HEALTH & MEDICINE

BOOTLEGGERS, BAPTISTS, AND E-CIGS

Unlikely allies from the tobacco wars try to fight off a game-changer.

BY JONATHAN H. ADLER, ROGER E. MEINERS, ANDREW P. MORRISS, AND BRUCE YANDLE

Durable regulation emerges most often when there are two distinctly different special interest groups that seek the same policy outcome. One group takes the moral high ground by pursuing a public-interested goal and gives the cooperative politician the ability to justify his actions on normative grounds. The other group, seeking the same policy outcome, is motivated by pecuniary interests, hopes to feather its nest, and is often willing to share some of the gains with the politicians who deliver the goods. Such collusion, intentional or not, is the basis for the "Baptist and Bootlegger" model of regulation developed by Bruce Yandle. Yandle originally discussed this model in *Regulation* ("Bootleggers and Baptists: The Education of a Regulatory Economist," May–June 1983) and recently coauthored a comprehensive book, *Bootleggers and Baptists* (Cato Institute, 2014), on the topic with his grandson, Adam Smith.

For example, both Bootleggers and Baptists like Sunday closing laws that shut down liquor stores one day a week. For Baptists, the law serves a high moral purpose. For Bootleggers, it eliminates competition one day a week. The fact that both interest groups seek the same policy outcome makes life more pleasant for politicians who seek to satisfy interest group demands for political favors.

Now consider the situation with electronic cigarettes (e-cigs) and their incumbent competitors: tobacco companies that produce and sell traditional cigarettes and drug companies that produce nicotine replacement therapies (NRTs). The U.S. cigarette market has been regulated, one way or another, since colonial times. Along the way, federal regulation—coupled most recently with the state attorneys general Master Settlement Agreement (MSA, about which we say more later)—effectively cartelized the industry, bringing increased profits to the industry and higher cigarette prices and reduced cigarette consumption throughout the nation. Falling cigarette consumption gladdened the hearts of health advocates, who fought for the elimination of tobacco products, while higher industry profits brought joy to tobacco company owners.

This happy Bootlegger/Baptist equilibrium is now threatened by the exploding sales of e-cigs, a new technology for delivering nicotine to all who want it without simultaneously bringing the harmful combustion-induced chemicals associated with burned tobacco.

Today, there are many e-cig producers and numerous small shops selling e-cigs and customized nicotine-dispensing products. It is a rapidly evolving market that has been relatively open to new entrants and innovation in product design. Given the

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quick growth in e-cig use (much of which comes at the expense of cigarette sales), previous political deals that stabilized tobacco industry profits are at risk. The major tobacco companies are understandably not sitting idle. They, too, have entered the e-cig marketplace and are responding in other ways to the new competition. The major pharmaceutical companies have not been idle either. The makers of smoking cessation products, including NRTs such as the nicotine patch and nicotine gum, are major players in the politics of tobacco and nicotine.

The producers of traditional nicotine delivery devices and NRTs are at work trying to stop the disruptive e-cig producers. These Bootleggers are joined by health advocates (Baptists) who raise questions about unknown potentially harmful effects that may be associated with e-cig use. Both groups—cigarette and NRT producers on the one hand, and health advocates on the other—would like to stop new e-cig producers or severely crimp their ability to compete.

THE CIGARETTE INDUSTRY AND THE MSA

The 1998 MSA between the nation's largest cigarette manufacturers and state attorneys general (AGs) heavily influences the structure of today's cigarette industry. The agreement included a series of regulatory restrictions on the industry that suppressed competition and reinforced the dominant market position of existing manufacturers.

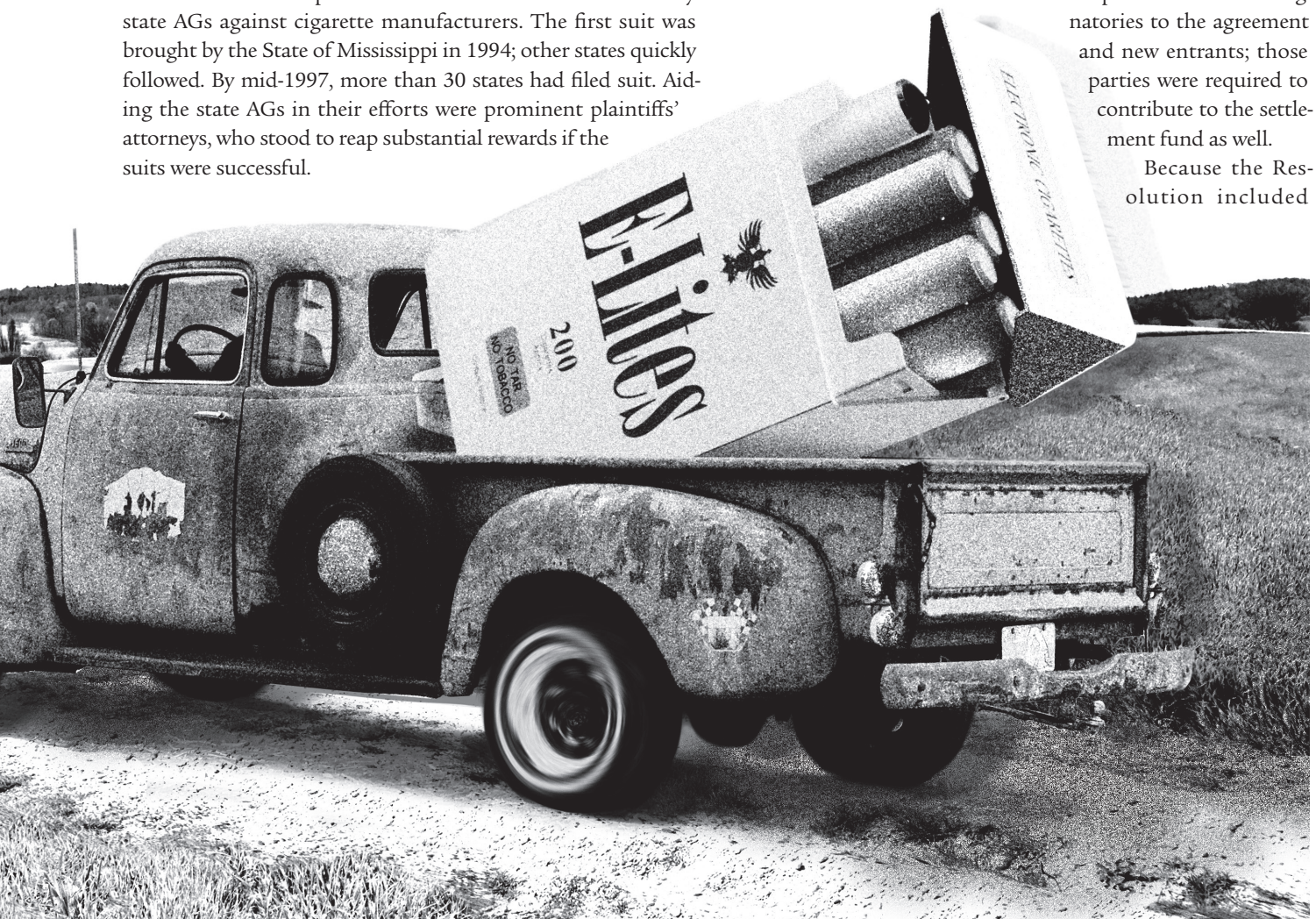
The MSA was adopted to resolve a series of lawsuits filed by state AGs against cigarette manufacturers. The first suit was brought by the State of Mississippi in 1994; other states quickly followed. By mid-1997, more than 30 states had filed suit. Aiding the state AGs in their efforts were prominent plaintiffs' attorneys, who stood to reap substantial rewards if the suits were successful.

Efforts by former smokers to seek damages from tobacco companies for the health consequences of smoking largely failed. Plaintiffs found it difficult legally to claim they had been harmed by the cigarette industry's deceptions about the health risks of smoking when every package of cigarettes carried a government-mandated warning. The tobacco companies also benefited from the widespread view among potential jurors that the dangers of smoking were well known.

The state lawsuits were different. The states sought reimbursement for the health care expenditures they incurred from caring for smokers under the Medicaid program. Unlike the claims brought by former smokers, these suits could not be deflected by turning the focus to the smokers' choices.

The cigarette manufacturers recognized the state AG lawsuits as a potential existential threat and sought a truce. In 1997, industry lawyers began negotiating with the AGs in an effort to buy "peace forever." By June they had reached a tentative agreement ("the Resolution") under which the cigarette companies agreed to pay $10 billion initially and $15 billion annually in perpetuity in return for protection from future lawsuits. The result was that cigarette consumers bore much of the cost in the form of higher cigarette prices. The Resolution also provided for limited U.S. Food and Drug Administration regulation of the industry and contained provisions protecting participating cigarette companies from non-signatories to the agreement and new entrants; those parties were required to contribute to the settlement fund as well.

Because the Resolution included



changes in federal law (such as legislative authorization of FDA regulation of cigarettes), it needed congressional approval. Although the Resolution promised total payments well in excess of $300 billion, antismoking activists thought the deal was insufficient, particularly because of the limits on litigation and federal regulation. Moreover, all the payments were to go to the participating states, leaving the federal government with nothing. Not surprisingly, Congress sought a share of the benefits, adding a $1.10 per pack increase in federal cigarette taxes. This was too much for the industry to stomach. The cigarette companies opposed the legislation authorizing the Resolution and it failed to pass.

Both the state AGs and the cigarette manufacturers still wanted a deal. Secret negotiations between several AGs, plaintiffs' lawyers, and cigarette industry attorneys produced a new agreement, the MSA. After its release in late 1998, it was quickly endorsed by 46 state AGs. (The remaining four states had already reached separate settlements with the cigarette companies; these were preserved under the MSA.)

Like the Resolution, the MSA promised substantial payments to the states by the then-four dominant cigarette companies, which the companies planned to fund with cigarette price hikes. Like the Resolution, the MSA would protect participating cigarette companies from competition and restrict industry advertising and promotional efforts. Unlike the Resolution, the MSA did not green-light FDA regulation or offer federal immunity from suit. As a consequence, the MSA, unlike the Resolution, did not need congressional approval. As a consequence, the AGs, plaintiffs' lawyers, and tobacco companies were able to cut Congress out of the deal.

The heart of the MSA was the promised payment of $206 billion by the four participating cigarette companies to the participating states. Those payments would be tax deductible and the costs would be paid by consumers in the form of higher cigarette prices. (Because cigarette consumption is highly price inelastic, the cost of the price increase was largely borne by consumers rather than producers.) The MSA presented state legislatures with a simple choice: either accept the MSA, in which case they would be able to spend their state's share of the billions of dollars raised from smokers, or reject the proposed statute and their states' smokers would still pay the higher prices necessary to fund the deal but they would lose their claim on the money. Not surprisingly, every state legislature took the money.

Responsibility for the payments was allocated among the cigarette companies in proportion to their current market share, thereby reducing the incentive for the participating cigarette companies to engage in price competition to increase their respective market shares. The structure of the MSA thus provided a powerful incentive for each company to be satisfied with the status quo.

The MSA also attempted to protect the major cigarette companies from new competition. At the time of the agreement, the four participating cigarette companies accounted for about 99 percent of domestic cigarette sales. Increasing cigarette prices to pay for the settlement risked a loss of market share to marginal competitors or new entrants. Therefore the MSA provided that for every percent of market share over 2 percent lost by a participating cigarette manufacturer, the manufacturer would be allowed to reduce its payments to the states by 3 percent, unless each participating state enacted a statute to prevent price competition from non-participating manufacturers (which each state did). The statutes require non-participating cigarette producers to make payments equal to or greater than what they would owe had they been participants in the agreement, to eliminate any cost advantage.

The MSA also included restrictions on cigarette marketing practices agreed to by the participating producers. The advertising limits were portrayed as a public health measure because they reduced advertising that could influence young adults and teens. The limits also reinforced the anticompetitive nature of the MSA by making it more costly for new brands or entrants to secure market share through promotional efforts.

The MSA's cartel-reinforcing provisions sufficiently suppressed competition to enable cigarette companies to take advantage of the price inelasticity of cigarette demand and obtain record profits. This made it possible for the major cigarette manufacturers to increase prices by more than was necessary to make the mandated MSA payments.

POST-MSA REGULATION

Although the MSA provided the dominant cigarette producers with some protection from competition, it did not have the force of federal law. Antismoking groups still wished to see increased federal regulation of cigarettes. And the cigarette industry was happy to go along if such regulation would reinforce the constraints of the MSA, deflect further tort litigation, and preempt some state and local regulation. Altria, the parent company of the nation's largest cigarette manufacturer, Philip Morris USA, in particular sought legislation granting the FDA authority to regulate cigarettes and other tobacco products. It spent years urging the passage of a federal tobacco regulation law that could preempt additional waves of tort litigation and help to suppress competition.

The Family Smoking Prevention and Tobacco Control Act of 2009 (FSPTCA) granted the FDA authority to regulate cigarettes and other tobacco products under a new regulatory regime tailored to the industry. The FSPTCA created a new division within the FDA—the Center for Tobacco Products—financed by fees on tobacco manufacturers. The act also barred flavoring regulated cigarettes other than with menthol, authorized the FDA to set product standards for cigarettes, and imposed more explicit warning labels on tobacco products. It limited cigarette advertising generally and imposed additional specific restrictions on the marketing of "modified risk tobacco products"—that is, non-NRT tobacco products that present reduced health risks—and created a mechanism through which the FDA could assert regulatory authority over nontraditional tobacco products, including e-cigs. The FSPTCA also created a requirement for premarket approval

of all new tobacco products unless the manufacturer could demonstrate that the new product was substantially equivalent to a product marketed prior to February 15, 2007.

The FSPTCA's regulatory provisions apply to cigarettes, cigarette tobacco, smokeless tobacco, and roll-your-own tobacco. The law provided the FDA the authority to subject other products "made or derived from tobacco" and "intended for human consumption" to its regulatory regime. Specifically, the FDA may "deem" other such products to be regulated "tobacco products" under the act. Such products become subject to many of the act's requirements, including the prohibition on adulterated or misbranded products, mandatory manufacturer registration and content disclosure requirements, restrictions on modified risk claims, and mandatory premarket review of products marketed after February 15, 2007. In April 2014, the FDA proposed deeming a wide range of products to be "tobacco products" under the FSPTCA, including e-cigs that contain nicotine derived from tobacco.

E-cig regulation is favored by a "Bootleggers and Baptists" coalition of health advocates, tobacco companies that see their market threatened, and state governments that worry about the loss of tobacco tax revenue.

FUTURE OF THE E-CIG MARKET

A Bootleggers and Baptists coalition favors the regulation of e-cigs. The coalition is composed of the tobacco companies (Bootleggers) that see their market threatened by a new product, health advocates (Baptists) who oppose e-cigs and wish to see them strictly regulated or prohibited, and state governments (Bootleggers) that have sold bonds backed by tobacco tax revenue that are threatened by the decline in cigarette sales.

Baptists/ Tar and other combustion products inhaled when smoking cigarettes are a cause of lung cancer and other health problems associated with smoking. E-cigs eliminate these primary known health dangers to smokers. The problems caused by secondhand smoke are also greatly reduced because e-cigs only produce vapor, rather than smoke. Most e-cigs deliver measured doses of nicotine, the addictive substance in tobacco. Users can, depending on the brand purchased, choose the dose level preferred. Vapor e-cigs are also available without any nicotine content.

Private and public health officials have long assailed cigarettes, as the MSA attests. They are the Baptists in this story—those concerned for the health of others. Based on what is known about the health effects of e-cig use, it would seem e-cigs might be hailed as an advance in public health insofar as they offer cigarette smokers a safer product. Even small reductions in the number of smokers or the amount of tobacco products smokers consume would likely produce substantial gains for public health. Yet e-cigs have been greeted with scorn by health researchers who focus on what is not known about e-cig health effects rather than what is known.

There are studies that find e-cigs to be beneficial for public health. A comprehensive report about e-cigs produced by Public Health England (the research arm of the United Kingdom's Department of Health) found e-cigs significantly less harmful than other tobacco products. Similarly, the Parliament Office of Science and Technology found e-cigs to be a good alternative to cigarettes from a public health standpoint but noted that some brands of e-cigs tended to be unreliable in dosage and had inadequate labels. These reports, like some others, find e-cigs to be a great improvement over other nicotine delivery devices, especially traditional cigarettes. While many writers disdain nicotine addiction, the prevailing view in the literature appears to be that "nicotine is not a significant health hazard."

Despite the emerging evidence that e-cigs reduce the risk from tobacco use, large cigarette manufacturers have begun to place detailed health warnings on their e-cig products, including messages that warn of the potential dangers of nicotine. Altria, for instance, has a warning that reads, in part, "Nicotine is addictive and habit forming, and is very toxic by inhalation, in contact with the skin, or if swallowed." These warnings are far more explicit than those required on cigarette packages, leading some to believe they are part of a cynical business strategy. The adoption of such labels may make the larger companies appear more responsible than smaller companies that do not place equivalent labels on their products and could help build support for the regulation of e-cigs—regulation that could work to the larger cigarette manufacturers' advantage.

Bootleggers/ E-cigs are a substitute for traditional cigarettes for some smokers. Thus e-cigs are a threat to the traditional cigarette industry. For this reason, traditional cigarette manufacturers have an incentive to either enter the e-cig market themselves, suppress competition from upstart e-cig manufacturers, or both. As one would predict, cigarette manufacturers have pursued both strategies, developing or acquiring their own lines of e-cig products and supporting regulatory measures that could suppress competition.

Altria, which produces Mark Ten e-cigs, has urged the FDA to regulate "all currently unregulated tobacco products." Among other things, Altria has urged the FDA to subject all such products to premarket review requirements. Such requirements would particularly burden smaller firms and new market

entrants, to the advantage of the tobacco giants. R. J. Reynolds Tobacco, the nation's second-largest cigarette manufacturer, has also urged greater federal regulation and supported the FDA's assertion of authority over e-cigs. Specifically, R. J. Reynolds has called upon the FDA to prohibit all Vaporizers/Tanks/Mods (VTMs) and all "open-system vapor products that do not attempt to "look like" cigarettes. Even though such systems can be used without nicotine, Reynolds argues that such products "create unique public health risks." Such products also appear to be increasingly popular and to pose the greatest competitive risk to established market players.

Just as the MSA served to protect the dominant cigarette manufacturers from smaller producers and new market entrants, extensive regulation of e-cigs—including limits on advertising and requirements that new e-cig brands or products become subject to an extensive permitting or pre-approval regime—could make it more difficult for newer and smaller e-cig manufacturers to compete. Larger, more established firms would have an easier time complying with such requirements than their newer and smaller competitors.

Tobacco-related state revenues appear to have peaked and seem likely to fall further in the future, creating uncertainty about payments that states must make to holders of bonds securitized with tobacco MSA revenues.

E-cigs are also a potential substitute for other products that may satisfy smokers' desire for nicotine. For some years now, NRT products (nicotine gum, lozenges, patches, and inhalers) have been the primary way smokers get nicotine doses without the unhealthy side effects of traditional cigarettes.

Pharmaceutical companies that make NRT products, such as GlaxoSmithKline (GSK), are among the Bootleggers in our story. They have benefitted from government encouragement that smokers use their products to aid in smoking cessation and government limitations on information on tobacco harm reduction through the use of e-cigs or smokeless tobacco products. Insofar as e-cigs are an alternative for smokers to satisfy their nicotine cravings, they are a threat to the profitability of NRT products. This is particularly so given recent research suggesting that NRT products do not help many smokers quit.

Unsurprisingly, GSK and other NRT manufacturers have pushed for greater regulation of e-cigs, in some cases calling for them to be as extensively regulated as medical devices. In comments to the FDA, GSK contended that e-cigs are "recreational" and "have not been proven to help smokers quit." (GSK's products, on the other hand, are described as "medicine," but appear to be no more effective at helping smokers quit.) According to GSK, e-cigs should be treated as the equivalent of cigarettes for regulatory purposes and be subject to the same advertising and other restrictions as traditional tobacco products.

Government revenue / State governments appear to be Bootleggers in our story as well. Tobacco sellers have become, in effect, tax collectors. As discussed earlier, the 1998 MSA established a large and continual flow of revenues to jurisdictions that it covered. On the date of the settlement, it was estimated that a total of $229 billion would be paid to state treasuries from 1998 to 2025.

MSA payments to the states were based on a negotiated formula that reflected individual state smoking rates, the level of cigarette taxes, Medicaid, and other health care expenditures. In 2002, MSA payments to the states were $7 billion; state tobacco excise taxes added $9.2 billion. By 2012, MSA payments fell to $6.2 billion because even though the MSA included an inflation adjustment, the decline in cigarette consumption has more than offset the annual adjustments. Excise revenues, however, increased to $17 billion because states raised tobacco excise taxes. As a result of those offsetting trends, total tobacco-related state revenues appear to have peaked and seem likely to fall further in the future, creating uncertainty about payments that states must make to holders of bonds securitized with tobacco MSA revenues.

Some states securitized all or part of the MSA cash flow by selling tobacco revenue bonds so they could immediately spend the present value of the future revenue. The sale of tobacco bonds created a new group of Bootleggers—the bondholders and the state agencies that issued the bonds—with intense interest in the future fortunes of the tobacco companies, their sales, and any competitor that might reduce those revenues.

Tobacco bonds were issued by 18 states and the District of Columbia, through 34 separate bond issues that generated $46 billion. As of 2014, debt outstanding, which includes subsequent issues for refinancing old debt, is reported to be $94 billion. Included in that total is a special bond category called capital appreciation bonds (CABs) that require low annual payments until maturity, when a large balloon payment must be made. CABs, issued by nine states, the District of Columbia, and a number of counties will require a $64 billion payoff when they mature. Some states that issued CABs have already experienced reduced credit ratings based partly on declining tobacco revenues.

From 2005 to 2012, the percent of the adult population that smokes fell 13.4 percent. With cigarette sales falling from new restrictions on smoking, higher cigarette taxes, increased health concerns, and booming e-cig sales, tobacco bondholders have

good reason to be more than a bit nervous. In May 2014, Moody's indicated that "from 65 percent to 80 percent of tobacco securities may fail to pay principal on time as demand for cigarettes falls short of assumptions."

The growth of e-cigs further threatens tobacco bonds. It should be no surprise that there is talk about revising the MSA to include e-cigs. Several U.S. senators who have been longtime supporters of tobacco regulation have urged states to classify e-cigs as tobacco products under the MSA. According to these legislators, e-cigs meet the definition of "cigarettes" under the MSA because they contain tobacco (specifically because they contain nicotine derived from tobacco, even though they need not—and frequently do not—contain other components of tobacco), are "heated under ordinary conditions of use," and are "likely to be offered to, or purchased by, consumers as a cigarette." Doing so would bring e-cigs under the same cartel-reinforcing regime as traditional tobacco products, including limitations on advertising. It is not clear, however, how the MSA could be applied to e-cigs or VTM systems that do not contain nicotine.

Expanding e-cig sales bring a second reason for state governments—along with a few tobacco companies—to enter the "Let's regulate e-cigs" discussion. With the exception of Minnesota and North Carolina, where e-cigs are taxed, state revenues fall each time a consumer substitutes e-cigs for regular smokes.

In fiscal 2013, state and local governments collected $17.1 billion in excise taxes. The average state excise tax per cigarette pack is $1.54; in July 2014, state taxes per pack ranged from $0.17 in Missouri to $4.35 in New York. Some municipal governments add another layer of tax; for example, New York City imposes a $1.50 per pack tax. The federal government adds an additional $1.01 per pack nationwide. Thus, cigarette consumers in New York City pay $6.86 per pack in taxes while e-cig consumers pay no excise taxes. Several bills have been introduced in Congress to impose federal excise taxes on e-cigs, but none have yet been acted upon.

CONCLUSION: WHAT ARE THE REGULATORY PROSPECTS FOR E-CIGARETTES?

Banning e-cigs is possible but unlikely in the United States. (Australia and Brazil have banned them in the name of public health.) Banning e-cigs would make life easier for traditional cigarette makers and could be supported by Bootleggers—the worried MSA bondholders and state issuers of those bonds, state governments concerned about declining tobacco excise tax revenues, and NRT peddlers—particularly if the ban stemmed the decline in revenues from traditional cigarettes. But Congress is unlikely to support a ban because there is weak scientific evidence that use of e-cigs is harmful, especially when compared to traditional cigarettes, and because there are at least some voices in the public health community praising the beneficial effects of e-cigs as a substitute product. A public that supports marijuana decriminalization is also unlikely to support a ban on e-cigs.

Regulation seems more likely than a ban. In April 2014, the FDA proposed asserting its authority to regulate e-cigs by deeming e-cigs containing nicotine to be "tobacco products" subject to regulation. The proposed regulations, if finalized, would define the next e-cig regulatory environment. Under the proposed rules, sales to minors would be prohibited, but e-cig sellers would be able to advertise and engage in web-based commerce.

These rules also would subject e-cigs to the 2009 FSPTCA's potentially stringent premarket review requirements. Those requirements apply to all new tobacco products that are not substantially equivalent to products that were marketed before 2007. This will greatly increase the cost of bringing new cigarette alternatives to market. Moreover, the FDA appears to be applying the "substantial equivalent" requirement quite stringently. Applied to e-cigs, these requirements could impose substantial burdens on smaller manufacturers and distributors and have the potential of enhancing the competitive advantage of traditional cigarette manufacturers as they seek to make inroads within the e-cig market.

The FDA's proposed regulations do not address the MSA revenue problem or the federal tobacco tax problem, however. To bring e-cigs under the MSA would require actions by the state attorneys general to deem e-cigs as cigarettes under the agreement because they "contain ... tobacco," insofar as they contain nicotine that is derived from tobacco and are "heated under ordinary conditions of use." If e-cigs are to be subject to federal excise taxes now applied to tobacco products, congressional action would be required.

Bootlegger/Baptist political forces will not rest until e-cigs are subject to the state and federal taxes that apply to cigarettes and e-cig revenues become subject to MSA rules. There is an obvious irony here. To the extent that e-cigs provide a less hazardous alternative to consumers who seek to break their smoking habit, regulations that limit e-cig competition produce a social cost measured in lost opportunities to improve human health. Regulatory actions that limit e-cig marketability introduce uncertainty for yet-to-be-discovered smoking alternatives that also destabilize the markets for traditional tobacco and smoking cessation products. For the sake of human health and freedom of choice, such innovation should be encouraged, not restricted. *R*

READINGS

- "Baptists, Bootleggers, and E-Cigarettes," Case Legal Studies Research Paper No. 2015-3, by Bruce Yandle, Roger E. Meiners, Jonathan H. Adler and Andrew P. Morriss. Case Western Reserve University School of Law, January 1, 2015. SSRN #2557691.
- *Bootleggers and Baptists: How Economic Forces and Moral Persuasion Interact to Shape Regulatory Politics*, by Adam Smith and Bruce Yandle. Cato Institute, 2014.
- "Bootleggers, Baptists and Televangelists," by Bruce Yandle, Joe Rotondi, Andrew P. Morriss, and Andrew Dorchak. *University of Illinois Law Review*, Vol. 2008, No. 4, (2008).
- *Smoke-Filled Rooms: A Postmortem on the Tobacco Deal*, by W. Kip Viscusi. University of Chicago Press, 2002.
- "The Ghost of Cigarette Advertising Past," by John E. Calfee. *Regulation*, Vol. 10, No. 2 (1986).