

New Tobacco Industry Products: The Phoenix Rises from the Ashes

Introduction

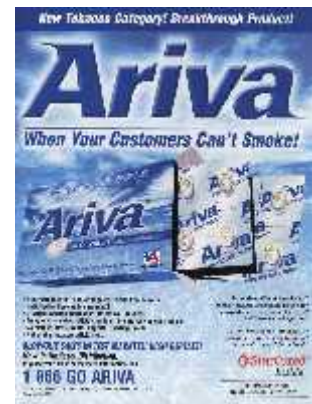
Tobacco industry innovation is not a new phenomenon. Tobacco companies widely introduced filtered cigarettes in the 1950's and then "light" and "mild" cigarettes in the 1970's to allay growing fears over the health risks of smoking and offer health-conscious smokers an alternative to quitting.

What is new is the breadth of new product development by the industry, the variety of new *tobacco* products as well as of new *nicotine* products, all of which have one thing in common—there is no combustion. Tobacco companies are devoting considerable resources—time, R&D, and money—to these endeavours for several reasons:

- They provide smokers with a source of nicotine for when they can't smoke;
- They offer smokers a more discrete and socially acceptable way to get nicotine, with less odour and mess and no smoke to bother others;
- They provide an ostensibly safer alternative to those concerned about the health consequences of smoking;
- They allow the industry to keep more users in the market and possibly to recruit new ones by offering a wide range of tobacco/nicotine products that address a wide range of needs and desires;
- They allow the industry to rehabilitate its image, at least partially, by offering reduced harm products and thus positioning themselves as part of the solution to the tragic loss of health and life caused by smoking.

Dissolvables

Dissolvable tobacco products were introduced to the US market in the early 2000s. Small manufacturer Star Scientific offered two forms of dissolvable tobacco product—Ariva, targeting cigarette smokers, and Stonewall, aimed at heavy smokers and users of smokeless tobacco.¹ Both products consisted of flue-cured powdered Virginia tobacco compressed into a small pellet, slightly larger than a Tic Tac mint² and were marketed as offering "real smoking satisfaction in all the places you can't smoke."



These dissolvables were one of the first products that narrow the differences between tobacco products and pharmaceutical nicotine products, with studies showing that the tobacco product Ariva and the pharmaceutical nicotine lozenge Commit produced similar levels of nicotine delivery and CO and gave rise to similar physiological effects.³

In December 2012, Star Scientific stopped manufacturing and selling Ariva and Stonewall, due to low sales and a prohibition under the US *Family Smoking Prevention and Tobacco Control Act* from making any statements

regarding reduced risk. The company claims that this prohibition “made it extremely difficult to effectively market our dissolvable tobacco products, notwithstanding that they represent a less hazardous alternative to cigarettes and to traditional smokeless tobacco products.”⁴ In August 2014, the US Food and Drug Administration (FDA) issued “not substantially equivalent (NSE)” orders for seven Star Scientific dissolvable products (4 Ariva flavours and 2 Stonewall), ruling that “the seven products had different characteristics compared to the predicate products ... and that the company failed to show that the new products did not raise different questions of public health.” Although Star Scientific was no longer selling these products, the NSE orders ensure that they cannot be reintroduced without FDA authorization.⁵

In 2009 RJ Reynolds became the first *major* tobacco company to sell a dissolvable tobacco product in the US, when it began test marketing several new products—strips, sticks, and orbs—all under the Camel brand name.⁶ All three products are made of finely milled compressed tobacco that is intended to be dissolved in the mouth and then swallowed. The company believed the products would serve as a more socially acceptable form of tobacco, producing no spit, no second-hand smoke, and very little litter.⁷



Camel Strips resemble breath strips, with each strip lasting 2-3 minutes and providing 0.6 mg of nicotine. Camel Sticks are similar to tooth-picks; they last 20-30 minutes and contain 3.1 mg of nicotine.⁹ Camel Orbs are lozenges about the size of a tic tac, each lasting 10-15 minutes and providing 1 mg of nicotine. In 2011, the packaging was redesigned, a variety pack was offered, and mint was the only flavour available.

Although the products were developed in part because of feedback from users of Camel snus who did not like loose tobacco or tobacco pouches and objected to having to dispose of the pouches after use,¹⁰ unlike Camel snus, the dissolvables never succeeded in gaining traction with users. From their introduction in three test cities in the US in 2009, to expansion to additional American markets and Taiwan in 2010,¹¹ by July 2013, the products were being marketed and sold in retail outlets in only two US cities and online only by RJ Reynolds. By March 2015, the products could no longer be found on the Camel consumer website or on the RJ Reynolds website under product offerings.

E-cigarettes

The tobacco industry entered the e-cigarette market in 2012, when US manufacturer Lorillard purchased Blu. Since then, virtually every major national and multinational tobacco company has either purchased an existing e-cigarette company or has launched its own product:

- Imperial Tobacco launched Jai in 2015; bought Blu in 2014; bought Dragonite (Ruyan) in 2013;
- BAT Voke inhaler granted medical licence in UK in 2014; launched Vype in 2013;
- PMI bought Nicocigs in 2014;
- Japan Tobacco bought E-Lites in 2014; reached agreement to market Ploom in 2012;

- Altria bought Green Smoke in 2014; launched MarkTen brand in 2013;
- Lorillard bought Skycigs in 2013; bought Blu in 2012;
- Reynolds American launched Vuse in 2013.

Both the tobacco control and vaping communities see advantages and disadvantages to Big Tobacco's foray into e-cigarettes. Tobacco companies have the resources to develop superior products and exercise greater quality control, and they have well-established, extensive distribution networks. On the other hand, e-cigarette proponents fear that the presence of Big Tobacco will lead to consolidation in the market, reducing competition, driving up prices, and stifling innovation.

Some believe that the primary goal of Big Tobacco is to protect its current business model, citing as evidence the fact that tobacco companies are supporting legislation that restricts the marketing and sales of e-cigarettes and bans their use in public places.¹² The growth of independent vape shops and tank style e-cigarettes is a further threat to Big Tobacco, since research suggests these newer models are more effective at delivering nicotine and thus more effective quit aids, and tobacco companies have primarily invested in early generation, cig-a-like models.¹³ According to Investment Analysts Wells Fargo, sales of tank style vaporizers in the US in 2014 exceeded sales of traditional e-cigarettes (\$1.2B vs. \$1B).¹⁴ Wells Fargo concluded that by the second quarter of 2014, the vapor trend had 'taken hold', increasing the rate of decline in sales of combustible cigarettes and leading retailers to reduce shelf space for disposable e-cigs to make room for "personal vaporizers" (rechargeable tank style e-cigarettes).¹⁵

First 'e-cigarette' approved as a drug

A significant development in the e-cigarette market is the recent approval of an e-cigarette-type product made by a tobacco company. British American Tobacco's Voke resembles an e-cigarette, although it produces no visible vapour and functions like a nicotine inhaler.



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In September 2014, Voke was granted a medicinal licence by the UK Medicines and Healthcare products Regulatory Authority, which means that it can be prescribed as a cessation device by healthcare practitioners and can make health claims.¹⁷

While many in tobacco control welcome the fact that there will be a regulated product available to smokers that has undergone the same type of rigorous testing for quality, safety, and efficacy as prescription drugs, some are concerned about the ethics of tobacco companies selling cessation products. As an e-cigarette enthusiast put it: "the biggest issue I have with this is the double-edged benefits BAT will get out of addicting people to smoking and then selling a product that helps them quit. This is like a candy company offering dentistry or an oil drilling outfit getting paid to clean up its own oil spill."¹⁸

The Industry's Latest "Reduced Risk Products"

Dr. Kevin Bridgman, Chief Medical Officer of BAT subsidiary Nicoventures provides insight into the industry's motivation in developing reduced risk products:

"Our goal is to help smokers on their journey to quitting by giving them an appealing, regulated alternative as a reduced-harm 'smoking replacement product'. In other words, we want to enable smokers to stop smoking in their own way."¹⁹

Tobacco companies are developing an array of 'less harmful' products to suit the needs of a broad spectrum of smokers. They are also seeking a regulatory framework that would allow them to make claims of reduced risk, enabling them to keep health-conscious smokers in the market longer than they might otherwise have done. Philip Morris International's (PMI) portfolio of "reduced risk products" exemplifies the direction the industry is taking:²⁰

"We have a multi-technology product portfolio that addresses a wide range of adult smoker preferences. Each of our product platforms is designed to significantly reduce or eliminate the formation of harmful and potentially harmful constituents ... in the aerosol, while preserving as much as possible the taste, sensory experience, nicotine delivery profile and ritual characteristics of combustible cigarettes."



The company has spent \$2 billion since 2008 researching and developing cigarette alternatives. As illustrated above, some of these products contain tobacco, but unlike traditional cigarettes, they heat it not burn it. RJ Reynolds test marketed Premier, a **heat-not-burn cigarette**, in the late 1980s and introduced a more advanced version, Eclipse, in the mid 1990s, both of which flopped with smokers,²¹ but PMI believes that technological advances make all the difference with these new products.

PMI began test marketing the Platform 1 device in two cities in late 2014, one in Japan and one in Italy, and is launching them nationwide in both countries in 2015. The patented device consists of an electronic holder and charger called the IQOS system, whose appearance and high-end packaging resemble those of the iPhone. The holder heats the tobacco in the stick, producing a flavoured aerosol that contains about the same amount of nicotine as a cigarette. (The tobacco in the stick is heated to less than 350°C, below combustion, in contrast to the tobacco in a burning cigarette which reaches temperatures of up to 800°C.)



The Marlboro-branded HeatStick comes in three flavours—rich, light, and menthol. By the end of 2016, PMI will have the capacity to manufacture 30 billion units per year in its new factory in Bologna, Italy.



PMI's Platform 2 device is likewise a heat-not-burn product. It resembles a traditional cigarette in look and feel, and the pressed carbon heat source can be lit with a match. The device will be launched in 2016.

PMI's goal with its line of new "nicotine containing products" is to overcome the well-known shortcomings of current e-cigarettes on the market that result in low rates of conversion from trial to regular use, including inadequate nicotine delivery, inconsistent product performance, and manual manufacturing. The Platform 4 product will be test-marketed in late 2016 and is expected to "provide a consistent aerosol with improved e-liquid and nicotine delivery profiles. The technology should also improve energy management and allow automated manufacturing, which will increase product reliability and reduce manufacturing costs."



The Platform 3 device is the least developed. It involves the creation of an aerosol of nicotine salt, which is formed by the chemical reaction of nicotine with a weak organic acid. PMI is testing both an electronic and non-electronic means of producing the aerosol. The product will replicate the feel and the ritual of smoking, without tobacco or combustion, and will have a price advantage over the PMI's other reduced-risk products.

Conclusions

The tobacco industry's sole goal in developing new products is to maximize shareholder value, by keeping current smokers in the market and/or attracting new customers. Given the unequivocal evidence that most of the health consequences from tobacco use stem from inhaling the toxins produced during combustion, product innovation in recent years has focused on non-combustible tobacco and nicotine products.

While past attempts by the industry to design a safer product proved disastrous for public health, most notably, the introduction of "light" and "mild" cigarettes, this does not mean that all product innovations have no merit. Innovations that serve to provide smoker satisfaction (nicotine plus the sensory experience of smoking) without combustion *could* reduce the health risks to individual smokers and have benefits for public health.

Unfortunately, the pace of product development far exceeds the pace of health research and government regulation. As well, the lag time of two or three decades between tobacco use and onset of a serious tobacco-caused disease means that the health consequences cannot fully be known for many years after a product is introduced. Nonetheless, there are measures that

governments can implement to minimize the risks both to individual users and to public health:

- Prohibit the marketing and sale of *all* tobacco and nicotine products to youth.
- Require disclosure of all industry research related to the development of new tobacco/nicotine products.
- Require pre-approval of all substantially new tobacco/nicotine products.
- Prohibit unsubstantiated health claims.
- Provide sufficient funding for robust industry oversight and research into new products.
- Ensure transparency in all dealings with tobacco companies.

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