A Proposal to Develop Meaningful Labeling for Cigarettes

SINCE the 1980s, tobacco researchers have understood that the advertised nicotine-yield ratings of cigarettes do not accurately predict nicotine intake by individual cigarette smokers.[1-5] Cigarette smokers obtain an average of 1 mg of nicotine from each cigarette they smoke, whether the nicotine yield is 0.1 mg or 2 mg.[4,6] However, smokers with whom we have spoken believe that their "light" or "ultralight" cigarettes are providing them with substantially lower doses of nicotine and other constituents of tobacco smoke. These smokers seem to assume that nicotine-yield ratings are equivalent to the content ratings provided on food products, and they are often distressed to learn that nicotine-yield ratings are not indicative of how much nicotine they can obtain.

We propose a new strategy for testing and labeling cigarettes that would provide consumers with improved information about how much nicotine they will absorb by smoking a particular brand of cigarette. Our proposal is roughly parallel to the approach of the Food and Drug Administration (FDA) for labeling food products with respect to constituents such as sodium and fat.[7]

Problems With the Present Rating System

A variety of terms are commonly misused in discussions of nicotine ratings. Most fundamentally, cigarette nicotine *content* is confused with cigarette nicotine *yield*. The nicotine content is the total amount of nicotine present in the tobacco cigarette. Nicotine yields are derived from tests using smoking machines that were originally developed to provide standardized comparisons of the characteristics of tobacco smoke from different strains of tobacco.[8] Unfortunately, neither content nor yield ratings accurately predict how much nicotine the individual is likely to absorb from a cigarette.[2,4]

The present testing method entails inserting cigarettes into the ports of automated systems, which then draw in smoke according to a set of parameters generally referred to as the Federal Trade Commission method.[9,10] According to this method of determining yields, one 35-mL puff of 2 seconds' duration is taken every minute until a specified cigarette butt length is reached; if there is a filter overwrap, approximately 10% of the tobacco might be left unburned. However, people smoke more intensively than the smoking machines. For example, data accumulated from 18 studies indicate that on average, smokers take 43-mL puffs at 34-second intervals.[4] Furthermore, when faced with a nominally low-yield cigarette or when faced with limited availability of cigarettes (owing, for example, to smoking restrictions, restricted access to cigarettes, or economic constraints), people smoke cigarettes more intensively to consume an adequate level of nicotine.[4,5,11-13] For example, smokers may take more frequent or deeper puffs or block the ventilation holes with their fingers or lips.[1-5,14]

The discrepancy between cigarette yield ratings and how much nicotine people obtain from cigarettes is explained by the differences between the testing-machine method and how people actually smoke cigarettes. Cigarettes have been designed to reduce machine-testing yields by diluting the mainstream smoke via the use of porous paper and filter ventilation.[15,16] Additional design features include placing less tobacco in each cigarette by using expanded tobacco and/or smaller diameters of cigarettes, shortening the cigarette length, increasing the burn rate of the paper, and increasing the length of the filter overwrap so that the machine is able to take fewer puffs before the cigarette is burned to its specified length.[1-5] However, regardless of their machine-yield rating, all marketed tobacco cigarettes contain approximately 6 to 11 mg of nicotine and enable cigarette smokers to readily extract sufficient levels to produce and sustain dependence.[4,15,16]

Proposed New Rating and Labeling System

We propose a new system of rating and labeling cigarettes. The food-labeling regulations implemented by the FDA in 1994[7] could provide a model for this reformation. Our strategy is summarized in Table 1. An additional strategy that could be used to assist consumers in making informed decisions would be to fully disclose the tobacco smoke constituents of potential health significance, analogous to harmful constitu-

From the Clinical Pharmacology Branch, Addiction Research Center, National Institute on Drug Abuse, Baltimore, Md (Dr Henningfield); the Program in Biobehavioral Health, College of Health and Human Development, Pennsylvania State University, University Park (Dr Kozlowski); and the Division of Clinical Pharmacology and Experimental Therapeutics and the Departments of Medicine and Psychiatry, University of California–San Francisco (Dr Benowitz).

The views expressed in this article are those of the authors and do not reflect an official position of the federal government or its agencies

Reprint requests to NIDA Addiction Research Center, PO Box 5180, Baltimore, MD 21224 (Dr Henningfield).

Table 1.—Strategies to Provide Meaningful Cigarette Labeling

- Use biologically meaningful categories that have plausible significance with respect to total daily nicotine intake and level of addiction.
- Develop machine-testing parameters based on data relevant to how people smoke and base yield ratings on maximal yields.
- Verify yield ratings with bioavailability testing of cigarette smokers to determine if humans can readily extract more nicotine than predicted by the machine tests.
- Limit the nicotine content of cigarettes in each category to limit maximal nicotine extraction and provide actual content values in the cigarette labeling.
- Link nicotine-rating categories to other factors of toxicological importance, eg, a *low nicotine rating would only be permitted if there was also low tar and carbon* monoxide delivery.
- Ban the use of terms such as "light" and "ultralight."

ent disclosure for foods.[7]

Our proposal involves categorizing cigarettes based on the amount of nicotine delivered (Table 2). These ratings would be included as part of a new label for cigarettes (Table 3). Developing meaningful categories for cigarettes is somewhat more complicated than for foods because a cigarette is a complex drug-delivery system,[5,17] but the principle is the same. We propose broad categories that should both serve consumer interests[18] and have plausible biological significance. The categories are based on nicotine delivery for two reasons. First, nicotine intake by smokers can be accurately measured. Second, nicotine delivery from cigarettes can be controlled to a maximum limit by controlling the nicotine content of the tobacco. It should be noted, however, that tar and other combustion products of cigarette smoke are believed to be the primary cause of human disease rather than nicotine per se. Unfortunately, it is more difficult to quantitate human tar exposure or to predict tar delivery based on the composition of the cigarette.

Accurate categorization of cigarettes based on their nicotine delivery would also be useful if cigarette manufacturers are ever required to gradually eliminate nicotine from their cigarettes. Cigarettes meeting our criteria of very low nicotine or no nicotine are unlikely to be generally addicting.[14]

We suggest that cigarette descriptors such as "ultralight" and "light" not be allowed. In terms of the food-labeling model introduced earlier, the FDA has limited use of these designations for foods where there is an adequate level of consensus as to the general meaning of the terms and a consensus that products so designated might actually represent generally healthier choices for consumers than the standard products.[7] A similar level of consensus would need to be developed with respect to cigarettes. This may not be possible because terms such as "light" provide connotations that may be interpreted as "beneficial," when, in fact, even exposure to the smoke of a few cigarettes per day has well-documented adverse health effects.[19]

In the reform of food labeling by the FDA, one of the basic issues addressed was to insist that estimates of intake be based on meaningful serving sizes and the number of typical servings taken per day.[7] To this end, machines used to provide estimates of nicotine yield should be programmed with puffing parameters that are representative of the behavior of cigarette smokers. We believe that the actual nicotine content of cigarettes should be included on the label, just as fat content is for food, but such information should not constitute the basis of nicotine-yield categorization. Nicotine content, while providing information on the maximal possible yield, is not reliably predictive of yield when cigarettes are smoked.[2]

Smoking-machine tests should be modified to include the testing of each cigarette under an average smoking condition as well as a heavy smoking condition; in this way, consumers could be informed of the usual and maximal yields of a particular cigarette. The average smoking condition would be a closer approximation to typical smoking than the model currently used. The machines would be programmed to continue puffing until all the consumable tobacco is smoked in filtered cigarettes and until the smallest plausible smokable butt length is reached in nonfiltered cigarettes (eg, 10 mm).

Table 2.—Proposed New Nicotine-Delivery Categories for Cigarette Labeling, Based on Revised Machine-Testing Procedures and Validated by Bioavailability Testing

Cigarette Label	Maximum Nicotine Yield, mg
Nicotine free	0.01
Very low nicotine	0.17
Low nicotine	1.0
Regular	>1.0

Table 3.—Content of the New Cigarette Label

- Warning statement
- Nicotine-yield category
- Nicotine, tar, and carbon monoxide yields (average and maximal)
- Nicotine content
- Harmful additives
- Information about factors affecting nicotine delivery

For cigarettes in which ventilation holes are incorporated, if it is possible for vents to be blocked with the smoker's lips or fingers, then the vents would be occluded in the heavy smoking condition. Ventilation would be incorporated in the test condition only if the ventilation holes were (1) clearly visible, (2) far enough out (perhaps 15 mm) on the filter to discourage easy blocking by the smoker's lips, and (3) described on the package label with a warning to the smoker that blocking the holes would defeat the intent of the product and result in higher levels of exposure to nicotine and other tobacco smoke toxins. Labeling should similarly disclose the sources of nicotine yield variation (eg, puff size and number) and advise how individuals might minimize their intake of nicotine per cigarette.

Cigarettes are, in essence, sophisticated drug-delivery systems,[5,7,15,17] and therefore nicotine bioavailability should be evaluated to verify that human absorption does not exceed levels predicted by the new delivery ratings. Bioavailability testing of smoked drugs is more complex than with conventional drug-delivery systems. The bioavailability of smoked drugs can be affected by parameters both within and outside the control of the user.[1,4,5] However, when factors are known to affect the bioavailability of a drug in a medication, such factors are often noted in labeling and similarly should be noted on cigarette package labels. Bioavailability could be estimated by measuring levels of nicotine, or its metabolite cotinine, in the blood, urine, or saliva of cigarette smokers.[4] Such testing would be important to determine whether alterations in cigarette design affect bioavailability in ways that could affect the categorization of the cigarette.

Although our proposal focuses on nicotine delivery, the model could be applied to other smoke constituents such as tar and carbon monoxide. A precedent for this exists in the reformation of food labeling by the FDA, in which special categories are permitted based primarily on the level of one constituent when another constituent also remains within certain boundaries. Thus, a product high in fat cannot be labeled "cholesterol free," regardless of its cholesterol level.[7] Similarly, we recommend that a cigarette be accorded one of the reduced-nicotine labels only if its tar and carbon monoxide yields are below certain levels. For example, the designation of a cigarette as low nicotine might require that the maximum bioavailability be less than 1 mg of nicotine, 5 mg of tar, and 5 mg of carbon monoxide. Of course, the tar content and carbon monoxide content of cigarettes are not meaningful concepts, because these substances are products of tobacco combustion. However, the ratio of tar or carbon monoxide yield to nicotine yield can be controlled by the design of cigarettes[16,17,20] and may also be useful to include on the label as information to consumers who wish to minimize their exposure to tar and carbon monoxide.

An implication of the present proposal is that few, if any, currently marketed tobacco cigarettes would meet the criteria for a designation other than "regular." To achieve a rating such as "low nicotine," the cigarette would need to be lower in nicotine content, and other design changes involving the use of filters and ventilation holes might be necessitated. It is possible that the proposed rating system would encourage the development of cigarettes useful in helping smokers to lessen their intake of nicotine and other constituents.

Health Benefits

The enhanced labeling system should inform smokers that smoking cigarettes with reduced nicotine yield may facilitate their efforts to quit smoking but may provide little if any general health benefit compared with regular cigarettes. Ultimately, and of greater public health importance, the proposed labeling changes could lessen the prevalence of tobacco smoking. This could come about in several ways. Many consumers are already highly motivated to smoke cigarettes with lower nicotine yield for their presumed health benefits[21]; cigarettes currently labeled "lower yield" (less than 16 mg of tar) account for approximately 60% of the market.[18] If such misleading labeling is prohibited and replaced with an accurate depiction of nicotine yield, health-conscious smokers may be more motivated to attempt to quit. In addition, if manufacturers were to develop and market cigarettes reflecting a broad range of nicotine yields, these products might facilitate the efforts of motivated smokers to effect a gradual nicotine-weaning process. The major goal of improved labeling, however, would be to provide the basic information that can now be obtained with most other consumable products, including alcoholic beverages.

Jack E. Henningfield, PhD
Lynn T. Kozlowski, PhD
Neal L. Benowitz, MD

1. Kozlowski LT. Tar and nicotine delivery: what a difference a puff makes. *JAMA*. 1981;245:158-159.
2. Benowitz NL, Hall SM, Herning RI, Jacob P III, Jones RT, Osman AL. Smokers of low-yield cigarettes do not consume less nicotine. *N Engl J Med*. 1983;309:139-142.
3. Kozlowski LT, Rickert W, Robinson J, Grunberg NE. Have tar and nicotine yields of cigarettes changed? *Science*. 1980;209:1550-1551.
4. *The Health Consequences of Smoking: Nicotine Addiction: A Report of the Surgeon General*. Washington, DC: US Dept of Health and Human Services; 1988. DHHS CDC publication 88-8406.
5. Henningfield JE. Behavioral pharmacology of cigarette smoking. In: Thompson T, Dews PB, Barrett JE, eds. *Advances in Behavioral Pharmacology*. Orlando, Fla: Academic Press; 1984;4:131-210.
6. Benowitz NL, Jacob P III. Daily intake of nicotine during cigarette smoking. *Clin Pharmacol Ther*. 1984;35:499-504.
7. US Dept of Health and Human Services, Food and Drug Administration. 21 CFR §1, et al. Food labeling; general provisions; nutrition labeling; label format; nutrient content claims; health claims; ingredient labeling; state and local requirements and exemptions; final rules. *Federal Register*. Washington, DC: US Government Printing Office; January 6, 1993:pt 4.
8. Kozlowski LT. Physical indicators of actual tar and nicotine yields of cigarettes. In: Grabowski J, Bell CS, eds. *Measurement in the Analysis and Treatment of Smoking Behavior*. Washington, DC: Dept of Health and Human Services; 1983:50-61. National Institute on Drug Abuse Research monograph 48; DHHS publication ADM83-1285.
9. *Tar, Nicotine, and Carbon Monoxide of the Smoke of 455 Varieties of Domestic Cigarettes*. Washington, DC: US Federal Trade Commission; 1991.
10. Pillsbury RC, Bright CC, O'Conner KJ, Irish FW. Tar and nicotine in cigarette smokers. *J Assoc Off Anal Chem*. 1969;52:458-462.
11. Kozlowski LT, Heatherton TF, Frecker RC, Nolte HE. Self-selected blocking of vents on low-yield cigarettes. *Pharmacol Biochem Behav*. 1989;33:815-819.
12. Benowitz NL, Jacob P III, Yu L, Talcott R, Hall S, Jones RT. Reduced tar, nicotine, and carbon monoxide exposure while smoking ultralow- but not low-yield cigarettes. *JAMA*. 1986;256:241-246.
13. Benowitz NL, Jacob P III, Kozlowski LT, Yu L. Influence of smoking fewer cigarettes on exposure to tar, nicotine and carbon monoxide. *N Engl J Med*. 1986; 315:1310-1313.
14. Kozlowski LT, Pope MA, Lux JE. Prevalence of the misuse of ultra-low-tar cigarettes by blocking filter vents. *Am J Public Health*. 1988;78:694-695.
15. Benowitz NL, Henningfield JE. Nicotine threshold for addiction: implications for tobacco regulation. *N Engl J Med*. In press.
16. *Hearings Before the Subcommittee on Health and the Environment of the US House of Representatives, 103rd Cong, 1st Sess* (March 25, 1994) (testimony of David A. Kessler, MD, JD, on behalf of the Food and Drug Administration).
17. Browne CL. *The Design of Cigarettes*. New York, NY: Hoechst Celanese Corp; 1990.
18. Shapiro E. FTC confronts 'healthier' cigarette ads. *Wall Street Journal*. April 21, 1994:B7.
19. *The Health Consequences of Involuntary Smoking: A Report of the Surgeon General*. Washington, DC: US Dept of Health and Human Services; 1986. DHHS CDC publication 87-8398.
20. Young JC, Robinson JC, Rickert WS. How good are the numbers for cigarette tar at predicting deliveries of carbon monoxide, hydrogen cyanide, and acrolein? *J Toxicol Environ Health*. 1981;7:801-808.
21. Cohen JB. Research and policy issues in Ringold and Calfee's treatment of cigarette health claims. *J Public Policy Marketing*. Spring 1992;11:82-86.

Printed and Published in the United States of America