SESSION V RESPONSE PANEL

Moderator: Kenneth E Warner

Panellists: Neal L Benowitz, George Bigelow, Robert Robinson, Frank J Vocci

Introduction

Kenneth E Warner

Our panel has been assigned the job of reacting to the first day of this meeting day in all of its breadth and glory, so we have no specific assignment other than to give our own reactions as we see fit.

I will have a shot at that more formally tomorrow when I give my policy presentation and, hence, I will not give any of my comments at the outset. I usually find myself unable to resist jumping in, so I may do that at a later stage, but for now I will simply serve as moderator and introduce the other panellists.

Dr Neal Benowitz is Professor of Medicine, Psychiatry and Pharmacy and Chief of the Division of Clinical Pharmacology and Experimental Therapeutics at the University of California, San Francisco. Dr Benowitz was a scientific editor of the Surgeon General's report on smoking and health that gave a very prominent new emphasis to nicotine addiction.

Dr George Bigelow is Professor of Behavioural Biology in the Department of Psychiatry and Behavioural Sciences at Johns Hopkins School of Medicine. He is also the president-

elect of the College on Problems of Drug Dependence.

Dr Bob Robinson is Assistant Director for Program Development for the Office on Smoking and Health. Dr Robinson's interest in tobacco policy research was influenced by the recognition that the historical relationship between the tobacco industry and the African-American community and the underrepresentation of African-Americans in mainstream tobacco control movements were interrelated, and I think it is quite safe to say that, for at least the past several years, he has been one of the most influential and important voices in dealing with an issue that all of us recognise has been much underrepresented in our collective agendas.

Finally, Dr Frank Vocci is the Deputy Director of the Medications Development Division at the National Institute on Drug Abuse. In his current capacity he is responsible for instituting research and development activities for medications targeted for the treatment of substance abuse and dependence.

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I would like to provide a perspective from three different areas of my professional activity: first, as a researcher studying the human pharmacology of nicotine and nicotine addiction and the role of nicotine in smoking cessation; second, as a teacher of rational therapeutics and rational use of drugs; and third, as a clinician involved in the practice of cardiology, not focused on smoking cessation in particular. I work in a busy cardiology clinic and a lot of my patients are smokers. Smoking clearly impacts adversely on their illnesses, and I struggle with how to get patients who have failed on many occasions to stop smoking in the setting of a 10- or 15-minute visit during which I must deal with multiple cardiologic problems

A case presentation would be illustrative in light of some of the things we have heard today. Mr Fields, a 52-year-old former construction worker with a history of hypertension, presented to the hospital about a year before I first saw him at the clinic with unstable angina. Unstable angina is a pre-heart attack syndrome. The patient underwent coronary

angioplasty and did very well. At that time he was a smoker, of about a pack and a half of cigarettes per day. In the clinic I spent a lot of time explaining that smoking is the number one factor that will cause restenosis after the angioplasty, and he tried to stop smoking. He stopped smoking for a couple of weeks; and then, in the context of personal stress, started again.

Within three months, he had recurrence of angina. He underwent coronary angioplasty again, and again we discussed the detrimental effects of smoking. He stopped smoking once more for a couple of weeks and then relapsed, precipitated by personal stress. Subsequently he told me, "I really would like to stop smoking. I've tried the gum before, I don't like it; it doesn't work well with me. How about the patch?"

I said that sounds like a reasonable idea, but San Francisco General Hospital, like many other public hospitals, has severe financial constraints. The policy of our pharmacy and therapeutics committee is that patients have to pay for nicotine patches. The hospital supplies

other drugs to indigent patients, but such patients have to pay for nicotine patches. So I prescribed his four anti-anginal drugs and his lovastatin to lower serum cholesterol; and three months later he died suddenly.

Questions raised by this case are: Was treating this patient elective (as Dr McGinnis suggested before) and is it cost-effective to prescribe four anti-angina drugs and a cholesterol-lowering drug and not be able to prescribe a medicine to help him stop smoking?

I would like next to compare and contrast standards of care for hypertension and cigarette smoking. Hypertension, which is very common, is a success story in preventive medicine. In the 1970s it was recognised that a substantial fraction of the population was hypertensive, that very few hypertensive patients were being treated, and that a huge impact on health could be made by the control of hypertension. Today, most hypertensive patients are being diagnosed, most are being treated, and benefits in terms of reduction of hypertension-related cardiovascular diseases have been clearly documented.

It's interesting to compare hypertension to cigarette smoking. Mild hypertension, which accounts for 75 % of hypertension, is a chronic illness. It's indolent, and people develop complications after 30 or 40 years of mild hypertension. Behavioural treatments as well as medications are available for physicians to treat hypertension. Cigarette smoking can be viewed as a chronic illness that shares many of these characteristics, but while the overall health risks of mild hypertension are less than those of cigarette smoking, hypertension is being treated successfully and smoking is not.

I'd like to tie together the things we've heard today by focusing on the medical management of hypertension, describing what we've done successfully in treating hypertension, and what we might do in treating cigarette smoking.

Let us look first at public awareness. Over the past 20 years there has been considerable success in educating the public about hypertension. For smoking, we've also done pretty well; most patients know that smoking is bad for them and that they should quit.

Next let's look at physician commitment. Every physician knows that a hypertensive patient should be treated, and every physician knows that it's his or her job to treat hypertension. We heard here today from a couple of speakers that only 30 or 40 % of patients who see physicians are advised to quit smoking. Clearly many physicians who recognise that their patients are smokers still feel that smoking cessation treatment is not something they are comfortable with, or not something that they really want to do. Many physicians do not feel an obligation to manage smoking cessation. Certainly many physicians are committed, but there are also physicians who have not made the same commitment to undertake smoking cessation treatment as they have to treat hypertension.

If one looks at physician knowledge and skills, there is a well-developed base of information on hypertension in the US. There is

a national committee that deals with the evaluation and treatment of hypertension, and that every 3 or 4 years prepares a comprehensive report outlining the current guidelines for evaluation and treatment for various levels of severity of hypertension. Every physician has access to this information. Considering smoking cessation therapy, a few interested physicians have developed the skills and knowledge, but most practitioners are not trained in smoking cessation therapy, and do not feel very comfortable performing such therapy.

Let us look at some of the specific elements of the treatment of hypertension. The first one is risk stratification, which means the more risk factors a person has, the more important it is to treat that patient's hypertension. Most doctors have an appreciation of this concept as it applies to smoking, although I don't think it's as globally appreciated as for hypertension.

Let us consider motivation of patients. Most physicians know they must motivate their patients to take anti-hypertensive drugs and/or to change their diets. Some physicians do better than others, but nearly all recognise the responsibility to motivate their patients. For smoking, I think a minority of physicians considers it their duty to work with their patients persistently over time until they're motivated to quit. There are, of course, big differences between hypertension and smoking; no patient wants to have hypertension, but many patients like to smoke. Thus, the motivational challenges are really somewhat different for these two disorders, but still I think we have a way to go in developing the commitment for physicians to motivate smokers to quit smoking.

We've heard about individualisation of treatment. With hypertension we select medications based on the aetiology of hypertension in individual patients, on the age of patients, sometimes the race of patients, and on co-existing medical conditions. We also adjust doses of anti-hypertensive medications based on end points. In contrast, there is very little information on the basis of which to individualise smoking cessation therapy. We have a little information that suggests that more-dependent smokers benefit more than less-dependent smokers from nicotine replacement therapy, but aside from that, we have little basis to match patients with treatments.

Follow-up is a key element in the successful treatment of a chronic disease. No physician who treats hypertension thinks he or she can give a pill for hypertension and not see the patient again for a year or two. Hypertension is accepted as a chronic condition that requires follow-up, and a physician will see a patient every three or six months on a long-term basis. With smoking cessation therapy, a source of failure in many physicians' offices is giving the advice to stop smoking, but not following up or following up only once. The more frequent the follow-up (and it doesn't have to be a follow-up in person – telephone follow-up is effective) the more effective is the treatment.

Another major element in successful treat-

ment of hypertension is involvement of other health care professionals. Nurses record blood pressure; nurses often get dietary histories and offer dietary advice; pharmacists can advise about medications. For smoking cessation we don't have that sort of organisation in most offices, although clearly nurses and pharmacists can play a major role in smoking cessation treatment.

I would like to conclude by emphasizing three points. First, we need a clear standard of care that says it's a physician's obligation to help patients stop smoking – the obligation of every physician, just as it is for treating hypertension. Second, we need clear-cut guidelines that define briefly, in simple language, ways that are time and cost-effective in which physicians should counsel patients, and guidelines for medication use to assist smoking cessation. Much obviously has still to be learned because we don't yet know how to use medications optimally for smoking cessation. Third, we need a user-friendly financing system. We need to have a health care system in which my patient, who likely died as a consequence of his (inadequately treated) tobacco addiction, could have been treated.

George Bigelow

My background is as a behavioural pharmacologist. Much of my work has been conducted in the human laboratory, examining factors that influence drug self-administration and drug effects in human volunteers. I have also worked in outpatient treatment research settings with heroin abusers, cocaine abusers, alcohol abusers and tobacco-dependent patients. I will comment primarily from this perspective of tobacco dependence being just one of a variety of substance abuse problems encountered in health care settings.

The general theme I want to emphasize from the presentations here is that of the commonalities we encounter across substance abuse disorders. I am especially struck by the breadth and extent of commonalities between tobacco-dependence problems and other patterns of drug dependence, both with respect to the nature of the disorders, and with respect to the problems and hurdles we face in integrating their treatment into routine medical care. There is resistance to incorporating substance abuse disorders into routine medical care, and I think this is an important obstacle that we need to overcome.

One of the very positive features of this conference and of the data being developed in the tobacco-dependence area is that our approaches to tobacco dependence can serve as a model for how we respond to and integrate other varieties of substance abuse into routine health care. This carries with it a risk also, in that tobacco dependence may be stigmatized by this association with other varieties of substance abuse. However, it is important that we recognise that tobacco dependence and the other substance abuse disorders have a great deal of similarity in their natures: they are all

chronic relapsing, addictive disorders in which drugs are functioning as reinforcers, and in which both behavioural and pharmacological treatments and processes are involved in intervention and treatment. It is my hope that we will be able to set a standard of proper professional care in our reactions to tobacco dependence in health settings and use this as a model for teaching physicians and other health care providers how to recognise and respond to addictive disorders in general and how to engage in the necessary behavioural and pharmacological interventions to change all addictive disorders.

A second topic upon which I want to comment is that of individualisation of treatment. Several presenters have mentioned the need for individualisation of treatment, that we need to do what is appropriate for individual patients. An implication of this is that it may at times be appropriate to use nicotine replacement products in ways that are basically 'off label'. We need to remember that the labelling of products is basically driven by how the particular studies were designed that proved efficacy to the FDA. The FDA will word the labelling to correspond to the procedures that were used in those studies. However, efficacy is not necessarily limited to those situations in which it was initially demonstrated. There may be other populations to whom the medication should be extended; perhaps longer durations of treatment will be appropriate. We need to be flexible in individualising our treatment to meet the needs of patients rather than be driven too narrowly by the labelling instructions provided in packaging information.

And, finally, the presentations this morning demonstrated that we have effective behavioural treatment methods and we have effective pharmacological treatment methods. At times we have worded these in an either/or fashion, as though we must choose between them. One of the things that I hear in these presentations is that our real goal needs to be the effective integration of behavioural and pharmacological treatments. The goal is not to learn which is better, but to learn how to integrate and combine them most effectively. This goal is appropriate across substance abuse disorders. For opiate addiction and cocaine addiction, as well as tobacco dependence, we need to learn to integrate and combine behavioural and pharmacological techniques. In order to achieve this, we need improved training in behavioural sciences and behavioural methods for health care providers. We need to recognise more fully the role of behavioural factors in health care and to improve the education of health care providers in providing the full range of appropriate interventions for producing behaviour change.

Robert G Robinson

Prior to coming to the Office on Smoking and Health, I spent five years at the Fox Chase Cancer Center and had the privilege of work-

ing closely with Dr Tracy Orleans, developing tobacco cessation self-help programmes. One such programme was Clear Horizons, which targeted older adults. However, the major focus of my activity concerned the development of the Pathways to Freedom Programme, which is targeting the African-American community.

In his opening remarks, Dr Gary Giovino talked about the implications of the Uptown Coalition as a potential reason for the decrease of smoking prevalence among African-Americans during 1990 and the subsequent increase that was observed in 1991. We believe it is possible that the Uptown experience may have stimulated actual quitting, followed by significant levels of relapse; or that the decrease in 1990 was due more to underreporting because of the stigma associated with tobacco.

For those of you who don't remember the Uptown situation, that was an event that happened in 1989–90 when RJ Reynolds went into Philadelphia with a cigarette specifically targeted to the African-American community. It was the first time that a tobacco company explicitly named a brand for a particular community. What made the Uptown situation so momentous was that it was also historically the first time that a community actually came together from the grass roots and defeated the tobacco industry. It also represented the most significant evidence of community-based leadership from the African-American community willing to assume a vocal and lead role in tobacco control. The Uptown Coalition was an African-American-led movement, and included diverse representation from health, medical, and voluntary organisations throughout Philadelphia. It was a movement that succeeded, and it really awoke the African-American community around the country. People in Philadelphia were talking about tobacco in a way they had never talked before, not only in the newspapers but in the streets. People were talking about the Uptown situation on buses and in public transit. It reinforced, as well as ignited, other movements across the country: Chicago, California, Detroit, Harlem. This was an issue that had widespread impact, and I think it's at least plausible that there was a negative reaction to being labelled a smoker at that time, and therefore, some underreporting, and perhaps even a positive effect of African-Americans actually quitting.

It is not a surprise that we observe significant levels of relapse among African-American smokers. Preliminary data from California supports the finding that African-Americans have higher relapse rates than whites. I believe we all understand the reasons, or at least the possible reasons, why this should be the case. It is difficult to argue against the fact that African-Americans have to deal with tremendous stress simply due to race. Economic conditions only exacerbate this reality.

Dr Giovino also discussed the prevalence differences among black and white youth. This is certainly a very significant phenomenon in terms of tobacco prevalence. I suspect that

some of the decrease in prevalence among African-American 18- to 24-year-olds is not real, that some of it may, in fact, be attributed to lack of representation in the survey. That is to say, when you consider the incredibly high incarceration rates in the African-American community, it is conceivable that some of the low prevalence may simply be a reflection of the very high incarceration rates within that age strata of 18 to 24.

It is also important to consider the relationship of lower prevalence of cigarette smoking to potential increases in smokeless tobacco. This is actually a relationship that is favourable to African-Americans. First, the decrease in cigarette prevalence may not be a decrease in tobacco prevalence because some people are actually turning to smokeless tobacco, which we don't capture when we look only at the indicator of tobacco smoking. This phenomenon is a positive outcome for African-Americans because smokeless tobacco, for the most part, is simply something in which the African-American community does not indulge. There are some data that suggest that African-American women in the south have higher rates of use of snuff, but for the most part, that behaviour is not something that we adopt.

The other explanation used to explain the increase in tobacco prevalence among African-Americans is the one that truly concerns me. I believe the increase of generic brands and the introduction of low-cost cigarettes is potentially very significant.

Other presenters discussed the efficacy of self-help quitting methods. Comments were made during the presentations about how we evaluate the mix of cessation and environmental strategies, how we get to the hard-to-reach smoker. What I would caution here is that we not throw the baby out with the bath water. We should be taking a look at the self-help materials that we are utilising and building other purposes into those programmes other than just purely cessation. The audience attending this conference is very focused on the clinical phenomenon: the individual smoker trying to quit.

When we put together the Pathways to Freedom materials at the Fox Chase Cancer Center, what we had in mind was not just cessation, but also environmental change. Creating community leaders and empowering community-based organisations; creating materials that were relevant to African-American leadership. I believe we succeeded. We utilised a paradigm in our materials that dealt not just with the individual smoker but with the community. We addressed quitting methods, but focused equally on the role of the tobacco industry in terms of advertising and promotion. We talked not just in terms of the social support that needed to be provided to the individual smoker, but the social support that needed to be provided to the community in terms of galvanizing itself for environmental, legislative-related changes. So that the outcomes necessary to evaluate when these materials are distributed are not just individual

quit rates or stage of change of individual smokers, but what happens to the community at large.

Now we have succeeded, with the help of the American Cancer Society, in distributing the Pathway to Freedom materials in eight divisions (seven states, including the District of Columbia). What we're finding (and this is 'soft' data, based on a qualitative evaluation that we're completing now) is that the materials have a tremendous amount of appeal to the community, and that a cessation message can be the first step in your approach to the African-American community. But Step 5 or Step 6 or Step 10 will be to pull leadership from those communities into a process of tobacco control advocacy where they're moving, not just to enhance cessation, but promoting and advocating for environmental issues.

So, again, what I'm saying is that we should look creatively at the materials that we're producing, and I think this is not just relevant for the African-American community but for the Latino community, the Asian community – there's a whole gamut of special populations. We have to look at our materials and make them responsive to the needs of those communities, and that's a different kind of focus than the one being articulated at this conference.

There was a statement concerning smoking by people of low socioeconomic status, and that being synonymous with cocaine use. I would be cautious about the language that we use and the potential harm of stereotyping. Conversely, what we may be looking at, in my view, is a positive opening across the substances. We've talked about the relationship between alcohol and illicit drugs and tobacco. However, going beyond the concept of tobacco being the lead agent in the aetiology of substance abuse, what we really have is the potential for assessing the need and developing comprehensive programmes at the community level that truly look at all of these issues.

If you look at coalitions from the community perspective, and consider alcohol coalitions and illicit drug coalitions and tobacco coalitions from the perspective of community empowerment and community development, what we're actually dealing with are fragmented communities. Fragmented because each of these coalitions represents its own interest and constituency. What we really need to do is approach this from a different kind of perspective, and I think we're on the verge of that. For example, the Synar Amendment is a regulatory hammer that is making these alcohol and illicit drug communities relate to tobacco or lose their block grant money. This is positive move from a policy perspective, but from a programme development perspective, it's not very helpful because we are dealing with federal agencies and components of State Health Departments that are not familiar with tobacco. It is not easy for them to talk to one another. What we need is a process that is open-ended and encourages dialogue and consensus building, and you're not necessarily

going to get that in an environment guided by regulatory prescriptions.

In closing, I think the moment is quite challenging. There are possibilities opening up all over the place, at both the community, state and federal levels. We are possibly on the edge of conceptualizing a multiple-drug approach, especially in regard to community-based coalitions, and I am looking forward to the next 10 years as being a very exciting time in prevention and health promotion. Public health can advance if we are able to succeed in developing programmes based on an integration of these issues, and by so doing integrate community forces in a manner that results in more empowerment and cohesion.

Frank J Vocci

I'm an escapee from the FDA, where I worked for 11 years in the drug abuse section, reviewing drugs for effectiveness in the treatment of substance abuse disorders. I was the reviewer for Nicorette, and the reason I want to tell you this is because I'm one of the culprits responsible for the labelling that's been referred to today in the discussion of this comprehensive treatment programme concept. I had no idea at the time that it would spur so much research, but I'm glad it did because I think it's actually been beneficial to the field of treatment services research.

What we had in 1984 when we were looking at the new drug application were two clinical trials which were run as randomised, double-blind, placebo-controlled trials of cigarette smokers who entered into a treatment programme. There were psychosocial and behavioural measures in one trial or another. There were diaries that were kept. The subjects were seen, not only to turn in their diaries and their medications charts but also in a therapeutic sense. Nicorette increased the quit rate in both studies, and it increased it in the heavy smokers more than the light smokers, so there was, in effect, dose response. Also in both trials the drug beat placebo, even in the light smokers, so we thought the drug was effective.

The question then arose as to how the drug was going to be used. I said that's a good question because it will probably be used in ways we would not be able to imagine, so let's not try to imagine how to do it. Let's let the field figure out the best way to give it.

Well, my boss was basically against that, so we compromised and said let's put something in there about the fact that you have to use it in some sort of a treatment programme, and let's let the field define exactly what will be done and what a comprehensive treatment programme is. I told my boss at the time I thought that would take 10 years. Well, we're nine years into that process. You all have one more year to figure out what a comprehensive treatment programme really is and that's your challenge when you leave today.

If you think about this, you have a body of evidence from controlled clinical trials. Then

you're going to allow a drug to be marketed and it's going to go out into this sea of medical practice, with local and state restrictions and even federal restrictions in certain areas. There are a lot of impingements on how a drug is used in the practice of medicine, and I think we thought correctly that to try to define what a comprehensive treatment programme was would do more harm than good. So, with some deliberation and conscious action on our part we said that the drug, these drugs, should be used in a treatment programme.

Now, if you find in the future that a comprehensive programme, such as has been described today, may be different for an upper middle class educated person than it is for someone who has less education and a lower socioeconomic class, then it's a dynamic concept and one that you have to actually fit to the individual. And that's probably the best kind of comprehensive treatment you can get.

If a person only needs X treatment, then don't give him 10X. But if he really needs comprehensive services, if he is a cocaine abuser who also abuses alcohol and you realise this person has a co-existing psychiatric disorder or whatever, then you may have to go full bore. We're running a clinical trial right now in a narcotic-addicted population, and some of the investigators have said that these people not only fit the criteria for narcotic addiction, but they could actually diagnose most of them with three other substance-abuse disorders. This multiple-dependence diagnosis is what you're seeing now coming into drug treatment.

In some ways, comprehensive drug treatment is going to be defined not only by what the field thinks the absolute full-bore treatment is, but what the needs of the patient are. I think you're going to have to do this on a grid rather than saying that this is a type of treatment that can be applied willy-nilly to every patient who walks in the door.

Many have commented that nicotine addiction is not unlike a lot of other substance-abuse disorders, and they are correct. If you look at the survivor curves of people who remain abstinent or who remain in treatment,

this is exactly the kind of data we see in heroin abusers and in cocaine abusers. People who smoke, in terms of staying in treatment, present the same way as people with other substance-abuse disorders. I don't know if there's some neurobiological correlates to this, but I suspect there are. This is something I think that people will be working in terms of what causes early dropout and then what causes this later dropout that you call relapse. We label these as being different, but I'm not so sure that they are.

Dorothy had some interesting comments today about withdrawal and the effect of the medication on withdrawal and the fact that it's not dose related. I think we're still defining what nicotine withdrawal is. We know with the opiates that there is an acute withdrawal syndrome and a protracted withdrawal syndrome, and it's not clear whether there's a protracted withdrawal syndrome with nicotine dependence, and if there is, that may have implications for treatment.

The data on these survivor curves look like there's probably at least a 3–4% dropout rate in the first six weeks of a trial, followed by about a 1% weekly dropout rate up to about a year. The higher dropout rate in the beginning is probably related, at least in part, to withdrawal. Not necessarily all of it is due to withdrawal, because withdrawal may be only one component of what is driving drug-seeking behaviour. There may be positive components of what drives drug-seeking behaviour, conditioned effects and other effects that we have yet to define but which I think are very real.

My final comment is that what I've been struck by today is that this is a field that is working, not only working in the sense of doing good work, but running the full gamut of taking investigations from the laboratory into clinical pharmacology labs into controlled clinical trials, out into the practice of medicine and then studying treatment services, research and delivery. I think this is something that is a credit to all of you. You're doing good work, and I congratulate all of you.

Questions and answers

CHARLES R SCHUSTER: I was intrigued by Dr Benowitz's clinical anecdote, and I would like to pose a question to both him and to Frank Vocci, who, although he's no longer with FDA, had sufficient experience there to make his comments on this worthwhile.

I'm impressed by the fact that we seem to have the feeling that total abstinence is the only acceptable goal for any treatment. So I would ask Dr Benowitz, if you had given the nicotine patch to an individual who had cut down from 30 cigarettes a day to five cigarettes a day, would you consider that successful and

would the FDA consider that an acceptable end-point? Because all I've heard today is abstinence as seemingly the only goal.

NEAL L BENOWITZ: Well, unfortunately for sudden death in coronary heart disease, there is not a very good dose-response. If you look at cigarettes per day, you see a substantial risk even in the one to five group and then it sort of plateaus. If it were lung cancer, I'd say yes, there would have been a big benefit. For coronary heart disease, unfortunately, it doesn't work.

FRANK J VOCCI: As far as things go historically, you're correct. The thinking was that we wanted a drug with which you could actually increase abstinence in the immediate quit attempt period. I think now the FDA is coming around to the concept of lapses and relapses, and when you throw in the concept of lapse, you're actually throwing in some additional drug use.

They're also looking at something like a rolling quit rate. How many people tried to quit and started at Week 1 and how many actually quit by the end of Week 6, as opposed to people having a quit day and being successful from that day on. There is also an idea that people may be trying to quit and using nicotine or smoking while they're attempting to quit, but eventually, four to six weeks on, there may be a second group that actually has quit.

In terms of the other issues, I think we are all coming around to looking at this as reduced use, especially with heroin and cocaine, may reduce morbidity and mortality and spread of AIDS and hepatitis, and that may, in and of itself, be beneficial to the patients and to society at large. That's something we're discussing right now with the FDA.

How to incorporate that in this field is difficult because one of the things that people are aware of here is that individuals can, just by sheer will, cut their cigarette smoking down for a period of time. It can then go back up, so that you can get a lot of false positives, just possibly by a Hawthorne effect.

ELLEN GRITZ: I'd like to ask Bob Robinson to comment upon the dramatic decrease in smoking prevalence among African-American youth which seems to be replicated across several national studies and in different states and doesn't seem to be an artifact of 'in school' or 'out of school' or whatever. Is smoking now becoming a behaviour that African-American youth do not adopt, and, if so, what's the secret?

ROBERT ROBINSON: Whatever the secret is, nobody knows it. I think the data is definitely real, however. Anecdotally what you're getting is, perhaps, some real differences in community norms around such issues as how I look. Anecdotally you're getting the distinction that white youth are much more concerned about their physical appearance, how much they weigh, *et cetera*. One very interesting comment that I heard from a high school student who was working in our office in Philadelphia was that white kids go to the beach during the summer and we go to amusement parks.

So the secret is real but still unknown. The economic factor's a real critical issue as well. They do get a low cash flow in this community and, consequently, they're not smoking as an economic option as well.

JANE MOORE: A few moments ago I looked again at the title of the conference, who quits and who pays, and I couldn't help but reflect

that for apparently 80–90% of people who successfully quit, no one has to pay, and from a public health perspective, I'd like to see more research and encouragement for that group of people. What can do to promote that personal decision that has such a high probability of being successful?

I think the California experience and the ASSIST Program, as it gets into its intervention stage, will offer us some of that, but I feel that that's a whole arena that hasn't been touched on here and certainly needs to be encouraged.

EDWARD ANSELM: In my last comment I obviously warned against the excesses of addiction. In this one I'd like to comment on the failure of treatment, and Dr Benowitz's case is very pertinent.

I recently heard testimony from an individual speaking before the State Commission in New York, who said that he had been trying to stop smoking for a number of years and had been trying to obtain some reimbursement for counselling. Now that nicotine patches and gum are available for that, he was unable to be reimbursed because he was told that they only work on average between 10 and 15 or 20% of the time. I find it interesting to recount exactly what he said to us, that if we had a treatment for AIDS that was able to guarantee the recipient of that therapy a normal life and only worked 10 to 15% of the time, and it was relatively cheap and safe and freely available, people would be swarming the gates of NIH and chaining themselves to the Governor's helicopter.

The question is where's the outrage, and that's his question to us and my question to you, where's the outrage about the failure to treat appropriately, with counselling and, when indicated, pharmacotherapy, for smoking cessation? Where is it? Where are the patient advocacy groups that we have for so many other diseases and problems? Where is the Heart Association, the Lung Association? Why aren't people speaking up more forcefully? I'm curious to hear your perspectives.

ROBERT ROBINSON: My gut reaction to that is, when you look at the money that's been invested in tobacco control research, it has been targeted solely to cessation. It has been targeted to predominantly white communities time and time again. If you extrapolate some of your discussions today in terms of the intensity of your treatment, the complexity of your treatment, the fact that you're not even close to having a delivery system that can implement the kinds of treatments you're talking about, to the kind of high-risk populations that need your treatment, except for talk about bringing in a comprehensive approach at the community level to alcohol, illicit drugs and tobacco. And I'm supposed to get excited about that in terms of the African-American community? You find me a delivery system that can give 20 minutes of care to African-Americans in this community and I say yes, I'll be outrageous with you.

What we really need is more policy-related dollars, more dollars that are targeted towards community development, coalition development, legislative, environmental changes. I'm not saying don't treat, I'm simply responding to why no outrage. My response to you is... give me a break!

SCOTT LEISCHOW: Bob, you mentioned the Synar Amendment, which basically will cut funds if measures aren't taken to prevent kids from smoking and having access to cigarettes. One of the things that struck me is it doesn't appear to me that we do enough to reinforce positive behaviour. We tend to develop policies that are punitive. And with what you were just talking about, how do you see that mix between punitive measures like the Synar Amendment and more positive reinforcements for behaviour change like the ASSIST Program that funded those states that did well under the COMMIT Program?

ROBERT ROBINSON: I think there's another way to be punitive, and that's to redirect our policies in such a way that we're punitive vis-a-vis the tobacco industry. I think we need to figure out a way to tax them for their advertising, or to eliminate their advertising in a way that is consistent with the First Amendment. I think we need to be more punitive, but I think it's targeted at the wrong person. I think we need to figure out how to penalise the industry.

JOHN HUGHES: I have a comment on any behavioural analysis of contingency management both on a patient level and on a provider level. Neal, you mentioned hypertension; I think that hypertension would not be diagnosed if I had made a big pitch for people to diagnose hypertension but told them, by the way, you can't be reimbursed for this. I think reimbursement is a contingency. I think having questions on Board examinations about smoking is a contingency. I think having insurance companies reimburse differently for people who smoke and don't smoke is a contingency. I think there are a lot of behavioural contingencies that can occur at a local level that we can arrange.

DAVID PL SACHS: A brief comment for you, Ken, and then a question for Dr Robinson. I think that to respond to your comments on Neal's case, the dilemma he felt himself in, and I have certainly felt myself in as a clinician, is that there's a double standard here. If you want to play fair, then counselling, channel blockers and the anti-cholesterol agents and anti-hypertensive agents are, likewise, not covered by a formulary, so the patient has to make a decision, what's he or she going to do. It's the double standard aspect that bothers me a lot. And then the other thing is, had the other agents not been on formulary and had the patient not been able to afford them, would he have died sooner? Or maybe at the same time?

Now, my question for Dr Robinson, I'd like to change gear and tenor a bit because you

raised some very interesting questions for me that I've puzzled about a lot since my days at University Hospitals of Cleveland in the '70s and early '80s. The question I'd like to ask you is with regard to the African-American community. I can envision issues which are truly ethnic. I can also envision a separate set of issues which are socioeconomic. And I base that simply on the fact that, when I was in Cleveland, and I was recruiting broadly through the general medicine clinic, whenever a television news story ran on the 6 pm news about one of my smoking research projects, the next day our phone went off the hook from the wide crescent around Cleveland's inner city and from occasional blacks in that predominantly white crescent, but nobody from the inner city in Cleveland ever called. Now, the inner city, in Cleveland, as you know, is predominantly black so this got me thinking about the different contingencies and what I was actually seeing here. Was it really African-American, per se, or was it more a function of socioeconomic status, and then is it appropriate to even try to change the sense of priorities when, as one of my black patients put it to me, my biggest concern is whether I'm going to get done in by the Saturday Night Knife and Gun Club in downtown Cleveland.

ROBERT ROBINSON: I think we need to stretch the hypertension model and really look at some of the public health applications. In terms of hypertension, when hypertension moved into church-based programmes, that did a tremendous amount in terms of increasing the awareness of African-Americans of what hypertension was. You have a level of involvement from African-American institutions in regard to hypertension that they don't even come close to in terms of tobacco. So, we need to identify the same kinds of issues and doors that bring that community into the arena of hypertension, to bring them into tobacco. What's locking those doors is the tremendous amount of investment that the tobacco industry makes in those communities.

So I don't think the issue is to think of it in terms of whether it is a socioeconomic issue or an ethnic issue; it's a historical issue. When we look at the relationship between the tobacco industry and the African-American community, we see four decades of very intense investment at every level in terms of their leadership and in terms of their community-based organisations, and we need to be dealing with those issues as a way of recruiting African-American leadership and African-American involvement in the tobacco control issue if we make the appropriate investments in those communities. That's our challenge.

JUDITH K OCKENE: I just wanted to emphasize and support the idea that cessation does not necessarily have to be the only end point with regard to intervention. I think that, with regard to that end point, physicians especially, are often very discouraged to think that they need to get the patient to the point where he absolutely stops smoking. I think

that we need to continue to entertain the stages of change model that was presented by David earlier today and that this model is a way of increasing physicians' feeling of efficacy if they can see themselves making progress with patients.

CAROLE TRACY ORLEANS: I have just one comment, and that is that we have an unprecedented opportunity right now to harness the policy changes that are taking place and to use those policy changes as incentives and bridges to effective treatment. I think that we're in a position to couple every policy

advance with a treatment advance. If we're making schools smoke free, we should put adolescent and faculty cessation programmes within reach of the populations affected. If we're raising excise taxes, we should use some of those revenues to help subsidise treatments that have not been available to large segments of the American population. If we're going to ban smoking in hospitals, then we'd better organise some kind of support for those smokers so that they can turn the ban into a successful quit attempt. And the spirit of this meeting has been very much along those lines, and that's really been exciting.