ConsumerDemand
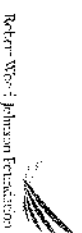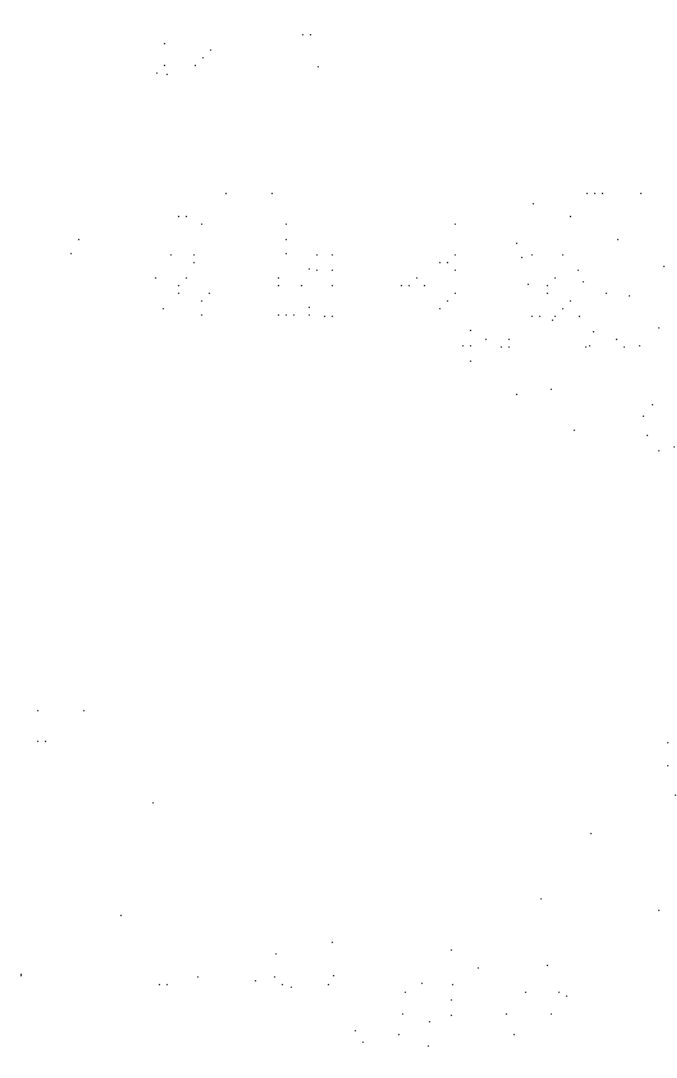
INNOVATIONS IN BUILDING

ConsumerDemand

FOR TOBACCO CESSATION PRODUCTS AND SERVICES

6 Core Strategies for Increasing the Use of
Evidence-Based Tobacco Cessation Treatments

May 2007

Consumer Demand:
The degree to which smokers and other tobacco users who are motivated or activated to quit know about, expect, seek, advocate for, demand, purchase, access and use tobacco cessation products and services that have been proven to increase quitting success.

Building Consumer Demand

Six core strategies for building demand among smokers for proven tobacco cessation products and services include:

Viewing smokers as consumers and taking a fresh look at quitting from their perspective.

Redesigning evidence-based products and services to better meet consumers' needs and wants.

Marketing and promoting cessation products and services in ways that reach smokers — especially underserved smokers — where they are.

Seizing policy changes as opportunities for "breakthrough" increases in treatment use and quit rates.

Systematically measuring, tracking, reporting and studying quitting and treament use — and their drivers and benefits — to identify opportunities and successes.

Combining and integrating as many of these strategies as possible for maximum impact.

Helping More Smokers Quit — An Extraordinary Opportunity

The premise of the Consumer Demand Initiative is simple:

- 44.5 million Americans smoke, and there is no better way to improve the nation's health and reduce health disparities than to help these smokers quit.

- Most smokers who try to quit fail — especially those with the least education and income.

A key reason: **most smokers who try to quit don't use treatments that could significantly improve their success rates.**

Smokers with the least income and education try as often to quit, but use treatments less often and fail more often.

While access to treatments can be a barrier, treatment use is low even when they are available free of charge and are covered by health insurance.

Increasing demand for tobacco cessation products and services represents an extraordinary opportunity. But it is a challenge that will require bold thinking, innovation, changes in practices and new approaches that start with the consumer perspective.

Providing consumers with tobacco cessation products and services that they find both appealing and effective could substantially boost the nation's quit rate. A higher quit rate would create huge benefits for our nation's health, healthcare system and productivity, which is why the Institute of Medicine identified tobacco dependence treatment as one of the top priorities for national improvement in its 2003 report, *Priority Areas for National Action: Transforming Health Care Quality.*

"One of these days
I know I'll quit."

BARBARA
Current smoker
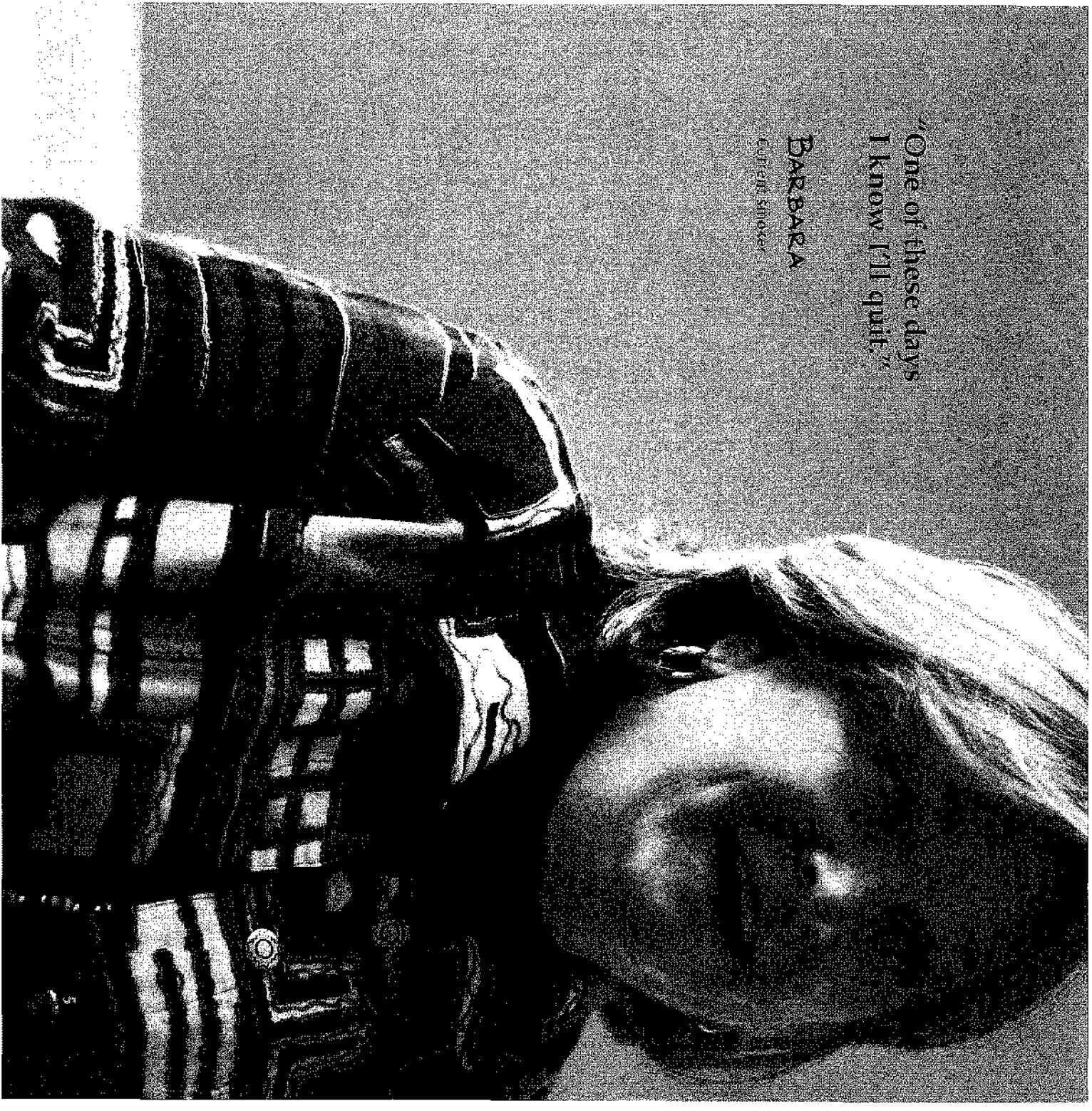
Addressing the Challenge of Building Demand for and Use of Proven Cessation Treatments

The American Cancer Society, American Legacy Foundation, Centers for Disease Control and Prevention, National Cancer Institute, National Institute on Drug Abuse and Robert Wood Johnson Foundation began to focus on the issue of building greater demand for tobacco cessation products and services as part of the National Tobacco Cessation Collaborative (NTCC) in early 2005.

These national tobacco control organizations developed the vision of a Consumer Demand Initiative with the goal of:

- Identifying innovative strategies for substantially increasing the demand for, and use of, evidence-based tobacco cessation products and services — particularly in underserved low-income and racial/ethnic minority populations where tobacco use is highest and treatment use is lowest.

The Academy for Educational Development (AED) hosted three Consumer Demand Roundtable meetings in December 2005, February 2006 and June 2006. These Roundtable meetings focused on:

- Generating new ways of thinking about increasing demand for evidence-based tobacco cessation products and services.

- Identifying and catalyzing feasible innovations in product design, research funding, practice and policy that could significantly improve the use and impact of current evidence-based treatments.

Participants included leading tobacco cessation researchers, providers, practitioners, policy advocates, consumer product designers and marketing experts.

This report summarizes the key concepts and ideas that emerged from the Roundtable meetings.

Only about 4.7 percent of U.S. smokers per year quit smoking for at least three months.

(Source: 2000 National Health Interview Survey, www.cdc.gov/mmwr/preview/mmwrhtml/mm5129a3.htm)

**PHS CLINICAL PRACTICE GUIDELINES
LIST OF EFFECTIVE TREATMENTS**[1,2]

The PHS Clinical Practice Guidelines provide the following assessment of effective tobacco cessation treatments:

- Tobacco use screening and brief intervention in routine medical care, provided by a variety of providers—including physicians, nurses and dentists—using the 5As:
  - Ask all patients about tobacco use.
  - Advise all users to quit.
  - Assess quitting readiness.
  - Assist with brief counseling (1-3 minutes for most smokers, 5-15 minutes for pregnant smokers) and FDA-approved pharmacotherapies if appropriate.
  - Arrange follow-up assistance and referral if needed.

- Three types of counseling and behavioral therapies that should be included in smoking cessation interventions:
  1. Providing smokers with practical counseling (behavioral problem solving skills/skills training).
  2. Providing social support as part of treatment.
  3. Helping smokers obtain social support outside of treatment.

- Proactive telephone counseling should be used.

- Effective pharmacotherapies should be used for smoking cessation except in the presence of special circumstances.
  1. Recommended first-line FDA-approved pharmacotherapies include bupropion SR (Zyban or Wellbutrin), nicotine gum, nicotine inhaler, nicotine nasal spray and nicotine patch.
  2. Second-line pharmacotherapies include clonidine and nortriptyline.
  3. Newly FDA-approved cessation medications include nicotine lozenges and varenicline (Chantix).
  4. Combination nicotine replacement therapy (combining the nicotine patch with a self-administered form of nicotine replacement therapy) should be encouraged if patients are unable to quit using a single type of first-line pharmacotherapy.

- Intensive interventions are more effective than less intensive interventions and should be used whenever possible – including face-to-face or telephone.

- Long-term smoking cessation pharmacotherapy should be considered as a strategy to reduce the likelihood of relapse.

Note: This report focuses primarily on building consumer demand for products and services to quit cigarette smoking. However, many of the same strategies apply to cessation of other tobacco products. The focus is also on tobacco cessation among adults. Treatment evidence is strongest for adults, and guidelines currently recommend the same treatments for youth until more effective and appealing youth-tailored options can be developed.

STRATEGY 1: Viewing smokers as consumers and taking a fresh look at quitting from their perspective

"To build a deeper understanding of smokers, those wishing to boost consumer demand for proven treatments need insight not only into smokers' expressed needs and preferences, but also into their latent, unmet needs…"

When most companies develop a product or service, they begin the process by understanding what consumers need and want. But smokers have often been viewed as passive treatment beneficiaries rather than treatment consumers. The first step in building consumer demand for proven cessation treatment products and services involves viewing smokers as consumers, and going beyond testing products for their efficacy to determining how they can best meet quitters' wants and needs.

DEVELOPING A BETTER UNDERSTANDING OF QUITTERS' PREFERENCES AND NEEDS

While focus groups and survey research have provided tremendous insight into smokers' lives and preferences, the under-use of evidence-based treatments shows there is still much to be learned.

To build a deeper understanding of smokers, those wishing to boost consumer demand for proven treatments need insight not only into smokers' expressed needs and preferences, but also into their latent, unmet needs — needs that they often can't articulate, but that still have a powerful influence on their behavior.

Such latent needs may include a smoker's need to try a product before committing to a full package, or the desire to find cessation products that are aesthetically pleasing and compatible with their lifestyles.
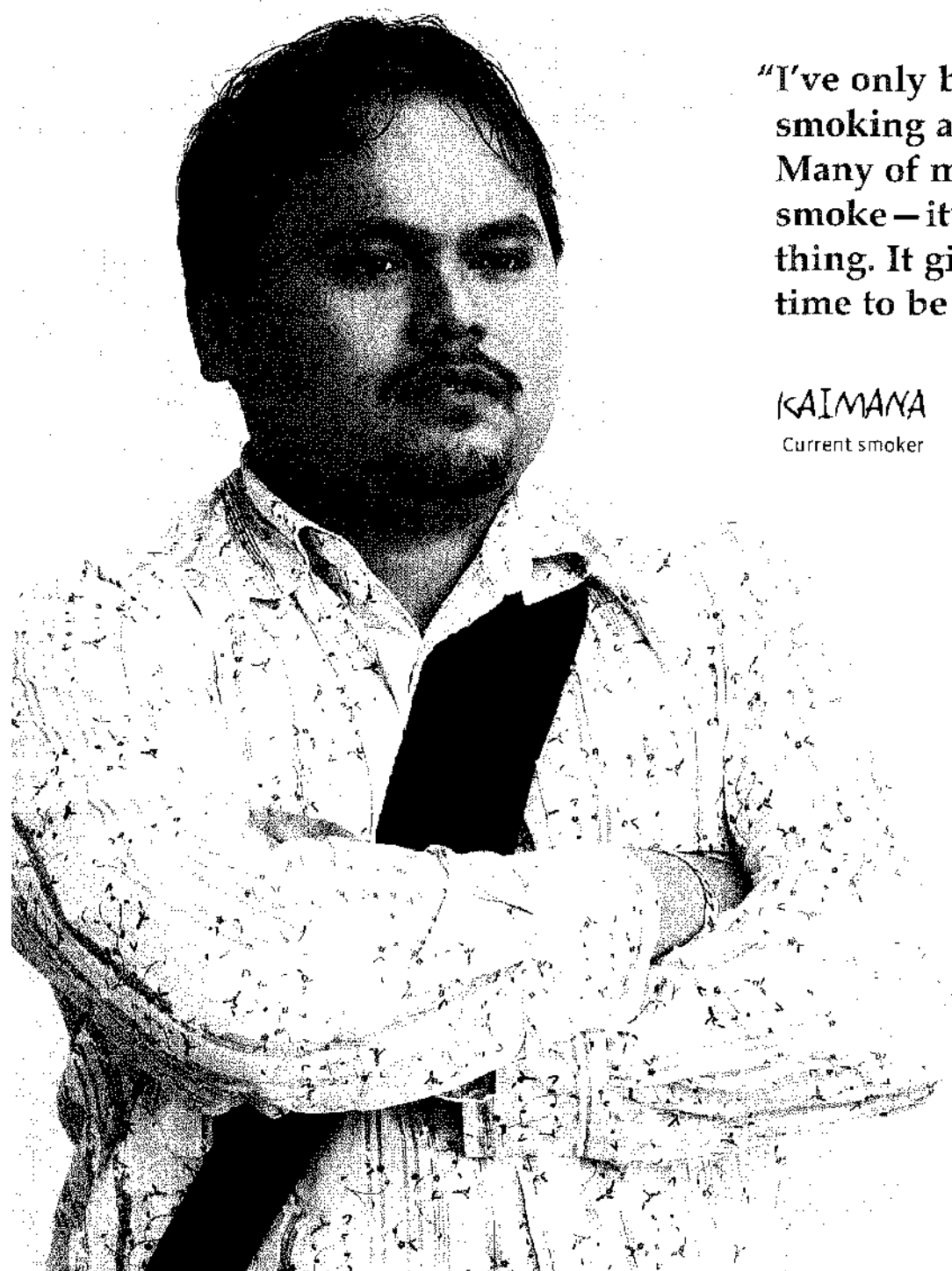
"I've only been
smoking a year.
Many of my friends
smoke — it's a social
thing. It gives us
time to be together."

KAIMANA
Current smoker

IDEO uses a number of research techniques to gain consumer insight. A few of these techniques include:

- *Shadowing* — observing smokers where and when they smoke, and where they go for help in quitting.

- *Consumer Journey* — keeping track of all the interactions smokers have with cessation products and services.

- *Extreme Users* — interviews with individuals who really know a lot (or know nothing) about cessation products and services. From these individuals, researchers and product design experts can more easily elicit passions and emotional drivers related to the product, service or behavior of interest. IDEO's experience indicates that the extreme users amplify what people in the middle are thinking or feeling and give greater clarity about opportunities to design for everybody.

- *Storytelling* - prompting people to tell personal stories about their consumer experiences, and using these stories to inspire the creation of relevant smoking cessation products and services.

Increasing the use of research methods that produce deeper knowledge into smokers' needs and wants may provide new insights into how to help smokers quit.

FOCUSING ON THE "CONSUMER EXPERIENCE"

The consumer experience is about more than just proven product efficacy. The consumer experience involves every aspect of a product or service — the advertising, packaging, product and service features, ease of use, and reliability — all the ways a consumer interacts with a product or service.

As part of the Consumer Demand Roundtable, the product design firm IDEO discussed the need to focus on improving the "consumer experience." IDEO has worked with a number of organizations on creating new and more engaging consumer experiences. Two examples of this work follow.

Example 1: "Keep the Change" Account Service for Bank of America

Facing the challenge of enticing people into opening new accounts, Bank of America came to IDEO in search of ethnography-based innovation opportunities. To better understand the target market, IDEO and members of Bank of America's innovation team conducted observations in several cities. They discovered that many individuals would often round up their financial transactions for speed and convenience. In addition, the team found that many had difficulty saving money, whether due to a lack of resources or willpower.

After these observations, the team arrived at a solution that uses existing habits to resolve the problem. Ultimately dubbed "Keep the Change," the service rounds up purchases made with a Bank of America debit card to the nearest dollar and transfers the difference from individuals' checking accounts

into their savings accounts. The convenience and ease of rounding up now helps members save money over the long run.

After Bank of America's extensive testing and refinement of prototypes, "Keep the Change" launched in October 2005. In less than one year, "Keep the Change" attracted 2.5 million customers who have opened more than 700,000 new checking accounts and one million new savings accounts.

Example 2: Redesigning the Hospital Experience

IDEO worked with Kaiser Permanente to improve the patient experience in hospital settings. Kaiser staff, including nurses, doctors and facility managers, as well as IDEO's social scientists, designers, architects and engineers, observed patients as they made their way through medical facilities.

IDEO and Kaiser concluded that the patient experience can be awful, even when people leave treated and cured. The observation revealed that:

- Patients and family often become annoyed and anxious because checking in was terrible, waiting rooms were uncomfortable, and patients were often left alone because family and friends who came with them were not allowed to stay.

- Patients hated examination rooms because they often had to wait alone for long periods of time in gowns, with nothing to do, surrounded by threatening needles and tools.

After this process with IDEO, Kaiser realized it needed to make patients more at ease by offering more comfortable waiting rooms, a lobby with clear instructions on where to go, and larger exam rooms that have space for three or more people and curtains for privacy.

UNDERSTANDING THE QUITTING JOURNEY AND ENGAGING SMOKERS ALL ALONG THE WAY
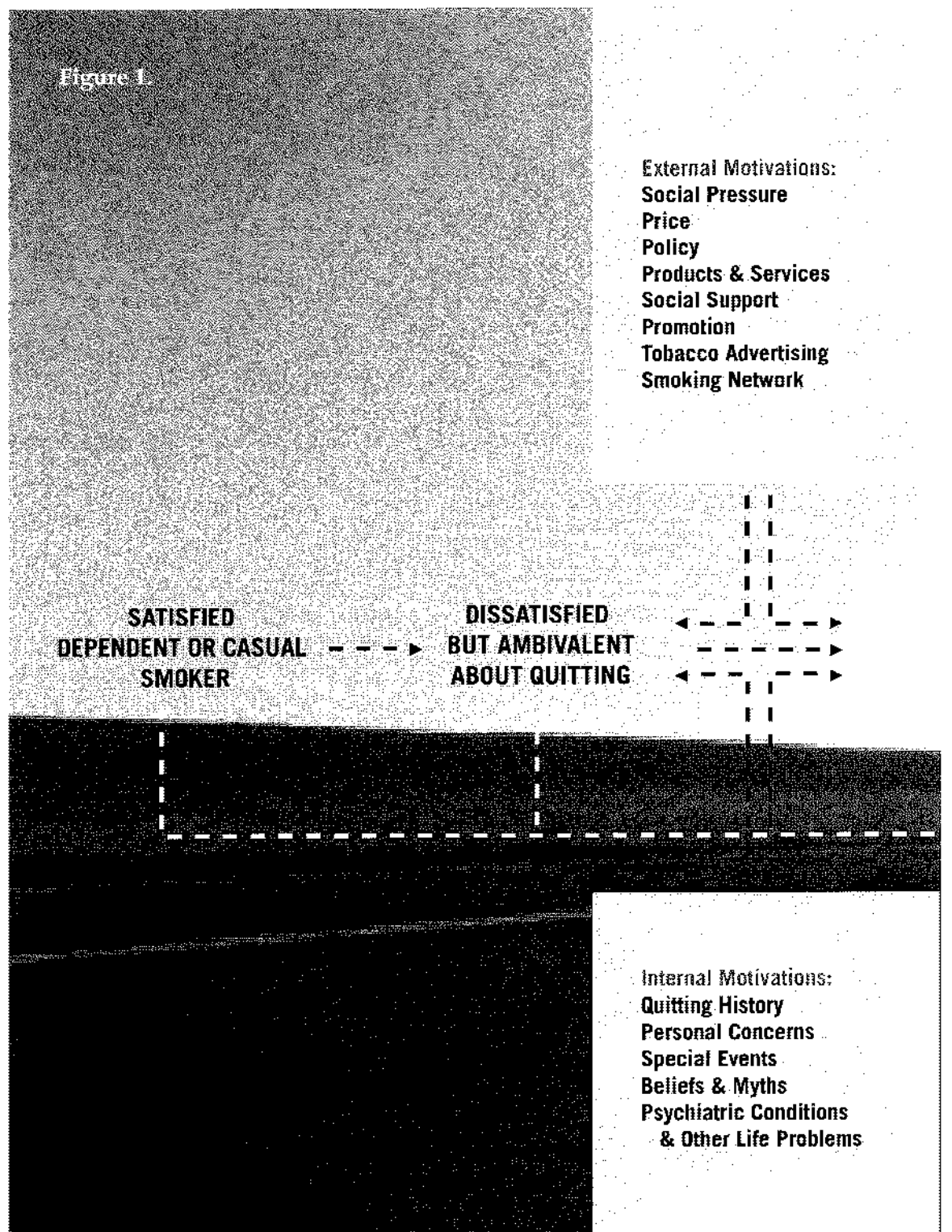
To free themselves from nicotine addiction, each smoker makes a very personal journey on the road to successfully quitting smoking. That journey can be long and arduous, often marked by ambivalence, desires, decisions, hopeful attempts, frustrating failures, persistence, planning, prioritizing, and finally, in the best case, both short- and long-term success.

There are opportunities to build consumer demand for smoking cessation by engaging those who are trying to quit throughout their journeys — not just during the first few days and weeks of their quit attempts.

The challenge of the journey for those who might assist is to make solid connections with smokers that last over time, to develop a better understanding of the needs of these consumers at various points along
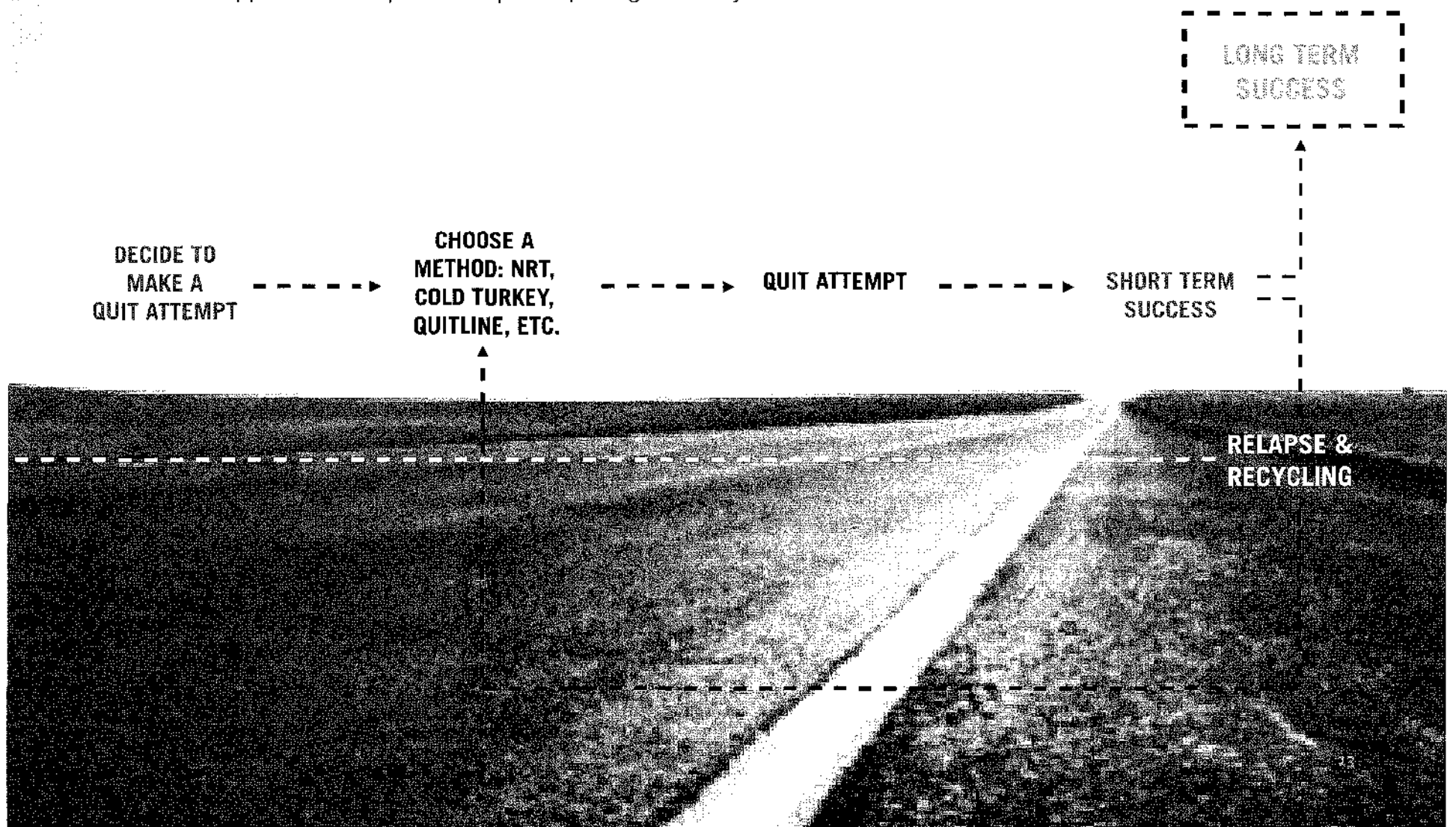
the journey, and to treat smokers and
their quitting efforts with respect.
Smokers benefit from different kinds
of help and support at different
stages of their journeys as well.

Figure 1 shows one depiction of the
quitter's journey.

Figure 1

External Motivations:
Social Pressure
Price
Policy
Products & Services
Social Support
Promotion
Tobacco Advertising
Smoking Network

**SATISFIED
DEPENDENT OR CASUAL – – – ▶
SMOKER**

**DISSATISFIED
BUT AMBIVALENT
ABOUT QUITTING**

Internal Motivations:
Quitting History
Personal Concerns
Special Events
Beliefs & Myths
**Psychiatric Conditions
 & Other Life Problems**

THE QUITTER'S JOURNEY

Once smokers are triggered to quit, both external and internal motivations influence the quitting process as they learn about quitting, set quitting goals, choose a quitting process, and attempt to quit. As smokers succeed or fail, they continue to customize their approach and repeat attempts at quitting until they are successful.

LONG TERM
SUCCESS

DECIDE TO
MAKE A
QUIT ATTEMPT

CHOOSE A
METHOD: NRT,
COLD TURKEY,
QUITLINE, ETC.

QUIT ATTEMPT

SHORT TERM
SUCCESS

RELAPSE &
RECYCLING

STRATEGY 2: Redesigning evidence-based products and services to better meet consumers' needs and wants

"Using consumer-centered design principles may help ensure that smokers find treatments appealing as well as effective."

While many effective cessation products and services exist, consumers don't always have positive experiences with them. Using consumer-centered design principles may help ensure that smokers find treatments appealing as well as effective.

USING CONSUMER-CENTERED DESIGN PRINCIPLES

The consumer experience with cessation products and services could be improved by applying a set of design principles identified by IDEO.

These design principles include the following:

- Allowing smokers to "kick the tires" by giving them an opportunity to test or experiment with a service/product before buying into it.

- **"Lowering the bar"** to make the initial quit attempt less costly, both psychologically and financially. This includes reducing the costs of products for quitters and breaking the process of quitting into manageable steps.

- **Designing aesthetically pleasing products, tools and services** that create a positive and compelling consumer experience for each smoker trying to quit.

Opposite page: An example of what someone who wants to quit with an NRT product may encounter in a pharmacy.
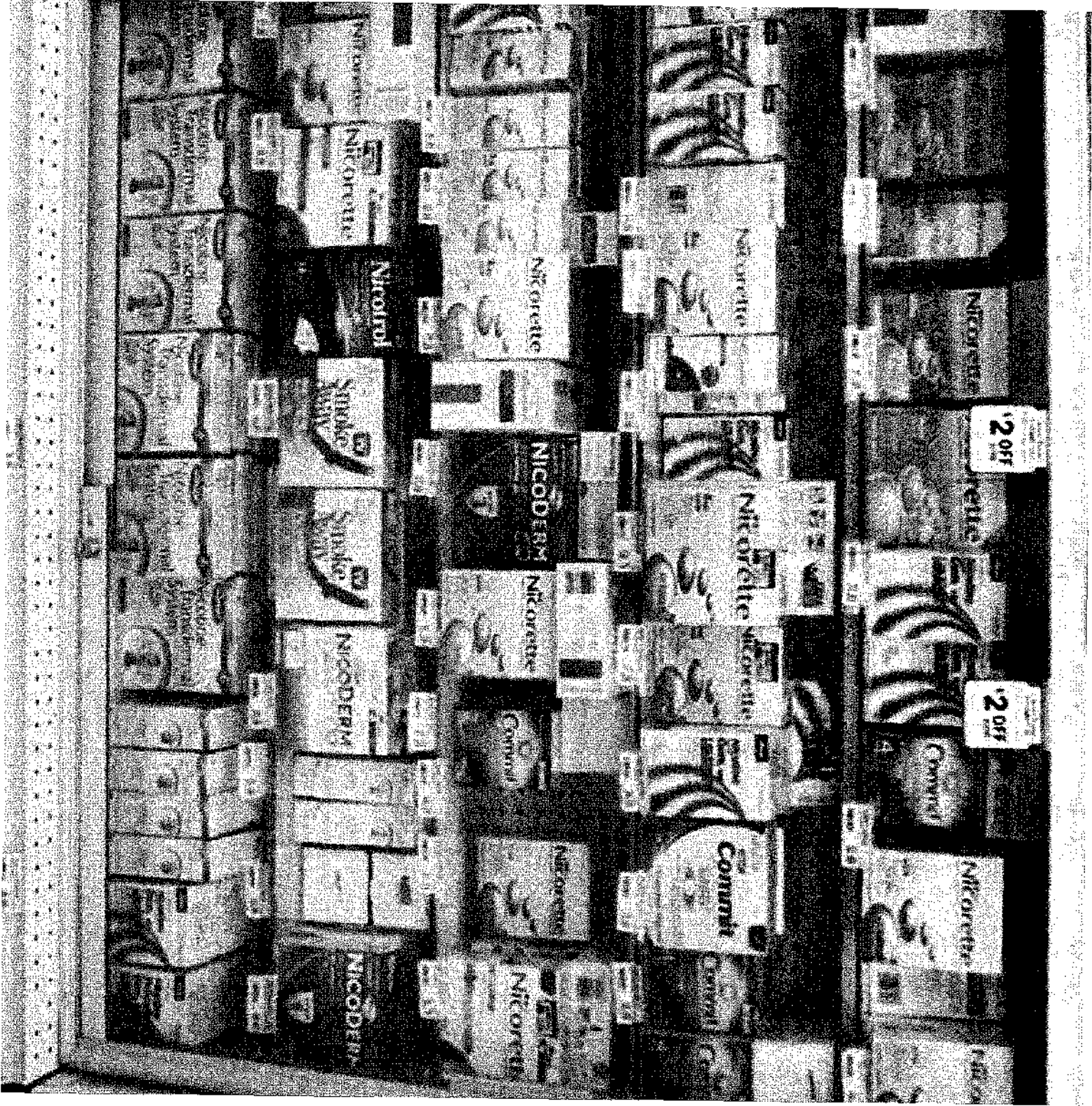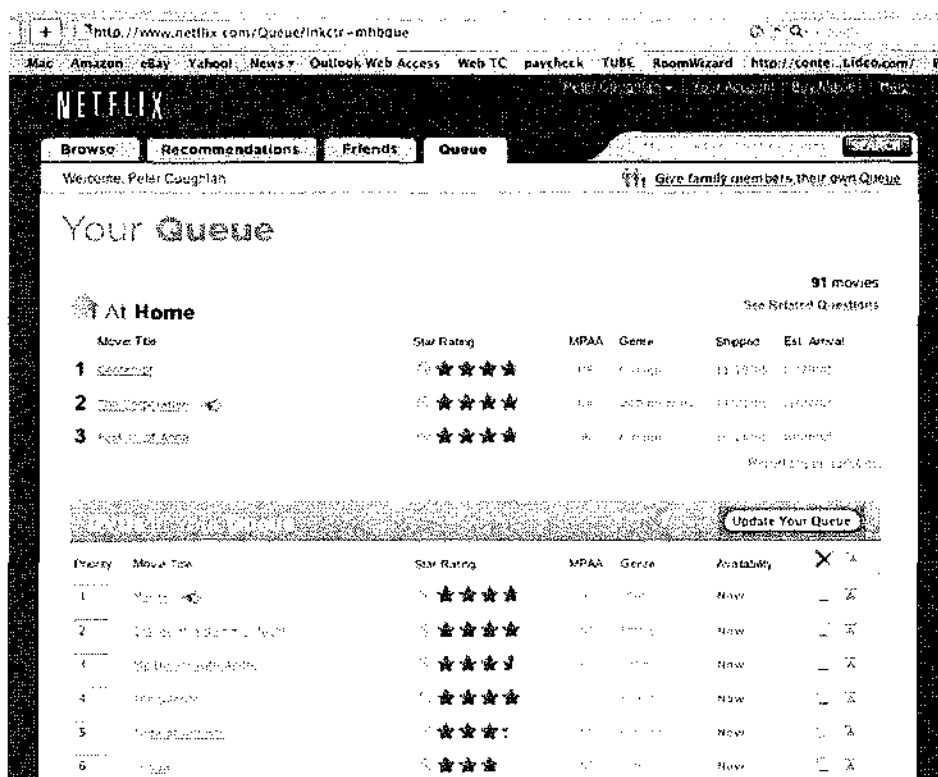
Netflix complete y redesigned the movie rental experience that for years centered around the local video rental store. Netflix incorporates many consumer-centered design principles, such as providing a free two-week trial, having a user-friendly and appealing interface, tracking movies that have been viewed, allowing a personalized queue of movies, and offering a variety of plans.

- **Facilitating transitions** to ensure that smokers get appropriate tools, as well as professional and social support, as they move from step to step through the stages and processes of smoking cessation. Helping quitters make it from one step to the next involves bridging activities and tools to assist in the transition process while anticipating challenges throughout each step of the smoker's journey.

- **Making progress tangible** to allow smokers to see, acknowledge, and celebrate small steps that enable them to advance toward their overall goal and to appreciate the nature of the journey. **Tracking progress** and receiving incentives and rewards along the way can help to reinforce smokers' dedication and commitment to quitting.

- **Fostering community** so that smokers and quitters are appropriately linked to a real or virtual social support network to help them in their journey towards sustained smoking cessation.

- **"Connecting the dots"** to link products, services and delivery systems/providers into a cohesive, accessible system so that smokers receive the best treatment available and engage in a more integrated delivery system or "web" of support and assistance. This principle includes linking products with promotions and policies that catalyze their use.

- **Connecting to the rest of smokers' lives** by showing an understanding that, for many smokers, quitting is a lifestyle decision—not exclusively a health decision—that affects them in many ways.

- Allowing smokers to **"make it their own"** by tailoring products and services to their needs and their lives.

Some existing products and services already incorporate many of these design principles. Many quitlines, for example, lower the bar by offering a toll-free number, facilitate transitions by working with callers throughout their quitting process, foster community by offering online forums, and connect the dots by using fax referrals with providers.

When thinking about existing evidence-based cessation products and services, are there opportunities to incorporate more of these design principles?

"Helping quitters make it from one step to the next involves bridging activities and tools to assist in the transition process while anticipating challenges throughout each step of the smoker's journey.

ENSURING PRODUCTS AND CESSATION MATERIALS FOLLOW HEALTH LITERACY PRINCIPLES

A product or service is more than the actual patch, gum or quitline call. A "product" includes everything the consumer comes into contact with: the product name, packaging, instructions and accompanying cessation materials.

Recent data show that many Americans, especially those with the least income and education, have trouble understanding and using health information. To create a better consumer experience with cessation products and services, especially for smokers in low-literacy and low-income groups (where smoking rates are highest and treatment use rates are lowest), it is helpful to ensure these other components of a product/service follow health literacy principles.

An initial review of tobacco cessation materials and product instructions shows that many may not be appropriate for smokers with lower health literacy skills, and may contribute to the under-use of evidence-based products/services. New FDA labeling for over-the-counter and prescription medications may be needed to ensure most smokers can properly use these products.

Smoking by education level
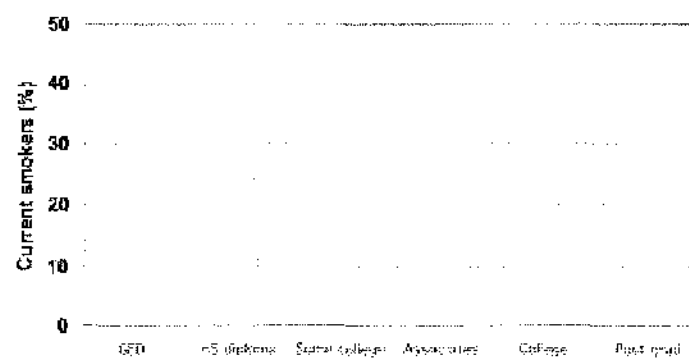
Source: CDC, MMWR Tobacco Use Among Adults —United States, 2005. October 27, 2006.

Health literacy scores by education
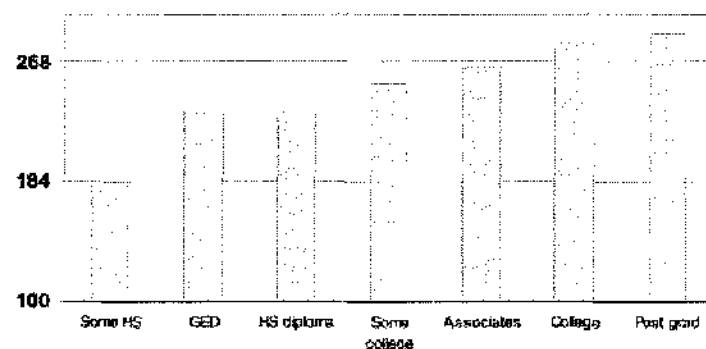
Source: National Assessment of Adult Literacy 2003, The Health Literacy of American Adults, September 2006.

The National Tobacco Cessation Collaborative (NTCC) is addressing health literacy and its role in limiting cessation treatment use and demand by:

- Conducting an environmental scan of low-literacy cessation materials to determine their appropriateness for under-served smoker populations—those with the least income and education, including working class and blue-collar smokers. This environmental scan will help NTCC assess how well the field is meeting the needs of lower-literacy smokers who are trying to quit.

- Developing a health literacy guide for organizations to follow in creating engaging and understandable low-literacy cessation materials and media.
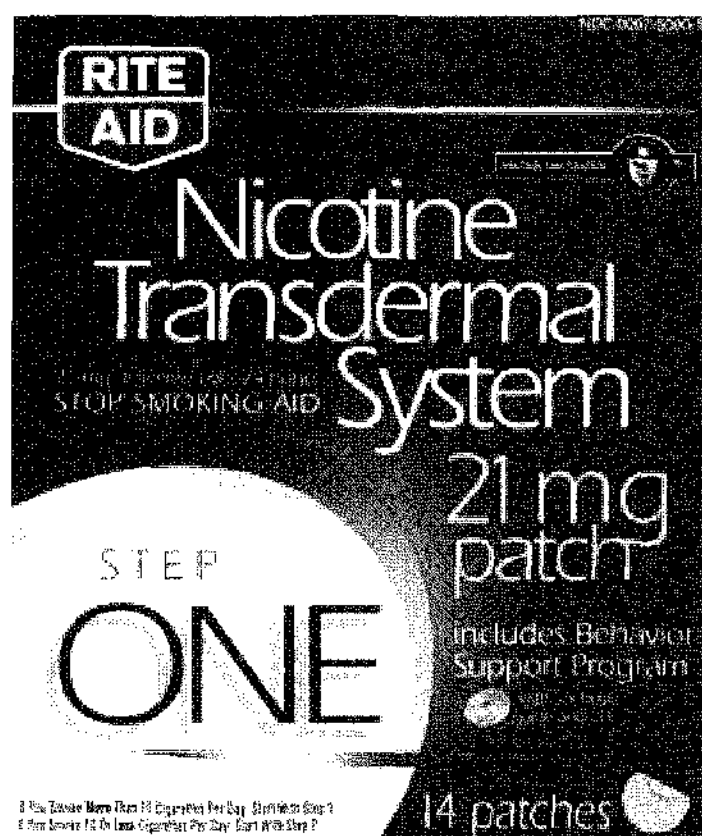
How could this labeling be improved for low-literacy consumers?

STRATEGY 3: Marketing and promoting cessation products and services in ways that reach smokers—especially underserved smokers—where they are

GSK's NASCAR program features brand signage on race cars and public relations with drivers emphasizing the importance of being tobacco-free.

Compared to cigarettes, cessation products/services are not widely promoted. Many smokers are not aware of quitline services, and many in health plans that offer and even subsidize proven treatments do not know that these treatments are available.

Cessation media campaigns and direct-to-consumer marketing of quitting services and products can significantly boost quit attempts, treatment use and population quit rates.[3] Even barrier-free treatments like quitlines depend on adequate promotion for their use. Effective ads and promotions can be targeted to high-risk and under-served populations, including those in low-income groups and

racial/ethnic groups where treatment use is most limited.[4]

ENGAGING SMOKERS IN NEW WAYS AND IN NEW PLACES

Why not take a page from the book of the tobacco industry when it comes to going where smokers are to offer cessation products?

This means expanding cessation efforts beyond the doctor's office, to the places that smokers work, socialize and play. The tobacco industry reaches their consumers and markets their products in many different ways, from traditional mass media advertising to buzz marketing events that spur Internet chatter, promotional offers and giveaways, and price promotions

and direct mail. Philip Morris, for example, has a database of more than 26 million smokers to whom it sends everything from birthday cards to free tickets for local concerts.[5]

Some in tobacco cessation are beginning to take this approach. For example, GlaxoSmithKline (GSK) follows this strategy to promote its therapeutic nicotine products and support programs. Katie Kemper, now with the Campaign for Tobacco-Free Kids and previously with GSK, described its NASCAR racing sponsorship to illustrate this concept—building a relationship with NASCAR fans by going to where they go.

• NASCAR fans are a large audience (75 million in the U.S.) that is disproportionately likely to smoke. The NASCAR following also skews to the lower income brackets.

Right: To make tobacco cessation products and services more accessible, the "Winner's Circle" onsite education center at NASCAR races features cessation counselors, interactive risk assessment kiosks, product samples, coupons and information.
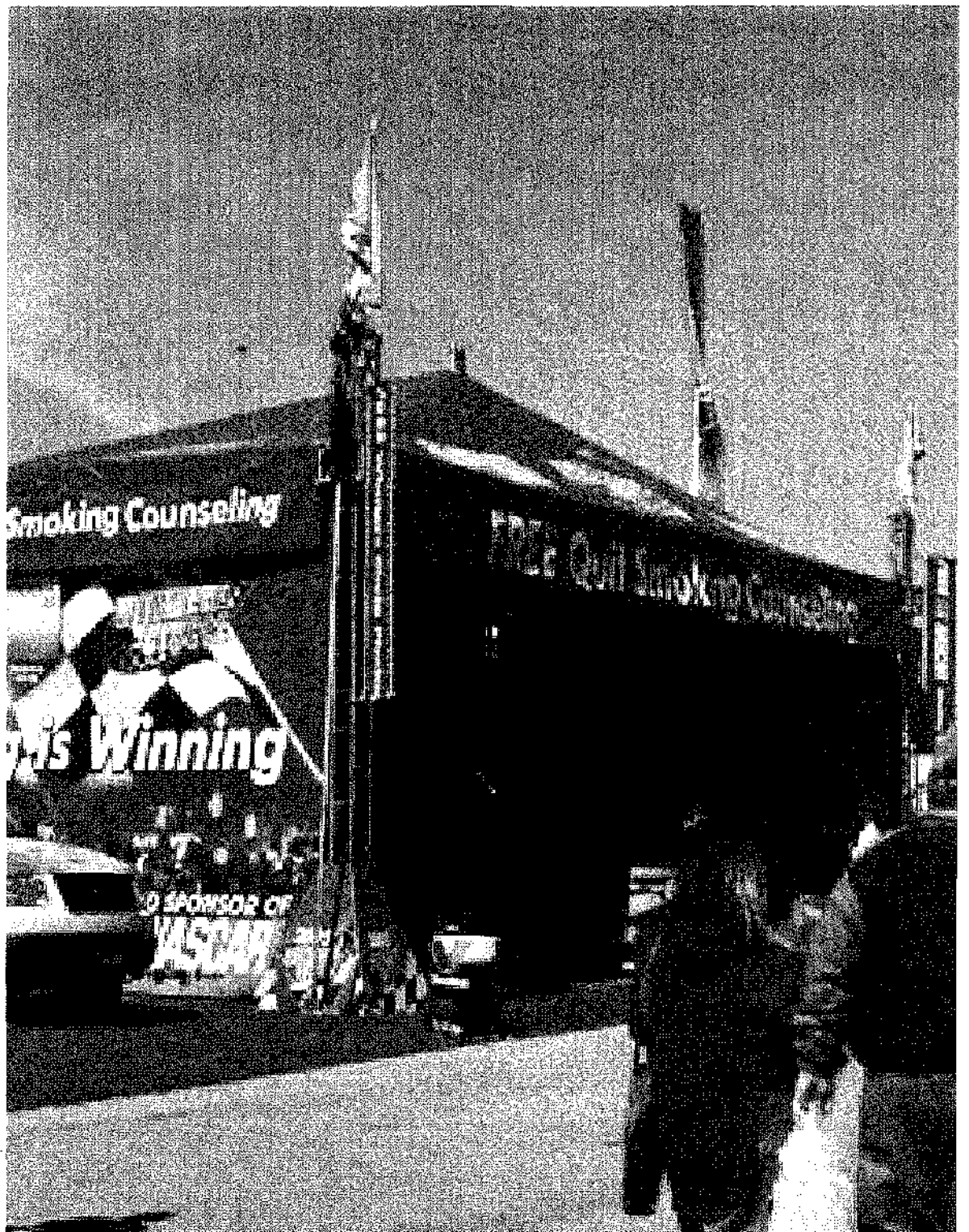
Free & Clear® created videos that show potential program participants how an evidence-based program works by telling others' stories of success.

- As Winston's 25-year title sponsorship of NASCAR ended, GSK recognized the opportunity to reach an audience with a high percentage of smokers and raise awareness of cessation products and programs.

- Now in its second year, GSK's NASCAR program features brand signage on race cars and public relations with drivers emphasizing the importance of being tobacco-free. Tie-ins with major trade accounts (e.g., Target) include in-store NASCAR-themed displays.

- The "Winner's Circle" onsite education center at NASCAR races features cessation counselors (often GSK sales representatives trained in cessation counseling), interactive risk assessment kiosks, product samples, coupons and information. This removes NRT cost barriers and allows smokers to "kick the tires" before they commit to quitting or to a particular product.

- The "Quit Crew" program provides cessation support (NRT and counseling) to NASCAR pit crews/mechanics. Public relations activities reinforce the concept of quitting as a team.

- The NASCAR program has been found effective in raising awareness of GSK's cessation brands and increasing product sales in NASCAR-themed displays. Of the over 200,000 smokers counseled, 33 percent made a serious quit attempt.

TELLING A STORY IS MORE POWERFUL THAN SIMPLY SHARING FACTS AND INFORMATION

Personal, emotional stories engage smokers and make them reflect upon the impact of smoking on them and/or their loved ones. Programs have had success using these types of testimonials to convince smokers of the important reasons to quit (J. Webb, personal communication, June 2006 and [6, 7, 8, 9]). Testimonials have also been used to give smokers hope that they can quit by showing others' stories of success. These ads focus on how to approach quitting, including providing information about available services and resources. [10, 11, 12]

Free & Clear®, a tobacco treatment program, created three videos that invited successful program participants to talk about their challenges in quitting, how they worked with their Quit Coaches™ and how they relied on other elements of the program to finally succeed where they had failed before. The videos have been an excellent way to show potential participants how an evidence-based program works without relying on vast amounts of text or a lot of scientific study citations.

> "*Personal, emotional stories engage smokers and make them reflect upon the impact of smoking on them and/or their loved ones.*"

USING EVIDENCE-BASED PROMOTION PRINCIPLES

There are several efforts underway to distill key principles for cessation media campaigns, tobacco counter-advertising and cessation treatment marketing.

For example, staff at the Institute for Global Tobacco Control at Johns Hopkins Bloomberg School of Public Health and the Global Dialogue for Effective Stop Smoking Campaigns conducted an international review of published literature on smoking cessation campaigns and then combined those data with key unpublished data from cessation campaigns around the world.

They grouped lessons learned and recommendations from the review into four main topics:

- Advertising
- Promotion of Cessation Services
- Media Planning and Placement
- Collateral Support (i.e., non-mass media marketing elements and news media coverage).

The recommended evidence-based principles for promotion are available online at www.stopsmokingcampaigns.org.
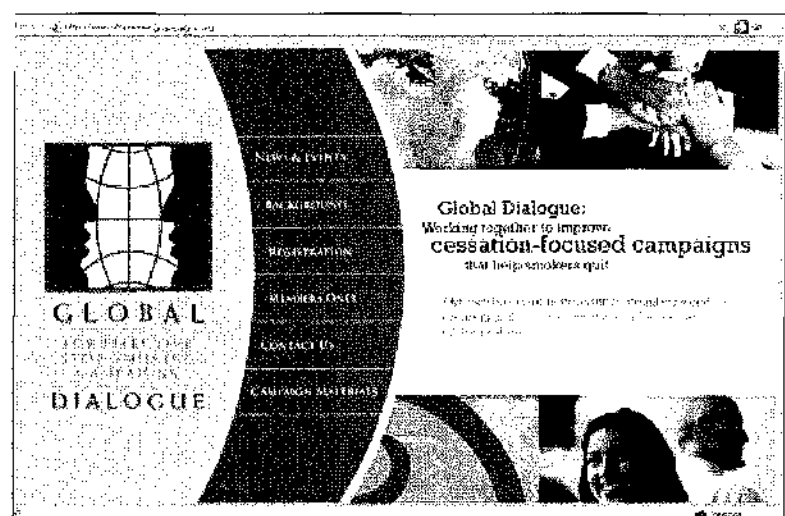

The Global Dialogue for Effective Stop Smoking Campaigns' lessons learned and recommendations for effective smoking cessation campaigns are available on their Web site.

USING NEW FORMS OF MARKETING TO REACH SMOKERS

Technology-based marketing is becoming increasingly important to reach internet-connected consumers, such as many young adult smokers. It is no mystery that the landscape of communications is changing rapidly. Several years ago, no one really knew what a blog was—because they didn't exist. Technorati, a blog search engine, now estimates that a new blog is created every second of every day, and that the size of the "blogosphere" is doubling every five months.

The world is witnessing the rise of a generation that has never known a world without TiVo, iPods, mobile phones, Google, instant messaging, broadband, Wi-Fi, and, of course, blogs. This generation is more adept at receiving and sharing information than adults over age 35 will ever be.

Social networking sites, such as Facebook, MySpace and Friendster, now offer people ways to share information with large networks of people. Many sites that feature user-generated content, such as Youtube and Wikipedia, are having a major impact on people's lives, influencing everything from political races to movie popularity.
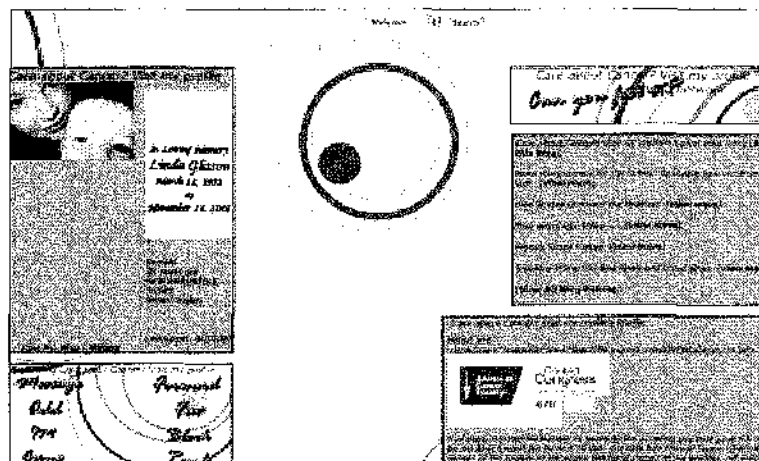
M'che'le Vandever's MySpace page promoting tobacco cessation.

"Technology-based marketing is becoming increasingly important to reach internet-connected consumers, such as many young adult smokers."

Many mainstream Web sites now allow users to rate products or provide feedback on them.

The implications of user-generated content for tobacco cessation are great: Many people give greater credence to first person accounts than to paid media messages. This user generated content may not always be accurate.

The field of tobacco cessation must find ways to engage in these forms of dialog to ensure that correct information about quitting smoking is provided.

CORRECTING MISPERCEPTIONS ABOUT WHAT WORKS AND WHAT DOESN'T AND ABOUT NICOTINE REPLACEMENT THERAPIES (NRT)

One of the barriers to treatment use is consumer perceptions of the effectiveness of products and services, both proven and unproven. In one survey, evidence-based smoking cessation methods

perceived as most effective included:

- Help from a doctor (77 percent).
- Help from clinics or support groups (73 percent).
- Using a nicotine patch (58 percent).

However, less than half of respondents perceived that some evidence-based treatments were effective, including:

- Prescription (cessation) medication (47 percent).
- Nicotine gum (45 percent).
- Nicotine tablets, lozenges or inhalers (37 percent).

Also, less than a quarter of respondents thought that using a telephone quitline (24 percent) was an effective cessation strategy. Methods without evidence like acupuncture, hypnosis, self-aids and even quit smoking programs offered by tobacco companies were perceived as more effective than telephone quitlines. [13]

There are many misconceptions about the safety of NRT as well. Some smokers falsely believe that nicotine and NRTs are a cause of cancer and heart attacks. Some providers report similar beliefs. These misperceptions help to explain the under-use of FDA-approved NRTs.

More specifically, several studies have documented wide misconceptions about the safety and efficacy of NRT, especially among smokers with the least education. [14] In a nationally representative random-digit-dialed telephone survey of current smokers:

- Only one-third correctly reported that nicotine patches were less likely to cause a heart attack than smoking cigarettes.
- 67 percent incorrectly believed that nicotine causes cancer.
- Fewer than half reported that nicotine gum and patches were less addictive than cigarettes. [14, 15, 16]

Weighted estimates from the 2004-2005 *Assessing the Hard Core Smoker Survey* of U.S. adult smokers found that 36 percent falsely believed that stop smoking medications might harm their health.[17]

To address some of these concerns, the National Tobacco Cessation Collaborative (NTCC) has developed a factsheet on the misperceptions of nicotine and distributed it to the tobacco cessation community.

Organizations that produce cessation materials were asked to review their materials to ensure they included accurate information about nicotine. The factsheet is available on the NTCC website at www.tobacco-cessation.org.

Key Points to Help Dispel the Myths about Nicotine and NRT

For Consumers, Patients, Quitline Operators, and Health Care Providers

To address misconceptions about the safety and efficacy of NRT, NTCC has created a factsheet and distributed it to the tobacco cessation community.

STRATEGY 4: Seizing policy changes as opportunities for "breakthrough" increases in treatment use and quit rates

"Pairing...public health policy changes with efforts to improve treatment access holds great promise for major breakthroughs in treatment use and quit rates."

Along with effective cessation media campaigns and treatment promotions, the *CDC Guide for Community Preventive Services* recommends two tobacco control policy interventions that increase cessation and treatment use and demand at the population level. [3] They are:

- Increasing tobacco prices/taxes.
- Reducing out-of-pocket cessation treatment costs through coverage expansions.

In addition, there is growing evidence that smoking bans and restrictions may increase quit attempts, quitting and treatment use. Pairing these public health policy changes with efforts to improve treatment access holds great promise for major breakthroughs in treatment use and quit rates.

STIMULATING AND HARNESSING THE TREATMENT DEMAND THAT IS GENERATED BY TOBACCO CONTROL POLICY CHANGES

Increasing Tobacco Prices/Taxes

Higher cigarette prices induce smokers to quit, with the greatest effects on smokers in low-income and blue-collar populations where smoking rates are highest and treatment use is lowest. [18]

A 10 percent increase in cigarette prices reduces adult smoking prevalence by 2 percent, and it increases the probability of a quit attempt by 10-12 percent and of a

successful quit by 1-2 percent.[3, 19] More than 43 states and several cities (e.g., N.Y.C., Chicago) have raised their tobacco taxes in the last five years, and there are signs that this trend will continue. Cost and tax increases also can boost treatment use when treatment options are widely available.

For instance, Frank Chaloupka and colleagues found that a 40-cent per/pack increase in Illinois' state cigarette excise tax in 2002 more than doubled state quitline call volumes. Other studies have linked cigarette price increases to higher NRT sales.[20] Providing and promoting barrier-free cessation treatments at the time when tobacco prices or taxes take effect could help to convert more smokers to successful quitters.

Reducing Out-of-Pocket Treatment Costs

Reducing treatment costs by increasing insurance coverage and reimbursement also boosts the population quit rate.[3] The marked increases in public and private tobacco cessation treatment coverage over the past decade provide another key venue for boosting treatment use and quitting.

In 1995, only one state Medicaid program covered any tobacco dependence treatments. In 2005, 42 state Medicaid programs and 96 percent of U.S. health plans provided coverage for some form of evidence-based counseling or pharmacotherapy.[21, 22]

There is still much progress to be made in the number and type of treatments covered, and the extent of coverage. There is also a great need to promote these benefits.

One study found that only about 1/3 of smokers, and fewer than 2/3 of providers, in two states with generous Medicaid benefits were aware of these benefits.[23] There are similar findings for health plans.[24]

Several studies have now shown that smokers who are unaware of their treatment benefits are, not surprisingly, unlikely to use them!

Reaping the full quitting and health benefits of expanded coverage requires promoting the coverage and reducing non-financial treatment access barriers.

Free quitlines have gone a long way towards eliminating such barriers. An increasing number of quitlines are even mailing free NRT to quitline callers, following strategies pioneered by Michael Cummings and colleagues throughout New York State.[25]

100% Smokefree Laws at the State, County, and City Level
American Nonsmokers' Rights Foundation
In effect as of January 17, 2007
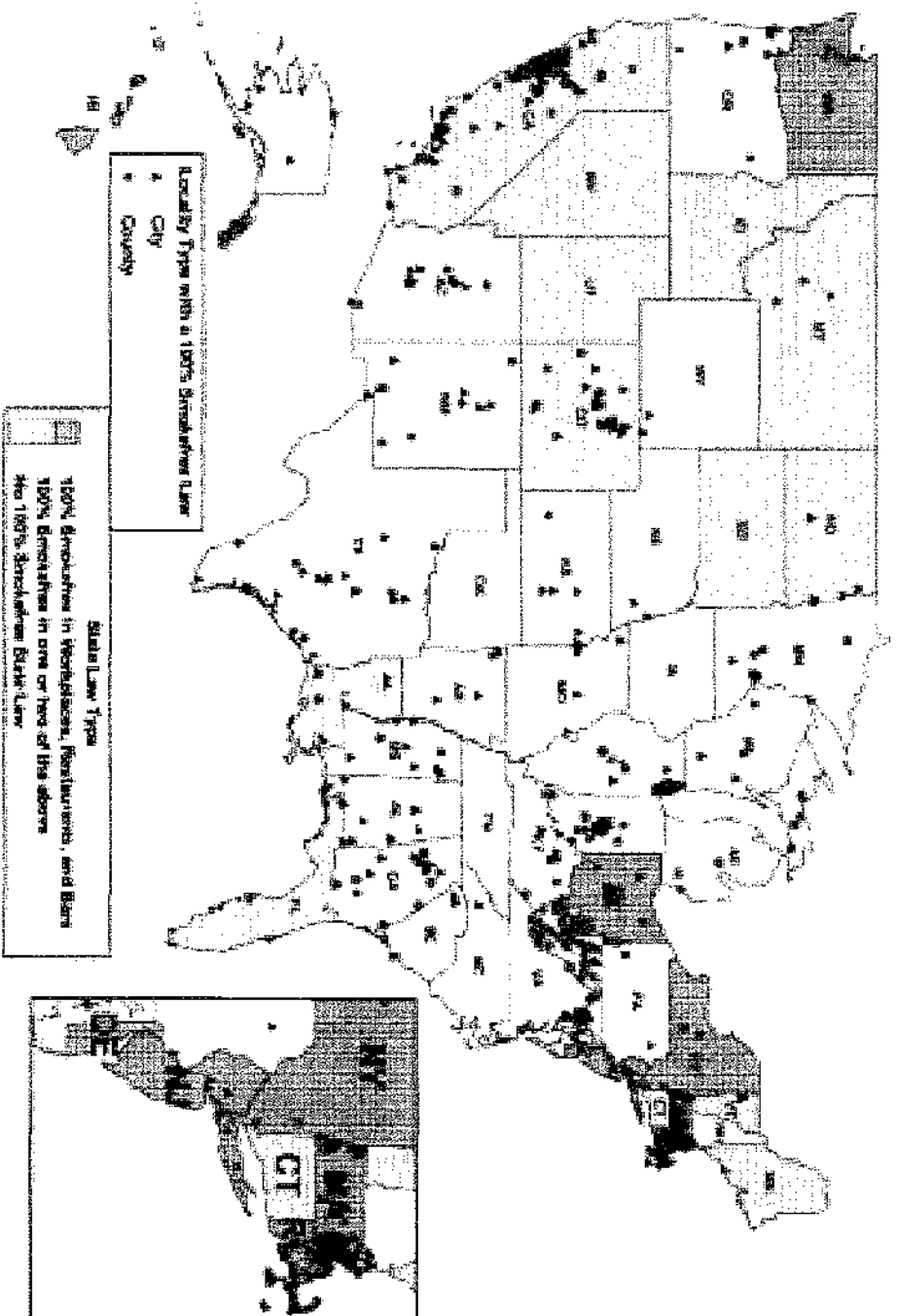
Smoke-Free Air Laws

As of January 2007, 22 states, Washington D.C., Puerto Rico and hundreds of municipalities had implemented or enacted 100 percent smoke-free provisions in workplaces and/or restaurants and/or bars—representing 52.9 percent of the U.S. population.

There is growing evidence that smoking bans and restrictions not only reduce harmful secondhand smoke exposure but also consistently improve revenue streams for bars and restaurants by attracting more business from nonsmokers. And they appear to significantly boost quitting motivation, quit attempts and treatment use.

For instance, quitline calls increased significantly following the implementation of New Zealand's 2004 expanded smoke-free legislation—without any increase in quitline advertising.[26]

Fully seizing these policy "pushes" requires being proactive—getting out ahead of the policy implementation to anticipate and accommodate increases in treatment demand.

For instance, in preparing for January 1, 2008, when Baltimore's new comprehensive smoking ban will take effect, Mayor Sheila Dixon has organized a NRT Initiative through which smokers can qualify for free nicotine patches or gum.

Similarly, several national groups and organizations—the National Tobacco Cessation Collaborative, North American Quitline Consortium, and Campaign for Tobacco-Free Kids—are working to develop policy "playbooks" to guide states/cities that pass smoke-free policies in ways to expand treatment access, capacity and promotion so they can take full advantage of the increase in quitting efforts and demand for treatment.

"There is growing evidence that smoking bans and restrictions not only reduce harmful secondhand smoke exposure but also consistently improve revenue streams for bars and restaurants by attracting more business from nonsmokers."
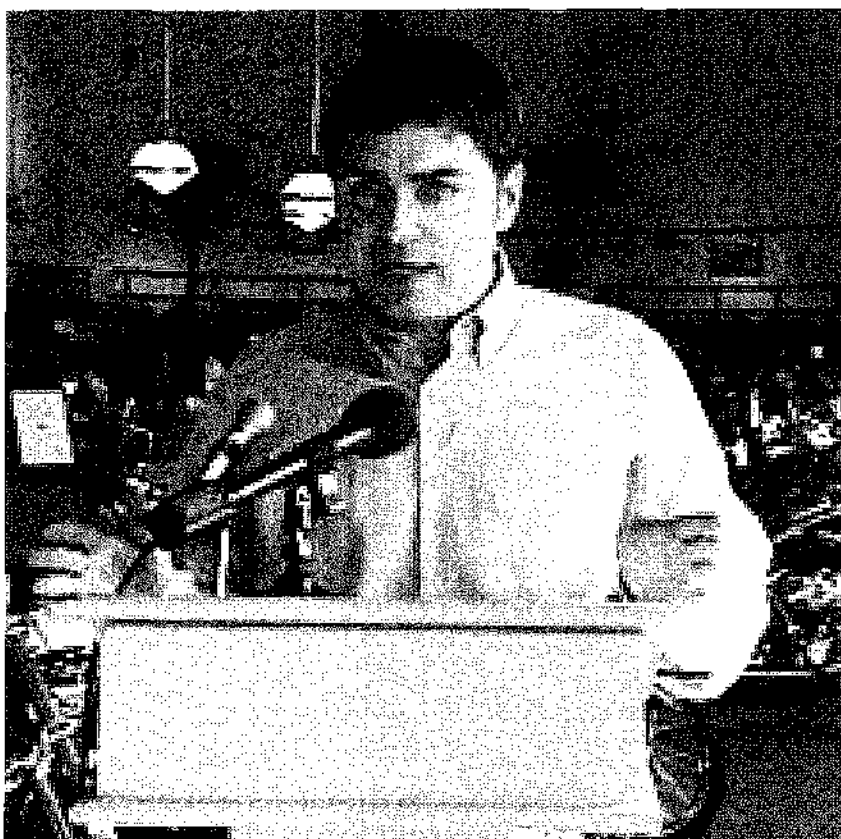
With a new understanding of the business and human tolls of tobacco use from Oregon's "Make it Your Business" campaign, Ed Wallace Jr. decided to invest in tobacco cessation after a mechanic suffered a heart attack while fixing a motorcycle at his Harley dealership.

CLARIFYING AND HEIGHTENING THE INCENTIVES FOR PURCHASERS, HEALTH INSURERS, AND BUSINESSES TO EXPAND TOBACCO CESSATION TREATMENT ACCESS AND COVERAGE

So called "meta-consumers" — health plans, employers and the government — have a tremendous influence on which products and services are offered to smokers and which are covered in part or in full.

Making the business case for tobacco dependence treatment is important. In addition to improving the health of employees, tobacco cessation products and services can improve employee productivity and performance. Good examples discussed at the Consumer Demand Roundtable meetings include:

• Oregon's "Make it Your Business Campaign," led by Dawn Robbins, starts by clarifying the true business costs of tobacco use, including the costs related to reduced smoker productivity. This campaign helped drive the

Public Employees Benefits Board, the state's largest health care purchaser, to offer a barrier-free tobacco cessation benefit.

- Partnership for Prevention, based in Washington, D.C., is developing a Workplace Program Guide as a tool to provide employers with guidance to implement the most effective and cost-effective health promotion interventions. Tobacco use screening and treatment top the list. The Guide will educate employers about the total costs of tobacco use, the total value of tobacco cessation activities (policies and treatments) and their impact on business success.

- Beginning in 1996, the National Committee on Quality Assurance (NCQA) added measures of tobacco cessation advice and assistance to its core HEDIS "report card" for managed care plans, and has promoted the use of these measures in federal (Medicare) pay-for-quality initiatives (e.g., the Doctors Office Quality initiative). Including tobacco cessation treatment metrics in new pay-for-performance initiatives will provide enduring incentives for their delivery.

- Similarly, the CEO Roundtable on Cancer has developed employer guidelines for companies to be Gold Standard-certified. Requirements for promoting healthy lifestyles and cancer prevention include implementing a full indoor and outdoor smoking ban at the workplace, and providing evidence-based counseling and prescription and non-prescription medications for smoking cessation at no cost to employees. The CEO Roundtable on Cancer was convened to support a C-Change initiative, which is focused on demonstrating the value and ultimate cost-savings associated with cancer prevention and early detection services and increasing coverage through employee benefit programs.

- The Healthy Workforce Act of 2007 being proposed by Senator Tom Harkin (D-Iowa) and his staff includes a tax credit of $200.00 per employee to businesses that offer comprehensive health promotion programs, including evidence-based preventive screenings, behavior change programs (including tobacco cessation treatments) and work environment and policy changes. To boost employee participation, companies would be encouraged to offer meaningful incentives, like reduced health insurance premiums.

To encourage businesses to offer cessation coverage, this guide provides information for businesses and government agencies on health insurance coverage for tobacco use treatments.

- America's Health Insurance Plans (AHIP), the advocacy organization for U.S. health plans and insurers, promotes findings from health economists at the Center for Health Research at Kaiser Permanente Northwest. The research shows that the return on investment (ROI) for tobacco cessation services yields savings in as little as two years, and sooner for pregnant smokers. In addition to providing details on the business case, the Web site (http://www.businesscaseroi.org/roi/default.aspx) includes an interactive on-line "ROI calculator" that health plans can use to estimate their own cost savings. [27]

- Many employers cite the lack of information about the cost of cessation benefits as a barrier to coverage. Now that quitlines provide free counseling to smokers across the U.S., their concerns focus increasingly on pharmacotherapy. Marguerite Burns and colleagues examined pharmacotherapy costs

among Wisconsin state employees and found that they averaged only 13-cents per member per month.[?]

- To encourage businesses to offer cessation coverage, the CDC created "Coverage for Tobacco Use Cessation Treatments," a guide that provides information for businesses and government agencies on health insurance coverage for tobacco use treatments. This document explains why insurance coverage for tobacco cessation is important, what treatments are available to help employees, and how to design the treatment benefits. It is available online at www.cdc.gov/tobacco/quit_smoking/cessation/00_pdfs/ReimbursementBrochureFull.pdf.

ALLOCATING MSA BONUS FUNDS FOR TOBACCO CONTROL: A "TWICE IN A LIFETIME" OPPORTUNITY

Unfortunately, less than 4 percent of the original Master Settlement Agreement (MSA) funds awarded to the states have been allocated for tobacco control. However, beginning in 2008, the states that have not securitized their MSA funds will have a second chance as MSA bonus funds become available. In the coming year, efforts to help states allocate sufficient dollars for comprehensive tobacco control from the final 2008-2018 MSA bonus payments represent a critical new policy initiative, and one with enormous potential impact on tobacco cessation treatment access, use and demand. In addition, creating business incentives for corporate investment in publicly funded services, such as quitlines, also holds promise. For more information on the use of MSA funds by states, visit the Campaign for Tobacco-Free Kids' website at http://tobaccofreekids.org/reports/settlements.

"Efforts to help states allocate sufficient dollars for effective comprehensive tobacco control... represent a critical new policy initiative, and one with enormous potential impact on tobacco cessation treatment access, use and demand."

STRATEGY 5: Systematically measuring, tracking, reporting and studying quitting and treatment use—and their drivers and benefits—to identify opportunities and successes

"Having data from longitudinal studies is like having a video tape of the quitting process."

In the United States, tobacco use is monitored via a series of annual cross-sectional surveys. These surveys inform the field about usage trends over time and about patterns of use among various demographic sub-groups in the population.

But they do not explain much about the natural history of quitting among individuals, how smokers quit, or about the treatments that they try and find helpful. The cross-sectional surveys provide snapshots—pictures of the population at one point in time—and do not systematically track quitting efforts, methods and successes.

The single most basic need is to embed more quitting questions in major U.S. tobacco use surveys so that quit attempts, methods and successes can be tracked systematically.

USING A LONGITUDINAL COHORT STUDY OF QUITTING MOTIVATION AND BEHAVIOR, TREATMENT BELIEFS, DEMAND, USE, COST AND BENEFITS AS A TOOL FOR ADVOCACY AND RESEARCH

Having data from longitudinal studies is like having a video tape of the quitting process. Researchers can see what happens to a representative group of people as they cycle in and out of the quitting process.

"I think the new
smoke-free laws are
great! Now I can go
out and not have
that urge to smoke."

Elisabeth
Former smoker
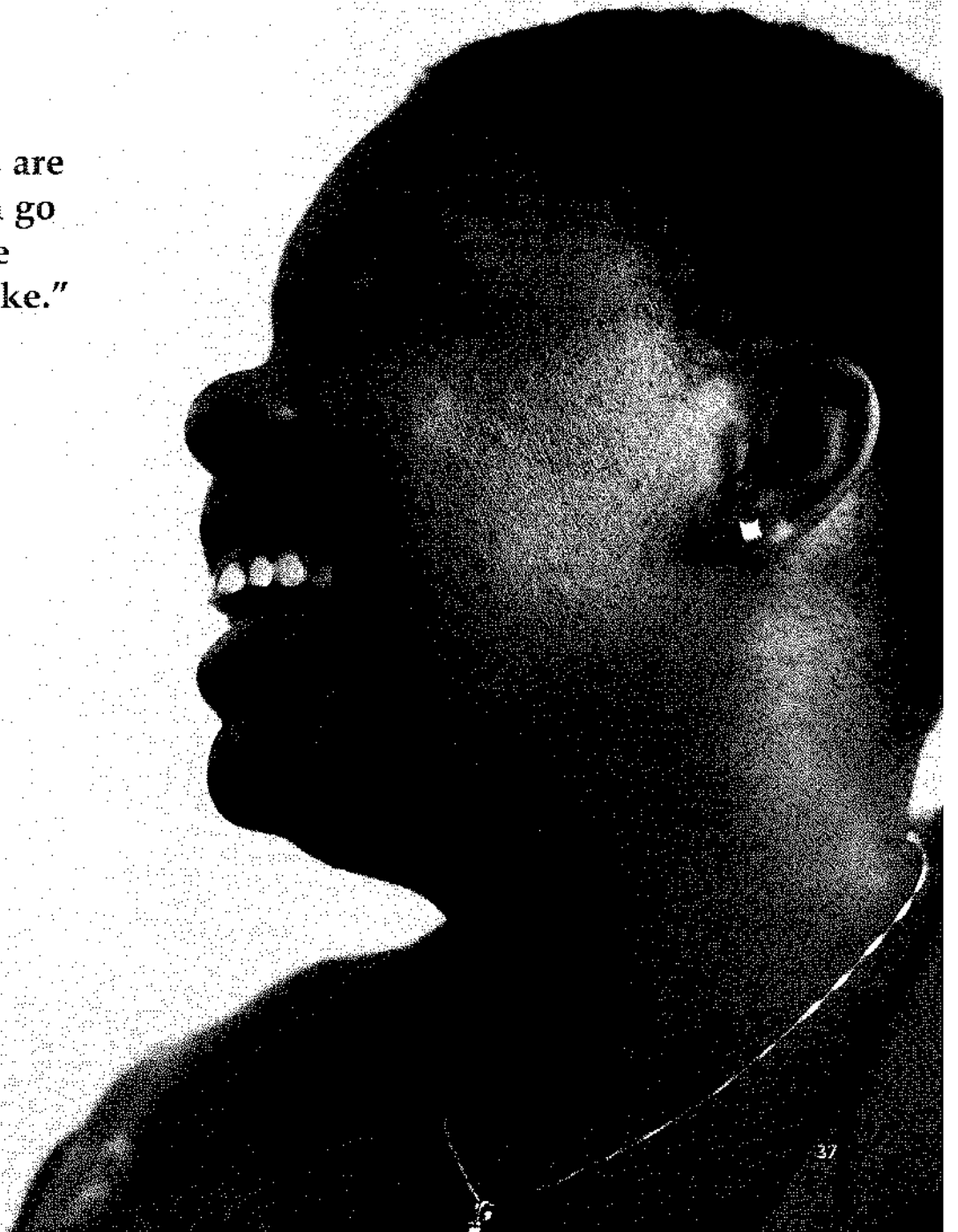
> *"To better help people stop smoking, there is a need to understand more about how people go about quitting in the real world."*

To better help people stop smoking, there is a need to understand more about how people go about quitting in the real world. A two- to three-year longitudinal study would enhance understanding of the processes U.S. smokers use to quit, the choices they make, their successes and predictors of each.

For example, there is a need to better understand what individual- and policy-level factors influence making a quit attempt, the choice of treatment strategies (e.g., Public Health Service-recommended, other treatment strategies and quitting without treatment), and the outcomes that follow the use of each approach.

There is also a need to understand which individual-level factors (e.g., dependence, motivation) can moderate these relationships. Repeating such a study every five years would help to understand if any changes in the process have occurred and, if so, to better

understand factors influencing those changes.

For example, some researchers are concerned that smokers are becoming more resistant to treatment over time. Rolling cohort studies of representative samples of the U.S. population could test this hypothesis.

These studies can also be used to assess how broader tobacco control programming affects quit attempts and the use and efficacy of proven treatments.

Multi-level research could best inform how prices of tobacco products and pharmaceutical treatments, along with the strength of local smoke-free laws and the use of effective counter-advertising strategies, can influence quit attempts and success among attempters. There is also a need to better understand how potential reduced-exposure products (PREPs) might undermine quitting, by reducing

the number of quit attempts and
increasing relapse among those who
try to quit.

FUNDING CONSUMER DEMAND RESEARCH

The NIH State-of-the-Science
Conference Statement on Tobacco Use:
Prevention, Cessation, and Control
meeting on June 12–14, 2006, identi-
fied research to boost consumer
demand for and use of evidence-based
treatments as a top priority. The
written statement prepared by the
Expert Panel issuing recommenda-
tions, based on two days of expert
public testimony and a comprehensive
commissioned evidence review,
included the following as "priority
aims for future research and public
health action": [29]

"I need to quit for my health, but I like smoking. When I quit, I'll use the patch — that will be it."

Pamela
Current smoker
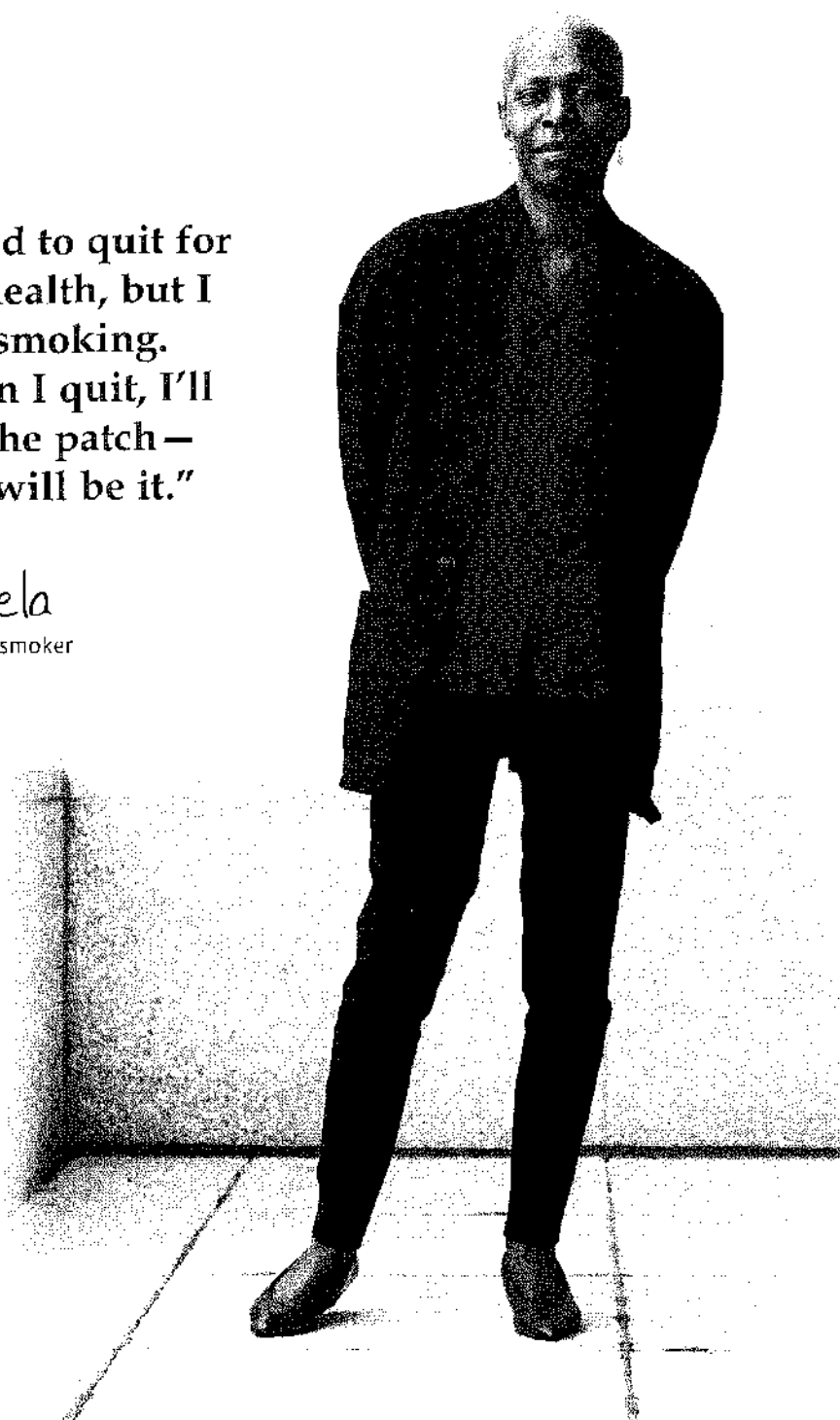
Improve and Implement Effective Interventions

- Understand the role of different media in increasing consumer demand for and use of effective, tobacco cessation treatments for diverse populations.

- Identify and reduce barriers faced by providers, insurers, policymakers and others to implementing effective strategies to increase and sustain demand for smoking cessation treatment.

- Examine the effectiveness of different components of telephone-based counseling programs (e.g., population quitlines vs. provider-associated programs; self-referral vs. provider referral to telephone-based counseling; bundling of services within programs).

- Develop and enhance pharmacologic and non-pharmacologic treatments.

Improve and Implement Effective Policies

- Increase policymakers' and the public's awareness of effective strategies for preventing tobacco use, promoting tobacco cessation, and decreasing harm from environmental tobacco smoke exposure.

- Identify and overcome barriers to implementing comprehensive statewide tobacco control programs, such as those used in California and Florida.

- Develop effective policies for reimbursing health care providers for offering tobacco-cessation interventions.

Develop New Population- and Community-Based Interventions

- Determine the effectiveness of implementing interventions in settings other than schools and health care facilities, such as homes, community organizations, religious institutions, pharmacies, stores, bars, workplaces, military institutions and correctional institutions.

- Determine the effectiveness of incorporating social context (e.g., culture, neighborhoods and social networks) in interventions to prevent or stop tobacco use.

- Evaluate the long-term effects of social marketing strategies on tobacco use, particularly media-based programs to promote cessation and counter tobacco advertising.

- Learn from "natural experiments" that result from implementation of new policies on pricing/taxation, smoke-free environments, or restrictions on the availability of tobacco products.

- Evaluate the effectiveness of public (health care) performance measures (e.g., publicly reported quality-of-care report cards) and financial incentives for increasing smoking cessation.

Infrastructure

- Promote surveillance programs that track tobacco use (e.g., initiation, quitting, intensity of smoking, use of smokeless tobacco); use of treatment; motivation to quit; new products; and marketing, policy and systems changes.

- Educate providers, including physicians, dentists, nurses and allied health professionals about the importance of tobacco-related diseases and the availability and delivery of effective interventions.

STRATEGY 6: Combining and integrating as many of these strategies as possible for maximum impact

"The best way to build consumer demand for tobacco cessation products and services is to combine and integrate as many of these strategies as possible."

The best way to build consumer demand for tobacco cessation products and services is to combine and integrate as many of these strategies as possible. When this has been achieved, real "breakthroughs" in treatment demand, delivery, reach and use have occurred, leading to substantial reductions in population-level smoking prevalence.

### ALIGNING MULTIPLE POLICY AND TREATMENT STRATEGIES: THE NEW YORK CITY EXAMPLE

New York City (NYC) provides proof that a comprehensive tobacco control plan can substantially reduce adult smoking prevalence. NYC's efforts made it harder to smoke and easier to quit. Key elements included:

1. Implementing a 2002 baseline survey to assess adult smoking and quitting at the neighborhood level and identify high-risk populations.

2. Increasing state and city tobacco taxes by a total of $1.81 in 2002.

3. Disseminating cessation-treatment recommendations to NYC's 60,000 medical providers in 2002-2003.

4. Implementing media campaigns in conjunction with the American Legacy Foundation to increase awareness of secondhand smoke risks and to promote quitting in 2003—with special targeting to high-risk populations and neighborhoods.

5. Enacting a Smoke-Free Air Act in 2002 requiring 100 percent smoker-free workplaces, restaurants and bars.

6. Promoting and launching a large quitline-based NRT give-away program in collaboration with the Roswell Park Cancer Institute in April/May 2003 — providing free six-week nicotine patch supplies with brief quitline counseling to the first 35,000 eligible adult smokers to call the State Smoker's Quitline.

7. Conducting city-wide assessments of program impact on smokers and city-wide NRT sales. [30]

The impact was immediate and dramatic:

- Over 400,000 smokers called the state quitline within the first few days of the cessation program launch.
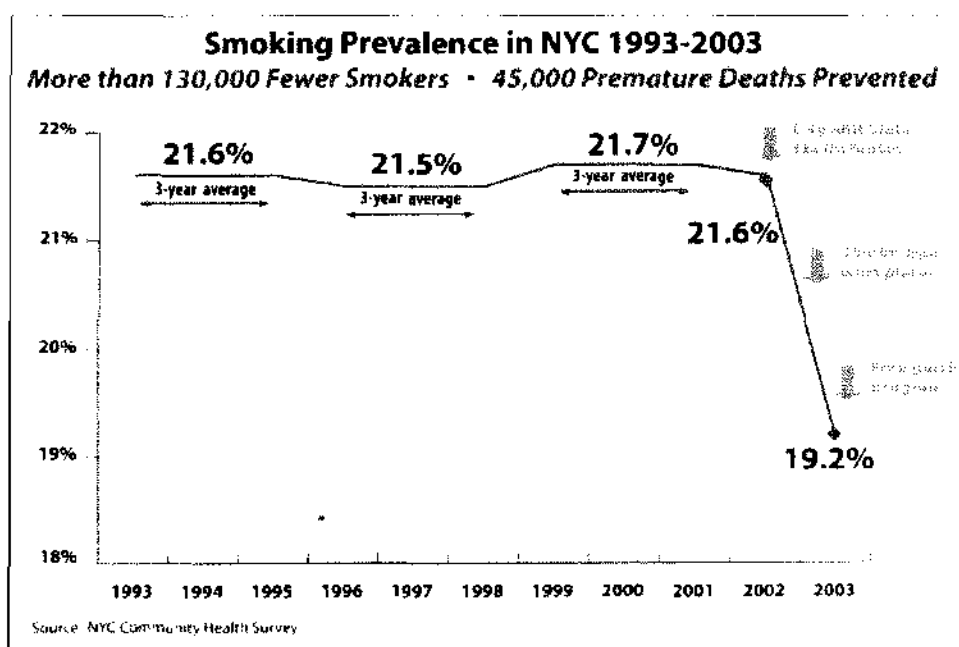
Smoking Prevalence in NYC 1993-2003
More than 130,000 Fewer Smokers · 45,000 Premature Deaths Prevented

From 2002 to 2003, the percent of adult New Yorkers who smoke declined from 21.6 percent to 19.2 percent — the fastest drop in smoking prevalence ever recorded.

Dr. Thomas Frieden, Commissioner of the NYC Department of Health and Mental Hygiene

- 35,000 New Yorkers received free six-week supplies of nicotine patches with an over-representation of smokers who were non-white, foreign-born or residing in low-income neighborhoods — 11,000 of whom are now ex-smokers. [31]

- City-wide nicotine patch sales increased 31 percent in the same week the free patch program was launched.

- From 2002 to 2003, the percent of adult New Yorkers who smoke declined from 21.6 percent to 19.2 percent, an 11 percent decrease — the fastest drop in smoking prevalence ever recorded nationally.

- This decline continued in 2004, when 18.4 percent of New Yorkers reported smoking — a 15 percent decrease from 2002. [32]

- As a result, by 2005, there were 200,000 fewer smokers and 60,000 premature deaths averted. [32]

According to Thomas R. Frieden, Commissioner of the NYC Department of Health and Mental Hygiene and chief architect of NYC's comprehensive two-year plan, "Fewer New Yorkers are smoking today than at any point in at least 50 years. Most smokers want to quit and, for the first time ever, there are more former smokers than there are smokers in New York City." [33]

Michael Fiore, nationally recognized expert on smoking cessation and Chair of the Interagency Committee on Smoking and Health, which released the 2004 National Cessation Action Plan that included many of the same elements combined so successfully in NYC, has declared the city's success a model for other states and communities and for the nation.

It was the National Cessation Action Plan that led to the organization of the national state quitline network, which now includes quitlines in all 50 states, the District of Columbia and Puerto Rico—providing unprecedented access to free cessation counseling for all U.S. smokers.

"New York City has done all the right things—reducing exposure to secondhand smoke, increasing the excise tax, and helping current smokers quit. As a result, rates of smoking have declined and needless illness and death has been prevented. New York City is a model for what we need to do across America," Fiore stated. [30]

In fact, there is important potential for replicating this model through:

- Continued efforts to seek funding to implement additional components of the national cessation action plan (e.g., provider education, free medication, strategic cessation research and surveillance). [18]

- Efforts launched by NTCC and Consumer Demand Roundtable members and participants to develop "playbooks" that will prepare states and communities to harness multi-strategy policy changes in a proactive way, to build consumer treatment demand and use.

Danny McGoldrick, director of research for the Center for Tobacco-Free Kids, notes that there are at least five states in which a "trifecta" of state issues (sales tax, smokefree laws and funding for prevention and cessation programs) is being actively proposed and considered by governors and state legislatures in the year 2007 — including Wisconsin, Oregon, New Mexico, Iowa and Maryland.

ALIGNING MULTIPLE HEALTHCARE POLICY AND SYSTEMS CHANGES: HEALTH PLAN EXAMPLES

Federal, state and community policy and environmental changes (e.g., clean indoor air laws, tobacco tax increases, treatment coverage expansions, counter-advertising and cessation media campaigns) provide powerful motivation, incentives and support for quitting at the population level.

Similar policy and environmental supports can be harnessed at the health plan or provider organization level (e.g., coverage expansions; computerized reminder systems and communication campaigns aimed at providers and patients; pay-for-performance incentives to reward HEDIS report-card scores for tobacco use screening and intervention).

Several leading health plans have implemented these kinds of health care systems and policy changes to achieve breakthroughs in the proportion of their enrollees who are screened and treated for tobacco use and dependence. These plans have drawn on internal and external quitting resources to increase treatment delivery and

"The New York City experience and the health plan examples show what is achievable by combining and integrating multiple strategies that build consumer demand."

reduce the burden on busy office staff. In some cases, plans worked to promote effective state tobacco control policies (tax increases, smoke free airs laws), and created systems to prompt, monitor and improve their progress. For example:

- Over a 10-year period, a smoking cessation initiative at Group Health Cooperative in Seattle reduced the prevalence of adult smoking from 25 percent to 15 percent, 5 percentage points below the Washington state average. [33, 34, 35]

- Kaiser Permanente of Northern California achieved enrollee adult tobacco use rates of 12 percent, the 2010 national prevalence goal and 4.5 percent lower than California's 16.5 percent smoking prevalence, by identifying smokers and referring them to effective health plan and external quitting programs. [35]

- Two federally qualified health centers serving predominantly low-income African-American smokers used participatory approaches to change multiple systems of care. [36] Within two years, provider quit advice and offers of cessation assistance reached impressive levels of 80 percent and 64 percent, respectively.

These case studies show what could be achieved by aligning health care systems and policy changes in health plans and provider organizations across the country. One of the unexpected benefits is that smokers who are offered help to quit report higher satisfaction with their overall care. [37]

The New York City experience and the health plan examples show what is achievable by combining and integrating multiple strategies that build consumer demand.

MAKE VARIED CESSATION TREATMENTS AND MODALITIES AVAILABLE IN A SEAMLESS SYSTEM OF CARE

All of the examples above involved taking a "systems approach" in making a range of proven cessation treatments accessible and freely available in a coordinated system of care management. This is the approach recommended by Consumer Demand Roundtable members David Abrams, director of the NIH Office of Behavioral and Social Sciences Research, and Amanda Graham. They point to the need for "second-generation" delivery systems that integrate multiple treatment modalities (e.g., telephone, web-based, face-to-face counseling, medication support, physician brief counseling, etc.) into a seamless system of support and assistance that can be tailored to meet the needs of various consumers throughout their quitting journey. Such systems allow for flexible self-tailoring and can harness the power of supportive tobacco control policies.

Many efforts are starting to take this approach:

- The North American Quitline Consortium reports that state quitlines are increasingly establishing links to and from physician offices (via fax referrals), directly dispensing NRT to eligible quitters, and connecting callers to integrated Web sites for 24/7 support.

- EX, a new cessation program developed by the American Legacy Foundation, provides smokers who want to quit with the information and resources they need to be successful. This multi-component program is designed to work in partnership with existing state and local organizations. EX employs media campaigns that drives smokers to 1-800-QUIT-NOW telephone counseling services (which can link callers to local providers and clinics for face-to-face counseling) and to the BecomeAnEX.org website for further information and assistance in developing a personalized quit plan. EX messaging focuses on building smoker confidence before they begin the quit process both via advertising and online exercises. The program is pilot-testing in multiple markets in early 2007 and — based on evaluation results — could launch nationally in late 2007 or early 2008 with the backing of an alliance of public and private partners. In preparation for a national launch, Legacy is currently developing EX materials for Latino and low-literacy populations.

Conclusion

Increasing interest in, demand for and use of proven tobacco cessation products and services represents an extraordinary opportunity to reduce adult tobacco use — the nation's largest cause of preventable death and disease, and a major source of burden in U.S. healthcare.

Providing more smokers with tobacco cessation products and services that they find both appealing and effective could lead to a significant increase in the nation's overall quit rate. But it is a challenge that will require bold thinking; innovation; comprehensive, integrated changes in policy and practice; and innovations that result from taking a "consumer perspective."

Use the checklist to see if you and your organization are doing all you can to build demand for cessation products and services.

CONSUMER DEMAND CHECKLIST

Are you and your organization:

Viewing smokers as consumers and taking a fresh look at quitting from their perspective?

- Developing a better understanding of quitters' preferences and needs?
- Focusing on the "consumer experience"?
- Understanding the quitting journey and engaging smokers all along the way?

Redesigning evidence-based products and services to better meet consumers' needs and wants?

- Using consumer-centered design principles?
- Ensuring products and services materials follow health literacy principles?

Marketing and promoting cessation products and services in ways that reach smokers—especially underserved smokers— where they are?

- Engaging smokers in new ways and in new places?
- Telling stories instead of simply sharing facts and information?
- Using evidence-based promotion principles to help guide the development and targeting of smoking cessation campaigns?
- Using new forms of marketing to reach smokers?
- Correcting the misperceptions about nicotine and nicotine replacement therapies (NRT)?

Seizing policy changes as opportunities for "breakthrough" increases in treatment use and quit rates?

- Stimulating and harnessing the treatment demand that is generated by tobacco control policy changes?
- Clarifying and heightening the incentives for purchasers, health insurers, and businesses to expand tobacco cessation treatment access and coverage?
- Allocating new MSA "bonus funds" for tobacco control?

Systematically measuring, tracking, reporting, and studying quitting and treatment use — and their drivers and benefits — to identify opportunities and successes?

- Using a longitudinal cohort study of quitting motivation and behavior, treatment beliefs, demand, use, cost and benefits as a tool for advocacy and research?
- Funding consumer demand research?

Combining and integrating as many of these strategies as possible for maximum impact?

- Aligning multiple policy and treatment strategies, such as New York City officials did?
- Aligning multiple healthcare policy and systems changes, such as some health plans have done effectively?
- Making varied cessation treatments and modalities available in a seamless system of care?

To participate in the Consumer Demand and NTCC activities described in this document, please contact Todd Phillips of AED at 202-884-8313 or at tphillip@aed.org.

For more information about NTCC, please visit www.tobacco-cessation.org.
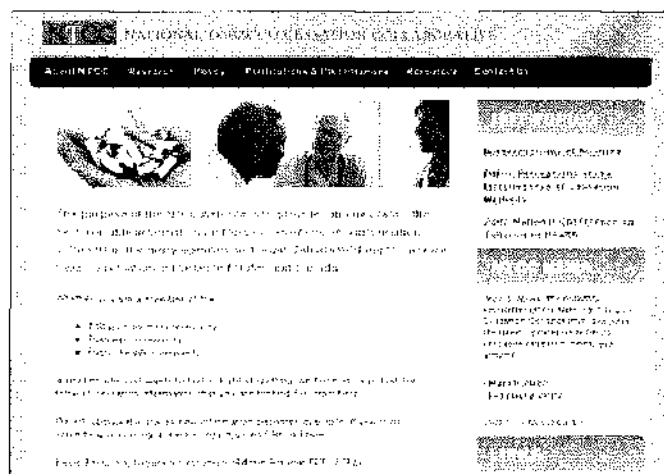
The NTCC web site provides the best available information on tobacco cessation from the many agencies and organizations working to increase tobacco cessation

Other Participants:

Cathy Backinger, Ph.D., M.P.H.
National Cancer Institute

Dianne Barker, M.H.S.
Public Health Institute

Peter Coughlan, Ph.D.
IDEO

Bill Furmanski
American Legacy Foundation

Gary Giovino, Ph.D.
Roswell Park Cancer Institute

Corinne Husten, M.D., M.P.H.
Centers for Disease Control and Prevention

Patricia Mabry, Ph.D.
National Institutes of Health

Ann Malarcher, Ph.D.
Centers for Disease Control and Prevention

Renee McPhatter
American Cancer Society

Adin Miller, M.P.A.
American Legacy Foundation

Marjorie Paloma, M.P.H.
The Robert Wood Johnson Foundation

John Pinney
Pinney Associates, Inc.

Connie Revell, M.A.
Smoking Cessation Leadership Center

Donna Vallone, Ph.D.
American Legacy Foundation

Brad Wible, Ph.D.
National Institutes of Health

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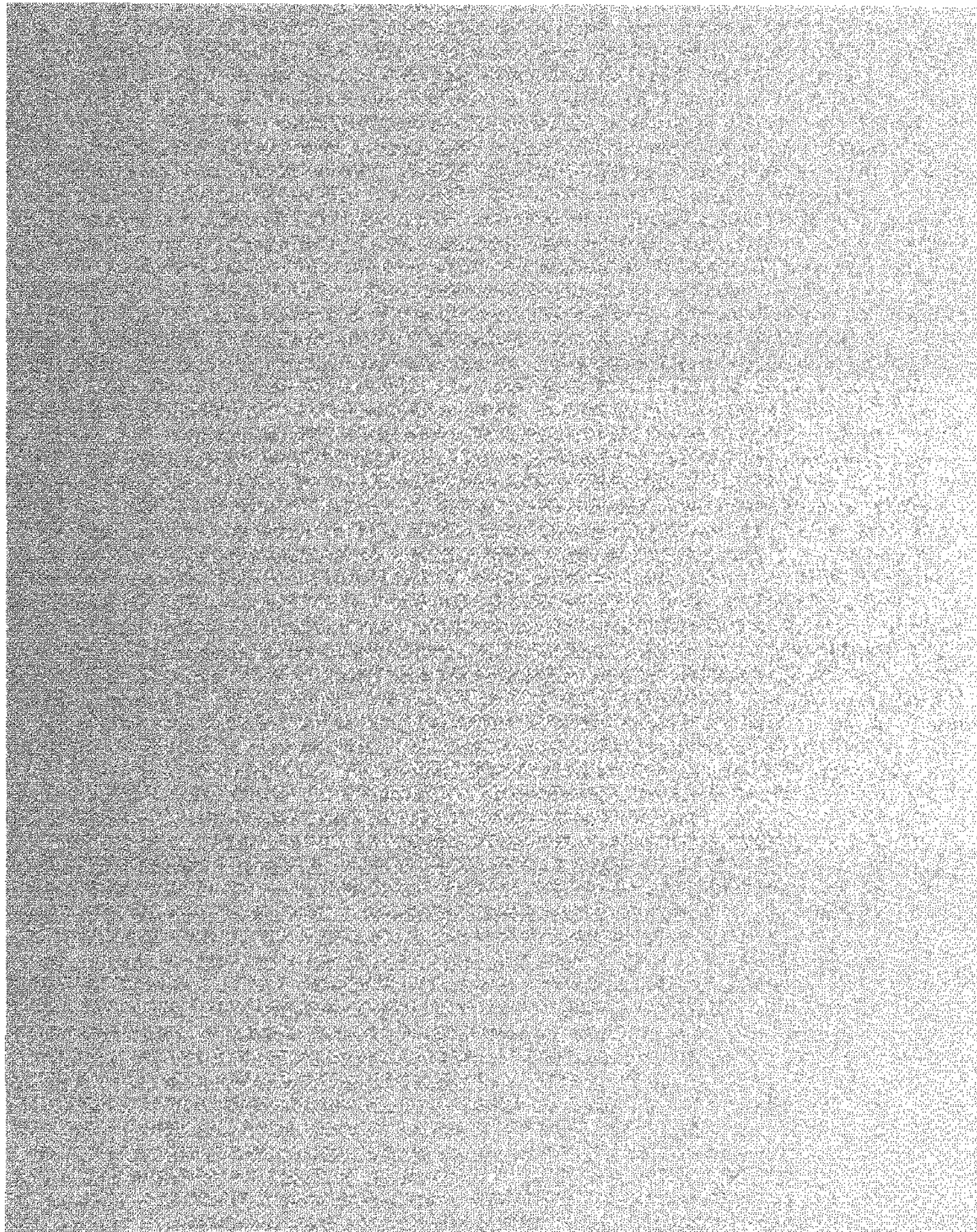
November 7, 2013 NJOY-OMB Meeting

Agenda

- Urgent need for addressing nation's leading public health problem

- Promise for e-cigarettes to meet this need

- Value of appropriate regulation

- Risk of inappropriate regulation

1

The NJOY Team

- Craig Weiss, CEO
- Jeffrey Weiss, General Counsel
- Dr. Richard Carmona, 17th Surgeon General, Director at NJOY
- Josh Rabinowitz, Princeton Professor, Cancer Researcher, Chief Scientist at NJOY
- David Graham, SVP Regulatory Affairs, 21 years of NRT experience

Smoking is this country's largest public health problem, and solving it represents the single most effective way to reduce health care costs

- **Deaths**
    - 440,000 annually (CDC)
- **Lost Productivity from Mortality**
    - $118 billion in annual lost productivity (CDC)
- **Lost Productivity From Morbidity**
    - 2.5 days of work each year missed for smoking-related health reasons (Gallup 9/13)
- **Health Care Costs**
    - $117 billion in total annual smoking-related health care expenses (CDC)
    - $85.4 billion in costs to taxpayers annually (CTFK)
    - $3.2 billion in Social Security payments to children of deceased smokers (CTFK)
    - $2,165 in excess health care costs to employers per smoking employee (Berman et al., *Tobacco Control* 6/13)

All dollar amounts adjusted to 2012 USD

Are e-cigs part of the problem, or part of the solution?

Everything flows from the answer to this question

E-cigarettes are a desperately needed new approach to stopping tobacco smoking

- Standard therapies not effective enough (93% revert to cigarettes within 6 mos)
- Percentage of smokers steady at 20% of adults
- E-cigarettes hold the potential to match the
  - Visual, motor, and psychological features of cigarettes
  - Style of nicotine delivery

  But with **no known toxic byproducts**
- Peer-reviewed study reported steady decrease in tobacco cigarette use among dual users, with 46% not smoking tobacco at 1 yr (Etter & Bullen 2013)
- If we are serious about reducing spiraling health care costs, there is no better way to have a dramatic and near term impact than fostering e-cigarette use
- The endgame is to make tobacco cigarettes obsolete

A tenet of behaviour change is that it is much easier to substitute a similar behaviour than to extinguish an entrenched habit

E-cigarettes are already having a positive effect

Wells Fargo: Consumption of e-cigs may overtake traditional cigarettes in the next decade. And they'll only evolve and improve as time goes forward.

Morgan Stanley: E-cigs will take the place of around 1.5 billion cigarettes this year, up 150% from last year.

Goldman Sachs: E-cigs could accelerate the decline of cigarette consumption
- "We see growth in e-cigs coming at the expense of conventional cigarettes"
- Cigarette volume decline could accelerate
    from 3.5% in the past three years
    to 4.5-5.5% in the next several years

"There are two products competing for smokers' business. One kills half the users, the other one is at least an order of magnitude safer. It makes little sense to try to cripple the safer one so the deadly one maintains the market monopoly."—Prof. Peter Hajek, Wolfson Institute

Reports concerning youth and e-cigarettes need to be viewed in perspective

Reports from a recent CDC survey have heightened concerns re e-cigarettes and youth.
 	
However,
 	
• 16% of high school age students smoke tobacco cigarettes
• Most of those who had tried an e-cigarette had already smoked a conventional cigarette (91%)
• Only a small minority (0.61%) of students who had never smoked a conventional cigarette have ever tried an e-cigarette
    – There is no evidence that any of these students did or will go on to smoke a tobacco cigarette
    – We don't know how many of these students would have gone on to initiate with a tobacco cigarette **BUT DID NOT** due to the existence of electronic cigarettes
	A scientific perspective from at an October 29, 2013 meeting of **American Association for Cancer Research:**
	
	Researchers surveyed 1,300 college students about their tobacco and nicotine use.
	
	• Only 3% of students said their first nicotine product was an e-cigarette.
	• Of that group, only one person (0.07%) went on to smoke regular cigarettes.
	• The vast majority who started with e-cigarettes said they weren't currently using any nicotine or tobacco.
	
	"It didn't seem as though it really proved to be a gateway to anything," said study author Theodore Wagener (U of Oklahoma).

NJOY actively works to prevent the sale, advertising, and sampling by minors 9

NJOY supports appropriate regulation of e-cigarettes

✓ Product registration
✓ Ingredients listing
✓ User fees
✓ Facility registration & inspections
✓ Reporting requirements for nicotine content and harmful and potentially harmful constituents (HPHCs)
✓ Reporting of unexpected and serious adverse events
✓ Minimum age requirement for purchase and sampling including requiring ID check
✓ Warning label reflecting established science on the risks of nicotine use
✓ Standards (but no ban) for advertising including on TV

Regulation must, however, allow for:

1. Continued innovation

2. Advertising & promotion, including TV, sponsorships, and sampling, with appropriate standards

3. Visibility and accessibility at point of sale

NJOY opposes any proposed regulations that:

☐ Force existing electronic cigarettes off the market by subjecting them to the same February 2007 grandfather date as tobacco cigarettes

☐ Prevent effective innovation by subjecting electronic cigarettes to the same pre-market approval requirements as tobacco cigarettes

☐ Prohibit the effective advertising of electronic cigarettes, including on television

☐ Force electronic cigarettes to the back counter of stores, where Big Tobacco has an effective monopoly

☐ Prohibit sampling of electronic cigarettes to age-verified adults

Proposed regulations alone can cause harm

- There may be a temptation to issue aggressive proposed regulations, with the idea of paring those back after the comment process
- However, proposed regulations could have immediate and devastating impact even if never approved, e.g.,
  - Proposed advertising restrictions equate to *de facto* TV ban
  - Proposed point of sale restrictions (e.g., back counter restrictions) equates to immediate and enduring loss of customers

Restricting e-cigarettes sales to behind the counter would entrench Big Tobacco dominance
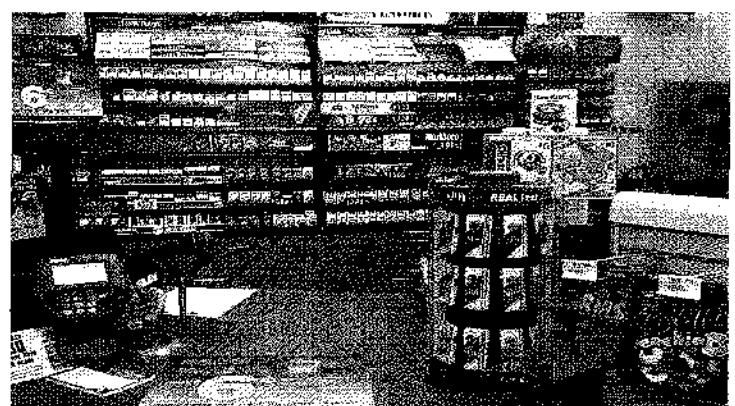
OMB Mandate:
- *"... least burden on society, including individuals, businesses of differing sizes"*
- *Consideration of alternatives*

High probability of immediate retailer restrictions even if only proposed in rule

◆ <u>On or in front of counter (APPROPRIATE)</u>
- Consumers able to assess the product before purchase
- Consumers who are trying to switch should not be forced to look at a wall of tobacco cigarettes every time they make a purchase decision

◆ <u>Behind the Counter (UNACCEPTABLE)</u>
- Inappropriate pairing with combustion cigarettes
- Extremely high entry barrier for a new product category
- Tobacco Industry power and ownership of the 'back wall'
- E-cigs only a niche competitor to tobacco cigs
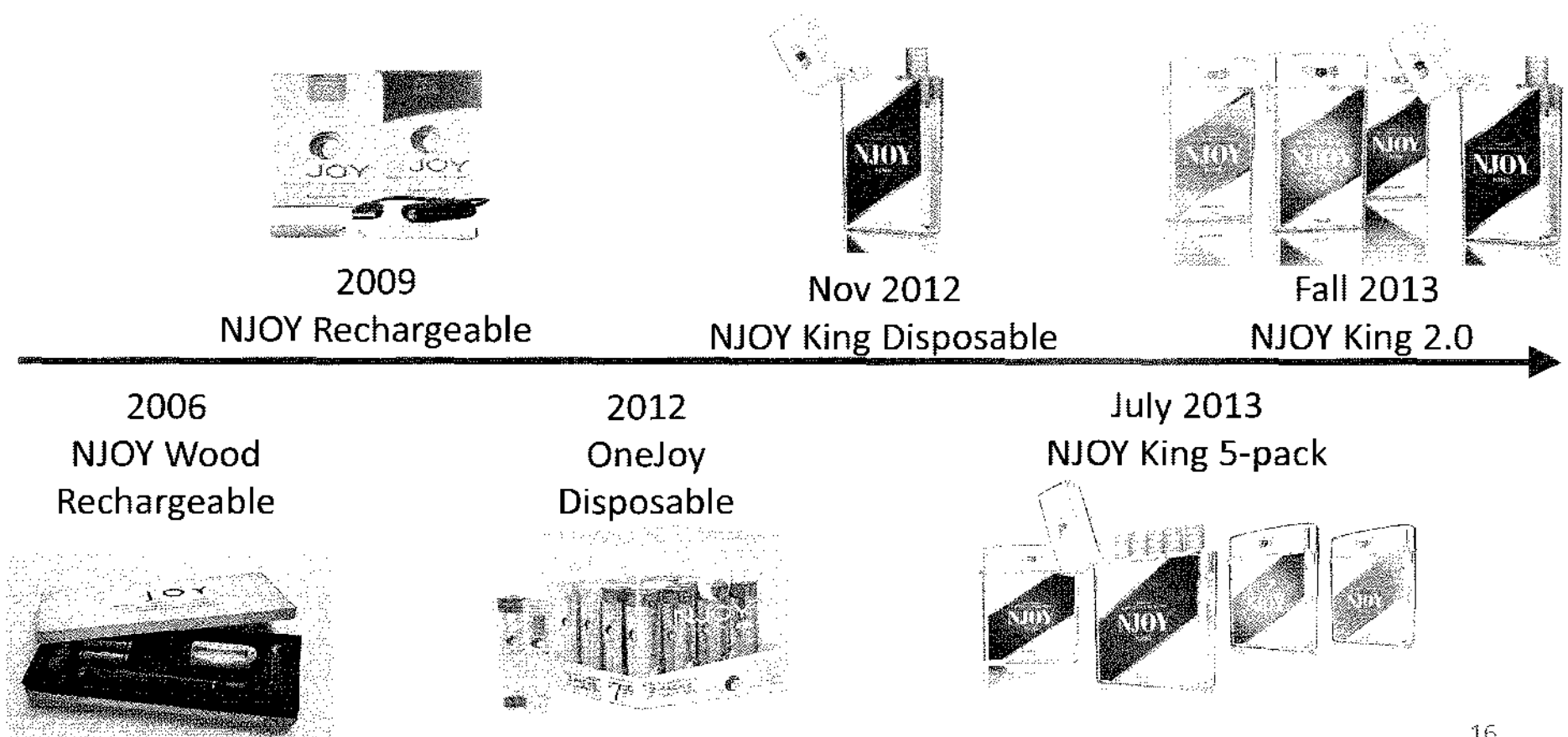- **Revolutionary health benefits lost**

Appropriate regulation should foster e-cigarette innovation

- Cigarettes have been marketed for ~ 400 years. In contrast, electronic cigarettes were invented only 10 years ago.

- While current e-cigarettes are already reducing smoking, they do not yet meet the needs of most smokers, though that is changing rapidly. Innovation is required to produce more effective products that will convert more smokers.

- Successful innovation will obsolete tobacco cigarettes, saving millions of lives and hundreds of billions of U.S. healthcare costs.

A case study in innovation

2009
NJOY Rechargeable

Nov 2012
NJOY King Disposable

Fall 2013
NJOY King 2.0

2006
NJOY Wood
Rechargeable

2012
OneJoy
Disposable

July 2013
NJOY King 5-pack

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Appropriate regulation should encourage not constrain e-cigarette innovation

Speed of innovation is not just a theory, but a reality of continuous product improvements

Application of pre-market approval would

- have a chilling effect on innovation
- freeze current options
- delay consumer access to better products more able to compete with conventional cigarettes and thus save lives
- support the status quo, playing into the hands of Big Tobacco

E-cigarettes should not be held to the same standards as indisputably more dangerous combustion cigarettes.

National Tobacco Cessation Collaborative

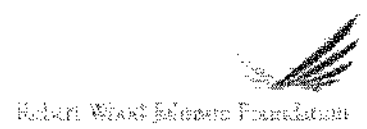"Why not take a page from the book of the tobacco industry when it comes to going where smokers are...'

National Tobacco Cessation Collaborative

- Formed in June 2005 to improve the public's health by increasing successful cessation among tobacco users in the U.S. and Canada. Collaborative members include **CDC, NCI, Legacy Foundation, NIDA, American Cancer Society.**

- 2007 report: "44.5 million Americans smoke, and **there is no better way to improve the nation's health and reduce health disparities than to help these smokers quit."**

- "A higher quit rate would create huge benefits for our nation's health, healthcare system and productivity . . . ."

- "Increasing demand for tobacco cessation products and services represents an extraordinary opportunity. But it is a challenge that will require **bold thinking, innovation, changes in practices and new approaches** that start with the consumer perspective."

National Tobacco Cessation Collaborative on **Nicotine**

- "Nicotine and NRT do not cause cancer"
- "Using NRT is not trading one nicotine addiction for another because the likelihood of long-term dependence to NRT is very low and NRT products are much safer than cigarettes."
- "Nicotine does not cause tobacco-related diseases; rather it is the toxins found in cigarettes, and not the nicotine, that causes the negative health effects."

National Tobacco Cessation Collaborative on
Television Advertising of Cigarette Alternatives

- "Compared to cigarettes, cessation products/services are not widely promoted."
- "Why not take a page from the book of the tobacco industry when it comes to going where smokers are to offer cessation products."
- "NASCAR fans are a large audience (75 million in the U.S.) that is disproportionately likely to smoke."
- "[GSK's] NASCAR program has been found effective in raising awareness of GSK's cessation brands and increasing product sales in NASCAR-themed displays."

Photo illustrating effective advertising of cigarette alternatives as shown in 2007 National Tobacco Cessation Collaborative report

To be clear
Electronic Cigarettes Are Not Cessation Devices

- Patches and gums promote cessation, but with very modest success (7% at 6 months)

- Electronic cigarettes provide a safer alternative to combustion smoking that appeals to smokers in a revolutionary new way – and the scientific evidence is mounting that they are far more effective

- The traditional pharmaceutical approach is not going to solve this problem – there are folks who want to "smoke" and are not looking for "therapy," but their desire to smoke shouldn't cost them their lives or the health care system billions of dollars

Television advertising is critical for cost effectiveness in competing with conventional cigarettes

WAY FORWARD

➢ SENSIBLE RESTRICTIONS ON ADVERTISING
Would define appropriate advertising standards, not ban TV ads irrespective of the message
  ✓ Run ads subject to accepted restrictions for other adult products (e.g., alcohol)
  ✓ Not depict anyone < 28 years
  ✓ Display disclaimer that this product is for adults (> 18 years)
  ✓ Avoid using images that appeal to youth e.g. cartoons
 	
➢ E-CIG TV ADS CAN BE PART OF THE SOLUTION & PROMOTE AN ANTI-SMOKING MESSAGE
    ➢ *e.g New NJOY Campaign*

A complete ban on television advertising is not justified

- TV advertising is foundational in building awareness and a highly cost effective medium to reach large national audience
- FDCA Section 906(d)(1) authorizes FDA to issue advertising and promotion regulations if "appropriate for the protection of public health"
- This public health standard requires an assessment of the "risks and benefits to the population as a whole, including users and nonusers of the tobacco product," taking into account the likelihood of cessation and initiation of tobacco usage
- Any advertising and promotion restrictions for e-cigarettes must meet this standard, which requires the support of data and science
- Where are the data and science?

The data and science are simply not there to make the public health finding

- "And right now, we have far more questions than answers." Mitch Zeller, Director, Center for Tobacco Products (Diane Rehm Show, 8/5/13)

- "As Mitch [Zeller] said, we have more questions than answers right now with e-cigarettes." Thomas Glynn, American Cancer Society (Diane Rehm Show, 8/5/13)

Summary

- E-cigs are a grass-roots movement towards reduced smoking harm and better public health

- E-cig product innovation is needed to meet smokers needs

- Marketing (TV, point-of-sale, sampling) is essential to reaching smokers and getting them to make the switch

- Appropriate regulation will ensure e-cig quality, limit youth access, and prevent inappropriate marketing

- The outcome will be millions of Americans lives and trillions in health care costs saved over the next decade

Questions?