

THE ANABOLIC STEROIDS ACT: BAD MEDICINE FOR THE ELDERLY

Jeffrey Hedges

The rampant abuse of anabolic steroids, and their harmful side effects, prompted Congress to classify steroids as a controlled substance. The Anabolic Steroids Control Act makes it a criminal offense for a physician to distribute steroids to a patient unless in the treatment of a disease or other recognized medical condition. While this legislation controls steroid abuse among athletes and minors, it also prevents the use of steroids in treating some legitimate conditions. The inability to prescribe steroid treatments has had a direct impact on the elderly.

Research suggests that the benefits associated with steroids, muscle growth and increased strength, help combat many of the illnesses and ailments associated with aging. However, further research in this area is useless if the treatments cannot be administered. In this note, Mr. Jeffrey Hedges explores the purpose and the effect of the Anabolic Steroids Control Act. He argues that although the legislation intended to prevent the abuse of steroids for nonmedical purposes, the expansive nature of the Act creates an unnecessary barrier to treating the degenerative effects of aging. Mr. Hedges suggests that the current legislation be amended to allow physicians to use their professional judgment in administering steroid treatment to the elderly. Only then might the revitalizing effects of a legitimate steroid treatment be fully explored and realized.

I. Introduction

Attorneys practicing in the area of elder law understand that an older client's needs extend far beyond legal dilemmas.¹ To effectively meet the needs of elder clients, attorneys must

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1. See Amelia E. Pohl, Note, *Introduction: What Is Elder Law Anyway?*, 19 NOVA L. REV. 459, 461 (1995). This article examines the practice area of elder law with special focus on the National Academy of Elder Law Attorneys (NAELA) and the National Academy of Elder Law Foundation (NAELF). NAELA was created to exchange information concerning the administration of benefit programs in differ-

move beyond conventional legal work and be capable and willing to offer practical assistance. Peter J. Strauss, author of several elder law publications,² states that often the attorney may be the right person to provide information about home care, nursing homes, special geriatric health problems, and adult day care.³ Specializing in elder law results in contact with insurance agents, geriatric care or case managers, and social service agency personnel. Because the practice of elder law leads to an accumulation of information and contacts, attorneys are rapidly becoming the "first-stop" in addressing issues outside of the legal context.

Part of the new role attorneys play in elder law includes scrutinizing legal issues and policies affecting clients. When circumstances create obstacles which hinder the quality of life for the elderly, it may be the responsibility of attorneys to seek change. On October 27, 1990, Congress passed the Crime Control Act of 1990.⁴ The legislation produced an anticrime package that included new banking and money laundering offenses, expanded the rights of crime victims, broadened the protection of child witnesses, enlarged correctional alternatives to prison, and expanded substance abuse prevention and treatment.⁵ The Anabolic Steroids Control Act of 1990⁶ was a product of the same legislation. In an effort to curb the misuse of steroids, Congress enacted laws regulating their possession and distribution.⁷ An unfortunate consequence, however, has been the restriction of steroid research and the legitimate use of steroids in the therapeutic treatment of the elderly.⁸

Health care costs continue to rise along with a push for legislation to increase the availability of medicine to all people. Reevaluating current laws which strangle beneficial treatments may be one method by which treatments for the elderly can become more efficient

ent states. *Id.* at 460-61. NAELF was created in an effort to require certification by way of examination for attorneys specializing in elder law. *Id.* at 462.

2. See, e.g., PETER J. STRAUSS ET AL., *AGING AND THE LAW* (1990).

3. See *id.* at 4.

4. Pub. L. No. 101-647, 104 Stat. 4789.

5. See Bennett L. Gershman, *The New Omnibus Crime Bill*, 18 WESTCHESTER B.J. 53 (1991).

6. Pub. L. No. 101-647, §§ 1901-1907, 104 Stat. 4851 (1990).

7. *Id.*

8. Although the legislation permits distribution to a patient only for the treatment of a disease, it qualifies that limitation for medical conditions recognized by the Secretary of Health and Human Services. 21 U.S.C. § 333(c) (1994); see also 137 CONG. REC. E450 (daily ed. Feb. 7, 1991) (statement of Rep. Hughes); H.R. REP. NO. 101-681, pt. 3, at 70-71 (1990), reprinted in 1990 U.S.C.C.A.N. 6472, 6474-75.

and affordable. This note offers an analysis of the current steroid legislation as it relates to the elderly and suggests that many persons who suffer from the deteriorating effects of age could benefit from the treatment of anabolic steroids. Such treatment will not occur, however, without a change in the legislation allowing physicians to use their professional judgment in administering steroid treatments to the elderly. The proposed modification would not take place at the expense of the congressional objectives in designing the current steroids legislation. The integrity of the Anabolic Steroids Control Act need not be sacrificed in order to allow legitimate treatment of the elderly.

II. Background

A. The Legislation

Pharmaceutical regulations originally dealt with drug safety and labeling.⁹ However, in 1962, federal pharmaceutical law began requiring drug manufacturers to demonstrate the effectiveness of the drugs they marketed.¹⁰ Many steroid manufacturers claimed that treatment of osteoporosis and growth hormone deficiency were valid medical uses of steroids.¹¹ The Food and Drug Administration (FDA) did not agree and rejected these claims.¹² In 1988, Congress passed the Anti-Drug Abuse Act¹³ which provided criminal penalties for anabolic steroid trafficking.¹⁴ A further step was taken in 1990, when Congress enacted the Anabolic Steroids Control Act.¹⁵ The Act places anabolic

9. See WILLIAM N. TAYLOR, *MACHO MEDICINE: A HISTORY OF THE ANABOLIC STEROID EPIDEMIC* 41 (1991).

10. See *Legislation to Amend the Controlled Substance Act (Anabolic Steroids): Hearings on H.R. 3216 Before the Subcomm. on Crime of the House of Representatives Comm. on the Judiciary*, 100th Cong. 73-74 (1988) [hereinafter *Hearings on the Controlled Substance Act*] (statement of Gloria Troendle, Deputy Director, Division of Metabolic and Endocrine Drug Products, Food and Drug Administration).

11. See *id.* This claim is still made not only by the drug manufacturers, but also by health care providers. See William C. Scott et al., *Medical and Nonmedical Uses of Anabolic-Androgenic Steroids*, 264 JAMA 2923, 2923 (1990).

12. See *Hearings on the Controlled Substance Act*, *supra* note 10, at 73.

13. Pub. L. No. 100-690, § 2401, 102 Stat. 4181, 4230 (codified as amended at 21 U.S.C. § 801 (1994)).

14. See *id.* The 1988 Act provided that an individual convicted of violation of the Food, Drug, and Cosmetic Act would be subject to forfeiture of specific property and imprisonment of up to three years or a fine or both if that individual distributed steroids without prescription. See Jeffrey A. Black, Comment, *The Anabolic Steroids Control Act of 1990: A Need for Change*, 97 DICK. L. REV. 131, 136 n.31 (1992).

15. H.R. 4658, 101st Cong. (1990).

steroids on Schedule III of the Controlled Substance Act (CSA).¹⁶ Schedule III drugs typically include those which may lead to moderate or low physical dependence or high psychological dependence.

16. See 21 U.S.C. § 812 (1994), which establishes the criteria for placement upon a Schedule and provides in relevant part:

(a) Establishment

There are established five schedules of controlled substances, to be known as schedules, I, II, III, IV, and V. Such schedules shall initially consist of the substances listed in this section. The schedules established by this section shall be updated and republished on a semiannual basis during the two-year period beginning one year after the date of enactment of this title and shall be updated and republished on an annual basis thereafter.

(b) Placement on schedules; findings required

Except where control is required by United States obligations under an international treaty, convention, or protocol, in effect on the effective date of this part, and except in the case of an immediate precursor, a drug or other substance may not be placed in any schedule unless the findings required for such schedule are made with respect to such drug or other substance. The findings required for each of the schedules are as follows:

(1) Schedule I

(A) The drug or other substance has a high potential for abuse.

(B) The drug or other substance has no currently accepted medical use in treatment in the United States.

(C) There is a lack of accepted safety for use of the drug or other substance under medical supervision.

(2) Schedule II

(A) The drug or other substance has a high potential for abuse.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions.

(C) Abuse of the drug or other substance may lead to severe psychological or physical dependence.

(3) Schedule III

(A) The drug or other substance has a potential for abuse less than the drugs or other substances in schedules I and II.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States.

(C) Abuse of the drug or other substance may lead to moderate or low physical dependence or high psychological dependence.

(4) Schedule IV

(A) The drug or other substance has a low potential for abuse relative to the drugs or other substances in schedule III.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States.

(C) Abuse of the drug or other substance may lead to limited physical dependence relative to the drugs or other substances in schedule III.

The Act also includes an official list of drugs to be considered "steroids" for the purpose of the Act.¹⁷

The classification of anabolic steroids as controlled substances has created criminal penalties similar to those for narcotic violations.¹⁸ Notably, the Act criminalizes a physician's distribution of steroids for any use in humans other than the treatment of a disease or other recognized medical conditions.¹⁹ In addition, although the FDA approved steroid use for nondisease conditions,²⁰ Congress gave the Secretary of Health and Human Services the power to exempt steroids from prohibition only if: (1) the substance is accepted for a rare dis-

(5) Schedule V

(A) The drug or other substance has a low potential for abuse relative to the drugs or other substances in schedule IV.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States.

(C) Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in Schedule IV.

17. See 21 U.S.C. § 802. The list includes 28 items. In 1991, two doctors voiced concern over a similar list in New York's steroid legislation. See Richard D. Amelar et al., *The Prescription and Proscription of Chorionic Gonadotropin*, 265 JAMA 1529, 1529 (1991). The doctors stated that by error other "useful" and "important" medication was included in the list to which the rules apply. See *id.* Unfortunately, drugs which were not anabolic steroids had found their way onto the list at the cost of great inconvenience, apprehension, and additional expense, but had not benefited anyone. See *id.*

18. See Anti-Drug Abuse Act of 1988, Pub. L. No. 100-690, 102 Stat. 4181. This Act was repealed in November of 1990, effective February 1991, by the Anabolic Steroids Control Act of 1990, Pub. L. No. 101-647 § 1905, 104 Stat. 4853.

19. See 21 U.S.C. § 333(e). The statute provides:

(e)(1) Except as provided in paragraph (2), any person who distributes or possesses with the intent to distribute any anabolic steroid for any use in humans other than the treatment of disease pursuant to the order of a physician shall be imprisoned for not more than 3 years or fined under title 18, United States Code, or both.

(2) Any person who distributes or possesses with the intent to distribute to an individual under 18 years of age, any anabolic steroid for any use in humans other than the treatment of disease pursuant to the order of a physician shall be imprisoned for not more than six years or fined under title 18, United States Code, or both.

20. See GOODMAN & GILMAN'S PHARMACOLOGICAL BASIS OF THERAPEUTICS 1451-54 (Alfred Goodman Gilman et al. eds., 1985) [hereinafter GOODMAN & GILMAN]. The approved conditions include "allergies, stunted growth in childhood, and maintaining muscle mass for geriatric patients who, although not suffering from a specific disease treatable by anabolic steroids, are in a state of debilitation." Black, *supra* note 14, at 140.

ease or condition, and (2) the substance has no significant potential for abuse.²¹

B. The Enhancers

Anabolic steroid use once existed only among elite athletes competing at the world-class level.²² It is now estimated that 5% to 75% of professional athletes and 2% to 20% of college athletes use steroids.²³ Other experts estimate that half of the 9000 athletes who competed in the 1988 Olympics used steroids at some time during their training.²⁴ Perhaps more alarming are reports indicating that as many as two million nonathletes have experimented with these drugs.²⁵ The widespread use of performance-enhancing drugs in sports has resulted in state and federal legislation restricting the distribution and use of anabolic steroids.²⁶

Despite the potential for abuse of steroids, these drugs can have beneficial effects. Most experts agree that steroids enhance the synthesis of proteins in the body, which ultimately leads to muscle growth.²⁷ As a result, these drugs remain useful in a variety of medical applications.²⁸

21. See 137 CONG. REC. E450 (daily ed. Feb. 7, 1991) (statement of Rep. Hughes).

22. See JAMES E. WRIGHT & VIRGINIA S. COWART, *ANABOLIC STEROIDS: ALTERED STATES 2* (Kendal Glandish ed., 1990).

23. See *Abuse of Steroids in Amateur and Professional Athletics: Hearings on H.R. 4658 Before the Subcomm. on Crime of the House Comm. on the Judiciary*, 101st Cong. 73 (1990) [hereinafter *Hearings on Steroid Abuse*] (statement by Robert E. Larsen, M.D., Team Physician, University of Minnesota Football Team).

24. See VIRGINIA ALVIN & ROBERT SILVERSTEIN, *STERIODS: BIG MUSCLES, BIG PROBLEMS* 65 (1992).

25. See *Hearings on Steroid Abuse*, *supra* note 23, at 67 (statement of Robert E. Larsen, M.D.).

26. See, e.g., Amelar et al., *supra* note 17, at 1529; 21 U.S.C. § 812(c) (1994).

27. See Herbert A. Haupt & George D. Rovere, *Anabolic Steroids: A Review of the Literature*, 12 AM. J. SPORTS MED. 469, 481 (1984).

28. Current medical applications include treatment of: "certain types of anemias, hereditary angio-edema, certain gynecologic conditions, and protein anabolism." William C. Scott et al., *supra* note 11. "They also may have a role or be useful in conjunction with: constitutional delay of growth, an adjunct to growth hormone therapy, and osteoporosis." *Id.* Steroids may also be used in the treatment of skeletal disorders due to the stimulation of protein in bone. WRIGHT & COWART, *supra* note 22, at 35. Surgeons prescribe steroids before an operation to improve the condition of certain patients or after surgery to promote wound healing. Other indications have been for fibrocystic breast disease, female breast cancer, and endometriosis. Due to the rehabilitating effects of the drug, doctors have prescribed steroids for the treatment of malnutrition and other conditions associated with advanced age. See *id.*

1. STEROIDS: WHAT THEY ARE AND HOW THEY WORK

Steroids are chemical compounds that affect metabolism—the process of changing food into energy.²⁹ Human sex hormones like testosterone, progesterone, and estrogen are also steroids.³⁰ Testosterone promotes constructive metabolism and tissue repair—often called the “anabolic effect”—and also induces secondary male sex characteristics—often called the “androgenic effect.”³¹ Anabolic-androgenic steroids were pioneered in the 1950s to separate the masculinizing (androgenic) and skeletal muscle-building (anabolic) effects.³² These steroids are synthetic derivatives of testosterone.³³ Currently, no steroid has been created which has a purely anabolic effect.³⁴ Anabolic steroids are often confused with corticosteroids which are “used to treat infections, arthritis (inflammation of the joints), asthma, and certain cancers.”³⁵ Corticosteroids, unlike anabolic steroids, do not build or enhance muscle tissue growth.³⁶

The anabolic process of steroids within the body is very similar to that of naturally occurring testosterone.³⁷ Testosterone is released into the bloodstream, where it attaches to cells throughout the body.³⁸ Once distributed throughout the body, testosterone promotes the formation of new deoxyribonucleic acid (DNA), which then results in protein production.³⁹ The protein, once outside the cell, forms new tissue or muscle.⁴⁰ Anabolic steroids cause these effects to occur much more rapidly than what occurs naturally.⁴¹ In addition, steroids help block the breakdown of existing muscle when they are exposed to strain, thereby preventing normal muscle fatigue.⁴² These beneficial

29. See SARAH STEVENS, *STERIODS* 6 (1991).

30. See *id.* at 7.

31. See Herbert A. Haupt, *Anabolic Steroids and Growth Hormone*, 21 AM. J. SPORTS MED. 468 (1993).

32. See Scott et al., *supra* note 11.

33. See *id.*

34. See *id.*

35. SCOTT E. LUKAS, *THE DRUG LIBRARY: STEROIDS* 8 (1994).

36. See *id.*

37. See *id.* at 35.

38. See *id.*

39. See *id.*

40. See *id.* at 35-37.

41. See *id.*

42. See *id.*

effects, however, can only be sustained through continued steroid use.⁴³

Inaccurate reports alleging that steroids were ineffective⁴⁴ and dangerous largely shaped society's opinion of steroid treatment.⁴⁵ Current research proves that increases in skeletal muscle mass result from steroid treatment.⁴⁶ Historic claims that the risks of steroid use outweigh any benefits are now being challenged.⁴⁷ Although scientists have documented numerous side effects of steroid use, these side effects are misleading as they usually occur at far greater dosages than those prescribed for medical conditions.⁴⁸ Those abusing the drugs often "stack" the dosages by taking many types of anabolic steroids concurrently.⁴⁹ Adding to the misinformation is the fact that reports documenting side effects typically refer to long-term usage.⁵⁰ These factors all combine to give a false impression of steroids and their legitimate medical applications.

2. HUMAN GROWTH HORMONE

Human growth hormone (hGH) is not an anabolic steroid, but is commonly used like anabolic steroids to stimulate muscle development.⁵¹ Like steroids, hGH is a naturally occurring hormone found in all individuals.⁵² Originally hGH was difficult and expensive to obtain because it had to be extracted from the pituitary glands of cadav-

43. See George Fan, Note, *Anabolic Steroid and Human Growth Hormone Abuse: Creating an Effective and Equitable Ergogenic Drug Policy*, 1994 U. CHI. LEGAL F. 439, 446.

44. See Scott et al., *supra* note 11.

45. As with most drugs, certain side effects accompany steroid treatment. See GARY I. WADLER & BRIAN HAINLINE, *DRUGS AND THE ATHLETE* 65-66 (1989). The inaccuracies of the mentioned reports concern the side effects associated with abusers of the drug. See *id.* at 66-67.

46. See Scott et al., *supra* note 11, at 2.

47. See Fan, *supra* note 43, at 444.

48. See Council on Scientific Affairs, *Drug Abuse in Athletes: Anabolic Steroids and Human Growth Hormone*, 259 JAMA 1703, 1704 (1988). The *Underground Steroid Handbook* is written, edited, and revised by athletes who themselves use steroids. See Fan, *supra* note 43, at 444. The authors of the handbook state that most medical claims about steroid side effects are untrue. *Id.* at 470 n.40.

49. See Scott et al., *supra* note 11, at 2924.

50. See, e.g., *id.*; Norma M. Reddig, Note, *Anabolic Steroids: The Price of Pumping Up!*, 37 WAYNE L. REV. 1647, 1649 (1991); John Burge, Note, *Legalize and Regulate: A Prescription for Reforming Anabolic Steroid Legislation*, 15 LOY. L.A. ENT. L.J. 33, 36 (1994).

51. See ROBERT VOY, *DRUGS, SPORTS, AND POLITICS* 62 (1991).

52. See *id.* at 57.

ers.⁵³ With the advent of synthetic replication, the supply of hGH is no longer limited.⁵⁴

hGH increases nitrogen retention and may increase the rate at which amino acids are transported and transformed into proteins,⁵⁵ the building blocks of muscle.⁵⁶ hGH also promotes quicker muscle growth by stimulating the conversion of fat into energy.⁵⁷ This process allows resources which are typically used for energy to be converted to muscle tissue.⁵⁸ Because it is an anabolic hormone, hGH also promotes protein accretion.⁵⁹ This helps conserve body protein in those patients with caloric restrictions.⁶⁰

The reported side effects associated with hGH treatment most commonly include acromegaly and gigantism.⁶¹ Acromegaly is a condition marked by the progressive enlargement of the hands, feet, and face due to excessive production of growth hormone.⁶² In contrast, individuals with gigantism usually suffer an overgrowth of the entire body.⁶³ However, because growth zones in adult bones have sealed, the effects of gigantism are restricted to adolescents.⁶⁴ The prevalence of acromegaly and gigantism is disputed, and many scientists and health care providers advocate that such risks can be eliminated with supervision and moderation.⁶⁵ Other health care professionals believe the advantages of hGH outweigh the risks.⁶⁶ Dr. Louis Underwood, Professor of Pediatrics at the University of North Carolina, testified before the House that hGH, "unlike anabolic steroids, [did not] en-

53. See Kaup R. Shetty & Edmund H. Duthie, *Anterior Pituitary Function and Growth Hormone Use in the Elderly*, 24 *ENDOCRINE ASPECTS OF AGING* 213, 220 (1995).

54. See *id.*

55. See Haupt, *supra* note 31, at 471.

56. See THE BANTAM MEDICAL DICTIONARY 355 (rev. ed. 1990) [hereinafter BANTAM].

57. See Haupt, *supra* note 31, at 471.

58. See *id.*

59. See Shetty & Duthie, *supra* note 53, at 225.

60. See *id.*

61. See Haupt, *supra* note 31, at 472.

62. See BANTAM, *supra* note 56, at 5.

63. See *id.* at 181-82.

64. See Haupt, *supra* note 31, at 472.

65. See Geoffrey Cowley, *Attention: Aging Men*, *NEWSWEEK*, Sept. 16, 1996, at 68, 74. Dr. Stanley Slater, director of hormone research at the National Institute on Aging, states that many of the side effects can be limited or eliminated by lowering a person's dosage. See *id.*

66. See *Anabolic Steroids Control Act of 1990: Hearings on H.R. 4658 Before the Subcomm. on Crime of the Comm. on the Judiciary*, 101st Cong. 81 (1990) [hereinafter *Hearings on Steroids*] (statement of Dr. Louis Underwood, Professor of Pediatrics at the University of North Carolina).

hance strength or athletic performance and did not cause aggressive behavior, psychological dependency, or withdrawal-related mood changes."⁶⁷ Dr. Underwood has treated approximately 200 children with hGH "in the hopes of obtaining normal growth and achieving normal adult stature."⁶⁸ Because the supply of hGH is no longer limited,⁶⁹ and there are minimal adverse risks associated with its intake,⁷⁰ this hormone is being tested in various clinical conditions that are unrelated to growth retardation.⁷¹

Unlike anabolic steroids, hGH is not scheduled by the federal government under the Controlled Substances Act.⁷² Congress chose to leave hGH off the list, in part, because there was no consensus within the scientific community that the drug posed a great risk of being abused in a manner like steroids.⁷³ Nor are the side effects associated with steroid use seen in users of hGH.⁷⁴

III. Analysis

As with most policy decisions, the development of antisteroid legislation required balancing any benefits that steroids offer against the perceived dangers.⁷⁵ This "give and take" approach was used in designing the Anabolic Steroids Control Act.⁷⁶ Fueled largely by the potential for steroid abuse and possible side effects, Congress chose to

67. *Hearings on Steroid Abuse*, *supra* note 23, at 85-88.

68. *Id.* at 85.

69. *See Shetty & Duthie*, *supra* note 53, at 220.

70. *See Hearings on Steroid Abuse*, *supra* note 23, at 87.

71. *See Shetty & Duthie*, *supra* note 53, at 220.

72. 21 U.S.C. § 812 (1994).

73. At the time of the congressional hearings concerning steroid legislation, Ronald G. Chesemore, Associate Commissioner for Regulatory Affairs for the FDA, testified that the scientific community had not reached a consensus regarding the abuse potential of hGH. *See Hearings on Steroid Abuse*, *supra* note 23, at 47 (statement of Ronald G. Chesemore, Associate Commissioner for Regulatory Affairs for the Food and Drug Administration). This was due in part to the strict controls placed upon the distribution of hGH by the manufacturers. The FDA also found that illegal distribution of hGH was much less prevalent than the illicit distribution of steroids. *Id.*

74. *See Hearings on Steroid Abuse*, *supra* note 23, at 84.

75. Clearly, anabolic steroids present serious problems, especially with adolescents. *See W.E. Buckley, Estimated Prevalence of Anabolic Steroid Use Among Male High School Seniors*, 260 JAMA 3441, 3445 (1988). One survey suggests that as many as 6.6% of male 12th graders have experimented with the drug. *See id.*

76. *See* 137 CONG. REC. E450-02 (1991). *See generally Anabolic Steroids Control Act of 1990: Hearings on H.R. 4658 Before the Subcomm. on Crime of the House Comm. on the Judiciary*, 101st Cong. 90 (1990).

stringently regulate distribution at the cost of limiting viable treatments and research.⁷⁷

A. Treatment Denied

Unfortunately, in the legislative trade-off, treatments using steroids to combat many of the illnesses and conditions associated with old age were negotiated into the banned category.⁷⁸ In order for physicians to prescribe steroids, they must be addressing a known disease approved for such treatment by the Secretary of Health and Human Services.⁷⁹ Even then the Secretary of Health and Human Services has the power to regulate such treatments.⁸⁰ Although many illnesses facing the elderly are within the legal confines of steroid treatment, perhaps the most significant benefit associated with the drug is not legally permitted, that being increased muscle growth and strength.⁸¹ Ironically, this was the very reason steroids were designed.⁸² When Congress limited steroids for body-building purposes, its focus was on deterring uses for fashionable results.⁸³ In so doing, Congress necessarily created a barrier for the drug's revitalizing and rejuvenating effects to be utilized in the treatment of the elderly.

77. See 137 CONG. REC. E450-02 (1991).

78. See the definition of "anabolic steroids" in 21 U.S.C. § 802 (1994).

79. See 21 U.S.C. § 333(e)(1).

80. See *supra* note 21 and accompanying text.

81. The prescription of steroids for other than the treatment of disease is a violation of the Act. Therefore, physicians who prescribed steroids for "body building" purposes would violate the very heart of the Act. See 21 U.S.C. § 333(e)(1).

82. It is claimed that in the 19th century, a European physiologist began testing the results of injecting testosterone from roosters. See John Pine, *Myth Surrounding Steroids Began in 19th Century Europe*, REUTERS N. AM. SERV., Sept. 28, 1988. The first clinical use of testosterone occurred in 1938 when doctors treated underweight patients in order to stimulate weight gain. See Morris B. Mellon, *Anabolic Steroids in Athletes*, AM. FAM. PHYSICIAN, July 1984, at 114. In the 1954 Vienna World Powerlifting Championship, Dr. John Ziegler administered steroids to the U.S. weight lifters. See Roy Bergman & Robert E. Leach, *The Use and Abuse of Anabolic Steroids in Olympic Caliber Athletes*, CLINICAL ORTHOPEDICS & RELATED RES., Sept. 1985, at 170. Impressed with the results, Dr. Ziegler began studies which resulted in the development of Dianabol, an anabolic steroid with fewer masculinizing properties than testosterone. See *id.*

83. See 136 CONG. REC. S16615-03 (1990). Congress seemed particularly worried about the growing number of adolescents who were discovering that steroids enhanced their muscle size and strength. See also W.E. Buckley et al., *Estimated Prevalence of Anabolic Steroid Use Among Male High School Seniors*, 260 JAMA 3441 (1988). Congress heard reports that athletes were the most common users of anabolic steroids. See Mimi D. Johnson et al., *Anabolic Steroid Use by Male Adolescents*, 83 PEDIATRICS 921, 922 (1989).

1. STEROID REPLACEMENT

As people age, and their bodies undergo the slow process of deterioration, bone density⁸⁴ and lean body mass will steadily decrease.⁸⁵ For instance, a typical man will lose between 12 and 20 pounds of muscle as well as 15% of his bone mass between the ages of 40 and 70.⁸⁶ Although most people experience only normal degeneration as they age, some suffer from unusually severe muscle strength and bone density loss.⁸⁷ These losses can require hospitalization and high medical costs. The administration of replacement hormones is ideally suited for people in this condition.⁸⁸ The beneficial effects of testosterone for this purpose are no longer disputed.⁸⁹ A team of physicians recently tested the effects of testosterone and concluded that the administration of androgens would have beneficial effects in patients with chronic and wasting disorders.⁹⁰ Recently, physicians have begun to seriously study the possibility of replacement hormone treatment for the general increase in body strength and overall sense of well-being in the elderly.⁹¹

Enthusiasts believe that hormones may be the ultimate antidote for aging in both sexes.⁹² These drugs include testosterone, dehydroepiandrosterone (DHEA), melatonin, and hGH.⁹³ Dr. William Regelson of the Medical College of Virginia believes that aging can be delayed.⁹⁴ He claims that by restoring hormones "it is possible to slow

84. See Joel R. Pittman & Natalie Kujdych, *Osteoporosis: New Perspectives*, 140 *DRUG TOPICS*, Aug. 19, 1996, at 108, available in 1996 WL 11132318.

85. See Shetty & Duthie, *supra* note 53, at 220; see also Cowley, *supra* note 65, at 70.

86. See Cowley, *supra* note 65, at 70.

87. See *id.*

88. See *id.* at 71.

89. See Shalender Bhasin et al., *The Effects of Supraphysiologic Doses of Testosterone on Muscle Size and Strength in Normal Men*, 335 *NEW ENG. J. MED.* 1, 1 (1996). Forty-three normal men were placed in one of four groups: placebo with no exercise, placebo with exercise, testosterone with no exercise, testosterone with exercise. The intake of energy and protein and the exercise stimulus were standardized. The four groups were similar with respect to age and weight, height, and body-mass index before treatment. The only side effect noted was mild acne. The group receiving testosterone combined with exercise had the greatest increase in muscle size, however, the group receiving testosterone without exercise had significant gains which superseded the gains made by men exercising without testosterone. See *id.* at 3-4.

90. See *id.* at 6.

91. See Cowley, *supra* note 65, at 70.

92. See *id.*

93. See *id.*

94. See *id.* at 70.

and even reverse the aging process."⁹⁵ Other professionals agree. Dr. Norm Mazer of TheraTech, a company that researches testosterone therapy, stated, "We give eyeglasses to people as they age to maintain visual acuity. Why not give them testosterone to retain muscle strength and prevent osteoporosis?"⁹⁶

One of the few diseases that characterize the elderly is osteoporosis.⁹⁷ The disease decreases bone mass or density, resulting in weakened bones which are more susceptible to fracture.⁹⁸ Although there is no cure, early treatment may slow the loss of bone.⁹⁹ Current costs of treating osteoporosis and related injury in the United States exceed \$10 billion.¹⁰⁰ That number is expected to double in the next 25 to 30 years.¹⁰¹ In women, the single most significant bone loss event is estrogen deprivation at menopause.¹⁰² Long-term estrogen replacement therapy is the only reliable means of preventing this loss.¹⁰³ Although there is no equivalent term such as "male menopause," middle age does bring on changes in men¹⁰⁴ that affect the density of bone mass.¹⁰⁵ Like treatment in women, hormone replacement in men appears to support promising results.¹⁰⁶ Testosterone is now being suggested as a potentially beneficial therapy for older men with low serum testosterone levels.¹⁰⁷ Preliminary studies indicate that therapy might benefit bone, muscle, and psychosexual functions, without significant risk of adverse effects.¹⁰⁸

95. *Id.*

96. Cowley, *supra* note 65, at 71.

97. See Pittman & Kujdych, *supra* note 84.

98. See *id.*

99. See *id.* The disease is considered a major health risk concerning Americans, 80% of whom are women. One and a half million bone fractures annually are related to osteoporosis. One-third of all women, along with one-sixth of all men over 90 years of age, will suffer at least one fracture. See *id.*

100. See *id.*

101. See *id.*

102. See *id.*

103. See *id.*

104. See *id.* The process begins in a man's 40s or 50s and affects strength, sexuality, and the general sense of contentment. See *id.* It is occasionally referred to as "andropause" or "viropause." See *id.*

105. See *id.*; see also Joyce S. Tenover, *Androgen Administration to Aging Men*, 23 CLINICAL ANDROLOGY 877, 879 (1994) (stating that after age 60, hip fracture rates double for each additional decade).

106. See Tenover, *supra* note 105, at 884. Treatment with testosterone has resulted in an increase in calcium retention and a decline in urinary calcium excretion. Androgen therapy also has resulted in an increase in body weight, an increase in lean body mass, and a tendency for a decrease in body fat. See *id.*

107. See *id.* at 887.

108. See *id.*

2. EFFECTS OF GROWTH HORMONE ON BODY COMPOSITION

Gerontologists studying physiologic and metabolic alterations during aging believe that hormonal deficiency often advances age-associated changes.¹⁰⁹ As the body ages from age 30 to age 75 years, the size of the liver, kidney, brain, and pancreas decreases by approximately 30%.¹¹⁰ After age 50, growth hormone secretion gradually declines.¹¹¹ In some individuals it becomes undetectable.¹¹² This deficiency manifests into functional losses, which restrict an elderly individual's ability to undertake activities, withstand trauma, resist infection, process foods, and excrete medications.¹¹³ The associated loss in muscle mass reduces strength, mobility, the ability to breathe and cough, and, ultimately, the capabilities necessary for an independent life.¹¹⁴

The beneficial effects of hGH have been documented in GH-deficient children and young adults.¹¹⁵ Similar studies¹¹⁶ on the elderly conclude that the desirable hormonal effects of expanding lean body mass can be achieved while the undesirable side effects avoided.¹¹⁷ One recent study, lasting 21 months and involving 45 independent men aged 61 to 81, resulted in significant changes to the participants' lean body mass.¹¹⁸ The average subject gained 6% in lean body mass; 4% in skin thickness; 8% in liver volume; 23% in spleen volume; and 11% volume in 10 tested muscle areas.¹¹⁹ It should be noted that side effects of hGH are reportedly infrequent in these short-term and long-term studies.¹²⁰ Researchers indicate that any complications can be prevented without sacrificing the beneficial effects on body composition.¹²¹

109. Shetty & Duthie, *supra* note 53, at 213.

110. *See id.* at 221.

111. *See id.*

112. *See id.*

113. *See id.*

114. *See id.* Those studying these effects have concluded that these age-related changes are undesirable for at least three reasons. First, there is a direct relation between work capacity and lean body mass. Second, geriatric atrophy of lean body mass organs is associated with diminished functional capacities in muscle strength. Third, increased adiposity predisposes negative changes in blood pressure, glucose clearance, and the plasma lipoprotein profile. *See id.*

115. *See id.* at 223.

116. *See id.*

117. *See id.* at 224.

118. *See id.* at 223.

119. *See id.*

120. *See id.* at 227.

121. *See id.*

B. Challenging the Antisteroid Legislation

The limitations imposed upon steroid treatment are the result of scheduling under the Anabolic Steroids Control Act of 1990.¹²² While the Act combats most of the steroid activity which concerned Congress, it also includes limitations on viable treatments for elderly patients. Congress could not have intended this particular limitation when developing this law.

1. LEGISLATIVE PURPOSE

In the 1980s, the federal government began suspecting that drug manufacturers were producing anabolic steroids far in excess of the legitimate medical demand.¹²³ Federal administrators targeted steroid abuse. By May 1986, personnel from the Department of Justice, the FDA, and the Federal Bureau of Investigation had joined their efforts to establish a steroid trafficking task force.¹²⁴ Federal prosecutors began actively charging distributors under the Federal Food, Drug, and Cosmetic Act.¹²⁵ As criminal prosecution began to increase for illegal distribution,¹²⁶ Congress initiated hearings to investigate the depth of steroid abuse.¹²⁷ These hearings resulted in the promulgation of the Controlled Substances Act¹²⁸ and eventually the Anabolic Steroids Control Act of 1990.¹²⁹

Legislative history reveals that Congress did not intend to restrict the distribution of anabolic steroids to the elderly even for muscle enhancing purposes.¹³⁰ Legislators believed that a number of suspected health risks were associated with the misuse of anabolic

122. Anabolic Steroids Control Act of 1990, Pub. L. No. 101-647, § 1901, 104 Stat. 4851, 4851 (1991) (codified as amended at 21 U.S.C. § 801 (1994)).

123. See Burge, *supra* note 50, at 42.

124. See WRIGHT & COWART, *supra* note 22, at 117.

125. See *Hearings on Steroids*, *supra* note 66, at 39-40.

126. See Paul J. Golstein, *Anabolic Steroids: An Ethnographic Approach*, in ANABOLIC STEROID ABUSE 74, 83 (National Inst. on Drug Abuse Research Monograph No. 102, 1990). By 1988, more than 60 trafficking prosecutions had been successful, and another 120 persons were facing charges. See *id.*

127. See *Hearings on Steroid Abuse*, *supra* note 23, at 73; *Legislation to Amend the Controlled Substances Act: Hearings on H.R. 3216 Before the Subcomm. on Crime of the House of Representatives Comm. on the Judiciary*, 100th Cong. 77 (1988).

128. See The Anti-Drug Abuse Act of 1988, Pub. L. No. 100-690, 102 Stat. 4181.

129. Anabolic Steroids Control Act of 1990, Pub. L. No. 101-647, § 1901, 104 Stat. 4851 (codified as amended at 21 U.S.C. § 801 (1994)).

130. Cf. Burge, *supra* note 50, at 41-42 (explaining that the Controlled Substance Act, which controls substance abuse, was implemented to regulate only those drugs which have a psychological effect or are psychologically addictive. Because steroids are taken to enhance appearance or performance, placing them on the scheduling list does not serve the congressional intent for creating the Act).

steroids and therefore greater control over distribution was necessary.¹³¹ Congress was particularly concerned with steroid use among minors.¹³² Senator Biden addressed Congress by stating that "steroid abuse is nearly as widespread as the use of crack cocaine among male high school students."¹³³ This concern was heightened by statistics showing that 6.6% of twelfth grade male students used anabolic steroids.¹³⁴ Congressman Beryl Anthony commented that "this is not merely a debate over whether or not an athlete has the right to use steroids to improve his performance. Sports heroes as role models have a profound influence on the social direction of our youth."¹³⁵

The concern over adolescent steroid abuse was so strong that legislators included in the proposal penalties directed at coaches and trainers who encourage steroid use among athletes.¹³⁶ Testimony included statements by coaches who said, "[I]t is the responsibility of coaches to instill proper training habits . . . without sacrificing [the athlete's] future."¹³⁷ This proposal failed to become law in 1990. However, due to the influential nature of a coach's position, Representative Hughes reintroduced similar legislation in the 1991 Act.¹³⁸ He stated that by making it criminal for coaches to encourage athletes to use steroids, "it would help put an end to such exploitation. [Coaches] must not be allowed to use their positions of trust and authority by sacrificing the athlete's health and values in a craven attempt to achieve a competitive edge."¹³⁹ Congress's concern for adolescent steroid abuse was reinforced by testimony concerning the teenage psyche.¹⁴⁰ One commentator explained that student athletes fail to be convinced that steroid dangers are real.¹⁴¹ These athletes

131. See 137 CONG. REC. E450-02 (1991).

132. See, e.g., 136 CONG. REC. S16615 (1990) (comments from Senator Biden).

133. *Id.*

134. See Buckley et al., *supra* note 83, at 3445.

135. 134 CONG. REC. E3138-01 (daily ed. Sept. 28, 1988).

136. See H.R. 4658, 101st Cong. § 2(a) (1990). Penalties for these actions include up to two years imprisonment and fines under Title 18. See *id.* If the individual being induced is under 18, imprisonment may go up to five years and fines may be imposed. See *id.*

137. *Hearings on Steroid Abuse*, *supra* note 23, at 44 (statement by Chet Parlavecchio, football coach at Bloomfield High School, N.J.).

138. See generally H.R. 867, 102d Cong. (1991).

139. 137 CONG. REC. E450, (daily ed. Feb. 7, 1991).

140. See *Hearings on Steroid Abuse*, *supra* note 23, at 49 (statement by Richard Sandlin, former assistant coach for strength and fitness at the University of Alabama).

141. See *id.*

often believe anything improving physical strength and appearance could never be bad.¹⁴²

It was not only the prevalent abuse by children which captured the attention of Congress, but also the profile of steroid users in general. A representative from the Department of Justice informed Congress that many steroid users were very goal oriented and did not take steroids "to get high or to escape from reality."¹⁴³ Unlike those who abuse other drugs for their mind altering effect, the motives behind steroid use were thought to be more calculated; the user actually compares the associated risks to the chance of achieving a target goal.¹⁴⁴ Thus, Congress felt that legislation must discourage abusers who were willing to sacrifice their health to achieve short-term success.¹⁴⁵ The goal was to reduce the availability of anabolic steroids for nonmedical purposes, stem the abuse of steroids, deter users, and punish those who promote steroid abuse by selling and inducing others to use them.¹⁴⁶ These combined factors, equating to a high potential for abuse, prompted Congress to place steroids on the controlled substance list. The negative aspects of steroid abuse overshadowed the medical testimony concerning viable steroid treatments. Congress believed that because steroids were prescribed legally for "certain limited medical uses,"¹⁴⁷ it was in the best interest of the public to criminalize distribution except in these limited uses.¹⁴⁸ It appears from the legislative history that Congress was zealously confronting what it perceived to be the abuse of anabolic steroids for *non-medical purposes*.

2. CRIMINAL TREATMENT

The Secretary of Health and Human Services is charged with the duty of approving steroids for specific medical treatments.¹⁴⁹ Cur-

142. *See id.*

143. *Hearings on Steroids*, *supra* note 66, at 19 (prepared statement of Leslie Southwick, Deputy Assistant Attorney General, Civil Division, U.S. Department of Justice).

144. *See Reddig*, *supra* note 50, at 1656.

145. *See id.*

146. *See generally* H.R. 4658, 101st Cong. (1990).

147. *Hearings on Steroids*, *supra* note 66, at 38 (prepared statement of Ronald G. Chesemore, Associate Commissioner for Regulatory Affairs, Food and Drug Administration).

148. *See* 137 CONG. REC. E450 (daily ed. Feb. 7, 1991) (statement of Rep. Hughes); *see also* H.R. REP. NO. 101-681, pt. 3, at 94-95 (1990), *reprinted in* 1990 U.S.C.C.A.N. 6472, 6498-99.

149. *See* 21 U.S.C. § 802(41)(B)(i) (1994).

rently, treatment with "any drug or hormonal substance, chemically and pharmacologically related to testosterone (other than estrogens, progestins, and corticosteroids) that promotes muscle growth"¹⁵⁰ is legally forbidden unless in the treatment of a disease or other recognized medical condition. Therefore, pursuing hormone treatment in the elderly for other than federally approved diseases places the prescribing doctor at risk for violating the Anabolic Steroids Control Act, despite the fact that there are very beneficial treatments for the restoration of muscle and strength in the elderly.¹⁵¹ Although the intent of the legislation is served, the sweeping stroke with which it is applied dismisses many favorable applications for the elderly.

The FDA has approved steroid treatment for maintaining muscle mass for geriatric patients who, although not suffering from a specified disease treatable by anabolic steroids, are in a state of debilitation.¹⁵² However, only the Secretary of Health and Human Services may exempt steroid treatment from the Act's prohibition.¹⁵³ In doing so, the Secretary must determine that the steroid treatment does not belong under Schedule III of the Act. Currently, the treatment approved by the FDA will fail under Schedule III standards.¹⁵⁴ This unfortunate result not only limits significant treatment to the elderly, it also subjects physicians to criminal liability for advancing steroid treatment for nondisease conditions approved by the Secretary.

For these reasons,¹⁵⁵ the American Medical Association vehemently opposed the scheduling of anabolic steroids during congressional debates,¹⁵⁶ stating:

The medical facts do not support scheduling anabolic steroids under the CSA. Anabolic steroids have an accepted use in the treatment of several medical conditions, including certain ane-

150. *Id.* § 802(41)(A). This definition also includes a list of 28 drugs and substances which are to be considered anabolic steroids for the purpose of this Act. *See id.*

151. *See* Cowley, *supra* note 65, at 71.

152. *See* Black, *supra* note 14, at 140.

153. *See* 21 U.S.C. § 802(41)(B)(i).

154. These standards include: (1) whether the substance is accepted for a rare disease or condition and (2) whether the substance has any significant potential for abuse. 137 CONG. REC. E450-02 (1991).

155. The AMA also felt that scheduling anabolic steroids would not result in a reduction of widespread use because a majority of users acquire the drugs from illegitimate means. *See* Virginia S. Cowart, *Support Lags for Research on Steroid Effects*, 262 JAMA 2500, 2501 (1989).

156. *See Steroids in Amateur and Professional Sports—The Medical and Social Costs of Steroid Abuse: Hearings Before the Senate Comm. on the Judiciary*, 101st Cong. 78 (1989); Scott et al., *supra* note 11, at 2926.

mias, hereditary angioedema, and breast cancer. Moreover, anabolic steroids can be used safely under medical supervision. . . . [A]nabolic steroids should not be scheduled under *any* other schedule of the CSA since abuse of the drugs does *not* lead to physical or psychological dependence as is required for scheduling under the Act.

In addition, scheduling of anabolic steroids would not adequately address the problem of abuse of these drugs because it would not affect the major illicit sources of the drug—shipments from foreign countries and from veterinary supply houses. Scheduling would curtail only the relatively small amount of abuse that results from diversion of licit sources.¹⁵⁷

While the AMA recognizes and supports legislation which addresses the problem of misprescribing steroids, it continues to oppose the barrier created by scheduling steroids under the Controlled Substance Act.¹⁵⁸

If a physician decides to administer steroids for maintaining muscle mass and increasing strength and overall well-being, that physician will likely bear the burden of producing some evidence that his prescription falls within the proper medical standards of reasonable care.¹⁵⁹ Although most cases involving distribution of prescription drugs have required the government to prove the physician's practice was outside the bounds of his "professional medical practice,"¹⁶⁰ federal violations have only recently been prosecuted, and the proper procedure is largely uncertain. What is certain, however, is that when physicians prescribe steroids for other than approved illnesses,¹⁶¹ they open themselves up to a presumption of illegality based upon the reading of the Anabolic Steroids Control Act.¹⁶² The underlying purpose of the Act was to discourage the illegitimate distribution and consumption of anabolic steroids by those seeking to exploit the muscle-building components.¹⁶³ Congress's concern for the safety and well-being of citizens resulted in the unfortunate plight now facing

157. *Steroids in Amateur and Professional Sports—The Medical and Social Costs of Steroid Abuse: Hearings Before the Senate Comm. on the Judiciary*, 101st Cong. 78 (1989).

158. See Scott et al., *supra* note 11.

159. See *United States v. Hooker*, 541 F.2d 300, 305 (1st Cir. 1976).

160. *Id.*

161. See *supra* note 150 (Secretary of Health and Human Services).

162. See *supra* notes 150-55 and accompanying text (Secretary of Health and Human Services and statute).

163. See 137 CONG. REC. E450 (daily ed. Feb. 7, 1991) (statement of Rep. Hughes); see also H.R. REP. NO. 101-681, pt. 3, at 94 (1990), *reprinted in* 1990 U.S.C.C.A.N. 6472, 6473 (Anabolic Steroids Control Act passed as Title III of the Crime Control Act of 1990 to address criminal actions which endanger the physical safety or health of citizens).

doctors who treat the elderly. This limitation upon medically supervised steroid treatment is even more unreasonable when facts show that less than 20% of all anabolic steroids are distributed through medical professionals.¹⁶⁴ In effect, Congress has attempted to remedy rampant steroid use by targeting those who should remain unencumbered. In writing this law, Congress ignored the very professionals who were capable of providing expert advice and guidance on an issue completely beyond the scope of congressional aptitude. Congress disregarded not only the American Medical Association's recommendation to leave anabolic steroids off the scheduling list,¹⁶⁵ it also failed to recognize the objections of other governmental posts. Both the FDA and the National Institute on Drug Abuse evaluated anabolic steroids and did not recommend any administrative action to control steroids under the Controlled Substance Act.¹⁶⁶ Despite the opposition advanced by medical professionals¹⁶⁷ and regulatory agencies, Congress enacted legislation restricting steroids from many legitimate medical applications.

The federal government is not alone in the fight to regulate steroid abuse.¹⁶⁸ Many states now have rules and penalties similar to the Anabolic Steroids Control Act.¹⁶⁹ State legislators appear to have targeted the same concerns as Congress in promulgating laws against steroid abuse.¹⁷⁰ In some instances, states specifically warned practitioners that prescribing steroids to increase muscle size and strength in a person of good health is not a valid medical purpose,¹⁷¹ while others required posting notices designed to educate the public on the dangers of using steroids.¹⁷² A remarkable difference between the legislation at the federal level and that developed by states is that many

164. See Cowart, *supra* note 156, at 2501.

165. See *supra* note 158 and accompanying text (AMA's opposition).

166. See *Hearings on the Controlled Substance Act*, *supra* note 10, at 74 (testimony of Dr. Gloria Troendle, Deputy Director, Division of Metabolic and Endocrine Drug Products, Food and Drug Administration).

167. See *supra* notes 155-56 and accompanying text (AMA's opposition).

168. See Reddig, *supra* note 50, at 1663.

169. See, e.g., ARIZ. REV. STAT. ANN. §§ 32-1996, -2551, -2531, 36-2544 (West 1992 & Supp. 1996); CAL. CIV. CODE § 1812.97(a) (West Supp. 1997); N.M. STAT. ANN. § 30-31-41 (Supp. 1996); TEX. EDUC. CODE ANN. § 38.008 (West Supp. 1991); 1990 Mich. Legis. Serv. 31 (to be codified at MICH. COMP. LAWS ANN. § 333.26301-26306).

170. See sources cited *supra* note 169.

171. See sources cited *supra* note 169.

172. These posting notices contain statements of the penalties for unlawful use, delivery, and possession, while others include warnings explaining the physical dangers. See CAL. CIV. CODE § 1812.97(a) (West Supp. 1997).

states yield to a physician's legitimate medical determinations.¹⁷³ Specifically, some states do not require that all steroid prescriptions be for the treatment of some recognized disease or condition, as does the federal act.¹⁷⁴ In recognizing and anticipating steroid applications for nondisease treatment, these states defer to medical professionals.¹⁷⁵ This approach helps ensure the safety and care of countless patients every year. These states refused to replace a physician's medical expertise with their own meager knowledge of complicated scientific health issues. In doing so, they developed rules which maximize deterrence of steroid abuse in athletes while providing protection for those patients who may benefit from a doctor's care. These laws stand in sharp contrast to the Anabolic Steroids Control Act, which does not allow for such good faith determinations.¹⁷⁶ The Act specifically limits those treatments which are accepted and provides severe penalties for those in violation.¹⁷⁷ By respecting the federal law, physicians may not prescribe steroids to advance the physical strength and condition of the elderly. By subverting a doctor's determination concerning the best interests of a patient, elders are penalized as well—not for violating the law, but by submitting to it.

3. JUDICIAL IMPACT

Congress's focus on deterring athletes, especially young athletes, from abusing steroids influenced those charged to prosecute physicians in violation of the Act. United States Attorney Terree A. Bowers summed up the intentions of the Justice Department in enforcing the Anabolic Steroids Control Act against physicians:

The distribution of dangerous drugs to athletes seeking to increase their performance through artificial means simply will not be tolerated. As seen by this prosecution, the federal government is committed in its effort to identify and prosecute any physician using his or her medical practice as a conduit to distribute steroids and other drugs illegally.¹⁷⁸

This statement supports the conclusion that Congress intended to prevent the legal prescriptions of steroids for athletic purposes. How-

173. See Black, *supra* note 14, at 143.

174. See *supra* notes 150-51 and accompanying text (Secretary of Health and Human Services and two requirements).

175. See *Perzik v. Superior Court*, 4 Cal. Rptr. 2d 1 (1991); *Laura N. Buckner v. Allergan Pharm., Inc.*, 400 So. 2d 820 (1987).

176. See Black, *supra* note 14, at 143.

177. See *id.*

178. *Burge*, *supra* note 50, at 58-59 (quoting news release from United States Attorney's Office, Central District of California).

ever, there is no guarantee that doctors will enjoy immunity from prosecution if they prescribe steroids in other ways which may promote a person's strength. The puzzling question for the Department of Justice is whether to prosecute physicians who knowingly prescribe steroids for viable, yet unapproved, treatments.¹⁷⁹ If the purpose of the Act was to prevent steroid consumption primarily by athletes, that purpose would not be served by policing the medical community for infractions involving the elderly. The question then becomes one for the judiciary to interpret. The Eighth Circuit of the U.S. Court of Appeals showed hesitation in dealing with similar prosecutions against physicians for improper actions.¹⁸⁰ The court suggested that medical decisions properly belong to those in the medical profession.¹⁸¹ The court was concerned that the best interests of the patient would not be served if health care professionals' decisions were reviewed by persons unskilled in that field.¹⁸² "Questions regarding medical treatment, the nature, amount, and manner of administration of medication, the cultures and other tests essential to proper diagnosis, and kindred matters, are not suitable for determination by juristic science. Appropriate deference to qualified medical judgment is required with respect to the substantive issues involved."¹⁸³ It seems that a physician's right to prescribe anabolic steroids for the treatment of advanced age is precisely what the court meant by "substantive issues"¹⁸⁴ better left to qualified medical judgment. Unfortunately, physicians who rely on such deference may find other courts to be less sympathetic.

Although there have been few criminal prosecutions of physicians under the Anabolic Steroids Control Act, a number of doctors have been charged for violating the Controlled Substance Act.¹⁸⁵ Steroids are scheduled under the CSA,¹⁸⁶ therefore, the Act is relevant to a discussion of criminal prosecution of those physicians who violate

179. Specifically, when doctors such as Norm Mazer or William Regelson treat elderly patients with steroids in an attempt to increase muscle strength, may the government prosecute under the Anabolic Steroids Control Act? See Cowley, *supra* note 65, at 71.

180. See *Everett, M.D. v. Franciscan Sisters Healthcare, Inc.*, 882 F.2d 1383 (8th Cir. 1989).

181. See *id.* at 1386.

182. See *id.*

183. *Id.*

184. *Id.*

185. 21 U.S.C. § 841(a) (1994).

186. See *id.* § 812(c).

prescription guidelines. One of the debated issues is whether prescribing doctors must satisfy the burden of proving a legitimate medical reason for their prescription.¹⁸⁷ Case law on this issue is inconsistent.¹⁸⁸ The CSA provides, "Except as authorized by this subchapter, it shall be unlawful for any person knowingly or intentionally . . . to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance"¹⁸⁹ However, "[p]ersons registered by the Attorney General . . . to manufacture, distribute, or dispense controlled substances are authorized to possess, manufacture, distribute, or dispense such substances . . . to the extent authorized by their registration."¹⁹⁰ As one court noted,¹⁹¹ a strict reading of the CSA permits physicians registered with the Attorney General to prescribe drugs with impunity. However, courts have refused to interpret the CSA so mechanically.¹⁹² The Seventh Circuit found it incumbent upon the defendant to prove that his actions were within legitimate professional standards of practice.¹⁹³ Fortunately, not all federal courts share this view. The Fifth Circuit has routinely held that the government must prove the lack of a legitimate medical reason in order to convict a registered physician of dispensing drugs in violation of 21 U.S.C. § 841(a).¹⁹⁴ The Fifth Circuit opined: "Without behavior beyond professional practice, there is no crime."¹⁹⁵ The court recognized the practical limitations of requiring physicians to

187. See *United States v. Outler*, 659 F.2d 1306, 1309 (5th Cir. 1981).

188. Case law has not resolved this issue. For instance, in *United States v. King*, 587 F.2d 956 (9th Cir. 1978), the court held that the prosecution had the burden of proof at trial. See *id.* at 964-65. However, in other cases, courts have indicated an unwillingness to find a doctor's prescription of anabolic steroids legitimate or medically reasonable without some probative evidence. See generally *United States v. Roy*, 574 F.2d 386 (7th Cir. 1978); *Perzik v. Superior Court*, 4 Cal. Rptr. 2d 1 (Cal. Ct. App. 1991); *State Med. Bd. of Ohio v. Murray*, 613 N.E.2d 636 (Ohio 1993).

189. 21 U.S.C. § 841(a)(1).

190. *Id.* § 822(b).

191. See *Outler*, 659 F.2d at 1309.

192. See *United States v. Moore*, 423 U.S. 122 (1975) (holding that a physician may be charged with the criminal violation of § 841(a) of the CSA whenever he prescribes a controlled substance without legitimate medical reasons. The Court held that implicit within the CSA is the a requirement that the physician behave beyond professional practice.).

193. See *United States v. Roy*, 574 F.2d 386 (7th Cir. 1978).

194. See *United States v. Rosen*, 582 F.2d 1032 (5th Cir. 1978); *United States v. Rogers*, 609 F.2d 834 (5th Cir. 1980); *United States v. Guerrero*, 650 F.2d 728 (5th Cir. 1981) (reversing district court decision on evidentiary grounds).

195. *Outler*, 659 F.2d at 1309.

defend themselves against every charged CSA infraction.¹⁹⁶ The court stated:

[T]he doctor always would have the burden at trial of proving the prescription was based on a legitimate medical need. The effect of this scheme would be a presumption that every physician who prescribes a drug does so without a legitimate medical reason. We do not believe Congress intended this result.¹⁹⁷

Although the First Circuit has held that a defendant claiming a medical exemption under 21 U.S.C. § 822(b)¹⁹⁸ bears the evidentiary burden with respect to its applicability,¹⁹⁹ the court has also agreed with the Fifth Circuit that the government has the task of proving that a practitioner's prescriptions were not issued for a legitimate medical purpose in the usual course of professional practice.²⁰⁰ These holdings leave a gray area of uncertainty for physicians wishing to prescribe anabolic steroids for conditions of advanced age. Any burden placed on physicians with respect to proving the viability of a chosen treatment will effectively discourage doctors from employing that option. With the passage of the Anabolic Steroids Control Act and the enthusiasm with which the Department of Justice has pledged to ensure its enforcement,²⁰¹ doctors would be taking a great risk in signing their name to any steroid prescription. This threat of prosecution has virtually eliminated all research and development as well as application of steroid treatments for aging conditions.²⁰²

Beyond the fear of criminal prosecution, physicians must also consider the financial cost of being charged with violating the Anabolic Steroids Control Act.²⁰³ In 1986, John D. Perzik, M.D., was in-

196. *See id.*

197. *Id.* at 1309 n.3.

198. 21 U.S.C. § 885(a)(1) (1994) provides: "It shall not be necessary for the United States to negative any exemption or exception set forth in this subchapter in any complaint, information, indictment, or other pleading or in any trial, hearing, or other proceeding under this subchapter, and the burden of going forward with the evidence with respect to any such exemption or exception shall be upon the person claiming its benefit."

199. *See United States v. Hooker*, 541 F.2d 300, 305 (1st Cir. 1976).

200. *See id.*; *see also United States v. Black*, 512 F.2d 864, 871 n.15 (9th Cir. 1975) (holding by the Ninth Circuit that the government bears the burden of showing a prescription falls outside the scope of professional conduct).

201. *See supra* note 179 and accompanying text.

202. Approved tests continue on a limited basis; however, the development of synthetic hGH has resulted in numerous tests being conducted on its hormonal benefits as applied to the elderly. *See supra* notes 61-71 and accompanying text.

203. *See generally Perzik v. St. Paul Fire & Marine Ins. Co.*, 279 Cal. Rptr. 498 (1991).

dicted in federal court for illegally dispensing steroids.²⁰⁴ In his effort to defend the action, Perzik consulted with his insurance company²⁰⁵ in an attempt to convince them to pay the costs of his legal counsel.²⁰⁶ His insurance company refused to pay.²⁰⁷ Perzik realized that his insurance company was likely to balk at paying any malpractice charges as well.²⁰⁸ Therefore, he filed a declaratory relief action seeking a determination that his insurance company had the duty to defend him as well as indemnify him for any and all damages arising from the federal investigation and criminal action.²⁰⁹ The court held for the insurance company on both issues stating, "It is clear to us that the federal criminal investigation and prosecution at issue here do not constitute covered 'professional liability claims,' no matter how broadly that phrase may be interpreted. Professional liability, in common parlance, refers to malpractice liability; it is quite distinct from criminal liability."²¹⁰ The distressing result of this case adds one more reason to the growing list of justifications for a physician to refuse to administer steroids to the elderly. In the face of possible criminal prosecution, and with the prospect of losing defense insurance and indemnification, it very well may be a fool who administers steroids for anything that is not a recognized medical condition under the Act.

IV. Recommendation

In restricting the possession and distribution of steroids, Congress has necessarily limited beneficial treatments available to the eld-

204. *See id.* at 499.

205. *See id.* The policy had an effective date of May 1, 1985. It stated in pertinent part:

This agreement provides protection against professional liability claims which might be brought against you in your practice as a physician or surgeon Your professional liability protection covers you for damages resulting from: 1. Your providing or withholding of professional services We'll defend any suit brought against you for damages covered under this agreement. We'll do this even if the suit is groundless or fraudulent. We have the right to investigate, negotiate and settle any suit or claim if we think that's appropriate. We'll pay all costs of defending a suit, including interest on that part of any judgment that doesn't exceed the limit of your coverage.

Id. at 500.

206. *See id.* at 500.

207. *See id.*

208. *See id.*

209. *See id.*

210. *Id.*

erly. This begs the question: Has Congress infringed upon the rights of physicians to administer medicine in ways which maximize the benefits of drug therapy? Certainly Congress has an interest in protecting society from the unwanted effects of prescription drugs. However, limitations placed upon the type of illnesses which are approved for treatment creates unnecessary obstacles while failing to meet the stated objectives.

By targeting the prescription of anabolic steroids and the treatments approved for their use, Congress has missed the mark. Deterrence and criminal enforcement could be achieved without restricting medically approved treatments. One commentator suggests removing steroids from Schedule III classification but requiring a mandatory "paper trail."²¹¹ Currently, every manufacturer, distributor, or physician who dispenses or conducts research with controlled substances must register with the Attorney General.²¹² This allows the Attorney General to set production quotas for scheduled drugs.²¹³ By removing anabolic steroids from the limitations of Schedule III but requiring a paper trail or record of sales and special duplicate order forms for anabolic steroid distribution, the objectives of Congress can still be met without undue burden on treatments for the elderly. This action would remove the automatic presumption of misprescription on the physician and return the burden of proving illegitimate conduct to the prosecutor.

The best solution may be to eliminate the criminal penalties levied against physicians who prescribe anabolic steroids for uses not recognized by the Secretary of Health and Human Services.²¹⁴ The law should allow physicians to determine when and if steroid treatments can be beneficial to their patients. The unreasonable limitation currently in place eliminates a doctor's professional judgment regarding new discoveries and treatments. Preventing the illegal distribution of steroids by physicians who knowingly violate the law is not

211. See Reddig, *supra* note 50, at 1671 (citing 21 U.S.C. § 823 (1988) and *Anabolic Steroids Control Act of 1990: Hearings on H.R. 4658 Before the Subcomm. on Crime of the House Comm. on the Judiciary*, 101st Cong. (1990) (statement of Rep. Levine explaining that pharmacists and manufacturers are required to keep records of certain sales and special duplicate order forms are issued by the Attorney General through the DEA)).

212. See *id.* (citing 21 U.S.C. § 822(a)(1)-(2) (1990)).

213. See *id.* (citing 12 U.S.C. § 826(a) (1990)).

214. The Anabolic Steroids Control Act makes it a criminal offense for a physician to knowingly distribute steroids for any use other than the treatment of a disease or other recognized medical condition. 21 U.S.C. § 333(e)(1) (1996).

the reason the Anabolic Steroids Control Act was advanced. Congress was aware that illegal steroids were purchased almost entirely on the black market,²¹⁵ and it targeted this problem effectively. Unfortunately, Congress also targeted the persons best qualified to make sound medical decisions about steroid treatment.

The law recognizes that physicians have a duty to use that degree of care, skill, and diligence which is used by ordinarily careful physicians in similar circumstances.²¹⁶ Courts and legislators have long recognized that medical decisions are better left to those trained and educated in that field. By enacting provisions which regulate steroid therapy and prevent the many beneficial uses available for the elderly, Congress has subverted an established principle. Patients must forgo an opportunity for better health and overall well-being because doctors will not prescribe strength-giving hormones. The most important characteristic of the doctor-patient relationship is the absolute trust patients have in their physicians—knowing that they will do everything possible to restore them to good health. Because the concepts of “good faith”²¹⁷ and “legitimate medical purpose”²¹⁸ are inherent limitations restricting the physician’s authority to prescribe medication, the need to criminally prosecute doctors for invalid use of steroids is not necessary.

V. Conclusion

There is a good reason for doctors to be reluctant in treating elderly patients with steroids. Many physicians are not convinced that the benefit of treatment outweighs the risks.²¹⁹ This is exactly the type of analysis patients expect from their doctors. We anticipate that physicians will inform themselves of the qualities and characteristics of potential treatments and of the products which they prescribe for

215. See 135 CONG. REC. S1807-02 (daily ed. Feb. 28, 1989). United Pharmaceuticals of Mexico used to distribute information through the U.S. mail directing people to a location in Mexico where steroids could be purchased. See *id.*

216. See *Zavalas v. Department of Corrections*, 861 P.2d 1026, 1028 (Or. Ct. App. 1992).

217. *Perzik v. Superior Court*, 4 Cal. Rptr. 2d 1, 3 (Cal. App. Ct. 1991).

218. *Id.*

219. See Leonard H. Calabrese et al., *The Effects of Anabolic Steroids and Strength Training on the Human Immune Response*, 21 MED. SCI. SPORTS EXERCISE 386, 386-92 (1989); Committee on Sports Med., *Anabolic Steroids and the Adolescent Athlete*, 83 PEDIATRICS 127, 127 (1989); J.W.M. Lenders et al., *Deleterious Effects of Anabolic Steroids on Serum Lipoproteins, Blood Pressure, and Liver Function in Amateur Body Builders*, 9 INT’L J. SPORTS MED., Feb. 1988, at 19-23.

medical care. We have grown to expect that doctors will exercise this kind of independent judgment, taking into account their knowledge of the patient as well as the proposed medical device or treatment. The patient places primary reliance upon that judgment, and courts generally recognize it as a professional duty.²²⁰ When reluctance to prescribe steroids for an age-related condition is based on medical perception, our reliance on good faith determinations is rewarded. However, when the reluctance is advanced by fear of government inquest, our trust in good faith judgments is eroded.

Most have difficulty contemplating their own approaching reality—that with longevity comes old age. Anabolic steroids and human growth hormone may not be the fountain of youth, but they do hold many promises for the growing population of senior citizens. Many illnesses requiring managed care possibly could be eliminated with hormone treatments. This would not only trigger a social benefit but a financial benefit as well. Congress has created a barrier for the revitalizing effects of steroids for the elderly. By simply allowing physicians to use their professional judgment in administering steroid treatments, congressional concerns about steroid abuse would still be addressed without infringing upon the rights of the elderly to receive proper care.

220. See, e.g., *Buckner v. Allergan Pharm., Inc.*, 400 So. 2d 820, 823 (Fla. Dist. Ct. App. 1981).