SESSION V QUESTIONS AND CLOSING REMARKS

Panel and open discussions

Moderator: John M Pinney

Panellists: Jack E Henningfield, John R Hughes, Saul Shiffman, Maxine L Stitzer

Saul Shiffman

I find myself wondering whether the conference has met our goals, and I find that it has – not because we have conclusions or a clear policy from it, however. Someone asked me what I thought was going to happen in the next year as a result of this conference, and my quick answer was, “Nothing”. In fact, I think we have accomplished our goals because we have raised the right questions. You have all seen the bumper sticker that says “Question authority”. The scientific version says “Question assumptions”, and I think we have done that for the last day and a half.

On the issue of the benefits of some kind of harm reduction strategy – and we did consider a diversity of these – my perceptions are pretty clear. The advantages of particular strategies remain to be established, but the benefits are definite, and the end goal of improving health with concomitant reductions in morbidity and mortality, is clear and underlines our commitment to the area.

The side effects of a harm reduction policy are more controversial. It is important in policy considerations to plan for the possibility that policies will have unintended consequences that often dwarf the intended consequences. It is one of those cases where the operation can be a success, but the patient expires. The concern I heard is that a policy promoting harm reduction would dissuade cessation and would provide a mixed message, particularly to youth in whom we are concerned with smoking prevention. No one raised this issue, but it strikes me that there is a potential for a mixed message with regard to the issue of secondhand smoke. If we are saying that a smoker can smoke in a way that is relatively less risky, are we not implying that the risk to a non-smoker is all that much smaller?

Another concern with harm reduction is that it would pull resources, whether those be dollars or brain cells, away from our current goal of cessation and prevention and toward harm reduction. With that said, I am struck by how much the concerns are really coloured by assumptions and by gut level or emotional reactions to the issues that were raised. In some ways, this reminds me of the discussions I have been grateful not to be a part of in the alcoholism treatment community.

For example, one of the goals of harm reduction is to do something for the people who are not ready to quit. We are close to saying, “Well, if they are not ready to quit,

they are going to have to wait until they hit bottom, and then they will come back to us for treatment, and we will have effective treatment”. Similarly, we are concerned about giving people a let out. Perhaps if we tell people that it is possible to reduce harm, they will continue smoking. But we have few data to support that point. In fact, it is striking that in the alcoholism area, the data from Bill Miller’s studies of controlled drinking suggest the opposite; that if you give people a choice of electing for reduced or controlled drinking, many of those same people will ultimately elect to stop drinking altogether. We have concerns about whether smoking reduction can or cannot be maintained, but again, I think we have to look to the data, either existing data or new data to decide those issues.

Finally, part of the issue that we started with was access, and I think we lost track of that. We started with the issue of access, in part on the premise that by offering alternative goals or avenues for smokers to deal with their addiction we were improving access; in fact, even if we had treatments that were effective, there are many people who have no access or are not availing themselves of the access that they have. It is important to consider that the ultimate goal is to reach people who are smoking and to reduce the harm that accrues to them as a result.

Jack E Henningfield

Where do we go from here? There are no simple solutions, and in fact we probably confused some people, but our intent was to get the issues out on the floor so that you would not be surprised by this minefield. I think you can see there are vast challenges and enormous opportunities. Mr Sweanor noted that the nicotine market penetration of pharmaceutical products was \$200 million in a potential \$50 billion market in 1994. There are also opportunities and challenges for researchers, voluntary agencies, regulatory agencies, and research organisations. For example, NIDA’s nicotine research programme is now widely recognised as a highly successful effort contributing to improved public health.

We have seen that many of our cherished beliefs are either not supported by data or are at odds with the data. The belief that people can write cheques for \$50 or \$100 for a prescription to help them stop smoking instead of for cigarettes is not acceptable to a lot of people in this country; specifically those people

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who have less money, which is in fact who most of the smokers are. This strategy is surely not going to impress people in developing countries, either.

New cars are presently too expensive for many potential buyers. So a third of the new cars are creatively financed or leased. We have got to get much more creative about how we get medications to people if we are going to reach the people who are smoking the heaviest.

The belief that there is no such thing as a heavily addicted smoker turned light smoker has not been addressed by much data. Similarly, to suggest that two to three months of treatment should be sufficient for all or even most smokers is probably short sighted. To assume that all nicotine dependent persons can live comfortably and function effectively without continued intake of nicotine might just be wrong.

Yesterday, Dr Hurt lamented that all of these diverse issues and approaches are like trying to fight world hunger, and that was a good analogy because we are talking about a half a billion of the world's current living population potentially dying of cigarette smoking unless we do something very different. The challenges are diverse and immense, but the opportunities are also diverse and immense.

Is there any person or agency or company that does not see that it is worth rethinking what we are doing and expanding the range of things and the range of approaches? I think it is going to take all of us to rethink our strategies and apply our resources to this problem.

We have 46 million smokers in the USA. To get more people to try to stop will take multiple strategies including educational efforts and policies, such as the Synar Amendment. Companies should be interested in that because this public health problem is the basis of a market. Only a small percentage of smokers are successful quitters. How do we increase those numbers? In part by providing better access to existing, effective treatments, but we clearly need a greater diversity of treatments to reach the people for whom current treatments either will not work or are unacceptable. For example, I think that non-nicotine medications could be successful for a lot of people who will not use a nicotine medication.

When I discussed this at the 1990 meeting in this series, I argued that greater product diversity was needed to reach a greater percentage of smokers. At that time – this is only five years ago – there was only one product on the market. It is amazing when you think of how the field has changed. Now there are two product types and several more around the corner. One of the things that is important to keep in mind is that the products do not enter the market passively. They do not enter regulatory agencies passively. They change the system and the response of the system to future products.

For example, showing that gum was an incredibly safe product helped to open the door for patches. With patch reaching more smokers we have seen both the benefits and the

limits of the current approaches, and I think those things are important for regulatory agencies, governmental agencies, and voluntary organisations to consider.

The message is simple: if you are planning for the future, do not accept the status quo or you are going to be left behind. Dan Quayle was right – prediction is difficult, especially when it is about the future. I am not sure how we read all the tea leaves that have been laid out this last day and a half, but if you are planning new research, you would think twice about recreating the same old clinical trial approaches you have been doing, with the same old assumptions.

Finally, our intention was to get the issues out in the open with terms like “alternatives” and “harm reduction”. I think these have been useful catalysts, but as I said yesterday, I would probably avoid the term “harm reduction” like the plague after this conference. I would focus on what it is you want to accomplish, such as reducing heart disease and improving health. I would emphasise working together on the diversity of efforts that will be needed to reverse the current situation where it is really easy to get tobacco products and really hard to get medications. Otherwise, we are just conceding disability and premature death for millions of Americans and half a billion across the world. I think we can do better than that.

Maxine L Stitzer

To put my highlights in perspective, we have to recognise that we have made some really important advances in smoking cessation technology. We have nicotine replacement products that have doubled cessation success rates; we have good behaviour treatments that have received a lot of research and development work; but yet the bottom line is that even with the most intensive combined smoking cessation therapies we can achieve only a 30–40% long term quit rate.

There is a sense of frustration that we have come up against a wall, and I think Shiffman wrote about this in one of his concept pieces for the *Journal for Clinical and Consulting Psychology*. We are not sure where to go, so we are casting around for new ideas. The value of a meeting like this is it allows us to brainstorm and to think together about new directions.

One point that deserves emphasis is that we cannot rest on our laurels; we have to be developing additional innovative treatments. This is true for both pharmacological and behavioural interventions, but particularly so for behavioural interventions, where there is less in the way of profit motive driving innovation. Dr Rose brought up this idea, and it is an important message. It is a timely message, too, because there is currently support within NIDA for research on behaviour therapy development under an announcement by the Treatment Research Branch.

I think we should be more aware of dissemination efforts and view them as a legitimate activity. The point has been raised that

the tobacco companies are very good at disseminating and marketing, and we need to become better at it. Dissemination is a researchable item; there is a science of dissemination, and this is another area where we could become more active. In fact, there is money for this too, because NIDA plans to devote a portion of their research budget to services delivery research.

I am excited by the new perspectives and challenges offered by a harm reduction approach and pleased that the concept has been put on the table at this meeting. Several individuals who offered an opinion on the overall impact of a harm reduction strategy emphasised the point that we must be careful to not subvert cessation attempts or indeed the message that cessation is by far the best harm reduction strategy available. Granting this point, it is nevertheless possible that smoking reduction could be a viable alternative for some smokers. Research from Hatsukami's laboratory, for example, supports the very mild withdrawal symptoms seen when smoking is reduced by 50%. A key question is whether sustained smoking reductions of this magnitude would provide any observable benefits in cancer and heart disease morbidity data. Another key question, given the pleasure seeking or drug reinforcement aspect of smoking behaviour, is whether smokers could in fact sustain reductions in smoking without gradually returning to their former smoking levels over time.

I was also struck by the variety and number of different options that we have to work to implement harm reduction goals, including strategies that range from altering cigarette characteristics, to tightening environmental smoking bans, to promoting cigarette taxation. Hopefully this meeting will not serve to polarise people into harm reduction believers versus non-believers but instead will stimulate interest in following up on some of these ideas and exploring smoking reduction as a treatment research endpoint.

Finally, it has been useful to draw on the expertise of political thinkers like Messrs Synar and Pertschuk who have important new perspectives to contribute. One thing to be learned is how messages can be packaged in ways that capture the enthusiasm of the public and of lawmakers and regulators for continued and expanded tobacco control efforts. Describing tobacco dependence as a paediatric disorder is an excellent example of a new and useful perspective on some well known facts about smoking initiation.

The new ideas generated here have been exciting. In the end, the value of a meeting like this one is that while it does not provide clear answers, it does provide the beginning of new dialogues, a chance to re-evaluate old assumptions, and the concepts on which new research and policy initiatives will be built in the future.

John R Hughes

I want to begin by thanking John Pinney as the

chair of this conference. Scientists really value people who prod them and move them along, and I think this is yet another example of how Mr Pinney has served our science very well.

One of the differences between going to a meeting of lay people and going to a meeting of scientists is that in theory scientists are amenable to changing their mind on the basis of data. Secondly, one of the functions of science is to take opinions and turn them into testable hypotheses, and that is where I would like to focus my comments. For me the crucial studies will be longitudinal studies or randomised controlled trials that take people who have switched to low tar cigarettes, be they high in nicotine or low in nicotine, and see what this does to long term cessation.

I have been convinced that I should add something to that point, and that is that we should also look at the unintended effects that Dr Shiffman mentioned earlier. There are ways, such as using focus groups of children and presenting them advertisements for harm reduction, to see what it does to their attitudes about smoking cessation.

The second thing we need before we go anywhere with harm reduction is some sensitive biological markers. If somebody cuts down their smoking by 70%, is their forced exhaled volume going to be changed? Is their urine mutagenicity going to be changed? We need a sensitive biological marker. I have looked at this field and am concerned this may be a major impediment.

Then, finally, I think those of us who are going to continue to do cessation studies need to change our dependent measures. Currently, abstinence is the only measure. I can remember coming into this field and seeing old studies that reported number of cigarettes per day in one group and number of cigarettes per day in the other group. I thought that was terrible, but I think we need to go back to that. In addition to reporting abstinence, we need to report the change in the number of cigarettes smoked per day, and the change in CO, cotinine, and tar, and report these data in two ways, one in all subjects and one in non-abstinent subjects. If I have a treatment that does not change abstinence rates, but decreases CO by 40%, what is the field going to say about that? I do not know, but we need the data to start challenging that as well.

General discussion

John M Pinney

I want to thank the planning committee, and I want to thank Dr Hughes also for your very kind comments. Let's take about 20 minutes to entertain brief closing questions and observations from the floor.

NEAL L BENOWITZ: The core issue is that tobacco is the cause of the tobacco related plague, and the vehicle is nicotine addiction. We have treatments available that are effective, but not very effective, and I think if we had

very effective treatments, they would be widely used. To me, there seem to be two opposite strategies that have a potential to be very effective. One is to have not enough nicotine in cigarettes to maintain addiction, which I think would get rid of the problem. The other would be to have cigarettes that maintain an addiction by giving people nicotine and allowing people to have the pleasure of smoking, but without any other toxins. Both of them would almost totally eliminate the tobacco and health problem. So we do have two viable possibilities that could be dramatically effective – not just doubling quit rates, but huge reductions.

I would also like to respond to what Dr Hughes and others said about looking at harm reduction by manipulating or studying the kinds of cigarettes people smoke, such as those of varying yields. I think people need to know that smokers smoke cigarettes in such a way that there is not much difference in what they take in from different cigarettes. The tobacco companies benefit a lot by our focusing on low yield cigarettes because they do not care what kind of cigarettes people smoke.

The fact of the matter is that if there is any risk reduction it is very small, and I do not think it is warranted to spend a lot of time looking at current yield cigarettes. I do not think people should be encouraged to smoke higher yield cigarettes, but I do not think a policy of differential taxation or even much research is warranted at this time with modern cigarettes of different yields when they all contain approximately the same amount of nicotine.

JACK E HENNINGFIELD: Regarding the two different approaches, one approach is aimed at drastically decreasing the prevalence of smoking, the other assumes continued maintenance of a high prevalence of tobacco use but endeavours to decrease the odds of premature death somewhat. Another approach is to develop a nicotine delivering device that does not deliver anything else – that is no longer a cigarette. There is nothing wrong with that approach in principle, but I cannot imagine why you would want a cigarette company to do that with little regulatory oversight as opposed to a pharmaceutical company doing it with the regulatory oversight of an agency such as FDA, which has extensive experience in evaluating such devices.

SAUL SHIFFMAN: The relationship between nominal FTC yields and biological exposure is critical. In all of these discussions, I think we have not said explicitly – but I hope we assume implicitly – that any of these policy options requires a careful technical examination to get the details right. So any regulation would have to be responsive to the kind of biological markers Dr Hughes talked about, and to actual bioexposure and not nominal yield.

JOHN BAER: I am particularly taken by the concern over mixed messages and what this is going to do, and I just want to say I believe

that to be an assumption. I am not a policy maker, and I do not have much experience in that area, but my clinical experience is that clients can handle this kind of message; that yes, it is best to quit, and it is also best to do as much as you can.

In the alcohol field, where I have had more experience in the last few years, there has been what I hope is a growing movement to try to engage more and more people in the treatment process, and the whole notion of harm reduction is to try to have more contact with more people who are committed to taking steps towards health.

GLADYS G MAN: I have two basic interests. My anthropological interest is in studying the exotic communities of the avid non-smoker and the smoker's rights people as subcultures. I think they would make wonderful anthropological studies. My second and primary interest is nicotine as a therapeutic agent for various cognitive dysfunctions, all the way from declining memory and old age, to prevention or protection against Alzheimer's and Parkinson's diseases.

JOHN R HUGHES: That there is some reason to believe that nicotine or nicotine analogues might be therapeutic for Alzheimer's disease or Parkinson's disease is of great interest. To me, this then raises a further point of interest relating to over-the-counter sales. For example, what if somebody started taking nicotine gum for Alzheimer's disease, not because it was effective, but because they heard that a company was developing a nicotine analogue? Also, what if RJR bought out Glaxo and decided to make an Alzheimer's drug?

TERRY PECHACEK: I believe that Drs Benowitz and Hughes are both correct, but I think Benowitz is exactly right in saying that some of the proposed research with existing cigarettes would not be the best.

What does the panel think of the concept of reviving what the National Cancer Institute used to have in the safe cigarette programme at the University of Kentucky? Should we not have some type of federal programme creating the technological base that could be used to investigate specifically these issues that are being talked about, such as the different ranges in modification, and both options of high nicotine/low tar and low nicotine?

JOHN R HUGHES: In my comments, I focused on low tar cigarettes. My same comments would also apply to people who had reduced numbers of cigarettes. With people who reduce the numbers, do they later have an increased or a decreased probability of quitting? The same thing could be done for Premiere or Eclipse for people who change to these cigarettes; do they experience an increase or a decrease in future cessation? I did not want to focus only on present low tar cigarettes.

JACK E HENNINGFIELD: It is controversial enough to postulate the reduction of disability with a medication. But when you are thinking of attempting to reduce tobacco disease with tobacco products, it is much more controversial; and for some very good reasons, as we learned from the smokeless tobacco experience in the USA. In fact, I think that any harm reduction approach that does not work towards shrinking the prevalence of smoking is going to have a tough battle.

SAUL SHIFFMAN: We have to be cautious about this kind of dichotomising. Acknowledging that there are limited resources, both financial and personal, and then taking some steps towards a harm reduction approach does not involve accepting current prevalence and does not involve giving up on cessation as a goal. I do not think anyone has advocated that.

MAXINE L STITZER: But I do not think that anyone has answered the question about creating research cigarettes. I think that the University of Kentucky is producing cigarettes again, but will they be flexible and produce what the scientists want?

JACK E HENNINGFIELD: One of the tools we need is a good placebo cigarette. If I would have known that Philip Morris's Next was going to be on the market for such a short time, we would have bought a boxcar full of them – it seemed to be a reasonable placebo. Think of any other drug field where you are working without a placebo? At the very least, we need a relatively palatable, tar delivering, CO delivering, non-nicotine cigarette.

JOHN R HUGHES: Another thought provoking item is that some of us do research as independent scientists for pharmaceutical companies. What if the tobacco industry did the same thing? How would we as scientists feel about that? If the tobacco industry came to me and said, "John Hughes, I have this new, better version of Eclipse. Will you test it out for me?" I am not sure how the community would respond to that, but that is the other way to start testing those kinds of cigarettes.

ED LICHTENSTEIN: We have heard two different approaches to harm reduction, one through product modification and development and the other through patient counselling and education. What struck me is that both approaches already seem very much *de facto* in evidence and to be flourishing well, albeit they are not terribly well recognised. It is an interesting question whether they should be more recognised and policy-boosted in some way, given the benefit of some policy acceleration.

What strikes me about the comment on the alcohol-smoking relationship – because it is, I think, seductive to look at controlled drinking for guidance – is that in alcohol, the people who are targeted for controlled drinking or harm reduction are the younger and/or lighter drinkers. In tobacco, it seems to me those who

are implicitly targeted are the older and more heavily dependent smokers who cannot stop – thus rather different kinds of persons are being targeted. You might keep that in mind in considering what you can learn from the alcohol literature in relation to the controlled smoking issue.

SAUL SHIFFMAN: There are a lot of dis-analogies, and perhaps the most important one is that in alcohol, the light non-abuse use of alcohol is (1) extremely prevalent, and (2) almost totally without harm, and there is no analogy to that in the case of smoking. The point I was making was not so much about the data and about inferring from one area what is possible in another. The point was more about the emotional politics of it; I hope we will not repeat the mistakes in the alcohol area as a scientific and policy community, closing our minds to policy options without giving them careful consideration.

SHARON JAYCOX: I believe we need to think about adolescents and trying to prevent children from starting to smoke. We give them one message which is, do not smoke. I think it is important, though it may be naive, to look at the AIDS/STD community and what they do with adolescents, because we all know adolescents are children who are slightly crazy. They give those children two messages, abstinence and safe sex with the use of condoms. Some people would say that there is no safe cigarette. Well, I am not so sure that condoms are 100% effective. You look at the sort of long term consequences of both, sexual activity and smoking, they are equally dire.

JACK E HENNINGFIELD: You have touched on a fundamental point. Breslau and some others are looking at the development of the addictive process and the importance of delaying it as a means of reducing the severity of the disorder. We are so narrowly focused on "Don't smoke" that we forget that another complementary approach is to do everything we can do to delay the development of addiction in the children who do try a few cigarettes, because most of them will.

CHARLES W GORODETZKY: It is very gratifying, Dr Henningfield, that after all the years we have worked together we find we are still working quite synergistically. You mentioned the beneficial effects of the introduction of new delivery systems, and I agree. There is certainly a lot of work going on, by large companies and small, in developing interesting new delivery systems, as well as non-nicotine products, as we talked about briefly yesterday.

What I would like to do in this regard, however, is also jump on Dr Hughes's hobby-horse plea for appropriate clinical research to determine how best to use these new pharmacotherapeutic options. I still see them as pharmacotherapeutic options, and we have to know how to use them appropriately, both the ones we currently have available and the new ones that will become available.

Secondly, we have come back several times to this issue of a device for delivery of pure nicotine, and I agree with Henningfield that it is not a cigarette. I think that the development of such a device does not necessarily imply long term maintenance of huge populations on such a device as a "safe cigarette". Depending on the direction from which you approach this, this product is another pharmacotherapeutic option which may be used, indeed, for its immediate positive reinforcing effects, as part of a continuum of treatment options.

PARTICIPANT: Dr Henningfield began to address this same question, and perhaps you could elaborate on what the opportunities might be during the development of the addiction process. Obviously, your proposal to have non-addicting cigarettes is one way to do that, but we really haven't discussed other options for people in the initiation phases. Initiation of the addiction is a process that develops over an extended period of time; are there other opportunities to intervene during that process rather than trying to treat the mature addiction somewhat after the fact? If there are, what do you think are at least avenues that could be explored to that end?

JACK E HENNINGFIELD: I think that right now we have an overly narrow approach to prevention in youth that is typified in the wording: "Don't smoke. Your girlfriend or boyfriend will think they are kissing an ashtray". That is great for children who have not started yet, but I think we have to think about treatments for children who have started, and are just smoking a little bit, to see what we can do to help them and guide them to treatment before they become heavily addicted. We have to throw every potential roadblock in the way to raise the cost of developing addiction. Even with animals in the laboratory, if the cost of the drug is raised, they may never develop addiction. Raise the price, decrease access, this is where it takes a concerted effort. Increase efforts with families to enlist their help in discouraging any use. The voluntary agencies, the organisations that develop the messages, have to think much more expansively, not just prevention in isolation, but prevention messages linked to treatment options.

Pharmaceutical companies seem scared to death, maybe for good legal reasons, of doing treatment research with children. But it has to be done. We cannot continue to let children wait until adulthood, when their addictions are nearly intractable, to get real treatment.

JUDITH K OCKENE: When we were preparing the 1989 Surgeon General's Report, we found in the literature that there were two studies that had been done looking at cessation in children. At that point in 1989, we said there needed to be more studies in this area. We are now in 1995, and we are still saying that. We need really to do some development on this.

SAUL SHIFFMAN: I think we have charac-

terised our youth prevention efforts as putting all of our eggs into the basket of preventing children from having that first cigarette, and what we are seeing are the effects of a zero-tolerance policy. One effect in an abstinence oriented policy is that the people who have breached that unbreachable barrier are now outside the pale. We basically said "We are going to try to keep you from having the first cigarette". The child who has the first cigarette then says, "Well, now they have nothing for me, and they are not interested in me, and I am inevitably on a course towards lifelong addiction". That is an example of an unintended effect of a policy, and indeed, I think we have missed a lot of opportunities to help children avoid addiction.

John M Pinney

I am now going to deliver some closing remarks, which are what I used to get Dr Warner to do. One of the reasons I am doing it is because the end result of prodding scientists, as long as I have been doing it, is they eventually get their own back, and the planning committee said I had to do this. I shall try to share a few observations on what I think we have heard and perhaps what we may take away from this conference.

At the beginning, we introduced a goal, originally the Surgeon General's goal and now the national goal for a Smokefree Year 2000, of reducing prevalence by encouraging quitting and improving access. This conference introduced an alternative or perhaps complementary goal that dealt with reducing exposure in continuing smokers, and we spent quite some time discussing whether or not we should move from reducing prevalence as the only goal to reducing harm as the only goal or whether we could find some common ground or accommodation.

I do not think we have an answer to that except to say that most of what I have heard in the last day and a half suggests there is room for expanding our view of how we achieve the prevalence goal and that harm reduction in one form or another may help us to achieve that. But no one, including Dr Reuter, who studied harm reduction in its illicit drug context, suggests that we move all the way to dropping our prevalence goal to pure harm reduction. I am not sure anyone could define for us what pure harm reduction was going to be.

We talked also about treatment in many ways, and one question that will linger in my mind is how realistic is it to expect that the health care system will meet the challenges of delivering treatment and delivering it in the ways and with the sensitivities and consideration that we heard are essential, particularly if we are going to reach medically underserved populations.

Mr Anselm made a comment yesterday regarding who should be primarily accountable for achieving the goals – providers? payers? smokers? the government? That responsibility has been passed around somewhat and, I think,

is shared to a great extent by all of us. I think the economic imperative ultimately will drive much of what finally occurs. Payers, the people who pay for health insurance, including consumers who pay an increasing share of their health insurance coverage as a group, ought to be better informed about why they need these kinds of services to be available, either for themselves and their families or hopefully to reduce the costs that they are shouldering for the addiction of other people in their health plans.

I think we did hear a strong caution not to deal in absolutes about harm reduction and prevalence. I heard a message which I thought was provocative and true, that public health and morality do not mix. If we inject too much moral judgment into our approach to treatment, we may end up foregoing treatments which have great promise and thus sentencing smokers to a long addiction without relief.

I think my lesson from this is that we all need to liberalise our concept of treatment and reflect it in how we address treatment, how we study it, how we write our insurance coverage for it, how we design products for it. There is enormous room and opportunity, and there is need.

Our research needs to reflect, as Dr Hughes has pointed out, endpoints other than absolute cessation in six weeks. I think the AHCPR representatives, including guideline panel members, all heard the message that their guidelines must be implemented and institutionalised but be flexible enough not to create a rigid treatment definition which we all may come to regret.

One caution I would add is that many of my colleagues in this field spoke in terms of a degree of treatment intervention, a degree of hands-on treatment which I am afraid is wholly unrealistic for the majority of people who either need to stop smoking or are trying to stop smoking. And I think that the economic models, the treatment delivery models, and the financing models all argue that while we need those treatments for people who can afford them and we need ways of getting them to such people, they must be part of a broader spectrum of treatment. We cannot put all our eggs in one basket. We cannot criticise one form of treatment as too minimal and set a standard too high, because we will go back to my earlier conversation about setting up treatment failures before people even get into the system.

Now, as far as this conference is concerned, the five of us on the planning committee had a primary goal in mind to broaden our collective thinking about treating tobacco addiction. I think that we have achieved that. I hope we have. I think it was important in this process to look at how new products and approaches could be blended into the stepped care model. Stepped care is a wonderful construct, but again, it should not be exclusive to the different kinds of treatments and different products that

we are developing. It is a framework, not an absolute.

We also must keep in mind that the dynamics of the free enterprise system in which we live may drive things that are beyond our control. On the one hand, I think that that is a very unsettling thought. On the other hand, again, I feel that there is a great deal of opportunity. The blend of people in this room is something which I find personally and professionally gratifying to observe – and I am sure the committee joins me. We had people in various disciplines from private industry, from government, from voluntary health agencies, and professional societies, and they are all an important influence in how that free enterprise system evolves.

We have a force at work here that may be an extremely important element in how the future is shaped. There is enormous economic power in this room. There is also enormous truth and data and technical expertise in this room to help shape how that economic power delivers products to the marketplace, and I think that is all to the good. The more there are alliances along appropriate lines between these various interests, the more we can look for productive outcomes.

I am particularly grateful for the active participation of the federal government in this, and I want to thank our sponsors in general. I think the fact that we had federal sponsors, and the fact that we had an unprecedented number of private sector sponsors – companies interested in the smoking cessation problem, developing products in this area – is an enormously encouraging development.

In conclusion, I want to thank you as an audience. You have been a fantastic group. You have been as much a part of the success of this conference as anyone. You participated, you have been patient, and you even laughed at me more than you laughed at Mr Califano, and I cannot tell you how good that made me feel.

I want to take this time also, in addition to thanking the sponsors, to thank the planning committee who shaped this programme and worked very hard at it. Someone accused me of being a slave driver, but these people do not need to be driven. They are committed to the subject, and I cannot think of a finer group of colleagues and a more impressive group of minds to work with, and it has been a tremendous pleasure working with all of you.

I want to thank my staff who have moved this major undertaking along since its initial conception over a year ago. I called Dr Brady and asked, “Would you like to do it again?”, and he said, “I think it would be a great idea”. I then called Dr Glynn at the Cancer Institute, and he was ready to sign on, and the Office on Smoking and Health has also signed on with a major conference grant. We also are very grateful that so many of the corporations who are interested in this field said they were ready to sign on. It has been a long process, but I believe it was worth the effort, and I thank you all again.