

AO

United States General Accounting Office
Department of Justice
Washington, D.C. 20548

ARTICLE 181

DEPARTMENT OF JUSTICE
NATIONAL INSTITUTE OF JUSTICE
WASHINGTON, D.C. 20531
GENERAL ACCOUNTING OFFICE
WASHINGTON, D.C. 20548

133490

U.S. Department of Justice
National Institute of Justice

This document has been reproduced exactly as received from the person or organization originating it. Points of view or opinions stated in this document are those of the authors and do not necessarily represent the official position or policies of the National Institute of Justice.



Permission to reproduce this copyrighted material has been granted by
Public Domain
U.S. General Accounting Office
to the National Criminal Justice Reference Service (NCJRS).

Further reproduction outside of the NCJRS system requires permission of the copyright owner.

133490

Human Resources Division

B-235236

August 18, 1989

The Honorable Joseph Biden
Chairman, Committee on the Judiciary
United States Senate

Dear Mr. Chairman:

This report is in response to your November 22, 1988, request for information on the use, distribution, production, and health risks associated with anabolic steroids and human growth hormone. In accordance with your request, which parallels the requirements of the Anti-Drug Abuse Act of 1988, we obtained information on the estimated use of anabolic steroids among high school and college students and the adult population. We developed information on the (1) legal and illegal distribution of anabolic steroids and (2) health consequences associated with their use. We also obtained comparable data, when available, on human growth hormone.

Background

The Food and Drug Administration (FDA) has approved anabolic steroids, synthetic derivatives of the male hormone testosterone, as prescription drugs, which may be prescribed only by a licensed physician. Like the hormone testosterone, anabolic steroids have both androgenic and anabolic properties. The androgenic properties are responsible for the development of masculine characteristics, such as the growth of body and facial hair, deepening of the voice, and genital growth during puberty. The anabolic properties of testosterone promote the retention of dietary protein and muscle growth.

Anabolic steroids have been approved for the treatment of a small number of diseases, such as certain anemias, hereditary angioedema,¹ and breast cancer. These steroids, however, have also been used for non-therapeutic purposes. The first such use was reported during World War II, when anabolic steroids were given to German troops to increase aggressiveness. Based on anecdotal reports, their first use in athletics was by the Russians in 1954.

Since then, the use of these drugs has increased significantly among athletes. Initially, the use of anabolic steroids was believed to be largely confined to world class athletes participating in power sports, such as weightlifting and shotputting. Over the years, however, anabolic steroid

¹Recurring attacks of swelling appearing in areas of the skin or mucus membrane.

use has spread to professional, college, and high school sports. Anabolic steroids are taken to enhance performance or body image. Because of the possible competitive advantage and the health risks associated with their use, concerns have been raised about the inappropriate use of these drugs.

Human growth hormone, or somatotropin, is a hormone secreted by the pituitary gland. Body organs depend on growth hormone for proper growth and development. The most apparent effects of growth hormone during puberty are an increase in linear bone growth and in skeletal mass. Overproduction of this hormone in adults results in acromegaly, a disease that almost always shortens the life span of those it afflicts and that is marked by the progressive enlargement of the hands, feet, and face and may affect the major organs of the body, particularly the heart. Athletes use growth hormone because they perceive that it might affect athletic performance. It is suspected that the administration of high dosage levels of synthetic human growth hormone to normal adults, such as athletes, could result in acromegaly.

Objectives, Scope, and Methodology

On the basis of discussions with Committee staff, we focused our work on obtaining, to the extent available, information on the (1) use of anabolic steroids among students, both high school and college, and athletes; (2) health consequences resulting from anabolic steroid use; (3) policies and regulations developed by sports associations to monitor athletes' use of anabolic steroids; and (4) quantity of legal and illegal anabolic steroids that are produced and distributed both domestically and internationally. We obtained similar information for human growth hormone. Additionally, we obtained information from FDA on state laws and regulations to control the misuse of anabolic steroids and human growth hormone.

We reviewed current scientific literature to obtain information on (1) the prevalence of the use of anabolic steroids and human growth hormone and (2) medical consequences resulting from their use. We identified only 15 studies on the prevalence of use of anabolic steroids in the U.S. population; of these studies, 8 focused on use among high school students and 7 on college students and athletes. We did not identify any prevalence studies for human growth hormone use.

We also interviewed FDA and National Institute of Drug Abuse officials, leading researchers in the area, and representatives of medical societies and manufacturers of these drugs to obtain (1) a perspective on the

prevalence of steroid and growth hormone misuse and (2) the associated adverse medical consequences.

We interviewed officials of several of the U.S. Olympic Committee's National Governing Bodies, the National Collegiate Athletic Association, and the National Football League to obtain information on monitoring policies and regulations of sports associations for steroid and growth hormone use, such as (1) drug-testing policies and testing results and (2) the prevalence of drug use among athletes.

From FDA, we obtained information on (1) the legal distribution of anabolic steroids and (2) federal and state laws developed to control drug misuse. From the Department of Commerce, we gathered information on the quantity of anabolic steroids imported into the United States. To the extent available, we obtained data on illegal production and distribution of steroids and growth hormone from the Department of Justice.

Results in Brief

Published studies and other information we obtained indicate that anabolic steroids are being misused primarily by high school, college, and professional athletes to enhance their performance and, to a lesser extent, by others participating in sports. A national study found that more than 6 percent of male high school seniors, mostly participants in sports, use or have used anabolic steroids. A more limited study covering five colleges found that about 20 percent of athletes used steroids. Misuse of human growth hormone appears to be a lesser problem.

In view of suspected health risks associated with the misuse of anabolic steroids and indications from the Department of Justice that their misuse is a growing problem, we support federal and state efforts to exercise greater control over their distribution and use.

The information we obtained is summarized below and presented in more detail in appendixes I-VII.

Anabolic Steroid Use Among High School and College Students and Athletes

We identified 15 studies that address the prevalence of anabolic steroid use (see app. VIII); most of these studies were carried out on high school and college students. One study purported to provide results representative of a national sample. Most studies limited the sampling universe to schools from a specific geographic locality, high school, or sex group. These studies showed that male athletes were the primary users of anabolic steroids.

Misuse of Anabolic Steroids Associated With Health Risks

The national study, conducted in 1987, indicates that as many as 6.6 percent of the 12th grade males in the United States use or have used anabolic steroids.² According to this and other studies, athletes are the most common users of anabolic steroids among high school and college students. One high school study found that 84 percent of anabolic steroid users participated in sports.³ According to a 15-year study of college students at five universities, between 15 and 20 percent of the college athletes reported using anabolic steroids.⁴

Less information is available on the prevalence of anabolic steroid use outside of high school and college. The two studies we identified addressed use in relatively small samples of weightlifters. The results show that a high percentage of weightlifters studied use steroids. However, the results cannot be projected beyond the weightlifters included in the studies.

Athletes are reported to consume high dosage levels of anabolic steroids or several steroids at one time. These levels are believed to be greater than those commonly used during medical treatment.⁵ Much media attention has been given to the health risks of anabolic steroids among athletes and bodybuilders. No systematic studies of the health risks to athletes have been conducted, however. Thus, information on health risk is lacking.

Studies do exist, however, on the health risks of anabolic steroids in (1) medical use—for example, in the treatment of some rare diseases—and (2) athletes in a limited number of case reports. These studies suggest that anabolic steroids may increase the risk of heart disease; produce liver toxicities; affect sex characteristics and reproductive capacity; cause possible psychological disorders and tendon and ligament injury; and, in children and youth, result in stunted growth.

²William E. Buckley and others, "Estimated Prevalence of Anabolic Steroid Use Among Male High School Seniors," *Journal of the American Medical Association*, Vol. 260 (Dec. 16, 1988), p. 3441.

³Mimi D. Johnson and others, "Anabolic Steroid Use by Male Adolescents," *Pediatrics*, Vol. 83 (June 1989), p. 922.

⁴T. L. Dezelsky and others, "Non-Medical Drug Use Behaviour at Five United States Universities: A 15-Year Study," *Bulletin on Narcotics* (United Nations publication), Vol. 37 (1985).

⁵Anecdotal reports suggest athletes take doses that are from 4 to more than 100 times greater than the manufacturer-recommended guidelines for approved purposes.

Although some adverse affects are reversible when drug use is discontinued, they can be serious. For example, anabolic steroids may cause changes in the cardiovascular system, such as upsetting the balance of high density and low density lipoprotein (HDL/LDL), an increase in total serum cholesterol levels and blood pressure, increasing the risk of arteriosclerotic disease and possible heart failure. Children's use of steroids may prematurely close the growth centers of the long bones, stunting growth.

Use of Anabolic Steroids Prohibited by Sports Associations

Several sports associations have adopted drug policies that condemn and prohibit the use of anabolic steroids by athletes because of the combination of (1) potential health and safety risks with (2) the potential competitive advantage. Many of the sports associations have implemented drug-testing programs to monitor the use of anabolic steroids among their athletes.

Most of these programs have an announced policy to test athletes competing at scheduled events. According to some experts, the results of such announced tests for anabolic steroid use are poor indicators of true use. Given advance notice, athletes can abstain from the use of these drugs before the test to avoid detection.⁶ Although the use of human growth hormone cannot be detected in drug-testing procedures, the sports associations we spoke with—the U.S. Olympic Committee, the National Collegiate Athletic Association, and the National Football League—have also included this drug among their list of banned substances.

Anabolic Steroid Distribution by Manufacturers

Data on the quantity of anabolic steroids produced are not publicly available. From FDA, however, we obtained data on the legitimate distribution of anabolic steroids manufactured in the United States. These data indicate that (1) during the 10-year period 1979 through 1988, U.S. manufacturers distributed 53.2 million grams of anabolic steroids in the United States and abroad; and (2) during 1984 through 1988, hospitals and retail pharmacies in the United States purchased an estimated 26.1 million grams of anabolic steroids. According to Department of Commerce data, 26.2 million grams of anabolic steroids, in bulk rather than dosage form, were imported into the country during 1979 through 1988. Of the total distributed, 92 percent were accounted for by five drugs:

⁶According to one expert, detectable traces of oral anabolic steroids are apparent in the urine for 1 to 2 weeks after discontinuing use. Injectable steroids may be present from 1 week to 1 month after use.

Danazol, Testosterone Cypionate, Methyltestosterone, Testosterone Enanthate, and Fluoxymesterone.

In addition to the legitimate distribution, the Department of Justice estimates that on the black market, the annual sales of these drugs is about \$300 to \$400 million. Justice believes that the source of black market steroids is divided evenly between clandestinely manufactured goods, smuggled products, and diverted legally manufactured products.

Human Growth Hormone

We did not find any studies that document the use of human growth hormone by high school students, college students, or athletes. Reports of its use among athletes are anecdotal and suggest that athletes use growth hormone because (1) they perceive it to increase body growth and strength potential (however, these perceptions have not been confirmed scientifically) and (2) no drug-testing procedure has been developed for its detection in the urine. According to the Council on Scientific Affairs of the American Medical Association, the abuse of human growth hormone, to the extent that it exists, is a recent phenomenon.

The health risks of an oversecretion of human growth hormone in children include abnormal bone growth and dysfunction of the thyroid gland. In adults, oversecretion results in acromegaly, which almost always shortens the person's life span. At this time, there are no reported cases of acromegaly among athletes associated with the use of synthetic human growth hormone.⁷

Between 1985 and 1988 approximately 7,768 grams of synthetic growth hormone were legally distributed for medical purposes in the United States; we were not able to obtain data on the amount produced in this time period. Human growth hormone is much less available on the black market than steroids.

Federal and State Laws on Anabolic Steroids and Human Growth Hormone

Because of the increased interest in the use of anabolic steroids and the potential health risks associated with the use of these drugs, there has been considerable legislative and administrative activity in this area. For example, in 1988, the Congress passed the Anti-Drug Abuse Act of 1988 (P.L. 100-690), which includes several provisions to control the use

⁷Before 1985, human growth hormone was commercially derived through the extraction of the hormone from the pituitary gland of cadavers. In 1985, pituitary extracted human growth hormone was withdrawn from the U.S. market. Synthetic human growth hormone has been marketed since 1985.

of anabolic steroids and human growth hormone. FDA data show that as of June 16, 1989, 25 states have enacted laws or promulgated regulations to control the use of anabolic steroids. Five of these states have enacted laws or promulgated regulations to control the use of human growth hormone.

The Anti-Drug Abuse Act of 1988 provides for the forfeiture of specified property of an individual convicted of a violation of the Federal Food, Drug, and Cosmetic Act⁸ involving anabolic steroids or human growth hormone, if the violation is punishable by imprisonment for more than 1 year. The Anti-Drug Abuse Act of 1988 also specifies that violators are subject to imprisonment for up to 3 years or a fine or both if they (1) distribute or (2) possess anabolic steroids with the intent to distribute for any use in humans other than the treatment of disease based on the order of a physician.

Information provided by FDA shows that some states have classified anabolic steroids as controlled substances, and at least one state has promulgated rules regarding the medical profession's responsibility in prescribing, dispensing, or delivering these drugs. Anabolic steroids are regulated as controlled substances under state law in nine states; in addition, six states have legislation pending that would classify anabolic steroids as controlled substances. One state has classified human growth hormone as a controlled substance.

According to FDA, state controlled substances acts are either identical or similar to the federal Controlled Substances Act. The federal act classifies drugs that can be physically or psychologically harmful into categories or schedules based on their potential for abuse, accepted medical use, and whether abuse of the drug may lead to physical or psychological dependence. The schedule under which a drug is placed determines the nature and degree of control exercised to prevent its abuse and diversion. Anabolic steroids and human growth hormone are not classified under the federal Controlled Substances Act.⁹

As arranged with your office, unless you publicly announce its contents earlier, we plan no further distribution of this report until 15 days from

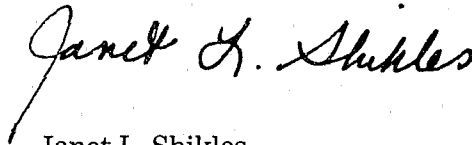
⁸The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) prohibits specified acts relating to the sale and distribution of misbranded or adulterated articles.

⁹The Attorney General has delegated to the Drug Enforcement Administration the authority for scheduling drugs under the federal Controlled Substances Act.

its issue date. At that time, copies will be sent to the appropriate Senate and House committees and subcommittees; the Attorney General; the Secretary of Health and Human Services; the Secretary of the Treasury; the Commissioner of FDA; and the Director, Office of Management and Budget, and we will make copies available to other interested parties upon request.

The major contributors to this report are listed in appendix IX.

Sincerely yours,



Janet L. Shikles
Director of National and
Public Health Issues

Contents

Letter		1
Appendix I		14
Use of Anabolic Steroids Among High School and College Students and Athletes	Use of Anabolic Steroids Among High School Students	14
	Estimates of Use Among College Athletes	16
	Use by Weightlifters	17
Appendix II		18
Health Risks Associated With the Misuse of Anabolic Steroids	Adverse Effects of Using Anabolic Steroids	18
Appendix III		22
Sports Associations Prohibit the Use of Anabolic Steroids by Athletes	U.S. Olympic Committee	22
	National Collegiate Athletic Association	23
	National Football League	23
Appendix IV		25
Distribution of Anabolic Steroids	Legal Distribution of Anabolic Steroids	25
	Imports of Anabolic Steroids	28
	Black Market Major Supplier	30
Appendix V		32
Human Growth Hormone	Use Unknown	32
	Adverse Effects of Human Growth Hormone	32
	Legal Production and Distribution	33
	Black Market Supply	35

<hr/>		
<p>Appendix VI Federal and State Governments Increase Control Over the Use of Anabolic Steroids and Human Growth Hormone</p>	<p>Federal Legislation State Laws on Anabolic Steroids State Laws on Human Growth Hormone</p>	<p>37 37 37 39</p>
<hr/>		
<p>Appendix VII Requirements for Reporting Distribution Data to FDA</p>		<p>40</p>
<hr/>		
<p>Appendix VIII Studies on Anabolic Steroid Use Among High School Students, College Students, and Athletes</p>	<p>Studies on Use Among High School Students Studies on Use Among College Students Studies on Use Among Weightlifters</p>	<p>41 41 41 42</p>
<hr/>		
<p>Appendix IX Major Contributors to This Report</p>		<p>43</p>
<hr/>		
<p>Figures</p>	<p>Figure IV.1: Distribution of Anabolic Steroids (1979-88) Figure IV.2: Top Five Anabolic Steroids Distributed (1979-88) Figure IV.3: Anabolic Steroid Prescriptions Dispensed (1984-88) Figure IV.4: Anabolic Steroids Imported by the United States (1979-88) Figure IV.5: Top Four Countries Exporting Anabolic Steroids Into the United States (1979-88)</p>	<p>26 27 28 29 30</p>

Abbreviations

AIDS	acquired immunodeficiency syndrome
DNA	deoxyribonucleic acid
FDA	Food and Drug Administration
HDL/LDL	high density and low density lipoprotein
NCAA	National Collegiate Athletic Association
NFL	National Football League

Use of Anabolic Steroids Among High School and College Students and Athletes

We reviewed 15 studies on the use of anabolic steroids among students and athletes.¹ Of these studies, one provides a national perspective on use; the others are limited to a specific geographical locality, school, or sex. Most studies, however, show that athletes are the most common users of anabolic steroids among high school and college students.² The national study found that more than 6 percent of male high school seniors, predominately participants in sports, use or have used anabolic steroids. A limited study covering five colleges found that almost 20 percent of athletes used steroids. Because other studies suggest that the misuse of anabolic steroids may pose serious health risks and Department of Justice data indicate that their misuse is a growing problem (see apps. II and IV), we support federal and state efforts to exercise greater control over their distribution and use.

Use of Anabolic Steroids Among High School Students

A national-based study found that 6.6 percent of male 12th graders use or have used anabolic steroids.³ According to the authors of the study, if this use rate is applied to the national population of males enrolled in secondary schools, it suggests that between 250,000 and 500,000 adolescents in the country use or have used these drugs. In four other studies, while not nationally representative, a similar or higher rate of anabolic steroid use among males was found, with study estimates ranging from 5 percent⁴ to 11.1 percent.⁵ In three of the four studies, anabolic steroid use was found to be much lower among females, ranging from 1 percent⁶ to 2.5 percent.⁷

¹A National Institute of Drug Abuse official informed us that a high school senior survey now in the data collection phase is soliciting information on the use of anabolic steroids.

²A listing of studies reviewed on anabolic steroid use by high school and college students and athletes is presented in appendix VIII.

³William E. Buckley and others, "Estimated Prevalence of Anabolic Steroid Use Among Male High School Seniors," p. 3441.

⁴Martha Newman, "Hazelden Health Promotion: Michigan Consortium of Schools Student Survey," Minneapolis, Minnesota: Hazelden Research Services, September 1986, p. 30 (unpublished).

⁵Mimi D. Johnson and others, "Anabolic Steroid Use by Male Adolescents," p. 922.

⁶Martha Newman, "Hazelden Health Promotion: Michigan Consortium of Schools Student Survey," p. 30.

⁷Rise Terney and Larry G. McLain, "The Use of Anabolic Steroids in High School Students," Loyola University, Chicago, Illinois, 1988, p. 2 (unpublished).

Athletes Most Frequent Users

Among high school students, male athletes were found to be the most frequent users of anabolic steroids. In the five studies we reviewed, information was provided on the use of anabolic steroids and participation in sports activities. A 1988 study of students at an Illinois high school found that 5.5 percent of student athletes of both sexes used steroids; the rate was 6.6 percent among male athletes and 3.9 percent among female athletes. Athletes participating in football (9.3 percent) and wrestling (12.2 percent) had the highest use.⁸

A second study included students from five high schools in both affluent and less affluent school districts in one city. In this study, 10.2 percent of male athletes from affluent school districts used steroids as compared with 2.8 percent of those from less affluent school districts.⁹

In the third and fourth studies, a large percentage of steroid users participated in sports. In the third study, the national study of 12th graders, 65 percent of steroid users participated in sports. In the fourth study, based on a sample of 11th grade male students in six Arkansas schools, 84 percent of steroid users participated in sports.¹⁰ The fifth study was a survey of varsity head coaches from 621 high schools in Michigan; according to the coaches' perceptions, the use of steroids among football players during the period 1985-87 ranged from 11.1 to 13.9 percent.¹¹

The most frequent reasons cited for using steroids were (1) to increase strength, size, and speed and (2) to improve athletic performance. In the Arkansas study, 64 percent of steroid users reported that they wanted to increase strength, 50 percent wanted to increase size, and 27 percent wanted to improve physical appearance. In the national study of 12th graders, the largest percentage of users (47 percent) reported that their main reason for using the drug was to improve athletic performance. Another 27 percent of users reported "appearance" as the main reason for using anabolic steroids.

⁸Rise Terney and Larry G. McLain, "The Use of Anabolic Steroids in High School Students," pp. 4-6.

⁹Robert Windsor and Daniel Dumitru, "Prevalence of Anabolic Steroid Use by Male and Female Adolescents," *Medicine and Science in Sports and Exercise*, forthcoming October 1989.

¹⁰Mimi D. Johnson and others, "Anabolic Steroid Use by Male Adolescents," pp. 921-922.

¹¹E. James Swenson, Jr., "Perspectives on Anabolic Steroids: Statewide Survey of High School Varsity Football Medical Coaches," Michigan State University, East Lansing, Michigan, Fall 1987, pp. 1 and 3 (unpublished).

In the Illinois study, 9.4 percent of students reported that they would use steroids if it would help them obtain a college athletic scholarship. Two percent of students also reported encouragement of this use from a coach or faculty member, while 4.8 percent reported encouragement from another person.

Estimates of Use Among College Athletes

We identified only five studies on the extent of steroid use among college students. Two studies on general drug use in a representative sample of the general student body from five universities were carried out over a 15-year period, 1970-84. The first study reported results for 1970 and 1973; the second, for 1970, 1976, 1980, and 1984. In the general student body of the five schools, data for 1970 and 1973 showed that 0 to 2 percent of students had ever used steroids.¹² When data from this study were examined for athletes only, 15 percent of athletes reported using anabolic steroids in 1970. This rate increased to 20 percent for 1976, 1980, and 1984.¹³ In 1984, only 1 percent of nonathletes in the study reported steroid use.

The third and fourth studies examined steroid use by sport. In the third study, which was conducted in 1980 and focused on intercollegiate swimmers at six universities, 6 percent of male swimmers reported steroid use.¹⁴ No female swimmers reported use. In the fourth study, involving 2,048 intercollegiate athletes conducted in the fall of 1984 at 11 universities, the national prevalence rate was found to be 4 percent for steroid use in athletes for eight different sports.¹⁵ The highest rate of use was found among male football players (9 percent), followed by male basketball, track, and tennis athletes (each 4 percent); 1 percent of female swimmers reported steroid use.

¹²Brice W. Corder and others, "An Analysis of Trends in Drug Use Behavior at Five American Universities," *The Journal of School Health*, Vol. 44 (September 1974), pp. 386-387.

¹³T. L. Dezelsky and others, "Non-Medical Drug Use Behaviour at Five United States Universities: A 15-Year Study," pp. 49 and 52.

¹⁴J. V. Toohey and B. W. Corder, "Intercollegiate Sports Participation and Non-Medical Drug Use," *Bulletin on Narcotics* (United Nations Publication), Vol. 33 (1981), pp. 23-25.

¹⁵William A. Anderson and Douglas B. McKeag, "The Substance Use and Abuse Habits of College Student-Athletes," Research Paper No. 1, Michigan State University, East Lansing, Michigan, 1985, pp. 1-3 (unpublished).

The fifth study, published in 1988, provided information on 1,010 male students at three universities.¹⁶ Results from this study also support a higher rate of steroid use among athletes than among nonathletes. Of varsity athletes at two of the three schools in the study, 17 percent reported steroid use. This rate is significantly higher than the 2 percent of all males who reported using steroids in the total survey sample of the three schools.

Use by Weightlifters

For adults who participate in sports activities but are not a part of a college athletic program, few studies have been carried out on anabolic steroid use. We identified two studies of steroid use among weightlifters. One study was based on 250 weightlifters from three gymnasium weight rooms in the metropolitan Chicago area.¹⁷ This study found that 44 percent (110) of the weightlifters reported steroid use at some time. A subgroup of 50 of the 110 weightlifters who used steroids were interviewed in greater detail to obtain information on the pattern, dose, and type of drugs used, as well as the source of the drugs; 40 percent reported drug use for 1 year or less; the rest had been using the drugs for 2 or more years. The majority of users in the subgroup studied obtained their drugs illegally, but 20 percent claimed to have received them by prescription.

The second study was based on a sample of 61 athletes who competed in the 1987 National Championship of the U.S. Powerlifting Federation.¹⁸ Only 45 competitors responded to the survey; of these, 33 percent reported steroid use. As found in studies of high school and college students, the reason given most often for using steroids was to improve athletic performance. The black market was also identified as the primary source for purchasing steroids by 73 percent of the users. In this study, the "black market" was defined as other athletes and gym owners or managers.

¹⁶Harrison G. Pope, Jr., and others, "Anabolic-Androgenic Steroid Use Among 1,010 College Men," The Physician and Sportsmedicine, Vol. 16 (July 1988), pp. 75-76.

¹⁷Mark A. Frankle and others, "Use of Androgenic Anabolic Steroids by Athletes," Letter to Editor, Journal of the American Medical Association, Vol. 252 (July 27, 1984), p. 482.

¹⁸Charles E. Yesalis III and others, "Self-Reported Use of Anabolic-Androgenic Steroids by Elite Power Lifters," The Physician and Sportsmedicine, Vol. 16 (December 1988), pp. 91-94.

Health Risks Associated With the Misuse of Anabolic Steroids

No well-controlled longitudinal studies have been carried out on the health risks to athletes of anabolic steroid use. Consequently, the risks are not well established for consuming massive doses or for consuming multiple steroids at one time ("stacking"), as some athletes have done. There are, however, some case reports documenting medical problems in athletes who have taken high doses. Scientific studies on health risks have been carried out in the treatment of patients who have taken anabolic steroids in normal therapeutic doses. These studies and case reports found that steroids may increase the risk of heart disease and produce liver toxicities, temporary changes in sex characteristics and reproductive functioning, possible psychological disorders, possible injury to tendons and ligaments, and stunted growth in children.

Adverse Effects of Using Anabolic Steroids

Although there has been controversy among researchers about the advantages of anabolic steroid use for athletes and body builders, many researchers and sport medical experts have reported advantages: gains in lean muscle mass, strength, and endurance can be achieved by trained athletes who use steroids and maintain their training and a high protein diet. Experts also report that anabolic steroids do not increase aerobic power or capacity for muscular exercise. These drugs are also reported to increase aggressiveness and tolerance of stress, characteristics considered important in sports.

Currently there are no well-controlled longitudinal studies of the effects of anabolic steroids in athletes, bodybuilders, and teenagers, particularly none that document the effects of taking massive doses, or "stacking." Most of the available information on adverse effects has been reported in the treatment of patients who have taken anabolic steroids in normal therapeutic doses.¹ Some information on adverse effects has also been reported by sports physicians and in a limited number of studies of athletes and bodybuilders.

Most adverse effects have been associated with orally administered anabolic steroids. Orally administered steroids are easier to take and have a shorter detection time in the urine than injected anabolic steroids. In addition, athletes who use anabolic steroids that are injected may risk contracting acquired immunodeficiency syndrome (AIDS) and other diseases, such as hepatitis from infected needles. One case of AIDS in an

¹Anecdotal reports suggest that athletes take doses that are 4 to more than 100 times greater than manufacturer-recommended guidelines for approved purposes.

athlete, who reported using injectable steroids and had no other known AIDS risk factors, has been reported in the literature.

Cardiovascular Problems

Among the most dangerous consequences of taking large amounts of steroids over a prolonged period of time, sports physicians and researchers say, are changes in the cardiovascular system, for example: upsetting the balance of high density and low density lipoprotein (HDL/LDL), elevated blood pressure, and increased total serum cholesterol level. Although these changes are probably reversible, they may result in arteriosclerotic disease and heart failure. According to medical reports, one young athlete had a serious heart attack and two others had strokes possibly associated with steroid use.

Liver Toxicities

Anabolic steroids that are orally administered have been implicated in liver toxicities and in the development of blood-filled cysts (peliosis) and in the formation of benign tumors in the liver. Cases of malignant liver tumors have also been reported in men, including one athlete, using anabolic steroids. In addition, two cases of benign liver tumors have been reported in athletes. Some of these conditions have disappeared once the steroid therapy was discontinued. But deaths have been reported that are associated with tumors and the rupture of the cysts.

Sexual Changes

Changes in sex characteristics and in reproductive functioning are common among athletes who take steroids. Males may suffer from atrophy of the testis, low sperm count, or enlargement of the prostate gland. These side effects are generally considered to be reversible. Males may also develop enlarged breasts, which may not be reversible. One case of prostatic cancer in an athlete who used steroids has also been reported. Females may experience increased hair growth on the face, enlargement of the clitoris, and deepening of the voice. They may also experience a cessation in menstruation. Acne is another common side effect reported in users of both sexes.

Psychological Changes

Sports physicians and athletes report that there are psychological changes when athletes and bodybuilders take steroids. They feel good with increased energy; they are more competitive and have greater capacity to endure pain. They are more irritable, however, and more prone to increased aggressiveness. When the athletes discontinue using steroids, some become depressed and apathetic.

There have been several reports of psychotic reactions. Two physicians nonrandomly solicited responses from 41 bodybuilders and football players who had used anabolic steroids and found 9 who displayed a full affective syndrome² and 5 who experienced psychotic symptoms; 5 subjects developed a major depression while withdrawing from steroids.³ Paranoid psychosis has also been reported in some clinical studies for patients treated for depression with antidepressants and an anabolic steroid. When the steroids were discontinued, the paranoia disappeared.

The behaviors, opinions, and attitudes of a segment of adolescent anabolic steroid users, described in a study to be published in 1989, are consistent with the definition of psychological dependence.⁴ In addition, at a 1989 National Institute of Drug Abuse Technical Conference on Anabolic Steroids, information presented supported the possibility of a potential link between using anabolic steroids and psychological dependence. More research is necessary, conference participants acknowledged, to clarify the effects of anabolic steroids on mood and behavior, as well as their potential for psychological dependence.

Tendons and Ligaments

Anecdotal reports from sports physicians suggest that the risk of ruptured tendons and ligaments, as well as tendonitis, is increased when anabolic steroids are used. This results, they believe, from an imbalance between the increased strength of the muscles and the strength of tendons and ligaments, which is not changed by the steroids.

Stunted Growth in Children and Youth

Anabolic steroids may prematurely close the growth centers of the long bones. Pediatricians and sports physicians have reported that pre-puberty children and adolescents who take anabolic steroids may be in danger of stunting their growth. Little information exists about the adolescent anabolic steroid user's knowledge of the possible adverse effects of steroids. A study of male, high school students, however, indicates that a segment of the adolescent population is using anabolic steroids without appropriate knowledge about the adverse effects of these

²An affective syndrome is characterized by excessive mood changes.

³Harrison G. Pope, Jr., and David L. Katz, "Affective and Psychotic Symptoms Associated With Anabolic Steroid Use," American Journal of Psychiatry, Vol. 145 (Apr. 1988), pp. 487-489.

⁴Charles E. Yesalis and others, "Anabolic Steroid Use: Indication of Habituation Among Adolescents," Journal of Drug Education, Vol. 19, No. 2 (1989), p. 113 (forthcoming).

**Appendix II
Health Risks Associated With the Misuse of
Anabolic Steroids**

drugs.⁵ In another study we reviewed, 38 percent of male users initiated anabolic steroid use at age 15 or less.⁶

⁵Mimi D. Johnson and others, "Anabolic Steroid Use by Male Adolescents," p. 924.

⁶William E. Buckley and others, "Estimated Prevalence of Anabolic Steroid Use Among Male High School Seniors," p. 3443.

Sports Associations Prohibit the Use of Anabolic Steroids by Athletes

Because of the possible competitive advantage and health risks to the athlete, several amateur and professional sports associations have placed anabolic steroids on their lists of banned drugs. A recent review of drug testing in sports noted that an adequate methodology for detecting anabolic steroids in the urine was not used in a drug screening program until the 1976 Montreal Olympic Games.¹ Since then, the U.S. Olympic Committee and other sports associations have implemented drug-testing programs for these drugs.

Most of these programs have announced policies to test athletes competing at scheduled events. According to some experts, the results of such announced tests for anabolic steroid use are poor indicators of true use. Given advance notice, athletes can abstain from the use of these drugs before the test to avoid detection.

U.S. Olympic Committee

We contacted seven of the U.S. Olympic Committee's National Governing Bodies concerning their testing policies for anabolic steroids: The Athletic Congress; U.S. Amateur Boxing Federation; U.S. Cycling Federation; U.S. Modern Pentathlon; U.S. Swimming, Inc.; U.S. Weightlifting Federation; and USA Wrestling. No athlete has had a confirmed positive test for anabolic steroid use, according to the U.S. Boxing Federation, U.S. Modern Pentathlon, and USA Wrestling, since testing was implemented. The U.S. Cycling Federation reported one positive urine test during 1987 (280 tested) and 1988 (300 tested). The U.S. Swimming, Inc., reported one positive urine test between 1978 and 1988.

The Athletic Congress and the U.S. Weightlifting Federation have had more positive urine tests. According to The Athletic Congress, since 1983, 12 Athletic Congress athletes have tested positive during activities sponsored by the U.S. Olympic Committee or The Athletic Congress. In the 785 urine tests conducted in 1988, no U.S. athletes were found to be positive for anabolic steroids. Athletes who tested positive were suspended from domestic and international competition for life, with the exception of one athlete. In this case, the athlete appealed the suspension, and an appeals board upheld the appeal because of irregularities in the procedures used to ship and test the urine sample.

In response to a resolution submitted by the Athletes' Advisory Committee asking for random out-of-competition drug testing, The Athletic Congress has established a year-round drug testing program. The program

¹Gary I. Wadler and Brian Hainline, Drugs and the Athlete, F. A. Davis Company, 1989, p. 195.

Appendix III
Sports Associations Prohibit the Use of
Anabolic Steroids by Athletes

requires the top 25 performers in each event during a ranking year, as well as athletes receiving financial assistance through any amateur sports organization, to be subject to random year-round drug testing, which includes testing for anabolic steroid use. This program was scheduled to begin in July 1989.

The U.S. Weightlifting Federation reported that 39 urine samples of 1,300 tested were positive for anabolic steroids during 1984-88. In 1984, 9 percent of the 132 urine samples tested were positive. Since 1984, the number of samples found positive decreased substantially. By 1988, only 3 of the 518 samples tested (less than 1 percent) were found to be positive.

**National Collegiate
Athletic Association**

The National Collegiate Athletic Association (NCAA) has implemented two drug-testing programs, the Post-Season Testing Program and the Off-Season Anabolic Steroid Testing Program. The Post-Season Program is the association's primary testing program. This program provides for random testing of athletes either before, during, or after participation in an NCAA championship or in any postseason football game certified by the NCAA. In 1988, less than 1 percent of athletes tested in this program were found positive. The Off-Season Program is a voluntary program for institutions with a football program. Preliminary program test results provided to us by NCAA officials show that 3.3 percent of 546 football players tested positive in 1988.

**National Football
League**

A National Football League (NFL) official told us that between 6 and 7 percent of 2,600 players tested were found to be positive for the use of anabolic steroids in 1987 and 1988. In a recent hearing before the Senate Committee on the Judiciary, the NFL Commissioner testified that in 1987 and 1988 pre-season testing steroid use had been "solidly documented" in 6 to 7 percent of NFL players. In 1989, the NFL announced a new testing policy for anabolic steroids and related substances. This policy specified that all NFL players will be tested for anabolic steroids and related substances, as well as "masking agents," which are used to try to suppress steroid detection. Testing will be conducted in 1989 pre-season training camps or after if a player reports late for training camp.

A positive result will prohibit the player from participating in his team's activity for a minimum of 30 days. In addition, the player will be subject to frequent reasonable-cause testing in the future. A player who has previously tested positive for steroids is also subject to reasonable-cause

**Appendix III
Sports Associations Prohibit the Use of
Anabolic Steroids by Athletes**

testing. If a player tests positive on a second test during the season, the player will be suspended for the rest of the season.

Distribution of Anabolic Steroids

During the 10-year period 1979-88, U.S. manufacturers distributed 53.2 million grams of anabolic steroids domestically and abroad. During the same period, an additional 26.2 million grams of these drugs were imported into the country.

According to the Department of Justice, clandestinely manufactured goods, smuggled products, and legitimately manufactured U.S. products that have been diverted are the sources of the growing numbers of anabolic steroids sold on the black market. Justice officials estimate the retail sales of these drugs on the black market to reach approximately \$300 to \$400 million yearly.¹ They report that over 4 years of investigation, the retail prices for anabolic steroids have increased. They support this finding with price lists confiscated from the black market, one from 1985 and one from late 1988, that show, for example, the price of one anabolic steroid, Maxibolin, was \$25 in 1985 and \$42 in 1988.

Legal Distribution of Anabolic Steroids

Data on the amount of anabolic steroids produced are not publicly available.² However, FDA did provide us with distribution data covering a 10-year period beginning in 1979 for 14 approved anabolic steroids manufactured by various companies under 25 brand and generic names. FDA advised that data for 1988 are incomplete because all manufacturers have not sent distribution data for that year; therefore, conclusions based on these data are understated.

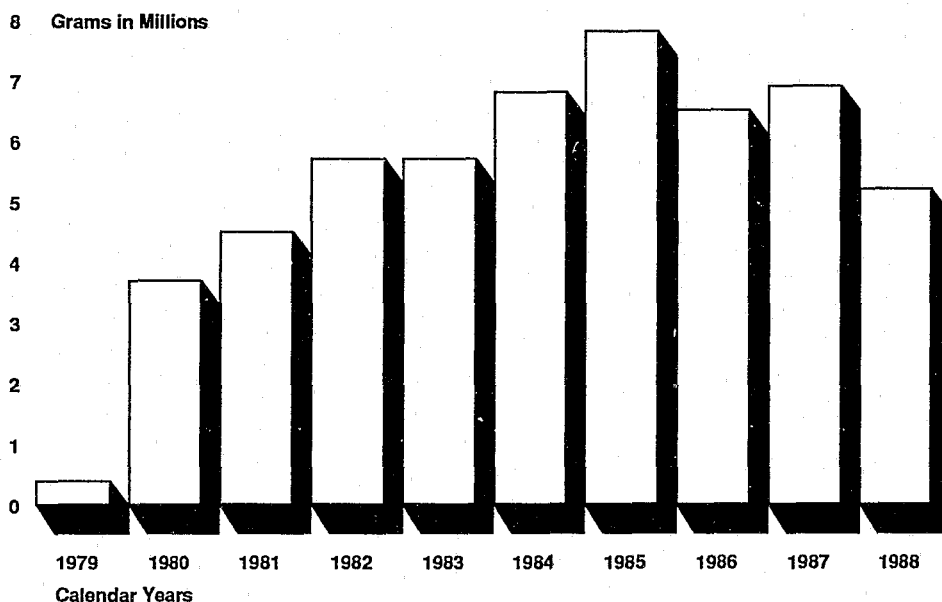
During 1979-88, manufacturers distributed 53.2 million grams of anabolic steroids. The smallest annual quantity of steroids distributed during the period was about 386,000 grams in 1979 (see fig. IV.1). Since then, the distribution of anabolic steroids increased until 1985, when 7.8 million grams were distributed; distribution for 1986 and 1987 was lower, and distribution data for 1988 are incomplete.

¹Includes human growth hormone, which is found on the black market to a much lesser extent than anabolic steroids.

²Appendix VII provides information on the difficulties in obtaining anabolic steroids production data.

Appendix IV
Distribution of Anabolic Steroids

Figure IV.1: Distribution of Anabolic Steroids (1979-88)



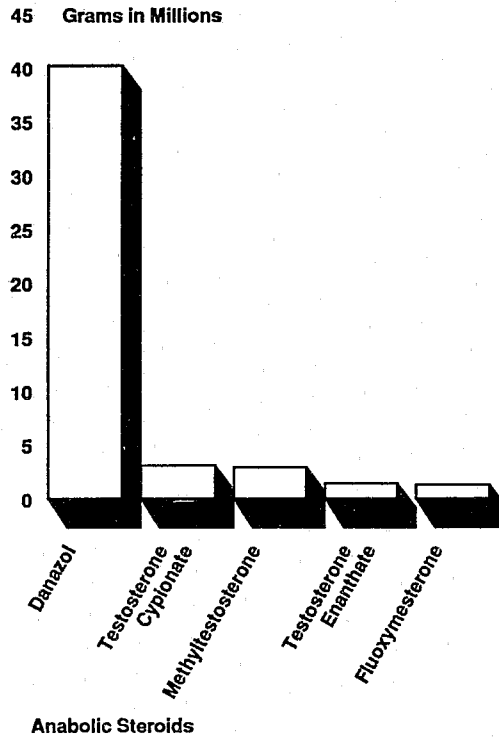
Note: Data for 1988 do not include data from all manufacturers (the data include anabolic steroids that are manufactured domestically and distributed in the United States and abroad).

Source: Manufacturers' annual reports submitted to FDA.

Five drugs accounted for 92 percent of the anabolic steroids distributed between 1979 and 1988. In order of the greatest quantity distributed, these were Danazol, Testosterone Cypionate, Methyltestosterone, Testosterone Enanthate, and Fluoxymesterone (see fig. IV.2). Danazol, Methyltestosterone, and Fluoxymesterone are oral anabolic steroids; Testosterone Cypionate and Testosterone Enanthate are injectable. The distribution of Danazol is highest (40.2 million grams) because it is the drug of choice to treat endometriosis and fibrocystic breast disease, two common diseases that affect women.

Appendix IV
Distribution of Anabolic Steroids

Figure IV.2: Top Five Anabolic Steroids Distributed (1979-88)



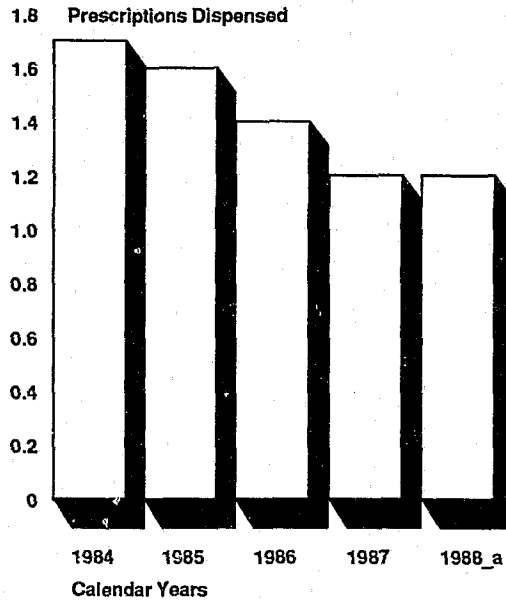
Source: Manufacturers' annual reports submitted to FDA.

During the 5-year period 1984-88, hospitals and retail pharmacies purchased an estimated 26.1 million grams of anabolic steroids.³ During the same 5 years, about 7.1 million prescriptions were dispensed for anabolic steroids. However, since 1984, the number of prescriptions has declined. About 500,000 fewer prescriptions were written in 1988 than in 1984 (see fig. IV.3).⁴

³These data were based on IMS America, Ltd.'s, audit of pharmacies and hospitals.

⁴Data were based on IMS America, Ltd.'s, prescription audit.

Figure IV.3: Anabolic Steroid
Prescriptions Dispensed (1984-88)



Note: Prescription data include only what is prescribed by the physician and what is dispensed by the pharmacist.

^aData for 1988 do not include information for December.

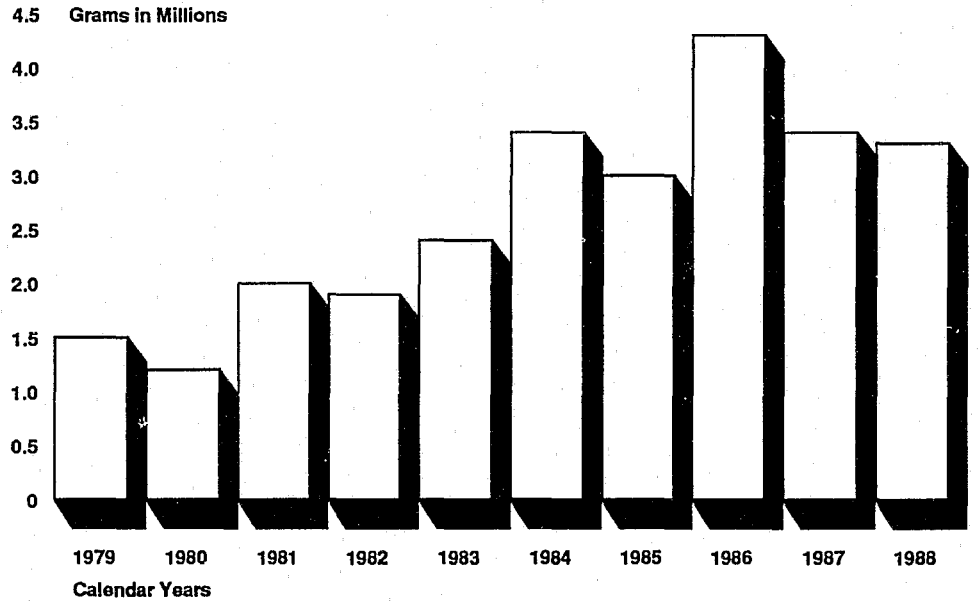
Source: IMS America, Ltd's, national prescription audit.

Imports of Anabolic Steroids

The United States imports anabolic steroids from various countries. Between 1979 and 1988, the United States imported 26.2 million grams, totaling \$20.6 million. According to a Department of Commerce official, these imports were in bulk rather than dosage form. The amount imported over a 10-year period, beginning with 1979, is shown in figure IV.4.

Appendix IV
Distribution of Anabolic Steroids

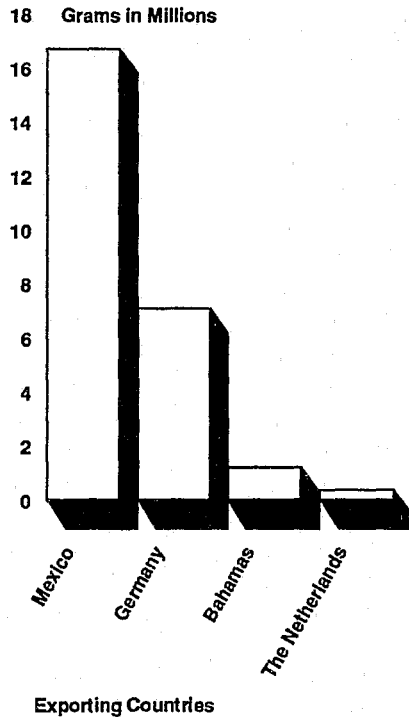
Figure IV.4: Anabolic Steroids Imported
by the United States (1979-88)



Source: Department of Commerce imports reports.

The top four countries exporting steroids to the United States were, in order, Mexico, Germany, the Bahamas, and the Netherlands (see fig. IV.5).

Figure IV.5: Top Four Countries
Exporting Anabolic Steroids Into the
United States (1979-88)



Source: U.S. Department of Commerce imports reports.

Black Market Major Supplier

Information provided by the Department of Justice documents the existence of a growing black market traffic in anabolic steroids. In January 1985, FDA asked the Office of Consumer Litigation in the Department of Justice's Civil Division to coordinate a national investigation into the black market distribution of anabolic steroids because of the potential health risks associated with the misuse of these drugs. This interagency collaborative effort was motivated by FDA's need for assistance in conducting undercover investigations in the black market trade. Justice's senior litigation counsel and FDA's national anabolic steroids coordinator were designated the focal points for this initiative.

In conducting investigations, confiscating drugs, halting clandestine manufacturing operations, and prosecuting individuals and companies, Justice and FDA have worked with the U.S. Customs Service, the U.S. Postal Service, the Federal Bureau of Investigation, and state and local law enforcement agencies. Since 1985, Justice and FDA officials report that investigators have seen an evolution in illegal trafficking. The

evolution began with the diversion of legitimately manufactured domestic anabolic steroids by people without prior criminal activity and moved to: (1) the wholesale smuggling of foreign manufactured products into the United States; (2) the domestic, clandestine manufacture of counterfeit steroid products; and (3) the involvement of criminals.

Drugs get to the black market by several routes. First, drugs can be diverted from the legal market through theft, resale by consumers, or the filling of fraudulent prescriptions. Second, drugs can be counterfeited. These include mislabeled drugs, drugs that are subpotent or adulterated with other substances, or totally bogus drugs that contain none of the substances they purport to contain. These drugs may be produced domestically or smuggled in from other countries. Department of Justice officials report that the proportion of counterfeit anabolic steroids on the black market has increased over the past 4 years. Since 1986, Justice and FDA have uncovered more than 35 different counterfeit drug products and more than 85 different labels used in their distribution.

Confiscated drugs have been manufactured in many countries, including Brazil, France, Italy, Belgium, Canada, Germany, Switzerland, the United Kingdom, and Mexico. According to Justice officials, the majority of confiscations have been made in California.

Based on its drug seizures and other information, Justice believes the supply of black market anabolic steroids is divided about equally between three sources: clandestinely manufactured goods, smuggled products, and diverted legitimately manufactured U.S. products. According to Justice officials, the black market in steroids is of national scope with operations in every sector of the country.

As of April 25, 1989, 440 cases have been generated for investigation as a result of Justice and FDA activities over the past 4 years. Justice conservatively estimates that the total value of the anabolic steroids that have been seized is \$16 million.⁵

⁵Justice officials provided us with data books derived from reports on drug products that have been seized during investigations. These books contained only a small portion of drugs that were seized and purchased through undercover efforts. Justice uses this information to show trends in the black market and to track the many counterfeit drug products; it is not intended to provide a comprehensive catalog of the black market. Thus, we were unable to use the books to provide information on the total quantity and type of drugs found on the black market.

Human Growth Hormone

We did not find any studies that document the use of human growth hormone among high school students, college students, or athletes. Reports of its use among athletes are anecdotal. According to the Council on Scientific Affairs of the American Medical Association, the abuse of human growth hormone, to the extent it exists, is a recent phenomenon.

Production data on human growth hormone were not made available to us by manufacturers. Available distribution information indicates that between 1985 and 1988, 1,553,556 vials or 7,768 grams of human growth hormone were legally distributed in the United States. Small quantities have been found on the black market, but to a much lesser extent than anabolic steroids.

Use Unknown

We were not able to identify information on the extent, if any, of human growth hormone use among high school or college students or among amateur and professional athletes. Anecdotal reports suggest athletes use the hormone because they perceive it to increase body growth and strength potential; athletes believe the hormone (1) prevents the breakdown of muscle after anabolic steroids are discontinued and (2) strengthens tendons and ligaments, thus preventing ruptures or tears. According to researchers and sports physicians, these perceptions that lead athletes to believe human growth hormone might affect athletic performance have not been confirmed scientifically. No studies have been identified that examine an interaction between human growth hormone and anabolic steroids.

According to anecdotal reports, athletes favor growth hormone over steroids because it is undetectable in current drug testing procedures. Even though the use of human growth hormone cannot be detected, the U.S. Olympic Committee, the National Collegiate Athletic Association, and the National Football League have included this drug among their list of banned substances.

Adverse Effects of Human Growth Hormone

Secreted by the pituitary gland, human growth hormone acts as part of the endocrine system to stimulate growth throughout the body. It is particularly active during puberty, contributing to the growth spurt that takes place at that time; deficiency in childhood results in dwarfism. In this rare disease, children fail to grow because the pituitary gland does not produce sufficient growth hormone. Human growth hormone is necessary to treat this disease because growth hormone from other animal

species is ineffective. It is estimated that there are about 10,000 to 15,000 cases of dwarfism, which are treated by about 450 pediatric endocrinologists throughout the country.

Although the only approved indication for the hormone is the treatment of dwarfism, FDA officials and other experts state that some ongoing research concerns wound healing, the treatment of Turner's Syndrome in girls,¹ and the treatment of osteoporosis and obesity. The greatest interest is in the possible use of human growth hormone to make short children taller; it has not, however, been approved for this purpose. The administration of the hormone to normal children with short stature is controversial. Some physicians believe psychosocial problems associated with short stature may be reduced with the hormone treatment. Other physicians are uncertain about this treatment, however, since there are short-term risks of abnormal bone growth, dysfunction of the thyroid gland, and creation of antibodies to human growth hormone that have been associated with clinical treatment.²

Overproduction of growth hormone in adults may result in acromegaly, a disease that usually becomes obvious in the third or fourth decade of life. It is marked by progressive enlargement of hands, feet, and face. The symptoms may include excessive growth in the skull, other bones, and soft tissue; thickening of the skin; diabetes mellitus; cardiovascular disease; goiters; menstrual disorders in females; decreased sexual desire; and impotence in males. Acromegaly almost always shortens the life span of the persons it afflicts. At this time, there are no reported cases of acromegaly among athletes.

Legal Production and Distribution

Before 1985, human growth hormone was derived commercially through the extraction of the hormone from the pituitary gland of cadavers. Given this source, the availability of the hormone was limited. The National Hormone and Pituitary Program of the National Institutes of Health played an important role distributing the hormone to patients with clinically confirmed dwarfism. According to a National Institutes of

¹Turner's Syndrome is caused by a genetic defect in females that is characterized by such symptoms as short stature, webbed neck, sterility, and heart problems.

²Representatives from Genentech, Inc., one of the manufacturers of human growth hormone, told us that they actively discourage the use of their product for the treatment of short-stature children and that the company is not filing for additional approval from FDA to use this drug for this purpose.

Health official, close to 90 percent of the available hormone was distributed by the program, which treated between 2,300 and 2,500 patients over a 20-year period.

In 1985, the distribution of the pituitary-extracted hormone was halted after several children died after being treated with extracted hormone. Their deaths were caused by Creutzfeldt-Jakob disease, a slow virus that affects the nervous system; it was believed that the disease resulted from the use of contaminated pituitary extracts. Since the withdrawal of pituitary extracts from the U.S. market, two recombinant deoxyribonucleic acid (DNA)-derived human growth hormone products have been approved by FDA for marketing in the United States and are available commercially. These synthetic growth hormones are produced by two pharmaceutical companies: Genentech, Inc., which began marketing it under the trade name Protropin in 1985, and Eli Lilly and Company, which began marketing it under the trade name Humatrope in 1987. The human growth hormone produced by both companies must be administered by injection.

We were unable to obtain data on the production of Protropin and Humatrope; we did, however, obtain information on the distribution of both drugs since their commencement of marketing. According to annual reports to FDA, 1,553,556 vials or 7,768 grams of human growth hormone have been distributed domestically by Genentech and Eli Lilly.³

The distribution of synthetic growth hormone differs greatly from that of anabolic steroids, for which no known controls exist. Both manufacturers of the hormone have voluntarily developed distribution controls for their product.

A Genentech representative told us that all patients being treated with Protropin receive the drug through Caremark, a home health care company, or a hospital pharmacy on the basis of a prescription. According to Genentech, Protropin is not available from an ordinary retail drugstore. Genentech said that its distribution system enables the company to identify by age, diagnosis, and dosage 91 percent of the patients who receive the product. This is made possible through Caremark's required recordkeeping and Genentech's annual post-marketing surveillance study of 63 percent of the patients being treated with Protropin.

³According to Genentech representatives, the usual average dosage of human growth hormone required for a child of 30 kilograms is 0.3 mg per kg per week or 1.8 vials per week, or a total of 93.6 vials per year. Each vial contains 5 mg of human growth hormone. The usual average dose required for a 50 kg teenage boy is 0.3 mg per kg per week or 3 vials per week, or a total of 156 vials per year.

Lilly has also developed a system of control similar to that of Genentech. Both Genentech and Lilly believe that the potential for diversion of legally produced human growth hormone is significantly smaller than that for anabolic steroids.

Black Market Supply

The amount of growth hormone sold on the black market is unclear. It appears, however, that the amount confiscated is significantly smaller than that for anabolic steroids. According to the data provided by Justice and FDA, at least 115 vials of drugs purporting to be synthetic human growth hormone were confiscated on 13 different occasions during October 1985 and December 1988. At least 14 vials of genuine Protopin were confiscated on eight different occasions, with five occurring between 1985, when the drug was first distributed, and May 1987. In November 1988, a total of 48 vials labeled as Protopin, although none contained it, were confiscated on three occasions. Human growth hormone produced by Lilly has also been found on the black market by Justice and FDA investigators. A total of 53 vials of human growth hormone produced for research purposes were seized between October and December of 1988.

In addition to the synthetic hormone, small quantities of pituitary-extracted somatotropin (which had been withdrawn from the U.S. market) were seized from the black market. In 1983 and 1985 three vials of counterfeit Asellacrin, an extracted growth hormone produced by Serrono Laboratories, Inc., were confiscated. Also in 1985, 28 vials of a genuine extracted growth hormone, called Crescormon, distributed by Pharmacia Inc., were confiscated.

Genentech representatives believe that the following factors contribute to limiting the unauthorized distribution of human growth hormone: (1) the knowledge regarding the use of recombinant DNA technology necessary to make human growth hormone is not widely diffused even in the pharmaceutical industry, (2) the costs of constructing a facility to produce growth hormone illegally are prohibitive, and (3) their rigid distribution controls make the availability of their product on the black market difficult.

The Civil Division of the Department of Justice acknowledges the efforts that the manufacturers have made to control the distribution of their products; however, FDA and the Civil Division take the position that the currently manufactured human growth hormones are drugs

Appendix V
Human Growth Hormone

that are being abused by athletes and are being traded on the black market. Justice officials estimate that human growth hormones are selling on the black market for \$500 to \$1,500 per unit.

Justice officials said that the fact that the federal government has been able to buy some of the drugs on the black market leads them to conclude that there is enough trade in these products to justify penalties for the illegal distribution or possession of these drugs similar to penalties that apply to anabolic steroids under the Anti-Drug Abuse Act of 1988 (see p. 37).

Federal and State Governments Increase Control Over the Use of Anabolic Steroids and Human Growth Hormone

Because of concern over the possible health effects of anabolic steroids and human growth hormone, the federal and many state governments either adopted regulations or enacted legislation to reduce the misuse of these drugs. For example, in 1988, the Congress passed the Anti-Drug Abuse Act of 1988 (P.L. 100-690), which includes several provisions to control the misuse of anabolic steroids and human growth hormone. According to FDA, as of June 16, 1989, 25 states had enacted laws or promulgated regulations specifically concerning the distribution of anabolic steroids, and 5 of these states had enacted legislation specifically concerning the distribution of human growth hormone. In addition, 26 states are considering a total of 61 bills intended to provide more effective control over the use of these drugs.

Federal Legislation

The key provisions of the Anti-Drug Abuse Act of 1988 that relate to the misuse of anabolic steroids and human growth hormone are in sections 2401 and 2403. Section 2401 provides for the forfeiture of specified property of an individual convicted of a violation of the Federal Food, Drug, and Cosmetic Act involving anabolic steroids or human growth hormone if such a violation is punishable by imprisonment for more than 1 year.

Under section 2403, which applies only to anabolic steroids, violators are subject to imprisonment for up to 3 years or a fine or both if they (1) distribute or (2) possess steroids with the intent to distribute for any use in humans other than the treatment of disease based on the order of a physician. Violators who distribute, or possess with the intent to distribute, to a person under 18 years of age are subject to imprisonment for up to 6 years.

State Laws on Anabolic Steroids

According to FDA, the 25 states that have enacted laws or promulgated regulations dealing with anabolic steroids are Alabama, Arizona, Arkansas, California, Colorado, Connecticut, Florida, Georgia, Hawaii, Idaho, Indiana, Kansas, Louisiana, Minnesota, New Hampshire, New Mexico, North Carolina, North Dakota, Ohio, Oklahoma, South Carolina, Texas, Utah, Virginia, and Washington.

These laws and regulations vary in the nature and level of control exercised to prevent abuse. For example, some states have enacted legislation or promulgated rules classifying anabolic steroids as controlled substances; at least one other state has promulgated rules specifying the

Appendix VI
Federal and State Governments Increase
Control Over the Use of Anabolic Steroids
and Human Growth Hormone

medical profession's responsibility in prescribing, dispensing, or delivering these drugs. Accordingly, the penalties associated with the violation of these laws or regulations also vary by state.

According to FDA's State Law Coordinator, 9 of the 25 states (Alabama, California, Florida, Idaho, Kansas, Minnesota, North Carolina, Texas, and Utah) have classified anabolic steroids pursuant to categories or schedules under their controlled substances acts. FDA indicates that the states' controlled substances acts are either identical or similar to the federal Controlled Substances Act. The federal Controlled Substances Act classifies drugs that can be physically or psychologically harmful into categories or schedules on the bases of the potential for abuse, accepted medical use, and potential for physical or psychological dependence as a consequence of abuse. The federal Controlled Substances Act classifies drugs into five categories or schedules. The schedule under which a drug is placed determines the nature and degree of control exercised to prevent its abuse and diversion. Schedule I controlled substances (1) have a high potential for abuse, (2) have no accepted medical use in the United States, and (3) may lead to severe psychological or physical dependence. Schedule II through V controlled substances have accepted medical uses and abuse potentials correlated to their assigned schedule number, with Schedule II the most dangerous and Schedule V the least. Anabolic steroids and human growth hormone are not currently classified under the federal Controlled Substances Act.

According to FDA, state penalties for the illegal manufacture, distribution, and possession of anabolic steroids vary from misdemeanors to felonies and may result in the imposition of a range of fines and terms of imprisonment, and in some states, the distribution of anabolic steroids to minors may result in harsher penalties. In addition, in one state, a physician's unauthorized distribution of anabolic steroids may violate regulations governing the practice of medicine in that state and may result in revocation or suspension of that physician's license to practice medicine.

According to FDA, 26 states have pending legislation dealing with anabolic steroids.¹ Proposed legislation in six of these states would classify anabolic steroids as a controlled substance.

¹Some of the 26 states already have laws regulating the use and distribution of anabolic steroids.

State Laws on Human Growth Hormone

According to FDA, Arkansas, Idaho, Ohio, Texas, and Washington have enacted legislation or adopted regulations to control the illegal distribution and possession of human growth hormone. Under the Arkansas law, any person who distributes, or possesses with intent to distribute, human growth hormone for any use in humans other than the treatment of disease at the order of a physician is guilty of a felony. The penalty may be harsher for distribution to a minor. The Ohio law prohibits administering human growth hormone for the purpose of enhancing athletic ability. Physicians who violate this law are subject to reprimand, probation, or license suspension or revocation.

According to FDA, Idaho classified human growth hormone, along with anabolic steroids, under its controlled substances act. The Texas law prohibits medical practitioners from dispensing, delivering, or administering human growth hormone or causing human growth hormone to be administered except for a valid medical purpose and in the course of professional practice. Medical practitioners or pharmacists cannot prescribe, dispense, or deliver human growth hormone without a written prescription that meets the requirements of the Texas Pharmacy Act.

The FDA State Law Coordinator told us that the Washington law prohibits practitioners from prescribing, administering, or dispensing human growth hormone for the purpose of manipulating hormones to increase muscle mass, strength, or weight, or for the purpose of enhancing athletic ability without a medical necessity to do so. The law also requires that patient medical records, including the diagnosis and purpose for prescribing, administering, or dispensing, be completed and maintained. Under the Washington law, any person in illegal possession of more than eight 2-cubic-centimeter bottles of human growth hormone is guilty of a felony.

According to FDA, legislation regarding human growth hormone was also introduced in 1989 into the legislatures of California, Delaware, Florida, Maryland, Nebraska, Ohio, Pennsylvania, Rhode Island, Texas, and Washington.

Requirements for Reporting Distribution Data to FDA

According to FDA officials, FDA has no authority to require drug manufacturers to submit production data to the agency. However, FDA requires firms that market FDA-approved drugs to submit distribution data in their annual reports submitted in compliance with the Records and Reports section of the Federal Food, Drug, and Cosmetic Act, section 505(k).

The annual reports are required to be submitted within 60 days of the anniversary date of FDA's approval of the drug for marketing rather than on the basis of a calendar or fiscal year. Because drugs that were marketed before 1938 are exempt from the premarket approval and report submission requirements of the act, the distribution data available from FDA may not reflect the total anabolic steroid distribution in the United States. Additionally, the data the manufacturers submit to FDA should include both domestic and foreign distribution, but no requirement asks for separate identification of the two; most manufacturers submit only the total amount distributed. FDA does not verify the accuracy of these data.

Since FDA does not receive production data, FDA officials stated they could not correlate steroid distribution with production. The officials indicated that the nature of drug production is such that manufacturers would very likely produce relatively large amounts of a specific drug product in one time period, then cease production of that particular product until the supply is exhausted. Therefore, production data may not correlate well with distribution data.

The amount of steroids used for medical purposes cannot be precisely estimated. According to FDA, there is no federal requirement that (1) physicians report prescriptions for medications other than for controlled substances or (2) manufacturers estimate the number of patients who would use a drug.

Studies on Anabolic Steroid Use Among High School Students, College Students, and Athletes

Studies on Use Among High School Students

Bosworth, E., and others. "Anabolic Steroids and High School Athletes." Abstract. Medical Sciences, Sports, Exercise, 20 (May 25, 1988), S3.

Buckley, William E., and others. "Estimated Prevalence of Anabolic Steroid Use Among Male High School Seniors." Journal of the American Medical Association, 260 (Dec. 16, 1988), 3441-3445.

Corder, Brice W., and others. "Trends in Drug Use Behavior at Ten Central Arizona High Schools." Arizona Journal of Health and Physical Education, Recreation, and Dance, 18 (1975), 10-11.

Johnson, Mimi D., and others. "Anabolic Steroid Use by Male Adolescents." Pediatrics, 83 (June 1989), pp. 921-924.

Newman, Martha. "Hazelden Health Promotion: Michigan Consortium of Schools Student Survey." Minneapolis: Hazelden Research Services, September 1986 (unpublished).

Swenson, E. James, Jr. "Perspectives on Anabolic Steroids: Statewide Survey of High School Varsity Football Medical Coaches." East Lansing: Michigan State University, Fall 1987 (unpublished).

Terney, Rise, and Larry G. McLain. "The Use of Anabolic Steroids in High School Students." Chicago: Loyola University, May 1988 (unpublished).

Windsor, Robert, and Daniel Dumitru. "Prevalence of Anabolic Steroid Use by Male and Female Adolescents." Medicine and Science in Sports and Exercise, forthcoming October 1989.

Studies on Use Among College Students

Anderson, William A., and Douglas B. McKeag. "The Substance Use and Abuse Habits of College Student-Athletes." East Lansing: Michigan State University, 1985 (unpublished).

Corder, Brice W., and others. "An Analysis of Trends in Drug Use Behavior at Five American Universities." The Journal of School Health, 44 (September 1974), 386-389.

Dezelsky, T. L., and others. "Non-Medical Drug Use Behaviour at Five United States Universities: A 15-Year Study." Bulletin on Narcotics (United Nations publication), 37 (1985), 49-53.

Appendix VIII
Studies on Anabolic Steroid Use Among High
School Students, College Students,
and Athletes

Pope, Harrison G. Jr., and others. "Anabolic-Androgenic Steroid Use Among 1,010 College Men." The Physician and Sportsmedicine, 16 (July 1988), 75-81.

Toohey, J. V., and B. W. Corder. "Intercollegiate Sports Participation and Non-Medical Drug Use." Bulletin on Narcotics (United Nations publication), 33 (1981), 23-27.

**Studies on Use Among
Weightlifters**

Frankle, Mark A., and others. "Use of Androgenic Anabolic Steroids by Athletes." Letter to Editor, Journal of the American Medical Association, 252 (July 27, 1984), 482.

Yesalis, Charles E. III, and others. "Self-Reported Use of Anabolic-Androgenic Steroids by Elite Power Lifters." The Physician and Sportsmedicine, 16 (Dec. 1988), 91-100.

Major Contributors to This Report

**Human Resources
Division
Washington, D.C.**

Janet L. Shikles, Director of National and Public Health Issues,
(202) 275-5451

Albert B. Jojokian, Assistant Director

Beryce W. MacLennan, Mental Health Advisor

Rose Marie Martinez, Assignment Manager

Millie D. Baskin, Evaluator-in-Charge

REPORT OF THE BOARD OF DIRECTORS OF THE COMPANY

FOR THE YEAR ENDING 31st DECEMBER 1954

AND STATEMENT OF FINANCIAL POSITION

AS AT THAT DATE

AND STATEMENT OF PROFIT AND LOSS

AND STATEMENT OF CHANGES IN RESERVES AND EQUITY

AND STATEMENT OF CASH FLOWS

AND STATEMENT OF DIVIDENDS

UNITED STATES
GENERAL INVESTIGATIVE DIVISION
WASHINGTON, D. C. 20535

OFFICE OF THE DIRECTOR
WASHINGTON, D. C. 20535

POSTAGE & FEES PAID
GAO
Permit No. G100

