University of Virginia School of Law

Public Law and Legal Theory Research Paper Series 2014-34

May 2014

The Impending Collision Between First Amendment Protection for Commercial Speech and the Public Health: The Case of Tobacco Control

by

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ABSTRACT

Tobacco policy in the United States is being transformed from the laissez faire *approach (accompanied by a stunning history of industry deception) that prevailed for most of the twentieth century to a uniquely aggressive scheme of regulation reflected in the federal Tobacco Control Act of 2009, FDA regulations, and state and local tobacco control restrictions. The widely acknowledged aim of current national policy is to suppress consumption as a means of reducing tobacco-related morbidity and mortality. The nation's aggressive regulatory policy, explicitly framed as an alternative to prohibition, has four subsidiary goals: reduce initiation among young people; help smokers quit; reduce harm among people who are unable to quit; and protect non-smokers from environmental tobacco smoke. Although many innovations mandated by the Tobacco Control Act and by the FDA's implementing regulations have survived industry challenge, others have not. Two federal circuit courts have opined, respectively, that the First Amendment entitles tobacco companies to use colorful images to promote smoking while it forecloses the government from trying to discourage smoking by requiring the companies to include graphic health messages on cigarette packs. This incoherent conception of the First Amendment narrows the available policy space and forces the government to choose between prohibition and a tepid form of regulation. If tobacco were an illegal product, no one would have a right to promote its use and government would be free to use all available media to discourage it. Under these two misguided precedents, however, by allowing tobacco to remain legal, the government is constitutionally foreclosed from using potentially effective tools of regulation to protect the public health. One naturally wonders whether the First Amendment also forecloses meaningful public health regulation of marijuana if prohibition is abandoned.*

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To avoid unnecessary repetition, I begin by echoing Fred Schauer's opening remarks: Just as John Jeffries and Tom Jackson warned in 1979,[1] the Court's misguided decision in *Virginia Board of Pharmacy*[2] has invited aggressive judicial interference with a wide range of traditional commercial regulation. I also embrace Steve Shiffrin's observation that the creative, public-spirited advocates for the plaintiffs would have been dismayed if they had known that their victorious effort to invalidate allegedly paternalistic suppression of price competition for drugs would bring promotional advertising by tobacco companies within the protection of the First Amendment. They would have been flabbergasted if they had known that the Court's decision in *Virginia Board of Pharmacy* would be deployed by the tobacco industry to inhibit effective governmental efforts to inform smokers about the hazards of tobacco use, especially when it is needed to counteract decades of deception by the tobacco industry. Over the last decade, we have seen an ever-expanding array of implausible constitutional attacks on public health regulation become plausible – and even successful – due to a legally tenuous extension of First Amendment jurisprudence that had a weak foundation from the beginning.

We are on a collision course between public health and the First Amendment along two fronts at once: restrictions on advertising and mandated labeling requirements. I have been watching the Court blunder its way toward this train wreck for twenty years. There are a number of off ramps still available, and some have been mentioned by Steve Sugarman and Caroline Corbin in their papers for this conference. Rather than go over this same territory, I want to address the topic from a somewhat different perspective – not as a legal commentator but rather as an architect of tobacco policy. In brief review, I have served as a member and chair of a series of scientific studies of tobacco policy for the Institute of Medicine (IOM), a component of the National Academy of Sciences. *Growing Up Tobacco Free* (1994)[3] provided scientific support for key elements of the FDA's Tobacco Rule, proposed in 1995 and adopted in 1996, which, inter alia, limited tobacco advertising to a black-and-white, text-only format in venues with high youth exposure. *Clearing the Smoke* (2001)[4] addressed

[1] Thomas H. Jackson & John Calvin Jeffries, Jr., *Commercial Speech: Economic Due Process and the First Amendment*, 65 VA. L. REV. 1 (1979).

[2] Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc., 425 U.S. 748 (1976).

[3] INSTITUTE OF MEDICINE, GROWING UP TOBACCO FREE: PREVENTING NICOTINE ADDICTION IN CHILDREN AND YOUTHS (Barbara S. Lynch and Richard J. Bonnie eds., 1994) [hereinafter GROWING UP TOBACCO FREE].

[4] INSTITUTE OF MEDICINE, CLEARING THE SMOKE: ASSESSING THE SCIENCE BASE FOR TOBACCO HARM REDUCTION (Kathleen Stratton et al. eds., 2001) [hereinafter CLEARING THE SMOKE].

the scientific and policy challenges of regulating tobacco products to reduce health risks and provided a framework for eventual Congressional action. Finally, *Ending the Tobacco Problem* (2007)[5] set forth a blueprint for reducing tobacco use to a level that would no longer constitute a public health problem. The blueprint included a strong recommendation for large graphic warnings on tobacco packages.

Many of the recommendations of these reports are reflected in the landmark Family Smoking Prevention and Tobacco Control Act[6] (hereinafter the Tobacco Control Act) enacted by Congress in 2009. In crafting these recommendations, and justifying them, the respective IOM committees have been mindful of potential First Amendment challenges to tobacco regulation and have tried to anticipate these challenges by reviewing and synthesizing the evidence that would likely be needed to formulate these policies and defend them in court. Over the course of these discussions, I have contended that sensible regulation of tobacco advertising and labelling would survive constitutional challenges under the Court's post-*Virginia Board of Pharmacy* rulings if the cases were properly argued, notwithstanding pessimism of tobacco control advocates[7] and the views of many First Amendment commentators.[8] I admit that my optimism has been shaken by the recent decisions of the Sixth Circuit striking down the black-and-white, text-only advertising rule in *Discount Tobacco City* and *Lottery v. United States*[9] (hereinafter *Discount Tobacco City*) and of the D.C Circuit striking down the graphic warnings in *R.J. Reynolds Tobacco Company v. FDA*[10] (hereinafter *RJR v. FDA*). However, the game is still in its middle innings and I hope that the proceedings at this symposium will convince the Supreme Court to redirect the misguided path that the law of commercial speech now seems to be taking in the federal courts.

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[5] INSTITUTE OF MEDICINE, ENDING THE TOBACCO PROBLEM: A BLUEPRINT FOR THE NATION (Richard J. Bonnie, Kathleen Stratton, & Robert B. Wallace eds., 2007) [hereinafter ENDING THE TOBACCO PROBLEM].

[6] Pub. L. No. 111-31, 123 Stat 1776 (2009).

[7] *See, e.g.*, Ronald Bayer, Lawrence Gostin, & Daniel Marcus-Toll, *Repackaging Cigarettes – Will the Courts Thwart the FDA?*, 367 NEW ENG. J. MED. 2065 (2012); Ronald Bayer & Matthew Kelly, *Tobacco Control and Free Speech – An American Dilemma*, 362 NEW ENG. J. MED. 281 (2010); Kevin Outterson, *Smoking and the First Amendment*, 365 NEW ENG. J. MED. 2351 (2011).

[8] *See, e.g.*, Martin H. Redish, *Tobacco Advertising and the First Amendment*, 81 IOWA L. REV. 589 (1996). IOM committee member Cass Sunstein also expressed reservations as to the constitutionality of regulation of tobacco advertising. ENDING THE TOBACCO PROBLEM, *supra* note 5, at 324 n.6.

[9] *See* Disc. Tobacco City & Lottery, Inc. v. United States, 674 F.3d 509 (6th Cir. 2012).

[10] R.J. Reynolds Tobacco Co. v. FDA, 696 F.3d 1205 (D.C. Cir. 2012). *See generally* Nathan Cortez, *Do Graphic Tobacco Warnings Violate the First Amendment?*, 64 HASTINGS L.J. 1467 (2013) (discussing *Discount Tobacco City* and *R.J. Reynolds*).

I. THE POLICY CONTEXT

The transformation of tobacco policy in the United States since the 1980s is summarized effectively in *Ending the Tobacco Problem* (2007)[11] and need not be reviewed here. It is sufficient for my present purpose to say that the nation is still in the process of transition from the *laissez faire* approach (and a stunning history of industry deception) that prevailed for most of the twentieth century to a uniquely aggressive scheme of regulation that emerged during the first decade of the twenty-first century. The widely acknowledged aim of current national policy, even in tobacco-growing regions of the country, is to suppress consumption as a means of reducing tobacco-related morbidity and mortality. The policy is explicitly framed as an alternative to prohibition.[12] It has four subsidiary goals: reduce initiation among young people; help smokers quit; reduce harm among people who are unable to quit; and protect non-smokers from environmental tobacco smoke.

Although prevalence of adult smoking has been gradually declining for decades, it seems to have leveled off at around 20% in the population as a whole, accounting for more than 480,000 premature deaths every year.[13] Like so many other areas of population health in the United States, however, huge disparities in smoking (and consequent smoking-related morbidity and mortality) are associated with education and income – smoking prevalence among the least educated and least affluent segments of the population approaches 40%. The core message of the 2007 IOM report was that it is time to abandon "business as usual." Even if the entire nation were to put the "pedal to the metal" on all the traditional measures

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[11] *See* ENDING THE TOBACCO PROBLEM, *supra* note 5, at ch. 3.

[12] *See* ENDING THE TOBACCO PROBLEM, *supra* note 5, at ch. 4, especially pp. 152-54 ("[C]igarettes and other tobacco products are not ordinary consumer products. For no other lawful consumer product can it be said that the acknowledged aim of national policy is to suppress consumption. For alcohol, the generally accepted aim of national policy is to suppress underage drinking and excessive or otherwise irresponsible use by adults; reducing consumption per se is not the nation's goal. Indeed, in many respects, state and federal governments aim to facilitate alcohol consumption, such as by liberalizing access. . . . In terms of its goal, tobacco policy has more in common with the nation's policy toward marijuana and other illegal drugs than it does with policies pertaining to alcohol . . . ."). Under the Tobacco Control Act, FDA may not ban specific classes of tobacco products, cannot require total elimination of nicotine from tobacco products (Section 907(d)(3)), cannot require a prescription to purchase tobacco products (Section 906(d)(1)), and cannot ban sales in any particular type of outlet (Section 906(d)(3)). Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (2009).

[13] OFFICE OF THE SURGEON GENERAL, THE HEALTH CONSEQUENCES OF SMOKING—50 YEARS OF PROGRESS 33, 11 (2014), *available at* http://www.surgeongeneral.gov/library/reports/50-years-of-progress/full-report.pdf [hereinafter SURGEON GENERAL'S REPORT].

of tobacco control known to be effective (including public smoking bans, youth access restrictions, and excise tax increases), adult prevalence in 2025 will still be at least 10%, and the most likely projection is that prevalence will be around 16%.[14] Since 2007, in the wake of the prolonged recession, tobacco control expenditures have substantially eroded while industry promotional efforts have exceeded eight billion dollars annually.[15]

So, the IOM committee asked, what can be done to reduce tobacco smoking in a substantial way? What is the "end game" for the tobacco problem? Prohibition is politically impossible and morally unacceptable in the context of forty-two million addicted smokers.[16] It would be possible, in theory, to eliminate private manufacturing and distribution in favor of a state-operated monopoly, or to continue to allow private manufacture while distributing the product exclusively through a government-licensed purchasing monopsony and thereby eliminating brand identity,[17] but both of these approaches are cumbersome and politically infeasible. Instead, new post-*laissez faire*, non-prohibitionist policies have to be superimposed on the existing structure of the industry.

However, it is possible to envision and implement an aggressive and comprehensive regulatory approach within the existing structure that deploys all the policy levers at the government's disposal, including regulating tobacco products to reduce risk; raising the price by increasing excise taxes; curtailing industry pricing promotions; banning smoking in most public locations, thereby protecting non-smokers and reshaping social norms; funding media campaigns to discourage young people from initiating smoking and to help current smokers quit; curtailing youth access to tobacco products; restricting lifestyle advertising; requiring display of health warnings in advertising and product labeling; and many others. These interventions are all set forth in the blueprints for regulation in two IOM reports, one that focuses on harm reduction[18] and the other on reducing prevalence.[19] Many features of these blueprints are included in the Tobacco Control Act of 2009 and others are being implemented in varying degrees of intensity by states and localities.

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[14] ENDING THE TOBACCO PROBLEM, *supra* note 5, at 249-53.

[15] FEDERAL TRADE COMMISSION, CIGARETTE REPORT FOR 2009 AND 2010, at 6, 1 (2012), *available at* http://www.ftc.gov/sites/default/files/documents/reports/federal-trade-commission-cigarette-report-2009-and-2010/120921cigarettereport.pdf [hereinafter FTC CIGARETTE REPORT].

[16] SURGEON GENERAL'S REPORT, *supra* note 13, at i.

[17] Ron Borland, *A Strategy for Controlling the Marketing of Tobacco Products: A Regulated Market Model*, 12 TOBACCO CONTROL 374 (2003).

[18] *See* CLEARING THE SMOKE, *supra* note 4.

[19] *See* ENDING THE TOBACCO PROBLEM, *supra* note 5.

Just as tobacco regulation is in transition, so too is the tobacco industry itself. Ironically, the interests of manufacturers and regulators are gradually coming into closer alignment on developing and marketing reduced-risk products, although this effort raises huge scientific, ethical and regulatory challenges.[20] However, tobacco manufacturers and retailers are still deeply antagonistic to aggressive government efforts to curtail the prevalence of smoking. The industry spends billions of dollars each year trying to hold on to current smokers and recruiting new ones.[21] For this reason, a comprehensive approach to tobacco regulation necessarily includes policies designed to curtail and counteract the industry's promotional activity. The government aims first to restrict industry conduct intended to promote smoking and second, to utilize a wide range of media and channels of communication to discourage young people from initiating smoking and to encourage addicted smokers to quit.

II. KEY COMPONENTS OF THE BLUEPRINT

By way of example, consider three specific aspects of the blueprint for "ending the tobacco problem" set forth in the 2007 IOM report.

A. Restricting Advertising

Ending the Tobacco Problem reiterated a recommendation first made in the IOM's 1994 report on preventing adolescent tobacco use – that the federal government should restrict advertising to a text-only, black-and-white format. The 1994 report expressed concern about the constitutionality of a complete ban on advertising and decided that the "tombstone" approach would be more likely to survive a constitutional challenge as a "less restrictive alternative" to a complete ban as a necessary means of preventing youth initiation.[22] The committee concluded that an advertising restriction should focus exclusively on industry efforts to

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[20] These challenges are evident in the debate about regulating so-called e-cigarettes. *See, e.g.*, David B. Abrams, "Promise and Peril of e-Cigarettes: Can Disruptive Technology Make Cigarettes Obsolete?," 311 JAMA 135 (2014); Jean-Francois Etter, "Should Electronic Cigarettes Be as Freely Available as Tobacco?," 346 BRIT. MED. J. 16 (2013). FDA issued a Notice of Proposed Rulemaking on e-cigarettes, cigars and cigarillos, and hookahs on April 25, 2014. *See* Deeming Tobacco Products to be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products, 79 Fed. Reg. 23,141 (Apr. 25, 2014) *available at* https://www.federalregister.gov/articles/2014/04/25/2014-09491/deeming-tobacco-products-to-be-subject-to-the-federal-food-drug-and-cosmetic-act-as-amended-by-the.

[21] FTC CIGARETTE REPORT, *supra* note 15, at 1.

[22] *See* GROWING UP TOBACCO FREE, *supra* note 3, at 128-33.

associate tobacco use with attractive lifestyles and arouse other positive emotions toward tobacco products.[23] A narrowly tailored restriction would eliminate the promotional images and colors – which glamorize smoking and counteract anti-smoking messages – while vindicating the consumer's interest in receiving accurate information on the product and its price. The FDA's 1996 Tobacco Rule embraced this approach, while limiting its application to media with youth exposure greater than 15%.[24] Unfortunately, that restriction was nullified four years later when the Supreme Court held that the FDA has no authority to regulate tobacco products at all under the Food, Drug and Cosmetic Act in the absence of a therapeutic claim.[25]

Ending the Tobacco Problem took another look at the advertising issue in 2007.[26] In this report, the IOM further adjusted its recommendation to accommodate legitimate First Amendment concerns. Recognizing that color and image might sometimes be important in communicating accurate information about product characteristics, particularly the design of reduced-risk products, the report recommended that any subsequent advertising restriction to a black-and-white text-only format allow exceptions "for depictions of the product design as they relate to the health effects of smoking."[27] For example, the committee mentions advertising of products that purport to heat rather than burn tobacco as potentially showing "a diagram of the heating element, tobacco column, [or] specialized lighter[.]"[28] In addition, the committee emphasized that the restriction should not be limited to advertising with high exposure to youth. Instead, the committee emphasized that the government also has a compelling interest in encouraging current smokers to quit and in reducing industry promotions that aim to promote smoking.[29] In 2009, the Tobacco Control Act directed the FDA to re-promulgate the 1996 Tobacco Rule, including the ban on color and image advertising in media with substantial youth exposure.

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[23] *Id.* at 130-31.

[24] *See* C. STEPHEN REDHEAD & TODD GARVEY, CONG. RESEARCH SERV., R41304, FDA FINAL RULE RESTRICTING THE SALE AND DISTRIBUTION OF CIGARETTES AND SMOKELESS TOBACCO 10 n.44 (2010) (discussing the provisions of a 2010 reissue of the 1996 Tobacco Rule).

[25] FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120 (2000).

[26] ENDING THE TOBACCO PROBLEM, *supra* note 5, at 323-29.

[27] *Id.* at 327.

[28] *Id.* at 326.

[29] *Id.* at 325.

B. Transforming the Retail Environment

A second important component of the strategy recommended in *Ending the Tobacco Problem* is transforming the retail environment so that it becomes a channel for encouraging cessation (and as risk-reduced products are developed, encouraging their use) rather than for promoting smoking. The Tobacco Control Act, which codified many provisions of the Master Settlement Agreement and revived the 1996 Tobacco Rule, banned sale of tobacco products in vending machines, self-service displays, free samples and sale of cigarettes in packets of fewer than twenty.[30] Although the Act confers extensive authority on FDA to regulate retail distribution,[31] few steps have yet been taken by FDA or by states and localities to transform the retail environment from a channel for marketing tobacco products to a channel for promoting public health. If aggressively implemented, this approach would entail restrictions on point of sale advertising, mandated displays of cessation messages and cessation products, and regulation of pricing to 2-for-1 promotions and other pricing discounts.[32] Restricting the number of outlets has also been proposed.[33] Although Congress is forbidden by the Tobacco Control Act from banning tobacco sales by any particular category of retailer, states have the authority to do so.

C. Package Regulation and Graphic Warnings

A third area of regulatory innovation endorsed by the IOM report is package regulation. Again, the committee emphasized the fundamental proposition that the government has dual interests in curtailing the industry's use of cigarette packages to promote smoking while using the

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[30] Food and Drug Administration, Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, 21 C.F.R. § 1140 (2010), *available at* http://www.regulations.gov/#!documentDetail;D=FDA-1995-N-0259-0002.

[31] Section 906(d)(1) of the Tobacco Control Act provides: "The Secretary may by regulation require restrictions on the sale and distribution of a tobacco product, including restrictions on the access to, and the advertising and promotion of, the tobacco product, if the Secretary determines that such regulation would be appropriate for the protection of the public health." Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (2009).

[32] ENDING THE TOBACCO PROBLEM, *supra* note 5, at 299-308.

[33] *See* B.R. Loomis et al., *Density of Tobacco Retailers and Its Association with Attitudes Toward Smoking, Exposure to Point-of-Sale Tobacco Advertising, Cigarette Purchasing, and Smoking Among New York Youth*, 55 PREVENTATIVE MED. 468 (2012); Carol J. Schmitt et al., *Public and Policy Maker Support for Point-of-Sale Tobacco Policies in New York*, 28 AM. J. HEALTH PROMOTION 175 (2014). Notably, CVS pharmacies recently announced that they will no longer sell tobacco products. Stephanie Strom, *CVS Vows to Quit Selling Tobacco Products*, N.Y. TIMES (Feb. 5, 2014), http://www.nytimes.com/2014/02/06/business/cvs-plans-to-end-sales-of-tobacco-products-by-october.html?_r=0.

package as a channel for protecting the public health – i.e., communicating health-related information to smokers and encouraging them to quit.[34]

The tobacco industry has long used cigarette packaging to identify and market its products, and governments have long used cigarette packaging to convey messages about tobacco risk and exposure. As legal restrictions have increasingly reduced or eliminated media advertising, the importance of the package as a vehicle for promotion has increased. The packages carried by smokers serve as mobile advertisements for particular products. Anyone who walks into a convenience store and looks at the dazzling array of colors and images on cigarette packs will recognize that promotional displays of these colorful and attractive packages in retail outlets are important marketing tools. In response to the increasing importance of the package in promotion, governments have begun to exert more control over packaging characteristics for the dual purposes of limiting this form of marketing and communicating directly with consumers.[35]

One of the key elements of the IOM's recommended strategy of package regulation was to require at least 50% of the package for graphic images relating to the health dangers of smoking, modeled after the approach that had already been implemented in Canada, Australia and other countries.[36] The IOM considered "plain" (generic) packaging as an alternative to graphic warnings, but concluded that the public health impact of the graphic images would be greater than that achieved by generic packaging.[37] The Tobacco Control Act strengthened the federally

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[34] ENDING THE TOBACCO PROBLEM, *supra* note 5, at 289-99.

[35] As the IOM report points out:

> Among the reasons for regulatory interest in tobacco packaging are
> - communicating product information to consumers and potential consumers,
> - warning consumers about hazards and thereby discouraging consumption,
> - communicating other health information (e.g., cessation hotline numbers),
> - preventing smuggling (by requiring documentation of excise tax payment),
> - preventing misleading messages by tobacco companies and providing corrective information to counteract previous deceptions,
> - reducing promotional messages by tobacco companies as other avenues of advertising are curtailed, and
> - "denormalizing" tobacco products.
>
> The use of packages to convey tobacco-related health risks has a number of potential advantages over other forms of communication. The frequency of exposure is high. The messages are delivered at the moment a smoker desires another cigarette. The messages on packages also communicate information to the public at large, and not merely the consumer.

Id. at 289-90.

[36] *Id.* at 291-95.

[37] Richard J. Bonnie, *Letter to the Editor on "Tobacco Advertising and Freedom of Speech,"* 288 JAMA 1587 (2012). *See generally* Jonathan Liberman, *Plainly Constitutional: The Upholding of Plain*

mandated health warnings for advertising and packaging and conferred authority on the FDA to update and revise these warnings periodically.[38] In addition, Congress directed the FDA to require rotating color warnings covering 50% of the front and rear panels of the package "depicting the negative health consequences of smoking."[39] After researching the effectiveness of various images, the agency selected nine images to accompany the statutorily prescribed warnings in the Final Rule on Required Warnings for Cigarette Packages and Advertisements in June 2011.[40]

Two normative suppositions are implicit in the communications strategy recommended by the IOM in *Ending the Tobacco Problem*. One is that the government (and other organizations sponsoring messages aiming to reduce smoking and the harms associated with it) should be permitted to use whatever communications approaches, including content as well as formats and channels, that are likely to be effective in communicating health-related information and in discouraging smoking or promoting cessation. Effective communications often draw on affective responses as well as cognitive ones, and are likely to use colorful images. Conversely, the industry's communications with consumers in commercial messages and in packaging should be limited to conveying information about product characteristics, health effects and price. Purely promotional messages aiming to encourage tobacco use should be substantially curtailed, and industry messages purporting to convey health-related information should be regulated to assure that they are truthful and non-misleading. Images and color should be permitted in industry messages only when these features are plausibly necessary to communicate accurate information about product characteristics and health effects.

Tobacco Packaging by the High Court of Australia, 39 AM. J.L. & MED. 361 (2013) (discussing the requirements of Australia's plain packaging scheme and subsequent litigation); Andrew D. Mitchell & David M. Studdert, *Plain Packaging of Tobacco Products in Australia*, 307 JAMA 261 (2012) (discussing legal challenges to plain packaging regulations in Australia); Melanie Wakefield et al., *Do Larger Pictorial Health Warnings Diminish the Need for Plain Packaging of Cigarettes?*, 107 ADDICTION 1159 (2012) (comparing plain packaging to branded packs of cigarettes and concluding that plain packaging probably plays a superior role in undermining brand appeal and purchase intent).

[38] Family Smoking Prevention and Tobacco Control Act, § 202(d), Pub. L. No. 111-31, 123 Stat. 1776 (2009).

[39] *Id.* § 201(d).

[40] FDA Required Warnings for Cigarette Packages and Advertisements, 76 Fed. Reg. 36,628 (June 22, 2011) (to be codified at 21 C.F.R. pt. 1141).

III. THE COLLISION

The comprehensive regulatory approach formulated in *Ending the Tobacco Problem* is a potentially effective alternative to prohibition. The federal government set out to implement various aspects of this strategy in the Tobacco Control Act of 2009 and in regulations subsequently adopted by the FDA. Some of the implementing regulations have survived industry challenges and have gone into effect. Others have not, mainly because they are said to violate supposed First Amendment protections for commercial speech. In a word, two federal circuit courts have opined, respectively, that tobacco companies have a constitutional right to promote smoking and that the First Amendment forecloses the government from using the package to discourage it.

If these rulings prevail, the government would have one hand tied behind its back in its enlightened and no longer controversial effort to implement an aggressive regulatory strategy to suppress smoking. As forecast by Professors Jackson and Jeffries more than three decades ago,[41] this incoherent conception of the First Amendment narrows the available policy space and forces the government to choose between prohibition and a tepid form of regulation. If tobacco were an illegal product, no one would have a right to promote its use and government would be free to use all available media to discourage it. However, by allowing tobacco to remain legal, the government would be constitutionally foreclosed from using some of its most effective tools of regulation.

I readily concede that many constitutional protections, including the First and Fourth Amendments, trade off compelling interests, such as national security and crime control, for greater protection of free expression and privacy. However, no genuine First Amendment value justifies such a trade-off in the context of commercial advertising that aims not to inform consumers but to encourage them to use a demonstrably harmful product, thereby subverting a compelling public health objective. Nor does any genuine First Amendment value justify such a tradeoff when the only liberty interest being vindicated is the "right" to distribute a dangerous product without an accompanying government-directed message designed to tell prospective users exactly how dangerous the product is. In sum, important and long-needed innovations in tobacco control have put the Supreme Court's unthinking approach to commercial speech on a collision course with the public's health and the government's moral and

[41] *See* Jackson & Jeffries, *supra* note 1.

political obligation to protect it. It is time for the Court to find an off-ramp from this dangerous and misguided course. Fortunately, it is not too late.

IV. THE OFF-RAMP

Taken together, the rulings of the Sixth and District of Columbia Circuit Courts have held that the First Amendment protects the right of tobacco companies to use color and graphic images on the packaging of their products and in their advertising for the purpose of promoting use of these admittedly dangerous products while it also forbids the government from using graphic package warnings to discourage use of these products. The only way for the states and the federal government to avoid these impediments to effective and rational tobacco policy is to use their unquestioned constitutional authority to prohibit commerce in tobacco products altogether, denying more than 40 million adult smokers lawful access to the product. These rulings are implausible under any rational understanding of the history of the First Amendment or the internal logic of the constitution.

For the moment, however, these erroneous rulings stand, and the FDA is reconsidering the two invalidated regulations.[42] It is nearly certain that both regulations will be revised, reissued, challenged, and eventually reviewed by the Supreme Court. I remain hopeful that a majority of the Court will uphold them, ruling that the government may use graphic messages on tobacco packages to nudge users to quit and that tobacco companies have no constitutional right to persuade tobacco users to continue smoking. In explaining these rulings, the Court would not have to retreat from of any of its precedents or from well-established First Amendment principles. They would leave the companies entirely free to convey information about their products to smokers and to criticize the aggressive tobacco control policies.[43]

A. Advertising

The FDA's litigation strategy for defending revised rules requiring graphic warnings and advertising restrictions should be linked. The FDA should not fold its hand on the black-and-white text-only advertising restriction. It should redraft the invalidated advertising rule to respond to

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[42] Corinne Husten & Lawrence Deyton, *Understanding the Tobacco Control Act*, 381 THE LANCET 1570, 1576 (2013).

[43] In my view, the companies have a right to criticize tobacco policy in every forum and channel of communication except on the tobacco package.

the Sixth Circuit's concern that the restriction was not sufficiently tailored to serve the government's declared interest in preventing youth initiation of tobacco use by young people. I assume that the Court will continue to apply the *Central Hudson* test and will be as aggressive in doing so as it was in *Central Hudson* and *Lorillard Tobacco Company v. Reilly*.[44]

Two important adjustments should be made in the advertising regulation. First, as recommended by the IOM in 2007,[45] the agency should create an exception to the black-and-white, text-only restriction for any advertisement that uses color and/or images to convey accurate information about the characteristics or health effects of the product. Doing so would rectify the constitutional deficiency identified by the Sixth Circuit in *Discount Tobacco City*.[46] Second, the agency should explicitly declare that the restriction is designed to reduce initiation among young adults as well as among adolescents.[47] Even if the sole purpose of these restrictions is to reduce initiation, there is no constitutional magic about the age of 18. The government has a strong interest in curtailing initiation of smoking by anyone, but this interest is especially weighty, both epidemiologically and ethically, for adolescents and young adults because very few people begin smoking after their early 20s.[48] It is possible that a substantial proportion of states will increase the age of purchase for tobacco products to 21 over the next five years.[49]

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[44] 533 U.S. 525, 565 (2001) (striking down a Massachusetts ban on billboard advertising of smokeless tobacco products because it was not narrowly tailored to target messages to minors).

[45] ENDING THE TOBACCO PROBLEM, *supra* note 5, at 326-27.

[46] 674 F.3d 509, 561 (6th Cir. 2012).

[47] It is important to emphasize that the FDA advertising restriction cannot be expected to have a substantial impact on its own. Industry promotional efforts are increasing in social media and in direct-to-consumer electronic channels, as well as in point of sale "adult" venues. *See, e.g.*, Vinu Ilakkuvan, Jennifer Cantrell, & Donna Vallone, *'Action, Adventure, Special Offers.': How Marlboro Engages Consumers on Its Website*, TOBACCO CONTROL (2013). Donna Vallone, Youth and Young Adults: The Role of Media in Shaping Tobacco Use Behavior, Presentation to the Institute of Medicine (Apr. 10, 2014). However, the restriction interacts with other aggressive tobacco control measures to denormalize tobacco use and reducing exposure to messages that encourage its use.

[48] Among adults who ever were daily smokers, almost 90% began smoking before they were 18. Virtually no initiation of cigarette smoking and few transitions to daily smoking occur after 26. U.S. DEPT'T OF HEALTH & HUMAN SERVS., PREVENTING TOBACCO USE AMONG YOUTH AND YOUNG ADULTS: A REPORT OF THE SURGEON GENERAL 134 (2012), *available at http://www.surgeongeneral.gov/library/reports/preventing-youth-tobacco-use/full-report.pdf.*

The government also has an interest in helping current smokers quit and reducing the attractiveness of the product and denormalizing its use, but it need not rely on this interest because the proposed rule does not cover "adult" advertising venues.

[49] The Tobacco Control Act precludes FDA from raising the minimum purchase age above 18 (Section 906 (d)(3)(ii)) while allowing states to do so. Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1796 (2009). Section 104 (1) of the Act also directs the The Secretary of HHS "convene an expert panel to conduct a study on the public health implications of raising the minimum age to purchase tobacco products" and FDA has commissioned IOM to conduct

B. Graphic Warnings

In a 2-1 decision in *RJR v. FDA*, a divided panel of the D.C. Circuit struck down the graphic warnings rule, holding that it failed intermediate scrutiny under *Central Hudson*.[50] However, the panel members disagreed fundamentally about the premises of the constitutional analysis as well as every detail of its application. On one side, Judges Brown and Randolph made it abundantly clear that they think that the graphic warnings rule should be subject to the most demanding First Amendment scrutiny because it amounts to compelled ideological speech;[51] for them, the case is governed by *West Virginia State Board of Education v. Barnette*[52] and *Wooley v. Maynard*.[53] On the other side, Judge Rogers' dissenting opinion concludes, correctly in my view, that the rule should be upheld as a mandated disclosure under the rational basis standard used in *Zauderer v. Office of Disciplinary Counsel*[54] (or under *Central Hudson*'s intermediate scrutiny, if it is applicable).[55]

Preliminarily, it is important to emphasize that the tobacco companies in *RJR v. FDA* did not challenge the text of the strengthened warnings prescribed by the Congress (e.g., "smoking can kill you" and "tobacco smoke can harm your children") or the increased package space devoted to the warnings. They focused their objection solely on the graphic images.[56] While the textual statements would be subject to *Zauderer* scrutiny, the panel majority insisted that requiring cigarette packages to carry a graphic warning about the dangers of smoking compels the tobacco companies to convey the state's "ideological message" that people shouldn't smoke and therefore implicates the core value of the First Amendment:

> The Companies contend that, to the extent the graphic warnings go beyond the textual warnings to shame and

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this study, which is being chaired by the author. Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1841 (2009). The government also has an interest in helping current smokers quit and reducing the attractiveness of the product and denormalizing its use, but it need not rely on this interest if the rule does not cover "adult" advertising venues.

[50] 696 F.3d 1205, 1222 (D.C. Cir. 2012).

[51] *Id.* at 1211-12.

[52] 319 U.S. 624 (1943).

[53] 430 U.S. 705 (1977).

[54] 471 U.S. 626 (1985).

[55] *R.J. Reynolds*, 696 F.3d at 1237-38 (Rogers, J., dissenting).

[56] *Id.* at 1211. The companies also successfully objected to the portion of the rule that required each graphic message to include the telephone number for the National Cancer Institute's network of tobacco cessation quit lines. *Id.* at 1236-37.

> repulse smokers and denigrate smoking as an antisocial act, the message is ideological and not informational. "[B]y effectively shouting well-understood information to consumers," they explain, "FDA is communicating an ideological message, a point of view on how people should live their lives: that the risks from smoking outweigh the pleasure that smokers derive from it, and that smokers make bad personal decisions, and should stop smoking." In effect, the graphic images are not warnings, but admonitions: "[D]on't buy or use this product." No one doubts the government can promote smoking cessation programs; can use shock, shame, and moral opprobrium to discourage people from becoming smokers; and can use its taxing and regulatory authority to make smoking economically prohibitive and socially onerous. And the government can certainly require that consumers be fully informed about the dangers of hazardous products. But this case raises novel questions about the scope of the government's authority to force the manufacturer of a product to go beyond making purely factual and accurate commercial disclosures and undermine its own economic interest—in this case, by making "every single pack of cigarettes in the country [a] mini billboard" for the government's anti-smoking message.
>
> Even assuming the Companies' marketing efforts (packaging, branding, and other advertisements) can be properly classified as commercial speech, and thus subject to less robust First Amendment protections . . . how much leeway should this Court grant the government when it seeks to compel a product's manufacturer to convey the state's subjective—and perhaps even ideological—view that consumers should reject this otherwise legal, but disfavored, product?[57]

Compelling a person to endorse or utter a statement (e.g., "Live Free or Die") with which he does not agree, making the person a mere mouthpiece for the government's message, is deeply antithetical to the freedom of conscience. But Judges Brown and Randolph were carried away by their

[57] *R.J. Reynolds*, 696 F.3d at 1211-12 (internal citations omitted).

own rhetoric. In what sense is the interest of a global corporation in encouraging people to use a dangerous product that is inimical to the public health analogous to the demand of respect for individual dignity that lies at the very core of individual liberty? The government's effort to discourage smoking is not "ideological speech" in any meaningful understanding of that term. The package is being used as a vehicle for conveying a highly regulated dangerous product to a consumer. The company has no constitutionally protected interest in selling the product in the first place. Nor does the company have a constitutional right to use the package to encourage smoking.[58] Package regulation is a well-established component of product regulation. Just as the government can regulate the packaging of poisons to curtail dangerous use (rather than ban it or restrict access), so too can it regulate tobacco packaging as a means for curtailing dangerous use of tobacco products. The government has authority – if not a moral duty – to promote the health and safety of the population. No one any longer doubts the dangers of smoking and its huge public health consequences. The Supreme Court itself has characterized tobacco use as "the single most significant threat to public health in the United States."[59] Discouraging smoking is no more "ideological" than discouraging drunk driving, removing lead from paint or gasoline, or encouraging drivers to wear seatbelts.

The argument that a mandated graphic warning amounts to compelled ideological speech is a distraction. But how should the graphic warnings be analyzed in constitutional terms? The government argued that the justifying purpose of the graphic images is to increase the salience of the

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[58] Of course, the government may not suppress a tobacco company's billboard claim that "The Government should leave smokers and their cigarettes alone!" or even that "The Government is exaggerating the dangers of cigarettes!" These statements lie at the core of political expression protected by the First Amendment for individuals and companies alike. But one key question in tobacco package regulation is whether the companies have the right use *a cigarette package* for such statements. This issue is directly raised by "generic" or "plain" packaging, recently adopted in Australia and being considered elsewhere. *See supra* note 37. Setting to one side whether use of trademarks may be banned, adoption of plain packaging in the United States would not raise substantial First Amendment problems in my view. A tobacco package is not a recognized medium of communication similar to a billboard or a flyer. It is a channel for conveying products to consumers and package regulation is a standard feature of product regulation. If the companies want to criticize the government or object to restrictions on promotional advertising, for example, they can use traditional forums for political speech.

Quite a different intriguing question is whether the government could commandeer the package for messages criticizing the companies and their views. Pursuing this issue would stray far beyond the scope of this paper, but I think this question implicates broader questions about constitutional limitations on government speech. *See* R.J. Reynolds Tobacco Co. v. Shewry, 423 F.3d 906 (9th Cir. 2005).

[59] FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 161 (2000).

warnings, compared to the existing textual warnings, in order to enhance the prospective consumer's awareness of the dangers of smoking and to offset the accumulated effects of decades of industry deception. So understood, the new warning requirements might sensibly be characterized, in constitutional terms, as a corrective "mandated disclosure" (using pictures as well as words) necessitated by the tobacco industry's history of deceiving consumers and the failure of the previously required package warnings to communicate the health effects of tobacco use effectively. Assuming that heightening consumer awareness of and attention to the dangers of smoking is the justifying interest,[60] the regulation should be subject to the more deferential standard of judicial scrutiny applied to factual disclosures under *Zauderer*. If viewed in this way, the pictorial warnings are "reasonably related" to the government's interest in effectively conveying the negative health consequences of smoking to consumers. This was Judge Roger's analysis in *RJR v. FDA*[61] and it strikes me as sound.[62]

To sum up, heightened scrutiny is not warranted for mandated statements or images in advertising, inserts, or packages that are required by the government for the purpose of informing potential consumers about

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[60] The panel majority sows confusion about whether the relevant government interest for First Amendment purposes is to convey health information more effectively to smokers or to reduce smoking rates. *See R.J. Reynolds*, 696 F.3d at 1218. The majority pretends that they are separable and independent and that the first, although permissible, is being used pretextually to obscure the second, an impermissible (or at least questionable) one. *See id.* at 1221. Assuming that the government's *real* interest is in reducing rates, the panel concludes that the warnings cannot pass First Amendment scrutiny unless the government can show that prescribing the warnings will actually reduce smoking rates. *See id.* at 1218-21. The majority is somewhat gleeful in its effort to chastise the government for insisting that *Central Hudson* does not require it to show that prescribing the warnings will reduce smoking rates even though this is acknowledged to be the ultimate goal of the rule. *See id.* at 1221.

The government's position is perfectly straightforward, of course: As a policy matter, getting smokers' attention and reinforcing their desire to quit is a means of increasing cessation rates. Of course, it is one of many means of increasing cessation that must be included in a comprehensive tobacco control strategy. For First Amendment purposes, the justifying interest is "effectively communicating health risks to smokers and potential smokers." It is hoped and expected that doing so will interact with other interventions and programs to increase cessation and reduce smoking rates, but the government does not have to produce evidence that warnings have had this desired effect on behavior in order to justify the intervention. Were this required, no innovation in tobacco control aiming to discourage consumption in the United States could ever be justified unless and until it had already been adopted and proven to be effective in another country.

[61] *Id.* at 1233 (Rogers, J., dissenting).

[62] In *Discount Tobacco City & Lottery, Inc. v. United States*, a divided panel of the U.S. Court of Appeals for the Sixth Circuit rejected a facial challenge to the graphic warning requirement in Section 201(d) of the Tobacco Control Act under the *Zauderer* standard because pictorial images could be designed to convey information effectively and should be subject to the same level of deferential scrutiny as textual disclosures or warnings. 674 F.3d 509, 561 (6th Cir. 2012). This decision did not address the FDA rule itself or the actual images required by the FDA in the rule.

the characteristics and effects of the product. Preventing tobacco-related disease and death is a sufficient government interest to warrant mandated statements or images concerning the health effects of tobacco use and the benefits of quitting. Warnings are a standard feature of health and safety regulation. In effectuating these objectives, the government has an interest in communicating its messages effectively, and doing so in some contexts may warrant attention-getting words or images to make the message more salient.[63] Mandated informational requirements do not warrant the degree of scrutiny (assuming it is heightened at all) required for restrictions of commercial speech and certainly do not warrant the degree of scrutiny to which genuine compelled speech is subject. The sole aim of judicial oversight of mandated health disclosures is to assure that the government has a reasonable basis for judging the information to be accurate and non-misleading.[64]

One final observation is warranted. Perhaps neither of these two characterizations of the graphic warnings ("mandated factual disclosure" or "coerced speech") is an apt approach for constitutional purposes. A third approach is possible: The graphic warnings could be characterized (at least in part) as "persuasive" government speech, rather than a "mandated factual disclosure," aiming to counteract decades of deceptive and highly persuasive promotional speech by the tobacco companies, using a well-established form of commercial product regulation (packaging and labeling) as a channel of communicating with consumers. Doctrinally speaking, this formulation would present novel First Amendment issues. However, it does fit roughly within the paradigm of a compelled subsidy for government speech and the constitutionality of the warnings would perhaps be sensibly reviewed under intermediate scrutiny identified with the *Central Hudson* test rather than the more deferential scrutiny required under *Zauderer*. The heart of the policy issue is then clearly exposed: Is the government's interest in reducing tobacco use important?[65] Does the evidence show that these warnings are likely to make the dangers of

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[63] As noted earlier in text *supra* note 45-46, the companies have a similar interest when they are communicating information, and may also be entitled to use attention-getting words or images to convey information, e.g., in harm-reduction contexts.

[64] Judge Rogers is clearly right about the meaning and reach of the *Zauderer* principle – it is not limited to counteracting deception and it includes images as well as words if they are designed to communicate information. *See R.J. Reynolds*, 696 F.3d at 1222-23 (Rogers, J., dissenting).

[65] The panel opinion in *R.J Reynolds Tobacco Co. v. FDA* expressed skepticism "that the government can assert a substantial interest in discouraging consumers from purchasing a lawful product, even one that has been conclusively linked to adverse health consequences." 696 F.3d at 1218 n.13. The court grudgingly acknowledged that the Supreme Court "has at least implied that the government could have a substantial interest in reducing smoking rates . . . " *Id.*

smoking more salient and heighten smokers' resolve to quit and thereby substantially advance the interest in reducing tobacco use?[66] So understood, the companies' implausible claim of conscience, and its genuine economic interest in selling more cigarettes, recede to the background and the interests of the actual stakeholders – people who become hooked on tobacco as young people, wish they hadn't, and want to quit – come to the fore where they belong. The current evidence is more than adequate to satisfy the *Central Hudson* standard.

V. HIGH TIME TO CHANGE COURSE

If the impact of commercial speech jurisprudence on tobacco control were not reason enough to sound the alarm about the oncoming collision, consider the increasingly likely prospect of legalization of marijuana. Libertarian inclinations and the costs of prohibition have suddenly aroused interest in legalization. Regulatory regimes have taken effect in Colorado[67] and Washington.[68] But the histories of alcohol regulation and tobacco regulation provide clear cautionary tales about the likely public health consequences of giving private enterprises vested interests in promoting the use of marijuana. Indeed, a consensus has emerged among highly regarded drug policy specialists that any regulatory scheme for marijuana that replaces the current prohibition should avoid commercialization.[69] Alternatives include legalizing only cultivation for personal use and small-scale distribution, creating a state cultivation monopoly or a state-operated

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[66] As Judge Rogers demonstrated, the FDA's survey and findings from other countries clearly satisfy the *Central Hudson* standard. However, the majority insisted that the government had to show not only that the warnings are more salient than the previous warnings and that they increase smokers' intention to quit, but also that exposure to the new warnings increases cessation rates and reduces prevalence of smoking. *R.J. Reynolds*, 696 F.3d at 1218-21. Under this view, an innovation like the graphic warnings could never be constitutionally validated based on domestic data because the sort of longitudinal study needed to demonstrate an effect on cessation rates can be conducted only after the requirement has been promulgated. Moreover, aggressive measures of this kind are virtually never be adopted alone, and it would be nearly impossible to isolate the independent effects of the graphic warnings from the effects of the other measures.

[67] COLO. CONST., art. XVIII, § 16, (amended 2012).

[68] WASH. INITIATIVE 502 (Washington Marijuana Legalization and Regulation) (2012).

[69] *See* Jonathan Caulkins, Beau Kilmer, Robert MacCoun, Rosalie Pacula & Peter Reuter, *Design Considerations for Legalizing Cannabis: Lessons Inspired by Analysis of California's Proposition 19*, 107 ADDICTION 865, 869 (2011); Mark A.R. Kleiman, *Cannabis Policy: Moving Beyond Stalemate*, 106 ADDICTION 1194, 1195-96 (2011) (book review); Robert J. MacCoun, *What Can We Learn from the Dutch Cannabis Coffee House System?*, 106 ADDICTION 1899, 5-6 (2011); Robert MacCoun & Peter Reuter, *Assessing Drug Prohibition and Its Alternatives: A Guide for Agnostics*, 7 ANN. REV. L. & SOC. SCI. 61, 70-71 (2011); THOMAS BABOR, ET AL., ALCOHOL: NO ORDINARY COMMODITY (Oxford University Press 2003).

(or authorized) purchasing monopsony. If producers and retailers are licensed, as in Colorado[70] and Washington,[71] licensing should be conditioned in compliance with substantial restrictions on promotion.

There are certainly good reasons for reconsidering marijuana prohibition, and there are many good reasons to keep the government out of the business of cultivating and selling marijuana. But either of those options – retaining prohibition or a government monopoly – would be preferable to a model in which manufactures and retailers are allowed to promote use of legalized marijuana. If we have learned anything from the history of tobacco policy and post-Prohibition alcohol regulation, it is that formulating effective policies toward addictive drugs is a complicated policy problem. The regime for marijuana regulation should be carefully designed from the outset to protect the public health. The regulatory goals should be curtailing use by young people, discouraging heavy use, and containing the overall prevalence of use as a means of minimizing addiction and heavy, chronic use.

First Amendment obstacles to effective public health regulation of tobacco have clear and unmistakable implications for marijuana regulation. Once the product is legal, will marijuana manufacturers and retailers have a constitutionally protected interest in promoting its use? Would a restricted license that bars or restricts advertising and promotion amount to an "unconstitutional condition"? Once the product is legalized, does government's power to discourage its use become curtailed? Is marijuana packaging off limits to governmental efforts to discourage consumption or restrict the new industry's efforts to promote and glorify marijuana use? If this is so, states that otherwise might be inclined to abandon prohibition will surely be reluctant to do so.

The only difference between the current posture of marijuana policy and the current state of tobacco policy is that policymakers are considering a transition from prohibition to regulation in the case of marijuana and are trying to tighten regulation as an alternative to prohibition in the case of tobacco. If restricted licensing is a constitutionally permissible regulatory option for marijuana, why isn't an equivalent policy constitutionally permissible for tobacco?

Courts would be a lot less aggressive in questioning legislative and regulatory judgments about package regulation and advertising restrictions for tobacco products if they understood that curtailing the regulatory space

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[70] COLO. CONST., art. XVIII, § 16, (amended 2012).
[71] WASH. INITIATIVE 502 (Washington Marijuana Legalization and Regulation) (2012).

for tobacco control would also curtail the available regulatory space for marijuana policy.