Patterns of over-the-counter nicotine gum use: persistent use and concurrent smoking

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ABSTRACT

Aims To examine the occurrence of persistent use (i.e. use beyond 12 weeks) and concurrent use of nicotine gum with cigarettes among consumers who purchase nicotine gum over-the-counter (OTC).

Design Assessment of gum use was conducted in the context of a smoking cessation trial among smokers who purchased Nicorette gum and enrolled in the optional Committed Quitters smoking cessation program. Eligible participants were contacted by telephone 6 weeks and 12 weeks following their self-selected target quit date. Those who reported gum use at 12 weeks were contacted again at week 24.

Participants A total of 2655 current smokers who purchased nicotine gum and enrolled in a clinical efficacy trial of the Committed Quitters program.

Measurements Detailed information on smoking and gum use, including frequency of use, amount used and reasons for use was obtained at each of the three follow-up assessments.

Findings At the 24-week assessment, 6% of participants reported current use of nicotine gum (i.e. persistent use). Those engaging in persistent use averaged 4.7 (SD = 2.5) days of gum use per week and 3.2 (SD = 3.5) pieces of gum per day. Sixty-six per cent of persistent users reported at week 24 that they were not currently smoking, and 67% of persistent users reported they were using gum to establish or maintain abstinence. At the 6-, 12- and 24-week assessments, 14%, 10% and 2% of participants, respectively, reported current use of nicotine gum and current cigarette smoking (i.e. concurrent users). Those concurrent users reported at the 12-week follow-up that they did so an average of 4.4 (SD = 2.1) days per week, that they chewed an average of 2.6 (SD = 3.5) pieces of nicotine gum per day and that they smoked an average of 8.7 (SD = 8.6) cigarettes per day.

Conclusion Extended use of nicotine gum is rare. Concurrent use with cigarettes is uncommon. In both cases, the amount of gum use is small. OTC marketing of nicotine gum does not appear to have increased use contrary to labeling nor resulted in patterns of use that should warrant clinical or public health concerns.

KEYWORDS Abuse, dependence, nicotine replacement, over-the-counter medication, smoking, smoking cessation, tobacco use disorder.

INTRODUCTION

Nicotine polacrilex gum, the first medication approved for the treatment of tobacco dependence, was made available for over-the-counter (OTC) sales in the United States in 1996. Since becoming available without a prescription, nicotine gum is estimated to have helped many Americans quit smoking (Shiffman *et al*. 1997). Prior to its OTC approval, there were concerns about potential misuse and abuse of nicotine gum if it were made more easily available. For example, without recurring contact with a physician for prescription renewal, consumers might use nicotine gum longer than recommended, perhaps leading to dependence.

During the 12 years nicotine gum was marketed as a prescription medication, patients were instructed to discontinue use after 6 months. A meta-analysis of 24 experimental studies involving prescription use of either 2-mg or 4-mg nicotine gum showed 17% of patients continued to use the gum at 6 months, and 8% continued to use at 1 year (Hughes 1991). However, the generalizability of these results from controlled research is unclear. When nicotine gum was switched to OTC status, the recommended period of use was halved to 3 months.

Several studies have been conducted examining the use of nicotine gum outside carefully controlled research settings. In a large population of patients who received their prescriptions for nicotine gum during the course of routine outpatient medical care, 11% reported using the gum for longer than 6 months (Johnson *et al*. 1992). Among smokers who had purchased nicotine gum in community pharmacies in Scotland, 4 months after completion of the recommended 3-month course of nicotine replacement therapy, 49% were still using nicotine gum, and 11% were using a combination of cigarettes and gum (Sinclair *et al*. 1995). However, low response rates at follow-ups (around 20%) may have biased the results.

In a recent study of US OTC use, household purchase data from a national panel that had agreed to scan all household purchases of all items were analyzed for runs of continuous purchase of nicotine gum (Shiffman *et al*. 2003). The estimated incidence of persistent use for 6 months or more ranged from 2.3% to 6.7%, depending on assumptions. Use at 1 year was estimated at 1.0–2.8%. However, those data tracked purchase, not use, and then only at the household level, and did not address patterns or reasons for use.

In the present study we obtained detailed data on nicotine gum use beyond the recommended 12-week period. We also assessed frequency and patterns of concurrent smoking and nicotine gum use. Nicotine gum is indicated for smoking cessation, and the labeling advises against smoking while using the gum. However, because abstinence is sometimes induced only gradually and smoking is sometimes reinstated gradually during relapse, some smokers may engage in concurrent smoking and gum use. Although concurrent smoking and gum use does not carry any notable medical risk—Murray *et al*. (1996) found no impact on medical outcomes—such use is contrary to a strict interpretation of nicotine gum's labeling.

Our analyses were based on data from a clinical sample. We studied smokers who purchased OTC nicotine gum (Nicorette; GlaxoSmithKline, Pittsburgh, PA, USA; Pharmacia outside the United States) through normal retail channels, elected to enroll in the Committed Quitters Program—a tailored, behavioral program offered by free enrollment to purchasers of nicotine gum—and were recruited into an efficacy trial of the Committed Quitters Program (see Shiffman *et al*. 2000). Participants who reported current gum use at 12 weeks (the end of the indicated period) were re-interviewed at 24 weeks to assess persistent gum use and concurrent smoking and gum use.

METHODS

Subjects

Participants in this study were smokers who were enrolled in a clinical efficacy trial of the Committed Quitters Program, a smoking cessation program offered free to purchasers of Nicorette nicotine gum via a call to a toll free telephone number (see Shiffman *et al*. 2000 for description of that trial and its outcomes). That trial was conducted among smokers who purchased Nicorette nicotine gum (2 or 4 mg) in an OTC setting, and who called to enroll in the Committed Quitters Program between 18 July 1996 and 9 August 1996. Of the estimated 95 000 individuals who purchased nicotine gum during this period of time, approximately 7% called to enroll in the Committed Quitters Program (GSK data on file).

To be included in the original efficacy study, participants were required to meet the following criteria: (1) current cigarette smoker; (2) age 18 years or older; (3) purchased 2- or 4-mg nicotine gum; (4) attempting to quit smoking cigarettes (i.e. not smokeless tobacco); (5) agreed to be contacted for follow-up calls at 6 and 12 weeks; and (6) had a target quit date (TQD) that was either the day they called in or within 7 days of the enrollment date. However, for purposes of this analysis, the requirement regarding timing of the TQD was waived.

A total of 6894 calls were received, 4944 callers were considered eligible and 3962 enrolled in the trial and were assigned randomly to one of three behavioral intervention groups. This includes 3627 subjects reported in Shiffman *et al*. (2000) and 335 additional subjects who had data on smoking and gum use, but did not meet

inclusion criteria for the original efficacy study because the TQD was either prior to enrollment or not within 7 days of the enrollment call.

Those assigned to the control group received no treatment beyond that provided in the retail package, which included the user's guide and an audiotape, both of which included brief sections on how to quit and maintain abstinence based on cognitive–behavioral methods. A second group received the user's guide and audiotape at the time they purchased nicotine gum, as well as CQP program materials. In addition to the user's guide, audiotape and CQP program materials, a third group also received a brief telephone call approximately 2 days after their TQD. See Shiffman *et al.* (2000) for a description of the tailored cessation program and its outcomes. For purposes of this study, however, the data for all three treatment groups were combined, because there were no statistically significant differences among the three groups with respect to the percentage of subjects interviewed ($\chi^2(2) = 1.61$; $P < 0.446$) or the percentage of subjects using nicotine gum ($\chi^2(2) = 0.20$; $P < 0.905$) at 12 weeks.

Procedures

Using a computer-assisted telephone interviewing system, eligible participants were contacted 6 weeks and 12 weeks following their self-selected TQD. The primary purpose of the interviews was to assess smoking status, to determine the efficacy of the smoking cessation intervention (Shiffman *et al.* 2000). During the interviews, participants were asked about their current smoking status, abstinence history, usage of CQP materials and nicotine gum use.

Of the 3962 randomized participants, 822 were never interviewed during the study, leaving a sample of 3140. Of those 3140, 2389 were contacted and interviewed 6 weeks following their TQD. Of those 2389 interviewed at 6 weeks, 1904 were again contacted and interviewed at 12 weeks. Additionally, 751 individuals who were not reached for the 6-week follow-up interview were subsequently contacted and interviewed at the 12-week follow up, for a final sample of 2655 people interviewed at 12 weeks.

To assess the use of nicotine gum beyond the recommended 12 weeks, those participants who reported at the 12-week follow-up that they were still using nicotine gum ($n = 645$, 24%) were re-contacted at week 24 and asked to provide information on their nicotine gum use and cigarette use. Of the 645 individuals for whom contact was attempted, 496 (76.9%) consented and provided the additional information, 31 (4.8%) declined to be interviewed and 118 (18.3%) could not be contacted. Those who could not be contacted were not included in the analyses. Subjects who were eligible for the 24-week interview but did not participate ($n = 149$) and those who did provide data ($n = 496$) did not differ significantly on any demographic or smoking history characteristics. Those participants who had already discontinued gum use by week 12 were not re-contacted at week 24. At each time-point there was a 2-week window to contact participants; up to eight call attempts were made. Participants were offered up to $25 for completing the 6- and 12-week follow-up calls, and an additional $10 for completing the 24-week follow-up call.

Information on frequency and amount of gum use was based on responses to the following questions: 'How many days last week did you chew Nicorette?'; 'Thinking about last week, on an average day how many pieces of Nicorette did you chew?' Daily average gum use was calculated as: (Number of days used * Number of pieces used on days of use)/7. Reasons for engaging in persistent use were also explored.

At each assessment, those who reported current use of nicotine gum and current use of cigarettes were considered to be engaging in concurrent use. Because the most complete data on concurrent use was obtained during the 12-week assessment, information from this assessment was used to examine reasons for concurrent use, and frequency and amount of gum use and smoking. Information on frequency of concurrent use was based on responses to the following question: 'How many days last week did you smoke and chew Nicorette on the same day?' Information on smoking rate was derived from the following two questions: 'In the last week how many days have you smoked at all?' and 'In the last week how many cigarettes a day have you smoked on average?' No data about adverse effects of smoking or gum use were collected.

Statistical analysis

In order to characterize persistent users (those using gum at 24 weeks), we compared the demographic and smoking history characteristics of three distinct groups: (1) persistent users: those who reported current gum use at both the 12-week and 24-week assessments (2) 12-week users: those who reported current gum use at the 12-week assessment, but not at the 24-week assessment, and (3) and early terminators: those who reported no nicotine gum use at 12 weeks.

Group comparisons were made using Pearson's χ^2 for categorical variables and analysis of variance (ANOVA) for continuous variables. All analyses were considered statistically significant, $P < 0.05$. Data analyses were performed using SAS version 8.2 for Windows.

RESULTS

Table 1 shows the demographic and smoking characteristics of the sample ($n = 2655$).

Persistent use of nicotine gum

Table 2 shows the percentage of participants who reported current nicotine gum use at each of the three follow-up assessments. The rates were similar for 2-mg and 4-mg gum. At the 6-week and 12-week assessments, 42% and 24% of participants, respectively, reported current use of nicotine gum. About 6% ($n = 149$) reported current use of nicotine gum at the 24-week assessment and were thus considered persistent users.

Compared to early terminators (no gum use at the week 12 assessment, $n = 2010$), those using gum at both 12 and 24 weeks were significantly older and were more likely to have tried nicotine patch and gum previously, but were otherwise similar in demographic and smoking history characteristics (Table 1). Among people who were using gum at 12 weeks, those who persisted to 24 weeks were older. At 12 weeks, those who would go on to persistent use reported using more pieces of gum each day [3.2 (SD = 3.1) pieces per day for persistent users versus 2.4 (3.0) pieces per day for 12-week users; $t(1,424) = 2.67$; $P < 0.01$], but reported using gum for a similar number of days each week [5.3 (2.1) days for persistent users versus 5.1 (2.2) days for 12-week users; $t(1,494) = 1.12$; $P < 0.27$].

Patterns of persistent gum use at 24 weeks

At week 24, about half (51%) of the persistent users reported less than daily use of nicotine gum, with the average frequency of use reported to be 4.7 (2.5) days per

Table 1 Demographic and smoking history characteristics ($n = 2655$).

Demographic characteristics	*Total sample (n = 2655)* Mean (SD)	*Early terminators (n = 2010)* Mean (SD)	*12-week users (n = 347)* Mean (SD)	*Persistent users (n = 149)* Mean (SD)	*Omnibus test statistics* Test	P-value
Age	42.2 (12.8)	41.2 (12.7)[A]	44.4 (12.6)[B]	49.2 (13.1)[C]	34.71	<0.01
Income (in $1000 s)[1]	39.4 (22.0)	38.6 (21.8)[A]	42.3 (20.9)[B]	40.7 (24.3)[A,B]	4.08	0.02
Education (years)[1]	13.6 (2.1)	13.5 (2.1)	13.8 (2.2)	13.7 (2.3)	1.43	0.24
% Female	55.8	57.1	51.0	60.4	5.49	0.06
Smoking history						
Cigarettes per day	26.6 (11.9)	26.3 (11.8)	26.8 (11.6)	27.8 (13.6)	1.17	0.31
Years of smoking[2]	23.5 (12.4)	22.6 (12.2)[A]	25.2 (12.6)[B]	29.7 (13.3)[C]	27.16	<0.01
Life quit attempts	5.4 (17.3)	5.6 (19.5)	4.6 (7.2)	4.7 (9.5)	0.52	0.59
Minutes to craving onset	15.0 (26.8)	14.9 (27.6)	15.9 (23.2)	11.3 (16.2)	1.31	0.27
% Previous patch use	37.0	34.6[A]	42.9[B]	50.3[B]	21.46	<0.01
% Previous gum use	21.9	19.3[A]	27.7[B]	35.6[B]	31.11	<0.01
% Previous quit attempt	91.6	91.3	92.8	93.3	1.37	0.51
Motivation to quit (1–5)	4.3 (0.8)	4.3 (0.8)	4.3 (0.8)	4.2 (0.9)	0.44	0.65
Confidence to succeed (1–5)	3.9 (1.0)	3.9 (1.0)	4.0 (1.0)	3.8 (1.1)	0.89	0.41

[1]From categorical data using a median value of category. [2]Not statistically significant when age-adjusted. Statistical tests are *F*-test for continuous variables and χ^2 for proportions (denoted with percentage) among the three gum use groups (early terminators, 12-week users and persistent users). Unadjusted pair-wise comparisons were conducted among the three gum use groups where omnibus test was significant at the $P < 0.05$ level, common superscripts are not statistically different at the alpha = 0.05 level.

Table 2 Current use of nicotine gum and concurrent use with cigarettes reported at follow-up assessments ($n = 3140$).

Follow-up assessment	*Participants interviewed* n	*Reported current use of nicotine gum* n	% (95% CI)	*Reported concurrent use of nicotine gum and cigarettes* n	% (95% CI)
6-week	2389	1006	42.1 (40.1, 44.1)	344	14.4 (13.0, 15.8)
12-week	2655	645	24.3 (22.7, 25.9)	271	10.2 (9.1, 11.4)
24-week	2506[1]	149	5.9 (5.0, 6.9)	50	2.0 (1.4, 2.5)

[1]The 2010 participants who reported no current gum use at the 12-week interview were considered not to be using gum at 24 weeks.

week. The average use was 3.2 (3.5) pieces of gum per day. This was considerably reduced from their initial rate of use at week 1, but similar to their use at week 12. Their reported use in weeks 1, 6, and 12 was 7.7 (4.8), 3.9 (3.6) and 3.2 (3.1) pieces per day, respectively. This reduction over time was significant ($F_{3,148} = 35.40$; $P < 0.001$), with pairwise comparisons showing a reduction of gum use from first week of treatment to each of the subsequent weeks (all $P < 0.001$) and no difference between latter assessments (all $P > 0.05$).

Two-thirds (66%) of persistent users reported at the week 24 assessment that they were currently abstinent from smoking, with nearly half (43%) having been continuously abstinent since their quit day. Persistent users were asked why they were using gum at 24 weeks. Two-thirds (67%) reported that they continued to use gum because they were still working on quitting smoking; 73% of those reported that they were not currently smoking at week 24. Additional reasons for persistent use included to reduce smoking (19%), an inability to stop using gum (10%), and 'other' reasons (4%). Among the one-third of the persistent gum users who reported current smoking at week 24, over 90% reported combating their smoking actively, with 53% still working on quitting smoking and 41% attempting to reduce their smoking. At week 24, the vast majority (86%) of persistent users reported that they were somewhat or very likely to stop using nicotine gum in the next 3 months.

Concurrent use of nicotine gum and cigarettes

At the 6-, 12- and 24-week assessments, 14%, 10% and 2% of all participants reported current use of both nicotine gum and cigarettes (Table 2). The rates were similar for 2-mg and 4-mg gum. Almost all (88%) of those reporting concurrent use at 12 weeks had achieved at least 1 day of complete abstinence, suggesting that concurrent use of gum and cigarettes most often arose in the context of a failed attempt to quit smoking. At 12 weeks, most (60%) reported that they were using nicotine gum to quit; another 29% endorsed reduction as their goal. Only 11% of concurrent users—about 1% of the total sample—reported that their primary reason for chewing nicotine gum was to use gum when they could not smoke.

Those engaging in concurrent use at the 12-week follow-up reported doing so an average of 4.4 (2.1) days per week, chewing an average of 2.6 (3.5) pieces of nicotine gum per day and smoking an average of 8.7 (8.6) cigarettes per day. This represents a significant (68%) reduction in the average number of cigarettes smoked per day when compared to baseline levels of smoking in this group [27.1 (13.0) cigarettes per day; paired *t*-test (269) = 24.24; $p < 0.001$].

Concurrent use implies a failure of cessation (because the respondent is smoking) and continued gum use in the face of that failure. To understand who did not stop using gum when smoking, we divided those smoking at 12 weeks ($n = 1548$) into those who were and were not using gum (18% were using gum) (Table 3). Those who were engaged in concurrent use of gum were significantly older and were more likely to have tried nicotine patch and nicotine gum previously when compared to those not concurrently using gum. No other statistically significant differences were observed.

DISCUSSION

Results from this study of 'real-world' users of OTC nicotine gum indicate that use beyond that indicated in product labeling (i.e. 12 weeks) is relatively rare. Only 6% of participants reported current use of nicotine gum 24 weeks following their quit date. This suggests that making nicotine gum available without prescription, thus presumably removing prescriber control of gum use, has not increased persistent use: under prescription, an estimated 8–11% of nicotine gum users exceeded the recommended duration of use (i.e. 6 months) (Hughes 1991; Johnson *et al*. 1992). The 5.9% estimate of persistent use

Table 3 Demographic and smoking history characteristics by concurrent use at the 12-week follow-up.

	Current smoking at 12-week follow-up (n = *1548*)	
Demographic characteristics	*Gum use at 12 weeks* (n = *271*) *Mean (SD)*	*No gum use at 12 weeks* (n = *1277*) *Mean (SD)*
Age	45.7 (13.0)***	40.9 (12.4)
Income (in $1000 s)[1]	39.4 (22.0)	39.3 (22.1)
Education (years) [1]	13.6 (2.2)	13.5 (2.1)
% Female	57.6	59.6
Smoking history		
Cigarettes per day	27.1 (13.0)	27.2 (11.8)
Years of smoking[2]	26.4 (12.8)	22.8 (12.0)
Life quit attempts	4.6 (5.0)	6.3 (23.8)
Minutes to craving onset	14.4 (20.3)	13.7 (25.3)
% Previous patch use	51.3***	37.6
% Previous gum use	27.7**	20.4
% Previous quit attempt	91.9	91.6
Motivation to quit (1–5)	4.1 (0.9)	4.2 (0.8)
Confidence to succeed (1–5)	3.8 (1.1)	3.8 (1.0)

[1]From categorical data using a median value of category. [2]Not statistically significant when age-adjusted. Statistical tests (not shown) are *F*-test for continuous variables and χ^2 for proportions (denoted with percentage). Significant comparisons between groups (at each follow-up interview) are denoted as: *$P < 0.05$; **$P < 0.01$; ***$P < 0.001$.

derived from this clinical sample of OTC gum users closely matches the estimate of 6.7% derived from household purchase data (Shiffman *et al.* 2003). The convergence of estimates from such different methods lends confidence to the findings. The data consistently demonstrate that the vast majority of nicotine gum users do not exceed the labeled period of use, even without the enforced medical supervision implied by prescription-only status.

Reports from smokers who were using nicotine gum for 24 weeks also helped characterize persistent use. Most persistent users were not using nicotine gum daily, and were using only modest amounts of nicotine gum. The majority were using gum in order to achieve or maintain abstinence from smoking, though a small minority was using gum to reduce smoking or maintain reductions. These uses are consistent with uses recommended in the clinical literature for nicotine gum (Jarvik & Henningfield 1993). A few participants reported spontaneously that their persistent use of gum had been endorsed by their physicians, but the study does not allow us to estimate how common this is. In any case, studies of persistent nicotine gum use, even with concurrent smoking, have found no increased medical risk due to persistent use (Murray *et al.* 1996). We did not collect any adverse event data in this study, however, so this data set does not address the safety of persistent use or concomitant smoking.

The data suggested that almost all persistent use is to combat smoking, rather than compulsive use due to dependence on nicotine gum. This was reinforced by clinical interviews we (S.S. and J.H.) conducted with persistent users in this sample, which turned up few indications of dependence on nicotine gum, and suggested that persistent users were struggling to achieve or maintain abstinence. The low rate of persistent use and dependence (10% of persistent users attributed their continuing use to an inability to stop using gum) is consistent with data suggesting that nicotine gum has very low dependence potential (Henningfield & Keenan 1993). One recent survey estimates that less than 2% of those who initiate gum use meet *Diagnostic and Statistical Manual* (DSM) criteria for dependence on the gum (Hughes *et al.* 2003). Consistent with this, Hurt *et al.* (1995) have demonstrated that simple interventions can help even very long-term persistent users wean themselves from nicotine gum, in contrast to the difficulty of treating tobacco dependence among smokers. Nicotine gum has low dependence potential because, unlike cigarette smoking, which provides rapid 'hits' of nicotine to the brain, in the form of arterial nicotine boli that reach the brain within 10 seconds of inhaling cigarette smoke (Benowitz 1990), nicotine gum produces modest blood nicotine levels that peak after 15–20 minutes of chewing (Benowitz *et al.* 1988).

Among those who used nicotine gum for the full 12-week indication, the only factor that distinguished those who continued into persistent use at 24 weeks was older age. It was notable and surprising that other indicators of nicotine dependence, such as smoking rate, did not differentiate persistent users from those who did not continue to use gum. This again suggests that nicotine dependence is not a major driver of persistent gum use. However, our assessment of baseline tobacco dependence was sparse, so strong conclusions cannot be drawn.

Although clinical evidence on concurrent use does suggest that no harm results from smoking while using nicotine gum (Murray *et al.* 1996), current labeling for all nicotine gum products recommends stopping nicotine gum use when smoking is resumed. In this study, concurrent smoking and nicotine gum use occurred at a modest rate, and decreased substantially over time. The data suggest that the majority of those who engage in concurrent use do so because they are 'still working on quitting', with fewer reporting doing so either to reduce their smoking or to 'tide them over' when they cannot smoke. Notably, almost all (88%) of those reporting concurrent use at week 12 had achieved at least 1 day of complete abstinence, documenting that concurrent use probably arises in the context of an effort to quit completely. Once an abstinent smoker has re-initiated smoking, the likelihood of relapse is very high (Kenford *et al.* 1994), but the process of resuming smoking is quite prolonged and intermittent (Brandon, Tiffany & Baker 1986; Shiffman *et al.* 1996). It may seem quite counter-intuitive to smokers who are struggling with abstinence to abruptly stop using their medication at the first signs of failure, while they see themselves as still struggling to become non-smokers. Thus, it is not surprising that about 20% of participants who were smoking at week 12 were also still using nicotine gum. The potential utility of nicotine gum to avert relapse following a lapse needs to be studied.

One limitation of our study was its exclusive reliance on self-report. Smokers may be inclined to under-report using gum contrary to the label, especially in a study sponsored by the company that markets the gum. Reliance on self-report has also characterized past studies of persistent use (Johnson *et al.* 1992; Sinclair *et al.* 1995).

The study sample consisted of nicotine gum purchasers who enrolled in the Committed Quitters program, which attracts only 7% of purchasers and thus may not be representative of all nicotine gum users. The sample consisted of people who bought nicotine gum in order to quit smoking, as evidenced by their decision to enroll in a behavioral smoking cessation program. The participants' elective enrollment in the Committed Quitters program may reflect greater motivation to quit and greater compliance, on one hand, and greater expected difficulty quitting, on the other hand. Indeed, participants tended to be

heavy and dependent smokers, who may be most at risk for over-use or abuse of nicotine gum. The representativness of the sample could also have been degraded by loss to follow-up, particularly loss between week 12, when eligibility for follow-up was ascertained, and 24 weeks, when persistent use was determined. Statistical tests demonstrated that those lost to follow-up did not differ from those who were reached and interviewed, but we cannot eliminate the possibility of unassessed differences.

On the other hand, the study had several strengths. Most prominently, the sample was recruited from among smokers who purchased nicotine gum from an OTC retail outlet, rather than being provided with nicotine gum in a research or clinical treatment setting. The sample was also large, and afforded a longitudinal perspective on nicotine gum use. Finally, data were available to characterize the pattern of use in some detail.

This study showed that the incidence of persistent use of nicotine gum is quite low, and appeared lower than the rate reported using prescription-only use (Hughes 1991). We also observed modest rates of concurrent smoking and gum use. In the vast majority of cases, users reported that they were using gum in order to achieve or maintain abstinence from cigarettes. Thus, we conclude that OTC marketing of nicotine gum has not increased use contrary to labeling nor resulted in patterns of use that should warrant clinical or public health concern.

DECLARATION OF INTEREST

This study was supported by GlaxoSmithKline Consumer Healthcare (GSKCH), which markets nicotine replacement medications, including nicotine gum, for smoking cessation. Drs Shiffman and Sweeney and Mr Di Marino serve as consultants to GSKCH on an exclusive basis regarding matters relating to smoking cessation. Dr Shiffman also has an interest in a new nicotine replacement product. In the last year Dr Hughes has received honoraria, consulting fees or research grants from several organizations including Pacific Pharmaceuticals, Pfizer Inc., Pharmacia, Sanofi Pharmaceuticals, and Stowic Pharmaceuticals.

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