

## Review

## Surveillance Methods for Identifying, Characterizing, and Monitoring Tobacco Products: Potential Reduced Exposure Products as an Example

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## Abstract

Tobacco products are widely sold and marketed, yet integrated data systems for identifying, tracking, and characterizing products are lacking. Tobacco manufacturers recently have developed potential reduced exposure products (PREP) with implied or explicit health claims. Currently, a systematic approach for identifying, defining, and evaluating PREPs sold at the local, state, or national levels in the United States has not been developed. Identifying, characterizing, and monitoring new tobacco products could be greatly enhanced with a responsive surveillance system.

This article critically reviews available surveillance data sources for identifying and tracking tobacco products, including PREPs, evaluating strengths and weaknesses of potential data sources in light of their reliability and validity. With the absence of regulations mandating disclosure of product-specific information, it is likely that public health officials will need to rely on a variety of imperfect data sources to help identify, characterize, and monitor tobacco products, including PREPs. (Cancer Epidemiol Biomarkers Prev 2009;18(12):3334–48)

## Introduction

Surveillance is “[c]ontinuous analysis, interpretation, and feedback of systematically collected data, generally using methods distinguished by their practicality, uniformity, and rapidity rather than by accuracy or completeness” (1). In tobacco control, surveillance efforts traditionally have focused on the prevalence of smoking, quitting rates, and numbers of cigarettes smoked (2–4). The tobacco control community in the United States has placed less emphasis on surveillance of tobacco products themselves, with the possible exception of brand share or preference (5–11). Indeed, tar and nicotine emissions, the traditional method of product surveillance, is regarded by the public health community as an inadequate and misleading way to characterize products (12–16). The dearth of objective data about products creates challenges for ongoing tobacco control efforts. The lack of adequate product surveil-

lance was manifested most dramatically in the late 1970s and 1980s, when systematic testing of tar and nicotine emissions was conducted without adequate scientific understanding of the effect of cigarette design and smoking behavior on measurements (15).

**Potential Reduced Exposure Products.** In the 1990s, tobacco manufacturers began introducing new and modified tobacco products with explicit or implicit claims of health benefits compared to regular cigarettes (17, 18). Among these have been cigarette-like products such as Accord, Premier, and Eclipse (which purportedly heat rather than burn tobacco); modified cigarettes such as Quest, Advance, Omni, and Marlboro Ultrasmooth; and smokeless tobacco products such as Ariva and Revel. A 2001 Institute of Medicine report (17) concluded that although data suggest that reducing risk of disease by reducing tobacco toxicant exposure is feasible, no current products have been sufficiently evaluated to show risk reduction. The Institute of Medicine developed the acronym PREP (potential reduced exposure products) to describe the class of products, and proposed a research agenda to investigate their exposure- and harm-reduction potential. They also noted the potential for PREPs to have adverse effects, both at the individual and at the population levels, by delaying quitting or fostering the resumption of tobacco use among former smokers. Additionally, the tobacco control community has cautioned that claims made

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about PREPs need to be evaluated by valid, independent data and studied under their actual conditions of use to ensure the data are relevant to actual human exposure and risk (19-22). There is, thus, a substantial need for accurate and timely data that reveal when, where, how, and what types of products have been introduced, as well as how the products are being used.

**PREP Surveillance in the Context of the Larger Tobacco Market.** To perform surveillance on PREPs, however, one must look to the larger product market to distinguish those products that might reasonably be expected to reduce exposures, or be perceived by consumers to do so, from those that do not. Recall that PREP is a term coined by the Institute of Medicine committee, used more by scientists than in product marketing. Thus, PREPs may not be self-identified. This is further complicated by the fact that even product characteristics may not be explicitly stated by the manufacturer, and exposure reduction messages may be communicated through indirect means.

There are imposing obstacles to achieving a reliable and valid surveillance system for tobacco products. Although the U.S. market is dominated by a few major manufacturers (e.g., Philip Morris, Reynolds-American, U.S. Smokeless Tobacco, and Lorillard) and “super brands” (e.g., Marlboro, Newport, Camel, Copenhagen, and Skoal), the overall market is quite fractured. The 2000 Federal Trade Commission (FTC) report on tar, nicotine, and carbon monoxide yields lists 1,268 separate cigarette brand or sub-brand products (23). The most recent New York State fire standards compliance list contains 1,381 tobacco brand or sub-brands (24). Added to this variation in cigarettes are product classes such as hand-rolled cigarettes, cigarette-like devices (e.g., Eclipse, Premier, Accord), smokeless tobacco (chewing tobacco, dry snuff, moist snuff), pipe tobacco, and large and small cigars, many of which have gained market share over the past several years (25-27).

Tobacco companies may introduce only one or two new distinct brands in a given year, if any. Brands comprise the product itself (e.g., features, design, and quality), accompanying marketing, and use by consumers such that “...over time a brand develops a series of attach-

ments and association that exist over and beyond the objective product” (28). However, the introduction of new styles or variants of an existing brand, called extensions, is common. Brand extensions are a heavily investigated area of marketing science—basically, for an extension to be successful, consumers must see the extension as sensible, and key brand associations are competence and image (28-30). As Polly and Dewhirst note: “Merit, as a free-standing brand, had difficulties in being perceived as flavourful, whereas in contrast, product line extensions like Marlboro Lights had the advantage of being perceived as more flavourful due to the taste reputation of the ‘parent’ brand” (31). Thus, significance attaches to whether a new product bears the name of an existing brand, or becomes its own brand. Table 1 shows a list of new tobacco products and line extensions introduced to the U.S. market in 2007 through Winter 2008 (the time this article was drafted). In the last year, most “new” products introduced have been extensions of existing product lines, in some cases, into new classes of product (e.g., using the Marlboro name for smokeless tobacco). Manufacturers may also modify existing brands in various ways, often without informing the public about changes to the brand.

For example, a report analyzing Massachusetts mandated disclosure data showed that nicotine levels of cigarettes had, on average, increased nearly 15% across the 1997-2005 period (32). Tobacco documents also describe the reengineering of Camel to match advertising claims regarding smoothness to increase appeal to youth (33). However, only a fraction of new products might be considered PREPs based on claims or design. Thus, PREPs are one element in a broader scheme of product innovation, which tobacco manufacturers can use to seek marketplace advantages over competitors. However, PREPs do present unique challenges to surveillance efforts because of the diversity of PREP products, their novel characteristics and use of innovative design features, and the potential of the marketing of these products to affect smoking-related behaviors.

**Tobacco Product Reporting Requirements in the United States.** U.S. Federal regulations regarding tobacco

**Table 1. New tobacco products introduced by major manufacturers in the United States, 2007-2008**

Company	Product	LE	NPC	Description
Philip Morris USA	Marlboro Smooth	X		Cigarette (menthol)
	Marlboro Virginia Blend	X		Cigarette (single leaf blend)
	Marlboro Snus	X		Smokeless pouches
	Marlboro Moist Snuff	X	X	Loose moist snuff
	Marlboro Ultralight 72s	X		Cigarette (72-mm length)
Reynolds-American	Camel No. 9	X		Cigarette
	Kool XL	X		Cigarette
	Kool Flow	X		Cigarette
	Kool Groove	X		Cigarette
	Camel Signature Blends	X		Cigarette (flavored)
	Camel Crush	X		Cigarette (crushable menthol filter pellet)
Lorillard	Newport M Blend	X		Cigarette
	Triumph Snus		X	Smokeless pouches
Liggett/Vector	Grand Prix Snus		X	Smokeless pouches
	Tourney Snus		X	Smokeless pouches
Swedish Match	Red Man Moist Snuff	X	X	Loose moist snuff
	Triumph Snus		X	Smokeless pouches
UST	Cope	X		Loose moist snuff

Abbreviations: LE, line extension; NPC, new brand or product class.

**Table 2. Potential sources of information about new and modified tobacco products**

Source	Location	Description	Advantages	Disadvantages	Utility		
					Identify	Characterize	Monitor
Disclosures to governments	<a href="http://www.ftc.gov/tobacco">http://www.ftc.gov/tobacco</a>	The last FTC report on cigarette yields was issued in 2000, covering brands tested in 1998. Later data can be requested under the Freedom of Information Act.	Legal mandate	Depending on required reporting cycle, data may not reflect currently available products	X	X	X
	<a href="http://www.mass.gov/dph/mtcp">http://www.mass.gov/dph/mtcp</a>	Massachusetts, Minnesota, and Texas require additional disclosure of product design features and smoke constituents such as nicotine in tobacco, ventilation, and smoking at alternate machine regimens.	Product-level data in many cases	Data fields limited by what was requested by law/regulation			
	<a href="http://www.sec.gov/edgar/searchedgar/companysearch.html">http://www.sec.gov/edgar/searchedgar/companysearch.html</a>  (see Supplementary Appendix A for full list)	State tax and finance departments require manufacturers to report the brands and/or varieties offered for sale in those states, pursuant to the Master Settlement Agreement.  The New York State Office of Fire Prevention and Control maintains a list of brand styles certified as compliant with the cigarette ignition propensity regulation.	Standard Industrial Classification (SIC) codes exist for companies dealing in Tobacco Products (SIC 2100) or Cigarettes (SIC 2111)				
Industry reports and communications	Business Source	Important pieces of data to extract are launches, market share, profitability, total product sales by category (cigarettes, smokeless, other), and profit margin.	Databases exist	Time and effort needed to extract data	X	X	X
	Hoovers Stock analyst reports Scientific meeting presentations		Designed for others in the industry and/or investors	At best hypothesis generating			
Internet	Various	Novel products may have dedicated websites with product information. Examine possible viral marketing on the web via chat rooms, blogs, message boards, YouTube, and social networking sites (e.g., MySpace, Facebook).	May gain direct insights from consumers	Difficult to determine accuracy/reliability of information Particularly difficult separating stealth comments made by marketers from legitimate consumer postings.	X	X	X
Local area tracking	N/A	The distinction between national rollout and local test markets can be important.	Assess point of purchase, a key marketing point	Coordination needed to ensure coverage of different retail environments	X	X	X
		States routinely perform compliance checks of retailers' youth sales practices under the Synar Amendment, which might provide an opportunity to examine the brand mix and pricing strategies in retail environments.	Know what is available in given market Allows data gathering for characterization of packaging, claims, and product engineering	Labor-intensive			

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**Table 2. Potential sources of information about new and modified tobacco products (Cont'd)**

Source	Location	Description	Advantages	Disadvantages	Utility		
					Identify	Characterize	Monitor
Newspapers	Lexis-Nexis	CDC created a system to track tobacco-related news stories in 2004; thus, in principle, it is feasible.	Databases search major domestic and international newspapers, and even TV and radio transcripts	Labor-intensive Requires precoded evaluation and abstracting	X	X	X
Patents	<a href="http://www.uspto.gov/patft/index.html">http://www.uspto.gov/patft/index.html</a> <a href="http://www.google.com/ptshp?tab=wt">http://www.google.com/ptshp?tab=wt</a> <a href="http://www.espacenet.com/index.en.htm">http://www.espacenet.com/index.en.htm</a>	The U.S. Patent and Trademark Office allows searches of published patent applications from March 1991 forward.	Technically descriptive  Requirement to describe prior art	Difficult to link to specific products May never be commercialized May contain misleading/incorrect information	X	X	
Internal tobacco industry documents	<a href="http://www.tobaccodocuments.org/legacy.library.ucsf.edu">http://www.tobaccodocuments.org/legacy.library.ucsf.edu</a>  <a href="http://www.pmdocs.com">http://www.pmdocs.com</a> <a href="http://www.rjrtdocs.com">http://www.rjrtdocs.com</a> <a href="http://www.lorillarddocs.com">http://www.lorillarddocs.com</a>	As a result of the Master Settlement Agreement, the major cigarette companies are required to disclose among other things internal reports and research on their products.	Required disclosure  Little motivation to mislead internally Availability of developmental work, laboratory notebooks, testing data	Lag between creation and release May reflect older thinking Some product specific information (e.g., brand formulas) may be considered proprietary and not made available. Incomplete record	X	X	
Correspondence with the company	<a href="http://www.altria.com">http://www.altria.com</a> <a href="http://www.philipmorrisusa.com">http://www.philipmorrisusa.com</a> <a href="http://www.reynoldsamerican.com">http://www.reynoldsamerican.com</a> <a href="http://www.lorillard.com">http://www.lorillard.com</a> <a href="http://www.ustinc.com">http://www.ustinc.com</a>	Massachusetts Tobacco Control Program has held meetings with tobacco manufacturers in an effort to learn about new product offerings such as Marlboro UltraSmooth, Taboka, Marlboro Snus, and Marlboro Moist Snuff.	Ability to ask targeted, direct questions May gain information not otherwise publicized	No guarantee of (truthful) response May be provided misleading information	X	X	
Informants	N/A	Former and current company employees, assuming they are not bound by confidentiality agreements, may be able to describe ongoing research in general terms. Wholesalers, distributors, and retailers may also be aware of upcoming product launches and may also be able to provide advance notice.	May gain information not otherwise publicized	No guarantee of accuracy of information	X	X	
Products introduced in international markets	<a href="http://www.tobaccojournal.com/">http://www.tobaccojournal.com/</a>	The major tobacco companies operate in multiple countries via partnerships, licensing agreements, and subsidiaries.	Actual products and associated marketing to examine	Product may fill a localized product niche, and stand little chance of being sold in the United States	X	X	

(Continued on the following page)

**Table 2. Potential sources of information about new and modified tobacco products (Cont'd)**

Source	Location	Description	Advantages	Disadvantages	Utility		
					Identify	Characterize	Monitor
Trade publications	<a href="http://www.tobaccoreporter.com">http://www.tobaccoreporter.com</a>	Trade publications include <i>Tobacco Reporter</i> , <i>Tobacco Journal International</i> , <i>Smokeshop</i> , and <i>Tobacco International</i> .	Information directly from and for those commercially interested in the products	May require corroboration from independent sources	X		X
	<a href="http://www.tobaccojournal.com">http://www.tobaccojournal.com</a> <a href="http://www.tma.org/tmalive/FrmMain">http://www.tma.org/tmalive/FrmMain</a>	The Tobacco Merchants' Association has extensive databases of product information that may be purchased by interested parties.		Require subscriptions Costly			
Magazine advertising	<a href="http://www.smr.com/">http://www.smr.com/</a> <a href="http://www.mediamark.com/">http://www.mediamark.com/</a> <a href="http://www.nielsenmedia.com/nc/portal/site/Public/">http://www.nielsenmedia.com/nc/portal/site/Public/</a> <a href="http://www.tns-mi.com/">http://www.tns-mi.com/</a>	Magazine advertising data are available from independent commercial data sources for consumer products such as Simmons Market Research, Mediamark Research, Inc., TNS Media Intelligence (TNS), TwelvePlus, and DoubleBase. <i>Key variables:</i> Readership demographics, Advertising volume, Expenditures, Placement information (magazine title, issue date, brands advertised, list price).	Databases exist and customized data sets can be ordered	Magazine advertising of cigarette products less common than in the past Costly		X	X
	Sales and use	<a href="http://www.nielsenmedia.com/nc/portal/site/Public/">http://www.nielsenmedia.com/nc/portal/site/Public/</a>	Commercial databases track consumer products including tobacco products for sale and price by sub-brand nationally and in selected markets that can be used to measure use and compare to conventional products and control for manufacturer's manipulation of price to affect sales.	Objective data on purchasing patterns Ability to examine trends	May not include certain retail outlet categories (e.g., convenience stores) Costly Little insight into reasons for purchase		X
Population surveys	<a href="http://www.oas.samhsa.gov/nhsda.htm">http://www.oas.samhsa.gov/nhsda.htm</a> <a href="http://www.cdc.gov/nchs/nhanes.htm">http://www.cdc.gov/nchs/nhanes.htm</a> <a href="http://www.cdc.gov/nchs/nhis.htm">http://www.cdc.gov/nchs/nhis.htm</a> <a href="http://www.monitoringthefuture.org/">http://www.monitoringthefuture.org/</a>	Brand and sub-brand level tobacco use data are obtained from a number of national and statewide tobacco surveys or other surveys with tobacco modules or questions, including the National Survey on Drug Use and Health, Monitoring the Future Survey, National Health and Nutrition Examination Survey, and the National Health Information Survey.	Representative samples Samples generally large enough to examine test marketing in limited geographic areas	Limited brand information, if any Can only ask limited set of questions about any given topic Difficult to field for quick response to emerging product			X
	Focus groups	Gather small groups of consumers to gain information about product perceptions.	Can be fielded rapidly in response to new products Opportunity for more in-depth questioning Can serve to inform other data collection modalities (e.g., surveys)	Tend to be unrepresentative Time-consuming			X

products currently lack central coordination. The FTC receives reports of industry marketing expenditures and has traditionally set standards for machine testing of tar and nicotine content for smoked tobacco products and received yearly reports of such data (public reports ceased in 2000). The Centers for Disease Control and Prevention receives annual lists of additives used in manufacture from cigarette and smokeless tobacco manufacturers; smokeless manufacturers are also required to report nicotine and related product details (total and unionized nicotine, moisture content, and pH). The Alcohol and Tobacco Tax and Trade Bureau of the Department of the Treasury is responsible for the licensure of tobacco product manufacturers, importers, and exporters for taxation purposes. There is current pending legislation in Congress that would place many of these functions, as well as additional requirements, under the purview of the Food and Drug Administration. Several states also have separate regulations governing tobacco products. For example, Massachusetts and Texas require product disclosures for nicotine yield on brands commanding at least 1.5% market share. Under a comprehensive regulatory system, surveillance could be conducted by federal regulatory agencies; however, this article addresses currently available sources of information that could serve surveillance purposes in the absence of such regulation.

Clearly, a surveillance system for PREP-like tobacco products needs to be developed, whether inside a regulatory framework (e.g., federal legislation, state health departments) or outside of regulation via partnerships between scientists and tobacco control advocates (19, 34-40). The purpose of this article is to critically examine existing methods for identifying and characterizing new and modified products in the tobacco marketplace that may be of interest to public health officials. This is not intended to be a review of product innovations as such, nor is this a review of surveillance systems of health effects and outcomes associated with tobacco products. Rather, we intend to describe how scientists and regulators could systematically identify and track PREPs in the context of the larger set of new or modified products. Our intended target audience is public health officials, to increase their urgency for moving forward with tobacco product surveillance activities in their respective jurisdictions.

We classify the methods identified by three phases of product surveillance: (a) identifying a PREP that has been or is about to be released; (b) characterizing that product in terms of claims, design, and other features; (c) monitoring the sales, trial, and adoption of the product. These phases were chosen to be inclusive of a wide range of available information that could give a broad picture of a PREP in the context of other tobacco products, both pre- and post-market.

## Materials and Methods

To identify literature pertaining to tobacco product surveillance, a systematic search of PubMed was done. Search terms included the following in various combinations: cigarette, tobacco, product, surveillance, monitoring, tracking, and marketing. To be included in this review, an article had to substantively address at least one of three areas of product surveillance (identification, characterization, and monitoring). Articles dealing solely

with surveillance of health effects of tobacco products or patterns of use (i.e., youth smoking) were excluded. Subsequent to the PubMed search, we examined other potential methods for identifying new and modified products in Tobacco Documents Online,<sup>7</sup> and by using databases such as PsycINFO, Business Source Complete, Hoovers, and Google. Search terms included new product development; competitor analysis; Strengths, Weaknesses, Opportunities, Threats (SWOT) analysis; product launch; market research; consumer psychology; and branding (in the context of tobacco products). Article citation lists were checked to locate any relevant articles not identified by the keyword searches.

The articles related to tobacco product surveillance identified ranged from reviews of tobacco industry documents and patents to survey studies to focus group research to analysis of retail scanner data. Because of the diverse range of methods used here, we take a qualitative, narrative approach to reviewing and synthesizing the literature.

## Results

**Surveillance Methods.** Based on our review of existing literature, Table 2 shows the methods that have been or could be used to identify, characterize, and/or monitor new and modified tobacco products in the marketplace. The ultimate use of a PREP surveillance system would be to understand and/or determine the effects on public health (41). However, methods for monitoring tobacco-related health effects will not be reviewed herein. Note that the relationship among the surveillance phases is not necessarily linear; that is, identification and characterization could be accomplished simultaneously. Each method had advantages and disadvantages, and these are listed in Table 2, with elaboration below.

**Reliability and Validity.** Surveillance of tobacco products has relied, in large part, on proxy data collected for other purposes. In general, the reliability and validity of the methods, in the traditional psychometrics sense, have not been established. Table 3 lists ways in which such data collection systems could in principle be assessed in terms of traditional reliability and validity criteria, although very little formal work has been done in this area. The strengths and weaknesses of these individual systems are described in more detail in the following sections. In general, methods involving coders to categorize or abstract text-based data (e.g., industry documents; newspaper articles) should rely on predetermined coding schemes, with a target inter-coder reliability of at least 85%. More quantitative data (e.g., contents and emissions, sales) can be checked against results from other sources, historical trends, or gold standards as appropriate. Assessing the overall reliability and validity of proxy measures broadly falls under the concept of triangulation (42). Triangulation refers to the principle of using multiple data sources and methods to study the same phenomenon, in this case PREP identification, characterization, and monitoring. The multitrait-multimethod matrix is one approach to triangulation created by Campbell and Fiske (43) to assess construct validity using distinct reliable and valid measures of an underlying trait or traits, to assess the proportion of variance in measure accounted for

by trait versus method. Houston (44) has proposed a construct validation for proxy data using a three-stage process: (a) theoretical specification; (b) measurement property assessment; (c) nomological validity. To assess the validity of the proxy data in question, one must have a working theory of how the measures do and do not relate to the surveillance outcome (e.g., PREP use prevalence) and a good sense of the measurement properties (e.g., reliability, repeatability) of the proxies. Nomological validity, then, refers to the degree to which a measure(s) of a construct relates to other measures in a way that is consistent with the underlying theory (44). Although performing such validation is beyond the scope of this article, we would recommend that the measures identified be subjected to this sort of inquiry before use in a surveillance system.

**Phase I: Identifying Products.** An approach to identifying products consists of (a) having intelligence regarding what PREP products are under development and have a reasonable chance of coming to market, and (b) knowing when products come onto the market. Under a comprehensive regulatory system for tobacco and nicotine products, new products and related claims could be required to undergo a pre-market approval process, including disclosure of information about product characteristics and related research. However, in the absence of regulation, outside data sources are necessary to aid the identification of new products.

Strategies used by corporations to assess competitors, sometimes called competitive intelligence (45), may provide a useful model for informing public health approaches to PREP surveillance. Competitive intelligence generally refers to systematically gathering, analyzing, and applying available information about other companies' products, markets, customers, and competitors to facilitate planning for one's own company, with the aim of gaining a competitive advantage. For example, a Philip Morris USA Research and Development strategic plan for 1993-1997 devotes several pages to in-depth analysis of the activities of the company's closest competitors (RJ Reynolds, Brown and Williamson, Japan Tobacco), including listings of patents awarded to each company, with analysis of how these might be used commercially (46). This information can be gathered by any number of ways but generally begins with publicly available information (e.g., websites, government filings, patents, and news stories) and then moves toward primary research (e.g., testing and reverse engineering products, tracking sales, networking, and trade shows). Other sources of such information are business databases (e.g., Business Source; Hoovers), where SWOT analyses, competitor analyses, and patent attainments can be searched simultaneously for specific companies. Whereas the ultimate aims of public health surveillance may be different from those of business competitive intelligence, some of these methods may be used to advance public health.

Information on patents registered with the U.S. Patent and Trademark Office can potentially serve as a source of information on new products prior to their introduction. Patents can be granted on any inventions that are novel, nonobvious, and useful. Individuals and companies, to protect new ideas and technologies through patent applications, must include a discussion of all "prior art" related

to the described invention (including foreign patents and nonpatent literature), and thus, these citations provide a means to identify similar and related developments. Patents may contain information that has yet to appear, or may never appear, in the published literature (47). A way to make sense of patents related to PREPs is to construct patent maps or a graphic illustration of interactions among different patents by a single company or across multiple companies (48). A patent map is most often focused on interrelationships between a given patent of interest and others that are related to it in some way (e.g., prior art, subsequent art, complementary processes), often built using other patents cited in the target patent. Seeber (47) recently provided a useful overview on patent searching for life sciences researchers. A potential drawback to patents is that they may contain false or misleading information. Companies may also secure patents on technologies they have no intention of commercializing, sometimes to prevent a competitor from coming to market with similar technologies. Both of these are risks in using patents to identify PREPs.

Internal industry documents can provide important additional context on the development of new and modified products by providing data on product characteristics and allowing better focus on further search strategies. Internal documents have been a rich resource on the industry's research and development practices for novel products. Public health researchers have made use of documents and patents in characterizing products such as Barclay, Premier, Eclipse, and Marlboro Ultrasmoother, as well as research programs into nicotine analogues and design innovations such as filters, flavor pellets, and additives to mask environmental tobacco smoke odor (13, 33, 49-64). Recommended methods exist for searching and analyzing internal tobacco industry documents, which can aid in reliability and validity of findings (65-67). However, industry documents made available through litigation may not necessarily provide comprehensive information on particular product or related industry activities; thus, these documents must be interpreted with caution, although they can provide essential information not available through other sources (68).

Marking the release of new products can be as simple as checking what is for sale on store shelves (69). Press releases or other official communications (e.g., Annual Reports) from companies may also reveal plans for recent and/or upcoming product releases. This can provide a justification to directly request information from tobacco companies or informants, a low cost, albeit ad hoc, means of learning about new technologies and products. Publicly traded companies in the United States must also file quarterly and yearly reports with the Securities and Exchange Commission, and these will contain information about upcoming initiatives expected to influence profits and losses. New product launches, performance of current product mix, and other information will generally be included. Companies may also meet with stock analysts from investment banks (e.g., Citigroup, Deutsche Bank) and present new initiatives, and thus stock analysts' reports of those companies may provide information about future plans. We could identify no published scientific reports making use of such data, but stock analyst reports, new product launches, and similar data are often reported in trade publications. Major companies

**Table 3. Concepts in reliability and validity assessment for potential product-level surveillance methods**

Source	Method(s)	Reliability	Validity
Patents	Keyword search; content analysis; patent mapping	Consistency across searchers (agreement >85%); prespecified search terms	Predictive (e.g., does a PREP come to market relying on a patent identified as important?)
Internal tobacco industry documents	Keyword search; semiotics; content analysis	Trained, blinded coders; systematized prespecified categories; inter-coder agreement >0.85	Convergent (e.g., does preliminary data in documents associate with patents or marketed products?)
Industry reports and communications	Content analysis	Prespecified search terms	Face
Government reports	Content analysis	Prespecified search terms	Face
Correspondence with the company	Interviews; questionnaires	NA	Face
Informants	Interviews	NA	Convergent (do different informants give similar information?)
Products introduced in international markets	Keyword search, interviews, questionnaires	Prespecified search terms	Predictive (e.g., does the foreign product or similar technology eventually appear on the U.S. market?)
Government databases	Frequency analysis	NA	Face
Trade publications	Content analysis	Prespecified search terms	Predictive (e.g., do advertising expenditures and ad content lead to increases in sales or beliefs about product safety?)
Magazine advertising	Readership demographics	Trained, blinded coders; systematized prespecified categories; inter-coder agreement >0.85; sourcing from multiple companies	
	Advertising volume		
	Placement information		
Internet	Keyword search; content analysis; semiotics	Trained, blinded coders; systematized prespecified categories; inter-coder agreement >0.85	Convergent (e.g., do blog postings about products correspond to sales and use data for those products?)
Sales and use	Scanner data	NA	Convergent (e.g., do sales data and reported use correlate positively?)
Local area tracking	Tax receipts	NA	Convergent (e.g., does product availability at retail correspond to sales and usage data?)
	Synar inspections; retailer licensing		
Population usage	Mall intercept; RDD; web survey; panels; focus groups	Test-retest; internal consistency	Face; predictive; convergent; divergent

have also presented information about new products at scientific meetings. The reliability and validity of such information is hard to judge, depending heavily on the credibility of the source, and thus these data might be best considered hypothesis generating.

Finally, noting the introduction of new products in markets outside the United States may, in some instances, provide an early view of new product technologies that may eventually be introduced in the United States. The major U.S. companies are multinational and/or have overseas partnerships and distribution agreements. Thus, it is reasonable to believe that a product marketed in other countries could be introduced into a U.S. market that remains highly profitable. However, the converse may also be the case—companies may preferentially introduce novel products into growing markets.

**Phase II: Characterizing Products.** As the WHO Scientific Advisory Committee on Tobacco (34) noted, "The first logical step in examining a product having potential to reduce the harm produced by tobacco use is to examine the characteristics of the product." This entails examining both the characteristics of the product itself and the manufacturers' claims about the product.<sup>8</sup> By nature, the specific steps to be taken are heavily dependent on

the product in question. This article reviews those methods most suited to ongoing surveillance of PREPs.

Tobacco manufacturers routinely examine and reverse-engineer one another's products, particularly to gain information about novel product innovations (55, 56, 70-72). An example is the Barclay 1 mg FTC tar cigarette introduced by Brown and Williamson in 1980. Because of its claims of low tar and reports of significant taste improvement relative to other 1 mg products, Philip Morris and RJ Reynolds reverse-engineered the product and within days discovered how the Actron filter "cheated" the FTC regimen, resulting in a lawsuit over the 1 mg FTC yield claim (56). There are useful lessons for public health science in understanding how tobacco manufacturers conduct rapid and ongoing assessments of competitor products.

**Characteristics.** The first level of analysis in assessing product design requires determination of whether the product is a combustible or noncombustible product, which can generally be accomplished by visual inspection. Clearly, there are differences in product characteristics, as well as potential risks, between combustible and noncombustible tobacco products (73, 74). Products that do not fall neatly into one or the other category (e.g., Eclipse and Accord) may need to be considered as a separate product class.

Previous investigations of combustible product characteristics have largely focused on tar, nicotine, carbon monoxide, and other toxicant emissions as measured by

<sup>8</sup> A full and detailed review of all possible methods for characterizing product contents, emissions, and biobehavioral effects is beyond the scope of this article.



smoking machines (75-80) or use *in vivo* in clinical studies (81-88), with less attention to the more basic aspects of physical design and packaging (80, 89, 90). However, when product design and context are not considered, findings from smoke chemistry and even clinical studies can be misleading, as in the case of filter ventilation and Light cigarettes, for example (14, 15, 34, 91). Combustible tobacco products can also be characterized for design features such as filter construction (e.g., length, weight, density, presence and type of charcoal), ventilation, and paper permeability (80, 90, 92). The WHO Study Group on Tobacco Product Regulation (35) has recommended mandated reporting on aerosol particle size, filter ventilation, filter length, filter fiber residues, filter charcoal content, cigarette circumference, paper porosity, percent reconstituted tobacco, percent expanded tobacco, moisture content, and product firmness (an indicator of tobacco density). For some of these, internationally adopted standard methods exist [e.g., International Organization for Standardization (ISO) 15152:2003 for nicotine, 6565:2002 for pressure drop, and 2965:1997 for paper permeability]. For others (e.g., assessment of blend composition, filter fiber residues), developmental activities would be necessary. The TobReg list of characteristics would seem to be useful for PREP surveillance, although it presumes a cigarette-like construction with a filter.

For noncombusted products, form (loose, pouch, tablet), nicotine content, moisture, and pH (which influences free nicotine availability) are key characteristics and can be measured relatively simply using established methods (93). A number of smokeless tobacco products exist (chew, dry snuff, moist snuff, pouches, and Swedish-style Snus). Tobacco-specific nitrosamines are also a major concern and are commonly measured (94-96) although other toxins such as metals and polycyclic aromatic hydrocarbons should also be considered. A significant gap in testing smokeless tobacco products is the wide variation in tobacco moisture and humectant levels, which makes weight-adjusted reporting of contents difficult and, therefore, makes comparisons across different smokeless products potentially unreliable.

A basic physical analysis can provide qualitative and quantitative data about general product differences but will not necessarily provide specific data about any of the novel features themselves or their effects on product performance. One may find it necessary then to test smoke chemistry to examine specific toxicant emissions (97-104), other tobacco contents (105-109), tobacco mutagenicity (110, 111), or the targeted reverse engineering of design elements (59, 64, 80, 112). Exactly what would be measured at this stage would rely heavily on hypotheses generated by the physical analysis and information gleaned from patents and product claims. Creative reverse engineering can explore more novel aspects of particular products such as the flavor-laden beads in Camel Exotic Blends (52), the charcoal beads in Marlboro Ultrasmooth (80), and the menthol capsule in the newly released Camel Crush (113).

The reliability and validity of certain standardized laboratory tests of tobacco products themselves (i.e., assay validity) have largely been established by groups such as the ISO. Interlaboratory variability in measures, as well as inherent variability in products, can lead to different results on repeated testing, which highlights the need to

rely on several data points rather than a single test in characterizing a new product.

**Claims.** One way to determine how something is new or may be a PREP is to examine what the manufacturer is saying about the product. Currently, tobacco companies lack a priori restrictions on product claims because no legally required pre-market approval or review exists. Some manufacturers have made seemingly explicit health claims [e.g., Eclipse ("responds to concerns about certain smoking-related illnesses... including cancer." And "The best choice for smokers who worry about their health is to quit. The next best choice is Eclipse."); ref. 114]. In most cases, however, PREP products are not accompanied by explicit health claims but by more subtle messages that communicate aspects of taste, enjoyment, or technological features (115). For example, manufacturers may tout a new filter technology (e.g., Marlboro Ultrasmooth), spit-free (Camel Snus), additive-free (Winston; American Spirit), or improved taste. There is evidence that consumers, nevertheless, perceive such implicit or nonspecific claims as health messages (116-120).

Product claims (both implicit and explicit) are commonly conveyed via advertising and other marketing materials as well as through the product packaging and characteristics. Content analysis of product advertising (31, 61, 65, 121) has been used in the past to highlight themes. For more novel products, instructions on how to use the product may be included within advertising or promotional material (e.g., dosing instructions for Camel Snus and Eclipse).

Three marketing channels that should be monitored for claims are mailing lists, point-of-sale advertising, and internet. Mailing lists allow companies to directly target smokers, as well as specific subsegments of smokers who are believed to be more receptive to the new product. Mailings may include coupons, bonus items, or other inducements to try the product (122-124) and may also include information about the product not presented in more public media. Point-of-sale advertising is associated with impulse purchasing (125) and thus can serve as a stimulus to try a new product. Examining the prevalence and content of retail advertising can also be important to assessing the likely success of a new product, and methods for this type of tracking exist (126-131). Tobacco advertising on the internet is growing and many smokers report seeing ads (132). Companies may create dedicated websites for new products<sup>9,10</sup> as a means to convey more detailed information than could be contained in either direct mail or point-of-sale promotions. For example, the Camel Snus website (at the time of this writing) features a video showing how and where to use the product.

The product package being the ultimate advertisement (133-135) is often the most prominent visual and tactile incarnation of the brand identity, and in the United States is prominent in the retail environment. Therefore, examining packaging is a critical component to characterizing new brands. To set new brands apart, new color schemes, packaging designs (nontraditional sizes, new shapes, new materials), and number of units per package may

<sup>9</sup> <http://www.snuscamel.com>

<sup>10</sup> <http://www.marlborsnus.com>

be manipulated. Descriptive words or statements may also be important indicators of potential claims. Another potential form of communication relevant to product claims can be product “onserts” or small booklets attached to packages. Philip Morris USA, for example, has placed informational onserts on some regular brands, as well as on their Ultrasmooth, Taboka, and Marlboro Snus products.<sup>11</sup> Some of these onserts describe the product, how to use the product, general information about health risks, or interpreting emissions numbers. These represent another avenue by which manufacturers convey information to consumers.

Claims can be collected systematically by having raters purchase and catalogue products and their associated advertising and marketing materials using a predetermined coding scheme. Raters would need to make note of the specific text of claims and make a determination as to which of a number of fixed categories it best fits. Other objects such as coupons, onserts, and free offers could be coded as to presence/absence, as well as content. Methods for qualitative analysis of documents and advertising, such as content analysis and semiotics (65, 136), can be used here to ensure systematicity and objectivity. Recording the package Universal Product Code is potentially critical—these are used by manufacturers to track inventory and sales of particular varieties. This would also allow one to more accurately follow a particular brand as well as facilitate linkage of these data to other databases.

**Phase III: Monitoring Products Introduced into the Marketplace.** Publicly available sources of data that can be applied to track brands include state brand registration lists related to the Master Settlement Agreement, as well as mandated certification of brand styles under cigarette ignition propensity (“fire-safe”) regulations. A record of state Master Settlement Agreement brand registration lists is included in Supplementary Appendix A. These lists may be updated periodically.

Tobacco industry trade publications such as *Tobacco Reporter*, *Tobacco Journal International*, and *Tobacco International* may discuss new products and may even give preliminary data on usage and uptake. These are searchable in business literature databases such as Business Source. A drawback to trade journals is that information quality may depend on the sources used.

News stories may be a way to track introductions and adoption of products. Publicly available databases such as Lexis-Nexis can be used to identify stories published in daily national newspapers (e.g., New York Times, Washington Post, Wall Street Journal). These databases may offer searching capabilities for television, radio transcripts, and international newspapers, offering an additional line of inquiry. The Office on Smoking and Health at the Centers for Disease Control and Prevention created a surveillance system for tobacco-related news stories in 2004 (137), and this could be routinized to serve as a platform for identifying stories about new products. News tracking, however, is labor-intensive and requires precoded schemes for classifying and abstracting stories.

Tracking magazine advertising, which can be accomplished via commercial services, can provide insight into the marketing campaigns for products, including who

might be target audiences. These data sources also provide important information about the demographics of magazine readership, which can be explored to determine to whom the product advertising is being marketed (age, sex, race). Reed et al. (138) showed that historical trends in magazine advertising for light cigarettes were predictive of increases in market share of these cigarettes, illustrating the utility of secondary data sources for tracking the adoption of new products. However, cigarette companies have become less reliant on print advertising, shifting to other areas of promotion (139), and thus the relevance of tracking magazine advertising has diminished.

Sales data can be very important to determining whether a brand is gaining significant market share (140). A valuable format is retail scanner data, which investigators have used to examine sales trends (141, 142). A potential drawback of scanner data is that it reflects purchases but provides no process data (143)—it tells one nothing of *why* a consumer bought the PREP at that time—and also that scanner data may only be available for a select group of participants or purchase locations, raising issues of representativeness (143).

**Integration.** Data sets representing market, advertising, and tobacco use information can be merged by Universal Product Code. For example, market share, sales, and price data for a certain year could be merged with nicotine yield and other product design data from the corresponding year in the Massachusetts Department of Public Health mandated reporting data, as well as magazine advertising placements data. This linkage across multiple data sources could give a more complete picture of the place of a PREP in the market.

**Assessing Awareness and Adoption.** Once a product is in the marketplace, surveillance of product awareness and uptake becomes essential to establishing whether a product may have a public health impact (117, 118, 144-151). Issues of population surveillance for the adoption of PREPs and consumer perceptions thereof have been covered by other authors in greater detail (152, 153).<sup>12,13</sup> The large national surveys where brand use information is available (National Survey on Drug Use and Health; National Health and Nutrition Examination Survey) can serve an important surveillance function for tracking long-term trends in tobacco products, particularly, PREPs. However, these large surveys take years to develop and implement in the field, making them less valuable for tracking short-term changes in the market. An alternative to population surveys is focus groups, wherein small groups of consumers similar in some characteristic(s) provide reactions to products and marketing materials (153, 154). Although weak in terms of generalizability and representativeness, these groups provide an opportunity to

<sup>11</sup> [http://www2.philipmorrisusa.com/en/health\\_issues/low\\_tar\\_cigarettes/onsert.asp](http://www2.philipmorrisusa.com/en/health_issues/low_tar_cigarettes/onsert.asp)

<sup>12</sup> Bogen K, Biener L, Garrett CA, Allen J, Cummings KM, Hartman A, Marcus S, McNeill A, O'Connor RJ, Parascandola M, Pederson L. Surveillance indicators for potential reduced exposure products (PREPs): developing survey items to measure awareness. *Harm Reduct J* 2009;6:27.

<sup>13</sup> Rees VW, Kreslake JM, Cummings KM, et al. Assessing consumer responses to potential reduced-exposure tobacco products: A review of tobacco industry and independent research methods. *Cancer Epidemiol Biomarkers Prev* 2009;18:3225-40.

ask more detailed questions about products than could be achieved in a survey.

The internet can be potentially valuable in tracking adoption—users of new products may post comments on blogs or social networking sites (155-157), which may provide some insight into consumer reactions. Google searching and passive monitoring of tobacco-related chatrooms, message boards, and blogs can provide interesting data related to new product usage directly from users. Indeed, some scientists have made similar recommendations about the misuse of prescription medications (158). Eclipse was intended to be marketed in part by “viral” means (49). Viral marketing, as commonly defined, seeks to exploit preexisting social networks to increase awareness or sales of products, usually by having consumers voluntarily disseminate a marketing message (159). A subset of viral marketing, stealth (also known as guerilla or buzz) marketing, often hijacks a social network by use of undercover “shills” paid to make positive comments about a product (157). Systematic assessment of internet postings is an emerging discipline. Particularly difficult would be separating out “stealth” comments made by marketers from legitimate ones made by consumers. However, like much qualitative research, reliability and generalizability would depend heavily on good training of raters, consistent coding criteria, and systematic synthesis of information from multiple sources (65, 68).

## Discussion

This article has reviewed the strengths and weaknesses of a range of different data sources for studying and tracking PREPs. Whereas the various information sources described have their own strengths and weaknesses, there are some overarching challenges for surveillance that emerge from the review. First, a significant gap is the lack of a formal investigation into the reliability and validity of these data sources. Second, whereas mandated government disclosure has the potential to be a vital and comprehensive source of information about products, current disclosure requirements are limited. Thus, the value of some types of data is diminished by the lack of a

formalized, legally mandated mechanism for reporting. Third, there is no single data source that is alone sufficient for identification, characterization, and monitoring of PREPs. Rather, a range of data sources are needed.

The reliability and validity of the methods may depend on the contexts and purposes to which they are applied. As an example, focus group studies provide an opportunity for in-depth questioning unavailable in larger population studies, yet focus groups are generally regarded as a weaker method in terms of generalizability. Information from companies can serve to confirm findings of new products in retail monitoring, and claims made by companies can be confirmed or countered by data gathered from retail sales databases, focus groups, product reverse engineering, and/or surveys. Data required to be disclosed via regulation has the advantage of force of law, although it does not guarantee that the data are accurate or easy to decipher. Only independent monitoring can provide a comparator against which to assess mandated disclosures for accuracy and completeness. For example, product contents and emissions data provided by companies can be checked by sending product samples to an independent laboratory for testing. Reported marketing expenditures and sales volumes can be checked against databases such as Nielsen and Mediamark. However, these databases themselves are limited by the number, location, and types of retail outlets and publications from which they draw their data. Thus, clearly, no single one of these data streams is sufficient to characterize PREPs—multiple data sources must be collected and compared before coming to any judgments.

Nevertheless, these data sources can be prioritized to some degree within the contexts of PREP identification, characterization, and monitoring. Table 4 describes the key types of data that are needed for each context and the corresponding measures that are prioritized for that context. Priority data sources are those with the highest validity and reliability, whereas secondary sources are those that can provide essential information but have methodologic limitations. However, when Priority sources are not available, more reliance on secondary sources may be necessary. For example, in the absence of government-mandated product constituent disclosures, more reliance

**Table 4. Priority measures for identification, characterization, and monitoring of PREPs**

	Identification	Characterization	Monitoring
Key data	Product name Launch date(s) and location(s)	Constituents and/or emissions Claims Design Marketing	Consumer response/perception Consumer uptake Sales
Priority sources	Industry reports Trade publications Local tracking	Government disclosure Independent scientific testing	Sales and use data Population surveys
Secondary sources	International market newspapers Internet	Industry reports Internal documents and patents Correspondence Newspaper articles	Industry reports Newspaper reports Magazine advertising Government disclosures
Rationale	To identify potential PREP-type products on the market, data sources should be highly sensitive (at the cost of specificity) and provide real-time information.	To effectively characterize PREP products, it is essential to have valid, independent information about the product's characteristics.	Monitoring requires reliable and consistent sources of information to identify trends and changes over time as well as the impact of products on the population (through tracking marketing and consumer perceptions).

may be needed on supplementary sources such as internal documents and patents for characterizing PREPs.

Currently, scientists and public health officials lack a standardized approach for identifying, defining, and evaluating tobacco products available for sale to consumers at the local, state, or national levels. This is a major gap both in tobacco control research and practice, as methods exist which could be used with greater frequency, coordination, and efficiency than they are currently. Groups such as the Global Tobacco Research Network,<sup>14</sup> Tobacco Harm Reduction Network,<sup>15</sup> and Tobacco Surveillance, Epidemiology, and Evaluation Network<sup>16</sup> have selectively tracked new products and their marketing. For example, various internet sites (e.g., Trinkets and Trash,<sup>17</sup> Campaign for Tobacco Free Kids,<sup>18</sup> Tobacco Products Wiki,<sup>19</sup> CigarettesPedia<sup>20</sup>) have attempted to catalogue and track products and marketing. However, such sites do not provide comprehensive surveillance or track innovation and new product development, branding, and market segmentation (demographic and geographic). The changing tobacco product marketplace requires surveillance to identify trends so that public health agencies can respond to new developments in products that could affect population health.

A recent series of articles emerging from the 2002 National Tobacco Monitoring, Research, and Evaluation Workshop (36-40) provides an excellent overview of the state of the science on tobacco surveillance broadly. The group deconstructed surveillance activities using the classic Agent-Host-Vector-Environment epidemiologic model and made specific recommendations about short- and long-term goals for each area (36). Among these were as follows:

- Develop a national tobacco surveillance clearing house for local, state, federal, and nonprofit agencies involved in conducting tobacco-related surveillance, research, and evaluation and in implementing tobacco control programs and policies.
- Support a National Clearinghouse for Tobacco Promotion Information.
- Begin surveillance of content and composition of unburned tobacco products; support research to identify toxicologic assays for subsequent use in monitoring.
- Develop best practices for identifying and collecting local laws, including timing, sample frame, and responsible practices for collection and analysis (36).

A surveillance system for PREPs would ideally be embedded within this larger framework, integrating the different data sources so that information is available to define types of products available, their unique design features, information on how the products are marketed, and data on consumer perception and use. Of particular

interest in the identification and tracking of PREPs are industry strategies such as brand innovation, product design, market segmentation, messaging, advertising and promotion, and pricing, as well as the individual and combined effects of the various marketing approaches on the population. Given the recent proposals to regulate the toxicity of tobacco products (12, 160), a systematic surveillance system for PREP tobacco products will provide critical baseline information to inform regulatory efforts and further monitoring.

A natural question arises as to whom the responsibility falls to coordinate PREP surveillance. Given that most PREPs tend to be introduced locally, rather than nationally, state health departments would appear to be the ideal loci for such activities. States already conduct local surveillance of adult and youth smoking prevalence and youth sales compliance; thus, adding product monitoring and support for other activities described herein, even if only in a coordinating role, would be helpful in getting a system up and running. This is in keeping with the Tobacco Use Monitoring Workshop recommendation vis-a-vis best practices for local evaluation and monitoring (36). Although this article has evaluated and prioritized the available data sources for surveillance, further work is needed to determine the best mechanisms for implementing these surveillance methods in practice.

## Conclusions

PREPs are a growing concern to tobacco control advocates. However, thus far, methods for monitoring the introduction, characteristics, and marketing of these products have been sporadic and not well integrated. A systematized approach to identify, characterize, and monitor PREPs and other novel tobacco products is needed, and steps are being taken to bring such a system to fruition (36-40). However, gaps related to the reliability and validity of secondary data sources must be overcome before such a surveillance system could be effectively implemented. By systematizing the collection of information about tobacco products offered for sale, ideally at the state or local level, public health officials can better understand the milieu in which smokers are immersed and better understand smokers' behavior and the potential implications for public health.

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<sup>14</sup> <http://www.tobaccoresearch.net/>

<sup>15</sup> [http://cancercontrol.cancer.gov/tcrb/Tobacco\\_Harm\\_Reduction\\_Flyer.pdf](http://cancercontrol.cancer.gov/tcrb/Tobacco_Harm_Reduction_Flyer.pdf)

<sup>16</sup> <http://www.sciencestorm.com/award/0535214.html>

<sup>17</sup> <http://www.trinketsandtrash.org/>

<sup>18</sup> <http://www.tobaccofreekids.org/adgallery/>

<sup>19</sup> <http://www.tobaccoproducts.org>

<sup>20</sup> [http://www.cigarettespedia.com/index.php/Main\\_Page](http://www.cigarettespedia.com/index.php/Main_Page)

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