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The New Generation of Performance Enhancement: The Use and Regulation of Cognitive Enhancers

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Class of 2009
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This paper is submitted in satisfaction of the course requirement

Abstract: Over the past decade, the use of steroids and other performance enhancing drugs has shaken the sports world. As athletes search for new and creative ways to gain advantages in their disciplines, nearly every major professional U.S. sports league as well as the National Collegiate Athletic Association (NCAA) and the United States Olympic Committee (USOC) has struggled to develop and enforce new rules against performance enhancing drugs. Much of the public attention and regulatory reaction has focused on anabolic steroid and hormone use, in part because these drugs appear to be the most commonly used substances and also because they are perceived to provide the most significant unfair advantages to athletes. However, while these drugs dominate the headlines, cognitive enhancers, also known as nootropics, have more quietly begun to assert themselves as the new generation of performance enhancement, promising implications far beyond the sports field. For centuries, certain foods and chemicals have been thought to increase cognitive abilities. Even today folk wisdom and marketers of supplements advocate the mental boosting properties of vitamins and "brain food" ranging from B5 to cranberries to chocolate. But an increasing number of drugs recently have been shown to improve memory, concentration and other cognitive ability. Three such drugs, Ritalin, Adderall and Provigil, have received Food and Drug Administration (FDA) approval for disorders such as narcolepsy and Attention Deficit/Hyperactivity Disorder (ADHD), but widely are being used off-label and without doctor supervision by athletes, students, businessmen, the armed forces and even scientists themselves for cognitive enhancement. As with any drug, though, unsupervised use poses risks of harmful side effects, drug interactions and addiction, risks that are still relatively poorly understood. But given the competitiveness and pressure of the modern world, it is hardly surprising that the promise of cognitive enhancers is seductive for so many. Furthermore, scientists agree that many more such drugs will be developed in the upcoming years. This paper will examine cognitive enhancers and their dramatic, somewhat unspoken increasing prevalence in our society. After analyzing efforts to regulate their use by various sports organizations and governing bodies, this paper then will address the reasons behind, and moral issues raised by the use of cognitive enhancers by others in society, ranging from university students to air force pilots. Finally, this essay will conclude by suggesting cognitive enhancers pose a new regulatory challenge that the FDA can no longer ignore: Countless Americans from a wide array of backgrounds already use cognitive enhancers illicitly, either obtaining them through acquaintances or sometimes by faking symptoms of ADHD or narcolepsy to a doctor. Because society stands on the precipice of an age in which psychoactive drugs will be used primarily for enhancement, rather than medical treatment, the FDA should recognize this new drug use reality and establish a separate, appropriate regulatory scheme for cognitive enhancers, one that responds to the common non-medical use of these drugs and best ensures their safety and efficacy.

Over the past decade, the use of steroids and other performance enhancing drugs has shaken the sports world. As athletes search for new and creative ways to gain advantages in their disciplines, nearly every major professional U.S. sports league as well as the National Collegiate Athletic Association (NCAA) and the United States Olympic Committee (USOC) has struggled to develop and enforce new rules against performance enhancing drugs. Much of the public attention and regulatory reaction has focused on anabolic steroid and hormone use, in part because these drugs appear to be the most commonly used substances and also because they are perceived to provide the most significant unfair advantages to athletes. However, while these drugs dominate the headlines, cognitive enhancers, also known as nootropics, have more quietly begun to assert themselves as the new generation of performance enhancement, promising implications far beyond the sports field. For centuries, certain foods and chemicals have been thought to increase cognitive abilities. Even today folk wisdom and marketers of supplements advocate the mental boosting properties of vitamins and "brain food" ranging from B5 to cranberries to chocolate. But an increasing number of drugs recently have been shown to improve memory, concentration and other cognitive ability. Three such drugs, Ritalin, Adderall and Provigil, have received Food and Drug Administration (FDA) approval for disorders such as narcolepsy and Attention Deficit/Hyperactivity Disorder (ADHD), but widely are being used off-label and without doctor supervision by athletes, students, businessmen, the armed forces and even scientists themselves for cognitive enhancement. As with any drug, though, unsupervised use poses risks of harmful side effects, drug interactions and addiction, risks that are still relatively poorly understood. But given the competitiveness and pressure of the modern world, it is hardly surprising that the promise of cognitive enhancers is seductive for so many. Furthermore, scientists agree that many more such drugs will be developed in the upcoming

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The History of Cognitive Enhancement

For hundreds, perhaps thousands of years, people have used foods and other substances for their psychoactive effects. [1] Today, the study of nootropics, or substances that enhance cognition, has become a legitimate scientific field, with researchers spending considerable time investigating the potential beneficial cognitive properties of various herbs and chemicals found in everyday food. [2] Marketers have been quick to capitalize on such studies (perhaps in some

[1] See e.g., Slotkin, J. S, *The Peyote Religion: A Study in Indian-White Relations*, New York: Octagon - Farrar, Straus and Giroux, 1975 (describing the use of Peyote in Indian culture, among other things, to aid "introspection").
[2] See e.g., "Herbal remedies boost 'brain power.'" BBC News, April 14, 2000, reporting that University researchers "showed that ginkgo biloba can improve the power of concentration, while ginseng sharpens up the memory." The article also notes that these substances have been used in China for thousands of years. http://news.bbc.co.uk/2/hi/health/713087.stm

cases helping to fund them) as well as the public's fascination with "brain foods." For example, industry associations such as The American Egg Board (AEB) and The National Confectioners Association (NCA) have each sought to highlight their products' possible cognitive benefits to consumers. The AEB draws attention to choline in eggs: "An essential nutrient, choline plays an important neurological role in the development of brain and memory functions. With 125 mg of choline, one egg provides at least 22% of an adult's daily requirement." [3] Similarly the NCA advocates that eating chocolate can help release "'feel good' neurotransmitters," and "it has been suggested that eating fat-containing foods like chocolate might increase endorphins and lift a person's mood." [4] The growth in popularity of dietary supplements has further flooded the market with products promising to improve both body and mind, and has caused significant regulatory battles between the FDA and Congress. [5]

Drugs Often Used as Cognitive Enhancers Today

But the quest for cognitive enhancement likely has entered a dramatic new phase following the discovery that a small group of drugs, approved by the FDA for the treatment of a variety of medical conditions, in fact improve memory, concentration and alertness in healthy individuals. Although several drugs currently are used off-label to obtain such benefits, Ritalin, Adderall and Provigil are among the most popular. Ritalin, the most common brand name of methylphenidate, is the oldest of the three drugs. First marketed in the 1950s to help treat chronic fatigue, depression, and psychosis associated with depression, Ritalin saw its use significantly

[3] "Egg Nutrition" The American Egg Board website. http://www.aeb.org/Retailers/nutrition.html
[4] "Nutritional Information – The Good News About Chocolate." National Confectioners Association website. http://www.chocolateusa.org/Science-and-Nutrition/good-news-about-chocolate.asp
[5] For an overview of dietary supplement regulation, and in particular the Dietary Supplement Health and Education Act of 1994, a bill passed "over the strong objection of the FDA," see Peter Barton Hutt, "U.S. Government Regulation of Food With Claims For Special Physiological Value," in Mary K. Schmidl and Theodore P. Labuza, eds., *Essentials of Functional Foods* (2000).

increase decades later, when researchers identified its effectiveness in treating ADHD. [6] As doctors began diagnosing ADHD with greater frequency, Ritalin's use ballooned even more. Illustrative of this trend, between 1990 and 1999, methylphenidate manufacturers reported a 500 percent increase in sales. [7] Equally remarkable, the Drug Enforcement Agency's (DEA) aggregate production quota for methylphenidate increased from 1,768 kilograms in 1990 to 14,957 kilograms in 2000; by 2008 the quota had reached 50,000 kilograms. [8]

As demand for ADHD treatments grew in the 1990s, competitors to Ritalin quickly emerged. In 1996, the British company Shire Pharmaceuticals introduced Adderall, a drug composed of mixed amphetamines salts that was approved by the FDA for ADHD and narcolepsy. [9] Adderall was marketed as a direct competitor to Ritalin, and its manufacturer was even warned by the FDA in 2000 for unsubstantiated comparative claims in journal advertisements. [10] Within a short time, Adderall gained a strong foothold in the drug market. While sales of methylphenidate (Ritalin), sold as a generic by various companies, totaled $60 million in 2004, Adderall XR (extended release) alone boasted $607 million in sales in 2004. [11] Adderall's reputation appeared to be in danger in February 2005 when Health Canada, the Canadian governmental drug regulator, suspended the sale of Adderall following reports of

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[6] "Ritalin." Center for Substance Abuse Research website, University of Maryland. http://www.cesar.umd.edu/cesar/drugs/ritalin.asp

[7] DEA Congressional Testimony of Terrance Woodworth, Deputy Director, Office of Diversion Control, DEA, before the Committee on Education and the Workforce: Subcommittee on Early Childhood, Youth and Families, May 16, 2000. http://www.usdoj.gov/dea/pubs/cngrtest/ct051600.htm#fig1

[8] Id.; "Aggregate Production Quota History." (data from 1998-2008) DEA Office of Diversion Control website. http://www.deadiversion.usdoj.gov/quotas/quota_history.htm. According to Deputy Director Woodworth's testimony, "Each year, the DEA establishes an aggregate production quota for each Schedule I and II controlled substance. This quota is based on sales and inventory data supplied by the manufacturers as well as information supplied by the FDA regarding legitimate medical and research needs."

[9] The immediate release version is indicated for both ADHD and narcolepsy, while a later extended release Adderall was approved only for ADHD. FDA approved label for Adderall 20, NDA no. 011522, June 7, 2007. http://www.fda.gov/cder/foi/label/2007/011522s040lbl.pdf; FDA approved label for Adderall XR 20, NDA no. 021303, May 22, 2007. http://www.fda.gov/cder/foi/label/2007/021303s015lbl.pdf.

[10] FDA warning letter dated November 9, 2000. http://www.fda.gov/cder/warn/nov2000/dd9153.pdf

[11] Aaron Smith, "FDA eyes heart risks of ADHD drugs." February 2, 2006, CNNMoney.com. http://money.cnn.com/2006/02/01/news/companies/adhd/index.htm

sudden unexplained death (SUD) in children taking the drug. However, the FDA chose to not emulate their Canadian counterparts, and the ban eventually was lifted in Canada after six months and additional investigations. [12]

The initial success of Ritalin and Adderall appear strongly related to the higher rates of ADHD diagnoses. Although a full discussion of the history and current discourse of ADHD is outside the scope of this paper, it should be noted that the disorder is plagued by controversy both in the medical community and among the general public. [13] According to the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revision (DSM-IV-TR), the criteria for diagnosis of ADHD includes a series of symptoms relating to hyperactivity and/or inattention that causes significant impairment in daily functions. [14] Although some in the public doubt ADHD's existence, within the medical community a debate continues about how the disorder should be diagnosed and treated. [15] In particular, disagreement exists about the rate of incidence of ADHD in the U.S., and how those figures compare to worldwide numbers. [16] Some researchers have questioned whether ADHD is "an American condition," although other experts have countered that ADHD rates worldwide are around five percent, with fewer reported cases in areas such as the Middle East and Africa resulting from a dearth of studies and methodological differences in those parts of the world. [17] Still, questions remain regarding when the condition warrants medication. Although the DSM-IV-TR requires that a series of symptoms persist for at

[12] Id.; See also, FDA Alert for Healthcare Professionals, http://www.fda.gov/cder/drug/InfoSheets/HCP/AdderallHCPSheet.pdf
[13] See generally, Connie Lenz, "Prescribing a Legislative Response: Educators, Physicians, and Psychotropic Medication for Children. *22 J. Contemp. Health L. & Pol'y 72*.
[14] "Attention-Deficit/Hyperactivity Disorder (ADHD)," DSM-IV-TR, American Psychiatric Association, 2000.
[15] Schonwald A, Lechner E (April 2006). "Attention deficit/hyperactivity disorder: complexities and controversies". *Curr. Opin. Pediatr.* 18 (2): 189–95.
[16] Guilherme Polanczyk et. al. "The Worldwide Prevalence of ADHD: A Systematic Review and Metaregression Analysis." *Am J Psychiatry* 2007; 164:942-948.
[17] Id.; See also Joseph V. Faraone et. al. "The worldwide prevalence of ADHD: is it an American condition?" *World Psychiatry*. 2003 June; 2(2): 104–113.

least six months before a doctor can diagnose ADHD, qualifying behavior such as "often fails to give close attention to details or makes careless mistakes in schoolwork, work, or other activities;" "often fidgets with hands or feet or squirms in seat," and "often talks excessively" invite subjective interpretations by both doctors and parents. [18] Furthermore, additional clinical difficulties arise when adult patients complain of ADHD symptoms. Although the DSM-IV-TR stipulates that some symptoms must be present before the age of seven, doctors face difficult diagnostic decisions when confronted with adults who claim they are experiencing difficulty maintaining focus or alertness, especially when the patients insist they may have been suffering for years. [19] In addition, legal responses to ADHD may have contributed to higher rates in the U.S. The 1990 Individuals with Disabilities Education Act (IDEA), which mandates special education and related services for eligible children, including those with ADHD, may have prompted parents to pressure doctors to provide a diagnosis that entitled their children to special education benefits. [20] A 1999 United Nations Study estimated that the U.S. accounts for nearly 85 percent of world Ritalin use, suggesting that whatever the worldwide ADHD rates, U.S. doctors rely heavily on certain medications to treat the disorder. [21] In 2002, a staff background paper for the President's Council on Bioethics conceded that, "With millions of children diagnosed with ADHD, and large amounts of Ritalin and amphetamine being prescribed to treat them, it is not surprising that some of these drugs are being resold or given to others for non-therapeutic use." [22] More troublingly, a recent Congressional investigation has alleged that top child psychiatry experts from Harvard Medical School and leading advocates of the effectiveness

[18] "Attention-Deficit/Hyperactivity Disorder (ADHD)," DSM-IV-TR.
[19] Id.
[20] Staff Background Paper, "Human Flourishing, Performance Enhancement and Ritalin." The President's Council on Bioethics, 2002. http://www.bioethics.gov/background/humanflourish.html
[21] Quoted in DEA Congressional Testimony of Terrance Woodworth, May 16, 2000.
[22] "Human Flourishing, Performance Enhancement and Ritalin." See also 22 J. Contemp. Health L. & Pol'y 72, 81.

of psychoactive drugs for ADHD patients may have failed to disclose significant consulting fees from ADHD drug producers. [23]

Another drug that has shown promise in combating ADHD, [24] but was rejected by the FDA for that purpose is Modafinil, marketed most commonly as Provigil. [25] Approved by the FDA in 1998, Provigil currently is indicated for narcolepsy, obstructive sleep apnea and shift work sleep disorder. [26] Unlike Adderall and Ritalin, which are Schedule II drugs, Provigil currently is classified as a Schedule IV drug, reflecting less potential for abuse. [27] However, a 2009 study published in the *Journal of the American Medical Association* found greater potential for addiction than previously thought, arguing that, "considering the increasing use of modafinil, these results highlight the need for heightened awareness for potential abuse of and dependence on modafinil in vulnerable populations." [28] Although subtly stated, the "increasing use" of modafinil by "vulnerable populations" mentioned in the JAMA article alludes to its common link with Ritalin, Adderall and Provigil: widespread off-label use as a cognitive enhancer, or "smart drug." Provigil, despite being rejected for ADHD use, recorded nearly one billion dollars in sales in 2008, an impressive figure for a drug indicated only for narcolepsy, obstructive sleep apnea

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[23] Gardiner Harris and Benedict Carey, "Researchers Fail to Reveal Full Drug Pay." *The New York Times*, June 8, 2008. http://www.nytimes.com/2008/06/08/us/08conflict.html

[24] See Biederman J, Pliszka SR (March 2008), "Modafinil improves symptoms of attention-deficit/hyperactivity disorder across subtypes in children and adolescents." *J. Pediatr.* 152 (3): 394–9. Joseph Biederman, a leading child psychiatrist, is one of the doctors being investigated by Congress for undisclosed payments by pharmaceutical companies, see id.

[25] Elizabeth Mechcatie, "Modafinil to Treat ADHD is Rejected by FDA." *Pediatric News* September 2006 (Vol. 40, Issue 9, Page 11).

[26] "Provigil Consumer Information." FDA website. http://www.fda.gov/cder/consumerinfo/druginfo/provigil.HTM

[27] "Drug Scheduling," Drug Enforcement Agency, Department of Justice. DEA website. http://www.usdoj.gov/dea/pubs/scheduling.html

[28] Nora D. Volkow, et. al. "The Effects of Modafinil on Dopamine and Dopamine Transporters in the Male Human Brain." *JAMA*. 2009; 301(11):1148-1154. For the response of Modafinil's manufacturer, Cephalon, see "Cephalon Response to JAMA Article 'The Effects of Modafinil on Dopamine and Dopamine Transporters in the Male Human Brain.'" http://www.cephalon.com/media/on-the-record/cephalon-response-to-jama-article-the-effects-of-modafinil-on-dopamine-and-dopamine-transporters-in-the-male-human-brain/

and shift work sleep disorder. [29] The stark reality is that many otherwise healthy individuals in the U.S. are using Ritalin, Adderall, Provigil and other similar drugs for cognitive enhancement. The following sections of this paper examine how these drugs are increasingly being used in professional sports, where small gains in performance can translate into large increases in salary, and how the general public is increasingly experimenting with non-medical use of cognitive enhancers as well.

Cognitive Enhancers in Sports

The Ethics and Use of Performance Enhancing Drugs in Sports

The use of performance enhancing drugs in sports, in particular anabolic steroids and human growth hormone (HGH) has generated intense public discussion and increased regulatory oversight over the past few decades. Although the new steroid rules in baseball in 2005, [30] the introduction of drug testing in professional golf in 2008, [31] and the establishment of the World Anti-Doping Agency in 1999 [32] demonstrate that most fans and sports officials seem to favor strictly controlling such drug use and punishing those who break the rules, the underlying ethical and policy justifications are far from clear. For example, although doctors generally agree that anabolic steroids promote muscle growth, [33] there is a more tenuous connection between

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[29] "'Smart Drug' Provigil May Be Addictive." The Associated Press, March 18, 2009. http://www.newsmax.com/health/Provigil_addictive_smart/2009/03/18/193213.html

[30] "MLB, MLBPA announce new drug agreement." Press release, Major League Baseball and Major League Baseball Players Association, November 15, 2005 (describing increased penalties for those testing positive for steroids, including a 50-game suspension for first time offenders). http://mlbplayers.mlb.com/pa/releases/releases.jsp?content=111505

[31] "PGA Tour begins a new era with drug testing this week at AT&T National." July 2, 2008, The Association Press. http://www.pga.com/2008/news/pgatour/07/02/drug060208.ap/index.html?eref=sitesearch. For women's golf, See "LPGA releases Prohibited Substance Classes and Prohibited Methods List for drug-testing program. March 21, 2007, LGPA website. http://www.lpga.com/content_1.aspx?pid=10100&mid=4

[32] "WADA History," World Anti-Doping Agency website, http://www.wada-ama.org/en/dynamic.ch2?pageCategory.id=253

[33] Cf. "Anabolic Steroid Act of 2004," Statement of Joseph T. Rannazzisi, Deputy Director, Office of Diversion Control, DEA, Before the House Committee on the Judiciary, Subcommittee on Crime, Terrorism, and Homeland

resulting increased muscle mass and improved performance in sports. Many sports such as baseball, basketball and even seemingly pure strength sports such as weightlifting require a blend of strength, endurance and technique to be successful at the professional level. According to David Greenblatt, chief of clinical pharmacology at the New England Medical Center Hospital and professor of psychiatry and medicine at Tufts University School of Medicine, there exists "no scientific evidence to show that anabolic steroids would enhance performance in any athlete. For instance, no one ha[s] scientifically demonstrated that any possible improvements in strength would translate into enhanced performance for football players." [34] In fact, in *Hill v. National Collegiate Athletic Assn*., a California appeals court, relying on the testimony of several similarly-minded doctors and NCAA drug committee members, found that the "NCAA failed to carry its burden of proving that anabolic steroids enhance performance in any NCAA sport." [35] But notwithstanding unanswered questions of the metaphysical causation between steroids and performance enhancement, their widespread use suggests that many professional athletes believe they provide the tools to enhance performance and prolong careers. Even assuming this is true, though, steroids hardly are magic pills enabling anyone to become a professional athlete. In the words of one scholar, "As such, they may bring out the inherent ability of the athlete by assisting him or her to overcome certain performance inhibitors such as passiveness, insufficient strength, underdeveloped musculature, premature exhaustion, and so forth." [36] Although steroids alone likely cannot turn the average American into a professional athlete, they nevertheless are almost universally condemned. One justification for this disapproval is that given the significant health

Security, March 16, 2004. (Arguing that statutory requirements to demonstrate a substance promotes muscle growth substantially hampers DEA efforts to classify new steroids as Schedule III anabolic steroids).

[34] Quoted in *Hill v. National Collegiate Athletic Assn.,* 18 Cal. App. 4th 1290, 1317 (Cal. Ct. App. 1990)

[35] 18 Cal. App. 4th 1290, 1318. This opinion was superceded by a grant of review under California law.

[36] Quoted in Michael H. Shapiro, "The Technology of Perfection: Performance Enhancement and the Control of Attributes." 65 S. Cal. L. Rev. 11, footnote 319.

risks steroids pose, allowing their use essentially forces athletes to sacrifice physical well-being to compete at the highest professional levels. [37] But as Judge Richard Posner succinctly has countered, "A football lineman will not be criticized for blowing himself up into a 400-pound freak if he does it without the aid of drugs, even though the long-term effects on his health of the added weight are very bad and even though his weight gain may place pressure on other linemen to match it." [38]

The Shift to Cognitive Enhancers in Sports

Whatever the counterarguments, most U.S. sports leagues have enacted strict policies against steroid use. In the wake of such tight regulation, athletes appear to be turning to cognitive enhancers for an edge. Recent trends in Major League Baseball (MLB) provide an illustrative example. For decades, amphetamines, known as "greenies" were a mainstay in baseball locker rooms. Some players have claimed that amphetamine use was so widespread that large communal jars of pills were openly available in clubhouses to any player who wanted them. [39] Because amphetamines improve concentration, reaction times and provide energy boosts, they offered significant benefits to professional baseball players, who greatly rely on hand-eye coordination and stamina during their 162-game season. [40] In fact, one doctor who served as the New York Mets team psychiatrist from 1985 to 2003 publicly stated that the "No. 1 drug use of sports is really amphetamines… [they]are the real performance-enhancing drugs that people

[37] "NIDA InfoFacts: Steroids (Anabolic-Androgenic)." National Institute of Drug Abuse, National Institutes of Health, http://www.nida.nih.gov/Infofacts/steroids.html
[38] "Doping Athletes – Posner's Comments." The Becker-Posner Blog, August 27, 2006. http://www.becker-posner-blog.com/archives/2006/08/doping_athletes.html
[39] *Hustle: The Myth, Life and Lies of Pete Rose*. Michael Sokolove, Simon and Schuster, 2005. p. 78.
[40] Michael S. Schmidt, "Baseball is Challenged on Rise in Stimulant Use." January 16, 2008. The New York Times. http://query.nytimes.com/gst/fullpage.html?res=9D03E7DB103AF935A25752C0A96E9C8B63&sec=&spon=&pagewanted=all

should always have been worried about." [41] But even as more sophisticated stimulants such as Adderall (mixed amphetamine salts), Provigil and Ritalin were developed by major pharmaceutical companies, stimulants were banned only in the 2006 season, several years after the steroid and HGH scandals had been exposed in baseball. Even under the current regime, stimulant users face lesser penalties than steroid abusers: while first time steroid offenders receive a mandatory 50-game suspension, first time stimulant users simply face mandatory follow-up testing, with a second positive result leading to a 25-game suspension. [42]

Major League Baseball's Joint Drug Prevention and Treatment Program, the official name of baseball's new drug policy, was heavily negotiated by MLB and the Major League Baseball Players' Union (MLBPA). The agreement allows for a Therapeutic Use Exemption (TUE) of banned substances for "medically appropriate prescription[s] provided by a duly licensed physician." [43] Interestingly, during the Congressional oversight hearings of the Mitchell Report (MLB's investigation of steroid use in the sport), Congressman John Tierney obtained previously unreleased data showing that the number of TUE's for ADHD increased from 28 players during 2006, the first year of the ban, to 103 in 2007. [44] Although 103 players represent about 8 percent of all MLB athletes, a rate only slightly higher than generally-agreed national ADHD rates, according to Congressman Tierney, "When you see the number 28 one year go all the way to 103, it makes you think that we have a loophole here with performance-enhancing drugs." [45] Some players, however, have defended their TUE, and even becomes advocates for

[41] Id.
[42] "Major League Baseball's Joint Drug Prevention and Treatment Program." MLB and MLBPA, 2005, p. 17. http://mlbplayers.mlb.com/pa/pdf/jda.pdf
[43] Id. p. 10.
[44] Preliminary Transcript, "The Mitchell Report: The Illegal Use of Steroids in Major League Baseball." January 15, 2008, House of Representatives, Committee on Oversight and Government Reform. http://oversight.house.gov/documents/20080205163114.pdf
[45] In 2009, 106 players received TUE for ADHD. Christian Red and Nathaniel Vinton. "Report: Amphetamines Still in Play in MLB. January 9, 2009. New York Daily News.

increased awareness and acceptance of ADHD. Adam LaRoche, a first-baseman for the Pittsburgh Pirates, openly has talked to the media about his ADHD diagnosis and use of Ritalin during the baseball season. LaRoche, who had been benched by past teams for being a "lazy" player, credits Ritalin for helping his performance on the field, "It helps me to focus for three hours when I'm playing and not be spacing out or thinking about a million different things. We're still experimenting with dosages." [46] LaRoche has also stated that several teammates privately have asked to discuss ADHD with him, and LaRoche suspects, "a ton of adults have it — maybe some so mildly that they don't really know." [47] Publicly admitting to any psychiatrist disorder is embarrassing and potentially financially damaging to an athlete's career, and consequently it is unfair to question the motives of all players requesting ADHD TEU's. However, given the potential for performance enhancement that stimulants such as Adderall and Ritalin can provide, it is noteworthy that few, if any players, use Atomoxetine (marketed as Strattera), the only non-stimulant medication FDA-approved for ADHD. [48]

Baseball, is not the only sport, though, that has been forced to confront cognitive enhancers. Because of Congressional oversight of baseball, more data has emerged concerning stimulant use in that sport than in others. However, in the 2005 NCAA Study of Substance Use Habits of College Student-Athletes, a study conducted every four years since 1997, the organization reported that while anabolic steroid use was down from the previous study,

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http://www.nydailynews.com/sports/baseball/2009/01/09/2009-01-09_report_amphetamines_still_in_play_in_mlb.html

[46] Patty Rasmussen, "Q&A with Adam LaRoche." ChopTalk Magazine, August 29, 2006, Atlanta Braves. http://atlanta.braves.mlb.com/news/article.jsp?ymd=20060829&content_id=1634633&vkey=news_atl&fext=.jsp&c_id=atl

[47] Seth Livingstone, "Affliction Bonds Pirates' LaRoche and Gorzelanny." USA Today, July 19, 2007. http://www.usatoday.com/sports/baseball/nl/pirates/2007-07-18-PiratesADD_N.htm

[48] Shelby L. Corman; Bethany A. Fedutes; Colleen M. Culley, "Atomoxetine: The First Non-Stimulant for the Management of Attention-Deficit/Hyperactivity Disorder." American Journal of Health-System Pharmacy, Vol. 61, Issue 22, 2391-2399

amphetamine use "has continually increased since 1997." [49] The report also concluded that two-thirds of amphetamine use by college athletes began in high school. [50] Interestingly, though, based on athletes' self-reported answers to questionnaires given to them by the NCAA, the organization concluded that, "use of amphetamines to improve athletic performance appears to be down significantly from the 2001 study. The main reason stated for using amphetamines is for the treatment of attention deficit disorder followed by using to get more energy." Although this statement reveals a somewhat dubious distinction among both athletes and NCAA officials between the use of stimulants such as Ritalin and Adderall to boost energy and mental functions versus their use as "performance enhancers," both Adderall and Ritalin are banned from NCAA competition, unless the athlete receives a Medical Exemption. [51] However, in guidance explaining medical exemptions to its athletes, the NCAA arguably sends mixed messages about the appropriate circumstances for which ADHD medication should be used. The memo specifically names Ritalin and Adderall, and although it warns that those seeking to use the drugs must follow NCAA protocol, it notes, "Frequently a student-athlete may find that the demands of college present difficult learning challenges. They may realize that some of their teammates are benefitting [sic] from the use of these medications, and figure they should ask their team physician or family doctor to prescribe the same for them." [52] Arguably such advice further confuses an already murky boundary increasing ADHD awareness and encouraging cognitive

[49] "2005 NCAA Study of Substance Use Habits of College Student-Athletes." January 2006, The NCAA Research Staff, p. 2. According to NCAA data, approximately four percent of the nearly 20,000 student athletes surveyed admitted amphetamine use.
http://www.ncaa.org/wps/wcm/connect/resources/file/ebe49048bccf651/NCAADrugUseStudy2005.pdf?MOD=AJPERES&attachment=true
[50] Id. p.3.
[51] "NCAA Banned-Drug Classes 2008-9." NCAA website
http://www.ncaa.org/wps/wcm/connect/resources/file/ebb83308f4d9141/banned%20drugs%202008-09%2006-20-08.pdf?MOD=AJPERES&attachment=true
[52] "NCAA Medical Exceptions." NCAA, March 11, 2008.
http://www.ncaa.org/wps/wcm/connect/resources/file/eb824202fa063e0/medicalexceptions080311.pdf?MOD=AJPERES

enhancement in student-athletes; however, the statement likely is reflective of NCAA attempts to offer realistic alternatives to its athletes given the prevalence of Ritalin and Adderall on college campuses, a phenomenon explored later in this essay.

The use of cognitive enhancers has crept into numerous other sports. Provigil, a stimulant that currently is not banned by the NCAA, but is on the World Anti-Doping Agency's (WADA) Prohibited List, [53] was found in six U.S. athletes, including three hurdlers, two sprinters and a hammer thrower during two track and field meets in 2003. [54] The Nevada Athletic Commission, which relies heavily on the WADA Prohibited List to define its illegal substances,[55] removed popular mixed martial artist Tim Credeur from a televised match, but declined to punish him further in 2008 following a positive test for Adderall. [56]

It is difficult to know the real reasons athletes take cognitive enhancers like Ritalin, Adderall and Provigil. Some may be seeking a simple boost in energy, similar to athletes' amphetamine use in past decades. Others may appreciate more specific effects, like increased focus during competition. And some no doubt genuinely use them to treat ADHD, real or perceived. Another class of drugs that further blurs the line between performance and cognitive enhancement are beta-blockers. Beta-blockers reduce blood pressure by blocking the effects of adrenaline. Consequently, they act primarily on the heart, lowering the rate and force of heartbeats. [57] However, beta-blockers also can nullify symptoms of anxiety. For instance, classical musicians reportedly have been using them for years because of their ability to decrease

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[53] "The 2009 Prohibited List, International Standard." World Anti-Doping Agency. http://www.wada-ama.org/rtecontent/document/2009_Prohibited_List_ENG_Final_20_Sept_08.pdf
[54] Rob Gloster, "White among seven athletes to fail drug tests." The Associated Press, December 30, 2003.
[55] Nevada Athletic Commission Regulation 467.850(f)
[56] Ken Pishna, "Credeur's drug test finds Adderall T.U.F. bout scrapped." MMAweekly.com June 23, 2008. http://sportsillustrated.cnn.com/2008/mma/06/23/credeur.cancelled/index.html?eref=si_latest
[57] "Beta Blockers." Mayoclinic.com. http://www.mayoclinic.com/health/beta-blockers/HI00059

hand tremor and nervousness during performance. [58] The ethics of their use during competitions and auditions is still debated within the music community. [59] The WADA has banned beta-blockers in several sports, including golf, gymnastics, shooting and wrestling. [60] The International Olympic Committee, using the WADA guidelines, stripped a North Korean athlete of silver and bronze medals in Air Pistol competitions after testing positive for the beta-blocker propranolol. [61] And following rumors that some of its top competitors were using similar drugs, the Professional Golf Association (PGA) also began testing for beta-blockers in 2008, as part of its new comprehensive policy against performance enhancing drugs. [62] Because beta-blockers are not psychoactive drugs, it may be difficult to classify them as cognitive enhancers. However, if beta-blockers are being used to control the physical manifestations of a psychological phenomenon, namely anxiety, a closer nexus to cognitive enhancers emerges. [63] Presumably beta-blockers' relatively limited ban in sports stems from a belief that a lowered heart rate and control of nerves offer significant performance advantages only in certain sports, particularly ones that rely on fine-motor skills. And although no data exists on how many athletes use beta-blockers, it is not difficult to imagine a wide range of situations where the ability to suppress symptoms of anxiety would be greatly beneficial: from the basketball player who needs to sink

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[58] Dianna T. Kenny, "Music performance anxiety: Origins, phenomenology, assessment and treatment." *Context: A Journal of Music; 2006*.
http://www2.fhs.usyd.edu.au/bach/staff/kenny/Documents/Music%20Psych/Chapt%20in%20Books/Origins%20Phenomenology%20and%20Assessment.pdf

[59] Paul Kwak, "Combating Stage Fright with Beta Blockers." *The Julliard Journal Online*, Vol. XX No. 7, 2005.
http://www.juilliard.edu/update/journal/j_articles521.html

[60] "The 2009 Prohibited List, International Standard," supra, note 53.

[61] "IOC Executive Board Decision Regarding Jong Su Kim." International Olympic Committee. August 15, 2008.
http://multimedia.olympic.org/pdf/en_report_1352.pdf

[62] "PGA Tour begins a new era with drug testing this week at AT&T National," supra, note 31. See also Damon Hack, "In Steroid Era, Will Golf's Integrity Stand?" The New York Times, August 14, 2007.
http://www.nytimes.com/2006/08/14/sports/golf/14pga.html?pagewanted=print

[63] Cf. Kenny, supra, note 58 at 8 (noting that researchers believe beta-blockers counteract somatic symptoms, but likely do not affect the mental state of the user. However, this argument seems to create a paradox of how an athlete can be anxious without feeling any physical symptoms of anxiety).

the winning free throw to the football place kicker asked to win the game with a field goal, it would not be surprising if beta blocker was higher than currently suspected.

Cognitive Enhancers in Schools, Business, the Scientific Community and Armed Forces

Given the large salaries and performance bonuses that professional athletes can receive, it is not remarkable that some seek any edge that modern medicine can provide. But cognitive enhancers' impact on society stretches far further than the sports field. High achievers from many walks of life had learned that stimulants such as Adderall, Ritalin and Provigil can provide a mental edge at work and at school. Such widespread non-medical use of cognitive enhancers raises new ethical and legal issues that the medical community and FDA should no longer ignore, and it may challenge the public's perception of performance enhancement generally.

Teenaged and college-aged students often are the first to seek out and master the latest consumer technologies. The same appears to be true for cognitive enhancers: by all accounts, students represent a large contingent of the countless Americans using psychoactive drugs to "upgrade" their brains. Much like the "greenies" that were available to athletes for decades before the invention of drugs like Adderall, products like "No-Doze" or even coffee have fueled exam cramming and late-night paper writing for years. But students have been quick to experiment with the new current generation of cognitive enhancers. Although reliable statistics are difficult to obtain, one study of Harvard and University of Michigan researchers found that nearly seven percent of college students admitted to non-medical use of Ritalin, Dexedrine or Adderall; at some colleges, the rate was as high as 25 percent. [64] A U.S. government study also reported that "full-time college students aged 18 to 22 were twice as likely as their counterparts

[64] McCabe SE, Knight JR, Teter CJ, Wechsler H., "Non-medical use of prescription stimulants among US college students: prevalence and correlates from a national survey." *Addiction* 2005:99:96-106. http://www.hsph.harvard.edu/cas/Documents/stimulants/McCabe_2005.pdf

who were not full-time college students to have used Adderall nonmedically in the past year." [65] Anecdotally, as an article in the Harvard Crimson opined, "Everyone on campus knows about illegal Adderall or Concerta usage and knows where these drugs can be obtained quickly." [66] A simple Google search of Adderall reveals many school newspaper articles acknowledging widespread campus use of the drug. [67]

But curious college students are not the only non-athletes using cognitive enhancers. Adderall usage is also common on Wall Street, where the pressure to perform can be as great as on any playing field or classroom. [68] In 2003, the U.S. Air Force released guidelines regulating its approved use of Provigil as a "Go Pill" for fighter pilots to combat fatigue. [69] Since introducing that policy, the Air Force also has prosecuted airmen for illegal distribution and use of Adderall. [70] Perhaps most intriguingly, an informal survey by the science journal Nature revealed that approximately 20 percent of respondents, mainly scientists, used cognitive enhancers. [71] More specifically, 62 percent of this group admitted using Ritalin, 44 percent reported using Provigil and 14 percent utilized beta-blockers. [72] In another anonymous

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[65] "Nonmedical Use of Adderall among Full-Time College Students," The National Survey and Drug Use and Health Report, Substance Abuse and Mental Health Services Administration, Department of Health and Human Services. April 7, 2009. http://www.oas.samhsa.gov/2k9/adderall/adderall.htm

[66] Lawrence Diller, "A Misuser's Guide to Adderall." *The Harvard Crimson*, April 28, 2009.

[67] See e.g., Craig Zieminski, "Adderall abuse runs rampant at SMU." Hilltopics (Southern Methodist University), November 22, 2004. http://smu.edu/univhonors/hilltopics/issues/volume1/1-8.pdf
Sarah Ryan, "Adderall use, legal and illegal, prominent on campus," April 2, 2008, *The Hawk* (St. Joseph's University).
http://media.www.sjuhawknews.com/media/storage/paper763/news/2008/04/02/News/Adderall.Use.Legal.And.Illegal.Prominent.On.Campus-3295200.shtml
Alla Abramov, "Adderall Use Prevalent on Campus: Faculty and Administration in the Dark." April 28, 2005, *Concordiensis* (Union College). http://www.vu.union.edu/~concordy/backissues/20050428.pdf

[68] Jeanne Sahadi, "How Wall Street Can Wreck Your Life." October 26, 2006. CnnMoney.com (citing interview with clinical psychologist who works with workers on Wall Street).
http://money.cnn.com/2006/10/26/commentary/sahadi/index.htm

[69] "Modafinil and Management of Aircrew Fatigue." December 2, 2003, Department of the Air Force.
http://www.hep.afrl.af.mil/HEPF/Policy/modafinil.pdf

[70] See, e.g. U.S. v. Airman Basic Michael L. Ennis, U.S. Air Force Court of Criminal Appeals, ACM S31415. (2009).

[71] Brendan Maher, "Poll Results: look who's dopin." *Nature*, Volume 452, Issue 7188, pp. 674-675 (2008).

[72] Id.

questionnaire by researchers, a British professor offered a typical explanation for taking Provigil, claiming it "increases mental energy [and] improves sustained, hard thinking." [73] Such use among intellectuals should not be surprising: Benzedrine, an amphetamine mixture and precursor to modern cognitive enhancers, was used by several great minds. Jack Kerouac was said to have written his novel *On the Road* largely under the influence of the drug, while Jean-Paul Sartre said amphetamines provided him with, "a quickness of thought and writing that was at least three times my normal rhythm." [74] One of the greatest mathematicians of the 20th century, Hungarian Paul Erdos, is reputed to have been so addicted to Benzedrine that a close friend challenged him to a bet to quit the drug for a month. Erdos won the wager, but chided his friend, "You've showed me I'm not an addict. But I didn't get any work done. I'd get up in the morning and stare at a blank piece of paper. I'd have no ideas, just like an ordinary person. You've set mathematics back a month." [75]

The New Ethics of Performance Enhancement

How should society respond to such prevalent use of drugs like Ritalin, Adderall and Provigil? Recently, several prominent scholars from medicine, law and bioethics publicly advocated research into broader non-medical use of cognitive enhancers, and encouraged the public to resist attaching a stigma to their use. [76] Indeed, a national discussion concerning cognitive enhancers inevitably will raise several contentious issues and may have implications for the ethical debate over steroids in sports. For instance, Stanford Law School Professor Henry

[73] Barbara Sahakian and Sharon Morein-Zamir, "The Professor's little helper." *Nature* Volume 450, Issue 7173, pp. 1157-1159 (2007).
[74] Joshua Foer, "The Adderall Me." Slate.com May 10, 2005. http://www.slate.com/id/2118315/#correction
[75] Paul Hoffman, *The Man Who Loved Only Numbers.* Hyperion, 1998, p. 16.
[76] Henry Greely, et. al., "Towards responsible use of cognitive-enhancing drugs by the healthy." Towards responsible use of cognitive-enhancing drugs by the healthy." *Nature*, Volume 456, Issue 7223, pp. 702-705 (2008).

Greely (one of the leading advocates for greater scientific and public debate on the use of cognitive enhancers), Judge Posner and many others have noted that unlike steroid use in sports, cognitive enhancers offer "the potential for real personal and social benefits." [77] This assertion is debatable because thousands of athletes stand to significantly improve their livelihood and financial security by steroids. Furthermore, although the actual social benefit is questionable, there seems to exist substantial marketing value in athletes who can hit more home runs, throw longer passes, and knock other men out faster in a ring. But the sports analogy nevertheless raises an important point: for most Americans today, performance-enhancing drugs essentially serve an entertainment function. Fans may feel duped when an athlete's superior physical ability is revealed to partly result from steroids, but the public's outrage against steroid use in sports may dissipate once performance-enhancing drugs become relevant to the average American. To be sure, not everyone is welcoming of the age of cognitive enhancers; comparisons already exist between the "taint" of the sports steroid era and the effects of Adderall on college campuses, with some even suggesting drug testing students before exams. [78] Interestingly, students' use of cognitive enhancers challenges another oft-repeated anti-steroid justification that their use sets a bad example for children. [79] This rationale may be less credible if children – or even their parents – come to view cognitive enhancers as a vehicle for educational and career benefits. Indeed, such drugs cannot be explained away as minor study aids. Some bioethicists have

[77] "Brain Boosters: How should we deal with cognitive-enhancing drugs?" Interview with Professor Henry Greely, Stanford Magazine, March/April 2009. http://www.stanfordalumni.org/news/magazine/2009/marapr/farm/news/greely.html; see also "Doping Athletes – Posner's Comments," supra, note 38.
[78] See James Pavisian, "The Case for Human Ingenuity: How Adderall Has Sullied the Game." 48 Washburn L.J. 175 (2008).
[79] See "Doping Athletes – Posner's Comments," supra, note 38.

likened their use to drinking coffee during late nights or smoking cigarettes to calm nerves. [80] But such an analogy underestimates the sophistication and neurochemical effect of drugs such as Ritalin, Adderall and Provigil. And although a philosophical debate is likely to continue over whether cognitive enhancers actually increase intelligence and complex thinking or simply provide the tools to study longer and more effectively (a causation question similar to that of anabolic steroids and increased athletic performance, see supra), [81] it is important to remember that scientists agree that new generations of cognitive enhancers already are being developed by pharmaceutical companies. [82] As the use of cognitive enhancers becomes more common, society will need to redefine their conceptions of "cheating" and legitimate enhancement. For example, the use of beta-blockers during a presidential debate may remain unpalatable to the majority of Americans, while perhaps a surgeon's use of Ritalin during an operation, or an Air Force pilot's use of Provigil during combat will seem justified. Finally even more difficult ethical questions likely will be posed in the longer term, for example, whether employers can mandate taking Adderall as a condition of employment or whether governments should create tighter patent protections and distribution controls to ensure certain countries will have a monopoly on the most effective cognitive enhancers.

The Future Regulation of Cognitive Enhancers

Such moral and ethical questions however, are premature until a regulatory regime is developed to ensure the safety and efficacy of drugs used specifically for cognitive enhancement.

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[80] Kate Zernike. "The Difference Between Steroids and Ritalin Is…" March 20, 2005. *The New York Times* (quoting University of Pennsylvania bioethicist Arthur Caplan). http://www.nytimes.com/2005/03/20/weekinreview/20zern.html?_r=1

[81] "A Misuser's Guide to Adderall," supra, note 66 (arguing that Adderall will not improve reading comprehension but will allow the user to go over the paragraph multiple times to obtain the answer).

[82] Towards responsible use of cognitive-enhancing drugs by the healthy," see supra, note 76.

Drugs such as Ritalin, Adderall and Provigil are regulated by the FDA for certain medical indications, but the FDA can no longer ignore that many Americans are seeking these drugs for non-medical, cognitive enhancement purposes. Such drug use, even if often illegal, is no longer on the periphery of society. Although the DEA and FDA could reduce aggregate production quotas to curb illicit use of cognitive enhancers, considering that a market demand clearly exists for such drugs, and that several more such drugs are likely to appear soon (albeit for other medical indications), the FDA should recognize cognitive enhancers as a separate product class for the purposes of regulation. Medical and technological developments in the past have caused the FDA to create new categories of regulated products, such as dietary supplements and biologics, and a similar time has come for the administration to create an appropriate regulatory regime for cognitive enhancers.[83]

Current FDA regulation of cognitive enhancers is inadequate for several reasons. By ignoring the cognitive enhancement function of certain drugs, the FDA encourages a black market for this use. For example, in addition to buying, selling or forging prescriptions, students even fake the symptoms of ADHD or narcolepsy to doctors to gain access to cognitive enhancers. [84] Also, the manufacturers of these drugs are fully aware of the lucrative off-label market for their products. And although FDA rules prohibit advertising off-label uses of medication, some companies have tested the boundaries in an effort to exploit the underground popularity of cognitive enhancers. For example, the makers of Adderall were warned by the FDA in 2008 for releasing a testimonial of television star Ty Pennington on youtube.com in

[83] See, e.g. 42 U.S.C. Section 262 "Regulation of biological products and Dietary Supplement Health and Education Act of 1994, Public Law 103-417, for regulatory responses to new classes of products.
[84] Margaret Talbot, "Brain Gain." The New Yorker, April 27, 2009. http://www.newyorker.com/reporting/2009/04/27/090427fa_fact_talbot?currentPage=all (describing a Harvard undergraduate student who researched ADHD symptoms to convince a doctor to prescribe Addreall).

which he claimed Adderall, "literally changed my life, and gave me the confidence to achieve my goals." [85]

Off-label drug use has been a controversial topic in drug law for many years. But the off-label usage of drugs such as Ritalin, Adderall and Provigil as cognitive enhancers is too vast to ignore and has proven to be an exceptional case. The cognitive enhancers of the future are drugs likely to be discovered during the development of medical-use drugs like new Alzheimer's medications. [86] But by acknowledging cognitive enhancers as a distinct class, the FDA can direct manufacturers to perform detailed studies to better establish efficacy and appropriate dosages for an enhancement indication. Currently, individuals are left to guess or consult their friends or the Internet concerning correct dosing, potential side effects and drug interactions. Adderall, Ritalin and Provigil all have potential side effects, and all pose serious health risks when not used as directed. [87] In addition, government research suggests that non-medical Adderall users are significantly more likely than their peers to abuse alcohol and "recreational drugs" such as marijuana, cocaine and pain killers.[88] In an increasingly competitive world, it is understandable that people look for new ways to gain a mental edge. But until the FDA regulates cognitive enhancers directly, rather than turn a blind eye to their off-label and unsupervised use, it invites misunderstanding and abuse of these drugs among the public. And although individual institutions in society such as sports governing bodies, school systems and the armed forces may be the final arbiters about the permissibility of cognitive enhancers in their individuals fields of endeavor, rather than establish their own rules on an ad hoc basis, many organizations likely

[85] "Warning Letter." September 25, 2008, Food and Drug Administration. http://www.fda.gov/cder/warn/2008/AdderallXR_Letter.pdf
[86] Towards responsible use of cognitive-enhancing drugs by the healthy," supra, note 76.
[87] Modafinil, FDA approved labeling, August 17, 2007. http://www.fda.gov/cder/foi/label/2007/020717s020s013s018lbl.pdf; "FDA approved label for Adderall," supra, note 9; Approved FDA label for Ritalin, http://www.fda.gov/cder/foi/label/2002/18029slr032lbl.pdf
[88] "Nonmedical Use of Adderall among Full-Time College Students," see supra, note 65.

would welcome increased regulation by the FDA to ensure efficacy and safety as well as establish guidelines for use, labeling and dosage.

Ultimately, however, the FDA is not in the business of regulating the practice of medicine. The medical community, and perhaps psychiatrists in particular need to take a more critical look at ADHD. The subjectivity of ADHD symptoms, the fact that doctors frequently can be manipulated by patients into diagnosing the disorder, and the reality that so many supposedly healthy individuals believe ADHD medication improves their lives suggests diagnostic criteria and treatment options of ADHD need refining, especially when doctors diagnose adult patients. Nearly everyone loses focus and becomes forgetful at times, and it is not surprising for athletes and others to wonder if they suffer from some form of attention deficit, however mild, especially if they see colleagues benefiting from drug use. However, an ADHD diagnosis, like that of any mental disorder, carries a social stigma, and could have legal implications for a person's employment or health insurance. Thus, even if non-medical use of drugs like Ritalin, Adderall and Provigil becomes an accepted practice, the line between cognitive enhancement and treatment for ADHD will continue to be blurred until the medical community can provide a clearer distinction between the two. The DSM-V, an updated version of the American Psychiatric Associations manual for mental disorders currently is being prepared and is expected to be released in 2012, providing a timely opportunity for renewed discussion regarding the unresolved clinical issues surrounding ADHD. [89] Finally, assuming that the FDA would require prescriptions for certain cognitive enhancers, the broader medical community will need to take a position on how it views its role as gatekeepers between patients and such drugs. This may be a particularly complicated issue; although some commentators have noted that enhancement questions already confront doctors working in areas such as plastic

[89] "DSM-V: The Future Manual." American Psychiatric Association. http://www.psych.org/dsmv.asp

surgery and fertility clinics, the analogy is not incomplete. [90] Cognitive enhancers will raise even more complicated ethical issues for doctors than current enhancement procedures because their use will be on a much larger scale, and if ADHD diagnoses are a guide, there will be significant pressure for patients to begin them at an earlier age.

The era of cognitive enhancers is not on the horizon; it is already here. Athletes, businessmen, scientists and students have discovered their potential and have begun to incorporate them into their lives, legally and otherwise. It is time for the FDA and the medical community to acknowledge their widespread use. By recognizing cognitive enhancers as a separate class of product regulation, the FDA can direct manufacturers to begin to investigate the short and long-term effects of these drugs and determine appropriate dosage rates and labeling. And by acknowledging a non-medical, enhancement indication for psychoactive drugs, the FDA will be ready for the future generation of cognitive enhancers and be equipped to protect the health and safety of the many who will use them.

[90] Towards responsible use of cognitive-enhancing drugs by the healthy," supra, note 76.