Thinking about expanding your OTP section by adding e-cigarettes? If so, proceed with caution.

While many tout the profit potential of these electronic smoking alternatives for c-stores, others decry a foggy future.

At the root of the worry is an influx of information, misinformation, litigation and propaganda about e-cigarettes that makes it hard to gauge the bona fide pitfalls along with the real potential for profits. Added to that mix are many unknowns that further cloud the picture, including looming Food and Drug Administration (FDA) regulation and oversight; tobacco taxation that has expanded to e-cigs (consider Minnesota’s new 70% tax rate on these items); banning efforts across the country; general lack of support by international governing bodies; and legal concerns over one company’s acquisition of a U.S. patent for the product.

“These products have the potential to literally replace most of the cigarette market share,” says Bill Godshall, executive director of Smokefree Pennsylvania, a grass-roots anti-smoking organization that enthusiastically touts e-cigs as a less-hazardous alternative to smoking. Sales figures are hard to confirm, but Godshall estimates impressive sales for e-cigs—upwards of $200 million—mostly via the Internet and tobacco stores since their U.S. debut in 2006. And these sales occurred despite an FDA ban on importing e-cigs, which accounts for the majority of the products distributed in the United States.

Electronic cigarettes are the latest smoking alternative to come under regulatory fire, following in the footsteps of smokeless tobacco. The hurdle is to see through the smokescreen of e-cig drama and filter out the truth. It’s a challenge for trading partners who want to add e-cigs to their OTP offerings.

“The e-cigarette is the most effective smoking-cessation aid available,” says Godshall, citing use by half a million U.S. consumers. “I can make that claim, but a manufacturer better not or FDA will be down his throat,” he says. “Consumers want these products, but FDA is targeting e-cigs and misleading the public to believe they are not safe alternatives to cigarettes.”

Even actress Katherine Heigl was lambasted for using an e-cigarette on “The Late Show with David Letter-...
man.” She claimed the device helped her quit smoking entirely, which drew criticism from some public-health figures who would prefer she stick to “approved” ways to kick the habit.

On top of FDA scrutiny, e-cigarettes face mounting bans, stirring Godshall’s group to constantly put out fires. His group helped defeat legislation to ban e-cig sales in five states—New York, Maryland, California, Illinois and Utah—just this past year. Several countries have banned or restricted e-cigarettes, including Canada, Australia, Israel, Brazil and Singapore. The state of Oregon has reached settlements to prevent major e-cigarette companies from selling there. And in July the University of Florida became the only tobacco-free campus in the state. The use of any tobacco product is now a violation.

Lou Maiellano of TAZ Marketing & Consulting, Sevierville, Tenn., says tobacco alternatives in general have great potential for growth. The smokeless category, for example, has been exploding. But while e-cigs hold promise, the depth of the opportunity is unclear.

In contrast to Godshall’s enthusiasm, Maiellano suggests, “Electronic smoking alternatives are seeing some success out there, but I’m not sure how large the opportunity is in light of all the challenges. I’m concerned about the future of these products. A lot needs to be thought through.”

Bill Bartkowski, president of e-cigarette maker Ruyan America of Minneapolis, agrees. “Manufacturers, importers, distributors and retailers have experienced some level of success with this category, albeit in limited fashion for some,” he says. “The visibility and awareness for e-cigs has risen consistently over the years, and consumers are accepting them, buying them and rebuying them.”

In addition to the ambiguity over FDA oversight and how e-cigs will be regulated, now buyers and sellers of e-cigs need to take note of Ruyan’s pending U.S. patent for electronic cigarettes. (Ruyan’s parent company is Hong Kong manufacturer Dragonite International Ltd.) Ruyan is the original inventor of the e-cigarette and has registered patents in more than 40 countries since 2003. In July the U.S. Patent and Trademark Office granted an allowance for patent, and the actual patent is expected to be issued before year’s end.

“Generally speaking, many in the supply chain have remained woefully ignorant with respect to intellectual property,” says Bartkowski. In other words, they aren’t really paying attention. Dragonite has been successful in other countries in enforcing the patent and it can be expected the same will eventually happen in the United States, he says.

Distributor Eby-Brown, Naperville, Ill., begs to differ, at least from its own experience. “With all new products, we conduct the due diligence necessary to make sure the manufacturer is financially solid with ample warranties and product-liability insurance,” says Ron Coppel, senior vice president of business development. “We cannot check patents and copyrights of every product, but we are currently doing our due diligence with a supplier as it relates to the patent on the product we are purchasing.”

FDA TURNS UP THE HEAT

E-cigarettes’ biggest hurdle may come as no surprise: the FDA, specifically the agency’s insistence that the products are unapproved smoking-cessation “drug devices” and its subsequent attempt to ban imports, which caused two large importers to sue the FDA last year. In January, a federal judge sided with the e-cigarette companies and ruled that the FDA could only regulate the products, not ban imports. A DC appeals court is now considering the case. If the court upholds the judge’s ruling, then FDA is likely to add e-cigarettes to the bucket of tobacco products
FDA Acts Against E-Cig Companies

In September the FDA sent warning letters to five electronic-cigarette suppliers for various violations of the Federal Food, Drug, and Cosmetic Act (FDCA), including unsubstantiated claims and poor manufacturing practices.

At the same time, in a letter to the Electronic Cigarette Association, the FDA said the agency intends to regulate electronic cigarettes and related products “in a manner consistent with its mission of protecting the public health.” For a drug product to gain FDA approval, a company must demonstrate that the product is safe and effective for its intended use. The company must also demonstrate that manufacturing methods are adequate to preserve the strength, quality and purity of the product.

The FDA has determined that the electronic-cigarette products addressed in the warning letters to the distributors, and similar products, are subject to FDA regulation as drugs. Under the FDCA, a company cannot claim that its drug can treat or mitigate a disease, such as nicotine addiction, unless the drug’s safety and effectiveness have been proven. Yet all five companies claim without FDA review of relevant evidence that the products help users quit smoking cigarettes.

The companies receiving warning letters were E-CigaretteDirect LLC; Ruyan America Inc.; Gamucci America (Smokey Bayou Inc.); E-Cig Technology Inc.; and Johnson’s Creek Enterprises LLC.

Some of the companies were also cited for marketing drugs in unapproved liquid forms. Visit www.fda.gov for more information.

placed under its watch last year under the Family Smoking Prevention and Tobacco Control Act. This scenario, of course, creates myriad uncertainty concerning how the agency would regulate e-cigarettes, although it would provide more protection from an outright ban.

Either way, there are implications for any company that makes, buys or sells e-cigarettes. If classified as a drug device, all tobacco products, but not those that specifically apply to cigarettes or smokeless tobacco. The agency also could promulgate additional regulations for e-cigarettes, a one- to two-year process.

Unlike Maiellano, Godshall of Smokefree Pennsylvania is less dire: “Since the new law requires the FDA to base new regulations on evidence, it is unlikely e-cigarettes would be required to display misleading warnings like those Congress imposed on smokeless tobacco products.”

“What’s amazing is that 75% of the mouth-cancer deaths are caused by cigarettes,” Godshall says. “How many companies have the wherewithal and resources to accomplish this?” he says. “It would be the demise of many manufacturers.”

If the FDA decides to treat e-cigs as tobacco products, they would be required to comply with the new 2010 provisions that currently apply to all tobacco products, but not those that specifically apply to cigarettes or smokeless tobacco. The agency also could promulgate additional regulations for e-cigarettes, a one- to two-year process.

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“We believe that we have appropriately and properly addressed this issue with the FDA in our response to their letter to us of Sept. 8, 2010. Products containing lobelia are not smoking-cessation products and will not be labeled or marketed as such.”

NJOY, another e-cig manufacturer, declined comment on advice from counsel until the D.C. court has “ren-
dered its decision.”

Despite the uncertainty, other tobacco companies are investing in e-cig technology to be ready to launch their wares pending legal and regulatory resolutions. “FDA is entering some unchartered territory with e-cigarette products. In September, they invited e-cig manufacturers to seek approval for their products, but manufacturers are asking: What are the standards and criteria that we are supposed to submit against?” says John Geoghegan, director of brand development for Moorpark, Cal.-based Kretek International.

“As far as I know, FDA has not promulgated any guidance or rules regarding levels of nicotine, purity standards, flavor standards, size, battery power or anything,” he continues. “We want to be ready when [FDA] are, so we are developing a series of white papers that outline the different technical aspects of our products, such as inspections, ingredients and purity standards.

“We are being very careful with our labeling and claims. Until e-cigs are proven to help people quit smoking, we are staying away from that. This is a convenience product for adults who find themselves in an occasion where they aren’t allowed to smoke.”

WHO’S FRETTING?

Despite the dire warnings, many folks in the convenience industry aren’t that worried about selling electronic cigarettes. As Eby-Brown’s Coppel puts it, “There’s no downside to speak of from our perspective. We are in the business to distribute legal products to our customers; we look at the viability of a product and whether consumers want it or not. We know consumers want this product, and we are going to provide it.”

Eby-Brown’s Carolyn Ousterout, vice president of special projects, says the company has placed its first e-cig order, Smoke 51 by Vapor Corp., which was scheduled for delivery in mid-November. “Our retailers are indicating they want this product in their stores,” she says. “At least a dozen suppliers approached us, and we conducted a great deal of research before choosing Vapor Corp.”

What if the FDA bans e-cigarettes? Worst-case scenario, says Coppel, is “we are stuck with maybe 10 cases of product out of 100.” But if a ban were to go in effect, it would not be immediate and the industry would most likely be forewarned. As Coppel puts it, “At the end of the day, e-cigs are just another SKU to us, like a new candy bar. Nothing less, nothing more.”

The American Wholesale Marketers Association encourages distributors to exercise caution when making choices about purchasing electronic cigs. Anne Holloway, vice president of government affairs, says, “The jury is truly still out on the future of e-cigs. At your own risk is what we advise. FDA is gunning for the manufacturers of these products. Their perspective is the makers of e-cigs are acting like this is a safe alternative to smoking, and it has not been proven by the agency.”

Holloway says unsubstantiated claims and unregulated products from China are the prime issues earning FDA’s eagle eye. She encourages companies to check out the FDA’s website at www.fda.gov to stay abreast of developments. “Under the current law, they can’t ban e-cigs. But who knows what will happen to change that law,” she says.

Kretek introduced a new line of upscale e-cig starter kits for the c-store segment at the NACS Show in October. Geoghegan says feedback from the retailers was positive and they “didn’t seem too worried about the future of e-cigs and FDA regulation. They really want to offer this product to consumers. The demand is there and their job is to provide what consumers want,” he says.

Jaco Oil Co., dba Fastrip Food Stores, has considered selling e-cigs but has been held back by inventory cost and display space concerns. “Our primary supplier has decided to carry them, but we did not agree on the product they were distributing,” says Fred Faulkner, director of sales and marketing for the 53-store chain, based in Bakersfield, Calif. “We are now in discussions with manufacturers to select a product.”

Is he worried about FDA regulation and how it could affect the company’s e-cig offerings? “Not really,” Faulkner says.

Word has it 7-Eleven has contracted with NJOY to sell its electronic cigarette products in about 1,000 of its stores. Both 7-Eleven and NJOY declined comment, but a reporter saw the product being promoted in a window sign at an East Coast location.