

Consumer and Health Literacy

The Need to Better Design Tobacco-Cessation Product Packaging, Labels, and Inserts

Stephanie M. Weiss, ScM, Stephanie Y. Smith-Simone, PhD, MPH

Abstract: Tobacco-cessation product packaging and instruction materials may not be appropriate for some smokers and may contribute to the underuse and misuse of evidence-based treatments. The dual goals of this project are to analyze literacy levels of Food and Drug Administration (FDA)-approved and non-approved tobacco-cessation product packaging, directions, and claims, and to identify and categorize claims found on product packaging. The Campaign for Tobacco Free Kids (CTFK) maintains the Quitting and Reducing Tobacco Use Inventory of Products (QuiTIP) database, which catalogs products marketed and sold to consumers to reduce or quit use of tobacco products. It also includes all medications approved by the FDA for tobacco cessation as well as a sample of non-approved products such as homeopathic, herbal, nutritional, or dietary supplements commonly marketed as either cessation aids or alternative tobacco/nicotine products. This paper assesses the reading levels required to understand product packaging, labeling, and instructions using the Simple Measure of Gobbledygook (SMOG) and identifies claims on the product package labels using standard qualitative methods. Key findings show that the average reading levels needed to understand instructions for both FDA-approved and non-approved cessation products are above the reading levels recommended to ensure maximum comprehension. Improving the packaging and directions of evidence-based tobacco-cessation products so that they are preferably at or below a fifth-grade reading level, along with using consumer-based design principles to develop packaging, may help smokers take advantage of and correctly use products that will greatly increase their chances of successful quitting.

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Introduction

A smoker trying to quit must sort through a great deal of information and face many options when looking for quit assistance. With numerous cessation aids and methods available, it can be tricky for smokers to know which products are safe, effective, and well suited to their individual needs. There are currently seven tobacco-cessation products on the market that are approved by the Food and Drug Administration (FDA) that compete in a constantly evolving marketplace with literally hundreds of products that have not been tested by the FDA for safety or efficacy. Evidence-based cessation products, including over-the-counter (OTC) nicotine replacement therapy (NRT) and prescription tobacco-dependence medications can double a smoker's

chances of quitting successfully.¹ Unfortunately, of the 42.5% of smokers who try to quit each year, only 20% to 30% use an evidence-based treatment.² In addition to smokers who do not use FDA-approved treatments, some smokers who are using treatments do not use them as directed, thereby decreasing the likelihood of successfully quitting.^{3,4}

Several factors affect a smoker's decision about whether and how to use cessation products. These factors include characteristics of the patient, such as literacy and knowledge about options; and characteristics of the products, such as appeal, cost, access, safety, and efficacy. Understanding and using health information is challenging for many Americans, and this issue of health literacy is closely aligned with health disparities, and has special implications for tobacco-using populations.⁵

Despite overall decreases in smoking prevalence, disparities still persist, and smoking continues to be disproportionately higher among less-educated, low-income adults. Research shows that low-income, less-educated smokers are no less likely to want to quit or make quit attempts compared to other smokers.^{6–9} However, they are less likely both to use FDA-approved treatments and

From the Robert Wood Johnson Foundation (Weiss), Princeton, New Jersey; and the Children's Hospital of Philadelphia (Smith-Simone), Philadelphia, Pennsylvania

Address correspondence and reprint requests to: Stephanie M. Weiss, ScM, Robert Wood Johnson Foundation, College Road East, Princeton NJ 08543. E-mail: sweiss@rwjf.org.

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to quit successfully.^{10–13} Recent data from the National Adult Literacy Survey showed that more than one third of the U.S. population had the lowest level of health literacy skills; these rates are disproportionately higher among those who are less educated and have a low income level.¹⁴ Adults with limited health literacy skills are at a disadvantage in making informed consumer choices about their health. The reasons that less educated, low-income smokers fail to utilize these treatments may include access, cost, and misperceptions about the safety and efficacy of these products.^{15,16} Healthy People 2010 recognizes that the ability to read and comprehend materials is related to health and is crucial to reducing health disparities.¹⁷

The consumer experience for a smoker in search of a product to help them quit can be overwhelming, even for those with more advanced literacy skills. Although there are a handful of FDA-approved, effective, and safe products on the market for tobacco cessation, they compete with hundreds of non-approved products that are easier to access, often claiming to deliver faster, safer, or better results. A smoker trying to quit can become easily confused trying to distinguish and understand which product they should use, if any. Cessation-product packaging and instructions can provide consumers with information about the health benefits of quitting, the usefulness of the product in helping them quit, and directions on how to successfully use the product. Existing product packaging and instruction materials may not be appropriate for some smokers and may contribute to the underuse and misuse of evidence-based treatments. The dual goals of this project are to analyze literacy levels of FDA-approved and non-approved tobacco-cessation product packaging, directions, and claims, and to identify and categorize claims found on product packaging. These two discrete objectives work toward the common goal of improving product packaging to increase consumer demand for evidence-based cessation products. The current objective is to examine the products from the perspective of some of the thousands of consumers, and to shed some light on how improvements can be made that may help boost understanding about and use of these evidence-based products.

Methods

The Quitting and Reducing Tobacco Use Inventory of Products (QuiTIP) is a database compiled by the Campaign for Tobacco-Free Kids (CTFK) that catalogs products marketed and sold to consumers to help them reduce or quit their use of tobacco products.¹⁸ The QuiTIP database includes all treatments currently approved by the FDA for tobacco cessation ($n=7$) as well as a nonrandom sample of

non-approved products such as homeopathic, herbal, nutritional, or dietary supplements commonly marketed as either cessation aids or alternative tobacco/nicotine products ($n=110$). The sample of non-approved products listed in the QuiTIP database was identified by CTFK staff through Internet-based searches or mass media. Product information was transcribed verbatim from the label on the product; package inserts (if present); and the Internet website (if one existed). Information taken from the product label includes product name, manufacturer's name, manufacturer's address, product website address, directions for use, warnings and disclaimers, ingredients, and claims. Information abstracted from websites was limited to claims only.¹⁸ The total number of non-approved cessation products on the market is unknown because of the constantly changing marketplace.

Information on each product was directly extracted from the QuiTIP database, including information on product directions, and claims from product packaging. An assessment was made of the reading levels required for understanding product directions and claims by using the Simple Measure of Gobbledygook (SMOG).¹⁹ The SMOG estimates reading level to within 1.5 grades and comprehension of the material at that grade level at 90% to 100%. The SMOG was originally developed in 1969 and was used to analyze reading level using a formula that counts words of three or more syllables in three ten-sentence samples, then estimates the count's square root, then adds three. Since then, an online tool has been developed with which text can be pasted into a text box for analysis.²⁰ The calculator can analyze 2000 words maximum with a 30-word minimum. Text from the QuiTIP database was entered into the online SMOG tool to compute reading-level estimates. In cases in which text was less than 30 words, the protocol was modified, and the text was copied up to three times to get an approximate SMOG estimate. Frequencies, percentages, and means to describe the readability and comprehension levels were calculated. A *t*-test for independent samples was used to compare average grade reading level of the FDA-approved versus non-approved product directions and claims.

Immersion/crystallization methodology was used to analyze claims text. Immersion/crystallization comprises, "... the analyst's prolonged immersion into and experience of the text and then emerging, after concerned reflection, with an intuitive crystallization of the text."²¹ The process specifically involved a qualitative iterative cycle of data extraction, analysis, and refinement of theme identification highlighting key statements and looking for patterns and connections to identify dominant themes. The coauthors would examine five to ten products at a time independently immerse themselves in the text, and then independently reflect on the categorization. After a period of time, the analysts would meet to discuss the organization of the text and corroborate emergent themes. This cycle was repeated by the authors until interpretations were formulated and verified for all 117 products. Searches for alternative interpretations as well as

similarities and differences were also incorporated into the synthesis process. The results present the dominant themes from the claims text that emerged in the crystallization process: health, safety, efficacy, and other.

Results

Readability

The reading level of text provided in the product instructions and claims was assessed using the SMOG. The mean grade reading level of the seven FDA-approved product directions was 8.5 (range, 6.4–10.2). The average readability for claims on the FDA packaging was at a grade level of 12.7 (range, 10.1–15.3).

A sample of 110 non-approved cessation products listed in the QuiTIP database was analyzed for readability. The mean grade reading level of non-approved product directions was 8.5 (range, 3.0–13.5). The average readability for non-approved claims was at a grade level of 10.9 (range, 3.0–16.4). A comparison was made of mean literacy grade levels of FDA-approved versus non-approved directions and claims, and neither was significant; $p > 0.05$ (data not shown).

Claims

Four overarching themes were identified: health, safety, efficacy, and other. Health claims were defined by the authors as a written statement that implied the product would lead a person to quit smoking and treat symptoms associated with quitting, including withdrawal symptoms and urges and cravings, and/or improve an aspect of either mental or physical health. Safety claims implied that product use would not cause harm, was not dangerous, or had been tested for safe use. Efficacy claims were defined as written statements that implied successful results when the product is used correctly.

Health claims. All seven FDA-approved tobacco cessation products made health claims on their packaging. A total of four unique health claims were identified: (1) reduce withdrawal; (2) reduce nicotine craving; (3) quit smoking; and (4) reduce the urge to smoke. The majority of non-approved cessation products (77%) made health claims on their packaging. In contrast to the four unique health claims cited on FDA-approved packaging, non-approved products advertised more than 60 unique claims, suggesting that these products promise to aid in much more than quitting smoking. Samples of health claims are included in Table 1.

Safety claims. Previous research has shown that most smokers are misinformed about the health risks of nicotine and the safety and efficacy of nicotine medications.²² None of the FDA-approved cessation treatments made

safety claims on their packaging, whereas 36 unique safety claims were noted on non-approved cessation products. Examples of safety claims are noted in Table 1.

Efficacy claims. Three of the seven FDA-approved products (Zyban and Nicotrol Inhaler and Nasal Spray) contained a written statement about the product's efficacy. For example, the Nicotrol Inhaler and Spray did not directly claim that the product was efficacious but that the consumer would be more successful if it was used in conjunction with a comprehensive behavior program. Zyban more clearly indicated that "... studies have shown that more than one third of people quit smoking for at least 1 month while taking Zyban[®] and participating in a patient support program." There is clear room for improvement in designing packaging that will promote the efficacy of these products. Approximately one third of non-approved cessation products listed bold claims promoting the product's efficacy (37 unique claims), and examples are included in Table 1.

Other claims. Several claims did not fit into the categories of health, safety, or efficacy and were classified as "other." A majority (85%) of non-approved products in the database contained "other" claims. Products that were FDA-approved did not list any "other" claims on their packaging. Table 1 provides examples of "other" claims, such as lifestyle, economics, and conflicting or false information found on non-approved products. Additional themes worth noting arose in the classification of product claims. The first of these themes included a reference to FDA approval on non-approved packaging. Examples include non-approved products that advertised they were manufactured in an FDA-inspected and approved manufacturing plant; products containing ingredients that are FDA-approved and comply with FDA regulations; and products approved by other foreign FDAs (e.g., Korean FDA). These claims may contribute to a falsely perceived level of safety or efficacy by the consumer. Another theme found on non-approved products was the recommended use and directions for use by children and teens. One non-approved smoking-cessation product provided dosing instructions for children aged 2–6 years. Another claimed it was not recommended for children aged <12 years, whereas others provided usage instructions for those aged ≥ 16 years, or for teens aged 13–19 years. Most adolescents, like adults, want to quit, yet their quit attempts fail at higher rates than adults.²³ Although little is known about adolescent use of non-approved cessation products, they are readily available for purchase over the Internet and often at prices lower than those of FDA-approved products.

A final theme found on non-approved cessation products was the presence of conflicting and sometimes false

Table 1. Sample claims on FDA-approved and non-approved packaging

Type of claim	FDA-approved	Non-approved
Health	<ul style="list-style-type: none"> ● Reduces withdrawal symptoms, including nicotine craving, associated with quitting smoking 	<ul style="list-style-type: none"> ● Reduce smokers cough, free radicals, allergy symptoms; increase energy, stamina, immune function. ● Helps combat most symptoms of quitting smoking as well as detoxifying the blood, curbing appetite, enhancing concentration, enhancing energy and stamina, providing nutrients and vitamins, and fighting nonpathologic stress and anxiety. ● Maintain ex-smoker's health. ● No side effects. No weight gain. ● This product is designed to mimic the pharmacologic effects of nicotine, but not the physiologic addiction. ● Wonderful blood cleansers and tonics. Improves digestion. Beneficial for the heart. Stimulates circulation. ● All-natural, denicotinizing and detoxifying formula designed to boost your energy, repair the smoke damaged tissues and rid your body of the nicotine and other addictive toxins deposited over the years so you can quit for life. ● Clean up your teeth. Clean up your breath. Clean out the nicotine.
Safety	No claims made	<ul style="list-style-type: none"> ● This product is nontoxic and non-habit forming. ● Unlike nicotine patches, the continued use of these herbal patches for >6 weeks does not endanger the body. ● Safe for teens. ● Safe for daily intake by almost every adult men and women. ● Safe, effective. No known side effects. ● No side effects. No need to switch brands. ● Safe and non-addictive. ● 100% safe, physician recommended. ● Clinically tested. ● FDA in Korea approved it as 1st Smoking Cessation Aid Device.
Efficacy	<ul style="list-style-type: none"> ● Studies have shown that more than one third of people quit smoking for ≥ 1 month while taking ZYBAN[®] and participating in a patient support program. ● People who use Nicotrol[®] inhaler with a comprehensive behavioral smoking cessation program are more successful in quitting smoking. 	<ul style="list-style-type: none"> ● Clinically proven results. ● Homeopathic medicines are effective. ● Physician tested to effectively curb your cravings, calm your nerves, and help you quit smoking quickly and easily, without withdrawals or increased appetite. ● The most effective nicotine habit reduction product in existence. ● 98% effective for those who want to quit smoking. ● Money back guarantee.
Other	No claims made	<ul style="list-style-type: none"> ● Don't just replace smoking with another nicotine addiction. ● Made from approved food grade ingredients and is not subject to medical licensing. ● Recommended by the Lung Cancer Institute of Colorado. ● Ideal for use in all nonsmoking areas: buses, airplanes, trains, hospitals, offices, theaters, restaurants, public areas and homes. ● Pacifies oral and handling gratification. ● Product is manufactured in...an FDA inspected and approved manufacturing plant. ● Mimics the effects of nicotine in the brain but is not addictive. ● Modifies the cigarette instead of medicating the smoker. ● The psychologist's natural choice. ● No tobacco tax.

FDA, U.S. Food and Drug Administration

information. For example, two claims found on non-approved products touted differing information about nicotine. While one product made the statement that “. . . medical authorities agree nicotine is the most harmful ingredient in tobacco smoke . . .” another claimed that “. . . nicotine is found naturally in potatoes and tomatoes . . . most people ingest daily . . .,” perhaps implying safety. The current marketplace for tobacco-cessation products is contaminated with information that may contribute to false perceptions about how to quit successfully.

Discussion

The results of these analyses support the idea that smokers are inundated with confusing and conflicting information about products to help them quit smoking. Consumers with low literacy levels are particularly burdened by the high reading levels required to understand package instructions and claims. Directions and claims on packaging for FDA-approved tobacco-cessation products are written at a level requiring high school- or college-equivalent reading skills. This finding is notable considering that more than one third of the U.S. adult population has the lowest level of health literacy, and these rates are even lower and more pronounced among certain racial/ethnic minorities and low-income adults—a disparity also observed in smoking rates.¹⁴ However, smokers with higher education and literacy levels would benefit from materials written at a lower level, and past research has documented that even people with advanced reading skills have difficulty with complex instructions and materials.²⁴

The way both FDA-approved and non-approved product packaging and labeling is currently designed may contribute to misinformation, misinterpretation, and misuse because of the advanced reading skills needed to follow and interpret the instructions and because of the claims made on the packaging. Redesigning FDA-approved tobacco-cessation product instructions and claims for the low-literate consumer using the design principles outlined in this supplement may help to improve overall usage rates and to lessen disparities in use of evidence-based tobacco-cessation products among lower-income and undereducated populations. The following sections present suggested ways to apply the consumer demand design principles to better promote cessation among smokers.

Recommendation #1

The first recommendation is to design products and packaging with plain language and instructions that can be easily understood by all consumers. Experts recommend that health information be written at a fifth–sixth

grade reading level or below to ensure maximum comprehension.²⁵ This demonstrates that there is room for improvement in designing product-packaging instructions and claims that will be easily understood and used by smokers who are trying to quit. Current FDA regulation requires that OTC medication labels be written “. . . in such terms as to render them likely to be read and understood by the ordinary individual, including individuals of low comprehension, under customary conditions of purchase and use.”²⁶ New FDA labeling for OTC and prescription medications may be needed to ensure that most smokers can use these products correctly.

Efforts to improve packaging and instruction comprehension should, however, include more than lowering the reading level. Designing packaging and instructions in multiple languages, along with altering typographic and layout features, may also increase comprehension and use. Evidence-based label standards presented as part of the IOM report *Standardizing Medication Label: Confusing Patients with Less* should be considered as new packaging and labels are developed.²⁸ These recommendations include: use of a recognizable visual aid to convey dosage and use instructions, use of simple language without use of medical jargon, use of large sans serif font, use of numeric instead of alphabetic characters, use of horizontal text only, and organization of the label in a patient-centric manner.²²

Findings from the packaging claims analysis indicate that in addition to literacy issues there are broader consumer literacy issues that may get in the way of consumers purchasing and correctly adhering to usage instructions. This analysis also documented the extent to which claims on FDA-approved cessation-product packaging differed from non-approved product packaging across various types of claims. In all cases, the non-approved products surpassed the FDA-approved products on number and types of claims. Conflicting or absence of information on product packaging may contribute to the concerns many smokers have regarding the safety and efficacy of evidence-based cessation products, specifically NRT. Many smokers are misinformed about the risks of nicotine, believing that nicotine is a cause of cancer and can make you sick.²⁷

Recommendation #2

The second recommendation is to design cessation products and accompanying materials that educate smokers about tobacco dependence–treatment safety and efficacy. Knowledge plays a role in decisions about whether to continue smoking and about cessation aid options. Smokers who are more knowledgeable about evidence-based products, including their risks and efficacy, are more likely to use them.²⁸ There is a great opportunity

Table 2. List of products in QuiTIP database

FDA status	Product name	Manufacturer
Approved	Bupropion Hydrochloride SR—Brand name Zyban	DSM Pharmaceuticals, Inc.
Approved	Nicotine Inhaler—Brand name Nicotrol Inhaler	Pharmacia Consumer Healthcare
Approved	Nicotine Lozenge—Brand name Commit	GlaxoSmithKline Consumer Healthcare
Approved	Nicotine Nasal Spray—Brand name Nicotrol Nasal Spray	Pharmacia Consumer Healthcare
Approved	Nicotine Polacrilex (Nicotine Gum)—Brand name Nicorette (and Generics)	GlaxoSmithKline Consumer Healthcare
Approved	Nicotine Transdermal System (Nicotine Patch) —Brand name NicoDerm, Nicotrol, and generics	GlaxoSmithKline Consumer Healthcare
Approved	Varenicline tablets—Brand name Chantix	Pfizer Labs
Non-approved	7 Day Smoke Away	7-Day Systems
Non-approved	AcuOne	Axas Development
Non-approved	Aeros Smokeless Cigarette	Woodleaf Corporation
Non-approved	Aqua Filter	Lee Pharmaceuticals
Non-approved	Artificial Cigarette	E-Z Quit, Inc.
Non-approved	Away with Smoking, Formula A-D	Suzanne's Natural Foods
Non-approved	Bacc Off	Dipstop, Inc.
Non-approved	Blue Whale Smokeless	Blue Whale LLC
Non-approved	Boiron Care Kit	Boiron
Non-approved	Bravo	Safer Smokes Corporation
Non-approved	Butt It Out (Capsules and Oral Spray)	Paradise Promotions, Ltd.
Non-approved	Chattahoochee Herbal Snuff	Chattahoochee Herbal Snuff, Inc.
Non-approved	Cigaban	Synchronicity, LLC
Non-approved	Cigamint Mint Inhaler	www.cigamint.com
Non-approved	Ciganot Smokeless Cigarette	Ciganot Incorporated
Non-approved	CigArrest	MDG
Non-approved	CigCess	TriMedica
Non-approved	CigNo—Homeopathic Tincture	M.E. Cody Products, Inc.
Non-approved	CigSation	Vitamerica Corporation
Non-approved	Citrol	MGA Development Corp.
Non-approved	Crave Curb	National Center for Addiction Recovery, LL
Non-approved	Curb Your Cravings	Curb Your Cravings, LLC
Non-approved	DCF, Disposable Cigarette Filters	DCF Distribution Inc.
Non-approved	Denicotea	Lane Limited
Non-approved	De-Nics	Mountain Top Herbs
Non-approved	Endit	Cirrus Healthcare Products
Non-approved	Final Smoke	Final Smoke, Inc.
Non-approved	Golden Eagle Herbal Chew	Coltsfoot, Inc.
Non-approved	Habit Regulator	ConceptWorks, Inc.
Non-approved	Herbal Nicotine Buster	Herbal Care (NZ) Ltd.

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Table 2. (continued)

FDA status	Product name	Manufacturer
Non-approved	HerbaQuit (No Longer Commercially Available)	Natural Answers, Inc.
Non-approved	High Balance	PureBotanics
Non-approved	Jack Link's Shredded Jerky Chew	Jack Link's Jerky Chew
Non-approved	Kikit Coconut Chew	Kikit, Inc.
Non-approved	Life Sign For Teens and Young Adults	PICS, Inc.
Non-approved	Linkman	Brady Development, Inc.
Non-approved	lipNIX Lipstick	Distributed by Joey NY Specialty
Non-approved	Lite'N Up 90	Lee Pharmaceuticals
Non-approved	Native Remedies—Crave-Rx Drops	Native Remedies, LLC
Non-approved	Native Remedies—Triple Complex NicoTonic	Native Remedies, LLC
Non-approved	NaturalStop Smoking Cessation System	Dolisos America
Non-approved	Nic Lite	Nico Worldwide, Inc.
Non-approved	NicCess	Sterling Grant Laboratories
Non-approved	Nicitout (Quit, Cleanse, Rejuvenate Formulas)	USA Herbals
Non-approved	Nicoban—Formulas A-D and Triple Hormone	Young Again Nutrients
Non-approved	NicoBloc	Rosen U.S., LLC
Non-approved	Nicobrevin	Pro-Health Products Limited
Non-approved	Nicocure	Ultra Herbal
Non-approved	Nicocure Capsules	Nicocure
Non-approved	NicoDrops	Nicodrops Company
Non-approved	Nico-Free	Pro Health, Inc.
Non-approved	Nicogel	Nicogel Limited
Non-approved	NicoLite	Nicolite Products, Inc.
Non-approved	Nicoquit	Nature Direct, Inc.
Non-approved	NicoRx Nicotine Free 2-Part Quit Smoking Program (“Anti-Craving Gum” and “Detoxifying”)	NatraBio
Non-approved	Nico-Save	3G Care Co., Ltd
Non-approved	Nicotine Lollipops	Compounding pharmacists (e.g., White Lake)
Non-approved	Nicotine Wafer	Nicotinewafer.com
Non-approved	Nicotinex	Life Works, Inc.
Non-approved	Nic-Out	Safety Aid Supplies, Inc.
Non-approved	NicoWater—Nicotine Water (No Longer Commercially Available)	Nico International, Inc.
Non-approved	Nicozan	Selmedica Healthcare Corporation
Non-approved	Njoy	Sottera, Inc.
Non-approved	Nocigarettes	Henan Tiansheng Technology Development Co.
Non-approved	NosmoQ	3G Care Co., Ltd.
Non-approved	One Step	Numark Laboratories, Inc.
Non-approved	Phaseout Cigarette Modification System	Quest Products Corporation

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Table 2. List of products in QuiTIP database (continued)

FDA status	Product name	Manufacturer
Non-approved	QT Quitting Time Watch Smoking Cessation System	ElectroMed Technologies, LLC
Non-approved	Quit For Sure—Addictive Nicotine and Toxins Solutions/ Quit Smoking Herbal Tea	Shafa Herbal Solutions
Non-approved	Quit For Sure—Cigarette Craving Solution/Smokefree Cigarettes	Shafa Herbal Solutions
Non-approved	Quit For Sure—Nicotine Craving Solution/All-Natural Herbal Capsules	Shafa Herbal Solutions
Non-approved	Quit For Sure—Stress and Anxiety Solution/Aromatherapy (Inhaler and Roll-On)	Shafa Herbal Solutions
Non-approved	Quit For Sure—Tobacco and Food Cravings Solution/Herbal Chewing Gum	Shafa Herbal Solutions
Non-approved	Quit For Sure—Toxins and Nicotine Residue Solution/ Detoxifying Liquid Herbal Extract	Shafa Herbal Solutions
Non-approved	Quit Now/Quit For Life	Nutracor, LLC
Non-approved	Quit Smoking Support System	Gama Health Systems, Inc.
Non-approved	ResolveQS—Resolve to Quit Smoking	IGM Laboratories
Non-approved	Root 100 Ginseng Chew	Endurance Enterprises
Non-approved	Smoke Away Stop Smoking Support Program	Emerson Direct, Inc.
Non-approved	Smoke Break	Nx Health Systems, Inc.
Non-approved	Smoke Control	KingBio Pharmaceuticals
Non-approved	Smoke Free	Daniel Gagnon, Medical Herbalist, Herbs, Etc.
Non-approved	Smoke Free In 3	Smoke Free In 3, Inc.
Non-approved	Smoke Free Naturally	Boericke & Tafel, Inc.
Non-approved	Smokease	Unicity, Inc.
Non-approved	Smokeless	Green World, S.M. Corporation
Non-approved	Smoke-Less	Karemore International, Inc.
Non-approved	Smokeless (aromatherapy)	Premier Enterprises
Non-approved	Smoke-No-More No Smoking Mouthwash	Unidecor Ltd.
Non-approved	Smokerlyzer	Bedfont Scientific, Ltd.
Non-approved	Smoker's Control	Nutrition for Life International, Inc.
Non-approved	Smoker's Edge	Smokers Edge,
Non-approved	Smokers Health	SATSONG, Inc.
Non-approved	Smoker's Herbal Aroma	Longherb Health Products, Inc.
Non-approved	Smoker's Option	NASCO
Non-approved	SmokeRx	Life Miracle Products, Inc.
Non-approved	Smokey Mountain Snuff Herbal Chew	Smokey Mountain Snuff
Non-approved	Smoking Solution	eUniverse Network
Non-approved	Smoking Withdrawal Relief	Natra-Bio
Non-approved	Stop It	Natra-Bio
Non-approved	Stop Smoking	Natureplex
Non-approved	Stop Smoking Formula—Specialized Chinese Herbs	Coast Herbal

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Table 2. (continued)

FDA status	Product name	Manufacturer
Non-approved	Stop Smoking Homeo-Care	Homeo-Care
Non-approved	Stop Smoking Patch	Nature Queen International
Non-approved	Stop-It!	New Sun, Inc.
Non-approved	TarGard	Venturi
Non-approved	The Breather	PN Medical
Non-approved	The Smart Ashtray	RASCO Braun LLC
Non-approved	Viable Herbal Solutions—Independence Stop Smoking Program	Viable Herbal Solutions
Non-approved	We Quit Topical Patch	Smith Bristol
Non-approved	XPL Smoker's Gum	XPL Innovations, Inc.
Non-approved	Young's Chew	Young's Farm Nursery
Non-approved	Zero Nicotine	EyeFive, Inc.
Non-approved	Zhen Ya Quit Smoking Perfume	Beijing Zhenya Health Protection Technical

FDA, U.S. Food and Drug Administration

here to design products and packaging that educate smokers about the safety and efficacy of evidence-based products. Manufacturers of tobacco-cessation pharmacotherapies may want to alter product packaging and inserts to help consumers understand the risks and benefits of nicotine medications and expected results from product use.

Recommendation #3

The third recommendation is to design products for and by smokers. Consumer involvement is necessary in focus groups to both design relevant appropriate packaging, and for comprehension testing to ensure that the products are designed for appropriate use. Many of the non-approved products used consumer design principles that may increase their appeal to the smoker by helping them “kick the tires” through trial packs or “lowering the (psychological) cost” by boasting satisfaction guaranteed claims. Currently, there are no FDA-approved tobacco-cessation products for smokeless tobacco, and the current marketplace for smokeless tobacco blurs the line between cessation and tobacco product. For example, some smokeless tobacco products are marketed as cessation products and others as harm-reducing alternatives to smoking. Taking a critical look at the whole cessation marketplace may provide insights on how to design evidence-based products and packaging that will fit into the tobacco user's everyday life.

Recommendation #4

Actively work to increase the reach of evidence-based tobacco-cessation products by improving opportunities

for comprehension. There is an opportunity to meet consumers where they access evidence-based tobacco cessation products and provide resources to encourage use and help ensure correct usage. For example, there are a disproportionate number of smokers among the Medicaid population compared to the general population, and the average reading level of Medicaid and Medicare enrollees is equivalent to that of fifth grade.^{29,30} In many states, Medicaid provides tobacco-dependence treatments. A collaborative partnership may be considered by both the FDA and the Centers for Medicare and Medicaid Services (CMS) through the federal government's plain language initiative to develop written NRT instruction materials tailored to the Medicaid population (go to www.plainlanguage.gov/).

There is another opportunity to engage pharmacies and pharmacists as a resource for smokers seeking guidance on tobacco-cessation products. Consumers with low literacy levels are more likely to make pharmaceutical errors, and the average patient typically adheres to only 50% of their medication doses.^{31,32} Most pharmacies do not make any efforts to identify and counsel patients with low health literacy, yet pharmacists are in a unique position to educate patients about proper medication use.³³ Pharmacies should also consider ways they can provide written information in other languages. A recent study found that few pharmacies are capable of translating prescription labels into other languages besides English—which is a growing problem, especially in areas of the country with predominantly Spanish-speaking populations.³⁴ Finally, pharmacies can play a role in driving consumer demand for OTC NRT by positioning prod-

ucts in stores so that consumers know they are available and can browse, compare, and ask questions about their choices.

Limitations

Several limitations to this study should be noted. First, the analysis was limited to products catalogued in the QuiTIP database (Table 2). Although all currently available FDA-approved products were included, packaging information for their generic equivalents was not reviewed. Also, the list of non-approved products in the database is not comprehensive, and some products may not currently be available in the marketplace. Next, actual product packages were not reviewed; therefore, no evaluation was made of any package information that was not in the QuiTIP database, including pictures, graphics, or typographic or layout features that may aid in comprehension. It is not known how consumers interpret and use the information found on the product packages, and little information is available about consumer non-approved cessation-product use. It is logical to assume that if a consumer understands the package and directions, that they will use it correctly; however, research in this area is limited. Despite these limitations, this is one of the first studies to examine the literacy levels and claims of various types of FDA-approved and non-approved tobacco-cessation products. There are some key insights on how to make evidence-based products more appealing to smokers who are trying to quit.

Conclusion

Tobacco use is one of the leading causes of preventable death and disease in the U.S., yet an estimated 43.4 million American adults—19.8% of the population—are current smokers.³⁵ In order to reduce disparities in tobacco-related disease, improvements need to be made to cessation-product packaging to help increase consumer demand for evidence-based tobacco-cessation products. One way to do this is by designing FDA-approved product packaging that conveys to consumers easily digested messages about product safety, effectiveness, and appeal. The manner in which evidence-based tobacco-cessation products and directions are currently written and designed may not be appropriate for the current smoking population who are trying to quit. Improving the packaging and directions of evidence-based cessation products so that they are preferably at a fifth-grade reading level or below may help consumers take advantage of and correctly use products that will greatly increase their chances of successful quitting. In addition to making packaging that can be better comprehended by smokers, there is room to improve the appeal of these products. Using

consumer-centered design principles may help ensure that smokers find treatments appealing, acceptable, and effective.

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