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The Pharmaceuticalization of the Tobacco Industry

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INTRODUCTION

Is developing and legitimizing pharmaceutical-like reduced-harm tobacco products giving the tobacco industry a new lease on life? Cigarettes constitute over 90% of tobacco industry profits, and with population growth the number of smokers is increasing worldwide. Simultaneously, smoking prevalence is declining, threatening cigarettes' long-term profitability. While transnational tobacco companies (TTCs) promote smoking aggressively in low and middle income countries, they have also diversified their product lines to include more socially-acceptable alternative nicotine products, marking an industry-wide shift (1, 2). This pursuit of new standardized, designer, possibly government-certified nicotine products – a process we call *pharmaceuticalization* – may fundamentally change how policymakers and the public perceive both the tobacco industry and its products.

WHAT IS PHARMACEUTICALIZATION?

In medical ethics, pharmaceuticalization is “the translation or transformation of human conditions, capabilities and capacities into opportunities for pharmaceutical intervention” (3). Applied to tobacco, pharmaceuticalization represents the tobacco industry’s actual and perceived transition into a pharmaceutical-like industry through the manufacture and sale of noncombustible tobacco and nicotine products for smoking cessation or long-term nicotine maintenance without the testing and oversight required of traditional pharmaceutical products. TTCs selling nicotine products, such as Zonnic nicotine gum in the US through Reynolds American Incorporated (RAI) subsidiary Nicotivum, and British American Tobacco (BAT)’s Voke nicotine inhaler and e-Voke electronic cigarette in the UK, heralds a convergence between tobacco industry nicotine products and pharmaceutical nicotine replacement therapy (NRT). Pharmaceuticalized tobacco products share three key elements with pharmaceuticals: (1) standardized dosage, (2) sleek medical design, and (3) implicit or explicit certification or approval by relevant health authorities (Table 1).

Two intertwined assumptions facilitate pharmaceuticalization: that there are significant numbers of “inveterate” smokers who cannot quit, and that most smokers require pharmacotherapy to quit. These premises may guide policy away from prevention or complete cessation, supporting prolonged use of safer nicotine products. While exemplary

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tobacco control efforts eschew alliances with tobacco companies (4), tobacco harm reduction accepts a nicotine maintenance industry, potentially recasting TTCs as partners to health institutions providing nicotine products.

Health authority endorsement by certifying noncombustible products as cessation devices (in the UK) or modified-risk tobacco products (MRTPs, in the US) validates TTC and e-cigarette company claims and confers public legitimacy. New nicotine products lacking sanction by medical authorities may benefit from a halo effect, whereby their appearance leads consumers to perceive these products as pharmaceuticals. Without new drug approval, alternative nicotine products cannot be advertised as cessation devices; nonetheless, consumers may regard these as de facto NRT analogs. Vaping advocates and some public health organizations cast e-cigarettes as cessation aids irrespective of drug authority authorization. In this way, the industry assumes the mantle of medical legitimacy by association.

AN INDUSTRY IN TRANSITION

All major TTCs have made major investments in pharmaceuticalized tobacco products. Since 2008 Philip Morris International (PMI) has spent more than \$2 billion researching reduced-risk products (1,2). In 2016, PMI spent another 500€million on its heat-not-burn product IQOS, and submitted a multi-million page MRTP application to the FDA to certify IQOS as a reduced-harm product. PMI ultimately aims “to replace cigarettes with RRP [reduced risk products] as soon as possible,” following a “scientific assessment program [...] inspired by standards and practices long adopted by the pharmaceutical industry” (2). Signaling pharmaceuticalization as a broader trend, in 2016 PMI also invested \$20 million in Syqe Medical, an Israeli medical marijuana vaporizer manufacturer allowing doctors to prescribe “therapeutic” doses (5).

RAI similarly sought to “migrate” smokers “outside traditional tobacco [to] (Pharma)...to cover tobacco dependence, beyond cessation” (6). In 2017, BAT acquired RAI for \$49 billion, expressing specific interest in their “Next Generation Products” including RAI’s best-selling U.S. e-cigarette brand Vuse (7). Imperial Tobacco launched the e-cigarette Puritane in 2014, while their subsidiary Fontem Ventures purchased e-cigarette patents from Dragonite International for \$75 million, and Blu Ecig, the second best-selling e-cigarette brand globally, in 2015. Japan Tobacco International bought UK e-cigarette brand E-Lites’ parent company Zandera in 2014, the third-largest US e-cigarette company, Logic, and, in 2015, the heat-not-burn and vaping company Ploom.

The UK National Health Service’s (NHS) approval of BAT’s e-cigarettes as prescription cessation devices represents the paradigmatic case of tobacco industry pharmaceuticalization (8). The UK’s Medicines and Healthcare products Regulatory Agency 2013 ruling deemed long-term NRT use, including e-cigarettes, eligible for medical licenses. In 2014, BAT subsidiary Nicovations was the first company to receive licenses for its nicotine inhaler, Voke, and its e-cigarette, e-Voke, which British doctors will be able to prescribe.

IMPLICATIONS FOR HEALTH

The health consequences of pharmaceuticalization are threefold. Pharmaceuticalization contributes to the dilution and confusion surrounding the real process and trust implied in the imprimatur of legal prescription pharmaceuticals. Based on the quality of current evidence, US health authorities do not recommend e-cigarettes for cessation (9). Yet, e-cigarettes are widely perceived by patients and clinicians as cessation devices. Second, pharmaceuticalization complicates the regulatory process, expanding a class of products that appear like but might not be subject to regulation as drugs, devices or combination products. The FDA's 2017 rule on tobacco drugs and devices permits manufactures to apply for MRTP authorization with evidence that their products verifiably reduce harm, while those forwarding therapeutic claims require drug/device regulation (10). However, lookalike tobacco products without therapeutic claims entering the market with only premarket review or substantial equivalency may gain a reputation for safety or cessation efficacy by association, bypassing more stringent regulatory processes. Third, pharmaceuticalization legitimizes the tobacco industry as a partner and producer of innovative nicotine products, ignoring the ethics of both producing and profiting from addiction and its treatment (4).

By transitioning the cigarette business to the nicotine business, TTCs stand to profit from smokers, new nicotine users, and would-be quitters. They seek to rehabilitate their image by appearing responsive to public health concerns and exonerate themselves from the responsibility of having addicted smokers by offering long-term modified-risk nicotine maintenance. And, they ensure profitability amid increasingly strict regulations and renormalize the tobacco industry and nicotine use. Pharmaceuticalization represents the next phase of the tobacco industry, and a new threat to public health.

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Table 1

Pharmaceuticalized nicotine (and marijuana) products owned by transnational tobacco companies.

Company	Sample Image	Subsidiary and Products	Date	Notes
Altria/PMI		PMI		PMI invested \$20 million in the Israeli pharmaceutical marijuana company Syqe Medical, whose products claim to “consistently deliver metered doses at pharmaceutical-level precision”, which keeps the user in the “therapeutic” zone between pain and psychoactive thresholds.
		iQOS (heat-not-burn cigarette) <i>(pictured bottom-left)</i>	2014	
		NuMark		
		MarkTenXL (e-cigarette)	2014	
		Verve		
		Verve (lozenge)	2012	
		Green Smoke		
		Green Smoke (e-cigarette)	2014	
Reynolds American		Niconovum		Vuse top-selling US. Zonnec is a tobacco-industry sold, FDA approved NRT product.
		Zonnec (gum, pouch, spray)	2009	
		Reynolds Vapor Company		
		Vuse (e-cigarette) <i>(pictured left)</i>	2013	
Japan Tobacco International		British Zandera Ltd.		E-lites is one of the top-selling e- cigarettes in the UK. Ploom was acquired by JTI in 2015; it offers an e-cigarette and heat-not-burn products.
		E-Lites (e-cigarette)	2014	
		Logic Technology Development		
British American Tobacco		Nicoventures		Vype e-cigarette sold at Lloyd's Pharmacy in the UK against the advice of the Royal Pharmaceutical Society. In 2014, Nicovations became the first company to receive licenses for both its nicotine inhaler, Voke, and, a year later, for its e-cigarette, e-Voke. As soon as the products launch, British doctors will be able to prescribe the products as smoking cessation devices covered by the NHS.
		Vype (e-cigarette)	2013	
		Nicovations		
		*Voke (inhaler) <i>(pictured top left)</i>	2014	
		*e-Voke (e-cigarette) <i>*not yet released</i>	2015	
		Chic Group - Poland Volish, PI, Provog, Cottien, LiQueen (e-cigarettes)	2015	
		British American Tobacco		
		Glo iFuse (tobacco heating product) <i>(pictured bottom left)</i>	2015	
		Glo (non-combustible cigarette)	2016	

Company	Sample Image	Subsidiary and Products	Date	Notes
Imperial Tobacco		Fontem Ventures blu (e-cigarette) <i>(pictured left)</i> Puritane (e-cigarette) Jai (e-cigarette)	2014 2014 2015	Puritane e-cigarettes are available exclusively at UK pharmacy chain Boots, against the advice of the Royal Pharmaceutical Society.