

a new independent anti-doping agency. We view this support as a critical step forward in the fight against drug use in sport.

In early 2000, we will stand up the White House Task Force on Drug Use in Sport called for in our newly released national strategy on combating the use of drugs in sport. We look forward to keeping the Congress informed of the task force's efforts to achieve the goals and objectives articulated in this strategy.

We expect this task force to identify a number of areas where specific Congressional action may be necessary and/or appropriate. For example, it is ONDCP's view that Congressional action will be required for the independent drug-testing agency now being developed by the USOC to have the quasi-governmental authorities needed to be fully effective.

Other areas we expect the task force to review will include: current sentencing guidelines for steroids, the appropriateness of treating certain performance enhancing substances as unregulated food supplements, and the growing criminal involvement in steroid trafficking. Each of these areas, as well as others, may result in recommendations for Congressional action.

ONDCP appreciates the support Congress has already provided to our efforts. We look forward to continued support and collaborating with this Committee and the Congress as this effort moves forward.

RESPONSE TO WRITTEN QUESTIONS BY HON. JOHN MCCAIN TO GARY I. WADLER, M.D.

Question 1. When we compare drug testing technology to the performance-enhancing drugs themselves, which are even designed to mask their identity, how far behind the curve are we?

Answer. From a drug testing technology perspective, there are a number of endogenous (naturally occurring) substances which remain particularly problematic in the ongoing battle between those determined to use performance-enhancing drugs and the forensic detectives of the laboratory. Most notable amongst these are injectable testosterone, human growth hormone and the related substance, IGF-1, and erythropoietin (EPO).

With respect to these hormones, three elements are necessary before testing can be employed to detect their abuse. The first is the development of a methodology. The second is the validation of the methodology. This validation needs to incorporate such variables as gender, race, age and physical activity. The third element requires that the methodology be able to withstand legal scrutiny.

Currently, both Australian and British scientists have independently claimed that they have developed blood tests that will enable the detection of hGH abuse. However, these investigators claim that an additional \$5 million are needed to validate the methodology.

Similarly, Australian sports medicine physicians have developed a methodology using blood to detect the abuse of EPO. As with hGH, funds are needed to validate the methodology.

The method traditionally used to detect the abuse of injectable testosterone esters is the so-called T/E ratio, where T stands for Testosterone and E stands for Epitestosterone. The body normally produces both of these hormones in a ratio of less than 6:1, although there are biologic outliers approximating one in 2,000 individuals. This test is used as an indirect measure of testosterone abuse. It has been challenged on a number of grounds including the fact that it has never been validated in women by a body of peer-reviewed science.

Currently, scientists are working on a so-called carbon isotope test, a method which would distinguish between natural testosterone from synthetic testosterone. This, too, is at the stage of requiring scientific validation.

What about the future? Synthetic hormones like hGH and EPO were the products of tremendous pharmaceutical advances. New drugs continued to be developed. Inevitably and unfortunately, they also will be abused by those determined to win at any cost and the scientific community will once again be challenged to detect such abuse. With genetic engineering now a reality, it is inevitable that the challenges to detect such abuse will be even greater than they are today.

Question 2. Can we accurately test for performance-enhancing drugs other than caffeine and amphetamines?

Answer. There is an array of performance-enhancing drugs that can be detected using current technology. For example, there are numerous synthetic anabolic steroids that are readily detectable in urine and have been for many years. Beta-blockers and masking agents such as diuretics and probenecid can be tested for, as can the over-the-counter stimulants and caffeine. With respect to over-the-counter stimulants, when the Controlled Substances Act of 1970 markedly limited the avail-

ability of the amphetamines, substances widely abused by athletes during the 1960s, athletes attempted to achieve an amphetamine-like stimulant effect by combining caffeine, ephedrine (or pseudoephedrine) and the popular diet pill, phenylpropanolamine. While federal law limited the combining of these substances into a single formulation, their ubiquity certainly continues to enable the mixing of these substances. The wide availability of the OTC stimulants and the large number of positive drug tests associated with their therapeutic use caused the NCAA to cease testing for these substances.

Question 3. Would you say it is the trainers or the athletes who are perpetuating this problem of performance-enhancing drug use?

Answer. There have been many self-reporting surveys that have tried to address the very important question: "What is the source of performance-enhancing drugs?" However, the question is more complicated than it would appear to be on first blush. For example, many of the drugs used by young people today are not used to enhance athletic performance but rather are used to enhance physical appearance.

Multiple sources of performance-enhancing drugs have been identified. Historically, sources have included friends, teammates, trainers, coaches and physicians. However, in recent years, the sources have increasingly become illicit. In the United States, most anabolic steroids in the illicit market are smuggled from other countries with little diversion of domestically produced anabolic steroids. Testosterone, primarily of foreign origin, is the anabolic steroid most frequently identified in the illicit market.

Federal legislation has also impacted on how individuals use drugs for enhancement purposes. For example, in 1988, federal law made it a crime, punishable by long prison terms, to dispense anabolic steroids outside a bona fide doctor patient relationship and for purposes other than for the legitimate treatment of a disease. Subsequently, the Controlled Substances Act of 1990 categorized anabolic steroids as Schedule III controlled substances.

However, the notoriety associated with Mark McGwire's use of androstenedione raised new issues. Androstenedione, a naturally occurring steroid hormone, is converted by the human body into the male hormone, testosterone. This simply biologic fact underscored the question: What is a drug?

Stated differently, the federal Dietary Supplement Health and Education Act (DSHEA) of 1994 resulted in the classification of androstenedione and related substances as dietary supplements, not as drugs. However, as previously noted, the Controlled Substances Act of 1990 had previously classified testosterone as a controlled substance. The net result, DSHEA enabled the circumventing of the Controlled Substances Act with respect to testosterone, a fact not lost on the manufacturers of androstenedione. Ingest a supplement, manufacture a controlled substance! The net result is that fact that androstenedione and related substances, such as 19-nor androstenedione have been promoted extensively on the web and elsewhere suggesting that one can get around the Controlled Substance Act with respect to testosterone by ingesting androstenedione. The result has been at least a quintupling of sales of androstenedione. It certainly might be argued this is an example of the law of unintended consequences and that unwittingly, federal law has facilitated the use of performance enhancing "drugs."

The reclassification of androstenedione and related substances at least as prescriptive drugs, if not as controlled substances, would send a clear message that these substances should not be taken without the advice, consent and prescription of a physician and further, such a reclassification would shift the burdens of proof of safety, efficacy and purity to the manufacturer. Data is readily available indicating that products sold as androstenedione has been shown to contain controlled anabolic steroids.

The November 16, 1999 Federal Trade Commission settlement with two marketers of androstenedione and related substances requiring them to place safety warnings on androgen supplement labeling and advertising is a step in the right direction.

RESPONSE TO WRITTEN QUESTIONS BY HON. JOHN MCCAIN TO NANCY HOGSHEAD

Question 1. Several of the witnesses testified about the need to educate young people about the perils of performance enhancing drugs. Do you think an educational program would be beneficial? If yes, at what level should athletes be targeted and when should it begin?

Answer: An educational program would be very beneficial. While testing (doping control) is absolutely essential, it alone cannot solve the problem. What's needed is a comprehensive approach that involves research, education, prevention, detection,

deterrence and international collaboration. Any one of these elements alone will not succeed.

Canadian research (National School Survey 1993) suggests that, on average, kids are making decisions about drug-use in sports at around 14, and as early as 11. (There is similar research in the USA.) The good news is that the research also shows that kids can be highly influenced toward drug-free sport based on the promotion of positive attitudes and beliefs concerning drug-free sport.

Question 2. During the hearing, some members expressed concern about ensuring the proposed IOC and USOC drug testing proposals protect the rights of athletes. Do you feel the current proposals will provide athletes with sufficient protections to ensure the testing process is both accurate and fair?

Answer: In order to ensure the rights of the athletes, there must be an independent agency that is publicly accountable. This means being open to athletes' and public scrutiny. The current IOC/USOC proposals are unclear in this regard.

The best way to protect athletes' rights is to develop programs based on athlete consent.

The IOC proposals do not approach the issue that way; the WADA seems primarily designed to provide services to international sport federations, which have their own interests (and conflicts of interest), and they do not approach athletes' rights in the same way. For example, many do not allow their athletes access to the International Court of Arbitration—the federation has to agree first. Rights of appeal and reinstatement are inconsistent. The criteria for appeals and reinstatements are also inconsistent, vague and not readily available to athletes. Processes (e.g., hearings) for appeals and so on are often not independent of the original decision-makers.

As an asthmatic, I am very sensitive to this issue. There are certain medications that allow me to participate on the same playing field as my competitors, and other medications that I could take that may give me an unfair advantage by having a speed-like side effect. Some rules seem painfully harsh at first blush—Senator Stevens talked about receiving medication while he was unconscious that would have disqualified him from Olympic competition. (Of course, this might not be Alaska's loss.) While harsh, they may only be considered patently unfair when the rule is imposed from above, rather than by consent. Remember: Athletes suffer the effects of doping, of cheating. And it is athletes who are asking for tougher doping control. There is also the question of athletes' privacy. For example, once you get past the scientific and ethical requirements to carry out blood testing, who are athletes going to trust to take and analyze blood samples? How will athletes be protected against these samples being used for purposes other than doping control?

There are generally two existing models in doping control: the European and North American. The European model is a very administrative, regulated approach, and does not necessarily protect the rights of the athletes in a way that we would find acceptable in North America. The European approach tends to work under the assumption that all athletes are cheating and that it's the job of sport administrators to catch them. Doping control programs tend to run in a somewhat clandestine "spy versus spy" manner in order to "catch the cheats." New research and detection methods are kept relatively secret and are not published in peer-reviewed scientific journals. While this is slowly changing (very slowly), it is still the prevailing philosophy among international sport federations.

The North American model works on the assumption that all athletes are drug free unless there is a clear and convincing evidence to the contrary. Doping control programs are designed to help athletes remain drug-free, monitor for doping, provide general deterrence based on an "anyone, anytime, anywhere" approach, and protect athletes' rights to natural justice/due process. The North American model tends to rely on outside expertise, debating the issues publicly and trying to develop a collective agreement within the sport community on how best to deal with doping.

In terms of accuracy of tests, the doping-control detection science is quite rigorous and sound. The problem lies in the accreditation of laboratories (currently handled by the IOC, involving directors of laboratories who obviously have conflicts of interest). A group of countries have successfully developed International Standards for Doping Control recognized by the International Standards Organization which has issued a "Publicly Accessible Specification" status to these standards. Among other things, these standards are specifically designed to protect athletes' rights, including measures to ensure that procedures and processes are accurate, fair, well recorded and open to scrutiny. While the IOC initially suggested the WADA would adopt these standards, that is no longer the case.

Please do not hesitate to contact me if I need to clarify any of these answers. Thank you for your patience!

RESPONSE TO WRITTEN QUESTIONS BY HON. JOHN MCCAIN TO RICHARD W. POUND

Question 1. I have seen a recent survey that suggests 71% of Americans are less likely to watch the Olympics if the athletes are using performance-enhancing drugs. What effect would such a reduction in American viewers have on the IOC monetarily?

Answer: I am not familiar with the survey to which you refer.

I can say, however, that the research conducted on behalf of the IOC shows that the public in the United States and the other ten countries included in our surveys overwhelmingly supports the ethical approach to sport that the IOC exemplifies. People respect the efforts of the Olympic Movement to differentiate itself from professional and other unregulated sport that do not reflect the same commitment and effort.

I believe that American viewers are, in essence, no different from others around the world that want Olympic sport to be drug-free and that they both recognize and support efforts to make this dream a reality. I believe they will support the cooperative efforts of governmental and sport authorities to further this goal, through education and prevention.

The monetary effect on the IOC, were the scenario to which you refer actually to occur, is difficult to gauge. In the first place, the survey appears to reflect only a reduced likelihood to watch the Games, not a decision to refuse to watch. I presume that the survey was conducted during the recent period of adverse publicity regarding doping in sport. I would hope that, once the new arrangements we contemplate for the fight against doping in sport are in place and operating, there would be a much higher level of public confidence that the Olympic ideals are being observed.

Many of the existing contracts apply to the Games as far away as 2008, so they are already in place. I cannot predict whether contracting parties might seek to abrogate such contracts, nor on what legal basis they might seek to do so. The IOC itself receives only a small portion of the revenues derived from such contracts, since it acts, essentially as a granting agency to Organizing Committees, national Olympic committees (including the United States Olympic Committee) and international sports federations.

Question 2. The IOC has been criticized for its policy of self-governance and lack of external oversight. Is the IOC willing to risk losing American sponsors in order to continue on the current path?

Answer: It is certainly true that the IOC has been criticized for its policy of self-governance and lack of external oversight. Some of this criticism has been helpful and constructive; some has been based on a lack of understanding of the role of the IOC and the need for its independence and has not been helpful.

The IOC has acted quickly to institute significant reform, especially in matters of governance, and many of these reforms are already in place, including an externally-dominated Ethics Commission and a Code of Ethics applicable, *inter alia*, to IOC members. Others will be adopted by the special Session of the IOC that will take place on December 11 and 12, 1999. These reforms have been widely publicized, but, should you not have the contents of them available, I would be pleased to provide copies of the documentation for your review and consideration.

The IOC does not wish to lose any sponsors, American or otherwise, as a result of improper conduct and is determined to make the changes necessary to demonstrate that it is the appropriate body to direct the Olympic Movement for the future. I believe that the reforms we have instituted and that we expect to adopt will demonstrate this commitment to sponsors and the public-at-large.

Question 3. I understand that in the case of drug violations reported during the Atlanta Games, the Organization did not seek to pursue the matter because the testing technology used, a high resolution mass spectrometer, was not convincing. Does the IOC lack confidence in this testing method because of its technical inaccuracy, or because the standards for the Court of Arbitration in Sport are more demanding?

Answer: The operations of the laboratory used during the Atlanta Games were, as I understand it, deficient in certain respects. The IOC was advised, in writing, by the IOC accredited laboratory in Cologne, Germany that the procedures used in respect of certain samples were unreliable. Given possession of this information, it was the judgment of the IOC Executive Board that, as (in effect) prosecutors, it would have been morally reprehensible to proceed with efforts to disqualify athletes without disclosing to the athletes involved our possession of such advice. In addition, any disqualification that might have been pronounced in such circumstances would almost certainly have been overturned by the Court of Arbitration for Sport. This led to the IOC's decision, in those particular circumstances, not to proceed.

The technology, generally, has proven to be quite reliable and, unless some technology, demonstrably more reliable is developed in the future, I believe that mass spectrometry of urine sample will continue to be used. This technology does not purport to apply to all substances and new tests are being conducted to allow detection of other substances at a level that provides the necessary standards for due process and the protection of athletes' rights.

Question 4. How does this testing technology compare to other methods used in the past?

Answer. It is the same basic technology, with some refinements to provide for more accuracy in respect of certain substances.

Question 5. The Savannah International Training Facility in Georgia provides Olympic-caliber athletes the opportunity to train and become the best athletes they can be. Currently there are athletes from across the globe training at this facility. What role does this Center play in the training of athletes to compete in future Olympic Games? What are the current contractual agreements with the Center so far as reimbursement for the training and housing of athletes from the IOC? What has been the cause for the recent disputes concerning [these] reimbursements?

Answer. I am not personally familiar with the Savannah International Training Facility in Georgia nor with its particular mandate, funding model, objectives and expectations.

I do know that the IOC, through its Olympic Solidarity Programme, provides scholarships to aspiring athletes in many countries throughout the world. These may contemplate training in countries other than their own and reimbursement of certain types of expenses within the limits contemplated by the terms of each scholarship.

I have, for purposes of responding to your question, made inquiries of the IOC secretariat responsible for the implementation of the Olympic Solidarity program. In the case of those athletes receiving Olympic Solidarity scholarships and who may be attending at the Savannah Facility, the IOC agreed to pay a fixed amount per month in respect of services rendered at the Savannah Facility for each such scholarship athlete. This is similar to the agreements that Olympic Solidarity has with other high level training centers. I am not aware of any failure of the IOC or Olympic Solidarity to comply fully with any such obligations.

I understand that the Savannah Facility intends to close in November 1999 and have had sight of some correspondence in that regard. It appears there has been some misunderstanding on the part of the Savannah Facility as to the role of Olympic Solidarity and the extent of its involvement therein. The IOC is not and has not been a partner in any facility of this nature. The agreement with the Savannah Facility was unequivocal in providing that the Facility was not entitled to designate or refer to itself as an official "Olympic" training center or derivation thereof. Olympic Solidarity is prepared to fund certain scholarship athletes for a portion of their training and living costs and has done so on many occasions, but that is the extent of its financial commitments.

If this subject, as it relates to the IOC, is a matter of further concern to your Committee, I would be pleased to pursue any additional line of inquiry that you may suggest.

Question 6. Please tell me which of the World Anti-Doping Agency's functions will be completely independent from the IOC? For example:

Answer. Please bear in mind that the Agency, although legally constituted at the time of this response, has not yet met, so my answers should be taken against that background.

- **Will the new Agency collect specimens?**

Answer: I should think that, initially, the Agency will rely upon existing national agencies (e.g., in Norway, Australia, Canada, Sweden, France, Italy) to collect the specimens. Once the Agency is fully developed, it may well be that it will have its own capacity to collect specimens, but this will have to await the development and staffing of the Agency, which should occur by early in the year 2000.

- **Will it conduct the testing?**

If, by this question, you mean that the Agency will do the analysis (as opposed to collection of specimens), I should think that the analysis of specimens will be conducted in accredited laboratories, the accreditation of which is presently granted by the IOC, but which will be granted in future by the Agency. If you mean who will determine which athletes are to be tested, that will be a matter to be worked out with the international federations, who will be in a position to identify the "high

risk" athletes for purposes of out-of-competition testing. In-competition testing will be conducted according to the rules of each international federation or other governing authority of the competition (e.g., the IOC in the case of the Olympic Games or the IAAF in the case of the World Athletics Championships). In the case of most professional sports, as you know, the Olympic Movement has no jurisdiction over such organizations (e.g., the NFL, NHL, MLB or NBA).

• **Will it prosecute the athletes that have been charged?**

Answer: The "prosecution" of athletes will be done by the responsible organization, on the basis of the results of the tests. Thus, if a track and field athlete has tested positive, the international federation (IAAF) has the jurisdiction to impose the sanction. At the Olympic Games, the IOC will impose its sanction of disqualification and withdrawal of the medal, if any.

• **Will it sanction athletes who are found guilty of using performance-enhancing drugs?**

Answer: The sanction will be imposed by the responsible international federation or by the IOC at the Olympic Games. In cases of a positive test at the Olympic Games, there will be two sanctions: one by the IOC (disqualification and withdrawal of medal) and by the IF (suspension for two years, etc.). In general, this model would apply with other Games, such as, for example, the Pan American Games, except that it would be a combination of PASO, as the governing authority of the Pan American Games, and the relevant IF.

Question 7. General McCaffrey called into question the level of international support for the IOC's proposal. Do you believe you have the support of international governments and if you do not, what is the IOC doing to develop support?

Answer: I believe there is widespread support for the IOC's proposal of the WADA as an independent agency in the fight against doping in sport and the demonstrated fact that the Agency will not be under the control of any party involved.

The remaining element of government participation is how best to integrate the national governments into the governance structure of the WADA. Clearly, it will not be possible to involve all 200 national governments on a daily basis. We will work diligently to find an appropriate formula, which may be, for example, on a continental basis or to involve the host countries of past, present and future Olympic host countries. I do not want to suggest that a definitive solution has yet been found, but we will work with governments to find the most appropriate mechanism for the purpose and will propose it to the WADA at the earliest opportunity. I understand that a working group has been established among national governments to seek ways to provide the essential input to the process and I have been in direct contact with General McCaffrey and the Canadian sports minister for precisely that purpose. I hope we can reach a mutually agreeable solution prior to the first meeting of the WADA. I believe there is an understanding that no single party has all of the answers or a cure-all solution, but there seems to be a common purpose and commitment to finding a solution that works for everyone.

I should add that, for the first time, I believe all the parties necessary to finding a solution to the problem of doping in sport are ready and committed to doing whatever is required to bring about that solution. This could be a pivotal moment for sport and we must be ready to seize the opportunity that this confluence represents. The Olympic Movement pledges its full and complete support in this regard and I am sure that governments are of like mind.

I hope these are responsive to your questions, but if there is anything that I may have omitted or misunderstood, please do not hesitate to contact me and I will do my best to complete the answers.

RESPONSE TO WRITTEN QUESTION SUBMITTED BY HON. JOHN MCCAIN TO
SCOTT SEROTA

Question: In the Healthy Competition Foundation's Survey on Performance Enhancing Drugs, done in cooperation with Blue Cross/Blue Shield, there are some alarming statistics that surface: 1-in-4 kids in this country know of other children using performance enhancing drugs. Does your survey draw any correlation between the use of these drugs by children and what they have seen done by some international stars in the Olympics and other athletic competition?

Answer: Speaking on behalf of the Blue Cross and Blue Shield Association (BCBSA) and the Healthy Competition Foundation, Mr. Serota pointed out that research commissioned by BCBSA revealed alarming statistics that one in four teenagers in this country know of other teens who use performance-enhancing drugs.

While our research did not draw any direct correlation between the use of these drugs by teens and what they have seen done by international Olympic athletes or other highly visible athletic competitors, our research found that the respondents favorably perceive Olympic athletes. Respondents also noted that athletic celebrities like Michael Jordan, Ken Griffey, Jr. and Mark McGwire top the list of favorite athletes. These findings lead us to believe that Olympic athletes and celebrity athletes serve as role models for America's youth.

RESPONSE TO WRITTEN QUESTIONS BY HON. JOHN MCCAIN TO WILLIAM HYEL

Question 1. The USOC's proposed Independent Organization has been criticized for lack of independence. Some people are concerned that the selection process is not independent because the members of the USOC family select the members of the organization. Do you plan to change the selection process to address this criticism?
 Answer: The criticism is not warranted. The six Public Sector Members of the Board of Directors of the United States Olympic Committee, who will be selecting five of the nine Board Members of the new drug externalized agency, serve as trustees of the "public interest." These six independent directors will seek broad public input and will encourage outside entities and individuals to make nominations for the new agency's board. General Barry R. McCaffrey, Director of the Office of National Drug Control Policy, has been invited to make nominations. As to the role of the other four board members, the Task Force recommended that the selections by the NGB Council and the Athletes' Advisory Council not be limited to current members of those two Councils, but consideration should be given to all nominees of the highest caliber. Any criticism of this process should be reserved until after the Board of the new agency is selected. This will be the real test on the issue of independence.

Question 2. It is my understanding that the USOC's out-of-competition testing program has less than a 75% success rate in actually testing athletes. How will the new program ensure that out-of-competition testing will actually take place?

Answer: The No Advanced Notice ("NAN") testing program is a year-round program in which the testing collectors show up at the athlete's doorstep, training facility, etc. to conduct unannounced tests. The 75% figure refers to first attempts to test the athletes. When not contacted the first time, the athlete remains in the NAN pool and is subsequently tested regardless of the number of attempts required. USOC rules require all athletes to notify their respective NGB of any changes of address within 72 hours. It is understandable that an athlete may not be at the designated address when the collector comes to test. For example, an American Track and Field athlete training and competing abroad is very difficult to contact on a first attempt. The new agency will continue the NAN testing program, with the number of tests significantly increased.

Question 3. The adjudication process envisioned in the USOC Select Task Force Report does not specify who will represent the athlete in the process. Will the USOC provide the athletes with representation and will that representation include expert witnesses?

Answer: Athletes are free to select their own counsel. This is the current practice and the Task Force felt there was no need for a change. Also, the athletes made it clear that it was imperative that an individual accused of a doping offense be entitled to select his or her own attorney. However, the USOC does have a fund through which athletes who are successful in defending themselves in doping cases may seek reimbursement of reasonable defense costs.

October 14, 1999

MEMORANDUM FROM GARY I. WADLER TO HON. JOHN MCCAIN,

Doping in Sport: From Strychnine to Genetic Enhancement, It's a Moving Target

I want to begin today by taking a moment to recount an event that took place more than 100 years ago.

The year was 1886, a period characterized by the genesis of new industries and the creation of great wealth. A period when we believed anything was possible. A period, in short, much like today.

1886 is a significant year for our conference because it marked the first recorded fatality from a performance enhancing drug.

An English cyclist died of an overdose of what is only known as "trimethyl," during a race between Bordeaux and Paris.

Of course, in the more than 100 intervening years, doping in sports, like the rest of technology, has grown in scientific and ethical complexity. Indeed, so complex is this issue that we will see later in my remarks how we cannot even agree on precisely what constitutes doping—and these dueling definitions point to the heart of the problem.

The multi-stranded nature of the subject of doping is also reflected in the diversity of backgrounds of the participants here today.

In fact, looking over the list of this conference's attendees, I noted that only four participants in this conference are physicians. That's not as surprising as it might seem on the surface. It reflects the longstanding traditional orientation of the medical establishment.

Back when I was in medical school, our focus was on how drugs benefitted patients. After all, by statute, physicians are the ones who write prescriptions. Physicians are the conduit for new drug development with the scientific community.

Our principle concern, as physicians, was, and is the proper use of drugs, not their abuse.

Doping in sports was a subject that only a handful of physicians cared about. I suspect we barely spent 30 seconds on the subject in pharmacology. However, the same as with other forms of drug abuse, that is, sadly, no longer sufficient.

As my opening story suggests, the use, misuse and abuse of drugs have long shaken the foundations of both amateur and professional sports.

Competition, at its most basic level, appears to drive athletes to do whatever it takes to win. Perhaps the need to win at all costs is a Darwinian response, an adaptive mechanism, but we will leave that thought for another day.

We've seen that the problem is not new. History demonstrates that since recorded history began, athletes sought a competitive advantage by using various substances we call ergogenic aids.

Even as long ago as the 3rd century B.C., the Greeks, inventors of democracy and the Socratic method, were known to ingest hallucinogenic mushrooms to improve athletic performance. In the Roman era, gladiators used stimulants in the famed Circus Maximus (circa 600 B.C.) to overcome fatigue and injury, while other athletes experimented with caffeine, alcohol, nitroglycerine, opium and even the potent stimulant, strychnine.

Fast forward.

A new inflection point of abuse appeared in the 1950s with anabolic, androgenic steroids.

How prophetic were the words of Olga Fikatoyna Connolly, when in 1956, she proclaimed: "these awful drugs (anabolic steroids) have changed the complexion of track and field."

So did amphetamines change sports.

In the 1960s, the Danish cyclist, Knud Jensen and the English cyclist, Tommy Simpson died when their search for one kind of speed brought them fatally to another.

Remarkably, though the testing of horses for performance enhancing drugs dates back to 1910, the testing of humans for drug use in sports is a phenomenon of only the past quarter century.

It was as recent as 1965 that Arnold Beckett first applied sensitive gas chromatographic techniques to monitor drug abuse at an athletic event, the Tour of Britain cycle races.

And it was only in 1968 that the IOC medical commission actually published a banned list of drugs for the 1968 winter Olympics.

The introduction of the banned list was coincident with the development of new technologies in the laboratory and this confluence set the stage for a 35-year contest between those determined to gain an unfair athletic advantage by using drugs and the forensic detectives of the laboratory.

It's a struggle between the manipulators versus the investigators and each side's armaments grow more advanced each day.

Since the 1960s, an explosion of science and technology have brought countless new drugs to market, black and otherwise.

In what seems to be a variation of Newton's third law, which states that "For every action there is an equal and opposite reaction," it appears as if for every new drug that is developed, some athlete, determined to gain athletic advantage, will misuse or abuse that drug. This should come as no surprise. We live in a culture where individuals seek to maximize performance by what ever means available.

Let's examine steroids as an example of Newton's third law meeting sports.

First isolated, structurally identified, and synthesized in the 1930s, anabolic steroids were used to promote a positive nitrogen balance in starvation victims and

as a means of hormone replacement for those deficient in testosterone by means of disease or trauma.

New, positive applications of steroids continue to emerge. As recently as April 1999, two articles were published in J.A.M.A. exploring the therapeutic uses of anabolic steroids in the management of aids, and in dialysis patients.

Unfortunately, since its initial isolation in the 1930s, it didn't take long for anabolic steroids to become widely misused and abused by athletes—a problem that continues to plague sports to this very day.

And as science marches on, abuse is not far behind.

Some twenty years have passed since the first recombinant DNA molecules were constructed at Stanford University. Since then, the applications of genetic engineering, that is the artificial manipulation of the genetic code, have been numerous.

The techniques of altering the DNA of cells in order to change or produce biologicals has given rise to human growth hormone and to erythropoietin, to name but a few. Recombinant human growth hormone means normal height for children otherwise destined to be dwarfs, but for the drug abusing athlete it means bigger, albeit not stronger, muscles. Erythropoietin means renewed vitality for those with anemia, but for the drug abusing athlete, it means greater endurance.

The dramatic abuse of the latest biotechnology breakthroughs crystallizes the need for an accepted working definition of the word doping.

This definition sits at the heart of any doping control program. Doping, a term that derives from the Dutch word "doop" referring to a viscous opium juice that was the drug of choice of the ancient Greeks.

In 1963, the Council of Europe established a definition of doping which the IOC slightly modified and adopted. It defined doping as "The administration of or use by a competing athlete of any substance foreign to the body or any physiologic substance taken in abnormal quantity or taken by an abnormal route of entry into the body with the *sole intention* of increasing in an artificial and unfair manner his/her performance in competition. When necessity demands medical treatment with any substance which, because of its nature, dosage, or application is able to boost the athlete's performance in competition in an artificial and unfair manner, this too is regarded as doping."

It is a definition that I happen to like, but a definition that has been abandoned. According to the *IOC Medical Code* currently posted on the IOC web site, doping is presently defined as "the use of certain substances and methods *intended* to enhance and/or having the effect of enhancing athletic performance, such practices being contrary to medical ethics." However, like the banned drug list itself, the definition of doping is a moving target.

And speaking of lists, the banned drug list must be based on a generally recognized body of science, and where one does not exist, it must be based on some clearly reasoned rationale, including issues related to laboratory science. I am sure we would all agree that the current IOC list falls short in this regard.

Most recently, the *Olympic Movement Anti-doping Code*, as articulated in February of this year in *The World Conference on Doping* defined doping "as the use of an *artifice*, whether substance or method, potentially dangerous to athletes' health and/or capable of enhancing their performances, or the presence in the athletes' body of a substance, or the ascertainment of the use of a method on the list annexed to the Olympic movement anti-doping code."

It is a good thing we are holding this conference in a law school!

Although I personally prefer the first definition of doping that speaks of sole intent, it is still problematic. The linchpin of that definition is the notion that we can actually assess one's intent, both qualitatively and quantitatively.

About intent, Peter Marc Latham in the early 1800s wrote: "Poisons and medicines are the same substance given with different intent."

Since there is no way to measure an athlete's intent, a surrogate measure, the testing of bodily fluids, especially urine, has become a marker for assessing intent.

However, the neuro-chemical-biological pathways from what is on an athlete's mind, call it intent or call it artifice, to what comes out in his or her urine is tortuous and replete with physiologic treachery.

It has led to expensive and explosive litigation centered around the concept of strict liability, a subject I am sure we will hear much more about at this conference.

Creatine underscores a second problem when defining doping.

All would agree, that in recent years, the physiologic substance creatine has been taken in large amounts by an extraordinary large number of athletes, a process called creatine loading.

All would agree that at least in certain high intensity, short duration exercises, it enhances performance.

But, to date, there is no practical way to ban the practice and many would argue that beyond pragmatism, there is no definitional basis to ban it. Not only is creatine naturally produced by the body, it is widely found in a variety of food stuffs, such as meat and fish, thus raising the question: when is a physiologic substance considered to have been taken in abnormal quantity with the intent of gaining an unfair athletic advantage?

Employing urinary cut-off levels to eliminate its abuse remains a possibility. However, because creatine is so ubiquitous, the use of urinary cut-off levels probably would devolve into little more than an attorney's field day.

Inherent in any definition of doping is the notion that the technology exists that permits the definitive detection of substances foreign to the body or physiologic substances taken in abnormal quantity. Good luck!

Because advances in biotechnology have outpaced advances in laboratory science, the detection of certain drugs or biologicals is today either impractical or impossible. To wit, human growth hormone, erythropoietin and most recently, IGF-1.

IGF-1 is a polypeptide that is indirectly responsible for most of the growth-promoting effects of hGH. It is associated with a plethora of physiologic functions many of which are shared with hGH. These include increased protein synthesis, decreased protein breakdown and increased fat metabolism—all attractive to athletes.

Its approved uses in the United States are for a certain form of dwarfism and a rare form of insulin resistant diabetes. Like hGH, IGF-1 is not detectable with current screening methods and like hGH it needs to be administered intramuscularly. One of the newer performance enhancing drugs, relatively little is known about its abuse patterns, cost, availability and long term side effects. The cost of IGF-1 is about \$3 thousand per month and counterfeit products are problematic.

It is noteworthy that phase II trials are currently underway utilizing a novel complex of IGF-1 and its major binding protein BP-3 to treat the degradation of muscles in a variety of medical conditions.

Those are some of the drugs we know but what about those we don't know? New drugs that are not listed. Heni Verbruggen, head of International Cycling Federation has suggested that "undetectable drugs are 90 percent of estimated doping cases."

We were told that in Atlanta, performance enhancing drugs would meet their match in high resolution mass spectrometry. And yes, it is an effective technique—but when investigators introduce something so new, it often takes a number of years for the technology to withstand legal challenges. To wit, O.J. And DNA. That's why the Atlanta games were clouded by the presence in the urine of the "new" stimulant drug, bromantan, and why political machinations resulted in five athletes being cleared of a doping offense by the on-site court of arbitration in sport.

Too often, it seems, we define international sports competitions and events, not by the city or country in which they were held, but by the drug that made the headlines—the Clenbuterol Olympics, the Bromantan Olympics, the Growth Hormone Games, the Steroid Pan Am Games, or the EPO Tour de France, or as some have suggested the Tour des Drugs.

There is good reason for this. If we look at the number and kind of new drugs that have come to market since the introduction of doping control in the Olympic movement in 1960s, the number is staggering.

This complicates life for every athlete who is faced with taking a drug or a biological substance for any reason whatsoever. He or she must first ask a series of questions: Is it banned? Will it adversely affect my performance and is it safe?

Those determined to gain an unfair advantage will ask the additional questions: Does it work? How does it work? Can it be detected during competition or out of competition, and perhaps, he or she might even be concerned about its long and short term safety?

That's today. But what about tomorrow? What is around the corner—brake drugs, blood substitutes, genetic manipulation? It is not a matter of a brave new world, but of brave new worlds.

Cyproterone acetate, also known as a Cyprostat and Androcur, is a synthetic steroid antiandrogen and contraceptive hormone used in the treatment of prostate cancer in men, hair loss in women and precocious puberty in children.

Not available in the United States, this so-called "brake drug" which has been associated with the development of liver tumors has allegedly become popular amongst female gymnasts because it puts the brakes on sexual development keeping the hips narrow and the breasts small.

And just as researchers are closing in on a method to detect the abuse of EPO, a potentially dangerous new EPO replacement, which is likely to increase endurance, has surfaced.

The substance is perfluorocarbon, or PFC, a substance with enormous oxygen-carrying capacity. It has been suggested that the abuse of this synthetic blood—like substance first surfaced in Nagano where it had been allegedly abused by cross-country skiers and speed skaters.

The International Cycling Federation has issued warnings about PFC to its national federations.

Although not officially on the market in the United States, there is active research into PFCs for legitimate medical use. PFC can significantly increase endurance by delivering more oxygen to working muscles.

With the global market for blood substitutes probably exceeding \$2 billion, the number of new products will undoubtedly continue to grow. For example, active research is continuing using purified bovine hemoglobin rather than products of human origin or the use of PFCs to carry oxygen, and work continues on genetically engineered blood substitutes.

As we move into the next millennium, we are at the cusp of gene therapy for the correction of defective human genes that cause or promote certain genetic diseases, and designer genes cannot be far behind. Human skin has already been genetically engineered.

Combining cloning with genetic engineering, so called germ line therapy, will make possible the passage of genetic changes from one generation to the next.

It was only six months ago that scientists achieved one of the most coveted goals in biology, isolating from human embryos, a primitive cell, called a pluripotent stem cell, that can grow into every kind of human tissue, including muscle, bone and even brain.

Already stem cells have been used to grow human heart muscle cells which beat in unison in a petri dish, as well as nerve cells, bone, cartilage and skeletal muscle. To insure that stem cell research is conducted in an ethically sound manner, just last month, an NIH special working group was formed by the director of the NIH to develop research guidelines.

If this sounds like the twilight zone, think twice. Only five months ago, researchers at the University of Pennsylvania discovered a form of gene therapy to counter muscle degeneration associated with aging.

The injection of this gene limits the effect of IGF-1 to the skeletal muscles into which the gene is directly injected obviating any adverse effects of IGF-1 on the rest of the body.

With this technique young mice experienced a 15% increase in muscle strength, and old mice a 27% increase. Accordingly, the gene has been dubbed the "fountain of youth" for skeletal muscles.

But in the world of doping, milestones become millstones.

The author of the original study has already expressed concern that this technology may be sought out by athletes who are seeking a competitive edge. Interestingly, muscle strength increased without any exercise and there was no way to detect the use of gene therapy from analyzing the blood.

Trials are to begin in monkeys and, in the not too distant future, the first human study may be done in people with a form of muscular dystrophy.

And in another study, IGF-1 producing genes have been successfully introduced into mouse embryos. Is it a stretch that with the new technologies of genetic engineering that we are arming parents with the tools to create designer offspring whether inside the uterus or out of it?

Of course, the ethical, moral and biological debate transcends sports. Indeed, it touches on the transcendent as George Wald, the Nobel Prize-winning biologist and Harvard professor, opined: "Recombinant DNA technology (genetic engineering) faces our society with problems unprecedented not only in the history of science, but of life on earth. It places in human hands the capacity to redesign living organisms, the products of some three billion years of evolution."

We stand at the brink of an uncertain future. But I personally believe that the unpredictability and the velocity of change are not an excuse for reserving judgment about some profound distinctions that should fundamentally govern our perspective on the role of sports in our social fabric.

With that in mind, I would like to conclude by quoting the columnist George Will who reminds us: "A society's recreation is charged with moral significance. Sport—and a society that takes it seriously—would be debased if it did not strictly forbid things that blur the distinction between the triumph of character and the triumph of the chemistry."

And finally, in order that we not blur the distinctions George Will speaks of, what we must do in this complex and challenging environment, is confront the issues related to doping from the broadest possible perspective.

Tempting as it is to get consumed by the intricacies of anabolic steroids, EPO or hGH, I urge you to think expansively and inclusively, to keep the big picture in mind, and to maintain an aerial view, for these drugs are only specific examples that stretch along the continuum from strychnine to genetic engineering. Only in that way can we hope to forge a consensus, a unified, expert-wide point of view that will help us put the details and the subtleties in proportion. Stay tuned.

October 13, 1999

MEMORANDUM FROM DORIANE LAMBELET COLEMAN

Re: Evaluation of Proposals by IOC and USOC to Reform their Doping Control Programs

In preparation for my testimony on October 20, 1999, before the United States Senate Committee on Commerce, Science, and Transportation, I have reviewed the IOC and USOC proposals to reform their doping control programs. The evaluation which follows is based on the proposals contained in the following documents of the IOC and USOC, which were the most recent that I was able to obtain:

- With respect to the IOC, I have reviewed the document designated as "Draft 5-9th September 1999, Foundation: World Anti-Doping Agency—Statutes," and the document designated as the "Olympic Movement Anti-Doping Code 1999" with an effective date of January 1, 2000.
- With respect to the USOC, I have reviewed the *Special President's Newsletter Number Six*, dated September 28, 1999, and the *Report of the USOC Select Task Force on Drug Externalization*, dated September 30, 1999.

1. SUMMARY EVALUATION OF THE IOC'S PROPOSAL

The IOC's proposal can be easily characterized as yet another false start. It is primarily show over substance, and does not seriously respond to the public's call for the Olympic Movement's anti-doping program to be made independent of and externalized from the IOC and the subsidiary organizations within that Movement.

The proposal suggests the creation of a new entity that is not formally tied to the Olympic Movement, which it calls the "Foundation," but it does not give that Foundation any real authority whatever in connection with the Olympic Movement's anti-doping program. Thus, for example, the Foundation would not do or cause to be done scientific research relevant to the anti-doping effort; it would not develop a new drug testing program, even one based on the existing program; it would not do drug testing; it would not do sample analysis (or cause laboratories that it would accredit pursuant to standards that it would establish); it would not evaluate suspicious samples; and it would not prosecute athletes charged with positive tests. It would not even know about the existence either of suspicious samples or positive tests. In sum, the proposal suggests nothing more than the creation of a blue ribbon advisory board controlled by the IOC and its subsidiary organizations.

As I will detail below, the proposal suggests that the Foundation would have a hand in "supporting," "promoting," or "coordinating" aspects of the Olympic Movement's anti-doping efforts, but the responsibility actually to make decisions and to undertake the efforts would continue to reside exactly where they are today, namely with the IOC and the Olympic Movement generally. Put another way, the IOC's proposal would neither externalize nor make independent of that organization any significant anti-doping responsibilities.

When one considers the additional fact that the proposal suggests a governing structure for the Foundation that leaves the balance of power in the hands of the Olympic Movement so long as it is willing to pay for that power (quite literally), the illusory nature of the proposal as a whole becomes crystal clear.

A. The Principal Merits of the Proposal

Having said this, the IOC's proposal does contain one positive aspect: It reflects that, for the first time, the IOC is willing to consider some truly independent observation of and participation in some aspects of the Olympic Movement's anti-doping program. It does this by allowing for individuals on the Foundation's Board to be "designated by the intergovernmental organizations, governments, public authorities or other public bodies involved in the fight against doping."

B. The Principal Defects of the Proposal

As I suggested above, the principal and overriding defect of the IOC's proposal is that it neither externalizes nor makes independent of the IOC or the Olympic Movement any significant aspect of the anti-doping program. As I will detail below, the Foundation would neither have the independent authority to do anything—apart from “promoting” anti-doping efforts, and “recommending” measures to the IOC, for example—nor would its governing Board be independent of the IOC or the Olympic Movement, as it is explicitly contemplated that the balance of power would remain with the IOC so long as that organization was willing to pay for it. Needless to say, given that the calls for reform uniformly required both externalization and independence of the anti-doping program, this proposal is a non-starter. Given this, it is my view that the proposal is not even a good-faith effort to respond to those calls for reform, and cannot legitimately be the basis for an honest negotiation between the IOC and those in and out of government who seek that reform.

The Foundation would be located in Switzerland, the seat of the IOC. To the extent that the appearance of independence matters, this is not an appropriate situs for the new agency.

- The Foundation would not assume the doping control responsibilities of the Olympic Movement. Indeed, it appears that all the Foundation would be authorized to do would be to “promote,” “coordinate,” and “reinforce,” “encourage,” and “support” the anti-doping efforts of others, and to “organize” persons and entities interested in the fight against doping. Reading the Foundation document together with the proposed Anti-Doping Code, it becomes clear that any real authority the Foundation might have is illusory, as the Code repeatedly refers to the Foundation's ability only to “recommend” anti-doping measures to the IOC's Executive Committee, including updates to the list of prohibited substances and standards for laboratories. Ultimately, the significance of this lack of authority is that the IOC's proposal does not contemplate the externalization of any significant aspect of its anti-doping program.
- The Foundation Board would be comprised of at least thirteen individuals from the Olympic Movement, including six designated by the IOC itself (three presumably by its Executive Committee or President, and three by its Athletes' Commission), three from the International Federations, and three from the Association of National Olympic Committees. The document specifically provides that there will be an equal allocation of power on the Board between those members who are from the Olympic Movement and the public authorities who would comprise the remaining members. Again, to the extent that the reform effort is intended to result in independence from the stakeholders, this is not accomplished in the IOC's proposal.
- The Foundation document also specifically provides that members from the Olympic Movement would out-number the public authority members by at least one so long as the Olympic Movement contributes more of the operating budget of the Foundation relative to the contributions of the public authorities or others. The Foundation Board also would be authorized to select its own “chairman,” etc. Because Mr. Samaranch has already announced that in exchange for a seat on the Board, he intends to contribute \$25 million from the IOC's coffers to start the Foundation, unless the public authorities or others are willing to ante up \$25 million plus \$1, the Olympic Movement and perhaps even Mr. Samaranch himself will control the Foundation. This result would bring the matter of the Olympic Movement's anti-doping program back to ground zero, and nothing will have been accomplished.
- The Foundation Board is required to meet only once a year. Given the complexity and multitude of problems that need to be addressed, this is clearly insufficient. Moreover, when considered in conjunction with the provisions that would establish an Executive Committee of the Board, which would actually run the Foundation, it is at best unclear that the Board is intended to do anything of real substance.
- The Foundation would be entitled but not required to act in consultation with legal and scientific advisors. Given that the issues that plague the Olympic Movement's anti-doping program lie squarely at the intersection of law and science, it must be required to act in consultation with such experts.
- The Foundation would be required to publish reports of its activities only once each year. Given that transparency is a real concern, this proposal is certainly deficient.
- The proposal contemplates that “the actual management and running of the foundation” would be done by an Executive Committee of the Board, comprised of five-to-nine members selected by the Board itself. Assuming that the majority

of the Board is comprised of individuals from the Olympic Movement, it is entirely possible, if not probable, that the entire composition of the Executive Committee would be individuals from the Olympic Movement. Again, this is back to ground zero; nothing will have been accomplished.

2. SUMMARY EVALUATION OF THE USOC'S PROPOSAL

In stark contrast to the IOC proposal, it is clear from the text of the USOC's proposal that at least its Task Force on Drug Externalization is seriously committed to effective drug testing, and to the principle of externalization. In this latter regard especially, the USOC's proposal is strong: it contemplates the externalization of *all* aspects of the USOC's anti-doping efforts. Thus, the Task Force has suggested that the new agency would have all the authority that the USOC itself now has, in conjunction with the NGBs, to undertake or commission relevant research; to conceive an effective drug testing program; to do drug testing; to investigate suspicious samples; and to prosecute athletes whose samples are positive. It is evident that the Task Force has done a thorough and thoughtful job in proposing its version of a new anti-doping program to the Executives and the Board of the USOC. Thus, while this proposal is defective in certain respects which are important and which I detail below, it is in general a very good beginning, and the Task Force ought to be commended on its effort.

A. The Principal Merits of the Proposal

- 1 The domestic anti-doping program would be completely externalized (with the exception of laboratory analysis).
 - The NGBs also would be out of the business of drug testing and particularly of prosecuting their own athletes.
 - Substantial monies would be devoted to the effort, including money for peer-reviewed research, especially relating to the endogenous substances, EPO, hGH, and testosterone.
 - All sample collection and testing would be conducted in accordance with the relevant International Standards Organization (ISO) Standards.
 - There would be a substantial increase in no-notice testing of athletes who are subject to the anti-doping program.
 - The adjudications process would be developed independently of the Olympic Movement, namely by AAA in conjunction with CAS.
 - All drug testing results should be screened by experts for probable cause before a prosecution is commenced; and that the work of the new agency should be transparent.
 - That positive and prophylactic educational measures are essential to reinforce the ethical culture of young athletes in particular.
 - That a partnership with Olympic sponsors and the Federal Government is appropriate in this area.

B. The Principal Defects of the Proposal

The principal defect of the proposal is actually its Achilles Heel; if it is not remedied, all other reform *risks* being illusory. While the Task Force, with the apparent support of President Hybl, has proposed *externalization* of all drug testing operations, it has failed simultaneously to provide for *independence* for the new agency that would administer them. Specifically, by proposing that all members of the board of the new agency are to be selected from among members of the USOC or by members of the USOC, the Task Force in essence has proposed the creation by the USOC of a wholly-owned (and controlled) subsidiary. This formula would guarantee that the stakeholders in the enterprise will continue to govern the new agency. Stakeholder control of Olympic drug testing has in principal part caused the drug crisis with which we are faced with today; to permit continued stakeholder control of the new agency would be to perpetuate the status quo.

The proposal's other principal defects include:

- Its failure to provide an opportunity for the public, including government officials and others, to comment on the details of the new agency's proposed structure, responsibilities, and procedures, including its adjudications procedures, as the proposal is being developed and before it is implemented. While the Task Force is certainly comprised of qualified and thoughtful individuals, they do not represent the spectrum of interests and experience that is necessary to assure the best program possible. And the USOC itself is similarly handicapped.

- Its failure to detail how the new agency would be staffed; again, the significance of complete independence from the Olympic Movement in this regard is critical to the success of the effort.
- Its failure to detail how the "highly-qualified [scientific] experts" who will advise the new agency in several respects are to be selected. This has been a problem for the USOC in the past, as it has tended to use only experts who were part of the Olympic Movement or at least not in conflict with the larger (economic) interests of the Movement. The new agency must be required to develop a list of experts who are unassailably independent, specialized in the appropriate respects, and otherwise highly-regarded in the larger scientific community.
- Its inclusion of the current IOC laboratories in its proposed distribution of research monies. These laboratories are fraught with conflicts-of-interest which have been largely responsible for the current system's failures: they make their money developing tests for prohibited substances for the Olympic Movement, processing urine samples, and defending both their tests and the sample processing as part of any subsequent prosecution. Moreover, because they are heavily invested in their existing scientific positions, many of which have been subject to legitimate challenge, it is likely that they would expend at least part of any research monies given to them under this new program to shore up those positions, rather than to work toward an independent view of their merits or flaws. Finally, these laboratories have, with some exceptions, typically refused to have their research and conclusions peer-reviewed.
- Its failure to address squarely the problem of endogenous substances. The USOC has acknowledged that its procedures (handed down by the IOC and the IF's) for detecting the use of testosterone, EPO, and hGH are either flawed or non-existent. Nevertheless, it continues to list these as prohibited substances and, in the case of testosterone and possibly EPO, it continues to subject athletes to prosecution under the current flawed procedures.

While including these substances on the prohibited substances list may be justified for its *in terrorem* effect, there is no justification for prosecuting or allowing the prosecution of athletes based on flawed scientific theories. To do so in circumstances where it knows that the theories are defective is not only reckless, but also in flagrant disregard for its statutory authority to protect the rights of athletes to compete.

Additionally, such prosecutions do (in the case of testosterone) and will (in the case of EPO and hGH) to burden both the system and the athletes with fatally defective allegations, and ultimately tarnish the integrity of the entire system. (It is no justification that these flawed procedures are all that exist.)

On the other hand, because the endogenous substances appear to be the drugs-of-choice among some elite athletes, it is critical that the initial research efforts be concentrated in these areas, so that, if possible, iron-clad tests for the detection of the use of these substances are developed.

Alternatively, until such a test is developed, some other less punitive sanction should be conceived for a suspicious sample that does not include the unfair stigma of a public charge of doping.

- Its failure to provide defense counsel and related expertise for athletes who cannot afford their own. Athletes who are well-known and who have money have a significant advantage in drug testing proceedings, principally because those proceedings often require expert testimony to counter the prosecution's own expert witnesses. The system will not be fair unless all athletes are afforded at least a competent defense.
- Its failure to assure that all athletes similarly-situated are treated similarly in the adjudications process. It is essential to the fairness of the new system that all athletes are treated consistently. The proposal also fails to ensure that, in developing the new adjudications process, AAA and CAS will be required to develop a system of precedents. Incredibly, the proposal also affirmatively proposes that arbitrators in individual cases be permitted to set the burden and standard of proof. *The standard and burden of proof must be uniform across all cases; the burden must be on the prosecutor; and at least until we are confident that the science, collections, transport, and analysis that are involved in drug testing cases are strong enough to reduce to almost zero the possibility of false positives, the burden must remain as it is in the existing rules, "beyond reasonable doubt."* The Olympic Movement is plagued by the legitimate criticism that it is arbitrary in the manner in which it handles drug testing cases, favoring some athletes in some circumstances, disfavoring others athletes in other circumstances. The principal cure for this is the establishment of a fair adjudica-

tions process, based on precedents and a uniformly-applied standard and burden of proof "beyond reasonable doubt."

- Its continued reliance on the "standard documentation package" for purposes of evaluating probable cause, etc., that an athlete has engaged in doping. This "standard documentation package" is referred to in various existing documents having to do with the obligations of the Olympic Laboratories and the USOC to provide information about the analysis of a sample to the NGB and the athlete at issue. (I do not know whether it is an IOC term or one devised by the USOC.) This package is almost always materially deficient, as it generally contains only the bare minimum of information. Athletes subject to doping charges routinely and reasonably demand all of the documentation relevant to their sample. The inherent unfairness of denying an athlete access to *all* such information (some of which might be exculpatory) currently results in an almost routine determination (by the relevant hearing panel or the NGB, for example) that the laboratories should provide that additional information. This document production is typically done piecemeal, thereby delaying the resolution of doping cases. Thus, while there is nothing wrong with the term "standard documentation process," its meaning must be understood to include all documents that are relevant to the testing and investigation of a suspicious sample.

REPORT FROM THE DULCE CONFERENCE ON DOPING

FINAL CONFERENCE REPORT

The Necessary Components of an Anti-Doping Program and Related Documents

On May 7 and 8, 1999, the Duke Center for Sports Law and Policy hosted the Duke Conference on Doping in Sport. The objectives of the conference included the gathering together of experts and leaders from the world of sport to discuss the principal problems implicated by doping, and to develop a summary of the necessary components of a proper anti-doping agency or program. The group met both in plenary and break-out sessions. The break-out sessions were specifically designed to facilitate discussion of such an agency or program's structural, scientific, and legal components. What follows is a summary description of those components.

I. The Necessary Structural Components of an Anti-Doping Agency or Program

A. Externalization is necessary and should be put into effect immediately. Functions to externalize include:

1. selection of athletes to be tested
2. sample collection
3. sample analysis
4. reporting of analytical results
5. screening of results and referral (or not) to adjudication
6. adjudication

7. possibility of externalization of sanctions should be studied. Sanctions should remain with the NGB, but a potential conflict of interest involves NGBs sanctioning their star athletes too lightly, in which case rectification by an independent agency might become necessary.

B. The Canadian Model looks very good in the current international context and is a model to which future programs can aspire.

C. Educational activities should remain with the USOC and the NGBs.

D. Public health concerns should be a top priority, and all governments should do a better job in this area. Effective doping control requires public health education about doping in order to attract public support and funding.

E. The USOC should recognize that it has an image and credibility problem in the international community and must make strenuous efforts to rectify the situation, by means of externalization, for the sake of the anti-doping effort and the integrity of Olympic and amateurs sports as a whole.

F. The Court of Arbitration for Sport is still too entangled with the IOC and should be located somewhere other than Lausanne.

1. It should be supported by truly independent funding.
2. It should have a Charter of Principles to guide its adjudications.
3. It should provide access to counsel for athletes.
4. It should include people possessing relevant scientific expertise.
5. All of its panels should adopt regularized procedures and report out both judgments and the reasons for those judgments.

G. The independent international anti-doping agency or program should make research, standards, and models a top priority.

1. It should develop minimum standards that are expressed in a protocol for determining which substances are placed on the banned substances list and for revising testing procedures.
2. It should recognize different physiological standards for males and females.
3. It should include a government liaison with an intelligence-gathering capacity for collecting information about doping practices, drug trafficking, and the behavior of coaches and others who have access to high-performance athletes.

II. The Necessary Scientific Policy Components of an Anti-Doping Agency or Program

A. The objective of any anti-doping program should be to eradicate the use of drugs in sport.

1. The use of drugs in sport is unethical.
2. The use of drugs in sport in some instances is detrimental to the health and well being of the athlete.

B. This objective must be approached from two perspectives.

1. The society must subscribe to a program of prevention through values and health-based education.
2. The society must subscribe to a program of deterrence and punishment through a strong drug testing program.

C. The following are essential with respect to the program of prevention through values and health-based education.

1. It should focus on the public health aspects of drug use, including both psychological/ethical and physical health.
2. It should be built into the sports system at its origins. Understanding the importance of training and competing with integrity, and of long-term physical and ethical health cannot be accomplished with rhetoric and billboards directed at mature athletes.
3. It should be designed to counteract the negative commercial messages that encourage athletes to do drugs. For example, it must counteract the message that sport supplements are not only acceptable but desirable; and the message that the only place that counts is first place.
4. It is the responsibility of every adult who is involved with athletes, including parents, teachers, coaches, sports governing bodies, commercial enterprises that sponsor sporting events, and local and national government.

D. The following are essential with respect to the drug testing program:

1. It must be comprehensive and national/international. Harmonized drug testing in all sports is essential. Children and athletes must not get mixed messages depending upon the sport about whether drugs are or are not acceptable.
2. It must be scientifically sound. Peer-reviewed research must exist to back-up the tests that are conducted. The tests must be designed to achieve a low-to-nonexistent rate of false positives.
3. Prosecutions must be brought only on strong evidence of guilt. They must be backed-up by peer-reviewed research, the sample's chain of custody must be intact and thoroughly documented, and the athlete must be presented with a complete packet of forensic information on the sample.
4. The laboratories/scientists that conduct the relevant research and the sample analyses must be independent of the sports governing bodies. The existing IOC laboratories are a good beginning, and the group supports their evolution toward independence; however, the following additional measures must be implemented:

- a. The laboratories must become completely independent.
- b. They must permit outside audits of all of their operations, including of the development of the underlying science, their relationships, and forensic toxicology.
- c. All of their procedures must meet the standard established by the International Standards Organization (ISO), and with respect to the analytical work, the ISO standards should be forensic rather than clinical.

d. They must allow their research to be peer-reviewed, and because they continue to lack certain critical expertise, this research must be complemented by that of independent scientists in relevant fields.

5. There must be an independent oversight board charged with the supervision of the drug testing program, including of the laboratories and research, that is comprised of outside qualified experts in the fields of science, law, and public policy.

6. The list of banned substances must be compiled based upon the reasons for doping control, i.e., protecting the public health and preventing unethical competition. The list should include endogenous substances that are proven in accordance with accepted procedures and protocols to be ergogenic aids and/or detrimental to the public health. However, cases must not be brought based on an endogenous substance unless there is a test for that substance that is scientifically sound and validated in accordance with accepted procedures and protocols.

III. The Necessary Legal Components of an Anti-Doping Agency or Program

A. The adjudication process should be entirely independent of the governing bodies.

1. The governing bodies should have an educational role, informing athletes of the dangers of doping and of the ethical foundation of sports.
2. National governing bodies should not be placed in an adversarial role vis a vis their athletes in doping cases.

B. The adjudicatory process must include the following safeguards:

1. Prosecutions will be based on scientifically determined violations.
2. All prohibited substances must be detectable in the athlete's urine or body fluids through a method that is scientifically valid.
3. All prohibited substances must be banned on the basis of research that takes into consideration such relevant factors as ethnicity, age, gender, and medical history.

C. The adjudicatory process should proceed in three distinct stages.

1. *Stage 1.* There should be a preliminary review by a panel composed of relevant experts, including physicians, other scientists, and lawyers.

a. The purpose of this review is to determine if all procedures were followed for the collection, storage, transportation, and testing of the athlete's sample and if, based on the laboratory report, the results of the analysis are sufficiently strong evidence of the athlete's guilt.

b. During this preliminary stage of the proceedings, the identity of the athlete is held strictly confidential.

c. If the review panel finds that the published mandatory procedures for the collection, storage, transportation, and testing of the sample were not strictly followed, it must declare the sample invalid and end the process.

d. If the review panel determines that the collection, storage, transportation, and testing of the sample complied fully with the rules, and that the analysis provides sufficiently strong evidence of the athlete's guilt, it will forward the case for prosecution. At that point, there may be a rebuttable presumption of the athlete's guilt.

e. The independent anti-doping agency or program will be responsible for the prosecution of all doping cases.

f. The review panel will make periodic public reports of the number of cases dismissed in this manner, and the basis for each dismissal. The names of the athletes involved will not be disclosed.

2. *Stage 2.* The determination of whether a doping violation took place must be decided by qualified decision makers.

- There currently are two possible models, neither of which in its present form would satisfy the requirements for inclusion in the new process. Each model has advantages and disadvantages.
- (1) The first is the American Arbitration Association (AAA).
 - One of the advantages of AAA is its familiarity and suitability for emergency disputes.
 - (2) The second is the International Court of Arbitration for Sport (CAS).
 - One of the advantages of CAS is its potential international acceptance, and thus potential for finality.
 - b. One of the most important criterion for the body ultimately selected to decide the merits of cases is the employment of adjudicators with experience deciding contested scientific disputes.
 - c. There must be regularized procedures for all hearing panels.
 - (1) Panels must publish all decisions, and the bases for the decisions.
 - (2) If CAS is used, it would have to establish regional panels to streamline the process.
 - d. There must be a process for providing counsel to athletes accused of a doping violation.
 - (1) This might be accomplished through a Judge Advocate General-type structure, which would provide both the prosecutors and the defense counsel, under the direction of an independent overseer.
 - (2) Another possibility is the reliance on pro bono counsel.
 - (3) A third possibility is the use of an approved list of counsel.
 - (4) In the end, some combination of these three might be employed.
 - e. One issue left unresolved was at what point an athlete should be suspended.
 - (1) There was agreement that liability should not attach before a suspicious sample was confirmed by a second analysis of the sample.
 - (2) There was some support for this confirming analysis being done by a different laboratory than the one that performed the initial analysis.
 - (3) There also was support for the athlete's early involvement in the preliminary stage of the process, to raise limited compliance issues before the review panel. There was not agreement about whether this would constitute a hearing for purposes of the Amateur Sports Act, which bars a suspension prior to a hearing.
 - f. There was agreement that an athlete's certification of the sample collection procedures could be used against him or her in a contested hearing, although the athlete still could challenge the collection.
 - (1) For this reason, one of the important functions of the national governing body would be the education of its athletes in the process and their rights under the program.
3. Stage 3. The final stage of the process involves proceedings in the athlete's national courts or before international federations.
- a. There was agreement that a credible and bona fide arbitration process as outlined above would result in minimizing the role of civil courts.
 - (1) Either party could seek confirmation of the administrative decision, and thus largely protect the arbitration decision and the underlying dispute from further court scrutiny.
 - b. There was agreement on the need for harmonization among the rules of the various federations to which an athlete might be subject.
 - (2) Any obligation that a national governing body had for doping disputes under the rules of its international federation would have to be delegated to the independent doping agency.
 - Thus, a sample tested outside the United States would be subject to the same preliminary compliance review that a sample generated in the United States would receive.
 - And the failure to follow the requirements for the collection, storage, transportation, and testing of the sample by the foreign entity would result in the sample being declared invalid.

CONFERENCE CONCEPT

There is growing and substantial evidence that individuals across the spectrum of athletic competition—including children, collegians, Olympic performers and traditional professionals—are using drugs to enhance their training potential and ultimately, their chance of achieving competitive and financial success. The recent, highly-publicized drug busts at the Tour de France, the suspensions of Olympians Michelle Smith de Bruin, Randy Barnes and Dennis Mitchell, Mark McGwire's use of androstenedione and reports that sales of that substance surged as a result of his achievements are but the prominent tip of the iceberg.

The issue of drug use by athletes thus transcends the relatively narrow interests of single organizations. For example, the IOC and its constituent organizations, including the USOC, primarily are concerned with defining what constitutes illegal drug use in Olympic competition, funding the programs necessary to implement their elite drug control programs, and the impact of their efforts on the image of the Olympic Movement and its fund-raising capabilities. On the other hand, the larger domestic and international society is concerned with the impact of drug use among elite athletes on its ability to protect the health, ethics and expectations of children, on the social significance and value of sport that is drug-ridden, and on assuring the protection of individual rights including the right to work, the right to due process of law, and the right to privacy.

The Duke University School of Law, in conjunction with its Center for Sports Law and Policy, will host a working conference in two parts, beginning on January 16, 1999, and reconvening on May 7-8, 1999, to address in an independent and comprehensive manner these broader societal concerns, and to provide an agenda for organizations that wish effectively to tackle the issue of drugs in sport. The conference will include individuals spanning a spectrum of society, including persons and groups interested by the issue of drugs in sport. Specifically, Duke will invite both independent experts in the relevant fields of law, ethics, sociology, education, medicine, and athletics, and members of the affected sports organizations, including athletes and officials, and their corporate sponsors, to participate in a focused discussion of the problem of doping in sport. Special emphasis will be placed on (1) independence and the structure that independent governance of drug testing programs might take; (2) the science of doping and doping control; and (3) the legal concerns of accused athletes and governing organizations in maintaining effective doping control. In the course of the deliberations, current proposals for action pending before the United States and International Olympic Committees will be discussed. Although the conference will be by invitation only, the complete work of the participants will be open to the press, and all reports and papers presented or developed at the conference will be available to the public.