 U.N. Conference on Psychotropic Substances.

The pharmaceutical manufacturers are correct in their assertion that purchasing direct-to-consumer advertisements in print and electronic media for Schedule II drugs does not violate U.S. federal law. Since 1971, however, the United Nations Convention on Psychotropic Substances⁵⁶ (hereinafter the 1971 Agreement) has served as an international agreement between nations and the pharmaceutical industry not to market Schedule II controlled substances to consumers.⁵⁷ Specifically, Article 10 of the 1971 Agreement provides that each party to the agreement “shall, with due regard to its constitutional provisions, prohibit the advertisement of such substances to the general public.”⁵⁸ The United States was among the seventy-one nations to sign this agreement.⁵⁹ This international agreement is subject to monitoring by the United Nations Narcotics Control Division.⁶⁰

Prior to 1971, drug manufacturers of psychotropic substances like Ritalin only marketed their products to physicians and pharmacists.⁶¹ Following the 1971 Agreement, Congress failed to codify Article 10’s prohibition into United States law. The deputy director of the DEA’s Office of Diversion Control acknowledged the non-statutory limits of the 1971 Agreement, stating that the agency merely “had a 30-year

56. 1971 Agreement, *supra* note 6.

57. *See* Petersen & Zernike, *supra* note 5, at A1.

58. 1971 Agreement, *supra* note 6, at Article 10.

59. *Id.* at Article 1.

60. Lawrence H. Diller, *An End To Marketing Victory: Drug Makers Find Ways to Circumvent an Advertising Ban and Promote Psychiatric Drugs for Children* (Oct. 18, 2001) at <http://archive.salon.com/mwt/feature/2001/10/18/drugads/index.html>.

61. *See* Petersen & Zernike, *supra* note 5, at A1.

agreement with the pharmaceutical industry not to advertise controlled substances.”⁶²

B. FDA Oversight of Direct-to-Consumer Drug Advertising

The adherence to the 1971 Agreement by nations and industry underscores that there is no explicit U.S. federal statute or regulation prohibiting the direct advertisement of Schedule II pharmaceutical drugs to consumers. The 1971 Agreement has operated in the United States merely as a gentlemen’s agreement between the pharmaceutical industry and the federal government not to engage in this type of marketing.

However, this gentlemen’s agreement is no longer honored as faithfully between the government and the pharmaceutical industry. Now, direct-to-consumer advertising is increasingly being used for psychotropic drugs. This new phenomenon warrants an assessment of the relevant and controlling statutory framework. First, the ability of the DEA to prohibit or control such advertising is severely restricted. The DEA’s jurisdiction over direct-to-consumer advertising is limited to cease-and-desist letters that the agency sends to companies when it determines the companies have crossed the line in their advertisements. One such letter was sent to Celltech regarding the Metadate CD advertisements.

The FDA is the federal agency with primary jurisdiction over direct-to-consumer marketing of prescription drugs.⁶³ The FDA is authorized by the Food, Drug and Cosmetic Act⁶⁴ (FDCA) to regulate the development, distribution and promotion of pharmaceutical products. While the statute itself does not define “advertising,” the FDCA’s implementing regulations do so in great detail.⁶⁵

An important component of the FDCA relating to advertising is the statute’s prohibition on “misbranding.”⁶⁶ Under the FDCA, a prescription drug is considered “misbranded” if the manufacturer does

62. *Id.* at A30.

63. Tamar V. Terzian, *Direct-to-Consumer Prescription Drug Advertising*, 25 AM. J.L. & MED.149, 154 (1999) (The Federal Trade Commission, not the FDA, maintains federal jurisdiction over over-the-counter drug product promotion).

64. 21 U.S.C.S. § 352(n) (1998).

65. *See* 21 C.F.R. § 202.1 (2002).

66. 21 U.S.C. § 331 (2000).

not provide a “true statement” of the drug.⁶⁷ The “true statement” is required to include the following information: the product’s scientific name; the product’s formula; and a “brief summary relating to [the product’s] side effects, contraindications, and effectiveness.”⁶⁸ This “true statement” must be present in “all advertisements and other descriptive matter issued or caused to be issued by the manufacturer.”⁶⁹ Specifically, the FDCA’s implementing regulations include the following types of advertisements within the scope of the Act: “advertisements in published journals, magazines, other periodicals, and newspapers, and advertisements broadcast through media such as radio, television, and telephone communication systems.”⁷⁰

The “brief summary” aspect of the “true statement” provides the FDA with the basis to propose advertising regulations consistent with the FDCA.⁷¹ To satisfy the statutory “brief summary” requirements, the FDA has recently established new guidelines for both print and electronic direct-to-consumer advertising.⁷² The prescription drug advertising regulations distinguish between print and broadcast advertisements.⁷³ To comply with federal law, print advertisements must include the “brief summary,” which normally contains each of the risk concepts from the product’s approved package labeling.⁷⁴

The requirements for broadcast advertising are considerably more detailed and are a relatively new phenomenon. Prior to 1997, the “brief summary” requirement effectively precluded the type of pharmaceutical advertising seen on television today because the lengthy risk disclosure requirement was cost prohibitive and ill-suited to the brief nature of electronic advertising.⁷⁵ During this time, the only electronic advertisements sponsored by drug companies were reminder

67. *Id.* § 352(n).

68. *Id.*

69. *Id.*

70. 21 C.F.R. § 202.1(k)(1)(1) (2002).

71. *Id.*

72. 21 C.F.R. § 202.1(l)(1) (2002).

73. *See* 21 C.F.R. § 202.1 (2002).

74. U.S. FOOD AND DRUG ADMIN., GUIDANCE FOR INDUSTRY: CONSUMER DIRECTED BROADCAST ADVERTISEMENTS, available at <http://www.fda.gov/cder/guidance> (last visited Sept. 30, 2001) [hereinafter Guidance].

75. Anne Brown, *The Direct-to-Consumer Advertising Dilemma*, 35 Patient Care (Mar. 30, 2001), available at 2001 WL 26231381.

advertisements.⁷⁶ Reminder advertisements, which name the brand product but not the illness for which it treats, are exempt from the FDCA's "brief summary" requirement.⁷⁷

In 1997, the FDA clarified its interpretation of broadcast advertising regulations. As an alternative to the "brief summary," sponsors of broadcast advertisements may make an "adequate provision" to disseminate "the approved or permitted package labeling in connection with the broadcast presentation."⁷⁸ A broadcast advertising sponsor may fulfill the "adequate provision" requirement by providing "reasonably convenient access to the advertised product's approved labeling"⁷⁹ to a potentially diverse consumer audience. The FDA has outlined four items that must be present in a broadcast media advertisement to ensure "reasonably convenient access" exists: (1) a toll-free number, (2) a reference to DTC print advertisements, (3) an Internet web page address, and (4) a statement directing consumers to doctors and/or pharmacists to receive additional information about the advertised product.⁸⁰

The FDA also maintains additional enforcement duties over the advertising practices of pharmaceutical companies and prescription drugs. Although pharmaceutical companies are not required by law or statute to submit the content of their advertising materials to the FDA before using them, the agency does have the authority to review the advertisements post-publication or broadcast.⁸¹

The actions available to the FDA to deal with pharmaceutical companies that violate the advertising requirement are the following: sending a company in violation of requirements a letter outlining the agency's objections to the current advertisement; issuing a cease-and-desist letter and/or suggesting proper remedies; seizing the affected products or enjoining use of promotions making similar claims; or prosecuting the appropriate company or individual under criminal law.⁸² Since the broadcast regulations were relaxed in 1997, the FDA has sent more than seventy-five notices to sponsors, notifying them that their advertisements violate the law.⁸³ Most commonly, the

76. *Id.*

77. 21 C.F.R. § 202.1(e)(2)(i) (2002).

78. *Id.* § 202.1(e)(1).

79. See Guidance, *supra* note 74.

80. See *id.*; See also Terzian, *supra* note 63, at 150.

81. See Terzian, *supra* note 63, at 153.

82. *Id.* at 153.

83. Brown, *supra* note 75, at 22.

companies present insufficient risk information and overstate the product's efficacy or the extent of its application.⁸⁴

C. Effect of Direct-to-Consumer Advertising

The recent change in FDA guidelines has opened the floodgates for prescription drug advertisements on America's televisions and radios. In 2000, the pharmaceutical industry spent \$2.5 billion on print and broadcast advertising,⁸⁵ an increase of \$700 million from the prior year.⁸⁶ In fact, overall spending on consumer advertisements for prescription drugs is predicted to reach \$7.5 billion a year by 2005.⁸⁷ As discussed above, the potential proliferation of advertisements for Schedule II psychotropic drugs will only drive this figure higher.

The dramatic increase in direct-to-consumer advertising for prescription drugs is also beginning to show an effect on patients. One recent analysis reveals that the fifty most heavily advertised drugs in 2000 experienced a thirty-two percent increase in sales from the previous year.⁸⁸ Not only was this increase more than double the industry average, but the data further indicates that the increase was due to a sharp rise in the number of prescriptions filled for those fifty drugs.⁸⁹

Another recent study of direct-to-consumer advertisements for prescription drugs found that a majority contained sparse scientific information to assist people in making informed choices about treatment options.⁹⁰ More specifically, the study's findings show that the advertisements "rarely quantify a medication's expected benefit."⁹¹ In another study, consumers were queried on their response if a physician refused their request for an advertised drug.⁹² Nearly one-

84. *Id.*

85. John A. MacDonald, *Drug Pitches Raise Profits and Alarms; Some Ask: Are Ads Helping Medicine or Increasing its Costs*, HARTFORD COURANT, Oct. 21, 2001, available at 2001 WL 25328086.

86. Ivan Oransky, *Doctors Step Out, Drug Salesmen Step In*, USA TODAY, July 5, 2001, at A11.

87. Michael Booth, *Drug Marketing Putting Pressure on Doctors*, DENVER POST, Sept. 16, 2001, available at 2001 WL 27933835.

88. *See* MacDonald, *supra* note 85.

89. *See id.*

90. *DTC Ads' "Emotional Appeal" Slammed*, MARKETLETTER, Oct. 22, 2001, available at 2001 WL 9081199.

91. *Id.*

92. *See* Brown, *supra* note 75.

half of the respondents said they would try to persuade the physician to prescribe the requested drug, while almost one-quarter said they would attempt to obtain the prescription from a different physician.⁹³

It was responses such as these that led to a June 2001 vote by the American Medical Association on a resolution urging the prohibition of direct-to-consumer prescription drug advertisements.⁹⁴ While the vote was ultimately unsuccessful,⁹⁵ it indicates the concern that exists in the medical community with widespread prescription drug advertisements aimed at consumers. Such studies and early indicia regarding the effect of prescription drug advertising on consumers underscore the extremely sensitive nature of advertising Schedule II controlled substances that have highly addictive properties.

D. Congressional Activity & Direct Consumer Advertising

Although state legislatures have not moved quickly to legislate on this issue of Ritalin and related drugs, key congressional committees are taking a close look at direct-to-consumer advertising.

In the House of Representatives, Representative W.J. "Billy" Tauzin, a Louisiana Republican who chairs the House Committee on Energy and Commerce, held a hearing on developments that may impact consumer access to, and demand for pharmaceuticals.⁹⁶ In his opening statement, Chairman Tauzin indicated he was "especially interested in learning whether these ads lead to increased utilization of inappropriate therapies."⁹⁷

Although the committee received testimony that information is inadequate concerning potential risks associated with prescription drugs that are advertised directly to consumers,⁹⁸ there is not total agreement among experts. In addition, the Director of the FDA's Center for Drug Evaluation and Research testified that, at present, the "FDA is not aware of any evidence that the risks of [direct-to-

93. *Id.*

94. *See* MacDonald, *supra* note 85.

95. *See id.*

96. *Recent Developments which May Impact Consumer Access to, and Demand for, Pharmaceuticals: Hearing Before the House Comm. on Energy and Commerce*, 107th Cong. (2001).

97. *Id.* (opening statement of Chairman Tauzin).

98. *Id.* (testimony of John Golenski, Executive Director, Rx Health Value, Washington, D.C.).

consumer] promotion outweigh its benefits.”⁹⁹ This position of the FDA was re-iterated later in 2001 at a hearing before a key subcommittee in the United States Senate.¹⁰⁰

Another member of Congress is attempting to restrict direct-to-consumer advertising by amending the federal tax code. Representative Pete Stark, Democrat of California, is the chief sponsor of the Fair Balance Prescription Drug Advertisement Act.¹⁰¹ In order for a pharmaceutical company’s advertisements to be tax deductible, this legislation would require that the company devote equal text size or air time to describing the potential dangers and benefits of the medication.¹⁰² For print advertisements, Representative Stark explains that the advertisement would be required to display the pros and cons of a particular drug in equal typeface and space, and on the same or facing pages.¹⁰³ In television and radio advertisements, Representative Stark says that risk and benefit descriptions would be allotted equal airtime and volume level.¹⁰⁴ Under the legislation, pharmaceutical companies that do not follow such guidelines would be ineligible for a federal advertising tax deduction.¹⁰⁵

While there is no direct legislation in either chamber of Congress specifically targeting direct-to-consumer advertising of Schedule II controlled substances, the activity discussed above does illustrate a degree of concern in Congress surrounding wholesale prescription drug advertising.

99. *Id.* (testimony of Jane Woodcock, M.D., Director, FDA, Center for Drug Evaluation and Research).

100. *Direct-to-Consumer Advertising of Pharmaceutical Medicines: Hearing Before the Subcomm. on Consumer Affairs, Foreign Commerce and Tourism Senate Comm. on Commerce, Science, and Transportation*, 107th Cong. (2001) (statement of Nancy Ostrove, Ph.D., Deputy Director, Division of Drug Marketing, Advertising and Communications, FDA, Center for Drug Evaluation and Research).

101. H.R. 2352, 107th Cong. (2001).

102. H.R. 2352, 107th Cong. § 3 (2001).

103. Press Release, Stark Introduces Fair Balance Prescription Drug Advertisement Act (June 27, 2001) (on file with author).

104. *Id.*

105. *Id.*

IV. RESTRICTING CONSUMER ADS FOR SCHEDULE II CONTROLLED SUBSTANCES: THE NEED TO SURVIVE CONSTITUTIONAL SCRUTINY

Building on all the information above, the final section of this comment will focus on how to construct legislation to restrict the direct-to-consumer advertising of psychotropic drugs in a manner consistent with First Amendment constitutional scrutiny.

This section will explore strategies for restricting consumer targeted advertising of Schedule II controlled substances in a manner that would survive First Amendment review. First, the Constitution and the Supreme Court's history on commercial speech will be discussed. Second, the current standard of judicial review for commercial speech restrictions will be outlined. Third, there will be an analysis of how Congress could narrowly tailor a psychotropic drug advertising restriction that could withstand scrutiny by the courts.

A. Background: The First Amendment and Commercial Speech

The First Amendment prohibits Congress from making any law "abridging the freedom of speech."¹⁰⁶ Understanding what constitutes commercial speech is key to understanding the degree of First Amendment protection. The speech in question, commercial advertising, is speech that does "no more than propose a commercial transaction."¹⁰⁷

The Supreme Court has made it clear that under the First Amendment, commercial speech enjoys limited constitutional protection.¹⁰⁸ In 1976, the Court ushered in the modern development of its commercial speech doctrine in *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council*.¹⁰⁹ The Court rejected the "highly paternalistic" view that the government has absolute power to

106. U.S. CONST. amend. I.

107. *Pittsburgh Press Co. v. Human Relations Comm'n*, 413 U.S. 376, 385 (1973).

108. See generally Michelle D. Ehrlich, Note, *Doctors can 'just say no': The Constitutionality of Consumer-Directed Advertising of Prescription Drugs*, 12 HASTINGS COMM. & ENT. L.J. 535 (1990) (discussing the evolution of the Court's commercial speech doctrine).

109. 425 U.S. 748 (1976) (holding unconstitutional a Virginia statute that held licensed pharmacists guilty of unprofessional conduct if they advertised or promoted prices for prescription drugs).

suppress or regulate commercial speech.¹¹⁰ Even if an advertiser's interest is solely economic, it "hardly disqualifies" him from First Amendment protection.¹¹¹ Commercial speech has some degree of constitutional protection, however, the Court clearly distinguishes between commercial speech and other varieties of speech.¹¹² This distinction has led the Court to afford lesser protection to commercial speech than to other constitutionally guaranteed expression.¹¹³ The level of protection for commercial expression, discussed below, depends both on the nature of the commercial expression and the stated governmental interests served by its regulation.¹¹⁴

B. Current Standard: Commercial Speech & the First Amendment

Several cases¹¹⁵ following *Virginia Board of Pharmacy*¹¹⁶ expounded on the Court's rationale for offering limited constitutional protection for commercial speech. The Court, however, did not outline a definitive test until 1980 in *Central Hudson Gas & Electric Corp. v. Public Service Commission*.¹¹⁷ Under *Central Hudson*, if the commercial communication or advertisement is neither "misleading nor related to unlawful activity" the government's ability to regulate speech is restricted.¹¹⁸ The bounds of the government's restriction are contained within *Central Hudson*'s four-part test.

The first inquiry concerns the previously mentioned unlawful or misleading activity. Advertising must pass a four-prong test in order to survive First Amendment scrutiny. First, the commercial speech must not be "misleading or related to unlawful activity."¹¹⁹ The second prong requires the state to assert a substantial interest that will be served by

110. *Id.* at 770.

111. *Id.* at 762.

112. *See Ohralik v. Ohio State Bar Ass'n.*, 436 U.S. 447, 455-56 (1978).

113. *Id.* at 456-57.

114. *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of New York*, 447 U.S. 557, 563 (1980).

115. *See generally Friedman v Rogers*, 440 U.S. 1 (1979); *Ohralik v. State Bar Ass'n.*, 436 U.S. 447 (1978); *Bates v. State Bar of Arizona*, 433 U.S. 350 (1977).

116. 425 U.S. 748 (1976).

117. 447 U.S. 557 (1980).

118. *Id.* at 564.

119. *Id.*

commercial speech restrictions.¹²⁰ If the first two prongs are answered affirmatively, the third step is whether the regulation “directly advance[s] the state interest involved.”¹²¹ Here, if the regulation provides merely “ineffective or remote support” for the government’s interest, the regulation may not be sustained.¹²² Finally, if the governmental interest could be served by a “more limited restriction, then the restriction on commercial speech cannot survive.”¹²³

In the two decades following *Central Hudson*, the Court has used this test to invalidate statutes prohibiting the mailing of unsolicited commercial advertisements for contraceptives,¹²⁴ banning in-person solicitation by certified public accountants,¹²⁵ prohibiting beer labels from displaying alcohol content,¹²⁶ disallowing the advertisement of liquor prices¹²⁷ and prohibiting the broadcast of lottery information.¹²⁸

The application of *Central Hudson* in the above instances concerned various regulations prohibiting truthful, non-misleading speech about a lawful product. The Court stated that absolute commercial speech prohibitions “rarely survive constitutional review,”¹²⁹ while reiterating that the state does not have broad discretion to “suppress truthful, non-misleading information for paternalistic purposes.”¹³⁰ In addition, the Court appears comfortable retaining the *Central Hudson* standard, saying as recently as 1999, that it saw “no need to break new ground.”¹³¹ With the trend clearly against blanket prohibitions on commercial speech, the constitutionality of a prohibition on direct-to-

120. *Id.*

121. *Id.*

122. *Id.*

123. *Id.* In applying the newly developed test, the Court found that New York’s interest in energy conservation was clearly substantial and directly advanced by advertising restrictions, but held the regulations were too restrictive and that less restrictive regulations could have protected the asserted interest just as effectively.

124. *Bolger v. Youngs Drug Products Corp.*, 463 U.S. 60 (1983).

125. *Edenfield v. Fane*, 507 U.S. 761 (1993).

126. *Rubin v. Coors Brewing Co.*, 514 U.S. 476 (1995).

127. *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484 (1996).

128. *Greater New Orleans Broad. Ass’n., Inc. v. United States*, 527 U.S. 173 (1999).

129. *44 Liquormart*, 517 U.S. at 504.

130. *Id.* at 510.

131. *Greater New Orleans*, 527 U.S. at 184.

consumer advertising of Schedule II prescription drugs must be analyzed with great precision.

C. Surviving Constitutional Scrutiny: Prohibiting the Direct Consumer Advertising of Schedule II Prescription Drugs.

A step-by-step analysis of the Central Hudson test and subsequent interpretations, illustrates the arguments the federal government must make to ensure legislation prohibiting direct-to-consumer advertisement of Schedule II controlled substances will survive judicial review.

1. Speech Must Not Be Untruthful or Misleading.

Step one of the Central Hudson analysis is determining whether or not a commercial advertisement of Schedule II drugs like Ritalin is eligible for constitutional protection. Under this test, commercial speech “at least must concern lawful activity and not be misleading,” for First Amendment protection to attach.¹³² There is no dispute that the use of Schedule II prescription drugs is a lawful activity, so attention must turn to whether such advertising would be “misleading”.

The “misleading” element of the first step of Central Hudson is split into two categories, “inherently” misleading and “potentially” misleading.¹³³ If speech is “inherently” misleading, the restriction is valid and the rest of the Central Hudson analysis is unnecessary.¹³⁴ The key determination is whether the speech is “more likely to deceive the public than inform it.”¹³⁵ Given the current FDA guidelines for prescription drug advertising, it is highly doubtful that consumer advertisements for psychotropic prescription drugs would deceive the public in such a manner as to be branded “inherently” misleading.

The second category is commercial speech that is “potentially” misleading. If speech is “potentially” misleading, there can be no proscription without completing the Central Hudson test.¹³⁶ The Ninth Circuit has held that courts should evaluate a speech restriction by

132. *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm’n of New York*, 447 U.S. 557, 566 (1980).

133. *See W. States Med. Ctr. v. Shalala*, 69 F. Supp. 2d 1288, 1298 (D. Nev. 1999).

134. *Id.*

135. *Cent. Hudson*, 447 U.S. at 557.

136. *W. States*, 69 F. Supp. 2d at 1298.

“focusing on its potential for deception in light of the lessons of experience and the nature of the target audience.”¹³⁷ In the context of Schedule II drugs, such as Ritalin, advertising ban proponents could assert that such advertisements are potentially misleading because there is no conceivable manner in which the advertisements could convey the highly addictive nature of psychotropic prescription drugs. This is especially the case when considering the “target audience” of such advertisements consists of lay people with no medical background. Regardless of whether or not such advertisements are potentially misleading, it is most likely that such advertisements, generally, would not be viewed by the court as untruthful or inherently misleading to a degree that would preclude further constitutional analysis.

2. Government Must Assert a Substantial Interest

The second step of the Central Hudson analysis is whether the government has asserted a “substantial” interest in targeting the protected speech.¹³⁸ The state does not have the authority to “regulate speech that poses no danger to the asserted state interest.”¹³⁹ Prior cases before the Court indicate that this is not a rigorous standard to meet.¹⁴⁰

The most obvious governmental interest in prohibiting direct-to-consumer advertisements of Schedule II prescription drugs is the health and safety of American citizens. The problems associated with these controlled substances are well documented. The DEA says that Ritalin and other stimulants rank among the most frequently stolen prescription drugs.¹⁴¹ Such theft and inappropriate use has created a growing, illegal traffic of what are potent and dangerous speed-like stimulants.¹⁴² A recent report by the Associated Press supports the

137. Ass’n.of Nat’l Advertisers, Inc. v. Lungren, 44 F.3d 726, 732 (9th Cir. 1994).

138. *Central Hudson*, 447 U.S. at 564.

139. *Id.* at 557.

140. See 44 Liquormart, Inc. v. Rhode Island, 517 U.S. 484, 503 (1996)(finding Rhode Island’s interest in reducing alcohol consumption by its citizens was “substantial”); *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 483-84 (1995). (Court agreed that the government’s interest in curbing alcohol “strength wars” was “substantial” in the type of social harm the government hoped to prevent); *Central Hudson*, 447 U.S. at 569 (Court said New York’s concern that rates be fair and efficient represents a clear and substantial government interest).

141. Petersen & Zernike, *supra* note 5, at A1.

142. *Id.*

DEA's claim that one in five college students uses Ritalin, or related stimulants, recreationally.¹⁴³ One study reported that drug-related emergency room admissions for ten to fourteen-year old patients are just as likely to involve prescription stimulants as they were cocaine.¹⁴⁴ Yet another study, conducted for the Massachusetts Department of Public Health, found that among students in grades six through twelve, abuse of ADHD drugs ranked higher than that of cocaine and amphetamines, and almost as high as inhalants.¹⁴⁵ Noting that most dealers are children who are prescribed the stimulants, DEA pharmacologist Gretchen Feussner sums up the substantial government interest involved, saying, "[t]here already is not the oversight we'd like to see of this drug, and ads can only make it worse."¹⁴⁶

Although not as compelling as the governmental interest in curbing drug abuse and illegal trafficking of Ritalin and related stimulants, another interest the government could assert is preventing the inappropriate or over-medicating of America's school children. The number of children taking psychiatric drugs increased by 650% between 1990 and 1997.¹⁴⁷ This increase comes despite the fact that many in the medical community dispute the widespread diagnosis of ADHD.¹⁴⁸ In fact, the recent actions taken by Minnesota and Connecticut were in large part due to a concern that educators were contributing to the growing number of students on Ritalin-like stimulants.¹⁴⁹

Proponents of prohibiting consumer advertising for Schedule II stimulants would likely satisfy the "substantial" interest prong of the Central Hudson test. In noting that a state has a substantial interest in reducing alcoholism and its attendant costs, the Supreme Court has held that the government has a "significant interest in protecting the

143. See White, *supra* note 3.

144. *Id.* Seventy-five percent of those emergency room admissions involved recreational use of prescription stimulants.

145. See Lazar, *supra* note 41, at A1.

146. Thomas, *supra* note 1, at D1.

147. Fine, *supra* note 17.

148. See Diller, *supra* note 60 (discussing lack of medical basis for ADHD diagnosis and influence of pharmaceutical industry on public perception of ADHD); See also White, *supra* note 3 (Dr. Mary Ann Block says "There is no such thing as ADHD. It is a made-up diagnosis.").

149. Fine, *supra* note 17.

health, safety, and welfare of its citizens.”¹⁵⁰ The D.C. Circuit in *Pearson v. Shalala* stated that “[a]t this level of generality, . . . a substantial government interest is undeniable.”¹⁵¹ Moreover, the very fact that an international agreement preventing the promotion of psychotropic drugs has existed for thirty years is compelling evidence to their harmful nature and susceptibility to abuse and trafficking.¹⁵²

The last two steps in the *Central Hudson* analysis are the most difficult for surviving constitutional scrutiny. These two steps are closely intertwined. The first step asks whether a prohibition on such advertisements “directly advance[s] the state interest involved,”¹⁵³ while the second step queries whether the relationship between the government’s ends and the regulation chosen to accomplish those ends is a “reasonable fit.”¹⁵⁴

3. Restriction Must Directly Advance Government Interest

To satisfy the third, “directly advance” step, the burden is on the government, as the party seeking to uphold a restriction, to “demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree.”¹⁵⁵ Furthermore, this burden cannot be satisfied by “mere speculation or conjecture.”¹⁵⁶

There is a direct link between direct-to-consumer advertising of prescription drugs and an increase in the use of these drugs. Previously cited statistics reveal that the fifty most heavily advertised drugs in 2000 experienced a thirty-two percent increase in sales from the previous year.¹⁵⁷ It is not likely that the pharmaceutical companies would spend \$2.5 billion on print and broadcast advertising in 2000¹⁵⁸ unless it would increase the sales of their product. These ads in turn mean more products are available in society. It is the prevalence and potential increase of Schedule II stimulants in the public that the

150. *Rubin*, 514 U.S. at 485.

151. *Pearson v. Shalala*, 164 F.3d 650, 656 (D.C. Cir. 1999).

152. *See* 1971 Agreement, *supra* note 6.

153. *Cent. Hudson Gas & Elec. Corp.*, 447 U.S. at 564.

154. *Board of Trustees of the State Univ. of New York v. Fox*, 492 U.S. 469, 480 (1989).

155. *Edenfield*, 507 U.S. at 770-71 .

156. *Id.* at 770.

157. *See* MacDonald, *supra* note 85.

158. *Id.*

government seeks to prevent. If the DEA already ranks Ritalin-like stimulants on its list of most abused and stolen prescription drugs, it can be extrapolated that consumer advertisements leading to increased prescriptions for stimulants will further inflate the abuse and illegal trafficking of these highly addictive drugs.

While similar arguments were offered relative to drug regulation and the Central Hudson analysis, a regulation prohibiting the narrow class of Schedule II prescription drug advertisements can be distinguished. The D.C. Circuit rejected the claim by the FDA in *Pearson v. Shalala*¹⁵⁹ that the public health would be directly advanced by prohibiting drug producers from making health claims about FDA-approved dietary supplements.¹⁶⁰ The court held that the FDA did not assert a claim that these products were harmful and rejected the agency's underlying premise that consumers were too "simplistic" to investigate the health claims being made by dietary supplement producers.¹⁶¹ The Ninth Circuit, in deciding a case challenging the advertising prohibition on particular compounded drugs, noted that the FDA did not assert such drugs were harmful and that the stated interest in reducing the volume of compounded drugs to serve public health is not directly advanced by "broad prohibitions on truthful and accurate speech."¹⁶²

Prohibitions on the advertising of controlled substances can be distinguished from those on compounded drugs or dietary supplements because the harms associated with Schedule II prescription stimulants are real and significant as the above evidence indicates. The Court in *Central Hudson* said that the commercial speech regulation "may not be sustained if it provides only ineffective or remote support for the government's purpose."¹⁶³ The evidence establishes that there are societal harms associated with an increase in Schedule II prescription drugs. The increase is statistically inevitable if widespread direct-to-consumer advertising of those products is allowed. This argument satisfies the third part of the *Central Hudson* analysis that the government interests asserted must be directly advanced by a prohibition on consumer advertising of Ritalin-like stimulants.

159. 164 F.3d 650 (D.C. Cir. 1999).

160. *See id.* at 656.

161. *Id.*

162. *W. States Med. Ctr.*, 69 F. Supp. 2d at 1306.

163. *Cent. Hudson*, 447 U.S. at 564.

4. Restriction Must Not Be More Extensive than Necessary.

The fourth and final step in the Central Hudson analysis is a determination of whether a restriction on consumer advertising for controlled substances is “more extensive than is necessary to serve” the government’s interest.¹⁶⁴ The Court elaborated on this standard when it explained that the final prong of the test does not require that a restriction be “absolutely the least severe that will achieve the desired end.”¹⁶⁵ Instead, the Court requires a “fit’ between the legislature’s ends and the means chosen to accomplish those ends, . . . a fit that is not necessarily perfect, but reasonable.”¹⁶⁶

The final “reasonable fit” prong has proven difficult to meet because of numerous state restrictions. In *44 Liquormart, Inc. v. Rhode Island*,¹⁶⁷ the Supreme Court held Rhode Island’s ban on liquor price advertising to be more extensive than necessary, and pointed to alternatives, such as raising liquor taxes, that were a less speech-restrictive means of promoting the state’s asserted interest of temperance.¹⁶⁸ In *Greater New Orleans Broadcasting Ass’n. v. United States*,¹⁶⁹ the Supreme Court held a statute restricting gambling advertising was suspect and invalid because it “sacrifice[d] an intolerable amount of truthful speech about lawful conduct when compared to all of the policies at stake and the social ills that one could reasonably hope such a ban to eliminate.”¹⁷⁰

A narrowly tailored prohibition on Schedule II prescription drug advertising can be distinguished. For example, the Court was correct in *Greater New Orleans* in saying that a prohibition on particular types of gambling advertisements was not the proper vehicle for combating the social ills of gambling.¹⁷¹ Also, the Court in *44 Liquormart* noted that other non-speech alternatives existed that the state could exercise in encouraging temperance among its citizens.¹⁷² There are two major differences, however, concerning a prohibition on advertising Schedule II stimulants in order to reduce their abuse and illegal trafficking. The

164. *Id.* at 569-70.

165. *Board of Trustees of the State Univ. of New York*, 492 U.S. at 480.

166. *Id.* (citations omitted).

167. 517 U.S. 484 (1996).

168. *Id.* at 509.

169. 527 U.S. 173 (1999).

170. *Id.* at 194.

171. *Id.* at 186-87.

172. *44 Liquormart*, 517 U.S. at 507.

first difference concerns the government interest in preventing illegal behavior, while the second involves the limitations of alternative means of reducing the abuse and trafficking of Schedule II stimulants.

The first difference is that the government interest and harm the government seeks to prevent focuses on illegal behavior. Abusing or trafficking in Ritalin-like prescription drugs is illegal criminal activity. This is not the case with the harms associated with the legal activities of alcohol consumption and casino gambling the Court addressed in 44 *Liquormart* and *Greater New Orleans*. While the activities involved in those instances may be termed as “vice” activity, the Court rejected any notion of a “vice” exception to the constitutional protection afforded commercial speech.¹⁷³ Specifically, the Court did not support such an approach when applied to products that may be “lawfully” purchased on the open market.¹⁷⁴ Again, the very activity the prohibition of advertising seeks to reduce is not lawful activity, but the illegal abuse and trafficking of prescription drug stimulants.

The second difference involves the availability of alternative means of reaching the stated end of reducing the abuse and trafficking of Schedule II stimulants. One example is in 44 *Liquormart*, where the Court discusses different options at the State’s disposal to meet the goal of temperance.¹⁷⁵ Another example is in *Greater New Orleans*, where the Court notes areas in which federal law supports, at least implicitly, legal gambling and that those statutes contradict the government’s stated interest to limit gambling.¹⁷⁶ These problems would not be present in the creation of a federal statute prohibiting the direct-to-consumer advertising of Schedule II prescription drugs for numerous reasons.

First, there are no viable non-speech alternatives the government can undertake to reduce the abuse or illegal trafficking of Schedule II prescription stimulants. The DEA already maintains tight controls over the production of Ritalin-like stimulants¹⁷⁷ and severe criminal penalties currently exist for dealing or trafficking in these controlled substances.¹⁷⁸ Furthermore, an individual can only receive Schedule II prescription stimulants from a licensed pharmacist after receiving a

173. *Id.* at 514.

174. *Id.*

175. *Id.* at 507.

176. *Greater New Orleans*, 527 U.S. at 191-92.

177. *See* Diller, *supra* note 60.

178. U.S. Drug Enforcement Agency, Federal Trafficking Penalties, *available at* <http://www.dea.gov/agency/penalties.htm> (last visited May 15, 2003).

prescription from a licensed physician. Despite all of these measures, abuse and trafficking of Schedule II prescription stimulants is on the rise.¹⁷⁹ Second, unlike the instance in Greater New Orleans, there does not appear to be any federal statute contradicting the government's interest in curtailing the abuse and illegal trafficking of Schedule II prescription stimulants.

The only conceivable alternative that opponents may raise as evidence that a complete prohibition on prescription stimulant advertising is more extensive than necessary is the use of disclaimers. In *Pearson*, the D.C. Circuit Court cited numerous Supreme Court cases for the principle that disclaimers are "constitutionally preferable to outright suppression."¹⁸⁰ This proposition was followed by the Ninth Circuit where the court found a complete prohibition on the advertising of compounded drugs invalid.¹⁸¹ The Ninth Circuit held a FDA disclaimer requirement would be an alternative to the advertising prohibition and would "clearly represent a far less restrictive means to accomplish the FDA's asserted goals."¹⁸²

Requiring a disclaimer in lieu of an outright ban on the advertising of Schedule II prescription stimulants merits discussion. While conceding that the requirement of a disclaimer may represent a less restrictive means to accomplish the government's interest in not inappropriately or over-medicating its school children, such an alternative would likely not satisfy the government's interest in reducing the abuse and illegal trafficking in prescription drug stimulants. Requiring a disclaimer in every print or electronic direct-to-consumer Schedule II prescription drug advertisement saying, "Ritalin (or other brand name) is a highly addictive stimulant like cocaine and morphine and should only be taken while under the care of a physician," may certainly be adequate to warn parents and children of the risks associated with psychotropic drugs and over-medication.

179. Petersen & Zernike, *supra* note 5, at A1.

180. *Pearson*, 164 F.3d at 657; *see also* *Peel v. Attorney Registration & Disciplinary Comm'n of Illinois*, 496 U.S. 91, 110 (1990); *Shapero v. Kentucky Bar Ass'n*, 486 U.S. 466, 478 (1988).

181. *W. States Med. Ctr.*, 69 F. Supp. 2d at 1308.

182. *Id.*

Similarly, a required disclaimer contained in an advertisement for a Ritalin-like stimulant could say, "There is currently no objective test to determine the presence of attention deficit/hyperactivity disorder and you are encouraged to talk to your doctor." While admittedly outrageous, this disclaimer would certainly serve a governmental interest in slowing the explosive growth of ADHD diagnoses and stimulant prescriptions.

Such disclaimers, however, do nothing to advance the government's interest in reducing the abuse or illegal trafficking in Schedule II prescription stimulants. Even with the most descriptive disclaimer imaginable, the purpose of direct-to-consumer advertising is to increase sales of a product to the general public. This increase in sales, as discussed above, can be reasonably calculated to lead to an increase in the availability of Schedule II stimulants for abuse and illegal trafficking.

V. CONCLUSION

It is clear that the courts are hostile to restrictions on truthful and non-misleading commercial speech. The compelling and substantial state interest in preventing increased abuse and illegal trafficking of Schedule II prescription stimulants, however, provides an excellent opportunity for the government to attempt to narrowly tailor legislation to codify what had been a voluntary thirty-year international agreement to prohibit the direct promotion of these highly addictive drugs to consumers. As the proliferation of direct-to-consumer advertising of stimulants continues, Congress must not remain silent. If Congress is to approve legislation aimed at restricting direct-to-consumer advertising of stimulants, interested lawmakers must start compiling the evidence needed to demonstrate the presence of a substantial government interest in deterring the abuse and illegal trafficking of Schedule II stimulants. Only a solid foundation built upon evidence of a substantial government interest coupled with the absence of viable alternatives will withstand judicial review.

Hudson analysis