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Panel discussion

Moderator: Maxine L Stitzer

Panellists: Michael C Fiore, Ellen R Gritz, Michael Pertschuk

Michael C Fiore

I shall briefly summarise the process involved in preparing the *Smoking cessation and prevention clinical practice guideline*, sponsored by the US Agency for Health Care Policy and Research (AHCPR), including its rationale, process, intended audiences, implications, and schedule.

Effective clinical treatment of tobacco addiction is a necessary component of our overall national tobacco policy. While frequently stated, clinicians as well as health care managers and administrators have been reluctant participants in achieving this key goal. John Pinney summarised some of those data yesterday when he said that 70 % of smokers see a clinician every year, but up to half of them report they have never been asked and advised by their clinician to quit. In a survey of health care delivery systems and HMOs, only 65 % offered any coverage in their basic benefits package for smoking cessation and prevention. In contrast, virtually 100 % of them offered coverage for the outcomes of smoking, whether they be pulmonary disease, acute myocardial infarction, or cancer.

Both clinicians and health care administrators frequently cite two reasons for their lack of participation: first, they say that there are no known and effective treatments for smoking cessation; and secondly, there is no consensus on what is effective treatment. The rationale for the smoking cessation guideline, therefore, is to produce a consensus statement based on current knowledge, with specific recommendations on how to implement the guidelines.

The process includes a panel of about 25 individuals – experts in smoking cessation, clinical practitioners, and consumers. While sponsored by AHCPR, this is a non-government panel. We have been charged with systematically reviewing all of the data on smoking cessation – more than 3000 articles.

Virtually every article that has been published on clinical smoking cessation since 1975 has been reviewed.

We have done meta-analyses and used other strategies to determine which treatments are effective. The panel is using these data to make a recommendation on what is state-of-the-art treatment; in the absence of data, panel expert opinion will serve as the basis for recommendations.

We are now in the process of actually writing the guideline. It will be peer reviewed and then disseminated by AHCPR. It will be widely available to both clinicians and policy makers.

There will be three products from this process: a guideline of about 100 pages, quick reference guides for key audiences, and a patient guide to help those considering quitting.

There are three key audiences for the guideline and quick reference guides. The first is the primary care clinician. With this audience, our goal is to increase the number of smokers who receive a clinical cessation message. We hope to change the current status quo that allows smoking to be ignored with impunity in clinical practice and, instead, to put it more in the context of a serious medical condition. The second audience is clinical managers, managed care administrators, and insurance providers. These individuals have the capacity to institutionalise smoking assessment and intervention in every clinic in America. The third audience is smoking cessation experts, for whom we shall provide a synopsis of effective cessation treatments. It should be noted that the guideline will focus on cessation and not on primary prevention and is limited to clinical, not policy, interventions.

What, then, are some of the implications of producing a clinical practice guideline on smoking cessation? The first one is that we

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now have a new player within the government, the AHCPR, which is highlighting tobacco use as an important medical problem. A second implication is that the guideline may influence reimbursement agencies, whether they be the Health Care Financing Administration (HCFA) or Medicare, Medicaid, HMOs, or private insurance companies. This may result in smoking cessation services being covered as part of many basic benefits packages. For the managed care environment, the guideline has the potential for being a blueprint for implementing a systematic approach to smoking cessation within clinical environments. In this way, it will not be just another set of recommendations for clinicians; it may move us to a model where we institutionalise the identification of all smokers who come into clinical settings so that all tobacco users receive an intervention.

In essence, the guideline may serve as a challenge to two key groups. The first is clinicians who have frequently ignored their important role in smoking cessation because of the lack of consensus on what works. The second challenge is for managed care administrators and insurers who will no longer be able to report that there is no consensus in smoking cessation interventions that warrant reimbursement. I personally hope that we move to a point where virtually everyone who desires medical care for smoking cessation will have this option included as part of their basic benefits package or as one of their covered services.

Regarding the timeline for this process, the panel was convened in January, 1994. We are a little more than half way through the process, and our goal is to release this document in the first quarter of 1996. A mechanism for updating the clinical practice guideline on a periodic basis is included. I think this mechanism is important as we develop new smoking cessation treatments.

I want to make one last point on the specific issue of harm reduction and how that relates to this clinical practice guideline. Because this guideline is based on *published* scientific data as its primary source, we have been very limited in addressing this area. Dr Stephen Rennard has done some work in the field, but there is a limited database and this topic will not be a focus of the current guideline.

Ellen R Gritz

I should like to take the opportunity to address the implications of harm reduction strategies as they relate to children and medical patients.

As Dr Stitzer has outlined our broad anti-smoking policy goals, the first is to reduce smoking prevalence. I am very concerned that if we adopt goals other than absolute non-initiation of smoking in children, and total cessation of smoking among youth and adult populations, this may carry messages to children which will run counter to continuing efforts to reduce overall smoking prevalence.

Unfortunately, since approximately 1980, initiation rates in children and adolescents

have not declined. All subgroups have been approximately stable, despite ongoing public health efforts, school programmes, educational efforts, and other attempts to reduce initiation among youth, except for one very interesting group, African-American youth, whose smoking initiation rate is one quarter that of white youth. Currently, there is no explanation for this decline, other than a cultural propensity to view smoking as *not cool* and as a behaviour not identified with being African-American. This hypothesis requires further investigation, and several groups, including our own, are studying what factors might protect against initiation. However, for the majority population in the country, smoking initiation remains flat and, in some cases, there are indications that it may be rising.

Recently, the Institute of Medicine published a report called *Growing up tobacco-free*, and I had the honour of being on the panel that produced that report. We came out strongly in favour of several policy initiatives which have been shown to reduce initiation. These include restriction of advertising and bans on advertising; increased taxation; enforcement of youth access laws; increased parental disapproval of children's smoking, and mandated school smoking prevention programmes; restrictions on smoking at the local, city, and state level; bans on vending machines; and strengthened federally mandated warning labels, including labelling cigarettes as addictive. All of these have either established effectiveness or the potential for reducing initiation. Altering the national message about the viability of continuing to smoke and the potential to smoke safely will have unknown effects on youth.

Secondly, Dr Henningfield showed some interesting data about the introduction of spit tobacco into the youth population. A substantial advertising effort has been implemented to create a cohort of adolescents and young adults who are now using spit tobacco, a problem that did not exist a number of years ago. We do not yet know the adverse medical effects of this trend. Potentially, we could see tremendous increases in dental problems and in cancers of the oral cavity. Also, we do not know whether young people, who often start out thinking that smokeless tobacco is safer than cigarettes, will in their early adult years switch to cigarettes. They might make such a transition because it is socially unacceptable to continue using spit tobacco, thereby addicting a generation of youth who might otherwise not have begun to smoke. So, *starter* products and the use of *alternative* or *safer* products may have the untoward consequence of eventually increasing smoking prevalence, not decreasing it.

In the short term, the major effect of altering cigarettes may be disease promotion for another generation. If we choose as an ultimate goal to wean the nation off cigarettes by gradually lowering the tar and nicotine content, we shall still have a 20 year period during which individuals will start to smoke. Tobacco-related diseases will continue to be

initiated and promoted, and children will continue to become addicted to nicotine. This is because cigarettes will not yet have reached the drastically reduced nicotine level purported to not sustain addiction. My bottom line remains *against* altering cigarettes because I fear that the potential for creating harm is equivalent to or greater than the potential for reducing harm.

Next, I should like to briefly address issues of morbidity and mortality effects. We cannot really generalise from the older data that we have been presented with at this conference. Those studies dealt with cigarettes that bear very little similarity to what is on the market now. Also, the lower dose smokers, those smoking less than 15 cigarettes per day, were self selected individuals. We have just been talking about influencing individuals to cut down the number of cigarettes smoked per day if they cannot quit entirely. We do not know whether that is a sustainable goal, and what compensatory patterns in smoking may develop.

Furthermore, the disease epidemiology graphs we were shown referred to lifetime use at given smoking levels, not use that began in middle age. We do not know what decline in risk might occur, if any. We do know that for at least 10 years after stopping smoking, ex-smokers remain at increased risk of developing lung cancer. So we have no idea what disease reduction effects might occur as a result of switching in middle age to cigarettes that theoretically produce less tar and nicotine.

The tobacco industry has never publicly released the list of ingredients in cigarettes, and what little information has been leaked is not quantitative. This highly proprietary information has been carefully guarded against open scientific investigation of health damaging effects. Of course, we do know the identity of many of the toxic and carcinogenic compounds in cigarettes. In addition, changes in cigarette formulation over time may even have produced additional health hazards to those documented 15 or 20 years ago.

On another point, ultra low yield cigarettes are not smoked to yield ultra low amounts of tar and nicotine. Individuals compensate by covering the ventilation (dilution) holes or squeezing the ventilation tubes, so that those cigarettes can then deliver greatly increased levels of tar and nicotine. Therefore, generalisation from today's use of ultra low yield cigarettes to what eventually might become a harm reduction formulation is both logically and physiologically questionable.

From a clinical vantage, populations with smoking related diseases are particularly endangered by continued smoking of altered cigarettes or at lower levels. Take, for example, lung cancer and head and neck cancer patients, who are at increased risks of recurrent disease, for second primary cancers, and for early mortality. They may be particularly sensitive to any dose of carcinogen. Also, I would invite a pulmonologist to comment upon the implications for patients with chronic obstructive pulmonary disease.

Our goal has to be *complete* cessation of tobacco use for those medical populations, no matter what. Approximately 50% of lung cancer patients and approximately 50% of head and neck cancer patients stop smoking when they are diagnosed and treated, but we do not have much long term data describing whether they eventually go back to smoking. While the glass may be half full with 50% stopping, unfortunately 50% continue to smoke, greatly increasing further risk of disease.

Finally, I would like to support Dr Fiore's point about health care providers, and underscore that we need to educate, support, enhance, and make into a standard of practice the message of complete cessation. We must not give mixed messages to smokers about potentially safer ways to smoke and safer products to smoke, because we have at present no demonstration that such safety exists.

Michael Pertschuk

As someone who works with people who deal primarily in policy advocacy, one of the things I heard yesterday reaffirmed the strong commitment of most tobacco control advocates to at least two major policy initiatives: excise taxes and clean indoor air. It seemed to me that both have been reinforced by the evidence given in this conference. Certainly, substantial increases in excise taxes and cost are an incentive to quit, and they may also be an incentive to cut down. And they do not give a mixed message because they do not give a message in the same way that other messages are given.

I was particularly impressed by Dr Ockene's paper about the need to develop an infrastructure if cessation treatment is to be effective. Although I am also not an expert on health care delivery, I would be highly sceptical, given all of the pressures towards the reduction of health care services and the economic disincentives to provide preventive services, of the probability that cessation services will be added by HMOs in the next few years. But the excise tax initiatives, with the allocation of substantial funds to tobacco control, do provide an opportunity, as in Massachusetts, Michigan, and California, for underwriting the infrastructure development for cessation services. That seems to reinforce the importance and the desirability of excise taxes, and also excise taxes at the state level are feasible.

I gather that Vermont was very recently added to the list of states taking initiatives, despite the conservative trend in the country, and Arizona passed a substantial increase in excise taxes. It is on the agenda of most tobacco control groups, and so it seems to me of continuing importance.

I was intrigued by the reintroduction of the concept of designing excise tax increases based, to some extent, on tar differentials. I remember that, among others, Russell Long was a great advocate of differential taxation based on tar and nicotine yields of cigarettes back in the

sixties and seventies. New York City actually adopted a differentiated excise tax. That experience should be studied.

The prime rationale for clean indoor air policies and the source of public support is really to protect the freedom of the non-smoker to breathe clean air, and this is the primary reason why that kind of legislation at the local level has been so successful. Some of us are less comfortable talking about the social engineering aspects of clean indoor air policies, but I was impressed by the fact that not only do these policies appear to affect prevalence, but they also clearly cause a reduction in use. There had been questions raised earlier about whether smokers who are not able to smoke on the job compensate and smoke just as much off the job. Watching smokers puff violently suggests that that is happening, but I gather the data do not suggest such an effect, all of which again seems to me to reinforce the desirability of giving priority to clean indoor air policy.

We have got into the habit of talking about the four horsemen of tobacco control: taxes, clean indoor air, advertising and marketing regulation, and youth access, for which Mr Synar has been one of the great leaders. It now seems to me that a fifth horseman has emerged over the past year: the whole question of product regulation.

As someone who is both appreciative and sceptical of entrepreneurial energies, I have always been reluctant to think about the consequences of making nicotine replacement treatment an over-the-counter product, but I have been persuaded by the evidence given here that this has some value. The prospect of unleashing the entrepreneurial energies of the drug companies in competition with the tobacco companies is really quite an appealing one, although it is also an appalling one if certain kinds of scenario are played out.

Encouraging the FDA to allow the over-the-counter marketing of certain devices under a very strict supervision and regulation has appeal, as long as there is an opportunity to get the horse back into the barn if it proves to be destructive.

Finally, it seems to me critical that every interest that is represented at this conference supports the efforts of Commissioner Kessler and the FDA to show that tobacco products are nicotine delivery devices and therefore subject to full FDA regulatory authority.

I heard many different and intriguing ideas about what can be done with tobacco products. I came away yesterday with this scheme: the FDA ought to adopt the Benowitz/Henningfield plan and gradually reduce nicotine yields so that children are not hooked, but at the same time the FDA should authorise high nicotine/low tar cigarettes on a prescription basis to heavy smokers and thereby have the best of all possible worlds.

That, of course, is an incredibly complex set of regulatory initiatives, and it is based upon several tenuous assumptions that may or may not work, all of which calls for – although it goes greatly against the current distaste for

heavy handed government regulation – heavy handed government regulation. It calls for a monitored and exercised regime of regulation by the FDA over years, with the opportunity to shift as the technology develops and as experience gives feedback on what works.

What seems to be happening is that the FDA under Kessler's direction has no intention whatsoever in the immediate future of proposing to regulate the nicotine content of cigarettes, partly because it would be a political disaster and partly because no-one is quite sure what ought to be done. But it is also clear that Kessler is preparing to assert jurisdiction, but primarily focused on his analysis of tobacco use as a paediatric disease, which is a very powerful way of framing the issue. Those who have read his statements can guess that what he proposes will be along the lines of the IOM report, with measures targeted toward the reduction of environmental influences on youth, youth access along the lines of the Synar amendment, perhaps even the banning of vending machines, and also zeroing in on the target marketing of tobacco products to youth. The attack on tobacco use as a paediatric disease is probably the only political frame that could survive in today's antiregulatory environment. Even William Buckley, a self avowed libertarian, was persuaded by Kessler's framing of the issue, and, to the extent that tobacco use is a paediatric disease, even he recognises that it is appropriate for the FDA to exert jurisdiction and regulatory authority.

Once the FDA has established jurisdiction over cigarettes, even if the regulatory regime does not deal with the issues that we are talking about, then it becomes possible in the future for the FDA to look at other ways of approaching tobacco products, including some of the initiatives that have been discussed today.

Though Synar is going to comment on the current legislative environment, I can tell you as a preview that it is dreadful. The significance of Kessler's initiative is that it does not require Congress to act, and all of the other regulatory schemes that have been talked about over the last few days requiring Congress to act are pipe dreams. Congress is neither responsive nor subtle in the ways in which it responds to policy.

What is happening right now is that delegations of Democrats from the tobacco growing states are saying to the White House, "If you allow David Kessler to assume jurisdiction over tobacco products, you will never get another Democrat elected to the House or Senate, nor win a presidential majority from tobacco growing regions." The White House, so far as anyone can tell, has not made up its mind whether it is a good thing for it to stand in support of Kessler and the regulation of tobacco products on behalf of children. Polls funded by the Robert Wood Johnson Foundation show enormously strong support for regulation of tobacco products. This support comes from tobacco growing states, and especially from low income Democrats, the very ones that the Democratic Party has lost. Nevertheless, the White House is searching its

soul as to whether it stands with Kessler or stands up against him in order to demonstrate to the tobacco states that Clinton is, indeed, a moderate president. So the immediate task for

all of us concerned is to use whatever avenues of approach to the White House that we have to persuade it that it would not only be wrong but idiotic to stop Kessler from proceeding.

Questions and answers

JED ROSE: My comment speaks to the viewpoint, specifically from Dr Gritz, that we should stay on the safe and sure road of total abstinence for smokers and not take the unknown risks of advocating harm reduction. As somebody who has spent the bulk of his professional career trying to devise new smoking cessation alternatives, I fully support vigorous efforts to develop new treatments which also fall under the free choice belief shared by most adult Americans.

By the same token, I think we should realise that it may still be an equally dangerous course to insist on total abstinence because even with the technologies that might be developed over the coming years, it is entirely conceivable that we shall not be able to improve on, for example, a 60–70% efficacy rate in terms of long term cessation, which would still leave in excess of 10 million Americans smoking cigarettes.

ELLEN R GRITZ: Dr Rose, I would just like to say that clinicians are probably forced to implement harm reduction in terms of alternative goals when they are unable to help a patient stop smoking using cessation as their absolute goal, and that is true if people are in less than the action stage of smoking cessation. It is true if you have an ill patient who, no matter what you do, is so addicted that they cannot stop, but it is not the policy.

The policy is to push for total cessation by continuously assisting your patient over time to stop, but in the interim, our nicotine replacement strategies are becoming more and more effective. There are new ones under development. There are drugs such as antidepressants that may ameliorate some of the affective problems in cessation, especially with ill patients. Our technology is becoming ever more sophisticated. As Dr Hurt said, we are just at the beginning of that technology exploration, not at the end of it.

So I think there is an official policy goal of absolute cessation, and then there is the clinician's attempt to use harm reduction while they pursue that absolute goal.

MICHAEL C FIORE: Both yesterday and today we have been putting all harm reduction into one basket, when in fact there are several different ways to reduce harm, particularly if one makes a distinction between a product that does not contain tobacco, but only nicotine or another pharmacological agent, and a product that does not have major cardiovascular effects (that is, it does not have bolus delivery). With those distinctions, people who have reserva-

tions about harm reduction might not be so reluctant about such strategies.

JOHN M PINNEY: We talked yesterday about managed care, and I said that it has not lived up to its commitment to prevention. We read a lot about managed care in the press now and about its excess cash flow, how managed care is the cornerstone of health care reform at the state level, and the rising administrative costs at the federal level. Managed care is essentially unregulated, and yet we are looking at Medicare managed care and Medicaid managed care as a solution to health care cost in those areas. Do you think there is a likelihood that the federal government will apply regulation to managed care in this Congress?

MIKE SYNAR: No. I do not think it is very likely we will take up the health care issue in this Congress. We may look at insurance reform, which I think would be a disaster by itself.

One of the things I think the President and the task force were correct on is that you cannot do this in piecemeal fashion. The echo chamber that exists between the health care providers – the hospitals, the insurance companies, the consumers, and the doctors – is a very sensitive one. If you start fiddling and fixing only one of the parts, then things all start to go haywire.

With that said, the federal government traditionally has been – and I know this may be hard to believe – a leader in forcing the type of sensitivity and reform in the private sector. If we are able to put preventive measures in packages that the federal government is providing, then the private sector will necessarily follow.

Secondly, if consumers are smart – and I am not suggesting they are not – they are going to begin to move towards those types of managed care units that provide the sort of preventive health care that can drive down cost.

Finally, the medical community itself, which is engaged with the insurance industry in this effort, must take a stand. More doctors are going to have to come forward as they enter these plans and say, “I am not going to practice medicine in this environment unless I have the type of preventive measures and tests that I can provide for my patients to give them full service”. So all three of those have to be in place, but I think it is going to be an evolution versus a mandated type of approach.

KENNETH E WARNER: I noted a fascinating progression here. With Dr Fiore, we started talking about getting older people to quit, down to Mr Synar, where we talked about getting younger people not to start, and it made me think about the very concept of harm reduction, which we have been talking about in a monolithic manner up until now. We have been talking about harm reduction as what happens with the adult who cannot quit.

It strikes me that the single most important issue in the area of tobacco control today is the fact that not only do we have the same proportion of kids smoking as we have for the past 15 years, but if you add in smokeless tobacco use, it is possible that paediatric nicotine dependence is at an all time high. Maybe if we want to really think about harm reduction in an important way, we ought to turn from smoking cessation in older folks and think about good ways to hit this principal problem.

Also, Mr Synar mentioned the \$5 billion in resources the industry puts into advertising and promotion. I have been tooting this horn for years to some avail in some states, and maybe that is where the action has to take place, but I will give you a federal example. Suppose we got a dollar federal tax increase, and suppose we took 10 cents of that and allocated it to a paid media campaign to make smoking look as absurd as it is. That would be \$2 billion for using an institution that the industry at least in theory is not allowed to use. That is hard to do at the federal level for reasons that Mike Pertschuk and Mike Synar have stated, but it is much less difficult to do it at the state level, and several of our states are doing it.

JACK E HENNINGFIELD: I first want to thank Mr Synar. It is amazing from a federal agency perspective how a very small number of people have affected the whole climate, and Mr Synar is one of those people who gave NIDA room to run in this area. These are the things that enabled AHCPR to move ahead. A very small number of leaders – and it is always remarkable to me how you can look at two or three people, such as Synar, Waxman, Koop, and now Kessler – a handful have really created this climate that has made it possible for us to even be addressing these issues.

The Robert Wood Johnson Foundation did a survey a few months ago showing that the attitudes of Americans about smoking controls is not a party issue, and it is not really a regional issue either. Republicans in Mississippi felt about the same way as Democrats in Minnesota. How do you read the Congress? How much is it a partisan issue in Congress? How do we get the public view more in Congress, and to what degree does who is in control in Congress affect issues like third party reimbursement?

MIKE SYNAR: Let's break this down into three parts. First of all, it is not *who* is for it or against it, but *where* are those people who are against the position? Having Chairman Bliley

as the chairman of the health subcommittee pretty well guarantees that a legislative effort is not going to happen.

Secondly, you need to appreciate the tobacco industry's approach to lobbying. They pick no favourites. Wherever two members are gathered together, the tobacco industry is there providing the resources, and they do not care if it is Democrats or Republicans.

They are not up on the Hill advocating their position of trying to undo legislation of the past. They are not even up there trying to promote new legislation. They are trying to make it uncomfortable through personal friendships of members of Congress to do anything. Generally, their approach is to come to members, both Democrat and Republican, and say, "We have got so many other health care issues out there, there are so many other things to do, why do we have to fiddle with this?"

As Mike Pertschuk pointed out with the White House, those members from tobacco states can go to their leaders, both in the Republican and Democratic parties, and suggest that what is at stake is the entire South.

I would argue, as you did, that the South is not in the balance on the tobacco issue; you can go to Raleigh, you can go to Greenville, you can go to Jackson, and people's positions on tobacco will not change a bit. But we have let a very small group of political leaders dictate the national agenda based not upon the tobacco issue, but upon the need for both parties to have those key players on a variety of other issues. As I have said for a number of years, if we ever got a clean vote on tobacco subsidies or the tobacco programme, it would be gone, but we never get that clean vote because of well positioned members of Congress and in the Senate.

We have to continue to look for opportunities. We have not lost a tobacco vote on the floor of the House in my tenure. It is just too expensive for the tobacco industry to lock up the House of Representatives. Where they have been successful is in the subcommittee and the committee levels, where one or two votes can make the difference.

Also, during the 1970s and 1980s, the tobacco industry realised that their welcome had been worn out, and they went to groups like the National Association for Stock Car Auto Racing (NASCAR) circuit, to the Marlboro Rodeo circuit, to the American Civil Liberties Union (ACLU), to all these groups that had a vested interest in the money, and used them to front for them. You never see the tobacco industry fronting on these types of issues. At the same time, we were fighting it strictly on the terms we always have done, but now I think we need to recognise that the public is starting to look for people who are not part of a vested interest as advocates and third party validators.

PETER REUTER: Regarding Mr Synar's comment about the impossibility of considering an absolute prohibition on tobacco, I am not arguing that he is politically incorrect.

He certainly is correct. I want to suggest that as a matter of public policy it is not obvious that it should be off the table, but I need to do this conflict of interest disclaimer: I am here as an outsider who studies illegal markets. I may be looking for a new market...

But consider this: here we have the 400 000 in excess deaths; we could tolerate a lot of corruption and a certain amount of intrusion into civil rights in order to cut that from 400 000 to some modest number like 100 000.

There are large stakes here. As you increasingly demonise this drug and those who use it, the possibility of moving towards a prohibition becomes more feasible politically, and secondly, as you develop nicotine replacement treatments, the argument that this is inhumane may become less compelling. So I want to suggest that, while this is clearly a very long term consideration, we should not ignore the charms of prohibition.

MIKE SYNAR: My only disclaimer is to ask if you have 218 votes for that concept?

JUDITH K OCKENE: I understand your concern, Dr Gritz, about the mixed messages. I also have worked with chronically diseased populations and find that we often do a triaging where we start with cessation and then move to the possibility of reduction for individuals who cannot stop; and we know there is a large group of individuals who have great difficulty and just cannot stop smoking.

My concern is that if we do not have some message that reduction is alright in certain instances, there is a lot of guilt in this population; guilt of causing their illness and incapacity. I have some concerns about supporting that guilt by not at least allowing and discussing the possibilities of other alternatives with them, as part of a stepped care approach to a diseased population.

ELLEN R GRITZ: My approach for dealing with that guilt is to not blame the victim, but to blame the tobacco companies and the product and to tell these individuals that this is not a habit. It is an addiction. It is a drug dependence. So I try to shift the blame away from the individual. It is a sickness. It is not a sin. In that sense, you can deal with reduction and stepped approaches towards cessation without letting the individual feel that they are still promoting their own illness.

JUDITH K OCKENE: Dr Fiore, you mentioned that you were hoping that the AHCPR guidelines for providers will become a standard for providers, especially physicians, to do intervention. How will you make it a standard without some teeth and regulation?

MICHAEL C FIORE: There are some people here from AHCPR who may be made uncomfortable by hearing that, because it is explicit that it is not intended to be a standard of care. It has, though, the potential to become a standard that clinicians will follow. Probably the way it would have the greatest chance of

doing that is if managed care and insurers, and clinician groups – whether it be the AMA or a particular type of clinician – adopt and endorse the guidelines as a reasonable approach that covers the whole gamut of clinical smoking cessation services.

ELLEN R GRITZ: It is incredibly frustrating to hear you talk, Mr Synar, about these third party validations when we know what is feeding the third parties is tobacco money. Do you think that a strategy of educating the public on the funding of third parties – NASCAR, Virginia Slims Tennis circuit, the restaurant associations – can do anything toward producing a reverse invalidation or the validation of anti-smoking and prevention that we are requesting?

MICHAEL PERTSCHUK: Let me just jump in and give you a case study from California. The counter-example to Mike Synar's example is what happened with Proposition 188. Most of you are familiar with the fact that in California there was an initiative which was not identified as a tobacco industry initiative. It was a statewide initiative to develop a moderate state clean indoor air law. The early polling showed that the public was generally split, about 50/50, in support of reasonable statewide measures that did not go too far.

The California Wellness Foundation spent some \$3 million on a non-partisan public education campaign which had only one message: who is for Proposition 188 and who is against it? It was the reverse legitimisation by identifying that the primary sponsors were Philip Morris and RJ Reynolds and the rest, but it also supported your third party validation because it said those who were for it were the Cancer Society, the Lung Association, the Heart Association, and the Medical Association, and of course, the proposition lost.

MIKE SYNAR: This is what the tobacco industry was able to do with the Synar Amendment. They realised their game was up in the federal level, so they thought they could have a better chance in the state legislatures, and they have. I do not think our state legislators are any less active, but they just do not have the expertise in this area that the federal officials have after having fought these people for years.

I want to go back to the discussion about blame. There is no question the tobacco industry is a great villain. But it is my general impression – and I mentioned this in my comments – that the public believes that we all are in charge of our own destiny. Just recall the fight that we had to go through on seat belts, then helmets with motorcycles, and then with guns: the public thinks people should be held accountable for their own acts. Too often, people would come up to me, given my visibility on tobacco, and say, "Mike, I absolutely agree with you on the tobacco issue, but isn't it everyone's choice?"

Even though Dr Kessler has now set the stage

for definitive medical and statistical evidence that this is no longer a choice or a habit but an addiction, we are not there with the public yet. Look at the advertisements that the tobacco industry took out as recently as three months ago, with the theme, "It is your choice as an American". Until we go over that hurdle, Americans are going to continue not to blame them, but say this is a free choice by Americans.

CHARLES W GORODETZKY: Dr Stitzer, in your presentation, you mentioned low tar/high nicotine cigarettes, and yesterday the issue was raised about the pharmaceutical industry and the tobacco industry coming together towards a pure nicotine delivery device that might match the pharmacokinetic parameters of nicotine absorption from a cigarette. Although, in fact, we might be coming closer together, I think there is an important difference of approach that was implied by Henningfield's remarks yesterday.

Tobacco companies might be approaching it as a "safer cigarette for mass consumption" and dragging along with it their current exemption from any FDA regulatory control. The pharmaceutical industry is approaching it from the other direction, with full acknowledgement of FDA regulatory authority, and trying to devise its appropriate use as a pharmacotherapeutic option, as revealed by appropriate clinical research.

I think this attitude also is very pertinent to Mr Pertschuk's remarks. We would approach the prescription to over-the-counter conversion in exactly the same way. I can assure you we are keenly aware that this product should and will be marketed as a pharmacotherapeutic option, but not in competition with cigarettes for mass consumption.

DAVID B ABRAMS: I think we are very obsessed with high-tech solutions, and as long

as we are at the level where we are looking for an innovative nicotine delivery system, my concern is that it really does not matter whether the initiative comes from the drug company side or the tobacco side. If you get to that middle grey area where you are sharing a common attempt to develop something that will work as well as a cigarette, but be safe, I think the danger is that you are getting distracted from the real issue which is, as Gritz has said, tobacco dependence and nicotine as an addiction.

GAIL REGAN: We had an experience in the Navy in 1993 where we had several commanding officers of United States ships, the USS *Roosevelt* being one of them, who wanted to go smoke-free. This was a unique opportunity to witness the policy in action, and in fact, the captain of the *Roosevelt* was successful in carrying it out for several weeks; then eventually, however, he was backed down by the Chief of Naval Operations, who was probably backed down by the Congress.

What it did was to set the stage for establishing a very restrictive smoking policy, and we were successful several months later in pushing that through. Smoking has now been restricted significantly in the armed forces, and in the Navy in particular, where you have several thousand men living and working on an aircraft carrier.

MIKE SYNAR: Do you still have subsidised sales at the commissaries?

GAIL REGAN: Yes, we do. We were working very hard to support the Bingaman Bill which would make cigarette prices competitive with the state that they were selling in, and we actually got support from the Army and the Navy. Unfortunately, the Air Force and the Marine Corps did not support that bill. I am guessing that it died in committee, and I do not expect to see it resurrected again.

Political realities

Mike Synar

I was at the height of the campaign in August of last year, in Grove, Oklahoma. I represented the northeast corner of the great State of Oklahoma, and I was trying to address a group of younger Cub Scouts, known as Webelos. They were all seated in front of me, and I was trying to get their attention, and they had the same problem as many of my constituents on election day – a small concentration span. I thought I would get them in a dialogue about government in general. I said, "Let me ask you guys something. What is the difference between your Cub Scout troop and the United States Congress where I serve?" One of the

little Webelos raises his hand and I called on him. He stood up and said, "Adult supervision."

That is when I knew I was in trouble.

Two weeks right before the election, I was down at Hilldale Junior High School, which is just south of my hometown of Muskogee, Oklahoma. When I go to high schools and junior high schools I talk to the kids for about five minutes and then open the session up for questions. I finished my remarks, and I said, "Are there any questions?"

There were two little girls seated right up front. The first raised her hand and I called on

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