Letters to the Editor

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OTC NICOTINE GUM

To the Editor:

Although it's true that "patients who use tobacco but want to quit face many barriers,"[1] moving nicotine gum from prescription to over-the-counter (OTC) status does not create "another potential barrier to tobacco cessation." In fact, only by increasing access to, and education about, safe and effective smoking-cessation methods can we help the 48 million Americans overcome their addiction to smoking.

The authors of the above-mentioned letter inaccurately compare the likelihood of OTC availability of nicotine gum to the likelihood that the FDA would approve "an antihypertensive agent with only a 16% rate of successful response." The term *successful response* deserves clarification, as it is often a source of misunderstanding among physicians and patients. Nicotine replacement therapies (NRT [nicotine gum and nicotine patch]) are indicated for the *alleviation of nicotine withdrawal symptoms* and can claim a high rate of success in doing so.[2] "Successful response," however, is more often defined as achieving long-term abstinence from smoking, a more complex process that involves both behavioral and physical components. Nicotine gum successfully relieves the physical cravings for nicotine and frees the smoker to concentrate on the behavioral aspects of quitting.

Unfortunately, too many patients and physicians view NRT as the "magic bullet." Nicotine is a highly addictive drug that is inculcated into behavioral patterns that can trigger the urge to smoke. The 1988 Surgeon General's Report compares it to heroin: "The use of tobacco is not a matter of free choice, but the result of an addiction as scientifically valid as the addiction to heroin and other narcotics. . . ."[3] When a smoker combines the environmental stimuli (habit) with an addictive drug, the result is a strong addiction that is very difficult to overcome.

Recent studies confirm the efficacy of nicotine gum, and a recent *British Medical Journal* article found that the use of nicotine polacrilex (nicotine gum) could help one third of highly addicted smokers to quit.[4] Although there are no panaceas and no treatment is adequate without personal motivation, researchers have found that NRT is the only method proven to double a smoker's chances of successfully quitting when compared with counseling alone.[3–6]

There are several major problems with the gum. First, the medication is being prescribed incorrectly; 52% receive prescriptions without ever seeing a physician. Second, it is chewed incorrectly. The typical chewer chews too quickly. Doing so extracts too much nicotine from the gum and generates excess saliva, which is then swallowed and may result in undesirable side effects, ie, indigestion and hiccups. The proper method to chew the gum is to chew five to eight times until the user receives a tingly, peppery feeling. Once this occurs, the smoker "parks" the gum in the gingival groove so that nicotine can be absorbed through the buccal lining. Third, virtually all the studies reveal that patients use insufficient nicotine replacement (too few pieces of gum). The insert for the 2-mg gum notes a minimum of 10 to 12 pieces of gum per day. The insert further indicates that the smoker can use up to 30 pieces per day; however, the average daily use is 5 pieces. Consequently, the smoker does not receive sufficient nicotine replacement, experiences withdrawal symptoms, reverts to smoking, and then claims the gum does not work.[7] Fourth, many physicians do not understand the importance pH plays in the absorption of nicotine in the buccal lining. The mouth normally has a pH of approximately 7.3 to 7.4; the nicotine gum is buffered to bring the pH in the mouth to 8.0 to 8.5 for more efficient absorption. When a smoker eats or drinks liquids, the pH in the mouth is altered. For example, if a smoker has consumed a cola drink that has a pH of 2.2 to 2.7 (close to battery acid), then 20 minutes later decides to use a piece of nicotine gum to assist with withdrawal, the pH will rise to approximately 6.0 to 6.5, which blocks nicotine absorption; consequently, there is insufficient nicotine replacement, continued withdrawal, and the potential to revert to smoking.[7]

The gum is an example of an excellent product being used incorrectly. For maximum success with the gum, the smoker should: (1) be motivated, (2) receive sufficient nicotine replacement, (3) use gum for a sufficient length of time, (4) possess realistic expectations of the nicotine gum (guided by a health professional), and (5) receive some counseling and social support. Our research experience indicates that it is not counseling that makes the difference, but proper instruction regarding use of the gum. Many physicians spend time with the patient, not on counseling but on patient education and instruction, (ie, providing information about the medicine, such as the name of the medicine; how often to use it; when to use it; how long to use it; what foods, beverages, other medicine, or activities to avoid while using the gum; what side effects are possible and what to do if they occur; and written materials to take home).

Smoking cessation methods are as individual as smokers themselves: not everyone can quit "cold turkey." Although 88% of smokers have quit on their own and do not need NRT, today's smoker is more addicted than in years past. In 1915, the average smoker smoked 10 cigarettes per day. Today the average is closer to 30 cigarettes per day.[8] Consequently, smokers who could quit on their own have used the "cold turkey method." Today's cessation strategies must address the needs of today's smoker. The two thirds of smokers who want to overcome their nicotine addiction and those persons who have made several attempts at quitting smoking deserve increased access to the options that are proven safe, effective, and that can improve their odds of successfully quitting.

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To the Editor:

An editorial by Timothy J. Ives and Adam O. Goldstein in the July 1994 issue of *The Journal of Family Practice* expressed concern over attempts to move nicotine gum from prescription to over-the-counter status. The authors cited five reasons for their concern. I would like to go on record supporting the move to make nicotine gum available as an over-the-counter aid to assist patients in quitting smoking.

I would like to address each of the points about which Ives and Goldstein stated concern.

1. *The largely unrestricted access of nicotine containing smoking cessation products.*
According to the Office of Smoking and Health, approximately 3.1 million adolescents, currently obtain nicotine through a delivery system (cigarette) that also provides 4000 additional chemicals and four dozen carcinogens.

2. *Potential danger of unrestricted access to nicotine containing products.*
Plasma nicotine concentrations produced by 2-mg nicotine gum are less than one half of that obtained by smoking.[2] Patients with hypertension arrhythmias or other cardiac conditions who continue to smoke expose themselves to far greater levels of nicotine, as well as carbon monoxide and numerous other injurious agents.

3. *No mechanism to ensure appropriate counseling and follow-up.*
While I agree that appropriate counseling and follow-up improve the success of any smoking-cessation program, most patients who are using nicotine gum as it is currently prescribed do not receive these.[3]

4. *Over-the-counter nicotine gum would be available to smokers who have no desire to quit.*
The availability of nicotine gum would in no way change the motivation of smokers who are not contemplating quitting smoking; however, its availability will significantly enhance the efforts of smokers who have previously used ineffective over-the-counter methods to help them quit.

5. *Nicotine gum has had poor success in practice.*
A recent meta-analysis of nicotine replacement therapies published in *The Lancet* by Silagy et al,[4] demonstrated an increased odds ratio of abstinence of 1.61 for nicotine gum vs placebo. They reviewed 28 randomized trials of 2-mg nicotine gum and in self-referred patients (which is analogous to patients wanting to quit using over-the-counter nicotine gum), an overall 11% success rate was demonstrated. While 11% is not tremendous, 11% of the current 46 million smokers would be over 5 million patients if all of the current smokers were to attempt to quit using this method.

Since the FDA has removed unproven products for smoking cessation, the availability of nicotine gum as an over-the-counter smoking-cessation aid provides a much better opportunity to "let the buyer beware."

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The preceding letters were referred to Drs Goldstein and Ives, who reply as follows:

We appreciate the very thoughtful responses by Drs McKenna and Glover to our recent letter regarding concerns we have about making nicotine gum available over the counter. From their letters it is clear that both of them are concerned about nicotine addictions and are dedicated to helping smokers in smoking cessation.

We agree with Drs McKenna and Glover on most of the fundamental issues raised in their letters. We agree that a major problem with nicotine gum is the lack of physician and patient compliance with suggested protocols for using such products. The modest success of the nicotine patch has diminished the need for nicotine gum, thus prompting the gum manufacturers to try making the product directly available to the public. We agree that nicotine is addictive, and we do not underestimate the difficulty some patients have when trying to quit smoking. However, almost 90% of all people who smoke cigarettes can quit on their own and do not need nicotine replacement therapies; thus, such therapies are useful adjuncts only for the 5% to 10% who smoke and may need pharmacological assistance. Most of the patients who require a pharmacologic aid would prefer to use the nicotine patch rather than the gum.

Unfortunately, both authors seem to miss the fundamental reasons for our concern. To make a product available to the public over the counter (OTC), the product should fulfill at least three criteria. First, it should be safe. Second, it should be effective. Third, the public should be informed about both the safety and effectiveness of the product.

Nicotine gum is clearly a "safer" product than cigarettes. Although no one would deny this fact, it is irrelevant in the argument for making nicotine gum available OTC. That cigarettes are available OTC is an unfortunate and a historic quirk that is also irrelevant. If nicotine is so highly addictive, "as addictive as heroin," why are we advocating making the product readily available to the general population, including children?

More important is the issue of effectiveness. It is clear that nicotine gum has been, at best, a modest failure in general practice. There is a clear difference between the efficacy shown in clinical trials and the effectiveness in general practice

There is no good evidence that the gum will work any better as an OTC product, and there is good reason to believe that it would be even less effective. In our minds, an "excellent" product is not one from which 90% of the people who use it will receive no benefit whatsoever. Moreover, people who use the gum and then relapse have lower self-efficacy as a result of their "failure." It is ironic that some researchers argue that the drug is good, blaming physicians and patients for its failure, when an equally plausible scenario is that physicians and patients know when a product is good and when it is not.

Finally, although the issue of informed consent is not raised by either Drs McKenna or Dr Glover, it is central to our concerns. What are patients told about the effectiveness of nicotine gum when they enroll in clinical trials, either in research laboratories or in the recent effort that we described to have the product changed to OTC status? Are they told information such as the number of people who must use a nicotine patch in order for one person to receive a benefit (range, 20 to 30 smokers)? To trust that pharmaceutical companies will advertise an OTC product in a way that accurately reflects its ineffectiveness as a prescription product is tenuous at best. The direct-to-the-public advertising of pharmaceutical products that many physicians do not prescribe due to concerns about effectiveness (eg, Rogaine) is discernible. Science should not be driven by market forces.

We suggest that nicotine gum should remain available on a prescription basis and that physicians and patients alike should become better educated in the administration of nicotine replacement therapies. The suggestions by Drs Glover and McKenna on how to use the gum more appropriately will help achieve such goals. To achieve substantial gains in smoking cessation, however, our OTC drug of choice is to increase patients' motivation and plans for smoking cessation rather than to prescribe nicotine gum. Increasing patients' motivation is not addictive, not costly, and already available without a prescription, yet it has received almost no research, compared with that invested in nicotine replacement therapy.

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OCCUPATIONAL DERMATITIS

To the Editor:

Clusters of dermatitis cases in the workplace setting suggest chemical or allergic reactions, microbial infections, or infestation/bites from insects or arachnids. These incidents may be associated with products used on the job or with other types of interactions between employees.[1,2] When the job involves contact with plant materials, the etiologic agent could be the oils of the plants, fungi, eg, *Sporothrix schenckii*, or infestation by various species of mites.[3] On October 1, 1993, the Kansas City Health Department in Kansas City, Missouri, was notified by the owner of a floral store that an outbreak of dermatitis of unknown origin was occurring among three of his four employees. An investigation was initiated that day.

Among the employees who prepared floral arrangements, three had similar dermatitides on the arms or trunk. The outbreaks consisted of many individual red raised wheals with a vesicular center and were described as itchy, especially at night. The workers described the dermatitis either as "hives" or "bites." The fourth individual had no symptoms despite performing the same job duties.

Just prior to the onset of symptoms in the index case, a shipment of dried ornamental flowers, grasses, and several varieties of wheat had been received from a new supplier. The index case was the first person to come into contact with these materials. She sat on the floor and sorted the items into a circle around her. Within 16 hours, she was symptomatic. The onset of dermatitis in the other two affected workers occurred within 4 days of coming into contact with the new plant material. The owner of the business became the fourth case when he removed all the suspect material from the premise. He had protected all his skin surfaces with the exception of his neck, where a dermatitis appeared within 24 hours. The three affected employees, but not the owner, sought medical assistance. Two were prescribed topical ointments for symptomatic relief of the intense itching. Worsening symptoms in one woman led to her hospitalization. The third person was prescribed a pediculicide that she applied only to the affected left side of her body. The dermatitis was observed to migrate to her untreated right side, before she used the pediculicide properly.

There were no apparent violations of proper usage of any chemicals at the floral shop. Samples of new plant materials were obtained for laboratory examination at the Department of Entomology, University of Kansas in Lawrence for the presence of itch mites and at the Missouri Department of Health for mycotic agents. The grain or itch mite, *Pymotes tritici*, was identified on samples of wheat, but not on the other plants. *Sporothrix schenckii* was not recovered from any of the plant samples examined, although *Penicillium* sp were found on 50% of the wheat samples. No other potentially pathogenic fungi were recovered. The association of the *Penicillium* and *Pymotes* has been reported previously, although its significance is unknown.[4]

The epidemiology of this outbreak was consistent with that reported in association with the grain or itch mite *P tritici*[5] and illustrates the ease with which this mite can be spread and the index of suspicion required of the physician. This mite has been identified as the etiologic agent in other outbreaks of dermatitis illness, one involving up to 1700 cases, in which the affected persons had contact with various plant materials.[6,7] *P tritici* are parasites that infest the soft-bodied larvae of insects that live on cereal grains and in the stalks of these grains. Humans are incidental and transient hosts.[8–10] The mites are only 0.2 mm in size and usually are not recoverable from the environment even if their presence is suspected and sampling is done. The reaction to the bite of the mite is delayed by 10 to 28 hours. Infestation is usually self-limited and unless more severe allergic reactions occur, often a physician is not consulted. Treatment in less severe cases is palliative.

The physician needs to be aware of *P tritici*, particularly when presented with a dermatitis of unknown origin in a person who has occupational or recreational contact with plants.

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ENSURING PATIENT CONFIDENTIALITY

To the Editor:

There are many ways in which patient confidentiality may be breached in an office setting. Through use of Quality Care Review (QCR),[1] an office-based quality assessment program sponsored by the Ohio Academy of Family Physicians (OAFP), procedures that did not protect patient confidentiality were identified and corrected.

An administrative audit from the QCR program was performed at a family practice center in a community-based residency program. Patient confidentiality was evaluated as specified by the program. Over a 1-week work period, unknown to other staff members, the receptionist inspected areas visible to the public for exposed charts and confidential material. After completion of the initial audit, a two-pronged intervention was initiated. Two additional audits were conducted 3 and 12 months after the intervention.

The initial audit revealed that phone messages from patients were clipped to the outside of their charts and prominently displayed in locations where other patients might see them. It also revealed that patient scheduling lists, including names of patients and their diagnoses (eg, AIDS), were publicly posted at several sites throughout the family practice center where other patients might easily see them.

The intervention consisted of two changes in policy: (1) reversing placement of charts, with attached phone messages in chart holders so that phone messages could not be seen; and (2) eliminating diagnoses from patient scheduling lists. These policies were suggested to the business manager, who altered the format of the scheduling list and informed the staff of the changes.

The intervention resulted in 100% compliance on re-audit at 3 months. A re-audit for maintenance 12 months later revealed overall continued compliance. Only one chart was inappropriately exposed to the public. This oversight emphasized the need for continued vigilance to protect confidentiality.

Swoboda et al[2] define confidentiality as: "a general standard of conduct that obliges a professional not to divulge information about a client to anyone." This definition should apply to information contained in medical records. One of the 10 principles developed by the Canadian Health Record Association is: "Health information and records shall be kept in a secured area and not left unattended in areas accessible to unauthorized individuals."[2]

Although this principle may seem self-evident, not every individual who handles medical records is familiar with or has adopted a code of ethics. While physicians and nurses are comfortable with their responsibility to protect patient confidentiality, others in the health care information system (unit clerks, receptionists, billing staff, etc.) usually have not been formally exposed to a code of ethics to guide them in making decisions or establishing policies regarding patient information.[3]

It would be prudent for all staff members to be educated about the necessity of patient confidentiality and of limiting unpermitted disclosures regarding patients. Guidelines regarding placement of charts, so that information is secure, should be implemented.

Office systems should be safeguarded against unauthorized, unnecessary access to patient information. Simple measures such as limiting information on patient scheduling lists, posting schedules in nonpublic areas, and shielding charts from public view, can serve as first steps toward achieving patient confidentiality with regard to medical records. Other frequently reported measures important in achieving confidentiality include ensuring private telephone conversations, limiting staff questioning of patients to private areas, and securing medical records after hours.

The use of a formal program can help identify opportunities for improvement of quality in patient care. Attention was directed to two interventions that helped maintain patient confidentiality: chart placement to ensure that phone messages are kept from the view of others, and deliberate omission of diagnoses from patient scheduling lists.

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