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Allison Hoffman, PhD
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Food and Drug Administration
Silver Spring, MD

Re: 21 CFR Part 15
Docket no. FDA-2017-N-6529

The Food and Drug Administration's
Approach to Evaluating Nicotine
Replacement Therapies; Public
Hearing; Request for Comments

Dear Dr. Hoffman,

We are writing as stakeholders on behalf of the Association for the Treatment of Tobacco Use and Dependence (ATTUD), the leading professional organization for clinicians providing evidence-based interventions for tobacco users. Below please find [our executive summary of recommendations and detailed comments on the Request for Comments regarding Nicotine Replacement Therapies \(NRT\)](#):

Executive Summary Conclusions:

1. All OTC and prescription NRT medication directions should be written in uniform, clear, and plain language at a 6th grade literacy level. The FDA should accept the utilization of all combinations and permutations of FDA-approved medications. Most importantly, the safety of continuing to using these medications, including in combinations, must be discussed, relative to the risks of continued smoking. Updated, evidence-based labeling normalizes the use of quitting medications and reduces fears and myths surrounding their safety. Consequently, FDA should allow the marketing of all tobacco treatment medication combinations and permutations, while clinical decisions should be evidenced-based relying on the art and science of tobacco treatment.
2. The best quit rates are achieved when smokers receive support from tobacco treatment specialists or their healthcare provider, while using any quitting smoking medications at the same time. Medication labels and directions therefore need to explicitly state that "medications work best when smokers receive counseling from a health care provider, such as a tobacco treatment specialist, doctor, or counselor."
3. There are two safe and effective approaches to using NRT.

- A. Preloading NRT or gradually reducing smoking while using NRT (particularly the patch) at the same time, prior to a quit date (possibly for 1-6 months), is safe and may be effective for many populations of smokers, particularly when implemented in face-to-face treatment settings (Fucito et al., 2014).
 - B. Starting to use the NRT on the quit date.
4. Tobacco users should continue using NRT if they are having “slip-ups” (i.e., smoking some cigarettes during a quit attempt) and have not yet completely quit. This is safe – NRT does not cause cancer, as evidenced by its use by millions of people over the past 30 years with no indication of attributable increased cancer rates. Additionally, NRT is safe even with patients with established cardiovascular problems (Woolf et al., 2012) and using NRT at the same time as smoking does not lead to serious health problems (Moore et al., 2009). For some tobacco users, this may necessitate using different combinations of medications together, possibly using NRT with a non-nicotine pill medication (e.g., bupropion or varenicline), and often in combination with best practices “high intensity” counseling, for months, and in some cases, for years. This is exactly how clinicians treat many other chronic medical, behavioral health, and other addiction conditions, such as hypertension, diabetes, and opioid addiction.

Questions for Commenters to Address

Although FDA welcomes all feedback on any public health, scientific, regulatory or legal considerations relating to NRT products and their use in tobacco use cessation, we encourage commenters to consider the following questions as they prepare their comments or statements. Responses to questions should include supporting scientific justification.

1. Might there be ways to improve upon the currently available delivery systems to yield new OTC NRT products that might be more effective? If so, what evidence would be needed to support such changes, and how should they be evaluated?

NRT box labeling is basically unchanged for the last 34 years. In 2013, FDA permitted some labeling changes on OTC boxes; however, most boxes of patches, lozenges, and gum and prescription NRT labeling have not been changed. In the meantime, in the last 15 years cigarettes have become more addictive in terms of nicotine yield/cigarette (Jarvis, Giovino, O'Connor, Kozlowski, & Bernert, 2014; Land et al., 2014; U.S. Department of Health and Human Services, 2010). For example, Jarvis et al (2014) reported that the yield of nicotine per cigarette (based on cotinine levels) has increased by 42% over a period from 1988-2012. Thus, it remains very likely that many moderately to highly addicted tobacco users will need higher levels of NRT to minimize cravings/withdrawal symptoms and successfully quit tobacco and that NRT product boxes and inserts with directions for use need to be updated accordingly.

Clinically, the effectiveness of an OTC NRT product would be enhanced by its ability to deliver higher doses of nicotine, more rapidly to the brain, in a safe manner. Such a product would be effective in reducing cravings and withdrawal symptoms, and provide a safer and satisfying nicotine substitute.

2. Are there additional indications or regimens for OTC NRT products that could be explored? Concepts to consider could include relapse prevention, craving reduction, maintenance, reduce to quit, use of short- and long-acting products in combination, or cessation of non-cigarette tobacco products. What evidence would be needed to support each indication or regimen?

Use of more than one OTC NRT product at the same time (e.g., nicotine patch with nicotine gum or lozenge) has already been shown to be safe and to be more effective than using a single NRT (Fiore et al., 2008; Siu & Force, 2015). Additionally, smoking reduction or preloading with patch for at least 1-6 months prior to a quit date has already been shown to be safe and may be effective (Fucito et al., 2014; Lindson & Aveyard, 2011; Stead et al., 2012). These strategies (combination NRT and/or preloading) likely dramatically extend the reach and clinical impact of NRT in helping a number of smokers who may be anxious, contemplating quitting, want to quit more gradually (Fucito et al., 2014), or have difficulty quitting with a single NRT (Fiore et al., 2008). Additionally, these approaches are now fairly common in specialist tobacco treatment centers. This also is the standard treatment protocol frequently used with bupropion or varenicline involving flexible stop dates (Rennard et al., 2012). The specific amount of time recommended for preloading NRT before the quit date may differ depending on populations of smokers, smoker preference, and setting of implementation (i.e., phone, brief vs. intensive treatment).

Many tobacco users are still not aware through television advertising or discussions with their physicians that it is safe to continue using the patch if there are slip ups and to keep the patch on if slips occur and/or that combination medications are safe and effective (Food and Drug Administration, 2013). Some patients erroneously conclude that smoking even a few cigarettes per day while wearing the nicotine patch as a preloading strategy is unsafe. Unfortunately, many of the NRT packaging boxes still have not included the recommended update from the FDA (2013). These misunderstandings and at times other common and unfortunate myths (e.g., “NRT causes cancer”; “smoking while on the patch causes heart attacks”), often lead to smoker non-compliance with medications, aborted quit attempts, and continued smoking.

All NRT box labeling instructions need to be uniform and clearer, particularly for heavily dependent smokers. Examples of new usages on boxes could include: “Heavy smokers may need to use 2 patches at the same time (i.e., 21mg patch, plus 21mg patch = 42mg; 21mg patch plus 14mg patch = 35mg). Keep meeting with your certified tobacco treatment specialist and/or healthcare provider for best results and help with best dosing amounts of quitting medications, if you are not 100% quit from tobacco or have any concerns.”

In many cases, NRT can safely be used with other quitting medications such as Zyban (bupropion) or Chantix (varenicline) (Chang et al., 2015; Koegelenberg et al., 2014; Steinberg et al., 2009), helping smokers achieve higher quit rates. Therefore, NRT labeling changes need to also be updated, giving smokers clear directions about the best available treatments. For example, “Talk to your tobacco treatment specialist or health care provider about the best combinations of medications that will help you quit. Specialized counseling plus using quitting medications together has been shown to increase your long-term chances of success by at least three times, compared to no support (Shahab, 2015).”

3. What data would be required to demonstrate health benefits of reduction in consumption of combustible tobacco products?

As smokers reduce combustible forms of tobacco (e.g., cigarettes/cigars/cigarillos), tobacco treatment specialists can assist smokers during the quitting progress by measuring the level of reduction in dangerous chemicals, for example, carbon monoxide. Breath carbon monoxide testing can be incorporated as a behavior change intervention at counseling visits. This quantitative data will also help

smokers achieve small goals during the quitting process, assess tangible levels of quantitative progress, address smoking overcompensation (smoking fewer cigs/day, but inhaling more deeply), while also building motivation to completely quit (Goldstein, Gans, Ripley-Moffitt, Kotsen, & Bars, 2018; West, Walia, Hyder, Shahab, & Michie, 2010).

Assuming the FDA may develop and implement a completely new policy of mandating severely lowered cigarette nicotine yield (to “non-addictive levels”) in all cigarettes, more studies like Jarvis et al (2014), will need to continue tracking yield of nicotine/cigarette. This may prove to be particularly important for those tobacco users who use menthol cigarettes, “roll your own” cigarettes, use cigarillos, and have health disparities. Many of these populations may smoke fewer cigarettes/day, but overcompensate or inhale more deeply, sustaining high levels of addiction and ingesting many tobacco toxins.

4. Are there OTC NRT products that could be studied for use in combination that might result in reduced tobacco-related health impacts? What evidence would be needed to support the safety and efficacy of these products when used in combination?

This is already addressed by the PHS Guidelines (Fiore et al., 2008; Siu & Force, 2015). As we have stated, combination NRT has already been shown to be safe and more effective than single monotherapy NRT. The next step is to permit pharmaceutical companies to sell boxes of patch (long-acting) and gum/lozenge (short-acting) together, all in one box. Canada has successfully done this. This will go a long way towards normalizing the use of adequate doses of quitting medications for tobacco users who want to quit, but are unsure of correct NRT dosing/regimens, as well as normalize combination medication regimens.

Additionally, FDA needs to go further. Starter quit kits (e.g., boxes with 2-3 patches and 10-20 lozenges), should immediately be sold, because many smokers who are willing to try NRT are unwilling to commit to investing \$25-50 to purchase 1 full-size box of NRT. These starter quit kits would cost only about \$4-8 and would directly compete against 1 pack/ day of cigarettes. Finally, since NRT is so much safer than cigarettes, NRT needs to be made available everywhere at the same point of cigarette sales (e.g., gas stations, convenience stores, grocery stores). This easy access mirrors what hospitals do, and will help potential quitters have tools immediately available and could mirror (in some ways) similar access of Narcan for the opioid epidemic. NRT should also be immediately available in airports as many tobacco users binge smoke prior to flying.

A number of typical practice setting studies (Burke, Ebbert, Schroeder, McFadden, & Hays, 2015; Dobbie et al., 2015; Foulds et al., 2006; Kotz, Brown, & West, 2014; Steinberg, Foulds, Richardson, Burke, & Shah, 2006; Steinberg et al., 2009; UMDNJ-School of Public Health, 2007), have reported very high rates for NRT use and compliance when medications are combined with “high intensity” short-term counseling, partly focusing on proper use of NRT. Therefore, box labeling could clearly indicate: “The best quit rates occur when you use quitting medications combined with specialized counseling from a tobacco treatment specialist.”

5. Is there other information that could be added to labeling for currently approved or new dosage forms of OTC NRT products that would maximize their ability to be used to support smoking cessation?

Please consider changing various sections of the Drug Facts labeling, including the Uses, Warnings, and Directions sections.

Uses:

Updated (Food and Drug Administration, 2013) labeling new directions are vague and unclear and use language that is indecipherable to many lower SES tobacco using populations.

For example, words: "concomitant use" (included in the allowable 2013 FDA update) needs to be changed and simplified to 6th grade literacy.

An improvement would be: "Using two medications (for example - patch and lozenge) at the same time is safe and is often more effective than just using one medication. "

Nicoderm side of box: Use with a support program.

Change to: "Use with face-to-face counseling from a tobacco treatment specialist, your doctor or other health care provider, or Quitline counselor (1-800-Quit-Now)."

Warnings:

The warnings unfortunately are overly extreme and scare many smokers away from using the products. Warnings have created a situation where many smokers are more afraid of these medications than they are of combustible tobacco. They need to be changed and updated – giving smokers the clear facts, showing the relatively severe dangers of smoking compared to the low risks of potential mild side effects from NRT.

Examples of clear, plain language facts: "Cigarettes - kill about 480,000 Americans/year (U.S. Department of Health and Human Services, 2014). Also, > 14,400,000 smokers are living with smoking-caused serious illness or disability/year."

"Quitting medications are thousands of times safer than tobacco and should always be used instead of cigarettes. This is because cigarettes have 7,000 chemicals, including hundreds of poisons such as lead, carbon monoxide, cyanide, arsenic, 70 carcinogens, etc. This is exactly why your treatment team gives you the patch/gum/lozenge or other nicotine replacement products when you are in a hospital."

"Quit smoking medicines only have one active ingredient - a slow form of nicotine that does not cause cancer. These quitting aids help shrink your cravings and curb withdrawal symptoms such as irritability, anxiety, concentration problems, etc. This makes it much easier to work on developing new behaviors and thinking habits as you transition into becoming an "ex-smoker."

Nicoderm patch box: If you are pregnant or breast-feeding... this medicine is believed to be safer than smoking.

Change to "this medicine is known to be safer than smoking"

Ask a doctor before use if you have:

“Heart disease... recent heart attack:”

Change to: “Nicotine medications have been shown to be safe in people with heart disease. For those who have suffered a heart attack in the last two weeks, unstable chest pain, or severe rhythm issues, nicotine medications are still safer than continuing to smoke, but should be used after discussion with a health professional.”

Ask a doctor or pharmacist.... If you are taking medication for depression or asthma... your prescription dose may need to be adjusted.

Change to: “If you are taking a medication for a psychiatric condition such as depression, tell your prescriber that you are using nicotine replacement therapy, as your prescriber may want to change the dose of your psychiatric medication(s) as you are reducing cigarettes and after you completely quit.”

Stop use and ask a doctor

Change to “Stop use and ask your tobacco treatment specialist or healthcare provider.”

Directions

Nicoderm... begin using the patch on your quit date.

This needs to be changed and updated.

“There are two safe and effective ways to use the patch, gum, lozenge and prescription NRT products – chose the option that seems most comfortable for you:”

1. Gradually quitting: Start using the patch before you quit. Use the patch while you continue to smoke and begin to reduce your smoking. This has been shown to be safe and effective for a period of at least 1-6 months.
2. Quitting Fast: Begin using the patch on the day of your quit day.

Since, many patients don't even know that their health insurance likely covers at least 1 of 7 of the quitting medications (often at 100%), and since cost of quitting medications is often a major barrier or perceived barrier (Curry, Grothaus, McAfee, & Pabiniak, 1998; Fiore et al., 2008) to quitting, direction labels could indicate this updated (Departments of Health and Human Services, 2014) insurance coverage: “As part of the healthcare reform law, your insurance will likely cover many of the quitting medications, often at 100%. Talk to your tobacco treatment specialist or doctor about how to find out what your specific quitting medication coverage is.”

Nicoderm Questions or comments:

“Call toll free 1-800-834-5895 or your tobacco treatment specialist, your doctor or other healthcare provider, or your Quitline counselor.”

6. Generally, the labeling of OTC NRT products contains a dosing schedule based on duration of use, and FDA has recommended the labeling on OTC NRT products be modified to include the following: “If you

feel you need to use [the NRT product] for a longer period to keep from smoking, talk to your health care provider.”

Improved guidelines would increase smokers psychological comfort level regarding the length of NRT use. For example, box guidelines could say: “Many tobacco users have safely used the patch for more than one year. If you have slip ups, it is very important to keep using the patch every day. If you have concerns see your certified tobacco treatment specialist or healthcare clinician for best quitting results.”

What is the impact of longer term NRT treatment?

Studies have shown that some people may need to use gum/lozenge/patch on and off for months or a few years to get to 100% quit – that is, completely off tobacco products (Anthonisen et al., 1994; Anthonisen et al., 2005; Hall et al., 2011; Hall et al., 2009). Enhanced medication compliance could potentially be augmented by more engagement in face-to-face treatment, which was clearly seen in the Lung Health Study (Anthonisen et al., 2005), where extended counseling, plus extended access to free gum demonstrated improved health outcomes and resulted in long-term quit rates four times higher than usual care. Thus, longer-term NRT is safe and effective. Again, this is the same approach clinicians use with other chronic conditions.

What is the impact on likelihood of cessation or relapse prevention?

Longer-term use of quitting medications works best when tobacco users consult with a tobacco treatment specialist or a healthcare provider to continue using medications at the same time as working on behavior change techniques. “Your tobacco treatment specialist or health care provider will also help you with the proper dose and amounts of your quitting medications, including how to effectively wean off medications after you quit tobacco products.”

What data would support an affirmative recommendation to use approved OTC NRT products for durations that exceed those currently included in the Drug Facts labeling of approved OTC NRT products, or would support a chronic or maintenance drug treatment indication for such products?

It is well recognized that for heroin dependence a subgroup of patients who are addicted may need methadone or Suboxone long term, possibly for years. It is also likely that a subgroup of tobacco users (i.e., perhaps about 1-5% of the daily smoking population) may need the same longer-term use of NRT, as a part of a harm reduction strategy. The Lung Health study (Anthonisen et al., 2005) showed no health problems from long term nicotine gum use and clear health benefits from those who received “highly intensive” tobacco treatments; these treatments demonstrated quit rates four times higher than control treatment, after five years.

Sincerely,

Audrey Darville, PhD, APRN, CTTS, FAANP

ATTUD President and on behalf of the Board of Directors

Chris Kotsen, PsyD, CTTS

Chair ATTUD Business Practices Committee

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