The FDA needs to look beyond nicotine alone in developing its standard for nicotine delivery in tobacco products

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The FDA is considering its proposed nicotine product standard as part of its "comprehensive nicotine policy." The FDA's description of this proposal to date appears to focus narrowly on the pharmacological properties of nicotine. By reducing nicotine delivery in cigarettes, this standard would encourage smokers to switch to other nicotine delivery systems, including those made by tobacco companies, so as to reduce the harm caused by tobacco products. In the best case scenario, reduced-nicotine cigarettes will prompt smokers to quit smoking altogether, and cease use of all tobacco products. Second best, smokers will switch to non-combustible tobacco products yet maintain their nicotine addiction.

Compared to the tobacco industry's understanding of nicotine addiction, however, such a model overly simplifies the complexity of the smoking problem in ways that could promote policies that protect tobacco companies at the expense of public health. ***The FDA's understanding of nicotine addiction must be at least as sophisticated as the tobacco industry's.***

Philip Morris International's (PMI's) current public communications claim that only nicotine product substitution will diminish cigarette smoking prevalence.[1] Using previously secret internal company documents, however, we found that from the mid-1990s until at least 2006, PMI's parent company, Philip Morris (PM, now Altria) consistently understood the user's biology, psychology, social milieu and environment as at least as important as nicotine in driving use.[2] In 1997, for example, PM executives privately concluded that the "nicotine addiction hypothesis [i.e. the idea that people smoke exclusively to acquire nicotine] is much too simple to explain this complex behavior in which nicotine plays a significant, but not exclusive role."[3] PM's scientists maintained this position internally through the mid-2000s, even after company statements began publicly emphasizing nicotine as the primary cause of addiction.[2]

PMI's current public emphasis on nicotine as the chief driver of smoking[4] allows the company to redirect policy away from proven social and environmental interventions and toward the promotion of novel tobacco products. So long as these non-pharmacological drivers remain in place, PM estimated that anywhere from 50-98 percent of smokers would continue using cigarettes.[5] This multifactorial understanding of smoking implicates the tobacco industry itself as a vector of addiction – beyond the provision and manipulation of nicotine in cigarettes, the industry's marketing, lobbying and litigation against effective tobacco control policies all influence users' psychology, social milieu and environment, which in turn determine use.

The tobacco industry may have contributed to the historical over-simplification of nicotine addiction. British psychiatrist Michael Russell, whose scholarship is summarized by his 1991 hypothesis that people "smoke for the nicotine but die from the tar," [6] is today widely regarded as the father of tobacco harm reduction. [7, 8] Russell collaborated extensively with tobacco companies through at least the early 1990s.[9] In the late 1970s, Russell collaborated with British American Tobacco on two 'safer' cigarette studies[10] and received £55,000 ($402,420 inflation adjusted to 2018) to test medium nicotine, low-tar cigarettes.[11, 12] In 1988, Russell contacted RJ Reynolds (RJR), soliciting funding for a study on RJR's "heat-not-burn" tobacco product, Premier.[13, 14] In subsequent communications, Russell stated *a priori* that publication of study results could improve consumers' and regulators' perception of Premier [15]. Russell also offered to "'lose' records" of reimbursement from RJR,[15] and suggested the company pay him to undertake research on Premier,[16] which he anonymously endorsed as a "near-perfect low tar cigarette" while representing *The Lancet* in a 1991 editorial.[17] As consumers became increasingly health conscious, RJR scientists believed Russell's endorsement indicated that new tobacco products, "uniquely perceived…as less hazardous," could "stabiliz[e] or revers[e] market decline" as smoking prevalence fell and bolster RJR's "long-term vitality." [18]

Tobacco companies now claim to support users' switching from cigarettes to alternative tobacco products.[1] Any population-level success with product substitution, however, would be at odds with public health history. Population studies consistently show that unassisted cessation (e.g. policy interventions, going cold turkey, cutting-down-to-quit) is the most common and successful cessation method, leading nicotine replacement therapies (NRT) by a wide margin.[19] Fully two-thirds[20] to three-quarters[21] of ex-smokers quit unaided. These data suggest that neurobiology and pharmacology explain only a small part of cessation. Nonetheless, tobacco companies have a vested stake in reducing smoking to a problem of nicotine administration, treatable not through proven policy interventions, but through the potentially life-long use of an alternative industry product, with uncertain health claims.[22]

While nicotine in cigarettes should be lowered to non-addictive levels, the FDA should not expect these reductions alone to solve the smoking problem. Instead, reductions in nicotine should complement increased access to proven NRTs and behavioral counseling, coupled with ever-stronger societal level restrictions on both tobacco use and industry influence. Both public health history [19, 23-25] and the tobacco industry's own understanding of addiction suggest that social and environmental interventions – e.g., advertising restrictions, plain packaging, tobacco taxes, and widespread smoke-free restrictions – lessen addiction's tenacity far more effectively than changing individual users' nicotine delivery source alone. These policy interventions become even more important as smoking becomes increasingly concentrated within society's most vulnerable populations, which have least access to pharmacotherapy, cessation services or potentially reduced harm products.[26-28]

To improve addiction outcomes and public health, FDA should both reduce the nicotine levels permitted in cigarettes and other combustible tobacco products, while also expanding and strengthening social and environmental restrictions on cigarette smoking.

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