



California Smokers' Helpline

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January 11, 2011

Division of Dockets Management, HFA-305
Food and Drug Administration
U.S. Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

RE: Docket Number FDA-2010-N-0568, RIN Number 0910-AG41

Dear Colleagues,

On behalf of the California Smokers' Helpline, we would like to thank FDA for the opportunity to provide comments on the proposed rule regarding the inclusion of graphic warnings on cigarette packs and in cigarette advertisements. Our expertise is in the design, operation, promotion, and evaluation of telephone quitlines.¹ The California Smokers' Helpline was the first publicly supported, statewide quitline in the U.S. and has been in continuous operation for over 18 years. In that time, our group has maintained a dual focus on providing high-quality, accessible behavioral treatment to large numbers of Californians (over half a million so far) and on building the evidence base for tobacco cessation interventions. Based in part on our published research, the U.S. Public Health Service has found a "robust effect of quitline counseling" and recommends it as a central strategy to help tobacco users quit.

We strongly support FDA's proposed regulatory efforts in the area of enhanced graphic warnings on packs of cigarettes and in cigarette advertising. We recommend that you select the graphic warnings that are demonstrated to be most effective in discouraging tobacco use, and that you include in all warnings the toll-free telephone number for the national network of quitlines. The existence of a national network of quitlines with a single point of access, 1-800-QUIT-NOW, means that the infrastructure is already in place to provide evidence based treatment to tobacco users nationwide, should FDA decide to require inclusion of this important resource on packs of cigarettes and in cigarette advertising. We believe it should do so, for the following reasons.

1. As mentioned above, quitlines have a strong evidence base. The most recent Cochrane review of evidence for telephone counseling found that across multiple randomized, controlled trials, callers assigned to receive proactive, multi-session telephone counseling

¹ Zhu S-H, Anderson CM, Tedeschi G, Rosbrook B, Johnson C, Byrd M, Gutiérrez-Terrell E (2002). Evidence of real-world effectiveness of a telephone quitline for smokers. *New England Journal of Medicine*, 347, 1087-1093, and Anderson CM, Zhu S-H (2007). Tobacco quitlines: looking back and looking ahead. *Tobacco Control*, 16 (S1), i81-i86.

had an odds ratio for long-term quitting of 1.37 (95% confidence interval 1.26 to 1.50), relative to callers randomly assigned to receive self-help materials only.²

2. Quitlines are almost universally accessible; they are available in all 50 states, the District of Columbia, Puerto Rico and Guam. Calls made from within any state or territory are seamlessly and immediately routed to the quitline serving that area. No other form of live, one-on-one assistance to help tobacco users is as universally available across the nation. Quitlines range in age, but all are at least several years old. With their colleagues from Canada, all U.S. quitlines actively participate in the North American Quitline Consortium, a membership organization which promotes quitline quality and facilitates the adoption of best practices in the field. U.S. quitlines receive further technical support from CDC and NCI, and most also receive some level of financial support from CDC in addition to their state funding.
3. Quitlines can help address racial disparities in access to effective tobacco treatment. It has long been noted that tobacco users of racial minority backgrounds are less likely to seek treatment to quit smoking than tobacco users who are white.³ However, this does not appear to be the case with quitlines. In California, for example, African Americans have been significantly over-represented among quitline callers, relative to their proportion among tobacco users in the state. This pattern has been remarkably consistent over time.⁴
4. Quitlines can also help address disparities related to socioeconomic status (SES). Whereas in the general population the rate of cessation has been highest among high- and medium-SES tobacco users, we have found in California that utilization of quitline service is highest among low-SES tobacco users.⁵ In fact, over half of callers to the California Smokers' Helpline are Medicaid beneficiaries and another quarter have no insurance at all. The attractiveness of quitline services to low-SES tobacco users is related to the fact that services are provided at no charge and are accessible by telephone, eliminating the need to arrange for transportation or child care, which can be significant barriers for individuals with modest resources.

² Stead LF, Perera R, Lancaster T. Telephone counselling for smoking cessation. *Cochrane Database of Systematic Reviews* 2006, Issue 3. Art. No.: CD002850. DOI: 10.1002/14651858.CD002850.pub2.

³ Cokkinides VE, Halpern MT, Barbeau EM (2008). Racial and ethnic disparities in smoking-cessation interventions: Analysis of the 2005 National Health Interview Survey. *American Journal of Preventive Medicine*, 34(5), 404-412.

⁴ Zhu S-H, Gardiner P, Cummins S, Anderson CM, Cowling D, Wong S, Gamst A (In press). Quitline utilization rates of African American and White smokers: the California experience. *American Journal of Health Promotion*.

⁵ California Smokers' Helpline, unpublished data.

5. The access number for the national network of quitlines, 1-800-QUIT-NOW, is itself a cogent cessation message. In this regard it is the perfect complement to the graphic warnings, which are intended to sharpen the motivation to quit. To retain this benefit, it is vitally important that FDA require that the telephone number be printed in its spelled-out version. Otherwise, the tobacco industry may convert the letters in 1-800-QUIT-NOW to their numerical equivalents. This would not only make the telephone number much less memorable, but would obliterate the cessation message inherent in the words "quit now".

6. Health care providers are more likely to address tobacco use in their patients when they know of an effective program where they can refer them, and putting 1-800-QUIT-NOW on all packs of cigarettes will dramatically increase awareness of this resource among patients and providers alike. This is because patients ask their providers about resources that they have seen promoted on television or elsewhere, just as providers share resources with patients that they have seen promoted in professional journals or through other channels. Based on our experience in California, steady promotion of the quitline number over the years has been associated with a correspondingly steady increase in health care provider participation, to the extent that provider referrals are now the single largest source of calls to the quitline. Inclusion of 1-800-QUIT-NOW on packs of cigarettes and in cigarette advertising will provide state tobacco control programs with a powerful boost in their efforts to increase awareness of effective quitting resources among both patients and providers.

Thank you for the opportunity to provide input on a matter of great public health importance. Please do not hesitate to contact us if you would like additional information.

Sincerely,



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