

Expert Report of Michael C. Fiore, M.D., M.P.H.

1. My name is Michael C. Fiore. I am a Professor of Medicine and the Director of the Center for Tobacco Research and Intervention at the University of Wisconsin Medical School in Madison, Wisconsin. I founded and have served as Director for the Center for Tobacco Research and Intervention since it was established in 1992. I have been at the University of Wisconsin Medical School since 1988, holding the positions of Assistant Professor (1988-1994), Associate Professor (1994-1998) and Professor (1998-present).

2. I graduated from Bowdoin College in 1976 and then completed medical school at Northwestern University in 1981. Following medical school, I began and completed training in internal medicine at Boston City Hospital. I obtained a Masters of Public Health in Epidemiology from the Harvard University School of Public Health in 1985. I subsequently served as an Epidemic Intelligence Service (EIS) Officer at the Centers for Disease Control and Prevention (CDC) in Atlanta, Georgia before working as a medical epidemiologist and preventive medicine resident from 1987-1988 at CDC's Office on Smoking and Health in Rockville, Maryland.

3. I have written numerous articles, chapters and books on tobacco use, with a particular emphasis on smoking cessation, as reflected in my *curriculum vitae*, which is being provided with this expert report. I served as chair of the panels that produced the *AHCPR Clinical Practice Guideline (#18) – Smoking Cessation* in 1996 and the United States Public Health Service Clinical Practice Guideline: *Treating Tobacco Use and Dependence* in 2000. I also chaired the United States Department of Health and Human

Services Subcommittee on Cessation of the Interagency Committee on Smoking and Health, which produced a comprehensive plan for promoting tobacco cessation in the United States.

4. I intend to offer expert testimony concerning feasible, science-based action steps to promote and achieve tobacco cessation amongst all smokers, including those Americans most adversely affected by tobacco use – the poor, the least educated, certain racial and ethnic minority groups, and others. The opinions that I intend to offer at trial are based on my education, training and experience, and on the particular sources listed at the end of this expert report. In many instances language used to describe the components of a successful cessation program has been taken directly from *A National Action Plan for Tobacco Cessation* (Final Draft of February 13, 2003), prepared by the Subcommittee on Cessation of the Interagency Committee on Smoking and Health, of which I was the chair. A summary of this report was also published in the *American Journal of Public Health* in 2004.

5. A comprehensive, evidence-based cessation program should include: (1) a national tobacco quitline network that will provide universal access to evidence-based counseling and medications for tobacco cessation; (2) an extensive paid media campaign to encourage Americans to quit using tobacco; (3) a new, broad, and balanced research agenda (basic, clinical, public health, translational, dissemination) to achieve future improvements in the reach, effectiveness and adoption of tobacco dependence interventions across both individuals and populations; and (4) training and education to

ensure that all clinicians in the United States have the knowledge, skills and support systems necessary to help their patients quit tobacco use. It should also: (5) mobilize health systems to implement system-level changes that result in effective utilization of tobacco dependence treatments; (6) mobilize national quality assurance and accreditation organizations, clinicians, health systems, and others to establish and measure the treatment of tobacco dependence as part of the standard of care; and (7) mobilize communities to ensure that policies and programs are in place to increase demand for services and to ensure access to such services. The benefits of these steps will be both immediate and, if funded for a sufficient duration, sustained. These components are based upon the best scientific evidence available and hold tremendous promise for producing dramatic decreases in tobacco use and its resulting human and economic costs. It is important that a cessation program provide a full range of treatment options so that treatments can be targeted to the needs of individual smokers.

6. Recent comprehensive analyses of hundreds of research reports demonstrate that numerous, effective tobacco dependence treatments now exist. These evidence-based reviews of the literature including the United States Public Health Service Clinical Practice Guideline: *Treating Tobacco Use and Dependence*, the CDC's *Guide to Community Preventive Services*, the CDC's *Best Practices for Comprehensive Tobacco Control Programs*, and reviews of the extant tobacco dependence treatment literature by the Cochrane Collaboration. Not only do such treatments more than double a smoker's likelihood of achieving long-term abstinence, but research shows that such treatments are highly cost-effective:

- A persuasive body of research shows that proactive smoking cessation quitlines are a highly effective population-based strategy to help large numbers of individuals quit smoking. Proactive quitlines are those that initiate counseling calls to tobacco users once the individual has taken the first step of contacting the quitline. Quitlines may also contact tobacco users with their permission, after a healthcare clinician has provided the quitline with their names and contact information. Quitlines have the following benefits: they are effective, provide cessation treatment at relatively low cost, and are highly acceptable and accessible to a wide range of smokers, including the elderly, certain racial and ethnic minorities, and the uninsured, among others. The estimated cost of a national cessation quitline network, that provides both FDA-approved medications and evidence-based counseling for treating tobacco dependence, is \$3.2 billion per year.
- There is a substantial and consistent body of evidence that media campaigns, especially when they are integrated with other tobacco control actions, reduce the consumption of tobacco and the prevalence of tobacco use. Research on statewide tobacco control programs has shown that aggressive media campaigns have been effective in targeted ways such as prompting individuals to use evidence-based treatments such as quitline services or discouraging children and adolescents from starting to smoke. At least \$1 billion should be spent on a national media campaign annually

to counter the effects of tobacco company advertising and promotional activities (for which expenditures were more than \$12 billion in 2002).

- Current research support is not adequate to achieve sufficiently rapid progress in tobacco dependence science. Funding is too limited given the enormity of the health and economic impact of tobacco use. Current treatments for tobacco dependence, while more effective than unassisted quit attempts, still result in only 10% to 30% of smokers achieving long-term success. These quit rates, while comparable or superior to the effectiveness of treatments for other chronic diseases, discourage some clinicians from more actively intervening in tobacco dependence. Failure also discourages some smokers from making new quit attempts. Smokers typically wait months or years to mount a new quit attempt following a failure. Additionally, widespread successful cessation is difficult because certain populations either are not aided by current treatments, or are not adequately exposed to them. For example, treatments may not be adequately accessible to certain populations, or these populations may not have adequate information and motivation to seek treatment and benefit from it. Populations that are less likely to benefit from current treatments include, among others, those with psychiatric comorbidities (e.g., psychosis, depression), pregnant women, certain racial and ethnic minorities, adolescent smokers, and individuals with very high levels of nicotine dependence. These findings highlight the need for a significant enhancement of research funding for tobacco

cessation. Both the PHS Clinical Practice Guideline and the CDC's Guide to Community Preventive Services identified many future research questions pertaining to successful treatment of tobacco dependence that, if answered, could dramatically improve cessation rates and reduce health disparities due to tobacco use. The total funding required to implement this recommendation will be \$500 million per year.

- Clinical interventions provided in the context of regular health care delivery have been demonstrated to enhance rates of tobacco cessation. However, lack of training in such clinical interventions has served as a barrier to their widespread use. The PHS Clinical Practice Guideline states that both clinicians and clinicians-in-training should be trained in the delivery of evidence-based tobacco dependence treatment to improve clinician knowledge and help remove barriers to intervening with patients who use tobacco. The Guide to Community Preventive Services states that multicomponent interventions, consisting of both provider education programs and provider reminder systems, increase successful cessation. The PHS Clinical Practice Guideline also identified several research questions with regard to clinician training and supportive healthcare system changes that, if answered, could dramatically enhance existing and new clinician training programs. The total funding required for this training initiative is approximately \$500 million per year, with half (\$250 million) to fund training within the 145 accredited allopathic and

osteopathic medical schools in the U.S. and half (\$250 million) to fund training within other healthcare professional schools.

7. Recent comprehensive analyses have identified a number of evidence-based clinical and policy interventions that will dramatically reduce tobacco use by promoting smoking cessation. It is my opinion that the conclusions in the PHS Clinical Practice Guideline represent effective, experimentally validated tobacco dependence treatments and practices.

8. It is clear that reductions in smoking prevalence benefit not only smokers, but also their families, friends, and co-workers. Children in particular are harmed by secondhand smoke, both in terms of increased rates of illness and a greater likelihood that they will become smokers themselves if their parents smoke. The effects of tobacco use on the unborn child during pregnancy are also substantial.

9. Substantial disparities exist across populations in rates of tobacco use, harmful impacts, and availability of treatment. Thus, effects of tobacco use occur disproportionately among blue-collar workers, the impoverished, certain racial and ethnic minority groups, pregnant women, and the least educated. In addition, while numerous, effective smoking cessation treatments exist, many Americans do not have ready access to such treatments, and therefore the treatments remain underutilized, particularly by low income tobacco users and racial and ethnic minorities. As a result, the adverse health impacts of tobacco use are inflicted disproportionately on individuals of lower

socioeconomic status and on certain racial and ethnic minorities. Any national plan for tobacco cessation should have the potential to benefit all American tobacco users and their families, from adolescents to the elderly, thus addressing these disparities.

Significant funding is required to effectively target the heterogeneity of smokers including but not limited to those of different racial, ethnic, and socioeconomic status.

10. While tobacco use is a nationwide problem, great differences exist across states and communities with respect to availability of, and support for, evidence-based tobacco dependence treatments. Therefore, a new plan should be sufficiently funded to supply treatment resources to Americans regardless of where they live.

11. Any national cessation program should exert both significant immediate impacts and be sustained in terms of its effects. The steps that are identified in this expert report, if implemented, can be expected to eliminate tobacco use by a minimum of 1 million smokers in the first year. Only by ensuring that a national cessation program is sustained, can it adequately provide treatment for the large number of tobacco users who may need to make several quit attempts before attaining long term remission of the chronic condition of tobacco dependence. Additionally, the program must sow the seeds for future improvements in the understanding and treatment of tobacco dependence.

12. To achieve maximum effectiveness, a cessation program needs to be comprehensive and its individual components integrated. While each of the elements identified is effective by itself, the impact of the plan elements will be substantially

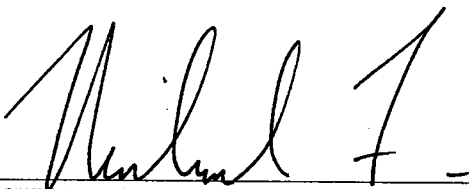
increased when implemented as part of a comprehensive effort. The comprehensive effort should be sustained for long enough to create an environment conducive to long term success in achieving reductions in prevalence – an environment that will result from the media campaign, quitline network, and related cessation efforts to create a population that is immune to tobacco marketing and misinformation about the true health effects of cigarettes. With approximately 45 million smokers in the United States and the expected elimination of tobacco use by 1 million persons per year under a national cessation program, it is reasonable to expect that it will take as many as 25 or more years to create the necessary environment. It is my understanding that one of the goals of a cessation program will be to prevent and restrain future conduct by defendant tobacco manufacturers through the reduction or elimination of smoking within many groups. This goal also counsels in favor of extending a cessation program for an extended period of time.

In support of my opinions, I rely on my education, training and experience. I also rely on:

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3. ICSH Action Plan on Tobacco Use Cessation report (August 2001).
4. Draft National Blueprint for Disseminating and Implementing Evidence-Based Clinical and Community Strategies to Promote Tobacco Use Cessation.

5. Fiore MC. *Preventing 3 Million Premature Deaths and Helping 5 Million Smokers Quit: A National Action Plan for Tobacco Cessation*, the references specifically cited therein, and testimony received from individuals and organizations during the process of developing recommendations.
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