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## **Moving Beyond "Gene Doping":** *Preparing for Genetic Modification in Sport*

## Joe Fore $^{\dagger}$

#### ABSTRACT

Advances in biotechnology have raised the specter of "gene doping," the use of genetic modification to enhance athletic performance. Although gene transfer therapies are relatively immature and still unfit for widespread human use, the potential for tremendous—and undetectable—performance gains makes these techniques alluring to athletes. International sporting organizations, acting in the name of athlete safety and promoting fair play, have preemptively condemned the practice of genetic modification in sport.

Implementing a strict ban on genetic modification, however, may prove difficult. While safety concerns currently provide adequate justification for a total ban, improvements in technology and greater societal acceptance of genetic therapies are likely to make genetic modification in sport more palatable to athletes and spectators. Furthermore, straightforward application of the punitive model used for traditional forms of doping is problematic because of the difficulty of detecting and punishing those who use the techniques and because the ethical arguments against traditional doping carry somewhat less force in the context of gene-based enhancement.

Accordingly, this Article examines how athletic organizations can accommodate genetic modification in sport, which would allow them to protect athlete safety and ensure a level playing field, while not stigmatizing genetic technology more generally. The Article concludes that while international sports regulatory bodies should play a role in discussing the role of genetics in society, they should withhold their strict condemnation of genetic modification in sport until broader cultural norms regarding the desirability of human genetic enhancement are more firmly established.

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<sup>&</sup>lt;sup>†</sup> Joe Fore is a member of the Class of 2011 at the University of Virginia School of Law and serves as Notes Editor of the *Virginia Law Review*. He received an A.B. in Biology and Public Policy Studies from Duke University in 2007.

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#### I. INTRODUCTION

"It is a matter of size, evolution. Isn't it, gentlemen? Drago is the most perfectly trained athlete ever. This other man has not the size, the strength, the genetics to win.... Drago is a look at the future!"<sup>1</sup>

There is something deeply unsettling about hearing these words while staring at the all-too-perfectly-chiseled body of Ivan Drago in the fourth installment of the Rocky series. The idea of using genetics to "breed" athletes brings to mind the ugly legacy of state-sponsored eugenics and conflicts with the romantic notion of sport as a triumph of the spirit over the body. Over the past twenty-five years, however, fears of mass-produced, genetically-engineered athletes have given way to concerns about "gene doping," the use of gene therapy techniques to increase the body's production of performance-enhancing proteins.<sup>2</sup> While altering an adult body through genetics may be

<sup>&</sup>lt;sup>1</sup> ROCKY IV (MGM STUDIOS 1985).

<sup>&</sup>lt;sup>2</sup> The idea of germ-line genetic alteration or genetic screening raises an incredible number of ethical issues dealing with autonomy and the essence of "humanness." *See generally* MICHAEL SANDEL, THE CASE AGAINST PERFECTION 45–62 (2007). While some of these issues are also present in the debates surrounding

somewhat less threatening than prenatal modification, it is also more imminent. Indeed, given the social and financial incentives to win, the athletic field may be one of the first places where genetic enhancement becomes a reality.<sup>3</sup> But what should be done about genetic modification in sport? Should authorities treat it like steroid use—an illicit, artificial practice to be banned at all costs? Or is it more like a permissible technological innovation that merely allows the athlete to better express his or her own skill, such as an advanced running shoe or a titanium golf club?

So far, largely in the name of protecting athlete safety, world anti-doping authorities have universally condemned genetic modification in sport. Given the hazards of gene therapy and the unpredictable consequences for its use in enhancement settings, a strict ban is appropriate and necessary for the time being. But what would happen should these gene transfer technologies become safe enough to employ? And what if genetic enhancement becomes broadly acceptable in society? In order to prepare for the likely inevitability of genetic modification in sport, world regulatory bodies should soften their tone with regard to genetic modification, even if that ultimately means these bodies accept genetic modification as a permissible technological improvement and create parallel venues in which biologically-enhanced athletes can compete.

#### II. THE SCIENCE AND ALLURE OF "GENE DOPING"

"Gene doping" refers to the use of somatic cell gene transfer to enhance athletic performance. The basic premise is to introduce desired genes into the body, where they will be incorporated into the athlete's own cells and expressed as a normal protein. "Gene doping" would rely on techniques already employed in clinical gene therapies, which, although highly touted for their potential to cure human disease, remain largely experimental. Although there are currently more than 1,000 gene therapy clinical trials underway,<sup>4</sup> few of these have progressed past the initial stages,<sup>5</sup> and even successful treatments can have lethal side effects.<sup>6</sup>

There are three primary ways in which the artificial genes could be introduced

somatic cell gene transfer, they generally present much less of a challenge in this context. This Article will focus exclusively on somatic cell genetic modification as applied to adult athletes and not on "breeding" or "engineering" embryos for improved athletic performance.

<sup>&</sup>lt;sup>3</sup> ANGELA J. SCHNEIDER & THEODORE FRIEDMANN, GENE DOPING IN SPORTS: THE SCIENCE AND ETHICS OF GENETICALLY MODIFIED ATHLETES 37 (2006) ("[S]port represents one of the early and most obvious areas of human activity in which serious attempts at genetic enhancement are likely to be made, and made fairly soon.").

<sup>&</sup>lt;sup>4</sup> Gene doping: Genetically Modified Olympians?, ECONOMIST, Aug. 2, 2008, at 80, available at http://www.economist.com/science/displaystory.cfm?story\_id=11839246.

<sup>&</sup>lt;sup>5</sup> SCHNEIDER & FRIEDMANN, *supra* note 3, at 27.

<sup>&</sup>lt;sup>6</sup> Perhaps the best-known example of the dangerousness of gene therapy occurred during French trials aimed at treating severe combined immunodeficiency disease (SCID), more commonly known as "bubble boy syndrome." More than three years after treatment, two of the ten boys treated developed leukemia, which was caused when the retrovirus vector inserted near a cancer-causing gene. *Id.* at 30. Another fatal example occurred in 1999 when an 18-year old boy in a gene therapy trial for liver disease died from an immune response just days after receiving the initial treatment. *Id.* at 29.

into an athlete's body: 1) cultured cells could be genetically modified ex vivo and then introduced into the body; 2) the foreign DNA could be injected directly into the muscle or bloodstream; 3) the genes could be packed into a virus, which would then "infect" the athlete's cells with the genes.<sup>7</sup> Because of their ability to carry a large amount of genetic material, adenoviruses, which cause the common cold, would likely be popular vectors.<sup>8</sup>

#### Α. Which Genes Might Be Used?

Previous gene therapy studies suggest that several genes that code for certain proteins might be prime candidates for gene doping. Erythropoietin (EPO) is a hormone produced by the kidneys that triggers the production of red blood cells, thereby increasing the body's oxygen intake.<sup>9</sup> EPO's ability to boost red blood cell production in patients with various types of cancer and kidney disease has made its synthetic counterpart, epoetin alfa, one of the world's most widely-prescribed drugs.<sup>10</sup> Endurance athletes also prize this enhanced oxygen-carrying capacity, which allows them to exert themselves for longer periods without tiring. For this reason, traditional doping with EPO became widespread, particularly in cycling.<sup>11</sup> In 2003, researchers at Stanford conducted ex vivo gene transfer experiments in which they introduced a normal mouse EPO gene into healthy mice, triggering increased production of red blood cells in the presence of an inducing steroid.<sup>12</sup> EPO gene doping, therefore, could replace traditional doping in longdistance sports, like cycling or running.

Athletes seeking increased strength might also profit from genetic modification. In 1998, Professor Lee Sweeney's research team conducted in vivo gene transfer studies in mice using the insulin-like growth factor 1 (IGF-1), a protein that stimulates muscle growth.<sup>13</sup> The gene transfers successfully increased the strength of the mice, leading the press to dub them "Schwarzenegger mice."<sup>14</sup> An additional benefit of this type of genetic modification is that the gene can be injected directly into a specific muscle, localizing the gene's effects.<sup>15</sup> This property might especially appeal to athletes such as baseball pitchers, soccer forwards, or tennis players, who may want to bulk up only in a certain location without becoming too muscular overall.<sup>16</sup> Sweeney and his team have also

<sup>&</sup>lt;sup>7</sup> Mehmet Unal & Durisehvar Ozer Unal, *Gene Doping in Sports*, 34 SPORTS MED. 357, 358 (2004).

<sup>&</sup>lt;sup>8</sup> Christie Aschwanden, Gene Cheats, NEW SCIENTIST, Jan. 15, 2000, at 24, 26, available at http://www.archway.ac.uk/Activities/Departments/SHHP/downloads/epo/Genecheats/genecheats.html.

<sup>&</sup>lt;sup>9</sup> Edward H. Jurith & Mark W. Beddoes, *The United States' and International Response to the* Problem of Doping in Sports, 12 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 461, 470 (2002).

<sup>&</sup>lt;sup>10</sup> SCHNEIDER & FRIEDMANN, *supra* note 3, at 44. Two of the leading brand names of epoetin alpha are

Epogen and Procrit. <sup>11</sup> Chris Boardman, *Cycling's 'Biggest Doping Scandal,'* BBC SPORT, June 30, 2006, http://news.bbc.co.uk/sport1/hi/other\_sports/cycling/5132616.stm.

<sup>&</sup>lt;sup>12</sup> SCHNEIDER & FRIEDMANN, *supra* note 3, at 44–45.

<sup>&</sup>lt;sup>13</sup> Melinda Wenner, How to Be Popular During the Olympics: Be H. Lee Sweeney, Gene Doping Expert, SCI. AM., Aug. 15, 2008, http://www.sciam.com/article.cfm?id=olympics-gene-doping-expert.  $^{14}$  *Id*.

<sup>&</sup>lt;sup>15</sup> Aschwanden, *supra* note 8, at 28.

<sup>&</sup>lt;sup>16</sup> Genetically Modified Olympians?, supra note 4, at 80 (noting the potential desire of javelin throwers and tennis players to achieve targeted increases in muscularity).

worked on inhibiting a protein called myostatin, which counteracts IGF-1 expression and also plays a role in depositing fat in the body.<sup>17</sup> Inhibiting myostatin function could increase muscle and reduce body fat, two benefits attractive to any athlete.

Finally, it may also be possible to adjust the metabolism of particular muscles. Studies of the PPAR delta gene in mice have shown that the factor is able to increase the number of "slow-twitch" muscle fibers, which are utilized more in endurance exercises.<sup>18</sup> The so-called "marathon mice" showed a reduction in body fat, and their muscles became more efficient at burning energy.<sup>19</sup>

#### **B.** The (Un)Detectability of Gene Doping

There are two primary reasons that athletes might find gene doping preferable to traditional pharmacological doping. First, the enhancement effects from genetic modification could become permanent.<sup>20</sup> Once the foreign genes are incorporated into an athlete's cells, they become part of the cell's own genetic material and are expressed like any other part of the native genetic code. This means that once an athlete undergoes genetic modification, he or she would not have to come back to be "re-upped," reducing both the cost of doping and the chances of being caught.

However, the real allure of gene doping is that it is currently all but undetectable. The main problem is that "proteins made by engineered genes look identical to the ones the body makes naturally."<sup>21</sup> Additionally, some potential gene doping products remain in the muscles and would not circulate in the bloodstream, where they could be detected by traditional tests.<sup>22</sup> In these cases, the only reliable method for detecting gene doping would be to do a muscle biopsy at the site of the injection, an extremely invasive procedure to which athletes are unlikely to readily submit.<sup>23</sup>

A more complex but less invasive approach involves looking for changes in the body caused by the introduction of foreign DNA. Using this method, researchers are trying to see how gene expression patterns change in response to introduced genes.<sup>24</sup> These genomic or proteomic changes could be recorded using microarray analysis to establish a molecular "signature" that would indicate the presence of certain foreign genes.<sup>25</sup> Other approaches for detecting gene doping utilize imaging technology<sup>26</sup> or look

<sup>&</sup>lt;sup>17</sup> Wenner, *supra* note 13.

<sup>&</sup>lt;sup>18</sup> SCHNEIDER & FRIEDMANN, *supra* note 3, at 46.

<sup>&</sup>lt;sup>19</sup> Id.

<sup>&</sup>lt;sup>20</sup> Kristin Jo Custer, Note, From Mice to Men: Genetic Doping in International Sports, 30 HASTINGS INT'L & COMP. L. REV. 181, 188 (2007).

<sup>&</sup>lt;sup>21</sup> Aschwanden, *supra* note 8, at 29.

<sup>&</sup>lt;sup>22</sup> Wenner, *supra* note 13.

<sup>&</sup>lt;sup>23</sup> See Custer, supra note 20, at 203 (describing how the biopsy method of detection would require "taking a slice of the muscle at the spot of DNA injection").

<sup>&</sup>lt;sup>24</sup> Wenner, *supra* note 13 (suggesting that it may "one day be possible to detect gene doping by looking for its more overarching impacts on the body and particular tissues").

<sup>&</sup>lt;sup>25</sup> See SCHNEIDER & FRIEDMANN, supra note 3, at 77.

for the presence of virus vectors in the body.<sup>27</sup> Still, none of these methods is yet reliable or practical enough to be implemented in athletic situations.

Given these difficulties, it would perhaps be better to focus on simply monitoring the gene products themselves as indirect evidence of gene doping. After all, the genes are only good if they produce the desired proteins that enhance performance. One problem with this approach, as noted above, is that some gene products remain localized in the muscle tissue and would not be detectable in other tissues or fluids. However, for products like EPO, measuring hematocrit levels (the percentage of red blood cells in the blood) is the standard method of testing; this method catches gene-doped athletes as well as athletes using traditional doping techniques.<sup>28</sup> One potential method for detecting EPO doping is to monitor an athlete's hematocrit levels over time to establish "reference ratings" for individuals.<sup>29</sup> Once these baseline levels are established for each athlete, subsequent tests can be compared to the normal ranges, and large deviations can be grounds for further investigation or even exclusion from individual events.<sup>30</sup> Sporting organizations are moving quickly to create reliable testing methods based on this idea of a "biological passport," and, in early 2009, the International Cycling Union planned to bring its first doping charges based solely on these changes in blood composition.<sup>31</sup>

However, it would be difficult to apply this idea of the hematocrit "passport" to the context of genetic modification. If and when gene doping is first introduced, it would be possible to watch for dramatic increases in an athlete's hematocrit levels, just as with current forms of EPO doping. However, subsequent generations of athletes would be able to undergo genetic modification before being tested in order to establish their baselines, meaning that their reference ranges would start out with high levels, masking their enhanced status. And because genetic modification is essentially permanent, an athlete could maintain consistently high hematocrit levels without producing any of the suspicious tell-tale "spikes" characteristic of traditional doping.

Another problem with only measuring gene product levels is that doing so would fail to distinguish "gene doped" athletes from athletes with natural genetic mutations that cause them to have high levels without artificial enhancement.<sup>32</sup> A perfect example is the case of Finnish cross-country skier Eero Mantyranta, who won two gold medals at the 1964 Winter Olympics, in part because of a naturally-occurring mutation that caused his body to produce twenty-five to fifty percent more red blood cells than an average person.<sup>33</sup> While testing methods might have been able to detect his higher hematocrit

<sup>&</sup>lt;sup>26</sup> World Anti-Doping Agency, *Gene Doping*, 1 PLAY TRUE 2, 6 (2005), *available at* http://www.wada-ama.org/rtecontent/document/Play\_True\_01\_2005\_en.pdf.

<sup>&</sup>lt;sup>27</sup> Genetically Modified Olympians?, supra note 4, at 81.

<sup>&</sup>lt;sup>28</sup> Jurith & Beddoes, *supra* note 9, at 470.

<sup>&</sup>lt;sup>29</sup> Unal & Unal, *supra* note 7, at 360.

<sup>&</sup>lt;sup>30</sup> Jurith & Beddoes, *supra* note 9, at 470.

<sup>&</sup>lt;sup>31</sup> Juliet Macur, *Cycling to Use Blood Profiles in Doping Case*, N.Y. TIMES, Feb. 28, 2009, at A1, *available at* http://www.nytimes.com/2009/02/28/sports/othersports/28doping.html.

<sup>&</sup>lt;sup>32</sup> Aschwanden, *supra* note 8, at 29.

<sup>&</sup>lt;sup>33</sup> *Id.* at 26.

levels or even the increased expression levels in his cells, there would be no way to distinguish this natural (and, thus, permitted) genetic gift from an artificial enhancement.

#### III. THE INTERNATIONAL ANTI-DOPING FRAMEWORK

Before analyzing what steps can and should be taken to prepare for the regulation of genetic modification in sport, it is essential to understand the political and regulatory framework in which decisions about doping are made and how that framework has already been applied to gene doping.

#### A. Anti-Doping Efforts

Over the past decade, sports doping regulations have become increasingly harmonized.<sup>34</sup> Frustration over a series of embarrassing doping incidents, particularly in the worlds of cycling and sprinting, led the International Olympic Committee (IOC) to call for a World Conference on Doping in Sport in Lausanne, Switzerland, in 1999.<sup>35</sup> From that conference, the IOC, with support from the International Sports Federations and National Olympic Committees, established the World Anti-Doping Agency (WADA).<sup>36</sup> WADA was charged with overseeing the development of international anti-doping policies with two goals in mind: to protect the well-being of athletes and to promote fair play.<sup>37</sup> One of WADA's most important functions is the publication and continual updating of the World Anti-Doping Code (the Code), which contains lists of all banned substances and methods.<sup>38</sup> Individual countries still play a major role in the monitoring of athletes and compliance with international standards. Since November 2001, anti-doping policies in the United States have been administered by the United States Anti-Doping Agency (USADA).<sup>39</sup>

#### B. International Regulatory Bodies and Genetic Modification

The threat of genetic modification in sport has loomed large in discussions about doping over the past decade. Experts and sporting organizations recognize it as a future challenge that will likely need to be confronted.<sup>40</sup> These organizations have fired a pre-emptive "shot across the bow" to discourage illicit applications of genetic technologies in

<sup>&</sup>lt;sup>34</sup> ANDY MIAH, GENETICALLY MODIFIED ATHLETES: BIOMEDICAL ETHICS, GENE DOPING AND SPORT 33 (2004).

<sup>&</sup>lt;sup>35</sup> Custer, *supra* note 20, at 191.

<sup>&</sup>lt;sup>36</sup> MIAH, *supra* note 34, at 33.

<sup>&</sup>lt;sup>37</sup> Andy Miah, *Gene Doping: Sport, Values, & Bioethics, in* THE ETHICS OF HUMAN GENETICS: CHALLENGES OF THE (POST) GENOMIC ERA 175 (J. Glasa ed., 2003), *available at* http://www.andymiah.net/documents/Miah2002GeneDopingGlasaBk.pdf.

<sup>&</sup>lt;sup>38</sup> SCHNEIDER & FRIEDMANN, *supra* note 3, at 8.

<sup>&</sup>lt;sup>39</sup> Jurith & Beddoes, *supra* note 9, at 480.

<sup>&</sup>lt;sup>40</sup> World Anti-Doping Agency, *supra* note 26, at 12.

sport.<sup>41</sup> For a regulatory industry often accused of responding too slowly to sophisticated, rapidly-evolving doping techniques, the immature state of gene transfer technology provides a unique opportunity to develop policies before the threat materializes.<sup>42</sup> Even so, regulators may not have much time. In 2006, during a doping investigation of German running coach Thomas Springstein, searches of his email showed references to Repoxygen, a substance used in conjunction with gene therapy for anemic patients.<sup>43</sup>

#### 1. **Early Discussions**

In 2001, shortly after the creation of WADA, the IOC convened a working group on gene doping.<sup>44</sup> The group's findings affirmed support for the medical applications of gene therapy but advised taking measures to keep genetic modification out of the realm of sport:

We endorse the development and application of gene therapy for the prevention and treatment of human disease. However, we are aware that there is the potential for abuse of gene therapy medicines and we shall begin to establish procedures and state-of-the-art testing methods for identifying athletes who might misuse such technology.<sup>45</sup>

In the early years of this decade, more than a half-dozen major meetings and discussions on the subject of gene doping were held by a number of organizations, including the IOC, the American Association for the Advancement of Science (AAAS) and the U.S. President's Council on Bioethics.<sup>46</sup>

However, perhaps the most important of these meetings was the Banbury Conference, hosted by WADA in 2002 and dedicated to the issue of gene transfer in sport.<sup>47</sup> In an opening address, WADA President Richard Pound warned that the sporting world "face[d] the prospect of genetic manipulation which will probably make drugs like [steroids] look like the dark ages."<sup>48</sup> The Banbury Conference urged better cooperation by natio3nal governments, calling for them to "expedite the development of a global social framework for the application of genetic transfer technologies that address the

<sup>&</sup>lt;sup>41</sup> Ted Friedmann, Potential for Genetic Enhancements in Sports, Address Before the President's Council on Bioethics (July 11, 2002), available at http://www.bioethics.gov/transcripts/jul02/ session4.html.

<sup>&</sup>lt;sup>42</sup> See MIAH, supra note 34, at 38 ("Unlike with the doping issue in general, ethical decisions about genetic modifications can be made *before* the technology is in place and is causing problems for sport. This provides a very useful opportunity to ensure that policy about the ethical status of genetics in sport is practicable and justified.").

<sup>&</sup>lt;sup>3</sup> Custer, *supra* note 20, at 187.

<sup>&</sup>lt;sup>44</sup> MIAH, *supra* note 34, at 12.

<sup>&</sup>lt;sup>45</sup> Id. (quoting Press Release, International Olympic Committee, IOC Gene Therapy Working Group— Conclusion (2001)).

<sup>&</sup>lt;sup>46</sup> See SCHNEIDER & FRIEDMANN, supra note 3, at 9. For a list of international discussions on gene doping, including meetings in Australia, Denmark, Austria, England, and Greece, see MIAH, supra note 34, at 52. <sup>47</sup> SCHNEIDER & FRIEDMANN, *supra* note 3, at 65.

<sup>&</sup>lt;sup>48</sup> *Id.* at 71.

potential misuse of these technologies in sport and a publicly stated deadline for the adoption of that framework."<sup>49</sup> Two major recommendations emerged from the workshop.

The first was a call to initiate a research program for the detection of gene doping.<sup>50</sup> Since then, WADA has responded by generously funding research in this area. Between 2003 and 2007, WADA awarded twenty-one grants in the fields of genomics, proteomics, viral detection, bioinformatics, and imaging, all with the goal of detecting gene doping.<sup>51</sup> These grants totaled \$7.8 million,<sup>52</sup> a quarter of WADA's entire research budget for the period between 2004–07.<sup>53</sup> The organization earmarked another \$6.5 million for use in similar lines of research.<sup>54</sup> In 2004, WADA also established a five-expert "Gene Doping Panel" to guide the organization's efforts in the area.<sup>55</sup>

The second key recommendation was for WADA and other regulatory bodies to include genetic modification in their definitions of "doping" and to list gene transfers alongside other banned substances and methods in the World Anti-Doping Code.<sup>56</sup> Eventually, the Code's Prohibited List was amended to include gene doping as an impermissible technique for athletic enhancement. The 2009 version of the Prohibited List contains the following proscription:

#### M3. Gene Doping

The transfer of cells or genetic elements or the use of cells, genetic element or pharmacological agents to modulate expression of endogenous genes having the capacity to enhance athletic performance, is prohibited.<sup>57</sup>

#### 2. Current Regulatory Attitudes Toward Gene Doping

The proscription against genetic modification in the Code typifies the currently dominant anti-modification stance. Generally, anti-doping organizations and officials are almost unanimous in their belief that gene transfer is best kept entirely out of sport.<sup>58</sup> As Richard Pound proclaimed, "This is a slippery slope we do not ever want to go down . . . .

<sup>&</sup>lt;sup>49</sup> Custer, *supra* note 20, at 200–01.

<sup>&</sup>lt;sup>50</sup> SCHNEIDER & FRIEDMANN, *supra* note 3, at 75.

<sup>&</sup>lt;sup>51</sup> Oliver Rabin, WADA Research Program on Gene Doping, PowerPoint Presentation at the WADA St. Petersburg Gene Doping Symposium, slides 7, 10 (June 10, 2008) *available at* http://www.wada-ama.org/rtecontent/document/2008 StPetersburg Declaration Dr.Rabin.pdf.

<sup>&</sup>lt;sup>52</sup> *Id.* at 9.

<sup>&</sup>lt;sup>53</sup> Genetically Modified Olympians?, supra note 4, at 81.

<sup>&</sup>lt;sup>54</sup> Id.

<sup>&</sup>lt;sup>55</sup> World Anti-Doping Agency, *supra* note 26, at 8.

<sup>&</sup>lt;sup>56</sup> SCHNEIDER & FRIEDMANN, *supra* note 3, at 75 ("The World Anti-Doping Code . . . should include language prohibiting the use of genetic transfer technologies to enhance athletic performance." (quoting the Banbury Conference conclusions)).

<sup>&</sup>lt;sup>57</sup> WORLD ANTI-DOPING AGENCY, THE WORLD ANTI-DOPING CODE: THE 2009 PROHIBITED LIST 6 (2008), *available at* http://www.wada-ama.org/rtecontent/document/2009\_Prohibited\_List\_ENG\_Final\_20\_Sept\_08.pdf.

<sup>&</sup>lt;sup>58</sup> See Miah, supra note 37, at 178 ("Presently, the emerging perspective in sport is to rid sport of GM before it even enters into competition.").

WADA will fight gene doping as vigorously as it has traditional doping."<sup>59</sup> These strong sentiments are echoed by Johann Olav Koss, a Norwegian speed-skating champion, IOC member, and medical doctor, who warns: "We have to do this in the early stages before any athlete starts using this. We need to act quickly to define the rules. I don't think sport has anything to benefit from having genetically enhanced athletes."<sup>60</sup> It seems clear that the very act of labeling this type of genetic modification as "doping" was a significant act, clearly connoting an official negative attitude toward the practice.<sup>61</sup>

The stringent tone adopted by Pound and Koss is reflected in WADA's most recent statement about gene doping, a product of the Third Gene Doping Symposium held in St. Petersburg, Russia, in 2008.<sup>62</sup> The St. Petersburg Declaration reaffirmed WADA's punitive approach toward genetic modification, focusing on continued development of detection methods and "appropriate sanction mechanisms for illegal and illicit application of gene transfer in sport."<sup>63</sup> While concerns over fairness and the ethics of competition informed the conference's conclusions, athlete safety remains the primary reason for prohibiting gene doping.<sup>64</sup>

#### 3. Safety Concerns

The dangers of gene therapy present a legitimate justification for the prohibition on genetic modification. As noted above, gene therapies in clinical applications have proven troublesome and potentially dangerous, and gene therapies aimed at enhancement would likely pose additional risks.

First, there is concern about the permanence of genetic modification: there may be no way to "turn off" a gene once it has been inserted into an athlete's body, leading to the potentially dangerous overproduction of a specified gene product.<sup>65</sup> While researchers working on some of the EPO gene therapy trials in mice developed strategies to control expression of the introduced gene,<sup>66</sup> it is not certain that all genes can be effectively regulated in this manner. Another potential complication arises from the interaction between the introduced gene and other genes. Increasing the expression of one gene could cause cascading effects throughout the genome, unbalancing gene expression

<sup>&</sup>lt;sup>59</sup> Richard Pound, Editorial, World Anti-Doping Agency, *supra* note 26, at 1.

<sup>&</sup>lt;sup>60</sup> MIAH, *supra* note 34, at 54.

<sup>&</sup>lt;sup>61</sup> Custer, *supra* note 20, at 197.

 <sup>&</sup>lt;sup>62</sup> Press Release, World Anti-Doping Agency, Gene Doping Symposium - Saint Petersburg 2008 (Jan. 2010), <a href="http://www.wada-ama.org/en/Science-Medicine/Scientific-Events/Saint-Petersburg-Symposium-2008">http://www.wada-ama.org/en/Science-Medicine/Scientific-Events/Saint-Petersburg-Symposium-2008</a>.

<sup>&</sup>lt;sup>63</sup> World Anti-Doping Agency, WADA St. Petersburg Declaration 1, June 11, 2008, *available at* http://www.wada-ama.org/rtecontent/document/2008\_StPetersburg\_Declaration.pdf.

<sup>&</sup>lt;sup>64</sup> See id. at 2 (describing the need for further development of gene therapy and extensive clinical trials before declaring them safe for use).

<sup>&</sup>lt;sup>65</sup> Aschwanden, *supra* note 8, at 27.

<sup>&</sup>lt;sup>66</sup> In the 2003 Stanford mouse EPO studies, researchers were able to regulate EPO production with the use of a cortisone-like steroid. In the presence of the steroid, the introduced gene produced EPO, but in its absence, the introduced gene was unable to function. *See* SCHNEIDER & FRIEDMANN, *supra* note 3, at 45.

throughout the cell or body, a condition known as pleiotropy. <sup>67</sup> Finally, genetic modifications that strengthen only muscles could put a tremendous strain on other body parts essential to movement such as tendons and ligaments, putting athletes at serious risk of injury.<sup>68</sup>

In response to these and other safety concerns, governments around the world have established strict protocols for the approval of gene therapy studies. In the United States, for example, researchers at federally-funded institutions who wish to undertake gene transfer studies must get approval from the FDA, NIH, and Recombinant DNA Advisory Committee before their local Institutional Review Board (IRB) is permitted to recruit research subjects. <sup>69</sup> Because of these concerns over unknown risks, the Recombinant DNA Advisory Committee has made clear that it is not yet willing to entertain proposals for gene transfer studies that are aimed at enhancement and not treatment.<sup>70</sup>

For this reason, it is almost certain that any attempts at gene doping would occur outside of the regular gene transfer oversight procedures.<sup>71</sup> Athletes would be driven to American laboratories doing illicit gene therapy, or, due to the fragmented nature of research regulations, to foreign countries to undergo modification.<sup>72</sup> The prospect of "black market" gene therapy could seriously endanger athletes. However, some would argue that prohibiting the practice based on athlete safety is overly paternalistic, and that athletes should be permitted to undertake the risks if they feel they are worth it. After all, many sports, such as football, skiing, or boxing are inherently dangerous, and, therefore, achievement in these sports actually requires a certain disregard for personal safety.<sup>73</sup> However, as the President's Council on Bioethics points out, "[T]here seems to be a difference between the uncertain dangers of the playing field and the deliberately self-inflicted harm of using performance-enhancing drugs."<sup>74</sup>

More importantly, the practice of genetic enhancement would undermine basic tenets of ethical medical practice, because they would not be the product of voluntary, informed consent, the hallmark of research with human subjects.<sup>75</sup> At this stage in the

<sup>&</sup>lt;sup>67</sup> MIAH, *supra* note 34, at 50.

<sup>&</sup>lt;sup>68</sup> See PRESIDENT'S COUNCIL ON BIOETHICS, BEYOND THERAPY: BIOTECHNOLOGY AND THE PURSUIT OF HAPPINESS 112 (2003), available at http://bioethicsprint.bioethics.gov/reports/beyondtherapy/index.html (describing how imbalanced muscle gains can cause "serious malfunction[s]" in the body).

<sup>&</sup>lt;sup>69</sup> SCHNEIDER & FRIEDMANN, *supra* note 3, at 61.

<sup>&</sup>lt;sup>70</sup> Id.

<sup>&</sup>lt;sup>71</sup> See id. at 58 ("Another test of the appropriateness of gene transfer application in athletics would be whether such work is carried out under the accepted current standards of regulation and oversight to which all legitimate gene transfer studies with human subjects and patients are subjected.").

<sup>&</sup>lt;sup>72</sup> Custer, *supra* note 20, at 202–03.

<sup>&</sup>lt;sup>73</sup> See PRESIDENT'S COUNCIL ON BIOETHICS, *supra* note 68, at 137 (suggesting that certain types of sports "require daring, toughness, and sometimes even contempt for 'mere safety' as being far less important than victory and achievement").

<sup>&</sup>lt;sup>74</sup> *Id.* at 138.

<sup>&</sup>lt;sup>75</sup> NAT'L INSTS. OF HEALTH, OFFICE OF HUMAN SUBJECTS RESEARCH, THE BELMONT REPORT pt. C.1, *available at* http://ohsr.od.nih.gov/guidelines/belmont.html#goc1.

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development of gene therapy, the unknown quantity of risks and benefits would make it virtually impossible to obtain truly informed consent for athletes wishing to undergo genetic modification.<sup>76</sup> Further complicating the concept of freely-given consent are the tremendous financial and social rewards that accompany athletic success. Respect for personal autonomy requires allowing individuals to make personal medical decisions based on voluntary, informed consent; however, in the gene doping context, this could be impossible:

[I]n the murky world of sport doping, it is unlikely that any or all of these basic requirements of experimental studies with human subjects would be satisfied. The risks would be hidden, the benefits exaggerated and the risk/benefit ratio merely a guess. Under those conditions, the subject—the athlete—could hardly be expected to give informed and voluntary consent.<sup>77</sup>

This coercive pressure could extend to even athletes who did not want to undergo genetic modification, but would feel pressure to engage in gene doping for fear of losing a competitive edge.<sup>78</sup>

WADA and other organizations play a crucial role in helping to educate athletes about the dangers of gene therapy. The St. Petersburg Declaration noted the obligation of groups to "provide objective and reliable information to athletes, trainers and physicians, to enable them to assess critically the claims made . . . regarding the 'power of genetics' to enhance athletic performance."<sup>79</sup> Given the unknown nature of the risks, and the associated difficulties in obtaining truly informed consent, it seems appropriate to continue to prohibit genetic modification in sport for the foreseeable future.

However, what happens if and when gene transfer becomes safe enough to be used effectively, even for purposes of enhancement? Once harm is reduced to a known, quantifiable amount, such that valid, informed consent is possible, then the desire to protect athletes is no longer a sufficient justification for banning genetic modification in sport.<sup>80</sup> At that point, "the deeper question . . . is whether genetic modification is still ethically acceptable in conditions where the technology is sufficiently safe."<sup>81</sup>

#### IV. PROBLEMS WITH BANNING GENETIC MODIFICATION

It is unclear whether genetic modification should be considered an impermissible

<sup>&</sup>lt;sup>76</sup> Miah, *supra* note 37, at 177.

<sup>&</sup>lt;sup>77</sup> SCHNEIDER & FRIEDMANN, *supra* note 3, at 63. Dr. Lee Sweeney, who conducted the pioneering studies on IGF-1 claims he has already been approached by athletes who are more than willing to volunteer for genetic modification, despite his warnings: "No matter what I say to them about [gene therapy] being dangerous and experimental . . . it doesn't slow then down—[athletes] just keep pushing, saying 'I want to be the guinea pig, I want to be the first person you try this on." Wenner, *supra* note 13.

<sup>&</sup>lt;sup>78</sup> SCHNEIDER & FRIEDMANN, *supra* note 3, at 4.

<sup>&</sup>lt;sup>79</sup> World Anti-Doping Agency, *supra* note 63, at 3–4.

<sup>&</sup>lt;sup>80</sup> MIAH, *supra* note 34, at 138.

<sup>&</sup>lt;sup>81</sup> Id.

biological enhancement like steroid use or a desirable technological improvement like better training methods or a more advanced tennis racket. However, even if genetic modification is found to be just as morally impermissible as traditional doping, there are a number of technical and ethical issues that would prevent the straightforward application of traditional doping sanctions in the context of genetic modification.

#### A. The Ethics of Genetic Modification vs. Traditional Doping

Both traditional doping methods and genetic modification have the potential to enhance athletic performance. However, this cannot be the sole ethical basis for keeping them out of sport. After all, athletes today benefit from a wide range of technological innovations that have vastly improved performance over previous generations of athletes. Graphite tennis rackets, better shoes and apparel, and even biological modifications like new training methods, nutritional supplements, and injury treatments have all become acceptable and necessary parts of modern sport.<sup>82</sup> Accordingly, with regard to genetic modification, the question becomes: "Is it to be treated as another form of doping? . . . Is it more like a lighter tennis racket, a drug, or something completely new and different?"<sup>83</sup> While some experts believe that gene transfer presents no novel ethical issues compared with traditional doping,<sup>84</sup> there are compelling reasons to think that gene doping presents a less clear-cut ethical violation.

One key difference is the nature of the technology and its mode of action in the body. Traditional pharmacological doping involves the introduction of foreign materials that directly stimulate growth in the body (e.g. human growth hormone and steroids) or the production of new tissues or cells (e.g. EPO). With gene transfer, however, only the genetic material is introduced, where it is assimilated into the individual's cells and then expressed as the desired gene product. There is a real distinction (albeit, perhaps a fine one): in gene doping, the introduced substance (the genetic material) is merely informational in nature and is useless on its own. It only becomes operational when expressed by the athlete's own cellular machinery.

There seems to be a compelling parallel in the recent debate over the use of portable "altitude tents," which "trick" the body into producing more red blood cells by simulating high altitude conditions.<sup>85</sup> In 2006, WADA ultimately decided not to place altitude simulators on its list of banned technologies.<sup>86</sup> Supporters point out that the tents simply elicit a perfectly natural response, triggered by low oxygen conditions. Just as in gene doping, the biological response (in this case, increased hematocrit levels) comes

<sup>&</sup>lt;sup>82</sup> See Richard A. Posner, In Defense of Prometheus: Some Ethical, Economic, and Regulatory Issues of Sports Doping, 57 DUKE L.J. 1725, 1731 (2008) ("[M]any uncontroversial technological and institutional improvements . . . have boosted modern athletic performance over that of earlier eras.").

<sup>&</sup>lt;sup>83</sup> MIAH, *supra* note 34, at 177.

<sup>&</sup>lt;sup>84</sup> Friedmann, *supra* note 41 ("I don't think that there is a new kind of ethical issue that separates genetic doping from pharmacological doping.").

<sup>&</sup>lt;sup>85</sup> MIAH, *supra* note 34, at 36.

<sup>&</sup>lt;sup>86</sup> Doriane Lambelet Coleman & James E. Coleman, Jr., *The Problem of Doping*, 57 DUKE L.J. 1743, 1756 (2008).

only as the result of an informational input, not a direct, chemical stimulus.

Some commentators have pointed out the genetic aspect of the altitude tent enhancement, which is extremely relevant to the gene doping debate. Coleman and Coleman note the difference between altitude tents and steroids, for example, is that the tents "do not and cannot cause the body to be more and perform differently than its genes would otherwise allow."<sup>87</sup> So, just as in the genetic modification context, these authors point out a distinction between substances that are introduced directly and products that are made by the athlete's own body. Similarly, the authors suggest that drugs are objectionable because they "cause[] bone and muscle development beyond that which would result from the expression of the athlete's own DNA; [these drugs] effectively trump[] that DNA."<sup>88</sup> In the genetic modification context, this idea raises a number of important and difficult questions. What constitutes the "athlete's own DNA"? Should it only include the DNA that he or she was born with? Does the introduced DNA become "the athlete's DNA" once he or she undergoes genetic modification?

While this debate would require far more discussion than is possible here, it is clear that biological distinctions between gene transfer and traditional doping prevent a seamless ethical transition from one to another. But even if genetic modification in sport resembles altitude tents or novel training methods, the President's Council on Bioethics suggests that this does not resolve all ethical debates, insisting that, "[t]he fact that . . . using genetic muscle enhancers could resemble, in some respects, using special diets or special bodybuilding programs does not by itself dissolve all our moral concerns."<sup>89</sup> However, apart from potential ethical qualms, the distinctions between drug-based doping and genetic modification mean that traditional sanctioning methods may be impossible to apply to genetic enhancement.

#### B. Difficulties in Sanctioning Genetic Modification

Attempts to locate and punish genetic modification within the existing doping regulatory framework will be difficult for a number of reasons. First and foremost is the difficulty of detection, as previously mentioned. Currently, the only reliable ways to detect gene doping, such as muscle biopsy, are too expensive or intrusive to be practicable.

However, even if effective and unobtrusive tests are developed, gene doping will still provide a challenge to established sanctioning mechanisms. First, there is the problem of distinguishing illicit gene doping from naturally-occurring genetic mutations. Even more problematic, though, is the permanent nature of genetic modification. Once the foreign genes are inserted, there would be no way to remove them from the athlete's

<sup>&</sup>lt;sup>87</sup> *Id.* at 1772.

<sup>&</sup>lt;sup>88</sup> *Id.* at 1771.

<sup>&</sup>lt;sup>89</sup> PRESIDENT'S COUNCIL ON BIOETHICS, *supra* note 68, at 124.

body, and, potentially, no way to disable them.<sup>90</sup> The consequences would be dire for any athlete who was caught, since "[a]nti-doping authorities . . . would have to ban an athlete for life if adhering to the espoused zero-tolerance policy. Such a policy would leave no room for a second chance or an opportunity to repent or come clean."91 This would certainly be at odds with current WADA policies, which mandate a two-year suspension for first-time offenders of doping policy.<sup>92</sup>

This policy could also pose a problem in the context of athletes wishing to use therapeutic gene therapies, which may someday become standard medical practice. Athletes, just like other injured people, deserve access to the best treatment available, which may include treatments with banned substances.<sup>93</sup> Existing protocols permit athletes to obtain "Therapeutic Use Exemptions" (TUE) when treatment requires the legitimate use of drugs not normally permitted in competition.<sup>94</sup> In the context of traditional doping substances, once the treatment is completed, the athlete can return to competition. However, this application of the TUE protocols would be unable to accommodate the permanent nature of gene transfer. For example, what if a boy underwent therapeutic EPO gene therapy as a small child, and then later recovered and developed a talent for running?<sup>95</sup> If that boy wished to enter the Olympics, should he be disgualified because he received a necessary medical treatment early in life?

Finally, there is a concern that any attempt to ban an athlete based on genetic composition could constitute genetic discrimination, which is at odds with international human rights standards. The United Nations Educational, Scientific and Cultural Organization's (UNESCO) "Universal Declaration on the Human Genome and Human Rights" states

Article 2: Everyone has a right to respect for their dignity and for their rights regardless of their genetic characteristics

Article 6: No one shall be subjected to discrimination based on genetic characteristics that is intended to infringe or has the effect of infringing human rights, fundamental freedoms and human dignity.<sup>96</sup>

It is not hard to imagine a claim being made before the Court of Arbitration in Sport by a banned genetically-modified athlete that he was denied the "fundamental

<sup>&</sup>lt;sup>90</sup> See Custer, supra note 20, at 208 ("Once an athlete is genetically doped, the effects of such a procedure are present for the rest of the athlete's life.").

<sup>&</sup>lt;sup>91</sup> *Id*.

<sup>&</sup>lt;sup>92</sup> *Id*.

 $<sup>^{93}</sup>$  SCHNEIDER & FRIEDMANN, *supra* note 3, at 49 ("Athletes need and deserve access to the best medical procedures and methods to repair their injured muscle, tendons, bones and all other tissues just as all injured patients need and deserve the best in medical repair technology.").

World Anti-Doping Agency, World Anti-Doping Code art. 4.4 (2003), available at http://www.wada-ama.org/rtecontent/document/code v3.pdf; Custer, supra note 20, at 205-06.

<sup>&</sup>lt;sup>95</sup> Custer, *supra* note 20, at 205–06 (posing, but not answering, the hypothetical scenario described in the text).

<sup>&</sup>lt;sup>96</sup>U.N. Educ., Sci. & Cultural Org. [UNESCO], Universal Declaration on the Human Genome and Human Rights arts. 2, 6, Nov. 11, 1997; MIAH, supra note 34, at 166 (quoting the UNESCO Declaration).

freedom" of pursuing his career because of his genetic composition.<sup>97</sup>

These difficulties suggest that a total ban on genetic modification in sport would, at best, be incompatible with the existing regulatory framework, and, at worst, technologically impossible. However, it is even more problematic that calls for prohibiting genetic modification in sport have come before society has passed judgment on genetic modification as an impermissible mode of enhancement.

#### C. Gene Doping and Society's View of Genetic Enhancement

The issue of gene doping extends far beyond the sporting world and has serious implications for how genetic enhancement is viewed in society. Indeed, given that genetic modification technologies are in their very earliest stages, the way they are addressed in the sports context could have tremendous impact on the public's perception of the role of genetic enhancement in society. The ability for these technologies to reach their full potential in society could be undermined by stubborn, preemptive measures to keep them out of sport, using an outdated "doping" paradigm. Already, simply "[b]y labeling genetic modification as a form of 'doping,' WADA has shown a negative perspective toward the practice."<sup>98</sup> Because of the great promise many of these technologies offer, it seems appropriate to wait and let society dictate how sport will use these technologies and not the other way around.<sup>99</sup>

This is not to say that sporting organizations should not have a say in shaping social attitudes toward genetic enhancement. Because the field of play is likely one of the first places that genetic modification will occur, sports regulatory bodies have an obligation to responsibly monitor the use of these enhancements. WADA's St. Petersburg Declaration states that

[T]he financial and personal rewards for enhanced performance in sport indicate that sport will be one of the areas in which gene-based enhancement is first likely to arise. The world of sport therefore serves as a very effective setting in which to examine broad societal issues of enhancement and the unclear boundary between treatment and enhancement.<sup>100</sup>

Certainly, sport provides a unique and valuable context through which to examine the ethics and limits of genetic enhancement, but decisions regarding the use of genetics

<sup>&</sup>lt;sup>97</sup> See, e.g., AUSTL. LAW REFORM COMM'N, ALRC 96 ESSENTIALLY YOURS: THE PROTECTION OF HUMAN GENETIC INFORMATION IN AUSTRALIA ch. 38 (2003), *available at* http://www.austlii.edu.au/au/other/alrc/publications/reports/96/38\_Sport.doc.html (discussing the legal and ethical implications of genetic testing of athletes, particularly for purposes of talent identification and injury prevention).

<sup>&</sup>lt;sup>98</sup> Custer, *supra* note 20, at 197.

<sup>&</sup>lt;sup>99</sup> See MIAH, supra note 34, at 165 ("[I]t is not even clear whether sporting authorities should have the power to make such decisions, given the broader context within which genetic modification would take place . . . .").

<sup>&</sup>lt;sup>100</sup> World Anti-Doping Agency, *supra* note 79, at 2.

in sport must reflect broader societal attitudes toward these technologies. In making these decisions, organizations such as the IOC and WADA "will benefit immensely from the expertise within non-governmental organizations and governmental committees, which have invested considerably into discussing the broad ethical issues arising from genetics in society."101 Sporting organizations must also be prepared to accept the fact that because genetic enhancement is in such an early stage, societies have not had enough time to decide to what extent it will be permissible.

A useful parallel can be found in one of the main justifications for banning steroids and other illegal drugs in sport: it sets a bad example for children.<sup>102</sup> Doping in sport is closely tied to the issue of illegal drug use, more generally, and it is widely believed that having sports role models who are doping is problematic because it could encourage young athletes to experiment with illegal drugs.<sup>103</sup> But, this is rooted in the fact that society has determined that illegal drugs are undesirable and that "Don't do drugs" is an acceptable stance. But what about "Don't alter your genes"? The difference is that "genetic modification does not come with the same cultural baggage that underpins drug taking."<sup>104</sup> "Genetic modification cannot be considered as a deviant practice."<sup>105</sup> As of yet, it does not appear that society has taken a definitive stance on whether genetic modification should be permissible. Ultimately, if genetic enhancements are deemed to be legitimate applications of biotechnology, then the sporting world may have a harder time justifying their prohibition.<sup>106</sup>

#### V. ACCOMMODATING GENETIC MODIFICATION IN SPORT

What if society does embrace genetic modification as an acceptable method of enhancement? How should sporting and anti-doping organizations respond? Should they adopt an "anything goes" attitude and simply permit athletes to use whatever substances they like? Not necessarily. Adopting a permissive attitude toward genetic modification in sport would not require the abandonment of all testing procedures or regulations. However, it might require some major rearrangements in how athletic contests are structured in order to preserve fundamental notions of fairness and maintain the essence of competition.

<sup>&</sup>lt;sup>101</sup> MIAH, *supra* note 34, at 39.

<sup>&</sup>lt;sup>102</sup> Coleman & Coleman, *supra* note 86, at 1788 ("Another constituency that has and must continue to receive substantial attention from commentators and regulators is children who are adversely affected by the influence of role model athletes who engage in doping.").

<sup>&</sup>lt;sup>103</sup> See MIAH, supra note 34, at 159 ("One can understand this kind of concern in relation to drug taking and doping in sport, which would seem inextricable from the concern about drug use more broadly.").

 $<sup>^{104}</sup>$  *Id*.  $^{105}$  *Id*.

<sup>&</sup>lt;sup>106</sup> See id. at 175 ("As genetic alteration becomes a legitimate way of being human, it is unreasonable to identify such changes as deviant or unacceptably unnatural. For this reason, to claim that genetically modified athletes would be unacceptable in sport would not be meaningful."); Custer, supra note 20, at 198.

#### A. Biological "Weigh-ins"

Ultimately, the difficulties in detecting and sanctioning gene doping could require a shift away from concerns about what is in the body or how it got there, focusing instead on how much is present. After all, even if it were impossible to distinguish between natural or artificial genetic composition, testers would still likely be able to measure the results of that increased genetic activity. This could be accomplished in one of two ways. The first would be to use the very same tests that are currently being used to measure gene product levels in drug-based doping.<sup>107</sup> For example, in EPO doping, red blood cell counts would show a measurable increase regardless of whether it was induced by traditional doping or genetic modification. Alternatively, testers might be able to utilize microarray technology to examine gene expression levels, under the theory that gene doping would lead to quantifiable, increased levels of expression of the desired genes.

Either way, the key point would be to quantify how much of a given product is present within an athlete's body. Cyclists and marathon runners could have their hematocrit levels established. Lifters and shot-putters could be examined for IGF-1 or myostatin expression levels. These measurements would then need to be compared to reference frames that define "normal" human parameters for athletes. Once that is accomplished, there are two possibilities for handling athletes whose levels are, for whatever reason, outside those boundaries. The first would be an outright ban. Any athlete with more than X amount of gene product or expression would be prevented from competing, a program similar to the current "biologic passport" system in cycling.<sup>108</sup> Of course, this seems particularly harsh in the case of natural mutations, and, if there were no way to regulate introduced genes, it would effectively bar genetically-modified athletes for life.

The second approach would be to group athletes into distinct categories, based on the amount of particular products present within their body.<sup>109</sup> For example, if a sprinter was expressing IGF-1 over a given threshold, he or she would be bumped from the "Normal"<sup>110</sup> class into the "Enhanced" division, or even a "Super-Enhanced" division.<sup>111</sup> This would permit all athletes to compete, while diminishing the ability for gene-doped

<sup>&</sup>lt;sup>107</sup> World Anti-Doping Agency, *supra* note 26, at 5 (describing a method of detection based on the fact that "the gene will express itself and produce more of a particular protein or enzyme, which can be detected and measured just as in the case of drug-based doping").

<sup>&</sup>lt;sup>108</sup> Macur, *supra* note 31.

<sup>&</sup>lt;sup>109</sup> MIAH, *supra* note 34, at 92 (suggesting that gene doping "might merely call for the creation of new kinds of sports, which distinguish contests by the level of technological acceptance").

<sup>&</sup>lt;sup>110</sup> The specific names of these divisions could be specially crafted to create disincentives to use genetic modification, a possibility that will be discussed below.

<sup>&</sup>lt;sup>111</sup> In some sports where the primary concern would be about a single gene product (e.g. EPO in cycling), it might be possible to classify athletes only with respect to that one gene product. However, in sports where athletes could be using multiple types of performance-enhancing genes, it would likely be necessary to test for the presence of several different gene products, and then move athletes into a different classification if the level of any single product exceeded the threshold. For example, athletes competing in a decathlon might be tested for EPO, HgH, IGF-1, and myostatin, and be moved up into an "Enhanced" category if their levels for any one of these products was outside the "normal" parameters.

athletes to obtain a surreptitious, unfair advantage on other "clean" athletes.

This idea of grouping athletes according to their number of red blood cells or levels of growth hormones might seem ungainly at first, but there are already many sports where sorting by any number of physical characteristics is perfectly acceptable. In boxing and weightlifting, we recognize the inherent unfairness in forcing a competitor weighing 70 kilograms to compete against another athlete weighing twice that amount. <sup>112</sup> Similarly, we hold separate events for male and female athletes, on the belief that controlling for that biological distinction allows us to more accurately compare relative levels of skill among the participants. The expression levels of certain gene products in the body could simply be another phenotypic trait that could be leveled out to allow us to gauge the athlete's ability compared to others with similar biological endowments. <sup>113</sup>

Of course, just because a "genetic weigh-in" is conceptually similar to other types of classifications does not eliminate the obvious practical limitations. With certain types of substances, such as intra-muscular IGF-1, it still might be impossible to measure the amount of the substance without taking invasive muscle biopsies because the proteins would not circulate more widely in the bloodstream. Another technical hurdle might be establishing "normal" biological levels in the first place, as studies show that even among relatively homogenous populations of athletes, various biological parameters (such as hematocrit levels) can vary widely.<sup>114</sup> Additionally, it might be impossible to reduce athletic performance to just a few substances. After all, how do you know these are the most meaningful products to monitor? The selection of any biological products would require the inevitable exclusion of others, which could allow athletes to simply find new doping targets that are not measured. One final challenge with this approach is that it would likely test the patience of sports fans, who would have to watch multiple rounds of events in order to determine a winner in each biological classification. Just how many different versions of the men's 100-meter final would fans be willing to sit through at the Olympics?

These technical challenges notwithstanding, making accommodations for genetically-modified athletes in sport would have several benefits, both for athletes and for society as a whole. By lifting the total ban on genetic modification and encouraging responsible use of the technology, sporting organizations could increase athlete safety. Athletes would be able to undergo gene therapy under safer conditions, and not in illicit research facilities. Additionally, sporting organizations would be able to monitor athlete health and work with the medical community to ensure that the athletes were receiving the safest, most effective types of gene transfer. Accepting genetic modifications in sport could also spark a gene therapy "arms race," as researchers would vie to find the most effective techniques in what would surely be a lucrative market. These improved gene

<sup>&</sup>lt;sup>112</sup> MIAH, *supra* note 34, at 155.

<sup>&</sup>lt;sup>113</sup> *Id*.

<sup>&</sup>lt;sup>114</sup> See, e.g., Luca Malcovati, Cristiana Pascutto & Mario Cazzola, *Hematologic Passport for Athletes Competing in Endurance Sports: A Feasibility Study*, 88 HAEMATOLOGICA 570, 578 (2003) ("[D]espite the homogeneity of biological characteristics (age, sex) and sport discipline in this population of athletes, there is a considerable variation in hematologic parameters from subject to subject.").

transfer methods would not only be beneficial to those seeking enhancement, but would also produce breakthroughs that could spill over into the therapeutic world, improving treatments for, perhaps, millions of patients.

One final benefit is that creating different categories based on gene product levels would reduce concerns about the unfairness of illicit gene doping. One of the current worries about genetic modification is that it would provide athletes in richer, more technically-savvy countries better access to illegal forms of enhancement.<sup>115</sup> However, rejecting a ban on genetic modification and classifying athletes according to biological factors could level the playing field and negate the unfair advantage that athletes in more developed countries would have.

While creating parallel venues for genetically-modified athletes to compete may help solve problems about fair play and access to technology, "clearly the ramifications for competitive sport would be immense."<sup>116</sup> Genetic modification has the potential to greatly improve athletic performance, and traditionalists would worry about the possibility of sport descending into mere spectacle. Thomas Friedmann notes that, taken to extremes, this could lead to achievements that are so outside our normal biological capacities, that they scarcely could resemble human achievement at all:

What are the endpoints of manipulation? . . . Is the hope to incrementally sneak up on the one-and-a-half-minute mile? Or six seconds for 100 meters? Is the question, How fully can we engineer the human body to do physically impossible things? If it is, what do you have at the end of that? Something that looks like a human, but is so engineered, so tuned, that it's no longer going to do what the body is designed to do.<sup>117</sup>

Of course, some would argue that this kind of improvement and innovation is precisely what sport is about. Isn't the very essence of sport the desire to be better, faster, and stronger? On the other hand, many feel that genetic modification would introduce an improper enhancement that would taint athletic achievement. However, even for those who cling to a more traditional notion of competition, there is little reason to fear that accommodating genetically modified athletes would undermine the values they find most enjoyable about sport.

#### B. The "Bio Olympics" and the Meaning of Sport

Certainly, in some settings, sport is about being the fastest, the strongest, the best, which can be determined by measuring objective, quantifiable outcomes. Gold medals at the Olympic Games are awarded only to those with the highest scores and lowest times, not to those who try the hardest or those who show the greatest improvement over their previous performances. Genetic enhancement has the potential to allow athletes to push

<sup>&</sup>lt;sup>115</sup> MIAH, *supra* note 34, at 149.

<sup>&</sup>lt;sup>116</sup> *Id.* at 178.

<sup>&</sup>lt;sup>117</sup> Id. at 56–57 (quoting Jere Longman, Pushing the Limits: Getting the Athletic Edge May Mean Altering Genes, N.Y. TIMES, May 11, 2001, at A1).

the boundaries of achievement, to break the limitations of the human body.<sup>118</sup> And, as Miah points out, "[I]sn't this what is exciting about sport?"<sup>119</sup> Michael Sandel sums up the consequences of adopting this viewpoint:

[I]f the purpose of the competition was to press the limits of human achievement to see what the people could do with the human body, then the logical thing to do would be to allow people to use whatever enhancements were available because that would be the way of pressing the limits of human achievement: how much weight could be lifted, how fast a hundred meters could be run.<sup>120</sup>

Of course, this is not the only reason that people enjoy sport. There are many different kinds of competitions, not all of which rely on purely objective success. The President's Council on Bioethics points out this distinction as being bound up in the very purpose of these different athletic contests:

In the real Olympics, we honor the best human runner, and we appreciate the fact that the excellence of human running is not relative; it can be truthfully and quantitatively measured. At the same time, we judge the Special Olympics according to a different standard. We regard their activity as a kind of excellence—of personal achievement rather than of absolutely superior performance—even as they compete in the same activity with much lower scores.<sup>121</sup>

Based on the different criteria on which athletes are judged, Dr. William Hurlbut suggests that a "Bio Olympics" should be added as an entirely separate contest altogether.<sup>122</sup>

The creation of separate biological categories need not detract from the meaning of the respective competitions. By separating athletes with excessive biological endowments, fans would be able to understand the circumstances under which they were watching athletes perform, permitting more accurate and meaningful comparisons among competitors. Miah points this out through the metaphor of an athlete using a motorcycle in a footrace, which "compromises the validity of comparing the ability of a user with a non-user. Yet it would not compromise the equality of a competition if all athletes were using a motorbike. Rather, it merely changes the kinds of activity and the kinds of skills being assessed."<sup>123</sup> In the same way, permitting biologically superior athletes to be judged on one standard, while not affecting the way non-enhanced athletes were viewed.

<sup>&</sup>lt;sup>118</sup> MIAH, *supra* note 34, at 178 (noting that, in the future "it will be the genetically modified athletes who will be breaking human barriers and surpassing known, physical limitations").

<sup>&</sup>lt;sup>119</sup> Id.

<sup>&</sup>lt;sup>120</sup> Friedmann, *supra* note 41.

<sup>&</sup>lt;sup>121</sup> PRESIDENT'S COUNCIL ON BIOETHICS, *supra* note 68, at 133.

<sup>&</sup>lt;sup>122</sup> Friedmann, *supra* note 41.

<sup>&</sup>lt;sup>123</sup> MIAH, *supra* note 34, at 93.

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Ultimately, though, there are fears that, because of the superior ability of the athletes, genetically-modified versions of sports would drive out "natural" versions. Judge Posner argues that this would just be an acceptable form of "consumer preference," that decisions about the permissibility of genetic modification should be left to fans, and that this would not undermine the meaning of sport: "So suppose that it turns out that the 'crowd' actually prefers spectacle to sport—that people want to see . . . genetically altered runners race at 50 miles per hour . . . . So what?"<sup>124</sup> Would fans prefer to watch "natural" athletes performing somewhat less-impressive feats without any genetic modification, or would they flock to the "enhanced" athletes, preferring to see longer home runs and faster running times? On one hand, if "genetically modified athletes [were] competing at a level that far exceeds the abilities of the non-enhanced, the public interest in the latter might wane immeasurably."<sup>125</sup> On the other hand, recent public resentment toward athletes accused of drug-based doping suggests that fans may be tired of viewing what they view as "unearned" achievements, and they may stick with traditional sport.

It seems unlikely that creation of distinct venues or divisions for geneticallymodified athletes (as well as those with natural, biological endowments) would completely displace traditional "non-enhanced" athletes. Certainly, some fans would prefer watching "natural" athletes competing against each other with fewer biological gifts. Enjoyment of sport is not always derived from watching the absolute strongest or fastest compete. Women's tennis, for example, is extremely popular, despite the fact that its matches are played at a significantly slower pace than the men's game. And collegiate sports, including football and basketball, enjoy huge followings, even though the talent level of the players is often well below that of their professional counterparts.

In 1976, William O. Johnson predicted that by the year 2000, enhancement of athletes would be so rampant and desirable that "there will be only one discussion in boxing, the heavyweight, all others having vanished because of boredom or bankruptcy."<sup>126</sup> Of course, since then, the commercial success of middle- and lightweight fighters, including Oscar de la Hoya, Floyd Mayweather, Jr., and Julio Cesar Chavez, Jr., suggests that fans are interested in more than simply watching the biggest, strongest three decades, fans still recognize and appreciate the talents exhibited by competitors working within different biological parameters, in this case, weight. In the same way, competitions that included biologically-enhanced athletes would not necessarily detract from the popularity of other events, and the two might be able to coexist successfully.

Creating separate categories for "enhanced" athletes may actually create a backlash against the use of such technology. After all, despite the enormous popularity of

<sup>&</sup>lt;sup>124</sup> Posner, *supra* note 82, at 1738–39.

<sup>&</sup>lt;sup>125</sup> MIAH, *supra* note 34, at 178.

<sup>&</sup>lt;sup>126</sup> Id. at 67 (quoting William O. Johnson, From Here to 2000, in A. YIANNAKIS, ET AL., SPORT SOCIOLOGY: CONTEMPORARY THEMES 226 (1976)).

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baseball home run stars like Mark McGwire and Sammy Sosa in the late 1990s,<sup>127</sup> fan sentiment has since shifted strongly against McGwire and other sluggers accused of steroid abuse, most notably Barry Bonds. Perhaps fans would become disenchanted with competitors' "artificially" inflated scores and reduced times and retreat to traditional, non-enhanced athletics, relegating genetically-modified athletes to the lower rungs of competition.

Sporting organizations could even use the structure of sporting events to create subtle incentives to dissuade genetic modification. Divisions for athletes with increased biological endowments could be labeled "Enhanced," "Unnatural," or "Biologically Assisted," which could indirectly influence public opinion of the athletes. Imagine the potential uproar that could arise if the IOC even suggested that it was considering such a measure. The announcement alone might generate sufficient public outrage against genetic modification in sport to dissuade athletes from even attempting it.

It is impossible to know precisely the effect of creating parallel contests for biologically-enhanced athletes. Maybe fans would shun the "gene dopers," and prefer watching "natural" athletes, even if their performances were, statistically, less impressive. Or perhaps spectators would flock to see genetically-modified athletes capable of performing at a higher level. However, because of the purely prohibitory stance taken by international sporting organizations toward genetic modification, fans may never even get the chance to have a say. And by refusing to acknowledge the possible legitimacy of genetic modification in sport, sporting organizations could find themselves in a difficult position if and when they are confronted with the use of genetic enhancement by athletes.

### VI. **RECOMMENDATIONS**

So, what should international sporting regulatory bodies do now to prepare for the possibility of sport in an era of genetic modification? While concern for athlete safety is currently a sufficient justification for taking a prohibitory stance toward gene doping, ultimately, one of two things seems likely to occur: either gene transfer technologies will become safer or society will develop a permissive attitude toward genetic enhancement. Should either of these come to pass, prohibition of genetic modification in sport will become a much less tenable position. This is not to say that sporting organizations will have to permit genetic modification, but, at the very least, they will likely be forced to adapt their enforcement regimes in ways that would contradict the staunch, zero-tolerance attitudes they have adopted thus far. To this end, there are several steps that sports and anti-doping organizations can take now to put themselves in a position to better accommodate genetic modification if and when it becomes necessary for them to do so.

#### 1. Focus exclusively on athlete safety as the justification for the prohibition of genetic modification, while maintaining a more neutral stance on the ethical nature of the practice. To this end, WADA should consider

<sup>&</sup>lt;sup>127</sup> Coleman & Coleman, *supra* note 86, at 1783 (discussing McGwire and Sosa's "unprecedented assault on baseball's single-season home run record" in the summer of 1998).

## replacing the heading "Gene Doping" in the Code with the term "Genetic Modification."

Protecting athlete safety is a more than sufficient justification for taking a prohibitory stance on genetic modification by athletes. However, by adopting a negative view toward the ethics of genetic modification, these groups unnecessarily influence the acceptability of gene therapy technology in other areas of society. By adhering to the safety rationale, sporting organizations can achieve their goals of promoting athlete health and keeping sport free of genetic modification, without hindering the adoption of gene transfer more broadly.

Similarly, replacing the term "Gene Doping" with the more descriptive and less inflammatory "Genetic Modification" would not alter the purpose or the effectiveness of the ban on gene transfer. Currently, "gene doping" is used only in the heading of the section on gene modification, which describes the banned methods in detail. Continuing to use the term "gene doping" conflates the issues of traditional doping and genetic modification, blurring the meaningful distinctions between the two.

# 2. Work with the scientific community to monitor the safety of new gene therapy techniques.

Sporting organizations should also continue to monitor developments in the field of gene therapy. They should maintain their commitment to providing athletes and trainers with the latest, objective information regarding the safety of gene transfer technology, which will help athletes make informed decisions and counter the (as yet) largely erroneous claims about the promises of genetic enhancement. Being on the cutting edge of research will also allow these groups to better predict when athletes are likely to begin using genetic modification. And in the event that these techniques ultimately become permissible in sport, groups will need to be familiar with the safest methods in order to monitor their use by competitors and protect athlete health.

# **3.** Establish relationships with international medical and ethical organizations that are capable of gauging public attitudes toward genetic modification.

Decisions about the use of genetic enhancement in sport have implications far beyond the field of play. And while sport offers a valuable lens through which to view the permissibility of genetic modification, sporting organizations should not have sole power to dictate how these technologies are adopted. The decision whether to accommodate genetic modification in sport, therefore, should be informed by broader societal beliefs about the acceptability of genetic enhancement. Partnering with nonsporting international bodies will allow sports and anti-doping groups to stay abreast of current public opinion regarding genetic technology and ensure that athletic organizations adopt policies that are consistent with prevailing social attitudes.

# 4. Expand the WADA research program to fund the development of methods for determining not only the presence, but also the amount of

#### performance-enhancing gene products within an athlete.

The similarities between gene products produced "naturally" and those produced by genetic modification, along with the difficulties in penalizing athletes who use gene transfer suggest that the mere detection of a particular substance could be meaningless. This realization could require the move to a "biological passport" or "genetic weigh-in" system in order to classify athletes, according to the levels of certain substances in their bodies. In order to accomplish this, it will be essential to have testing procedures that recognize enhancement, not in a binary sense, but in a quantifiable manner.

#### VII. CONCLUSION

At some point, due to technological development or societal acceptance, attempts at genetic modification by athletes seem inevitable. Detecting and sanctioning genetic modification may be impossible under the current regulatory regime and may even require the creation of parallel contests to accommodate athletes with increased biological endowments. However, because they have adopted a harsh, prohibitive attitude toward genetic enhancement, sporting and anti-doping groups may have backed themselves into a corner. By taking this stance, they may be squandering a chance to improve athlete health and performance, as well as leaving the door open for dangerous, illicit, and undetectable use of gene transfer technology by athletes seeking a competitive edge. However, by taking a more neutral position on gene transfer, focusing on athlete safety, and withholding premature judgment on the moral permissibility of these technologies, international sporting bodies can maintain the flexibility to adapt to the possibility of sport in an era of genetic enhancement.