

# The Current State of Gene Doping and the Future of Gene Therapy Regulations

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## I. INTRODUCTION

Genome editing, also referred to as “gene editing” or “gene therapy,” is no longer a theoretical eventuality of scientific progression; it is a reality of modern life. One of the numerous groups affected by this technology is athletes as “gene doping” becomes a more viable option to improve athletic performance each year. Some international agencies have begun to address the issues presented by gene doping, but there is no comprehensive international framework or regulations on the proper standards of use or punishment for those who abuse this new technology. International agencies must work together to establish regulations for human genome experiments and gene doping while these technologies are still in the infancy of their development. While unregulated, these technologies are dangerous and ripe for misuse. Without appropriate regulations, future controversies surrounding the misuse of genome editing can halt the growth of this powerful technology. The proper regulations must be set immediately, not to prevent the development of human genome therapy, but to ensure the safe and ethical progression of this technology.

## II. BACKGROUND

### A. *International Doping Regulations*

Before examining current international gene doping regulations, it is important to understand the agencies that developed the current international doping framework. Doping has been a longstanding issue in international sports, especially at the Olympic level. The International Olympic Committee (“IOC”) was created in 1894 for the purpose of running and regulating the Olympic Movement.<sup>1</sup> While the IOC is seen as the leader of the Olympic

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1. The Olympic Movement was founded by Pierre de Coubertin and encompasses the Olympic Games as well as all the constituents of the event, including but not limited to: the International Olympic Committee, the International Sports Federations, and the National Olympic Committees. *International Olympic Committee*, OLYMPICS, <https://olympics.com/ioc/overview> [<https://perma.cc/C8L5-XPJ6>]; *Olympic Movement*, OLYMPICS, <https://olympics.com/ioc/olympic-movement> [<https://perma.cc/5BF6-S6ET>]; *Pierre de Coubertin*, OLYMPICS, <https://olympics.com/ioc/pierre-de-coubertin> [<https://perma.cc/C7Y8-HYFG>].

Movement, it also coordinates with International Sports Federations (“IFs”) and National Olympic Committees (“NOCs”) to ensure the quadrennial Olympic Games event and to promote Olympic values.<sup>2</sup> The IOC derives its authority through the Olympic Charter and its mission is “to protect clean athletes and the integrity of sport, by leading the fight against doping, and by taking action against all forms of manipulation of competitions and related corruption.”<sup>3</sup>

The IOC recognized the need for an independent anti-doping agency after the doping scandal at the 1998 Tour de France caused an international controversy.<sup>4</sup> As a result, the IOC held an international conference which led to the development of the Lausanne Declaration on Doping in Sport.<sup>5</sup> This declaration created the World Anti-Doping Agency (“WADA”) to help combat the issue of doping in international sports.<sup>6</sup> WADA’s core activities are “scientific research, education, development of anti-doping capacities, and monitoring of the World Anti-Doping Code – the document harmonizing anti-doping policies in all sports and all countries.”<sup>7</sup> The highest policy-making body within WADA is its thirty-eight member Foundation Board.<sup>8</sup> This board has an equal number of IOC representatives and representatives of national governments.<sup>9</sup> WADA delegates its work to National Anti-Doping Organizations (“NADOs”) within individual

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2. These Olympic values include excellence, respect, and friendship. *IOC Principles*, OLYMPICS, <https://olympics.com/ioc/principles> [<https://perma.cc/35Z8-CMRC>]; see also *Olympic Charter* 9, 11, INT’L OLYMPIC COMM. (July 2020), [https://stillmed.olympics.com/media/Document%20Library/OlympicOrg/General/EN-Olympic-Charter.pdf?\\_ga=2.55413923.96033511.1630354196-2121199226.1630354196](https://stillmed.olympics.com/media/Document%20Library/OlympicOrg/General/EN-Olympic-Charter.pdf?_ga=2.55413923.96033511.1630354196-2121199226.1630354196) [<https://perma.cc/8ZYJ-WY6M>].

3. *Olympic Charter*, INT’L OLYMPIC COMM. 20 (July 2020), [https://stillmed.olympics.com/media/Document%20Library/OlympicOrg/General/EN-Olympic-Charter.pdf?\\_ga=2.55413923.96033511.1630354196-2121199226.1630354196](https://stillmed.olympics.com/media/Document%20Library/OlympicOrg/General/EN-Olympic-Charter.pdf?_ga=2.55413923.96033511.1630354196-2121199226.1630354196) [<https://perma.cc/8ZYJ-WY6M>].

4. *Who We Are*, WORLD ANTI-DOPING AGENCY, <https://www.wada-ama.org/en/who-we-are> [<https://perma.cc/C48Y-7VDH>] [hereinafter WORLD ANTI-DOPING AGENCY]; Jeremy Whittle, *The 1998 Tour de France: Police Raids, Arrests, Protests. . . and a Bike Race*, CYCLINGNEWS (Mar. 3, 2017), <https://www.cyclingnews.com/features/the-1998-tour-de-france-police-raids-arrests-protests-and-a-bike-race/> [<https://perma.cc/2QNT-YV52>].

5. WORLD ANTI-DOPING AGENCY, *supra* note 4.

6. WORLD ANTI-DOPING AGENCY, *supra* note 4.

7. WORLD ANTI-DOPING AGENCY, *supra* note 4.

8. *Governance*, WORLD ANTI-DOPING AGENCY, <https://www.wada-ama.org/en/governance> [<https://perma.cc/984A-ZG4Y>].

9. Members are appointed by their respective constituency groups, such as: Africa representatives, the Americas representatives, Asia representatives, Oceania representatives, etc. *Foundation Board*, WORLD ANTI-DOPING AGENCY, <https://www.wada-ama.org/en/foundation-board> [<https://perma.cc/HHB8-3LDN>].

nations and ensures these NADOs are in compliance with the World Anti-Doping Code.<sup>10</sup> WADA and IOC still have close ties to this day; many of those who hold leadership positions within WADA also hold leadership positions within IOC.<sup>11</sup>

### *B. Olympic Doping Scandals*

Since the modern Olympic games were revived, there have been numerous Olympic doping scandals.<sup>12</sup> These doping scandals have stained the public opinion of WADA and IOC as the premier doping regulatory agencies despite the current doping framework in place.<sup>13</sup> A recent and noteworthy Olympic doping scandal was the Russian state-sponsored doping scandal which was uncovered in 2014.<sup>14</sup> What makes this scandal noteworthy was the difficulty that IOC and WADA had when trying to determine the proper course of action and the proper punishment for the offenders.

WADA investigated the controversy in 2014 and released a two-part document detailing their findings which implicated more than 1,000 Russian athletes going back as far as 2011.<sup>15</sup> In response to this report, WADA called for a “blanket-ban” on all Russian athletes for the 2016 Rio Olympics, however, IOC rejected this suggestion and instead allowed the athletes respective IFs to determine eligibility.<sup>16</sup> After the 2016 Olympics, IOC announced its decision to ban Russia from the 2018 Winter Olympics

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10. *National Anti-Doping Organizations (NADO)*, WORLD ANTI-DOPING AGENCY <https://www.wada-ama.org/en/who-we-are/anti-doping-community/national-anti-doping-organizations-nado> [https://perma.cc/XJ7M-LQNT].

11. Rachel Axon, *WADA Needs Better Governance, Experts Say IOC Set to Meet*, USA TODAY (Oct. 6, 2016, 6:42 PM), <https://www.usatoday.com/story/olympics/2016/10/06/wada-russian-doping-scandal-ioc/91691936/> [https://perma.cc/8TED-QU DH].

12. *List of Olympic Games Scandals and Controversies*, WIKIPEDIA, [https://en.wikipedia.org/wiki/List\\_of\\_Olympic\\_Games\\_scandals\\_and\\_controversies#2020\\_Summer\\_Olympics\\_%E2%80%93\\_Tokyo,\\_Japan](https://en.wikipedia.org/wiki/List_of_Olympic_Games_scandals_and_controversies#2020_Summer_Olympics_%E2%80%93_Tokyo,_Japan) [https://perma.cc/538Y-YJMW].

13. See Rebecca R. Ruiz, Juliet Macur & Ian Austen, *Even with Confession of Cheating, World's Doping Watchdog Did Nothing*, N.Y. TIMES (June 15, 2016), <https://www.nytimes.com/2016/06/16/sports/olympics/world-anti-doping-agency-russia-cheating.html> [https://perma.cc/N4RY-L47S].

14. *The Olympic Doping Dynasty*, THE SPORTY LAWYER (July 25, 2020), <https://thesportylawyer.wordpress.com/2020/07/25/the-olympic-doping-dynasty/> [https://perma.cc/K9QZ-9WVN].

15. *Russian Doping: McLaren Report Says More Than 1,000 Athletes Implicated*, BBC (Dec. 9, 2016), <https://www.bbc.com/sport/38261608> [https://perma.cc/SX79-ARGE].

16. Eoghan Macguire, *Olympics: No Blanket Ban on Russian Athletes, IOC Says*, CNN (July 24, 2016), <https://edition.cnn.com/2016/07/24/sport/russia-ioc-olympics-ban/> [https://perma.cc/EZN6-ER26].

while still allowing certain Russian athletes not implicated in the scandal to compete as “Olympic Athletes from Russia.”<sup>17</sup>

By 2019, WADA endorsed a recommendation made by the independent Compliance Review Committee to impose a four-year “blanket-ban” on Russian athletes from participating in any major international sporting events unless they prove they were not implicated.<sup>18</sup> This ban was due to the country’s history of doping violations and non-compliance during WADA’s investigation.<sup>19</sup> IOC supported this decision after receiving much backlash for rejecting WADA’s original “blanket-ban” proposal in 2016.<sup>20</sup>

### C. Genome Editing/Gene Editing/Gene Therapy

Gene technologies are becoming more powerful and precise, making their application in modern health situations more realistic. Genome editing is a technology that allows scientists to change the DNA of an organism to alter the physical traits of that organism, such as eye color or disease risk.<sup>21</sup> There are two main types of gene editing: somatic cell edits and germline cell edits.<sup>22</sup> Somatic gene therapies involve modifying a patient’s DNA to treat or cure a disease caused by a genetic mutation and thus only affect the patient being treated.<sup>23</sup> Alternatively, germline gene therapies alter the genome of an embryo at its earliest stages and can impact not

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17. Rebecca Ruiz & Tariq Panja, *Russia Banned from Winter Olympics by I.O.C.*, N.Y. TIMES (Dec. 5, 2017), <https://www.nytimes.com/2017/12/05/sports/olympics/ioc-russia-winter-olympics.html> [https://perma.cc/RGL2-SV9G].

18. *WADA Executive Committee Unanimously Endorses Four-Year Period of Non-Compliance for the Russian Anti-Doping Agency*, WORLD ANTI-DOPING AGENCY (Dec. 9, 2019), <https://www.wada-ama.org/en/media/news/2019-12/wada-executive-committee-unanimously-endorses-four-year-period-of-non-compliance> [https://perma.cc/4LCL-AC3Q].

19. *Id.*

20. Sean Ingle, *Russia’s Athletes Escape Blanket IOC Ban for Rio Olympic Games*, GUARDIAN (July 24, 2016), <https://www.theguardian.com/sport/2016/jul/24/russia-team-escape-blanket-ban-ioc-rio-olympic-games> [https://perma.cc/8UE5-9YV3]; *Statement from the IOC on WADA Recommendation*, OLYMPICS (Nov. 26, 2019), <https://www.olympic.org/news/statement-from-the-ioc-on-wada-recommendations> [https://perma.cc/ZHU9-8WD8].

21. *What is Genome Editing*, NAT’L HUM. GENOME RSCH. INST. (Aug. 15, 2019), <https://www.genome.gov/about-genomics/policy-issues/what-is-Genome-Editing> [https://perma.cc/PTJ5-5XFM].

22. Mary Bergman, *Perspectives on Gene Editing*, THE HARV. GAZETTE (Jan. 9, 2019), <https://news.harvard.edu/gazette/story/2019/01/perspectives-on-gene-editing/#:~:text=Human%20genome%20editing%3A%20somatic%20vs.&text=While%20somatic%20gene%20editing%20affects,passed%20on%20future%20generations> [https://perma.cc/TN6C-CURH].

23. *Id.*

only the organism receiving the edits, but the organism's offspring as well.<sup>24</sup> Somatic cell edits only change the targeted cells (if successful), while germline cell edits affect all cells of the individual in question.<sup>25</sup>

One of the most rapidly evolving gene editing technologies is referred to as "CRISPR-Cas9" ("CRISPR"). CRISPR is an acronym for "clusters of regularly interspaced short palindromic repeats" which is a very specialized stretch of DNA.<sup>26</sup> It is through this specialized section of DNA and the Cas9 enzyme that scientists have been able to "guide" edits to the appropriate section of the genome.<sup>27</sup>

Although this technology allows for precision editing, preliminary experiments have shown there is plenty of room for improvement.<sup>28</sup> There are long-term implications of this technology, such as possible mental and physical health effects, that need more research.<sup>29</sup> Subsequent studies have shown that the CRISPR process turns off key anti-cancer mechanisms within the targeted DNA.<sup>30</sup> CRISPR may also result in "off-target" genetic errors—unexpected deletions and scrambling of genetic code.<sup>31</sup> As stated by Dr. Greg Licholai, a lecturer at Yale School of Medicine and Chief Medical and Information Officer at PRA Health Sciences, "[w]e think we are editing one letter of the book of life, but . . . actually entire pages might be getting altered in unintended areas."<sup>32</sup> The previously mentioned

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24. *Id.*

25. Britta C. van Beers, *Rewriting the Human Genome, Rewriting Human Rights Law? Human Rights, Human Dignity, and Human Germline Modification in the CRISPR Era*, 7 J.L. & BIOSCIENCES 1, 5 (June 9, 2020).

26. Aparna Vidyasagar, *What is CRISPR?*, LIVE SCIENCE (Apr. 21, 2018), <https://www.livescience.com/58790-crispr-explained.html> [<https://perma.cc/TBV5-V3HB>].

27. This specialized section of DNA has two prominent characteristics: nucleotide repeats and spacers. The nucleotide repeats are genetic information that can be modified, while the spacers are "breaks" between the repeated sequences. Cas9 protein is an enzyme that acts as a pair of molecular scissors able to slice DNA. This protein is bound with CRISPR RNA which guides the Cas9 to the proper section of DNA. After the DNA helix is sliced, the modified CRISPR nucleotide repeats are inserted. *See id.*

28. Of eighteen genome-edited embryos in Kathy Niakan's CRISPR experiment, twenty-two percent contained unwanted changes affecting large swathes of the DNA surrounding the edited genome area. Heidi Ledford, *CRISPR Editing Wreaks Chromosomal Mayhem in Human Embryos*, 583 NATURE 17, 18 (July 2, 2020), <https://www.nature.com/articles/d41586-020-01906-4> [<https://perma.cc/7S46-8M9N>].

29. Heidi Ledford, *'CRISPR Babies' are Still Too Risky, Says Influential Panel*, NATURE (Sept. 3, 2020) (online ahead of print), <https://www.nature.com/articles/d41586-020-02538-4> [<https://perma.cc/7SWH-UFZA>].

30. Daniel Oberhaus, *DNA Damage from CRISPR Has Been 'Seriously Underestimated'*, VICE (July 17, 2018), <https://www.vice.com/en/article/a3qv7a/dna-damage-from-crispr-has-been-seriously-underestimated> [<https://perma.cc/5HKD-F6HZ>].

31. *Id.*

32. Greg Licholai, *Is CRISPR Worth the Risk?*, YALE INSIGHTS (Aug. 21, 2018), <https://insights.som.yale.edu/insights/is-crispr-worth-the-risk#ref> [<https://perma.cc/A9MU-QJ8A>].

deficiencies of CRISPR show that this process is still evolving, which is leading to the development of new gene editing technologies.

A new gene therapy technique called Prime Editing (“Prime”) is proving to be more accurate for exact DNA placement than its predecessor CRISPR.<sup>33</sup> Unlike CRISPR, Prime does not rely on the ability of a cell to divide.<sup>34</sup> Scientists can use Prime to target cells that CRISPR cannot, such as nervous system cells.<sup>35</sup> Prime also does not involve cutting both strands of a DNA helix, thus mitigating the chances of unintended changes.<sup>36</sup> These two gene therapy technologies exemplify the current power and precision of gene editing; their progress suggests scientists will only continue to develop even more precise gene technologies.

#### D. Gene Doping

Although there are many potentially positive health applications of gene therapy, there also exists a potential for abuse of this technology in the form of gene doping. Gene doping refers to “the non-therapeutic use of genes, genetic elements and/or cells that have the capacity to enhance athletic performance.”<sup>37</sup> The allure of this type of doping is its potentially undetectable nature.<sup>38</sup> WADA included gene doping on its 2004 prohibition list as a preemptive effort to stop this form of gene editing.<sup>39</sup>

Several genes have already been identified as potentially increasing physical performance. In 1998, American scientist Lee Sweeney published a study explaining his team’s success in increasing the muscle strength in

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33. Rob Stein, *Scientists Create New, More Powerful Technique to Edit Genes*, NPR (Oct. 21, 2019, 4:09 PM), <https://www.npr.org/sections/health-shots/2019/10/21/771266879/scientists-create-new-more-powerful-technique-to-edit-genes> [https://perma.cc/4FHL-YEKG] [hereinafter *Scientists Create*].

34. *Id.*

35. *Id.*

36. *Id.*

37. World Anti-Doping Agency, *The 2004 Prohibited List, International Standard, Prohibited Methods: M3. Gene Doping*, THE WORLD ANTI-DOPING CODE 1, 7 (Mar. 17, 2004), [https://www.wada-ama.org/sites/default/files/resources/files/WADA\\_Prohibited\\_List\\_2004\\_EN.pdf](https://www.wada-ama.org/sites/default/files/resources/files/WADA_Prohibited_List_2004_EN.pdf) [https://perma.cc/6L6T-R5WG] [hereinafter *2004 Prohibited List*].

38. Melinda Wenner, *How to be Popular During the Olympics: Be H. Lee Sweeney, Gene Doping Expert*, SCI. AM. (Aug. 15, 2008), <https://www.scientificamerican.com/article/olympics-gene-doping-expert/> [https://perma.cc/5GPP-LKF6] [hereinafter Wenner].

39. Sarah Polcz & Anna Lewis, *Regulating Genetic Advantage*, 32 HARV. J.L. & TECH. 266, 273, 290 (2018).

mice by altering the IGF1 gene.<sup>40</sup> Sweeney identified a possible genetic doping method while attempting to solve the issue of muscular dystrophy.<sup>41</sup> Since his discovery, Sweeney has been a major proponent for further research of gene technologies, stating: “For me, gene doping will someday be possible and a reality . . . . The phase that we are in now is when it is potentially extremely dangerous.”<sup>42</sup>

Around the same time as Sweeney’s experiment, Philippe Moullier published a study detailing how his team successfully introduced the erythropoietin gene (“EPO”) to mice.<sup>43</sup> Simply injecting EPO into one’s bloodstream is both easily detectable and banned by WADA.<sup>44</sup> Like Sweeney, Moullier’s goal was not to find new ways to improve athletic performance, but rather to address a rare, genetic bone marrow issue.<sup>45</sup> At first it was unclear if this type of gene doping could be clearly detected,<sup>46</sup> but in a subsequent study Moullier found that EPO made through a recombinant hormone has a different isoelectric profile than naturally occurring EPO; a difference easily detectable in urine.<sup>47</sup> Likewise, there have been other EPO gene modification detection methods that examine the natural occurring EPO DNA sequence in athletes or look for the existence of viruses typically used for genetic modification.<sup>48</sup>

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40. IGF1 is the gene responsible for insulin-like growth factor one. Wenner, *supra* note 38.

41. Leslie Pray, *Sports, Gene Doping, and WADA*, NATURE EDUCATION: SCITABLE (2008), <https://www.nature.com/scitable/topicpage/sports-gene-doping-and-wada-764/> [<https://perma.cc/7YMT-KT63>].

42. Fabian Filipp, *Is Science Killing Sport? Gene Therapy and its Possible Abuse in Doping*, 8(5) EURO. MOLECULAR BIOLOGY ORG. 433, 435 (2007), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1866212/pdf/7400968.pdf> [<https://perma.cc/MR3M-LKHU>].

43. EPO is the hormone that controls the production of red blood cells. Tim Franks, *Gene Doping: Sport’s Biggest Battle?*, BBC (Jan. 12, 2014), <https://www.bbc.com/news/magazine-25687002> [<https://perma.cc/HT98-ZD5N>]; Delphine Bohl, Anna Salvetti, Philippe Moullier & Jean Michel Heard, *Control of Erythropoietin Delivery by Doxycycline in Mice After Intramuscular Injection of Adeno-Associated Vector*, 92 BLOOD 1512, 1512 (Sept. 1, 1998), <https://ashpublications.org/blood/article/92/5/1512/247395/Control-of-Erythropoietin-Delivery-by-Doxycycline> [<https://perma.cc/KMQ4-Q2T5>].

44. *EPO Detection*, WORLD ANTI-DOPING AGENCY, <https://www.wada-ama.org/en/questions-answers/epo-detection> [<https://perma.cc/4QNV-8MHY>] [hereinafter *EPO Detection*].

45. See Franks, *supra* note 43.

46. *Id.*

47. Françoise Lasne et al., “Genetic Doping” With Erythropoietin cDNA in Primate Muscle is Detectable, 10 MOLECULAR THERAPY 409 (Sept. 1, 2004), [https://www.cell.com/molecular-therapy-family/molecular-therapy/comments/S1525-0016\(04\)01358-9](https://www.cell.com/molecular-therapy-family/molecular-therapy/comments/S1525-0016(04)01358-9) [<https://perma.cc/AE3Y-FSTB>].

48. Sarah Everts, *New Tests to Identify Gene Tampering in Olympic Athletes*, IN CHEMISTRY (Oct. 10, 2016), <https://inchemistry.acs.org/content/inchemistry/en/atomic-news/rio-doping.html> [<https://perma.cc/VXN2-CW3Y>] (“Synthetic EPO DNA inserted during gene therapy is unlikely to have [the natural occurring] intron sequence.”).



Moreover, in 2004, Yong-Xu Wang, an associate professor at the University of Massachusetts Medical School,<sup>49</sup> published his study explaining how he was able to inject mice with a gene that encodes a fat-burning protein called PPAR $\delta$ .<sup>50</sup> The mice with the expressed gene were able to run distances twice that of the control mice.<sup>51</sup> Like those before him, Wang was not performing his experiment with the hopes of increasing the mice's athletic performance, rather he was performing his experiment with the hopes of combating type II diabetes.<sup>52</sup> A previous study showed that many of those suffering from type II diabetes have fewer type I muscle fibers, giving Wang's experiment possible therapeutic value.<sup>53</sup>

Since including gene doping on its prohibition list, WADA has taken several steps to try to recognize and regulate doping at this level. They designated an "expert group" tasked with studying the progress of genetic editing and developing realistic detection methods.<sup>54</sup> WADA took their first athlete samples for genetic doping testing during the 2016 Rio Olympics, but tests were not run during the games.<sup>55</sup>

In 2018, WADA considered requiring each Olympian to get their entire genome sequenced—a type of "gene passport."<sup>56</sup> This idea was not implemented in full due to the cost restrictions of sequencing the human genome at the time, but the price of sequencing the human genome has only continued to drop with further technological advancement.<sup>57</sup> WADA already uses an "Athlete Biological Passport" ("ABP") system for detecting blood doping and steroids, with the first Athlete Biological Passport Operating

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49. *Molecular, Cell and Cancer Biology*, UMASS CHAN MEDICAL SCHOOL, <https://umassmed.edu/mccb/faculty-MCCB/faculty-MCCB/faculty-profile-pages/wang/> [https://perma.cc/ELK6-PSC8].

50. Yong-Xu Wang et al., *Regulation of Muscle Fiber Type and Running Endurance by PPAR $\delta$* , 2 PLOS BIOLOGY 1532, 1532 (Aug. 24, 2004), <https://journals.plos.org/plosbiology/article?id=10.1371/journal.pbio.0020294> [https://perma.cc/TCM3-QCCG].

51. *Id.*

52. *Id.*

53. Pray, *supra* note 41.

54. *Gene Doping*, WORLD ANT-DOPING AGENCY, <https://www.wada-ama.org/en/gene-doping> [https://perma.cc/S28N-T6LM].

55. Everts, *supra* note 48.

56. Eric Niiler, *Olympics Could Require Athletes' Genetic Code to Test For Doping*, WIRED, (Feb. 5, 2018, 7:00 AM), <https://www.wired.com/story/olympics-could-require-athletes-genetic-code-to-test-for-doping/> [https://perma.cc/7TTE-YT9G].

57. *Id.*; *The Cost of Sequencing a Human Genome*, NAT'L HUM. GENOME RSCH. INST. (Dec. 7, 2020), <https://www.genome.gov/about-genomics/fact-sheets/Sequencing-Human-Genome-cost#:~:text=The%20estimated%20cost%20for%20advancing,sequence%20is%20~%24150%20million%20worldwide.> [https://perma.cc/HVC9-4DQ4].

Guidelines approved by WADA's executive committee in 2009.<sup>58</sup> WADA collects samples of athlete's blood and urine to determine the athlete's biological passport; this biological information is compared to later tests to detect for doping.<sup>59</sup>

WADA took its first steps towards implementing an EPO gene doping detection test when it collected athlete samples for the 2016 Rio Olympics.<sup>60</sup> With this intended method, the natural gene for EPO is examined to see if the intron DNA sequence, a sequence that would get cut out if the EPO gene was genetically modified, is still intact.<sup>61</sup> Since then, WADA has funded a similar test to apply to other potential doping genes.<sup>62</sup> This new method of detection was used to detect EPO, IGF1, and several other genes.<sup>63</sup> Even further, researchers hypothesize that an altered form of their current method could work for detecting CRISPR modifications.<sup>64</sup> While detection of a modified gene is possible, detection methods are still in the early stages of development and require more time and resources until they can be used routinely.<sup>65</sup>

### E. Genetic Experimentation Scandals

There has already been a human gene therapy scandal, suggesting it is only a matter of time before there is a human gene doping scandal. In 2018, Chinese scientist He Jiankui announced that his team used CRISPR gene editing on human embryos.<sup>66</sup> Jiankui claimed to have disabled CCR5,

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58. *Athlete Biological Passport*, WORLD ANTI-DOPING AGENCY, <https://www.wada-ama.org/en/athlete-biological-passport> [<https://perma.cc/8DJB-6XWL>].

59. *Athlete Biological Passport Operating Guidelines*, WORLD ANTI-DOPING AGENCY 3, 27 (June 2019) [https://www.wada-ama.org/sites/default/files/resources/files/guidelines\\_abp\\_v71.pdf](https://www.wada-ama.org/sites/default/files/resources/files/guidelines_abp_v71.pdf) [<https://perma.cc/JH3R-DZU8>].

60. Everts, *supra* note 48 (“[S]amples collected in Rio will be tested for gene doping at some point, even though the test was not run during the Olympics itself.”).

61. *Id.*

62. Eddie N. de Boer et al., *A Next-Generation Sequencing Method for Gene Doping Detection that Distinguishes Low Levels of Plasmid DNA Against a Background of Genomic DNA*, 26 GENE THERAPY 338, 338 (July 11, 2019), <https://www.nature.com/articles/s41434-019-0091-6.pdf> [<https://perma.cc/D9YZ-HPFX>].

63. *Id.*

64. *Id.* at 345. (“For [CRISPR-Cas9] gene doping to be detected, modification of our method will be required[;] . . . [i]n this way our method can detect induced alterations in gene expression.”).

65. *Id.* (“To summarize, our method outperforms existing PCR-based methods in many aspects and can be further developed into a routine method for detection of gene doping of multiple genes in all sports.”).

66. David Cyranoski, *What CRISPR-Baby Prison Sentences Mean for Research*, 577 NATURE 154, 154 (Jan. 3, 2020), <https://www.nature.com/articles/d41586-020-00001-y> [<https://perma.cc/XJ8D-3RB6>] [hereinafter *CRISPR-Baby Prison Sentences*].

a gene which encodes a protein that allows HIV to enter cells.<sup>67</sup> To complete his experiments, Jiankui forged ethics-review documents and swapped blood samples to circumscribe laws preventing the use of HIV-infected people in experiments involving reproductive technologies.<sup>68</sup> News of Jiankui's experiment emerged the week of his presentation at the Second International Summit on Human Genome Editing; he had posted YouTube videos previously but had never presented his experiment publicly.<sup>69</sup> Jiankui was subsequently fined three million yuan (around \$450,000), banned from ever working with human reproductive technology again, and sentenced to three years in prison for "illegal medical practice."<sup>70</sup>

Since Jiankui's experiment was announced, eighteen scientists from seven different nations have called for a global moratorium on all clinical experimentation of human germline cells.<sup>71</sup> The proposed moratorium is not intended to be a permanent ban, but rather a break to allow for the development of a proper international framework.<sup>72</sup> This proposed moratorium is a point of contention; some scientists fear it will drive other scientists to continue their experimentations "underground."<sup>73</sup> China's government responded to the controversy by approving a National Research Ethics Committee with the goal to "strengthen the coordination and implementation of a comprehensive and consistent system of ethics governance for science and technology."<sup>74</sup> The People's Republic of China Civil Code was promulgated in May of 2020 and contains a "Personality Rights" section which addresses the issues of human embryo and genome research.<sup>75</sup>

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67. David Cyranoski, *The CRISPR-Baby Scandal: What's Next for Human Gene-Editing*, 566 NATURE 440, 440 (Mar. 11, 2019), <https://www.nature.com/articles/d41586-019-00673-1> [<https://perma.cc/T7ZP-6W8S>].

68. *Id.*

69. David Cyranoski, *CRISPR-Baby Scientist Fails to Satisfy Critics*, 564 NATURE 13, 13 (Nov. 30, 2018), <https://www.nature.com/articles/d41586-018-07573-w> [<https://perma.cc/C26Z-H93T>] [hereinafter *Scientist Fails to Satisfy Critics*].

70. *CRISPR-Baby Prison Sentences*, *supra* note 66.

71. Rob Stein, *Scientists Call for Global Moratorium on Creating Gene-Edited Babies*, NPR (Mar. 13, 2019, 2:01 PM), <https://www.npr.org/sections/health-shots/2019/03/13/701549223/call-for-global-moratorium-on-creating-gene-edited-babies> [<https://perma.cc/F4TP-4287>].

72. *Id.*

73. *Id.*

74. Shaoni Bhattacharya, *China Approves Ethics Advisory Group Almost a Year after CRISPR Scandal*, BIONEWS (Aug. 12, 2019), [https://www.bionews.org.uk/page\\_144245](https://www.bionews.org.uk/page_144245) [<https://perma.cc/UNK2-Q9AT>].

75. Yanru Chen, *PRC Civil Code Series – 04: The Thing About Part IV Personality Rights*, CHINA JUST. OBSERVER (July 12, 2020), <https://www.china-justiceobserver.com/>

Despite the outcries for a moratorium, Russian scientist Denis Rebrikov still plans to proceed with a human germline experiment.<sup>76</sup> He plans to use CRISPR technology to “fix” a genetic mutation in the GJB2 gene that impairs hearing.<sup>77</sup> Rebrikov has not publicly announced a timeline for his experiment.<sup>78</sup> Meanwhile, the Russian Health Ministry has publicly supported the World Health Organization’s (“WHO”) moratorium stance against making inheritable changes to the human genome.<sup>79</sup> The difference between Rebrikov and Jiankui in relation to the moratorium is that Rebrikov has been transparent about his experiment and looks to pass his ethical review instead of avoiding it like Jiankui.

### III. APPLICABLE LAW

#### A. *International Doping Authority*

WADA has already banned gene doping, however, it is unclear whether WADA should be the agency regulating a technology with stakeholders not just in international sports, but other sectors such as health and science. Since WADA’s inception in 1999 with The Lausanne Declaration on Doping in Sport, it has been the forefront regulatory agency for doping in international sports.<sup>80</sup> In 2005, the United Nations Educational, Scientific and Cultural Organization (“UNESCO”) held the International Convention Against Doping in Sport.<sup>81</sup> Through this convention, WADA created guidelines for the previously drafted World Anti-Doping Code

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a/prc-civil-code-series-04-the-thing-about-part-iv-personality-rights [https://perma.cc/UB2F-YNGY].

76. See Dan Robitzski, *Russian Scientist Still Plotting to Create More CRISPR Babies*, NEOSCOPE (Sept. 4, 2020), <https://futurism.com/neoscope/russian-scientist-plotting-create-crispr-babies> [https://perma.cc/9LPH-GHPE].

77. Jon Cohen, *Embattled Russian Scientist Sharpens Plans to Create Gene-Edited Babies*, AM. ASS’N FOR THE ADVANCEMENT OF SCI. (Oct. 21, 2019), <https://www.sciencemag.org/news/2019/10/embattled-russian-scientist-sharpens-plans-create-gene-edited-babies> [https://perma.cc/5BAX-L5GS].

78. *Id.*

79. Olga Dobrovidova, *Calling Embryo Editing ‘Premature,’ Russian Authorities Seek to Ease Fears of a Scientist Going Rouge*, STAT (Oct. 16, 2019), <https://www.statnews.com/2019/10/16/russia-health-ministry-calls-human-embryo-editing-premature/> [https://perma.cc/ZTY2-NR49].

80. Angela Schneider, *The Concept of Doping*, in ROUTLEDGE HANDBOOK OF DRUGS AND SPORT 9, 10 (Verner Moller et al. eds., 2015); see WORLD ANTI-DOPING AGENCY, *supra* note 4.

81. *International Convention Against Doping in Sport 2005*, UNITED NATIONS EDUC., SCI. AND CULTURAL ORG. (Oct. 19, 2005), [http://portal.unesco.org/en/ev.php-URL\\_ID=31037&URL\\_DO=DO\\_TOPIC&URL\\_SECTION=201.html](http://portal.unesco.org/en/ev.php-URL_ID=31037&URL_DO=DO_TOPIC&URL_SECTION=201.html) [https://perma.cc/6Y3K-FT3Z].

(“The Code”).<sup>82</sup> The Code provides the international standards for testing, laboratories, prohibited substances, and code compliance.<sup>83</sup> Violations of The Code are reviewed with strict liability, with WADA as the enforcement agency.<sup>84</sup>

The Code contains the current gene doping ban,<sup>85</sup> but this ban is only reflective of WADA’s opinion of gene editing technologies. Regulations on gene doping should consider the opinions of all stakeholders involved, such as medical professionals and human genome researchers. Gene doping is currently regulated like any other form of doping even though its complexity and wide-reaching effects makes it vastly different from traditional doping methods.

### B. International Genome Editing Authority

There have been attempts by international organizations to address bioethical concerns surrounding human genome editing, but these attempts lack the requisite collaborative effort necessary to implement comprehensive international regulations. One of the first international bioethical human experimentation documents, the Helsinki Declaration, originated from the Geneva Convention in 1964.<sup>86</sup> This declaration set the ethical international human experiment standards and has been amended several times since its inception; the latest amendment came from the 64th World Medical Association General Assembly in 2013.<sup>87</sup>

In 1982, the World Health Organization (“WHO”) and the Council for International Organization of Medical Sciences (“CIOMS”) collaborated to release the International Ethical Guidelines for Health-related Research

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82. *Id.*

83. *The Code*, WORLD ANTI-DOPING AGENCY, <https://www.wada-ama.org/en/what-we-do/the-code> [<https://perma.cc/YLE5-6G8Q>].

84. *World Anti-Doping Code*, WORLD ANTI-DOPING AGENCY 13–14, 94 (Jan. 1, 2021), [https://www.wada-ama.org/sites/default/files/resources/files/2021\\_code.pdf](https://www.wada-ama.org/sites/default/files/resources/files/2021_code.pdf) [<https://perma.cc/PB75-CFQM>].

85. *World Anti-Doping Code International Standard Prohibited List*, WORLD ANTI-DOPING AGENCY 13 (2021), [https://www.wada-ama.org/sites/default/files/resources/files/2021list\\_en.pdf](https://www.wada-ama.org/sites/default/files/resources/files/2021list_en.pdf) [<https://perma.cc/FKF8-4W7Q>].

86. *WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects*, WORLD MED. ASS’N (July 9, 2018), <https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/> [<https://perma.cc/FS4N-ETT6>].

87. *Id.*

Involving Humans.<sup>88</sup> This document explains how the principals set out in the Helsinki Declaration should be applied in experiments involving humans.<sup>89</sup> Then in 1997, UNESCO released the Universal Declaration on the Human Genome and Human Rights.<sup>90</sup> This declaration states, “[n]o research or research applications concerning the human genome . . . should prevail over respect for the human rights, fundamental freedoms and human dignity of individuals.”<sup>91</sup>

Furthermore, WHO has taken additional steps to address potential ethical questions regarding human genome experimentation. In 2018, the WHO Expert Advisory Committee on Developing Global Standards for Governance and Oversight of Human Genome Editing (“The Committee”) was set up by the Director General of the WHO.<sup>92</sup> The Committee is tasked with examining the current scientific, ethical, social, and legal challenges surrounding human genome editing, as well as developing appropriate oversight and governance mechanisms for these experiments at all levels.<sup>93</sup> In 2019, the Committee approved the first phase of a global registry to track all research on human genome editing.<sup>94</sup> The registry would track both somatic and germline clinical trials and ensure these trials are proceeding in an ethical manner.<sup>95</sup> The Committee released its suggested governance framework in 2021.<sup>96</sup> This document discusses

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88. *International Ethical Guidelines for Health-Related Research Involving Humans*, COUNCIL FOR INT’L ORG. OF MED. SCI. ix (2016), <https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf> [<https://perma.cc/ERH3-88KA>].

89. *Id.* at 57.

90. *Universal Declaration on the Human Genome and Human Rights*, UNITED NATIONS EDUC., SCI. AND CULTURAL ORG. (Nov. 11, 1997), [http://portal.unesco.org/en/ev.php-URL\\_ID=13177&URL\\_DO=DO\\_TOPIC&URL\\_SECTION=201.html](http://portal.unesco.org/en/ev.php-URL_ID=13177&URL_DO=DO_TOPIC&URL_SECTION=201.html) [<https://perma.cc/AEJ5-Z8PQ>].

91. *Id.* art. 10.

92. *Call for Contribution: Advisory Committee on Developing Global Standards for Governance and Oversight of Human Genome Editing – Now Closed*, WORLD HEALTH ORGANIZATION [WHO] (July 10, 2020), <https://www.who.int/news-room/articles-detail/call-for-contribution-advisory-committee-on-developing-global-standards-for-governance-and-oversight-of-human-genome-editing> [<https://perma.cc/N44W-DVDL>] [hereinafter *Call for Contribution*].

93. *Id.*

94. *WHO Launches Global Registry on Human Genome Editing*, WORLD HEALTH ORGANIZATION [WHO] (Aug. 29, 2019), <https://www.who.int/news-room/detail/29-08-2019-who-launches-global-registry-on-human-genome-editing> [<https://perma.cc/L33C-GY6W>].

95. *Id.*

96. *WHO Issues New Recommendations on Human Genome Editing for the Advancement of Public Health*, WORLD HEALTH ORGANIZATION [WHO] (July 12, 2021), <https://www.who.int/news/item/12-07-2021-who-issues-new-recommendations-on-human-genome-editing-for-the-advancement-of-public-health> [<https://perma.cc/S3EA-QR47>].

various factors of good governance of human genome editing<sup>97</sup> and is an important step towards international governance of human genome editing. This document could be the basis for developing an international solution for this issue.

### C. National Genome Editing Authorities

National bodies have been developing regulations for human genome therapy at different rates, which could lead to potential conflicts in the future. In May 2020, the Civil Code of the People's Republic of China was adopted and contains a section that was a direct response to the He Jiankui scandal.<sup>98</sup> This provision states: "A medical and scientific research activity related to human genes, embryos, or the like shall be done in accordance with the relevant provisions of laws, administrative regulations, and the regulations of the State, and may not endanger human health, offend ethics and morals, or harm public interests."<sup>99</sup> This provision imposes civil liability on those who violate ethics and morals in human germline experiments on top of any possible criminal liability they may face.<sup>100</sup>

In contrast, the United States has taken a different approach. The US regulates human genome editing through its federal funding of the Food and Drug Administration ("FDA"). A "rider" provision of the 2016 spending bill bars the FDA from considering any clinical trial application "in which a human embryo is intentionally created or modified to include a heritable genetic modification."<sup>101</sup> This provision was added to every

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97. WHO Expert Advisory Commission on Developing Glob. Standards for Governance and Oversight of Human Genome Editing, *Human Genome Editing: A Framework for Governance*, WORLD HEALTH ORGANIZATION [WHO] (July 12, 2021), <https://www.who.int/publications/i/item/9789240030060> [<https://perma.cc/Z2FQ-5UEM>] [hereinafter *A Framework for Governance*].

98. Lingqiao Song & Yahn Joly, *After He Jianku: China's Biotechnology Regulation Reforms*, 21, MED. L. INT'L 174, 178 (Feb. 16, 2021), <https://journals.sagepub.com/doi/10.1177/0968533221993504> [<https://perma.cc/29PT-6CZJ>]; see Zhonghua Renmin Gongheguo Minfa Dian (中华人民共和国民法典) [Civil Code of the People's Republic of China] (promulgated by the Nat'l People's Cong., May 28, 2020, effective Jan. 1, 2021), art. 1009, P.R.C. LAWS.

99. *Id.* at art. 1009.

100. See generally *id.*

101. Jocelyn Kaiser, *Update: House Spending Panel Restores U.S. Ban on Gene-Edited Babies*, AM. ASS'N FOR THE ADVANCEMENT OF SCI. (June 4, 2019, 1:45 PM), <https://www.sciencemag.org/news/2019/06/update-house-spending-panel-restores-us-ban-gene-edited-babies> [<https://perma.cc/6LJA-JANL>].

subsequent spending bill, but was not included in the 2020 draft.<sup>102</sup> The National Institute of Health also refused to fund any gene therapy research that involves human embryos.<sup>103</sup> These regulations make public funding of human germline cell editing in the US practically impossible. Human somatic cell therapy is possible in the US, as the FDA approved the first treatment of this kind in 2020.<sup>104</sup> Scott Gottlieb, former FDA commissioner, predicted that by 2025 the FDA would be approving between ten and twenty gene therapies per year.<sup>105</sup> Additionally, the United States followed WADA's lead and banned gene doping outright.<sup>106</sup>

The United Kingdom was one of the first countries to set a regulatory framework in place for human genome editing. The Human Fertilization and Embryology Act of 1990 ("HFE") prohibits embryos that have had germline DNA altered from being placed inside a woman.<sup>107</sup> The HFE does allow other forms of human genome research on the basis of licenses issued by the Human Fertilization and Embryology Authority.<sup>108</sup> The HFE was the first national policy regulating the use of human embryos in the world and has been continuously amended by Parliament to reflect changing public opinion.<sup>109</sup> The HFE has some of the most extensive requirements of current national legislation: it has a license committee, it calls for random inspections of human genome research, and it sets strict

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102. *Id.*

103. Francis S. Collins, *Statement on NIH funding of Research Using Gene-Editing Technologies in Human Embryos*, NAT'L INST. OF HEALTH (Apr. 28, 2015), <https://www.nih.gov/about-nih/who-we-are/nih-director/statements/statement-nih-funding-research-using-gene-editing-technologies-human-embryos> [<https://perma.cc/53D5-U9DF>].

104. *FDA Approves First Cell-Based Gene Therapy for Adult Patients with Relapsed or Refractory MCL*, FDA (July 24, 2020), <https://www.fda.gov/news-events/press-announcements/fda-approves-first-cell-based-gene-therapy-adult-patients-relapsed-or-refractory-mcl> [<https://perma.cc/6JNZ-WJXV>].

105. Arlene Weintraub, *Pharma's Gene and Cell Therapy Ambitions Will Kick into High Gear in 2020-Despite Some Major Hurdles*, FIERCE PHARMA (Dec. 19, 2019), <https://www.fiercepharma.com/pharma/gene-and-cell-therapy-r-d-will-kick-into-high-gear-2020-despite-hurdles-experts-say> [<https://perma.cc/U3ET-HQQL>].

106. Office of National Drug Control Policy Reauthorization Act of 2006, H.R.6344, 109th Cong. § 701 (2006).

107. Francesca Lake, *UK Parliamentary Office Publishes Brief on Human Germline Genome Editing*, BIOTECHNIQUES (Jan. 22, 2020), <https://www.biotechniques.com/crispr/uk-parliamentary-office-publishes-brief-on-human-germline-genome-editing/> [<https://perma.cc/D2ES-VQM6>].

108. Britta van Beers, *Rewriting the Human Genome, Rewriting Human Rights Law? Human Rights, Human Dignity, and Human Germline Modification in the CRISPR Era*, 7 OXFORD J.L. & BIOSCIENCES 1, 19 (June 9, 2020), <https://academic.oup.com/jlb/advance-article/doi/10.1093/jlb/lsaa006/5841599> [<https://perma.cc/9W4W-9TP5>].

109. Jonathan LaTourelle, *Human Fertilisation and Embryology Act (1990)*, EMBRYO PROJECT ENCYCLOPEDIA (Dec. 19, 2014), <https://embryo.asu.edu/pages/human-fertilisation-and-embryology-act-1990> [<https://perma.cc/JF77-EGAM>].



standards for research centers to maintain their status as licensed for human genome research.<sup>110</sup>

#### IV. LEGAL ANALYSIS

The world will only benefit from gene editing technology if there are internationally agreed upon standards in all areas of human genome editing including detailed regulations on human germline edits, human somatic edits, and gene doping. As it currently stands, nations are developing regulations at different rates which could lead to international conflict if one nation allows human genome research that other nations consider unethical or unsafe. International standards are necessary for the enforcement of gene doping regulations, as uniform international guidelines can prevent the issue of different nations defining “therapeutic” use of genome editing at different levels. The current regulation of gene doping could potentially prevent further progression of gene therapy in the future; thus, it is important to develop a detailed and adaptive regulatory framework. Ultimately, the goal of international regulations should be to allow for the safe development and application of gene technology so there can be a time in the future where there is no negative stigma surrounding the use of safe gene therapy.

##### *A. Gene Doping Has a High Potential for Abuse*

Gene doping may appear to some athletes as a more attractive alternative to traditional doping because of its potentially undetectable application.<sup>111</sup> International athletes face high pressure to succeed, so the allure of gaining an undetectable competitive advantage could eventually persuade an athlete to attempt gene doping. WADA has taken steps to address this issue, but they will need a more comprehensive detection-based model to enforce gene doping regulations. As it currently stands, WADA’s current ban on gene doping is an empty threat without proper detection methods.

Many international athletes face pressure from their respective countries to win at all costs. The difference between first and second place may be a change of millions of dollars and national fame; athletes sometimes choose

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110. *How We Regulate*, HUM. FERTILISATION & EMBRYOLOGY AUTH., <https://www.hfea.gov.uk/about-us/how-we-regulate/> [https://perma.cc/XC8Z-285W].

111. Wenner, *supra* note 38.

shortcuts to achieve money and glory.<sup>112</sup> Lance Armstrong, a highly successful international cyclist who was caught blood doping, admits that he would “probably do it again” when asked if he would change anything.<sup>113</sup> There even appears to be a “cheater’s high” which boosts self-satisfaction when cheaters are able to get away with their scheme.<sup>114</sup> For these reasons, abuse of technology to improve athletic performance should be expected and the proper regulatory and enforcement methods must be set to dissuade the dangerous application of gene technology to doping. As Dr. Friedman, chair of WADA genetic panel has stated: “If you ask me how many years it’ll be before [gene doping happens], well, I’d say a very long time. But how many more years before some idiot does something stupid? That could be tomorrow.”<sup>115</sup>

As previously mentioned, WADA considered the idea of genome sequencing Olympians to provide a type of “gene passport.”<sup>116</sup> They dropped this idea due to the expense of genome sequencing every athlete, an issue no longer as influential today.<sup>117</sup> Adding a “gene passport” to WADA’s preexisting Athlete Biological Passport system is a viable detection-based model that should be implemented. Individual nations have already decided that this is a worthwhile task, as China announced that its athletes for the 2022 Olympics will be genome sequenced.<sup>118</sup> China’s actions are not an attempt to detect gene doping, rather they are attempting to identify laboratory standards for base genetic markers to help with their selection of future Olympic athletes.<sup>119</sup> Although this is a different usage of the “gene passport” proposed, the usage still lends itself to supporting the validity of the “gene passport.”

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112. *The Psychology of Cheating in Sports*, AURORA UNIVERSITY (Aug. 16, 2019), <https://online.aurora.edu/psychology-of-cheating-in-sports/#:~:text=However%2C%20the%20fundamental%20reason%20why,Athletes%20want%20to%20win.&text=As%20a%20result%2C%20some%20athletes,that%20being%20the%20best%20brings> [https://perma.cc/6UCB-UWF5].

113. Interview by Dan Roan with Lance Armstrong, *Armstrong on Drugs, History and The Future*, BBC: SPORT (Jan. 26, 2015), <https://www.bbc.com/sport/av/cycling/30984312> [https://perma.cc/3J4L-F6FV].

114. Nicole E. Ruedy et al., *The Cheater’s High: The Unexpected Affective Benefits of Unethical Behavior*, 105 J. PERSONALITY & SOC. PSYCH. 531, 532 (2013).

115. Maureen Salamon, *Could Gene Doping Be Part of Future Olympics?*, MEDICINET (July 26, 2012), <https://www.medicinenet.com/script/main/art.asp?articlekey=160697> [https://perma.cc/T3ND-DTRV].

116. Niiler, *supra* note 56.

117. *Id.*

118. Stephen Chen, *Gattacca by 2022? China to Select Winter Olympics Athletes by Their Genes*, SOUTH CHINA MORNING POST (Aug. 31, 2018), <https://www.scmp.com/news/china/science/article/2161866/china-genetically-screen-its-athletes-ensure-best-compete-2022> [https://perma.cc/96T9-RTAZ].

119. *Id.*

Genome sequencing appears to be a viable solution for detecting gene doping, but it might raise issues relating to genetic information, privacy, and discrimination.<sup>120</sup> If WADA attempts to set genetic markers as laboratory standards for “acceptable” athletic performance, it might go against the UNESCO Universal Declaration on the Human Genome and Human Rights.<sup>121</sup> This declaration states: “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>122</sup>

WADA must be careful if it wishes to implement genome screening as an additional requirement to their ABP program. WADA currently uses ABP to monitor athletes’ blood and urine for biological variables over time that suggest doping, not to determine threshold biological markers.<sup>123</sup> This difference is important, as attempting to set threshold biological markers could lead to genetic discrimination in the case of genome sequencing.

If WADA set biological markers to detect gene doping, athletes who did not perform gene doping but have natural mutations could become excluded from international sports. There are noted examples of athletes who have natural mutations that improve athletic ability, such as Eero Mäntyranta, the 1964 Olympic gold medalist for skiing who was reported to have unusually high amounts of red blood cells.<sup>124</sup> If genome sequencing is an added requirement of WADA’s ABP program, WADA must compare the athlete’s samples against the athlete’s past samples to determine if there are any unnatural changes instead of attempting to set threshold biological markers. This approach could work if athletes accept the idea, which current reports show that some are receptive to the idea if it is necessary to keep the sport clean.<sup>125</sup>

### *B. Decreased Public Opinion on Genome Editing Can Halt its Progress*

International standards for applying genome editing technology can decrease the potential for future scandals. An internationally agreed upon standard

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120. G.A. Res. 53/152, at art. 6, Universal Declaration on the Human Genome and Human Rights (Nov. 11, 1997).

121. *Id.*

122. *Id.*

123. *Athlete Biological Passport*, WORLD ANTI-DOPING AGENCY, <https://www.wada-ama.org/en/athlete-biological-passport> [https://perma.cc/4HHU-33AM].

124. Filipp, *supra* note 42, at 434.

125. See, e.g., Niiler, *supra* note 56.

could prevent abuse of this technology as nations develop their own human genome editing regulations, likely at varying levels of strictness. Scandals easily sway public opinion, and negative public opinion could halt the growth of gene therapy.

The Russian doping example shows how scandal can impact perception, especially when a responding regulatory body is unprepared for the situation. Due to the unprecedented nature of the Russian scandal, the IOC and WADA had no rules or procedures on how to handle such a situation.<sup>126</sup> Their unpreparedness was visible in their disjointed response. WADA's preliminary recommendation was for a "blanket-ban" on all Russian athletes for the 2016 Rio Olympics<sup>127</sup> which IOC rejected, rather deciding to let the individual IFs determine athlete eligibility.<sup>128</sup> The IOC did ultimately agree to a four year "blanket-ban" on Russia nearly five years after the controversy was discovered.<sup>129</sup> Their handling of the situation received a negative public reaction, with some viewing IOC's credibility as badly damaged.<sup>130</sup>

Genome editing and its lucrative potential will attract many researchers. As was the case with He Jiankui, some scientists willingly push ethical boundaries to complete experiments in this field.<sup>131</sup> Denis Rebrikov is another known scientist interested in human genome experiments,<sup>132</sup> but unlike him there may be others who are not as willing to pass ethical standards. If most of the public exposure to genome editing consists of scandals and foregone ethical practices, then harsh restrictions will likely limit the potential of genome technology.

He Jiankui is facing three years of jail time for "illegal medical practice,"<sup>133</sup> but would likely have faced more severe charges had his experiment taken place elsewhere. In the UK, the HFE bars human birth of genetically edited

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126. Alex Brokaw, *How does the International Olympic Committee Solve a Problem like Russian Doping?*, THE VERGE (July 19, 2016, 2:17 PM), <https://www.theverge.com/2016/7/19/12222086/international-olympics-committee-delays-decision-to-ban-russia> [https://perma.cc/FX6J-BCJM].

127. Macguire, *supra* note 16.

128. *Id.*

129. WADA Executive Committee Unanimously Endorses Four-Year Period of Non-Compliance for the Russian Anti-Doping Agency, WORLD ANTI-DOPING AGENCY (Dec. 9, 2019), <https://www.wada-ama.org/en/media/news/2019-12/wada-executive-committee-unanimously-endorses-four-year-period-of-non-compliance> [https://perma.cc/N29C-XMQ8].

130. See, e.g., Liam Morgan, *Exclusive: Radcliffe Claims Credibility of IOC Badly Damaged by Response to Russian Doping Scandal*, INSIDE THE GAMES (Oct. 25, 2017), <https://www.insidethegames.biz/articles/1057040/exclusive-radcliffe-claims-credibility-of-ioc-badly-damaged-by-response-to-russian-doping-scandal> [https://perma.cc/6QY5-Q3LU].

131. *Scientist Fails to Satisfy Critics*, *supra* note 69.

132. Cohen, *supra* note 77.

133. *CRISPR-Baby Prison Sentences*, *supra* note 66.

embryos<sup>134</sup> so Jiankui would likely have faced a minimum sentence of ten years for the violation of this law.<sup>135</sup> In the US, Jiankui would face penalties for failing to obtain FDA approval for his research, constituting a violation of the Federal Food, Drug and Cosmetics Act and carrying criminal penalties and imprisonment of up to ten years.<sup>136</sup> Although most people agree that the punishment for Jiankui is proportional to his actions,<sup>137</sup> moral and ethical lines may become blurred in a not so clear-cut case. If there is no internationally agreed upon standards, then each national legislature would develop their own set of human genome regulations at their own pace, which could lead to conflict regarding future scandals and unethical practices. Agreed upon international standards can act as the bare minimum requirement that national legislative bodies can build upon to fit their constituents' ethical views on genome technology.

### C. What is Proper Punishment for WADA's Current Gene Doping Ban?

To avoid a situation like the disjointed response to the Russian doping scandal, WADA and IOC must be prepared to enforce their regulations. It is too soon to tell how WADA and IOC would react if they discovered an Olympian gene doping, but a more extensively thought-out regulatory framework could solve this problem before it occurs.

If WADA and IOC uphold a ban on gene doping, they must also prepare for the possibility of state-sponsored gene doping. Both organizations were unprepared for the Russian scandal, but hopefully this experience has readied them for future enforcement actions. WADA has begun funding methods of detecting gene doping,<sup>138</sup> however, these tests are still in their preliminary stages and need the necessary lab infrastructure to implement.<sup>139</sup>

134. Lake, *supra* note 107.

135. Lie Lijie (刘立杰), *Three Legal Issues With Gene-Edited Babies* (基因编辑婴儿的三大法律问题), JRCB (Jan. 14, 2019), [http://www.jcrb.com/FYFZ/zxbd/201901/t20190114\\_1952628.html](http://www.jcrb.com/FYFZ/zxbd/201901/t20190114_1952628.html) [<https://perma.cc/3US8-YBWC>].

136. Josephine Johnston, *He Jiankui is Going to Jail. Would the U.S. Criminally Prosecute a Rogue Gene-Editing Researcher?*, STAT (Dec. 31, 2019), <https://www.statnews.com/2019/12/31/he-jiankui-jail-prosecute-rogue-gene-editing-researcher/> [<https://perma.cc/T2YK-X6RJ>].

137. *Expert Reaction to News That He Jiankui Has Been Sentenced to Three Years in Prison*, SCI. MEDIA CTR. (Dec. 30, 2019), <https://www.sciencemediacentre.org/prof-robin-lovell-badge-response-to-news-that-he-jiankui-has-been-sentenced-to-three-years-in-prison/> [<https://perma.cc/H83N-ABAX>].

138. *EPO Detection*, *supra* note 44.

139. De Boer, *supra* note 62, at 339, 345.

If traditional doping labs could be manipulated as they were during the Russian doping scandal,<sup>140</sup> then it is likely that the more complex gene detection results could also be manipulated.

IOC and WADA had a difficult time agreeing on a proper punishment for the Russian scandal and determining a proper punishment for gene doping will only become a more problematic task. If the punishment is too severe, then the advancement of gene therapy technology could suffer.<sup>141</sup> Scientists and athletes alike could be dissuaded from pursuing gene therapies that could greatly improve an athlete's quality of life but also improve athletic performance if they are worried of possible punishment. Some theoretical examples of possible gene therapy applications that fall in this grey area are procedures that could potentially improve an athlete's recovery from major injuries or procedures that could potentially increase an athlete's longevity.<sup>142</sup> If the punishment is not severe enough, then critics will call out IOC and WADA for failing to uphold principals of fairness. It is a no-win situation.

Current gene doping regulations are only reflective of international sports agencies' opinion of gene therapy when this potential abuse affects many different stakeholders. Cooperation between national governments and international organizations is needed to effectively manage all constituent parties in this matter. Theodore Friedmann, head of WADA's gene doping advisory panel stated that implementing gene doping in athletes is "very hard, [i]f you think about how hard it is to design and work through the technical and procedural issues for human gene therapy . . . . You can't just go throwing around things in experimental procedures with humans. There are international constraints."<sup>143</sup> Accordingly, WADA would benefit in collaborating with other international organizations and national bodies to develop an effective response to gene doping.

The current gene doping ban puts WADA in a difficult situation. An international framework developed by multiple stakeholders in this issue can guide responses to potential gene therapy abuses. WADA's outright ban of gene doping was a preemptive response to this technological advancement; it is only right that international regulations continue to adapt and expand with the growth of gene editing. These regulations

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140. Grigory Rodchenkov, director of Russia's anti-doping laboratory, was accused of being "at the heart" of the doping Russian scandal. *Russian Doping: Who is Whistleblower Grigory Rodchenkov?*, BBC (July 19, 2016), <https://www.bbc.com/news/world-europe-36833962> [<https://perma.cc/6533-FJV9>].

141. R. Alta Charo, *The Legal and Regulatory Context for Human Gene Editing*, 32 ISSUES IN SCI. & TECH. 3 (2016), <https://issues.org/the-legal-and-regulatory-context-for-human-gene-editing/> [<https://perma.cc/4U4L-87A7>].

142. See Huard, *infra* note 161.

143. Nüiler, *supra* note 56.

must not be so strict as to limit the development of gene therapy, but they must draw the ethical boundaries of acceptable practice so to continue the maturation of gene technologies.

*D. WADA Should Not be Treating Gene Doping as if it Were  
Any Other Typical Form of Doping*

The current gene doping ban lacks specificity and treats gene doping like any other doping violation prohibited by the World Anti-doping Code. Conflict can arise between what WADA considers as gene doping compared to what other national bodies consider as gene doping. More specifically, “therapeutic” uses of gene editing can be defined differently by different nations absent any international agreed upon standard. This ban also dissuades scientists from researching how gene doping could be applied for athletics, which will prevent the advancement of sports medicine.

Currently, if any issues arise between WADA or IOC and athletes, the conflict is resolved through arbitration or mediation with the Court of Arbitration for Sport (“CAS”).<sup>144</sup> CAS is based in Switzerland and hears sports-related arbitration cases and appeals.<sup>145</sup> The parties decide which law should govern their dispute, and absent any designation, Swiss law is applied.<sup>146</sup> In either case, the World Anti-doping Code would be influential in determining a resolution for the dispute. The World Anti-Doping Code bars “the non-therapeutic use of genes, genetic elements and/or cells that have the capacity to enhance athletic performance.”<sup>147</sup> This creates the potential issue of various national legislatures defining “therapeutic” genome edits at different capacities. A centralized international authority would help prevent an issue such as this.

Currently, different national bodies have different organizations that determine the definition of therapeutic use of gene editing. The US has the FDA which approves clinical applications of gene editing through its

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144. *Court of Arbitration for Sport*, WORLD ANTI-DOPING AGENCY, <https://www.wada-ama.org/en/court-of-arbitration-for-sport> [<https://perma.cc/ZUC7-CUMW>].

145. Matthew Buckle, *Court of Arbitration for Sport (CAS)*, NORTON ROSE FULBRIGHT (June 2018), <https://www.nortonrosefulbright.com/en-us/knowledge/publications/048b7aeb/court-of-arbitration-for-sport-cas> [<https://perma.cc/N9TG-CX4M>].

146. Court of Arbitration for Sport, *Procedural Rules, Special Provisions Applicable to the Ordinary Arbitration Procedure, R45: Law Applicable to the Merits*, CODE OF SPORTS-RELATED ARBITRATION 1, 21 (Jan. 1, 2019), [https://www.tas-cas.org/fileadmin/user\\_upload/Code\\_2019\\_en.pdf](https://www.tas-cas.org/fileadmin/user_upload/Code_2019_en.pdf) [<https://perma.cc/TSSN-J2Z8>].

147. *2004 Prohibited List*, *supra* note 37.

new drug application and biologics license application.<sup>148</sup> The UK has the Embryology Authority and the regulations set in the HFE.<sup>149</sup> China has its newly updated civil code.<sup>150</sup> All these potential authorities might find some human genome experiments as having more therapeutic value compared to other authorities. A clear international standard defining the limits of therapeutic human genome editing will help prevent future conflicts that can arise with different legislative bodies defining a term.

Furthermore, WADA must prepare for a situation where an athlete unintentionally gains an athletic advantage through therapeutic gene editing. What happens if an athlete who suffers from muscular dystrophy uses gene therapy and as a result of the treatment gains a competitive advantage?<sup>151</sup> This issue is similar to what happened when Oscar Pistorius wanted to compete in the 2008 Olympics as a double amputee.<sup>152</sup> An initial study done by the International Association of Athletics Federations concluded that Pistorius' carbon fiber blades that replaced his legs gave him an unfair advantage.<sup>153</sup> He was thus banned from competing in the 2008 Olympics.<sup>154</sup> Although Pistorius was able to reverse his Olympic ban with an appeal to CAS in time to compete for the 2012 games,<sup>155</sup> his initial ban from the games due to his alleged competitive advantage hints at what might happen in the muscular dystrophy hypothetical. Pistorius was able to appeal his ban because subsequent studies showed that many amputee and intact-limb subjects had similar physiological performance for sprinting events, the events in which he participated.<sup>156</sup> Though the gene editing for

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148. *What is Gene Therapy?*, U.S. FOOD AND DRUG ADMIN. (July 25, 2018), <https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/what-gene-therapy> [<https://perma.cc/ESE5-AZ8T>].

149. LaTourelle, *supra* note 109, at 1.

150. See Zhonghua Renmin Gongheguo Minfa Dian (中华人民共和国民法典) [Civil Code of the People's Republic of China] (promulgated by the Nat'l People's Cong., May 28, 2020, effective Jan. 1, 2021) P.R.C. Laws.

151. Guilherme Artioli et al., *terapia gênica, doping genético e esporte: fundamentação e implicações para o futuro* [Gene Therapy, Genetic Doping and Sport: Fundamentals and Implications for the Future], 13(5) REVISTA BRASILEIRA DE MEDICINA DO ESPORTE 349, 351 (2007) (Braz.), <https://www.scielo.br/j/rbme/a/RCv3Jk3Rm4xZL9QdNfWNVKc/?lang=pt&format=pdf>.

152. Joshua Robinson, *Study Suggests That Amputee Holds an Unfair Advantage*, N.Y. TIMES (Jan. 10, 2008), <https://www.nytimes.com/2008/01/10/sports/othersports/10track.html> [<https://perma.cc/D5WU-P2TE>].

153. *Id.*

154. Pistorius v International Association of Athletics Federations, Decision, CAS 2008/A/1480, 13 (Ct. of Arb. for Sport Appeals 2008), <http://classic.austlii.edu.au/au/journals/ANZSportsLawJl/2008/7.pdf>.

155. *Id.*

156. Peter Weyand, et. al., *The Fastest Runner on Artificial Legs: Different Limbs, Similar Function?*, 107 J. APPLIED PHYSIOLOGY 903, 909 (2009), <https://journals.physiology.org/doi/full/10.1152/japplphysiol.00174.2009> [<https://perma.cc/ZZ7T-6C4X>].



medical reasons such as muscular dystrophy might be for “therapeutic” reasons, the athlete may still be able to gain a competitive advantage and thus be at odds with WADA and IOC.

WADA has approached the issue of gene doping as if it were typical doping,<sup>157</sup> which is not the correct way to regulate this new technology. An outright ban might provide a temporary solution to this issue, but it could also halt the potential growth of this new technology. Future applications of gene therapy might not fall clearly in-between the “therapeutic vs non-therapeutic use” distinction as required by WADA.<sup>158</sup> Gene therapy could be used not only to improve athletic performance, but possibly also to improve athlete recovery times, extend athlete’s playing careers, and vastly advance sports medicine.<sup>159</sup> More research into how gene therapy can be used to improve international sports as a whole is currently dissuaded as the application of the technology in this way would be viewed as gene doping. It is unfair for one stakeholder to restrict the growth of gene therapy out of fear for the possibility of abuse. Action is necessary to ensure that gene therapy abuses are regulated, but with regulations that are reflective of all stakeholders involved and regulations that do not dissuade potential research and application of this powerful technology.

#### *E. Somatic Cell Edits or Gene Doping?*

WADA’s broad gene doping ban was the correct decision at the time the ban was enacted because of its dangerous and ethically questionable nature, but it is imperative that WADA holds an open mind towards somatic cell edits. If this technology becomes safe and admissible as ordinary medical practice, then it would be wise for WADA to hold a more nuanced approach towards their gene doping regulation.

CRISPR is one of the more widely used gene editing techniques, but there are still risks involved with this infant technology. Studies have shown that cells altered by CRISPR may be missing key anti-cancer mechanisms.<sup>160</sup> CRISPR may also introduce many “off-target” genetic errors—unexpected

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157. 2004 Prohibited List, *supra* note 37.

158. 2004 Prohibited List, *supra* note 37.

159. Johnny Huard et al., *Gene Therapy and Tissue Engineering for Sports Medicine*, 5 J. GENE MED. 93, 96–103 (2003), <https://onlinelibrary.wiley.com/doi/10.1002/jgm.344> [<https://perma.cc/RN2G-2FJ5>].

160. Daniel Oberhaus, *DNA Damage from CRISPR Has Been ‘Seriously Underestimated’*, VICE (July 17, 2018), <https://www.vice.com/en/article/a3qv7a/dna-damage-from-crispr-has-been-seriously-underestimated> [<https://perma.cc/5HKD-F6HZ>].

deletions and scrambling of genetic code.<sup>161</sup> The CRISPR method has improved greatly since its discovery,<sup>162</sup> which suggests that more research into this technology will make it safer. Prime editing, a gene therapy technique that is more precise than CRISPR,<sup>163</sup> is proof that human capacity to edit genomes will only improve with further research.

If future research proves that human gene editing can be performed safely, then the argument to maintain a gene doping ban becomes weaker. If gene therapy becomes a common and practical medical procedure in twenty-five years, then certain genome edits will be more comparable to LASIK eye surgery (“LASIK”) than to doping. IOC and WADA do not classify LASIK as doping or as a competitive advantage.<sup>164</sup> There will always be inherent risks for LASIK,<sup>165</sup> just as with gene therapy. Many Olympic athletes undergo LASIK to correct their vision; the US speed skating team has an official LASIK provider.<sup>166</sup> Improved eyesight increases athletic performance in many different Olympic sports.<sup>167</sup> While improved eyesight may not have the same effect on athletic performance compared to an increased muscle growth factor or improved oxygen delivery,<sup>168</sup> it still can improve athletic performance. Therapeutic aspects of somatic cell edits could result in athletes maintaining healthier muscles longer,<sup>169</sup> thus improving all international sports.

## V. PROPOSED SOLUTION

A solution for the issue of gene doping is to expand the current regulations on gene therapy technologies. This can be achieved through

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161. *Id.*

162. Heidi Ledford, *Super-Precise CRISPR Tool Enhanced by Enzyme Engineering*, NATURE (Feb. 10, 2020), <https://www.nature.com/articles/d41586-020-00340-w> [https://perma.cc/7GJL-CBU9].

163. *Scientists Create*, *supra* note 33.

164. *Olympians and LASIK*, NORTHWEST EYE CENTER, P.C. (July 16, 2018), <https://northwest-eye.com/olympians-and-lasik/> [https://perma.cc/WVD8-2PMV].

165. *LASIK Eye Surgery*, MAYO CLINIC (Nov. 8, 2019), <https://www.mayoclinic.org/tests-procedures/lasik-eye-surgery/about/pac-20384774> [https://perma.cc/Y4AM-LDKZ].

166. David Evans, *The Summer Olympics are Here! . . . So Let's Talk Winter Olympics*, BETTER VISION GUIDE (Aug. 14, 2018), <https://www.bettervisionguide.com/speed-skaters-pamel/> [https://perma.cc/J3BW-QYL6].

167. Sally Thompson, *Sports and LASIK: Which Athletes Benefit Most?*, LASIKPLUS, <https://www.lasikplus.com/lasik-resources/procedure/athletes-that-benefit/> [https://perma.cc/URL8-KQFS].

168. *See* Everts, *supra* note 48; *see* Franks, *supra* note 43.

169. Michael Le Page, *Gene Doping in Sport Could Make the Olympics Fairer and Safer*, NEWSCIENTIST (Aug. 5, 2016), <https://www.newscientist.com/article/2100181-gene-doping-in-sport-could-make-the-olympics-fairer-and-safer/> [https://perma.cc/TF8C-EXU8].

an international treaty where all stakeholders involved are able to agree upon acceptable human genome technology standards. The treaty should also create a new international organization that helps enforce the regulations set out in the treaty. In addition, WADA should look to implement genome sequencing to their Athlete Biological Passport by 2028 to begin a gene doping detection framework. The current gene doping ban is necessary today, but regulatory organizations must be willing to modify their regulations based on advancement in technology and changing societal expectations.

*A. An International Treaty Can Set International Bioethical Standards for Human Genome Technologies*

The first step towards addressing the issues surrounding gene doping would be for every nation to agree on bioethical human technology standards, covering areas including but not limited to: human germline cell edits, human somatic cell edits, and gene doping. While international organizations like UNESCO and WHO have released declarations of international bioethical standards, there have been no binding international treaties focused on the standards of gene therapy. UNESCO, WHO, CIOMS, WADA and other parties that have a stake in regulating human genome experimentation should be part of the conversation to determine the best course of action.

Since the Jiankui scandal, there have been many efforts towards increased human genome regulations. China updated its civil code to address human genome technologies,<sup>170</sup> and organizations such as the National Institute of Health have supported a global moratorium on the clinical application of human germline cells.<sup>171</sup> The next logical progression is the implementation of international regulations to stop any future scandals. A representative at the next United Nations (“UN”) General Assembly should propose an international convention on human genome technology and experimentation standards. A treaty could build upon the bioethical principles set out in the Helsinki Declaration,<sup>172</sup> the International Ethical Guidelines for Health-

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170. See *Zhonghua Renmin Gongheguo Minfa Dian* (中华人民共和国民法典) [Civil Code of the People’s Republic of China] (promulgated by the Nat’l People’s Cong., May 28, 2020, effective Jan. 1, 2021), art. 1009, P.R.C. LAWS.

171. Francis Collins, *NIH Supports International Moratorium on Clinical Application of Germline Editing*, NAT’L INSTS. OF HEALTH (Mar. 13, 2019), <https://www.nih.gov/about-nih/who-we-are/nih-director/statements/nih-supports-international-moratorium-clinical-application-germline-editing> [<https://perma.cc/4XS3-WWDV>].

172. *WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects*, WORLD MED. ASS’N. (July 9, 2018), <https://www.wma.net/policies-post/>

related Research Involving Humans,<sup>173</sup> and the Universal Declaration on the Human Genome and Human Rights.<sup>174</sup>

Ultimately, the governance framework<sup>175</sup> developed by the WHO Expert Advisory Committee on Developing Global Standards for Governance and Oversight of Human Genome Editing will be a useful document for developing an international human genome therapy treaty. The WHO is attempting to address the issue, but its authority would only be strengthened with the endorsement of the UN Member States. The governance framework emphasizes several core values:

- (i) openness, transparency, honesty and accountability; (ii) responsible regulatory stewardship; (iii) responsible stewardship of science and (iv) responsible stewardship of research resources. The values and principles to inform what decisions are made are (i) inclusiveness; (ii) caution; (iii) fairness; (iv) social justice; (v) non-discrimination; (vi) equal moral worth; (vii) respect for persons; (viii) solidarity and (ix) global health justice.<sup>176</sup>

These core values should be reflected in any international human genome regulation. This document also suggests that international regulations would have to come from a convention or treaty.<sup>177</sup>

Additionally, the governance framework addresses several different scenarios in which gene therapy technology could be applied. The framework explains a scenario and applies its core values to developing several important questions that need to be considered when forming governance measures.<sup>178</sup> After developing these questions, the document proceeds to list several plausible governance mechanisms. One of the several scenarios the document discusses is the use of gene therapy to enhance athletic ability.<sup>179</sup> The document's suggested solutions are:

- a) To establish legislation, regulation, and associated guidance distinguishing between treating a disease versus enhancing what is considered "normal", where international harmonization

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wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/ [https://perma.cc/55N8-XPSE].

173. *International Ethical Guidelines for Health-related Research Involving Humans*, COUNCIL FOR INT'L ORG. OF MED. SCIS. (4th ed. 2016), <https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf> [https://perma.cc/G2EK-SN57].

174. Universal Declaration on the Human Genome and Human Rights, UNESCO Gen. Conf. 29 C.Res.16 (Nov. 11, 1997), endorsed by the UN General Assembly, G.A. Res. 53/152 (Dec. 9, 1998), [http://portal.unesco.org/en/ev.php-URL\\_ID=13177&URL\\_DO=DO\\_TOPIC&URL\\_SECTION=201.html](http://portal.unesco.org/en/ev.php-URL_ID=13177&URL_DO=DO_TOPIC&URL_SECTION=201.html) [https://perma.cc/6DMT-HG3X].

175. *A Framework for Governance*, *supra* note 97.

176. *A Framework for Governance*, *supra* note 97, at 10–11.

177. *A Framework for Governance*, *supra* note 97, at 28.

178. *A Framework for Governance*, *supra* note 97, at 40.

179. *A Framework for Governance*, *supra* note 97, at 47–49.

of these legislative and regulatory frameworks are the most desirable;

- b) Allowing individual ministries to make policies governing this use of human genome editing;
- c) The use of research funds solely for the health purposes and not for the purpose of enhancing athletic ability;
- d) A moratorium on the use of genome technology in this capacity through use of bans by global governing bodies for professional and elite sports;
- e) Professional self-regulation through the use of ethical guidelines;
- f) Public advocacy and activism on the issue to determine the position of the many interest groups involved; and
- g) Development of research ethics guidelines and research ethics review by review committees.<sup>180</sup>

The framework goes on to list several other scenarios and possible solutions to them.<sup>181</sup> The framework lists out several suggested solutions to issues, but an ultimate satisfying solution can only be developed through collaboration of multiple international and national regulatory bodies. Many of the solutions recommended by the framework suggest that international harmonization of procedures and regulations is desirable, thus a collaborative effort is necessary to effectively regulate gene therapy technologies. Other national legislative bodies of work can be very influential in the development of an international treaty such as China's Civil Code<sup>182</sup> and the UK's Human Fertilization and Embryology Act.<sup>183</sup>

This newly formed treaty will provide general guidelines for what a violation of bioethical standards would look like. The treaty should set the bare minimum of international expectations for ethics and safety procedures of human genome technology. Should a nation think that additional regulations are necessary, then a nation may develop stricter laws and regulations with their own national legislature.

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180. *A Framework for Governance*, *supra* note 97, at 49.

181. *A Framework for Governance*, *supra* note 97, at 49–55.

182. See *Zhonghua Renmin Gongheguo Minfa Dian* (中华人民共和国民法典) [Civil Code of the People's Republic of China] (promulgated by the Nat'l People's Cong., May 28, 2020, effective Jan. 1, 2021), art. 1009, P.R.C. Laws.

183. LaTourelle, *supra* note 109.

*B. A New International Gene Editing Regulatory Agency  
Should be Developed*

The proposed international convention should develop a new agency to regulate and enforce agreed upon bioethical genome experimentation regulations. For the purpose of this paper, the organization will be called the International Office of Genome Editing Regulation (“IOGER”). The purpose of IOGER would be to allow scientific professionals a form of “self-regulation,” which is something some scientist adamantly support.<sup>184</sup> The organization’s board would be made up of scientific professionals, high-ranking officials from other international organizations that have a stake in this issue (WHO, UNESCO, WADA), and representatives from other national governments. This combination of scientific and political backgrounds could ensure that a scientific and political approach is taken towards development of regulations, rather than an approach that overly favors one side of the spectrum.

IOGER would achieve its goal of self-governance through an accreditation system with a genome experiment registry such as the one currently being developed by WHO.<sup>185</sup> Likewise, it would use the international registry to make sure all human genome experiments are known, thus preventing situations like the Jiankui scandal.<sup>186</sup> The agency would operate similar to the Embryology Authority in the UK, with the authority to perform random inspections for ongoing human genome experiments and license medical centers as approved for human genome experiments.<sup>187</sup>

The accreditation process would be one of the most important functions of IOGER. This organization would have an accreditation process for both scientists and their labs before human genome experiments are allowed. The license a scientist receives would be for a specific form of human genome experiments (i.e., a researcher would have to specify what type of experiment they wish to proceed with, whether it be germline or somatic). The scientist would have to pass an ethical checklist created by the international treaty, stating what the goal of their experiment is. All scientists who get approved would have their research posted on the international registry. This system would create transparency as to which scientists have the proper licensing to perform gene therapy experiments and which labs are properly set up for such.

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184. Benjamin Hurlbut, *Human Genome Editing: Ask Whether, Not How*, 565 NATURE 135 (Jan. 2, 2019), <https://www.nature.com/articles/d41586-018-07881-1> [<https://perma.cc/D46H-9BPA>].

185. *Call for Contribution*, *supra* note 92.

186. *CRISPR-Baby Prison Sentences*, *supra* note 66.

187. *How We Regulate*, HUM. FERTILISATION & EMBRYOLOGY AUTH., <https://www.hfea.gov.uk/about-us/how-we-regulate/> [<https://perma.cc/VS7D-5UUA>].

There is always the possibility that some will want to bypass these regulations to pursue their own interests in genome experimentation; to combat this possibility, the organization must attempt to incentivize scientist to work within the ethical limits set by the international treaty. Such limits could be achieved if IOGER developed their own scientific journal where international human genome experiments are published. IOGER could also develop their own International Summit on Human Gene Editing to give scientist a platform to present their genome research, like its current iteration run by the National Academy of Sciences, National Academy of Medicine, Chinese Academy of Sciences, and the Royal Society of the UK.<sup>188</sup> IOGER could restrict presentations at the international summit to only researchers who have the proper licensing or to scientist who have been published in their journal. IOGER's journal and summit would be the forefront reporting mechanism for human genome researching while also providing IOGER the potential to raise funds to further develop genome research infrastructure.

The goal of IOGER would be to implement the regulations decided upon in the international treaty. IOGER would help promote safe and ethical human genome experimentation through an accreditation process and would incentive scientists to work within IOGER's ethical boundaries by providing a platform to present their studies. A journal and national summit ran by IOGER would report the newest human genome editing advances while also providing a source for IOGER to fundraise money to help develop genome experiment infrastructure.

### C. WADA Should Look Towards Implementing Genome Screening by the 2028 Olympics

The most effective procedure in combatting gene doping appears to be the detection method which monitors athlete's genomes. IOGER could help WADA maintain athlete genome records, as the new organization would be equipped to handle this issue. Although the detection method might raise issues related to genetic information, privacy, and discrimination, it is the most effective and realistic modern detection method for gene doping.

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188. It was at the Second International Summit on Human Genome Editing in Hong-Kong where Jiankui presented his controversial experiment. *Scientist Fails to Satisfy Critics*, *supra* note 69; *International Summit on Human Gene Editing*, NAT'L ACADS. OF SCIS. ENG'G MED., <https://www.nationalacademies.org/our-work/international-summit-on-human-gene-editing> [<https://perma.cc/J6AC-CX4Y>].

WADA should look to implement a gene monitoring requirement as soon as possible before gene doping becomes more of a reality to guarantee at least some records of un-edited athlete genomes.

WADA should work with IOGER to maintain athletes' genetic information. IOGER would implement an international registry for Olympic athlete genome monitoring purposes, but this is another type of registry that would not be viewable to the general public so to maintain athlete genetic privacy. WADA would receive athlete samples before international sporting events, like the Olympics, and they would then archive the information with IOGER. By the next time a tested athlete participates in an international sporting event, WADA would be able to compare the athlete's previous genome with new samples from the athlete.

This type of testing would ensure that WADA does not create laboratory standards for genetic markers related to athletic performance, as that type of genome regulation could possibly see genetic discrimination liability. WADA would only be looking for changes within an athlete's genetic code. It is important for this genome requirement to be added to WADA's Athlete Biological Passport soon so "clean" athlete genomes can be sequenced before gene doping is attempted by an athlete. This method will not work if the first sample collected by an athlete is already tainted by gene doping. Scientist Lee Sweeney has stated:

If you are good enough in designing the gene doping, you may mimic what the body normally does. Unless you longitudinally follow a person and have enough early pre-doping data on them, you may not recognize that the person is anything out of the ordinary other than a highly talented athlete.<sup>189</sup>

The current state of gene doping makes this detection method effective, but additional detection tests will be necessary as gene doping technology advances.

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189. Filipp, *supra* note 42, at 434.



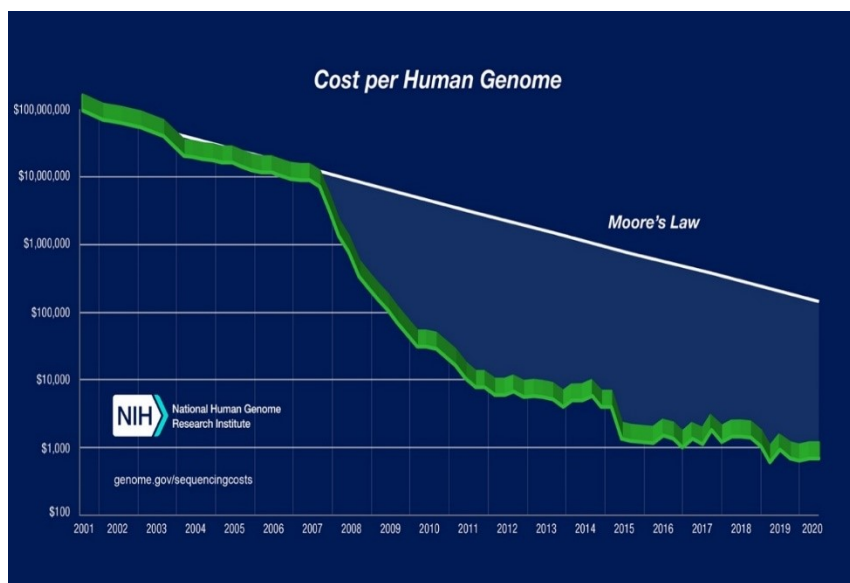


Figure 1: Cost Per Genome Data<sup>190</sup>

WADA has previously considered sequencing athletes' genomes but ultimately decided against it due to the cost of genome sequencing at the time.<sup>191</sup> However, the price to sequence a genome has been dropping every year, as illustrated in Figure 1. Although Figure 1 is a good visualization of the drop in cost over time of sequencing a human genome, it is not an accurate representation of large-scale application of this technology as there are additional costs not included in the cost presented in Figure 1.<sup>192</sup>

190. Kris A. Wetterstrand, *The Cost of Sequencing a Human Genome*, NAT'L HUM. GENOME RSCH. INST. (Dec. 7, 2020), <https://www.genome.gov/about-genomics/fact-sheets/Sequencing-Human-Genome-cost#:~:text=The%20estimated%20cost%20for%20advancing,sequence%20is%20~%24150%20million%20worldwide> [https://perma.cc/Z8J9-D9FU].

191. Niiler, *supra* note 56.

192. Wetterstrand, *supra* note 190 ("These data, however, do not capture all of the costs associated with the NHGRI Large-Scale Genome Sequencing Program. The sequencing centers perform a number of additional activities whose costs are not appropriate to include when calculating costs for production-oriented DNA sequencing.").

Even if sequencing athletes is a costly endeavor, it is surely worth it. Beginning sequencing in 2028 would give WADA enough time to determine the logistics of large-scale application. This might seem like a daunting task for WADA to achieve alone, but collaboration with IOGER would make this task much easier. IOGER would help develop the infrastructure of research centers and sample storage using the funds generated by their international journal and summit, while WADA would collect the samples and process the results. WADA does not have many other options for detection as their other methods are not yet ready to be implemented on a massive scale.<sup>193</sup>

Another issue is how much of an athlete's genome should be sequenced: just the portions related to improvement of athletic performance or the entire genome? The answer to this question will likely be based on the logistical capacity of WADA and IOGER. By sequencing the entire genome of an athlete, WADA and IOGER would have the most information to observe and compare with. While several genes that relate to athletic performance have been identified,<sup>194</sup> there can still exist other unknown enhancement genes. Some genes might work in conjunction with other genes to improve athletic performance. The more information that WADA can collect and observe, the higher the chances they would be able to detect gene doping.

Although collecting larger portions of genomes would make more forms of gene doping detectable, WADA's "gene passport" program should focus on collecting information known to be related to athletic performance. Genetic privacy issues could possibly arise if WADA attempted to sequence portions of the genome that have no relation to athletic performance. Other than the genetic privacy issues, sequencing a whole genome would require more work and would be more costly. It is a realistic goal for WADA and IOGER to identify the genes most closely tied to athletic performance and to then develop a system of monitoring these genes with athletes.

#### *D. Punishment for Violations*

The proposed treaty discussed in this paper should impose civil liability in the form of fines, at the very least, to those who violate the regulations. These fines would be reflective of the type of genome technology being used with human germline experiments resulting in the highest fines. Civil liability would provide for an international "floor" for human genome regulations; national legislatures can develop their own criminal penalties based off their constituents' ethical views of genome editing.

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193. De Boer, *supra* note 62, at 345.

194. Wenner, *supra* note 38; Franks, *supra* note 43; Wang, *supra* note 50.

It would be reasonable for other nations to adopt civil liability for unethical human genome experiments as China has already done.<sup>195</sup> This treaty, if adopted by its signatories, would allow nations to fine those who ignore or break the international regulations. These fines would make more scientists respect the regulations as there would be a fiscal penalty for not following the standards set in the treaty. Should a nation decide that a particular form of human genome manipulation calls for criminal liability, they are free to implement additional regulations through their national legislature. The goal of this international agreement would be to set international bioethical standards for human genome technologies; any nations that wish to implement even stricter regulations are free to do so.

On top of civil liability, violations could also result in a “blacklist” ban that would prevent scientists from working with human genome technology. IOGER could maintain a “blacklist” for scientists who apply genome technology in especially dangerous or unethical ways. Blacklisted scientists would be prevented from receiving any licensing for subsequent human genome experiments and would not be allowed to perform any research at specially licensed human genome research centers. Blacklisted scientists would also not be able to publish any of their findings in the IOGER scientific journal, nor would they be allowed to present at the IOGER International Summit on Human Gene Editing. These punishments, along with civil fines and possible criminal liability depending on national legislation where the experiment is performed, would likely be enough to persuade researchers to follow the international guidelines.

While creating a punishment “floor” is important, it is more important to promote safe testing and safe use of this technology. By promoting testing reviewed through an ethical checklist, the concerns surrounding the safe application of gene therapy can be alleviated. Once gene therapy has made substantial progress towards becoming a truly safe and ethical practice, it would be comparable to other medical procedures, like LASIK eye surgery. By keeping the organizational focus on preventative actions rather than retributive justice through harsh punishments, harm can be prevented and there is less likely to be a negative effect on future research.<sup>196</sup>

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195. Zhonghua Renmin Gongheguo Minfa Dian (中华人民共和国民法典) [Civil Code of the People's Republic of China] (promulgated by the Nat'l People's Cong., May 28, 2020, effective Jan. 1, 2021), arts. 995, 1009, P.R.C. LAWS.

196. See *CRISPR-Baby Prison Sentences*, *supra* note 66.

### *E. Regulations Reflecting Future Perspectives*

Regulations agreed upon in the international treaty must be subject to subsequent amendments to reflect changing public opinion. Gene editing technology has great potential to address many untreatable medical illnesses; improper regulations not subject to change would only prevent this technology from reaching its full potential. None of the regulations should deal in absolutes and the regulations should be subject to change at subsequent conventions.

Although there is a current gene doping ban, future applications of genome technology might not clearly fall in-between the spectrum of “therapeutic use” vs “non-therapeutic” use. Sports medicine, a field that could benefit from the application of safe gene therapy, is an example of this grey area. Bioethicist Andy Miah explains, “[g]enetics offers the possibility of allowing us to both repair but also enhance by using elements that are already within our bodies.”<sup>197</sup> How can a “therapeutic use” line be drawn if gene edits have both therapeutic and performance enhancement properties? This is an issue that WADA will face with its current gene doping definition as gene therapy continues to progress. Several of the current methods of possible gene doping were experiments that had therapeutic value.<sup>198</sup> Lee Sweeney has stated, “I think it’s unethical to withhold from someone something that would actually allow their muscles to be much healthier now and in the future.”<sup>199</sup> The ban on gene doping is proper right now, but it should be subject to change in the future to reflect changing technological progress and changing public opinion.

Every fifteen-years, the convention should reconvene to decide if any regulations should be changed. Gene technology raises plenty of ethical issues, but future technological advances and societal progress might alleviate these issues. Gene editing techniques will continue to evolve; previously unthought of applications might raise new regulatory questions. It would be improper to set strict, unmalleable regulations on this new evolving technology. By requiring future meetings and continued conversation on this topic, IOGER would ensure that international regulations will stay up to date. This would make the regulations flexible enough to change with public opinion and with changing gene editing techniques.

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197. Nick Busca, *Should Athletes Be Allowed to Enhance Their Genes?*, ONEZERO (Apr. 25, 2019), <https://onezero.medium.com/should-athletes-be-allowed-to-enhance-their-genes-c242dd007fa5> [<https://perma.cc/J53E-W58B>].

198. Wenner, *supra* note 38; Franks, *supra* note 43; Wang, *supra* note 50.

199. Le Page, *supra* note 169.

## VI. CONCLUSION

Gene doping, in its current iteration, is not safe and thus needs to be regulated. WADA's ban of gene doping was a first step to address this issue, but a clearer and more nuanced approach must be taken with gene technology. The unique pressure of international sports increases the possibility that an athlete may eventually attempt this form of doping. Genetic technology does not just impact international sports, so regulations should be reflective of all the stakeholders involved in this issue. Clear international standards can prevent future scandals in a way that also promotes the safe and ethical progression of gene technologies. Ultimately, gene doping needs clear regulations now while gene therapy techniques are still considered dangerous, however, these regulations cannot be so harsh as to limit the future potential of gene technologies.

As gene therapy continues to advance, it should be monitored how international law advances with it. More research into genetic privacy law, both at the international and national level, would be another area of interest to analyze as gene editing evolves. More attention on human gene technology will make people realize that time is not a luxury; human gene editing will become a common scientific practice within the next 50 years and the right regulations can create a positive future for this technology.

Society should not be fearful of the future of gene therapy. Instead, the world should be excited for its potential. The desire for agencies and governments to regulate this evolving field is understandable; gene therapy is a powerful technology that could have devastating generational effects if incorrectly used. While the consequences of failure are substantial, the possible beneficial applications of this technology are equally considerable. If it turns out that there are no safe gene editing technologies, then all forms of gene therapy should be banned. If gene therapy can be performed in a safe and ethical manner, then current regulations should be adjusted to reflect the public opinion. Gene doping could allow displays of athletic dominance reserved only to generational talents, and it could even have the potential to help athletes recover from serious injuries quicker. Genome technologies could advance sports medicine, and the world, to unbelievable heights.

