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The Pharmaceuticalization of the Tobacco Industry

Yogi Hale Hendlin, PhD; Jesse Elias, MA; and Pamela M. Ling, MD, MPH

Is developing and legitimizing pharmaceutical-like, reduced-harm tobacco products giving the tobacco industry a new lease on life? Cigarettes constitute more than 90% of the industry's profits, and the number of smokers is increasing worldwide with population growth. Smoking prevalence is simultaneously declining, threatening cigarettes' long-term profitability. Transnational tobacco companies (TTCs) aggressively promote smoking in low- and middle-income countries but 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. That TTCs pursue selling nicotine products—such as ZONNIC nicotine gum, which is sold in the United States through Reynolds American subsidiary Nicovum, and the Voke nicotine inhaler and e-Voke e-cigarettes, which were licensed by British American Tobacco (BAT) subsidiary Nicoventures in the United Kingdom—heralds a convergence between tobacco industry nicotine products and pharmaceutical nicotine replacement therapy. Pharmaceuticalized tobacco products share 3 key elements with pharmaceuticals: standardized dosing, sleek medical design, and implicit or explicit certification or approval by relevant health authorities (Figure).

Two false intertwined assumptions facilitate pharmaceuticalization: Substantial numbers of “inveterate” smokers cannot quit, and most smokers require pharmacotherapy to do so. These premises may guide policy away from prevention or complete cessation, supporting prolonged use of safer nicotine products. Although exemplary efforts to control tobacco eschew alliances with tobacco companies (4), harm reduction accepts a nicotine maintenance industry, potentially recasting TTCs providing nicotine products as partners with health institutions.

The endorsement of health authorities by certifying noncombustible products as cessation devices (in the United Kingdom) or modified-risk tobacco products (MRTPs) in the United States 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 resemblance to pharmaceuticals leads consumers to perceive them as such. Without new drug approval, alternative nicotine products cannot be advertised as cessation devices; nonetheless, consumers may regard these as *de facto* nicotine replacement therapy analogues. Vaping advocates and some public health organizations cast e-cigarettes as cessation aids regardless of certification by drug authorities. As such, the industry assumes the mantle of medical legitimacy by association.







AN INDUSTRY IN TRANSITION

All major TTCs have large investments in pharmaceuticalized tobacco products. Since 2008, Philip Morris International has spent more than \$2 billion researching reduced-risk products (1, 2). In 2016, it spent another €500 million on its heat-not-burn product iQOS and submitted a multimillion-page MRTP application to the U.S. Food and Drug Administration in the hopes of certifying it as a reduced-harm product. The company 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). A signal of pharmaceuticalization as a broader trend, in 2016 the company also invested \$20 million in Syqe Medical, an Israeli manufacturer of a medical marijuana vaporizer that allows physicians to prescribe “therapeutic” doses of cannabis (5).

Reynolds American similarly sought to “migrate” smokers “outside traditional tobacco [to] (Pharma) . . . to cover tobacco dependence, beyond cessation” (6). In 2017, BAT acquired Reynolds American for \$49 billion, expressing specific interest in the company's next-generation products, including its best-selling U.S. e-cigarette brand, Vuse (7). Imperial Tobacco launched the e-cigarette Puritane in 2014, whereas its subsidiary Fontem Ventures purchased e-cigarette patents from Dragonite International for \$75 million and blu, the second best-selling e-cigarette brand globally, in 2015. Japan Tobacco International bought U.K. e-cigarette brand E-Lites' parent company Zandera in 2014; the third-largest U.S. e-cigarette company, Logic Technology Development; and in 2015 the heat-not-burn and vaping company Ploom.

The U.K. National Health Service's approval of BAT's e-cigarettes as prescription cessation devices is

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

Company	Sample Image	Subsidiary and Products	Date	Notes
Altria Group/PMI		PMI iQOS heat-not-burn cigarette <i>(pictured top left)</i>	2014	PMI invested \$20 million in the Israeli pharmaceutical marijuana company Syqe Medical, whose products claim to “consistently deliver metered doses at pharmaceutical-level precision.”
		NuMark MarkTen XL e-cigarette	2014	
	Verve Verve lozenge	2012		
	Green Smoke Green Smoke e-cigarette	2014		
	Nicocig Nicolites e-cigarette Vivid e-liquid	2014		
		Altria Group/PMI invested in the Syqe Medical marijuana inhaler <i>(pictured bottom left)*</i>	2016	
Reynolds American		Niconovum ZONNIC gum, pouch, and spray	2009	ZONNIC is an FDA-approved NRT product sold by a tobacco company.
		R.J. Reynolds Vapor Vuse e-cigarette <i>(pictured)</i>	2013	Vuse is the best-selling e-cigarette in the United States.
Japan Tobacco International		Zandera (United Kingdom) E-Lites e-cigarette	2014	E-Lites is 1 of the top-selling e-cigarettes in the United Kingdom. Ploom was acquired by Japan Tobacco International in 2015.
		Logic Technology Development Various e-cigarette brands <i>(pictured)</i>	2015	
		Ploom e-cigarette and heat-not-burn products	2015	
British American Tobacco		Nicoventures Vype e-cigarette	2013	Vype e-cigarette is sold at Lloyd’s Pharmacy in the United Kingdom 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, its e-cigarette (e-Voke).
		Nicovations Voke inhalert e-Voke e-cigarette†	2014 2015	
		CHIC Group (Poland) VOLISH, PI, Provog, Cottien, and LiQueen e-cigarettes	2015	
		British American Tobacco glo iFuse tobacco heating product	2015	
		glo noncombustible cigarette <i>(pictured)</i>	2016	
Imperial Tobacco		Fontem Ventures blu e-cigarette <i>(pictured)</i>	2014	Puritane e-cigarettes are available exclusively at U.K. pharmacy chain Boots against the advice of the Royal Pharmaceutical Society.
		Puritane e-cigarette	2014	
		Jai e-cigarette	2015	

FDA = U.S. Food and Drug Administration; NRT = nicotine replacement therapy; PMI = Philip Morris International.

* Image courtesy of Syqe Medical.

† Not yet released.

the paradigm of tobacco industry pharmaceuticalization (8). The U.K. Medicines and Healthcare products Regulatory Agency announced in 2013 that all nicotine-containing products, including e-cigarettes, would be 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 would allow physicians in the United Kingdom to prescribe these products.

IMPLICATIONS FOR HEALTH

The health consequences of pharmaceuticalization are 3-fold. First, it contributes to the dilution and confusion surrounding the real process and trust implied in the imprimatur of legal prescription pharmaceuticals. On the basis of the quality of current evidence, U.S. health authorities do not recommend e-cigarettes for cessation (9). Yet, these products are widely perceived by patients and clinicians as cessation devices.

Second, pharmaceuticalization complicates the regulatory process, expanding a class of products that seem like drugs, devices, or a combination of both but might not be subject to regulation as such. The U.S. Food and Drug Administration's 2017 rule on tobacco drugs and devices permits manufacturers to apply for MRTP authorization with evidence that their products verifiably reduce harm, whereas those making therapeutic claims require drug or device regulation (10). However, look-alike 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 seeming 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 while renormalizing 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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