A Tough Pill to Swallow: Does the First Amendment Prohibit WV From Regulating Pharmaceutical Companies' Advertising Expenses to Lower the Cost of Prescription Drugs?

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A TOUGH PILL TO SWALLOW: DOES THE FIRST AMENDMENT PROHIBIT WV FROM REGULATING PHARMACEUTICAL COMPANIES’ ADVERTISING EXPENSES TO LOWER THE COST OF PRESCRIPTION DRUGS?

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I. THE EPIDEMIC OF RISING PRESCRIPTION COSTS AND STATES’ FIGHT TO REVIVE THE AFFORDABILITY OF PRESCRIPTION DRUGS

In 2002, New Line Productions produced the film John Q.¹ about a man who takes an emergency room hostage when he cannot afford an emergency heart transplant for his son. While drama of this extent is not common in the health care field, the basic struggle of the film’s protagonist resonates with many Americans who have felt his frustration with the unavailability of health care because of financial inhibitors. Furthermore, while most Americans are fortunate not to be faced with a care-versus-cost dilemma in the context of an

¹ JOHN Q. (New Line Productions, Inc. 2002).
emergency heart transplant, many face this decision monthly when they try to fill their prescriptions.

Prescription drugs are an important and necessary part of health care, but because of cost they are not always available to everyone. People who are ineligible for Medicaid or Medicare coverage and who cannot afford private insurance coverage\(^2\) often cannot afford to pay for the medications prescribed by their doctors. As a result, they are forced to skip doses or just not fill their prescriptions at all.\(^3\) Even worse is the fact that in the United States the cost of prescription drugs is on the rise, making the hope of attaining proper health care dimmer than ever for these people.\(^4\)

Focusing on West Virginia, home to one of the oldest\(^5\) and sickest populations in the United States,\(^6\) the problem is particularly disheartening. Along with Tennessee and Kentucky, West Virginia has the highest level of prescriptions per-capita in the nation.\(^7\) Each year the state pays over $500 million for prescription drugs through state-run health care programs, and West Virginia

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\(^3\) A 2001 study of Medicare beneficiaries in eight states found that approximately 25% of seniors without insurance failed to fill at least one prescription because of cost or skipped doses to make their medications last longer, and 20% cut back their expenses for basic necessities to be able to afford their prescriptions. Dana Safran et al., Prescription Drug Coverage and Seniors, How Well Are States Closing the Gaps? 261-63 (2001), available at www.healthaffairs.org/WebExclusives/2105safran.pdf (type Dana Safran in the “Author” box and follow link).


\(^5\) West Virginia ranks second, after Florida, for the percent of the total population that are over the age of 65. U.S. Census Bureau, United States and States: Percentage of People Who are 65 Years and Over, http://factfinder.census.gov/servlet/GRTable?_bm=y&-_box_head_nbr=R0103&-_ds_name=ACS_2004_EST_G00&-_format=US-30&-_CONTEXT=grt (last visited Sept. 11, 2006).

\(^6\) Dan Kurland, Prescription Drugs: West Virginia Leads in Fight Over Fair Drug Pricing, Charleston Gazette, July 14, 2004, at 5A.

\(^7\) The Henry J. Kaiser Family Foundation, Retail Prescription Drugs Filled at Pharmacies (Per Capita) (2004), available at http://www.statehealthfacts.org (follow the “50 State Comparisons” hyperlink, then the “Health Costs & Budgets” hyperlink, and then the “Retail Rx Drugs Per Capita” hyperlink).
residents pay over $1 billion for their prescriptions outside of these government programs.\textsuperscript{8}

Legislators, skeptics, public watchdogs, and medical professionals across the country suspect that the rising costs of prescriptions in the United States can be attributed in part to the excessive amount of money prescription drug manufacturers dump into advertising and marketing. For example, in 2000, Merck, the makers of Vioxx, spent $160 million on advertising; this is more than was spent to advertise Budweiser, Pepsi, Nike shoes, or Campbell’s soup.\textsuperscript{9} Even more concerning is the fact that in 2000, the top ten pharmaceutical manufacturers in the United States spent only 14\% of their revenue on research and development ("R\&D") but spent 36\% on marketing, advertising, and administration ("GAAP").\textsuperscript{10}

On the whole, the pharmaceutical industry spends an average of $7 billion per year advertising prescription drugs in the United States,\textsuperscript{11} approximately $4 billion of which is spent on direct-to-consumer advertising\textsuperscript{12} (marketing that targets patients rather than doctors).\textsuperscript{13} In addition to direct-to-consumer adver-

\textsuperscript{8} Dan Foster, Drug Costs: State has Opportunity to Save Money and Lives, CHARLESTON GAZETTE, Dec. 20, 2004, at 5A.

\textsuperscript{9} Don Perdue, Prescription-drug Legislation: West Virginia Must Move Quickly to Pass Landmark Bill, CHARLESTON GAZETTE, Nov. 8, 2004, at 5A.

\textsuperscript{10} Dan Kurland, Prescription Drugs: West Virginia Leads in Fight Over Fair Drug Pricing, CHARLESTON GAZETTE, July 14, 2004, at 5A. But see Uwe E. Reinhardt, Perspectives On the Pharmaceutical Industry: Granting All Americans Access to Prescription Drugs that Work Should be a Trivial Economic Challenge for this Wealthy Nation, 20 HEALTH AFFAIRS 136, 141 (2001), available at www.healthaffairs.org (search by author name) (warning that statistics comparing a company’s R\&D expenses to its GAAP expenses can be misleading because both categories are broad with fuzzy definitions and because the Generally Accepted Accounting Principles ("GAAP"), used to guide companies’ reporting to shareholders and the SEC, give companies leeway in deciding which expenses to assign to each category).

\textsuperscript{11} Josh Hafenbrack, Kiss Weighs Merger, Plan Saves Funds by Uniting Two Teacher Retirement Systems, CHARLESTON DAILY MAIL, Feb. 23, 2004, at 1A, see also Gzedit, Editorial, Insane Prescription Costs, CHARLESTON GAZETTE, May 19, 2006, at 4A (noting that “Americans are just 5 percent of the world’s population, yet they provide nearly half of all drug company profits worldwide, [sic] because U.S. prescription prices are uncapped. Other nations won’t tolerate profiteering, but in America, big-money pharmaceutical lobbyists inveigle politicians to stymie price controls.”).


\textsuperscript{13} For example, common direct-to-consumer advertising includes pharmaceutical advertisements on TV or in popular magazines other than medical journals read primarily by doctors. Manufacturers like direct-to-consumer advertising because it works to increase profits. For example, it is estimated that in 2000 the companies earned an additional $4.20 in sales for each dollar they spent on direct-to-consumer advertising. THE HENRY J. KAISER FAMILY FOUNDATION, IMPACT OF DIRECT-TO-CONSUMER ADVERTISING ON PRESCRIPTION DRUG SPENDING 2, 18 (2003), available at http://www.kff.org/rxdugs/6084-index.cfm (follow “report” hyperlink).
tising, pharmaceutical companies across the United States spend approximately $6 thousand to $7 thousand per doctor every year for marketing.\textsuperscript{14}

As a result of this excessive advertising, the prices of drugs are rising to compensate for the companies’ extra expenses.\textsuperscript{15} In response to this problem, states are developing legislation that aims to control prescription costs. Recently, ten states\textsuperscript{16} and the District of Columbia\textsuperscript{17} passed such legislation. These states’ tactics include, but are not limited to, disclosure requirements for marketing expenses, prohibitions on gifts to doctors and pharmacists, licensure requirements, access cards, preferred drug lists, and taxes on marketing expenses.\textsuperscript{18}

West Virginia is among the states in the forefront with its Pharmaceutical Availability and Affordability Act of 2004 ("the Act" or "West Virginia’s law").\textsuperscript{19} As physician and State Senator Dan Foster, commenting on the 2004 Act, put it, "Not only is West Virginia about to make history, we are about to make a difference in the quality of life for all our people."\textsuperscript{20} The Pharmaceutical Availability and Affordability Act provides that the Legislature, "in an effort to promote healthy communities and to protect the public health and welfare of West Virginia residents," has a duty to make prescription drugs more affordable.

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\textsuperscript{14} KEVIN OUTTERTON, W. VA. PHARMACEUTICAL COST MANAGEMENT COUNCIL, ADVERTISING AND MARKETING OF PRESCRIPTION DRUGS 7 (2005), available at http://www.state.wv.us/got/pharmacycouncil/sec/ (follow "Advertising and Marketing of Prescription Drugs" hyperlink under the heading "Documents from September 8, 2005 meeting").


\textsuperscript{16} CAL. HEALTH & SAFETY CODE § 119400 et seq. (West 2006); ME. REV. STAT. ANN. tit. 22 § 2697 et seq. (West 2006); MINN. STAT. § 151.461(1)-(7) (West 2006); VT. STAT. ANN. tit. 33 § 2001 et seq. (West 2006); W. VA. CODE § 5A-3C-1 et seq. (West 2006).

\textsuperscript{17} D.C. CODE § 48-833.01 (West 2006).

\textsuperscript{18} See, e.g., CAL. HEALTH & SAFETY CODE § 119400 et seq. (West 2006); CONN. GEN. STAT. § 17b-274d (West 2006); D.C. CODE § 48-833.01 (West 2006); FLA. STAT. § 409.9065 (West 2006) (repealed Jan. 1, 2006); ME. REV. STAT. ANN. tit. 22 § 2697 et seq. (West 2006); MINN. STAT. § 151.461(1)-(7) (West 2006); OR. REV. STAT. § 414.312 et seq. (West 2006); R.I. PUB. LAWS § 5-19.1-1 et seq. (West 2006); S.D. CODIFIED LAWS § 58-29E-1 et seq. (West 2006); VT. STAT. ANN. tit. 33 § 2001 et seq. (West 2006); W. VA. CODE § 5A-3C-1 et seq. (West 2006); see also National Legislative Association on Prescription Drug Prices, Model Legislation, http://www.nlaxr.org/modelleg/index.html (last visited Oct. 20, 2006).

\textsuperscript{19} W. VA. CODE § 5A-3C-1 et seq. (West 2006).

\textsuperscript{20} Dan Foster, Drug Costs: State has Opportunity to Save Money and Lives, CHARLESTON GAZETTE, Dec. 20, 2004, at 5A; see also Scott Finn, A Mouse Roars at the Drug Industry, CHARLESTON GAZETTE, Mar. 14, 2004, at 1A (describing West Virginia’s law as "bold" and "innovative" and quoting Richard Stevens of the West Virginia Pharmacists Association as stating "The bill puts West Virginia in the lead among states trying to curb prescription drug prices . . . . This Legislature has made a bold statement to the drug industry, [sic] that the soaring cost of prescription drugs must come under control.").
for state residents.\textsuperscript{21} To carry out this duty, the legislature created an agency,\textsuperscript{22} entitled the Pharmaceutical Cost Management Council ("the Council"), to study and oversee the implementation of the specific provisions of the Act. These specific provisions include a clearinghouse program,\textsuperscript{23} a discount card program,\textsuperscript{24} a pricing schedule,\textsuperscript{25} and mandatory reporting requirements.\textsuperscript{26}

Drug manufacturers and distributors are vehemently opposed to certain aspects of legislation like that proposed in West Virginia. The manufacturers and distributors, with the help of their primary lobbying organization, the Pharmaceutical Research and Manufacturers of America ("PhRMA"), have filed several actions across the country challenging the constitutionality of other states’ legislative attempts to curb the rising cost of prescription drugs.\textsuperscript{27} The

\textsuperscript{21} W. VA. CODE § 5A-3C-2 (West 2006).
\textsuperscript{22} Id. § 5A-3C-8.
\textsuperscript{23} Id. § 5A-3C-4.
\textsuperscript{24} Id. § 5A-3C-5.
\textsuperscript{25} Id. § 5A-3C-6.
\textsuperscript{26} Id. § 5A-3C-13.
\textsuperscript{27} For example, in 2002 PhRMA challenged a Florida statute, FLA. STAT. §§ 409.91195, 409.912, on preemption grounds in the case PhRMA v. Meadows. 304 F.3d 1197 (11th Cir. 2002). The Florida statute provided for prior authorization requirements for prescription drugs produced by manufacturers that do not agree to pay a rebate to offset the state’s Medicaid expenditures. Id. at 1198-99. Both the United States District Court for the Northern District of Florida and the Court of Appeals for the Eleventh Circuit held that Florida’s law was not preempted by the federal Medicaid program. Id. at 1212.

Additionally, in 2003, PhRMA challenged a Maine statute, ME. REV. STAT. ANN. tit. 22 § 2681, in the case PhRMA v. Walsh on the grounds that it violated the Commerce Clause and that it was preempted under the Supremacy Clause. 538 U.S. 644 (2003). This statute provided for a prescription pricing program for which the state planned to negotiate with drug manufacturers for rebates which could then be passed along to state residents purchasing the prescription drugs. Id. at 654. It further provided that the names of manufacturers that choose not to offer a rebate would be released to the public and that these manufacturers would be subject to the State Medicaid program’s prior authorization requirements. Id. This meant that their drugs could not be dispensed to Medicaid beneficiaries without prior approval by the State Medicaid administrator. In a very narrow holding, the Court found that PhRMA failed to prove that the Maine law created an impermissible reach or that it discriminated against interstate commerce in order to subsidize in-state retail sales. Id. at 699. It further found, in a plurality opinion, that PhRMA failed to overcome the presumption that the state law was preempted by the Medicaid program. Id. at 661-62. It did not hold, however, that the state law was in fact valid. Id.

PhRMA raised another challenge in 2005, this time against the District of Columbia in the case PhRMA v. District of Columbia. 406 F. Supp. 2d 56 (D.C. 2005). The D.C. law under attack allowed the government or consumers to sue drug makers if they believed that a drug price was excessive, meaning 30% higher than the comparable price in Europe, Canada, or Australia. D.C. CODE § 28-4551 et seq. (2005 Supp.). It placed a burden on the drug company to defend its price based on research and development costs, profit margin, and other factors or face civil penalties. Id. PhRMA again sought a preliminary injunction, arguing that this law violated United States patent law and the Commerce Clause. PhRMA v. D.C., 406 F. Supp. 2d at 64-71. The Court found the law unconstitutional and granted the injunction on Thursday, December 22, 2005. Id. at
West Virginia legislation has yet to be challenged in court. Council members suggest that this is because PhRMA was successful in stripping the most powerful provisions from the legislation before its passage. However, the Council, using its only remaining power – rulemaking – has drafted a legislative rule to make the disclosure requirements of the Act a reality. This rule has been provisionally approved by the Council but has yet to be approved by the Legislative Rule-Making Review Committee. Some members of the Council suggest that once this rule is enacted, it will only be a matter of time before the pharmaceutical companies initiate a judicial challenge to West Virginia’s law.

This Article is intended to serve as a roadmap for that litigation, when it occurs, by providing a constitutional analysis of the Act. The industry likely will raise several challenges to the Act; however, this Article focuses only on the potential First Amendment challenges that the industry may raise. This Article concludes that the Act will survive a First Amendment challenge despite the fact that it discourages pharmaceutical companies from driving up prescription drug prices by spending a significant amount of money on advertising campaigns and marketing. A First Amendment challenge has yet to be raised by the industry in any of the litigation involving other states’ statutes because there has been no opportunity to raise such a challenge against the other states’ legislation. However, West Virginia’s law is unique and contains two provisions that may open the door for the industry to try a new tactic.

This Article argues that West Virginia’s law should survive a First Amendment challenge. First, Part II of this Article introduces the Act, describing its provisions and how they work to lower the prices of prescription drugs in the state. Part II includes a summary of the Council’s progress in implementing these provisions since the Act was passed. Part II also identifies the two provisions of the Act which likely will be the subject of the industry’s First Amendment challenge and introduces the potential bases for the industry’s challenge. Part III describes the two applicable First Amendment standards, the commercial and compelled speech doctrines, upon which the companies will likely rely.

44. The Court held that the law violated the doctrine of interstate commerce and was preempted by federal patent law. Id. at 44.


29 Phil Kabler, Drug Companies Asked to Reveal Spending on Ads, CHARLESTON GAZETTE, Nov. 11, 2005, at 1A.

30 The rule was provisionally approved by the Council on November 10, 2005, but it awaits approval by the Legislative Rule-Making Review Committee in order to become effective. Phil Kabler, Drug Companies Asked to Reveal Spending on Ads, CHARLESTON GAZETTE, Nov. 11, 2005, at 1A. Since the Council made its provisional approval in November 2005, it has made some changes to the disclosure form. The Council is expected to approve the new version in 2007 before it sends its rule to the Review Committee. Lawrence Messina, Leaders Seek Broader Drug Disclosure Rule, CHARLESTON DAILY MAIL, Sept. 15, 2006, at 6A.

Finally, Part IV analyzes the provisions of the Act under the commercial and compelled speech doctrines, explaining why the Act likely will survive the industry's challenge.

II. WV'S RX: THE PHARMACEUTICAL AVAILABILITY AND AFFORDABILITY ACT OF 2004

To begin, this Section provides an overview of the Act, summarizing each of its provisions aimed at lowering prescription costs and describing any significant changes that have occurred since the Act was passed. This Section then highlights the two sections of the Act which may be subject to a First Amendment challenge. These sections are the focal point of this Article. Finally, this Section concludes by providing an overview of the arguments that may be raised by the pharmaceutical companies.

A. Tables in the Bottle of the Pharmaceutical Availability and Affordability Act

The Act was created for the purpose of “promoting healthy communities and . . . protect[ing] the public health and welfare of West Virginia residents.” In order to achieve this purpose, the Legislature found and clearly stated in the Act that “it is [the Legislature’s] responsibility to make every effort to provide affordable prescription drugs for all residents of West Virginia.” The Act, which has yet to be challenged in court, effects this purpose through several programs and provisions including the creation of a pharmaceutical council, a clearinghouse program, a discount card program, a pricing schedule, and certain mandatory reporting requirements.

The most extensive and elaborate provision of the Act creates the Pharmaceutical Cost Management Council and describes its discretionary authority and mandatory duties. Although the Act does not expressly articulate the purpose of the Council, its purpose – to serve as an administrative agency – can be inferred from the duties and authorities bestowed upon it. The Council has discretionary authority to form contracts; file suit; execute purchasing agreements; consider and develop strategies to manage increasing pharmaceutical costs (such

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32 W. VA. CODE § 5A-3C-1 et seq. (West 2006).
33 Id. § 5A-3C-2.
34 Id.
35 Id. § 5A-3C-8.
36 Id. § 5A-3C-4.
37 Id. § 5A-3C-5.
38 Id. § 5A-3C-6.
39 Id. § 5A-3C-13.
40 Id. § 5A-3C-8.
as mandatory manufacturer disclosure of advertising practices and costs and counter-detailing programs);\textsuperscript{41} explore licensing, education requirements, and fees for drug detailers; investigate the possibility of purchasing drugs from Canada; and promulgate emergency rules.\textsuperscript{42} The Council has a duty to report to the legislature on needed legislative action or on any other function established by the Article or requested by the legislature.\textsuperscript{43} It has a duty to study the fiscal impact on the state of the Federal Medicare Prescription Drug Improvement and Modernization Act of 2003.\textsuperscript{44} It must develop methods to evaluate the discount savings and clearinghouse programs created in Sections 5A-3C-4 and 5A-3C-5 of the Act.\textsuperscript{45} In summary, the Council’s ultimate purpose and duty is to use the provisions of the Act and the programs it creates to carry out the Legislature’s goal of providing affordable prescription drugs to state residents.

In addition to creating the Council, the Act also provides for the creation of a clearinghouse program.\textsuperscript{46} The clearinghouse provision requires brand pharmaceutical manufacturers to use existing private and public sector programs and prescription drug programs offered by manufacturers to create a new program that assists low income and uninsured state residents in accessing prescription drugs.\textsuperscript{47} It also requires the manufacturers to educate individuals and providers, cover the costs of establishing the program, and oversee the program until June of 2005.\textsuperscript{48}

PhRMA, the industry’s main United States lobbying organization, launched a clearinghouse program called “RxforWV” in April of 2004, shortly after the Act was passed.\textsuperscript{49} “RxforWV” was supposed to increase access to prescription drugs by simplifying the process for locating and applying to the nu-

\textsuperscript{41} Detailing is the promotion of pharmaceutical drugs by a sales representative employed by a pharmaceutical manufacturer. \textit{Id.} § 5A-3C-3(9). This service includes educating healthcare providers about the pharmaceuticals and providing samples and gifts. \textit{Id.} The Act does not define “counter-detailing,” but it is generally understood to include the act of making information available to healthcare providers to counter-balance the marketing of the pharmaceutical manufacturers. It is also called academic detailing. KEVIN OUTTERTON, W. VA. PHARMACEUTICAL COST MANAGEMENT COUNCIL, ADVERTISING AND MARKETING OF PRESCRIPTION DRUGS 11 (2005), available at http://www.state.wv.us/got/pharmacycouncil/sec/ (follow “Advertising and Marketing of Prescription Drugs” hyperlink under the heading “Documents from September 8, 2005 meeting”).

\textsuperscript{42} W. VA. CODE § 5A-3C-8(d)(1)–(7) (West 2006).

\textsuperscript{43} Id. § 5A-3C-8(d)(8).

\textsuperscript{44} 42 U.S.C. § 1395w-101 et seq. (West 2006).

\textsuperscript{45} W. VA. CODE § 5A-3C-8(d)(10)–(11) (West 2006).

\textsuperscript{46} Id. § 5A-3C-4.

\textsuperscript{47} Id.

\textsuperscript{48} Id.

numerous public and private assistance programs already available. Before the creation of the clearinghouse, residents had to go through an elaborate and time consuming process to locate and complete forms for each manufacturer’s program and for each prescription they needed. Each manufacturer’s form was different, asking for different information and proof of eligibility. The Clearinghouse eased the patient’s burden by making all of the program information available at a single, central location. However, the Clearinghouse did not alleviate the resident’s obligation to meet each company’s eligibility criteria and fill out each company’s form individually. Therefore, even after the creation of the Clearinghouse, the process remained elaborate and time consuming.

By June of 2005, the date set by the Act to sunset the manufacturers’ supervision of the program, “RxforWV” matched more than 44,000 state residents with patient assistance programs. However, this number represents the number of people who were matched with the appropriate paper work, not the number who actually were approved for assistance. In fact, in a public meeting of the Council, a representative of PhRMA admitted that there is no evidence that “RxforWV” has provided a single additional drug to any West Virginia resident. The month that the program sunset, the state declined to take over “RxforWV,” and PhRMA terminated the program and rolled it into a national clearinghouse program called Partnership for Prescription Assistance. West Virginia residents, along with residents from many other states, can access this program by logging onto the Partnership’s website.

In addition to the clearinghouse program, the Act provides for a prescription discount card program. Under the discount card program, the state

50 Id.
52 For example, some companies require copies of applicants’ federal income tax returns to document income, while other companies require copies of pay stubs or Social Security documentation. Id.
56 Id.
58 Id.
59 W. VA. CODE § 5A-3C-5 (West 2006).
will negotiate voluntary discounts with brand pharmaceutical manufacturers and pharmacists, and the discounts will be passed along to eligible residents at the point of sale when the resident presents a discount card provided by the state.\(^{60}\) Any uninsured resident who is not currently or has not recently been covered by a prescription drug program can apply for a discount card. Pharmaceutical manufacturers who refuse to participate will not be penalized.\(^{61}\) As of October 2006, however, negotiations between the state and pharmaceutical companies had not yet begun.\(^{62}\) Additionally, the prospects of this program do not look promising. The Council has evaluated several options and has concluded that the prices paid by PEIA and Medicaid are already cheaper than the cards, that West Virginia residents already have access to similar cards, and that an additional card would not help and would only add to the existing confusion.\(^{63}\)

Another provision of the Act asks the council to select a pricing schedule to be used when the state purchases prescription drugs.\(^{64}\) It requires the Council to recommend both a pricing schedule based on the Federal Supply Schedule ("FSS") or the prices set by Canada’s Patented Medicine Prices Review Board ("PMPRB") and a strategic plan to implement the schedule for the purpose of maximizing savings.\(^{65}\) The FSS price is the price that federal agencies pay for prescription drugs under the Veterans Health Care Act of 1992,\(^{66}\) which is set to reflect the prices manufacturers charge their "most-favored," non-federal customers under similar terms and conditions.\(^{67}\) In September of 2004, the Council recommended to the state legislators that they adopt the FSS.\(^{68}\) It also recommended the Australian Pharmaceutical Benefits Scheme

\(^{60}\) Id.

\(^{61}\) Id. § 5A-3C-5(3)–(4). Unlike the Maine and Florida laws challenged in PhRMA v. Meadows, 304 F.3d 1197 (2000), and PhRMA v. Walsh, 538 U.S. 644 (2003), which provided that manufacturers that refuse to participate would be subject to prior authorization requirements and public disclosure of their refusal to cooperate, the West Virginia legislation expressly states that failure to participate will not result in prior authorization requirements or the release of a preferred drug list.


\(^{64}\) W. Va. Code § 5A-3C-6.

\(^{65}\) Id.


\(^{67}\) W. Va. Code § 5A-3C-3.

pricing schedule as a backup.\textsuperscript{69} One month later, the Senate authorized the use of the FSS to establish "a benchmark for prescription drug prices for the negotiation and purchase of brand name drugs by the State of West Virginia."\textsuperscript{70} As of October 2006, the Council had not yet used this power.\textsuperscript{71}

To encourage innovation in the pharmaceutical industry, the Act gives the Council discretion to grant waivers from the FSS rate\textsuperscript{72} to manufacturers on an individual basis for a particular drug when the "development, production, distribution costs, other reasonable costs and reasonable profits . . . [are] more than the pricing schedule rate of the pharmaceutical or in those cases in which the pharmaceutical in question has a sole source."\textsuperscript{73} However, the Act excludes from the waiver all marketing and advertising costs.\textsuperscript{74} This means that a manufacturer cannot charge prices above those set by the schedule to compensate for any marketing or advertising expenses but may, if a waiver is granted, raise prices to compensate for development, production, and distribution. Because the FSS has not yet been implemented, no waivers have been granted yet.\textsuperscript{75}

Finally, the Act delegates to the Council the power to create legislative rules\textsuperscript{76} and emergency rules\textsuperscript{77} to establish mandatory reporting requirements under which all manufacturers and labelers of prescription drugs must report

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\textsuperscript{69} Id.
\textsuperscript{71} Interview with Kevin Outterson, West Virginia Pharmaceutical Cost Management Council, in Morgantown, W. Va. (Oct. 8, 2006).
\textsuperscript{72} W. VA. CODE § 5A-3C-6(h). This section of the West Virginia Code is one of two provisions that the industry is likely to challenge. See infra Parts II.B., IV.A.
\textsuperscript{73} A "sole source" is a drug that "provides a unique and powerful advantage available in the market to a broad group of patients established under federal law." W. VA. CODE § 5A-3C-3(11).
\textsuperscript{74} Id. § 5A-3C-6(h).
\textsuperscript{75} Interview with Kevin Outterson, West Virginia Pharmaceutical Cost Management Council, in Morgantown, W. Va. (Jan. 9, 2006).
\textsuperscript{76} Following the West Virginia legislative rule-making process, the Agency must first file its proposed rule with the Secretary of State for publication in the State Register along with a notice of a public hearing and a request for interested parties to submit evidence on factual determinations and inquires. W. VA. CODE §§ 29A-3-5, 7 (West 2006). After the public hearing, the agency must approve the rule for submission to the legislature. Id. §§ 29A-3-7, -9. The proposed rule will next be reviewed by the Legislative Rule-Making Review Committee, which will make a recommendation to the legislature. Id. § 29A-3-11. Finally, the proposed rule will be considered, and hopefully approved, by the legislature. Id. § 29A-3-12; see also MICHIES JURISPRUDENCE, ADMINISTRATIVE LAW § 9 (2003).
\textsuperscript{77} When an agency finds that an emergency exists, it may pass an emergency rule. Emergency rules are needed "(1) for the immediate preservation of the public peace, health, safety or welfare, (2) to comply with a time limitation established by [the West Virginia Code] or by a federal statute or regulation, or (3) to prevent substantial harm to the public interest." W. VA. CODE § 29A-3-15(f). To enact an emergency rule, the agency must file the proposed rule along with a statement of the circumstances constituting an emergency with the Secretary of State, who will file a notice in the State Register. Id. § 29A-3-15(a). The rule will become effective upon approval by the Secretary of State or the Attorney General, and it will remain effective for a maximum of fifteen months. Id.
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their advertising costs to the Council in order to help the state in its role as a purchaser of prescription drugs and administrator of prescription drug programs. The state needs this information in order to better understand the scope of advertising costs and the effect of advertising on the cost and availability of prescription drugs and healthcare services in West Virginia. The Act orders the Council to establish reporting requirements for manufacturers through legislative and emergency rules, including the form, manner, and timeline for reporting. The Council has some discretion in deciding what information the manufacturers and labelers must provide, but the Act provides for some mandatory disclosures and exemptions as well. The mandatory disclosures include expenses associated with advertising and direct promotion of drugs through radio, television, magazines, newspapers, direct mail, and phone conversations. The exemptions include free drug samples intended to be given to patients; payments to reasonably compensate expenses in connection with bona fide research studies designed to answer questions about vaccines, new therapies, and new uses of known treatments; and scholarships for medical students, fellows, and residents selected by professional associations to attend conferences.

On November 10, 2005, the Council provisionally approved a financial disclosure form to satisfy this section of the Act. This form asked pharmaceutical companies to report information including aggregate expenditures associated with drug sales representatives who worked in West Virginia (such as salaries, benefits, support staff, marketing program expenses, outside contractors, and expense accounts); gifts, grants, and payments made to West Virginia prescribers, patient support groups, and patient advocacy groups; promotional and informational programs for West Virginia pharmacies; and direct-to-consumer advertising that was intended to reach West Virginia residents. In July 2006, the Council voted to omit a requirement for disclosure of the amount spent on marketing to physicians. As of October 2006, the Council was still debating its authority to include such a provision but expected to draft a final version of the disclosure form in 2007 that would include the disclosure for marketing to

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78 W. VA. CODE. § 5A-3C-13. This section of the West Virginia Code is the second provision the industry likely will challenge. See Infra Parts II.B., IV.B.
79 Id. § 5A-3C-13(b).
80 Id. §§ 5A-3C-13(b)–(c).
81 Id. § 5A-3C-13(b).
82 Id. § 5A-3C-13(c)(1)–(3).
83 Phil Kabler, Editorial, Drug Companies Asked to Reveal Spending on Ads, CHARLESTON GAZETTE, Nov. 11, 2005, at 1A.
85 Lawrence Messina, Leaders Seek Broader Drug Disclosure Rule, CHARLESTON DAILY MAIL, Sept. 15, 2006, at 6A.
Once the final version is approved by the Council, the Council’s next step will be to send its proposal to the Legislative Rule-Making Review Committee for review and recommendations and then to the Legislature for approval.

B. The Industry’s Allergic Reaction to WV’s Rx: An Overview of the Problematic Sections in the Act and the Industry’s Probable Response

Two of the provisions of the Act and the accompanying regulation promulgated by the Council, namely the pricing schedule and the disclosure requirement, are likely to be challenged by the companies as a violation of the First Amendment’s guarantee of free speech. The companies likely will argue that these sections and the regulation discourage or restrict their ability to advertise their products.

First, the pharmaceutical companies may challenge Section 5A-3C-6 of the Act. This section provides for the implementation of a pricing schedule and prohibits pharmaceutical companies from receiving a waiver when the increased costs of distribution are attributable to advertising and marketing expenses. This section permits the Council to grant a waiver if the development, production, and distribution costs total more than the pricing schedule rate, but it expressly exempts advertising costs from the equation. The pharmaceutical companies may see this as a restriction on their ability to advertise because it limits the amount of money that they can charge for a drug and therefore the amount that they can collect from sales to pay for their advertising campaigns. Companies may feel discouraged from marketing their products, knowing that their revenues will be limited by the pricing schedule and that they will no longer be able to pass their marketing expenses onto consumers. They may even view it as a penalty for advertising. Because, from the industry’s point of view, this amounts to a restriction on their ability to advertise, the potential plaintiffs likely will rely on the commercial speech doctrine if they litigate this section of the Act.

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87 W. VA. CODE §§ 29A-3-11, -12.
88 Id. § 5A-3C-6.
89 Id. § 5A-3C-13.
90 The companies likely will bring more than just a First Amendment-based attack; they may also challenge the Act on Commerce Clause and Preemption grounds as they have challenged the legislation of other states. U.S. CONST. art. I, § 8, cl. 3; U.S. CONST. art VI, cl. 2. However, these other attacks are beyond the scope of this Article.
91 W. VA. CODE § 5A-3C-6(h).
92 Id.
93 See infra Part IV.A.
The commercial speech doctrine protects communication made for the sole purpose of selling products or services. While commercial speech does not receive the strongest degree of protection that the First Amendment can give, it does receive a heightened level of scrutiny. In order for the Act to survive this heightened level of scrutiny, the Government will have to prove that the Act directly advances a substantial governmental interest and that it is no broader than necessary. If the court applies this test, the Act likely will survive because although the state has several less restrictive alternatives available, such as the clearinghouse and discount card programs, these programs are insufficient to satisfy the State’s goals. Furthermore, the court may not even need to go as far as applying the intermediate standard; the state has a strong argument that the First Amendment does not even apply here because this is not really a restriction on speech but rather it is the state’s exercise of its spending power.

Second, the pharmaceutical companies may challenge Section 5A-3C-13 and the Council’s proposed legislative rule as restrictions on their freedom of speech. Section 5A-3C-13 mandates reporting by pharmaceutical companies of their advertising expenses. The proposed legislative rule provides for the actual disclosure requirements as promulgated by the Council. The Act protects the information collected by the Council as confidential but permits the Council to release the companies’ data in aggregate form.

The pharmaceutical companies may view this as a restriction on their freedom of speech because the information, even if released in aggregate form, may create bad publicity that discourages the public from buying brand pharmaceuticals. The companies may feel compelled to advertise less in order to provide better-sounding statistics to the Council and thereby avoid the inevitable public censure on the industry. In the interest of avoiding this criticism and maintaining the confidentiality of this information, the companies may chal-

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95 That is generally reserved for situations in which the Government forbids a citizen from stating his or her beliefs or opinions, or in other words, when the government regulates the content of speech. Rodney A. Smolla, Nimmer and Smolla on Freedom of Speech § 2:62 (1998).
97 See infra Part III.A.
99 Id. § 5A-3C-5.
100 Rust v. Sullivan, 500 U.S. 173, 199 (1991) (holding that the Government may use its spending power selectively by choosing to fund one program instead of another and that this choice does not violate the First Amendment).
102 West Virginia Cost Management Council, supra note 84.
103 W. Va. Code § 5A-3C-13(c).
lenge these provisions under the First Amendment compelled speech doctrine - a doctrine that protects the right to remain silent - on the grounds that the government is essentially requiring the companies to release information to the public that the companies do not want to release. The companies likely will argue that the release of this information unduly discourages them from advertising, which regardless of its effect on the price of pharmaceuticals, is a protected activity.

Under the compelled speech doctrine, courts have applied either intermediate or strict scrutiny depending upon whether the disclosure requirement was content-based or content-neutral. For the Act to survive strict scrutiny, the Government must prove that the Act is narrowly tailored to further a compelling governmental interest. If the court applies intermediate scrutiny, the Government will only have to show that the Act is no broader than necessary and that it furthers an important governmental interest. Even if the court puts the Act to the strictest scrutiny, the Act likely will survive because it furthers the state’s interest in protecting public health and because government disclosure requirements have previously been found to be narrowly tailored restrictions.

III. APPLICABLE FIRST AMENDMENT STANDARDS: VITAMIN C OR A SOURCE OF STRESS ON THE STATE’S IMMUNE SYSTEM?

As the preceding Section discussed, the pharmaceutical companies may contest two sections of the Pharmaceutical Affordability and Availability Act. This Section explores the legal framework upon which the companies may base their challenge.

The First Amendment provides that “Congress shall make no law... abridging the freedom of speech, or of the press.” These freedoms are valuable because they encourage the free flow of information, which promotes per-

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106 Id.
107 Id.
108 See, e.g., Fla. Bar v. Went For It, Inc., 515 U.S. 618, 625 (1995) (stating that “States have a compelling interest in the practice of professions within their boundaries, and... as part of their power to protect public health, safety, and other valid interests they have broad power to establish standards for licensing practitioners and regulating the practice of professions.”).
110 U.S. CONST. amend. I. This right is extended to states by the Fourteenth Amendment, so state governments, like Congress, must also be mindful of the freedoms of speech and press. U.S. CONST. amend. XIV; see, e.g., 44 Liquormart, Inc. v. Rhode Island, 517 U.S. 484 (1996) (extending the limitations imposed on Congress by the First Amendment freedom of speech to state governments).
sonal self-fulfillment, leads to the attainment of truth through the exchange of ideas, fosters societal participation in social and political decision-making, and strikes a balance between stability and change in society.\footnote{Javitt et al., supra note 94, at 287 (citing Thomas I. Emerson, Toward a General Theory of the First Amendment, 72 YALE L.J. 877 (1963)).} The First Amendment creates a fundamental right, and therefore, any restrictions on the content of speech are subject to strict scrutiny to ensure broad protection.\footnote{Id.} This is the court’s most restrictive standard. In contrast, the court applies intermediate scrutiny, a slightly lower level of scrutiny, to content-neutral restrictions.\footnote{Rodney A. Smolla, Nimmer and Smolla on Freedom of Speech § 2:12 (2003) (citing United States v. Carolene Prods. Co., 304 U.S. 144 (1938)).} Both of these standards will be discussed in more detail below.\footnote{See infra pp. 19-28.}

Traditionally, the First Amendment has been used to protect the exchange of ideas and political, social, scientific, or artistic expression.\footnote{Javitt et al., supra note 94, at 254.} However, since the 1970s it has been extended to commercial speech – communication for the sole purpose of selling products or services.\footnote{Id.; Pittsburgh Press Co. v. Pittsburgh Comm’n on Human Relations, 413 U.S. 376, 385 (1973); Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, 425 U.S. 748, 762 (1976).} The Supreme Court of the United States has stated that the mere fact that a speaker’s only interest in speaking is a purely economic interest is not enough to deny that speaker of the First Amendment’s protection.\footnote{Thompson v. W. States Med. Ctr., 535 U.S. 357, 365 (2002); Va. State Bd. of Pharmacy, 425 U.S. at 762.} The commercial speech doctrine will be discussed below in Subsection A.

Additionally, the First Amendment has been used to protect the right to refrain from speaking.\footnote{See Ogden, supra note 104.} The First Amendment compelled speech doctrine prevents the government from requiring citizens to profess beliefs which they do not wish to profess publicly – or perhaps beliefs which they do not even hold – and from requiring citizens to make disclosures that impermissibly discourage speech.\footnote{Id. (citing Pac. Gas & Elec. v. Pub. Util. Comm’n, 475 U.S. 1 (1986); Brown v. Socialist Workers ’74 Campaign Commn., 459 U.S. 87 (1982); Miami Herald Pub. Co. v. Tornillo, 418 U.S. 241 (1974); Talley v. California, 362 U.S. 60 (1960); NAACP v. Alabama, 357 U.S. 449 (1958); W. Va. State Bd. of Educ. v. Barnette, 319 U.S. 624 (1943)).} The compelled speech doctrine will be discussed below in Subsection B.
A. The First Amendment Standard for Commercial Speech

The First Amendment proscribes the government from prohibiting speech based on its content.\(^\text{120}\) In other words, the Government cannot forbid speech simply because it disagrees with or disapproves of the message conveyed. There are, however, several exceptions to this general rule. Four categories of speech are excluded from First Amendment protection by definition: (1) obscenity, (2) fighting words, (3) incitement, and (4) defamation.\(^\text{121}\) These categories of speech are excluded because they have low social value, because they do not contribute to the exchange of ideas and the search for truth, and because the social interests in order and morality outweigh any benefit that they produce.\(^\text{122}\) Commercial speech was once excluded for similar reasons, but as of the 1970s it became a protected classification of speech.\(^\text{123}\)

In 1976, the Supreme Court of the United States held in *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council* that commercial speech, or speech that does nothing more than propose a commercial transaction, is protected by the First Amendment.\(^\text{124}\) In this case, consumers challenged the constitutionality of a Virginia law\(^\text{125}\) that forbade licensed pharmacists from advertising the prices of prescription drugs. The court found the law invalid because it was a complete ban on commercial speech, which the court found was not "so removed from any 'exposition of ideas' and from 'truth, science, morality, and arts, that it lacks all protection.'"\(^\text{126}\) In coming to this conclusion, the court considered the interests of the pharmacists in their business, the interests of the consumers in obtaining information that could mean the difference between being able to afford a prescription or not, and the interests of society in general in obtaining information necessary to make intelligent and informed decisions.\(^\text{127}\) In responding to the Board's fears that permitting advertising would precipitate a race to the bottom, damage the professional image of the pharmacist, and destroy the personal relationships between customers and their

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\(^{120}\) Javitt et al., *supra* note 94, at 287 (citing Boos v. Barry, 485 U.S. 312, 315 (1988)). However, it does not prevent the government from making some restrictions as to the time, place, and manner of the speech, as long as the restriction is justified without regard to the content, the restriction is narrowly tailored to serve a significant governmental interest, and there are other open channels for expression. *Id.* at 287 (citing Members of the City Council v. Taxpayers for Vincent, 466 U.S. 789, 808 (1984); Clark v. Cnty. for Creative Non-Violence, 468 U.S. 228, 293 (1984)).

\(^{121}\) *Id.* at 288 (citing RUSSELL L. WEAVER & ARTHUR D. HELLMAN, *THE FIRST AMENDMENT: CASES, MATERIALS AND PROBLEMS* 89, 106, 435 (2002)). Other forms of speech are also not protected such as perjury, criminal solicitation, and attempted bribery.

\(^{122}\) *Id.* at 289 (citing Chaplinsky v. New Hampshire, 315 U.S. 568, 572 (1942)).

\(^{123}\) *Id.*

\(^{124}\) 425 U.S. 748, 762 (1976).


\(^{126}\) *Va. State Bd. of Pharmacy*, 425 U.S. at 762.

\(^{127}\) *Id.* at 762-65.
pharmacists, the court noted that a complete ban on advertising is a paternalistic approach and that it does not directly affect the standards of professionalism.\(^{128}\)

The Supreme Court further clarified its standard for commercial speech in its opinion in *Central Hudson Gas and Electric Corp. v. Public Service Commission of New York.*\(^{129}\) In this case, the court invalidated a state ban on advertising by electric companies.\(^{130}\) The court articulated a four-prong test to determine the validity of restrictions on commercial speech.\(^{131}\) Under this test, the court considers (1) whether the speech is false or misleading or fosters illegal activity, (2) whether the state has a substantial interest in restricting the speech, (3) whether the restriction directly advances the state's interest, and (4) whether the restriction is no broader than necessary to satisfy the state's interest.\(^{132}\)

Applying this standard to the ban on electric company advertising, the court found that the State failed to meet two of the four prongs of the test.\(^{133}\) Considering the first prong, the court found that the Government did not argue that the ads were inaccurate or used to promote unlawful activity.\(^{134}\) Therefore, the first prong was not at issue. Second, the court found that the Government had substantial interests in both conserving energy and preventing energy rates from inflating.\(^{135}\) Third, the court considered the link between the advertising ban and the state’s interest in controlling costs.\(^{136}\) The court found that this link was at best speculative and tenuous and therefore failed the third prong.\(^{137}\) However, it found that the link between the prohibition on advertising and the interest in conserving energy was direct because the ads were intended – and likely to – increase the company’s sales.\(^{138}\) Finally, the court considered the fourth prong of the test – whether the restriction was no broader than necessary.\(^{139}\) The court found that the regulation banned all marketing by electric companies regardless of whether the marketed service or device caused an upward pressure on energy consumption.\(^{140}\) Thus, the ban failed the fourth prong of the test because it was overly broad and not narrowly tailored.

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\(^{128}\) *Id.* at 769-70.

\(^{129}\) 447 U.S. 557 (1980).

\(^{130}\) *Id.* at 558-560.

\(^{131}\) *Id.* at 564.

\(^{132}\) *Id.* at 564.

\(^{133}\) *Id.* at 569-71.

\(^{134}\) *Id.* at 566.

\(^{135}\) *Id.* at 568-69.

\(^{136}\) *Id.* at 569.

\(^{137}\) *Id.*

\(^{138}\) *Id.*

\(^{139}\) *Id.* at 569-70.

\(^{140}\) *Id.* at 570.
Many of the recent cases following Central Hudson\textsuperscript{141} turn on the third and fourth prongs of the analysis\textsuperscript{142} because in recent years, the court has begun to impose a higher burden on the Government with respect to these two prongs.\textsuperscript{143} Under the third prong, a restriction must directly advance the state interest to be valid, or in other words, it must be an effective way of achieving the state’s ends.\textsuperscript{144} For example, consider the analysis in Edenfield v. Fane, which turned on the third prong of the test.\textsuperscript{145} In Edenfield, the State of Florida had passed a ban on “direct, in-person, uninvited solicitation” by a CPA of people or entities not already clients.\textsuperscript{146} The court found this statute invalid because it failed the third prong of the Central Hudson test.\textsuperscript{147} The State put forth two interests in restricting this form of advertising: (1) protecting consumers from fraud and (2) maintaining actual CPA independence and the appearance of that independence in auditing, both of which the court found to be substantial interests.\textsuperscript{148} However, the court found that the State failed to put forth any evidence that showed that its regulation directly advanced these interests.\textsuperscript{149} In fact, the court found that the State actually put forth evidence which tended to contradict rather than support its arguments.\textsuperscript{150} Thus, the court found the statute invalid because the State failed to meet its burden with respect to the third prong.\textsuperscript{151}

Cases also frequently turn on the fourth prong, which asks whether the restriction is too broad.\textsuperscript{152} In order to survive the fourth prong of the commercial speech test, a restriction must be narrowly drawn.\textsuperscript{153} A restriction is narrowly drawn if it regulates only speech that poses a threat to the state’s interest.\textsuperscript{154} This does not mean that the restriction must be the least restrictive means

\begin{footnotesize}
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\item Id. The stability of the Central Hudson test is uncertain. In recent commercial speech cases, several Supreme Court Justices have noted that they would like to revisit the standard when the right fact set is raised. See, e.g., Lorillard Tobacco Co. v. Reilly, 533 U.S. 525 (2001) (finding that laws prohibiting advertisements of tobacco products near schools and playgrounds violated the First Amendment because they were overly broad); Edenfield v. Fane, 507 U.S. 761 (1993) (finding that a ban on in-person solicitation by CPA’s violated the First Amendment because it did not serve the state’s substantial interests).
\item See, e.g., Lorillard Tobacco Co. v. Reilly, 533 U.S. 525 (2001) (finding that laws prohibiting advertisements of tobacco products near schools and playgrounds violated the First Amendment because they were overly broad); Edenfield v. Fane, 507 U.S. 761 (1993) (finding that a ban on in-person solicitation by CPA’s violated the First Amendment because it did not serve the state’s substantial interests).
\item See also Javitt et al., supra note 94, at 292-94.
\item Id. at 764, 447 U.S. at 564-65.
\item Id. at 761 (1993).
\item Id. at 764 (quoting FLA. ADMIN. CODE ANN. r. 21A-24.002(2)(c) (1992)).
\item Id. at 763, 770-73.
\item Id. at 768-70.
\item Id. at 771-73.
\item Id. at 772.
\item Id. at 763.
\item Id. at 565.
\item Id.
\end{enumerate}
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available. Rather, the court will look for a reasonable "fit" between the means and the end of the regulation. The government must prove that it has "carefully calculated" the burdens imposed by the requirement and that those burdens are justified in light of the weight of the state's interest. Parties opposing the government restriction on speech, however, may prevail on this factor if they can show that there are "numerous and obvious less-burdensome alternatives" available.

For an example of a prong-four analysis, consider Thompson v. Western States Medical Center, in which the court's decision turned on the breadth of a federal restriction. In this case, the court considered a federal statute that permitted pharmacists, pharmacies, and physicians to advertise compounding services but forbade them from advertising the specific compounded drugs. The court applied the Central Hudson test and found the statute unconstitutional because it was not narrowly tailored. Clarifying its reasoning as to the fourth prong, the court explained that if the government can find a means that does not restrict speech or that restricts less speech, it must do so. The court stated, "If the First Amendment means anything, it means that regulating speech must be a last – not first – resort." The court supported its conclusion by listing several less-restrictive alternatives that the government could have used to achieve its goal of preventing large-scale manufacturing of the compounded drugs.

The Central Hudson test is currently the fundamental test for evaluating restrictions on commercial speech. Thus, the four-prong approach of this test will be the framework for evaluating § 5A-3C-6 of the Pharmaceutical Availability and Affordability Act, the section that provides for the implementation of the pricing schedule and offers waivers for innovation but not marketing expenses.

155 Bd. of Trustees of the State Univ. of N.Y. v. Fox, 492 U.S. 469 (1989).
156 Id. at 470.
157 Id. at 480; compare 44 Liquormart, Inc., v. Rhode Island, 517 U.S. 484 (1996) (finding that the state failed the fourth prong because there were several alternatives that would be more effective and would not regulate any speech), with Posadas de P.R. Assoc. v. Tourism Co. of P.R., 478 U.S. 328 (1986) (upholding a state regulation because the legislature made a reasonable choice regarding the best way to achieve its interest).
161 Thompson, 535 U.S. at 364-65.
162 Id. at 371.
163 Id.
164 Id. at 373.
165 Id. at 372.
B.  The First Amendment Standard for Compelled Speech

In addition to a challenge based on the commercial speech doctrine, the pharmaceutical companies likely will advance an argument that the Act compels speech in violation of the First Amendment compelled speech doctrine. The First Amendment not only protects people from governmental restrictions on speech, but it also protects their right to choose not to speak at all.\(^\text{166}\) Generally, this freedom is thought to protect a person from being forced to profess beliefs—political, religious, or other—against his or her will;\(^\text{167}\) however, the state and federal governments can neither compel the expression of opinions nor require a factual disclosure that impossibly burdens or discourages speech.\(^\text{168}\) On the subject of the difference between compelled speech and compelled silence—the traditional First Amendment protection—the Supreme Court of the United States has stated, "There is certainly some difference . . . but in the context of protected speech, the difference is without constitutional significance, for the First Amendment guarantees 'freedom of speech,' a term necessarily comprising the decision of both what to say and what not to say."\(^\text{169}\)

The court has articulated two policy theories that support the freedom from compelled speech—one based on the freedom of consciousness or belief and the other based on the theory that compelled speech may discourage a speaker from expressing his or her own views.\(^\text{170}\) In recognizing these two underlying theories, however, the court has made it clear that both compelled statements of opinion and compelled statements of fact can burden protected speech and constitute a violation of the First Amendment.\(^\text{171}\) The Supreme Court has also extended the doctrine to compelled commercial speech.\(^\text{172}\) In the

\(^{166}\) Ogden, supra note 104.


\(^{171}\) Riley, 487 U.S. at 797-98.

\(^{172}\) Javitt et al., supra note 94, at 295 (citing United States v. United Foods, Inc., 533 U.S. 405, 413-16 (2001); but see Johanns v. Livestock Mktg. Ass'n, 544 U.S. 550 (2005) (holding that the First Amendment does not prohibit the government from requiring a private association to fund government speech).
commercial speech context, compelled speech cases usually involve government requirements that certain information be disclosed on a label\(^{173}\) or requirements that an industry subsidize advertisements.\(^{174}\)

The court has relied on two different standards in analyzing compelled speech cases: strict scrutiny and intermediate review.\(^{175}\) Generally, the court will apply strict scrutiny when a person is compelled to make a statement of belief or fact against his or her will and the requirement is content-based.\(^{176}\) Under strict scrutiny, the government must prove that its regulation is narrowly tailored to further a compelling governmental interest.\(^{177}\) When a court applies strict scrutiny, it presumes that the law is invalid and in most instances will strike it down.\(^{178}\) However, where the government compels speech in a manner that is content-neutral and imposes only an incidental burden on speech, the court will apply intermediate review.\(^{179}\) Under intermediate review, the government must prove that its regulation is no broader than necessary and that it furthers an important governmental interest.\(^{180}\) A regulation is content-neutral, and thus subject to intermediate review, if it is passed for reasons unrelated to the content of the speech.\(^{181}\) Generally, though not necessarily, content-neutral laws regulate the time, place, or manner of speech.\(^{182}\)

The essential First Amendment case involving compelled disclosure of facts is Riley v. National Federation of the Blind of North Carolina, Inc.\(^{183}\) In this case, the court considered a North Carolina law\(^{184}\) that in part required professional fundraisers to disclose to potential donors the gross percentage of

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\(^{173}\) See, e.g., Int'l Dairy Foods Ass'n v. Amestoy, 92 F.3d 67 (2d Cir. 1996) (granting an injunction against the enforcement of a statute that required disclosure on dairy product labels if the product was created with the use of bovine growth hormones).

\(^{174}\) See, e.g., United States v. United Foods Inc., 533 U.S. 405 (2001) (invalidating a federal statute requiring mushroom farmers to subsidize generic advertising for the industry because the statute coerced speech); R.J. Reynolds Tobacco Co. v. Shewry, 384 F.3d 1126 (9th Cir. 2004) (holding that it was acceptable for the government to tax tobacco companies and use the tax dollars to criticize the tobacco industry).

\(^{175}\) Klein, supra note 105, § 2[a].

\(^{176}\) Id.

\(^{177}\) Id.


\(^{179}\) Klein, supra note 105, at § 2[a].

\(^{180}\) Id.


\(^{182}\) Id.

\(^{183}\) 487 U.S. 781 (1988). Riley is part of a line of cases dealing with charitable solicitations that recognize that speech is particularly critical to grass roots organizations and advocacy groups. The other cases in this line, however, deal with regulations that limit speech rather than compel it. See, e.g., Sec'y of State of Md. v. Munson, 467 U.S. 947 (1984); Vill. of Schaumburg v. Citizens for a Better Env't, 444 U.S. 620 (1980); Watchtower Bible & Tract Soc'y of N.Y., Inc. v. Vill. of Stratton, 536 U.S. 150 (2002).

revenues actually turned over to the charities within the past twelve months. The court held that this law violated the fundraisers’ First Amendment rights.\textsuperscript{185}

Although the court recognized that the solicitation involved commercial speech, it applied strict scrutiny rather than the intermediate standard traditionally applied to commercial speech because, in the case of charitable solicitations, the commercial speech was “inextricably intertwined” with fully protected speech.\textsuperscript{186} The court found that strict scrutiny was the proper standard because the statute was a content-based regulation because “[m]andating speech that a speaker would not otherwise make necessarily alters the content of speech.”\textsuperscript{187} Under a strict scrutiny analysis, a law, to be upheld, must be justified by a “compelling” governmental interest and narrowly tailored to effectuate that interest.\textsuperscript{188}

Applying this standard, the court in \textit{Riley} found that the law was invalid because (1) the state’s interest was not compelling and (2) the law was unduly burdensome and not narrowly tailored because other less restrictive options were available to the state.\textsuperscript{189} In its discussion of this second factor, the court offered as an example of a less restrictive option the state’s ability to publish the financial disclosure forms of each of the professional fundraisers.\textsuperscript{190}

The opinion in \textit{Riley} has been criticized as being overly broad in its application of strict scrutiny to protect people from the threat of compelled speech.\textsuperscript{191} In particular, the court’s statement that compelling speech necessarily alters the speech’s content has received much criticism.\textsuperscript{192} Attorney David W. Ogden, a First Amendment scholar, has noted that the court’s opinion in \textit{Riley} casts a shadow of doubt on numerous contexts in which the government compels speech, including disclosures in federal and state tax returns, disclosures by employers about wages paid and funds withheld, financial disclosures by securities issuers, and disclosures by pharmaceutical companies of drugs’ side effects, among others.\textsuperscript{193} Ogden and other critics suggest that disclosure requirements and other forms of government-compelled speech should not be protected to the same extent as compelled silence.\textsuperscript{194} Compelled speech, they argue, is in line with the principles that underlie First Amendment freedoms.

\textsuperscript{185} \textit{Riley}, 487 U.S. at 784.
\textsuperscript{186} \textit{Id.} at 796.
\textsuperscript{187} \textit{Id.} at 795.
\textsuperscript{188} \textit{See, e.g.,} Sable Commc’n \textit{v.} F.C.C., 429 U.S. 115 (1989).
\textsuperscript{189} 487 U.S. at 798-801.
\textsuperscript{190} \textit{Id.} at 800.
\textsuperscript{191} \textit{See generally} Ogden, supra note 104.
\textsuperscript{192} \textit{See id.}
\textsuperscript{193} \textit{See id.}
including “truth-seeking” and the “market place of ideas.” Unlike compelled silence, disclosures increase the flow of valuable information to consumers. Despite this negative treatment by commentators, Riley is still controlling law and must be applied in an analysis under the First Amendment doctrine for compelled speech.

IV. BAD MEDICINE OR THE PERFECT RX: AN ANALYSIS OF WV’S LEGISLATION UNDER THE FIRST AMENDMENT

The previous Section and its two Subsections laid the foundation upon which a challenge must be mounted. This Section of the Article builds upon that foundation by applying each of the First Amendment doctrines described above to the two sections of the West Virginia Pharmaceutical Availability and Affordability Act that will likely be challenged by the companies. Subsection A addresses the pricing schedule waiver-restriction and applies the Central Hudson test for commercial speech, concluding that this section of the Act is likely to survive the Central Hudson intermediate level of scrutiny. Additionally, it offers, as an alternative, an argument that the First Amendment does not even apply to this provision because it does not restrict speech. Because the State could win under either of these arguments, Subsection A concludes that the pricing schedule likely will survive a First Amendment challenge. Subsection B analyzes the Act’s disclosure requirements under the First Amendment doctrine for compelled speech and applies strict scrutiny. It concludes that this section of the Act will also survive First Amendment scrutiny, regardless of whether the court applies strict or intermediate scrutiny.

A. The Pricing Schedule and Waivers

Section 5A-3C-6 of the Act provides that the Council shall establish a pricing schedule for pharmaceutical drugs in order to maximize savings for people in the state. It further provides that the manufacturers can request waivers from the pricing schedule for drugs whose “development, production, distribution costs, and other reasonable costs” – but not marketing and advertising costs – are greater than the pricing schedule rate. Because the statute expressly denies a waiver for marketing costs, pharmaceutical companies may view this section as an inhibition on their ability to advertise. In other words, they may view it as a penalty for their speech because, in effect, it limits their ability to charge a price that reflects their actual expenses, which would include advertising. Thus, the pharmaceutical companies may argue that the Central Hudson commercial speech analysis must be applied.

195 See Ogden, supra note 104, at 369.
196 Id. at 370.
197 W. Va. Code § 5A-3C-6(d) (West 2006).
198 Id. § 5A-3C-6(h).
In opposition, the State may argue that the First Amendment does not apply to this section. It may argue that the statute does nothing more than provide a subsidy for development while denying reimbursement for marketing expenses.199 In other words, it permits the government to subsidize development expenses in order to encourage innovation, which is something that the State is not required to do. As West Virginia Pharmaceutical Cost Management Council member Kevin Outterson has analogized, the IRS is not required to give a deduction for advertising, and the public purse does not have to support speech by giving a tax deduction for political contributions.200

Although the State may not unduly restrict speech, it is not required by the First Amendment to subsidize companies’ advertisements.201 For example, in Rust v. Sullivan the Supreme Court of the United States considered a regulation that restricted the use of funds granted under Title X of the Public Health Service Act202 to “preventive” family planning services.203 The regulation forbade the use of funds for services related to abortions.204 Faced with a First Amendment challenge alleging that the regulation imposed viewpoint discrimination, the court held that the Act was constitutional.205 The court reasoned that the Government may use its spending power selectively by choosing to fund one program instead of another.206 The Government’s mere refusal to “subsidize the exercise of a fundamental right does not infringe the right.”207

Here, West Virginia has acted much like the Federal Government in Rust. It has chosen to subsidize some forms of activity relating to the manufacture and distribution of pharmaceuticals, namely development, production, and distribution. At the same time, it has chosen not to fund other related activities such as advertising. As in Rust, West Virginia has merely subsidized one activity to the exclusion of another.208 This is a choice which the Government is permitted to make and which does not constitute an infringement of the pharmaceutical companies’ First Amendment rights.209

199 Id.
203 Rust, 500 U.S. at 179.
204 Id. at 179-81.
205 Id.
206 Id. at 193.
207 Id. (citing Regan v. Taxation with Representation of Wash., 461 U.S. 540 (1982)).
208 Id.
209 Id.
The companies may rebut, relying on a case in which the Supreme Court of the United States found that a monetary restriction amounted to a penalty on speech. The companies may argue that the waiver restriction acts like a penalty. For example, in Speiser v. Randall the court considered a tax assessor’s denial of property tax exemptions to all people who refused to sign an oath stating that they did not advocate the overthrow of the Government. The court held that this restriction violated the First Amendment because it denied a tax exemption to people who engaged in certain forms of speech and thereby effectively penalized them for speaking.

However, West Virginia’s restriction is distinguishable from the restriction in Speiser. In Speiser, the Plaintiffs were World War II veterans who had received and relied upon the tax exemptions for years and who were suddenly denied the exemption when the Government revised the statute and added the oath. Here, however, the whole pricing schedule is something new, and thus the waiver-restrictions are not a change from a past practice under which the state subsidized advertising. Because West Virginia is not taking away a subsidy that the pharmaceutical companies had come to rely on, the restrictions should not be viewed as a penalty.

The State’s spending clause-based argument should be the winning argument in this case, and the analysis of the pricing schedule and waiver-restriction should stop here. However, even if the court determines that the waiver-restriction acts like a penalty, the Act may nonetheless survive under Central Hudson’s intermediate scrutiny standard.

Under the Central Hudson test, the court will first consider whether the regulation targets speech that is false or misleading or that fosters illegal activity. Section 5A-3C-6 does not do any of this; therefore, it regulates protected speech and the court must continue with the rest of the test. This prong likely will not be disputed by either party in litigation.

Section 5A-3C-6 may also survive the second prong, under which the court considers whether the State has a substantial interest in restricting the speech. The government’s interest, as stated at the beginning of the Act, is in controlling and lowering the cost of prescription drugs in the state to make them more affordable to residents. Stated more broadly, the State has an interest in the public health and welfare of its residents. By making prescription drugs less expensive by controlling prices with a pricing schedule, the State hopes to

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211 Id. at 518.
212 Id. at 514-515.
214 Id. at 564.
215 W. VA. CODE § 5A-3C-2 (West 2006).
216 Id.
make prescription drugs more available and to "maximize savings to the broad-
est percentage of the population of [the] state."\textsuperscript{217} It would be difficult to argue
that the health of citizens is not a substantial governmental interest.\textsuperscript{218} In fact,
the Supreme Court of the United States has stated several times that states have
a substantial interest in public health and welfare.\textsuperscript{219} Thus, \textsection\textsection 5A-3C-6 likely
will also pass the second prong of the Central Hudson test.

Under the third prong, the court considers whether the restriction di-
rectly advances the State's interest or, in other words, whether the restriction is
an effective way of achieving the State's ends.\textsuperscript{220} Here the waiver restriction
advances the state's goal of lowering prescription drug costs because it limits
the types of expenses for which the Council can waive the pricing schedule. By
placing this restriction on the Council, the Act limits the number of times that
the Council will be able to waive the pricing schedule and the dollar amount for
which the Council will be able to waive it. Therefore, more companies will be
subject to the price controls, and the overall cost of prescription drugs will de-
crease. The companies will be hard-pressed to argue that the waiver restriction
will not directly affect the cost of pharmaceuticals in the West Virginia.

However, the State will have to put up a stronger fight to survive the
fourth prong. Under the fourth prong, the court considers whether the restriction
is no broader than necessary,\textsuperscript{221} or in other words, whether the law is nar-
rowly tailored, whether there are no less restrictive means available, or whether
the law regulates speech that poses no threat to the State's interest.\textsuperscript{222} This
prong may provide the companies with their best opportunity to convince the
court to invalidate \textsection 5A-3C-6 under the commercial speech doctrine.

The companies may argue that the West Virginia law is too broad be-
cause it is an overarching restriction on all companies' ability to advertise and
because it discourages even advertising by companies who have smaller budgets
for marketing. The companies may compare this restriction to the law in Central
Hudson, which banned all advertising by electric companies in order to con-
trol energy consumption.\textsuperscript{223} The companies may argue that like the law in Cen-

\textsuperscript{217} Id. \textsection 5A-3C-6(d).
\textsuperscript{218} See generally Kevin Outterson, Health Care, Technology, and Federalism, 103 W. Va. L.
interest in "preserving the effectiveness and integrity of the FDCA's new drug approval process"
and the protection of the public health that it provides to be a substantial interest); Rubin v. Coors
Brewing Co., 514 U.S. 476, 485 (1995) (stating "the Government here has a significant interest in
protecting the health, safety, and welfare of its citizens by preventing brewers from competing on
the basis of alcohol strength."); Thomas v. Collins, 323 U.S. 516, 536 (1945) (naming public
safety and health as examples of substantial interests).
\textsuperscript{221} Id. at 566.
\textsuperscript{222} Id. at 569-570.
\textsuperscript{223} Id. at 558-559.
tral Hudson, which the court found too broad because it applied even to advertising by electric companies that did not increase energy consumption. West Virginia’s law applies too broadly because it reaches all pharmaceutical companies regardless of how much the company spends on advertising and marketing.

The State may argue in response that § 5A-3C-6 is not an overly broad ban on advertising because it does not prohibit any companies from spending money on advertising; rather, it only forces companies to pay for their own marketing schemes. Thus, it only targets those companies that are spending a great deal on advertising and inflating their prices in order to pay for the advertisements, not those that employ reasonable advertising campaigns and do not need to inflate their prices. The restriction does not necessarily forbid marketing; it simply refuses to pay for marketing when the state purchases prescription drugs.

Alternatively, the companies may argue that the West Virginia law fails the fourth prong because there are several less burdensome alternatives available. The companies may point to some of the other programs implemented by the Act, such as the clearinghouse program and the discount card program. These programs both further the state’s goal of lowering drug costs for residents and neither restricts the companies’ freedom to advertise.

The State may respond to the companies’ suggested less restrictive alternatives by arguing that these alternatives have already been tried and have proven to be insufficient to achieve the state’s goal. It will draw on the court’s analysis in Thompson, where the court, after listing off several alternatives to the government’s ban on advertising compound drugs, considered whether there was evidence that all of the alternatives would be insufficient to attain the government’s goal. In Thompson, the court found that the government failed to offer any such evidence.

In contrast, here the State will be able to supply evidence that these programs are insufficient. The State may explain that these two programs alone

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224 Id. at 570-571.
225 See Morgan Kelly, Drug-price Group Meets in City, CHARLESTON GAZETTE, Oct. 22, 2005, at 1A. West Virginia House Speaker Bob Kiss has stated:

West Virginia is not against drug companies making a profit . . . . the state sets a base price for drugs and will negotiate with firms until a suitable price is reached . . . . What we will not pay for is advertising . . . . [the pharmaceutical companies] can still spend $10 million on advertising, but we ain't paying for it anymore.

Id.
227 W.VA. CODE § 5A-3C-4 (West 2006).
228 Id. § 5A-3C-5.
229 535 U.S. at 373.
230 Id.
will not be sufficient to directly advance the State's interest because both programs merely extend already existing assistance programs.231 The programs do not improve upon the currently existing conditions. Furthermore, both programs reach only a limited sector of the population because only those people who meet the qualifications for the programs -- qualifications that are set by the pharmaceutical companies -- will have access to the more affordable prices.232

The clearinghouse, for example, merely created a central location for obtaining assistance program information; it did not alleviate the patients' obligations to meet each manufacturer's unique eligibility requirements and fill out each manufacturer's unique form.233 Likewise, the discount card program would add nothing new to the existing conditions. In fact, the addition of another discount card may actually make prescription drugs more difficult to obtain because it would add to the already existing confusion.234 Thus these programs are insufficient to effectively advance the government's interest in decreasing the cost of pharmaceuticals and making prescription drugs more available to the "broadest percentage of the population" of West Virginia.235 Because these programs are insufficient to achieve its stated interest, the State may argue that they are not satisfactory alternatives. Unless the companies can propose a sufficient alternative, the State should prevail on this prong.

The clearinghouse and discount card programs are insufficient to achieve the State's named interests. The State has clear evidence that the clearinghouse has already failed and that the discount card would not be effective. One part of the Council's duties under the Act includes studying the effects of these programs. The Council has published several reports explaining the fail-

231 W. VA. CODE § 5A-3C-4(a) (stating "brand pharmaceutical manufacturers shall create and implement a program to assist state residents who are low income or uninsured to gain access to prescription medications through existing private and public sector programs and prescription drug assistance programs offered by manufacturers.") (emphasis added); id. § 5A-3C-5 (stating "There is hereby established a discount drug program to provide low-income, uninsured individuals with access to prescription drugs from participating brand pharmaceutical companies through . . . a program that extends current brand pharmaceutical manufacturer prescription drug assistance programs.") (emphasis added).


235 W. VA. CODE § 5A-3C-6(d) (West 2006).
Thus Section 5A-3C-6 likely will survive the fourth prong of Central Hudson, and therefore, it will survive the entire Central Hudson test. Even if the court is not convinced that the First Amendment does not apply because of the State’s permissive discretion in using its spending power, the Act will nonetheless survive because it passes all four prongs of the Central Hudson test.

B. The Disclosure Requirement

In addition to the pricing schedule, Section 5A-3C-13, the section that provides for mandatory disclosure of advertising expenses, may face a First Amendment challenge. The speech allegedly regulated in this provision is the companies’ disclosure of, or more accurately the companies’ desire not to disclose, their marketing expenses. The statute requires the companies to provide detailed information about their marketing expenses to the government, and it permits the government to turn that information over to the public in aggregate form. The companies likely will argue that this section is unconstitutional because it discourages them from advertising by essentially compelling them to disclose to the public information to which the public may negatively respond by boycotting brand pharmaceuticals. If the companies argue that they are being forced to speak in a way that actually discourages them from speaking, the standard for compelled speech is the appropriate standard to apply.

Again, the State may argue that the First Amendment does not even apply here. The State may argue that the body of case law regarding compelled speech does not discuss confidential disclosures to the government, but rather it discusses government requirements that certain information or opinions be made public. Thus, the State will distinguish this disclosure requirement from those struck down by the court. For example, the State may distinguish this disclosure requirement from the disclosure requirement invalidated in Riley v. National Federation of the Blind of North Carolina, Inc. In Riley, the court struck

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237 W. VA. CODE § 5A-3C-13 (West 2006).

238 See, e.g., Int’l Dairy Foods Ass’n v. Amestoy, 92 F.3d 67 (2d Cir. 1996) (involving a government requirement that labels on dairy products disclose whether the product was made using bovine growth hormones). The distinction between disclosure to the Government and disclosure to the public is a small distinction. Other regulations involving disclosure to the Government have been challenged before. However, these regulations have been challenged on due process and privacy grounds rather than under the First Amendment. See, e.g., Planned Parenthood of Se. Pa. v. Casey, 505 U.S. 833 (1992) (holding that a requirement that facilities that provide abortions keep and submit records of abortions performed did not violate the due process clause); Whalen v. Roe, 429 U.S. 589 (1977) (holding that a public health regulation requiring recordkeeping of all prescriptions for controlled substances did not violate patients’ privacy interests).

down a state law that required professional fundraisers to disclose their profits to potential donors during solicitation calls.\textsuperscript{240} Here, in contrast, the State is requiring disclosure to the State, not to the public, for the purpose of the State studying the relationship between the problem of rising prescription drug costs and the costs of pharmaceutical advertising. Similar disclosure requirements are part of many bodies of law in this country including federal tax\textsuperscript{241} and securities regulations.\textsuperscript{242}

The companies may respond that regardless of who the disclosure is made to, it will discourage speech, and therefore, it invokes the protection of the First Amendment. An absence of case law applying the First Amendment to these disclosure requirements does not necessarily mean that the First Amendment does not apply. Furthermore, the companies may remind the court that the law provides that the State may make this information public in aggregate form.\textsuperscript{243} Therefore, the companies may argue that the law essentially requires public disclosure, and in this sense, it is like the law invalidated in Riley.

If the court decides that there is in fact a restriction on the companies’ First Amendment freedoms, it will first need to determine which standard to apply – intermediate or strict scrutiny. The proper standard is probably intermediate scrutiny; however, the Act is likely to withstand even the strictest degree of scrutiny despite the fact that so few restrictions survive strict scrutiny.\textsuperscript{244} To survive strict scrutiny, the State must prove that these two sections are narrowly tailored to further a compelling governmental interest.\textsuperscript{245}

The State may argue that it has a compelling interest in the public health of its residents. This argument likely will persuade the court as it has previously held in other opinions that public health may be a compelling government interest.\textsuperscript{246} Next the State will have to prove that its regulation is narrowly tailored to its interest in public health. The companies likely will argue that like the law in Riley, West Virginia’s law is unduly burdensome.\textsuperscript{247} In Riley, the court found that a state law requiring professional fundraisers to disclose their profit to potential donors was unduly burdensome because it hampered the fundraisers’ legitimate efforts to raise money for charity and it discriminated against

\textsuperscript{240} Id. at 784.


\textsuperscript{242} 17 C.F.R. § 210.5-02 (2005).

\textsuperscript{243} W. VA. CODE § 5A-3C-13(e) (West 2006).


\textsuperscript{245} Sable Commc’n v. F.C.C., 492 U.S. 115, 131 (1989).

\textsuperscript{246} See, e.g., Fla. Bar v. Went For It, Inc., 515 U.S. 618, 625 (1995) (stating that “States have a compelling interest in the practice of professions within their boundaries, and . . . as part of their power to protect public health, safety, and other valid interests, they have broad power to establish standards for licensing practitioners and regulating the practice of professions.”); Roe v. Wade, 410 U.S. 113, 163 (1973) (finding under the Due Process clause that maternal health was a compelling interest that can be protected by narrowly tailored legislation).

small or unpopular charities. Here, the companies likely will argue that West Virginia's law is unduly burdensome because it discourages all pharmaceutical companies from advertising regardless of the cost of the companies' ads and thereby denies people access to the beneficial information available in these ads. The companies may explain that advertising is beneficial because (1) it informs consumers of the availability of new drugs and their benefits and side effects, (2) it raises public awareness of diseases, and (3) it encourages patients to dialogue with their doctors about appropriate treatment. They may argue that West Virginia's law unduly burdens these beneficial activities from occurring.

The State likely will respond that unlike the law in Riley, West Virginia's law is not unduly burdensome. The State will argue that these benefits of pharmaceutical advertising will not be lost entirely because it is unlikely that a disclosure requirement would cause the whole industry to completely stop advertising. In other words, the companies' argument that the disclosure requirement will discourage pharmaceutical advertising is purely speculative. The health care industry is unique in that it does not respond to economic market signals like most other industries. Bad publicity relating to cost may not affect the pharmaceutical industry as it would other industries because in the pharmaceutical industry there are not always alternative choices of medicine and because people rely heavily on the advice of their doctors. Consumers generally lack the information they need to make decisions about their health care (for example the decision of whether to buy the more expensive or less expensive prescription). Consumers place a considerable amount of trust in their doctors to make the right decision for them. Therefore, consumers give up, to a certain extent, their power to speak with their pocketbook about their disappointment with the industry's waste of money.

Furthermore, the State will be able to support this argument with a second argument that its law is narrowly tailored because there are no less-restrictive alternatives available. The dicta in Riley provides helpful insight to this conclusion. In Riley, the court held that a law that required professional fundraisers to disclose financial statistics to potential donors was not narrowly tailored. However, the court stated in dicta that the Government could instead publish the fundraisers' financial disclosure forms and that that would be an

248 Id. at 799-800.

249 MARJORIE E. POWELL, PhRMA, PhRMA GUIDING PRINCIPLES ON DTC ADVERTISING 2-6 (2005), available at http://www.state.wv.us/got/pharmacycouncil/sec/default.cfm (follow the "PhRMA Guiding Principles on DTC Advertising" hyperlink under the heading "Documents from October 20, 2005 Meeting").


251 Id. at 500.

252 Id.

253 Id.

254 487 U.S. 781, 800.
acceptable, less restrictive means. Here, the West Virginia law does not even go as far as the court suggests it legally might; rather, the West Virginia law proposes to publish the information only in aggregate form, so as not to single out any one pharmaceutical company.

Furthermore, the Supreme Court of the United States has previously found that disclosure requirements “trench much more narrowly” on a speaker’s interests than do flat prohibitions on speech. In Zauderer v. Office of Disciplinary Council of the Supreme Court of Ohio, the court considered a state disciplinary council’s decision to reprimand an attorney who advertised his legal services as fee-free unless the client recovered, but who failed to disclose in the advertisement that the client may be liable for litigation costs. The attorney challenged the council’s decision as violative of his freedom of speech. The court held that the council did not violate the attorney’s First Amendment rights because the council, in compelling full disclosure, did not attempt to “prescribe what shall be orthodox in politics, nationalism, religion, or other matters of opinion or force [the attorney] to confess by word or act [his] faith therein.” The court noted that the difference between disclosure requirements and prohibitions on speech are material. In some instances compulsion is just as violative as a prohibition, but in this case the attorney’s interest in concealing this factual information was minimal because of the value of the information to consumers.

As in Zauderer, where the court permitted the State’s compulsion of information because of its value to consumers, here the information requested by West Virginia is equally valuable to consumers and to the State in its interest in learning more about the extent of pharmaceutical advertising expenses in West Virginia. The State’s choice to compel disclosure is narrowly tailored to this interest. Thus, Section 5A-3C-13 will likely survive regardless of whether the court applies the strictest form of scrutiny under First Amendment law or whether the court finds that the First Amendment does not even apply.

V. JUST WHAT THE DOCTOR ORDERED

With the rapid rise in the cost of prescription drugs across the United States, West Virginia is only one of several states searching for the “perfect prescription” to cure the problem and make prescription drugs more affordable.

255 Id.
258 Id. at 630-33.
260 Id. at 650.
261 Id. at 651.
and available to state residents. Some of the states’ solutions are new and innovative, such as West Virginia’s disclosure requirement,\(^{262}\) while others extend old health care cost-reducing programs and make them more efficient, like the national clearinghouse program run by the Partnership for Prescription Assistance.

As each state adds a new, powerful tool to its legislative scheme, PhRMA, the industry’s main United States lobbying organization, quickly responds to ensure that the new legislation does not dig too deep into the industry’s pocket. This is precisely what will happen when the West Virginia Pharmaceutical Cost Management Council’s disclosure regulation passes the Legislature or when the Council begins to enforce the pricing schedule. When either of these events occurs, the pharmaceutical companies’ likely challenge will include a First Amendment challenge. This Article is intended to serve as a roadmap for that litigation.

As explained in the Article, the court will probably apply the commercial and compelled speech doctrines. Under these doctrines and general principles of First Amendment analysis, the court is likely to conclude (1) that the pricing schedule is merely an assertion of the State’s control over its financial expenditures and not a provision that infringes on any First Amendment rights, and (2) that although the disclosure requirement may invoke the First Amendment, it does not violate the pharmaceutical companies’ First Amendment right to remain silent. Thus, the court is likely to conclude that both provisions survive the industry’s First Amendment challenge. If West Virginia’s legislation in fact survives the challenge, along with any other Constitutional attack that the industry may raise, then West Virginia’s law may become a model for legislative reform across the United States as other states adopt similar provisions to make prescription drugs more affordable for their state residents.

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\(^{262}\) W. VA. CODE § 5A-3C-13 (West 2006).