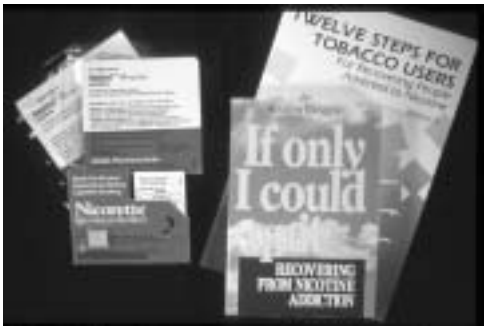
Don't Give Up on Over-The-Counter Nicotine Medications Just Yet

by Michael Steinberg, MD, MPH



For those of you wondering why we would be giving up on nicotine replacement medication, I am referring to the recent article by John Pierce and Elizabeth Gilpin, "Impact of Over-the-Counter Sales on Effectiveness of Pharmaceutical Aids for Smoking Cessation." (JAMA September 11, 2002; Vol 288 (10); 1260-1264). This article has stirred much debate over the effectiveness of Nicotine Replacement Therapy (NRT) now that it has gone to over-the-counter (OTC) status. Based on data from the California Tobacco Surveys from 1992, 1996 and 1999, the authors concluded that since becoming available OTC, NRT appears no longer effective in increasing long-term successful cessation in California smokers. It is important to evaluate these results in context, which unfortunately, media outlets rarely do. There have been many responses to this article by the public health community. I will not devote this article to the methodological critiques of the study (self-report, retrospective nature, lack of control group, sampling variation from year to year, specifying characteristics of quit attempts, etc.). Instead, I want to comment on how we can interpret these results for ourselves and for our patients.

Keep in mind that it is important to constantly re-evaluate our practices in tobacco dependence treatment. New data are always coming to the surface and should be examined with a critical eye. However, one study in California, based on retrospective survey data, should not undo nearly 100 clinical trials with over 35,000 patients demonstrating the efficacy of these products. There is not enough evidence in this one study to change our current practice of using NRT for tobacco dependence treatment. Just by the nature of becoming OTC, it is unlikely that a product will lose its effectiveness. It is more likely that these products are no longer being used as recommended, either from a dosing or duration standpoint. Like any product, if it is being used incorrectly, it will not perform up to expectations. Patients need to use the medication at appropriate doses, in appropriate ways, and for long enough duration. We, as tobacco treatment specialists, need to educate smokers how they should use them.

Over-the-counter status does have some advantages over prescription medications, and should not be abandoned. It eliminates a significant barrier to treatment for those smokers who do not regularly see a physician, have no prescription plan (many of which do not cover tobacco treatment anyway), or are less motivated. These smokers may experiment with the products, gain some familiarity, and a sub-group may become abstinent. By increasing availability, these products will reach a higher proportion of smokers. Even if the success rates may be lower, the overall number of smokers benefiting from medication will certainly increase.

Therefore, my take home message is that these products continue to be useful supplements to a tobacco treatment plan, though they do need to be explained, demonstrated and monitored to capitalize on their effectiveness. Additionally, as we have come to realize in this field, certain off-label uses of the medications (e.g. high-dose and combination therapy) are effective, yet will require the guidance of a trained professional. Therefore, tobacco treatment specialists are important providers who can achieve maximal impact of NRT, over-the-counter or otherwise, through their expertise and advice.

Visiting Professorship to Tobacco Dependence Program

by Jill Williams, MD

Recently, the Tobacco Dependence Program was visited by Dr. Robert Freedman of the University of Colorado, Health Sciences Center in Denver, as part of the 2002 Pfizer Visiting Professor Program. Dr. Freedman is a leader in psychiatric genetics and receptor chemistry. His work has focused on a subset of nicotinic receptors called the alpha-7 receptor. This receptor is believed to be linked to several brain disorders including schizophrenia, Alzheimer's disease and attention-deficit hyperactivity disorder (ADHD), and may help to understand the role of smoking in these disorders.

Schizophrenics are noted for rates of smoking that are 3-4 times greater than that of the general population. It is suspected that this reflects altered neurotransmitter systems in the brain. Dr. Freedman's work has found that cigarette smoking normalizes an abnormal auditory test in schizophrenic patients, called an evoked potential (P50). It is suspected that this relates clinically to the subject's perception of having an auditory hallucination as well as the ability to filter out other distracting noises. This electrophysiological abnormality has been linked to anatomical changes in the temporal lobe and limbic system. It has also been found in family members who do not have schizophrenia leading to the genetic discovery that it is linked to chromosome 15q13-14, the site of the alpha-7 nicotinic receptor.

Dr. Freedman is currently investigating the possibility of new compounds, which bind in lieu of nicotine at this same receptor, called nicotinic agonists. He has a study currently underway examining GTS-21, a selective alpha-7 agonist, in schizophrenic subjects.

It is hoped that better treatments for schizophrenia may contribute to reduced levels of smoking. Members of the Tobacco Dependence Program attended lectures given by Dr. Freedman and participated in research planning meetings and mentoring sessions with him.