Dr. Don Catlin
Director, UCLA/IOC Lab

I'm trying to figure out how to explain to you what I do and how we do it. It's not so simple. I live in a world of molecules, swimming around in a yellow, kind of smelly, fluid. And we get lots of those bottles coming in every day.

And, we have to figure out a way to get all those molecules extracted out of the urine and passed through an extraordinary complex series of chemistry steps and then into a very expensive instrument called a mass spectrometer. And then, build-up about this much documentation and then present it to the lawyers and hope and pray that we can win the case.

This is an extraordinarily complex job. I can't tell you. You are all invited to visit the lab and see what we do and how we do it. It is not simple. But we've learned how to do it. I got into this business in '82. And, somebody from the IOC came, I was a young, younger professor at UCLA in the Department of Medicine and Pharmacology. And this Professor, his name was Beckett, said, well, you need to build a lab here to help us.

I said, well, show me your list of drugs. And he gave me this long list of drugs. I looked at it and half of them I had never heard of and certainly didn't use, even though I was a medical practitioner. And, I said, no, we couldn't possibly do that. He went away and then he came back and he explained that there would be a contract. So, there was a contract, eventually.

And we became the first IOC lab in the U.S. And it was very exciting to me. I read everything I could find about drugs and sport. And I couldn't find very much, not very much. I went to Gold's Gym and I talked to people about steroids. Do you really get big and strong? Oh yeah, you do, and I watched them grow.

And then I started talking to, I couldn't believe, that young men and women who were the cream of the crop, they are athletes, are put in this intolerable position of taking drugs to win a game. I couldn't believe that it could happen. But, it does happen. Not all of them, by any means.

There are many, many athletes out there that you can put all the drugs in the world underneath their nose and they will never touch them. They are going to be clean. But, unfortunately, there are some that will cheat. And they are supported by an incredibly complex underground that runs rings around what we do. And, I could spin stories about this all day that would really curl your hair.

We got up and running. I became, I became addicted to this issue. It was extraordinary to me and it has been my life ever since. I've switched out of the other area and I've stayed with it. But, right after the '84 games, we had to close. We had no clients. Thank you very much, you did a wonderful job. Well, we did have some problems, but, we finished the games.

Then it was a year or two later, USOC came back and said, well, we need a drug testing lab. And then, suddenly, everything was changing in this country and internationally. We needed a lab

because we couldn't get international sport events on U.S. soil without a lab. So, would we reopen. Well, of course, yes, we reopened.

The USOC was there, and, suddenly there began to be some public concern. But, it was mainly about weightlifters and other sports that are, sort of, not quite mainstream that were taking drugs. It wasn't until '88 when Ben Johnson, track and field, competing against Carl Lewis at the Olympic games in Seoul, broke it wide open. Because now, suddenly, you were confronted as a public with the fact of life that here we are in this premier sport, the 100 meter, and we got a drug issue right here. And that, that helped a lot to move the process along.

And then right after the USOC came, NCAA came and the NFL came to us and asked if we'd build a program for them. And we worked with all three of them now and they are great clients. Frankly, I am sick of IOC bashing. They particularly like to bash the NFL because they say all professional sports in the U.S. are corrupt and dirty and drug taking. That's not true. I've been working with the NFL and their steroid program for, probably, 10 years or so. And they have a really solid program. It is very good.

And now, look where we are at. We've got NCAA coming along, with a much better program than they've ever had before. USOC has had, sort of, some meanderings for a few years, but now we have USADA. And that is a brand new ball game. And, internationally, we have WADA, and we have General McCaffrey to thank enormously for his efforts to make that, make all those things go. We need to give these new groups, WADA and USADA, a chance. They are brand new. I don't have to tell you how complex the whole issue is.

Let me just say a word about supplements. It's not andro, androstenedione, from my perspective, is not a drug I'm worried about. Why? Because, yes it is a steroid. But it doesn't really enhance performance unless you take huge amounts of it. It just doesn't.

I am much more concerned about the other substances, like 19 norandostenedione, that's a very serious drug. But andro, no. There is a misconception that we have a test for androstenedione. We don't. I don't have a test for androstenedione. Fortunately, some of them are contaminated with other steroids and we catch people on that. And then the athletes yelp because they took androstenedione and they got caught for 19 norandrostenedion.

I don't know, this doesn't make sense. But, it does make sense. Because all of the sport organizations in this country and the IOC, the major ones that deal with steroids, ban androstenedione. So you can't stand up and tell the Committee that you took androstenedione and you got caught positive for something else because you are admitted to using a drug.

But I would not want to focus so much on androstenedione. The thing you should focus on, why do we have a test for it? What do you mean you don't have a test for androstenedione, what do you do? We don't have a test for a lot of things, let me tell you.

We operate in a high tech business. We have to be, get it absolutely right. All these instruments and all these people and all these chains, it all has to work, and then we can win a case. But, we don't have any R&D underpinning it. Now you go to Eli Lilly and you say, well, really, thank you

Eli Lilly for developing all these lovely new drugs.

And, by the way, what percent of your income do you spend on R&D? Well, talk to Mark, 30%. You know, what do we spend? Zero. There is nothing. It's not quite zero, thanks to USOC and the NCAA and the NFL, we have a sport consortium that gives us grant moneys worth about $150,000.00 a year for the last few years.

I am forever thankful for them. Without that, we would have had nothing. It's not that I haven't tried to get money out of other agencies. We get money out of other places. We have to collaborate. I'll collaborate with endocrinologists who are working on some testosterone project, but, that's the way I piggy back my work, to try to get, that's how we did the androstenedione study, is we piggy back it. You don't get any direct funding for these kinds of things.

So, if you really want to make an impact on this issue, you've got to start looking at it from the bottom up and say, what kind of R&D is needed and how are we going to organize it and get it going? It's that simple. The testing, the overall quality of the testing, it's not that great.

I have to tell you. There are many, many holes. With the information I have, you could test me any day of the year and I'll take lots of drugs and you will never catch me. I absolutely guarantee that because I know how to miss it. You just can't. We've got to get really down to the nitty gritty and look at the technology. There is a lot of drugs that we don't have.

EPO, I'll just say, one word, the reason I'm worried about EPO, here in Salt Lake, is the Winter Games are generally mild with respect to drugs. It's not like the Summer Games. They weren't that bad in Sydney. Drugs made a lot of noise, but, if you actually looked at the details of what drugs were found, and what the real infractions were, they were minor.

We are getting somewhere. Drugs will always make a lot of noise. They will make noise here in Salt Lake. How much noise, nobody really knows. That's a risk of doing business. You shouldn't be afraid of it. Just take it head on, it's business as usual, and put together the best program you have and try to head off and deal, try to come to some negotiations with the IOC to stop them from bashing the United States of America and all of its sport.

That's just very annoying. I don't know quite how to do it, but, it is overdone. And if we have to go through that again, none of us will be very happy. We don't deserve that kind of bashing. We've done pretty darn well over the years. Yes, we have more to go.

What drugs will we have here in Salt Lake? We are going to have a lot of EPO. That is the drug for the Winter Games. A lot of different sports get benefits from EPO. We've got a lot of work to do on EPO. We did have a test in place in Sydney. It was interesting to watch the IOC falling over each other taking credit for it, after holding it back for some years, but, the issue is that it is a very complex test. And it needs a lot more work to get it online and to be robust, bulletproof and litigation proof.

And that, I think, is going to be a concern. Whether we can, in fact, get this done. It is going to take a lot of effort to work it through. And, without it, then you are not going to have a drug-free

games, you are going to have an EPO games. Just like, there is no way you can say Sydney was drug-free. You have no test for growth hormone, a major drug. It's not drug-free, but it sounds good.

And, I don't wish to paint a dismal picture, quite the contrary. I wish to paint a very progressive and happy outlook. I think things are going pretty darn well.

You know, back 20 years ago, we had no support. Now, look, we've got a room full of lots and lots of people and federal agencies and General McCaffrey who are really interested in this issue. And they are here because they care. That's why I stayed in the field. I don't need to do one more urine test, but I care about this. I really do care about this issue.

So, I'm absolutely and completely delighted to see so much interest. And, out of that, will come nothing but good things. It is not hopeless. Technology and testing, we can deal with this issue. There is lots of ways to deal with it. Now that we are beginning to harness the horsepower, we've got USADA coming on board and they are going to have some research funds. And we've got WADA. And the future looks just wonderful and I'm excited. Thank you.

Open Discussion

Question: I want to ask Mitt Romney if you want to add, because we did end with the panel on Salt Lake and the doping issues at the games, and –

Mitt Romney: I can't think of anything I'd add to that. That was very helpful. Dr. Katlin and our own team have been working together and I think we have very high hopes for doing an excellent job.

I think that Dr. Catlin makes a good point. It will not cover, identify everything, but, to the extent that modern medicine and modern science allow us to identify cheaters, we intend to do so and to take the steps necessary to do so.

Coach Steve Hill: Yes, thank you. May I just, we've heard from the research side and I would hate to have us end at that. You wouldn't have any young athletes left here in the room, they wouldn't understand. And, I think, in terms of education, there is not a lot of money that needs to be expended.

We have some fine organizations here already that have programs, the National Federation for Coaches. There are some vehicles already in place to help educate young athletes, their parents and their coaches. But, again, that information gets lost in the research.

Young athletes do not care about the side effects. They want the immediate results. And, when they see immediate results and they have a feeling that the things they are taking are going to bring about the accolades of success, then they are going to use. And they are going to use whatever is out there and whatever is available, research aside, side effects aside, that's not their concern.

They, the people who have emphasized that ethics, that value system, that's where we hit our young kids. And, I would hope that we don't lose sight that, often times when we "catch" those athletes cheating, often times that reinforces young athletes because they get that misperception that so many of these athletes have talked about that all successful athletes, all the lead athletes are using. That is the perception that is reinforced with them.

And, so, to have these elite athletes go to the media and have those media campaigns to say no, that's not the case, most athletes are not using. Those elite athletes that don't use need to have that forum to present their message.

Thanks.

Mickey Ibarra: Well, I'll tell you, I have enjoyed, so much, the opportunity to return to my hometown, Salt Lake City. And as the Co-Chair of this taskforce, I want to thank all of our taskforce members for their participation today. Also, I do believe that we learn most by listening, rather than talking.

And, I'll tell you this, I've certainly learned a lot today, as it relates to our panel on sports and

youth, hearing from our athletes, our science and research panel, the Salt Lake Anti-Doping Program, and also, of course, from the USOC.

And, I can pledge to you that we will do all that we can to insure that we capture this information and your recommendations. Consistent with the executive order of President Clinton, to report those recommendations to him and to the next President of the United States, to keep our progress moving forward.

I'd also like to thank Mitt Romney for the great leadership that he has provided here. He has been a wonderful partner to work with. I continue to look forward to doing that for 48 more days.

And, also to Barry McCaffrey, who, some of you may be aware, is going to get out the door just a couple of weeks before I do, on, I believe, January 7th. January 6th is actually his last day. And, again, I want to thank Barry McCaffrey for his continued leadership.

CLOSING REMARKS

BARRY R. McCAFFREY
Director, Office of National Drug Control Policy

Thanks, Mickey, for being my partner in all of this, along with Donna Shalala and Goody Marshall and others. There is a bunch of people in the room that should be recognized.

Just again, mention, Scott Blackman, we thank you for being here, your leadership. USOC has reinvented itself again. It was a pretty good team to start with and we look forward to the next group. And, you are under the spotlight for two years and we are very proud of the skills and the dedication you bring to bear in all this.

We thank Mitt for bringing us together out here and allowing the White House Task Force to engage in this conversation. To Frank Shorter, Terry Madden, USADA, you know, again, 15 years to build an institution. But, I think the first two years will show dramatic changes as we get a tool. Many have focused correctly on the notion that it is not catching cheaters that change the nature of the game, it is attitudes and ethics in sports.

Having said all that, many of you know, as well as I do, that when you put an effective drug testing regime in place, it allows the great kids, the young people to say, I can't use these drugs, I'd break the coaches heart, I'd let down my team mates. But you got to give them a tool and it's got to be credible.

And, so, Frank Shorter and to his effort and the research base, all of you who talk to the research base, we've got a lot to do. And, as Don Catlin mentioned, this is not beyond the frontiers of technology. It is a matter of getting organized. $150,000.00, that's embarrassing. You know, it is $200M to $400M to bring a drug online. We do that casually for lots of drugs.

All the athletes here, Donna de Varona, Johan Olav Koss, Brandon Slay, Heather Clarke, all of you, for, at end of the line, that is what this is all about and that is who we will perceive we are working for. Coach Hill for your remarks. You know, the big shapers of youth attitudes in America are the women and men who coach, not just visible sports, but all the way down to Little League and youth soccer.

We got all the federal participants in the room and they are staying into the next administration. The Department of Justice is here, Health and Human Services, Department of Education

You have suggested, today, it seems to me, an emerging agenda. We will write this down. We'll feed it back to you for your own comments. But, number one, you said we got an educational responsibility and it is targeted not just on young people, but also their mentors, their coaches, their team trainers, their physicians.

We are going to have to systematically build that, this again, can't be haphazard. You know, Rob Housman created the Coach-A-Thon in two months and we put it on the web and the Department of Justice and Health and Human Services whacked together a booklet and we sent it out. We got to be a little better organized than that. We've got to follow Donna de Varona's admonition and get people like Brandon out there talking to children. You know?

This is not high science. It's got to be changing one human heart at a time. And the people who have to be the spokesmen on that are people like Brandon and other heroes and heroines to American Youths. We've got to get Federal facilitation of this.

You know, at the end of the day, we don't have a minister of sports. I told Donna Shalala, you are it, she is a better athlete than the rest of us in the cabinet. I thought she would well serve the purpose. But we do have to have a continuing focus. That will be up to the Director of ONDCP and Health and Human Services Secretary.

And I think we ought to follow-up on Canada's offer of cooperation and help. You know, I make no bones about it, I was knocked out of my socks by how well the Australians were organized. I think the Canadians have thought through this thing and have a more coherent approach and we ought to learn from them and ask them to stand with us on the issue.

Point number two, we must raise the bar for Salt Lake. First of all, we've got to get going on science. As Don Catlin points out, EPO, we got to find out what can we do given the amount of time we've got, and investment research dollars we can bring to bear. We have a share of adequate federal support, DEA, customs education for the environment within which these games take place.

Every one that shows up in the United States of America in the coming two plus years for that competition, should understand when you set foot off the aircraft, you are now under the sovereign influence of U.S. Customs Inspection, Drug Enforcement Agency, etc. We must educate those coming to the games about that matter.

Third, we need to improve our own home. We have a problem as the host in which we are going to have to look and do something, as Gary Wadler says about things like supplements. And, we are going to have to build USADA until it is a credible organization, prior to the start of the games.

Fourth, we have to put the right structures in place. A lot of us have been impressed by what WADA has accomplished. It's got to be more than an observer. It's got to be an actor before the Salt Lake games.

Some deliverables, you know, what is it we are supposed to do coming out of this conference? I heard, quite clearly, show me the money. We have to go get adequate funding. This is not going to be difficult to do if you help. All right? And, I think part of it is just the transcript of this conference is going to be a step forward. We are going to go get the money.

Secondly, we do need to give Frank Shorter, Terry Madden and others some instrumentality of the United States status. We are going to have to make sure we do have an agency that can act as a

representative of the U.S. Government.

Third, we are going to have to do something about legal challenges. The Amateur Sports Act, the questions that were raised here today, DeShay. We are going to have to help with the legal challenges because at the end of the day sports associations aren't going to risk their future. People aren't going to serve on boards of directors if they think they are vulnerable to legal challenge.

We need serious research support. NIDA, you know, this is a $600M a year budget, this is 800+ scientists. These people are world class. We are going to have to get on the table with some continuing endorsement of this as a major area, scientific inquiry, and see if we can pull that together.

And then, finally, we, as a task force, the co-chair's, Mickey and I and others, must deliver to you the next administration. We may be leaving office, but we are not leaving the field of play. So, we will insure we do that.

That's what we owe you. Let me tell you what you owe me. And, I have four things, you might want to jot them down. First of all, you need to aggressively follow-up on these offers. You can't go home and think that was a tremendous exchange. I expect to see emails, letters and visits come out of here, in which, for one, you start tasking NIDA. You know, you understand how peer group science works, we need qualified requests for research funding hitting NIDA, so we get proposals from this community.

Secondly, you must help me work on legislation. If you live one kilometer beyond the Beltway, you have tripled the apparent credibility with Congress compared to those of us inside the Beltway. So, we are going to ask you not to become lobbyists, but, instead, to join us to provide a broad gauged endorsement for the requirement to change the law on some of these cases.

Third, when you see the new administration, whoever that may be, take shape, you've got to engage on them right off the spot. And, I'm going to make sure they know who the believable names are in this field. And then, you have to come up on the net and embrace them as they come in office and try and educate them and get them working immediately on these critical issues.

And, then, finally, it seems to me, one of the things that most encouraged me, you know, some of you in the room have been doing this for 20 years or longer. And, you know, you just, you've held it together, whether Don Catlin or Donna de Varona or Frank Shorter, whoever, now's the time not to lose faith. I think there is growing momentum. I thought, from the start, when I went to the IOC meeting, Lausane, Switzerland, I was in utter disbelief.

Like many Americans, you know, amateur athlete, college boxer, I've spent 10 years working with international organizations. I had never heard anything like this. I had never seen an organization that wasn't transparent, accountable, elected leadership, external audits, leadership that acted with a sense of integrity.

And, oh, by the way, we had these huge issues at stake, doping in sports, our children, and it was our money. When I say our money, it is Western European, it is the United States, and then we

listen to people like the South Africans, the Brazilians, the Mexicans, and they said, we will not tolerate this kind of unhealthy situation.

And, oh, by the way, we expect to have our voices heard. And, they are going to be heard. So, from the start, I thought there was an inexorable sense of momentum to all this. And, I think that's where it is going to come out.

We've got men and women of good will in the IOC, and, you know, the people that were added to office, I thought, were first rate. We have Dr. Henry Kissinger in the middle of the pile. I have, sort of, a primitive sense of belief in the man's ability to move issues along.

So, I think we are in good shape. But, at the end of the day, you know, we've got produce the goods. And, Mitt, again, thanks to you and your colleagues and the team you are assembling, and the 42,000 volunteers, and, we are behind you all the way.

Thanks very much all of you for being here.

Additional Comments from Genelabs Technologies for White House Task Force on Drug Use in Sports, December 7, 2000 Field Meeting.

Submitted by Marc Gurwith, M.D., Vice President Drug Development and Chief Medical Officer, Genelabs Technologies, Inc., 505 Penobscot Drive, Redwood City, CA 94063, (650) 562 1664, marcg@genelabs.com

During the White House Task Force meeting, a number of attendees made formal statements and informal comments deploring the fact that certain anabolic steroids such as DHEA (dehydroepiandrosterone), androstenedione, and related compounds are inappropriately and easily available as so-called dietary supplements. Genelabs Technologies, Inc. has been developing DHEA as a new drug for the treatment of SLE (systemic lupus erythematosus or "lupus"). Consequently, we have particular expertise and experience regarding DHEA. Therefore, our comments will be based mainly on our experience with DHEA, but, in general, apply to all such steroid hormones sold as dietary supplements. The evidence discussed herein supports that DHEA should not be available as a dietary supplement for two principal reasons: (1) it does not meet the definition of a dietary supplement under the the Dietary Supplement Health and Education Act (DSHEA) of 1994; and (2) it should be scheduled as a controlled substance under the Anabolic Steroid Control Act (ASCA) of 1990.

DHEA is a steroid hormone secreted by the adrenal glands. In humans, it is the most common hormone produced by the adrenals. In many tissues, DHEA is converted directly to androstenedione which is then directly converted to testosterone, and as such, DHEA is a direct precursor to testosterone, other androgenic, anabolic steroids, as well as estrogenic steroids. In the 1980s, researchers noted that women with lupus had abnormally low levels of androgenic hormones, including DHEA. It was shown in a mouse model of SLE that the mortality from SLE in these mice was considerably decreased by treatment with androgenic steroid hormones including DHEA. These findings, along with other studies of the immunologic effects of DHEA and other androgens, led to a number of studies of DHEA in women with lupus. These studies serve as the basis for Genelabs' NDA (New Drug Application) for DHEA as a treatment for lupus. The NDA is currently under review by the FDA.

Genelabs developed DHEA as a hormonal drug therapy for the treatment of lupus precisely because DHEA is an androgenic steroid hormone. The beneficial effects of DHEA and other androgenic steroids in lupus are related to immunologic and anabolic properties shared by these hormones. In our clinical studies, patients who received DHEA showed a significant increase in serum testosterone levels compared to placebo recipients. As described by several speakers including Coach Steve Hill, athletes similarly take high doses of androstenedione, DHEA or other related steroid hormones available as dietary supplements, for their performance-enhancing properties, specifically for their anabolic properties. However, unlike women with lupus, their levels of these hormones are not abnormally low. Their goal, whether they realize it or not, is to raise

their blood levels of these hormones, and consequently raise blood levels of testosterone, a controlled substance banned in the Olympics and most sports.

DHEA and other similar steroid hormones should not be available as dietary supplements. They are not found in the diet, but rather are potent steroid hormones similar to testosterone or estrogens. As steroid hormones, they have potential therapeutic benefits, but also carry long-term risks similar to those associated with testosterone or estrogens. These risks are particularly amplified in the case of steroid hormones masquerading as dietary supplements, since they are being taken without medical supervision and in inappropriate doses. Unsupervised access of these drugs to minors is particularly of great concern, since their effects on growth and sexual maturation of pre-pubertal children and adolescents in their growing phases are unknown. Young athletes taking anabolic dietary supplements in an attempt to enhance performance are in the age groups at highest risk.

Given the significant compelling medical concerns associated with the use and availability of DHEA and similar steroid hormones, this situation can easily be made better by simply having the government enforce the law (DSHEA) that sets the standards for dietary supplements. It is clear that these compounds (i.e., DHEA and similar steroid hormones) do not meet the definition of dietary supplements, as outlined in Supplement DSHEA. For a compound to be a dietary supplement, it has to be a vitamin, mineral, herb or other botanical, "dietary substance, " amino acid, or concentrate, metabolite, constituent, extract, or combination of the above. DHEA does not meet this definition. In addition, there are supplementary criteria outlined in DSHEA that DHEA also does not meet, such as the definition of "[A] dietary substance for use by man to supplement the diet by increasing the total dietary intake" since there is no dietary means to increase blood DHEA levels. DHEA is primarily secreted by and found in the adrenal glands, which are not part of the American diet.

It was emphasized by several participants that, in order to help support a drug-free Olympics, the FDA need only enforce DSHEA to remove DHEA and related anabolic steroid hormones from their easy and unsupervised availability under the guise of dietary supplements. As stated above, the safety concerns posed by the unsupervised use of these steroid hormones, of course, is an equally compelling reason for prompt enforcement of DSHEA with regard to these drugs.

As described above, DHEA does not meet the criteria for being freely available as a dietary supplement. In addition, it does meet the criteria for being scheduled as a controlled substance under the ASCA. Dr. Tolliver from the DEA described the four criteria and administrative procedure for scheduling a substance under ASCA. Eight related compounds including, androstenedione and DHEA, have been under review by the DEA for approximately two years. As he described, there is little question that DHEA (as well as androstenedione and the 6 other related compounds) meets three of the criteria: (1) DHEA is chemically similar to testosterone, (2) pharmacologically similar to it, and (3) is not an estrogen or progestin. However, according to the DEA, there is insufficient evidence from studies in humans for the fourth criterion: promotion of

muscle growth. For this reason, the DEA has started initial phases of animal studies to investigate whether androstenedione promotes muscle growth. In addition, animal studies to include all eight compounds, which will take two years to complete, are planned to be initiated during the summer, 2001, provided funding can be obtained. Under this proposed process, DHEA, androstenedione and related compounds would still not be treated as controlled substances before and during the Salt Lake City Olympics in 2002.

Although Genelabs is in favor of the conduct of studies, including studies in animal models, that may definitively confirm the anabolic effect of DHEA and related steroids, our experience with DHEA in toxicology studies has shown that animal studies may not be predictive of the human situation. In humans, DHEA is the most abundant steroid secreted by the adrenal glands. By contrast, DHEA is not a major steroid hormone in laboratory animals (Feher *et al*, 1977). In such animals, endogenous levels are considerably lower and its metabolism is different than in humans. In humans, the metabolite of DHEA, DHEA-S, which serves as a reservoir and a way of delivering DHEA to various tissues, circulates at blood levels 500 to 1000 times higher than DHEA itself. By contrast, in dogs, the ratio of blood levels of DHEA and DHEA-S is approximately 1:1. In dogs and other laboratory animals, the total of circulating DHEA and DHEA-S is less than 1% of that in humans.

Perhaps more relevant to the issue of demonstrating an anabolic effect in animal models is the fact that much higher levels of DHEA must be administered to laboratory animals to achieve blood levels comparable to that in humans. For example, in order to achieve blood levels of DHEA in the dog comparable to those achieved by orally administering 200 mg/day in humans (approximately 3 mg/kg/day), it was necessary to orally dose dogs with more than 30,000 mg/day (1500 mg/kg/day). Oral doses higher than 30,000 mg/day could not be practically administered to dogs. It is highly likely that a study in laboratory animals could not achieve levels of DHEA comparable to the levels expected for humans taking as much as 2000 mg/day.

Nonetheless, Genelabs believes there is already ample evidence demonstrating that DHEA is an anabolic steroid, and has submitted a Citizen's Petition to the DEA requesting that they follow the administrative procedures under ASCA to schedule DHEA as an anabolic steroid. A summary of the evidence for DHEA's promotion of muscle growth is provided below. As specifically provided under §1308.43(e) and §201(b) of the CSA (21 U.S.C.811(b)), to support a scheduling action only "substantial evidence" to support the rule is required; that is, evidence that is less than a "preponderance" but more than a "mere scintilla." For a scheduling decision on DHEA, clearly this test has been met.

There are a number of studies in humans demonstrating that DHEA promotes muscle growth. Genelabs has identified 7 published studies which are summarized in Table 1, and are described in more detail below. Although they used different methodologies for assessing increased muscle mass, four of these studies, Morales *et al.*, 1998, Diamond *et*

al., 1996, Nestler *et al.*, 1988, and Sugino *et al.*, 1998 demonstrated increases in muscle strength or muscle mass.

Table 1: Summary of Studies From the Literature

Literature Reference	Dose	Duration	Route	Study population	Criteria Assessed	Conclusions
Morales *et al.*, 1998	100 mg/ day	6 months	oral	healthy men and women 50-65 years	circulating sex steroids, body composition and muscle strength	in men lean body mass increased and muscle strength increased; in women lean body mass increased, but change was not statistically significant
Diamond *et al.*, 1996	3-5 g 10% DHEA cream (approx. 300-500 mg)/day	12 months	topical	60-70 year old women	mid-thigh fat and muscle area	femoral muscular areas were increased
Nestler *et al.*, 1988	1600 mg/ day	28 days	oral	healthy male subjects	body fat mass, serum lipids levels, tissue sensitivity to insulin	lean body mass increased
Sugino *et al.*, 1998	200 mg/ day	8 weeks	intra-venous	male patients with myotonic dystrophy	activities of daily living (ADL), muscular strength, percussion and grip myotonia, arrhythmia	improved ADL with increase in muscular strength and decrease in myotonia.
Usiskin *et al.*, 1990	1600 mg/ day	28 days	oral	young obese men	weight and body fat mass	no increase in lean body mass
Welle *et al.*, 1990	1600 mg/ day	4 weeks	oral	healthy men 20-43 years	energy expenditure and muscle protein synthesis	no significant effect on lean body mass.
Mortola and Yen, 1990	1600 mg/ day	28 days	oral	post-menopausal women	serum hormones, serum and urine chemistries, percent body fat and body weight	no increase in lean body mass

In a placebo controlled, double-blind, crossover trial, Morales *et al.*,1998, studied the effects of 100 mg/day of DHEA administered for six months to healthy, age advanced (50-65 years) men and women. In both men and women, lean body mass increased compared to baseline or to placebo, but the difference was statistically significant only in men. Muscle strength, as measured by tests of lumbar back and knee strength increased in men but not in women.

Changes in body muscle mass have also been reported in women receiving DHEA chronically. Diamond *et al.* (1996) evaluated the effect of DHEA replacement therapy in fifteen 60- to 70-year-old women who received a single daily percutaneous application of 3 to 5 grams 10% DHEA cream for 12 months (equivalent to approximately 300 to 500 mg DHEA applied percutaneously daily for 12 months). Seven of the women received a placebo cream for 6 months after cessation of DHEA therapy. Compared to baseline, there were no mean changes in body weight but a 9.8% reduction in subcutaneous skinfold thickness at 12 months ($P<0.05$). Mid-thigh fat was reduced by 3.8% ($P<0.05$) while femoral muscular areas were increased by a mean of 3.5% ($P<0.05$).

In an earlier study, Nestler *et al.* (1988) and colleagues compared DHEA and placebo in a double-blind, randomized parallel group design, in 10 healthy subjects. In contrast to the Morales *et al.* (1998) study, the population investigated was young men, the dose of DHEA was higher (1600 mg/day), but the duration was shorter (28 days). In the DHEA group, mean percent body fat decreased by 31%, with no change in weight, suggesting that the reduction in fat mass was coupled with an increase in muscle

Sugino *et al.* (1998) administered DHEA-sulfate ([DHEA-S] which is interconverted to DHEA intracellularly, and which acts as a transport and reservoir for DHEA) 200 mg/day intravenously for 8 weeks to 11 patients with myotonic dystrophy. Myotonic dystrophy is an autosomal dominant disease characterized by weakness, myotonia (tonic spasms of muscles), and multi-system abnormalities. Adrenal androgen levels are reduced in this disease, compared with age matched healthy controls. The study showed improved activities of daily living, muscle strength and decreased myotonia, consistent with anabolic effects of DHEA in males. As patients with this disease have low serum DHEA and DHEA-S concentrations which are probably due to decreased production rather than increased clearance, it would be anticipated that treatment with DHEA would improve muscle performance.

There have been three published studies where DHEA administration was not shown to increase muscle mass. Nestler's group conducted a study similar to their previous study (described above), comparing DHEA and placebo in six young obese men (Usiskin *et al.*, 1990). The dose and duration of DHEA were the same as in the previous study, but the latter study differed in design; it was a single-blind study where the study population received placebo for 28 days, followed by DHEA for 28 days. In this latter study, no differences from placebo in body weight, body fat mass, or waist-to-hip ratio was observed during the study

The authors offered several explanations for the lack of effect of DHEA administration found in this study compared with their earlier work. These included differences in study design and/or the possibility that obese individuals might be relatively resistant to effects of DHEA on metabolism. On a total weight basis, obese subjects received a dose which was 20% lower than that administered in the previous study; differences in body habitus (obese vs. non-obese) may in some way alter the catabolism of DHEA to androgens, estrogens or other metabolically active metabolites. In addition, since all subjects received DHEA only during the second 28 day phase (they were blinded as to treatment

order), there may have been a lack of compliance with a four time per day regimen during the later portions of the study.

Another study in men was conducted by Welle *et al.* (1990) where protein metabolism was studied in eight healthy men who received placebo and DHEA (1600 mg/day) for 4 weeks each in a double-blind cross-over study. There was no significant effect on body weight or two indices of lean body mass (total body water and total body potassium), and no effects on parameters of energy and protein metabolism, including resting metabolic rate, total energy expenditure, leucine flux (an index of whole body proteolysis), the non-oxidized portion of leucine flux (an index of whole body protein synthesis) and the rate of incorporation of leucine into muscle proteins.

Finally, Mortola and Yen (1990) treated six postmenopausal women with DHEA 1600 mg/day (in four divided doses) for 28 days in a double-blind, placebo-controlled cross-over study. Per cent body fat (determined by underwater weighing) did not change during either DHEA or placebo treatment, but this too is not a direct measurement of muscle mass and/or strength.

In summary, Genelabs has identified 7 published studies where the effect of DHEA on muscle mass has been investigated. These studies vary widely in type of patient or subject studied, dose and duration of DHEA, and types of assessment of changes in muscle mass or strength. Taken as a whole, the studies demonstrate that DHEA increases muscle mass. The most convincing data are from the studies in an elderly population (who are relatively deficient in endogenous DHEA and testosterone) with relatively high chronic dosing. The fact that some studies were negative largely reflects the fact that optimally to show an anabolic effect in young healthy volunteers, high doses of DHEA, chronically administered, accompanied by strength training may be required. As with testosterone, demonstrating that DHEA increases muscle mass is easier in populations with low levels of androgens, such as the elderly or hypogonadal males. To demonstrate an effect of testosterone on muscle mass in healthy young men required supraphysiologic doses and, in some cases, strength training (Bhasin *et al*, 1996.), precisely the setting where testosterone is abused and where DHEA and other similar steroid hormones, available as dietary supplements, are promoted.

This situation is not substantially different from early studies with testosterone. In fact, many of these studies were inconclusive due to a number of factors including lack of control for intake of energy and protein, lack of standardization of exercise stimulus, and most importantly, doses of androgenic steroids used in previous studies were too low (see Bhasin *et al*, 1996 for a discussion on these shortcomings). Surprisingly, it was not until 1996 when Bhasin for the first time administered 600 mg per week of testosterone enanthate to men that testosterone was conclusively shown to be anabolic in man. The dose of 600 mg per week was known to be lower than that used by body builders but was higher than any previously studied dose.

Thus, there are data showing that DHEA increases muscle mass in DHEA deficient or relatively deficient populations, when dosed at high enough and for a long enough time

period. It is apparent that to show anabolic effects would require studies in which volunteers would have to receive potentially dangerously high doses of DHEA (1000 to 2000 mg/day for many months) without any therapeutic benefit. Such studies, as well as being unethical, are unnecessary.

As described above, DHEA is a direct precursor of testosterone, and is converted to it in the body. Taking DHEA in the high doses reported anecdotally by athletes (as much as 2000 mg/day) will lead to high levels of testosterone, with testosterone's well-recognized anabolic effects and toxicity. For example, in the Genelabs' placebo-controlled studies of DHEA in women with lupus, there was a dose-related increase in blood levels of testosterone with the administration of DHEA. The most common side effects associated with DHEA in these studies were acne and hirsutism or facial hair growth, side effects expected from testosterone. Blood levels of testosterone, prior to receiving DHEA or placebo, were approximately 20 ng/ml or lower. After completion of up to one year of treatment, blood levels were slightly lower in the placebo group, while they doubled to approximately 40 ng/dl in women receiving 100 mg/day of DHEA, and were almost double again to approximately 70 ng/dl in women receiving 200 mg/day. [Note: These are the levels of testosterone achieved by women who were taking therapeutic doses of DHEA.] Young athletes indiscriminately and without supervision may take 10 times the amount of DHEA used in our studies, which would mean that these athletes would achieve substantially greater blood levels of testosterone than those described above.

In summary, ASCA requires that the DEA schedule substances as controlled drugs that meet the four criteria described previously. DHEA meets each of these criteria. Neither ASCA nor common sense require that every single study, no matter what its design, dose or patient population, show that DHEA does promote muscle growth. Studies that meet scientific and ethical standards have shown that DHEA promotes muscle growth. It is for this reason that DHEA is promoted and sold to athletes as a dietary supplement to increase muscle strength. Athletes take DHEA, frequently at doses that could not ethically be administered to volunteers in scientific studies, in order to achieve increased muscle strength and mass. Studies have shown that DHEA increases levels of testosterone and others potent anabolic steroids which are known to increase muscle strength. These studies have also shown that women receiving DHEA have the side effects associated with testosterone, i.e., acne and hirsutism or facial hair growth.

Thus, there is already sufficient evidence for the DEA to make an informed judgment. By planning and relying on animal studies of unknown relevance to the human situation, the DEA will needlessly delay for more than two years an important assessment. In fact, at least three other countries have already made this assessment: that DHEA and related androgenic steroids are anabolic steroids which should be scheduled as controlled substances. DHEA is considered an anabolic steroid in Canada, the United Kingdom, and Australia; and treated as a controlled substance in Canada and the United Kingdom and is banned in Australia. They are banned by most major sports and by the IOC. DHEA and similar steroid hormones, in the form of unregulated dietary supplements, for which DHEA and similar steroid hormones clearly do not meet the definition, have been shown to be contaminated by substances such as nandrolone, and to have the potential for

causing urine tests to be positive for nandrelone. The easy availability in the United States of DHEA and related steroid hormones continues to jeopardize athletes here, and now will jeopardize the upcoming Olympics.

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December 20, 2000

General Barry R. McCaffrey
Director, ONDCP
Executive Office of the President
Washington, DC 20503
RE: Task Force Record

Dear General McCaffrey:

Having worked as a senior communications specialist for the National Youth Anti-Drug Media Campaign during the past two years, I am pleased to see your sincere interest in working with sports and athletes as a vehicle to effectively communicate with America's youth.

The recent White House Task Force on Drug Use in Sports in Salt Lake City was an excellent place to begin the dialog of creating a strategy of reaching kids through the 2002 Olympic Games.

As discussed at the Task Force meetings, it is vital to continue research in the areas of doping among athletes. However, I am disappointed that little time was spent discussing the youth outreach anti-doping educational program even though the consensus was that education was equally as important as research.

It is unfortunate that the ONDCP's National Youth Anti-Drug Media Campaign does not currently allocate any resources to youth outreach through sports. The sports-related programs that have been developed by the Media Campaign's contractors have primarily been created as an appendage of other youth-serving organizational relationships that have been developed through the "partnership initiatives and stakeholder communications" aspect of the Campaign.

In order for the Task Force to be effective, resources for a "youth education through sports program" need to be allocated directly by the ONDCP or as part of the Media Campaign.

The Youth Empowerment Alliance's sole purpose is to develop these youth-serving educational programs through our vast network of grassroots organizations and media. We have been working closely with the 80,000-member World Olympians Association to develop an anti-doping platform. The ONDCP's financial support of this multi-media initiative would give it the power it deserves.

Again, thank you for your leadership in fighting drug use among America's youth.

With sincere regards,

Sherry Sacino, President
Youth Empowerment Alliance

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8. The Deseret News (Salt Lake City, UT), December 8, 2000, Friday, LOCAL;, Pg. B10, 556 words, SLOC vows to catch drug cheaters, By Derek JensenDeseret News staff writer

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11. National Public Radio (NPR), MORNING EDITION (11:00 AM on ET), December 8, 2000, Friday, 707 words, US DRUG CZAR'S TASK FORCE OUTLINES PLAN TO PREVENT DRUG USE AMONG ATHLETES ATTENDING 2002 WINTER OLYMPICS, BOB EDWARDS, HOWARD BERKES
12. The Salt Lake Tribune, December 8, 2000, Friday, Final; Pg. C1, 910 words, Task Force Tackles Sports Drug Abuse; Secrecy, diet supplements cited as big hurdles; Chemicals, CHRISTOPHER SMITH, THE SALT LAKE TRIBUNE

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18. The Associated Press, December 7, 2000, Thursday, BC cycle, Sports News, 502 words, Experts discuss goal of a clean Games, By C.G. WALLACE, Associated Press Writer, SALT LAKE CITY

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21. The Deseret News (Salt Lake City, UT), December 7, 2000, Thursday, WIRE;, Pg. A01, 442 words, Goal is drug-free Games, By Lois M. CollinsDeseret News staff writer

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31. The Deseret News (Salt Lake City, UT), December 6, 2000, Wednesday, WIRE;, Pg. A20, 583 words, Drug czar stresses strict tests, ethics, By Matt Kelley Associated Press writer

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33. The Salt Lake Tribune, December 6, 2000, Wednesday, Final; Pg. A6, 577 words, 2002 Backdrop for Anti-Drug Message, CHRISTOPHER SMITH, THE SALT LAKE TRIBUNE

The Deseret News (Salt Lake City, UT)

December 8, 2000, Friday

SECTION: LOCAL; Pg. B10

LENGTH: 556 words

HEADLINE: SLOC vows to catch drug cheaters

BYLINE: By Derek JensenDeseret News staff writer

BODY:
The Salt Lake Organizing Committee will run about 1,000 random, out-of-competition drug tests on athletes before and during the 2002 Winter Games.

"We will catch the cheaters," SLOC President Mitt Romney told members of the **White House Task Force** on Drug Use in Sports Thursday.

But making the Salt Lake Olympics the cleanest Games ever will require more than just random testing, according to members of the task force.

"Our program is designed to test drug-free athletes," Dr. Douglas Rollins, SLOC's **doping**-control medical director, said. "It's going to be your efforts in the next few months to see that drug-free athletes come to Salt Lake City."

The task force, chaired by White House drug czar Barry McCaffrey and made up of former Olympic athletes, doctors and representatives from SLOC, the U.S. Olympic Committee and International Olympic Committee, met for the first time Thursday in downtown Salt Lake City.

According to many on the task force, keeping drugs out of national and international competition requires a change in societal values.

"It's not catching cheaters that changes the nature of the game," McCaffrey said.

Canadian Olympic rower Heather Clarke said **doping** will only end when it becomes socially unacceptable.

"Young athletes do not care about the side effects, they care about the immediate results," Steve Hill of the Davis School District Safe School Staff said.

The focus needs to be returned to doing your best instead of being the best, Clarke said.

According to many on the task force, Sydney was a turning point for anti-**doping** efforts. But there were still the drug controversies surrounding U.S. shotputter C.J. Hunter and Romanian gymnast Andreea Raducan. Hunter tested positive for a banned substance in an out-of-competition test, although he was not on the U.S. Olympic team. Raducan had her gold medal stripped after she tested positive for a banned stimulant contained in cold medicine she took at the advice of a team physician.

"The Sydney experience may indeed be a net negative our public had on having a clean sport," said Canada's federal **doping** policy director Ole Sorensen. "At the inner levels, we can say we've definitely moved ahead."

Organizations such as the World Anti-**Doping** Agency and U.S. Anti-**Doping** Agency have brought together a worldwide coalition to fight against performance-enhancing drugs.

But keeping up with the ever-changing drug market is difficult because of the intense pressure many athletes are under to use drugs.

"They are supported by an incredibly complex underground that could run rings around what we do," said Dr. Don Catlin, director of the UCLA/IOC Lab.

Drug testing is usually a step or two behind the latest drugs on the market. SLOC and the IOC are working to develop a more accurate test for erythropoietin, commonly called EPO, for the 2002 Winter Games. EPO is a performance-enhancing hormone that boosts production of red blood cells, providing the body with more oxygen for a time. It will likely be the drug of choice for the Winter Games.

The first tests for EPO were conducted in Sydney for the 2000 Summer Games, but many questioned the credibility of those results.

"It's a very complex test and it needs a lot more work to get it online and to be litigation-proof," Catlin said.

E-MAIL: djensen@desnews.com

LOAD-DATE: December 8, 2000

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SHOW: MORNING EDITION (11:00 AM on ET)

December 8, 2000, Friday

LENGTH: 707 words

HEADLINE: US DRUG CZAR'S TASK FORCE OUTLINES PLAN TO PREVENT DRUG USE AMONG ATHLETES ATTENDING 2002 WINTER OLYMPICS

ANCHORS: BOB EDWARDS

REPORTERS: HOWARD BERKES

BODY:
BOB EDWARDS, host:

White House drug czar Barry McCaffrey says the next Olympics won't involve as much illicit drug use as the last. The 2002 Winter Games take place on American soil, and McCaffrey's pledge is made amid international skepticism of the American anti-**doping** effort. That drug-fighting plan was outlined yesterday in Salt Lake City, the host of the 2002 Winter Olympics. NPR's Howard Berkes reports.

HOWARD BERKES reporting:

Barry McCaffrey's **White House Task Force** on Drug Use in Sports convened in a downtown hotel, just across the street from the plaza where Olympic athletes will receive their medals, just up from the arena where skaters will glide for gold and just beyond the morning shadows of the Wasatch Range, where skiers, sledders and jumpers will compete. The task force set goals for the Salt Lake Olympics as lofty as that mountain backdrop.

Mitt Romney directs the Salt Lake Olympic Organizing Committee.

Mr. MITT ROMNEY (Director, Salt Lake Olympic Organizing Committee): Now I want you to know that we are 100 percent committed to having clean, drug-free Games in Salt Lake City in 2002.

BERKES: Mickey Ibarra is President Clinton's adviser on intergovernmental affairs.

Mr. MICKEY IBARRA (Clinton Adviser): Salt Lake will be the most drug-free Winter Olympic Games ever held. We think you can bank on that.

BERKES: And Barry McCaffrey is the White House drug czar.

Mr. BARRY McCAFFREY (White House Drug Czar): And what we want isn't to catch cheaters. It's to assure world-class athletes that you can go compete based on talent and expect to win or lose on that basis.

BERKES: More than 5,000 drug tests are planned before and during the Salt Lake City Games. Half will be surprise tests. But the task force's testing experts warn they don't necessarily keep pace with the development of new performance-enhancing substances. Gary Wadler is a physical and medical adviser to the task force.

Dr. GARY WADLER (Task Force Adviser): It seems like every time a new drug or technology is developed, an athlete determined to gain athletic advantage finds a way to misuse or abuse that drug or technology, perverting its original intent.

BERKES: And athletes who cheat figure out how to hide their use of banned substances. The drug of choice at the Salt Lake Olympics is expected to be EPO, which builds endurance. New drug tests for EPO premiered at last summer's Olympics in Sydney. They were credited with prompting more than two dozen athletes to pull out of the Games. But they're not fool-proof yet and probably won't be before the Salt Lake City Olympics, according to Don Katlan(ph) , who conducts drug tests for the International Olympic Committee.

Mr. DON KATLAN (International Olympic Committee): Look, 14 months away. This is a big project, and if you want to try to really carve new territory, you have to start it before. It takes a long time.

BERKES: Some at the meeting were also concerned that the rest of the world won't trust the Salt Lake City testing effort. That stems from revelations in Sydney and allegations and lawsuits that the US Olympic Committee suppresses positive drug tests of American athletes. This is how the international suspicion is describe by Johan Olva Koss, a speed-skating gold medalist and member of the International Olympic Committee.

Mr. JOHAN OLVA KOSS (Gold Medalist; International Olympic Committee): Perception internationally is bad about USA and what USOC or other national governing bodies has done to protect their athletes and help them cheat. This is the perception. I mean, there is no way you ask anyone outside United States to believe that American athletes has not been cheating.

BERKES: US Olympic officials say this is all a misunderstanding over the Amateur Athletics Act, which requires a hearing for athletes before positive drug tests are revealed. But American Frank Shorter disagrees. Shorter is a former marathon runner and chair of the new US Anti-**Doping** Agency.

Mr. FRANK SHORTER (Chairman, US Anti-**Doping** Agency): We used the Amateur Sports Act as an excuse not to give any information to anyone. It was not by law that this was required, and yet it was held out that it was by law that it was required.

BERKES: Shorter's agency will test American athletes competing in Salt Lake City and will make the results available on demand to accredited international Olympic groups. But the results won't be made public until after two tests, a scientific review and a hearing. That could take a month, which could still strain credibility. Shorter adds that his agency will preserve blood and urine samples indefinitely so that new tests for drugs can be applied later. An athlete testing positive long after the Games still might lose a medal. That, he says, should be a powerful deterrent.

Mr. SHORTER: It's the fear of getting caught that we're trying to create here. We're not really trying to catch anybody.

BERKES: The drug testing begins next year as athletes train and quality for the 2002 Games. Howard Berkes, NPR News, Salt Lake City.

LOAD-DATE: December 8, 2000

The Salt Lake Tribune

December 8, 2000, Friday

SECTION: Final; Pg. C1

LENGTH: 910 words

HEADLINE: Task Force Tackles Sports Drug Abuse; Secrecy, diet supplements cited as big hurdles; Chemicals

BYLINE: CHRISTOPHER SMITH, THE SALT LAKE TRIBUNE

BODY:

The effort to restore American credibility in the international fight against chemical cheating in sport faces two major hurdles: disclosure and dietary supplements.

Clearing both may require acts of Congress, members of the **White House Task Force** on Drugs and Sport were told Thursday in their inaugural meeting in Salt Lake City.

Testimony was unanimous in the threat that performance-enhancing drugs pose to all levels of sport -- from Little League to Olympics to the NBA -- and the public health crisis to children who use drugs and supplements to emulate athletic role models.

But the discussions were punctuated by two debates:

-- When and how disclosure of athletes who test positive on a drug screen should occur.

-- The need to declassify dietary supplements which become steroids after ingestion and reclassify them as prescription drugs or controlled substances.

The U.S. Olympic program is still suffering from international criticism leveled in Sydney that USA

Track and Field failed to report positive tests and covered up the positive test of shot-putter C.J. Hunter, who was named to the team but did not compete.

Track's national director, Craig Masback, said those charges are "demonstrably false," partially blaming the allegations on the American legal standard of due process that requires sporting bodies to maintain the confidentiality of the athlete until a final determination of guilt or innocence is made.

"The provision of the Amateur Athletic Act that you may not suspend or remove from competition someone who hasn't had a hearing ultimately undermines the overall effort we have here," Masback said, If an athlete tests positive in a medically reviewed drug screening, Masback said, "let's get that athlete off the playing field. Right now, the law of the United States prevents that."

The new U.S. Anti-**Doping** Agency assumed athletic drug test responsibilities for all U.S. Olympic sports in October. USADA boss Terry Madden said he believes in complete transparency.

"No longer do we expect our [national governing bodies of sport] to be accused of delaying testing or hiding test results," said Madden. "We have nothing to hide."

But USADA has joined with the U.S. Olympic Committee in asking a federal judge in Colorado to prevent public disclosure or discussion of hundreds of positive drug test results of Olympic hopefuls that the USOC's former drug control chief wants to use as evidence in a lawsuit. Asked how that desire to conceal test results squares with the United States' proclamation of transparency, White House drug czar Barry McCaffrey conceded, "It's very difficult."

"You can't jeopardize your standing by pouring your lifeblood into failed legal action," he said. "We will have to carefully step through this. USADA may not be built in a day. There may be a requirement to go back and re-look at national U.S. legislation."

USOC acting CEO Scott Blackmun said athletes are divided on the question of disclosure. "I would challenge U.S. athletes to answer the question whether the fundamental notion of due process embedded in our system should have application to **doping** issues," he said.

Salt Lake Organizing Committee President Mitt Romney said his guiding principal on drug testing for 2002 is simple: "It's inexcusable to hide the truth."

Another area of **doping** that may require congressional tinkering involves dietary supplements known as "steroid precursors." Although substances such as androstenedione and 19-norandrostenedione metabolize into anabolic steroids -- a controlled substance -- once they are ingested, they are sold over the counter to customers of any age under the Dietary Supplement Health Education Act of 1994, sponsored by Sen. Orrin Hatch of Utah.

"The legal stand in the U.S. is you don't necessarily have to say what is contained in these supplements, and a lot of these supplements are produced right here in Utah," said Johan Olav Koss, a physician and former gold medalist who serves on the World Anti-**Doping** Agency. "

The Drug Enforcement Agency's top researcher on dietary supplements, Jim Tolliver, said eight steroid precursors are currently sold as dietary supplements and they meet the definition of anabolic steroids in all but one category, scientific proof of muscle growth. Tolliver said the DEA needs $ 400,000 to study the muscle-building characteristics of the eight dietary supplements now marketed as performance enhancers.

Other experts called for immediate amendments to federal law to require the steroid precursors -- which have legitimate medical purposes such as treatment of lupus -- to be sold only as prescription drugs.

"We are enabling young people to increase their estrogen on a prolonged basis," said New York University **doping** expert Gary Wadler, noting the increased risk of breast and uterine cancer in women from estrogen supplements. "It's a public health crisis. I really ask Sen. Hatch to revisit that act,

specifically toward the definition of a steroid precursor, which isn't even mentioned in his legislation."

McCaffrey said he planned to meet with Hatch to discuss problems with the dietary supplement law.

"We put 50 years of work into getting the Food and Drug Administration laws to handle dangerous drugs," said McCaffrey. "Now, we've developed this parallel system of frequently goofy substances that are available in grocery stores. It doesn't make much sense."

GRAPHIC: Olympic medalists Brandon Slay, left, and Donna DeVarona discuss drug control policies with Barry McCaffrey, White House drug czar, Thursday in Salt Lake City.

LOAD-DATE: December 12, 2000

The Associated Press

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December 7, 2000, Thursday, BC cycle

SECTION: Sports News

LENGTH: 502 words

HEADLINE: Experts discuss goal of a clean Games

BYLINE: By C.G. WALLACE, Associated Press Writer

DATELINE: SALT LAKE CITY

BODY:
More aggressive drug testing will help keep the 2002 Winter Games clean, members of the **White House Task Force** on Drug Use in Sports said Thursday at their first meeting.

The group discussed how to develop tests to detect the ever-changing drugs used by athletes, and how to educate athletes, coaches and the public about the problem.

Scott Blackmun, president of the U.S. Olympic Committee, said the use of performance-enhancing drugs violates the spirit of the Games.

"What we're really talking about is competing to your best ability," he said. "And **doping** undermines that."

Frank Shorter, the chair of the U.S. Anti-**Doping** Agency, said substantially more athletes will be caught by drug testing during the next five years.

Shorter said his agency, which is running the USOC's anti-drug efforts, plans to conduct 5,000 drug tests next year - half of them unannounced, out-of-competition screenings.

But even while drug screening becomes more aggressive, scientists, athletes, politicians and researchers

agree that testing alone won't solve the problem.

Many suggested that the push to be the very best has overshadowed the pureness of competition.

"We must protect the overwhelming majority of athletes that play clean," said task force co-chair and White House drug czar Barry McCaffrey.

Another problem, McCaffrey said, is the widespread use of herbal supplements that "can be bought at the corner Safeway."

Dr. Gary Wadler, medical adviser to the Office of National Drug Control Policy, called the widespread use of supplements a public health crisis.

He said Sen. Orrin Hatch should hold hearings to revisit his 1994 Dietary Supplement Health and Education Act, which limited the authority of the Food and Drug Administration to test and regulate food supplements.

But the real issue, said Dr. Don Catlin, director of the joint IOC and University of California at Los Angeles drug-testing lab, is the banned performance-enhancing hormone called EPO, which will be the drug of choice for the Winter Olympics.

EPO, or erythropoietin, enhances endurance by boosting the production of oxygen-rich red blood cells.

The first test for EPO was introduced during the Sydney Olympics, although questions were raised about its credibility. Catlin said a new test must be developed before 2002.

"Without it, you're not going to have a drug-free games, you're going to have an EPO games," he said.

As for the Salt Lake Games, organizing committee president Mitt Romney vowed that no one will be above the anti-**doping** rules and it will be inexcusable to hide the truth.

Mickey Ibarra, task force co-chair and assistant to the President, said Utah has made much progress in preparation for the 2002 Olympics.

"Now I think we're building a level playing field," he said.

On the Net:

Office of National Drug Policy: http://www.whitehousedrugpolicy.gov

Salt Lake City Olympic organizers: http://www.slc2002.org

Anti-**doping** information: http://www.playclean.org

LOAD-DATE: December 8, 2000

The Deseret News (Salt Lake City, UT)

December 7, 2000, Thursday

SECTION: WIRE; Pg. A01

LENGTH: 442 words

HEADLINE: Goal is drug-free Games

BYLINE: By Lois M. CollinsDeseret News staff writer

BODY:
The nation's leading drug policymaker believes Utah's Winter Games in 2002 will be the most drug-free in recent memory, building on successful drug-free efforts in Sydney, but it will require a concerted effort to make that happen.

Some of the strongest support is coming from within the ranks of the athletes, said Gen. Barry McCaffrey, the federal drug czar. "Athletes are demanding that we do it.

"Winners are uniformly suspect," he said, and they are driving the move to "go transparent and respond to some international rules," including a "common code of banned substances."

"How can we have sports records that are being artificially generated by sports pharmacies?" McCaffrey asked.

Recent events have shown a change in attitude. When the United States suggested that Olympic anti-**doping** efforts should be overseen by an independent international agency, McCaffrey said he received "essentially a blow-off from the IOC."

But the United States was not standing alone in its desire to see the Games drug free. McCaffrey had what he calls a huge groundswell of support. And the World Anti-**Doping** Agency (WADA), a semi-independent agency, was born in time for the Sydney Summer Olympics.

The Sydney Games were "unquestionably the most drug-free Olympics in modern history," he said during a meeting with the Deseret News editorial board as part of his two-day stay in Utah to promote a no-drug-tolerance agenda for professional athletics. He also spoke Wednesday in Park City to the Utah Olympic Public Safety Command. Thursday, he was to convene the first-ever **White House Task Force** on Drugs and Sports in Salt Lake City.

During both the Atlanta and Los Angeles Games, McCaffrey said, "allegedly positive" drug test samples disappeared.

The antidrug message got through even before the Sydney Games. McCaffrey said China dropped 27 people from its team before it went to the Games. And athletes from all over the world who did use banned substances were disqualified and even stripped of medals

To promote the no-**doping** effort, Olympic officials will conduct 5,000 out-of-cycle drug tests of athletes in the next year -- half of them with no notice to the athletes.

Officials believe there may even be time to develop a test for human growth hormone before the Salt Lake Games.

There will be "absolutely greater safeguards in Salt Lake," McCaffrey said. "We have to get back to the purity of sports."

McCaffrey said that, as his term as drug czar comes to a close, "I'm astonished at what we did. I was not a volunteer. I did not want this job. But we came a long way. A lot more needs to be done."

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The Deseret News (Salt Lake City, UT)

December 6, 2000, Wednesday

SECTION: WIRE; Pg. A20

LENGTH: 583 words

HEADLINE: Drug czar stresses strict tests, ethics

BYLINE: By Matt Kelley Associated Press writer

BODY:
WASHINGTON -- Strict drug tests and a renewed focus on athletic ethics are needed to keep Olympic competitors from souping up their bodies with banned substances, White House drug policy director Barry McCaffrey said Tuesday.

McCaffrey will be in Salt Lake City to convene the **White House Task Force** on Drugs in Sports for discussions on ways to minimize **doping** in the 2002 Winter Games on Thursday.

While in Utah, McCaffrey will also meet separately with Mitt Romney, the president of the Salt Lake Organizing Committee, on Thursday, to discuss the **doping** issue. He was also to address the Utah Olympic Public Safety Command on Wednesday in Park City.

The task force includes Olympic officials, athletes, Utah Gov. Mike Leavitt and Brandon Slay, the American wrestler belatedly awarded a gold medal this year after his German opponent failed a drug test.

"What competitors want is an assurance that they don't have to use performance-enhancing drugs," McCaffrey said. "They're not after catching the cheaters. They want to make sure that when they go out to run, to ski, to jump, that it's a level playing field. I think that's what testing can do."

U.S. Olympic officials have turned over drug testing programs to an agency that plans 5,000 drug tests next year -- half of them unannounced, out-of-competition screenings.

The federal government also is chipping in $3.3 million for anti-drug efforts in the Salt Lake City Games. McCaffrey, who steps down as White House drug policy chief Jan. 6, said he thinks the drug screening process for the Utah games will be a strong deterrent.

"I think that right now, if you're out there in Ulan Bator or Hawaii or Beijing and you're looking at the Salt Lake Winter Olympics, you and your coach and your trainer ought to say, 'We'd better go with our talent, good nutrition and coaching, because we don't want to risk the shame of winning and being exposed,' " McCaffrey said.

McCaffrey has strongly criticized past anti-drug efforts by the International Olympic Committee and other sports groups, saying they were too lax to act as a credible deterrent. Drug testing during year's games in Sydney marked a turning point, however, McCaffrey said.

Dozens of athletes either failed drug tests or avoided the Olympics for fear of testing positive, and several medal winners were disqualified because of drug tests. Rather than sullying the Olympic image, those tests helped give fans confidence that the winners weren't chemically cheating, McCaffrey said.

The drug question also has dogged the U.S. Olympic Committee. Claims that the USOC was lax on drugs intensified when news leaked in Sydney that shot putter C.J. Hunter, husband of Olympic track medalist Marion Jones, failed four drug tests in Europe last summer.

In October, the USOC turned over its anti-drug efforts to the U.S. Anti-**Doping** Agency, an independent board headed by 1972 marathon gold medalist Frank Shorter. McCaffrey said he was confident Shorter's organization was independent and qualified enough to perform fair and accurate tests.

The International Olympic Committee also has created a semi-independent World Anti-**Doping** Agency, which McCaffrey said is a good step but needs more independence to be completely effective. Still, all the trends are in the right direction, McCaffrey said.

"I think we ought to be pretty optimistic," McCaffrey said. "If you feel it's hopeless, you turn off the TV set, walk away from athletic competition and do something else."

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The Salt Lake Tribune

December 6, 2000, Wednesday

SECTION: Final; Pg. A6

LENGTH: 577 words

HEADLINE: 2002 Backdrop for Anti-Drug Message

BYLINE: CHRISTOPHER SMITH, THE SALT LAKE TRIBUNE

BODY:

The Salt Lake City 2002 Olympics will be the backdrop for efforts by a White House panel to warn athletes and youth about the health dangers of performance-enhancing drugs in sport.

"It's a terrific opportunity to try and regain a competition based on God-given talent, in lieu of who has the best pharmacologist," said Gen. Barry McCaffrey, director of the Office of National Drug Control Policy, who will convene the first meeting of the **White House Task Force** on Drugs and Sport in Salt Lake City on Thursday.

The group was formed to recommend ways the federal government can raise awareness over the health dangers and competition fraud posed by steroids and other chemical performance enhancers. Participants at Thursday's meeting will include former Olympian Frank Shorter, who is now chairman of the U.S. Anti-**Doping** Agency; Johan Olav Koss, four-time Olympic speed-skating gold medalist; and USA wrestler Brandon Slay, who was awarded the gold medal after drug tests in Sydney disqualified the original medalist.

Although McCaffrey is resigning his post, he expects the White House -- regardless of who occupies it -- will continue the commitment to drug-free sport. Discussion items for the task force include ways to ensure a drug-free Games in 2002, using the Salt Lake Games as a vehicle for youth-oriented drug-free messages, and developing federal strategies for combating **doping.** The meeting is open to the public and runs from 8 a.m. to 1 p.m. at the Wyndham Hotel, 215 W. South Temple.

The task force also is studying the potential health impacts on adolescents of nutritional supplements marketed as muscle builders and endurance boosters. Sold over the counter and Internet to customers of any age, one of the most popular supplements is androstenedione or "andro."

A University of Iowa study published last month in the Journal of Clinical Endocrinology and Metabolism found ingestion of 100 milligrams of andro three times daily by men increases estrogen up to 80 percent, causes enlargement of the prostate and can cause a 10 percent to 15 percent increase in heart disease.

To help speed Food and Drug Administration review of andro as a potential controlled substance, the Healthy Competition Foundation of BlueCross BlueShield Association on Tuesday announced a clearinghouse to collect independent anecdotal evidence of adverse health effects from dietary supplements. Doctors and sports medicine officials can submit suspect andro case information via e-mail to AndroEvents.Healthy Competition@bcbsa.com.

"We're reaching out to medical organizations, pediatricians and endocrinologists to help us gather more evidence, particularly as it relates to children," said foundation director Iris Shaffer. "We have an opportunity to try to make it more difficult to obtain these dietary supplements, which is our goal."

Added Bernard Griesemer of the American Academy of Pediatrics: "Unregulated dietary supplements such as andro may be causing harm to children and teens, but today's users may not feel the full effect of that harm until they are adults."

McCaffrey said much of the problem lies in the federal law that allows sale of dietary supplements without prior scientifically validated proof of no ill health effects.

"We are selling substances in grocery stores that you ingest as a legal product and excrete as an illegal product," he said. "Why would we tolerate that?"

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