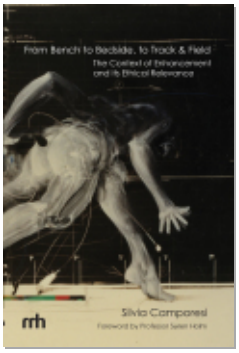
Chapter 4: Shifting the debate on enhancements from the ethical to the political level



Published by

Camporesi, Silvia.
From Bench to Bedside, to Track and Field: The Context of Enhancement and Its Ethical Relevance.

University of California Health Humanities Press, 2014.
Project MUSE. https://muse.jhu.edu/book/124666.

Chapter 4

Shifting the debate on enhancements from the ethical to the political level

4.1 A proposal to alter the payoff matrix in professional sports: shifting the burden of proof of doping to sponsors

It is a matter of fact that professional athletes often discount their future health in exchange for desired enhanced performances.[1] Some recent examples include Kobe Bryant of the Los Angeles Lakers, who publicly challenged teammate Dwight Howard to play through a torn labrum in his shoulder: "We don't have time for [Howard's shoulder] to heal," said Bryant (MacMullan 2013). In another example from the United States, National Football League athletes continue to play through concussions and head trauma, leading to long-term brain damage that has been linked to chronic traumatic encephalopathy (permanent brain damage associated with early-onset dementia), with disastrous consequences for the life of the footballer after his career. (Schwarz 2009; Kotz 2012) Professional athletes also discount their future health by engaging in doping behaviours. Commenting upon the recent doping scandals of Jamaican track & field athletes (Asafa Powell, Sherone Simson and three other world-class sprinters tested positive for the banned substance Oxylofrine in the summer of 2013), Dr Paul Wright, a senior drug tester with the Jamaican Anti-Doping Commission (JADCO), said in an interview to the BBC that the

1 This section and the next one first appeared in a longer version for *Reflective Practice* 2014, volume 15, issue 1, co-authored with James A. Knuckles with title "Shifting the burden of proof in doping: lessons from environmental sustainability applied to highperformance sport" and doi: 10.1080/14623943.2013.86920

scandals represented only "the tip of the iceberg." (Bond 2013) Wright added that since these tests occurred in competition, the athletes knew "months before" when and where they would be tested, leading Wright to infer that many more athletes must be planning their doping around competitions so as not to get caught. (Bond 2013)

Cases like these abound because high-performance athletes are focused more on their athletic achievements now than their future health status. They adopt therefore a "win at all costs attitude" as described by Krumer and co-authors (2011) that discounts future health for current athletic success. This becomes the middle step in a three-rung ladder towards doping, where money from sponsors based on records, recognition, and victories, leads to a win-at-all-cost mentality, which in turn leads to strong incentives for athletes to dope. Therefore, a vicious link between money and doping aimed at a constant improvement of performances takes place, with the consequence that professional sport may not be sustainable as a practice, both because athletes harm themselves by engaging in doping practices, and because uncoupling money from increased competition and quest for records and recognition is unlikely to happen under the current system.

How to alter this "discounting"? One solution might be to lift the ban on doping, and redefine it in a medical context. Indeed, this solution was recently presented by several authors, including Miah (2006), Savulescu, Foddy and Clayton (2004), and Savulescu (2013). As shown by Holm (2007) though (see discussion below), even if the ban on doping were to be lifted and doping were to be placed under "medical control," athletes would still have incentives to dope clandestinely, and a two-tiered system of doping would ensue. How to escape this seeming "Catch-22"? Here we propose an alternative way to alter the practice of high-performance athletes discounting their future health for current performance, without engaging in doping under a medical context, by shifting the burden of proof from the regulator and athlete to the private sector (i.e. sponsors), as well as providing the right incentives in the form of penalties to the sponsors for athletes found positive. In order to do so, we learn from similar discussions in the sustainability field, where it has long been proposed to shift the burden of proof of damaging the environment from regulators to the private sector.

Altering the discounting of the future health of professional athletes

Krumer et al. (2011) conducted a survey among professional athletes to measure subjective time discounting. Their sample included 74 professional Israeli athletes from different sports and 70 non-athletes in the control. The survey asked participants to indicate how much they would be willing to pay now in order to postpone a future payment (e.g., pay $10 now to postpone a $20 debt), and how much they would be willing to receive now in lieu of receiving a payment in the future (e.g., receive $10 now instead of $15 next month) (Krumer, Shavit, and Rosenboim 2011). As expected, the results suggested that "athletes discounted time more heavily than non-athletes" (i.e., the athletes more strongly preferred access to money in the present than non-athletes). The authors argue convincingly that athletes' time preference is affected by their sport orientation and a "win at all costs attitude." Waldron and Krane (2005) have also described the adoption of what they refer to as "whatever it takes" attitude in female professional athletes, who increasingly engage in health compromising behaviours such as playing when injured, sacrificing their bodies, and overtraining. Waldron and Krane write that "while the mind focuses on winning at any costs, the body can be compromised for the good of the cause" (Waldron and Krane 2005, 320), and describe how athletes endorse hiding pain and injury through an attitude of "irreverence" which can be, and very often is, very detrimental to the future health of the athlete.

Gymnastics offers one famous example: Kerri Strug, the US gymnast who vaulted through a sprained ankle to ensure the US gold medal in the 1996 Olympics. (Weinberg 2004) While her desire to push her body beyond its limits was not likely a result of her hoping it would land her a large endorsement contract, the sponsor endorsements that followed as a result of her bravery (in fact, after the 1996 Olympics, General Mills corporation featured her on the front of the Wheaties cereal box, and Strug received additional sponsorship from Visa corporation and others) did send a strong message to other athletes: if you push through pain, and become a hero, you will win a large sponsorship contract. An article written in the Chicago Tribune in 1996 aptly captured this sentiment:

> Even Nike, the quasi-spiritual sportswear monster, praises pain in a commercial that flashes images of boxers with bloodied faces, runners falling and grimacing, and some sorry competitor vomiting. Just do it. No pain, no gain. Whatever it takes. What does not kill me makes me stronger. (Gregory 1996)

Gymnastics may in fact be one of the sports where the win-at-all-costs attitude is most widespread in very young female athletes, who are often subjected to tortuous professional-style training when they are toddlers (Cintado 2007; Giordano 2010). In China, for example, Nanning Gymnasium Camp was recently featured by the UK Daily Mail magazine which portrayed harrowing pictures of toddlers crying for pain while being subjected to strenuous sessions that border on psychological and physical torture. (Blake 2012) Nanning Camp is not an isolated example but one of many training camps where children no older than 5 or 6 years old are sent by their parents to "learn to become champions" from an early age in preparation for the Olympics. (Blake 2012) More recently, these camps have been coupled to genetic tests to scout out children's talents, as described in the previous chapter. These examples clearly illustrate instances of professional athletes sacrificing tomorrow's health for today's victory.

As a result of this win-at-all-costs mentality, many athletes turn to doping to gain a competitive edge in their sport. One solution that has been proposed in this context might be to lift the ban on doping. For one example, see Foddy, Savulescu and Clayton, who argue that doping is not contrary to the spirit of sport, (Savulescu, Foddy, and Clayton 2004; Savulescu 2013) or Andy Miah, who argues that a pro-doping culture will not only be inevitable in the future of increasingly technological sports at the elite level, but that it is also an essential part of what we value in sport (and of why we are interested in it), i.e., pushing humanity to its limits and beyond. (Miah 2006) Commenting in the press on the recent doping scandals of American sprinter Tyson Gay and Jamaican sprinters Asafa Powell and Sherone Simpson, Savulescu has argued that:

> To keep improving, to keep beating records, to continue to train at the peak of fitness, to recover from the injury that training inflicts, we need enhanced

> physiology. Spectators want faster times and broken records, so do athletes. But we have exhausted the human potential. Is it wrong to aim for zero tolerance and performances that are within natural human limits? No, but it is not enforceable (Savulescu 2013)

Savulescu therefore proposes to legalise doping, or to put doping "under medical control." This type of solution has been addressed and refuted by Holm (2007). Holm spells out the two possible scenarios that would take place were a ban on doping to be lifted. In the first scenario, athletes have access to data on the effectiveness and side effects of the performance enhancing substances; while in the second scenario athletes get impartial advice from the sports doctor about when and how to dope. (Holm 2007) Importantly, Holm argues that in both scenarios, athletes would still have incentives to cheat, and a two-tiered system of doping (under a medical context and of secretive doping) would ensue. Athletes have strong incentives to keep doping practices secretive in order to maintain an exclusive use on a drug, and therefore a competitive advantage over fellow athletes. Holm identifies these incentives as an instance of a "take and hide" option that dominates other options in a Prisoner's Dilemma-style coordination game, the other options being not doping or doping and being open about it. In addition, as Holm points out, more often than not, the athlete's income is controlled by his/her employer (e.g. team and, ultimately, sponsor), and the degree of control that the athlete has over the decision to play/to compete is often limited. For these reasons, Holm describes how it is not lifting the ban on doping that will incentivize athletes to stop doping, but changing the "payoff matrix," characterised by high financial rewards for current athletic success. (Holm 2007, 139) In the next section we describe tools from the sustainability field that could be very useful when applied to the field of professional sport to change the payoff matrix, and therefore to alter the practice of athletes discounting their future health.

4.2 What can high-performance sports learn from the field of environmental sustainability?

In the sustainability field, we can draw parallels to each of the three elements of our argument outlined above: setting the principle, levying penalties, and

enforcing the regulations. Regarding the first element, it has long been argued that the burden of proof in cases of damages to the environment should not be on the relevant regulatory agency or local community, but instead should be on the entities whose actions might cause environmental damage. This concept of shifting the burden of proof has its roots in Principle 15 of the Rio Declaration, set forth at the United Nations Conference on Environment and Development in Rio de Janeiro, Brazil, in 1992. (United Nations 1992) Often referred to as the Precautionary Principle, it was first proposed as:

> In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation. (UN 1992)

More recent forms of the precautionary principle now often include a statement on burden of proof. This addition was brought to the forefront of international sustainability governance in 1997 with a high-level workshop in Lisbon, Portugal commissioned by the Independent World Commission on the Oceans and subsequent article in which the now famous principles for governing the world's oceans in a sustainable way was published. Known as the Lisbon Principles of Sustainable Governance, the third principle states:

> In the face of uncertainty about potentially irreversible environmental impacts, decisions concerning their use should err on the side of caution. *The burden of proof should shift to those whose activities potentially damage the environment.* [emphasis added] (Costanza et al. 1998)

The crux of this statement rests in its call for any entity whose actions could potentially damage the oceans to prove before and during the action that they are not doing any damage. Turning to the second element of our argument – penalties – we see that the Lisbon Principles do not mention penalties (or enforcement, which we address below). Yet other scholars have argued that the penalties for environmental damage should be proportional to the damages that are caused and should be imposed on the entity responsible for the

damage. Segerson and Tietenberg (1992) analysed penalties for environmental infractions, and conclude first that fines are preferable to incarceration because "the social costs associated with incarceration are so much higher." (Segerson and Tietenberg 1992, 180) They then conclude that "a fine should be imposed on each party [that damages the environment] in an amount equal to the damages that result from its actions." (Segerson and Tietenberg 1992, 181) Finally, they find that fines should be levied against the organization and not the individual, primarily because events that lead to environmental damage are usually the result of a complex chain of actions and responsibilities within the organization (Segerson and Tietenberg 1992).

In practice, however, while penalties – and liability – might fall on the organization and generally favour financial penalties over incarceration, it is difficult if not impossible to set the penalty at a level equal to the costs of the damage. First, limits on total liability for a company enshrined in law can prevent regulatory agencies from seeking penalties that match the costs of the damages. For example, the Canadian government limits "absolute liability" for offshore oil and gas drilling companies to CA$ 1 billion (for comparison, 2010 estimates of the BP oil spill in the Gulf of Mexico put the cost at around US$ 40 billion). (Wearden 2010; Rozmus 2013) Second, it can be very difficult to calculate the total costs of a particular damaging event or action, particularly because calculating economic costs of environmental damage is difficult and imprecise. Using the BP oil spill as an example again, a panel of experts has recently concluded that the United States government, after extensive research and countless studies, has still failed to determine the true costs of the disaster because it incorrectly and incompletely accounted for the economic costs of the loss of environmental services as a result of the oil spill. (National Research Council 2013)

As to the question of enforcement – enforcing penalties, conducting testing and monitoring, and taking regulatory action – a recent example comes from the US chemical industry. In their 2009 paper, Schwarzman and Wilson state:

> Given the size of the chemical enterprise, the extent to which it is woven into the fabric of society, and the backlog of unexamined chemicals, a new approach is needed that does not rely on resource-intensive, chemical-bio-

> chemical risk assessments in which government, at great public expense, bears the burden of proof. (Wilson and Schwarzman 2009, 1202)

This "new approach" is characterized by requiring chemical companies to prove their chemicals are safe, rather than waiting for the regulator to test each chemical. Addressing the issue of enforcement, Wilson and Schwarzman (2009) argue that because the US regulator – in this case, the Environmental Protection Agency – currently bears the full burden of proving whether or not a chemical causes environmental (or health) harm, it must obtain a high-level of certainty that the chemical is causing harm before setting its machinations in motion to take regulatory action against the chemical company. Furthermore, the chemical companies keep secret as much information on their chemicals as possible, and are known to either withhold information or create misleading information, causing the regulatory agency to doubt whether it has sufficient grounds to take regulatory action. (Wilson and Schwarzman 2009) In industries like the chemical manufacturing industry, where the very activities that drive profit can cause environmental harm, only the private sector has the capacity, information, and resources necessary to conduct adequate testing required to prove that their actions are not causing environmental damage. Enforcement – and imposing fines for noncompliance – is still the responsibility of the regulator, however, and the regulator needs to maintain its own testing in order to fully enforce its policies and effectively shift the burden of proof onto the private sector.

After more than twenty years of discussions around shifting the burden of proof away from regulators, it seems therefore that the current system in the field of sustainability is advancing slowly towards a higher degree of accountability of the companies for the consequences of their actions on the environment. Still, in the majority of cases when a company damages the environment, the burden of proof remains on the damaged region/community and relevant regulator to show that it was the company's fault. The process has been especially slow in the oil and gas industry, whose normal business operations can result in environmental harm. Companies in this industry therefore will strongly resist efforts to require them to prove that their actions are not damaging the environment, and in most cases, it remains the responsibility of the local authorities and regulatory agency to detect and

prove environmental damage.

In the examples above that describe shifting burdens of proof away from regulators and onto entities whose actions might damage the environment, we see that setting the general principle of identifying a level of penalty (e.g., equal to the damages that a chemical spill caused) is relatively straightforward. However, actually calculating that penalty (e.g., it may be easy to calculate the immediate clean up cost, but what about long-term effects like increased cancer risk or biodiversity loss?), or being legally allowed to impose the full amount, as well as enforcing regulations, has proven difficult in the sustainability field. As we will see below, these difficulties also carry over to the field of professional sports.

We can now draw some important lessons from the sustainability field and apply them to the professional sport context. First, the burden of proof principle can be translated to the sports context as the following: the burden of proof should shift to those whose activities may lead to doping in athletic competitions. We can also see that it is important to shift the burden of proof to the entities with the resources available to conduct case-by-case monitoring and testing (e.g., the chemical companies in the example above, and not the US EPA). Given these two lessons learned, and the link between sponsorship and doping that we highlight earlier, we argue that the burden of proof should be shifted to the companies that sponsor professional athletes. It should be the sponsors' responsibility to prove that each athlete they sponsor is "clean" before they sponsor him or her, and throughout the sponsorship contract.

Second, we see from the environmental sustainability examples that setting penalties on the organization and not the individual is preferable, as are financial penalties as opposed to incarceration. We argue similarly for the high-performance sports context: penalties should be imposed on the sponsoring organizations, and not on the specific individuals in the organizations responsible for the contract with the athlete who is found to be doping. The entity of the penalty should not be based on the costs of the damage caused by doping, but instead on amounts that would significantly impact the sponsoring company's financials (e.g., a percentage of the previous year's earnings), and without a maximum cap. Calculating a penalty based on publicly available financial data for the sponsoring companies is significantly easier (and less disputable) than calculating a penalty based on the social,

economic, and health costs of doping.

Third, we argue for WADA's continued enforcement of its anti-doping policies, with strengthened testing capabilities and research into doping methods and technologies, in addition to what it already does.[2] Strengthening its testing and research capacity and capabilities is important because if WADA finds that an athlete has been doping, it levies the penalty on the sponsoring companies irrespective of any test results that the sponsoring companies provide to WADA. WADA's testing determines whether an athlete has been doping, not the sponsors' testing; therefore, WADA's tests set the *de facto* testing standard for the sponsorship companies. The sponsors will undoubtedly conduct their own testing to verify that their athletes are clean, but if a WADA-initiated test finds that an athlete has been doping, the WADA test overrides any tests that the sponsor conducted.

Conversely, in the current system in professional sport, when an athlete turns out positive for doping, the sponsors dump her/him (and often sue him/her), while all along they had been closing one or both eyes to the practice of doping because they had an interest in the athlete continuing to win. The athlete suffers tremendously – in both financial, social and potentially health-related costs – and the sport as a whole suffers a tarnished reputation. The sponsors' images may be similarly tarnished, but usually for a much briefer time period, and at a far lower cost relative to their overall financial position. Yet, it was the sponsors' collective money that essentially paid for the athlete's doping, and created a win-at-all-costs mentality in the sport. Recent examples include Lance Armstrong and professional cycling illustrated below, several prominent athletes in the US Major League Baseball Association, (McLean 2013) and Marion Jones as a Track & Field star. (CNN Associated Press 2007)

Let us take a closer look at Lance Armstrong's case, for example. Lance has been one of the most successful, if not the most successful, road cyclist in modern history, winning the Tour de France seven consecutive times between 1999 and 2005, achieving an all-time record which has now been revoked as he was disqualified and banned for life from competition by United States

2 The full list of up-to-date WADA-funded research projects can be found here: http://www.wada-ama.org/en/science-medicine/research/funded-research-projects/ [accessed July 18, 2014]

Anti-Doping Agency (USADA) in 2012. After years of denials and lawsuits against those who accused him of doping, Lance admitted publicly to doping in January 2013, in an interview on television conducted by Oprah Winfrey (Winfrey 2013). The now "disgraced" Lance Armstrong faces a plethora of lawsuits: the Sunday Times, which Armstrong had previously sued in 2006 for alleging he was doping (The Guardian Associated Press 2013); the US Justice Department for the US$ 40 million that the US Postal Service spent to sponsor Lance's cycling team from 1998 to 2004 (Frieden 2013); and a group of discontented readers in California for false memoirs which were sold as non-fiction (yes, that is true). (Bury 2013) While we will not comment on the other lawsuits here as they fall outside the direct scope of this paper, we would contend that it seems unlikely that the US Postal Service was completely unaware of Armstrong's doping, or at least they remained purposefully unaware by not conducting their own testing. In this way, one could argue that the USPS was in some ways complicit in the doping activities (and indeed benefited financially from them), and therefore the current lawsuit seems to a certain extent to be hypocritical. In our proposed approach, the USPS, as one of Armstrong's primary sponsors, would be responsible for his doping actions and as we explain below there could be a contract between athlete and sponsor preventing the sponsor from suing the athlete.

To recapitulate, we argue that the athlete's sponsoring organisations should become accountable for their athletes' actions, and take on the burden of proving that the athlete is not doping prior to and while sponsoring that athlete. In addition, the penalties for doping should not fall on the athlete and his/her team and doctors, but instead should fall solely on the athlete's sponsors. The penalties should also be severe enough to have a significant impact on the financial operations of the sponsoring organizations. Finally, we argue that WADA should still be responsible for its own testing for doping and enforcement of penalties. In this way, the payoff matrix that leads to sponsors unwittingly (or otherwise) sponsoring an athlete that uses illegal performance enhancing drugs ceases to hold sway over professional sports, and consequently, athletes would no longer have strong financial incentives to discount their future health in exchange for current improvements in performance.

Of course, we recognize that this shift in the burden of proof would not be easy to implement in practice. In particular, we identify three possible

criticisms:

1) Many of the details of how this policy would be enforced remain unaddressed, including how often WADA conducts tests on athletes and whether these are planned or surprise tests, how often WADA updates its testing standards and whether it shares these standards with the sponsorship industry, and how multiple sponsors of the same athlete would conduct testing and how penalties would be assessed if their shared athlete was found to be doping.

2) This policy would seem to offer sponsorship companies even stronger reasons than those they currently have to sue any of their athletes found by WADA to be doping. The sponsorship company might argue, for example, that it cannot possibly monitor its athletes 24 hours per day, 365 days per year, and it had, to the best of its ability, monitored and tested the athlete who was now found to be doping. The sponsor would then argue that the athlete engaged in doping on his or her own accord, despite the sponsor's efforts to prevent doping, and the athlete is therefore at fault.

3) Sponsorship money enables professional sports to exist and be shared by millions of enthusiasts around the globe. Without sponsorship money, there would be no professional sport industry as we know it (and enjoy it) today.

We recognize the validity of the first criticism, and leave it open for discussion of possible solutions. Indeed, implementing this proposed approach would be complex, as it represents a major change to the status quo. The elements related to enforcement and testing that we mention are likely to be some of the more difficult and contentious implementation aspects of the proposed shift. As to the second possible criticism, since the sponsors would be held responsible for the actions of their athletes under the approach we propose, we suggest that the athlete-sponsor contract could be written to prevent such lawsuits, but this criticism remains open for further reflection, as some may want to argue that the athlete should be held at least co-responsible together with the sponsor for his/her actions, under the assumption that she/he is an autonomous subject making autonomous decisions. We would like to resist this solution of co-responsibility, though; as we and others have identified elsewhere, (King and Robeson 2007; King and Robeson 2013; Camporesi and McNamee 2014) athletes are often vulnerable subjects who find them-

selves at the centre of a payoff matrix which makes autonomous decisions very difficult if not impossible. We argue that the only way to break this payoff matrix leading to a "win at all costs attitude" and to incentives to doping is to hold only the sponsors responsible for the actions of their sponsored athletes.

Finally, while we are aware of the possibility that sponsors might withdraw significant money from the field of professional sport and of the consequences that such a withdrawal would have on the existence itself of professional sports, we think most sponsors would remain engaged in professional sport. The financial gains of product promotion would likely outweigh the costs of testing their athletes and being held accountable for their athletes' actions. In addition, sponsorship companies are already negatively affected by doping, (Straubel 2002) and therefore we think that they may be inclined to take up this idea if the proper international policy regime – including enforcement, testing, penalties, and positive incentives – were in place.

To conclude, the fields of sustainability and professional sport likely have much to gain from insightful comparisons, as both need to develop ethics and policy tools to alter the discounting of future good health (of the athlete, of the planet) in exchange for shorter-term returns (fame, sponsorship money, victory, economic gains). Currently, both athletes and the environment are being damaged as a result of a systematic, institutionalised payoff matrix that privileges shorter term gains over longer-term sustainability. The argument to shift the burden of proof that we propose here is a way to promote the long-term sustainability of professional sport by removing a key incentive for doping, and it draws on lessons learned from over twenty years of similar discussions in the environmental sustainability field. We can only hope that professional sport as an industry might succeed where environmental sustainability has up to now largely failed, and do so at a much quicker pace.

4.3 The case for research on enhancements

In this section I tackle the broader question of an ethical justification for research on enhancement or enhancement research (hence, ER). This question is surprisingly neglected in the bioethics literature on enhancement, as the leading critics of biomedical enhancement [Kass, Habermas, Annas, Fuku-

yama] have not addressed it directly. However, their statements against enhancement strongly suggest that research and development of enhancements would also be considered unethical from their point of view, on the basis of the argument that ER would promote an unethical practice, and should therefore be banned. However, I do not think that just because particular technologies aimed at enhancing human capacities are deemed to be not ethically permissible in a certain context, research on enhancement *per se* is also not ethically permissible. In this section I would like to start from this a reflection on the justifiability of ER in society.

To the best of my knowledge, the only authors that have raised the point about the necessity to establish a framework for, and to regulate, ER are Lev and co-authors (2010). They write:

> As with other biomedical interventions, research to assess the safety and efficacy of these enhancements in humans should be conducted before their introduction into clinical practice. (Lev, Miller, and Emanuel 2010, 101)

This is what should happen, but not what happens in practice. There is no system in place to regulate ER, and very little – if any – discussion about it. If this is the situation, it is also obvious that there are no safety precautions for the individuals who want to take on pharmacological enhancements, as there are no regulated trials that spell out the possible risks and harms, and benefits. Should this not be case? Or at least, should there not be a case for it? What could be the ethical justification for ER?

Lev and co-authors seem to justify research on enhancements on the basis of a health-related value:

> Categorically condemning research on biomedical enhancements as unethical is unwarranted, since at least some research on biomedical enhancements is likely to produce significant health benefits. Indeed, under certain circumstances enhancement research would be urgent, as it would address major public health concerns. Therefore, a blanket prohibition on enhancement research is unjustified. (Lev, Miller, and Emanuel 2010, 102)

While I agree with them that "a blanket prohibition on enhancement research is unjustified," it is not immediately clear that ER ought to be justified by having health-related social value, even though there might be some cases of "dual use" biomedical interventions, or interventions that can be used both as treatments and as enhancements. (Miller and Selgelid 2007) In such cases any health-related social value can be seen as an added value rather than a prerequisite. In all other cases, while the health of the research participant should of course still remain a primary concern, research on performance enhancing substances should have as its first epistemic goal the validity and reliability of performance enhancement claims. Of course this epistemic goal should be circumscribed by an ethical one, and thus the evaluation of risks and benefits needs to be modified when shifting from the clinical to the enhancement context[3]. Precisely what counts as benefit and risk in enhancement research need not be identical to what counts as benefit and risk in clinical research.

What policies would need to be put in place to regulate ER? To the best of my knowledge, the only existing analysis of the type of regulations that would need to be implemented has been carried out by US law and bioethics scholar Hank Greely (2011). Greely reviews the policy tools available in the US, and shows how not necessarily new regulatory frameworks or systems would have to be invented, since existing regulations could accommodate biomedical enhancements. (Greely 2011) This would happen because:

> FDA regulation already covers enhancements. If a firm were to seek approval to sell a new drug for enhancement purposes, no new safety regulation would be needed in the United States. The company would have to conduct serious clinical trials and to demonstrate to the satisfaction of the FDA that the drug was safe and effective for the intended use. (Greely 2011, 510)

Greely proceeds then to identify two main issues that would need careful consideration to assure the safety of enhancements, namely the regulation of off-label use of pharmaceuticals for enhancement purposes, and possibly the increased regulation of dietary supplements. As it is plausible to speculate,

3 For this argument I am indebted to Mike J McNamee (see Camporesi and McNamee 2014).

many and probably the vast majority of biomedical enhancements would be approved to treat disease and used off-label as enhancements. The off-label practice of use for pharmaceuticals is already a widespread practice in the US, so from this point of view the introduction of enhancements would not be substantially new.

What is off-label use? In the US, after a drug's approval, the FDA works with the manufacturer to create a drug label that contains information about the drug, how it should be administered, and the indications for which it has been approved. Since the FDA itself does not regulate the practice of medicine, off-label use of FDA-approved drugs is a legal and common medical practice: after approval, a licensed doctor can use a drug for any indication he/she consider appropriate. (National Task Force on CME 2013) I find the widespread use of off-label drugs in the US very problematic from a scientific and ethical point of view, since patients can be prescribed drugs by doctors *without any evidential basis* that the drug works in a context different from the one for which it was tested in clinical trials. Greely seems to concur with me on this point when he writes that:

> Drugs can be approved as safe and effective for one use against one disease, based on clinical trial evidence, but then prescribed off-label for uses in people without that disease, or perhaps any disease, without any proof that the drug is either safe or effective for the prescribed use. (Greely 2011, 511)

Contrary to very strong libertarian thinking, I do not think that the current off-label system promotes autonomy by empowering the individual with freedom of choice (note that this is indeed the rhetoric underlying so many proponents of DTC advertising), but that the patient needs and deserves some protection from the market's free reign. While the "empowering freedom" argument could work in an ideal society, in practice the intricate financial ties between pharmaceutical companies, lobbies and politics in the US create markets where there is no legitimate demand, and lead to ethically problematic situations such as the case of prescriptions for Ritalin or Adderall for adults under the rubric of adult ADHD. (Wilens et al. 2008) For all these reasons, I do not think that the entry of enhancements in society through the "off-label" system would be desirable. It would be equivalent to entering society "through

the back door" – to borrow an expression from Buchanan (2011) – as they are now. Once again that would happen without the appropriate regulation and demonstration of effectiveness and risks/harm data, and without any transparency, or accountability.

Another issue that needs to be taken into account when reflecting on the regulation of access of enhancements in society is the necessity to tighten up regulations regarding dietary supplements. In the US, regulation of such supplements is minimal according to the Dietary Supplement Health and Education Act (DSHEA 1994), which defines the FDA's power to regulate them. The manufacturer neither has to prove that the supplements are safe, nor that they are effective, in order to get approval to enter the market. On the contrary, the burden of proof rests on the FDA to prove to a court that a supplement is unsafe in order to remove it from the market. (Greely 2011) The only requirement for the manufacturer is that "that product label information is truthful and not misleading," and even that minimum requirement is often not respected. As a way of illustration of this trend, consider "think Gum," a chewing gum marketed in the US as a dietary supplement as the "brain boosting chewing gum."[4] According to the product website,[5] the chewing gum improves memory by 25 %, as demonstrated by a "peer reviewed study" (of course, there are no data on the peer-reviewed study whatsoever). It is interesting to note how the motto for the gum is "stop cheating, start chewing," therefore going contra one of the commonly raised arguments against using enhancements, namely that they are a way of cheating! The system in place for regulation of dietary supplements in the US seems therefore to be a very fruitful terrain for attempts to fraud scientifically or medically naïve individuals, in another instance of the 'sciencexploitation' phenomenon described by Caulfield (2011) and applied in section 3.2 to direct-to-consumer genetic tests to scout out children's talents. (Caulfield 2011; Camporesi 2013)

Therefore, it is plausible to speculate that biomedical enhancements which are manufactured as pills could also reach the market, at least in the US, as dietary supplements, therefore evading completely the purview of FDA. Even if they were marketed as pharmaceuticals to treat diseases, though, we

4 For this example I am also indebted to Greely (2011)

5 [http://thinkgum.com /] [accessed, July 18, 2014]

have seen how they could still be used off-label without having to demonstrate either the safety or the efficacy for that particular use. The possibility that pharmacological enhancement could enter the market in this way seems to me particularly worrisome. Instead, I think that a much better – and more accountable – way for enhancements to gain entry to society would be to put in place a regulatory system for clinical research, and for prescription of performance-enhancing substances outside the current disease (including off-label prescriptions) model.

In the next section I attempt to lay the ground for the discussion of how to shift the debate on enhancement technologies from the ethical level to a policy level. See (Camporesi and McNamee 2014) for a detailed discussion of the need to regulate the introduction of performance enhancing technologies in professional sports, which at the moment amounts to "unregulated clinical research" as defined by King and Robeson (2007).

4.4 A deliberative democracy approach to deal with moral disagreement in the bioethical debate

Is the enhancement debate satisfactorily answered with a discussion carried out at the ethical level? I start answering this question by analysing the original perspective put forward by Häyry in his book, *Rationality and the genetic challenge*.[6] (Häyry 2010) Häyry analyses three ways to deal with what he considers the challenges posed by genetics to society, which he refers to heuristically as neoconsequentialism, neo-virtue ethics, and neo-deontology. (Häyry 2010) A genetic challenge is defined as a "set of questions raised by the engineering of political and medical solutions to the original threats posed by nonhuman and human nature" to which "we cannot readily agree on what our reactions should be and on what grounds." (Häyry 2010, 2) As the subtitle of the book suggests, genetic challenges are understood as possible ways to "make people better." Häyry provides an extensive overview of the state of the field by analyzing seven case studies, namely, preimplantation genetic diagnosis

6 This section is a slightly revised form of the first half of a paper originally published on *Cambridge Quarterly of Healthcare Ethics* (2011): 20(2), 248-257, and co-authored with Paolo Maugeri.

(PGD), the possibility to design children, savior siblings, reproductive cloning, embryonic stem cell research, gene therapies, and considerable life extension techniques. As depicted by Häyry – even though such labeling may not be correct, as John Coggon and John Harris have suggested (Coggon 2011; Harris 2011) – the first framework ("neo-consequentialism" or "rational tangibility") focuses on persons and how they value life and is represented in the works of John Harris and Jonathan Glover; the second ("neo-virtue ethics" or "moral transcendence") puts the emphasis on traditions and is exemplified by Michael Sandel and Leon Kass; and the third ("neo-deontology") focuses on principles, with Jürgen Habermas and Ronald Green given as examples. Each of these frameworks reaches very different conclusions in terms of the ethical acceptability of the genetic challenges presented above. Although the central part of Häyry's book is devoted to the description of the state of the art concerning the seven wonders (or sins) of genetics, the most innovative chapter is the second, where Häyry spells out his methodological approach and the aim of the book. Häyry's original contribution to the discussion is the claim that it is not possible to argue with philosophical tools which of the three frameworks is best for assessing the ethical justifiability of a new biotechnological practice, as the three approaches differ in the fundamental values and principles they employ. Häyry tests the internal coherence of each position, and concludes that it is not possible to assess the superiority of any position over another on philosophical grounds. In his words:

> If different approaches (or rationalities or methods of genethics) cannot be universally graded and put into order, as I am saying, then conflicting normative views cannot be put into one rational order, either, and we have no philosophical way of telling once and for all whether we should or should not engage in procreative selection, reproductive or therapeutic cloning, genetic engineering, or considerable life extension. (Häyry 2010, 238)

According to this perspective, all ethical principles and judgments have respectable support if they meet the criteria of internal consistency and if in each case the combination of principles and judgments is a stable balance from the author's point of view (a so-called reflective equipoise). (Häyry 2010, 50) But, if Häyry's arguments are correct and ethical theories cannot be pre-

ferred on rational grounds, what are we readers left to do with his polite bystander view? As Häyry himself puts it: "Do we have any role in genethics, if all this [the content of the book] is to be believed?" (Häyry 2010, 238) In the last pages of the book, he lays out the work for the philosophically informed readers, when he writes that there are at least 72 stances that could be critically examined by the philosopher, resulting from the multiplication of three viable methods of ethics, three normative strands, and eight topics. (Häyry 2010, 239) We do not think that focusing our attention on such a nonconfrontational experience would necessarily be an improvement over the actual state of the field and over the recognition of the existence of moral disagreement concerning questions raised by the genetic challenges. What should we do with Häyry's nonconfrontationalism then? Should we take it as a claim about diverse methods in ethics, or rather as an insightful plea to confront views at another, more appropriate level? We think that confrontational ethics is still important in many respects and that, if properly framed, can inform debates and, hopefully, help at reaching the right conclusions.

Moral disagreement in society will persist, no matter what philosophers may say. This, however, is not an indication of the fact that all views in the field of philosophical ethics are equivalent or incommensurable. Rather, it highlights how, in practice, we face a political problem. The pressing questions posed by genethics do not allow us simply to acknowledge that moral positions differ and then nonconfrontationally to concern ourselves with ironing out internal inconsistencies. Instead, they demand a shift in focus from classical philosophical ethics to the realm of political philosophy. Writes Häyry:

> Philosophical considerations can show that some arguments are flawed and others open to discussion, but they cannot prove to everybody's satisfaction the rightness or wrongness of selection, cloning, or new treatments. (Häyry 2010, 238)

In this passage Häyry is conflating two issues that should be kept distinct for analytical purposes. One issue is whether philosophical considerations, or arguments, can prove the rightness of anything at all. Quite another is whether they can prove it to everybody's satisfaction. The first is a question about moral relativism, the second one of political pluralism, that is, the claim that there

exist different, and sometimes hard to reconcile, values in society. Let us tackle the first problem first. If Häyry's main claim were about moral relativism, then there would be several ways to spell it out that he does not attempt in his book. For instance, why is it impossible to say that something, say one of the genetic challenges, is ethically justifiable or not? Is it because there is no such thing as objective moral truth? Or, more simply, is it that, even if objective morality existed, it would be unreachable by ethical thinking? Whereas the former would be an ontological claim, the latter would be an epistemological one. Häyry's position seems to be orthogonal to all these options. What he really seems to say is that there are different ways of doing ethics, none of them being illegitimate, at least as long as they are internally consistent and in some accordance with how things are in the world. As Coggon puts it, "a claim in support of simultaneous, non exclusive, yet competing rationality is a claim about the rightness of pluralism in ethics." (Coggon 2011, 50) Accepting Häyry's position may mean that each of the three methods he outlines has contradictory claims that cannot be undermined by other approaches, thus giving rise to irresolvable disagreement. For example, does the fact that Sandel/Kass-like conclusions are drawn by appeals to traditional values render them invulnerable to critiques by the rational tangibility approach of Harris and Glover and vice versa?

As for the second issue we mentioned, namely, political pluralism, the absence of agreement on a particular issue poses the question of how to reach a reasonable consensus, even if provisional or revisable, in the *polis*. People may maintain their private rationalities (or rational moralities) on the basis of philosophical arguments, but reasonable people may think that it is still worthwhile to reach a consensus in order to make decisions at the policy level. The question at stake, therefore, is not so much one of politeness (referring to the polite bystander view proposed by Häyry) but is one of indicating at what level each kind of rationality can effectively prove insightful and, as a consequence, at what level confrontations should take place.

The genetic challenges as described by Häyry are public questions requiring, ideally, public answers. It is in this regard that we do not see Häyry's "polite bystander" approach as exhaustive. Practical questions such as who should decide on ethical issues related to genetic technologies cannot be answered solely by reference to internally consistent rationalities. On the contrary, we

think that, by following the route indicated by Häyry, we run the risk of ending up with a cornucopia of ethical perspectives, each internally consistent but providing mere philosophical amusement. If genetic challenges are to be taken seriously, as concrete instances of moral disagreement in the real world, then certain real-world questions concerning whose interests are challenged and how these can reasonably be reconciled cannot be escaped or masked behind the polite facade of a nonconfrontational notion of rationality. At least three levels ought to be distinguished here:

> 1) the nonconfrontational philosophical level described by Häyry, which is useful for assessing the internal consistency of each ethical position;
> 2) the confrontational philosophical level, which takes into account other ethical perspectives (after they have been assessed for consistency with the first approach);
> 3) the decision-making political level, in which moral disagreement is dealt with in practice.

As an alternative to the polite bystander approach, we suggest that the problem of "everybody's satisfaction" could be better addressed by engaging the different ethical perspectives in a process of public reason giving in the spirit of deliberative democracy (DD), as defined by Gutmann and Thompson (Gutmann and Thompson 2004) and applied to genethics issues by Farrelly. (Farrelly 2009) On this view, "first-order" theories are ethical perspectives that seek to resolve moral disagreement by demonstrating that alternative theories and principles should be rejected. First-order theories "measure their success by whether they resolve the conflict consistently on their own term. Their aim is to be the single theory that resolves moral disagreement." (Gutmann and Thompson 2004, 126) In Häyry's book, first-order theories can be assimilated to the three ways he describes to deal with the genetic challenges. Whereas Häyry's polite bystander view claims that the validity of first-order theories should be assessed only internally and not confronting one theory with another, a fruitful way forward in the discussion of the genetic challenge is a second-order theory approach, which deals with the moral disagreement residual of first-order theories. DD seeks a resolution to the moral disagreement by adopting a dynamic conception of political justification, which is both morally

and politically provisional. (Gutmann and Thompson 2004, 132) Within this DD perspective, the resolution of first-order moral disagreement needs to respect the DD principles of reciprocity, publicity, and accountability and seeks a mutually binding (though provisional, therefore, at a specific time) decision, on the basis of mutually justifiable reasons. Such a DD approach is not morally neutral, nor does it claim to be. Indeed, the quality of moral neutrality is both undesirable and unattainable according to Gutmann and Thompson. If we accept this direction, we could read Häyry's polite bystander view as a claim about first order theories, to which we could add as a further step our steering toward the realm of political philosophy. How can a second-order DD approach build on the confrontational analysis of first-order theories applied to genetic enhancements in sports that we discussed above? The details of this process in the context of decision-making in sports would, of course, need to be spelled out in practice, but in this regard we can say that the current process of decision-making in sports is unsatisfactory at best.

Consider, for example, the ruling made by the International Association of Athletics Federations (IAAF) concerning the admissibility of the runner Caster Semenya to compete with women after charging her of not belonging properly to the category, which was neither transparent nor respectful of her privacy. (Camporesi and Maugeri 2010; Karkazis et al. 2012) Furthermore, the reasons for Semenya's banning and subsequent readmission were never made public, though not respecting the criteria of publicity that is fundamental in the DD approach. In the context of decisions surrounding the ethical justifiability of a gene enhancement (or other kind of enhancement) practice in sports, we envisage a DD process that gives reasons to all the moral constituents involved in the field, where moral constituents is understood as all "those who are in effect bound by the decision, even though they may not have [but maybe they should have, as we argue] a voice in making them," (Gutmann and Thompson 2004, 135) therefore including at least, but not only, the athletes.

To recapitulate, Häyry identifies three competing approaches used by scholars in the debate on the ethics of genetic technologies (what he refers to as "genethics"): consequentialism; teleology or virtue-ethics and deontology. (Häyry 2010) Häyry argues that these three approaches are "incommensurable" because they respectively define (a) utility; (b) human flourishing or well-being, and (c) persons as the entities that matter in the ethical debate. Häyry also

argues that in practice the ethical judgments about the ethical permissibility of a technology depend ultimately on the choice of world-views, attitudes and ideas about what counts in the moral discussion. Therefore, if we do not agree on the "unit of measurement" itself of discussion, then it will be impossible to actually compare the outcomes of discussions grounded in different approaches. For Häyry, the three approaches can all be simultaneously valid, and the only necessary condition for their validity is that they are internally coherent/consistent. The only role for the philosopher in this field is to adopt a "polite bystander" role and assess the internal consistency/coherency of each account. Rather than adopting a "polite bystander" view, I think that a more productive way forward in the discussion of gen-ethics could be based on a "moderate pluralistic approach to public health policy and ethics" as the one delineated by Selgelid (2009, 2012) coupled with a DD approach as the one spelled out by Gutmann and Thompson (2004), and aimed at reaching publicly shared decisions about the acceptability of a particular technology.

Indeed, often individuals' motivations for seeking enhancements are that they see them as positional goods, able to give them a competitive advantage. Therefore, the differential access to enhancement technologies is likely to exacerbate the existing inequalities in society. Along similar lines to what is done by Häyry, Selgelid spells out the three main approaches used in the enhancement debate to try to – unsuccessfully – resolve controversies regarding the particular application of an enhancement technology. He refers to the three approaches as utilitarianism, egalitarianism, and libertarianism. (Selgelid 2012; Selgelid 2013) As each perspective tends to place absolute or overriding weight on the values they emphasize (respectively utility, equality, and liberty), consequently the current approach to the enhancement debate is not able to make any substantial progress. To obviate the current misbalance in debate between the value of liberty and other important values (such as equality and utility), Selgelid argues in favour of a contextual approach that spells out, and tries to balance between, the values by shifting the focus of the debate on enhancement towards the analysis of how to reach a "fair" trade-off between the different values. What would Selgelid's moderate pluralistic approach entail in practice? First, it would start with the aim to promote the three values of liberty, equality and utility as independently legitimate social goals, without any of them being by default overriding the other. Secondly, it would aim to strike

a balance and make trade-offs between the values in cases where they conflict, with the assumption that no value has priority over the others. (Selgelid 2009) Selgelid also argues that the only possible way to make tangible progress in the enhancement debate is to address the controversial issues through a rigorous empirical analysis and a case by case contextual approach, which is what I tried to do in this work. Therefore, for Selgelid, the way to resolve disputes about enhancement is not the polite-bystander view to which the philosopher is relegated as suggested by Häyry, but a fourth approach, which he refers to as a "moderate pluralistic approach to public health policy and ethics."

One potential problem with Selgelid's moderate pluralistic approach is the apparent incommensurability of the values of liberty, equality and utility. Hence, questions such as "How much utility overweighs how much liberty (or vice versa) in a particular case?" seem impossible to answer. Selgelid is aware of this issue, which may be irresolvable from a general, abstract philosophical viewpoint of comparing first order theories. Not so, however, when the level of analysis is shifted to the policy-making level, and when decisions need to be taken regarding the ethical acceptability of a particular technology, and the ethically justifiability limits – for example – on personal liberty in favour of equality or on equality in favour of utility and so on and so forth. This is where the DD approach comes into place.

On this DD view, "first-order" ethical frameworks (i.e. deontology, utilitarianism, virtue ethics; or libertarianism, egalitarianism and utilitariasnism) try to resolve moral disagreement regarding a particular technology by demonstrating why that particular ethical theory is superior to another. This approach anyway is deemed to fail since, as pointed out by Häyry, different ethical frameworks are incommensurable as they use different "unit-values" (person, utility, wellbeing or human-flourishing, etc.), and the choice of which ethical framework to adopt in the first place is guided by the preference of the individual for one "unit-value" over another. Notwithstanding the impossibility to reach a moral agreement with first order theories, individuals who adopt different approaches may still agree that questions raised by the intersection of genetics and society demand public answer, and therefore that confrontation needs to take place at the societal and public level. The DD approach deals with the moral disagreement residual of first-order theories and seeks a resolution by adopting a dynamic conception of political justification.

This second order approach aims at reaching a mutually binding (to all parties involved) consensus achieved through principles of reciprocity, publicity, and accountability on mutually justifiable reasons. (Gutmann and Thompson 2004) The consensus reached would be provisional, and subject to revision, depending on the consequences of the policy applications. For example, in the case of research on enhancements, it could be revised depending on the extent of the black market of pharmaceutical for enhancement purposes (which is at the moment a widespread problem for the case of Ritalin and Adderall).