Against the Odds

BY JOSEPH FUISZ

The vapor industry's implausible takeoff

As we approach the 10th anniversary of the vapor industry, it is a logical time to step back and look at how this industry started and has evolved. Vapor has experienced extraordinary growth and has the potential to continue this growth, and yet storm clouds—real and imagined—remain pervasive. In this article, I will explore the counterintuitive nature of vapor, the paradox of industry self-help in informing consumers about safety, the pronounced bifurcation of the market, the interplay of populism and regulation, and the future of industry regulation. In exploring these themes, the relative lack of success of snus tobacco provides a foil to help understand what went "right" with vapor.

Much has been made of the invention of e-cigarettes. This history begins with references to such devices in patent literature in the 1960s presaging inventor Hon Lik's more recent work in 2004. This begs the obvious question: Why didn't the vapor industry emerge sooner? For me, the answer is the counterintuitive nature of the e-cigarette and the early e-cigarettes in particular. These products were exceptionally bad at delivering nicotine (in terms of both speed and maximum amount), and there was little reason to expect that smokers would accept and use a product with such poor nicotine performance. Even the flavors were poor—top flavors like caramel working overtime to mask the flavor of USP nicotine.

Effective nicotine delivery has long been understood as central to the success of the cigarette, and I think anyone trying to market the e-cigarette to Big Tobacco in, say, 2005 would have promptly been shown the door. And Big Tobacco would have been right because the e-cigarette flew against accepted wisdom of the time.

Even in hindsight it is not clear why the e-cigarette took hold. Smokers clearly wanted alternatives—this was understood. The hand-to-mouth action and the vapor "smoke" may have offered a kind of placebo effect, causing users to be surprisingly patient with the product's slow nicotine delivery. But perhaps most importantly—and in an enormous contrast to the attempts of Altria, R.J. Reynolds and others to introduce snus tobacco to the American consumer—the nascent e-cigarette industry was telling the consumer that the e-cigarette was better for them than smoking. And whether or not they should have been making these claims the way they were, they were fundamentally correct.

THE PARADOX OF DISRUPTIVE SELF-HELP

From my perspective, coming from the pharmaceutical industry, it was painful to see many of the early marketing claims made by the nascent e-cigarette industry back in 2007. Companies would falsely describe their e-cigarettes as "harmless water vapor," and you could even find videos of "physicians" recommending the product in marketing videos. Consumers got the message. The data showed that e-cigarette users correctly understood that their e-cigarettes were safer than smoking, even if this correct conclusion was sometimes based on erroneous marketing claims.

At the same time, Altria and Reynolds were losing enormous sums of money on their snus introductions, carrying the same consumer warnings as other, less safe smokeless products. Despite 30 years of impeccable health data from Sweden, consumers still thought snus was as dangerous as cigarettes, and so smokers simply would not try or switch to the product in meaningful numbers.

As we look back, the early and frequently "irresponsible" health claims made by many worked and did more to educate

the consumer of the real benefits of the product than the so-called public health community and government regulatory authorities (despite the valiant, indefatigable efforts of tobacco harm reduction advocates such as professor Brad Rodu).

So while the e-cigarette industry did not emerge from Silicon Valley, its early growth fit squarely in the now-familiar Uber-style "disruption" paradigm of breaking the "rules" in a market and asking permission later. Despite the existence of U.S. Food and Drug Administration (FDA)-regulated nicotine inhalers, the early e-cigarette industry took the position that e-cigarettes were not drug-delivery devices. They also equally disclaimed the marketing restrictions that typically apply to the tobacco industry. And 10 years later—whatever one thinks of the FDA's Center for Tobacco Products—Director Mitch Zeller freely admits and repeats that vaping is better for the individual user than combustible cigarettes (all the while hedging on the Tobacco Control Act's impenetrable and unprovable notion of population effect).

This may be a paradigm that will not work for the next 10 years of vapor, but disruptive self-help served the vapor industry very well—and was arguably essential to its start. Luckily for the industry and public health at large, those early health claims—however irresponsible—contained a kernel of essential truth: Vaping is better for people than smoking.

MARKET BIFURCATION

The cigarette industry is characterized by a remarkable uniformity in product, sales and distribution. There are naturally differences in cigarette lengths, filters, flavor and packaging. But by and large cigarettes are made in the same way, sold in the same way and used in the same way.

Perhaps because e-cigarettes were thought of as a replacement for the cigarette, it was natural to imagine they would be similarly commoditized like cigarettes. Around the midpoint of this 10-year history, it became fashionable to believe that the cigalike user was merely a user in transition to larger, more powerful tank products.

I do not think this is the case today. The vape store channel has developed its own culture, analogous to although quite distinct from the cigar store. The consumer who uses a high-nicotine cigalike—the current convenience store product of choice—is not at the vape store flavor bar dripping. There is some overlap here, in the same way a cigarette smoker is more likely to become a cigar smoker than a nonsmoker is. But it's not a clear transition today, and I think it's unlikely to become one.

Supply is similarly bifurcated. Big Tobacco has successfully exercised its traditional strength with convenience stores and other conventional retailers, but the vape shop culture is profoundly anti-tobacco. One almost pities the Big Tobacco representative making a hypothetical sales call on a vape shop—she's likely to get an earful.

The term "cigarette" brought a lot of baggage, and one was the implicit assumption of a commoditized market. Vapor is far broader, akin to other tobacco products, and I think it will continue to be so.

POPULISM RULES, ALMOST

While the FDA's Center for Tobacco Products hems and haws with Swedish Match's compelling request to make modified-risk claims for snus, tobacco harm reduction advocates cry foul with relatively little consequence. Contrast these low-impact voices with the true gains made by vapor users during the crafting of the European Union's revised Tobacco Products Directive. The takeaway here is clear. Where large numbers of consumers value a product and believe it is healthier, they will exert effective political pressure to make sure it remains available. Healthier is important here because the fact is that smokers have been unable to combat the unending rise of cigarette "sin" taxes.

STORM CLOUDS OF REGULATION

The original sin of the Tobacco Control Act is the notion of approving products based on "population effect." That sounds sensible in theory, but the application is nearly impossible. Consider the way the FDA regulates drugs. First, you show your product is safe enough to try on humans. Safety of course is a relative concept, since many drugs have bad side effects, so think of that as "safe enough." Next, you show it is "effective," meaning it works better than a placebo for its intended purpose. Conceptually, that's all you do, and the studies required to do this are well understood.

But what if you applied "population effect" analysis to drugs? Pfizer's Viagra works effectively—far better than a placebo for erectile dysfunction. What if the regulator also had to consider "population effects" like whether it would improve or hurt marriages? How could you design a study to prove such a thing, and how many years of study would be required? The reality is that "population effect" is an unadministrable standard that Congress has given to the FDA, and it's an unachievable standard for the industry to meet. There is no way to predict whether investment in new products and technologies can be recouped.

Moving the grandfather date, which I think will eventually happen, is merely a Band-Aid on this unworkable regime. In contrast, for all its faults, the EU's revised Tobacco Products Directive will allow companies to continue to innovate.

For all the storm clouds, the sunshine remains: the inexorable truth that vaping is better than smoking. Regulators can muck up the picture, but over time this reality will tend to triumph, with a big assist from Public Health England's strong stance in favor of vapor. Public Health England's position will likely resonate in other jurisdictions.

U.S. and other regulators don't mind creating fear and sleepless nights for the vapor industry owners and workers. But at the end of the day, regulators are unlikely to force the vapor user back to cigarettes. And for this reason, the next 10 years look bright. V

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