December 12, 2012 House Hearing

“HGH Testing in the NFL: Is the Science Ready?”

Conducted by the House Committee on Oversight and Government Reform

Testimony of Dr. Larry Bowers

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Good morning, Mr. Chairman and members of the Committee. My name is Doctor Larry Bowers and I am Chief Science Officer of the United States Anti-Doping Agency (USADA). Prior to joining USADA in 2000, I was a professor for 24½ years at the University of Minnesota and Indiana University Medical Centers where I conducted (and published) research on drug metabolism and cutting edge analytical approaches to drug and metabolite detection. From 1992 to 2000, I was also the Director of the Athletic Drug Testing and Toxicology Laboratory at Indiana University, one of only two laboratories in the United States that was accredited by the International Olympic Committee at that time.

USADA has been recognized by Congress as the independent, national anti-doping agency for Olympic, Paralympic and Pan American sport in the United States, and we receive a portion of our funding from an appropriation from the Office of National Drug Control Policy. Our mission, at USADA, is to protect and preserve the health of athletes, the integrity of competition, and the well-being of sport through the elimination of doping. Since its inception, USADA has been an advocate for clean athletes and I would like to thank you, on behalf of USADA and the millions of athletes that USADA represents, for this opportunity to testify about and discuss the science behind growth hormone testing.

Human growth hormone is a performance enhancing drug that has been used by athletes to cheat in sport for over twenty years. Growth hormone is a naturally occurring substance responsible for a number of physiological actions that can be used, in its synthetic form, by athletes to increase skeletal muscle mass, decrease weight, enhance delivery to the tissues of nutrients necessary to build or repair tissue, and alter energy metabolism. There are also indications that growth hormone is frequently used in conjunction with other performance enhancing drugs, like steroids.

Over the last decade, as “anti-aging” clinics and practitioners touting the perceived benefits of growth hormone have become more commonplace, the use of growth hormone by healthy individuals has increased substantially. Interestingly, when Congress approved the medical use of growth hormone, the law expressly stated that it was only to be distributed for indications specifically authorized by the Secretary of Health and Human Services, making potentially dangerous off-label uses, such as performance-enhancement, illegal. Unfortunately, the potential adverse side effects of growth hormone abuse, such as an increased risk of diabetes or glucose intolerance, carpal tunnel syndrome, joint pain, muscle pain, peripheral edema, elevated triglycerides and the potential for long-term growth hormone use to cause cancer, have failed to garner as much attention as its perceived benefits and have led many

members of the public to wrongly conclude that the risks associated with growth hormone abuse are either minor or nonexistent.

There is no question that growth hormone is a drug that has been and continues to be abused by professional athletes. In 2007, the Mitchell Report detailed numerous incidences of established growth hormone abuse among Major League Baseball players going back as far as the late 1990s and up through the release of the report itself. More recently, in 2011, the Canadian sports doctor Anthony Galea pleaded guilty to smuggling unapproved drugs, including human growth hormone, into the United States to treat professional athletes. Dr. Galea's clients in the United States reportedly included NFL and MLB players, as well as professional golfers and other professional athletes.

Of course, the use of performance enhancing drugs by elite athletes is not just an issue for sports leagues, anti-doping agencies and law enforcement; it is also a public health issue for our youth. In 2010, USADA commissioned a survey of nearly 9,000 Americans in order to gain a better understanding of what Americans think about the role and significance of sport in society and to assess their views on sport ethics and values, role models, and aspirations.[1] One of the most notable findings of the study was that nearly 90% of the adults surveyed believed that well-known athletes have a responsibility to be positive role models for young people, whether those athletes like it or not, and that young people who seek to emulate the actions of professional athletes who use performance enhancing drugs will sometimes resort to the use of performance enhancing drugs themselves. Although USADA has always been involved in educational endeavors, the findings of the study prompted USADA to develop the True Sport educational initiative, which is designed to cultivate and champion sportsmanship and the positive ethical life lessons that sports teach.

If there was ever any doubt regarding the serious consequences that can result from the negative influence of elite athletes, it was resolved at the 2005 Congressional Hearings on Steroids in Baseball where witnesses testified about how their young sons lost their lives while trying to emulate the doping practices of the professional athletes they idolized.[2] Like steroids, the adverse health effects of growth hormone are particularly serious in adolescents.

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[1] *U.S. Anti-Doping Research Report: What Sports Means in America: A Study of Sport's Role in Society* (2010)

[2] *Restoring Faith in America's Pastime: Evaluating Major League Baseball's Efforts to Eradicate Steroid Use: Hearing Before the H. Comm. on Gov't Reform*, 109th Congress. 307 (March 17, 2005) (statement of Dr. Denise Garibaldi and Ray Garibaldi and statement of Donald Hooton).

I have been involved in the development of tests for abuse of growth hormone since 1999. The test that I will be discussing today has been developed during this period by well-respected researchers in the growth hormone research community who had minimal association with sport prior to developing a test for growth hormone abuse. Initial funding for this research came from the International Olympic Committee and the European Union, but funding of subsequent projects was provided by the World Anti-Doping Agency (WADA), USADA, the Partnership for Clean Competition and other national anti-doping organizations and governments. All of these organizations have a peer review process and review the results of the research projects when they are completed.

The current test for growth hormone in sport, the isoforms test, is a blood test[3] that has been used to detect the prohibited use of growth hormone on a limited basis since 2004 and on a worldwide basis since 2008.[4] During that time, almost thirteen-thousand athletes in a variety of sports, including track and field (including throwers), weightlifting, bobsled (in which retired football players have participated), boxing, triathlon, cycling, swimming and wrestling, have been tested globally for growth hormone abuse using this testing method. In addition, Major League Baseball has conducted approximately 1,700 growth hormone tests of its players using the isoforms test over the past two seasons.

Prior to being implemented in drug testing athletes, the isoforms test for the detection of growth hormone abuse in sport was validated and approved by the World Anti-Doping Agency. WADA's validation and approval of the isoforms test is significant because its authority to make that decision is set forth in the World Anti-Doping Code, which by virtue of the UNESCO International Convention against Doping in Sport, was ratified by the United States Senate and signed by President Bush in 2008.

[3] Growth hormone is one of several performance enhancing drugs that can only be detected for anti-doping purposes in blood. Although growth hormone can pass through the filter in the kidney, the body has an efficient mechanism in the kidney for recovering the amino acid building blocks of peptides. As a result, only about 0.01% of growth hormone is present in urine.

[4] A second complimentary test, called the biomarkers test, remains under development. This test is based on a score calculated from the concentrations of two compounds produced by the body when growth hormone is present in the blood. These two biomarkers are insulin-like growth factor-1 (IGF-1) and the N-terminal peptide of pro-collagen type III (P-III-NP). The biomarkers test is not intended to replace nor does it undermine the validity of the isoforms test. Rather, the isoforms and biomarkers tests are complementary and intended to be used together as they have different detection windows. The biomarkers test was used at the 2012 London Olympic and Paralympic Games and resulted in positive results for two Paralympic powerlifters. Following their positive tests, the athletes admitted use of growth hormone and were sanctioned. The admissions suggested that the athletes had taken GH about eight days prior to sample collection. Unfortunately, one of the four commercial immunoassays validated for use in the biomarkers test was recently removed from the market by its manufacturer. Although additional assays are in the process of being validated, I estimate that the biomarker test will not be available for worldwide use until at least the fourth quarter of 2013.

There is a broad consensus among the scientific experts who regularly work in the growth hormone field that the isoforms test is a reliable and valid test for the detection of synthetic growth hormone. The method has been the subject of four peer-reviewed publications and has also been the subject of numerous conferences and working groups that met regularly to discuss progress on research, advise on additional scientific work to be conducted and make recommendations regarding important elements of the test such as decision limits, which are the threshold guidelines for the test.

Keeping in mind the obvious limitations of this setting for a more detailed explanation, the principle of the isoforms test is as follows: The body produces many forms of growth hormone in the pituitary gland (as listed in Table 2 of the Baumann review[5] attached to my testimony). The various growth hormone forms (called isoforms) have different molecular weights. One of the major growth hormone isoforms has a molecular weight of 22 kilodaltons and is called 22 kD. Another has a molecular weight of 20 kilodaltons and is called 20 kD, and so on. The typical ratio of the 22 kD isoform relative to the other isoforms in the non-doping population using the isoforms test is approximately 0.8. The isoforms test works by measuring the ratio of 22 kD to the other isoforms secreted by the pituitary. Because recombinant (synthetic) growth hormone is only comprised of 22 kD, in persons who have been doping with recombinant growth hormone, the ratio of 22 kD relative to the other isoforms will be higher than found in the normal population. The analytical methods used to conduct the necessary measurements and analyses for growth hormone are relatively routine and capable of being performed at any WADA accredited laboratory.[6]

The Decision Limit for a positive result under the isoforms test was initially determined in 2009 following a normative study based on samples voluntarily provided by elite track and field athletes at the 2009 IAAF World Championships Berlin and a number of samples provided by the German National Anti-Doping Agency. The Decision Limit has initially been set very conservatively, which ensures that only those athletes who are actually abusing growth hormone will test positive under this testing method. In fact, using the growth hormone isoform test, the chances of an athlete who has not used synthetic growth hormone testing positive are comparable to the chance of that same athlete being struck by lightning during his or her lifetime. This conservative approach is not unusual for newer tests,

[5] Baumann GP. Growth hormone doping in sports: a critical review of use and detection strategies. Endocr Rev. 2012; 33(2):155-86.

[6] The two WADA accredited laboratories in the United States are the UCLA Olympic Analytical Laboratory in Los Angeles, California, and the Sports Medicine Research and Testing Laboratory in Salt Lake City, Utah.

although it increases the likelihood that there will be athletes using growth hormone who will avoid testing positive because their values fall under the Decision Limit. WADA intends to adjust the Decision Limit over time to reduce the likelihood of missed positives.

The isoforms test uses two separate testing kits (Kit 1 and Kit 2) to measure the ratio of 22kD to the other isoforms secreted by the pituitary. The Decision Limit for Kit 1 is a ratio of 1.81 for males and 1.46 for females. The Decision Limit for Kit 2 is a ratio of 1.68 for males and 1.55 for females. The Decision Limit for both Kit 1 and Kit 2 must be exceeded in the sample analysis for the sample to be declared positive for growth hormone.

As of August 28, 2012, WADA records show that 12,764 growth hormone isoforms tests have been performed globally, resulting in 12 positive tests. One positive test was for an athlete known to use growth hormone for therapeutic purposes, whose sample was collected because the agency wanted to demonstrate that the test worked – it did. Eight of the individuals admitted their growth hormone use and accepted a sanction – a rare phenomenon in anti-doping programs. The other three cases are in various stages of arbitration and appeal at this time.

Since 2008, USADA has conducted 1,387 tests, about 90% percent of which were no-notice out-of-competition tests. Of these tests, 99% have had ratios of less than 1.3, which is well below the Decision Limit. One of the above cases where the ratio exceeded the Decision Limit was the result of USADA testing. This athlete, a weightlifter who competed in the above 105 kg (231 lb) classification, admitted growth hormone use and accepted a two-year sanction. In three other tests conducted when this weightlifter was not abusing growth hormone, his ratio was below 1.1. In the two tests collected when he was abusing growth hormone, his ratio was 2.74 (Feb 7) and 2.56 (Feb 27); well above the 1.81 Decision Limit (Kit 1).

I should also point out that Major League Baseball's testing program has resulted in one "positive" test for growth hormone, and the minor league player (Mike Jacobs) admitted growth hormone use. To complete the North American experience with the growth hormone isoforms test, a first-year running back from the University of Waterloo in Canada tested positive for growth hormone in 2010, and was given a three-year ban for use of testosterone and growth hormone.

It has been suggested by the NFL Players Association in the press and their correspondence to WADA that NFL players are sufficiently different from other elite athletes, with regard to size and ethnicity, that an additional population study of 500 NFL players should be conducted in order to

establish alternate reference ranges and decision limits from those that are currently used for growth hormone testing in Olympic sports. In my scientific opinion, an additional population study is unnecessary because each of the concerns that have been raised regarding the applicability of the isoforms test to athletes in the NFL has already been raised and answered by growth hormone scientists.

1. Does the current test take the size of the athletes into account? Yes, and it was determined that the size of an individual has no relation to the ratio of growth hormone isoforms measured by the test.
2. Does the test accurately take into account growth hormone differences that may be attributed to an athlete's race or ethnicity? Yes, and the conservative approach to the Decision Limits reflects that consideration.
3. Does the test take into consideration the effect of strenuous exercise on growth hormone levels and ratio? Yes and to the extent growth hormone levels are affected by exercise, it has been determined that the effect is minor and virtually undetectable within 30 minutes after the conclusion of the physical activity, well short of the testing protocol requiring 2 hours of rest prior to sample collection.

In conclusion, I would like to point out that the only people who are still questioning the methodology and validity of the growth hormone isoforms test are lawyers, not scientists. The test has not only been put into use by Olympic sports, but MLB as well. Considerable resources, of both time and money, have been expended in order to develop this test and the experts who work in the growth hormone field every day, both inside and outside of the anti-doping movement, have universally accepted and recognized that the isoforms test is scientifically reliable and appropriate for the detection of growth hormone abuse in sport.

Once again, I would like to express my appreciation to the Committee for having me here to testify, and for their attention to a somewhat technical presentation.

Committee on Oversight and Government Reform
Witness Disclosure Requirement – "Truth in Testimony"
Required by House Rule XI, Clause 2(g)(5)

Name:

1. Please list any federal grants or contracts (including subgrants or subcontracts) you have received since October 1, 2010. Include the source and amount of each grant or contract.

None

2. Please list any entity you are testifying on behalf of and briefly describe your relationship with these entities.

United States Anti-Doping Agency
Chief Science Officer

3. Please list any federal grants or contracts (including subgrants or subcontracts) received since October 1, 2010, by the entity(ies) you listed above. Include the source and amount of each grant or contract.

ONDCP:
2010 - $10.0 M
2011 - $8.98 M
2012 - $9.0 M

I certify that the above information is true and correct.
Signature: Larry Bowers Date: 12-10-12

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EDUCATION:

Franklin and Marshall College, Lancaster, PA. B.A. (Chemistry), 1972.

University of Georgia, Athens, GA. Ph.D. (Chemistry), 1975.

University of Oregon Health Sciences Center, Portland, OR. Postdoctoral study (Clinical Chemistry and Clinical/Forensic Toxicology), 1975-1977.

EXPERIENCE:

United States Anti-Doping Agency, 2000- present
- CHIEF SCIENCE OFFICER, 2009 - present
- SENIOR MANAGING DIRECTOR, TECHNICAL AND INFORMATION RESOURCES September, 2000 - 2008.

Indiana University Purdue University at Indianapolis, 1992 - 2000
- PROFESSOR, Department of Pathology and Laboratory Medicine, 1992-2000.
- DIRECTOR, Athletic Drug Testing and Toxicology Laboratory, 1992-2000. The laboratory was one of two International Olympic Committee-accredited laboratories in the United States
- PROFESSOR, Department of Chemistry, Purdue University School of Science at Indianapolis, 1993-2000.

Visiting Associate Professor, Cornell University, Equine Drug Testing and Toxicology Mass Spectrometry Facility, March - June, 1987.

University of Minnesota, 1978-1992.
- PROFESSOR, Department of Laboratory Medicine and Pathology, 1988 - 1992.
- ADJUNCT PROFESSOR, Department of Chemistry, 1984-1992
- Assistant Director, Clinical Chemistry Section, University of Minnesota Hospitals (1988-1992)
- Director, Drug Analysis Laboratory, Clinical Chemistry Section, University of Minnesota (1980-92).
- Facility manager, Health Sciences Mass Spectrometry Resource, 1981-1992
- Member, University of Minnesota University-Industry Cooperative Research Center for Biocatalytic Process Technologies, 1984-1992

Postdoctoral Training, University of Oregon Health Sciences Center (1975 - 1977).

DISTINCTIONS:

U.S. Substance Abuse and Mental Health Services Administration, Drug Testing Advisory Board, 2009 – 2012

Franklin and Marshall College Alumni Citation Award for Outstanding Career Achievements, 2007

World Anti-Doping Agency
- Member, Independent Observer team, Sydney Olympic Games, 2000
- Member, Standards and Harmonization Committee, 2000 – 2003
- Chairman, Laboratory Harmonization and Quality Assurance Subcommittee, 2001 – 2003
- Chairman, Working Group, International Standard for Laboratories, 2002-2003
- Member, Laboratory Working Committee, 2004 – 2011

Organizer and Chair, USADA Annual Symposium on Anti-Doping Science
- Oxygen Transport Enhancing Agents and Methods; Atlanta, 2002.
- Application of Gas Chromatography/Combustion/Isotope Ratio Mass Spectrometry to Doping Control; Los Angeles, 2003
- Detection of Human Growth Hormone Abuse in Sport; Dallas, 2004
- Muscle Development and Recovery: Implications for Doping Control; Chicago, 2005
- Intra-individual reference ranges: Implications for Doping Control. Lausanne (Switzerland), 2006
- Oxygen Transport and Energy Production. Dallas, 2007

Organizer and Chair, USADA Annual Symposium on Anti-Doping Science (cont'd)
Mitochondria to Proteins: New Challenges for Anti-Doping Science. Colorado Springs, 2008
Detection of enhancement of O_2 transport: Seven years of progress. Vancouver, BC, 2009
Emerging Technologies. Lansdowne, 2010
Detection of Growth Factors. London, UK, 2011
Deterring Athletes from Using Prohibited Substances. Atlanta, 2012

U.S. Food and Drug Administration, Medical Devices Advisory Committee, Clinical Chemistry and Clinical Toxicology (Member, 2003-present; Consultant, 2000–2002).

Working Group on GC/MS Confirmation of Drugs, Clinical Laboratory Standards Institute, (Chairman, 1995 – 2005; Member 2007-present)

Member, Working Group on Identification of Substances by GC/MS, LC/MS, and MS/MS. US Substance Abuse and Mental Health Services Administration (SAMHSA), September, 2000.

Visiting Scientist, Anti-Doping Laboratory, Pan American Games, Montreal, Quebec, Canada, July 1999.

Deputy Director, Athletic Drug Testing Laboratory, XXV Olympic Games, Atlanta, GA, July 1996.

American Board of Clinical Chemistry – Certificate in Toxicological Chemistry #101, 1994; Certificate in Clinical Chemistry #562, 1979. (Current status: Emeritus)

Laboratory Director Certificate of Qualification (#B10438), New York State Department of Health, 1994.

Clinical Chemistry
Associate Editor, Toxicology/Therapeutic Drug Monitoring, 1994-2000
Board of Editors, 1988-1994, 2000-2003

Faculty, Advanced Analytical Techniques, Advanced Toxicology Workshop, American Association for Clinical Chemistry, Baltimore, MD, June, 1998; Alexandria, VA, 2000.

Chairman, Midwest Association of Toxicology and Therapeutic Drug Monitoring (MATT) annual meeting, Indianapolis, IN, April, 1997.

Chairman, 18th International Symposium on Column Liquid Chromatography, Minneapolis, MN, May, 1994.

Associate member, Commission on Nomenclature, Properties, and Units, International Union of Pure and Applied Chemistry, 1995 - present.

Representative, Joint Committee on Education in Toxicology (AACC; SOFT; CAT), 1996-1999.

Award for Outstanding Contributions to Clinical Chemistry in a Selected Area of Research, American Association for Clinical Chemistry, 1990.

Board of Editors, Therapeutic Drug Monitoring, 1992-present.

Faculty Member, AACC course Professional Practice in Toxicology: A Review, Cincinatti, OH, June 21-25, 1992; June 21-25, 1993; June 20-24 1994; and June 23-26, 1996.

Board of Directors, American Association for Clinical Chemistry, 1989-1991.

Board of Directors, American Board of Clinical Chemistry, 1985-91.

Co-chairman, Selected Topics, AACC/CSCC/IFCC International Meeting. San Francisco, CA, July,1990.

National Science Foundation Special Molecular Sciences Review Panel, NSF Science and Technology Center Initiative, April, 1988.

Leroy Sheldon Palmer Award in Chromatography, Minnesota Chromatography Forum, 1985.

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