

Refining Litigation as an Instrument of Tobacco Control Annotated Expert Testimony on Equitable Remedies

INTRODUCTION

Tobacco industry conduct has been the focus of extensive judicial scrutiny. Numerous individual and class action lawsuits also have been filed and many more lawsuits are expected both in this country and elsewhere. Judges and juries rely on expert witnesses to untangle complex scientific and technical questions in these cases.

Tobacco litigation encompasses two parts. The first part addresses liability and includes questions like “Was a cigarette manufacturer negligent,” “Did the manufacturer misrepresent the effects of its products,” or “Should the manufacturer be strictly liable for marketing such a dangerous product?” In addition, during the liability phase of litigation, defendant manufacturers have argued that the plaintiff’s irresponsibility – and not their own conduct – was the primary cause of any harm he or she may have suffered.

The second part of tobacco litigation involves identification of the proper remedy. In litigation brought by private litigants, the remedy involves a monetary award, which is in and of itself a powerful deterrent to future wrongdoing when the damage award includes punitive damages. (For more information on punitive damages, reference the annotated testimony by Robert Johnson.) Another type of remedies is called equitable remedies, and they are available in litigation brought by individuals or by governments. In *U.S. v. Philip Morris Inc. et al*, the Department of Justice sought a judicial order requiring the tobacco industry defendant to cease committing various frauds and to take certain affirmative steps. In *Scott v. American Tobacco Co.*, the plaintiff class sought a judicial order requiring the tobacco industry defendants to assist Louisiana citizens in quitting. The testimony excerpted and annotated below provides guidance on such equitable remedies. Testimony by Dr. Michael Fiore addresses the use of smoking cessation programs. Testimony by Dr. Cheryl Healtton addresses the use of counter-marketing to change youth smokers' attitudes towards smoking.

The following excerpts of expert trial testimony are intended to provide potential expert witnesses and other interested parties with a sense of how their research is presented and challenged in the courtrooms. These excerpts are selected from various cases. A brief description is provided at the beginning of each excerpt along with a citation. “Focus points” are included throughout the excerpts providing insight into the questioning attorney’s motivations for asking particular questions, comments on the expert’s testimony and overall trial strategy. The cited transcripts as well as others are available at the Deposition and Trial Testimony Archive (DATTA) housed at the *Legacy Tobacco Documents Library*. DATTA contains 4,850 transcripts of depositions and trial testimony, including a total of about 820, 000 transcript pages. (www.legacy.library.ucsf.edu)¹

¹ The commentary and annotations are for educational purposes only. They do not necessarily represent the opinions of the testifying expert or other parties involved in the litigation. This work is funded by a grant from the American Legacy Foundation.

ANNOTATED TESTIMONY

In this written testimony submitted to the court, the attorney for the plaintiff asks the expert witness to discuss his background and qualifications. Written testimony is very unusual, but was used in this case due to the large number of witnesses and range of testimony. Each witness was, however, made available for cross-examination by the other party based both on their written direct testimony and on any possible additional oral testimony. Direct Written Testimony of Michael C. Fiore (Plaintiff), *United States v. Philip Morris USA, Inc., et al.*, (Sept. 2005) Pp. 1-9.

Q: Dr. Fiore, what is your current professional position?

A: 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.

Q: I'd like to start by asking you about your educational and professional background. First, where did you receive your professional education?

A: I graduated Magna Cum Laude from Bowdoin College in Brunswick, Maine, in 1976 and then completed medical school at Northwestern University, earning a Doctor of Medicine degree in 1981. I also obtained a Masters of Public Health in Epidemiology from the Harvard University School of Public Health in 1985.

Q: What professional positions have you held?

A: I completed my internship and residency immediately after medical school in internal medicine at Boston Hospital. It was at the end of that time period that I applied to the Masters of Public Health program at Harvard University. I completed that program and received my M.P.H. in Epidemiology, as I mentioned, in 1985. Immediately after that, I began service as an Epidemic Intelligence Service (EIS) officer with the Centers for Disease Control and Prevention (CDC).

Focus Point: Direct testimony starts with a summary of the witness's qualifications to testify as an expert. Education, work experience and affiliations are all relevant for determining whether the witness is a suitable expert witness.

Note that this part of the testimony also defines the scope of the witness's testimony. Knowing exactly which questions he or she needs to answer, the attorney who has called the witness to the stand will guide the witness in articulating the exact scope of the testimony. The attorney's efforts in this regard actually continue throughout the entire direct examination. In this manner, the attorney can limit the issues subject to cross examination and fend off attacks by opposing counsel that the witness' testimony goes beyond his expertise.

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Q: Please tell the Court about your work at the Office on Smoking and Health.

A: I worked with the epidemiology group at the Office on Smoking and Health, which at that time had about 5 epidemiologists. My research, along with the group, focused on the epidemiology of tobacco use and the impact of public health policies on tobacco use. My colleagues and I analyzed data from the National Health Interview Surveys (NHIS), among others, to assess trends in tobacco use starting in the mid-1960s and projecting cigarette smoking prevalence to the year 2000. We also studied tobacco use prevalence

and ascertained that disparities that had developed over time as a function of educational and socioeconomic status. That is, if you were less educated, you were more likely to smoke compared to those with at least a high school education. The findings of these analyses were published in the *Journal of the American Medical Association* (JAMA) in 1989. As part of this three paper series in JAMA, my colleagues and I also analyzed data from the NHIS since the mid-1960's and documented that the smoking prevalence among men was decreasing at four times the rate of women. Additionally, we analyzed data from the 1986 Adult Use of Tobacco Survey to understand how smokers actually attempt to quit smoking. We learned that, in 1986, 80% to 90% of smokers who tried to quit reported they had used a "cold turkey" method – that is, on their own without any evidence-based treatment. At that time, few science-based treatments were available – nicotine gum was the only medication that had been approved by the FDA and little was known about effective counseling approaches. These findings were published in JAMA in 1990.

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Q: Before we discuss the Center for Tobacco Research and Intervention, can you tell the Court generally about the focus of your research at the University of Wisconsin?

A: Certainly. My research at the University of Wisconsin has focused on understanding tobacco dependence and developing effective strategies, both clinical and population-based, to facilitate treatment of tobacco dependence.

Q: How have you researched the issue of tobacco dependence?

A: One area of my research in understanding tobacco dependence has focused on the tobacco withdrawal syndrome as an explanatory measure for how treatments work and why, in some instances, they may not be as effective. My colleagues and I developed and tested novel measures of and approaches to withdrawal and dependence that were more sophisticated and sensitive than those used in previous studies. These measures revealed that withdrawal symptoms sometimes last much longer than was suggested by earlier work, that different components of the withdrawal syndrome were highly predictive of likelihood of treatment failure, and that efficacious pharmacotherapies work in part by suppressing these components of the withdrawal syndrome.

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Q: Can you describe some of the other research you have conducted while at the University of Wisconsin?

A: I have been involved in many studies of pharmaceutical treatments for smoking cessation, both as a Principal Investigator and as a co-investigator. My colleagues and I have performed some of the first research on the clinical efficacy of nicotine replacement therapies and bupropion SR (which was first sold as Zyban®). This research has been published in JAMA, the *New England Journal of Medicine* and elsewhere and has been widely cited by other researchers and in authoritative reviews. Among the principal information obtained from this research are the following: (1) efficacy estimates for specific pharmacotherapies – estimates that have been replicated by numerous other investigators; (2) specific strategies that lead to optimal success when using these pharmacotherapies, including which treatments are best for which populations (e.g., women, those with a history of depression); (3) the effectiveness of combining pharmacotherapy and behavioral counseling and the mechanisms by which they work;

and (4) the cost-effectiveness of pharmacotherapies, counseling, and their use in combination.

In this written testimony submitted to the court, the expert witness introduces a proposed structure for a national smoking cessation program. Direct Written Testimony of Michael C. Fiore (Plaintiff), *United States v. Philip Morris USA, Inc., et al.*, (Sept. 2005) Pp. 16-21.

Q: Dr. Fiore, in your opinion, is there a need for a comprehensive national smoking cessation program?

A: Yes. Reducing tobacco use is a public health issue of paramount and unparalleled importance. There is a substantial body of evidence documenting the toll that tobacco exacts in terms of years of life lost, excess health care costs, and other excess costs, such as lost productivity. Just as importantly, there are millions of smokers who want to quit but continue to smoke. A comprehensive national smoking cessation program has the potential to reach smokers of diverse populations, to normalize quitting, and to make sure that every smoker who wishes to quit has the opportunity to do so successfully using science-based treatments.

Q: Please provide the Court a general overview of what a comprehensive cessation program should address.

A: It is important that a comprehensive cessation program provide a full range of treatment options, both counseling and medications, so that treatments can be targeted to the needs of individual smokers. Moreover, it creates an environment that encourages quitting through a multifaceted media campaign, it includes a health care delivery system that includes clinicians who are trained and equipped in tobacco dependence treatments, and it supports a research infrastructure that identifies new treatments that assist all smokers to quit successfully – even those who haven't yet been able to quit with the currently available treatments. A comprehensive cessation program should also address disparities in tobacco use. Scientific data show that persons of lower socioeconomic status, lower educational attainment, and certain racial and ethnic minorities smoke at much higher rates than the general population in the United States. Such groups suffer disproportionately from the excess illness and death from tobacco use. A national cessation initiative should be designed to benefit all tobacco users and their families to help address these disparities. With a full range of treatment options and a program that reaches all smokers, we can help at least 1 million new smokers quit the use of tobacco successfully each year. And if the program exists for at least 25 years, we can work to help all smokers who wish to quit but are unable to do so.

Q: At the outset of your testimony on a comprehensive cessation program, can you briefly identify for the Court the key features of such a program?

A: Yes. The key components of a comprehensive, evidence-based cessation program are: (1) a national tobacco quitline network that will provide universal, barrier-free access to evidence-based counseling and medications for tobacco cessation; (2) an extensive paid media campaign to encourage all smokers in the United States 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. A comprehensive cessation program 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. In my view, a fully funded, comprehensive smoking cessation program will prompt some of the public-private mobilization efforts to occur. 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. In addition, each of the components of a comprehensive cessation initiative must be objectively evaluated to ensure that the activities undertaken are having their intended impact. It would not serve anyone well, particularly the tobacco users who are the intended beneficiaries of such an initiative, if the activities undertaken are not effectively reaching them and facilitating tobacco use cessation. A comprehensive cessation initiative should be sustained over time and securely funded. The best-designed initiative has little likelihood of being implemented and having sustained impact without a secure, ongoing funding source. Secure and sustained funding is also important to permit both short- and long-term evaluation of such initiatives to ascertain whether they are having their intended effect on the population. One very important point is that to maximize their effectiveness, the different parts of a comprehensive program must be integrated and viewed as interdependent parts. While each component I have recommended to the Court has a substantial science base documenting its independent effectiveness, integrated together, this comprehensive program can dramatically reduce tobacco use rates.

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Q: In your view, who should be eligible to participate in the cessation program – that is, what should be the criteria to assess whether a person is a smoker who “qualifies” to obtain cessation assistance from the program?

A: Every smoker in the United States should be eligible to participate. Having barrier-free access to evidence-based smoking cessation therapy is absolutely essential if a program is going to reach the largest number of smokers and thereby help the maximum number of smokers to quit. One of the reasons that comprehensive smoking cessation treatment is so underutilized in this country is that there are often barriers to use even where services are offered. Barriers may take the form of eligibility requirements, screening processes, co-payment obligations, language and other cultural barriers, limited access to services, lack of awareness, limits to covered benefits, and fragmentation of care.

After providing an overview of the structure of a national smoking cessation program above, the expert describes each component. He starts with a description of the quitline. Direct Written Testimony of Michael C. Fiore (Plaintiff), *United States v. Philip Morris USA, Inc., et al.*, (Sept. 2005) Pp. 28-31, 40-43.

Q: I want to turn to specific questions about the components of a national smoking cessation program that you are recommending to the Court, beginning with the telephone quitline. First of all, what is a telephone quitline as recommended?

A: A quitline provides telephone delivered, evidence-based counseling and medications to help smokers who want to quit to do that successfully. To access these treatments, a tobacco user calls a toll-free telephone number and speaks to a trained counselor, who provides information and assistance to the tobacco user in planning a quit attempt. Specifically, based on scientific evidence, the counseling discusses strategies that have been shown to increase the likelihood of successful cessation. But a quitline is not just a helpline; there are a number of essential components in order to insure effectiveness. First, it is important that the quitline services (both counseling and medications) be available to all smokers, without any cost or insurance barriers. Counseling services should be of sufficient intensity to maximize chances of success. For this reason and based on research findings, it is recommended that counseling include at least four person-to-person, proactive calls from trained counselors. It is also important that quitline counseling is augmented with free FDA-approved pharmacotherapy (either over-the-counter medications or vouchers for prescription medications). And it is important that quitline services be tailored to the language, culture, and educational background of the user. Another key feature of a quitline is having counselors who are trained to work with smokers to establish a detailed quitting plan, including the provision of specific advice on the types of medication that are most appropriate for the smoker in making the quit attempt. The trained counselors who staff the quitline should then be able to work with smokers both during the initial intake call and every step of the way through the process of quitting. Additionally, it is important that telephonic treatment be available 24 hours per day, seven days a week, so that whenever a smoker wants to make an assisted quit attempt s/he is able to do so.

Q: Have quitlines been used previously?

Focus Point: The question of whether others have tried implementing quitlines allows the witness to highlight the clinical evaluation of the cessation strategy.

The question also allows the witness to differentiate the cessation-related remedy being proposed in this case with the cessation treatments already in place. The attorney for the defendants will argue that the cessation-related remedy being proposed by the plaintiffs is unnecessary because it is duplicative of state cessation treatments.

A: Yes. The telephone quitline is a strategy that has been used to treat tobacco dependence and cessation on a population level in a number of states and by a number of health plans and businesses.

Q: What role will the quitline play in a comprehensive cessation program?

A: A national tobacco quitline network will provide universal access to evidence-based counseling and medications so that all smokers who want to quit can do so successfully. Effective treatments for tobacco dependence exist. The extant literature speaks eloquently to the effectiveness of both proactive telephone counseling as well as pharmacotherapy for smoking cessation. However, the reach or use of such treatments remains low. Further, research has shown that there are significant disparities in access to evidence-based treatment across geographic locations, among certain racial and ethnic minorities, and across socioeconomic groups. Population-based strategies are essential to address disparities in access to treatment, in order to ensure that all tobacco users, regardless of where they live, can obtain treatment without barriers. A proactive telephone quitline that provides both evidence-based counseling and medications is such an effective strategy because it has the capacity to be individualized to the particular characteristics of the caller, while at the same time provide the widest access possible to the full population of American smokers who want to quit.

Q: What is “proactive telephone counseling?”

A: In contrast to a typical helpline that only provides brief advice in response to incoming calls, proactive quitlines are characterized by two key components. First, when the smoker makes the first call, an extensive intake is completed, when all the critical information necessary to personalize an evidence-based quit plan is collected. Second, this extensive intake call is followed by a series of subsequent outgoing counseling calls, initiated by the quitline, to assist the smoker every step of the way as s/he works through the quit plan. The quitline is also equipped to receive additional incoming calls from smokers during a quit attempt – for example if a smoker trying to quit is having a day of particular difficult withdrawal symptoms, s/he can call the quitline and obtain individualized evidence-based advice. In essence, a proactive quitline is designed to serve as a real-time partner in successful quitting. Quitlines may also work with healthcare providers and, after receiving permission from a tobacco user, contact that person directly for the first intake counseling session.

Q: You also mentioned the literature that supports the effectiveness of proactive telephone counseling for smoking cessation. Please tell the Court about that evidence.

A: There have been a number of research studies published, including research published in the *New England Journal of Medicine* and *JAMA*, that has documented the clinical effectiveness of proactive quitlines in helping smokers to quit. In addition, this recommendation is supported by two published meta-analyses. First, a meta-analysis published in the 2000 United States Public Health Service Clinical Practice Guideline *Treating Tobacco Use and Dependence*, demonstrated a 1.2 estimated odds ratio for proactive telephone counseling. A more recent meta analysis published in 2002 by the Cochrane Collaborative involving 27 studies demonstrated a 1.56 odds ratio for proactive telephone counseling compared to less intensive intervention (e.g., self help quitting materials).

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Q: Is it your recommendation that a national telephone quitline replace existing state quitlines?

A: No. States should have the capacity to maintain their own quitlines and personalize that quitline to the state. What I'm recommending is that a national quitline network be funded so that all American smokers who want to quit can get access to telephone counseling and medications and that we build upon the state and regional network to ensure that local control can be maintained and built upon. Clearly there are state- and region-specific needs, and there are state and regional services that are best able to serve local populations. For this reason, I feel, and the Subcommittee felt incredibly strongly, that local control should be maintained but maintained in the context of a nationally funded system that delineates the core performance standards that will result in maximum reach and maximum effectiveness.

In describing the components of smoking cessation program, the witness reviews cessation medications. Direct Written Testimony of Michael C. Fiore (Plaintiff), *United States v. Philip Morris USA, Inc., et al.*, (Sept. 2005) Pp. 43-46, 49-50.

Q: Dr. Fiore, I want to ask now about medication to treat tobacco dependence. You stated earlier that the national quitline network should have the capacity to provide callers with universal access to smoking cessation medications. What are the medications to which you are referring?

A: FDA has approved six medications for smoking cessation. Five of these medications are nicotine replacement therapies – the nicotine gum, the nicotine patch, the nicotine lozenge, the nicotine inhaler, and the nicotine nasal spray. The sixth medication, bupropion SR, is an antidepressant that has been shown to be effective in treating tobacco dependence, presumably because of its capacity to block the re-uptake of dopamine and norepinephrine in the brain and nervous system. It has also been shown to relieve depressed mood. The nicotine gum and nicotine lozenge are available exclusively over-the-counter. The nicotine patch is also available over-the-counter, though a generic nicotine patch may be prescribed by a physician. The nicotine inhaler, nicotine nasal spray, and bupropion SR are only available by prescription.

Q: How would the quitline dispense approved pharmacotherapies?

A: Based on information in the FDA-approved package inserts, a trained quitline counselor will discuss with the smoker which medicine may be most appropriate, based on prior experience with the medicines, contraindications, patient preference and other factors as defined in the 2000 Guideline. If an over-the-counter medication is most appropriate, the medication will be sent directly to the smoker in the mail along with other personalized quitting information. If it was determined that the most appropriate medicine for the smoker was a prescription agent such as bupropion, when the quitline mails other quitting information to the patient, it would include a voucher for the prescription medication. At that point the smoker would have to visit a physician or other provider who would review the appropriateness of the medicine, sign the prescription, and allow the patient to get the voucher filled by a pharmacy.

Q: Isn't that a barrier to access?

A: If the caller did not have a regular physician, then yes, it would be a barrier. But for about 70% of smokers, it is anticipated that over-the-counter medications will be most appropriate for them and that medicine will be mailed directly to them. In addition, if the absence of a physician was identified as a barrier for a smoker, then the quitline counselor would not recommend prescription medications.

Q: Are there quitlines that have done this successfully in the past?

A: Yes, some quitlines have dispensed pharmacotherapies. For example, Minnesota has contracted to dispense over the counter medications with its quitline counseling, as has the State of Maine. In Wisconsin, in a program that targeted older smokers, we dispensed nicotine patches through the mail when smokers called the quitline. The demand for this program was extraordinary. We offered nicotine patches to smokers over 65 who called the state quitline for a six month period (a limited budget allowed us to run the program for only six months). With a series of news conferences as the only promotion, 5.5 percent of the population of senior smokers in the state called the quitline during these six months while nicotine replacement therapy was being offered.

Q: Are the smoking cessation medications that are available effective?

A: Yes.

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Focus Point: The effectiveness of any treatment plan depends on how many people utilize the treatment. Accordingly, strategies for increasing utilization and removing barriers for utilization are important.

Q: Does the ability for a quitline to provide FDA-approved medications as part of its services affect whether smokers utilize the quitline services?

A: Very much so. Utilization rates increase dramatically when nicotine replacement therapies are added to the range of treatments offered by a quitline. In Minnesota, for example, utilization rates jumped from 1-2% of smokers to about 6% of smokers when the state quitline was expanded to include provision of pharmacotherapies.

In describing the components of smoking cessation program, the witness reviews the sustained media campaign. Direct Written Testimony of Michael C. Fiore (Plaintiff), *United States v. Philip Morris USA, Inc., et al.*, (Sept. 2005) Pp. 53-58.

Q: This is a good time to focus questions on the second component of a national comprehensive cessation program that you identified, an extensive paid media campaign to encourage Americans to quit using tobacco. Please describe what you mean by “an extensive paid media campaign.”

A: A multifaceted media communications campaign is necessary to alert smokers to the existence and availability of the other services and components of the cessation program. Most fundamentally, if people do not know about the quitline or other available cessation services such as those provided by their clinicians, they will not be able to use them to help quit. I recommend a comprehensive media campaign such as that described by the Cessation Subcommittee that includes four goals: first, to promote the use of the national tobacco quitline and other effective cessation interventions: second, to motivate tobacco

users to make a quit attempt and increase demand for effective cessation services; third, to motivate parents to quit by informing them of the health risks that secondhand smoke poses to their families and informing them that their smoking increases the likelihood that their children will smoke; and fourth, to reach all segments of the population, including the most underserved and hard-to-reach populations such as low socioeconomic status, certain racial and ethnic minorities, and those of limited English proficiency.

Q: What are important characteristics for an extensive paid media campaign to have?

A: The promotional campaign needs to be guided by media and communications science as to the most effective messages and strategies to implement. It needs to be pervasive – that is, to be a consistent presence in the everyday lives of smokers in the same way smokers encounter tobacco marketing. To do that, the media campaign must use the full range of media – radio, television, print media, signage, Internet, etc.

Q: Should the annual budget for a media campaign be divided in any specific way between the four purposes that you have identified?

A: Not specifically. The Subcommittee wanted the Action Plan to have a series of characteristics that included powerful and effective messages that would be guided by media and communication science, that it be multifaceted and persuasive. But in terms of the allocation among those characteristics the Subcommittee felt, and I agree, that a standing group of communications experts would be best equipped to design it, evaluate it, and ensure that it was having the effectiveness intended.

Q: Are sustained media campaigns effective in contributing to cessation?

A: Yes. 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.

Q: What is some of that evidence?

A: The strongest evidence of effectiveness of such media campaigns comes from settings where they were implemented in the context of multicomponent programs. Such programs increased cessation across a variety of populations, indicating their widespread impact. This research was summarized by the CDC in 1999 as part of its publication, *Best Practices for Comprehensive Tobacco Control Programs*, cited in my expert report.

In describing the components of smoking cessation program, the witness reviews the research agenda. Direct Written Testimony of Michael C. Fiore (Plaintiff), *United States v. Philip Morris USA, Inc., et al.*, (Sept. 2005) Pp. 58-63.

Q: Turning to the next component of the national cessation program you identified, why are you recommending a new, broad, and balanced research agenda to achieve future improvements in the reach, effectiveness and adoption of tobacco dependence interventions across both individuals and populations?

A: It is vital that we implement a research agenda that provides for basic, clinical, public health, translational, and dissemination research in order to improve our tobacco control efforts.

Q: You use the terms “basic,” “clinical,” “public health,” “translational,” and “dissemination” to describe the research. What do you mean by those terms?

A: Basic research refers primarily to laboratory and bench research aimed at developing new and effective counseling and medications designed to treat smokers and help them quit. For example, it might investigate some genetic factors that may translate into greater difficulty in quitting. Clinical research refers to research that involves patients and often evaluates the safety and effectiveness of medications and counseling to help smokers quit. Public health research refers to the broader study of tobacco dependence treatments taking a population-wide approach. One such example is communications science interventions that lead specific segments of the population, such as different racial, ethnic, educational, and socioeconomic groups to try to quit. Translational research involves evaluating strategies that are designed to deliver findings from the laboratory to the patient, often involving scientists from a number of different disciplines who work together. Finally, dissemination research refers to studies that evaluate the impact of strategies that are designed to ensure that smokers or their clinicians use the research findings that were discovered.

Q: Does such a multidimensional research plan require oversight and coordination?

A: Yes.

Focus Point: Comparing the proposed remedy with a program that already works well gives the court more confidence that the remedy will work. The attorney for the defendant will point to the existing programs and suggest that the court ask itself why duplicate existing programs.

Q: Who should perform that role, and what would that entail?

A: One model is the Flight Attendant Medical Research Institute (FAMRI) research fund, which was set up in the settlement of tobacco litigation in Florida. In that instance, a Scientific Advisory Board guides FAMRI administratively through an identification of key scientific questions that need to be answered and a process to independently peer review the applications of scientists who propose to answer those questions. Such a model might be used to oversee the research activities of the National Action Plan. Of course, the NIH provides a wonderful model of how to run a large peer-reviewed research enterprise.

Q: Why are the types of research you have identified as important to include in a comprehensive cessation program?

A: The Subcommittee on Cessation identified two core needs for tobacco cessation research and I endorse those two key questions. We need to identify tobacco dependence treatments that first are effective in reducing the disparities in tobacco use and second, that increase long term successful cessation rates to at least 50%. Such a broad and balanced set of research initiatives is important to improve treatments for tobacco dependence and train the next generation of tobacco scientists. Current treatments for tobacco dependence, while significantly more effective than quitting on your own, still result in only 10% to 30% of smokers achieving long-term success. When viewed from a medical perspective, these quit rates are comparable or superior to the effectiveness of

treatments for other chronic diseases. By that, I mean the following - as a doctor, I would love to have a first line, safe, relatively inexpensive treatment for my patients with hypertension that results in 30% of those patients entering into long-term remission after just three months on the medication. Moreover, substantial declines in national smoking rates is difficult to achieve at present because certain populations either are not aided by current treatments, or are not adequately exposed to them. Populations that currently are less likely to benefit from available treatments include those with psychiatric co-morbidities such as depression, pregnant women, certain racial and ethnic minorities, adolescent smokers, and individuals with very high levels of nicotine dependence. My belief is that a well-funded, sustained research effort could develop interventions that produce long term success in 50% of smokers treated in a given quit attempt and will be effective in eliminating the disparities in tobacco use that exist today.

Q: Do you refer to smoking as a “chronic disease?”

A: Yes.

Q: Why?

A: Tobacco dependence shows many features of a chronic disease. As with other chronic diseases such as hypertension, hyperlipidemia, and diabetes, patients who smoke often cycle through multiple periods of relapse and remission. Moreover, a failure to appreciate the chronic disease nature of tobacco dependence may undercut clinicians’ motivation to treat tobacco use consistently, instead viewing the smoker or the clinician as a failure. Finally, recognizing the chronic disease nature of tobacco dependence places the treatment of tobacco dependence squarely within the scope of responsibilities of primary care clinicians.

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In describing the components of smoking cessation program, the witness reviews the clinical training and education necessary for the program. Direct Written Testimony of Michael C. Fiore (Plaintiff), *United States v. Philip Morris USA, Inc., et al.*, (Sept. 2005) Pp. 64-67.

Q: Let’s turn now to the fourth component of the comprehensive smoking cessation program that you identified – “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.” Please describe this feature of the integrated cessation program.

A: This, like all other parts of the comprehensive program, is closely linked to the other components. If we are going to invest in programs to improve no-barrier access to treatment, and to motivate smokers to try to quit smoking, we need to be sure that health care providers are educated and trained in the best evidence-based treatment strategies to address tobacco use and dependence. We want our healthcare professionals to make screening for tobacco use a routine part of their practice, and to give physicians the knowledge and tools to support their intervention with their patients to encourage quitting. We also want smokers to have effective treatment options. In addition to the proposed quitline, we want every smoker who visits a clinician each year to be provided with advice and assistance on quitting. And this is so important because 70% of smokers visit a primary care physician each year.

Q: How would this part of the program work?

A: The funds dedicated to training and education will be distributed as grants to medical and other healthcare professions schools to develop, implement, and evaluate curricula for evidence based treatment of tobacco dependence for healthcare professions students. The goals of such training will be broad and will establish a standard of care for treating and referring patients who use tobacco. Curricular components will include how to intervene effectively with tobacco using patients, how to implement systems changes to facilitate intervention, and how to access more intensive services for their patients. These funds would also go toward working with healthcare professions organizations and licensing bodies to ensure that licensure and certification examinations for health professionals are modified to include assessments of knowledge on treatment of tobacco dependence. The program would include grants to medical and health care profession schools to develop and evaluate advanced curricula for evidence-based treatment of tobacco dependence for specialists in the area of tobacco dependence treatment. Finally, the program would have to include research to create and evaluate uniform standards for certification of tobacco dependence treatment specialists.

Q: What is the basis for your testimony that this clinician training and education is an effective tool to increase smoking cessation?

A: Seven out of ten smokers visit a physician every year. Few of them are provided with the evidence-based treatments as defined by the 2000 Guideline. If we consider the even broader reach of clinicians who smokers encounter -- dentists, nurses, physicians assistants, nurse practitioners -- more than 80 percent of smokers encounter a clinician each year. The Subcommittee, including the representative from the American Medical Association, Dr. Ron Davis and other physicians and clinicians on the Subcommittee, felt very strongly that unless we seize this teachable moment and intervene with smokers as they present to health care delivery systems, then we're not going to be able to drive down tobacco use rates in the way that Secretary Thompson charged us to achieve. And this is particularly salient given that many of these smokers are presenting to clinics with health problems directly caused by their tobacco use.

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In describing the components of smoking cessation program, the witness reviews the integrating cessation treatment into existing health provider and payer systems. Direct Written Testimony of Michael C. Fiore (Plaintiff), *United States v. Philip Morris USA, Inc., et al.*, (Sept. 2005) Pp. 67-68.

Q: Another aspect of a comprehensive cessation program that you identified as important is that it should “mobilize health systems to implement system-level changes that result in effective utilization of tobacco dependence treatments.” Please describe this further.

A: Essentially, a comprehensive plan must include steps to ensure that our healthcare providers in all settings in which care is provided -- in both the private and public sectors whether that be in managed care organizations, in hospitals, in clinics, or elsewhere -- have systems in place that encourage clinicians to deliver effective tobacco dependence treatments. We want all healthcare delivery systems to make tobacco dependence treatment an integrated, essential part of the care they provide, by encouraging and providing the resources that will help these entities make systemic changes to incorporate tobacco dependence treatment part of their institutional framework.

Q: Please explain further about what a “system-level” change is and how it would come about as part of the comprehensive cessation program.

A: Traditionally, efforts to increase tobacco use intervention in the healthcare setting have targeted the individual clinician. However, to be truly effective, cessation interventions need broad support and participation from all stakeholders, such as managed care organizations, hospitals, medical groups, health clinics and centers, throughout the healthcare system. There is a real need for technical assistance and funding to create, implement, and evaluate the office, practice, and organizational systems of care required for the delivery of evidence-based tobacco dependence treatments. As clinician training and research results in tobacco dependence treatment becoming routinely incorporated into health care delivery and representing the standard of care, I would expect healthcare delivery systems and organizations to take steps to fully and efficiently integrate this aspect of care at the institutional level.

* * *

Focus Point: In ordering equitable remedies, courts prefer remedies that do not require courts to monitor compliance or adjust the remedy. They prefer finality. Additionally, if the cessation program proposed in this case actually would work to remediate the effects of the industry’s malfeasance, as the expert has testified, the court would logically want to know how much time is needed. For this reason, the plaintiff proposes a finite cessation program.

Q: Dr. Fiore, what is the necessary length of time that a comprehensive cessation program must run?

A: Given the current size of the smoking population – about 45 million people, about 30 million of who tell us they want to quit – it is reasonable to expect that it will take as many as 25 or more years to allow every smoker in America who wants to quit to do so successfully. We know that 7 in 10 American smokers wants to quit smoking, but only about 2.5% are able to quit in any given year. This is true despite the fact that about 40% of smokers attempt to quit every year. *Reducing Tobacco Use: A Report of the Surgeon General* (2000) (JD 004673). Given the current prevalence of smoking, the number of new smokers who begin every year, and the number of smokers who die and who already stop smoking every year, the implementation of a national smoking cessation program can be expected to dramatically reduce the population of American smokers who want to quit. Again, this will be achieved by assisting one million additional smokers to quit every year as a result of the program. Without the program, smoking rates will decline at a much slower rate. This whole program is designed to provide evidence based treatments to the great majority of smokers who are trying to quit and are currently not using such treatments. As a result, these motivated smokers who are quitting on their own are having extraordinarily low success rates. This program, based on the National Action Plan, will reach those people including some of the highest prevalence, hardest-to-reach smokers. It is designed to have a substantial immediate as well as sustained impact. It is also necessary that a program exist for a long enough period of time to create the necessary environment in which the population is immune to misinformation about the health effects of smoking, and an environment that is conducive to long term success in achieving reductions in smoking prevalence. Over time, smokers will be made aware

that, as a result of this National Action Plan, it is as easy to get help quitting smoking as it is to walk down to the corner store and buy a pack of Marlboros.

Q: You have indicated that one million smokers will quit each year through the program. What is that number based on?

A: That is the number of smokers that we can help quit by means of the comprehensive quitline (counseling and medication) alone. It is a very conservative estimate, and is based on the Subcommittee's conclusion that approximately five million smokers each year can be expected to undergo treatment – counseling and medication – through the quitline. The estimated success rate of one million smokers per year is based on an extraordinary body of scientific evidence, including the 2000 Guideline and the Cochrane reviews, the CDC analysis, and others.

Q: You also indicated that the program should, over time, create an environment that is conducive to long term success in achieving reductions in smoking prevalence. Can you explain your answer for the Court?

A: Yes, I can. A smoker should have the knowledge of not only existing resources, but the value of those resources, when they want to quit. From my own experience treating more than 10,000 smokers in Wisconsin over the past 17 years, I know that every day people who are motivated to quit are making the tragic decision to switch to low tar cigarettes in the mistaken belief that they are taking a step for health. They are trying to quit “cold turkey” and failing. They are finding reasons to postpone quitting. All of these are decisions that should and can be prevented with a comprehensive program.

In his live direct testimony before the court, the witness discusses the need for cessation services. Direct Testimony of Michael C. Fiore (Plaintiff), *United States v. Philip Morris USA, Inc., et al.*, (Sept. 2005) Pp. 21279-283.

Q. Dr. Fiore, what is depicted here in this exhibit?

A. Well, in this demonstrative I've tried to provide an overview of the total population of smokers in the United States. And what I did to -- the basis of this is the epidemiologic data from the Centers for Disease Control. And I rounded off numbers so that we could really talk big picture who are smokers in America today. What the data tell us is that there are about 47 million smokers. That's the total population of smokers. And that when we talk to them -- and the government does this: regularly to get a sense of what proportion of them want to quit, what proportion of them have already tried -- what we find out is that about 7 out of 10 smokers -- in fact, about 32 million smokers -- tell us that they want to quit. And the proposal that I submitted to the court, the: results of the Subcommittee on Cessation really have this 32 million, the people who want to quit as the target of the report, and those are the people that are the goal of a comprehensive program that would help people to quit. So among those 32 million, what we've been able to determine is that an incredibly large number of them not only want to quit, not only have tried to quit, but actually tried to quit every year.

* * *

The sad reality, though, is that most of them fail. And the bottom number, the current quit rate, reflects under current circumstances the approximate number of Americans who quit about 1.2 million Americans.

The expert discusses the need to remove barriers to utilization. Direct Testimony of Michael C. Fiore (Plaintiff), *United States v. Philip Morris USA, Inc., et al.*, (Sept. 2005) Pp. 21284-305.

Q. Dr. Fiore, why don't we move ahead to U.S. Exhibit 18265 and we can talk about some of these barriers that you've talked about. And to start with, in your opinion, Dr. Fiore, is there a scientific basis for the expected call rate of 16 percent for a comprehensive National Tobacco Quit Line, the bar that we see on the right side of U.S. Exhibit 18265?

A. Yes. It's both my opinion and that of the people who constituted the Subcommittee on Cessation of the Interagency Committee on Smoking and Health that that is an imminently achievable reach.

Importantly, that's how many people will call. The actual number of people that will use the treatment, the counseling and the medicine, is estimated to be about 10 percent.

* * *

Q. I want to talk about some of the reasons that we see, Current State -- the number that we see on the left side of the screen, which is Current State Quit Line utilization in the 1 to 2 percent range. And to start, can you provide the court with a general overview of what is available to smokers through state services today?

A. I'll be happy to. This is really -- I'm going to start with the good news. The good news is that over the course of the last 10 to 15 years a number of states have adopted very restricted Quit Line programs, so that is progress, because we now have between 40 and 42 states that have something, and what that something is reaching currently is between 1 and 2 percent of smokers. So what that reflects is our current reach. The bad news is that because these programs often limit the people who can participate, have an insurance requirement or many other barriers, they are unable to reach what we believe is a potential reach of a program like this.

Q. I want to talk about some of those specific factors that we have on this exhibit here and the specific factors that affect utilization rates. First of all, the exhibit shows a number of items under the heading Elimination of Barriers, and those are also listed in your direct testimony. So I want to take this opportunity to expand on what we see in the direct. Taking the first one. What do you mean by eligibility requirements?

Focus Point: Expert testimony is more effective when the expert sticks to one main point throughout direct and cross-examination. For instance, in this excerpt, the expert continually repeats the concept of having a remedy that does not erect barriers to accessing cessation treatment services.

A. Some of the Quit Lines in states actually limit the people who can call. For example, Utah when it first began limited its program to adolescents. Other states limited based upon whether a person is insured or not. There's a number of requirements that, in essence, if a smoker were to call thinking they would get help, is then told that they are ineligible because they don't fulfill some demographic or insurance or other requirement.

Q. Do eligibility requirements impact utilization?

A. Without a question. They basically take a large proportion of smokers, depending, of course, on what that eligibility requirement is, they could take a large proportion of the smokers out of the pool.

Q. I want to skip co-payment obligations, we will come back to that, but talk about a topic related to eligibility requirements, and that is screening processes. How does screening processes impact utilization rates?

A. Well, for many Quit Lines, if one calls -- and I'll use Minnesota as an example -- there's a very complicated and detailed assessment of what kind of insurance the person has, and based upon that, they can or cannot take advantage of the service, because if they have a certain type of insurance in Minnesota they are then switched to their insurance's Quit Line. In other instances these detailed intakes in essence leads some people to actually not even stay on the line because there's a number of screening questions that are asked before they are told, "You can get help in quitting."

Q. Let's take the one we skipped, co-payment Obligations. Explain the impact of co-payment obligations on utilization.

A. Well, there's a large body of data that tell us that if we put cost barriers in front of smokers who want to quit, that that will serve as an effective barrier to them using the program. And these cost barriers are particularly important because of the high rates of smoking among the impoverished in America, the high rates of smoking among people who don't have any insurance, and it leads to an effective barrier. And there's been well-published research that has looked at this issue of how costs keep smokers from utilizing treatments.

Q. While we are on the subject I want to look at one of those studies, and that's an article by Susan Curry that has been marked as U.S. Exhibit 64387. And we will hand you a copy of that. And first let me ask you if you're familiar with this article? I'll let you get your glasses.

A. Yes, I am familiar with this article.

Q. Can you tell the court briefly what this article tells us about the impact of co-payment obligations?

A. Well, Dr. Curry, in this article that was published in 1998 in the New England Journal of Medicine, looked at a comparison of the use of an insurance benefit that includes both medicine and counseling under various scenarios where the caller to utilize the benefit has to pay or not pay. So she actually compared four different scenarios. One was the standard coverage where the person would have a co-pay paid for half of the behavioral counseling and just the small co-pay on the medication. And the important comparison is a scenario where all coverage was provided so they didn't pay for the counseling at all and there was a very nominal co-pay on the -- nominal co-pay for the medication. What she found was a dramatically higher use rate, people called and took advantage of it when there weren't these barriers, and she also found that that translated downstream into more people quitting. And that of course is the goal, how many people can we get to quit.

Q. Let's take a look specifically at the results, and I want to turn to Page 676 in U.S. Exhibit 64387, and take a look at table 3. I believe it's the third page in, Charles -- fourth page in. What does the table here, Dr. Fiore, tell us about the impact of co-payment obligations on utilization of cessation services?

A. And this speaks to the really critical importance of reach. How many people can we get to call and take advantage of a good cessation program. And I'd focused really in on this total use, I'd focus in on year 2 when the intervention was in place and compare the

standard coverage rate, which is about 3.5 percent, to the full coverage rate of use of 11.6 percent. So in this instance, in a scenario where the counseling was provided, when the medicine was provided, there actually was a small co-pay but a nominal co-pay; that in that scenario 11.6 percent of the people who are a part of this study actually called.

Q. Is the provision of coverage for smoking cessation cost effective?

A. Yes, it is.

Q. Can you please explain how it's cost effective?

A. Well, there's lots of ways to examine this, but I think an excellent example is the work of Dr. Jerry Cromwell who did an analysis of the first age CPR guideline that was published in 1996 and did an analysis of how cost effective are these evidence-based treatments that were delineated in the guideline. Dr. Cromwell in that article -- and I'm a co-author on it -- determined that providing evidence based smoking cessation coverage is among the most cost effective interventions available today. One sort of way that cost effective analysts measure things are quality adjusted years of life lost, so years of life lost, and found that it cost about \$2,000 to earn a quality adjusted year of life lost. And to put that in some context, think about mammography screening, something that we always provide. That costs more than actually \$60,000 for a quality adjusted year of life lost. So, \$2,000 versus 40 or \$60,000, smoking cessation treatment has been referred to as the gold standard of cost effective medical interventions available today.

Q. If that's the case, Dr. Fiore, why don't more states offer comprehensive smoking cessation services?

A. Well, I think there are a number of reasons, but included among them is, of course, most states don't provide insurance for all of their residents. They serve as a system that provides particularly for the lowest income residents. And in this era where states are struggling with budget deficits, particularly in their Medicaid programs, it's a very difficult challenge to them to pay for health care, particularly to the poor.

* * *

Q. I want to talk about some additional barriers. And if we could go back, Charles, to our demonstrative Exhibit 18265. And if we could talk about two related topics: Language and cultural barriers, and access to services. First, can you explain in this context language and cultural barriers and the impact that they have on utilization rates?

A. In so many states, because their budget for their Quit Line is just very small, much less than what they would like to have to provide the services they know their residents need, they have to limit the services usually just to English or, in some instances, to English and Spanish. California is an exception that provides some Asian languages. But, for example, if a person calls the Wisconsin Quit Line, and I'm responsible for directing, we can't respond to the Monday callers there's a large population of Hmong that have moved to Wisconsin because we don't have any counselors that speak that language. Many of the Asian languages we can't respond to. So we are unable to provide services to these people who want to quit and call. In terms of cultural barriers, the one that is something I experience also in Wisconsin because there are so many Native American tribes, and there are very important cultural considerations about tobacco for Native Americans. And not having counselors that are sensitive to that or ideally have experienced the cultural importance of tobacco for Native Americans so that we can allow and encourage them to continue their traditions and their culture, but also remove the dangers of tobacco, serve as a cultural barrier to those callers. In terms of access to services, in many instances it is

similar. I will share just one very practical access to service limitation, and that is most Quit Lines are available for limited hours of the day, some are available not even 7 days a week. Just a couple of weeks ago while at the hospital at the University of Wisconsin I had a nurse come up to me and said, "I know you're the quit smoking doctor. What should I do?" And I said, you know, "I want you to call the Wisconsin Tobacco Quit Line. And that's a service, it could help you. That will be the first step of the way." A couple of days later she said, "I called it. I got off my shift at 11:00, I called it at about 12:30 and there was nobody there." And that's because we can't provide it 24 hours a day. We can't serve the population. In this instance, because nursing and smoking has been a big problem, it was an example of an access to service barrier.

Q. Dr. Fiore, does access to the health care system impact Quit Line utilization?

A. Very much so, and this is why a comprehensive program is so important. We know that if a -- first, the epidemiology, 7 out of 10 smokers visit a primary care physician every year. That's an incredible opportunity to seize their visit, often for a disease caused by smoking, and to urge them to quit and provide them with evidence-based treatments. What we find is that few smokers who visit their doctor are getting the kinds of counseling advice, prescriptions we know will make a difference. We also know that if the health care system is trained, if system level interventions are put into place to ensure that all smokers are identified and intervened with, then what we could have is a linkage between what happens when the smokers visits the doctor and using the Quit Line as an extender of care. And if there is a limitation in health care, and particularly if that smoker goes to a doctor who hasn't been trained, then what we end up having is a missed opportunity.

* * *

Q. I want to address the final large bullet point here on this demonstrative, and that's Awareness. Does a lack of awareness of cessation aids and Quit Line services impact utilization?

A. Very much so. There have been a number of studies that have looked at if people are made aware of the Quit Line, the use of it increases dramatically. And where this has been looked at primarily is in paid media campaigns where in some instances we've seen a doubling of the calls, in some a tripling, and some even a five fold increase. So, what the data tell us is, first, most smokers aren't aware of the Quit Lines because states just don't have the money to promote them. And I could speak to my experience in Wisconsin where at the end of last year we had a small amount of money to promote our Quit Line. We began doing it with some really simple TV ads, and we had a pull the TV ads and stop promoting it because the use rate had increased so much that we weren't going to have enough money to provide the Quit Line counseling through the end of the year because we had a limited budget. And the experience I had in Wisconsin has been repeated over and over again. There's a link between the promotion of Quit Lines and their utilization in states across America.

In this excerpt of cross examination testimony, the attorney for the defendant has the expert discuss services provided in existing quitlines. Cross Examination Testimony of Michael C. Fiore (Plaintiff), *United States v. Philip Morris USA, Inc., et al.*, (Sept. 2005) Pp. 21305-318.

Q. As you know, my name is Ted Wells and I represent Philip Morris.

I want to start my examination by focusing on what state and federal Quit Lines already exist and the types of services that they provide to at least some callers. Okay?

A. Yes.

Q. Now, the North American Quit Line Consortium is an organization that serves, in part, as a clearing house for information on state and national Quit Lines; correct?

A. That's correct.

Focus Point: The attorney for the defendant sets up a line of questioning where the witness agrees to a set of facts one question at a time. Then, the attorney will try to get the witness to concur with his opinion just because he has agreed with his facts. Look ahead to where the line of questioning is going and do not be led down a false trail; on the other hand, if the answer to a question is clearly "yes", say so.

Q. And hereafter, I will refer to it as NAQC. Okay?

A. All right.

Q. NAQC is funded, in part, by the Robert Wood Johnson Foundation and the American Legacy Foundation; correct?

A. I'm not familiar with all the details of their funding, but I believe that's correct.

Q. And for purposes of determining what states have Quit Lines, the data published by NAQC is viewed by you as a good source; correct?

A. I think it's an excellent source of what states have Quit Lines, what states don't, and what are the components of their Quit Lines.

Q. And, in fact, in your deposition you testified that the NAQC is, quote, a wonderful organization to turn to learn more about who has Quit Lines and who doesn't; correct?

A. It would help to see the context of that, but I'm in agreement with that statement, that it is a wonderful organization to provide information about who has Quit Lines and who doesn't, yes.

Q. Now, you are familiar that NAQC has a website where it publishes information about state Quit Lines; correct?

A. I am aware that they have a website, yes.

Q. I want to show you JD 055321, which is a page from the NAQC website that is entitled QuitLine Facts. Now, under QuitLine Facts, that page reads, "Information in this section is based on national statistics from Canada and the USA. NAQC's Quit Line survey for the USA and Canada's survey of Quit Lines for Canada." And you are familiar in your business that one of the things that NAQC does is to conduct a survey of various state Quit Lines; correct?

A. Correct.

Q. And then it goes on to state under USA, "There are 36 state managed Quit Lines. Five states with formal agreements for coverage by the Cancer Information Service at the National Cancer Institute, one state that receives services from the American Legacy

Foundation, and 8 states and DC with no formal arrangements for coverage (but the populations have access to interim services from the National Cancer Institute while state managed services are being established.)" Now my first question is, is it correct that for those states who do not have their own Quit Line, that persons in those states can be serviced by the Quit Line that is operated by the National Cancer Institute?

A. There is a very limited service available through the National Cancer Institute's Cancer Information Service. It's an extremely limited service. But anyone can call an 800 number to access that.

Q. But is it correct that what the National Cancer Institute has done is to attempt to provide a safety net for those limited number of states that do not have any state-managed Quit Line? Is that right?

Focus Point: The attorney for the defendant tries to get the witness to contradict the position he stated in his direct examination by minimizing the efficacy of the remedy he suggested and trying to posit that there are sufficient resources already in place to address cessation needs. The attorney returns to this theme throughout the cross-examination.

The expert correctly responds by defending the need for and efficacy of the proposed cessation remedy in this case.

A. Yes, a very limited safety net.

Q. Now, could we move on to the next page? I want to go to Page 2. Now, also under QuitLine Facts on Page 2 is the following: "The kinds of services provided by Quit Lines: Quit Lines provide a variety of services. The list below includes major categories of services." And it lists the types of services that are provided, including such things as proactive quit smoking counseling, reactive quit smoking counseling, group session programs, provision of quit smoking medication at low cost, provision of quit smoking medication at no cost. Now, as you indicated in your direct testimony a few minutes ago, not all callers who call a Quit Line will be eligible to receive all of the services that the Quit Line offers; correct?

A. Right, not only not will be eligible, but many of the Quit Lines and many of the states don't offer many of these services.

Q. My first question though is, is it correct that not all people will be eligible for the services offered? Yes or no.

A. That's correct.

Q. Thank you. Now, under the section I just read, it also reads, "Languages for counseling services: All Quit Lines offer counseling in English. In Canada, counseling in seven provinces is also provided in French. In the USA, counseling in most states is provided in Spanish. Two states, California and Massachusetts, offer counseling in three or more languages (other than English). Many Quit Lines have access to translation services for callers who speak languages other than those spoken by the counselors." Do you have any reason to doubt the accuracy of the information set forth there concerning languages that are offered for counseling services?

A. You've read that section correctly.

Q. Now, the next section reads: "No cost and low cost medications: In the USA, a growing number of states are providing medications at low cost (four states), or no cost (10 states) to all or some of their callers. NAQC will be compiling information about approaches to distributing medications."

Is it your understanding that in the future NAQC will in fact be studying the issue in terms of how to expand distributing cessation medications to callers?

A. I'm not aware of that, no.

THE COURT: Could you very briefly give me an idea of what types of costs are involved? I know the options range from over-the-counter medications to prescription medications. Just give me a high and low cost. What is an over-the-counter -- I think nicotine patches are over-the-counter and then, of course, the prescription medications would not be.

* * *

A: I would say a range of from about a hundred to \$150 for the medicine up to \$350 for a typical 8- to 12-week course of medicine to help a person quit.

Q. Is it fair to say, then, in terms of the nonprescription medicines, that the daily cost of the medicine is roughly equivalent to a pack of cigarettes?

Focus Point: With this question, the defendant's attorney returns to the theme that cessation services are already provided. He also implies that the smoker could afford to purchase cessation services out-of-pocket.

Note that in tobacco litigation defendants often try to blame the smoker for being negligent with his or her health, not caring about his or her health or otherwise being irresponsible in some way. This question may be an example of that trial strategy.

A. Well, a pack of cigarettes varies so enormously across states. That's really a hard question to answer.

Q. Let's assume a pack of cigarettes cost \$5. Is it fair to say that on a daily basis with respect to the nonprescription medications that it runs about \$5 a day?

A. For some of them, the lozenge is more expensive. The patch, for certain, one could get for \$5 or less per day.

* * *

Q. I'm sorry. Under Languages, it says list of 120 through Language Line Services; correct?

A. Correct. And just to clarify that. That does not mean that there are counselors speaking 120 languages, but there are -- there's a system where you can -- a very cumbersome system where a caller might be able to get access to languages that are not English or Spanish.

Q. The system exists, correct, for callers who do not speak English or Spanish to be connected to persons who speak their language? Yes or no.

A. To have a counselor who speaks their language, no.

Q. To have someone who can speak to them and then give them assistance. That system exists in the state of New York. Isn't that the truth?

A. Well, sir, I'd actually need to know more to talk with them, to get a sense of this, but I could share with you that in most states that's actually not what happens.

Q. Okay. We will get to it.

Let's see under Services Offered, then they check "Speak with a counselor within set hours." So you understand that means that within certain hours persons who call the New York Quit Line have the ability to speak with a counselor within certain set hours; right?

A. Correct. For example, on Saturday or Sunday it's only from 9 AM to 1 PM.

Q. Right. Because you're reading from hours of operation where it says Monday through Friday, 9 to 9 PM, Saturday and Sunday 9 to 1 PM; right?

A. Right. And that's an example of one of the kinds of time barriers, particularly for working people, that might serve as an effective barrier, correct.

Q. Now, under Services Offered, it says proactive quit smoking counseling and reactive quit smoking counseling; correct?

A. Correct.

Q. And whether a person is eligible to receive that type of counseling may depend on certain eligibility issues; right?

A. I would assume so, but I don't have the specifics of every state's detailed intake procedures in my head.

Q. Okay. In fact, it says, "Eligibility criteria for receiving proactive and/or reactive counseling," meaning that you have to meet some type of eligibility requirements. Fair statement?

A. I'm sorry, sir. Did you switch to the next page there?

Q. I just went down to the bottom where it says, "Eligibility criteria for receiving proactive and/or reactive counseling."

A. And your question was, sir?

Q. Isn't it correct that in order to receive that type of counseling you have to meet some type of eligibility screening; right?

A. Well, they list a couple issues here. Again, the intake procedures are extraordinarily complex in some of these Quit Lines. So, to -- I can't speak to the details of what is and is not an eligibility requirement in the state of New York.

Q. Okay. But you would agree as a general rule, in order for someone to be able to get proactive counseling, that person may in fact have to go through some type of eligibility screening; right?

A. In some instances, that's correct.

THE COURT: Does that line on the screen indicate that anybody calling up has to be enrolled in Medicaid?

MR. WELLS: No --

THE WITNESS: Well, in fact, what it means is -- these are important terms, understand. Reactive basically means anyone can call, often get a taped message, might be able to talk with someone briefly. Proactive is really what we're advocating, taking people every step of the way. And if we read this correctly, it suggests that unless you're a Medicaid recipient and unless you fulfill whatever the requirement they have in terms of ready to quit, you would be ineligible. But that's how I would read this, Your Honor.

THE COURT: For proactive counseling.

THE WITNESS: For proactive counseling, which is the one we know has an evidence base to support it.

Q. Now, Dr. Fiore, I want to hand you JD 055320, which is the Quit Line profile for each of the 50 states and the District of Columbia as they appear on the NAQC website. And

now I want to hand you JDEM 040437, which is a map which shows in blue which states have state-sponsored Quit Lines based on the individual state profiles contained on the NAQC website. And you can see I have up there states with existing Quit Lines, 38 states. You testified in your direct that you thought it was about 40; right?

Focus Point: The attorney for the defendant returns to his theme that cessation services already exist for most people. With the above question, he will try to have the witness conclude that every person has access to a state-based quitline or the quitline operated in part by the National Cancer Institute.

The witness continues to point out that existing quitlines contain numerous barriers that negatively affect utilization rates.

A. And I also mentioned that it's -- that it's -- it changes very frequently. For example, Oregon and Montana, which had Quit Lines, had to shut them down because of a loss of funding, then they came back up. So there's a lot of flux because of funding limitation.

Q. Right. And because there's a lot of flux, it is possible that the NAQC website might be off by 2 or 3, or your estimate that it's about 40 might be off, but the general numbers are somewhere in the range of 38 to 42. Would you accept that?

A. The general numbers are in that range, correct, sir.

Q. Okay. Now, the gray states are those states that do not have any state run Quit Line, but as you indicated earlier those persons can take advantage of the National Cancer Institute Quit Line; correct?

A. And again with the very important caveat that the Quit Line offered through the cancer information service of the National Cancer Institute is a very limited one.

Q. Now, Dr. Fiore, I would like to get out of here sometime tomorrow. And I asked you a very simple question, people could take advantage of the National Cancer Institute Quit Line. I did not ask you for caveats or whether there were limitations. I just asked you could those people who live in states where there is no Quit Line take advantage of the NCI Quit Line? The answer to that question is yes, correct?

Focus Point: The above question triggers an objection from the attorney for the plaintiff. Note the judge's response. The attorney conducting the cross examination must be afforded an opportunity to evaluate the witness's testimony from the perspective of the defendant. In this manner, cross examinations give the witness very little latitude in answering questions, in some situations restricting the witness to yes or no answers.

MR. BRODY: Your Honor, first of all, Dr. Fiore answered the question. Second of all, he answered it very succinctly. And if Mr. Wells is going to ask every question twice, that's what's going to keep us here longer. I think Dr. Fiore is being very responsive to the questions that are being asked and I don't think that an instruction from Mr. Wells is warranted, given the examination we've had thus far.

THE COURT: Let me say this to Dr. Fiore who is obviously extremely knowledgeable on this subject. Sometimes expert witnesses have a very understandable tendency to want to tell me everything they know. That's what the direct testimony is for. And, of course, the lawyers structure that direct testimony so that you tell me what is relevant to the

issues. On cross-examination, to the extent that you can, try to narrow your answers, try to answer only what is being asked of you, and to the extent that you can, try and limit it to yes and no answers, if you can. On redirect, the government will have a full opportunity to bring out anything that they think is not in the record. Don't forget, I've read your direct testimony. I've heard your direct examination already and I've paid very close attention to both. So, as I say, many experts have that tendency because they have a lot of knowledge and they want to share all that knowledge, but sometimes I don't need to hear it all. So, try and focus on the questions being asked.

In this excerpt of cross examination testimony, the attorney for the defendant has the expert discuss existing insurance coverage for cessation services. Cross Examination Testimony of Michael C. Fiore (Plaintiff), *United States v. Philip Morris USA, Inc., et al.*, (Sept. 2005) Pp. 21318-328, 21328-338, 21341-342.

Q. I want to go to a different area now. I want to talk to you about Medicaid, and I want to ask you some questions regarding the Medicaid program and then I'm going to turn to the Medicare program and then we're going to talk about private insurance. Okay?

A. Yes, sir.

Q. Now, first, I want to focus on the Medicaid program.

Now, the Medicaid program provides through the states insurance coverage to certain low income individuals; correct?

A. Correct.

* * *

Q. In the national population of smokers, the numbers run about 23 percent; right?

A. 21, 22, 23, yes, in that ballpark, sir.

Q. Yet among low income people, those people who comprise the Medicaid population, the percentage is 36 percent; right?

A. That's the number on the CDC document and I believe that's a number that we can trust.

Q. Okay. Now, I want to read the next yellowed section. It states, "This report summarizes the results of the survey, which indicate that as of December 31, 2002, one, 36 Medicaid programs covered some tobacco-dependence counseling or medication for all Medicaid recipients, two, four states offered coverage only for pregnant woman; three, two states offered coverage for all pharmacotherapy and counseling treatments recommended by the 2000 PHS guideline, and four, seven states covered all recommended medications and at least one form of counseling." Do you agree with that statement?

A. You read that correctly, sir.

* * *

Q. And, in fact, you can see near the bottom of the table next to the words "All Medicaid," that's where it shows that 36 states provide some smoking cessation benefits to its Medicaid recipients; correct?

A. That's what the table says, sir, yes.

Q. You can also see that, with respect to Zyban, 35 states provide some coverage; correct?

A. Some coverage, and you read that correctly, sir.

Q. And describe what Zyban is.

A. Zyban is Bupropion, an agent that was first found to have helped people with depression and then was shown to have people quit smoking. It works in the brain.

Q. And 27 states provide the nasal spray; right?

A. You read that correctly, sir.

Q. And 27 states provide the inhaler; correct?

A. Also that's what it indicates, yes.

Q. And 25 states provide the nicotine gum; correct?

A. That's correct.

Q. And 26 states provide the nicotine patch; correct?

A. That's what it says sir, correct.

Q. And in terms of counseling coverage, 8 states provide group counseling, 12 states provide individual counseling, and 3 states provide telephone counseling; correct?

A. Correct. And when you consider all together, you come up with only two that provide the coverages recommended in the PHS guideline from 2000.

Q. I'll get to that, but... Now, I want to go to Page 56 of the exhibit you have in front of you. [. . .] Under tab 25, there's a statement similar to the one that you just volunteered, and it reads, "Editorial note: During 2001, 2002 the number of Medicaid programs offering coverage for any form of tobacco-dependence treatments increased slightly. However, comprehensive coverage for treatments recommended by the 2000 PHS guideline remained low." That's what you meant a minute ago when you volunteered that very few states meet that 2000 PHS guideline; right? [. . .] And then it goes on and reads, "In addition, because only 28 percent of states that offer coverage inform their beneficiaries of these benefits, Medicaid recipients interested in quitting might not realize they can obtain financial assistance for tobacco-dependence treatments." Is it fair to say that what the CDC is recognizing in that editorial comment is that there is a need to have better communications with Medicaid recipients as to what benefits are available; correct?

A. I think that that's a fair characterization that there's an incredible under-recognition of limited benefits and why for any comprehensive program there needs to be a substantial investment in communication.

Focus Point: The attorney for the defendant will use this answer to argue that cessation services exist, but states are not doing what they can to correctly advertise the services. In essence, the industry will fault the states.

Focus Point: After reviewing Medicaid coverage for cessation services, the attorney for the defendant moves on to review Medicare coverage.

Q. Now, I want to turn to the area of Medicare. And I want to show you JD 055323, which is a document that was issued on March 22, 2005, by the Center for Medicare and Medicaid Services commonly known as CMS. Do you have that document, sir?

A. Yes, I do.

Q. March 22, that's only a few months ago; right?

A. Correct.

Q. And CMS is a coverage agency that oversees the Medicare/Medicaid programs?

A. That's correct, sir.

Q. What that document states, it says, "Decision memo for smoking and tobacco use cessation counseling. Decision summary. The Centers for Medicare and Medicaid Services, CMS, has determined that the evidence is adequate to conclude that smoking and tobacco use cessation counseling, based on the current US Public Health Service guideline, is reasonable and necessary for a patient with a disease or an adverse health effect that has been found by the U.S. Surgeon General to be linked to tobacco use, or who is taking a therapeutic agent whose metabolism or dosing is affected by tobacco use as based on FDA-approved information." Then in the yellow it continues, "Beyond that, Medicare will cover 2 cessation attempts per year. Each attempt may include a maximum of 4 intermediate or intensive sessions, with the total annual benefit covering up to 8 sessions in a 12-month period." Then it goes on to read, again in the yellow block section, "Intermediate and intensive smoking cessation counseling services will be covered for outpatient and hospitalized beneficiaries who are smokers and who qualify as above, as long as those services are furnished by qualified physicians and other Medicare recognized practitioners." Now, my first question is, is it correct that in order to receive the types of Medicare coverage for cessation that I just described, one has to actually go to their doctor as opposed to calling the Quit Line? Is that correct?

A. That's correct. It refers explicitly to qualified physicians and other Medicare-recognized practitioners.

Q. And the coverage that is described there is basically limited to persons who have exhibited an adverse health effect from smoking; correct?

A. Right. So one of the limitations or barriers is that it's limited to those individuals.

* * *

Q. Page 20 of the document under the heading Eligible Beneficiaries indicates that persons who would be qualified would include people who have cancer, heart disease, cognitive, bronchitis, and cataracts; correct?

A. You read that correctly, yes, sir.

Q. So if I went to my doctor and I was covered by Medicare and I told my doctor I was a smoker and I had a cough, I would be eligible to receive smoking cessation benefits at least as is suggested by that memorandum; correct?

A. Smoking cessation counseling, correct.

Q. Yes, sir. Now the March 2005 decision by CMS is limited to cessation counseling services and does not include cessation medications; correct?

A. That's correct, sir.

Q. And if we turn to Page 21 of the memorandum, it states as follows. "The counseling benefit will be available upon implementation of this decision in March 2005. The Medicare prescription drug benefit will be available January 1, 2006. For both benefits to be rolled out at the same time would delay the counseling benefit 9 months, which CMS declines to do." So it is your understanding that beginning on January 1, 2006, the Medicare prescription drug benefit will go into effect; correct?

A. Correct, with all --

Q. Yes or no, sir, please. I'm sorry.

A. You read that correctly.

Focus Point: In reviewing existing coverage for cessation services, the attorney for the defendant next turns to private insurance. Note that private insurance historically did not provide such coverage.

Q. Dr. Fiore, I want to move away now from the government insurance programs and talk about cessation treatments covered by private insurance plans. Do you agree that approximately 70 percent of the American public is covered by some type of private health insurance plan?

* * *

A. I think somewhere in the range of 60 to 80 percent. 60 to 70 percent probably is a reasonable estimate with, of course, the caveat of the incredible variety of what private insurance includes in America today.

Q. I'd like to show you JD 055325.

A. Thank you.

Q. And it's an August 2004 report from the US Census Bureau titled: Income, Poverty, and Health Insurance Coverage in the United States: 2003. Do you see that?

* * *

Q. I would like you to turn to Page 16 of the document and have you take a look at figure 5. You see there the title of the table is: Coverage by Type of Health Insurance: 2002 and 2003. Correct?

A. That's correct, sir.

Q. And down at the bottom it tells you the source is the US Census Bureau, Current Population Survey, 2003 and 2004 Annual Social and Economic Supplements; correct?

A. That's correct, sir. You're reading it correctly.

Q. And according to the census, it says that in 2003, 68.6 percent of all Americans were covered by health insurance; correct?

A. By any private plan, correct.

Q. And you don't have any reason to doubt the accuracy of that information reported by the US Census Bureau; correct?

A. No, I don't, sir.

Q. So can we agree that approximately 70 percent of all Americans are covered by some type of private health insurance?

A. Yes, we can, sir.

Q. Now, you would agree that some percentage of the private health insurers that provide coverage, it's almost 70 percent of the American public, offer some coverage for cessation services; correct?

A. Some coverage, correct, sir.

Q. And I want to show you an article from the journal Preventing Chronic Disease, which is JD 055326, and ask if you are familiar with that publication?

A. I believe you shared this with me during the deposition a week or two ago.

Q. This publication is published by the CDC?

A. That's correct, sir.

Q. And the article's title is: Addressing Tobacco in Managed Care: Results of the 2002 survey. And it's written by Carol McPhillips-Tangum and others; correct?

A. That's correct, sir.

Q. And underneath the title it says, it was peer-reviewed, right? Do you see that, sir, right here?

A. I see that, sir. That's correct, it says that.

Q. You don't have any reason to dispute it; right?

A. That it was peer-reviewed, absolutely not.

* * *

Q. Now, if we turn to Page 6 of the article -- and I'm going to read -- Page 6 is the top, Page 7 is the bottom. The article reads: "The number of health plans providing full coverage for any type of pharmacotherapy for tobacco cessation more than tripled in 2002, compared with previous years. In the 2002 ATMC survey, nearly 9 out of 10 plans reported providing full coverage for at least one type of pharmacotherapy for tobacco cessation. Consistent with recommendations based on the effectiveness of various prescription and over-the-counter tobacco cessation first-line pharmacotherapies, the majority of plans reported providing full coverage for --" how do you pronounce that?

A. Bupropion.

Q. Bupropion. What is Bupropion?

A. Bupropion is a medication that's been shown to be effective in helping people quit smoking.

Q. And then it goes on to read: "Consistent with literature citing the effectiveness of telephone counseling and that smokers are more likely to use telephone counseling than to participate in individual or group counseling sessions, approximately half of plans surveyed provide full coverage for telephone counseling." So, is it your understanding -- withdrawn. Is it your understanding that in terms of the trend in the United States with respect to coverage of cessation benefits by private insurance plans, that that trend is on an upward level?

A. This is a survey of HMOs. They are really different than private insurance, in general. So, the way you asked the question wasn't really a reflection of this article.

Q. I want to have a reflection of your state of knowledge. First question is, would you agree, with respect to HMOs, the trend is moving upward with respect to coverage by HMOs?

A. Over the last decade, without question, there's been an increase in coverage, but in many, and I would suggest in most instances, with requirements with barriers, with access issues preventing all enrollees from taking advantage of those.

Q. With respect to private insurance plans, putting the HMOs to the side, would you agree that in the last several years the trend has been upward with respect to providing some types of cessation treatments?

A. With all the caveats I shared with you just a moment ago, over the last 10 years I would suspect that even with private insurers defined as more broadly, that there's been an increase in coverage, although limited. And this, of course, is something that the National Action Plan supports and encourages.

Q. We're going to get to that. We're going to get to the National Action Plan. I promise you, sir.

A. Thank you, sir.

Q. Now, if you go back to Page 11, and I want to look at some of the other data in that survey.

A. Page 11 of this same article?

Q. Yes.

A. From ATMC. Okay.

Q. And I put together a demonstrative showing some of the other data. Could I have J-DEM 040442? And what that demonstrative shows is some of the information reflected on Page 11, and you will see there that as reported on page 11, 79.2 percent of the health insurance plans in the survey provided coverage for Bupropion. Is that correct.

A. Yeah. It's -- there's a typo there, but it's correct. Yes, it is, sir.

Q. And it also indicates that 35.8 percent said they provided full coverage for prescription NRT nasal spray and inhalers; correct?

A. Correct. It says that, sir.

Q. Do you disagree with the results of the survey?

A. Well, what I think is just the absolutely critical factor is this definition of full coverage, but the survey reports this.

Q. And then it says, with respect to counseling, that 51.7 percent said they provided full coverage for telephone counseling; is that correct?

A. That's correct and on this graph.

Q. And then it goes on to say that 41.1 percent provided full coverage for face-to-face counseling; correct?

A. That's what it says, yes, sir.

Q. Now, I want to show you an article that appeared in the Wall Street Journal on April 26, 2005, and it's entitled, "Case grows to cover quitting." And it's marked as JD 55327. Have you seen this article before, Dr. Fiore?

A. Yes, I have, sir.

Q. You're quoted in the article, aren't you?

Focus Point: Nearly anything that a witness has written, testified about or said can be used during cross examination to impeach the witness's credibility. The attorney for the defendant brings up the Wall Street Journal article to make his point that private insurance coverage for cessation services is increasing and also to impeach the witness's credibility by making the point that the need for the cessation remedy recommended by the witness is not as dire as stated during the witness's direct examination testimony.

A. Yes, I am, sir.

Q. Now, on the first page the article quotes a Greg Lehman, the CEO of a health management company, Gordian Health Solutions, as saying, quote, smoking cessation is the hottest program for us right now. It's the first thing employers are asking us about. Do you agree with that statement?

A. No.

Q. Why?

A. Well, I have actually had a lot of experience in talking to employers, and particularly blue collar employers, but a variety of employers which often have a high prevalence of tobacco use, and it is still a difficult challenge to convince them that this is an important and appropriate form of coverage for their employees and ultimately for then the enrollees of the health plan. The good news is we've made progress and this article reflects that. And I think it's great to see the progress we've made, but we still have many,

many covered lives, many, many employers in America who don't have coverage for tobacco dependence treatments as recommended by the PHS guideline.

* * *

Q. Well, on the next page, Dr. Fiore, you were quoted as saying, "The direction is definitely toward more coverage, and it's following the evidence that it works." When you made the statement, "the direction is definitely toward more coverage," were you telling the truth? True or false?

A. Yes, I was, sir.

The attorney conducting the cross examination inquires whether the budget for the proposed cessation programmatic remedy is too large. Cross Examination Testimony of Michael C. Fiore (Plaintiff), *United States v. Philip Morris USA, Inc., et al.*, (Sept. 2005) Pp. 21342-62.

Q. Let's talk about the National Action Plan. And I want to show you U.S. Exhibit 89464, which is a copy of the National Action Plan that was prepared by your subcommittee, and is dated February 13, 2003. Is it correct that the February 2003 National Action Plan sets forth a National Smoking Cessation Program that would cost \$5.2 billion per year?

A. That is correct, sir.

* * *

Q. Now, in your expert report and in your direct testimony you state that the National Action Plan should be funded at \$5.2 billion per year for 25 years; correct?

A. Correct, sir.

Q. Now, in fact, in the 2003 National Action Plan there is no statement to the effect that the plan should be funded for 25 years; correct?

A. Throughout the document it says that it should be sustained. There is no specific year attached to that.

Q. And the decision to use the 25-year number was a decision that you made after you had been retained by the government to be an expert in this case; correct?

A. The decision was made when I heard the charge that was given to me by the court.

Q. You had a conversation with Judge Kessler?

A. No, I didn't, sir.

Q. Well, in your deposition you said that it was Mr. Brody who gave you the charge. Do you recall testifying to that under oath?

A. That is correct. And I misspoke when I said the court; it was by the Department of Justice.

Q. Okay. And the person at the Department of Justice who gave you the charge to come up with the number of years that you should apply to the \$5.2 billion was Mr. Brody who gave you that charge after you had agreed to be an expert witness for the government; correct?

A. Mr. Brody asked me if we were going to help all Americans who wanted to successfully quit, how long it would take it to do that.

Q. And then you made a decision that it would take a minimum of 25 years; correct?

A. That's correct, sir.

Q. And it is your position in this courtroom that the \$5.2 billion in annual funding should be paid in each and every year of the 25-year period; correct?

A. Until the goal is reached, and that's to help all smokers who want to quit to do that successfully. If, after 20 years, the program is extraordinarily successful and every smoker who wanted to quit had succeeded, then I think the program could at that point be disbanded.

Q. Can I see Fiore Dep at 66, lines 15 to 18. I want to go to Page 66, sir, focus you on line 15. My question to you was, "Question: And under your program, the \$5.2 billion per year would be spent each and every year for a 25-year period, correct: "Answer: Correct." Now, is it correct that under your program \$5.2 billion would be paid in the first year, \$5.2 billion would be the amount paid in the 15th year and \$5.2 billion would be the amount paid in the 25th year?

A. It's my estimate, based on the data that I shared, that it will take approximately 25 years to do this, and that is what the 25-year number came from. For each of those 25 years and until the goal is reached, I believe that \$5.2 billion should be allocated towards achieving the goal.

* * *

Q. When I deposed you – [...] you state there, "Question: In your view, who should be eligible to participate in the cessation program? That is, what should be the criteria to assess whether a person is a smoker who qualifies to obtain cessation assistance from the program? "Answer: Every smoker in the United States should be eligible to participate. Having barrier-free access to evidence-based smoking cessation therapy is absolutely essential if a program is going to reach the largest number of smokers and thereby help the maximum number of smokers to quit." Now, I'd like to also, before I ask you a question, refer you to your direct testimony at Page 29, line 1, and there you state, "It is important that the Quit Line services (both counseling and medications) be available to all smokers, without any cost or insurance barriers." Do you recall giving that testimony?

A. Yes, I do, sir.

Q. Is it correct, Dr. Fiore, that if Warren Buffett, one of the riches men in the world, was a smoker and he called your proposed barrier free Quit Line, he would be entitled to get free counseling and free medication?

A. That's correct, sir.

Focus Point: The attorney for the defendant returns to his theme that the cessation remedy is not necessary with an exaggerated hypothetical to make the argument that the program fails to take into account existing cessation services and coverage. In other words, these existing services and coverage are already in place to address the industry's wrongdoing.

Q. And if someone with private insurance that covered cessation medication called your proposed barrier free Quit Line, that person would be entitled to get free medication without going to the trouble of paying an insurance co-pay or even having to deal with his or her insurance carrier at all; correct?

A. That person could go to their insurer their private doctor or they could call the Quit Line and they would get barrier free access to the treatments as outlined.

Q. If that person with insurance coverage called your proposed Quit Line and indicated he or she wanted to quit, they would be entitled to get free medication and they would not have to go to their insurance carrier at all; correct?

A. Correct.

Q. And if someone who was covered by Medicaid or Medicare for cessation medication called your proposed barrier free Quit Line, that person would be entitled to get free medication without going to the trouble of paying an insurance co-pay or having to deal with the Medicare or Medicaid system at all; correct?

A. Correct.

Q. And is it fair to say that you are asking Judge Kessler to implement a National Smoking Cessation Program that would require the tobacco company defendants in this case to pay for smoking cessation counseling and medication for persons who may, in fact, have those treatments covered in whole or in part by private insurance, Medicaid coverage or Medicare coverage; correct?

A. As proposed, they would continue to have access to their private insurance coverage, but anyone would be able to call the Quit Line and get counseling and medicine irrespective of whether they did or didn't have insurance coverage, they didn't have insurance coverage.

Q. And is it the correct that part of the rationale for having a barrier free program whereby smokers would not even have to worry about or even use their private or government insurance coverage is that you believe that a barrier free program will increase the participation -- participation rate of smokers who call the Quit Line?

A. Sir, would you be kind enough to say that one again?

Focus Point: The witness asserts that having a barrier-free program is more important than the fact that some would be able to use the program who could obtain the services elsewhere. This is the crux of his argument and he repeats it throughout.

Q. Part of the rationale for having a barrier free program whereby smokers would not even have to worry about or even use their private or government insurance coverage is that you believe a barrier free program will increase the participation rates of smokers who call the Quit Line?

A. I believe a barrier free program will definitely increase utilization rates' reach and ultimately the number of people who quit smoking.

Q. And that is part of the rationale for having a barrier free Quit Line to increase participation rates?

A. Yes, it is.

Focus Point: This is an important distinction. The attorney for the defendant has made the point that despite the imperfections, smokers can use existing cessation services and coverage.

In addition to saying that the imperfections in existing cessation services and coverage are actually very significant, the expert says that utilization rates are too low. The attorney for the plaintiff uses this information to argue that the millions of smokers who became addicted to nicotine as a result of tobacco industry malfeasance remain addicted. In essence, the consequences of the industry's wrongdoing continue, despite the efforts by states to provide cessation services and coverage.

Additionally, the attorneys for the government will link this conclusion to the evidence that the industry employs marketing that is designed to exploit smokers' health concerns. For example, they introduced evidence elsewhere in the trial that smokers switch to light cigarettes instead of quitting because they think light cigarettes are less harmful.

The attorney conducting the cross examination inquires whether the proposed cessation remedy will adversely affect existing cessation coverage and services. Cross Examination Testimony of Michael C. Fiore (Plaintiff), *United States v. Philip Morris USA, Inc., et al.*, (Sept. 2005) Pp. 21370-83.

Q. And the government has represented to the defendants that this document was produced from the files of HHS, and the first page of the document, the e-mail, was prepared by Dana Shelton of the CDC's Office on Smoking and Health and sent to Dr. Gerberding, that's what the document shows, correct?

A. Yes, that's correct, from Dana Shelton to Dr. Gerberding and a bunch of others.

Q. And Dana Shelton was the person responsible for staffing the Interagency Committee on Smoking and Health, correct?

A. Michael Schooley was the Executive Secretary. At some point he moved on. I just can't recall what date that was in relation to our final report. The report lists Michael Schooley, I believe, as the Executive Secretary.

Q. Is it your recollection that you testified at your deposition that Ms. Shelton staffed the Interagency Committee on Smoking and Health?

A. Yes, at some point she was switched from -- Michael Schooley moved on and she took over that role, correct.

Q. And she was a fairly high ranking public health official within the government?

A. No, I'm not one to judge where people fit in the government, but she was the Executive Secretary after Michael Schooley. She was a staff person.

Q. Okay. And in her capacity she would have been familiar with the National Action Plan, correct?

A. Correct.

Q. And Ms. Shelton is writing the e-mail 11 months after the submission of the National Action Plan, correct?

A. Well, 11 months after it was presented to the Interagency Committee on Smoking and Health. We formally presented it to Secretary Thompson in the summer of '04, so more like five or six months.

Q. So it was submitted to Secretary Thompson some time around June '04?

A. I think we -- he had us come in in August of '04, but I can't be exact on that date.

Q. Okay. And Dr. Gerberding, who is the recipient of the e-mail, she is the director of CDC, correct?

A. Correct.

Q. She runs the entire Center for Disease Control, she is the ultimate boss of CDC, right?

A. She's the Director.

Q. Now, let's look at the e-mail. And Ms. Shelton writes, "Dr. Gerberding, et al., attached is the joint CDC and NCI proposal on quitlines. Both agencies feel this approach would optimize current state and CIS efforts, as well as help to maintain current state investment in cessation and quitlines. It is strongly felt that solely by states and many in the tobacco control community that solely a national approach might serve to erode current state investments." So this e-mail is first referring to the fact that there is now a joint proposal on quitlines by the CDC and NCI, correct?

A. Yeah, and I believe in this attachment there's a number of options, if this is the document you shared with me when we had the deposition. So there are a number of options that follow for Dr. Gerberding to consider.

Q. And in addition to referring to the joint proposal, it indicates that both of those agencies feel that that approach would optimize current state and CIS efforts, right?

A. I could read that text as well.

Q. Okay. And it goes on, again, to talk about maintaining state investment and cessation in quitlines. Do you recollect that there was a concern among certain members of the public health community that if a National Quitline was put in place, that at the state level state investment might decrease?

Focus Point: Often, an expert witness will be asked to discuss why his or her opinions differ from those of other expert in the field.

In this case, the attorney pits the witness against natural allies in the field of tobacco control who the witness might find it difficult to openly critique. A divide and conquer strategy is at work here. The attorney continues on and mines any differences in the proposed cessation remedy and proposals by the National Cancer Institute and Centers for Disease Control and Prevention.

A. Well, I don't know if I would use the word "concern" but this was a major topic of the Subcommittee on Cessation, and that was how do we take the important local investments that the states have already made and build upon them. So the Subcommittee on Cessation felt very strongly that we should do nothing that would damage the important state investment.

Q. Right, and that's what part of that e-mail is talking about, "might serve to erode current state investments," because the concern was state legislatures, if they thought the federal government was going to come in and institute a National Quitline, they might pull the money at the state level. That, at least, was a concern that was being discussed, correct?

A. Well, I don't know what Dana Shelton is referring to, but there was specific discussion of the topic of making certain that any National Action Plan serve to protect the important investment and also the important state ownership so that it could really meet the needs of each state.

Focus Point: Later in this cross-examination, the attorney for the defendant returns to the theme that the proposed cessation remedy in this case might adversely affect state and private cessation services and coverage. The questioning goes as follows:

Q. Let me ask you this: Have you considered -- have you done any research to determine the impact that would be caused if Judge Kessler were to enter an order requiring the defendants in this case to pay for a National Quitline on the present increases and private insurance coverage of cessation benefits?

A. And your question was have I done research on it or do I have an opinion on it?

Q. Have you done any research on it?

A. Have I done research on that specific topic? No.

During redirect testimony, the witness explains the research into this question and states why the proposed cessation remedy in this case would not undercut existing cessation services and coverage.

* * *

Q. Right. Now, in your National Action Plan you stated it would cost \$2.1 billion a year to manage the National Quitline and to provide proactive counsel, correct?

A. Correct, that's the number that's in there for the counseling part and the management, exactly correct.

Q. Now, I want to go to the first page of the CDC-NCI proposal, which is captioned "Proposed National Cessation Program From Discovery to Delivery." And that document reads "Introduction. The following three proposals were created by NCI and CDC OSH staff in response to an HHS query to outline what can be done with respect to National Smoking Cessation Quitline Services with three budget amounts: 25 to 30 million, 100 to 150 million, and 250 million. The proposals build on one another with incremental funding increases and are considered annual allocations over five consecutive years. The proposed programs will be evaluated annually and at the end of the five-year funding term to determine continuation." So, at least according to the introduction, what is being considered is three possible proposals, the lowest one being 25 to 30 million, the highest being 250 million, that might build on each other, correct?

A. It's three proposals in response to an HHS request to propose what could constitute a national smoking cessation quitline service.

Q. Now, if we look at option number 1, it says "32.9 million for expansion of national and state quitline services." And it says "Goal: To provide proactive quitline services and Web-based support to expand coverage to states with no existing quitlines through the National Cancer Institutes Cancer Information Service, NCI-CIS, and provide enhancement grants to states with some level of service through the Center for Disease Control and prevention's National Tobacco Control Program, CDC, NTCP. This will ensure that all tobacco users have access to quality quitline services as recommended by the ICSH Subcommittee on Cessation." So it's fair to say that what is being stated in that particular paragraph is that option number 1 would be aimed at trying to build up the existing state quitline network that already exists, fair comment?

A. Yeah. I mean, you read it. It's quite exact and it is to expand coverage to states with no existing services and to enhance the states that do have some.

* * *

Q. Now, where it says option number 1, 32.9 million, and the introduction it talked about the lowest budget level being 25 to 30. Do you recall that?

A. 25 to 30 was the first option in the paragraph you read from above, yes.

Q. And in fact, what ultimately happens is that option number 1 is the one that is selected by Secretary Thompson and funded at the level of 25 million, right?

A. I don't know what -- all of the details of option number 1. I don't know if in the process of this -- as a proposal coming from CDC and NCI it evolved, so I wasn't in on those discussions that made those decisions. But the ultimate budget that was announced by Secretary Thompson about a month after the date of this e-mail was in the range of 25 to \$30 million.

Q. And that proposal that Secretary Thompson and HHS announced about a month after the e-mail was a proposal very similar to what is described under option number 1 in terms of putting out enhancement grants and trying to build up the existing system, correct?

A. It included capacity building grants for states that didn't have quitlines; it included enhancement grants for states that did. It also provided funding to the NCI's CIS to obtain and serve as a portal number, a single national number, 1-800-QUIT-NOW that was announced about 10 months after this e-mail.

Q. Now, if we go to option 2 on page 4 of the document, it states the 32.6 million for quitlines, plus 100 million for comprehensive media campaign equaling a total of 132.6 million, correct?

A. Correct, that's what it says.

Q. So in essence, proposal 2 builds on proposal 1 by starting with the \$32.6 million to provide proactive counseling and improve state quitlines, and then adds a \$100 million media campaign component, correct?

A. Well, that's what it says. I'm reading it along with you, sir.

Q. Now, in your National Action Plan, you stated that a national media program would cost \$1 billion per year, correct?

A. Correct.

Q. Now, if we turn to page 5 in the last paragraph -- page 5 in the last paragraph, it reads: "It is anticipated that about half of the campaign funds, 50 million, would be used for national media placements, with the other half, 50 million, awarded to states for localized efforts. Funding allocations for state campaigns would be based on a per-capita formula, such as those presented in Best Practices For Comprehensive Tobacco Control Programs, as media placement costs are closely tied to population size." So in terms of how NCI and CDC are proposing to spend the \$100 million for a media campaign, the proposal is to split it into two \$50 million chunks, correct?

A. Correct, for this media campaign that's exclusive for promoting the quitline.

Q. Now, in your National Action Plan, you propose \$1.1 billion per year for cessation medication, correct?

A. Correct.

Q. Now, if you look at the third proposal by NCI and CDC, which is on page 6, the heading at the top of that page says option 3, 32.6 million for quitlines, and that's proposal number 1, correct?

A. Correct.

Q. And then 100 million for comprehensive media and proposal number 2 is the 32.6 plus the 100 million, correct?

A. Right.

Q. And now they're adding a third component that reads plus 120 million for smoking cessation medication equals a total of 252.6 million, right?

A. That's correct, I'm reading it as well as you.

Q. So what the CDC at this point is proposing in option number 3 is a plan that involves a national media program for 100 million, medication for 120 million and upgrade of existing state quitlines and proactive counseling for 32.6 million, all for a total of 252 million, correct?

A. They define a plan costing 252 million, which is, of course, different from what the National Action Plan and the plans submitted to the Court would include.

Q. Now, the last sentence on that page says "This plan would provide medication for over 1.3 million smokers per year, who are currently not afforded a smoking cessation medication benefit." So is it fair to say that in terms of providing medication as part of the plan, what the CDC and NCI are doing is trying to expend money to make sure that people who have no type of cessation medication benefit can get such coverage or get such medication, right?

A. Well, I wasn't a party to producing this plan, so I don't know what the specific goals, what the specific reach, the intent of it was. I can read that sentence, though, as can you.

Q. Well, is it fair to say that nowhere do you see in this proposal by CDC and NCI a decision to ignore existing insurance coverage, but instead an attempt to fill the gap and expand coverage to persons who have no insurance coverage?

A. Well, I'd have to read through the document clearly, but the last statement says explicitly this would provide medications for smokers who are not currently afforded a smoking cessation medication benefit. You know, if you want me to take the time to read through the document, I assume that's correct based on that sentence.

* * *

Q. Okay. Now, about a month -- or withdrawn. In February of 2004, Secretary Thompson issued a press release announcing the establishment of a National Quitline; is that correct?

A. At some point -- yeah, it was in February, and it was -- and he did -- but I don't have the --

Q. I'm going to put it up.

A. -- the press release in front of me.

* * *

Q. And the press release is dated February 3, 2004, and it's from the U.S. Department of Health and Human Services and it says in the first paragraph, "HHS Secretary Tommy G. Thompson today announced plans for a national network of smoking cessation quitlines to provide all smokers in the United States access to the support and latest information to help them quit." And then it goes on to read, and I'm just going to read the yellow, "to provide the highest level of assistance to the smokers across the country that want to quit, this year HHS will establish a new toll free telephone number that will serve as a single access point to the national network of quitlines. By providing one easy to remember number, smokers in every state will have access to the tools they need to quit smoking."

And is it correct that in terms of the way the National Quitline actually works, that if someone calls the national number and identifies himself as being from the state of Michigan, that the quitline will then connect them to the Michigan state quitline?

A. It's even more automated to that. They call and the system is able to determine from where the call came, and when it is in a state that has a quitline, it's automatically transferred.

Q. Okay. And then the press release goes on to say that the program has three main components. First bullet. "States with existing quitlines will receive increased funding to enhance existing state quitline services. States could use these supplements to expand their hours of operation, hire bilingual counselors, build referral linkages with local healthcare systems or promote quitlines to more individuals." Second bullet: "States that do not have quitlines will receive grants to establish them to provide their residents the tools that they need to quit smoking." So in terms of the first two bullets, the first bullet is focused on enhancing existing state quitlines and the second bullet is focusing on encouraging those states who do not have a quitline to institute a quitline, correct?

A. That's correct.

Q. And then the third bullet reads: "HHS's National Cancer Institute, NCI, Cancer Information Service telephone counselors will provide assistance to individuals in states without quitlines." So this is an effort to continue what was referred to as a safety net for persons who live in states without any quitlines, right?

A. Right. That's the scaled down NCI program that provides, as you say, a safety net so that anybody in America could call that number and at least be able to talk to someone.

Q. And it's your understanding that the budgeted amount for all three of those proposals and for the National Quitline was \$25 million, correct?

A. The exact number, it's between 25 and 30 million, correct, sir.

Q. And basically, as I think you've already indicated, what Secretary Thompson adopted was, in essence, what is described as proposal number 1 in the August NCI-CDC memo; is that correct?

The attorney for the defense questions the witness about his relationship with pharmaceutical companies that manufacturer cessation medications. Cross Examination Testimony of Michael C. Fiore (Plaintiff), *United States v. Philip Morris USA, Inc., et al.*, (Sept. 2005) Pp. 21533-44.

Q. I want to go to a different area. Have you previously undertaken research that was sponsored by pharmaceutical companies?

A. Yes, I have.

Q. Is it correct that your center for tobacco research --

A. Could I just go back and answer that? In terms of research, the research always happens with the university. I've not sort of independently, but I direct a center that has done research for the pharmaceutical industry, that's correct.

Focus Point: The potential for bias is always a relevant line of inquire during testimony. In this excerpt, the attorney for the defendant will try to impute motives of greed and self-benefit to the witness as the reasons for why he is recommending a certain remedy. The witness correctly refrains from taking offense and fully discusses his relationship with the pharmaceutical companies.

Q. Now, your center for tobacco research and intervention at the University of Wisconsin conducts research sponsored by GlaxoSmithKlein, Pfizer, Sanofi, and Elan; correct?

A. At different points over the last 20 years it has conducted research by each of those companies.

Q. And each of those companies is involved in various medications to treat tobacco dependence; correct?

A. Yes. That's why they contacted us, because they wanted us to test medications that were under consideration to help people quit smoking.

Q. And GlaxoSmithKlein manufactures Zyban; correct?

A. That's correct.

Q. GlaxoSmithKlein manufactures Nicorette gum and Nicoderm patches; correct?

A. That's correct.

Q. Pfizer manufactures Nicotrol patches and inhalers; correct?

A. That's correct. I think they just bought the company that manufactures them, pharmacia.

Q. And would you agree that pharmaceutical companies that manufacture smoking cessation treatments stand to gain financially if the national program were enacted that increased the use of cessation medications?

A. I'm sorry. Could you ask that question again, sir, so I made sure I answer it accurately?

Q. Do you agree that pharmaceutical companies that manufacture smoking cessation treatments stand to gain financially if a national program were enacted that increased the use of cessation medications?

A. The National Action Plan and the recommendation I've made to the court would include medication that's provided by a variety of pharmaceutical companies that I suspect would make a profit from that endeavor.

Q. And last year about 16 percent of the \$6 million budget of your center at the University of Wisconsin came from pharmaceutical research funding; correct?

* * *

A. That's correct.

Q. Now, aside from doing research work for pharmaceutical companies, you have always been paid by pharmaceutical companies directly to give lectures and do other outside consulting work; correct?

A. That's correct.

Q. And you continue to do work for pharmaceutical companies even today; is that right?

A. I do a limited amount of consulting work, that's correct.

Q. And certainly in 2003 you continued to do work for pharmaceutical companies; correct?

A. I did a limited amount of consulting work in 2003.

Q. Now, in the mid-to-late 1990s GlaxoSmithKlein, which was then called GlaxoWellcome, decided to commit \$1 million in the form of a grant to the University of Wisconsin to establish a Chair for the treatment of tobacco dependence; correct?

A. That is correct.

Q. And prior to the time the \$1 million was committed you personally had discussions with Glaxo representatives that ultimately led to the \$1 million gift; correct?

A. Prior to the gift of Glaxo to the University of Wisconsin, I was asked by representatives of Glaxo how they might support the sorts of work we're doing in Wisconsin as well as in other centers across America. And so I discussed that with them at that time, yes, sir.

In this excerpt of re-direct testimony, the witness responds the defendants' argument that existing cessation services and coverage make the proposed cessation remedy in this case unnecessary. The witness explains the many barriers found in existing cessation services and coverage. Re-direct Testimony of Michael C. Fiore (Plaintiff), *United States v. Philip Morris USA, Inc., et al.*, (Sept. 2005) Pp. 21586-299.

Q. What does full implementation of the guideline entail?

A. Well, in this instance, it includes providing access to smokers to the menu of treatments that we know make a difference, the counseling approaches that could be available both by telephone but also from a managed care organization when a patient visits their clinic. It provides access to the medicine without barriers to the medicine. It also has systems in place in the clinic so that when a person walks in and their vital signs are checked, at the same time they're asked if they're a smoker and if they're identified as a smoker it leads to a whole variety of other actions that take place. So it's basically ensuring that every smoker who wants to quit is first identified, hears about the program and then is provided access to it.

Q. If we turn to the next page at the end of the first full paragraph on that page, we see the CDC estimate that 10 percent of all smokers age 18 and older would be expected to use full cessation services each year. How does the CDC estimate the 10 percent of smokers would use full cessation services, counseling and medications as opposed to just calling a line, each year compared to the estimate use to provide the recommendations contained in your direct testimony to the Court?

A. Well, in fact it was 10 percent that we recommended to the Court, 10 percent of individuals will access counseling and medicine, and that was the basis of our estimate of impact in terms of helping people quit.

* * *

Q. Let's continue to focus on the impact of providing comprehensive barrier-free cessation services on utilization and to follow up on some of the cross on utilization rates. I want to ask you some questions about the New York City Nicotine Patch Program and first, to orient the questioning. I know we touched upon this yesterday, but can you please provide a brief explanation about what the program involved?

Focus Point: On redirect, the attorney offers evidence that contradicts the defendant's argument that the proposed cessation remedy would adversely affect state programs. The attorney has the expert explain that states need help in responding to the demand for cessation services.

A. Well, New York state has a quitline, and a few -- well, now a year or two ago, the City of New York decided to have a special promotion where they would have people, allow

people who called the quitline from New York City receive a six-week supply of nicotine patches, and this was announced by the Commissioner of Health, I believe, in a news conference. It was picked up by the local media, and they were inundated with calls. They speak of more than 400,000 calls in the first couple weeks and exhausted their full supply of nicotine patches within just a few weeks.

* * *

Q. And can we see the bottom of the chart here, Charles, that would be great. And we can get the notes underneath as well. For New York City it indicates that between 4.7 and 5 percent of eligible smokers were enrolled in the program. Do you know approximately how long it took to reach the cap on the supply of medications and reach that 4.7 to 5 percent utilization?

A. I believe they reached the cap within just a couple weeks. They were overwhelmed within the first week, but I think they took a while to mail them all out.

* * *

Q. And I want to look at figure 1. Can you tell us what's depicted in figure 1?

A. Well, this is an example of call volume to their quitline. And as you can see -- I'd focus on the right part, actually, first, that there is a very, very modest number of calls coming in using this scale, but right around the time that the program was announced, which I assume occurred right around April 2nd, there were a total of more than 300,000 calls during that brief, I believe it is a 3-day period, 300,000 calls within a 3-day period.

* * *

Q. I want to go forward to another document and continuing with the subject of utilization. First, your written direct testimony in this case, by way of introduction, mentions Shu-Hong Zhu, and for the benefit of the Court who is Dr. Zhu?

A. He is the Director of the California Quitline, as well as a noted scientist in the field who has studied how to -- how effective quitlines can be in America. He provides services, of course, to the whole state of California.

* * *

Q. Do you agree with Dr. Zhu's assessment of the potential impact of proper promotion?

A. Yes, I do.

Q. I want to stay on the subject of the value of promotion, and I want to hand you a copy of a document that's been marked as JD 068087. And we're going to get you a copy of that.

A. Thank you.

Q. And this is an article from the *American Journal of Medical Sciences* by Debra J. Ossip-Klein and Scott MacIntosh titled: Quitlines in North America Evidence Base and Applications. Have you seen this article before?

A. Yes, I have.

* * *

Q. And I want to look at the first full paragraph in the second column under the bolded heading: "The role of promotion." The authors indicated "research has clearly demonstrated that broad based community proceedings increases quitline utilization. For example, Ossip-Klein, et al. demonstrated that free television, radio and newspaper promotions tripled call rates compared with promotion through smoking cessation alone." How does the conclusion that we see here from Ossip-Klein -- Doctors Ossip-Klein and MacIntosh concerning triple call rates compare to what the Subcommittee on Cessation

concluded on the impact of the media on the call rate for a comprehensive program achieved by the Group Health Cooperative?

A. Well, in fact, the subcommittee took a more conservative determination and said that a comprehensive program, beyond even what Dr. Ossip-Klein describes, with appropriate promotion would have a double of the utilization rate.

In this written testimony submitted to the court, the attorney for the plaintiff asks the expert witness to introduce the Court to the American Legacy Foundation and to discuss how her background prepared her to head the organization. Direct Written Testimony of Cheryl Heaton (Plaintiff), *United States v. Philip Morris USA, Inc., et al.*, (May 2005) Pp. 3-5.

Q: What is the American Legacy Foundation?

A: The American Legacy Foundation is the foundation described in the Master Settlement Agreement (MSA). The states obtained as part of that settlement an agreement for the creation of a foundation to combat youth smoking and other forms of youth substance abuse, to educate the public broadly about the hazards of tobacco product use, and to study and support programs to counteract the diseases associated with tobacco use. The states were so committed to the creation of the foundation that they allocated part of their recovery to fund it. The MSA is quite clear that the foundation was created at the behest of the states and not the tobacco companies. In fact, in the MSA the companies specifically disavow any responsibility for the foundation. The foundation was established in March 1999, less than six months after the MSA was signed. As set out in the MSA, it is a national, independent public health foundation located in Washington D.C. and organized pursuant to section 501(c)(3) of the tax laws. As anticipated, it has been funded primarily by payments designated by the settlement.

Q: How did you come to the foundation?

A: I was offered the job at the foundation in November 1999, after the Board of Directors completed a nationwide search. After several months commuting between my previous position at Columbia University and Washington DC, I went on the foundation's payroll on March 1, 2000. I have spent my entire career in public health and felt that my background uniquely prepared me for taking on the extremely exciting challenge of serving as the first President/CEO of the American Legacy Foundation.

Q: Tell me a little more about your career background?

Focus Point: Expert witness testimony always begins with a description of the expert's qualifications. The description has several purposes. It allows the expert's qualifications to be entered into the written record of the proceedings. It defines the scope of the expert's testimony and allows opposing counsel the opportunity to object to the expert's qualifications. Lastly, it allows the jury and judge the opportunity to assess the credibility of the expert.

Note that the scope of the expert's testimony is typically mapped out prior to trial.

A: I have worked in the area of public health for nearly thirty years. Most of my career before coming to the foundation was spent at Columbia University. Immediately before

coming to the foundation, I served as Head of the Department of Sociomedical Sciences and Associate Dean for Columbia's Joseph L. Mailman School of Public Health. I founded and directed Columbia's Center for Applied Public Health. I was an Associate Dean at the School of Public Health and an Associate Dean and Assistant Vice President at Columbia University, Health Sciences Division/College of Physicians and Surgeons. Before coming to Columbia, I was a Director of the Faculty Practice Plan, Cornell University Medical College and a Departmental Administrator, Department of OB/GYN, Columbia Presbyterian Medical Center. While much of my work had been in the area of HIV/AIDS, I had also done substantial work in connection with the tobacco epidemic which, of course, is the largest cause of preventable death in the U.S. today. I had lead or co-lead grant-funded projects for the Centers for Disease Control and Prevention (CDC) to study the effects of marketing and counter-marketing on youth tobacco use; developed a series of prevention partnerships linking public health researchers with New York State tobacco-health policy makers; evaluated intervention programs for the state's largest youth tobacco prevention program; worked at Columbia to bring an interdisciplinary approach to tobacco control and prevention, developing innovative grants which link academic researchers to public health practitioners; and written a chapter on cessation and smoking policy in the book, Treatment of the Hard Core Smoker.

Q: Please give a brief description of your other professional activities?

A: I have published nearly 100 articles, the substantial majority of which were in peer reviewed journals, abstracts, book chapters and reports on public health topics and have made dozens of presentations to academic and other conferences and meetings. I have been the principal investigator or co-investigator on numerous grant-funded initiatives. I have served on a wide array of professional organizations, committees, task forces and commissions for public health and policy issues related to tobacco, HIV/AIDS, violence and alcoholism. My professional contributions have been recognized by the United States Department of Health and Human Services, the American Public Health Association, the American Lung Association, the State of Hawaii and the New York Department of Health.

Q: Do you currently hold an academic appointment?

A: Yes. In addition to serving as President and CEO of the foundation, I currently hold an appointment as Professor of Clinical Public Health at the Columbia University School of Public Health. I am also Adjunct Professor in the School of Nursing and Health Studies at Georgetown University.

Q: What is your educational background?

A: I hold a Doctorate in Public Health (with Distinction) from the Columbia University School of Public Health, a Masters of Public Administration, Health Policy and Planning from the Robert F. Wagner School of Public Administration, New York University, and a Bachelor of Arts degree from New England College.

In this written testimony submitted to the court, the expert addresses a potential for bias. Direct Written Testimony of Cheryl Heaton (Plaintiff), *United States v. Philip Morris USA, Inc., et al.*, (May 2005) P. 2.

Q: Have you been paid for any of the time you spent preparing for your testimony or for testifying in this case?

A: No, other than my normal salary from the foundation.

Q: Why did you agree to testify in this case?

A: Ms. Eubanks asked if I would testify on behalf of the United States. I agreed to because I believed then and I believe now that it is the right thing to do.

Q: Has anyone in the Justice Department said that they would try to get money for the foundation if you were to testify?

A: No. I have been generally aware for some time from a press report that there was a possibility that the Justice Department might seek funds for youth prevention in this case. However, I have not discussed this case as a possible funding source for the foundation with anyone at the Justice Department. The foundation has absolutely not been offered anything in return for my testimony.

In this written testimony submitted to the court, the expert describes the American Legacy Foundation's work to reduce youth smoking rates. Direct Written Testimony of Cheryl Heaton (Plaintiff), *United States v. Philip Morris USA, Inc., et al.*, (May 2005) Pp. 3-15.

Q: Let's return to the American Legacy Foundation. What is the foundation's mission?

A: The foundation's mission is to build a world where young people reject tobacco and anyone can quit. In addition, the foundation has two goals that guide its work. They are, first, to arm all young people with the knowledge and tools to reject tobacco and, second, to eliminate disparities in access to tobacco prevention and cessation services.

Q: Are the mission and goals straight out of the MSA?

A: The substance is based directly on the MSA. Our Board of Directors approved the actual language after a lengthy board and staff process.

* * *

Q: Could you generally describe the foundation's programs?

A: The foundation develops both national and local programs to educate the public about the addictiveness, social cost and health effects of tobacco use through grants, technical training and assistance, youth activism, strategic partnerships, counter-marketing and grass roots marketing campaigns, public relations, and community outreach to populations disproportionately affected by the toll of tobacco. Our principal, but far from exclusive, focus is on youth. We are actively involved in smoking cessation efforts. We run our own telephone quitline, the Legacy Learn to Quit Line, which serves the Washington D.C. area including Northern Virginia and Maryland. In fact, the Legacy Learn to Quit Line is now Maryland's officially designated quit line. Other foundation cessation programs include the Great Start quitline for pregnant women and the associated provision of patient and provider materials, the Hollywood Quits program which is a program providing services to smokers in the entertainment industry in order

to raise awareness and promote change in Hollywood portrayals of smoking which adversely affect youth, and the Bob and Mary Quits “reality” cessation advertising and education programs. You may have seen the Mary Quits campaign which blanketed the DC area last fall. We also support the U.S. component of the North American Quitline Consortium.

Focus Point: The plaintiff also offered expert testimony on the efficacy of smoking cessation programs, including the use of quitlines. Nearly 70 % of smokers say they would like to quit. See Michael Fiore, et al., Treating tobacco use and dependence: clinical practice guideline. Rockville, MD: Public Health Service, 2000. Increasing the baseline quit rate from the current 2.5% of smokers to 10% ... would prevent 1,170,000 premature deaths. See Steven Shroeder, We Can Do Better – Improving the Health of the American People, 357 (12) The New England Journal of Medicine 1221 (2007). “No other medical or public health intervention approaches this degree of impact.” *Id.*

* * *

Q: What, if any, efforts does the foundation undertake with respect to secondhand smoke?

A: We are also involved in the effort to educate the public about the dangers of second hand smoke which kills an estimated 50,000 Americans every year. In 2002, approximately thirteen million children under the age of eighteen were exposed to second hand smoke in their homes. We have just launched an edgy public education campaign in collaboration with the Ad Council to encourage families to keep smoking out of their homes and cars. As with our work in cessation, we would like to do more in this very important area but do not have the resources to do so. Again, we believe that the \$100 million a year figure would be an appropriate estimate of the amount of money necessary to run an effective and comprehensive national public education campaign on second hand smoke. Such a campaign would have two main effects – reducing non-smokers’ exposure to second hand smoke and sharply increasing the quit rate. The U.S. Public Health Service 2010 objective for adult smoking is 12%. At current rates of decline, this will likely not be met. We also have an extensive evaluation program to determine whether our programs are effective and modify them as needed. I believe that I will discuss our evaluation programs in more detail later in my testimony.

Q: I want to ask you some questions about the foundation’s programs for youth. I will begin by asking what role do youth programs play overall at the foundation?

A: The bulk of our resources go to programs designed to prevent young people from smoking.

Q: Is there a particular reason the foundation devotes most of its resources to youth?

A: The great majority of smokers begin smoking before their 18th birthday. Between one third and one-half of youth who try a cigarette will go on to become daily smokers. The theory is straight-forward. If we can stop teen-agers from starting to smoke, the tobacco epidemic will slowly end as current smokers will no longer be replaced. Our youth programs consist of the truth® countermarketing campaign, our youth advisory board, the 2030 internship program, the speakers bureau, “streettheory”, and our youth empowerment grant program which is now winding down but which has supported state-level youth activism programs. In addition, we conducted a successful on-line program with AOL called “Eyeno” to reach pre-teens from 9 to 11, known as tweens. We hope to

bring this successful program back, resources permitting. There are also youth components of some of our other initiatives. truth® is principally directed at open-to-smoking, sensation seeking 12 to 17 year olds. Numerous foundation grants focus on underserved, low income as well as on gay youth. Our other programs are directed more at youth activists, as opposed to the kids who are most likely to take up smoking. However, all of our youth tobacco prevention programs are firmly based in our view that young people must be front and center in the effort to end what is properly called an epidemic, rooted in youthful experimentation followed by lifelong addiction and adverse health effects including, for a third of the young people who start smoking, premature death.

Q: What is the truth® campaign?

A: truth® is the foundation's advertising, grassroots, and online campaign to prevent youth smoking. It is designed to reach edgy 12 to 17 year olds, precisely the population that is most likely to begin experimenting with smoking. Its primary focus is what we call open-to-smoking or sensation-seeking teens. However, this program also reaches a substantial number of teens as well as 18 to 24 year olds. Since it was launched in February 2000, truth® has become the largest youth smoking prevention campaign ever mounted in this country, and, I believe, the world. I am extremely proud to say that truth® has helped reduce youth smoking rates to the historic lows we now see. Its success is imperiled by a loophole in the MSA – which I will address in more detail later in my testimony -- and the steady increase in tobacco marketing.

Q: I'd like to ask some general questions about the Foundation's other programs that are directed at young people. Could you tell me about the youth advisory board?

A: We have a youth advisory board consisting of 11 young tobacco control activists that advises the foundation on how to talk to young people about the health risks of tobacco products. Panel members provide a youth perspective on our initiatives as well as invaluable feedback on our youth outreach programs. One advisory board member serves as a youth liaison to our Board of Directors.

Q: You've mentioned that the foundation runs a youth internship program. What is that?

A: The Project 2030 internship program creates opportunities for committed young people from around the country to work with experienced professionals in reducing tobacco addiction in the U.S. The foundation provides summer internships in our Washington D.C. offices as well as year-round, semester-long internships with our staff and with our organizational partners in public health, advertising, and public relations. By the way, the name of the program is drawn from the World Health Organization's prediction that by the year 2030 – unless something dramatic is accomplished – tobacco will be the leading cause of adult death worldwide.

Q: What about the speaker's bureau?

A: The foundation recruits and trains a group of diverse speakers from a national pool of youth tobacco control groups and community organizations. These college-age youth give presentations to state and local tobacco control programs, conferences and summits, national and local youth organizations and schools.

Q: What is streetheory?

A: Streetheory is a website (www.streetheory.org) which links young tobacco activists across the country to share ideas about strategies, resources, local interventions, and activism ideas that are utilized in their own communities. The site offers facts and

information about tobacco prevention, as well as initiatives that activists can bring to their local communities. These initiatives do not involve any lobbying activities since the foundation isn't permitted to lobby – even for its own survival.

Q: Can you give me more information about the youth empowerment grants?

A: Yes. Through this five year matching grant program, the foundation awarded \$35 million to 19 states and the District of Columbia to establish and support state-wide youth movements against tobacco use. This program is now coming to an end, another program being terminated due to the end of the National Public Education Fund payments.

Q: Can you describe the foundation's other initiatives which have youth components?

A: Yes. Our Priority Populations Grants Initiative provides support to programs serving six populations, African Americans, Hispanics, Asian-Americans, Native Americans, GLBT (gay, lesbian, bi-sexual and transgendered persons) and low SES (socio-economic status) persons which bear a disproportionate share of the burden of tobacco. This is particularly true for lower income persons, among whom rates of smoking are two to four fold higher than among the college educated, depending on the state of residence. (States with low prices and/or low investments in tobacco control have sharply higher smoking rates.) Our Circle of Friends Grants Initiative builds social support networks to assist women in quitting tobacco use and staying quit. Our Community Voices Initiative includes research demonstration projects designed to integrate tobacco cessation and prevention into health care delivery systems for uninsured and underserved populations. The foundation's Great Start program provides education and assistance to pregnant women, many of them youth, to help them quit smoking. The foundation's Small and Innovative Grants Initiative provides support for small projects designed to test and explore new approaches to tobacco control. Finally, the Prevention Research Center component of our Research Demonstration Projects Initiative supports research and evaluation of best practices in tobacco control through a grant to the CDC Foundation. Our Legacy Research and Evaluation grantees include, among others, the Harvard School of Public Health, Columbia University, UC San Francisco, and the University of Michigan. Many of these collaborators are contributing to the amelioration of youth smoking. I think that's everything.

In this written testimony submitted to the court, the expert discusses the evaluation of the American Legacy Foundation's work and compares it to evaluations of youth smoking prevention programs run by the tobacco industry. Direct Written Testimony of Cheryl Healtton (Plaintiff), *United States v. Philip Morris USA, Inc., et al.*, (May 2005) Pp. 24-34, 39-47.

Q: Has Legacy evaluated the truth® campaign?

A: Yes.

Q: How has Legacy gone about its evaluation of the campaign?

A: From the outset of our campaign in early 2000, and very much on an ongoing basis, the foundation has committed considerable resources to a rigorous analysis to determine whether truth® is effective in preventing youth smoking. Obviously, we have no interest in a program that doesn't work and we want the very best information so we can structure the most successful possible program and, if warranted, abandon an ineffective program.

Based on the literature regarding the analysis of behavior change, we undertook this evaluation in two basic stages. The first phase of our evaluation focused on measuring changes in attitudes associated with the campaign and likely to be precursors of behavior change. The second phase looked at changes in behavior. Let me explain. Because attitudes predict behavior change, in the first year of the campaign we looked at whether there were demonstrated changes in tobacco-related beliefs and attitudes among teens. In the second phase, approximately two years after the campaign's launch, we examined whether exposure to truth® was associated with actual behavioral change -- reductions in youth smoking prevalence. Very briefly, we know from the Monitoring the Future survey conducted by the University of Michigan that the prevalence of youth smoking declined from 25.8% in 2000 to 18.0% in 2002. We looked at this decline in youth smoking prevalence and asked three basic questions. First, did truth® play a role in that decline? Second, if the answer to the first question was yes, how much of the decline was attributable to truth®? And, third, was the amount of truth® viewed associated with these declines (i.e., was more truth® associated with less smoking)? That is, what was the truth® effect?

Q: What conclusions, if any, were reached as a result of the evaluation of the truth® campaign?

A: Here I am speaking to the second phase of our evaluation: did the campaign result in behavior change? Our results indicate that the truth® campaign contributed approximately 22% of the overall decline in youth smoking rates between 2000 and 2002. This translates into approximately 300,000 fewer teen smokers in 2002 than there otherwise would have been and who will not face premature death and disease from the tobacco epidemic if they stay smoke-free. An article setting out our analysis and results has been accepted for publication by the peer-reviewed journal, the *American Journal of Public Health*. It appears in this March's edition of AJPH.

* * *

Focus Point: In the final opinion in this case, the presiding judge, Federal Judge Gladys Kessler, concluded that Philip Morris continues to increase its marketing expenditures in grossly disproportionate amounts to its spending on youth smoking prevention. Philip Morris's 2003 Financial Forecast Budget includes a budget of \$110 million for youth smoking prevention." In contrast, in that year, Philip Morris spent more than \$7.1 billion on sales incentives and product promotions. Additionally, Judge Kessler concluded that although Philip Morris and others have each supported the implementation of school-based youth smoking prevention programs, they are often not effective because of the failure to implement the programs as rigorously as the research study justifying it calls for.

In the following questions, the expert discusses the evaluation of some of the tobacco industry's programs for reducing youth smoking rates.

Q: Let's turn to the industry's so-called youth prevention campaigns. Has the foundation ever conducted any analysis of the effects of tobacco industry-sponsored youth smoking prevention programs?

A: Yes. Based on Waves I and II of the Legacy Media Tracking Survey, the foundation has examined the effect of tobacco company-sponsored youth smoking prevention

programs on knowledge and attitudes related to smoking and the tobacco industry. I would refer to my earlier testimony where I explained that we studied changes in attitudes and beliefs because they precede changes in behavior

Q: What do you mean by “knowledge and attitudes?”

A: By knowledge, I mean whether youth are aware of key facts about the addictiveness, health effects and social consequences of tobacco use and are armed with knowledge to help them reject tobacco. By attitudes, I mean the actual shifts in belief that occur as a result of the awareness of the impact of tobacco use on themselves and others. It is also important to shift teens’ attitude toward tobacco products and their manufacture and marketing to be certain that they are wary and informed consumers. I would refer back to my earlier testimony about the fact that attitudinal change precedes behavioral change. For example, one attitude we look for is a reported intent to smoke in the next year. If youth who have seen advertisements report a reduced intention to smoke, we know the advertisement is having the intended effect because evidence suggests that this reported intent is associated with the desired behavior.

Q: Were the results of the foundation’s study of tobacco company-sponsored youth smoking prevention programs ever published?

A: Yes. The results of that study were published by Legacy and RTI in a report titled “Getting to the Truth: Assessing Youths’ Reactions to the truth® and ‘Think. Don’t Smoke’ Tobacco Countermarketing Campaigns.” The study was also published in the June 2002 issue of the American Journal of Public Health under the title “Getting to the Truth: Evaluating National Tobacco Countermarketing Campaigns.” The American Journal of Public Health is a peer-reviewed journal that publishes articles relevant to the field of public health. I was a co-author on both of those publications.

Q: Is JD-065578 a copy of the article published in the June 2002 edition of *the American Journal of Public Health*?

A: Yes.

Q: Can you describe the Legacy Media Tracking Surveys?

A: These surveys measure exposure to tobacco marketing and counter-marketing, attitudes and beliefs toward tobacco, and tobacco use behaviors among youth. The surveys also contain questions about social and environmental influences and sociodemographic information. For example, the survey asks whether the interviewee has friends or relatives who smoke, whether there are smokers in the house, and the like. An initial baseline survey, which we refer to as LMTS-I, was conducted by telephone between December 6, 1999, and February 6, 2000, prior to the launch of the truth® campaign. A second telephone survey, which we refer to as LMTS-II, was conducted from September 8 to December 23, 2000. Both surveys were designed to produce nationally representative samples of youths ages 12 to 17 and young adults ages 18 to 24. These two surveys formed the basis of the published analysis. Based on the answers to the questions we were able to create a detailed model of youth attitudes towards smoking, including whether they think it is cool to smoke, whether they think it is dangerous, and whether they see it as a sign of independence; their reported intentions to smoke in the future; their current smoking behavior; and their feelings towards the tobacco industry.

* * *

Q: Did the survey show youth awareness of the tobacco company programs?

A: The results of LMTS-I showed an unaided awareness of 3.2% for the “Think. Don’t Smoke” program, and a less than 1% unaided awareness of the “Tobacco is Whacko if You’re a Teen” program. By unaided awareness, I mean respondents that reported awareness of the campaign without any prompting from the interviewer. The unaided awareness of these ads in LMTS-II was essentially unchanged. Respondents were also asked to confirm their awareness of advertisements by further identifying details of the ads. If the respondent correctly described the ad, responses were categorized as “confirmed awareness.” The confirmed awareness of “Think. Don’t Smoke” ads for LMTS-I was 70.5% and the confirmed awareness of “Think. Don’t Smoke” ads for LMTS-II was 65.5%. So, there is pretty good evidence that the “Think. Don’t Smoke” program was fairly well known among the target audience even though the unaided recall of the program was fairly low. Due to the less than 1% unaided awareness of the “Tobacco is Whacko if You’re a Teen” campaign, and the much smaller media buy for that campaign, the media reach of Tobacco is Whacko was insufficient to scientifically evaluate. We focused our in-depth analysis on the “Think. Don’t Smoke” campaign. We focused on two purposes: to differentiate its effects from those of truth® and to compare the relative effects of the two campaigns.

Q: What did the survey show about youth awareness of the foundation’s truth® campaign?

A: Keep in mind that LMTS-I was a pre-launch baseline survey, so that survey obviously showed no awareness of truth. The unaided awareness of the truth® campaign reported in LMTS-II was 21.9% (as opposed to the 3.2% for “Think. Don’t Smoke” as I previously stated). The confirmed awareness was 74.9%. Both the unaided and confirmed awareness for the truth® campaign in LMTS-II were already higher than “Think. Don’t Smoke” only ten months into the truth® campaign. This was despite the fact that “Think. Don’t Smoke” had been running for over two years with a budget of around a \$100 million dollars a year at that point.

Q: What is the significance of the survey findings?

A: All of this means that a respondent was nearly seven times more likely to have unaided recall of a truth® campaign advertisement than a “Think. Don’t Smoke” advertisement. This suggests that the truth® campaign captured the attention of youth and young adults at a much higher rate than the “Think. Don’t Smoke” advertisements.

Focus Point: In the following questions, the expert concludes that the American Legacy Foundation’s youth smoking prevention programs are more effective than the industry-sponsored ones.

Q: Are there reasons that the survey results show that the truth® campaign was more effective in communicating youth prevention messages?

A: The principles for creating an effective media campaign are well known. I have earlier discussed the Columbia Expert Panel Report. Keep in mind that the Expert Panel specifically advised against the sort of directive messages featured in the “Think. Don’t Smoke” and “Tobacco is Whacko if You’re a Teen” campaigns. Directive messages and those indicating that “smoking is for adults” inspire sensation-seeking youth to engage in these precisely forbidden activities. The Philip Morris and Lorillard messages couldn’t be a clearer example of this approach. Interestingly, it is my understanding from a group

dialogue with Dr. Carolyn Levy, who previously was with youth marketing at Philip Morris and then was in charge of the Philip Morris youth prevention program, that the “Think. Don’t Smoke” slogan was chosen by Philip Morris corporate and not the company’s youth smoking prevention team. I was told by Dr. Levy that this slogan had not been thoroughly tested with youth prior to the campaign’s launch in order to test their reaction and receptivity to the message. The tests that were done were mainly mall intercepts where youth were interviewed with their parents present, a particularly unreliable method and one virtually certain to result in under-reporting of the target: open-to-smoking youth.

Q: What did the foundation’s study show about the effect of the “Think. Don’t Smoke” campaign?

A: Among other findings, the study showed that exposure to “Think. Don’t Smoke” advertisements was associated with a 23% increase in the odds of reporting an intent to smoke in the next year. It is noteworthy that subsequent unpublished analyses we have conducted have confirmed this effect.

Q: That seems like a pretty astonishing finding. What accounts for this result?

A: It is actually entirely predictable. Since the teens who are most open to smoking tend to be risk-taking and rebellious, a “Don’t Smoke” message is likely to produce the exactly opposite response. If an authority figure tells this type of teen “Don’t do it,” the result is that they will be more likely to engage in the forbidden behavior. So, giving the open to smoking teen an order to “Don’t Smoke” is essentially an invitation to engage in smoking. The other hypothesis, which I believe is less likely, is that “Think. Don’t Smoke” ads have higher recall and appeal to those already smoking. This would suggest the ads are not reaching the open-to-smoking target but rather those who are already teen smokers. Either way, the campaign is not reaching the teens who are most likely to start smoking. What we have learned, and as I have discussed at length earlier, is that it is essential to take a very different approach to reach the teens most open to smoking. In order to reach the rebellious, risk-taking, open to smoking youth, the most effective approach is to give the young person a way to rebel – to be cool –other than by smoking. That is, to replace the allure of the tobacco brands with something else. You see how we have done that with truth® and how we have documented its success.

Q: Did the survey results show anything about youth attitudes towards tobacco companies themselves?

A: The study shows that exposure to “Think. Don’t Smoke” is associated with favorable feelings towards the tobacco industry. For example, the odds of agreeing with the statement “cigarette companies have denied that cigarettes cause disease” declined by 24% with exposure to any “Think. Don’t Smoke” advertisement, and exposure to additional advertisements reinforced this effect. Similarly, exposure to “Think. Don’t Smoke” was associated with a 20% decrease in the odds of a respondent agreeing with the statement “I would like to see cigarette companies go out of business.”

Q: What is the significance of youth attitudes about the tobacco industry ?

A: Youth attitudes are significant because we have demonstrated that one of the most effective strategies in preventing youth smoking is to educate young people about how tobacco products are created and manipulated and how they are marketed. If you shift key attitudes there is a high chance behavior change (here that would be not starting to smoke) will follow. “Think. Don’t Smoke” ads may well reinforce young people who

already smoke and those who never intended to smoke and it certainly seems designed to create good public relations for the company. But the bottom line is that it is not a program to counter youth smoking by appealing to edgy, open-to-smoking youth. Tellingly, the program has produced no publicly available evaluation results of its own nor have they shared any outcome results privately when asked. The contention raised post hoc that the program targets teens is curious since, to my knowledge, no national survey tracks data on smoking of students below grade 6, the grade levels of most teens.

In this excerpt of cross examination, the expert answers questions regarding the potential for funding for the American Legacy Foundation from remedies ordered in litigation. Cross Examination Testimony of Cheryl Heaton (Plaintiff), *United States v. Philip Morris USA, Inc., et al.*, (May 2005) Pp. 20830-36.

Q. . . . Are you aware that the Department of Justice has told Judge Kessler that they want this Court to grant a specific remedy that would require the tobacco companies to fund a long term and sustained youth smoking prevention campaign? Are you generally aware that that's a remedy that's being requested here?

A. Yes, I'm generally aware of that.

Q. And as far as that general remedy in this case which you are now testifying, if Judge Kessler should decide to provide such a remedy in this case on behalf of ALF [the American Legacy Foundation], do you want Judge Kessler to consider ALF as an organization to receive a large amount of that money for that program?

Focus Point: The attorney for the defendants questions the expert as to the financial affairs of the American Legacy Foundation and argues that the expert's decision to testify was in part motivated by the hope of getting funding from the case. Potential sources of bias are always relevant.

The expert adeptly responds to the question by explaining what the American Legacy Foundation does. In essence, the expert is testifying about how to effectively remedy harm caused by the tobacco industry. The expert might have noted that the industry agreed to create and fund the American Legacy Foundation in the 1998 Master Settlement Agreement, and accordingly, should not decry its continuation through virtually the same type of funding.

A. The American Legacy Foundation is presently the only organization in the United States of America that is providing advertising public education for young people. We will not be able to continue to do that. If that were a decision of this Court, that would obviously be a very good thing from the public health standpoint. If you're implying that's why I'm here, that's absolutely false.

Q. Well, actually, the Court will decide why you're here, all I'm going to do is ask you factual questions. You didn't answer any question, so I'm going to answer it again.

A. I actually did answer.

Q. Was the answer to any question "yes"?

A. Restate the question.

Q. I will. If Judge Kessler should decide to provide such a remedy in this case on behalf of ALF, do you want Judge Kessler to consider ALF as the organization to receive a large sum of money to fund youth smoking prevention?

A. I think continuing the "truth" campaign is important from a public health standpoint. If she were to do so, that would be terrific. That's -- I can't say no to that because one of the main focuses of my job is to be certain that we can continue to stop young people from smoking.

Q. I listened to your whole explanation, is the answer to my question "yes"?

A. Would I like her to do that?

Q. Yes.

A. Yes, of course.

In this excerpt of cross examination, the attorney for the defendants has the expert answer questions as to the methodology used by the American Legacy Foundation in evaluating the efficacy of youth smoking prevention programs run by the tobacco industry. Cross Examination Testimony of Cheryl Heaton (Plaintiff), *United States v. Philip Morris USA, Inc., et al.*, (May 2005) Pp. 20839-48, 20849-76.

Q. Dr. Heaton, let me turn to a little different topic. Could I hand the witness tab 120, JD 065578 which this is the June 2008 article which you talk about in your written direct examination. I'll hand it to you. Do you recognize that publication, that article?

A. Yes, I do.

Q. And you reference that in your written direct examination; is that correct?

A. Yes, I do.

* * *

Q. And you say here "among other findings, the study showed that exposure to "Think. Don't Smoke" advertisements was associated with a 23 percent increase in the odds of reporting an intent to smoke in the next year. It is noteworthy that subsequent unpublished analysis were conducted have confirmed this effect." Now, the 23 percent increase that you referred to there, the article itself that you derive that figure from, you are the coauthor of that article; is that correct?

A. Yes, I am.

Q. And the article itself, I think the lead author was Dr. Farrelly; is that correct?

A. Farrelly.

* * *

Q. He designed the survey questionnaire and methodology, he directed the data analysis and he prepared the original draft manuscript and you, Dr. Heaton, participated in the preparation of the final draft; is that accurate?

A. Yes, it is.

Q. Okay. Now, if we -- all of the research and all the work that went into developing and implementing this study -- strike the question. Tell the Court who Dr. Farrelly is or Farrelly?

A. He's with Research Triangle. He's an economist who is, I believe, the lead person on our contract with Research Triangle, Inc., which was a competitive bidding process. So he leads a fairly large team of people in North Carolina.

Q. And this organization called Research Triangle, Inc., is that a consultant to ALF?

A. Well, it's a contractor.

* * *

Q. I think you said in your deposition that you paid them, you think, probably upwards of \$16 million in recent years for work they've done; is that correct?

A. Um, I'm not certain of that figure. I don't recall. I actually recall \$21 million, I think, in my direct testimony.

Q. Okay. That's fine. You paid them about \$21 million in recent years; is that correct?

A. Right, to evaluate a broad range of programs.

* * *

Q. So, there's no question that this study that we're going to talk about with the Court where you reach this conclusion about Philip Morris advertisements, ALF was paying people to do a study of ALF's own advertisements; is that correct?

A. That's correct, yes.

Q. And you were paying ALF -- strike that. You were paying Research Triangle to do research that compared ALF's ads to Philip Morris's ads; is that correct?

A. That's how it worked out. I think it began as a control variable and when they saw the results, they realized there was a real issue.

Q. So is the answer to my question "yes"?

A. Yes, that's standard practice, that is what we do and that's what others do.

Focus Point: In criticizing the expert's evaluation of industry's youth smoking prevention programs, the attorney for the defendants attempts to cast the industry programs in a favorable light. The best conclusion would be to convince the judge (or jurors) that the tobacco industry is already remedying any harm that it may have caused.

In this excerpt, the attorney for the defendants explores the potential for bias in the contracting for research services. The expert correctly relied on the fact that the objectivity of the scientific evidence will speak for itself, instead of arguing that there is no potential for bias in the relationship.

Q. And are you the person who made the decision on behalf of ALF that when the article was published, there would be no disclosure in the acknowledgment section that ALF had funded the entire study?

A. No, I didn't make that and I'd be surprised if it doesn't say that.

Q. Well, let's look at -- I have acknowledgment section on the screen. Do you see that?

A. Um-hmm. You know, that surprises me, and no, I absolutely did not make such a decision. I'm surprised it doesn't because normally it does say what the source of funding is, so that's news to me.

Q. Well, you're the author --

A. I'm the author, I'm one of the authors, I read it carefully, I didn't notice that. I mean, I will say that in terms of the people who generally read this journal, the fact that RTI is the evaluator. A lot of Legacy's work is widely known, but it should have been there, absolutely.

Q. But when you read -- I'm sorry when you read this over as the author, you did not in any way recognize that the article itself contains no indication that ALF is paying

somebody to actually evaluate your ads versus somebody else's ads who is not paying for the study?

A. It doesn't say that there, but of course when it talks about the authors it says where we all are and I think people know you don't get this huge amount -- no one does this huge amount of work for nothing. It's extremely expensive.

Q. So we are to think that Philip Morris paid for this ad?

A. Pardon?

Q. A reader would know someone else paid for it either ALF or Philip Morris?

A. No, I think it's a fair criticism, it could have been NIH. It could have been a variety of sources, so I believe the article should have indicated, absolutely.

* * *

Q. Beyond that issue, Doctor, before this article was ever published, you became aware of some major problems with the study's methodology that called into question the accuracy of the results; is that correct?

A. That's not accurate.

Q. Well, let's start with this. Am I correct, the survey, the way the survey got structured is that somebody made a decision as to how to limit the age of kids that would be surveyed; is that correct?

A. I'm sorry, could you repeat the question?

Q. Yes. In order to do the survey, somebody had to decide who to limit the age group that would be part of the survey of the kids surveyed; is that correct?

A. Well, the age group -- the target of the "truth" campaign is age 12- to 17-year-olds.

Q. That's right. That's your ads, correct?

A. Yes.

* * *

Q. Now, you were comparing the "truth" ads to Philip Morris's ads, so I take it you must have asked yourself, I wonder what the target audience is for Philip Morris's ads; is that fair to say? Did someone consider that?

A. Um, I was not at the Foundation when the survey was designed. It ran for the first time, I think, in 1999 for baseline data, so I have a hard time answering specific questions about what went into the thinking. It's a very excellent survey. I know -- so I have no problems with the research methodology that was applied here.

Q. Well, we're going to find that out because we're going to go through it and find out if there are any problems. So we'll start with the first issue, is that -- when did you first become involved in this project?

A. In which project?

Q. In the study that is reflected in that article.

A. The moment I arrived at the Foundation, so that would have been late December '99.

Q. And at some point did you -- when you came on board, did you come to realize that you structured this thing to only study the target audience for the "truth" campaign and that you ignored the target audience for Philip Morris's campaign, did you learn that?

Focus Point: The expert correctly answers the methodology questions. Note that in the final opinion in this case, Judge Kessler found that Philip Morris and the other defendants direct their youth smoking prevention efforts towards early adolescents and ignore older adolescents. This is problematic, according to Judge Kessler, because about 1,250 young people per day become established smokers (defined as smoking more than 100 cigarettes lifetime) at ages fifteen through seventeen, while about 725 per day become established smokers at ages eleven through fourteen. Thus, nearly two thirds of adolescents who smoke become established smokers in the later age range of fifteen through seventeen. The youth smoking prevention programs operated by the tobacco industry largely ignore these children, and if the expert's testimony is correct, actually increase their risk for becoming smokers.

A. The first time I heard about Philip Morris's target audience for their campaign was in some documents related, I believe, to this case. That actually was news to me that they considered their target to be 9- to 11-year-olds because there's no systematic data collection for 9- to 11-year-olds from any major government agency that would ever allow them to evaluate the impact of the campaign.

Q. Well, let's find out what you learned -- strike the question. You learned before the article was published of a major problem because you surveyed the wrong target audience; is that correct?

A. No, there was no major problem and there was no wrong target audience. The target audience for a youth smoking campaign, a youth antismoking campaign, particularly one that's structured to reach those young people when they're making these decisions, would naturally be 12- to 17-year-olds.

Q. Well, let's see what you learned before the article was published. Could I show the witness tab 126, JD 055088, and I'm going to hand this to you, and I'll give you a chance to look at that for a moment. I have it on the screen. This is a letter sent to you -- sent to Dr. Haviland?

A. That's correct. Yes.

Q. Dr. Haviland was Executive Vice President of the American Legacy Foundation; is that correct?

A. Yes.

Q. She was number two in charge of the Foundation?

A. Not at this point, but eventually, yes.

Q. Okay. And Dr. Haviland is someone that you worked closely with at the Foundation?

A. Yes.

Q. She's one of the coauthors on this article; is that correct?

A. Yes.

Q. And this is dated -- go back, February 21, 2002; is that correct?

A. Yes.

Q. This is several months before the study was published; is that correct?

A. Yes.

Q. And if we go down to see what Philip Morris told you in a very professional way, it says "we want you to know that we are concerned that certain aspects of ALF's data collection methodology may have biased the results ALF obtained on the Philip Morris USA YSP advertisements. Some examples: Number one, Philip Morris USA's YSP

intended audience is kids aged 10 to 14. ALF interviewed kids aged 12 to 17. As a result, ALF missed 40 percent of Philip Morris USA's YSP's audience." Do you see that?

A. I do see that and now I recall in seeing the memo, I recall them making this -- you know, making this statement.

Q. And when this statement was made to you, at that time did you plan on being a coauthor of this article?

A. I was involved in a lot of discussions about how we were pursuing the research and I assumed that I thought of myself as a participant and an author. I can't directly remember, but I would assume I did.

Q. And did Dr. Haviland know she was going to be an author at that time of this article?

A. I would think she would know, yes.

Q. And I take it Dr. Haviland shared with you the content of this letter; is that correct?

A. Yes, but there's a problem, of course, with the age range, but I won't get into that. So -- I mean, there was a credibility issue here because that age range covers an age range that would require two separate campaigns because 9- and 10- and 11-year-olds are in one social developmental phase, and those who are older than that are in a very different one, so --

Q. Just so I understand, when Philip Morris told you that their target audience is kids age 10 to 14, did you believe that was a false statement by Philip Morris?

A. No, I'm just looking at it now and I'm thinking what would be the implications in terms of the results. In my view it would be very limited.

Q. When Philip Morris told you what their target audience was, did you go out and verify it so you could be certain of what Philip Morris told you was true?

A. No.

Q. Did you accept it as true?

A. Since I didn't even remember that they said it in this memo it's hard for me to recollect every thought that went through my mind when I read the litany of complaints that Philip Morris had then and continue to have about our work. But in this particular instance, you know, the first time I remember really being aware of their assertion about their age range was fairly recently. But obviously they said it then and I don't have before me our answer, but I could review our answer. My assumption is we addressed it in some way, but we address all their issues when they write to us.

Focus Point: The attorney for the defendants challenges the American Legacy Foundation's evaluation methodology and accused the witness of ignoring pertinent data. In response, the witness makes it clear that she and others tried to work with the tobacco industry but did not receive constructive input or cooperation.

Q. That's what I want to find out. When Philip Morris told you that, several months before the article was published, did you do something to change the survey so that it would fairly compare Philip Morris's target audience and not exclude 40 percent of Philip Morris's target audience from the survey? Did you do something about that?

A. Well, I would expect that we looked at it and we thought to ourselves, okay, we've missed 10-year-olds, but since we're surveying, you know, 8th grade and up we probably have people who are about to turn 12, because really the survey was grade based. So my sense is we probably did not go back out and try to talk to people who -- 10 and 11 or 10.

I would say because we do have some 11-year-olds in the sample. If we did it would be completely out of sync when all the various ads were running, so it would be very difficult to retrospectively address that.

Q. Okay, so --

A. And I don't think it would have any impact on the data, certainly not the data for how their campaign resonates with 12-, 13- and 14-year-olds because they obviously were in the sample and those were the years of onset of smoking.

Q. I want to make sure the Court understands what you are saying. When you found out that you were considering publishing -- could I have that back on the screen -- considering publishing a survey in an article in a journal and you were told that the ads, that the comparison that you were making between your ads and Philip Morris's ads had excluded 40 percent of Philip Morris's audience, did you make the decision to ignore that and change nothing in the survey?

A. Just to be clear, the survey was, the data collection was over. You can't go back after the fact and fill things in. The only way to fix it, if we chose to fix it, would be moving forward, and I do not believe we changed the age range because we frankly think it's very difficult to have that kind of conversation with a 10- and 11-year-old.

In this excerpt of cross examination, the attorney for the defendants asks whether one of the American Legacy Foundation's educational campaigns is effective. Cross Examination Testimony of Cheryl Heaton (Plaintiff), *United States v. Philip Morris USA, Inc., et al.*, (May 2005) Pp. 20950-61.

Q. As far as whether or not your "truth" campaign has the type of effect on smoking prevalence that you've set forth, as I understand it, your own organization actually has done your own study on your own data to analyze that. Is that correct?

A. You would have to give me more information. We've done a great number of study -- we've done a great number of work -- a great deal of work about the campaign, so I would have to know precisely what you're referring to.

Q. Here is where I'm going. We know that this article that you published that we've been talking about was based on data that you did not physically have in your possession.

A. Some of it, yes.

Q. And my question is: Has your own organization, though, done your own -- your own research where you actually have actual data to see what impact your "truth" campaign is having?

A. Yes. We've done a fairly large study of the national youth tobacco survey looking at baseline prior to the launch of the campaign and a measure after the campaign had been on the air for 16 months.

* * *

Q. Now, you're also aware that some very prominent members of the public health community have looked at your article and have found significant reasons to criticize your conclusion that you contributed to a decline in youth smoking; is that correct?

Focus Point: Disagreements in the expert's field of study are always relevant. Note that such debate often gives the attorney conducting the cross-examination fodder to challenge the expert's opinion. In some cases, where experts provide testimony that appears contradictory, the attorney will ask his or her expert to explain the difference.

A. If this is in reference to Michael Siegel and Dr. Moskowitz, then yes, I'm aware of those two individuals.

Q. Well, let's talk about Dr. Moskowitz first. Am I pronouncing it -- is it --

A. It's Moskowitz.

* * *

Q. Okay. Let's just -- for the record, Dr. Joel Moskowitz is with the public health community. He's a director at the Center for Family and Community Health, the School of Public Health, University of California at Berkeley. That's what it says here; is that correct?

* * *

A. Mm-hmmm.

Q. You became aware at some point that he had written a letter or had issued some critique of your study; is that correct?

A. Yes.

Q. And if we just go through so the court understands what the critique is -- now, actually, Jamey, I need to go up higher. Doctor, if you would bear with me. Go into the middle of the first paragraph. Do you see the sentence that begins, "The authors failed to find a significant linear relationship." Do you see that?

A. Yes.

Q. "The authors failed to find a significant linear relationship between GRP --" I'm calling -- can I call that exposure to the ads?

A. I think you could.

Q. I'm trying to --

A. King's English here.

Q. And smoking prevalence, and he says that the authors failed to find that. Do you see that?

A. Yes, I do.

Q. Do you agree with that?

A. I'd have to look back at the article because it is really required to analyze it with the quadratic because it's a yes/no answer for the dependent variable.

* * *

Q. And he goes on to say -- which I would assume that you would consider to be significant comment -- he says, "Yet, the paper obscured this finding and failed to address its policy implications. Did an overdose of 'truth' render the campaign ineffective? Or were the models improperly specified to estimate campaign effects?" Now, his observation there, he is correct that when you read over your article, you do not see any discussion of this issue of the fact that in major metropolitan areas there was not a reduction in smoking behavior?

A. That's because it's not true. But there is discussion very specifically in this paper that I would like to point you to that directly addresses the point being made here.

* * *

Q. Okay. Well, let's go back to what Dr. Moskowitz said to your editor. Could I have that back up, Jamey, which is JD -- let me get it for you, Jamey. Tab 119. JD 55221.

If we go down to the bottom what Dr. Moskowitz then says, "When examined by grade level the effect of "truth" advertising on smoking prevalence was significant only for students in grade 8 in media markets with moderate exposure, Table 2." Now by the way, do you agree with that statement by Dr. Moskowitz?

A. No. It was significant for all grades combined as well.

Q. And Dr. Moskowitz's next statement to your editor was "That the campaign's impact did not sustain through high school suggests that "truth" advertising was no more effective than school based, smoking prevention programs." Do you agree with that statement by Dr. Moskowitz?

A. No, and I think he misunderstood the study and knows he did.

In this excerpt of cross examination, the attorney for the defendants reviews youth smoking prevention programs operated by one of the tobacco manufacturers. Cross Examination Testimony of Cheryl Heulton (Plaintiff), *United States v. Philip Morris USA, Inc., et al.*, (May 2005) Pp. 20973-90.

Q. Are you generally aware that Philip Morris has a Youth Smoking Prevention Program that they fund with approximately \$100 million a year?

A. I knew you had a program. I didn't know once you stopped the ads that it was a hundred million dollars. So certainly I know you have a program.

Q. The ads you're talking about are the "Think. Don't Smoke" ads?

A. Yes.

Q. And the parent ads?

A. I don't know how much you spend on the parent ads, but I'll -- for purposes this discussion, obviously I'll take your word for it.

Q. You were aware that Philip Morris had a program that had a communications function that included ads; is that correct?

A. Yes.

Q. And included grants to third parties who had Youth Smoking Prevention Programs; is that correct?

A. Yes.

Q. You were aware that Philip Morris had programs regarding access prevention?

A. Yes.

Q. And you were aware that Philip Morris did research, is that correct, in the area of youth smoking behavior?

* * *

Q. So after that person [employed by a tobacco manufacturer] identifies the methods to reduce the incidence of youth consumption of tobacco products, after the methods are identified, is it your testimony that the companies are to do absolutely nothing to implement or carry out the methods identified?

A. No. I think they should do everything to carry them out. I believe this is a reference to your own activities which have operated on the opposite direction.

Q. I'm sorry. The executive level manager is supposed to identify methods to reduce the incidence of youth consumption. Do you see that?

A. Yes, much of which is in response to your activities. So I think this is a watchdog within your organization. That's my understanding from Attorneys General with whom I have spoken.

Q. Well, you have spoken to a lot of Attorney Generals about Philip Morris's Youth Smoking Prevention Program?

A. Well, I spoke to Chris Gregoire and Bill Sorrell to clarify what -- I'm sorry. I spoke to Bill Sorrell and Chris Gregoire to try to understand what this section of the agreement meant, and my understanding was it was basically telling you to do business differently.

Q. We can see -- do you see what the words say here?

A. Yes. "There are many things that you are doing within your company that promote youth consumption." I think what they are saying is having an executive manager and within your own company, you know, identify ways to stop promoting, you know, youth smoking.

Q. Actually, what it says, "identify methods to reduce the incidence of youth consumption." Do you see that?

A. Right. I mean --

Q. Do you see that?

A. I do see that, yes.

Q. Now, just so I know -- strike that. Go to the next paragraph. The next paragraph says, "that we are committed to encouraging our employees to identify additional methods to reduce youth access to, and the incidence of youth consumption of, tobacco products." Do you see that?

A. Yes.

Q. Now, after we go to that trouble and our employees come up with great ideas about how to reduce the youth consumption of tobacco products, is it your testimony that the tobacco companies are to do nothing to implement or carry out those ideas?

A. I think it's a clear conflict of interest.

Q. Okay. Well, let's talk about that. One reason why you believe that is because you view the tobacco companies as your competitors in the area of youth smoking prevention; is that correct?

A. Certainly that would be a dimension of it.

Q. But in spite of that, you also recognize, do you not, that -- of all the tobacco -- let me call back. Will Philip Morris and you are doing about -- could I call up, Jamey, tab 21, J-DEM 040032. I showed you this a moment ago. These are the areas in which Philip Morris carries out youth smoking prevention activities with about a hundred million dollars a year in funding. What Philip Morris does and what ALF does is essentially the same thing; is that correct?

Focus Point: The testimony on the American Legacy Foundation was provided during the remedy phase of the litigation. An important question before for the court in this excerpt of testimony was whether any of the work carried out by the American Legacy Foundation should be used to remedy the harm caused by tobacco industry malfeasance.

The defendants' responded that programs are already in place to address the possible harm that may have been caused by tobacco industry marketing. This is a common theme for the defense. In many cases, including this one, the defendants have argued that remedies are no longer necessary because the marketing restrictions contained in the 1998 Master Settlement Agreement will prevent future malfeasance. In her final opinion in this case, Judge Kessler disagreed and concluded that the Agreement was insufficient to stop the industry's racketeering activities.

Note that tobacco litigation of any type encompasses two major questions: liability and damages. In private tobacco litigation, damages are remedied primarily through monetary awards, although equitable damages of the type considered in the Department of Justice litigation could also be imposed in private litigation.

A. I beg to differ.

Q. Well, do you have nationwide TV ads to convince kids not to smoke?

A. We have nationwide TV ads that result in kids not smoking.

Q. Does Philip Morris have nationwide ads?

A. Not directed at youth, directed at adults.

Q. I'm sorry?

A. You have -- yes, you have national ads, and I believe the main focus is to parents, adults, and a campaign to -- you know, that appears to be attempting to help people quit.

Q. Philip Morris at one time had the "Think. Don't Smoke" campaign; is that correct?

A. Yes.

In this excerpt of cross examination, the expert discusses the American Legacy Foundation's policy of not giving grants for organizations that also accept tobacco industry funds. Cross Examination Testimony of Cheryl Heaton (Plaintiff), *United States v. Philip Morris USA, Inc., et al.*, (May 2005) Pp. 20990-98.

Q. Let me ask you this. We just established that both Philip Morris and ALF are in the business of giving grants to worthy third parties in the area of youth smoking prevention. Is that correct?

A. We've established the fact that we both make grants, right. Presumably to worthy parties.

Q. And could I have tab 52? This is J-DEM 0040035A, tab 52.

This is a chart that was used earlier in the case. It just is a quick visual summary of some of -- Philip Morris makes grants of about \$110 million to 139 organizations, and some of the organizations I've set forth here on this chart. Do you see that?

MS. EUBANKS: Objection, Your Honor. This is beyond the scope of the written direct, what kind of grant programs Philip Morris might engage in. That's way beyond the scope.

MR. WEBB: Your Honor, this is not beyond the scope. This witness, her entire testimony is attacking Philip Morris's programs, and she talks about her grant. I'll tell you what. I only have one question in this area, Your Honor.

THE COURT: No. The objection is sustained. That was not discussed in the direct. Her direct obviously focused on advertising.

* * *

Q. I take it ALF believes in grants to third-party organizations can be an effective way of preventing youth smoking behavior; is that correct?

A. Yes.

Q. But ALF has developed a formal policy that you've published which tells potential grantees that they cannot receive any ALF grant money if they receive any grant money or benefits from any tobacco company; is that correct?

A. The board -- yes, the board passed that policy and reaffirmed it.

Q. Let me show it to you. Tab 46. This is JD 054764. And I believe what I've handed you is a document that is ALF's, the American Legacy Foundation, grant guidelines; is that correct?

A. Yes.

Q. And could you go to Page 4, and I'll cull out the section, the provision I'm talking about. What you tell grantees that part of the guidelines, if they want money from ALF, it says, "To avoid any real, potential, or perceived conflict of interest between Legacy's grant recipients and tobacco-related entities, Legacy will not award a grant to any applicant that is in current receipt of any grant monies or in-kind contribution from any tobacco manufacturer, distributor, or other tobacco-related entity." "In addition, Legacy expects that a grantee will not accept any grant monies or in-kind contribution from any tobacco manufacturer, distributor, or other tobacco-related entity over the duration of the grant." Did I read that correctly?

A. You read it correctly. There's a further fact sheet for them on Clause 12. We don't apply it to the entire institution or the entire state government. But, yes, this is what appears here. But there's an additional Q and A, I believe, about Clause 12.

Q. Is this the -- is this your policy?

A. It's the policy, but then how we apply it has a Q and A, and everyone is aware that we don't apply it -- it was a university, across the whole university --

Q. I'm sorry. I just can't hear you.

A. I'm sorry. People understand that we don't apply it across an entire university, it's at the school level. In a government, it's at a departmental level.

Q. Well, am I correct. In a very professional way Philip Morris came to ALF and explained to ALF that what you were doing was very detrimental to youth smoking prevention activities across the country. Is that correct?

A. We did receive a letter. Are you referring to the letter that was sent to me by Denise Keane?

Q. Yes.

A. Yes, I am familiar with that letter.

Q. I'll show it to you. Tab 47, JD 050278. This is a letter, I believe it's dated August 28, 2001, from Denise Keane to you. Is that correct?

A. Yes.

Q. And if you look -- the letter is entitled, American Legacy Foundation funding restrictions. Do you see that?

A. Yes.

Q. And if you go over to the next page, Ms. Keane explains to you some of the problems that's created because of your restriction. Is that correct?

A. Yes. I know she gave her perspective on it and the perspective of the company.

Q. Let's see quickly what Philip Morris asked you. Philip Morris says, "The funding restrictions imposed by ALF impact governmental, public health, academic and other entities and serve to prohibit those entities from accepting funding from a tobacco company in circumstances where no conflict exists. The restrictions impact a wide variety of initiatives that can very substantially limit Philip Morris USA's ability to fund relevant organizations in the participating states. More importantly, the restrictions can negatively impact efforts to address the health risks of smoking and to reduce the incidence of youth smoking". "We believe that it would be appropriate for ALF to except Philip Morris USA from the funding restrictions in the absence of a reasonable basis for assuming or believing that the tobacco source of funding is likely to present an actual or potential conflict of interest." "Specifically, Philip Morris USA respectfully requests that the board adopt the position that on ultimate control and authority for conducting scientific research into smoking and health will related issues, or the creation and implementation of programs intended to reduce youth smoking incidence and increase positive youth development, resides with the researcher or program grantee, there is no actual or potential conflict of interest." That was called to your attention; is that correct?

A. First to Chris Gregoire and then to me, yes.

Q. And it was called to your attention because Philip Morris explained that when they give grant money to third-party organizations, like the 4-H or the Boys and Girls Club, those organizations make decisions about the money, not Philip Morris; is that correct? That's what you were told.

A. These are grants. They are not -- you know, so you do have control -- you do have control. You could stop giving them.

Q. I understand you can stop. Once you give the money and fund it to an organization, the organization gets to spend the money the way they want on their program; is that correct?

A. Not normally.

Q. Well, actually, is that what Philip Morris told you they did with their program?

A. I don't believe so. I think what they said is they don't exert control, but I certainly asked them for an itemized budget and asked them what they are going to do.

Q. After Philip Morris sent you this letter asking you to exempt Philip Morris you responded and said no; is that correct?

A. I think my -- I don't think I did. My counsel did in response to a unanimous vote of the board not to provide such an exemption.

* * *

Q. And which you tell Philip Morris that the request for the exception will not be allowed; is that correct?

A. Yes. Communicating the board's unanimous vote, yes.

Q. ALF has actually stated that one of the reasons it has this restrictive policy regarding grants is because of ALF's desire to prevent tobacco companies from achieving respectability; is that correct?

A. I don't recall that statement.

Q. Is that one of the reasons why you have the policy?

A. I think the primary reason that we have the policy is to avoid our making a grant, Philip Morris making a grant, and the next office over someone else with a similar purpose, and then saying, you know, "Oh, we all did a great job together."

In this excerpt of cross examination, the expert discusses a provision in the 1998 Master Settlement Agreement that prohibits the American Legacy Foundation from vilifying tobacco manufacturers or their employees while carrying out its mission to reduce youth smoking rates. Cross Examination Testimony of Cheryl Heulton (Plaintiff), *United States v. Philip Morris USA, Inc., et al.*, (May 2005) Pp. 21006-10, 21013-15, 21019-30.

Q. Now, Doctor, let me move to a little different subject and direct your attention to, if you have your written direct examination there. Jamey, this is tab 84. This will be on Page 67 of your written direct examination. And I'm going to ask you some questions about this. You told the court in your written direct. "Question: Let's turn back to the topic of the "truth" campaign. What was the tobacco industry's reaction to the "truth" campaign when it was first launched in February 2000?" You start your answer with the word, "Unfortunately, the industry aggressively attacked both the initial ads and Legacy. Philip Morris criticized the foundation as violating the MSA and threatened to pull its funding from the Foundation. I was asked by our board chair and others who weighed in to meet, with our lawyers, with Philip Morris lawyers to discuss these issues and I did so. "Question: Did this interfere with the campaign itself?

"Initially, it absolutely did." Now. When you gave that testimony to the court were you trying to make it appear to the court that the tobacco companies and my client Philip Morris acted unreasonably to that first group of commercials that ALF released?

A. Yes.

Q. Let's talk about that. Did ALF intentionally create youth smoking prevention commercials knowing that they were in direct violation of a specific provision of the MSA that prohibited ALF from using tobacco company money to develop advertising that personally attacked or vilified the tobacco companies or their executives?

A. May I consult with my attorney? I don't know if I can answer that. Can I answer that?

Focus Point: This line of questioning is an attempt by the attorney for the defendants to get in through the back door the subject of other litigation, litigation which was brought by a tobacco manufacturer against the American Legacy Foundation. The lawsuit alleges that parts of the Foundation's media campaign violated the non-vilification clause in the Master Settlement Agreement.

The witness effectively points this out and is careful how she answers the questions.

Q. Your Honor, I don't believe a witness can consult with an attorney.

A. We're in other litigation.

THE COURT: No. I believe I'm aware of some tangential litigation, but, first of all, it's civil, not criminal, and that doesn't preclude the witness from answering the question. So you will have to do your best to answer it.

A. I'm happy to answer it. Could you just restate it?

Q. The tobacco companies got upset because when ALF created your youth smoking prevention commercials you did so in a way to violate what was known as the vilification clause of the MSA; is that correct?

A. I do not believe we violated the clause.

Q. Well, let's look at the clause.

* * *

Q. Let's look at what this tells. It says, "This National Public Education Fund," that's the fund that had 250 or \$300 million a year funded into it, is that correct, by the tobacco companies?

A. Yes.

Q. "That fund shall be used only for public education and advertising regarding the addictiveness, health effects, and social costs related to the use of tobacco products and shall not be used for any personal attack on, or vilification of, any person, whether by name or business affiliation, company, or governmental agency, whether individually or collectively." That language you know it as the vilification clause; is that correct?

A. As the vilification and personal attack clause, yes.

Q. And when you were hired by ALF as the president you were familiar with the clause or became familiar with it; is that correct?

A. Yes.

* * *

Q. Could I have -- are you familiar with -- don't play anything yet -- are you familiar with one of your TV ads called Shredder?

A. Yes.

Q. And we're going to play that. What we will see, am I right, Doctor, is that the way you designed this is that we are going to see a wood chipper actually pull up outside of my company's actual corporate headquarters in New York at 120 Park Avenue; is that correct?

A. Yes, we had a permit for that. Yes, we did do that.

Q. You chose to actually film that right in front of Philip Morris's corporate headquarters; is that correct?

A. Yes, that is correct. Not identified, of course, in the ad but, yes, it's correct.

Q. And it's identified as outside a major tobacco company in the commercial; is that correct?

A. That's correct.

Q. And what we're going to see is two teenagers using bullhorns and they act out an info commercial for the Shredder 2000; is that correct?

A. Yes.

Q. And these teenagers are going to explain that the shredder can be used for the tobacco companies to shred embarrassing documents; is that correct?

A. Yes.

Q. And certain documents are actually discussed on the commercial; is that correct?

A. Actual, yes. Actual quoted documents.

Q. Could I play this commercial? It's tab 94, JD 055249. And play that ALF commercial. (Video being shown.)

Q. That particular commercial, is that commercial that the Judge just saw only addressing the addictiveness, health effects, and social costs related to the use of tobacco products?

A. I think it's principally addressing the fact that young people are a target of the industry to become their new customers, and just pointing out to young people that they are a market share.

Q. So you worked real hard to make sure that the only thing that commercial dealt with and addressed is the message of the addictiveness and health effects of smoking; is that correct?

A. I think that you are narrowing way too far what it takes to get a young-open-to-smoking kid to stop. The campaign is structured on creating wary consumers, kids that understand -- you help them reframe the \$13 billion worth of marketing promotions coming their way.

Q. Did you understand my question? Did you as the president of ALF work real hard to make sure that the only message that came out of that commercial is one that communicates to the public about the addictiveness and health effects of tobacco products?

A. Yes, I did. 4.6 young people -- 4.6 million young people smoke right now.

Q. Just so I know. Just tell the court --

A. -- and that's a huge health effect.

Q. -- tell the court where in that commercial did you talk to about addictiveness.

A. We talked about the fact that focus groups --

THE REPORTER: Excuse me.

A. Yes, were being undertaken with sixth graders and very young children in order to understand how to appeal to them to get them to become smokers. We know that you don't stay a smoker unless you become addicted. It's a highly addictive product.

Q. Did you hear any discussion on the commercial at all about the addictiveness of tobacco?

Do you want to put a transcript up line by line and go through it?

Focus Point: The witness effectively explains that Legacy's methodology is more complex and has shown to be more effective than that being suggested by the attorney, which he probably knows but nevertheless is ignoring as a way of putting the witness on the defensive.

Note that the tangential litigation and this line of questioning indicates that the 1998 Master Settlement Agreement allowed the tobacco industry to maintain influence in how the provisions of the Agreement were carried out. Query whether future tobacco settlements or equitable remedies ordered by the court should be insulated from such influence.

A. You can do that. But again, I would simply say that the campaign has to work and resonate with young people. We can't just put up an ad and go -- you know, you get lung cancer, you get this, you get this, you get that. I think it's well documented, very well documented that that doesn't work --

* * *

Q. And that is communicating the addictiveness of cigarette smoking?

A. It is in a way that will resonate with young aged kids.

Q. That's the clearest way you could think of to communicate that?

A. Clarity is not always the best way to communicate with young people who you're trying to have resist a \$13 billion marketing machine. I think -- with all due respect, I don't think there's any evidence at all that that kind of communication would work.

Q. Doctor, so -- I just want to make sure. Is that the best -- just tell the court --