New Product Marketing Blurs the Line Between Nicotine Replacement Therapy and Smokeless Tobacco Products

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Tobacco companies have begun to acquire pharmaceutical subsidiaries and recently started to market nicotine replacement therapies, such as Zonnic nicotine gum, in convenience stores. Conversely, tobacco companies are producing tobacco products such as tobacco chewing gum and lozenges that resemble pharmaceutical nicotine replacement products, including a nicotine pouch product that resembles snus pouches.

This convergence of nicotine and tobacco product marketing has implications for regulation and tobacco cessation. (Am J Public Health. Published online ahead of print April 14, 2016: e1–e4. doi:10.2105/AJPH.2016.303057)

In response to declining cigarette sales, Reynolds American Inc. (the second largest US cigarette manufacturer) and other cigarette companies have ventured into the manufacturing and sales of smokeless tobacco and other nicotine-containing products. In 2009, Reynolds American acquired the Swedish company Niconovum AB, which makes nicotine replacement therapy (NRT) products, including nicotine gum and oral spray. In September 2012, Reynolds American began test marketing Zonnic nicotine gum, the company’s first NRT product to be sold in the United States, in the state of Iowa and in Omaha, Nebraska.

Each package of Zonnic nicotine gum contained 10 pieces of mint-, cinnamon-, or fruit-flavored gum and cost $3.65, about half the price of a pack of cigarettes in Des Moines, Iowa. Zonnic is available in both 2-mg and 4-mg strengths, delivering 1 and 2 mg of nicotine, respectively, less than the amount typically delivered by cigarettes. However, gum products do not deliver nicotine as quickly as cigarettes. Zonnic is currently sold nationwide, primarily in convenience stores and gas stations.

In contrast to Zonnic, most nicotine gum and lozenge products traditionally have been packaged as 80 to 100 pieces for $20 and up and have been sold mainly in drugstores. According to Tommy Payne, president of Niconovum USA Inc. (and former Reynolds American executive vice president of public affairs), the company is seeking to “bring smokers into NRT that haven’t been in the category before, whether because of cost, access and motivation.”

Evolving Smoking Cessation Advertising

Niconovum claims that it takes “an inspirational, positive approach” in its marketing communications, which state that “[e]ach cigarette not smoked is a victory” and emphasize the benefits of a gradual reduction in cigarettes for smokers who cannot “go from all to nothing.”

Zonnic’s advertising includes Web commercials and direct mailings.

Zonnic’s advertising messages may encourage smokers to use NRT to cut back on cigarette smoking without quitting. Cutting back as a cessation strategy has been proposed in the United Kingdom, where “cut down to stop” was endorsed by Action on Smoking and Health in 2005. Changes in NRT regulations in the United Kingdom reduced restrictions on use and allowed extended NRT use to cut down on smoking (or cigarettes smoked) as a step toward quitting, endorsing concurrent use of NRT and cigarettes over an extended period of time. According to several early evaluation studies, the cut down to stop approach in the United Kingdom resulted in increased sales of NRT but had very limited, if any, impact on patterns of nicotine replacement use or cessation rates. Nonetheless, in June 2013, the National Institute for Health and Care Excellence in the United Kingdom issued public health guidance on tobacco harm reduction approaches recommending reducing to quit as a viable approach to cessation.

In April 2013, the Center for Drug Evaluation and Research (CDER) of the US Food and Drug Administration (FDA) issued a Federal Register notice announcing that it was softening the warnings on the labeling of over-the-counter NRT products regarding the concomitant use of these products and cigarettes in the United States. However, CDER rejected a request that it add a formal indication for the use of NRT as part of a “reduce to quit” approach. The Zonnic Web site references the new FDA approach on its “News from the FDA” Web page and implies that the FDA approves a reduce to quit approach: “The FDA is on your side. Now if you need more time, you can take it.”

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In addition, the company frames the FDA’s argument on less abuse liability associated with NRT use to claim that there is no risk of product dependence: “Sources you can trust (like the FDA) have agreed that people don’t find themselves dependent on gums like ZONNIC.” This statement misrepresents the FDA language.12 It is unknown how the introduction of easily accessible NRT products such as Zonnic will affect cessation rates. Some tobacco treatment specialists have expressed concern that previous limitations on NRT sales and marketing inhibited its uptake among smokers; others have argued that simply marketing it over the counter without linking NRT promotion to counseling may not be effective. In fact, there is evidence that promotion of over-the-counter NRT directly to consumers has not been accompanied by an increase in population cessation rates. Reynolds American’s marketing tactics do not link Zonnic to counseling and further divorce NRT use from a therapeutic context by making it available for sale mainly in convenience stores rather than pharmacies. Furthermore, the new packaging and promotional strategies for Zonnic (which include reframing cessation in terms of success with each single cigarette reduced) might encourage situational use of NRT rather than increasing cessation.

The Zonnic advertising may be part of a larger trend in NRT advertising. The 2013 Nicorette Web site includes features that are similar to Zonnic advertisements and highlights “new” smaller “pocket packs” and “starter packs” of 20 pieces. In addition, recent commercials for Nicorette lozenges celebrate “each cigarette not smoked,” and the Web site also makes references to the new FDA approach. Furthermore, as NRT products such as Zonnic become more readily available to consumers in convenience stores or gas stations and are prominently displayed next to the check-out register (Figure 1), there may be an increase in use among people, especially youths, enticed to use nicotine recreationally or for other reasons unrelated to smoking cessation, such as weight loss.16,17

REGULATION CATEGORY
NRT product manufacturing and marketing by companies that sell cigarettes and other tobacco products are expanding. For example, Reynolds American is testing Zonnic pouches in clinical trials in New Zealand; these pouches resemble Camel Snus and are packaged in round cans similar to those used for smokeless tobacco (Figure 2).18–20 Altria recently announced the launch of Tju “chewing tobacco gum” in Denmark and of Verve tobacco-derived nicotine discs, which are currently being test marketed in Virginia.21 Camel Orbs produced by RJ Reynolds, which were introduced in 2011 in Charlotte, North Carolina, and Denver, Colorado, are analogous in appearance to Nicorette Mini Lozenges.22 Although not directly promoted as smoking cessation aids, these tobacco products resemble NRT products and so may be perceived as analogous to NRT gums and lozenges in regard to product safety. Research is needed to address how the marketing of new smokeless tobacco products that resemble NRT, or as line extensions of leading cigarette brands (e.g., Camel), influences the perceived risks and benefits, adoption, and use of these products.

In 2009, the Family Smoking Prevention and Tobacco Control Act (HR 1256) gave the FDA’s Center for Tobacco Products authority to permit a company to market a product as a “modified risk tobacco product” (MRTP) if the manufacturer could...
demonstrate that the product, as used by consumers, would “significantly reduce the risk of tobacco-related diseases to individual tobacco users” as well as “benefit the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products.”23 By contrast, the FDA’s Center for Drug Evaluation and Research regulates over-the-counter and prescription drugs, including NRT products and other smoking cessation medications. If a company is to market a product as a smoking cessation aid, it must submit research to prove that the drug is safe and effective for its intended use. The generic drug version of Zonnic gum was approved by CDER before Reynolds American acquired Niconovum.24

By submitting new nicotine-containing products to CDER as NRT, the tobacco companies are able to circumvent the MRTP submission process of the Center for Tobacco Products, which includes a population health standard. Although the CDER approval process is generally regarded as quite rigorous, it does not regulate pricing or venues for sales distribution. To date, few applications for novel smokeless products have been received by the Center for Tobacco Products for MRTP review.

Although the Zonnic nicotine gum product itself appears to be similar to traditional NRT gum products, changes in package size, sales locations, marketing channels, and consumer communications may radically change how this product is used, and the resulting effects on the health of the population are unknown. Tobacco companies have a strong motivation to exploit the market potential of alternative nicotine products to generate new profits, without losing existing profits from cigarettes, by creating new forms of nicotine and tobacco use.25

**RESEARCH AND REGULATORY NEEDS**

The tobacco industry is engaging in development of pure nicotine and pharmaceutical products worldwide.26,27 It is important to monitor the development of these products. Monitoring should be accompanied by research to determine whether the increasing resemblance between novel tobacco products and NRT affects consumer perceptions of health risks associated with NRT-like tobacco products and changes in perceptions of what constitutes cessation (i.e., whether cutting down increases successful quit attempts or whether it is perceived as an alternative to cessation). In regard to Zonnic specifically, research is needed to determine whether the “Each cigarette not smoked is a victory” messages enhance or deter cessation. In the United States, tracking and comparing tobacco industry applications to the FDA for NRT products and novel tobacco products could help prevent exploitation of the regulatory system to get new products intended for recreational use approved as NRT. Such efforts could ensure that promotion of these novel products is not detrimental to public health.

Tobacco products and NRT products are evolving to become increasingly similar to each other in appearance, with more widespread availability through nonmedical channels, reduced pricing, and an increased variety of flavored options (e.g., Zonnic is produced in mint, fruit, and cinnamon flavors, which are the most popular flavors on the smokeless tobacco market other than wintergreen28). In addition, the marketing of these products is beginning to converge with similar messages (i.e., cutting down to quit or situational use of nicotine). Finally, the regulatory framework may allow the tobacco industry to introduce new tobacco products as NRT products.

The result is a blurring of the lines between cessation products and novel tobacco products and potentially confusion and misuse by consumers which may result in initiation or situational and dual use of tobacco products. Since the first surgeon general’s report in 1964, evidence has linked smoking and tobacco use to diseases of nearly all organs of the body.29 The recommendation of the 2014 surgeon general’s report 50 years later is to employ only proven, evidence-based tobacco control strategies and programs, such as counseling and promotion of cessation treatment in clinical settings, to help achieve a society free of tobacco-related death and disease.29

**CONTRIBUTORS**

All of the authors conceptualized the article. G. Kostygina collected the data and led the writing. All of the authors contributed to revisions and reviews of the article.

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**HUMAN PARTICIPANT PROTECTION**

No protocol approval was needed for this research because no human participants were involved.
REFERENCES