



## **PROCEEDINGS**

PARIS - 12 NOVEMBER 2012









Paris – 12 November 2012



**NEW PARTNERSHIPS FOR CLEAN SPORT** 

### **EXECUTIVE SUMMARY**

The International Conference on "The Pharmaceutical Industry and the Fight Against Doping: New Partnerships for Clean Sport," was the first event of its kind, bringing together biopharmaceutical companies and their representative associations with the authorities in charge of the fight against doping in sports. The key objective of the conference was to strengthen and develop the efforts between these entities to better prevent misuse of drugs in development with doping potential in sports.

The many successful collaborations in recent years between individual pharmaceutical/ biotechnology companies and the World Anti-Doping Agency (WADA) demonstrate the feasibility of a mutually beneficial partnership model to develop anti-doping tests for new drugs with doping potential to deter their abuse by athletes.

Based upon such experiences, practical tools have been developed jointly by the biopharmaceutical industry and WADA to facilitate information transfer. Encapsulated under the 2 FIELDS 1 GOAL Campaign launched in July 2012, these tools are available to biopharmaceutical companies willing to address the risk of doping potential of any drug in their developmental pipelines.

This conference led to strong support from all participating parties of the innovative, collaborative partnership model. Several recommendations and initiatives were highlighted to further strengthen and expand the model in the near future, for the benefit of biopharmaceutical companies and anti-doping authorities – WADA in particular – and with the full backing of the international public authorities attending.



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## THE PHARMACEUTICAL INDUSTRY AND WADA: UNITING FOR CLEAN SPORT

### **Valérie Fourneyron**

Minister of Sports, Youth, Non Formal Education and Voluntary Organizations

Mister President of the International Olympic Committee, Jacques Rogge,

Mister President of the World Anti-Doping Agency, John Fahey, Madam Deputy Secretary General of the Council of Europe, Gabriella Battaini-Dragoni,

Mister Deputy Director General of UNESCO, Getachew Engida, Parliamentarians,

Presidents and directors of national anti-doping agencies, Presidents and directors of pharmaceutical groups, Mister President of the National Olympic and Sports Committee of France, Dear Denis,

By way of introduction to my speech, I would like to say what a huge honor and pleasure it is for me not only to open this conference, but especially to welcome to Paris, to France, and within the walls of the National Assembly that I know so well – which are the heart of French democracy and central to republican debate – what a pleasure it is to welcome such figures from the world of international sports, such major world and European political figures, and such important pharmaceutical industry decision-makers, all united under the same banner and bound by a common conviction that we must not relent in the fight against doping.

Mister President Jacques Rogge, it is a great pleasure to welcome you to Paris today, and I thank you for doing us the honor of attending this very first international conference dedicated to cooperation between the pharmaceutical industry and anti-doping authorities.

Your presence is further proof of the international Olympic and sports movement's commitment to the fight against doping. Everyone in this room knows what the international fight against this scourge owes to you and to the IOC, and I wanted to take this opportunity, at the outset, to thank you once again on behalf of France.

The fight against doping also owes a great deal to two other entities represented here alongside me:

Mr. Engida, UNESCO made the fight against doping one
of the cornerstones of its sports policy, a policy rolled out
around the world to serve the noble cause of education
and culture.

And I take the liberty here of quoting the UNESCO International Charter of Physical Education and Sport of 1978, which was amended in 1991 to address the issue of doping: "No effort must be spared to highlight the harmful effects of doping, which is both injurious to health and contrary to the sporting ethic, or to protect the physical and mental health of athletes, the virtues of fair play and competition, the integrity of the sporting community and the rights of people participating in it at any level whatsoever."

I could not have said it better myself, and UNESCO's efforts to breathe life into these ideals on the five continents should be recognized.

In 2005, those efforts, among others, led to this International Convention against Doping in Sport, which is so important.



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 Turning now to Ms. Gabriella Battaini-Dragoni, we also should not forget the Council of Europe's decisive role in our fight.

Historically, doping has been the Council of Europe's primary sports-related concern, since, as early as 1967, the Committee of Ministers drew up the first international legal instrument against doping by athletes. Since then, you have never stopped strengthening your commitment to this fight, and I thank you for it.

The same historic determination to conquer doping is the common thread of our presence in this room today. The positions taken by the IOC, UNESCO, the Council of Europe, and numerous governments and international bodies, made it possible to set up the World Anti-Doping Agency (WADA), over which Mr. John Fahey, who is also here today, presides. We all wanted the Agency; we called for it and helped shape it. Those who already had responsibilities in the fight against doping in 1999, many of whom are in this room, remember how difficult it was. Reluctance, doubts and suspicions had to be overcome. But we saw it through.

We can now be proud of what has been accomplished. We can be proud of what is being done. I mean to say that this burning issue has shown us, over the past few weeks, that doping and those who set up a system around it, have met their match.

During this conference, we obviously will not be able to avoid coming back time and again to the Armstrong case and the lessons we should all learn from it. In this regard, I would like to acknowledge Mr. Travis Tygart, CEO of the U.S. Anti-Doping Agency, who is here with us this morning, because – let it be said – what he has accomplished is exceptional. With his professionalism, drive, commitment to bringing out the truth, exigency and integrity, he brought down the man who claimed to be the greatest cyclist in the world, but who was in fact merely the biggest cheat.

This is absolute proof, for those who still had doubts, that there will never be impunity in doping, that the truth will catch up with those who flout the very spirit of sport: Fair results.

However, a great deal remains to be done. As I was saying a moment ago, the Armstrong case and its outcome, with all of its twists and turns, should teach us some lessons and force us to reflect collectively on ways of further improving our anti-doping tools. Nothing should ever be taken for granted. Perhaps even less so in the fight against doping than in other arenas.

This conference – a joint project initiated by WADA, the French Ministry of Sports, UNESCO and the Council of Europe – is a perfect illustration that this is shared, and that we are arming ourselves to move forward and gain ground together.

I believe this event is actually a global first in the history of the fight against doping, not only because of the chosen topic, but also because of the international nature of the initiative. As a result, it should be viewed as giving hope to all of the partners gathered here, as it gives strong and concrete impetus to this wonderful cooperation.

This conference should be a pivotal moment for acknowledging the pressing need for collaboration as far upstream as possible between the pharmaceutical industry and anti-doping authorities. WADA already signed a Joint Declaration on Cooperation in the Fight against Doping in Sport with the International Federation of the pharmaceutical industry in July 2010; we have to keep moving in this direction.

The practical and effective implementation of such a collaborative measure is a subject that is as important as it is difficult to achieve. It seems to me that this goal should be based on a shared interest. It should give every stakeholder reason to be satisfied with it. Anti-doping authorities should gain more reliable and responsive resources from it in order to identify doping substances or methods that are currently very difficult to detect. The pharmaceutical industry should reinforce its commitment to this cooperation through a quality process that provides virtuous public health and ethics-related responses.

The effective anti-doping policy we are all calling for should be based on three main cornerstones:

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- Unfailing support for the fight against trafficking (through network and internet surveillance, and so on) and support for any strategy that improves the effectiveness of tests by confirming that they are truly unexpected and targeted.
- 2. Close cooperation with the pharmaceutical industry in order to anticipate the marketing of potentially doping molecules and the development of corresponding detection methods. This type of cooperation requires a strict confidentiality policy, but also a sound knowledge on the part of industrial scientists of the physiological and biological bases underlying the achievement of a given physical performance.

The presence of everyone in this room shows that this process is achievable with the large pharmaceutical groups. However, we should also consider the small laboratories all over the world and biotechnology laboratories, which are difficult to identify (such as startups or university laboratories) and which have the greatest confidentiality concerns but which must nevertheless be included in our work.

3. Finally, the fight against doping should include the structured partnering of anti-doping laboratories with the university-based scientific world so that they can access the most reliable analytical methods, especially in genetic engineering and high-throughput techniques. There again, these types of relationships currently remain to be established, making a point of protecting confidentiality and independence on both sides within the framework of their mission.

The extent and pace of advances in cooperation between partners who have to meet both individual and collective interests will depend on our collective ability to respond adequately to all of these issues. I am convinced that we will be able to find positive answers and that, in the future, this conference – the Paris conference – will be a seminal step in bringing together two worlds that are not always accustomed to working together, but whose collaboration will be key to building and enforcing cleaner sport in the future.

Martin Luther King said, "He who accepts evil without protesting against it is really cooperating with it." We cannot let it be said that we did not do everything we could to fight doping, that we did not take every measure, or that we did not try every solution.

In France – and I know this example will be cited and expanded upon during the various speeches – we had a great example of effective cooperation between anti-doping authorities and the pharmaceutical industry. And we were able to measure the results. I want to talk about the marketing of the thirdgeneration form of EPO (CERA), which in 2008 made it possible to set up an ad hoc test during the 2008 Tour de France, thanks to cooperation between ROCHE (Swiss pharmaceutical group), WADA, the French anti-doping agency (Analysis Department) and the laboratory in Lausanne. Of the six cyclists who tested positive during that Tour de France, four had taken that third-generation form of EPO. This is a convincing example that I believe can be used as a model for the kind of cooperation everyone in this room is hoping for.

Cooperation, consultation, joint effort: These are the key words for this conference. We are stronger together, and this conviction should be carried throughout this work day, of which we all expect a great deal for the future.

As you may know, I am extremely concerned about doping by virtue of my training as a sports physician, my duties with professional sports teams, my past and current work with the Ministry of Sports, and my political involvement at the local and national level.

Now, with the trust the Council of Europe has placed in me by appointing me as its representative on the WADA Executive Committee, and if WADA approves that appointment, I will take my convictions to the international level – those that remind me that we cannot, that we must not, compromise on doping, and that we have to carry on, without interruption, working not against sports, but for athletes.

Because we must not forget that, behind every athlete who dopes, is a person jeopardizing his or her health.

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We must fight together, side by side, in order to protect athlete health, the essence of their practice and the beauty and spirit of sport. I am also convinced, and recent events only confirm my conviction, that we cannot leave the responsibility for fighting against and screening for doping to the sports federations alone.

It is imperative that we help the federations in their fight — which I know to be important — against this scourge, together with WADA and the national anti-doping agencies. It is always difficult and complicated to promote a sport and to oversee it at the same time. Being both judge and party is always tricky. And it is no insult to the sports movement — quite the contrary — to tell it that it has to work even more closely with the independent agencies and rely on their expertise, in order to protect the fairness of results and dispel the suspicions that are so soul-destroying to sport.

Those close to athletes must also be fully aware of their responsibilities. I am thinking of medical teams, athlete managers and so on. They are doing a phenomenal job of supporting high-level athletes. But their responsibility when it comes to athlete doping cannot be ignored. There will be no impunity for them either. Allowing no personal interest in athlete results seems to me to be the only option if we hope to eradicate the harmful influences that make some heed the siren call of doping.

I could talk about these issues for hours, but there is quite a number of speakers of rare quality here today, so it is my great pleasure to yield the floor to the other organizers of this event and then, of course, to President Rogge.

In closing, this sentence written by d'Alembert in a letter to Voltaire perfectly captures my state of mind: "What purpose would it serve to have so many honest people in the ministry if the scoundrels win again?"

#### Gabriella BATTAINI-DRAGONI

Deputy Secretary General of the Council of Europe

Madam Minister of Sports, Youth, Non Formal Education and Voluntary Organizations

Mr Deputy Director General of UNESCO,
Mr President of the World Anti-Doping Agency,
Mr President of the International Olympic Committee,
Ladies and Gentlemen,

It is a great honor and a pleasure for me to welcome you to this International Conference.

I would first of all like to thank you, Madam Minister, for hosting this event in this emblematic building of the French Republic, and also for having mobilized all your colleagues, whose sustained efforts over the past months have made today's event possible.

[The Council of Europe's role]

As you know, the Council of Europe is an intergovernmental organisation with 47 European Member States. Our aim is to actively promote the fundamental European values of human rights, democracy and the rule of law.

Sport is of course a vehicle for learning about these values, which are essential for generations of sports enthusiasts of all ages, particularly by instilling the spirit and values of sport and respect for others, via participation in the sports activities themselves or in the bodies which structure the sports movement, from the local clubs to the major international federations.

However, for an institution such as the Council of Europe, sport is also a challenge in terms of public health and action against corruption and organized crime.

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These major issues are dealt with at the Council of Europe by such agencies as the European Directorate for the Quality of Medicines (also known as the European Pharmacopoeia), the Pompidou Group (which combats illegal trafficking in substances), the Group of States against Corruption (GRECO), to which all the Council of Europe Member States are Parties, along with the United States, and the European Committee on Crime Problems (CDPC).

These bodies have drawn up such instruments as MEDICRIME, the Council of Europe Convention on counterfeiting of medical products and similar crimes involving threats to public health and, obviously, the Council of Europe Anti-Doping Convention. Furthermore, the Council of Europe is currently preparing a new Convention to combat illegal betting and match-fixing.

I would like to welcome to this meeting the many delegations of the Monitoring Group of this Anti-Doping Convention, as well as Mr Parkinson, Chair of the Ad hoc European Committee for the World Anti-Doping Agency, whose task is to liaise between the different Council of Europe bodies and the World Anti-Doping Agency.

### [Creating new partnerships...]

The Council of Europe already has a range of facilities and bodies directly or indirectly supporting the efforts of European states to combat doping.

However, for the Council of Europe and all the European public authorities, we cannot go on indefinitely pouring more and more resources into this fight. Most of our countries are facing difficult economic situations that are forcing us to review our working methods and to show creativity, particularly by identifying new synergies with new partners.

It is naturally within this framework that cooperation between the pharmaceutical industry and the anti-doping authorities is emerging as a promising field in which to develop the potential for significantly reinforcing the relevance and effectiveness of action against doping in sport.

### [... in order to improve the effectiveness of our work]

All the players involved in combating doping have noted a proliferation of new pharmaceutical substances and new medicines on the market. The Monitoring Group of the Council of Europe Convention has dealt with this question and, at a meeting of its Advisory Group on Science in March 2010, took the decision to organize an international conference on the subject in cooperation with the World Anti-Doping Agency (WADA). I would like to sincerely thank WADA for agreeing to join this initiative.

On the one hand, the proliferation of pharmaceutical substances and medicines is a very positive outcome of the work of the pharmaceutical industry, reflecting improved provision for pain, suffering and illness, which can only be welcomed.

On the other hand, it may also be the result of the nefarious activities of counterfeiters. I would like to draw your attention to the fact that we will not be able to control the incessant influx of new substances available on to the market simply by attempting to form a partnership with the official industrial actors. We must take action against the black market and the counterfeiters. This is why I would stress the importance of such international legal instruments as the MEDICRIME Convention.

In order to guarantee the success of our Conference, I consider it vital to advocate extensive and swift ratification of this Convention, by European and non-European states, while emphasising the major potential role of the World Anti-Doping Agency in promoting this Convention.

However, we must address all the aspects of the problem. This is why I am glad to see that this Conference has attracted not only the institutional players but also a broad panel of public figures representing the pharmaceutical industry. With you we can endeavour to build up new partnerships which, in a difficult budgetary context, will help make our anti-doping action increasingly rapid and relevant, and therefore increasingly credible.

Madam Minister, Ladies and Gentlemen,

I would wish you all a very pleasant, fruitful and rewarding day's work.

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Deputy Director-General, UNESCO

Ms. Valérie Fourneyron, Minister of Sports, Youth, Non Formal Education and Voluntary Organizations of France,

Excellency Gabriella Battaini-Dragoni, Deputy Secretary General of the Council of Europe,

Excellency Mr. John Fahey, President of the World Anti-Doping Agency,

Dr. Jacques Rogge, President of the International Olympic Committee,

Distinguished Guests, Ladies and Gentleman,

I would first like to thank the French government for its warm welcome, and for its resolute commitment to the fight against doping.

Minister, your presence among us today, and the venue of this Conference, the French National Assembly, both demonstrate the willingness of France, a great sporting nation, to consistently associate sporting practices with respect for the values that lie at the heart of any strong and dynamic society: Health, respect for oneself and others, equality, and justice.

UNESCO has its headquarters in Paris and, as a result, our organisation feels particularly close to France, and I am delighted to have the chance to reiterate this in your presence.

I wish to thank also the Council of Europe, with whom UNESCO has worked closely to develop an international convention, to spread the principles of the World Anti-Doping Code and to drive home the universality of anti-doping in sport.

I also wish to express gratitude to the International Olympic Committee and the World Anti-Doping Agency for their leadership.

Working every day on the frontline of the struggle against doping, the World Anti-Doping Agency is more aware than most of the variability of doping controls.

The Agency has been especially helpful in shaping the theme of this Conference.

However challenging, we must develop stronger partnerships with the pharmaceutical companies that produce and market substances used by athletes.

We must rethink how each of us can help others to achieve our common goals.

We need a new deal for clean sport.

The news this year has been decidedly mixed.

On the one hand, the London Olympics and Paralympics have shown what we can achieve, but the revelations about Lance Armstrong must only deepen our resolve.

There are no chemical shortcuts to victory – a doped victory carries no triumph.

Doping violates the principle of fair play at the heart of sport, and it is a danger to the health and well-being of athletes.

The fight against doping must be as wide and deep as are the challenges it raises.

This must start with the athletes themselves, with their coaches, with their supporters and families.

It must be taken forward by the sports federations that oversee competitions and set standards, with the international sports movement, with anti-doping agencies and Olympic committees.

This struggle must, indeed, include also the private sector and the pharmaceutical industry.

We are all in this together – this is our message today.

At the heart of all our efforts stand the *World Anti-Doping Code* and the *International Convention against Doping in Sport*, adopted by the UNESCO General Conference in 2005 and speedily approved by 170 States.

This is the world's first truly global anti-doping convention, and it provides a strong legal framework by integrating the non-binding *World Anti-Doping Code* into national laws and regulations.

We have laid the foundations for the fight against doping —we must now build on them.



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All Governments must translate its principles into policy.

This is why UNESCO established in 2008 the *Fund for the Elimination of Doping in Sport* – to help Governments in strengthening prevention programs, in adopting appropriate legislation and in bolstering capacities for monitoring.

The fight must start as early as possible – by sensitising young people to the medical, legal and moral consequences of doping.

These are the goals of UNESCO's educational and prevention programs.

The fight must also be fought on the frontlines of research and science – to offset the relentless development of new substances that are ever more difficult to detect.

We must work hand-in-hand here with the private sector, especially pharmaceutical companies – to review the development of new substances and their entry onto market, to develop control tests in parallel, to build effective prevention measures against doping.

This is not about burdening the private sector or harnessing the tremendous potential of research. This is about laying the foundations for clean sport and about creating new forms of partnership.

We need a new deal, because we need the power of sport today.

Sport is about passion, it is about community and it is about values – the values of competition on a level playing field, of teamwork and courage.

Doping violates all of this, and undermines the foundation for healthy societies.

There is also a business dimension to this, as doping weakens the appeal of sport and the loyalty that accompanies it.

Ladies and Gentlemen,

This Conference comes at just the right time, when Governments are in need of guidance, when we need precisely this kind of open dialogue.

All of us are here today because we love sport.

This must remain our starting point and the measure of our success as we move forward together.

I wish to thank you for your commitment to this goal we share.

### SOME BACKGROUND FIGURES/STATISTICS/INDICATORS

In France, a law was adopted earlier this year (loi n°2012-158 voted in February 2012) that strengthens sport ethics, and specifically aims at preserving the exemplary nature of sport, and fighting against doping.

### The UNESCO Fund against Doping in Sport

The UNESCO Fund for the Elimination of Doping in Sport was set up by the very states that signed the International Convention and is funded by them on a voluntary basis. Since its creation in 2008, it has supported 73 national and regional projects all across the world, aiming to enhance anti-doping capacities (total funding of \$1.2 million US). Each of these projects reflects at least one of the three funding priorities: (1) education; (2) public policy; and (3) mentoring and capacity development.

One remarkable example comes from the successful implementation of three anti-doping projects in Cameroon, where the Fund UNESCO Fund for the Elimination of Doping in Sport has provided financial support. The first projects were really awareness-raising programs targeting high-level athletes and their entourages – and later, school athletes. The third project built on the success of those first two initiatives. It produced the framework text for a national anti-doping in sport policy, which is now being discussed at governmental level. This illustrates the potential of small initiatives, small investments, to move us toward a lasting anti-doping strategy.



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#### Hon. John FAHEY

President, World Anti-Doping Agency (WADA)

Minister of Sports, Youth, Non Formal Education and Voluntary Organizations of France, Deputy Secretary General of Council of Europe Deputy Director General of UNESCO President of the International Olympic Committee Distinguished Guests, Ladies and Gentlemen,

Good morning and, on behalf of the World Anti-Doping Agency (WADA), a very warm welcome to today's international conference.

First of all, I would like to thank the French Ministry of Sport for hosting this event, as well as to the other co-organizers – the Council of Europe and UNESCO.

WADA is extremely encouraged that so many parties and organizations are here to take an active part.

Today's conference is the first of its kind. It has been designed to enable the pharmaceutical industry and members of the world's anti-doping community to gather under one roof to further explore ways that they can work together – for the sake of sport, and for the sake of clean athletes.

Doping in sport is not a new problem. It has been around for a number of generations now, maybe longer. But it is a problem that we all share.

It is no longer confined to sport – rather, it is an issue that has a negative impact on many areas of society, and one that deserves to be addressed in such a way.

For the anti-doping community and sport movement, doping threatens the very integrity of what we hold dear: Sport in its purest form, allowing talent and dedication to be recognized and rewarded under the fairest possible terms, and without undue interference.

For the pharmaceutical industry, doping leads to the misuse and abuse of medicines. It has the potential to drive up the unlicensed production of products that are designed to improve the health of populations worldwide, not risk to the health of athletes, and especially the children within that extensive group.

As some of you will know, WADA was founded in 1999 when the sport movement and governments of the world first decided that a specialist, independent agency was required to deal with what was a growing problem.

That problem persists today. Indeed, there is plenty of evidence to strongly suggest that it is still on the rise.

The Festina doping scandal at the 1998 Tour de France was the catalyst for this unified sport-governmental approach, and one, which I might add, that led to the creation of an organization that is unique in many ways.

Indeed, WADA's very existence is proof enough of the enormity of the challenge that we face.

But it is also proof that no socio-sporting problem, however serious and complex, is insurmountable if there is a will to address it.

Just as sport and government came together at the end of the last Millennia, and just as governments now show their support for anti-doping through the UNESCO International Convention against Doping in Sport, so we must continue to engage more parties in the fight.

Athletes who choose to dope more often than not have the support of a well-funded entourage. This entourage can include scientists, doctors, coaches, nutritionists, and agents – sometimes even parents.



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WADA has worked very hard over the last 12 years to put in place testing programs and protocols to try to deter athletes from cheating, and to catch them when they do.

Indeed, WADA invests approximately 20 percent of its budget every year in science research, and so far has dedicated more than \$60 million US to this cause.

We rely on scientific institutions to conduct much of research and development of detection methods, and fund these efforts as best we can.

But it is a challenge to keep pace with the science of the unscrupulous individuals who help athletes to cheat in this way.

Such is the money and the rewards on offer in modern sport that those who develop and supply doping substances are very well financed. And more often than not, they operate with the support and criminal expertise of the underworld.

So WADA has adopted other methods to enhance the fight against doping in sport. This includes the development of memorandums of understanding with law enforcement and government agencies, and collaboration with pharmaceutical and bio-technology companies.

Testing and analysis alone will not be enough for the antidoping community to gain parity with the underground organizations that provide athletes with the means to dope. These are often the same organizations that control the supply of recreational drugs and often are involved in corrupt and illegal betting on sport. They are organizations that operate outside the jurisdiction of sport.

WADA is fully aware of this, and it is the reason why we are all here today.

Already, WADA has in place partnerships with a number of organizations from the pharmaceutical industry, partnerships that have assisted the Agency in its fight against doping.

We know such partnerships work, and it is now time to explore ways in which to broaden their scope.

We must make it more difficult for athletes and their entourage to misuse pharmaceutical products, and more difficult for underworld organizations to produce them illegally for athletic enhancement.

Doping is no longer confined to the sports sector, and WADA needs help and support to tackle what is now an issue that affects the whole of society.

It is WADA's hope that, through this conference, the antidoping community and pharmaceutical industry can explore tangible ways in which to develop their cooperation – for the benefit of clean athletes, for the health of our society and to help minimize the misuse of pharmaceutical products.

I wish you all a constructive and enjoyable day, and thank you once again for attending.



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### **Dr. Jacques ROGGE**

President, International Olympic Committee

### Minister,

Deputy Secretary General of the Council of Europe, Deputy Director General of UNESCO, President of the World Anti-Doping Agency, Ladies and Gentlemen,

I want to start by thanking the World Anti-Doping Agency, the Council of Europe, UNESCO, and the Ministry of Sports, Youth, Non Formal Education and Voluntary Organizations of France, for bringing us together to build new and stronger partnerships in the fight against doping. The International Olympic Committee has seen the value of collaboration many times in our fight against doping over the past 50 years.

The scourge of doping in sport is too complex and too widespread for any single organization to confront it alone. Doping is an affront to the Olympic values and makes a mockery of fair play.

But it is not just a problem for sport, it is also a problem for society.

The corruption of sport inevitably involves other forms of corruption.

Sophisticated doping operations often involve organized criminal networks that operate across national boundaries.

The substances that cheaters misuse are often obtained by theft or through bogus prescriptions written by morally bankrupt physicians.

In some cases, drugs are diverted for misuse while they are undergoing tests in clinical trials.

The Internet is another major source of supply, supported by an underground network of clandestine laboratories.

Interpol is waging a constant battle against these operations.

Barely a day goes by without a report that Interpol has shut down a Web site and seized massive quantities of illegal substances or counterfeit drugs.

Unfortunately, many of these illicit Web sites reappear almost immediately.

To combat doping effectively, we need help from governments, law enforcement agencies, scientists, the medical community, educators and the pharmaceutical industry – as well as athletes, coaches, agents and sport administrators.

The need for better cooperation among all sectors of society became painfully obvious in the 1998 Festina case, which exposed a large-scale doping ring at the Tour de France.

The IOC responded to the scandal by convening the First World Conference on Doping in Sport in early 1999, a landmark event that heralded a new era in the fight against doping.

The conference led to the creation of the World Anti-Doping Agency (WADA) and transformed a sporadic and disorganized effort into a unified global campaign.

To ensure WADA's success, the IOC provided its entire funding for the first two years, giving governments time to come up with their 50 percent share.

The Olympic Movement continues to match government funding dollar for dollar.

The IOC and sports organisations within the Olympic Movement support and augment WADA's efforts in ways that go well beyond our direct financial contribution.

We take the lead in testing competitors for evidence of doping.



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The IOC is responsible for the testing program at the Olympic Games, the Olympic Winter Games and the winter and summer editions of the Youth Olympic Games. The International Federations and National Federations are responsible for testing throughout the year.

The National Olympic Committees oversee testing at Continental Games and other events under their control.

The number of doping tests has grown exponentially over the past 10 years, both before and during competition.

The 2012 London Games featured the most comprehensive drug-testing program in history.

A total of 5,132 tests were conducted during the period of the Games, but efforts to keep cheaters out of the Games started long before the Olympic Village opened.

In the six months before the Games, more than 71,000 tests were conducted on athletes competing in summer Olympic sports at events around the world.

At least 107 competitors were declared ineligible for the Games.

Although we cannot know how many of them would have qualified for the Olympic Games, we can be certain that none of them competed with an unfair advantage in London.

Pre-Games testing is an essential element of any effective anti-doping program.

It is the best tool we have against athletes who seek to avoid detection by using prohibited substances only while in training.

We must continue to expand our efforts in this area to detect cheaters well before they arrive at the Olympic Village.

Pre-Games testing, educational programs and other antidoping activities sponsored by the Olympic Movement come at a significant cost, over and above the \$13 million US that we contribute to WADA's budget. Some International Federations spend more than half of their budgets on the fight against doping.

National Olympic Committees are making comparable efforts, working in close collaboration with their National Anti-Doping Organizations on out-of-competition testing programs and education programs that meet WADA standards.

The biggest challenge we face in the fight against doping is the unceasing struggle to stay ahead of the cheaters and the criminal networks that support them.

Doping cartels are constantly seeking new ways to avoid detection and new substances to exploit for unfair advantage.

We need the help of the pharmaceutical industry to keep up.

It is important to remember that nearly every substance that is misused by cheaters in the world of sport has a legitimate and valuable medical purpose.

The pharmaceutical industry is at the forefront of medical advances that have improved the length and quality of life for millions of people around the world.

By sharing this knowledge with scientists working on the fight against doping, the industry is helping us identify new areas of abuse – and the analytical methods needed to counter them.

We have seen the benefits of this cooperation many times. At the 2002 Olympic Winter Games in Salt Lake City, the IOC and WADA collaborated with AMGEN to detect the use of darbepoietin alfa, commonly known as Aranesp.

AMGEN developed Aranesp to treat anaemia in patients with chronic kidney disease and cancer patients undergoing chemotherapy, but it didn't take long for cheaters to exploit its benefits.

Our collaboration with the pharmaceutical and biotechnology industry has expanded in recent years.



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In 2008, in the framework of its European Union presidency, France announced its desire for collaboration between the pharmaceutical industry and the public authorities, under WADA's aegis.

The result was an agreement to identify substances that could be misused for doping while they are still under development.

To encourage even closer collaboration, in 2010, the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) and WADA signed the Joint Declaration on Cooperation Against Doping in Sports.

The agreement established a framework for pharmaceutical companies to work with WADA when developing products that could be misused.

Several pharmaceutical companies, including Merck, Roche, GlaxoSmithKline and Sanofi, have contributed to anti-doping efforts.

This past summer, in advance of the London Games, WADA, the IFPMA and the Global Biotechnology Industry Organization launched a new campaign to strengthen collaboration, under the theme "2 FIELDS1 GOAL: Protecting the Integrity of Science and Sport."

The initiative includes the dissemination of "Points to Consider," a booklet that will help biotechnology companies identify substances that could be misused by athletes.

It also offers guidelines for sharing confidential information with anti-doping experts and for protecting against the diversion of products during clinical trials.

The International Olympic Committee is grateful for the invaluable assistance that the pharmaceutical industry has provided in the fight against doping.

We have made great progress together, but we must do more.

We must build on the framework for cooperation that we have established to create a true partnership.

This conference is an important step in that direction. We have agreed on a common goal.

We have established ways to deal with confidentiality agreements and other technical challenges that complicate cooperation.

Our focus here should be on action, on turning good intentions into good deeds.

Working together, we can combat corruption in sport and in society, and protect the health of young people around the world.

I thank all of you for your contributions to this important cause.

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### SOCIETAL AND ECONOMIC RISKS OF DOPING

### **David HOWMAN**

Director General, World Anti-Doping Agency (WADA)

Doping is no longer an issue confined to elite sport. Rather, it is a problem that permeates other areas of our society, and has a much wider impact than it did in the past. WADA focuses on elite athletes but analysis of the issue reveals a problem throughout society at large, which is present in schools, prisons, our security forces, and through organized crime. Amateur athletes are also involved in doping, not to mention issues such as match-fixing and corruption.

In the area of public health, there is little regulation over clandestine laboratories.

We need to put a stop to this ongoing decline in our societies. The criminal world is increasingly involved in supplying these products, with enormous returns on investment, in the order of 10 to 1. If we had laws governing this area, the police could intervene. We encourage our member countries to take action in relation to this issue. It is a matter of public health and should be of concern to governmental authorities.

The Danish government has published a study examining the problem from a wider social perspective. WADA is well aware that the same people who engage in the distribution and trafficking of prohibited substances are involved in corruption and fraud. We do not have the mandate to act in this area, but we can work with those who do.

In terms of the black market for pharmaceutical products, we know that many of these products are available through a variety of channels, including some that are even stolen while still in the pipeline.

Dopers are using increasingly sophisticated methods, as the Armstrong affair has shown. WADA is not in a position to tackle this type of sophisticated cheating. We know that we will not be able to catch all dopers. WADA has an annual budget of \$30 million US a year, or just twice as much as the salary of a professional footballer in Europe.

Doping affects the elite end of sport, but we are also seeing a trickle-down effect into sport as a whole. This is partly due to easier access to substances, but it is also clearly a result of changing values. In many areas of our society, cheating has become increasingly acceptable as long as you do not get caught. Without integrity, there can be no genuine achievement.

WADA continues to deliver its message through education programs, but we need to recognize that doping exists at many different levels of society.

High school athletes are choosing to dope in order to win professional contracts, for example, in South African rugby. It is also true of amateur athletes.

We must fight against these developments to stop this trickle-down effect.

The entourages surrounding athletes are also a problem. In most cases, athletes do not act alone. They are assisted, counselled, sometimes tricked, and occasionally forced into cheating. These people who should know better make a mockery of their responsibilities and thus betray athletes.

Our objective is to not only sanction athletes for doping offences, but also the doctors, trainers, lawyers, and agents who are involved. Appropriate tools are required to do this, and we need help from governments to review the relevant regulations and standards. We need to form stronger alliances with the authorities, particularly as we recognize the fact that doping is not limited to elite athletes. And we need partnerships to spread this message throughout society.



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### **Dr. Timothy ARMSTRONG**

Coordinator, Surveillance and Population-based Prevention Unit, World Health Organization (WHO)

I am honored to be here with you today.

I will start by reminding participants of the role of the World Health Organization (WHO). This specialized agency of the UN was created in 1948 to tackle public health issues. It employs 8,000 staff around the world. The WHO sets norms and standards and advises Member States. Its objective is the attainment of the highest possible level of health by all people.

In September 2011, the United Nations organized a high-level international conference on non-communicable diseases, such as diabetes, cancer and cardiovascular disease.

The incidence of these diseases can be reduced by increasing levels of physical activity and reducing the consumption of harmful products. Governments have a significant role to play in promoting health, healthy environments and physical activity.

Civil society also plays an important role, as does the pharmaceutical industry. A number of recommendations were drawn up at the conference, which concern the private sector in particular:

- Promotion of healthy environments;
- Contribution to the goal of ensuring the appropriate use of medication in the prevention of non-communicable diseases.

The WHO has many years' experience of working with the pharmaceutical industry. In particular, we have been working together to combat counterfeiting. We are in constant dialogue with pharmaceutical companies.

Last year, we agreed on an international framework to combat non-communicable diseases. The Member States drew up an implementation timetable and monitoring indicators. Two of these objectives involve the world of sport. The international community agreed to implement measures to encourage physical activity in children and teenagers by 2025, and to ensure that doping does not spread further in our society.

The consequences of doping on cardiovascular disease and cancer are well known. Mental health can also be adversely affected by doping. Despite this, only a limited number of surveys and studies have been conducted on the incidence of doping and its significance in sport, generally. We are promoting this initiative in order to combat doping and medication abuse, both for athletes and for populations as a whole.



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### **Philippe LAMOUREUX**

Director General, LEEM (Association of French Pharmaceutical Companies) and Council Member of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA)

I am delighted to be here this morning alongside WADA and WHO representatives to explain the point of view of the pharmaceutical industry on this persistent issue of doping, which for many years has undermined the image of sport as a whole and the reputation of great competitions such as the Tour de France.

In addition, doping poses a direct threat to the health and physical well-being of athletes. I would like to explain the concerns of our industry on this issue.

Medication is designed to heal and assist the sick, and not to make supermen and women out of certain athletes in violation of sporting principles, which can also lead to serious and sometimes fatal disorders.

Over the last few years, the phenomenon has reached a worrying level of sophistication. We are a long way from the homemade methods employed a few years ago. The diversion of drugs and therapeutic procedures from their intended purpose is now a common source of doping, and cheating athletes are often one compound ahead of the anti-doping authorities.

Diversion of compounds and therapeutic procedures causes significant harm to the pharmaceutical sector. It is not acceptable for the industry I represent to see that doping cases use products diverted from their intended purpose. How can we tolerate the ongoing existence of criminal networks working to this end, while we are fighting against counterfeiting and encouraging our fellow citizens to consume drugs intelligently and in moderation?

It was against this background that in 2008 the Association of French Pharmaceutical Companies, the French Ministry of Health, Youth and Sport, and WADA signed a declaration of cooperative intent in order to ensure that the anti-doping authorities had the earliest possible knowledge of pipeline compounds with doping potential.

I'm delighted that the IFPMA and WADA signed a declaration in 2010 in order to facilitate voluntary cooperation between pharmaceutical companies and the Agency. This initiative was inspired by several fruitful bilateral collaborative projects.

The objective for us is to convince more and more manufacturers to provide preventive information on substances they are working on that could be appropriated for doping purposes.

We are convinced that cooperation is more effective than coercion, and we are encouraging our members to be particularly vigilant on this issue.

In July 2012, we launched the 2 FIELDS 1 GOAL campaign supported by the IFPMA, BIO and WADA. The aim of the campaign is to encourage the voluntary cooperation of pharmaceutical companies.

I sincerely hope that the fight against doping makes significant progress over the coming months, thanks to the efforts of all the parties involved.

Finally, although the focus tends to be on professional athletes, we should not forget the challenges facing amateur sports.

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### **Prof. Arne LJUNGQVIST**

Vice President, World Anti-Doping Agency (WADA)

Madame Minister, Distinguished Guests, Ladies and Gentlemen,

It is my great pleasure to be here with you today to take part in what I consider to be a most important conference, and one that I hope proves to be a landmark event for anti-doping.

Already this morning we have heard reference to the fact that doping is no longer an issue confined to the sports movement.

Yes, it remains a major problem for sport – an increasing problem that has the potential to threaten the very existence of certain sports – but it is also very clear to those involved in anti-doping substances that it is now a health issue that affects more than just sportsmen and women.

Doping is a multi-layered problem that must be confronted by society as a whole. It is no longer just about elite athletes; it is about amateur athletes and age group athletes.

It is about the youth of today putting their health at risk in order to build themselves up to look like so-called role models on the cover of magazines. It is about members of security forces abusing substances to reinforce their feelings of power and strength.

You will hear this message time and again throughout the course of this conference, and I make no apologies for stressing its importance once again.

Indeed, my commitment to highlighting this issue is quite clear from a symposium I hosted in Stockholm in September, which was titled, "Doping as a Public Health Issue." From the beginning of my own sporting career, and continuing through my medical career with the International Olympic Committee and WADA, I have seen the issue of drugs in sport develop over the last six decades.

Doping in sport is nothing new. Athletes have always sought to gain an advantage by using whatever substance or method available.

Much has been written about the use of doping substances by American athletes throughout the 1960s, about the systemic doping in the former Eastern bloc in the '70s and '80s, and the infamous Ben Johnson case from the 1988 Seoul Olympic Games.

More recently, there was the BALCO scandal featuring a number of world-class track athletes. And over the last decade, professional cycling has been fighting a battle for its very existence, due to the entrenched doping culture that had been allowed to develop – with many highly worrying details coming to light during the last few weeks in the Lance Armstrong case.

It is very clear to all involved with sport that a doping problem exists; indeed, that is the very reason for WADA's existence. Just how big that problem is, we are not quite sure, and it is a challenge that WADA and various sporting organizations have been trying to identify.

What we do know is that we are very often one step behind the sophisticated doping athlete. We have reasons to believe that the problem of doping is largely underestimated, and will remain so until we have applied appropriate tools in an objective way. Consequently, the problem of doping in sport

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continues to be underestimated. It is, perhaps, human nature not to focus on the downside when sport has so many exciting elements.

Looking back into doping history, there are cases of athletes gaining access to substances that never reach the market – the so-called 'clear' that was abused by athletes in the BALCO case is the best-known example of this. But overall, evidence suggests that athletes who choose to dope do so mostly with legitimate medicines.

We have seen that this can happen while a medicine is in development – this was the case with Micera before and during the 2008 Olympics – but usually it will happen after a medicine has come on to the market.

Once a medicine is available it is very easy for someone with training in biology to ascertain whether or not it has potential as a performance enhancer. We recognize this, so the rationale has to be, what can we do about it?

And that is why this conference is so important, so that we can explore ways of developing closer ties between the anti-doping community and the organizations that produce the medicines, namely the pharmaceutical industry.

It is no secret that the sports industry is a huge global business, one worth hundreds of billions of dollars a year worldwide. The anti-doping community – and WADA in particular – does not have access to these sorts of funds.

WADA has to manage the development of detection methods – and complete its other duties – on an annual budget that currently hovers around the \$26 million US mark.

Funding research into the development of detection methods is therefore a significant challenge, so WADA must try to involve the knowledge and resources of the companies that make the substances and already have the scientific and regulatory expertise.

Nor is there any logic in either party duplicating the work of the other. There is no sense in WADA and its research partners spending time and money studying a compound when a pharmaceutical company already holds that information.

The pharmaceutical industry has acknowledged that the abuse of their medicines for sport, and now for other wider uses in society, presents not only a health problem, but also throws up ethical and moral issues that they wish to address – not to mention the economic threat posed by unlicensed production of their medicines.

Doping is a common problem and there should be greater collaboration between the anti-doping community and the pharmaceutical industry.

It is my sincere hope that this conference finds ways to enhance such collaboration.

Thank you.

#### **Philip THOMSON**

Senior Vice President, Global Communications, GlaxoSmithKline (GSK)

It is a great honor for me to be here and I would like to thank the organizers for inviting GlaxoSmithKline (GSK) today.

Doping is a worrying problem both for sport and for society as a whole. This has already been clearly stated. It is not, however, an insurmountable problem. We have no reason to believe that cooperation is impossible.

We work in the health industry and, as a result, our standards are incredibly high. We need to create trust. Our new commercial strategy – implemented five years ago – is based primarily on the need for trust and transparency.

We therefore publish all our clinical trials, whatever the results, and we adapt our prices to national markets. We want to go even further, in particular through the implementation of partnerships to discover new drugs, or in collaboration with NGOs.

We were partners of the 2012 Olympic Games, and this had a significant impact in the company. Our employees demonstrated outstanding levels of commitment to this initiative.



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This leads me to our collaborative project with WADA. We learned that the Agency wanted to be one step ahead in the detection of new substances, and we signed an agreement to this effect in June 2011. Any new pipeline drug with potential performance-enhancing capabilities is reported to WADA so that the Agency can start its detection work.

We have made good progress on the project. We now have a coordinator with WADA, and we are working with her on three new drugs. We have provided the Agency with highly advanced

technical details that will allow the creation of detection methods. This has produced convincing results, while the confidentiality of our information has also been maintained.

I would like to publicly thank the scientists who work for WADA.

We will continue working in this area, and invite our colleagues from the pharmaceutical industry to also engage in this form of cooperation. GSK feels that the initiative is a very positive one, and we also believe that we have a duty to contribute to the good health of athletes and all sports practitioners.

#### James C. GREENWOOD

President and CEO, Biotechnology Industry Organization (BIO)

The Biotechnology Industry Organization (BIO) represents more than 1,100 biotechnology companies working on critical issues such as disease, hunger and pollution. They are at the leading edge of biomedical innovation.

We are working to improve human health but realize that our drugs can be diverted from their intended purpose. Doping adversely affects the critical mission of our industry.

The advances we are making can contribute to well-being, but biotechnology products misappropriated for doping purposes undermine our work. They may be used to improve endurance or muscular performance.

We must therefore ensure that our medical technologies are used only to assist patients. Our products must be evaluated by the competent authorities and doctors.

The issue of a drug's risk-benefit ratio assumes different proportions in the context of doping. Some dopers seek out pipeline compounds that have not yet been tested and are difficult to identify, and this can also lead to illicit production.

Doping undermines the role of research.

We emphasise the primary objective of research, namely the promotion of health. Our goal is therefore to improve transparency and the transmission of information. We encourage our members to evaluate the doping potential of the products they are developing. We are very much in favour of partnerships between WADA and the relevant industries in order to combat the problem of doping together. In addition, many BIO members are small companies that can be seriously affected by counterfeiting.

We are encouraging our members to cooperate with WADA, particularly so that they can work upstream on raising awareness of doping among young people. Together, we can work to combat doping, while at the same time marketing and developing innovative pharmaceutical products.

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# THE PHARMACEUTICAL INDUSTRY AND ANTI-DOPING AUTHORITIES: PAST EXPERIENCES AND LESSONS LEARNED

### **Dr. Olivier RABIN**

Science Director, World Anti-Doping Agency (WADA)

Minister, Ladies and Gentleman, Dear Colleagues, Dear Friends,

When I took on the job of Science Director at the World Anti-Doping Agency just over 10 years ago now, I dreamed of a conference like the one we are taking part in today.

As I left the world of the pharmaceutical industry to join that of anti-doping, it was already obvious to me that these two worlds – which were so close, but rarely interacted – did in fact share the same fundamental values and objectives.

Some of these values have already been pointed out by previous speakers, but respect for human beings, their health and integrity, support for ethical and social values, and commitment to a better world for people were, I felt, objectives already shared by the pharmaceutical and biotechnology industries on the one hand, and the anti-doping community on the other.

My deep conviction in the possibility of a closer working relationship came to fruition in early 2003, with an attempt to approach the pharmaceutical industry globally through the creation of a representative association for the industry. The project was relatively short-lived, however, because at the time, the gap was still too great between a well-established pharmaceutical industry facing major economic challenges in its sector, and WADA, which was still finding its feet in terms of its prerogatives and authority.

It therefore became necessary to convince the industry of the mutual benefits that could be derived from this model of global collaboration, not in terms of theoretical concepts, but through concrete achievements. The latter become a reality over the next few months with the launch of a collaborative project in 2004 with the Swiss multinational Hoffmann-LaRoche for the detection of Mircera.

At the time, the anti-doping community was seriously questioning its ability to detect the new erythropoiesis-stimulating agents that were appearing in the portfolios of several pharmaceutical and biotechnology companies. So with Roche, we explored the possibility of a new relationship between a large pharmaceutical company and WADA, in order to establish an effective collaborative framework that would respect the requirements of both partners.

This first collaborative project not only allowed us to lay solid scientific foundations for the development of anti-doping methods derived from the detection methods developed by Roche, but also to create the principles of the legal and operational framework for this type of collaboration.

In 2005 and 2006, still faced with the growing threat of pipeline erythropoiesis-stimulating agents, we started a collaborative project with Shire for the detection of Dynepo, known under the name of EPO delta, and also with Affymax for peginesatide, known as Hématide at the time. The latter collaborative project is particularly interesting because it involved a biotechnology company that agreed to share the results of their only product under development, in the context of a partnership that appeared to be riddled with challenges and risks for a company of that size.

I would like to draw your attention to the absolute obligation of confidentiality on WADA's part to each of its partners, while we found ourselves in possession of highly sensitive information on several competing pipeline substances – with all the economic stakes that that involved.



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Collaborative initiatives were also set up for other substances, such as SARMs with Merck-GTx – a new class of substance with good anabolizing potential – and ciclesonide produced by Nycomed, a new glucocorticoid, to give just a few notable examples.

This cooperation around products, or classes of products with doping potential, allowed us to not only develop anti-doping methods for these substances banned in sport, but also to consolidate the principles and practical foundations of collaboration between manufacturers and WADA – whether these manufacturers were leading international pharmaceutical groups or smaller biotechnology companies.

Trust, confidentiality and common commitment – underpinned by constructive scientific discussion – formed the basis for this success, which today has resulted in more global agreements, such as those signed with the IFPMA and GlaxoSmithKline.

I'm particularly happy that today WADA is recognized by the industry as a partner who is credible, and I would even say essential, in terms of risk management of pipeline substances with doping potential.

Manufacturers are now engaging with WADA to further improve cooperation, and make it effective and efficient within a framework of mutually beneficial relationship. The mechanisms and expertise now exist to support manufacturers who want to take the path of voluntary collaboration with WADA, either on a one-off basis or over the longer term.

Past successes have demonstrated the raison d'être and validity of such collaborative initiatives, and it is now up to manufacturers themselves, and the organizations that

represent, them to expand the number of these bilateral agreements. WADA is ready to respond to this demand and to provide the conditions necessary for constructive and productive discussions with interested manufacturers.

It would be ambitious, some might even say unrealistic, to think that all pharmaceutical and biotechnology companies will voluntarily or automatically contact WADA as soon as they start developing one or more substances with doping potential. It will therefore be important to also mobilize national and international medicines agencies to ensure that they also act as responsible stakeholders, and direct manufacturers to WADA when substances with doping potential that have not been not identified as such, get to the marketing authorization stage.

The collaborative agreement model we are suggesting clearly demonstrates the usefulness for both manufacturers and the anti-doping community of contributions to shared interests, leading to undeniable benefits for society. However, this model will only make sense if it leads to clear commitment from manufacturers, and the support of medicines agencies to protect the human and social values underpinning the legitimacy of our individual and collective actions to combat doping in sport. This model calls on you to remember your responsibilities towards athletes, sporting values and the common interest of a fairer human society.

I would like to sincerely thank you for your attention and for your presence at this conference, and I hope that we will remember this day as an important step on the road to collaboration between health manufacturers and WADA.



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### **Dr. Philippe VAN DER AUWERA**

Global Head of Drug Safety, Roche

The process of developing a new drug focuses on its projected conditions of use, based on a given medical need. Traditionally, the possibility of the drug being used to enhance sports performance is not taken into account in this context.

It was therefore a surprise when in 2004 Olivier Rabin approached my predecessor to discuss rumours of fraudulent use of an erythropoiesis-stimulating agent still under clinical investigation.

This was an unknown area for our scientists, and we immediately collaborated by providing the means to detect our product. It was a very rewarding piece of work. The Swiss Laboratory for Doping Analyses based in Lausanne took part in the project.

We examined all possible detection procedures, and we incorporated early assessment of doping potential in the development process. We also had to implement measures to prevent any diversion to illicit use throughout the development phase.

We now have an integrated risk management plan for all our products, before any administration to humans takes place, which includes in particular the identification of any potential risks based on preclinical data.

This approach allows us to determine issues that require clarification through specific studies.

In practice, any clinical protocol benefits from this risk management strategy. This document accompanies the entire development process, before being converted into a risk management plan submitted to the health authorities with the marketing authorization application.

We have also worked with WADA since 2008 on the production of a series of best practices covering evaluation of products with doping potential, and procedures for contacting the Agency in such cases.

Preventive effectiveness is also based on concerted work with other laboratories. We have therefore collaborated with other members of the International Federation of Pharmaceutical Manufacturers in order to establish a universal voluntary approach, and systematic collaboration with WADA. This agreement was signed in 2010 and supported by BIO.

This event led to the 2 FIELDS 1 GOAL campaign initiated by WADA, the IFPMA and BIO in July 2012. The aim is to provide tools and resources so that the members of these organizations can implement their own anti-doping work. We are proud to have been involved in this unprecedented development.

For such an initiative to produce results, high-level managerial support and practical procedures will be required. We have incorporated doping detection and risk management in our Drug Safety Department from the translational research stage. Surveillance is also integrated throughout the product lifecycle.

The risk management plan for all our products also includes a component on illicit use.

We are convinced that we can make an effective contribution to the prevention and detection of doping.



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### **Hon. John FAHEY**

President, World Anti-Doping Agency (WADA)

I would like to thank the speakers for their contributions. They have confirmed that today we find ourselves in a unique situation. In the early days of the fight against doping, the partnership established had many detractors, but the results of the last few years have shown that it has produced positive outcomes. However, the need to go further and expand our network will always exist.

It is therefore obvious that sample analysis is not sufficient. We also need to identify the substances that exist and are distributed.

Over the last few years, partnerships have therefore extended to other stakeholders, including law enforcement agencies. For example, INTERPOL in Lyon has an agent working exclusively on this issue. We have also made contact with the customs authorities.

Finally, you have seen how we have developed partnerships with the pharmaceutical industry. The contributions from Roche and GSK have clearly demonstrated the effectiveness of this work in preventing the illicit use of compounds that are perfectly legitimate in other circumstances.

We know that doping is not confined to elite athletes. We want our young people to live healthy lives. This is also the objective of the pharmaceutical industry, and we have seen this morning that it is possible to produce positive results in this area.

I think that these presentations have effectively prepared the ground for the discussions we will have this afternoon on the methods we need to implement and develop.

Any doubts I might have had on the willingness of the pharmaceutical industry to cooperate have been swept aside by this morning's contributions.

At the WTO Doha Ministerial Conference, governments and the pharmaceutical industry agreed to provide access to AIDS drugs for all patients. This clearly demonstrates the willingness of the pharmaceutical industry to take action that leads to results when the stakes are high enough.

We also need to involve the small companies that are making discoveries and scientific advances. We must collaborate with them. I would like to thank Philip Thomson, who responded to those who have concerns about respect for intellectual property rights in the context of the fight against doping.

We have demonstrated this morning that if we have the will to do so, we can all work together to combat substance abuse, wherever it takes place.

Thank you very much. Your contributions have demonstrated your willingness to do the right thing. The time has now come to transform good intentions into concrete actions.

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From the political concept to raising awareness among stakeholders: What kind of network to build and how to include all stakeholders?

Moderator: Prof. Arne LJUNGQVIST, Vice President, World Anti-Doping Agency (WADA).

Reporter: Jean-Pierre BOURELY, Head of Office "Promotion of Health, Protection of Population, and Prevention of Doping," French Ministry responsible for Sport.

Dr. Laetitia BIGGER, Senior Manager, Vaccines Policy, IFPMA.

Dr. Timothy ARMSTRONG, Coordinator, Surveillance and Population-based Prevention Unit, World Health Organization (WHO).

Andy PARKINSON, Chair of the Ad Hoc European Committee (CAHAMA) for WADA, and Chief Executive, UK Anti-Doping.

Andrew EMMETT, Managing Director, Science and Regulatory Affairs, US BIO.

Alexander SCHISCHLIK, Team-Leader, Anti-Doping and Sports Programme, UNESCO.

### Jean-Pierre BOURELY, Reporter

I will now draw some conclusions from this round table discussion.

We can use as our starting point the UNESCO Convention, which is now 17 years old and has been ratified by 172 out of 193 States.

Doping is an important issue that motivates governments to act, because it affects not only sport, but society as a whole. It is also an issue of public health, as it concerns not only elite athletes, or even athletes generally, but the entire population. We have seen how the pharmaceutical industry was particularly sensitive to the problem of doping, because it raised questions of responsibility for the sector. It cannot disassociate itself from the way in which drugs are consumed.

The whole of society is therefore affected. This should be underlined. Educating patients and consumers is an important aspect of the fight against doping. We also need to identify appropriate procedures for early detection of substances that are being misused. The intervention of AFNOR is an interesting one from this point of view, as we can draw a parallel with dietary supplements: Their consumption is not essential, and we must ensure that they are not harmful. We need to use the lessons learned from this experience.

Doping is bad for sport, but also for public health. Elite athletes employee highly sophisticated and technologically advanced doping practices.

The challenge is to convince the parties involved, and initiate a win-win dialogue based on cooperation willingly given. We have to jointly create a mechanism so that all aspects of this collaborative process are capable of providing what the parties involved need.

The authorities that work to combat doping want more effective investigation resources. The pharmaceutical industry must be convinced of the positive benefits of its involvement in the fight, particularly in terms of PR and the prevention of illicit drug use. The pharmaceutical industry is involved in a public health initiative that will also require prevention and education.

We also need to guarantee the preservation of industrial secrets for the pharmaceutical industry, both in technical and legal terms. In this regard, the IFPMA has allotted the resources to construct this kind of cooperation by distributing information, while also preserving confidentiality.

We need an intelligent dialogue between WADA and international pharmaceutical groups, but also at a local level, and with the same guarantees. Through its role of global cooperation, WADA will ensure the overall consistency of the project.

Finally, the Council of Europe must play a structural role by inviting its members to become actively involved in this cooperation between the pharmaceutical industry and its Member States.



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### **ROUNDTABLE 2: CONCLUSIONS**

What framework is needed for cooperation between the World Anti-Doping Agency and stakeholders in the health sector?

Lessons learned: From raising awareness to implementation

Moderator: Dr. Steve ELLIOTT, Scientific Executive Director, Amgen (Retired)
Reporter: Dr. Patrick DELAVAULT, SrVP, Chief Medical Officer, IPSEN Group
Barbara LEISHMAN, Head of Safety Science Quality Risk Management, Roche
Melodi MCNEIL, Director, Regulatory Policy and Intelligence, Abbott
Mark LUTTMANN, WADA Cooperation Coordinator, GlaxoSmithKline

Dr. Anne-Marie DULIEGE, Chief Medical Officer, Affymax

Dr. Olivier RABIN, Science Director, WADA

### **Patrick DELAVAULT**

It seems to me that there are four key challenges that have been highlighted by our discussions.

You spoke about war, but who is the enemy? This has yet to be determined. I don't have a firm opinion on this question. The first message is therefore to identify the enemy, and to realize that doping is a threat to health. Today, performance is very highly valued in our societies, and some are willing to do anything to achieve it. So it's a serious social issue that is no longer confined to elite sport.

Doping is the use of drugs for purposes other than their original intention, which leads to health risks. It's our responsibility, as the pharmaceutical industry, to act with WADA to combat doping.

The pharmaceutical industry is a key player but the regulatory authorities also have a role to play.

The second message consists of integrating the fight against doping into the culture of the pharmaceutical industry. It's not so much a question of resources or time, but more a change

of culture. The issue of the doping potential of a product should be integral to discussions throughout the development of a compound, within the context of risk management. This is especially important, as doping also harms the image of the pharmaceutical industry and represents a counterfeiting risk.

The third point is that the organization of this conference is a sign of the progress made in cooperation to combat doping. The IFPMA and WADA are today working more closely together to identify drugs with doping potential, to exchange information and to explore testing methods. This cooperation has developed on a voluntary basis. It is simple to implement. The examples given today show us the steps we need to follow, and this document should be widely distributed in the pharmaceutical sector.

Finally, in order to promote this cooperation, we must expand it further. We need to identify pharmaceutical companies that want to set up information flows and cooperate with WADA. The network of contacts between the IFPMA and WADA should be strengthened. We should also capitalize on the results of this conference, which we could be repeated in 2014.



### **CONFERENCE SUMMARY**

How to build on the work already accomplished, and further develop cooperation through an action program?

### **Bruno GENEVOIS**

President, French Anti-Doping Agency (AFLD)

The debates have been full of interest and wide-ranging, and I will draw two conclusions from them: WADA has played an essential role in cooperation with the pharmaceutical industry, and should continue to do so. However, it cannot act alone.

WADA has acquired important experience since 2004, particularly in terms of centralizing information. In addition, it is capable of guaranteeing the requirement of confidentiality. It also has power of initiative, and because of its relations with national agencies, is able to provide the feedback that some contributors have requested.

However, it cannot act alone. It needs contact with representatives from the pharmaceutical industry, in particular the smaller companies. Cooperation must be extended to the entire sector. The difficulty lies in finding a sufficient motive through which to cooperate. Regarding the large firms, we have seen that they have understood the advantage of being involved in the fight against doping. There may be less motivation for a smaller organization, and we therefore need to encourage it.

Other partnerships are also necessary for WADA. These concern national stakeholders first. Here, I'm thinking about the laboratories accredited by WADA. The Chatenay-Malabry laboratory, for example, was entrusted with the specific task of detecting a given product. National medicines agencies can also spread WADA's work. They need to be made aware of the impact of products with doping potential when granting market authorizations. There's still progress to be made in this area.

National anti-doping agencies can also promote WADA's work. They should be able to benefit from the results obtained by WADA in its collaboration with the pharmaceutical industry.

ISO standards have been mentioned. I can't see what role they could play in terms of new compounds, but in the area of dietary supplements, they are indeed useful.

The European Union also has a medicines agency that could play the same role as the national bodies, but at European level.

I agree that the Council of Europe represents an excellent forum for extending WADA's action.

Finally, UNESCO also has a role to play in completing this work. Through the 10th anniversary of its Convention, we could plan to include an article on the usefulness of collaboration with the pharmaceutical industry for anti-doping purposes.

After hearing these debates, I am more than ever convinced of the usefulness of adding an SO line to the list of substances banned by WADA, which would include new compounds not yet tested.

Finally, if we succeed in developing this collaboration, we will at last be able to say that the fight against doping is one of yesterday's wars.



Paris – 12 November 2012



Director General, World Anti-Doping Organization (WADA)

From my point of view, this conference has been very positive. I would like to thank our hosts. It's unusual for governments to organize such an event for the private sector. I would like to congratulate the representatives from the pharmaceutical industry, who have come here at the invitation of public stakeholders.

It is significant for WADA that manufacturers felt it was important to participate in this work, and I would like to thank you for your collaboration.

We have been talking about doping athletes, but the vast majority of clean sportspeople that we support are hidden from view. Dopers are bad people, supported by bad teams. They do not respect our values, and all they think about is success, regardless of the price.

The pharmaceutical industry and WADA have produced a globally applicable operational model. We are working with multinationals, but also with smaller companies. We have learned to trust each other. This conference is the living proof of that.

I would like us to organize a new conference on this subject in a few years' time, and I would like to thank you for your participation and your contribution.