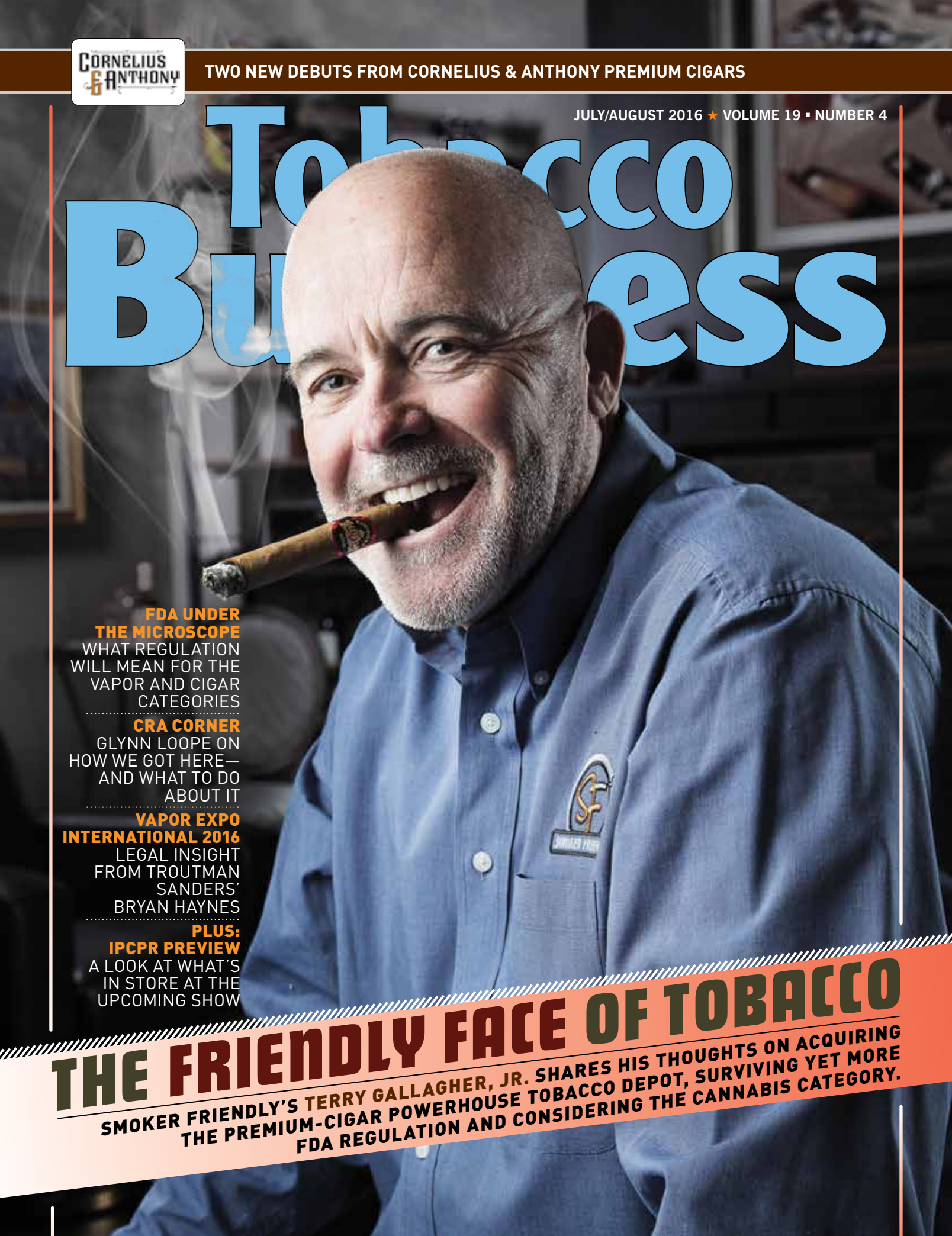
JULY/AUGUST 2016 ★ VOLUME 19 ▪ NUMBER 4

Tobacco Business



FDA UNDER THE MICROSCOPE
WHAT REGULATION WILL MEAN FOR THE VAPOR AND CIGAR CATEGORIES

CRA CORNER
GLYNN LOOPE ON HOW WE GOT HERE—AND WHAT TO DO ABOUT IT

VAPOR EXPO INTERNATIONAL 2016
LEGAL INSIGHT FROM TROUTMAN SANDERS' BRYAN HAYNES

PLUS: IPCPR PREVIEW
A LOOK AT WHAT'S IN STORE AT THE UPCOMING SHOW

THE FRIENDLY FACE OF TOBACCO

SMOKER FRIENDLY'S TERRY GALLAGHER, JR. SHARES HIS THOUGHTS ON ACQUIRING THE PREMIUM-CIGAR POWERHOUSE TOBACCO DEPOT, SURVIVING YET MORE FDA REGULATION AND CONSIDERING THE CANNABIS CATEGORY.

IPCPR and Beyond—Celebrating Cigars, Weathering FDA Regulation

Having Smoker Friendly's Terry Gallagher grace this issue's cover is particularly fitting. After all, the nation's best-known tobacco outlet chain has just recently acquired Tobacco Depot, one of the country's best-known families of cigar stores.

That transaction is emblematic of many changes taking place in our industry—from FDA's controversial decision to bring cigars into the agency's regulatory domain, to consolidation and new alliances as companies within the industry join forces to fight for survival. It's a time when the fast-growing vapor category, just coming into its own, faces its first real threat in the form of the same regulatory oversight that combustible tobacco has grappled with for more than a decade. And, even as the future legality of some products comes under question, an entirely new category—cannabis—is gaining ground, literally, as a legal commodity.

In this issue of *TBI*, you'll find the perspectives of veterans from different channels of retail, as well as a wide range of product categories, on these and other forces shaping the future of our industry.

We also bring you insights from the cigar side of the business, including the debut of our new column, CRA Corner. Turn to page 86 for a thought-provoking op-ed on FDA's regulatory oversight of cigars by the CRA's own Glynn Loope. Be sure not to miss the views of Paul Warner, owner of Silo Cigars, who shares his story in Trench Marketing (page 62) and his views of FDA regulation in our FDA roundup feature (page 72).

You'll also hear plenty of voices both representing and commenting on the vapor category, including VMR's Jan Verleur, who joins Warner in our FDA roundup feature *TBI*'s coverage of the Vapor Expo International Show—a rousing success—includes comprehensive coverage of a presentation on FDA regulation by Troutman Sanders' Bryan Haynes assessment of vapor's future (page 78). And our Electric Alley column shares early reactions from vapor industry observers (page 50).

There's no denying that these are turbulent times in tobacco, yet in researching these stories and talking with the people who form it, we at *TBI* have found that spirits remain high and outlooks remain confident.

There's no denying that these are turbulent times in tobacco, yet in researching these stories and talking with the people who form it, we at *TBI* have found that spirits remain high and outlooks remain confident. Yes, there is acknowledgement of the challenges ahead, but the majority of those representing the broad spectrum of newly regulated product categories are confident that reason will ultimately prevail and that the industry—accustomed to such challenges—will find a way to adapt. As Smoker Friendly's Terry Gallagher put it, "It's not the way we like to spend our productivity—figuring out how to deal with legislative issues—but we will do what we need to do."

—The Editors

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Vapor Industry Advocates for Cole-Bishop Bill

Members of the Vapor Technology Association went to Washington in support of the Cole-Bishop Appropriations Amendment.

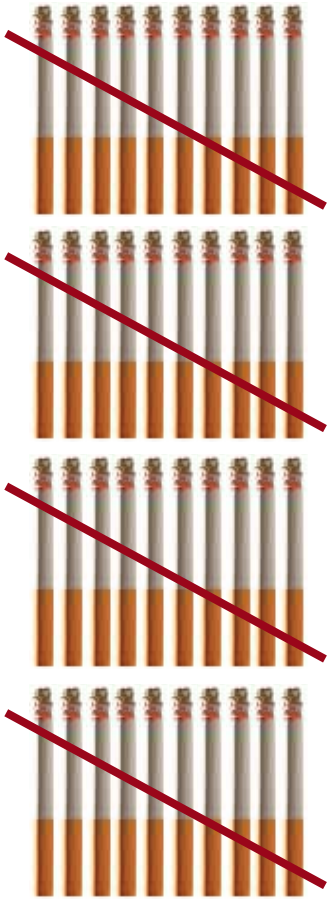
In June, members of the Vapor Technology Association (VTA) traveled to Capitol Hill from all over the United States to advocate in support of the Cole-Bishop Appropriations Amendment, legislation that would "provide much needed regulation of vapor products as the new technology that they are, rather than the tobacco products that they are not," explains a VTA spokesperson. The effort came in the wake of the regulatory policy issued by FDA in May, which VTA says will "only serve to eliminate vapor products from the market, ultimately harming the broader public health goal of deterring tobacco use, and put thousands of small businesses out of business."

"There is no question that vapor products are a healthier alternative to tobacco cigarettes for thousands of adult consumers in this country," says Tony Abboud, VTA's national legislative director. "While FDA's recent rulemaking threatens to eliminate them entirely from the market, the Cole-Bishop Amendment takes the responsible approach by preserving the industry, while implementing common-sense regulations that will protect youth and ensure the safety of consumers."

Part of the Agriculture, Rural Development, Food and Drug Administration bill, the amendment authored by U.S. Reps Tom Cole (R-Okla.) and Sanford Bishop (D-Ga.) would amend the "predicate date" from February 15, 2007 to the effective date of the final deeming regulations. The Cole-Bishop Amendment restricts youth marketing and youth access to vapor products by:

- Limiting newspaper, magazine or other print advertising of vapor products to adult publications;
- Requiring face to-face sales, thereby banning self-service displays and vending machines, except at age-restricted venues;
- Requiring FDA to issue labeling regulations within 12 months to include "Keep Out of Reach of Children," "Underage Sale Prohibited," and accurate nicotine content.

The Cole-Bishop Amendment also requires retailers to register their establishments, unless the retailer is already required to register under a state law or federal law.



49%

OF VAPERS

say they will go back to smoking if e-cigs are off the market

Source: V2 survey of 300 adult vapers

California Ban on Selling Tobacco Falters

An effort to restrict the sale of tobacco products to 18-and-over cigar shops has failed.

California State Senator Bob Wieckowski's bill (S.B. 1400) faltered before reaching the California Assembly Business and Professions Committee. The bill would have changed the definition of a retail location that's able to obtain a license to sell tobacco to businesses that generate 60 percent or more of gross revenue annually from tobacco-related products. In effect, the legislation would have made c-stores and grocery stores ineligible to sell tobacco products.

The bill, which passed the Senate, but failed to receive a crucial support motion, was widely protested by retailers. Many protested vigorously, noting that the bill went too far and that being restricted from selling tobacco products would have decimated their businesses, which rely heavily on both the profits and traffic that selling tobacco brings. Committee members apparently agreed to let it fade away.

New CFO for Nicopure

Nicopure Labs has appointed Jim Caci as chief financial officer.

Jim Caci, newly appointed CFO of Nicopure Labs, will be responsible for managing the strategy and growth of fiscal functions and operations at the Tampa, Florida-based company, a leading e-liquid manufacturer.

"I have become familiar with the Nicopure team over the last several years and have been impressed with their leadership position and success in the vaping industry," says Caci, who previously held the CFO post at Conductor and Avepoint. "As the industry continues to grow and go through major changes, I'm thrilled to be joining Nicopure at such an exciting time and applying all that I have learned throughout my career to help contribute to the company's long-term success."

Caci will focus on developing performance measures and implementing tactical initiatives that support the strategic goals and long-term growth of the company.

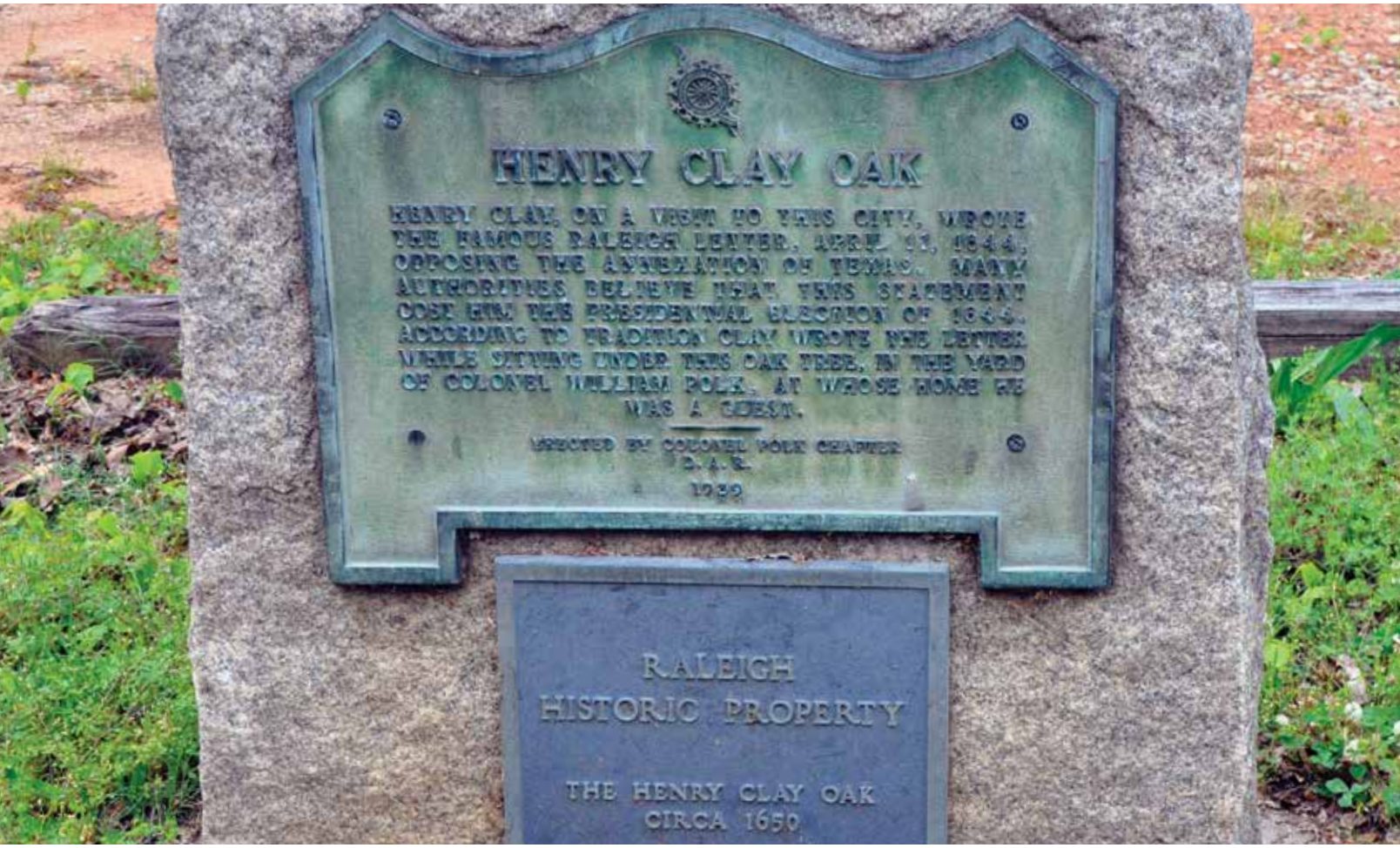
"Jim has earned himself a reputation globally as a financial operations expert in the technology industry," says Jeff Stamler, CEO at Nicopure Labs. "His professional know-how is the ideal match for our company's relentless expansion and our commitment to maintaining high standards in all aspects of our business.

"Jim's experience as the head of finance for two publicly held technology companies will give us a competitive advantage and unique insight [so] we [will be] prepared for all possibilities," Stamler adds.

$5.87

Average Price of a Package of Cigarettes in the U.S.

Source: RBC Capital Markets



Celebrating Cigars and History

Politicians and cigar lovers alike turned out for North Carolina's Third Annual Henry Clay Day.

More than 200 legislators, judges and lawyers gathered in April for Henry Clay Day, an event honoring the well-known Southern statesman. Fittingly, the event was held on the grounds of the Hawkins Hartness House across the street from the Henry Clay Oak, the tree under which Clay wrote his famous "Raleigh Letter" detailing his opposition to the war with Mexico over acquiring Texas. Clay was widely respected as a patriot for his many contributions to American history, including keeping the states working together for unity until the Civil War.

"I regard all wars as great calamities, to be avoided, if possible, and honorable peace as the wisest and truest policy of this country," wrote Clay, whose political career encompassed terms in both the House of Representatives and the Senate, as well as service as Speaker of the House and Secretary of State. The letter was thought to tip the scales against Clay in the 1844 election.

Participants at the event enjoyed RC Colas, Moon Pies and Henry Clay Cigars as former Secretary of State Rufus Edmisten received the Henry Clay Award from Lt. Governor Dan Forest, who came up with the idea for the annual event and worked tirelessly to make it happen. Among those credited with contributing to the evening's success were Altadis' Javier Estades, who supplied Henry Clay Cigars, and M&R Holdings' Dean Rouse, who contributed smoking accessories.

"Our company was very honored to be part of such an event that reminded us all of the contributions our forefathers made to make this country great," said Rouse. "Bringing together North Carolina leaders in an environment that allows enjoyment of fine tobacco products was indeed a pleasure that we look forward to supporting for years to come."

"It did our hearts good witnessing the huge delegation of North Carolina legislators lighting up and enjoying a fine cigar," added Ed O'Connor, publisher emeritus of *TBI*.

"To me personally, the event meant bringing our North Carolina leaders together for an event where we could remember Henry Clay's accomplishments, honor those that carry on his leadership, such as [former] Secretary of State Rufus Edmisten, and allow all of us to remember the founding declarations that make our nation strong, including the right to agree and disagree on personal freedoms guaranteed by the Constitution," added Rouse. "Our company will always support events that deliver these messages to our leaders, and we were honored to do our part along with others."


STATE OF NORTH

BREAKING NEWS FROM THE TMA

The following are excerpts from harm reduction, tobacco regulation and other tobacco-related news.

Farrell Delman, President, TMA

ON THE FDA…

…The **redline version of the FDA's final deeming regulations**, reflecting all changes that the White House's Office of Management and Budget (OMB) made after receiving it in October 2015, shows that the OMB deleted FDA's language that would have removed newly deemed flavored tobacco products from the market until they obtained FDA authorization. OMB also deleted FDA's rationale for the policy on flavored products, which noted "a dramatic rise in youth and young adult use of typically flavored tobacco products, like e-cigarettes and water pipe tobacco, and continued youth and young adult use of cigars." Dr. Edward Anselm, a senior fellow with the R Street Institute, said that the White House showed "a degree of insight into an important public health problem" by deleting references to flavor in the FDA regulations.

…Tampa, Florida-based **Nicopure Labs** filed a lawsuit in the U.S. District Court for the District of Columbia on May 10 claiming that FDA's final deeming regulations violate the First Amendment "by prohibiting manufacturers, including Nicopure, from making truthful and nonmisleading statements regarding vaping devices, e-liquids, and related products." Nicopure General Counsel and Chief Compliance Officer Patricia Kovacevic said, "[t]he government's role is not to regulate for the sake of regulation; regulation must be based on sound science and robust procedure, and it must accomplish certain public health goals."

…*Forbes* contributor and *Reason* magazine's senior editor Jacob Sullum said that Nicopure Labs' lawsuit against **FDA's deeming rule** highlights the "censorship of potentially lifesaving information about e-cigarettes," since even the companies that survive the "shakeout" caused by the new regulations would not be allowed to inform consumers that vaping is a less hazardous alternative to smoking combustible products unless they first obtain prior FDA approval to market their e-vapor product as a "modified-risk tobacco product." If a company truthfully describes its e-vapor product as "smokeless" or "smoke-free," FDA could still render them "adulterated," though FDA said it will evaluate the use of those descriptors "on a case-by-case basis." Companies are also banned from providing a straightforward chemical comparison of the aerosol from an e-vapor product and the smoke produced by a combustible cigarette, meaning that "FDA is actively suppressing truthful information that would encourage people to make healthier choices," Sullum said.

…Los Angeles-based e-vapor company **Lost Art Liquids** filed a lawsuit in the U.S. District Court for the Central District of California challenging FDA's "purported authority to deem and regulate e-liquids and other vapor products as 'tobacco products' under the Tobacco Control Act." The lawsuit also accuses FDA of violating the Regulatory Flexibility Act, the First and Fifth Amendments, and the Administrative Procedures Act. CEO Brian Worthy said, "FDA continues to confuse and conflate vapor products with tobacco and chooses to ignore years of well-established research that shows the relative safety of the products compared to combustible cigarettes."

…**Altria Group** filed a civil complaint with the U.S. District Court for the District of Columbia protesting FDA's deeming regulations, which, among other measures, prohibits the sale and distribution of tobacco products with modified-risk descriptors such as "light," "low" and "mild," unless authorized by the agency. Altria alleges that this measure violates the First Amendment that protects trademarks and brand names as well as the Fifth Amendment that deals with privacy and property rights. Altria also argued that the use of the word "mild" in its Black & Mild cigar brand, manufactured by its subsidiary John Middleton Company, describes "taste and body" and does not convey anything about health, risk or safety.

…In what is the **fourth legal challenge to FDA's deeming regulations**, Miami, Florida-based Global Premium Cigars filed a lawsuit June 1 in the U.S. District Court in Miami, arguing, among other things, that the rules violate the First and Fifth Amendment rights of the company and its owner Enrique Sánchez. The company, which owns the 1502 Cigars brand, urged the court to vacate the deeming rules and issue a preliminary injunction to prevent FDA from taking any action pending resolution of the case on the merits.

…An outflow of comments followed FDA's Final Rule, "Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act," that

Farsalinos believes that FDA researchers are "very clever and very well aware of the e-cigarette reality," yet agency officials were legally obliged to create the deeming rule.

was released May 5 and goes into effect on August 8, 2016:

• **Prof. Michael Siegel of Boston University's School of Public Health** said that companies "have a right to voluntarily disclose their ingredients" and "not disclosing that [their] products do not contain tobacco and do not produce smoke…would be misleading." Siegel also noted that Nicopure has made a valid point that FDA has interpreted the term "tobacco products" so broadly that it included not only e-liquids, which contain nicotine, but also batteries, wicks, electronic displays, and glass vials, which do not contain nicotine and are not derived from tobacco or any constituent of tobacco, Siegel said.

• **Jonathan Adler, law professor and director of the Center for Business Law and Regulation at Case Western University School of Law**, said that the FDA rule might help protect public health insofar as it subjects "actual tobacco products" like cigars to the same regulations as cigarettes, but deeming e-cigs and other electronic nicotine delivery systems to be tobacco products and subjecting them to extensive regulatory requirements is likely to do more harm to public health than help it. The Electronic Nicotine Delivery System (ENDS) market will shrink as a consequence of the requirement for FDA approval of all deemed tobacco products, while "Big Tobacco will be in a better position to dominate what's left," thereby replacing a "vibrant competitive market" with a cartel, Adler said. He also questioned whether the FDA ban on the sale of ENDS to minors would actually help public health, citing studies by Yale and Cornell researchers that found a correlation between restrictions on e-cig sales to youth and an *increase* in teen smoking rates.

• **Dr. Konstantinos Farsalinos of the Onassis Cardiac Surgery Center** said that many people may think that FDA and its scientists "created a totally inappropriate regulation" because of their ignorance about how ENDS are used, but Farsalinos believes that FDA researchers are "very clever and very well aware of the e-cigarette reality," yet agency officials were legally obliged to create the deeming rule. "This is the cost for classifying e-cigarettes as tobacco products," Farsalinos said.

• **Jeff Stier, a senior fellow at the National Center for Public Policy Research**, said that while FDA "wasn't wrong to regulate e-cigarettes," the agency was wrong to "effectively ban, by its own estimate, up to 98.5 percent of the e-cigarettes on the market today" when responsible regulation would have been to institute battery standards, a ban on underage sales, and marketing restrictions.

• **Ray Story, founder and CEO of the Tobacco Vapor Electronic Cigarette Association (TVECA)**, said that the FDA rule is "a complete disaster" that "essentially bans the product across the land" and sends vapers back to cigarettes.

• **Julie Woessner, executive director for the Consumer Advocates for Smoke-Free Alternatives Association (CASAA)**, said that the FDA rule eliminates "choice and diversity in the marketplace" and "is an appalling breach of public trust by FDA."

• **Cynthia Cabrera, president and executive director of the Smoke-Free Alternatives Trade Association (SFATA),** said that the rule "pulls the rug out from the 9 million smokers who have switched to vaping, putting them in jeopardy of returning back to smoking."

…U.S. Sen. Ron Johnson (R-Wis.), chair of the Senate Homeland Security and Governmental Affairs Committee, sent two **letters to FDA Commissioner** Robert Califf expressing his concerns about the agency's recent e-vapor regulations. In the first, Johnson pointed out that the new regulations "could result in negative unintended health consequences," and asked if it will revise the rules if there is sufficient data showing that e-vapor products are a safer alternative to conventional cigarettes. In the second, Johnson asked for Califf's "assistance in understanding the consequences that this new regulation may have on small businesses and the public's health." He also urged FDA to be "transparent and accountable in its regulatory actions."

…FDA unveiled an **updated online tool** to make it easier for consumers to report problems with e-vapor, hookah, cigarettes, cigars and smokeless tobacco products. The agency said users can report burns or other injuries, allergic reactions, poisoning and problems with the quality of the product, alongside other issues, using the tool.

…FDA's May 25 Q&A session on deeming regulations answered **questions from retailers**, many of them pertaining to e-liquid sales, with much of the answers referring back to the statutory definition of a retailer, a manufacturer or a tobacco product and its components or parts. On questions concerning nicotine-free e-liquids, FDA said that the deem

Stier responded by charging that FDA "set up an alternate universe detached from reality, in which it categorizes e-cigarettes as tobacco products and effectively bans them."

ing rules apply because they are considered a component of a tobacco product that can alter the composition, performance or characteristic of the product and is intended for human consumption. On questions about what to do with existing products after August 8, 2016, FDA said that they can be marketed for up to three years while a pre-market authorization application is submitted within 24 months and reviewed, reportedly, within 12 months thereafter with the Center for Tobacco Products (CTP) to decide on a case-by-case basis, should its review be incomplete, whether to allow the product to remain on the market. On questions about self-service displays, FDA said that the ban on self-service displays does not apply to newly deemed products. FDA also repeated that manufacturers have to register with FDA, but retailers do not.

…Some of the claims that FDA has made in relation to its final deeming rule are already being challenged: 1) Regarding a CTP spokeswoman's claim that "we're talking about products that kill people," which she stated on a Texas Public Radio news show *The Source*, **Boston University's Prof. Michael Siegel** said, "products that kill people…are not called e-cigarettes, they're called real tobacco cigarettes." 2) **University of Ottawa adjunct law professor David Sweanor** countered CTP Director Mitch Zeller's explanation during an FDA media briefing that the UK Royal College of Physicians' findings of the harm reduction benefits of vaping did not apply in the U.S. because "[w]e have skyrocketing use of e-cigarettes by kids." Sweanor noted that the difference is not in youth vaping, but in how the data is tracked, since nearly 80 percent of youth who have tried vaping say they used a non-nicotine variety, so "say[ing] that this is a huge problem is pretty ridiculous."

…FDA said in a Twitter exchange with **Jeff Stier at the National Center for Public Policy Research** that it "recognizes that some tobacco products have the potential to be less harmful than others, but more research is needed" when asked whether e-cigs are safer than regular cigarettes. Stier responded by charging that FDA "set up an alternate universe detached from reality, in which it categorizes e-cigarettes as tobacco products and effectively bans them."

…**Center for Tobacco Products** announced May 12 that the University of Kentucky's Center for Tobacco Reference Products has produced 50 million "reference cigarettes" called 1R6F, developed under a cooperative agreement with CTP, that "resembles the types of cigarettes commonly sold in the U.S." The reference cigarette comes with a certificate of analysis on measurements of its chemical and physical properties, including harmful and potentially harmful constituents (HPHCs), and can provide reference points for comparison to help manufacturers gather accurate data about the content of their own cigarettes, CTP said.

…Clarityse, a strategic consultancy for the "self-care" sector and an advocate of consumer empowerment, said that the **UK Royal College of Physicians' report** endorsing vaping as a form of harm reduction is "great news for vapers," but FDA's final deeming rule is "potentially disastrous" and "effectively amounts to prohibition" of e-vapor products because of the sheer scale of the regulatory burden. The FDA rule does not mean all vapers will stop vaping, however, since what happens in response to prohibition is that vapers will find a way around the law, giving rise to a black market of "criminal behavior, no controls, way poorer quality products and no reliable data regarding what's going on," Clarityse said.

…American Enterprise Institute resident scholar and *Forbes* contributor Sally Satel writes that in the UK, policymakers are "years ahead of [the U.S.] in pursuing…a revolution in nicotine delivery," while in the U.S., FDA is **protecting the cigarette market** and crushing the e-vapor industry with its final deeming rule on products that were not previously regulated. U.S. Department of Health and Human Services Director Sylvia Burwell's statement about "a new generation of Americans who are at risk of addiction," and her apparent exclusion of adult smokers who could benefit from e-vapor products echoes the "ill-founded rhetoric" of CDC Director Tom Frieden, the Campaign for Tobacco-Free Kids, and other anti-vaping groups that are "largely fixated on a yet-to-be demonstrated impact on children, yet pay little attention to the established benefit to smokers," Satel said.

…**Vapor Expo International 2016** (vaporexpointernational.com), which took place June 15-16 at the Donald E. Stephens Convention Center Hall A in Rosemont, Illinois, featured TMA President Farrell Delman, Smoke-Free Alternatives Trade Association's Cap O'Rourke, American Vaping Association's Greg Conley, and Vapor Technology As

Major cigar associations are expected to gather shortly to plan out a strategy to address the FDA's final deeming rule that includes premium cigars in its oversight.

sociation's Tony Abboud in a panel discussion about FDA's final deeming rule and shared their views on how manufacturers of newly regulated products will respond to the announcement, what the decision will mean for the competitive landscape, and what the status is on efforts to change the predicate date.

…***The New York Times'*** **"Room for Debate" column** asked the question "How will the FDA's decision affect anti-smoking efforts?" to four debaters. Kenneth E. Warner, public health professor and former dean of the School of Public Health at the University of Michigan, said that the new FDA regulation "is likely to squander an opportunity to hasten the demise of the enormous toll of combusted tobacco" because it is "hugely unbalanced, emphasizing the hypothetical risk to children while ignoring the potential harm-reduction benefits for adult smokers." Harold P. Wimmer, president and chief executive of the American Lung Association, said that the FDA's new rules represent "an important step forward in protecting public health and preventing a new generation of youth using and becoming addicted to nicotine," and "[u]nproven claims that e-cigarettes can help smokers quit are troubling." Amy L. Fairchild, professor of sociomedical sciences at Columbia University's Mailman School of Public Health, said even if the final rule is so burdensome that it effectively bans e-cigs, the document also states FDA's belief that "inhalation of nicotine (i.e. nicotine without the products of combustion) is of less risk to the user than the inhalation of nicotine delivered by smoke from combusted tobacco products," and therefore stakeholders need to use the FDA rule "as a lever to elevate tobacco harm reduction as a foundation of U.S. tobacco policy" and a challenge to the abstinence-only scare tactics approach. Delmonte Jefferson, executive director of the National African American Tobacco Prevention Network, said that the FDA rule "is a huge step in tobacco prevention, and it will protect underprivileged communities who disproportionately suffer death and disease due to these products," but the agency also needs to ban the "sale of mentholated tobacco products," given that menthol cigarettes are smoked by nearly 75 percent of African American smokers.

…Major cigar associations are expected to gather shortly to plan out a strategy to address the FDA's final deeming rule that includes premium cigars in its oversight. The **premium cigar industry** lobbied for several years for an exemption from FDA regulations, and some industry representatives, including Eric Newman of J.C. Newman Cigar Company of Tampa, Florida, said that they will meet with members of Congress or take legal action to fight the new rules.

…The bill H.R. 5054, introduced April 26 by U.S. Rep. Robert Aderholt (R-Ala.), would make appropriations for Agriculture, Rural Development, FDA, and Related Agencies programs for the fiscal year starting October 1, 2016, and includes the rider (originally proposed as H.R. 2058) by U.S. Reps Cole (R-Okla.) and Bishop (D-Ga.) to **change the February 15, 2007 predicate date** for currently unregulated tobacco products that would be deemed subject to FDA oversight. H.R. 5054 would also exempt "traditional large and premium cigars" from FDA regulation and require, no later than 12 months after the date on which the deeming regulations for e-vapor products are issued, that a notice be issued of a proposal to establish a product standard for e-vapor product batteries, with a final product standard for such batteries to be published within 24 months.

It also sets marketing and sales regulations for e-vapor products such as: banning ads in any publication other than an "adult publication" (defined in the amended rider); requiring retailer establishment sales of e-vapor products to be in direct face-to-face exchanges without the use of "any electronic or mechanical device (such as a vending machine)… that is not in an area restricted to those over 18," but exempts "mail-order" sales; and requiring final regulations for the labeling of e-vapor products that would include the phrases "Keep Out of Reach of Children," "Underage Sale Prohibited," and an "accurate statement of nicotine content." Those who "own or operate an establishment in any state engaged in the retail sale of a vapor product" are required to register with the Secretary of Health and Human Services "within the later of 60 days after the date of enactment…or 30 days after first engaging in such retail sale," unless the establishment is already under state regulation or is regulated under Section 905 of the FD&C Act.

…The Keller and Heckman (K&H) law firm, explaining what would have to follow the April 19 vote on House Report 114-531 by the U.S. House Appropriations Committee, a vote that took

K&H attorneys Chowdhury and Dietle write it is unclear when the bill would move through Congress and reach the president, and it is "very possible, if not probable," that the deeming regulation will be published before H.R. 5054 becomes law.

place prior to the formal introduction of H.R. 5054 on April 26 to include the above, wrote that "there remains a long road ahead before this **budget amendment** can effectively change the statutory grandfather date for deemed products." Both the House and Senate will have to pass H.R. 5054 with the amendment, which also requires a presidential signature. K&H attorneys Chowdhury and Dietle write it is unclear when the bill would move through Congress and reach the president, and it is "very possible, if not probable," that the deeming regulation will be published before H.R. 5054 becomes law.

ON OTHER TOBACCO-RELATED NEWS…

…The CDC's National Youth Risk Behavior Surveillance report for 2015, which included public and private school students in grades 9-12 in all 50 states and the District of Columbia, found that during the past 30 days, 10.8 percent of **high school students** reported smoking at least once, down from 15.7 percent in 2013; 7.3 percent of students used smokeless tobacco, compared with 8.8 percent in 2013; 10.3 percent smoked cigars, cigarillos or little cigars, down from 12.6 percent in 2013; and 24.1 percent of students had used e-vapor products, for which comparative figures were not available for 2013.

…Professional service company KPMG's study titled "Project SUN" conducted to estimate the scale of the **illicit cigarette market** in the 28 EU countries plus Norway and Switzerland, commissioned by Imperial Brands, BAT, JT International and Philip Morris International, found that smokers in the EU consumed 53 billion contraband/counterfeit cigarettes in 2015. That figure accounted for one in 10 cigarettes smoked, depriving the governments of up to $12.8 billion in lost tax revenues, although illegal cigarettes as a proportion of total consumption declined marginally from 10.4 percent in 2014 to 9.8 percent in 2015.

…In a letter to World Health Organization (WHO) Director-General Dr. Margaret Chan, a coalition of 47 think tanks, advocacy groups and organizations from across the world said that **plain packaging of tobacco products** infringes on intellectual property rights (IPR). The groups say that IPRs promote trade in developed and emerging economies, and that weakening it threatens public health and safety by forcing consumers to make "uninformed decisions" like tapping the illicit market.

…European Commissioner for Health and Food Safety Vytenis Andriukaitis announced that all 28 EU countries need to comply with the **Tobacco Products Directive** as of May 20, 2016. The European Commission listed some of the key changes for tobacco products sold in the EU under the new TPD:

1) Graphic health warnings with cessation information will cover 65 percent of the front and back of cigarette and RYO tobacco packs and will be rotated every year;
2) Cigarettes and RYO tobacco are no longer permitted to have characterizing flavors like menthol, candy and vanilla, though flavored products with more than a 3 percent market share, like menthol, have until May 20, 2020 to comply;
3) The labeling on tar, nicotine and carbon monoxide will be replaced with an information message stating that "Tobacco smoke contains over 70 substances known to cause cancer";
4) Cigarette packs must have a "cuboid shape" and have a minimum count of 20 pieces, with no "promotional and/or misleading features" such as references to lifestyle benefits and environmental advantages;
5) Manufacturers are required to report electronically on ingredients in all their products sold in the EU;
6) E-vapor products must come in child-resistant packaging, with the e-liquid size not exceeding 2ml for tanks and 10ml for bottles, while the nicotine concentration must not exceed 20mg/ml;
7) E-vapor packaging must carry a list of ingredients, nicotine content information, and a health warning that they contain nicotine and should not be used by nonsmokers;
8) E-vapor manufacturers must notify EU Member States of all products they place on the market and report their sales volumes and consumer preferences and trends, while Member States must monitor the market for evidence, if any, of e-vapor products leading to nicotine addiction or tobacco consumption;
9) EU countries may choose to ban cross-border sales of tobacco products to prevent access to products that are not TPD-compliant; and
10) Measures to combat illegal trade, including an EU-wide track-and-trace system and security features like holograms, will be introduced for cigarettes and RYO tobacco in 2019 and for other tobacco products in 2024.

…UK-based e-liquid manufacturer **8Bit Vape**, which allows customers to order customized e-liquids by choosing from five bottle sizes, seven nicotine strengths and any combination of its 108 flavors, said it will stop its custom production as of May 20 and eventually close its business because of the TPD. **TBI**

The New Normal

With gas prices down and a stable economy, consumers are returning to premium brands.

"We've had a good run," says Nik Modi, tobacco analyst for New York-based RBC Capital Markets, reporting on cigarette sales. "We have seen consumers trading up to branded premiums and exiting the e-cigarette category to go back to branded premium cigarettes, so it has been a good 18 months for the industry."

Noting that cigarette sales actually increased slightly in the first quarter of 2016, Modi cautioned retailers not to expect that trend to continue. "We are starting to see wobbling of the data," he reports. "We expect cigarette volumes to return to a -3 percent to -4 percent annualized decline. If you think about it, there has not been structural change as to why consumers have been smoking more. The only thing I can point to is a return of consumer confidence where we might be seeing more smoking per smoker as people go out more."

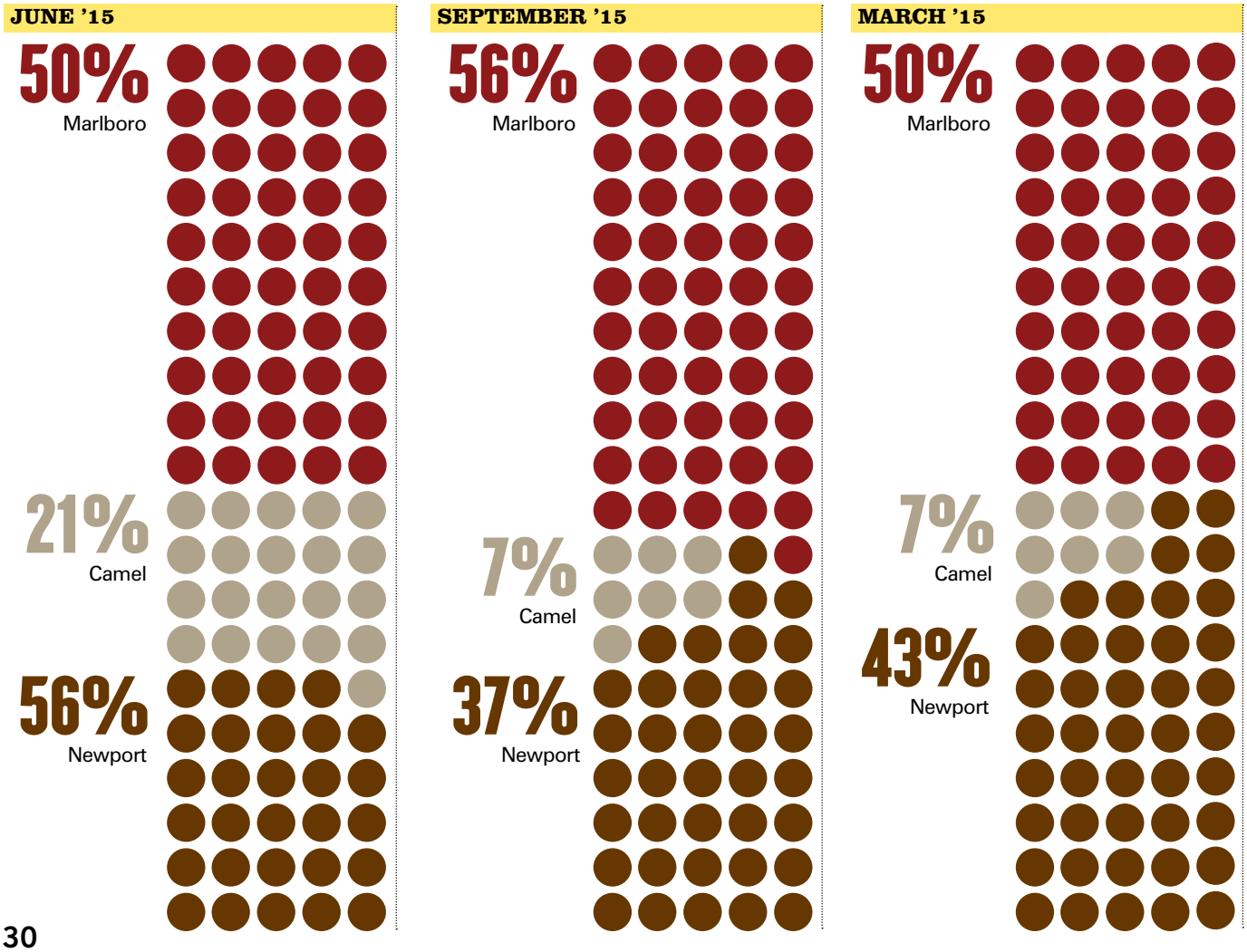
While combustible cigarettes are having a relatively good run, e-cigarettes are not faring as well, according to Modi, whose research suggests that c-store retailers in particular are losing enthusiasm for the vapor category. In fact, 95 percent of c-store retailers in a recent survey reported that sales of open systems never really got started or are starting to decline.

"I get a lot of criticism for being too negative on e-cigarettes," he notes. "But I try to be a realist. The reality is [that the category] will be big in the future, but product efficacy is not where it needs to be. The hard-core, pack-a-day smoker needs a certain amount of nicotine and the e-cigarettes cannot deliver that no matter what they tell you. The R&D will get there, but who will invest in it without more clarity on the regulatory climate?"

The charts on the pages to follow offer a snapshot of some of Modi's latest research on the cigarette and vapor categories.

CIGARETTE BRAND EXPECTATIONS

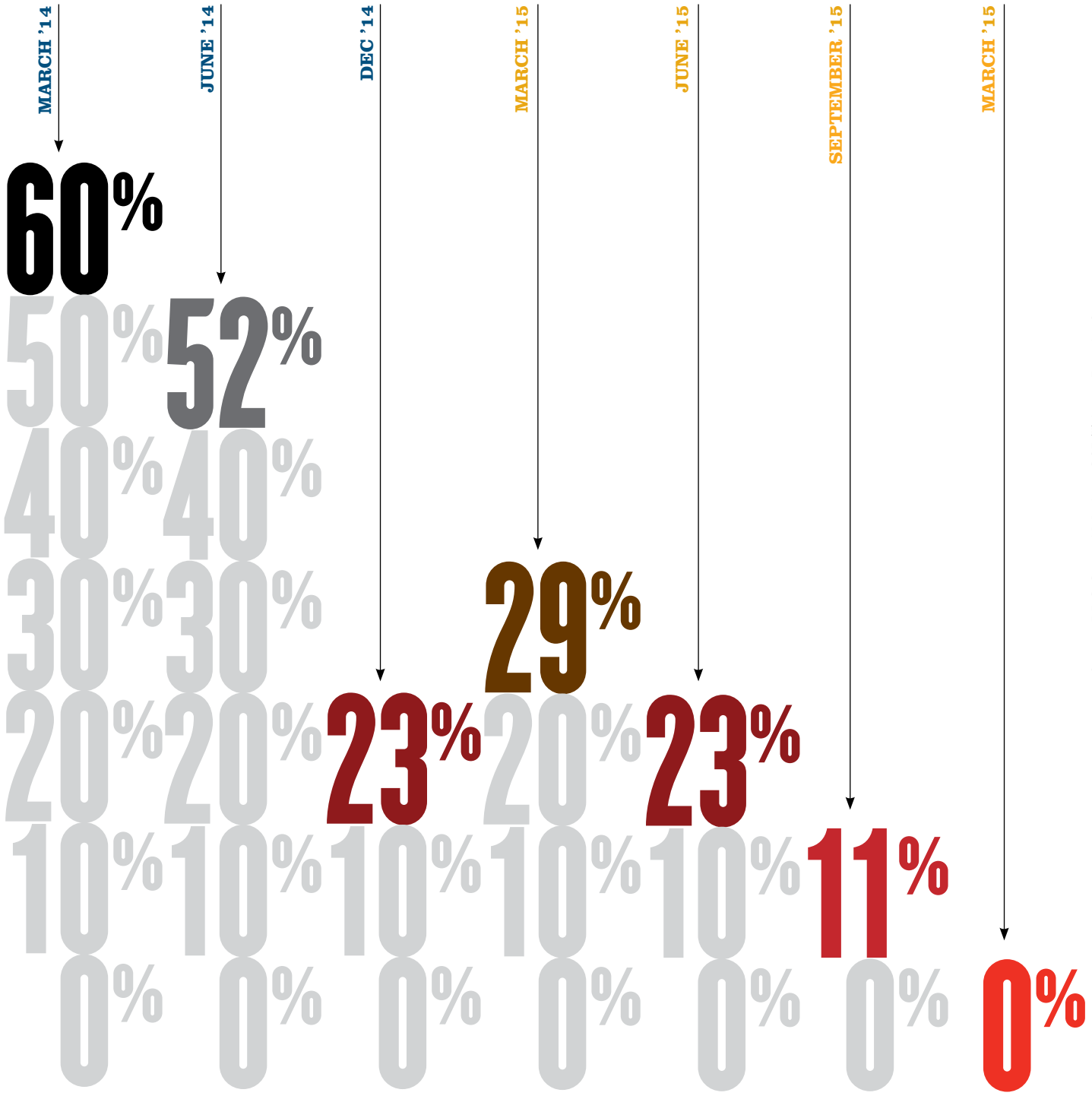
Which brand do you expect to gain the most market share in 2016?



Source: RBC Capitol Markets-CSP Tobacco Retailer Survey

C-Stores No Longer Expanding E-Cig Assortment

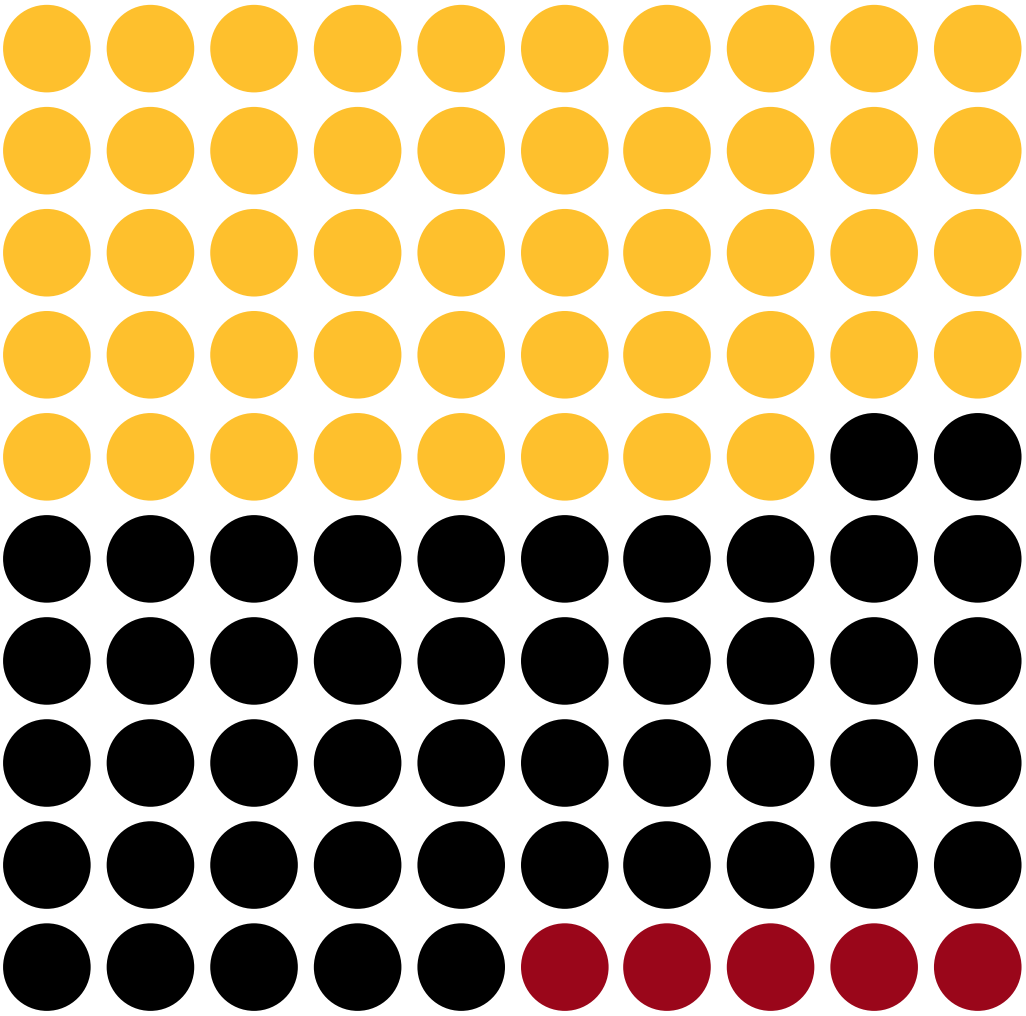
Are you further expanding your selection of e-cigarette offerings? (% responding "yes")



Source: RBC Capitol Markets-CSP Tobacco Retailer Survey

Open System Still Closed for C-Stores

If you sell open systems, please indicate how trends are progressing.



48%
Never really got started

47%
Slowing down

5%
Booming

Source: RBC Capitol Markets-CSP Tobacco Retailer Survey

Top E-Cig Brands at Retail

How have the following e-cig brands performed in your stores? (1=below expectations, 10=above expectations)

Source: RBC Capitol Markets-CSP Tobacco Retailer Survey

Stogie Uncertainty Offset by Passion and Perseverance

The final deeming regulations were an unwelcome surprise, but cigar industry veterans say passion and patience will prevail.

By Renée Covino

A brave new world in Stogieland has begun. When the Food and Drug Administration (FDA) released its long-awaited final deeming rule in May, the agency's authority was extended to cigars, including premium cigars, which were not exempt from the regulations as the industry had hoped and argued for as "Option Two."

"We scoured all the comments" and the Center for Tobacco Products (CTP) could not find any public health justifications to exclude premium cigars, Mitch Zeller said, speaking at the Tobacco Merchants Association's (TMA's) 101st Annual Meeting and Conference just days after the finalized regulations were released. More specifically, the available evidence did not provide a basis to conclude that the patterns of premium cigar use sufficiently reduce the health risks to warrant exclusion, according to the agency.

Reacting to this news, Barry Schaevitz, a partner with the law firm Fox Rothschild, expressed surprise. "The first time the Cigar Association met with FDA more than five years ago, the agency seemed to understand there was a risk continuum of tobacco products, meaning some were less harmful, and they seemed to indicate [that] they would take that into account," he says. "Zeller expressed that 'Option Two' was rejected because there was no basis to exempt [cigars], but he didn't say the industry showed there is a risk continuum—that was completely ignored. We took the agency on their word [that] they would go where [the] science took them. We showed them where [the] science went, and they chose to ignore that. So going forward, we have to figure out how to deal with that reality."

It should be noted that the industry is still urging all cigar supporters to contact both their Congressional representatives in the United States Senate and in the House of Representatives to ask them to support S. 441 and H.R. 662, which would exempt premium cigars from FDA regulation and oversight. Interested parties are also advised to support language adopted by the House Committee on Appropriations on April 19, 2016, calling for an exemption for premium cigars from FDA oversight.

Another long-contended focus of the deeming rule has been the grandfather, or predicate, date, which subjects newly regulated products to a pre-market review process. The final rule sets the date that defines these "new" products as those created after February 15, 2007—the same date that applies to cigarettes, smokeless tobacco and roll-your-own products, spelled out in the Family Smoking Prevention and Tobacco Control Act of 2009.

"Although there is still a lot of uncertainty, good news—as well as bad—is good; uncertainty and limbo is not good"

According to Zeller, the agency did not see a basis for changing that date, nor did it receive any public comments describing a legal basis for a change.

Therefore, the finalized deeming rules require all cigars that were introduced into the U.S. market after February 15, 2007 to get approval from FDA, either by way of an SE (Substantial Equivalence) application, an Exemption from SE application, or a Pre-Market Tobacco Application (PMTA). FDA estimates that the application process could take up to 1,700 hours for cigar manufacturers, yet industry experts say it will take a lot more time—as much as 5,000 hours. Also, despite FDA estimates that filing a PMTA will cost up to $330,000 per product, industry estimates put that figure closer to $1 million.

New products that are not on the U.S. market as of August 8, 2016 cannot be sold until FDA gives approval, while products that are on the market as of August 8 have one to three years (depending on which of the three routes are taken for approval) to submit an application (see sidebar, "More FDA Compliance Dates").

The way Bill Sherman, executive vice president of Nat Sherman, sees it, getting the finalized plan was a step in the right direction, even though the rules, as they stand now, are not easy for the cigar industry to digest. "Although there is still a lot of uncertainty, good news—as well as bad—is good; uncertainty and limbo is not good," he offers.

So what now? As expected, legal battles began almost immediately after the news hit of the finalized deeming rules.

Miami, Florida-based Global Premium Cigars, which owns the 1502 Cigars brand, filed a lawsuit in early June in the U.S. District Court in Miami, arguing, among other things, that the rules violate the First and Fifth Amendment rights of the company and its owner Enrique Sanchez. The lawsuit is asking the court to vacate the deeming rules and issue a preliminary injunction to prevent FDA from taking any action under the rules pending resolution of the case. Global Premium Cigars claims that the rule for warning labels on cigar packaging (see sidebar, "Warning: Cigar Warning Mandates") infringes on its First Amendment rights as it hinders the plaintiff's "ability to communicate with the public through packaging, advertising and intellectual property."

Global Premium Cigars additionally contends that the grandfather date is arbitrary and therefore violates the Due Process standard of the Fifth Amendment. Sanchez acknowledged recently that he expects this court battle to be long

and tough, but he believes "that the fight is important."

From the Big Tobacco side, Altria Group's wholly-owned subsidiary John Middleton Company, makers of the Black & Mild cigar brand, recently filed a lawsuit against FDA, claiming that the agency's final deeming rules prohibiting the sale and distribution of tobacco products with modified-risk descriptors such as "light," "low," and "mild," unless authorized by the agency, are "arbitrary and capricious, a violation of its free speech rights," according to Courthouse News Service. In its complaint filed with the U.S. District Court for the District of Columbia, John Middleton noted that "a per se ban on certain words in a trademark or brand name, without regard to their meaning or context, does not advance any legitimate government interest, much less a compelling one."

John Middleton, which is seeking a court order declaring the FDA rule as void, said that the regulation "terminates the iconic brand name on the bare supposition that the word 'mild' impermissibly communicates to consumers that Black & Mild products are safer than other cigars and pipe tobacco." John Middleton said that FDA did not cite any evidence that the Black & Mild name "conveys any message about the health risks of the products." The agency also ignored evidence that consumers understand the term "mild" to refer to taste, and not the health risks of the cigar, according to the company, which claims the descriptor "mild" carries "no safety-related connotation for cigars and pipe tobacco products, especially when it is integrated into a well-established brand name like Black & Mild."

But aside from the individual court battles, a unified effort remains with an industry that prides itself on unity.

The three associations representing the cigar industry are taking a careful and calm approach. The International Premium Cigar & Pipe Retailers Association (IPCPR), the Cigar Association of America (CAA) and Cigar Rights of America (CRA) issued a joint letter to their members apprising them of the action the agencies are taking on behalf of the entire industry to understand FDA's final deeming regulations. According to the letter, members of the boards of directors of the three agencies have agreed not to take any independent action, either in the courts or at the FDA level, but develop joint industry strategies. The three agencies also requested industry members not take any independent action.

"It's scary, but we will get through this. We are a strong industry," asserts Craig Williamson, president of CAA. "It's important that we all comply with regulations, so we're trying to get members as prepared as possible to go through a long process that will, at times, be very bumpy."

The intention seems to be to take one day at a time, one step at a time, acquiring knowledge with patience and passion.

"We must keep raising questions with the agency [and] presenting solutions we think are viable," says Schaevitz. Initial talks seem

All About Timing

IN ADDITION TO THE effective health warning dates outlined in the sidebar: "Warning: Health Warning Mandates," the following are key regulation dates for the cigar industry to pay attention and adhere to:

August 8, 2016: For retailers, minimum age of sale is required, vending machine sales are prohibited and sampling consumers is prohibited. For manufacturers, the establishment of registration and product listing with FDA is required.

Before December 31 of each year: Annual registration requirements for manufacturers include the release of foreign locations, product list, consumer info, sample ads, etc.

February 8, 2017: Manufacturer submission deadline for product health information, specifically: ingredient reporting, toxicity, etc.

August 8, 2017: Manufacturer submission deadline for Substantial Equivalence (SE) Exemption requests

February 8, 2019: Manufacturer submission deadline for SE Reports/ Application

August 8, 2019: Manufacturer submission deadline for Pre-Market Tobacco Product Applications (PMTAs), plus the manufacturer submission deadline for product health information, specifically: HPHCs

SOURCE: FDA/Davidoff USA

"to present somewhat of a gloomy picture, but a year from now we will be someplace, we will be selling cigars, and companies that are smart and patient will figure out a way to maintain their business."

The most important first step for manufacturers, according to him, is to know their product history. "It's really important to see what information they have pre-2007 to establish products on the market currently, whether the product has changed or not," he advises. "Having that information ready is most important."

CAA intends to help with a lot of education, especially needed by the smaller companies who do not have an FDA attorney on staff the way many larger companies do, Williamson offers. "We are going to try the best we can to get everyone through this because if one manufacturer fails, we all fail," he adds.

"We really are a family and that is such a critical part to our success," says Diane Kalambokas, director of Tax, Treasury and Corporate Affairs for Davidoff of Geneva. "Sharing information and conversations about the next steps is vital; we need the experience of others to help us through and maintain the viability of the industry that we are."

Sherman believes teamwork will prevail. "This is a very passionate industry based on relationships, and as a third-generation company, it's always been about 'we.' I think moving forward, that will only get stronger across the board."

And some of that strength can be found in industry events. The 3rd Annual Rocky Patel Cigar Yacht Cruise will take place on August 6 on the FantaSea One Yacht in Marina del Rey, California. The event, sponsored by Sevilla Local Media, is organized to honor Rocky Patel for his efforts in the fight against the proposed FDA regulation of the cigar industry. **TBI**

Warning: Cigar Warning Mandates

HEALTH WARNINGS ARE NOW a reality for the cigar industry, thanks to the finalized deeming regulations. The effective dates are:

May 10, 2017: Cigar manufacturers, distributors, importers and retailers must submit a cigar warning plan. Quarterly rotations of cigar warning statements in cigar advertising is required.

May 10, 2018: The cigar industry must stop manufacturing or advertising cigars without a health warning. This date also marks the time that cigar retailers must display a POS cigar health warning statement for cigars sold individually without product packaging.

June 11, 2018: The cigar industry must stop distributing cigars without a health warning, regardless of the manufacturing date.

Cigars, cigar packages and advertisements must bear one of the following six health warning statements, in accordance with an FDA-approved warning plan:

1. WARNING: Cigar smoking can cause cancers of the mouth and throat, even if you do not inhale.
2. WARNING: Cigar smoking can cause lung cancer and heart disease.
3. WARNING: Cigars are not a safe alternative to cigarettes.
4. WARNING: Tobacco smoke increases the risk of lung cancer and heart disease, even in nonsmokers.
5. WARNING: Cigar use while pregnant can harm you and your baby.

Or

SURGEON GENERAL'S WARNING:

Tobacco Use Increases the Risk of Infertility, Stillbirth and Low Birth Weight.

1. WARNING: This product contains nicotine. Nicotine is an addictive chemical.

SOURCE: FDA Center for Tobacco Products (CTP)

First Perspectives A.D. (After Deeming)

By Renée Covino

Just days after the finalized deeming regulations hit, industry experts shared initial perspective on an e-cigarette/vapor category under new regulatory light.

The deeming clock began ticking in May, when the industry finally had a (step one) finalized plan from the FDA. Immediately, analysts chimed in with chatter and clamor. Here are a few of those off-the-cuff e-cig/vapor perspectives, post-deeming regulation finalization, certain to spin and evolve with the weeks and months ahead:

The "Big Tobacco" Irony

Essentially, the way some analysts see it, what was once a thorn in traditional tobacco's side is now a growing tree of victory.

Vapor caught the cigarette business and Big Tobacco off guard a bit, according to Michael Lavery, director and senior tobacco analyst at Credit Lyonnais Securities Asia (CLSA). He explains that just before Lorillard bought the blu brand, 99 percent of the business was coming from cigarette users who helped blu achieve year-over-year growth at over 40 percent at one point. This was when blu and other e-cig players were becoming a huge threat to giant tobacco companies.

"It's a little bit ironic now that the deeming regs favor bigger players who are savvy with regulation and have more resources," Lavery says. "It's funny how we got here. Unwittingly, now they are the ones best positioned to succeed, and competitive dynamics could change now that the bigger companies have more of a vested interest. If there is further consolidation among competitors, it might get a little bit easier to make money in the category.

Across the board, industry experts view the deeming regulations as a potential boon for Big Tobacco. "If you asked me two years ago, I thought large tobacco companies would have waved a magic wand if they could to make vapor go away, knowing they weren't going to get their fair share," says Bill Marshall, vice president and

senior tobacco analyst with Barclays. "A couple of years later, Reynolds wants to see progress and is moving down the risk continuum in the category; it bodes well for the big players. It will get more challenging for smaller players—not impossible, but it is no longer a situation where the larger ones want it to disappear."

That unhappy reality has many in the vapor industry outraged. Some even argue that this outcome is no accident. As a columnist at Vape Beat put it, "If everything goes to plan for the FDA and its cronies, small, independent vape labs are going to be squeezed out of the marketplace they created in order to make way for big tobacco-produced e-liquids and cig-alike products."

The Heat-Not-Burn Holdup

In addition to complaining that the deeming regulations favor larger companies, many fear a stifling of innovation under FDA regulation. Analysts opine that the promise of heat-not-burn technology will go unrealized, in limbo for at least another three years before making it to the U.S. market.

"We won't see it here before 2019—we think that's the most likely date," says Vivien Azer, managing director and senior tobacco research analyst for Cowen and Company. She is basing that somewhat on the "process we've seen Swedish Match go through" with its so-far-unapproved Modified-Risk Tobacco Product (MRTP) application for its General brand of snus. (It did, however, receive FDA approval to market improved snus products long on the market in Sweden, now on U.S. shelves, through a Pre-Market Tobacco Application—PMTA, the process that tobacco products which were not on the market before the predicate date of February 15, 2007 must undergo to stay on store shelves). Azer said that heat-not-burn is "a truly novel innovation, and because there's no predicate, we don't know what framework they will base it on."

Marshall agrees that "we're several years out now" with heat-not-burn becoming a reality to the market.

While substantial equivalence (SE) applications—applications that seek FDA approval by demonstrating that a given tobacco product is substantially equivalent to one already on the market prior to the predicate date—are moving through the system, the PMTA process is far more intensive, notes Lavery. "SEs are moving more quickly now, but Swedish Match had a couple of MRTPs that are even more difficult to get through—it's like brand new activity," he says. "So, I, too, think something around 2019 is a best-case scenario."

He adds that, "anyone who is following the government and FDA knows that nothing is quick to go through; usually, no matter what they say, it takes significantly longer."

The Category Profit Catch

Beyond heat-not-burn, the bigger picture of e-vapor being a truly profitable category is largely stalled given the new regulations. Even big companies like R.J. Reynolds "had a target to get the next-gen[eration] product profitable, but will now have to back off," says Azer. "Tobacco is a scale business, and e-cigs are no different. We need to get more devices in people's hands to drive profitability. What gets us to category growth is innovation, which is now stifled a bit."

Marshall says there is speculation on larger companies acquiring innovative e-vapor companies (as opposed to e-cig companies) as time moves forward with new regulation, because consumers in the category are "always looking for more and what's next."

> **"Vapor could grow exponentially for five years, and it would still be a niche category."**

Lavery observes that "these have been the times of unusually strong category momentum and pricing momentum," which should be a plus for the industry moving forward.

Azer steers it back to big-picture reality: "Vapor could grow exponentially for five years, and it would still be a niche category," she says.

Vape Shop Viability?

Vape shops (and tobacco shops selling vapor, for that matter) that "play by the rules" in the vapor category have a good shot at viability, according to analysts, who view online sales of e-vapor in dire straits under the new regulation.

Where vape shops will be most affected initially is in the e-liquid category, specifically those that currently mix their own liquid, thereby qualifying them as a small manufacturer and subject to the same exorbitant user fees (ranging between approximately $800,000 and $1.2 million in the first two years, by some estimations). Azer expects vape shops that currently mix their own e-liquid will not be doing so much longer; instead, they will be sourcing liquid only from FDA-approved manufacturers over time, she says. **TBI**

For more perspectives on the impact of deeming regulations in the marketplace, see ***FDA Under the Microscope****, p. 72.*

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THE FRIENDLY FACE OF TOBACCO

Smoker Friendly's Terry Gallagher, Jr. puffs as he ponders the company's recent premium-cigar-focused Tobacco Depot acquisition, adapting to the FDA's "no surprise" ruling, why the Colorado locations aren't in cannabis yet, and how the Rocky Mountain powerhouse can help established tobacco outlets that are ready to call it quits.

BY RENÉE COVINO ★ PHOTOGRAPHY BY ANTHONY CAMERA

The lobby of Smoker Friendly headquarters in Boulder, Colorado, boasts eye-catching tobacco artifacts, including a shelved collection of unique humidors.

In the turbulent tobacco skies, it's nice to fly with a friendly face—and even better if that face belongs to a calm and competent pilot. Flash to Terry Gallagher, Jr.'s stogie-smoking grin, backed with decades of experience in a family-run business, and it's no wonder that the managing partner and "face" of the industry's leading tobacco outlet brand has attracted such an industry following of authorized dealers and company-owned acquisitions.

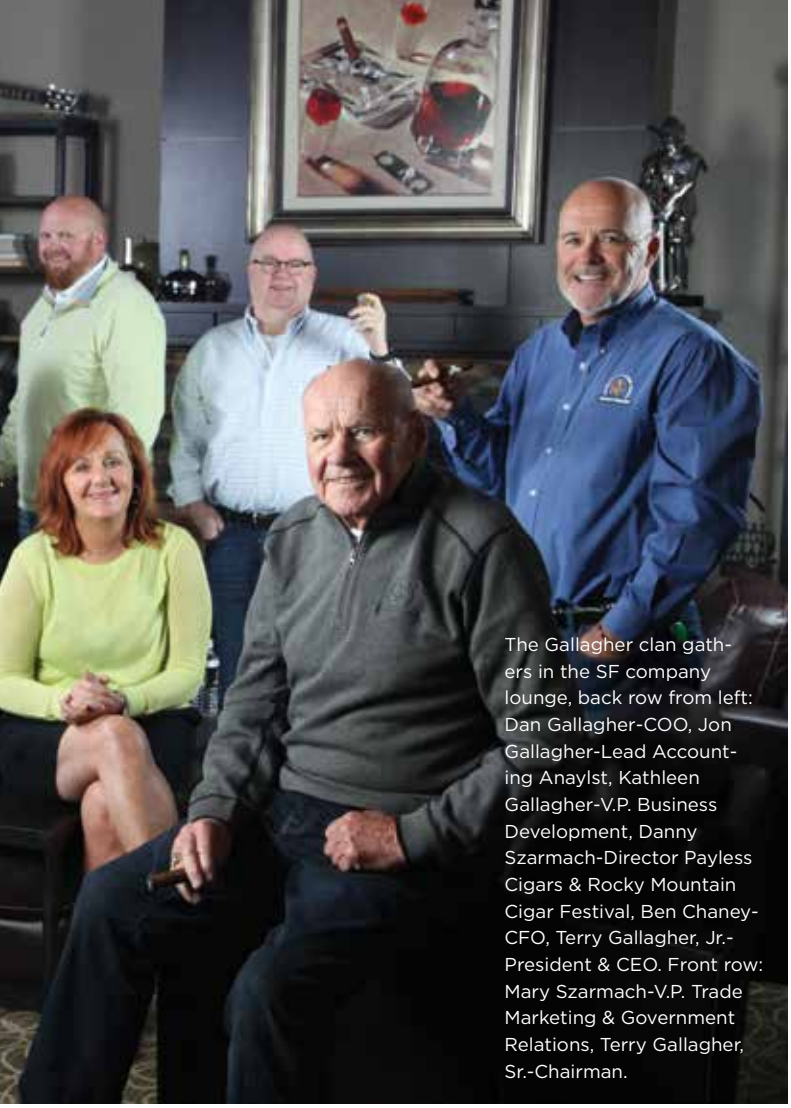
Smoker Friendly International now boasts more than 850 locations, nearly 100 of them owned by The Cigarette Store Corp. (TCSC), of which Gallagher is founder and president. Well-loved for his candor, passion and understated humor in an industry that is used to taking blow after blow, Gallagher is clearly a big part of the reason why many operators want to climb aboard and fly their businesses with the "friendly" tobacco brand.

ENTER, TOBACCO DEPOT

One of those is Fred Hoyland, an industry icon himself, who owned and operated the premium-cigar-focused Tobacco Depot chain in Tampa, Florida for over 20 years. Hoyland recently exited the industry after an acquisition agreement was struck with Gallagher and his brother, Dan Gallagher, COO of TCSC. For now, Smoker Friendly will continue to operate the stores under the Tobacco Depot banner, but will begin co-branding the stores with "Smoker Friendly" in the near future. In the meantime, it will be introducing the Smoker Friendly brand family of private label tobacco products (see sidebar, "Flying the Private Banner") in the Florida stores.

Gallagher, Jr., who praises Hoyland and his team for building a thriving 13-store business, sees the Florida stores as an excellent "bolt-on" to TCSC's existing company stores in the mountain states.

"For one, they are all profitable stores with a good, long history in an extremely strong premium cigar market; we like the seasonality difference between us," he says. "We're going into the high season now in Colorado, and Tampa is losing its snowbirds, but when the snowbirds go into Florida and stay until May, that's their peak season, and those are some of our tougher months. Whether it's cigarettes, cigars or pipes, when you're in cold weather country



The Gallagher clan gathers in the SF company lounge, back row from left: Dan Gallagher-COO, Jon Gallagher-Lead Accounting Anaylst, Kathleen Gallagher-V.P. Business Development, Danny Szarmach-Director Payless Cigars & Rocky Mountain Cigar Festival, Ben Chaney-CFO, Terry Gallagher, Jr.-President & CEO. Front row: Mary Szarmach-V.P. Trade Marketing & Government Relations, Terry Gallagher, Sr.-Chairman.

The Gallagher Family grin—and business acumen—began with the patriarch, Terence P. Gallagher, Sr.

without the ability to smoke everywhere, smoking consumption goes down. So the mirror of the two seasons is very attractive."

What's more, Tobacco Depot "sells more premium cigars on average than we do and we like that business," notes Gallagher. "We like how that complements the premium cigar business in our brick-and-mortars. It also helps with our Rocky Mountain Cigar Festival (to be held in Broomfield, Colorado on August 20, 2016) and it just strengthens our relationships with the numerous cigar manufacturers."

Conversely, while Tobacco Depot is strong in vape, "there's an opportunity to grow some categories Fred didn't focus on; we think we can grow cigarettes, domestic cigars, moist tobacco and more for those stores," says Gallagher. "We do a really good job in our corporate stores focusing on all categories. We don't let any of them go by the wayside. Even as it gets tougher, we don't totally give up. We will evolve and figure out how to sell them, maybe not like in the past, but we are not walking away from being a total tobacco outlet. We do focus on our Smoker Friendly private brands really well, but we also focus on other brands. We know the importance of [different] brands."

"Well-loved for his candor, passion and understated humor in an industry that is used to taking blow after blow, Gallagher is clearly a big part of the reason why many operators want to climb aboard and fly their businesses with the "friendly" tobacco brand.

PREMIUM CIGAR ADAPTATION

With the Tobacco Depot acquisition, premium cigar brands are certainly part of the company's ever-evolving strength, but how will that change given FDA's recent finalization of the deeming regulations, essentially stopping the innovation and release of new cigar brands after August 8?

"We have a couple of years to sell what's in our stores now, and we're going to push all those categories and products that are affected," says Gallagher. "We think a lot of the manufacturers, especially on the premium side, will figure out how to adapt. It may not be as easy for boutique manufacturers that don't meet the predicate date; they have a different hurdle, in my mind, especially if legislation doesn't step in or help push the dates back. But even if everything stayed the same, there are a lot of blends in our marketplace, or old blends before the predicate date, to fill our humidors. So we will adapt to how the market goes, and we'll evolve with those."

Manufactured by industry leaders, the Smoker Friendly private label brand includes a full line of tobacco products and accessories.

He adds that he does not see the sales of premium cigars being affected at his retail stores in any drastic way, especially since "right now we can stay in a self-service situation, which is important for walk-in humidor business. Hopefully that won't change, but if it did, we'd figure out how to adapt to that, too," he says. "It's not the way we like to spend our productivity— figuring out how to deal with legislative issues—but we will do what we need to do."

Smoker Friendly keeps its "ear to the ground," according to Gallagher, with a government affairs director that interacts with all the key industry associations. "We try to stay very proactive, not reactive," he maintains.

The company's FDA attorneys in Washington, D.C. are scouring the new regulations and providing information for its dealer network, which encompasses many retailers who "don't have their own attorney—they look to us for this," states Gallagher.

He and the SF team were ready for this recent FDA battle and more; Gallagher maintains that he was not one bit shocked by the FDA ruling. "From our standpoint, there were no surprises there. We expected them to come out as tough as they did," he says. "There's no reason to think [that] the FDA would do anything favorable for our industry. They are anti-tobacco and hate our industry."

Acknowledging that e-cigs and vapor were part of the recent FDA attack, Gallagher still sees potential for that part of the business. "While it really remains to be seen what happens, there's no question: the big guys will be able to be in the ballgame if they want to be," he says. "It can be vape, heat-not-burn, [or] some version like cig-alikes, but whoever has the money and the patience to go through the process for approval will get to play in it." As a well-rounded merchandiser, Gallagher admits that he may not like "being boxed in" by the major brands, "but if that's the way it turns out, that's what we'll do."

On the plus side, he feels strongly that the alternative category is not going to go away. "It's too far down the road and there's too much investment from the majors," he says.

CANNABIS: A SIDEWAYS APPROACH

A FEW YEARS AGO, WHEN COLORADO was on the forefront of legalizing cannabis from a recreational standpoint, Gallagher and Smoker Friendly took a serious, hard look at it. The company decided not to jump into selling pot—at least not yet—but instead to approach it from a "sideways" stance. Smoker Friendly moved into the glass accessories business, beginning with a side chain, and then developed a program that authorized dealers can incorporate into their stores: Glass Werx.

"We have a real nice licensed program and partnership with Glow Industries, which allows our retailers who want to get into the glass business—but know nothing about it—a way to do it," Gallagher explains. The sets can range from 2- to 8-foot counters, fully planogrammed with "the right products at the right price points," he explains, adding that "if [a SKU] doesn't sell, we can swap it out."

This is the tasteful and conservative way the company says it decided to go—for now. When the Gallagher family looked into it, the yellow flags that popped up mostly had to do with banking and federal law concerns. "The issue about wanting to open up new bank accounts and not being able to bank the money was a big concern for us," he says. "The way a lot of operators do it is with management companies, but that was fraudulent for us."

The other concern has to do with the fact that cannabis is still illegal from a federal standpoint. "If we are breaking the law federally, what might that do to our liquor licenses and tobacco licenses?" reflects Gallagher. "As long as it is not legal federally, we can't take that risk with our core business today. So while the category is still very attractive to us, we haven't moved that way at this point."

Premium-cigar-focused Tobacco Depot is the most recent established tobacco outlet chain to take advantage of Smoker Friendly's exit strategy.

EXIT, STAGE SF

Smoker Friendly can offer experience and expertise to retailers through its authorized dealer program, but the tobacco outlet icon is also leveraging a different kind of strategy for those who want out, a la Tobacco Depot.

"There are a lot of family tobacco outlet businesses out there that have been around for 20 or 25 years, a lot of one-generation operators that would like a way out," offers Gallagher. "We think we can provide a good exit strategy for them and we're interested in those type of opportunities. We have the scale and the technology and a really good team of people that can take that on to finance the acquisition and grow it to another level."

Smoker Friendly's plan under Gallagher and the team is to grow its core competency as tobacco retailers, with the understanding that there is still very much a need for this niche retail business.

"As more Millennials enter the corporate world with their negative attitudes about the tobacco business and more pharmacies and local community businesses are opposed to it philosophically, there is more room for operators like us to operate somewhat on the fringe in the tobacco arena," says Gallagher.

Moving forward, he is adamant that the tobacco retail business of today is more dependent on powerful industry relationships and partnerships than ever. "This is the cornerstone of our success, which I attribute to my dad in the oil business, who passed it on to us: how important it is to have outstanding supplier, distributor and association relationships," he says. "Looking long term, we look at building for a viable future. As times change, so does the nature of the business, and you never know when those relationships on the back burner will move to the forefront and be necessary to help your business grow."

That, and the Gallagher grin, will prevail at Smoker Friendly. **TBI**

FLYING THE PRIVATE BANNER

As part of the Smoker Friendly (SF) authorized dealer program, the Smoker Friendly private label brand includes a full line of tobacco products and accessories, including:

- ★ Eleven styles of cigarettes/MSA compliant
- ★ Six flavors of filtered cigars
- ★ SF Grande's
- ★ SF Cigarillos in four flavors
- ★ Six styles of premium pipe tobacco
- ★ Nine lines of premium cigars: Dominican, Honduran, Nicaraguan, Dominican Select, SF Big Pig & Piglet, Cuban Castaways, Cast Offs, and Smoker Friendly by Rocky Patel
- ★ SF It's a Boy, SF It's a Girl
- ★ Three styles in two sizes of pipe tobacco
- ★ Cigarette tubes and RYO/MYO accessories
- ★ E-cig kits and disposables
- ★ Lighters

The line is manufactured by industry leaders Altadis, Davidoff, Rocky Patel, J.C. Newman, Commonwealth, Republic Tobacco, National Tobacco, Xikar, CAI, Inc., Swisher, and US Flue Cured Tobacco Growers, Inc.

TIMELINE: Key Career Dates

1984: Terry Gallagher, Jr. began his career with Gasamat Oil Corp. of Colorado (GOCC), purchased by the Gallagher family business patriarch, his father, Terrence P. Gallagher, Sr.

1991: The Cigarette Store Corp. (TCSC) is incorporated; Terry Gallagher, Jr. is founder and president

1995: Smoker Friendly International (SFI) is founded

2003: The retail operations of GOCC are merged into TCSC

2005: Terry Gallagher, Jr. begins serving as managing partner of SFI

A PERFECT BLENDSHIP

How Paul Warner founded and grew a thriving cigar shop in Tennessee. **By Peter Barry**

Paul Warner, the president of Silo Cigars, would appear to be a man without a care in the world: late 40s with short salt-and-pepper hair, casual summer clothes, metal-framed glasses and the aromatic trail of cigar smoke swirling behind him. It's before 10 in the morning and he's at work. He looks like a man doing what he wants to do.

In fact, sitting in the spacious and comfortable smoking lounge at Silo Cigars in Knoxville, Tennessee in one of the many overstuffed leather chairs in this haven for cigar smokers, it seems to me to be a pretty good scene—in other words, nice work if you can get it.

But don't be fooled. I met with Paul Warner on the day of the new FDA ruling that went against tobacco products and its retailers, and it became clear over the course of our discussion that the headwinds against selling tobacco products have never been stiffer than they are today, with little sign that the creeping ostracism from an environmentally correct society won't continue to get worse in years to come.

However, Paul has had to deal with setbacks from the very beginning. They started back in 2007, when Paul and his friend Kevin Phillips formed a partnership and made their first foray into the cigar business (Paul has since taken sole ownership by mutual agreement). They chose their name based on an old barn with a 60-foot brick silo they contracted to lease for their shop. The plan was to use both the silo and the barn for display and lounge areas, adding colored bands of light to the silo to make it look like a giant lit cigar for miles around—a dramatic and memorable marketing image. Then, at the last minute, they were told that they wouldn't be allowed to use the silo structure interior at all, only the barn, but that the lease price would stay the same.

Some might take that as a bad omen for a startup, especially since the duo had already completed the paperwork registering the name of Silo Cigars and didn't want to incur the expense of refiling. Instead, the nascent operation became Silo Cigars without a silo in sight, and no compelling marketing angle for promoting their name. The first shop opened quietly in a light industrial area in South Knoxville, mostly because of very cheap rent and a lack of neighbors who might complain about the smoke. They nailed cedar panels to the walls of a 10-foot-by-12-foot office, plugged in the humidifiers, and opened the doors.

Without much foot traffic to distract them, Paul turned to his background in computers and technology—he had worked for many years for Seagate Technology, a maker of disc drives, in Chicago, Illinois. Hours on end were put into figuring out how to get Google's search engine to list the shop. That effort paid off in a big way when the highest percentage of their sales in those early years came in through online sales.

Things were going well, so they moved from their out-of-the way digs to a small strip of stores in suburban Farragut, just south of the city of Knoxville. They chose the location for its upscale demographic, and because it was a popular area for locals to retire. It was also a conscious choice not to step on the toes of any established shops closer to the downtown area. By the second year, sales were impressive: $250,000 online and $100,000 in-store.

CARVING A NICHE

Their second strategy was to carve out a niche with the boutique cigar brands. Relationships were cultivated within the industry, and chances were taken on unknown or little-known brands and cigar makers who were making good products. Today they are respected names, like Pete Johnson, José "Don" Pepin Garcia, Andre Farkas and Dion Giolito, all of whom were just emerging in Silo's early days. Many of the brands that Silo featured couldn't produce enough cigars for the mass distributors, but they still needed retail outlets. "There were a series of these very limited distribution cigars—they didn't have the capacity to make a lot of cigars—that were looking for outlets, and there were a lot of the conventional cigar stores that were used to ordering the big names that everyone's heard of, so there weren't a lot of places you could get these brands," Warner explains. "Ultimately, we were offered things that other people didn't want to spend the time or effort on."

They found a home in Silo Cigars. Silo also separated itself from other online outlets by being willing to sell single sticks at the discount box price and to sell small orders online. Not requiring the curious to purchase full boxes allowed the consumer to taste-test the product. Then, Warner and Phillips took to online forums, such as Brothers of the Leaf and Cigar Family, and shared their knowledge and passions with others, growing their company's reputation in the process and reaching people in far-flung areas with little or no local access to the burgeoning brands.

With solid sales growth and deepening relationships with the cigar makers under their belts, Silo's owners began to find unique opportunities coming their way. By working with Willy Herrera at El Titan de Bronze in Miami, Silo stepped into the world of creating customized cigars, products only available through their shop and website. Using Nicaraguan tobacco, they created a line, "Sudeste Cubano," with six cigar sizes (Robusto, Toro, Perfecto, etc.) in two wrappers: *Habano* and maduro. The cigars were good, but rolling small batches in Miami put their price point too high to be truly competitive. Still, lessons were learned. The duo enjoyed the process and their customers enjoyed the result.

BUILDING ON RELATIONSHIPS

The strong relationships they were building within the industry also translated to in-store promotional opportunities. Warner smiles as he remembers the time they invited Willy Herrera into the shop for a cigar-rolling event. It was before Herrera became the master blender for the popular Drew Estate line of cigars. That's the great thing about fostering good relationships when you're in a close-knit community like the cigar industry: as people transition through the business, relationships travel, too, creating new connections and opening up new possibilities.

There were also bumps along the road to success. In 2010, Warner's partner needed to opt out of their business for personal reasons, which was an unexpected turn of events. Around this time, Warner also started having trouble with his web hosting service. Things turned so toxic between them that this critical relationship became an impossible situation. This necessitated the need to move the website to a new host company and new servers. Unfortunately, such a move causes the loss of all the original site links, and thus cost Silo Cigars its coveted first page listing in Google's search engine. This quickly translated into a steep decline in online sales.

Rebuilding that side of the business hasn't been easy. As time has gone by, the online world has matured: Silo soon suffered its first credit card fraud from online sales, losing both the product and the payment. By 2012, fraudulent sales exceeded legitimate sales during some months. Next, competitive sellers online began to undercut prices, making it harder to compete while playing fair. Add to this the risk of fines from MasterCard and Visa on non-face-to-face credit card transactions for tobacco products, and the environment for online sales may never be the same again. Says Warner, "We've been grouped into an unsavory business classification, so I no longer have access to the same tools that every other seller on the Internet has."

But Warner has continued working with cigar makers to create special blends and to offer single-size variations of popular lines that are only made available through Silo. Over time, some of the products that were created were a complete line of Pinar del Rio Chevetta made in the Dominican Republic and, more recently, an exclusive lancero-size version in broadleaf and *Habano*, of the *La Sirena*. Since the store is only a few miles off Interstate 75, a main corridor from the Great Lakes to Southern Florida, it has become a destination for many of the snowbirds that head south to escape the cold winters.

In 2015, Silo Cigars made the move to its current home, less than a mile away from the old shop, after Warner was told by his former landlord that its lease wouldn't be renewed, mostly because a cigar store no longer fit with the other family-friendly businesses. The upside to this marketplace reality is that the new space, over 2,200 square feet, allowed for an even bigger walk-in humidor, and for the creation of a large, members-only lounge and event space.

Through all the changes in the marketplace, Silo has remained something of a purist play: "Pipe tobacco wasn't really feasible because it was well-covered in Knoxville," explains Warner, "and it wasn't worth elbowing into the vaping market because I find that to be an essentially dif-

ferent clientele." He's found that the two camps don't always see eye-to-eye: vaping produces billowing clouds that cigar smokers find annoying, while cigar smoke is unsettling to vapers, who are often trying to quit real cigarettes. Silo does carry a small selection of hard-to-find brands of specialty cigarettes like Nat Sherman, Dunhill and others. It also offers traditional cigar-smoking accessories: cutters, lighters, humidors and such.

MAKING THE MOST OF MARKETING

To drive local awareness of Silo Cigars, Warner makes use of a focused mix of marketing outlets. He currently hosts about two in-store special events per month, often featuring a visit from a favorite cigar brand offering special deals and exclusives. He promotes these events through the thousands of participants on Silo's email and texting lists. He also makes use of Facebook, Twitter and Instagram, although Warner admits he's not an avid user of social media, and tobacco products are limited in what they can do in online promotions.

He says he also gets good results from promoting upcoming events with ads on a local radio station, which offers a companion direct-mail insert featuring local businesses. Silo will even run TV ads around Christmas and Father's Day because Warner finds that when customers actually see the size of the walk-in humidor, its selection and the comfort of the members' lounge area with its multiple TV screens, it helps to separate his place from the competition. Because his local area is split between cable companies, he finds he gets the best coverage by running the ads on a local Fox affiliate that is carried by all the cable and dish companies. In fact, Silo gets the best response when it runs its ads during the show *Two and a Half Men*.

With the new space, Warner says the opportunity for customers to become members has been well-received, although he's still tweaking the multiple tiers of membership. He currently offers three levels, with the top tier including a private cigar locker, access to members-only events

and promotions, and the ability for members to reserve the lounge for their own private events. He also offers day passes for visitors to partake in the lounge area with its TV and Wi-Fi, though the day passes don't apply to member-only events. And if you're in Tennessee in the fall, you know this is Vols (University of Tennessee Volunteers) football territory, so the huge array of TV screens keeps the hard-core fans happy.

But with all the recent legal pressure against tobacco retailers, Warner feels the need to keep reaching further and further afield: "Manufacturers are spending more of their time courting the European market where they're far more tolerant of smoking." He says this shift makes it harder for retailers to get and keep the attention of the manufacturers and their reps, and harder to book their time for visits and in-store promotions. It also definitely limits any availability for making special production cigars.

Recently, Silo held a charity fundraiser to help support the building of a local rugby field, yet it won't be allowed to have a sponsor's plaque because of its tobacco affiliations. Unfortunately, that's just the cost of doing business in the world of tobacco today. Warner still believes it's a way to make new friends, create new relationships and expand the awareness of the shop to local folks.

If you're reading this article, you may already be at the IPCPR show. You may see Warner there, renewing old relationships, making new ones, and looking at the new launches. He's also a member of CRA (Cigar Rights of America), and in Tennessee he's president of the retail association for cigar shops. Warner is an advocate for local cigar retailers to band together to build a war chest to defend against upcoming attacks on their livelihood within their own state.

So what lies ahead? With pressure from all sides squeezing the business, is there room for optimism about the future? Warner thinks so. He looks at the opening up of Cuba as a positive, not just because Cuban cigars will become available and that will attract interested buyers, but because the tobacco itself will become available to master blenders and cigar makers, and in that the possibilities are promising. Warner is of the belief that Cuban cigars have a mystique, but the quality gap has been closed in the years they've been illegal; the embargo pushed the industry to mature in other countries. "It's the availability of the leaf that will add a new color to the master blender's palette," says Warner.

As Warner looks at the marketplace and sees the boom of craft and boutique beers everywhere, as well as the trend toward local farm produce, he sees a similar trajectory for the cigar industry, with boutique customization, hybrid blends and the continuing growth of small craft artisans within the cigar industry.

Of course, that vision could now be in jeopardy because of the FDA's recent ruling, which will make it prohibitively expensive to launch new cigars and new blends—even for the biggest players. "With this new ruling, what I spoke about could be done," Warner notes. "Even the established Cuban brands won't be grandfathered, so they'll have to apply, too. You can imagine how the Cuban government will feel about that! The hope is that a separation can be created for premium cigars, but how exactly is that going to be defined?" Whatever happens, Paul Warner at Silo Cigars will be focusing on the people—his friendships within the industry, and his relationships with his customers—and the cigars that they love. **TBI**

The FDA's Tobacco Deeming Regulations

On May 10, 2016, the U.S. Food and Drug Administration (FDA) issued the long-awaited final deeming regulations, which extended the agency's regulatory authority to premium cigars, domestic cigars, pipe tobacco, e-cigarettes, e-hookah, e-cigars, vape pens, advanced refillable personal vaporizers, electronic pipes, hookah tobacco, dissolvable tobacco products, and nicotine gels. The deeming regulations go into effect on August 8, 2016.

Most of the new deeming regulations apply to tobacco manufacturers and the products that they make. However, the deeming regulations do prohibit retailers from selling the deemed tobacco products (including over the Internet) to individuals under 18 years of age. Also, FDA did not prohibit retail self-service displays of the deemed tobacco products, nor did the agency ban flavored deemed tobacco products.

Manufacturer Regulations

The manufacturers of the deemed tobacco products must comply with several FDA regulations, including: 1) submission of ingredient lists for each deemed tobacco product and reporting of harmful or potentially harmful constituents (HPHCs); 2) registration of tobacco product manufacturing facilities and a list of all tobacco products manufactured; 3) removal of modified-risk descriptors (e.g., "light," "low" and "mild") from products, and 4) filing substantial equivalency (SE) or pre-market tobacco applications (PMTA) for products introduced in the marketplace after February 15, 2007, which is known as the predicate or grandfather date.

SEs Vs. PMTAs

A manufacturer can submit an SE application if a product introduced to the market after February 15, 2007 is substantially similar to a product that was already on the market on or before that date. A substantially similar product is known by FDA as a "predicate product." If there were no substantially similar predicate products for a manufacturer to rely on, then the manufacturer would need to file a PMTA for its products with FDA.

Based on the fact that the predicate/grandfather date has not been changed in the deeming regulations and that the majority of cigars and pipe tobacco and virtually all e-cigarettes were introduced in the market after February 15, 2007, manufacturers will be required to file SE or PMTA applications for a great number of cigars, pipe tobacco and e-cigarettes. The number of SE and PMTA applications will be so high because FDA believes that a separate SE or PMTA application will likely be necessary for just about each product SKU. FDA estimates that on average it will take 1,713 hours to compile one PMTA application and cost upwards of $330,000 for each application.

Manufacturers have until February 8, 2018 to file SE applications with FDA and until August 8, 2018 to file PMTA applications with the agency. During these timeframes, manufacturers can keep their products on the market. If a manufacturer does not file an SE or PMTA application then its products will no longer be sellable as of February 8, 2018 for SE applicable products, and as of August 8, 2018 for PMTA applicable products.

Future Regulations

According to FDA, the final deeming regulations differ from most other public health regulations in that they are enabling regulations, meaning that FDA can issue further regulations related to the tobacco products that are appropriate to meet the agency's standard of protecting the public health.

Specifically, FDA indicated in the deeming regulations that it may consider banning retail self-service displays in the future if the agency believes it would be appropriate to further limit youth access to tobacco products. Moreover, FDA states in the deeming regulations that it intends to issue a proposed product standard that, if finalized and adopted, would eliminate characterizing flavors in all cigars, including cigarillos and little cigars.

Industry Lawsuits

Since the deeming regulations were released, four separate lawsuits have been filed seeking to overturn either the entire set of deeming regulations or to prevent the enforcement of a specific regulation with respect to particular products.

Nicopure Labs filed a lawsuit in the United States Federal District Court for the District of Columbia seeking to have the court vacate and set aside the FDA deeming regulations, as well as issue a preliminary injunction preventing FDA from enforcing the deeming regulations. Nicopure Labs is a manufacturer of closed-system and open-system vaping devices, and nicotine-containing and non-nicotine-containing e-liquids.

The second lawsuit against FDA was filed by John Middleton Company. It seeks to set aside and enjoin the enforcement of that provision in the tobacco deeming regulations that prohibits the company from using the word "mild" in its "BLACK & MILD" trademark.

The third lawsuit was filed by Lost Art Liquids and seeks to set aside the entire set of deeming regulations, claiming that FDA did not fully consider the financial impact of the deeming regulations on small businesses and that the agency overstated the benefits of the deeming regulations while grossly underestimating the costs of compliance, leading to an erroneous conclusion that the benefits of the deeming regulations outweigh the costs.

Global Premium Cigars also filed a lawsuit that alleges that the new cigar warning labels required for cigar boxes, which would need to cover 30 percent of each of the two principle display panels of the package, violate First Amendment free speech rights because the labels would reduce space for advertising the product name. Also, the suit claims that being forced to allot space on cigar boxes for the warning labels is a taking of property rights that requires just compensation.

Since the deeming regulations were released, three separate lawsuits have been filed seeking to overturn either the entire set of deeming regulations or to prevent the enforcement of a specific regulation with respect to particular products.

With the majority of the deeming regulations going into effect on August 8, 2016, the plaintiffs in these lawsuits are requesting that the respective courts issue a decision on the requests for a preliminary injunction on or before the August 8 effective date. **TBI**

Thomas Briant is the executive director and legal counsel of NATO, the National Association of Tobacco Outlets.

FDA Under the Microscope

Three industry veterans offer their perspectives on how new FDA regulation will affect cigars, vapor products and more. **By Jennifer Gelfand**

They were a long time coming, but finally, the word is out and the regulations are in—FDA has officially asserted its control over all tobacco products, even those that do not yet exist. This development has been brewing for so long and with such fervor that the industry collectively breathed a sigh of relief when the seemingly endless period of suspense and uncertainty came to an end.

However, that reprieve lasted about a nanosecond before each and every newly regulated category promptly began to churn over what exactly the regulations would mean for their businesses and what should be done in response. In the roundup to follow, four experts share their perspectives on how the announced regulations will affect different areas of tobacco.

Joe Teller, Director, Category Management, Swedish Match, weighs in on what the regulations mean for the cigar industry.

Deeming Regulations for Cigars

On how the regulations matched up to expectations...

"A lot of what is in the regulations is what everyone expected: minimum age, sampling ban and warning labels—a lot of the same stuff that was applied to cigarettes and smokeless products back in 2009. Some people were unsure that premium cigars would be included, but they were. There is no self-service ban yet and flavors weren't banned. Everyone assumes these things are coming down the pike, but at least they were not in regulations as they were released."

On what FDA's decision to maintain the existing predicate/grandfather date means for cigar companies...

"FDA looked at a lot of options for changing the date, but came to the conclusion that it was only Congress that had the authority to change it and [Congress's] read of the law said that it should be February 15, 2007. This will definitely be a challenge for the industry. It's the same date that was used when the Tobacco Control Act was passed, but that was in 2009 so people only had to go back and fill out applications for products that had been newly introduced over two years. Now it's 2016, so everything introduced over the past nine-and-a-half years has to be submitted with the proper application for FDA approval.

"If manufacturers were smart, they were already compiling information and putting some of this together in advance of official notice of regulations. There will be thousands of applications; we estimated 7,000 and I saw another estimate of 10,000. So that is a whole bunch of product applications that will need to be put together, and then FDA will need to review those and make decisions on [each of] them. There is already a big backlog now—thousands—just from 2009 regulations, so there is a lot of work to be done by FDA as well as manufacturers.

"This 2007 [predicate] date will be difficult for everyone involved; I am sure there will be some manufacturers out there who do not have the necessary data they need to properly fill out the applications. Some will struggle with that. I don't know how anyone *wouldn't* struggle with it. It will just be a challenge for the industry [overall]."

On what to expect going through the Substantial Equivalence (SE) and Pre-Market Tobacco Product Application (PMTA) processes:

"We went through the [PMTA] process with smokeless tobacco products; you have to do an application for every single item not covered by the grandfather date. It costs hundreds of thousands of dollars to create an application and hundreds of thousands for testing. From our perspective, it was more costly than we had thought it would be going in.

"You do have 18 months to put an SE application together. It is likely that cigar com-

Since the earliest the change could be made is late 2019, maybe things will stay more or less the same for retailers for at least a few years, but there could be pretty big changes coming by mid- to late-2019."

—JOE TELLER

panies will be able to use substantial equivalence because products were on the market before 2007.

"The Pre-Market Tobacco Product Application (PMTA) is more costly, and only eight have been approved since the 2009 law. You do have more time—24 months—to submit this, however, it took years when we filled out one of these, so 24 months might be tight if you haven't started yet."

On how soon the regulations will impact retailers...

"The guidelines call for making a decision in 12 months, but with the backlog they have now and the number of applications coming, how long will it take? I don't think anyone can guess at this point. Since the earliest the change could be made is late 2019, maybe things will stay more or less the same for retailers for at least a few years, but there could be pretty big changes coming by mid- to late-2019."

On more changes to come...

"Flavors were not banned in the deeming regulations, but if you dig through the announcement enough you can find where FDA stated that [it does] intend to issue some additional rules. This is a foundational rule and others will come in the future, so I'm sure that flavors will be addressed and possibly banned.

"The question, given the thousands of applications coming in, is how many things can FDA do concurrently? What will be prioritized? Because some will happen now and others later, but all indications show that flavors will probably be banned at some point in time."

On what a flavor ban will mean for the cigar industry...

"Banning flavors is a big one for cigars. Much depends on how FDA defines a characterizing flavor. If you include 'sweet' as a flavor, then somewhere between 50 and 75 percent of category volume comes from flavored cigars. It is a huge part of the business. There are everyday-flavored items and in-and-out, limited-time flavors that would go away or be replaced with other items. The in-and-out items would go away right away since having to fill out an application for each new one would be [cost prohibitive]."

On how consumers will be affected...

"In the next two years there could be drastic changes coming. Small companies unable to bear the cost and time burden of the process will go out of business, so there will be more consolidation as big companies get bigger. For retailers, this means larger manufacturers with even more power and leverage than they had before. And when a category is regulated, manufacturers and retailers have to divert resources to complying with laws that could have been used for more productive purposes, such as product innovation. At the end of the day, there will be less product variety as consumers come into the stores and industry growth could also be impacted."

On whether the regulations have staying power...

"Legal challenges have already been filed by Nicopure Labs and Lost Art Liquids, which claim the regulations violate existing laws. I assume [that] there will be additional lawsuits centering around First Amendment rights and the cost of the regulations versus the benefit to the population, as well as potential conflicts with the implementation of this law against other laws on the books. Lawsuits take years to get settled. In the meantime, there is nothing we can do but guess at the outcome and just wait.

"The other thing that could have an impact is the presidential election, which could change the makeup of the CTP [Center for Tobacco Products]. If Hillary Clinton wins, maybe things could stay the same, [but] with [Donald] Trump, no one knows what might happen, so there's a lot coming down the pike and a lot of changes we will have to deal with."

What's In?

Sampling Ban
Minimum Age to Purchase
Warning Labels (New)
No Modified-Risk Claims
Product Applications Required
Premium Cigars (Not Exempted)

What's Not In?

No Flavor Ban
No Self-Service Ban
No Mention of Continuum of Risk
No Product Standards (Ingredients)

Jan Verleur, co-founder and CEO of VMR Products, shares his insights on how the deeming regulations will play out for the vapor category.

E-Cigarettes & Vapor

On the viability of FDA regulation…

"We are hopeful the Cole bill will prevail. We are very much in support of VTA; we were one of the founding members of SFATA but we split off of there to support VTA and back the Cole bill. SFATA wanted to say there shouldn't be any regulations at all, but there were legislative realities that had to be faced.

"To a certain extent, the Cole bill is a poison pill to swallow as far as maybe it doesn't protect future innovation and support research and development, but it protects employees and current business. In the U.S. alone, we have 155 employees so we had to make the decision that would best preserve our business.

"But at the end of the day, we are all on the same side—the side of allowing this industry to continue. It is not outside the realm of reason that we might cooperate closely together; at this point SFATA also is advocating the Cole bill. If we prevail there, we avoid an Armageddon scenario for the industry."

On how his company will respond to the regulations…

"At VMR, we are also looking at the litigation side of the equation. The 'injunctability' of the bill is high given that it went through the process without any material change from the House Appropriations Committee. We are planning to file against FDA within the next 30 days. We are not discussing our litigation strategy publicly yet."

On current legal challenges to the deeming regulations…

"Nicopure did a great job filing; you may see other companies join their lawsuit. It doesn't matter who the first mover is—at the federal level, the suits will all get combined. Ultimately, you will see one major suit."

On the deeming regulations broadly…

"FDA is on a slippery slope here. At the end of the day, it is their obligation to protect consumer health. If you take 5 million [vapor consumers] and force them back to combustibles or limit their options to innovation, you are certainly not serving the public health.

"There are standards—a responsible approach to regulating e-liquid content and dealing with irresponsible battery manufacturing and the absence of short-circuit protection—that we can do responsibly to regulate [ourselves]. But the fundamental point that combustion is bad is indisputable. We are not saying our products are as healthy as breathing air, but they are certainly better than combustibles.

"This is the largest victory that Big Tobacco has achieved in years. They are eliminating innovation. They are behind the Cole bill because it protects the investment they made in trade brands. The Cole bill serves their existing SKUs and they don't want to be in a position where someone who finds the magic [device] can bring it to market and challenge an empire. It is unfortunate, but to an extent FDA has become the [protector] of Big Tobacco."

On how the regulation will impact the industry…

"Economically, it doesn't impact the industry until 2018 since we have two years before enforcement. We hope for resolution before Q1 of 2017 on the Cole bill. In the meantime, we continue to remain committed to the industry. We have one of the largest R&D teams in America. We are the largest non-Big Tobacco vapor company in terms of revenue, certainly in terms of employees.

"We continue to think that where there is risk, there is opportunity. We will find out whether or not we were making the right bets. We have 152 regulator precepts launching before August 8. We are still optimists.

"We have hired consultants to that end and made lists of SKUs that we would undergo the application process with. I reserve the right to file applications pretty quickly if I have to, but right now we are looking for other ways."

"This is the largest victory that Big Tobacco has achieved in years. They are eliminating innovation. They are behind the Cole bill because it protects the investment they made in trade brands."

—JAN VERLEUR

Paul Warner, owner of Silo Cigars in Knoxville, Tennessee, discusses what the deeming regulations mean for premium cigars.

Premium Cigars

On youth access and cigars…

"There are a lot of statistics in the FDA document that cite a high percentage of youths as having their first tobacco experience with cigars, but I think that those are cigars from the huge brands made with homogenized wrappers on machines—the White Owls, the Philly Blunts, the Grenadiers—all found at the checkout counter at gas station marts. So they should split us from them, if possible. Of course, those brands are owned by the large cigarette manufacturers."

On whether the regulations have staying power…

"The cigar lobbies are trying to fight [the ruling], but unfortunately it's a 10-headed monster and there's no unified single front."

"This ruling is a governmental cop-out. If tobacco is as bad as they make it out to be, have the balls to outlaw it and live with the consequences: the loss of revenue from all the taxes collected on tobacco, the loss of jobs, etc."

—PAUL WARNER

On how the regulations will impact retailers…

"The big negatives for me are: 1) I have to post a sign right by the register with all the tobacco warnings usually shown on packaging because I sell singles, 2) I'm obligated to verify IDs for anyone who appears to be under 27 years old, and, probably the most damning to me, 3) I cannot give a free cigar to anyone. Reps can't give me free cigars to let me look like a hero to my customers, and manufacturers at the trade shows can't either, so how do I know if I want to purchase what they're selling?"

On the deeming regulations broadly…

"This ruling is a governmental cop-out. If tobacco is as bad as they make it out to be, have the balls to outlaw it and live with the consequences: the loss of revenue from all the taxes collected on tobacco, the loss of jobs, etc. They tried this with alcohol and it didn't work, it just created a mob-controlled bootlegger, and the American public felt okay violating a law [that] they thought was B.S. We're in the same kind of thing [now]: as long as tobacco is legal, why back us into a corner and see how hard they can make this to consume?"

Nik Modi, Managing Director, RBC Capital Markets, on how the regulations will impact the tobacco industry.

Vapor Products and the Tobacco Industry

On the financial implications for other tobacco products…

"We estimate the cost for each pre-market application [historically] will be $2 million for the initial application and $1 million after as compared with FDA's estimate of $300,000. So the cost is more than three times what they expected. Vapor manufacturers will need to quantify the levels of aerosol constituents and must contract with a lab to do that, which could cost up to $270,000."

On how compliance will impact the industry…

"I can't see how these smaller guys will come up with the funds to comply. A lot of vape shops will be under some duress, so c-stores may see business come back to them. Entrepreneurs have been pretty active in this industry, but in this case you need legal and scientific resources. Being an entrepreneur can't get you through that morass. Navigating this regulatory regime right now will require some real core competencies.

"Barriers to entry have gone up and it will make it tougher on smaller players. Regulations will favor big companies because they have the resources to comply. Weaning people off nicotine has not been part of the discussion."

On the affect on vapor product innovation…

"As of August 8 no new vaping products will be allowed on the market. Essentially, the vaping market will freeze on August 8. Even small changes, such as changes to the battery of an e-cigarette, will not be allowed. To me, this is the single biggest [issue] right now in this category. No one will invest in R&D because of the lack of clarity, and an estimated 16,000 vape shops will go out of business."

On whether the regulations have staying power…

"Litigation seems inevitable. The regulations could [be in] violation of the First Amendment by prohibiting companies from making truthful and non-misleading statements, such as stating that the products are less harmful than cigarettes or that they can help people quit smoking. Or FDA may have interpreted the term 'tobacco product' too broadly, including things like batteries, wicks and electronic displays.

"There are [other] legal avenues companies might pursue, such as that FDA regulations are arbitrary and impose a huge burden on business without any rational connection to the protection of the public's health. The August 8 date also seems arbitrary."

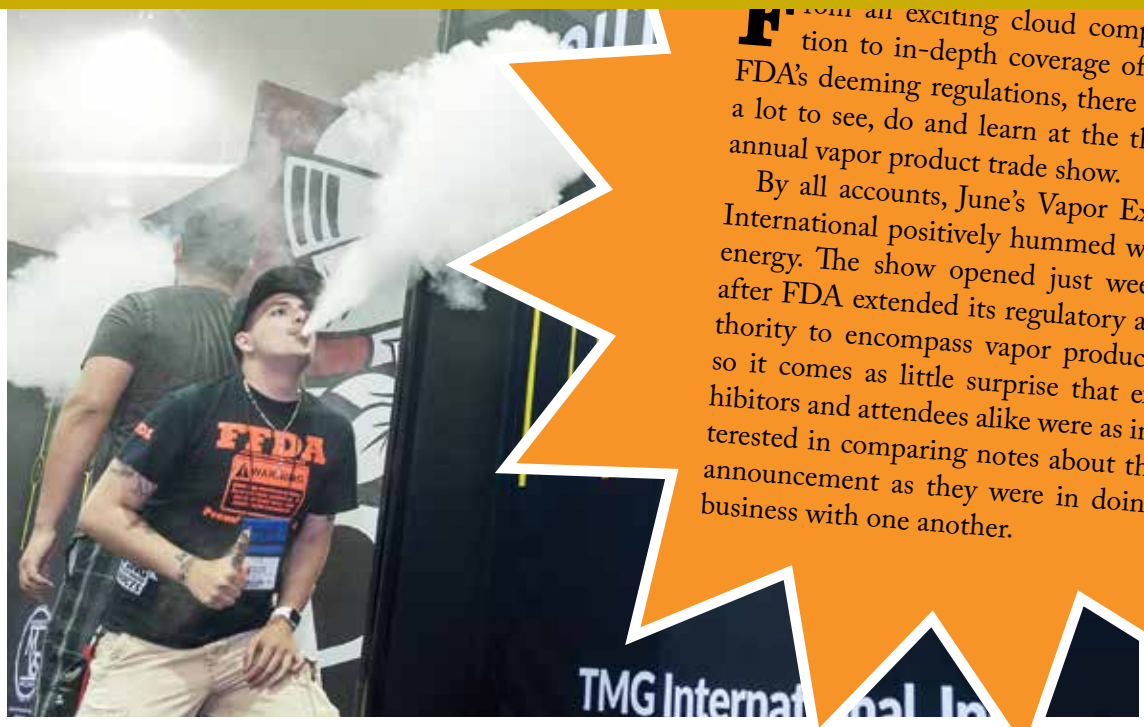
On how the presidential candidates stack up on regulation…

"Tobacco has not been a leading discussion among candidates, so maybe we will see no change. We have heard more about marijuana than tobacco in this campaign. It's hard to gauge. Trump has touted his straight lifestyle—no cigars, no drugs—[so] he is a wild card on this issue. But Hillary Clinton is a strong advocate of public health." **TBI**

"Essentially, the vaping market will freeze on August 8…no one will invest in R&D because of the lack of clarity, and an estimated 16,000 vape shops will go out of business."

—NIK MODI

Vapor Expo International



From an exciting cloud competition to in-depth coverage of the FDA's deeming regulations, there was a lot to see, do and learn at the third annual vapor product trade show.

By all accounts, June's Vapor Expo International positively hummed with energy. The show opened just weeks after FDA extended its regulatory authority to encompass vapor products, so it comes as little surprise that exhibitors and attendees alike were as interested in comparing notes about the announcement as they were in doing business with one another.

Highlights

By Jennifer Gelfand

MSA's Don Burke

(L to R) Troutman Sanders' Bryan Haynes, AVA's Greg Conley, VTA's Tony Abboud, TMA's Farrell Delman

The Good, the Bad and the Mostly Ugly

"I've spent every waking moment—and a lot of sleeping moments—thinking about deeming regulations over the last six weeks," said Troutman Sanders' Bryan Haynes, who kicked off VEI with an educational session on industry regulation and taxation. His statement got a lot of rueful smiles from audience members in the packed session room, most of whom had done exactly the same.

Haynes went on to offer a detailed analysis of the deeming regulations, beginning with the good—yes, there is some—points. First and foremost, of course, was the absence of bans on flavors and on open systems, which would have decimated the industry.

Haynes also found other points to celebrate. "FDA did not impose user fees on this industry, which might be regarded as a positive," he pointed out. "There are some provisions for small entity compliance that might ostensibly help some folks in this room, and FDA gave the industry some time for the pre-market review process. Also, there had been concern that all the products currently on the market would need to come off of store shelves as of the effective date of the regulations—that didn't happen."

By now, those in the vapor business are bound to be familiar with some of the not-so-positive provisions of the regulations, such as the need for age verification and warning labels, the requirement to test products for harmful constituents and to list ingredients with FDA, as well as the bans on free samples, on modified-risk claims and on adulterated or misbranded items. And then there's the biggie: the need for pre-market review and authorization of "new" tobacco products.

"There were lots of things FDA could have done differently with pre-market review—what they did was about as bad as it could have been," said Haynes. "There were lots of calls to shift the grandfather date to the date of the FDA regulations, [but] they didn't do that. There is also an extremely limited window (through August 8, 2016) to get products to market so that you can sell them without getting FDA's approval first. By comparison, when the Tobacco Control Act passed in 2009, companies had until 2011 to provisionally get products to market."

What's more, newly regulated companies back then could continue to market their products until they were given the thumbs down from FDA. By contrast, FDA now says that "if they haven't acted on your application within a year, thereafter your product is subject to enforcement action," explained Haynes, who sees this as a surprising and unwelcome change in procedure. "What does that mean? I don't know."

Haynes sees a distinct possibility of many vapor product reviews still pending a year after the application deadline. "FDA has been

notoriously slow in acting on applications," he told his audience of vapor industry veterans. "Many [tobacco companies] are still waiting on applications submitted back in March 2011, but there have been no complaints [that] those products can continue to be marketed. Regulatory inertia works in that scenario. It will not work for you. I suspect I will get a lot of frantic calls in August of 2018 with people saying, 'FDA hasn't ruled—what do I do?'"

Another surprise Haynes pointed to as problematic is FDA's decision to lump components in with the regulated products. "In layman's terms that means anything used with something derived from tobacco or is expected to be used with something derived from tobacco," he explained, noting that he expects to see this challenged in court. "If you sell a vaporizer that doesn't include any tobacco-derived components, but is expected to be used with tobacco-derived nicotine, then it is regulated. I vehemently disagree with that. I don't think they have that authority. I think it will be teed up in litigation and hopefully whoever rules on the issue will see it correctly, but it is the law of the land for now, according to FDA."

Courts to the Rescue (Not)

Acknowledging that several lawsuits have already been filed challenging the regulation, Haynes cautioned vapor companies against counting on the courts coming to the rescue. "It is too early to tell how these cases will play out, but I can tell you from experience that cases against the government are hard to win," he noted. "The rules are heavily skewed toward the government.

"For example, you might argue that the pre-market review process is unfair because you are being treated differently from cigarette companies—a good, persuasive, factual argument with which I agree wholeheartedly. The problem is that FDA will come and say, 'Your challenge is right for a decision because you haven't yet submitted an application, and we haven't yet ruled on it.' So until you go through that process—spending all that time and money—a court can't look at your case. That is a legitimate tactic that FDA and other government agencies frequently rely on."

Clouding It Up

This ... tured its first Super Cloud Competition, where contestants competed for prize belts and cash awards in the outlaw and trick categories.

TBI congratulates David Lupkin and Dylan Massey of Southern Tradition Liquid, winners of VEI's Big Cloud Competition

Viable Options

What can companies do in the face of potentially business-threatening regulatory overreach? Haynes advises a pragmatic approach to just how much time and energy to spend applying for FDA approval. "They have a process called refusal to file, which means they take a quick peek [at your application] and if you haven't satisfied the basic requirements, you lose," he notes. "At the same time, this is just guidance, so you don't necessarily have to satisfy *all* [of] these requirements. In fact, in the only pre-market tobacco application that won approval so far, Swedish Match did not give the FDA every single thing they were looking for—that [fact] was acknowledged, but there was an explanation for it."

Another viable option is to look for ways to work around the rules. "I'm a car guy, so I put everything in car terms," says Haynes. "They want a Ferrari, but can you get by with a Honda? Maybe. People ask, 'If I spend this time and money to build a Ferrari and send it over there, will I be accepted?' I say, 'No, there are no guarantees.' They may say it's got too much horsepower; we would rather have a Bentley.

"The other option is maybe you think about an Uber—something that is not quite inside the box, maybe not sending FDA anything at all. I have been working this industry for 13 years, I have seen different regulations and I've seen the industry adapt in interesting and unanticipated ways. This happens all the time. The government creates rules; the industry figures out different ways to live under them." **TBI**

Look for editorial coverage of VEI's Industry Association Panel and MSA's presentation on retail trends at tobonline.com and in the next issue of *TBI*.

"I have seen different regulations and I've seen the industry adapt in interesting and unanticipated ways. This happens all the time. The government creates rules; the industry figures out different ways to live under them."

The Moment the Cigar Industry Changed Forever

I wrote my first article on the threat of cigar regulation by the U.S. Food and Drug Administration (FDA) on June 12, 2009. Since then, there have been dozens of articles and speeches; hundreds of congressional briefings, agency and industry sessions (with Latin American embassies, the White House, and coalitions of supporting organizations); tens of thousands of emails; hundreds of hours of conference calls, research, and consultants working around the clock, as all of us who have a passion for great cigars have worked to make our voices heard and to protect one of life's simple pleasures.

On May 5, 2016, President Obama's administration decided to ignore all of that and issue 499 pages of regulations, with a solid 30 pages attacking premium cigars, for the first time in history.

It's the arrogance of the document that is most striking. The FDA opted to ignore all submitted data on health analysis, as it specifically pertains to premium handmade cigars. The agency chose to change the game of statistical analysis by tossing in the demographic of "young adult" to reach the age of 29 to dramatize the number of people who enjoy cigars. FDA specifically attacked the remaining cigar factory in America by subjecting the J.C. Newman Cigar Factory in Tampa to the same harsh standards as all other tobacco products. The agency specifically noted how boutique and limited release cigars would be subject to the same bureaucratic rigor and expensive compliance measures as all other products and releases. FDA also specifically noted, in condescending and belittling language, that you can no longer enjoy a complimentary cigar at your local shop. This is social engineering and "nanny state" measures at their worst.

The most damaging components of the final regulation are summarized as follows:

FDA's Flawed Final Rule

In recent years, Congress has noted through Appropriations report language the distinction between premium handmade cigars and other tobacco products, particularly as it relates to youth access and the negative health effects of addiction and inhalation. Youth under the

age of 18 are already prohibited from purchasing premium cigars and robust enforcement of that requirement exists. Premium cigars are not marketed to or sought by those under the age of 18. FDA admits that the studies it cites in the final rule do not actually deal with premium cigars, so it "create[s] [its] own analysis," while rejecting the objective studies provided by the Cigar Rights of America (CRA) via public comment submission, calling them "not persuasive." Amazing.

Ban on Samples

The ability of manufacturers and retailers to provide samples of products to adult consumers is central to the development and introduction of new brands to the market. Traditionally, such events are held in retail stores where adult customers are afforded the opportunity to try a cigar before deciding whether to purchase it. Just as wine and craft beer merchants sample products to determine which to stock, so, too, do premium cigar retailers.

The industry's trade shows and other large events generate significant revenue for local economies as well. All such events would be jeopardized by the final rule. In its regulation covering smokeless tobacco, there is a system in place for adults to receive limited free samples. FDA fails to appropriately show why such a system would not be effective for premium cigars.

Pre-Market Review

Premium cigar manufacturers estimate that a significant reduction in new product lines will result from the final rule. FDA's own analysis indicates as many as 50 percent of all cigar brands will be eliminated from the market. We believe that figure to be much higher—as many as 80 percent will be eliminated.

Impact on Latin American Trading Partners

Throughout the rulemaking process, representatives from Nicaragua, Honduras and the Dominican Republic expressed their concern about the impact of regulation on their countries. More than 300,000 jobs are sustained in those countries by the premium cigar industry.

Future HPHC Testing

While the final rule indicates a subsequent rulemaking and three year implementation window for Harmful and Potentially Harmful Constituent (HPHC) testing, this would be the final straw for small and medium-size premium cigar manufacturers. This expense alone would sink most companies.

FDA Fails to Estimate Significant Costs

Executive Order 12866 requires FDA to assess all costs and benefits of a proposed rule. FDA's deeming rule fails to assess some of the most critical costs to the premium cigar industry. FDA's estimates for new products, which would be subject to regulation and testing requirements annually, is significantly underestimated by the final rulemaking.

But this story is not over.

On April 9, the U.S. House of Representatives Committee on Appropriations passed language that prohibits FDA from advancing regulations on cigars and, in the same hearing, the committee changed the "predicate date" from February 15, 2007 to the time of the final rule. This is where the battle also lies. This budget needs to pass the full U.S. House of Representatives, and then pass the U.S. Senate.

That is where you come in. Every member of Congress needs to hear from every constituent who has a passion for great cigars, each of whom should state that they expect support in the passage of the Appropriations Committee language to protect the premium cigar industry.

CRA will be posting the contact information for every member of Congress that is needed to advance this legislation, while all interested parties are considering every legal and political option, to defend the simple ability to enjoy a cigar. Go to CigarRights.org to learn more. Be a cigar voter. **TBI**

That is where you come in. Every member of Congress needs to hear from every constituent who has a passion for great cigars, each of whom should state that they expect support in the passage of the Appropriations Committee language to protect the premium cigar industry.

J. Glynn Loope is executive director of Cigar Rights of America.

IPCPR 2016 Preview: "Band Together!"

The 84th annual cigar and pipe industry show opens in Las Vegas on July 24.

In July, International Premium Cigar and Pipe Retailers members will gather at the Sands Expo & Convention Center to network with tobacco industry peers, glean relevant insights, and shop for special deals and new products. In addition to a show floor featuring nearly 400 exhibitors, this year's IPCPR offers a compelling lineup of education sessions, including a regulation-themed session on the new FDA deeming rules.

Also new to this year's event is a "Lunchtime Learning Series"—daily lunch-hour educational sessions on topics ranging from best practices for retailers to premium cigar trends. Finally, on the last day of the convention, a lucky retail attendee will receive $10,000 in the IPCPR's annual Grand Prize Giveaway.

Here's a detailed look at the events taking place at this year's IPCPR:

SHOW SCHEDULE

Sunday, July 24, 2016

9:00 a.m. – 5:00 p.m. Registration Open
10:00 a.m. – 11:30 a.m. Manufacturer Seminar/The FDA Seminar (Dave Clissold of Hyman Phelps, Barry Schaevitz of Fox Rothschild and Blake Rutherford of Cozen O'Connor, moderated by Kip Talley of IPCPR)
1:00 p.m. – 2:00 p.m. Lessons From the Retail Titans (Dave Ratner, Dave's Soda and Pet City)
2:30 p.m. – 3:30 p.m. Engaging Employees; Improving Performance (Juan Gonzalez, Axiom Consulting Partners, McLean, VA)
4:00 p.m. – 5:00 p.m. – Living with the FDA - A Seminar for Retailers (Dave Clissold of Hyman Phelps, Barry Schaevitz of Fox Rothschild, Kip Talley of IPCPR, moderated by IPCPR Board Members)
5:00 p.m. – 6:00 p.m. Government Affairs Strategy (IPCPR Legislative Team; Matt Dogali, Rachel Hyde, Kip Talley)
6:00 p.m. – 10:00 p.m. Cocktail Reception

Monday, July 25, 2016

8:00 a.m. – 10:00 a.m. IPCPR Annual Meeting and Breakfast (Venetian Ballroom) featuring keynote speaker Jon Taffer of Spike TV's *Bar Rescue*
9:00 a.m. – 5:00 p.m. Registration Open
9:30 a.m. Trade Show Opens to PAC VIP's
10:30 a.m. – 5:00 p.m. Trade Show Open
11:30 a.m. – 2:30 p.m. Free Lunch for Retail Members
12:30 p.m. – 1:30 p.m. IPCPR Lunchtime Learning Series—Shockproof: How to Hardwire Your Business for Lasting Success (Show Floor, back of Hall C)

Tuesday, July 26, 2016

9:00 a.m. – 5:00 p.m. Registration Open
8:00 a.m. – 10:00 a.m. State Association Breakfast Meeting (Casanova Rooms 601 and 602)
10:00 a.m. – 5:00 p.m. Trade Show Open
11:30 a.m. – 2:30 p.m. Free Lunch for Retail Members
12:30 p.m. – 1:30 p.m. IPCPR Lunchtime Learning Series—Cigar Manufacturer Panel (Show Floor, back of Hall C)

Wednesday, July 27, 2016

9:00 a.m. – 5:00 p.m. Registration Open
10:00 a.m. – 5:00 p.m. Trade Show Open
11:30 a.m. – 2:30 p.m. Free Lunch for Retail Members
12:30 p.m. – 1:30 p.m. IPCPR Lunchtime Learning Series—Retailer Best Practices featuring top premium retail tobacconist (Show Floor, back of Hall C)
7:00 p.m. – 10:00 p.m. IPCPR Cigar Bash (The Light Night Club at Mandalay Bay)

Thursday, July 28, 2016

8:00 a.m. – 12:30 p.m. Registration Open
9:00 a.m. – 1:00 p.m. Trade Show Open
12:30 p.m. $10,000 Grand Prize Grand Prize Giveaway!
1:00 p.m. Trade Show Closes

May Selva Presents the Prensado

Maya Selva Cigars, U.S., is adding a "prensado" vitola to its Flor de Selva Maduro collection. The new Grand Pressé will be officially released at this year's IPCPR trade show and initially only available in the United States market.

The Grand Pressé features a naturally fermented Honduran *Habano* wrapper and a Brazilian Mata Fina binder, as well as Honduran fillers, providing a well-balanced, medium- to fuller-bodied cigar. Flor de Selva Maduros have received various accolades in recent years, and have become fast favorites amongst maduro cigar connoisseurs. It will come in elegant cedar 10-count boxes at an MSRP of $11.75.

"After assessing our portfolio, and analyzing the field as to what niche we had yet to cover, we came to the determination that a 'prensado' was the natural choice to round out our maduro collection," explains Gabriel Alvarez, the company's U.S. director of sales. Maya Selva Cigars, mayaselvacigars.com

IPCPR Highlight:
Strike Gold With JM Tobacco

The cigar company will give away prizes to the best blackjack players at this year's show.

JM Tobacco is inviting IPCPR show attendees to try their luck at winning their share of valuable prizes at its booth, No. 2651. Like lightning striking, the company's Strike Gold is infrequent and exciting—occurring only once every five years, says a spokesperson, who notes that JM Tobacco introduced it at IPCPR 2006, then again in 2011, and now this year.

Unlike lightning, show attendees welcome it eagerly, because everyone wins while competing for prizes that culminate in a lush grand prize. The 2011 winner went home with a 1-ounce solid gold coin valued at over $1,600. This year, the grand prize is going digital: an Apple iPad Air 2 Gold.

The fun begins with a mailer that JM Tobacco sends to all current IPCPR members. The mailer includes a gold-and-black poker chip affixed to a card with playing instructions and a list of prizes. Recipients bring their chip to the JM booth during show hours, sit down at a poker table and play blackjack. The number of his/her consecutive winning hands is recorded, and the player with the highest number by the end of the show is awarded the iPad Gold. Lesser winners receive other enviable swag, like JM hats and T-shirts.

Even those who go bust on their first hand enjoy some choice JM premium handmade cigars. This year, the featured cigar is JM's Nicaraguan, a sweet smoke with a flavor and body tailored to the three-to-four-a-day smoker. The value-priced (less than $3 MSRP), all-tobacco, handmade Nicaraguan is available in the same eight shapes as all other JM value-priced cigars. It comes in Sumatra, Corojo, Connecticut and Maduro wrappers.

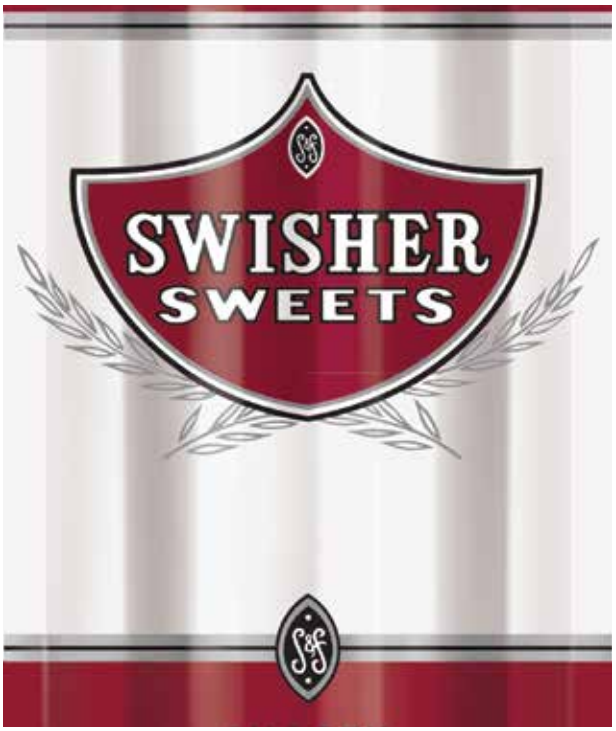
"Strike Gold has been a great success," says Anto Mahroukian, JM's president. "It brings people together in an atmosphere of camaraderie, combined with gaming excitement. It also scratches the gambling itch in us all."

Arango Cigar Company Unveils New Torino by Ascorti Briar Pipe Line at IPCPR 2016

Arango Cigar Company, a national tobacco products distributor, is now offering the limited availability "Torino by Ascorti Briar Pipe." This pipe has been created exclusively for Arango by world-renowned Italian master carver Roberto Ascorti. The pipe line is featured at IPCPR 2016, in the Arango pavilion.

The Torino by Ascorti pipes use briar that is specially selected by Ascorti. He then dries and seasons the briar for a pleasing smoke. The pipes are available in black Sandblast and polished Natural finishes, with six classic models being offered in each finish. All shapes have black acrylic mouthpieces. Both the Natural and Sandblast models carry the Ascorti name on their shanks, with the Sandblast selections highlighting it in a contrasting natural panel.

"Our Torino by Ascorti pieces are perfect for smokers who appreciate quality at an affordable price," reports Arango's president, Michael Gold. "The Torino by Ascorti comes from the same family workplace where Roberto Ascorti creates esthetic and creative pipes that are priced into the collectible range." The MSRP for the Sandblast version is $74.95, with the Natural retailing for $89.95. All models of the Torino by Ascorti are now available from Arango Cigar Company.



New Tastes for Swisher Sweets

Swisher Sweets has introduced two new tastes to the lineup of its popular Swisher Sweets BLK Tip Cigarillos: Swisher Sweets BLK Grape and Swisher Sweets BLK Berry. Enjoy the "scentsational" aroma and smooth smoke of BLK's pipe tobacco filler, a fusion of hand-selected air- and fire-cured tobaccos that deliver a unique taste like no other tipped cigar.

Swisher Sweets BLK Grape and Swisher Sweets BLK Berry are available now for shipment to retailers. All BLK blends are offered in "save on two" and "two for 99 cents" pouches. Swisher, 800-874-9720, swisherblk.com

EAS Expands Liquid Soul Brand to Reach Sophisticated Vapor Consumers

E-Alternative Solutions (EAS) has announced the launch of the new Liquid Soul Amaranth Vapor Series with HydraVapeMax Technology. EAS debuted the new series at the Miami World Vapor Expo and at the Vapor Expo International show in Chicago, Illinois, this month. The new sophisticated e-liquid line takes inspiration from the Amaranth flower, known to the Ancient Greeks as "the flower that never fades." For centuries it has been the symbol of immortality because it retains its freshness and vibrant colors after being picked. The flower's seeds are mixed with chocolate and honey and used in the Day of the Dead celebrations in Mexico as part of the process to make sugar skulls.

Amaranth Vapor is offered in four blends reminiscent of the tastes enjoyed during the Mexican "Dia De Los Muertos" celebration with Churro, Cocoa Berry, Limón Dulce, and Crema Caramel. These four introductory blends are offered in 0mg, 3mg, and 6mg nicotine levels in 30ml Child Resistant Certified-glass bottles and a beautiful premium gift box.

Formulated in 70/30 VG/PG combination, Amaranth Vapor is made with the exclusive HydraVapeMAX technology, a proprietary process that uses tobacco-free nicotine (TFN) and no known harmful ingredients to produce a consistent vape at any standard temperature, delivering powerful long-lasting flavors with minimal vape tongue.

"As an homage to this magical unfading flower, our exclusive HydraVapeMAX technology with TFN delivers crisp, long-lasting flavors that will satisfy even the most sophisticated vapor consumer," explains Jacopo D'Alessandris, president of E-Alternative Solutions. "Amaranth is an extension of EAS' Liquid Soul Vapor brand, which launched last year and is available in over 1,000 retail stores and online at LiquidSoulVapor.com." EAS, LiquidSoulVapor.com, 866-440-3644

J. Grotto's Happy Anniversary Boutique Cigar

Paul Joyal's Ocean State Cigars has debuted a Double Robusto addition to the J. Grotto Anniversary boutique premium cigar line. The 5.5x54 cigar is offered in box-pressed configuration, sought after for its comfort in the mouth and fingers.

The Anniversary line is handmade with 100-percent long-filler tobacco. The Double Robusto shares the same blend and construction details as the four original Anniversary shapes. Its double-capped wrapper is a naturally fermented maduro Connecticut-grown broadleaf, while the binder is a Dominican-grown *Habano*.

The Anniversary line is blended and manufactured by Phil Zanghi, whose Dominican operation shares factory space with the Reyes' family of tobacco producers, which supply 70 percent of all the tobacco used by Dominican cigar makers. One can expect the Anniversary to use some of these top-quality tobaccos.

Like all Anniversary shapes, the Double Robusto is a medium-bodied cigar, departing from all other J. Grotto cigars, which are medium-full- to full-bodied. "Although many cigar lovers rave about full-bodied cigars, most buy medium-bodied brands," notes Joyal. "Make no mistake, Anniversary's rich flavor is the full equal of highly-touted full-bodied cigars, many of which actually lack flavor despite their power.

"Anniversary has earned the term 'succulent,' with a classic Connecticut-broadleaf sweetness, plus some subtleties like cocoa, coffee and nuts," he adds. "For smooth smoking, all tobaccos are aged at least three years; the finished cigars [are aged] another three to four months."

The high-quality Spanish cedar box holds 10 cigars and bears artwork that reflects the special nature of the Anniversary name. The line's 2014 debut marked a year of wedding anniversaries for Joyal's family: his parents' 65th, and Joyal and his wife's 30th. Gold coins in the box art also bear the initials of several immediate family members. Joyal describes Anniversary's most appealing features as "super-premium quality and performance at a consumer-friendly price—$8.50." Like all J. Grotto cigars, the Anniversary Double Robusto is only available to brick-and-mortar tobacco shops, not Internet or mail-order discounters. Ocean State Cigars, West Warwick, RI, 401-822-0536, OceanStateCigars.com

Freshening ACID G-Fresh Cigars

In collaboration with Drew Estate, Swisher is reintroducing ACID G-Fresh Cigars in innovative G-Fresh foil pouches that ensure longer lasting shelf life and promise consistent product quality for each individually packaged cigar. In addition to the updated and improved packaging, ACID G-Fresh will also feature new blends only available in the G-Fresh format. The classics, Kuba Kuba and Blondie, will continue to be offered in their traditional infusions with their signature blue cigar bands. Additions will include Blondie Red, a bold infusion with a dark Cameroon wrapper, and Blondie Morado, a rich and robust ACID in a Maduro wrapper. Drew Estate and Swisher continue to work on additional specialty blends to be added to the G-Fresh lineup in late 2016. Swisher, 800-874-9720, experienceacid.com

Two New Debuts from Cornelius & Anthony Premium Cigars

Cornelius & Anthony will debut two additional lines, Venganza and Meridian at the 2016 IPCPR Show. The Venganza delivers an unmatched experience. This rich and flavorful powerhouse has a silky Ecuadorian wrapper that is highlighted by its Nicaraguan filler tobaccos. Venganza starts with a blast of bold flavor. This spice forward blend has a lingering sweetness and a long smooth finish that highlight its bold complexity. It is the pinnacle of balanced perfection.

Venganza is rolled at the La Zona factory in Estelí, Nicaragua. Also produced in four sizes and presented in boxes of 20, the venganza boxes feature an illustration of the 1876 patent form for The Bailey Machine Gun. Available in Gordo (6x60), Toro (6x50), Robusto (5x52) and Corona Gorda (5.5x46).

Produced in Estelí, Nicaragua, Meridian is a cigar that will stop you in your tracks. Produced in four sizes and presented in boxes of 20, this beautiful Rosado has an oily Ecuadorian wrapper that surrounds Nicaraguan and Dominican filler tobaccos. The blend has rich notes of spice and wood with a lingering sweetness that creates a creamy refined balance. Meridian is a solid medium-bodied cigar that comes in the following sizes: Gordo (6x60), Toro (6x50), Robusto (5x52) and Corona Gorda (5.5 x 46).

The two new cigars join The Cornelius, a hand-rolled, Cuban-style, medium-bodied cigar with a triple cap, and the Daddy Mac, which features a rich Brazilian wrapper and Ecuadorian binder with exquisite Nicaraguan filler tobaccos.
corneliusandanthony.com

Display Debut by Vaporlakes

Vaporlakes is launching colorful new six-bottle display cartons for their premium e-liquid SKUs, designed to improve retail presentation and easier stock management. Each carton has a unique die-cut front to display the bottles on the shelf. The carton lid is simple to fold up, forming a display header with price space. The benefit for both wholesalers and retailers is simplified inventory and stock management of Vaporlakes e-liquid SKUs. The cartons come complete with compliant warning labels, UPC coding, and re-order information.

Vaporlakes offers three distinctive brands in a total of 29 flavors, four nicotine levels, with maximum cloud power in VG/PG ratios. Each carton carries six bottles of the same SKU. Master shippers hold up to 12 cartons (72-bottles) so minimum carton purchases can be up to 12 different SKUs per master shipper. Opening Order promotions are available for product in the new cartons.

Customers can choose from three advertised brands: 1-ounce bottles of Specimenz in 13 flavors, Bathtub Brew in 1.3-ounce bottles and Popbot beverage flavors in 1-ounce bottles. All bottles are pre-sealed with child resistant squeeze-dropper caps. Vaporlakes, 800-787-3315, wholesale@vaporlakes.com

The Ultimate Cigar Book Returns

Well-known pipe/cigar author and authority Richard Carleton Hacker has released a revised fourth edition of *The Ultimate Cigar Book*, first published in 1993. The new edition includes exclusive color photographs and updated material on every major cigar brand. The book starts with a recount of the history of cigar smoking, followed by chapters on cigar making, cigar selection, smoking techniques, accessories, pairing whiskies and wines with cigars, an updated "CigarSpeak" dictionary, and a compendium of every major cigar brand in the world, plus many minor brands.

Published by Skyhorse Publishing, this 390-page hardcover retails for $24.99 and can be purchased at bookshops and tobacconist shops, as well as online at B&N.com, Amazon.com and Indiebound.org. Retailers interested in carrying the book for sale should contact Kathryn Mennone at kmennone@skyhorsepublishing.com or 860-664-0344.

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