

Citizen's Petition Pursuant to 21 CFR 10.30 to the Secretary of Health and Human Services and the Food and Drug Administration Requesting Expansion of Availability of Nicotine Replacement Therapy to Consumers Who Use Tobacco

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The undersigned submits this petition under 21 CFR 10.30 of the Federal Food, Drug, and Cosmetic Act to request the Commissioner of the Food and Drug Administration to (1) allow the sale of over-the-counter (OTC) nicotine replacement therapy (NRT) in all retail locations where cigarettes are sold, including in convenience stores, gas stations, tobacco specialty stores, grocery stores, and other retail businesses that sell tobacco; (2) allow OTC NRT to be sold in "daily" units (containing an amount of NRT that would typically be consumed in a 24-hour period) at prices competitive with one 20-count pack of cigarettes; and (3) modify labeling requirements in order to fully disclose to smokers the benefits of OTC NRT use relative to continued cigarette use, with risks associated with OTC NRT compared to risks associated with continued cigarette use.

A. Action requested

Specifically, the undersigned requests the Commissioner of the FDA to withdraw the conditions specified in Approval Letter to Application Number 18-612/S025 and 20-066/S007 that (1) restrict distribution of NRT to "drugstores, mass merchandisers and supermarkets where other OTC drugs are sold. The products will not be distributed to other channels, including convenience stores and vending machines;" and (2) prohibit the offering of "Trial size" or "sample" packs (e.g., packs small enough to be priced competitively with cigarettes).

Further, the undersigned requests the Commissioner issue a policy regarding the packaging and sale of OTC NRT, including the following conditions. (1) OTC NRT may be sold wherever cigarettes are sold; (2) OTC NRT may be packaged in units of a size that can be competitively priced with cigarettes and/or in units containing an amount of OTC NRT product that would typically be consumed in a 24-hour period; (3) OTC NRT

may be advantageously positioned relative to cigarettes and tobacco products in order to promote the sale of the OTC NRT product.

Finally, the undersigned requests the Commissioner modify the required package labeling and warnings to recognize the following. (1) OTC NRT is safe for use by smokers and safer for use than continued cigarette use; (2) OTC NRT is appropriate for use in situations of temporary abstinence from cigarettes in order to moderate symptoms of nicotine withdrawal associated with periods of smoking restriction (e.g., in the work place); (3) Grave risks are not associated with the use of OTC NRT for those who do not completely abstain from tobacco use.

B. Statement of grounds

1. Over the counter (OTC) nicotine replacement therapy (NRT) should be more widely available to smokers in order to increase use, increase quit attempts and, eventually, increase quit success.

OTC NRT should be well-positioned to compete with cigarettes in both price and availability (size of packaging and location of purchase). The current restricted framework governing the packaging and sale of OTC NRT does not adequately balance the benefits and risks of OTC NRT use in the context of the comparatively unrestricted sale and packaging of other hazardous sources of nicotine, such as cigarettes. The benefits and risks of OTC NRT use should be weighed against the benefits and risks of continued use of cigarettes, use which will occur when access to OTC NRT is restricted (McNeill 2001). One of every two continuing smokers dies prematurely as a direct result of cigarette use (Doll 2004). The risks associated with nicotine delivered without the smoke toxins are lower by several orders of magnitude (Benowitz 1998), suggesting that OTC NRT should be available at least as widely and accessibly as cigarettes, and should compete with cigarettes directly on price and sales locations.

While use of NRT increased substantially following the switch from prescription to over-the-counter availability (Shiffman 1997, Shiffman 2007), currently too few smokers use OTC NRT for these products to have a measurable impact on population behavior and health (Cummings 2005). There are likely numerous factors responsible for low use of OTC NRT. However, limited availability of the product due to restrictions on the types of outlets that can offer OTC NRT, perceived high cost due to the large package size requirements, and concerns about safety resulting in part from onerous labeling requirements, all contribute to low utilization of OTC NRT (Hyland 2005, Cummings 2004, Kozlowski 2007). Regulations that restrict only the safest nicotine products, and remain largely silent on the most dangerous nicotine products are hard to justify (Gray 2005, Sumner 2005).

2. Increased availability of OTC NRT will not lead to increased abuse by adolescents.

A study from Tennessee in 2003 reported that five percent of youth self-reported ever using NRT and 18 percent of these five percent were never smokers (or 0.9 percent of youth) [Klesges 2003]. A subsequent study by the same investigators reported that most stores that sold OTC NRT completed sales to minors, and that NRT vendors that also sold alcohol were less likely to complete an OTC NRT sale to a minor (Johnson 2004). Hyland et al (Hyland 2005) found NRT abuse rates among adolescents to be low and to have remained unchanged following the switch to OTC availability. NRT abuse rates among youth were far lower than abuse rates of other medications routinely available for sale (e.g., diet pills).

3. OTC NRT is safe and safer than cigarettes for all smokers

The three OTC NRT products (patches, gum and lozenges) constitute safe nicotine delivery systems (Hughes 1993, Shiffman 2007), while cigarettes are an extremely dangerous nicotine delivery system. Use of OTC NRT is safer than continued cigarette use for all smokers, including those with cardiovascular disease (CVD) (Marsh 1995, Murray 1996, Benowitz 1997, Hillis 2000, McRobbie 2001, Joseph 2003a, Joseph 2003b), those who are pregnant (Benowitz 1991, Oncken 1996, Oncken 1997) and adolescents aged 12 and older (Smith 1996, McNeill 2001, Moolchan 2005). In fact, both the United Kingdom (UK) and France license OTC NRT for use by adolescent smokers, pregnant women who smoke and smokers with cardiovascular disease (Shiffman 2007). For all groups, the benefits of using NRT and stopping smoking should be weighed against continued use of cigarettes (McNeill 2001). For pregnant women, additional research is needed to fully explicate relative risks and benefits (Wisborg 2000, Oncken 2003)

Unfortunately, smokers have insufficient information and misplaced concerns about the safety and efficacy of NRT (Siahpush 2006). While only a small number of studies has assessed smoker knowledge of and attitudes toward medicinal nicotine products, these studies (Etter 2001, Bansal 2004, Cummings 2004) found that smokers are misinformed about the safety of OTC NRT, believe that use of nicotine patches is more likely than use of cigarettes to cause a heart attack, and would benefit from more accurate comparisons regarding the relative safety of OTC NRT and cigarettes.

4. Use of OTC NRT for situations of temporary smoking restriction in order to moderate transient withdrawal, as a substitute for smoking, and concomitantly with cigarette use in order to reduce consumption (and eventually quit) is safe and even desirable to advance public health.

Several studies have found no evidence that concomitant use of NRT and cigarettes is associated with adverse health events or increased side effects (Murray 1996, Marsh 2005). Two studies investigated the use of OTC NRT to reduce the number of cigarettes smoked as a strategy to move smokers toward cessation. Wennika et al (Wennika 2003) found that, among smokers unwilling to quit, study subjects assigned to use OTC NRT decreased the number of cigarettes smoked daily and achieved a higher smoking cessation rate than those not using OTC NRT. Intake of smoke toxins was lower than

baseline levels, but higher than would be expected given the number of cigarettes smoked (suggesting some compensatory smoking was occurring). No adverse events were reported and the authors concluded that OTC NRT promoted cessation in a population of smokers unwilling to quit. Batra et al (Batra 2005) reported similar findings among smokers unwilling to quit. Those assigned to the OTC NRT study arm sustained greater reductions in consumption and point prevalence abstinence from smoking, compared to those who did not use OTC NRT. In addition, the authors found concomitant use of OTC NRT and cigarettes to be well tolerated by study subjects. Several countries, including Norway, Austria, the UK, France, and Sweden license OTC NRT for use in conjunction with other tobacco products (McNeill 2001, Shiffman 2007). Further, long-term use of NRT can be appropriate for highly dependent smokers in order to maintain abstinence from smoking (Hajek 2007). Thus, a complete and permanent switch from cigarette smoking to long-term use of OTC NRT would dramatically reduce the substantial health risks associated with smoking.

These findings support the request to increase availability of OTC NRT by expanding the types of retail outlets that may offer OTC NRT for sale, permitting a "daily" package size, and modifying labeling requirements to accurately address smoker misconceptions about the relative risks and benefits of OTC NRT use. These changes will likely increase smokers' access to and comfort with OTC NRT, increase the likelihood that smokers will use OTC NRT experimentally and, eventually, that OTC NRT will effectively contribute to measurable population-level behavior change and reductions in cigarette use. Failure to adequately address the imbalance in the regulation of OTC NRT condemns millions of New Yorkers to completely avoidable smoking-caused disease and premature death.

C. Environmental impact

None.

D. Economic impact

The purpose of this request is to position OTC NRT more competitively with cigarettes and make them more available and attractive to consumers as alternatives to cigarettes or other tobacco products. The anticipated economic impact is to expand sales of OTC NRT, make them more affordable to consumers, and reduce sales of cigarettes and other tobacco products.

E. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Richard F. Daines, M.D.
Commissioner of Health

Encl: Citations

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