Approved 2-28-89
Date

MINUTES OF THE SENATE COMMITTEE ON PUBLIC HEALTH AND WELFARE.

The meeting was called to order by SENATOR ROY M. EHRLICH at
Chairperson

10:00 a.m./p.m. on February 20, 1989 in room 526-S of the Capitol.

All members were present except:

Committee staff present:
Emalene Correll, Legislative Research
Bill Wolff, Legislative Research
Norman Furse, Revisors Office
Clarene Wilms, Committee Secretary

Conferees appearing before the committee:
Richard Gannon, Executive Director, Kansas Board of Healing Arts
Tom Hitchcock, Executive Secretary, Kansas State Board of Pharmacy
Chip Wheelen, Director of Public Affairs, Kansas Medical Society
Peter S. Lepse, M.D., Orthopedist, Topeka
Charles Konigsberg, Jr., M.D., Director, Division of Health, Kansas Department of Health and Environment
Daric S. Smith, Attorney, Topeka
Ben Coates, Director of Policy, Department of Social Rehabilitation Services

Richard Gannon, Board of Healing Arts, appeared in support of SB-181 stating that the uncontrolled and harmful use of anabolic steroids, and more recently, growth hormone is becoming an increasing hazard to the health and welfare of the young people of the state of Kansas. He related many effects of these steroids on various systems of the body when used without medical supervision. (Attachment 1) Copies of an article from the February 20, 1989 Sports Illustrated relating to the use of steriods was also included as part of his testimony. (Attachment 2)

Staff expressed concern over the provision of making young people in possession of these drugs guilty of a felony and questioned what real assistance that might be to them in terms of their health. Mr. Gannon stated that this would be a decision for the committee and ultimately the legislature to make but his organization felt some control was needed.

Tom Hitchcock, State Board of Pharmacy, appeared in support of SB-181 stating the abuse and misuse of anabolic steroids has been around this country for many years but has now become a rather large problem in Kansas. He referred to numerous difficulties caused by steroid use. (Attachment 3)

Chip Wheelen, Kansas Medical Society, spoke in support of SB-181. He stated that an amendment might be considered which would avoid any measurement of the steroids and would make possession by anyone other than a pharmacist or practioner unlawful unless obtained by a prescription order. He stated that the abuse of anabolic steroids is a problem that appears to be worsening while medical researchers continue to discover harmful side effects from prolonged use, especially when taken in high level dosages. (Attachment 4)

Peter S. Lepse, M.D. who has been involved on the athletic side of the issue, told the committee of many difficulties presented by the use of these drugs. One particularly alarming effect on the adolescent population is a phenomenon known as "steroid rage" brought about from high dosage and results in very agressive behavior. He stressed that the use of these substances is prevalent, the amounts and combinations being used are so wide that it is difficult to be certain just what side effects will be.

MINUTES OF THE SENATE COMMITTEE ON PUBLIC HEALTH AND WELFARE,

room 526-S Statehouse, at 10:00 a.m./~~p.m.~~ on February 20, 1989

Staff questioned whether or not these drugs now legally require prescription and was told that they did. However, many are being obtained on the black market which has no standards at all. Staff also asked whether or not there was a criminal penalty connected with unlawful of prescription drugs and was told there was no state law.

Charles Konigsberg, Jr., M.D., Division of Health appeared in support of SB-181 stating his department's concern about this matter. He echoed mentioned concerns about the amounts of substance named in the bill. (Attachment 5)

Richard Gannon, Board of Healing Arts, appeared in support of SB-198 stating this bill would deal with examinations for respiratory therapists and would raise fees from $100 to $250. (Attachment 6)

Staff questioned whether or not consideration had been given to wording this bill similarly to others which allow the board to charge the cost of the examination. Mr. Gannon replied that doing so would be appropriate.

Attention was called to the minutes which will be presented for approval or correction tomorrow.

Daric S. Smith appeared requesting a committee bill dealing with rights of voluntary patients, specifically, minors, 14 years of age and above. (Attachment 7)

Senator Langworthy moved, with a second by Senator Strick, that this bill be accepted as a committee bill. The motion carried.
Senator Kanan requested his NO vote on the above motion be recorded.

Ben Coates, SRS, appeared to request committee bills as follows:

1. To allow the secretary of SRS to sell and convey certain property currently being used as a workshop for the blind. (Attachment 8)
2. Concerning patients in certain state institutions; relating to payment for maintenance, care and treatment must be paid by the patient, the conservator of such patient's estate or by any person bound by law to support such a patient.
3. concerning payment of claims to medical vendors for care of needy persons.
4. Concerning care of children relating to certain persons prohibited from maintaining homes for children.
5. Concerning records and reports of child abuse or neglect.

Senator Kanan moved, with a second by Senator Walker, that the committee accept these bills as committee bills. The motion carried.

The meeting adjourned at 10:55 a.m. and will convene at 10:00 a.m. Tuesday, February 21, 1989 in room 526-S.

SENATE
PUBLIC HEALTH AND WELFARE COMMITTEE
DATE February 20, 1989

(PLEASE PRINT) NAME AND ADDRESS	ORGANIZATION
Charlene K. Abbott	Board of Healing Arts
Richard H. Harmon	11
Tom Hitchcock	Bd. of Pharmacy
Bob Williams	Ks. Pharmaceutical Assoc
DARIC S. SMITH	SKINNER & SMITH
Matt Treuel	AP
Chip Wheelen	Ks Medical Society
Martin McCluskey	WEA
Charles Konigsberg, M.D.	KDHE
John Bales	SRS
	SRS
Bob Corkins	Ks. Hospital Assoc.
KEITH R LANDIS	CHRISTIAN SCIENCE COMMITTEE ON PUBLICATION FOR KANSAS
Kevin Kelly	SUN newspapers
Carla Dale	KDDE
Virginia L Tucker, M.D.	KDHE
Karen Higginbotham	KDHE
Paula Marmet	KDHE
John Peterson	Ks Assn Pvt Psych Hospitals

SENATE
PUBLIC HEALTH AND WELFARE COMMITTEE

DATE February 20, 1989

(PLEASE PRINT) NAME AND ADDRESS	ORGANIZATION
Andy Nioce II	(PS150) Student of Public Speaking

Office of
RICHARD G. GANNON, EXECUTIVE DIRECTOR
CHARLENE K. ABBOTT, ADMINISTRATIVE ASSISTANT
LAWRENCE T. BUENING, JR., GENERAL COUNSEL
JOSEPH M. FURJANIC, DISCIPLINARY COUNSEL

State of Kansas

Landon State Office Building
900 S.W. JACKSON, SUITE 553
TOPEKA, KS 66612-1256
(913) 296-7413

Board of Healing Arts

TESTIMONY SB 181

The uncontrolled and harmful use of anabolic steroids and, more recently, growth hormone, among young aspiring athletes has become an increasing hazard to the health and welfare of the young people of the State of Kansas. Seemingly apparent, reported, and perceived remarkable improvements in total muscle mass and strength have produced pressures on young athletes--and, unfortunately, many times upon their parents and certain coaches--to help impel these young people to gain what is thought of as "competitive edge" without appropriate regard for the side effects and harmful long-term effects of these drugs. Further, the drugs as they are used are often poorly identified, not completely understood, and may well be used in a dosage up to 100 to 1,000 times the dose used for any rarely treated condition. Although these drugs have been used for some time, the harmful effects of this drug usage are being discovered as time goes on. This is to say that we probably do not know the full harmful effects of these drugs used in the megadoses in which they are misued.

There are a few specified medical uses for these drugs, as the appended copies of the PDR (Physicians' Desk Reference) on Anivar,

SPHW
2-20-89
Attachment 1

Anadrol, and Winstrol, these three being examples of anabolic steriods. However, these are such specialized and unusual situations that many physicians want an endocrinologist or a hematologist to prescribe them. Growth hormone has been a real boon to the tiny (extremely rare) segment of the pediatric population which has deficiency in growth hormone due to pituitary disease at an early age. However, this is such a specialized group that, indeed, the use of this medication should be in the province of a pediatric endocrinologist. What are the side effects or deleterious effects of these drugs, even in "therapeutic doses" in the very few situations where their use might be indicated? Biochemical changes are seen in the blood lipid pattern, with the high-density lipoproteins being decreased. This is the protective fraction of the lipids which tends to diminish the effect of the low-density lipoproteins. If the low-density lipoproteins are increased, this is a signficant risk factor in arteriosclerosis such as in coronary artery disease. The use of anabolic steroids further is associated with high blood pressure. In the very young athlete, the anabolic steroids tend to stop bone growth permaturely so as to cause the overall height of the individual to be less than without their use, if the anabolic steroid is used before the growth centers close normally. Anabolic steroids have an effect upon many systems of the body. Every one of the anabolic steroids also has to a greater or lesser extent, some androgenic (male hormone) properties. Although, initially, libido and potency may be increased, with the long-term use of the anabolic steroid, the normal testis is suppressed. Sperm production is markedly

decreased. This decrease in sperm production is to the level that there is concern about what massive doses over a long period of time, or what the "wave" or cyclic administration of massive doses of anabolic steroids could do over a protracted period of time. Skin changes are marked, with increase in acne and hair growth over different portions of the body. Liver tumors have been described, both benign cysts and malignant tumors of the liver. Also, marked changes in emotional status of the individual have been described. Sources of steroids primarily are from outside of the United States, largely from Mexico. It is amazing to realize how relatively inexpensive and available these drugs are to the young of our State.

Although fatalities have been poorly publicized, an article in the February 20, 1989, issue of Sports Illustrated, shows the reported sad death of an young athlete on steriods.

...antihypertensive agents. Treatment with Aldactone should be continued for at least two weeks, since the maximum response may not occur before this time. Subsequent dosage should be adjusted according to the response ...

... Aldactone in a dosage ranging from 25 mg to ... useful in treating a diuretic-induced hypokalemia ... oral potassium supplements or other potassium-... are considered inappropriate.

...PLIED

... tablets are round, light yellow, film coated, ... and 1001 debossed on one side and ALDAC-... on the other side; bottles of 100, 500, 1,000, and ... of 100 unit-dose individually blister-sealed

... tablets are oval, light orange, scored, film ... SEARLE and 1041 debossed on the scored side ... TONE and 50 on the other side; bottles of 100 ... of 100 unit-dose individually blister-sealed tab-

... mg tablets are round, peach colored, scored, ... with SEARLE and 1031 debossed on the scored ... ACTONE and 100 on the other side; bottles of ... of 100 unit-dose individually blister-sealed

... Federal law prohibits dispensing without pre-

A05446-7

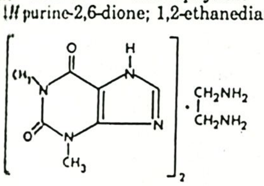
... in *Product Identification Section, page 429*

...HYLLIN™ Tablets ℞
[...'fi-lin]
...

...TION

... contains 100 mg or 200 mg of aminophylline ... as the dihydrate, which is equivalent to 79 ... mg of anhydrous theophylline, respectively. ... USP (anhydrous) is a soluble complex con-... approximately 85% anhydrous theophylline and ... diamine. Aminophylline is white or slightly ... granules or powder, having a slight ammoniacal ... bitter taste.

... formula of aminophylline (3,7-dihydro-... 1H purine-2,6-dione; 1,2-ethanediamine) is:



... ingredients of Aminophyllin 100-mg tablets include ... starch, magnesium stearate, potassium ... sodium sulfate, and sodium sulfite. Inactive in-... Aminophyllin 200-mg tablets include corn ... magnesium stearate, potassium phosphate, sodium ... talc

... directly relaxes the smooth muscle of the ... airways and pulmonary blood vessels, thus acting ... bronchodilator, pulmonary vasodilator, and ... relaxant. The drug also possesses other ac-... of the xanthine derivatives: coronary vasodi-... cardiac stimulant, cerebral stimulant, and ... stimulant.

...ONS AND USAGE

... Tablets are indicated for the relief and/or ... symptoms from asthma and reversible bron-... associated with chronic bronchitis and emphy-

...INDICATIONS

... should not be administered to patients with ... ulcer disease, since it may increase the volume ... gastric secretions.
... history of hypersensitivity to aminophylline ... should not be treated with the drug.
... should not be administered with other xan...

... may be expected to be toxic. Some children ... sensitive to aminophylline. Toxic syner-... ephedrine and other sympathomimetic bronchodi-... occur. Halothane anesthesia in the presence ... may produce sinus tachycardia or ventric-

... sulfite, a sulfite that may cause allergic-... including anaphylactic symptoms and life-... less severe asthmatic episodes in certain sus-... The overall prevalence of sulfite sensitivity ... population is unknown and probably low. Sulfite sensitivity is seen more frequently in asthmatic than in nonasthmatic people.

Usage in Pregnancy. Safe use in pregnancy has not been established relative to possible adverse effects on fetal development. Therefore, aminophylline should not be used in pregnant women unless, in the judgment of the physician, the potential benefits outweigh the possible hazards.

PRECAUTIONS

Use with caution in patients with severe cardiac disease, hypertension, hyperthyroidism, acute myocardial injury, cor pulmonale, severe hypoxemia, hepatic impairment, or alcoholism, and in the elderly (especially males) and in neonates. Particular caution in dose administration must be exercised in patients with a history of peptic ulcer since the condition may be exacerbated. Chronic oral administration in high doses may be associated with gastrointestinal irritation.

Caution should be used in giving aminophylline to patients in congestive heart failure. Serum levels in such patients have persisted for long periods following discontinuation of the drug.

Theophylline half-life is shorter in smokers than nonsmokers; therefore, smokers may require larger or more frequent doses.

Aminophylline may lower the seizure threshold.

Elevated serum levels of theophylline may occur in patients treated concomitantly with aminophylline and cimetidine, troleandomycin, erythromycin, allopurinol, or oral contraceptive steroids. The addition of ephedrine or other sympathomimetic drugs to regimens of aminophylline increases the toxicity potential and may result in symptoms of overdosage, due to the additive pharmacological effects of these compounds. Co-medication with phenobarbital, phenytoin, or rifampin may increase theophylline clearance and an increase of the aminophylline dose may be required. The excretion of lithium carbonate is increased in patients receiving aminophylline. Aminophylline may antagonize the effects of propranolol.

Consumption of coffee, tea, cola beverages, chocolate, or acetaminophen contributes to falsely high serum theophylline levels when theophylline is measured spectrophotometrically without previous isolation by chromatography.

Mutagenesis: Theophylline has been shown to be mutagenic in *Escherichia coli* and other lower organisms (*Euglena gracilis* and *Ophiostoma multiannulatum*) and to produce chromosome breaks in cultured mouse cells and cultured human lymphocytes. The drug had no mutagenic activity *in vivo* in a dominant lethal test using mice.

Limited animal studies have shown teratogenic activity of theophylline in mice and rats.

Theophylline is excreted in breast milk and may cause adverse effects in the infant. Caution must be used when prescribing aminophylline to a nursing mother, taking into account the risk/benefit of this therapy.

Due to the marked variation in theophylline metabolism in infants under 6 months of age, aminophylline is not recommended for this age group.

ADVERSE REACTIONS

The most consistent adverse reactions observed with *therapeutic* amounts of aminophylline are:

1. Gastrointestinal: Nausea, vomiting, anorexia, bitter aftertaste, dyspepsia, heavy feeling in the stomach, and gastrointestinal distress.
2. Central nervous system: Dizziness, vertigo, lightheadedness, headache, nervousness, insomnia, and agitation.
3. Cardiovascular: Palpitation, tachycardia, flushing, and extrasystoles.
4. Respiratory: Increase in respiratory rate.
5. Dermatologic: Urticaria.

OVERDOSAGE

The most consistent reactions observed with *toxic* overdoses of aminophylline are:

1. Gastrointestinal: Nausea, vomiting, epigastric pain, hematemesis, and diarrhea.
2. Central nervous system: In addition to those cited above, the patient may exhibit hyperreflexia, fasciculations, and clonic and tonic convulsions. These are especially prone to occur in cases of overdosage in infants and small children.
3. Cardiovascular: In addition to those outlined above, marked hypotension and circulatory failure may be manifest.
4. Respiratory: Tachypnea and respiratory arrest may occur.
5. Renal: Albuminuria and microhematuria may occur. Increased excretion of renal tubular cells has been observed.
6. General systemic effects: Syncope, collapse, fever, and dehydration.

Management of Toxic Symptoms:

1. Discontinue drug immediately.
2. There is no known specific antidote.
3. Gastric lavage.
4. Emetic medication may be of value.
5. Avoid administration of sympathomimetic drugs.
6. Intravenous fluids, oxygen, and other supportive measures to prevent hypotension and overcome dehydration.
7. Central nervous system stimulation and seizures may respond to short-acting barbiturates.
8. Monitor serum levels until below 20 mcg/ml.

DOSAGE AND ADMINISTRATION

The oral dose for adults should be adjusted according to the need and response of the patient. Usually a daily dose in the range of 600 to 1600 mg, administered in 3 or 4 divided doses, will provide the desired therapeutic effect. Similarly, the dose for children should be adjusted according to the response. An oral dose of 12 mg/kg/24 hours, administered in four divided doses, will usually provide the desired therapeutic effect in children.

Therapeutic serum levels are considered to be between 10 mcg/ml and 20 mcg/ml. Levels above 20 mcg/ml may produce toxic effects. There is great variation from patient to patient in dosage needed to achieve a therapeutic serum level and in the duration of action of oral aminophylline. Because of these wide variations and the relatively narrow therapeutic serum level range, dosage must be individualized with monitoring of theophylline serum levels, particularly when prolonged use is planned.

HOW SUPPLIED

Aminophyllin Tablets are supplied as:

Round, white, scored tablets with 1231 debossed on the scored side and SEARLE on the other side, each tablet containing 100 mg of aminophylline.

NDC Number	Size
0014-1231-31	bottle of 100
0014-1231-52	bottle of 1,000
0014-1231-34	carton of 100 unit dose

Oval, white, scored tablets with 1251 debossed on the scored side and SEARLE on the other side, each tablet containing 200 mg of aminophylline.

NDC Number	Size
0014-1251-31	bottle of 100
0014-1251-52	bottle of 1,000
0014-1251-34	carton of 100 unit dose

Dispense in a tight, non-PVC container.

Caution: Federal law prohibits dispensing without prescription.

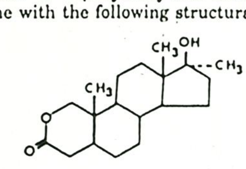
A05230-9

Shown in Product Identification Section, page 429

ANAVAR® ℞
[an 'uh-var]
(oxandrolone)

DESCRIPTION

Anavar oral tablets contain 2.5 mg of the anabolic steroid oxandrolone, a synthetic derivative of testosterone. Oxandrolone is 17β-hydroxy-17α-methyl-2-oxa-5α-androstan-3-one with the following structural formula:



Inactive ingredients include corn starch, lactose, magnesium stearate, and methylcellulose.

CLINICAL PHARMACOLOGY

Anavar is used primarily for its protein anabolic effect and its catabolism-inhibiting effect on tissue. Nitrogen balance is improved by anabolic agents, but only when the intake of calories and protein is sufficient. It has not been established whether this positive nitrogen balance indicates a primary benefit in the utilization of protein-building dietary substances. Some clinical effects and adverse reactions reported demonstrate the androgenic properties of drugs of this class. Complete dissociation of anabolic from androgenic effects has not been achieved. The actions of anabolic steroids are therefore similar to those of male sex hormones with the possibility that serious disturbances of growth and sexual development may be caused if given to young children.

Use of androgens in children over long periods of time may result in fusion of the epiphyseal growth centers.

Anabolic steroids have been reported to increase low-density lipoproteins and decrease high-density lipoproteins. Serum lipid determination should be done periodically.

During exogenous administration of anabolic androgens, endogenous testosterone release is inhibited through inhibition of pituitary luteinizing hormone (LH). At large doses spermatogenesis may be suppressed through feedback inhibition of pituitary follicle-stimulating hormone (FSH).

Continued on next page

Searle & Co.—Cont.

INDICATIONS AND USAGE

Anavar is indicated as adjunctive therapy to promote weight gain after weight loss following extensive surgery, chronic infections, or severe trauma, and in some patients who without definite pathophysiologic reasons fail to gain or to maintain normal weight, to offset the protein catabolism associated with prolonged administration of corticosteroids, and for the relief of the bone pain frequently accompanying osteoporosis. (See *Dosage and Administration.*)

CONTRAINDICATIONS

1. Carcinoma of the prostate or male breast.
2. Carcinoma of the breast in some women.
3. Nephrosis or the nephrotic phase of nephritis.
4. Pregnancy, because of possible masculinization of the fetus. Anavar has been shown to cause embryotoxicity, fetotoxicity, infertility, and masculinization of female animal offspring when given in doses 9 times the human dose. No *in vitro* mutagenicity tests have been conducted.
5. Hypercalcemia.

WARNINGS

ANABOLIC STEROIDS DO NOT ENHANCE ATHLETIC ABILITY.

Geriatric patients treated with anabolic/androgenic steroids may be at an increased risk for the development of prostatic hypertrophy and prostatic carcinoma.

There have been rare reports of hepatocellular neoplasms, including carcinoma, and peliosis hepatis in association with anabolic/androgenic steroid therapy.

Cholestatic hepatitis and jaundice may occur with 17-alpha-alkylated androgens at a relatively low dose. If cholestatic hepatitis with jaundice appears or if liver function tests become abnormal, Anavar should be discontinued and the etiology should be determined. Drug-induced jaundice is reversible when the medication is discontinued.

Hypercalcemia may develop both spontaneously and as a result of hormonal therapy in women with disseminated breast carcinoma. Anavar therapy should be discontinued if hypercalcemia occurs.

Edema with or without congestive heart failure may be a serious complication in patients with preexisting cardiac, renal, or hepatic disease. Therapy with Anavar may increase the edema.

In children, androgen therapy may accelerate bone maturation without producing compensatory gain in linear growth. The effect on bone maturation should be monitored. (See *Precautions/Laboratory tests.*)

PRECAUTIONS

General: Women should be observed for signs of virilization (deepening of the voice, hirsutism, acne, clitoromegaly, and menstrual irregularities). Discontinuation of drug therapy at the time of evidence of mild virilism is necessary to prevent irreversible virilization.

Suppression of clotting factors II, V, VII, and X has been observed.

Information for patients: The physician should instruct patients to report any of the following side effects of androgens:

Prepubertal males: Too frequent or persistent erections of the penis.

Females: Hoarseness, acne, changes in menstrual periods, or more facial hair.

All patients: Nausea, vomiting, changes in skin color, or ankle swelling.

Laboratory tests:

1. Women with disseminated breast carcinoma should have frequent determination of urine and serum calcium levels during the course of therapy (see *Warnings*).
2. Because of the hepatotoxicity associated with the use of 17-alpha-alkylated androgens, liver function tests should be obtained periodically.
3. Periodic (every 6 months) x-ray examinations of bone age should be made during treatment of prepubertal males to determine the rate of bone maturation and the effects of androgen therapy on the epiphyseal centers.
4. Serum lipid determinations should be done periodically as anabolic androgenic steroids have been reported to increase low density lipoproteins and decrease high-density lipoproteins.
5. Serum cholesterol levels may increase during therapy. Therefore, caution is required when administering these agents to patients with a history of myocardial infarction or coronary artery disease. Serial determinations of serum cholesterol should be made and therapy adjusted accordingly.

Drug interactions

Anticoagulants: C-17 substituted derivatives of testosterone have been reported to decrease the anticoagulant requirements of patients receiving oral anticoagulants. Patients receiving oral anticoagulant therapy require close monitoring, especially when androgens are started or stopped.

Insulin: In diabetic patients the metabolic effects of androgens may decrease blood glucose and insulin requirements.

Oral hypoglycemic agents: Anavar may inhibit the metabolism of oral hypoglycemic agents.

Adrenal steroids or ACTH: In patients with edema, concomitant administration with adrenal steroids or ACTH may increase the edema.

Drug/Laboratory test interactions: If thyroid function tests are performed, the physician should be aware that androgens may decrease levels of thyroxine-binding globulin, resulting in decreased total T_4 serum levels and increased resin uptake of T_3 and T_4. In addition, a decrease in PBI and radioactive iodine uptake may occur.

Alterations in the metyrapone test have occurred.

Carcinogenesis, mutagenesis, impairment of fertility

Animal data: In two-year chronic oral rat studies, a dose-related reduction of spermatogenesis and decreased organ weights (testes, prostate, seminal vesicles, ovaries, uterus, adrenals, and pituitary) were shown. Anavar has not been tested in laboratory animals for carcinogenic or mutagenic effects.

Human data: There are rare reports of hepatocellular carcinoma in patients receiving long-term therapy with anabolic/androgenic steroids in high doses. Withdrawal of the drugs did not lead to regression of the tumors in all cases.

Geriatric patients treated with androgens may be at an increased risk for the development of prostatic hypertrophy and prostatic carcinoma.

Pregnancy: Teratogenic effects; Pregnancy Category X. See *Contraindications.*

Nursing mothers: It is not known whether anabolic steroids are excreted in human milk. Because of the potential for serious adverse reactions in nursing infants from Anavar, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric use: Anabolic/androgenic steroid therapy should be used very cautiously in children and only by specialists who are aware of the effects on bone maturation. Skeletal maturation should be monitored every six months by an x-ray of hand and wrist. (See *Warnings.*)

ADVERSE REACTIONS

The following adverse reactions have been associated with use of anabolic steroids:

Endocrine: Masculinization of the fetus, increased or decreased libido, inhibition of gonadotropin secretion, and premature closure of epiphyses in children.

In *males:*

Prepubertal
- Phallic enlargement
- Increased frequency or persistence of erections

Postpubertal
- Inhibition of testicular function and oligospermia
- Gynecomastia

In *females:*
- Hirsutism, male-pattern baldness, deepening of the voice, and clitoral enlargement. (These changes are usually irreversible even after prompt discontinuance of therapy and are not prevented by concomitant use of estrogens.)
- Menstrual irregularities
- When administered to a pregnant woman, anabolic/androgenic steroids cause virilization of external genitalia of the female fetus.

Gastrointestinal: Nausea, abdominal fullness, loss of appetite, vomiting, and burning of the tongue.

Dermatologic: Acne (especially in females and prepubertal males).

Hepatic: Cholestatic jaundice, alterations in liver function tests and, rarely, hepatocellular neoplasms and peliosis hepatis (see *Warnings*).

General: Bleeding in patients on concomitant anticoagulant therapy.

Fluid and electrolyte disturbances: Retention of sodium, chloride, water, potassium, calcium, and inorganic phosphate.

Metabolism: Increased serum cholesterol.

OVERDOSAGE

No symptoms or signs associated with overdosage have been reported. It is possible that sodium and water retention may occur.

The oral LD_{50} of oxandrolone in mice and dogs is greater than 5,000 mg/kg. No specific antidote is known, but gastric lavage may be used.

DOSAGE AND ADMINISTRATION

Therapy with anabolic steroids is adjunctive to and not a replacement for conventional therapy. The duration of therapy with Anavar (oxandrolone) will depend on the response of the patient and the possible appearance of adverse reactions. Therapy should be intermittent.

Adults: The *usual adult dosage* of Anavar is one 2.5-mg tablet two to four times daily. However, the response of individuals to anabolic steroids varies, and a daily dosage of 2.5 mg or as much as 20 mg may be required to [illegible] desired response. A course of therapy of two to [illegible] usually adequate. This may be repeated [illegible] indicated.

Children. For children the *total daily dosage* is 0.25 mg per kilogram or 0.12 mg per pound of [illegible]. This may be repeated intermittently as indicated.

HOW SUPPLIED

Anavar 2.5-mg tablets are oval, white, and scored, debossed on the scored side and SEARLE on the [illegible] bottles of 100.

Federal law prohibits dispensing without prescription.

Shown in Product Identification Section, page [illegible]

CALAN® Tablets

[*cal'an*]

(verapamil hydrochloride)

PRODUCT OVERVIEW

KEY FACTS

Calan, a calcium ion antagonist, exerts its pharmacologic effects by modulating the influx of ionic calcium across the cell membrane of the arterial smooth muscle as well as conductile and contractile myocardial cells. Calan increases myocardial oxygen supply, reduces myocardial oxygen consumption, and is a potent inhibitor of coronary artery spasm, making it an effective antianginal agent. By decreasing the influx of calcium, Calan prolongs the effective refractory period within the AV node and slows AV conduction in a rate-related manner, thereby slowing the ventricular response in patients with chronic atrial flutter or fibrillation. Calan exerts antihypertensive effects by decreasing systemic vascular resistance, usually without orthostatic decreases in blood pressure or reflex tachycardia.

MAJOR USES

Calan Tablets are indicated for: angina at rest (including vasospastic and unstable angina); chronic stable angina; control (in association with digitalis) of ventricular rate at rest and during stress in patients with chronic atrial fibrillation or atrial fibrillation; prophylaxis of repetitive paroxysmal supraventricular tachycardia; management of hypertension.

SAFETY INFORMATION

See complete safety information set forth below.

CALAN® Tablets

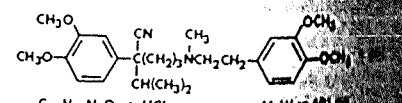
[*cal'an*]

(verapamil hydrochloride)

DESCRIPTION

Calan (verapamil HCl) is a calcium ion influx inhibitor (slow-channel blocker or calcium ion antagonist) available for administration in film-coated tablets containing [illegible] 120 mg of verapamil hydrochloride.

The structural formula of verapamil HCl is



$C_{27}H_{38}N_2O_4 \cdot HCl$ M.W. = 491.06

Benzeneacetonitrile, α-[3-[[2-(3, 4-dimethoxyphenyl) ethyl] methylamino]propyl]-3,4-dimethoxy-α-(1-methylethyl) hydrochloride.

Verapamil HCl is an almost white, crystalline [illegible] practically free of odor, with a bitter taste. It is soluble in water, chloroform, and methanol. Verapamil HCl is not [illegible] related to other cardioactive drugs.

Inactive ingredients include cellulose, corn starch, hydroxypropyl cellulose, hydroxypropyl methylcellulose, iron oxide, lactose, magnesium stearate, polyethylene glycol, talc, and titanium dioxide.

CLINICAL PHARMACOLOGY

Calan is a calcium ion influx inhibitor (slow-channel blocker or calcium ion antagonist) that exerts its pharmacologic effects by modulating the influx of ionic calcium across the membrane of the arterial smooth muscle as well as conductile and contractile myocardial cells.

Mechanism of action

Angina: The precise mechanism of action of Calan as an antianginal agent remains to be fully determined but includes the following two mechanisms:

1. *Relaxation and prevention of coronary artery spasm.* Calan dilates the main coronary arteries and coronary arterioles, both in normal and ischemic regions, and is a potent inhibitor of coronary artery spasm, whether spontaneous or ergonovine-induced. This property increases myocardial oxygen delivery in patients with coronary artery spasm and is responsible for the effectiveness of Calan in vasospastic (Prinzmetal's or variant) as well as

...sible revisions

...A PEEL

...Protective...

...PTION

...PEEL is a wafer skin protectant containing the ...WAH hydrophilic polymer—to provide moisture ...high molecular weight synthetic rubber poly- ...vide elasticity and strength; low molecular ...netic rubber polymers—to provide adhesion to ...karaya gum powder—to provide adhesion to ...

...IONS AND USAGE

...PEEL wafers applied to the peristomal area in ...or to the area surrounding draining wounds, aid ... the skin against contact with exudates. ...PEEL may also be applied to pressure points of ...patients to help preserve skin integrity and reduce ...recurrence of decubitus ulcers. SWEEN-A-PEEL ...proven effective when incorporated into a decubitus ...atment procedure.

...AINDICATIONS

...tivity to any components of the preparation.

...UTIONS

...heat and humidity. Store below 77°F (25°C). ...ntainer after each use.

...ISTRATION

... 1. Cleanse entire area thoroughly. 2. Remove ...from weeping, excoriated areas as effectively as ...sure maximum adherence of SWEEN-A-PEEL. ...Care. 1. Important: Use measuring guide to trace ...pattern of stoma base. Transfer pattern to wafer ...al), then cut. 2. Remove backing paper and position ...refully onto skin. 3. Apply even, gentle pressure to ...th palm of hand for 30–60 seconds to aid in even ...

...Wound Care. Use the same procedure as above. ...ttern of wound, cut, position in place and apply gen-...ing hand pressure. Continue with prescribed ...re procedure.

...UPPLIED

...five 4" × 4" individually sealed wafers, tub of 20 ...d 12" × 12" square in packages of 2 and 12.

...N CREAM®

...Cream]

...Cream

...IPTION

...ing cream consisting of Water, Lanolin Oil, Cetyl ...Glycerin, Ichthyo Liver Oil (Natural Vitamins A & ...m Lauryl Sulfate, Beeswax, Xanthan Gum, Fra-...Quaternium-15, Methylbenzethonium Chloride and ...ealth Related Item (HRI) 11701-002. Fragrance-Free ...on is also available. Health Related Item (HRI) ...

...ATIONS AND USAGE

...CREAM is an effective preparation for use on skin ...such as urine scald, diaper rash, rectal itch, psori-...burns, diarrheal breakdown, chafing and itching. ...skin before taping, SWEEN CREAM aids in the ...of tape burns. SWEEN CREAM is used in long-...of incontinent, geriatric and para/quadraplegic ...tions. Also apply to folds of skin subject to perspi-...ration, to dry or cracked skin and to pressure sensi-... For ostomy care, apply a small amount on peristo-...for protection before attaching appliance. This re-...ng and improves adhesion.

...RAINDICATIONS

...tivity to any components of the preparation.

...UTIONS AND ADVERSE REACTIONS

...rnal Use Only. Avoid contact with eyes. SWEEN ...is not toxic by oral ingestion and is not considered a ...eye or skin irritant under normal use conditions.

...E AND ADMINISTRATION

...erally as required.

...UPPLIED

... and 5 oz. tubes; 2-oz. and 9-oz. jars; 3 oz. pump.

...N PREP™

...Skin Barrier Film

...IPTION

...PREP is a medicated, liquid skin barrier which con-...oxylenol (PCMX), a well known antimicrobial ... protective film forming base.

INDICATIONS AND USAGE

SWEEN PREP applies to the skin as a liquid, with the aid of the special "Dab-O-Matic" applicator, the non-aerosol sprayer or the single use wipe. It dries rapidly to form a tough film which provides a visible shield on the skin... a barrier between the skin and irritants. This protective film creates a surface other than the skin itself for the application of tapes, cements and doublefaced adhesives.

CONTRAINDICATIONS

Hypersensitivity to any components of the preparation.

PRECAUTIONS AND ADVERSE REACTIONS

For External Use Only. Do not use near eyes. Will cause eye irritation. If contact occurs, flush with water for 15 minutes and consult physician. Keep out of the reach of children. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately.
Flammable. Do not use near open flame or while smoking.

DOSAGE AND ADMINISTRATION

Wash the skin area thoroughly, rinse and pat dry. Apply SWEEN PREP liberally to the entire area to be protected (slight stinging may be experienced if the skin is excoriated). Allow to dry (approximately 2 minutes) and apply tapes, adhesives, etc., in the normal manner to the SWEEN PREPPED skin. SWEEN PREP may be removed from the skin with soap and water or for easier removal, with isopropyl alcohol. Removal is, however, not necessary and the skin may be recoated as frequently as required.

HOW SUPPLIED

Unit dose wipes (NDC 11701-007-20), 2 fl. oz. "Dab-O-Matic" applicator (NDC 11701-007-03) and 4 fl. oz. non-aerosol spray (NDC 11701-006-04).

Syntex (F.P.) Inc.
HUMACAO, PUERTO RICO 00661

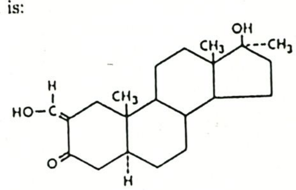
Syntex Laboratories, Inc
3401 HILLVIEW AVE.
P.O. BOX 10850
PALO ALTO, CA 94303

Syntex Puerto Rico, Inc.
HUMACAO, PUERTO RICO 00661

ANADROL®-50 ℞
[an 'ă-drawl]
(oxymetholone)
50 mg. Tablets
A product of Syntex Laboratories, Inc.

DESCRIPTION

ANADROL (oxymetholone) tablets for oral administration each contain 50 mg of the steroid oxymetholone, a potent anabolic and androgenic drug.
The chemical name for oxymetholone is 17β-hydroxy-2-(hydroxymethylene)-17-methyl-5α-androstan-3-one. The structural formula is:



Inactive Ingredients—lactose, magnesium stearate, povidone, starch

CLINICAL PHARMACOLOGY

Anabolic steroids are synthetic derivatives of testosterone. Nitrogen balance is improved with anabolic agents but only when there is sufficient intake of calories and protein. Whether this positive nitrogen balance is of primary benefit in the utilization of protein-building dietary substances has not been established. Oxymetholone enhances the production and urinary excretion of erythropoietin in patients with anemias due to bone marrow failure and often stimulates erythropoiesis in anemias due to deficient red cell production.
Certain clinical effects and adverse reactions demonstrate the androgenic properties of this class of drugs. Complete dissociation of anabolic and androgenic effects has not been achieved. The actions of anabolic steroids are therefore similar to those of male sex hormones with the possibility of causing serious disturbances of growth and sexual development if given to young children. They suppress the gonadotropic functions of the pituitary and may exert a direct effect upon the test...

INDICATIONS AND USAGE

ANADROL-50 is indicated in the treatment of ane... caused by deficient red cell production. Acquired aplastic anemia, congenital aplastic anemia, myelofibrosis and the hypoplastic anemias due to the administration of myelotoxic drugs often respond.
ANADROL-50 should not replace other supportive measures such as transfusion, correction of iron, folic acid, vitamin B_{12} or pyridoxine deficiency, antibacterial therapy and the appropriate use of corticosteroids.

CONTRAINDICATIONS

1. Carcinoma of the prostate or breast in male patients.
2. Carcinoma of the breast in females with hypercalcemia; androgenic anabolic steroids may stimulate osteolytic resorption of bones.
3. Oxymetholone can cause fetal harm when administered to pregnant women. It is contraindicated in women who are or may become pregnant. If the patient becomes pregnant while taking the drug, she should be apprised of the potential hazard to the fetus.
4. Nephrosis or the nephrotic phase of nephritis.
5. Hypersensitivity to the drug.

WARNINGS

The following conditions have been reported in patients receiving androgenic, anabolic steroids as a general class of drugs:

Peliosis hepatis, a condition in which liver and sometimes splenic tissue is replaced with blood-filled cysts, has been reported in patients receiving androgenic anabolic steroid therapy. These cysts are sometimes present with minimal hepatic dysfunction, but at other times they have been associated with liver failure. They are often not recognized until life-threatening liver failure or intra-abdominal hemorrhage develops. Withdrawal of drug usually results in complete disappearance of lesions.
Liver cell tumors are also reported. Most often these tumors are benign and androgen-dependent, but fatal malignant tumors have been reported. Withdrawal of drug often results in regression or cessation of progression of the tumor. However, hepatic tumors associated with androgens or anabolic steroids are much more vascular than other hepatic tumors and may be silent until life-threatening intra-abdominal hemorrhage develops.
Blood lipid changes that are known to be associated with increased risk of atherosclerosis are seen in patients treated with androgens and anabolic steroids. These changes include decreased high density lipoprotein and sometimes increased low density lipoprotein. The changes may be very marked and could have a serious impact on the risk of atheroclerosis and coronary artery disease.

Cholestatic hepatitis and jaundice occur with 17-alpha-alkylated androgens at relatively low doses. If cholestatic hepatitis with jaundice appears, the anabolic steroid should be discontinued. If liver function tests become abnormal, the patient should be monitored closely and the etiology determined. Generally the anabolic steroid should be discontinued, although in cases of mild abnormalities, the physician may elect to follow the patient carefully at a reduced drug dosage.
In patients with breast cancer, anabolic steroid therapy may cause hypercalcemia by stimulating osteolysis. In this case, the drug should be discontinued.
Edema with or without congestive heart failure may be a serious complication in patients with pre-existing cardiac, renal or hepatic disease.
Geriatric male patients treated with androgenic anabolic steroids may be at an increased risk for the development of prostate hypertrophy and prostatic carcinoma.
Anabolic steroids have not been shown to enhance athletic ability.

PRECAUTIONS

General:
Women should be observed for signs of virilization (deepening of the voice, hirsutism, acne, and clitoromegaly). To prevent irreversible change, drug therapy must be discontinued, when mild virilism is first detected. Such virilization is usual following androgenic anabolic steroid use at high doses. Some virilizing changes in women are irreversible even after prompt discontinuance of therapy and are not prevented by concomitant use of estrogens. Menstrual irregularities may also occur.
The insulin or oral hypoglycemic dosage may need adjustment in diabetic patients who receive anabolic steroids.

Continued on next page

Syntex—Cont.

Anabolic steroids may cause suppression of clotting factors II, V, VII, and X, and an increase in prothrombin time.

Information for the patient:

The physician should instruct patients to report any of the following side effects of androgens.

Adult or Adolescent Males: Too frequent or persistent erections of the penis, appearance or aggravation of acne.

Women: Hoarseness, acne, changes in menstrual periods, or more hair on the face.

All Patients: Any nausea, vomiting, changes in skin color or ankle swelling.

Laboratory Tests:

Women with disseminated breast carcinoma should have frequent determination of urine and serum calcium levels druing the course of androgenic anabolic steroid therapy (see WARNINGS).

Because of the hepatotoxicity associated with the use of 17-alpha-alkylated androgens, liver function tests should be obtained periodically.

Periodic (every 6 months) x-ray examinations of bone age should be made during treatment of prepubertal patients to determine the rate of bone maturation and the effects of androgenic anabolic steroid therapy on the epiphyseal centers.

Anabolic steroids have been reported to lower the level of high-density lipoproteins and raise the level of low-density lipoproteins. These changes usually revert to normal on discontinuation of treatment. Increased low-density lipoproteins and decreased high-density lipro proteins are considered cardiovascular risk factors. Serum lipids and high-density lipoprotein cholesterol should be determined periodically.

Hemoglobin and hematocrit should be checked periodically for polycythemia in patients who are receiving high doses of anabolics.

Drug Interaction:

Anabolic steroids may increase sensitivity to anticoagulants; therefore dosage of an anticoagulant may have to be decreased in order to maintain the prothrombin time at the desired therapeutic level.

Drug/Laboratory Test Interferences: Therapy with androgenic anabolic steroids may decrease levels of thyroxine-binding globulin resulting in decreased total T_4 serum levels and increased resin uptake of T_3 and T_4. Free thyroid hormone levels remain unchanged and there is no clinical evidence of thyroid dysfunction.

Anabolic steroids may cause an increase in prothrombin time.

Carcinogenesis, Mutagenesis, Impairment of Fertility:

Long-term studies in animals have not been performed to evaluate the carcinogenic potential of oxymetholone. There are rare reports of hepatocellular carcinoma in patients receiving long-term therapy with anabolics in high doses. Withdrawal of the drugs did not lead to regression of the tumors in all cases.

Pregnancy:

Pregnancy category X. See CONTRAINDICATIONS.

Nursing Mothers:

It is not known whether anabolics are excreted in human milk. Because of the potential for serious adverse reactions in nursed infants from anabolics, women who take oxymetholone should not nurse.

Pediatric Use:

Anabolic/androgenic steroids should be used very cautiously in children and only by specialists who are aware of their effects on bone maturation.

Anabolic agents may accelerate epiphyseal maturation more rapidly than linear growth in children, and the effect may continue for 6 months after the drug has been stopped. Therefore, therapy should be monitored by x-ray studies at 6-month intervals in order to avoid the risk of compromising the adult height.

ADVERSE REACTIONS

Hepatic:

Cholestatic jaundice with, rarely, hepatic necrosis and death. Hepatocellular neoplasms and peliosis hepatis have been reported in association with long-term androgenic-anabolic steroid therapy (see WARNINGS).

Genitourinary System:

In Men:

Prepubertal: Phallic enlargement and increased frequency of erections

Postpubertal: Inhibition of testicular function, testicular atrophy and oligospermia, impotence, chronic priapism, epididymitis and bladder irritability.

In Women

Clitoral enlargement, menstrual irregularities

In both sexes

Increased or decreased libido

CNS: Excitation, insomnia.

Gastrointestinal: Nausea, vomiting, diarrhea.

Hematologic: Bleeding in patients on concomitant anticoagulant therapy, iron-deficiency anemia.

Leukemia has been observed in patients with aplastic anemia treated with oxymetholone. The role, if any, of oxymetholone is unclear because malignant transformation has been seen in blood dyscrasias and leukemia has been reported in patients with aplastic anemia who have not been treated with oxymetholone.

Breast: Gynecomastia.

Larynx: Deepening of the voice in women.

Hair: Hirsutism and male-pattern baldness in women.

Skin: Acne (especially in women and prepubertal boys.)

Skeletal: Premature closure of epiphyses in children (see PRECAUTIONS, Pediatric Use.)

Fluid and Electrolytes: Edema, retention of serum electrolytes (sodium, chloride, potassium, phosphate, calcium).

Metabolic/Endocrine: Decreased glucose tolerance (see PRECAUTIONS), increased serum levels of low-density lipoproteins and decreased levels of high-density lipoproteins (see PRECAUTIONS, Laboratory tests), increased creatine and creatinine excretion, increased serum levels of creatinine phosphokinase (CPK). Reversible changes in liver function tests also occur including increased bromsulphalein (BSP) retention and increases in serum bilirubin, glutamic oxaloacetic transaminase (SGOT), and alkaline phosphatase.

OVERDOSAGE

There have been no reports of acute overdosage with anabolics.

DOSAGE AND ADMINISTRATION

The recommended daily dose in children and adults is 1–5 mg/kg body weight per day. The usual effective dose is 1–2 mg/kg/day but higher doses may be required and the dose should be individualized. Response is not often immediate and a minimum trial of three to six months should be given. Following remission, some patients may be maintained without the drug; others may be maintained on an established lower daily dosage. A continued maintenance dose is usually necessary in patients with congenital aplastic anemia.

HOW SUPPLIED

ANADROL-50 (oxymetholone) is supplied in bottles of 100 white scored tablets imprinted with "2902" and "SYNTEX" (NDC 0033-2902-42).

CAUTION: Federal law prohibits dispensing without prescription.

02-2902-42-5 © Revised April 1986

Shown in Product Identification Section, page 432

ANAPROX® ℞

[an 'ă-prox]

(naproxen sodium)

Tablets

A product of Syntex Puerto Rico, Inc.

DESCRIPTION

ANAPROX filmcoated tablets for oral administration each contain 275 mg of naproxen sodium, which is equivalent to 250 mg naproxen with 25 mg (about 1 mEq) sodium. It is a member of the arylacetic acid group of nonsteroidal anti-inflammatory drugs.

The chemical name of naproxen sodium is 2-naphthaleneacetic acid, 6-methoxy-α-methyl-, sodium salt, (—).

Naproxen sodium is a white to creamy white, crystalline solid, freely soluble in water.

Each ANAPROX tablet contains naproxen sodium, the active ingredient, with lactose, magnesium stearate, and microcrystalline cellulose. The coating suspension may contain hydroxypropyl methylcellulose, Opaspray® K-1-4210A, polyethylene glycol 8000 or Opadry® YS-1-4215.

CLINICAL PHARMACOLOGY

ANAPROX, the sodium salt of naproxen, has been developed as an analgesic because it is more rapidly absorbed. Naproxen is a nonsteroidal anti-inflammatory drug with analgesic and antipyretic properties. Naproxen anion inhibits prostaglandin synthesis but beyond this its mode of action is unknown.

Naproxen sodium is rapidly and completely absorbed from the gastrointestinal tract. After administration of naproxen sodium, peak plasma levels of naproxen anion are attained at 1–2 hours with steady-state conditions normally achieved after 4–5 doses. The mean biological half-life of the anion in humans is approximately 13 hours, and at therapeutic levels it is greater than 99% albumin bound. Approximately 95% of the dose is excreted in the urine, primarily as naproxen, 6-0-desmethyl naproxen or their conjugates. The rate of excretion has been found to coincide closely with the rate of drug disappearance from the plasma. The drug does not induce metabolizing enzymes.

The drug was studied in patients with mild to moderate pain, and pain relief was obtained within 1 hour. It is not a narcotic and is not a CNS-acting drug. Controlled double-blind studies have demonstrated the analgesic properties of the drug in, for example, post-operative, post-partum, orthopedic and uterine contraction pain and dysmenorrheic patients, the drug reduces the level of prosta[illegible] in the uterus, which correlates with a reduction in [illegible] quency and severity of uterine contractions. Analg[illegible] tion has been shown by such measures as reduction [illegible] intensity scores, increase in pain relief scores, decr[illegible] number of patients requiring additional analgesic [illegible] tion, and delay in time for required remedication. The [illegible] gesic effect has been found to last for up to 7 hours.

The drug was studied in patients with rheumatoid [illegible] osteoarthritis, ankylosing spondylitis, tendinitis [illegible] tis, and acute gout. It is not a corticosteroid. Improv[illegible] patients treated for rheumatoid arthritis has been [illegible] strated by a reduction in joint swelling, a reduction [illegible] reduction in duration of morning stiffness, a reduc[illegible] disease activity as assessed by both the investigator [illegible] tient, and by increased mobility as demonstrated by a [illegible] tion in walking time.

In patients with osteoarthritis, the therapeutic action [illegible] drug has been shown by a reduction in joint pain or [illegible] ness, an increase in range of motion in knee joints, [illegible] mobility as demonstrated by a reduction in walking [illegible] and improvement in capacity to perform activities [illegible] living impaired by the disease.

In clinical studies in patients with rheumatoid ar[illegible] osteoarthritis, the drug has been shown to be comp[illegible] aspirin and indomethacin in controlling the afore[illegible] measures of disease activity, but the frequency and [illegible] of the milder gastrointestinal adverse effects (nau[illegible] pepsia, heartburn) and nervous system adverse effects [illegible] tus, dizziness, lightheadedness) were less than in [illegible] aspirin- and indomethacin-treated patients. It is not [illegible] whether the drug causes less peptic ulceration than [illegible]

In patients with ankylosing spondylitis, the drug has [illegible] shown to decrease night pain, morning stiffness and [illegible] rest. In double-blind studies the drug was shown to [illegible] fective as aspirin, but with fewer side effects.

In patients with acute gout, a favorable response to the [illegible] was shown by significant clearing of inflammatory [illegible] (e.g., decrease in swelling, heat) within 24–48 hours, [illegible] as by relief of pain and tenderness.

The drug may be used safely in combination with [illegible] and/or corticosteroids; however, in controlled clinical [illegible] when added to the regimen of patients receiving [illegible] oids it did not appear to cause greater improvement [illegible] that seen with corticosteroids alone. Whether the drug [illegible] be used in conjunction with partially effective doses [illegible] costeroid for a "steroid-sparing" effect has not been [illegible] quately studied. When added to the regimen of [illegible] ceiving gold salts, the drug did result in greater [illegible] ment. Its use in combination with salicylates is not [illegible] mended because data are inadequate to demonstrate [illegible] the drug produces greater improvement over that [illegible] with aspirin alone. Further, there is some evidence that [illegible] rin increases the rate of excretion of the drug.

Generally, improvement due to the drug has not been [illegible] to be dependent on age, sex, severity or duration of [illegible]

In ^{51}Cr blood loss and gastroscopy studies with normal [illegible] teers, daily administration of 1100 mg of ANA[illegible] proxen sodium) has been demonstrated to cause [illegible] significantly less gastric bleeding and erosion than [illegible] of aspirin.

INDICATIONS AND USAGE

ANAPROX (naproxen sodium) is indicated in the [illegible] mild to moderate pain and for the treatment of primary [illegible] menorrhea.

It is also indicated for the treatment of rheumatoid [illegible] osteoarthritis, ankylosing spondylitis, tendinitis and [illegible] tis, and acute gout.

CONTRAINDICATIONS

The drug is contraindicated in patients who have had [illegible] gic reactions to ANAPROX® (naproxen sodium) [illegible] NAPROSYN® (naproxen). It is also contraindicated [illegible] tients in whom aspirin or other nonsteroidal [illegible] matory/analgesic drugs induce the syndrome [illegible] rhinitis, and nasal polyps. Both types of reactions [illegible] potential of being fatal.

WARNINGS

Gastrointestinal bleeding, sometimes severe, and [illegible] ally fatal, has been reported in patients receiving [illegible] Among 960 patients treated for rheumatoid arthritis [illegible] oarthritis during the course of clinical trials in [illegible] States (260 treated for more than two years), 16 [illegible] tic ulceration were reported. More than half were [illegible] comitant corticosteroid and/or salicylate therapy [illegible] a third had a prior history of peptic ulcer. Gastr[illegible] bleeding, including nine potentially serious cases, [illegible] reported in this population. These were not always [illegible] by premonitory gastrointestinal symptoms. Alth[illegible] of the patients with serious bleeding were receiving [illegible] tant therapy and had a history of peptic ulcer, [illegible] should be kept in mind that the drug also has the [illegible] for causing gastrointestinal bleeding on its own. The[illegible] should not be given to patients with active peptic [illegible] less the potential benefit outweighs the potential [illegible]

1-7

nrop Pharm.—Cont.

Clinical relevance or relationship to TORNALATE administration of rarely reported elevations of SGOT, decrease in platelets, decreases in WBC levels or proteinuria are not known.

In comparing the adverse reactions for bitolterol mesylate treated patients to those of isoproterenol treated patients, during three month clinical trials involving approximately 400 patients, the following moderate to severe reactions, as judged by the investigators, were reported for both steroid and non-steroid dependent patients. The table does not include mild reactions or those occurring only with the first dose.

PERCENT INCIDENCE OF MODERATE TO SEVERE ADVERSE REACTIONS

Reaction	Bitolterol N = 197	Isoproterenol N = 194
Central Nervous System		
Tremors	9.1%	1.5%
Nervousness	1.5%	1.0%
Headache	3.5%	6.1%
Dizziness	1.0%	1.5%
Insomnia	0.5%	0%
Cardiovascular		
Palpitations	1.5%	0%
PVC—Transient Increase	0.5%	0%
Chest Discomfort	0.5%	0%
Respiratory		
Cough	4.1%	1.0%
Bronchospasm	1.0%	0%
Dyspnea	1.0%	0%
Oro-Pharyngeal		
Throat Irritation	3.0%	3.1%
Gastrointestinal		
Nausea (Dyspepsia)	0.5%	0.5%

NOTE: In most patients, the total isoproterenol dosage was divided into three equally dosed inhalations, administered at three minute intervals. This procedure may have reduced the incidence of adverse reactions observed with isoproterenol.

OVERDOSAGE

Overdosage with TORNALATE (bitolterol mesylate) may be expected to result in exaggeration of those drug effects listed in the ADVERSE REACTIONS section. In such cases therapy with TORNALATE and all β-adrenergic stimulating drugs should be stopped, supportive therapy provided, and judicious use of a cardioselective β-adrenergic blocking agent should be considered bearing in mind the possibility that such agents can produce profound bronchospasm. As with all sympathomimetic aerosol medications, cardiac arrest and even death may be associated with abuse. The oral LD_{50} of TORNALATE in rats was greater than 5,000 mg/kg and in mice greater than 6,000 mg/kg.

DOSAGE AND ADMINISTRATION

The usual dose to relieve bronchospasm for adults and children over 12 years of age is two inhalations at an interval of at least one to three minutes followed by a third inhalation if needed. For prevention of bronchospasm, the usual dose is two inhalations every 8 hours. The dose of TORNALATE (bitolterol mesylate) should never exceed 3 inhalations every 6 hours or 2 inhalations every 4 hours. Medical consultation should be sought prior to an increase in the frequency of dosing because this may indicate a need for reevaluation of the patient's condition.

HOW SUPPLIED

TORNALATE (bitolterol mesylate), Metered Dose Inhaler, is supplied in 16.4 g (15 mL) self-contained aerosol units (NDC 0024-1060-01).
Refill of 16.4 g (15 mL) NDC 0024-1061-01.
Store at controlled room temperature between 15 °C and 30 °C (59 °F and 86 °F).
Distributed by Winthrop-Breon Laboratories
Division of Sterling Drug Inc. New York, NY 10016
Manufactured by Sterling Pharmaceuticals Inc.
Barceloneta, Puerto Rico 00617

TW 275 F

TRANCOPAL®

R

brand of chlormezanone
Nonhypnotic Antianxiety Agent

DESCRIPTION

TRANCOPAL, brand of chlormezanone, is [2-(*p*-Chlorophenyl)tetrahydro-3-methyl-4*H*-1, 3-thiazin-4-one 1, 1-dioxide], a white, virtually tasteless, crystalline powder with a solubility of less than 0.25 percent w/v in water.
Inactive Ingredients—Caplets® 100 mg: Dibasic Calcium Phosphate, FD&C Yellow #6, Magnesium Stearate, Saccharin Sodium, Starch; CAPLETS 200 mg: Dibasic Calcium Phosphate, D&C Yellow #10, FD&C Blue #1, Magnesium Stearate, Saccharin Sodium, Starch.

CLINICAL PHARMACOLOGY

TRANCOPAL improves the emotional state by allaying mild anxiety, usually without impairing clarity of consciousness. The relief of symptoms is often apparent in fifteen to thirty minutes after administration and may last up to six hours or longer.

INDICATIONS AND USAGE

TRANCOPAL is indicated for the treatment of mild anxiety and tension states.
The effectiveness of chlormezanone in long-term use, that is, more than 4 months, has not been assessed by systematic clinical studies. The physician should periodically reassess the usefulness of the drug for the individual patient.

CONTRAINDICATION

Contraindicated in patients with a history of a previous hypersensitivity reaction to chlormezanone.

WARNINGS

Should drowsiness occur, the dose should be reduced. As with other CNS-acting drugs, patients receiving chlormezanone should be warned against performing potentially hazardous tasks which require complete mental alertness, such as operating a motor vehicle or dangerous machinery. Patients should also be warned of the possible additive effects which may occur when the drug is taken with alcohol or other CNS-acting drugs.
Usage in Pregnancy. Safe use of this preparation in pregnancy or lactation has not been established, as no animal reproduction studies have been performed; therefore, use of the drug in pregnancy, lactation, or in women of childbearing age requires that the potential benefit of the drug be weighed against its possible hazards to the mother and fetus.

ADVERSE REACTIONS

Adverse effects reported to occur with TRANCOPAL include drowsiness, drug rash, dizziness, flushing, nausea, depression, edema, inability to void, weakness, excitement, tremor, confusion, and headache. Medication should be discontinued or modified as the case demands.
Jaundice, apparently of the cholestatic type, has been reported as occurring rarely during the use of chlormezanone, but was reversible on discontinuance of therapy.

OVERDOSAGE

Overdose with amounts as low as 7 grams has resulted in coma, hypotension, absence of reflexes, and flaccidity. Ingestion of higher doses may also result in alternation between coma and excitement.

DOSAGE AND ADMINISTRATION

The usual **adult** dosage is 200 mg orally three or four times daily but in some patients 100 mg may suffice. The dosage for **children from 5 to 12 years** is 50 mg to 100 mg three or four times daily. Since the effect of CNS-acting drugs varies, treatment, particularly in children, should begin with the lowest dosage which may be increased as needed.

HOW SUPPLIED

100 mg (peach colored, scored CAPLETS)
bottle of 100 (NDC 0024-1973-04)
200 mg (green colored, scored CAPLETS)
bottle of 100 (NDC 0024-1974-04)
bottle of 1000 (NDC 0024-1974-08)

Shown in Product Identification Section, page 435

TW 72-M

WINSTROL®

R

brand of stanozolol tablets, USP
For Oral Administration

DESCRIPTION

WINSTROL, brand of stanozolol tablets, is an anabolic steroid, a synthetic derivative of testosterone. Each tablet contains 2 mg of stanozolol. It is designated chemically as 17-methyl-2′*H*-5α-androst-2-eno[3,2-c]pyrazol-17β-ol.
Inactive Ingredients: Dibasic Calcium Phosphate, D&C Red #28, FD&C Red #40, Lactose, Magnesium Stearate, Starch

CLINICAL PHARMACOLOGY

Anabolic steroids are synthetic derivatives of testosterone. Certain clinical effects and adverse reactions demonstrate the androgenic properties of this class of drugs. Complete dissociation of anabolic and androgenic effects has not been achieved. The actions of anabolic steroids are therefore similar to those of male sex hormones with the possibility of causing serious disturbances of growth and sexual development if given to young children. They suppress the gonadotropic functions of the pituitary and may exert a direct effect upon the testes.
WINSTROL has been found to increase low-density lipoproteins and decrease high-density lipoproteins. These changes are not associated with any increase in total cholesterol or triglyceride levels and revert to normal on discontinuation of treatment.
Hereditary angioedema (HAE) is an autosomal dominant disorder caused by a deficient or nonfunctional C1 esterase inhibitor (C1 INH) and clinically characterized by episodic swelling of the face, extremities, genitalia, bowel wall, and upper respiratory tract.
In small scale clinical studies, stanozolol was effective in controlling the frequency and severity of attacks of angioedema and in increasing serum levels of C1 INH and C4. WINSTROL is not effective in stopping HAE attacks while they are under way. The effect of WINSTROL on increasing serum levels of C1 INH and C4 may be related to an increase in protein anabolism.

INDICATIONS AND USAGE

Hereditary Angioedema. WINSTROL is indicated prophylactically to decrease the frequency and severity of attacks of angioedema.

CONTRAINDICATIONS

The use of WINSTROL is contraindicated in the following:
1. Male patients with carcinoma of the breast, or with known or suspected carcinoma of the prostate.
2. Carcinoma of the breast in females with hypercalcemia. androgenic anabolic steroids may stimulate osteolytic resorption of bone.
3. Nephrosis or the nephrotic phase of nephritis.
4. WINSTROL can cause fetal harm when administered to a pregnant woman.

WINSTROL is contraindicated in women who are or may become pregnant. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to the fetus.

WARNINGS

PELIOSIS HEPATIS, A CONDITION IN WHICH LIVER AND SOMETIMES SPLENIC TISSUE IS REPLACED WITH BLOOD-FILLED CYSTS, HAS BEEN REPORTED IN PATIENTS RECEIVING ANDROGENIC ANABOLIC STEROID THERAPY. THESE CYSTS ARE SOMETIMES PRESENT WITH MINIMAL HEPATIC DYSFUNCTION, BUT AT OTHER TIMES THEY HAVE BEEN ASSOCIATED WITH LIVER FAILURE. THEY ARE OFTEN NOT RECOGNIZED UNTIL LIFE-THREATENING LIVER FAILURE OR INTRA-ABDOMINAL HEMORRHAGE DEVELOPS. WITHDRAWAL OF DRUG USUALLY RESULTS IN COMPLETE DISAPPEARANCE OF LESIONS.
LIVER CELL TUMORS ARE ALSO REPORTED. MOST OFTEN THESE TUMORS ARE BENIGN AND ANDROGEN-DEPENDENT, BUT FATAL MALIGNANT TUMORS HAVE BEEN REPORTED. WITHDRAWAL OF DRUG OFTEN RESULTS IN REGRESSION OR CESSATION OF PROGRESSION OF THE TUMOR. HOWEVER, HEPATIC TUMORS ASSOCIATED WITH ANDROGENS OR ANABOLIC STEROIDS ARE MUCH MORE VASCULAR THAN OTHER HEPATIC TUMORS AND MAY BE SILENT UNTIL LIFE-THREATENING INTRA-ABDOMINAL HEMORRHAGE DEVELOPS.
BLOOD LIPID CHANGES THAT ARE KNOWN TO BE ASSOCIATED WITH INCREASED RISK OF ATHEROSCLEROSIS ARE SEEN IN PATIENTS TREATED WITH ANDROGENS AND ANABOLIC STEROIDS. THESE CHANGES INCLUDE DECREASED HIGH-DENSITY LIPOPROTEIN AND SOMETIMES INCREASED LOW-DENSITY LIPOPROTEIN. THE CHANGES MAY BE VERY MARKED AND COULD HAVE A SERIOUS IMPACT ON THE RISK OF ATHEROSCLEROSIS AND CORONARY ARTERY DISEASE.

Cholestatic hepatitis and jaundice occur with 17-alpha-alkylated androgens at relatively low doses. If cholestatic hepatitis with jaundice appears, the anabolic steroid should be discontinued. If liver function tests become abnormal, the patient should be monitored closely and the etiology determined. Generally, the anabolic steroid should be discontinued although in cases of mild abnormalities, the physician may elect to follow the patient carefully at a reduced drug dosage.
In patients with breast cancer, anabolic steroid therapy may cause hypercalcemia by stimulating osteolysis. In this case, the drug should be discontinued.
Edema with or without congestive heart failure may be a serious complication in patients with preexisting cardiac

hepatic disease. Concomitant administration of adrenal cortical steroids or ACTH may add to the edema.

Geriatric male patients treated with androgenic anabolic steroids may be at an increased risk for the development of prostatic hypertrophy and prostatic carcinoma.

In children, anabolic steroid treatment may accelerate bone maturation without producing compensatory gain in linear growth. This adverse effect may result in compromised adult stature. The younger the child, the greater the risk of compromising final mature height. The effect on bone maturation should be monitored by assessing bone age of the wrist and hand every six months.

Anabolic steroids have not been shown to enhance athletic ability.

PRECAUTIONS

General.

Anabolic steroids may cause suppression of clotting factors II, V, VII, and X, and an increase in prothrombin time.

Women should be observed for signs of virilization (deepening of the voice, hirsutism, acne, and clitoromegaly). To prevent irreversible change, drug therapy must be discontinued, or the dosage significantly reduced when mild virilism is first detected. Such virilization is usual following androgenic anabolic steroid use at high doses. Some virilizing changes in women are irreversible even after prompt discontinuance of therapy and are not prevented by concomitant use of estrogens. Menstrual irregularities may also occur.

The insulin or oral hypoglycemic dosage may need adjustment in diabetic patients who receive anabolic steroids.

Information for the Patient. The physician should instruct patients to report any of the following side effects of androgens:

Adult or Adolescent Males. Too frequent or persistent erections of the penis, appearance or aggravation of acne.

Women. Hoarseness, acne, changes in menstrual periods, or more hair on the face.

All Patients. Any nausea, vomiting, changes in skin color, or ankle swelling.

Laboratory Tests. Women with disseminated breast carcinoma should have frequent determination of urine and serum calcium levels during the course of androgenic anabolic steroid therapy (see WARNINGS).

Because of the hepatotoxicity associated with the use of 17-alpha-alkylated androgens, liver function tests should be obtained periodically.

Periodic (every 6 months) x-ray examinations of bone age should be made during treatment of prepubertal patients to determine the rate of bone maturation and the effects of androgenic anabolic steroid therapy on the epiphyseal centers.

As common with other anabolic steroids, WINSTROL, brand of stanozolol tablets, has been reported to lower the level of high-density lipoproteins and raise the level of low-density lipoproteins. These changes usually revert to normal on discontinuation of treatment. Increased low-density lipoproteins and decreased high-density lipoproteins are considered cardiovascular risk factors. Serum lipids and high-density lipoprotein cholesterol should be determined periodically.

Hemoglobin and hematocrit should be checked periodically for polycythemia in patients who are receiving high doses of anabolic steroids.

Drug Interaction. Anabolic steroids may increase sensitivity to anticoagulants; therefore, dosage of an anticoagulant may have to be decreased in order to maintain the prothrombin time at the desired therapeutic level.

Drug/Laboratory Test Interferences. Therapy with androgenic anabolic steroids may decrease levels of thyroxine-binding globulin resulting in decreased total T_4 serum levels and increase resin uptake of T_3 and T_4. Free thyroid hormone levels remain unchanged and there is no clinical evidence of thyroid dysfunction.

Carcinogenesis, Mutagenesis, Impairment of Fertility. WINSTROL has not been tested in laboratory animals for carcinogenic or mutagenic effects. No tumorigenic or cancer-promoting properties of WINSTROL, brand of stanozolol tablets, were seen in one-year toxicity studies in rats.

WINSTROL administered orally (intragastrically) to pregnant rats at dosages of 2.5 mg/kg/day to 20 mg/kg/day increased the ano-genital distance in rat fetuses, indicative of a feminizing effect. WINSTROL prevented pregnancy when given orally to rats from the 1st to the 21st day of gestation.

Teratogenic effects or congenital malformation were observed in offspring of rabbits given 0.5 mg/day, 1.0 mg/day, and 2.0 mg/day of WINSTROL from the 8th through the 16th day of pregnancy, nor were there any adverse effects on the course of pregnancy at these dose levels.

Liver cell tumors have been associated with prolonged use of androgenic anabolic steroids (see WARNINGS section).

Cancer patients treated with anabolics may be at an increased risk for prostatic hypertrophy and prostatic carcinoma.

Pregnancy Category X. See CONTRAINDICATIONS section.

Nursing Mothers. It is not known whether anabolic steroids are excreted in human milk. Many drugs are excreted in human milk and because of the potential for adverse reactions in nursing infants from WINSTROL, a decision should be made whether to discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use. Anabolic agents may accelerate epiphyseal maturation more rapidly than linear growth in children, and the effect may continue for 6 months after the drug has been stopped. Therefore, therapy should be monitored by x-ray studies at 6 month intervals in order to avoid the risk of compromising the adult height. The safety and efficacy of WINSTROL in children with hereditary angioedema have not been established.

ADVERSE REACTIONS

Hepatic: Cholestatic jaundice with, rarely, hepatic necrosis and death. Hepatocellular neoplasms and peliosis hepatis have been reported in association with long-term androgenic-anabolic steroid therapy (see WARNINGS). Reversible changes in liver function tests also occur including increased bromsulphalein (BSP) retention and increases in serum bilirubin, glutamic oxaloacetic transaminase (SGOT), and alkaline phosphatase.

Genitourinary System: *In men. Prepubertal:* Phallic enlargement and increased frequency of erections.

Postpubertal: Inhibition of testicular function, testicular atrophy and oligospermia, impotence, chronic priapism, epididymitis and bladder irritability.

In women: Clitoral enlargement, menstrual irregularities.

In both sexes: Increased or decreased libido.

CNS: Habituation, excitation, insomnia, depression.

Gastrointestinal: Nausea, vomiting, diarrhea.

Hematologic: Bleeding in patients on concomitant anticoagulant therapy.

Breast: Gynecomastia.

Larynx: Deepening of the voice in women.

Hair: Hirsutism and male pattern baldness in women.

Skin: Acne (especially in women and prepubertal boys).

Skeletal: Premature closure of epiphyses in children (see PRECAUTIONS, **Pediatric Use**).

Fluid and Electrolytes: Edema, retention of serum electrolytes (sodium, chloride, potassium, phosphate, calcium).

Metabolic/Endocrine: Decreased glucose tolerance (see PRECAUTIONS), increased serum levels of low-density lipoproteins and decreased levels of high-density lipoproteins (see PRECAUTIONS, **Laboratory Tests**), increased creatine and creatinine excretion, increased serum levels of creatinine phosphokinase (CPK).

Some virilizing changes in women are irreversible even after prompt discontinuance of therapy and are not prevented by concomitant use of estrogens (see PRECAUTIONS).

DOSAGE AND ADMINISTRATION

The use of anabolic steroids may be associated with serious adverse reactions, many of which are dose related; therefore, patients should be placed on the lowest possible effective dose.

Hereditary Angioedema. The dosage requirements for continuous treatment of hereditary angioedema with WINSTROL should be individualized on the basis of the clinical response of the patient. It is recommended that the patient be started on 2 mg, three times a day. After a favorable initial response is obtained in terms of prevention of episodes of edematous attacks, the proper continuing dosage should be determined by decreasing the dosage at intervals of one to three months to a maintenance dosage of 2 mg a day. Some patients may be successfully managed on a 2 mg alternate day schedule. During the dose adjusting phase, close monitoring of the patient's response is indicated, particularly if the patient has a history of airway involvement.

The prophylactic dose of WINSTROL, brand of stanozolol tablets, to be used prior to dental extraction, or other traumatic or stressful situations has not been established and may be substantially larger.

Attacks of hereditary angioedema are generally infrequent in childhood and the risks from stanozolol administration are substantially increased. Therefore, long-term prophylactic therapy with this drug is generally not recommended in children, and should only be undertaken with due consideration of the benefits and risks involved (see PRECAUTIONS, **Pediatric Use**).

HOW SUPPLIED

Tablets of 2 mg, scored, bottle of 100 (NDC 0024-2253-04)

Distributed by Winthrop Pharmaceuticals
Division of Sterling Drug Inc
New York, NY 10016

Manufactured by Sterling Pharmaceuticals Inc
Barceloneta, Puerto Rico 00617

Shown in Product Identification Section, page 435

WW 5-X

ZEPHIRAN® CHLORIDE OTC
brand of benzalkonium chloride

(See PDR For Nonprescription Drugs)

Wyeth Laboratories
Division of American Home
Products Corporation
P.O. BOX 8299
PHILADELPHIA, PA 19101

Product Identification Codes

All oral solid dosage forms manufactured by Wyeth are imprinted with their respective National Drug Code (NDC). The portion of the number indicating product and strength appears on each tablet and capsule, together with the name Wyeth.

The following is a numerical list of NDC code numbers with their corresponding product names for all oral solid dosage forms manufactured by Wyeth.

Numerical Listing

Product Ident. Code	Product
1	Equanil® (meprobamate) Tablet 400 mg.
2	Equanil® (meprobamate) Tablet 200 mg.
6	Serax® (oxazepam) Capsule 15 mg.
13	Amphojel® (dried aluminum hydroxide gel) Tablet 0.6 Gm. (10 gr.)
19	Phenergan® (promethazine HCl) Tablet 12.5 mg.
22	Aludrox® (alumina and magnesia) Tablet
27	Phenergan® (promethazine HCl) Tablet 25 mg.
28	Sparine® (promazine HCl) Tablet 50 mg.
29	Sparine® (promazine HCl) Tablet 25 mg.
33	Equanil® (meprobamate) Tablet, Wyseals® 400 mg.
51	Serax® (oxazepam) Capsule 10 mg.
52	Serax® (oxazepam) Capsule 30 mg.
53	Omnipen® (ampicillin) Capsule 250 mg.
56	Ovral® (each tablet contains 0.5 mg. norgestrel with 0.05 mg. ethinyl estradiol) Tablet, white
57	Unipen® [(nafcillin sodium) as the monohydrate] Capsule 250 mg.
59	Pen•Vee® K (penicillin V potassium) Tablet 250 mg. (400,000 units)
62	Ovrette® (norgestrel) Tablet
64	Ativan® (lorazepam) Tablet 1 mg.
65	Ativan® (lorazepam) Tablet 2 mg.
71	Mazanor® (mazindol) Tablet 1 mg.
73	Wytensin® (guanabenz acetate) Tablet 4 mg.
74	Wytensin® (guanabenz acetate) Tablet 8 mg.
75	Nordette-21® (each tablet contains 0.15 mg. levonorgestrel with 0.03 mg. ethinyl estradiol) Tablet
78	Lo/Ovral® (each tablet contains 0.3 mg. norgestrel with 0.03 mg. ethinyl estradiol) Tablet, white
81	Ativan® (lorazepam) Tablet 0.5 mg.
85	Wygesic® (each tablet contains 65 mg. propoxyphene HCl, U.S.P., and 650 mg. acetaminophen, U.S.P.) Tablet
91	Equagesic® (meprobamate with aspirin) Tablet
92	Wytensin® (guanabenz acetate) Tablet 16 mg.
119	Amphojel® (dried aluminum hydroxide gel) Tablet 0.3 Gm. (5 gr.)
165	Bicillin® (penicillin G benzathine) Tablet 200,000 units
200	Sparine® (promazine HCl) Tablet 100 mg.
227	Phenergan® (promethazine HCl) Tablet 50 mg.
261	Mepergan® Fortis (meperidine HCl and promethazine HCl) Capsule
267	Phenobarbital Tablet 15 mg. (¼ gr.)
268	Phenobarbital Tablet 30 mg. (½ gr.)
269	Phenobarbital Tablet 100 mg. (1½ gr.)
308	Meperidine HCl Tablet 50 mg.
309	Omnipen® (ampicillin) Capsule 500 mg.
313	Aspirin Tablet 300 mg. (5 gr.)
317	Serax® (oxazepam) Tablet 15 mg.
320	Phenobarbital Tablet 60 mg. (1 gr.)
326	Codeine Sulfate Tablet 30 mg. (½ gr.)
360	Pathocil® (dicloxacillin sodium monohydrate) Capsule 250 mg.
389	Tetracycline HCl Capsule 250 mg.
390	Pen•Vee® K (penicillin V potassium) Tablet 500 mg. (800,000 units)
434	Phenergan® -D (promethazine HCl with pseudoephedrine HCl) Tablet
445	Ovral® -28 pink inert tablet
464	Unipen® [(nafcillin sodium) as the monohydrate] Tablet 500 mg.

Continued on next page

Teen-ager on steroids risks his life

We are worried about our son. Jimmy is 17, a high school senior, a really good boy, but he keeps to himself a lot. He is a fine student, plays in the band and has a few nice friends. He always wanted to be a great athlete but never was able to excel in any sport.

For the last six months Jimmy has been working out at a gym. He spent

Ann Landers

his Christmas money on barbells so he can work out at home as well.

A few days ago when I was cleaning his room I found some pills. I showed them to my brother, who is a pharmacist. He said at once, "The kid has been taking steroids."

Ann, please tell us how to handle this. I remember reading about a fine Canadian athlete who had to return his Olympic gold medal because it was discovered that he had been taking these same pills.

Why are steroids dangerous? What do they do? Please tell us so we can speak to our son intelligently. Thanks for your help.

Syracuse Parents

Dear Parents: For openers, nonprescription use of steroids is illegal, but like all such drugs they can be bought on the black market.

People who take these pills should be aware that they could pay a big price for those bulging muscles and improved performance on the track, football field or wherever physical prowess is measured. The side effects can cripple and kill.

Long-term abuse of this substance can produce liver cancer, heart trouble and impotence. In a nutshell, steroids are dangerous. Anyone who takes them is risking his health and maybe his life.

12-16-88
Topeka Journal

Steroids in the high schools

Usage of steroids rising among high school boys

By BERNARD SCHOENBURG
Associated Press writer

CHICAGO — As many as half a million teen-age boys may be using anabolic steroids to improve their appearance or athletic performance, despite possible dangerous side effects, a researcher said Thursday.

"We're talking about potentially abusive behavior that has to be addressed directly or we may have individuals who grow up and suffer adverse health consequences," said W.E. Buckley, assistant professor of health education at Pennsylvania State University.

In a survey of 3,403 senior boys at 46 public and private high schools nationwide in the fall of 1987, 226 boys, or 6.6 percent of those responding, said they had used steroids, Buckley and associates reported in today's Journal of the American Medical Association.

Although the research wasn't based on a random sample of the nation's high schools, the study suggested that 250,000 to 500,000 adolescents are using or have used steroids.

"I didn't have any idea it would be this high," Buckley said, calling his study the first of its scope in the nation.

Androgenic anabolic steroids are synthetic derivatives of male hormones some athletes take to help build up their muscles. Doctors have reported in recent years that steroids have been linked to serious side effects such as mood swings, severe acne, baldness, temporary sterility, abnormal liver function, high blood pressure, cardiovascular disease and possibly cancer of the liver and testicles.

While nearly half the boys in the study using steroids said they did so to improve athletic performance, 26.7 percent said they popped them or injected them for the muscular appearance the drugs can help produce.

"It's the new-age, body beautiful, fitness people out there as well who are using anabolic steroids," Buckley said in a telephone interview.

About 10 percent said they used steroids to treat sports-related injuries and 7.1 percent cited social reasons, such as peer pressure.

The study also showed that about one in five seniors claiming to take steroids said they got the drugs from a doctor, pharmacist or veterinarian, and 38.3 percent said they first took the drugs at age 15 or younger.

The study called for starting education to head off steroid use as early as junior high school, noting that 35 percent of those who said they used steroids did not participate in school sports.

Societal attitudes must be changed to get young people to avoid the quick-fix they think steroids can provide, Buckley said.

"You have to change the values," he said. "We're the ones putting all the emphasis on sports. We're the ones putting all the emphasis on appearance."

Focus on steroid use intensified after the Summer Olympics, where Canadian sprinter Ben Johnson was stripped of his gold medal in the 100-meter dash when it was determined he had used the anabolic steroid Stanazolol.

Parents looking for steroid use should watch for unusually fast muscle growth, mood swings or flare-ups of acne in their children, Buckley said.

Most studies on the long-term effects of steroids have involved people using them legally for other ailments, so further study of the drugs' effects — particularly on healthy, growing adolescents — is needed, Buckley added.

In the short term, steroids reduce sperm production, Buckley said. Some studies indicate steroid use can stop natural growth of bones, meaning they could make young steroid users shorter than they would have been over time.

In an accompanying JAMA editorial, Dr. Wayne V. Moore of the University of Kansas Medical Center in Kansas City urged doctors to avoid prescribing steroids to adolescents except in rare cases of medical needs.

Directing children into sports more suitable for their projected adult sizes also "might remove the temptation to enhance strength and-or size in an adolescent who does not possess the genetic capacity to be the biggest, strongest, and fastest," he wrote.

Steroid can hamper teens' normal growth

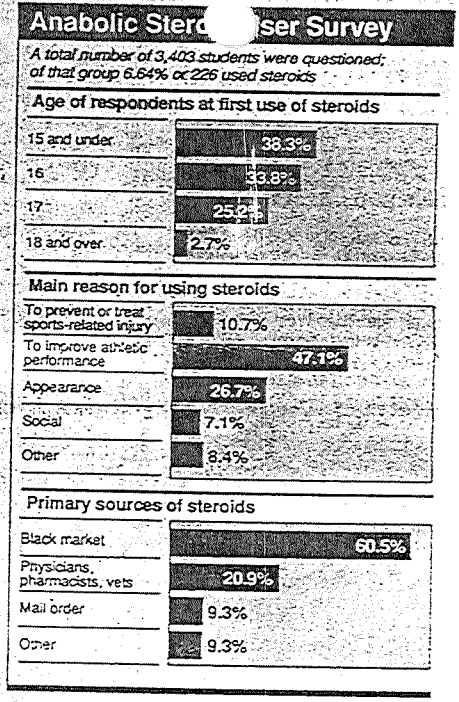
NEW YORK (AP) — Anabolic steroids, the substances taken to help build muscle, are man-made versions of a male sex hormone called testosterone.

In children and teen-agers, steroids can make bones stop growing prematurely and prevent a child from reaching normal height, the U.S. Food and Drug Administration warned last year.

Health authorities also say steroids can cause breast enlargement in men, along with testicle shrinkage, impotence and enlarged prostate. In women, steroids have been linked to deepened voice, beard growth, baldness and breast diminution.

Steroid users of either gender may also show liver disorders and "'roid rage," which is increased aggression and antisocial behavior. A study of steroid-taking athletes published earlier this year found mental problems ranging from deep depression to impulsive buying sprees and outbursts of violent rage.

Anabolic steroids are different from anti-inflammatory steroids, which are commonly used in medicine. Anabolic steroids also have some medically approved uses, such as treating certain types of anemia.



Steroids usually obtained on black market, in gyms

By JOHN NELSON
AP sports writer

Most of the dangerous, muscle-building steroids used in the United States are obtained through the black market and less often from doctors prescribing the drug illegally, experts say.

Some of the drugs are manufactured in the United States, but most of them are smuggled into the country from places such as Mexico, where they are available over the counter.

"There are some little home labs where they're importing the drug and then printing up phony labels," Dr. Bob Goldman, chairman of the Amateur Athletic Union's medical committee, said Thursday. He said fake steroids from East Germany, Italy and France "are really hot now" among young users.

Drugs also come into the country with "athletes who travel overseas and come back to the states with suitcases filled," Goldman said.

"In terms of getting it from a physician, that's dropped off a lot because of litigation and changes in the repercussions," Goldman said.

While penalties have gotten stiffer in the United States for trafficking steroids, doctors also are more aware of dangerous possible side effects, such as liver cancer and heart disease.

A study by Pennsylvania State University assistant professor W.E. Buckley, released in today's Journal of the American Medical Association, shows that one in 15 high school senior boys have used anabolic steroids.

Although nearly half of those using steroids said it was to improve athletic performance, 26.7 percent of 3,403 surveyed said appearance was the main reason.

"The majority of steroids are consumed by individuals who are concerned by how they look — factory workers, lawyers, policemen and firemen — and there is even a smaller market now in kids," U.S. attorney Phillip Halpern told The New York Times in a copyright series of stories last month.

The annual black market in steroids is estimated at $100 million. Officials told the Times there were from five to 20 clandestine labs in the United States manufacturing steroids. The rest come from outside the country.

When Olympian David Jenkins was sentenced earlier this month in San Diego for steroid trafficking, it was estimated that the Mexican smuggling ring in which he was involved was responsible for up to 70 percent of the drug in the United States.

"I get them as young as 12, 13, 14 and 15," Goldman said. "That's the new group we see coming in strong. What do they watch Saturday morning on television? Cartoons. And what do they all look like? He-Man. They all look like gorillas."

Goldman, a former weightlifter, said the drugs often are obtained by young people at private gyms or in their own school locker rooms in much the same way they might obtain cocaine on the playground.

"Wherever somebody's going to weight train, there's a market," Goldman said. "Here's a typical scenario. There's one muscular guy in the gym, and he's been working for $5 an hour. Now, he suddenly sees he can make thousands by selling steroids.

"Some of the transactions go on right in the locker rooms at the schools, the transactions as well as the shooting up. The kids store the stuff in their lockers."

Goldman said a teen-age user "can get started for $10 or $20" with a small bottle of one of the cheaper steroids. "Then, once they get into it, they can be spending hundreds of dollars a month," he said.

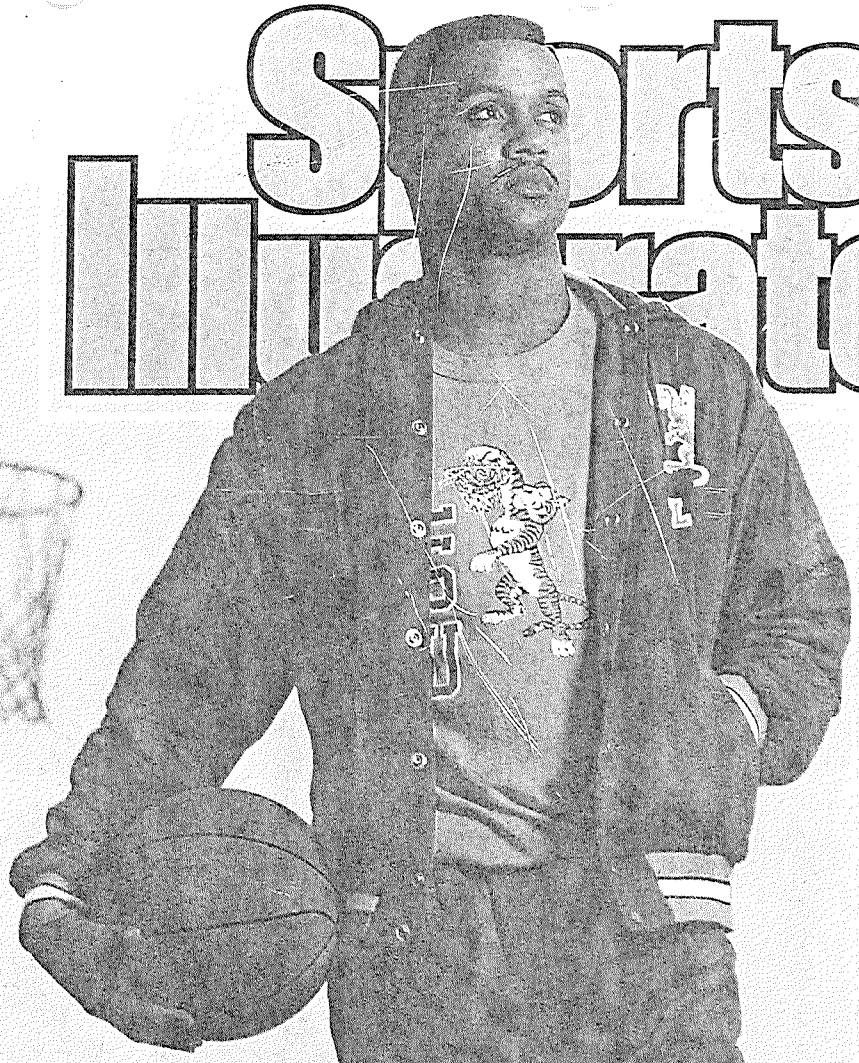
The Times' series quoted authorities as saying major distribution points were body-building gyms and fitness centers, where steroids can be purchased directly or a connection can be made.

"The scary part is, here we have the finest product of this country — our young, aggressive people — and we're going to have an entire patient population developing diseases they never should have had in the next five to 10 years," Goldman said. "And they're our finest product."

FEBRUARY 20, 1989

$2.25

Sports Illustrated

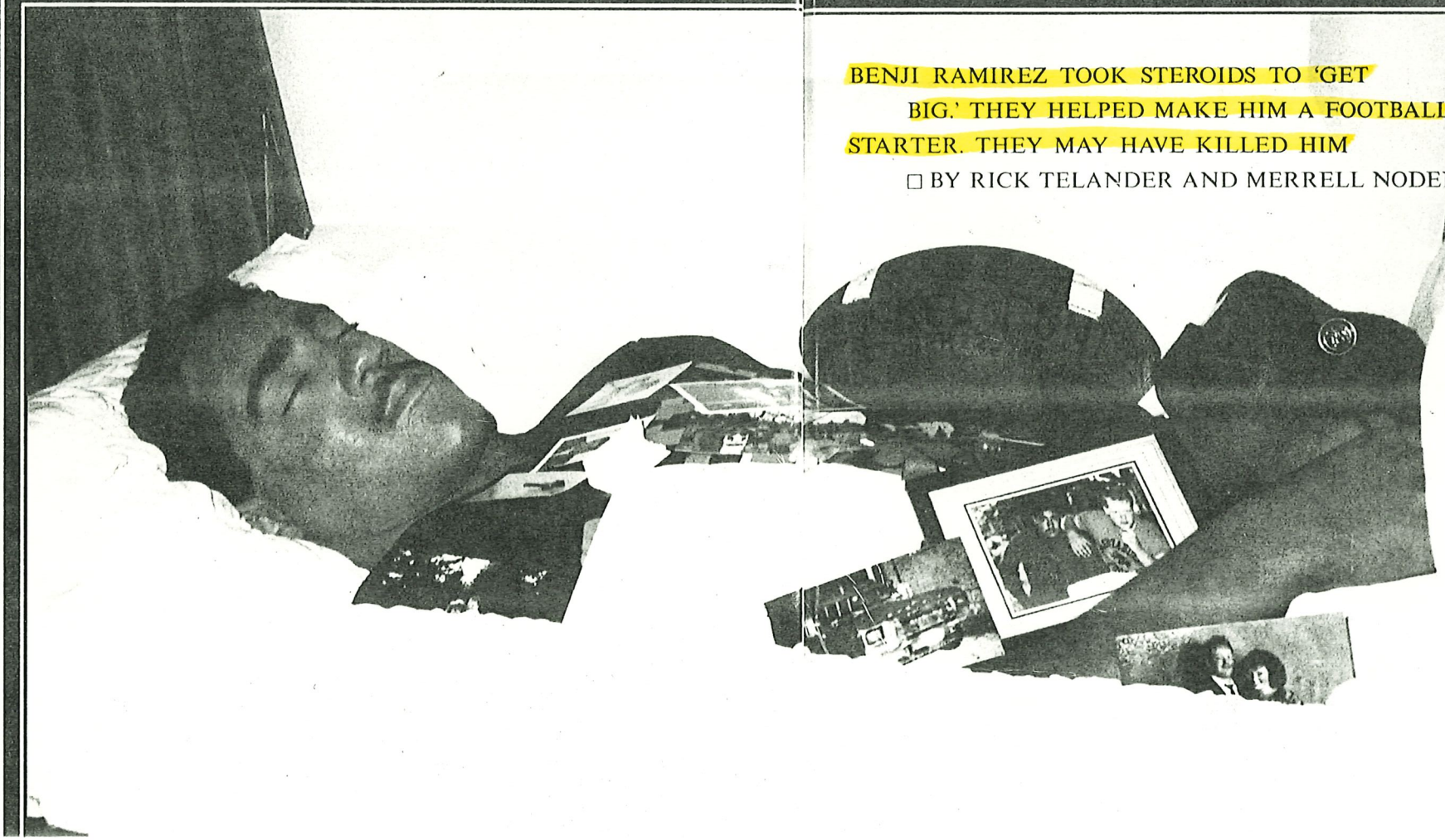


HE'S A PISTOL

LSU SUPER FROSH CHRIS JACKSON EVOKES MEMORIES OF PETE MARAVICH

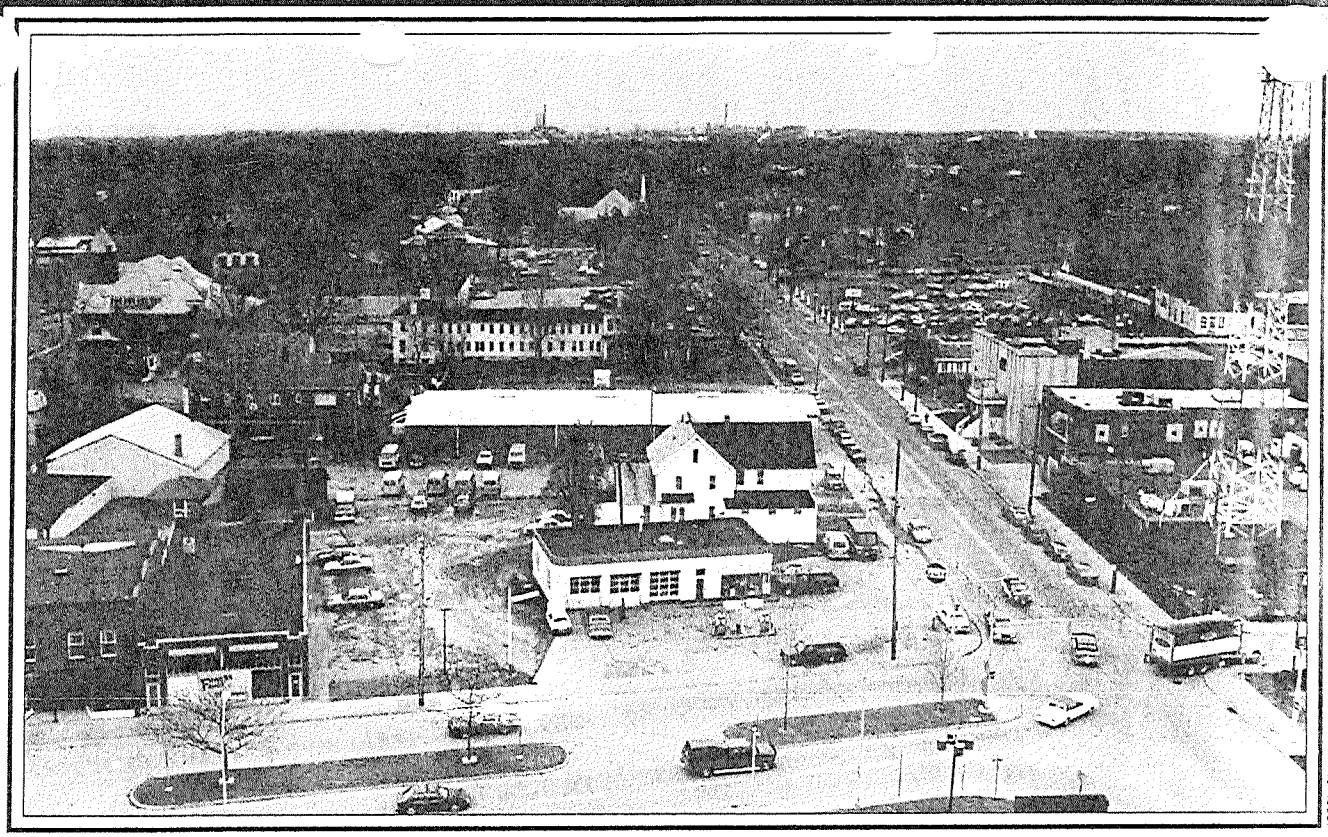
SPokW
2-20-89
Attachment 2

The DEATH *of an* ATHLETE



BENJI RAMIREZ TOOK STEROIDS TO 'GET BIG.' THEY HELPED MAKE HIM A FOOTBALL STARTER. THEY MAY HAVE KILLED HIM

□ BY RICK TELANDER AND MERRELL NODEN



PHIL HUBER

Physical fitness is one of the few growth businesses in Ashtabula, which has been devastated by the loss of several manufacturing companies.

IT RAINED HARD THE DAY THE Ashtabula (Ohio) High football team faced Northeastern Conference rival Conneaut High in October. The field was a quagmire, but that didn't stop Benji Ramirez, a 17-year-old senior defensive tackle, from playing the game of his life. He made four tackles and recovered a fumble as the Panthers won 21–6. "Benji stuck a lot of dudes that night," says Ashtabula defensive end Fred Gage. For his efforts, Ramirez was named the Panthers' defensive lineman of the game.

Three nights later, on Halloween, Ramirez collapsed during practice after a tackling drill. He was taken to the Ashtabula County Medical Center, where, at 6:02 p.m., he died, apparently of a heart attack. He was buried three days later in his football uniform, the bright yellow BULA on his shirt almost obscured by poems, pictures and other mementos placed on his chest by grieving friends. Four hundred people attended the funeral, including city officials, his coaches and his teammates. Everybody liked Ramirez.

"He was a really nice guy," says Aaron Morris, a senior at Ashtabula High and one of Ramirez's closest friends since second grade. "I don't think Benji had any enemies. He was really low key. He didn't even like rock 'n' roll."

One of the mourners was Mark Craffey, a first-team all-county offensive tackle, who wrote an essay about Ramirez's death for an English class. "Benji Ramirez died today," Craffey's piece began. "I don't even know exactly how to write about it. I feel cheated and helpless." Craffey concluded, "I asked Benji to tell me how. I asked God to tell me why. There was no answer and I cried."

Indeed, at first Ramirez's death seemed to defy explanation. The practice had not been strenuous, and the weather wasn't hot. The 6′ 3″, 201-pound Ramirez appeared to be strong and fit. He was a member of the Ashtabula High wrestling team as well, and he was an avid weightlifter. After two years as a jayvee player in football, Ramirez had finally cracked the varsity lineup and seemed to be improving every day. He had even received a letter from Youngstown State expressing interest in him. A year earlier, he would never have dreamed that he could even be considered for a college football scholarship. "He'd come a long way as a football player," says Sean Allgood, the Panthers' star quarterback. "Everybody was really surprised."

But as Ramirez's dazed friends struggled to console one another in the hospital halls shortly after his death was announced, Tony Rivera, team manager for the Panthers, took Ashtabula High coach Jim Orr aside and told him what many of Ramirez's friends suspected or

Before dying, Ramirez had the game of his life.

ASHTABULA STAR-BEACON

knew: Ramirez had been using anabolic steroids. Orr passed the information on to Jeff Brown, an investigator for the Ashtabula County Coroner's Office. Coroners don't routinely test for steroids, but after a shocking death like Ramirez's, they will follow every possible lead. According to Dr. Robert A. Malinowski, the county coroner, the rumors of steroid usage by this young, healthy athlete changed the focus of his office's investigation. "We conducted it with that in the backs of our minds," he says. "Benji had no history of heart problems, so there was basically no reason for him to die."

Because the pathologist who normally would have performed the autopsy was unavailable, Ramirez's autopsy was performed by the coroner's office in Cleveland, which sent its findings to Malinowski. In an interim report released on Dec. 14, Malinowski announced that Ramirez had died of cardiac arrhythmia, a heart condition caused in this case by a diseased and enlarged heart. On Jan. 10, Malinowski released his final report, which included two findings. First: "Although we were not able to identify any specific steroid in the blood of Benjamin Ramirez, we can conclude through field investigation and some changes seen in the body at autopsy that Benjamin Ramirez did use anabolic steroids." Second: "It is the strong opinion of County Coroner Dr. Robert A. Malinowski that use of anabolic steroids did in some way contribute to the death of Benjamin Ramirez."

Malinowski, the father of 10 children and an avid football fan, is quick to point out that a coroner's report can't always deal in incontrovertible facts, and that steroid use wasn't listed as the cause of Ramirez's death but as a contributing factor. "I've been very careful to say it's my opinion," says Malinowski. "We don't have to prove anything beyond a reasonable doubt in this business. We don't have to read people their Miranda rights. Yes, it's possible I could be wrong. But I doubt it."

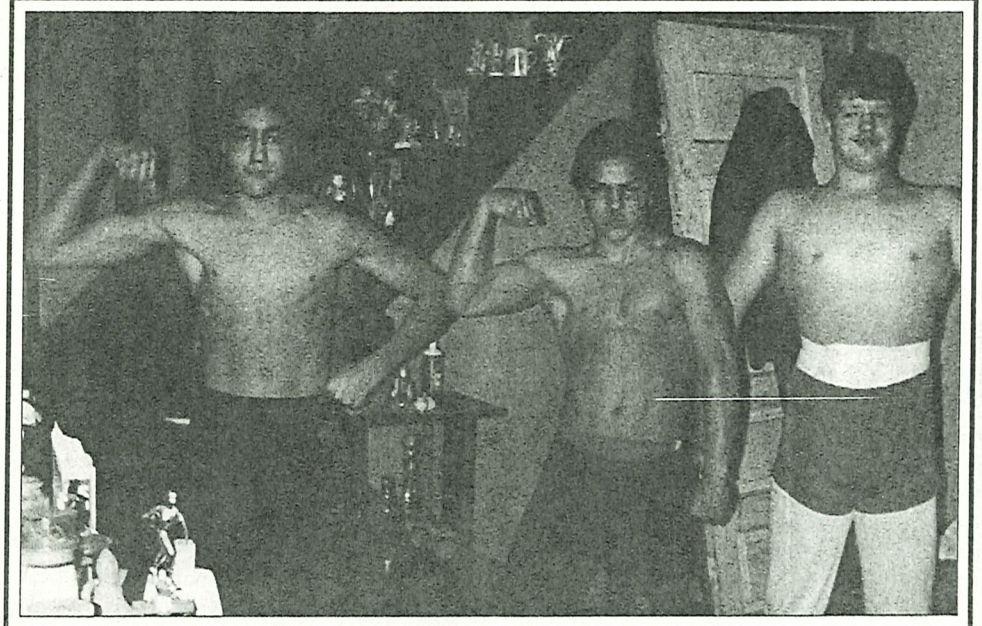
If Malinowski is right, Ramirez is the first U.S. athlete whose death has been linked officially to the use of steroids, a practice that, by all accounts, is spreading across the country faster than experts can track it.

On Jan. 31, the tiny St. John High gym on Station Avenue in Ashtabula was rocking. St. John, which had a 14–2 record, was taking on 13–2 Ashtabula High, which had handed St. John one of its two defeats of the basketball season. The gym had filled long before the end of the preliminary jayvee game, and many fans who couldn't get inside stood outdoors by the windows, trying to gauge the course of the game by the crowd noise. The scene seemed cut from the pure, mythical heart of America. Here was high school sport drawing folks together in a celebration of youth, competition and rock-solid, middle-class values.

But nothing these days is quite what it appears. That night in another part of town the Ashtabula Area City Schools Substance Abuse Committee was holding its first meeting. While the idea for the committee was developed before Ramirez's death, there is no doubt that the tragedy added urgency to its deliberations. The group discussed the need for a comprehensive drug-education program in local schools as well as for some sort of drug-testing procedure for athletes. Not as a punishment, said school superintendent Elinor Scricca, but as "an evaluation of behavior and physical prowess."

"It's obviously an extremely timely problem," added committee member Dr. Jeff Brodsky. "I don't want to see more kids go through what [Ramirez] went through."

At halftime back at the school gym, Morris thought once again about his buddy. "Benji asked me if I wanted to use steroids," said Morris. "I was tempted, but I don't need to get bulkier; I'm a baseball player. The thing about kids these days is that physically we're in a rush to be adults, but mentally and emotionally we want to stay teenagers."



RHONDA HAYES

Ramirez (left) didn't think the body he had three years ago was big enough to "get girls."

Jim Smith, the football coach at St. John, doesn't believe that kids have changed that much. But the world around them certainly has; the temptations they must face have increased tenfold. Smith stood in the gym hallway and observed the girls running past and giggling, the boys strutting, the same adolescent ebb and flow one has always found in high schools. "I think if kids had known about something like steroids 20 years ago, they would've taken them then, too," said Smith, shaking his head sadly.

Certainly Ashtabula (pop. 24,000) has changed in the last two decades. Located 55 miles northeast of Cleveland on Lake Erie, the town was once a vital manufacturing and transportation hub

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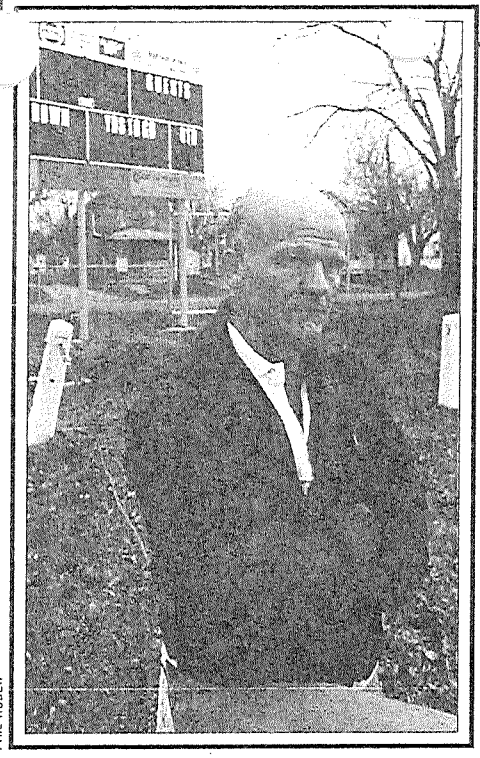


PHIL HUBER

Orr admitted his ignorance of the signs of steroid use.

feeding materials to the rubber companies in Akron and the steel mills in Youngstown. But the manufacturing slump that hit the Midwest in the '70s devastated Ashtabula. Two of the area's biggest employers, True Temper, a toolmaker, and Rockwell International's brake manufacturing plant, added to Ashtabula's woes of the past decade by pulling out of town.

Today Ashtabula is pocked with vacant, graffiti-covered buildings, and a sense of used-to-be pervades the town like a chill wind. "We should develop our recreational side, our beaches and the Ashtabula River," says acting police chief Gus Powell. "But all we're getting are a large number of welfare recipients because of our empty houses [and the resulting low rents]."

Ironically, one of the few growth businesses in town is physical fitness. The health clubs are jumping in Ashtabula. The message seems to be: If you can't control the world around you, you can still control your physique. The largest and most elaborate of the bodybuilding centers is the New Life Health Club. When it opened in 1979, New Life had 22 members—all women—10 pieces of equipment and 1,000 square feet of space. Now it has nearly 1,000 members, 15,000 square feet of space, three tanning rooms, a lounge with video games and card tables, and three well-equipped weight-and-exercise rooms—one coed, one for women only and one for men only.

"The main reason for all this is the public's awareness that you need to control your own health," says New Life owner Jim Harrington as he conducts a tour of the facility. The flaw in that kind of reasoning is the equating of muscle development with good health. A fit-*looking* body is not necessarily a fit body. Ramirez proved that point. He looked pretty good, though he wasn't a sculpted hunk by any means. "I laugh when people make him out to be this big Arnold Schwarzenegger–type guy," says Morris. "He was thick, but he was no muscle-bound critter."

In fact, in addition to the limited cosmetic benefits that steroids gave Ramirez, his body was undergoing other changes as well, including the atrophying of his testicles. He also had the puncture wounds in his thighs from injecting the drugs. When used to promote rapid muscle development, anabolic steroids—natural and synthetic testosterone—can cause many physical and psychological side effects, among them liver and kidney disorders, temporary acne and balding, hypertension, decreased sperm count, aggressive behavior, depression and irritability. Like most users, however, Ramirez thought either the steroids were not actually harming him or that the result was worth the risk.

The primary reason Ramirez took steroids was not to become a better athlete, though his new strength helped him in that regard. "Oh, no, this had nothing to do with football," says Morris. "Benji was not a diehard football player. He used steroids because he wanted to be big and get girls."

On the bulletin board at New Life is a cartoon of Santa Claus looking at a reindeer with huge antlers that look like two trees. "Blitzen," says Santa, "have you been using steroids again?" On a nearby bulletin board is a sign stating that the club strongly opposes the use of steroids and that anyone promoting that use at the club will forfeit his membership.

It's a nice touch—the antisteroids message—but it's undermined, particularly for young men, by the glossy posters on other walls in the club of muscle gods Franco Columbu, Lou Ferrigno and, of course, Schwarzenegger, in one of his many greased and bulging poses. On a table are muscle magazines with more photos of grotesquely swollen iron-pumpers. Nobody can look like that, no youngster, anyway. The kids all know that the bodybuilding ranks are riddled with steroid-abusing athletes, who seem to embody the power and confidence that many male adolescents seem so desperately to crave.

"I've got a lot of old mag-

Malinowski reported that steroids did "contribute to the death."

PHIL HUBER

azines with guys like Steve Reeves and Charles Atlas in them," says Danny Wells, 25, who won the Northcoast lightweight bodybuilding championship, a regional competition with participants primarily from eight Midwestern states, in 1987 and '88. "Back then there was a smoother, more natural look. Now it's how far can you take your body. You've got to be ripped, hard, down-to-the-bone, and that's what's really hard to do without taking steroids."

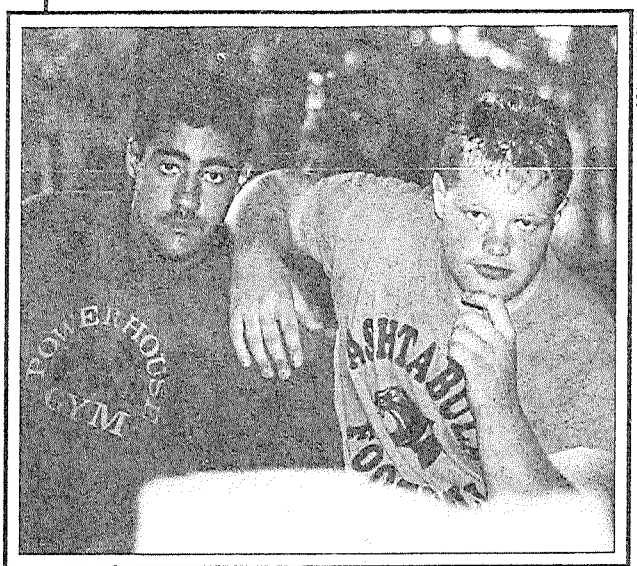
Wells used steroids for almost five years, and though he's only 5' 7", he once weighed 220 pounds and sported 21-inch biceps. He said he quit using steroids when he became convinced he would die if he kept taking them. "My body just completely broke down," says Wells.

He now works at the Zip-Zap Brushless Car Wash in Ashtabula and says he's happy just to be alive, a notion he tried to impress on Ramirez several years ago when Ramirez approached him about taking steroids. "I was in training," says Wells, "and he said, 'Man, you're huge!' I said, 'Yeah, but a couple of trophies aren't worth risking your life for. If you want to play football, go train. Don't take steroids at an early age.' He seemed to listen to me, but I knew he got on them later. I know a juicer when I see one."

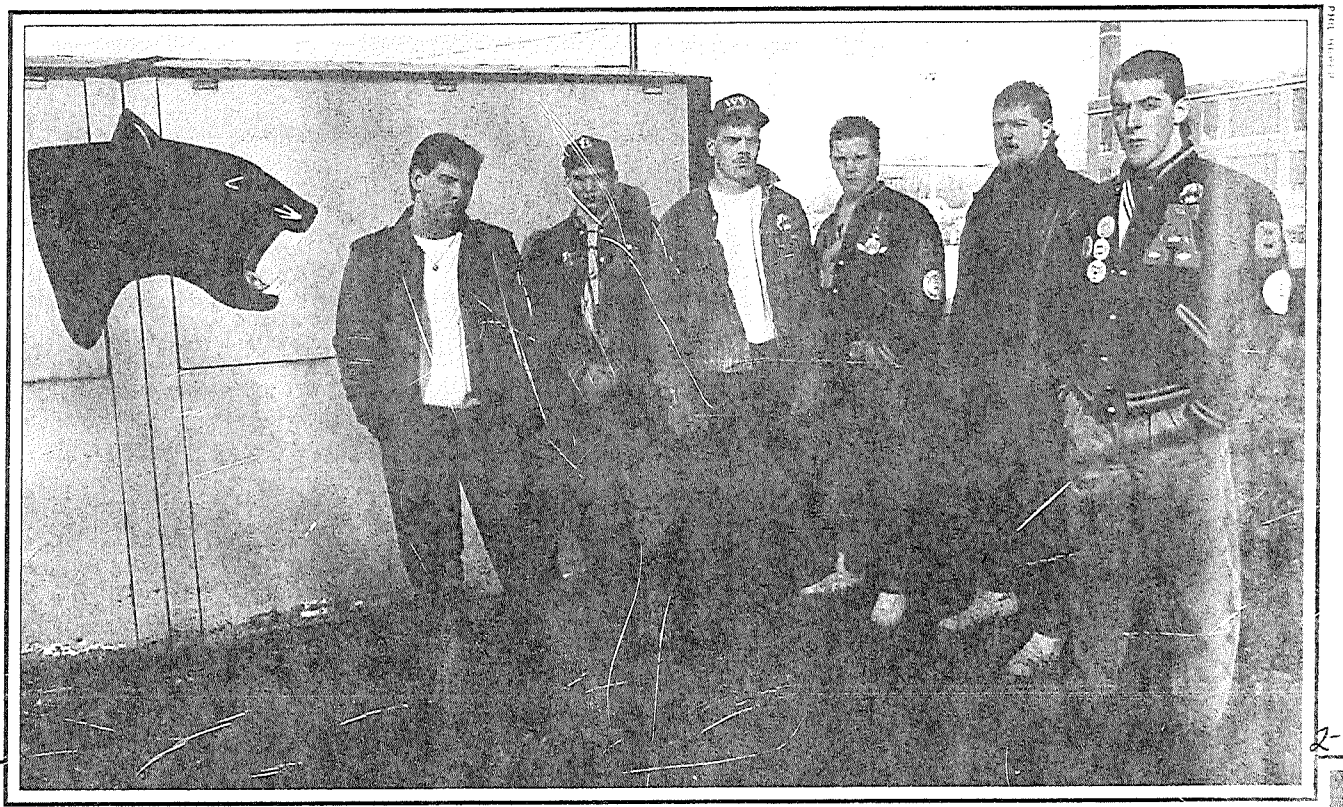
Wells no longer trains at health clubs because he has grown weary of young men—and some older ones as well—approaching him about getting on steroids so they, too, can develop the ripped look. Wells's mistakes have made him reflective. "I think every guy wants to be powerful," he says. "But kids don't understand that [Sylvester] Stallone weighed about 165 pounds in *Rambo*—that's the big screen. It's all an illusion. You have to think about life, what's real."

Ask any of Ramirez's friends why he used steroids, and they'll look at you in amazement. "To get big," says Rico Velez, an Ashtabula High sophomore. The word "big" has taken on new meaning for teenage boys. To be big means to be in control, macho, bad. It means you have bypassed adolescence and jumped straight to manhood. Joe Weider, the guru of modern bodybuilding and the editor of several muscle magazines, sells a bodybuilding protein powder that's called BIG.

Michele Heath, a junior who knew Ramirez well, believes that the first time she heard of steroids was sometime in her junior year, when an antisteroid poster was placed on a wall in one of the high school's hallways. Before long someone wrote Ramirez's name on the poster. "Benji said the steroids were increasing his growth," says Heath. "He thought he'd be big eventually, but he



RHONDA HAYES


PHIL HUBER

Many of his high school buddies knew that Ramirez (left, with Morris) was on steroids.

PHIL HUBER

Cole says Ramirez took steroids "to fit in."

said he needed it now. He said he was speeding up time. He was impatient. He didn't want to wait."

According to Karey Cole, who worked with Ramirez at the Ponderosa Steakhouse in Ashtabula and had been a friend of his since seventh grade, he began to use steroids about a year before his death. "I know he started doing them in the late fall of 1987," she says. "He just came out and told my girlfriend and me. I think he took them because he wanted to fit in."

Another friend, Orlando Lopez, says that last summer he went into Ramirez's bedroom and watched him inject himself with steroids. Lopez also says that "anytime we saw a mirror, we'd always stop and flex in front of it. I wanted to be big, too. I always wanted to try steroids, but I didn't have the money." Lopez pauses and then continues, "Every picture I got of Benji and me, we're flexing."

Ramirez's mother, Milagros, and father, Benjamin Sr., who are both from the Dominican Republic, were divorced about 10 years ago, shortly before Milagros and her family moved to Ashtabula from New Jersey, where Benji had been born. Back then Benji was a skinny kid who often was teased because of his slight Spanish accent. "He looked like E.T.," says Morris. "He always had a big head, and his chest was sunken and his stomach stuck out a little. When people picked on him, he'd either back down or come get me."

In high school Ramirez was still insecure. Self-improvement was his obsession. "He wanted to better himself in everything," says Craffey. "Not just in football but in wrestling, at the Y, socially." Ramirez lifted weights almost every day at the YMCA. Although he was a woeful wrestler—he once lost a high school match in less than 30 seconds—he helped coach younger kids in wrestling classes at the Y.

Orr is still stunned by Ramirez's death. For a while Orr was painted as the bad guy, the coach who should have recognized Ramirez's steroid problem and taken swift action to correct it before things got out of hand. "My life has been nothing but hell since Benji died," he told the Ashtabula *Star-Beacon* on Jan. 13. "I'm damn tired of trying to defend myself when nobody is supporting me."

In fairness it should be said that Orr probably did no more or less than most coaches would have done in the same situation. "I'll admit ignorance about this," he says. "I'll admit that the kinds of training coaches have to go through doesn't at this point include the kind of information you need to identify this problem. I recently talked to our county coaches, and every one of them admitted he wouldn't have known the signs."

Coaches aren't alone in their ignorance. No one knows just how widespread steroid use is, in high schools or anywhere else. Almost always the drugs are bought and sold on the black market, making users difficult to track. Nonetheless, Charles Yesalis, a professor of health and human development at Penn State, suspects that "steroids are being used in epidemic proportions." Indeed, a 1988 study that Yesalis worked on found that 6.6% of male high school seniors were using steroids. FDA Commissioner Frank Young estimates that 10% of all high school students use steroids.

Compounding the problem is the fact that in many states, Ohio included, the possession and use of steroids

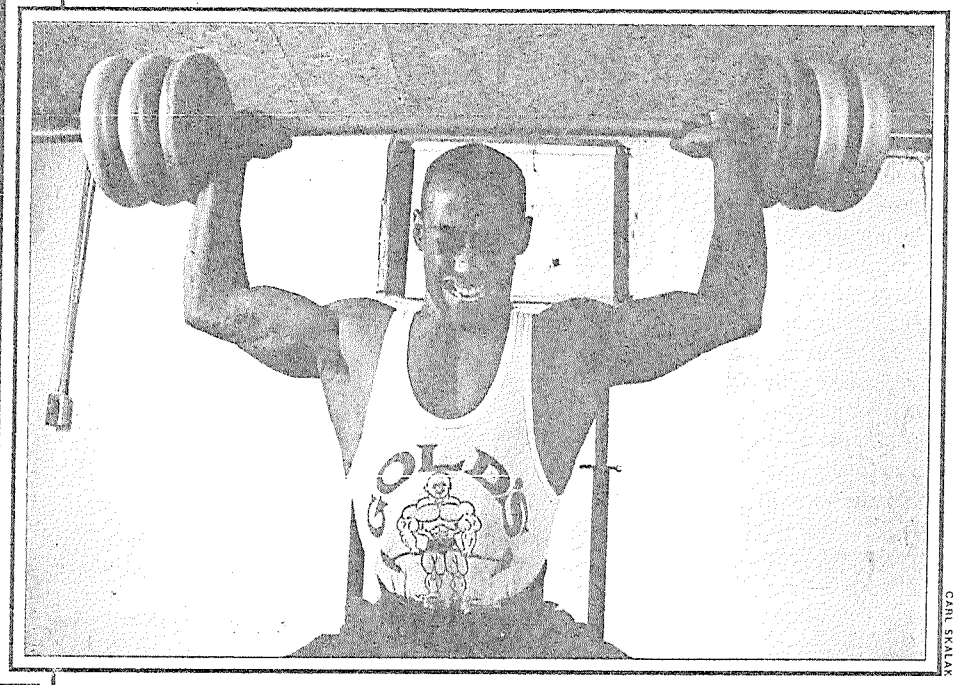
is perfectly legal, though selling them in Ohio is a misdemeanor. Moreover, purchasing syringes—as Ramirez did to inject himself with the drugs—is as easy as going to the corner drugstore, presenting an I.D. and laying down your money. Hoffman's Pharmacy, where Ramirez bought boxes of syringes on several occasions, is only a few yards from Racquet West, where Ramirez sometimes pumped iron.

Milagros Ramirez sits in the family dining room near her son's framed Army Certificate of Enlistment. Before he received the feeler from Youngstown State, he had decided to join the Army in hopes of becoming a pilot. She insists in broken English that her Benji could not have been using steroids because he had vowed to her that he didn't take drugs. She pulls out the Spanish edition of the *Reader's Digest*'s medical encyclopedia and turns to a page that describes myocarditis and its range of symptoms. The entire entry is circled in red ink. "He had them all," she says of the symptoms. "He had them all."

"We explained to her that Benji was probably being honest with her," says Malinowski. "These kids don't even see steroids as being drugs."

By all accounts, Ramirez's hero was his older brother, John, 24, an amateur bodybuilder who onced finished second in the Mr. Golden Isles competition in Brunswick, Ga. "His brother was strong and really got the girls," says Gage, who was near Ramirez when he collapsed. "Benji wanted to be like him."

John, who is studying to be an air-traffic controller in Oklahoma City, denies ever using steroids and says that last spring, when he got a call from Morris and classmate Kevin Cherry telling him that Benji was using steroids, he called his brother. "I told him that if he was taking them, to stop, and if he was thinking about it, not to," says John. "I told my mom and I told Aaron that they should let me know about it. That was the last I heard about it."



CARL SKALAK

Wells, who says he now bulks up without using drugs, told Ramirez to avoid steroids.

No one who knew Ramirez well should have been surprised to learn he had used steroids. His nickname was Roids. Last March, when Orr heard that Gage and Ramirez were using steroids, he called each of them into the assistant principal's office and questioned them separately about the rumors. "Benji admitted that he had thought about it," says Orr. "I asked him, 'Are you using them, or have you been using them?' He said, 'No, and I promise you I won't.' " Gage, to this day, denies that he ever used steroids.

But Ramirez *was* using steroids. Sometimes, according to Morris, he would even shoot the drugs on game days, hoping for a rush that would carry over into the game. Morris went into Ramirez's bedroom the night after his death and found a used syringe in an old shoe in a wastebasket. "The cap was on the needle, but you could still see juice on it," says Morris. "It looked so fresh, I wasn't about to let his parents find it."

Morris says he kept the syringe until the day of Ramirez's funeral, when he turned it over to Dave DeLeone, the assistant principal at Ashtabula High. DeLeone in turn gave the syringe to the police, who sent it to the coroner's office. Brian Hubbard, an investigator for that office, says there wasn't enough material in the syringe to identify any drug, just as there was not enough urine in Ramirez's corpse to test for steroids. Although no drugs were found in or on Ramirez, Powell, the police chief, says he "would love to tie the sale of steroids to someone [in this case]. That could lead toward a manslaughter or homicide charge."

What remain for Ramirez's friends are images of a young man with a drug problem he either did not understand or had no control over. Shane Clinard, a senior at Ashtabula High, says that last spring he walked in on Ramirez injecting himself with steroids in his bedroom. After that, according to Clinard, "he did it openly in front of me. He used a 3-cc needle. He would fill it up to 2½ cc's, squirt a little bit out and then tap it to make sure the bubbles were out."

Craffey says, "Benji openly admitted his use to me after people started talking about it. I saw a vial, too, at school. It was the first time I had held one. It was in English class."

Some of Ramirez's friends also noted that the normally mild-mannered Ramirez became more aggressive. "I noticed the change because he played over me in scrimmages," says Craffey. "People would tease me, saying,

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"What's the matter? You can't take on Benji anymore?' " Gage remembers that when a "a biker girl" threw beer in Ramirez's face last summer, "he freaked out. He went crazy. I'd never seen him like that. He could've ripped somebody's head off."

Another of Ramirez's classmates, who asked not to be identified, says that on two occasions last summer he purchased steroids from Ramirez and used them in his company. In both instances Ramirez injected the classmate in the buttock and then injected himself. Says the classmate, "Benji talked to me about the side effects—that his nose would bleed and he'd have bad breath and get pimples on his shoulders—but he said it wasn't all that bad."

Another classmate who requested anonymity says that last summer he drove Ramirez to a house in Ashtabula and waited in the car while Ramirez went inside to buy steroids. When he returned to the car, Ramirez showed the classmate a bottle two inches long and told him it contained steroids. The classmate then drove to the YMCA, where he dropped Ramirez off and where, according to friends, Ramirez had first met this steroid supplier.

Bob Hile, the director of the Y, acknowledges that when he took over in 1985, "I found a syringe and a vial and turned it over to the police for testing. They told me it was anabolic steroids. I went down to the weight room and stopped everyone from working out. I told them it was our policy not to allow drugs on the premises. We had about six guys leave, and that was the last we heard about it until this."

At the Giant Eagle grocery store in the Saybrook Shopping Plaza on the western edge of Ashtabula, the March edition of *Muscle & Fitness* is on sale. Ramirez liked looking through the magazine, with its colorful photos of highly muscular men and women. "He always talked about [bodybuilder] Lee Haney," says Morris. "He'd turn a page and say, 'God, look at this!' " The March issue contains a feature that promotes "living sexier through bodybuilding," advertisements that sell every form of bodybuilding supplement *except* steroids, and an article on silicone implants, the latest thing for "calf augmentation."

What does any of this have to do with health? Nothing. Indeed, Ramirez apparently started to feel sick not long before he died. James Barksdale, 26, a cook at the Ponderosa, says that in mid-October Ramirez complained of chest pains and admitted that he was injecting himself with steroids again. "He had quit taking them for a while and had just started back," says Barksdale. "He was smart enough to know it was hurting him." Milagros recalls that during "the last months Benji said to me all the time, 'Mom, I don't feel good. Mom, I don't feel good.' "

But as Morris says, "Whenever Benji saw a big person, he'd comment, 'I want to look like that.' He wanted *the look*." And he wanted it now.

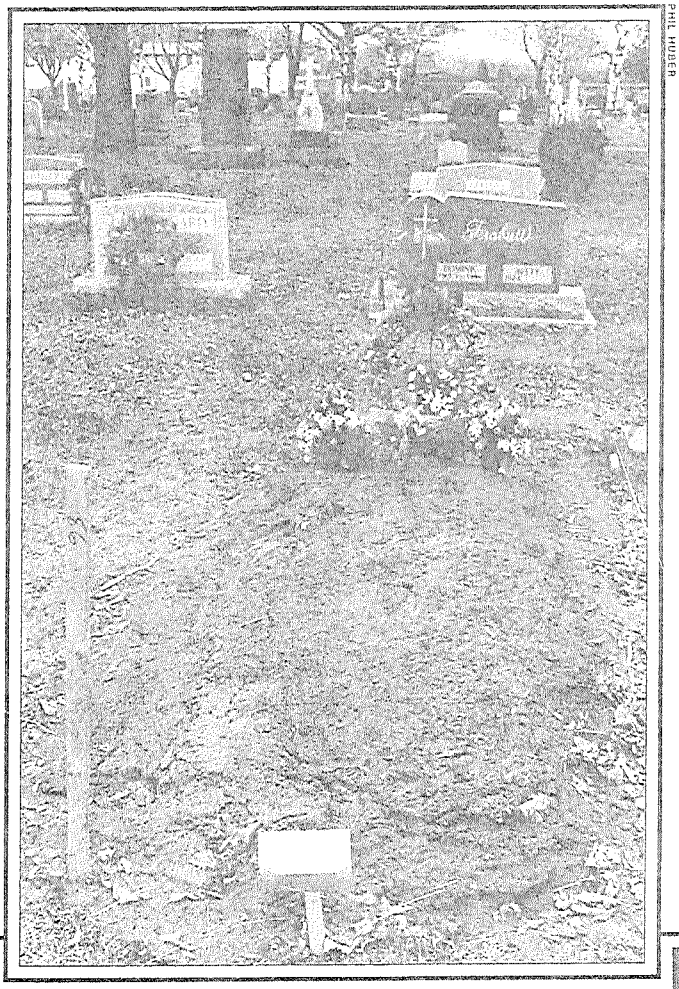
"All girls freak over bodies," says Gage. "I remember Benji saying he was starting to get the girls. Girls would say, 'Benji, you're getting big,' and he liked that. He liked the results."

After hearing the coroner's verdict, Vivian Cortes, a 15-year-old Ashtabula High sophomore, told the *Star-Beacon*, "I guess he did it [used steroids] to be more popular. He didn't have to do it, he was already popular."

Back in the St. John gym, the home team holds on to beat Ashtabula 64–61 in a thriller. "This was the biggest game ever played in this gym . . . it's probably the most important game I've ever had as a coach . . . it's probably the most exciting game I've ever seen," Heralds coach John Bowler tells the press. His enthusiasm is understandable. Clear-cut victories are few and far between these days, particularly in the ever-confusing world of American high schools. For instance, in the next morning's *Star-Beacon*, a few pages before the story on the St. John–Ashtabula game, there was a letter from Rev. Ronald J. Nuzzi of St. John High explaining why the school was standing firm in its decision to sponsor the play *AIDS: I Don't Want To Talk About It*.

We live in troubling times. But troubling times can also be rewarding times for those who struggle and ultimately find their way. It's a shame Benji Ramirez isn't here to look for his reward. ■

Ramirez's grave is a sad reminder that fitness means more than big muscles.



PHIL HUBER

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Kansas State Board of Pharmacy

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STATE OF KANSAS

MIKE HAYDEN
GOVERNOR

SENATE BILL 181

SENATE PUBLIC EHALTH AND WELFARE COMMITTEE
10 a.m. - February 20, 1989

Mr. Chairman, members of the Committee, I am Tom Hitchcock, Executive Secretary for the Kansas State Board of Pharmacy. I appear before you today on behalf of the Board to speak in support of Senate Bill 181.

The abuse and misuse of anabolic steroids has been around in this country for many years but has finally become a rather large problem in Kansas. As long ago as 4 years the Arkansas Board of Pharmacy Newsletter stated that various media sources indicated a serious national problem in the misuse of steroids. Some examples being:

1. A 26 year old body builder died of liver cancer after using steroids for 3 years.
2. Two heart attack deaths of athletes with no prior history of heart trouble but a strong history of steroid use.
3. A 23 year old athlete who suffered a stroke.
4. A 29 year old world class athlete who suffered a stroke.
5. AIDS transmitted to a body builder who shared a steroid injecting needle.

Again, the Board of Pharmacy respectfully requests the passage of Senate Bill 181 in an effort to curb the abuse and misuse of anabloic steroids in Kansas.

Thank You.

SP&W
2-20-89
Attachment 3

KANSAS MEDICAL SOCIETY
1300 Topeka Avenue • Topeka, Kansas 66612 • (913) 235-2383
Kansas WATS 800-332-0156 FAX 913-235-5114

February 20, 1989

TO: Senate Public Health and Welfare Committee

FROM: Kansas Medical Society

SUBJECT: Senate Bill 181, As Introduced

The Kansas Medical Society appreciates the opportunity to express our support of SB 181. The abuse of anabolic steroids is a problem that appears to be worsening and demands a response in the form of penalties.

Medical researchers continue to discover harmful side affects of prolonged use of anabolic steroids, particularly if taken in high level dosages. Some of the known side affects are high blood pressure, cancer of the liver, and psychological disturbances.

There remain, however, a few medical uses for anabolic steroids that depend largely on the uniqueness of a patient's endocrin system. This is why it is important to allow prescription and dispensing of anabolic steroids for "a valid medical purpose." Examples of such medical uses include controlling the growth of a child with glandular dysfunctions, providing therapy to elderly persons who have lost the will to survive, and reversing severe osteoporosis.

For the above reasons we respectfully request that you recommend SB 181 for passage. Thank you for your consideration.

CW:nb

SPHW
2-20-89
Attachment 4

Steroids can hamper teens' normal growth

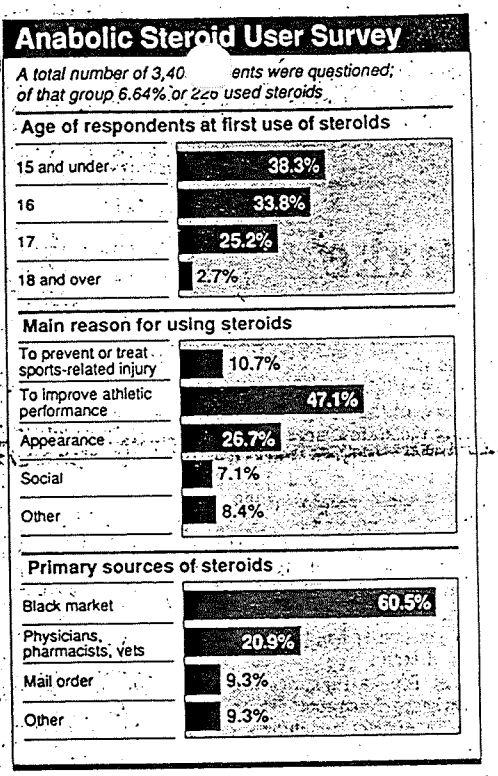
NEW YORK (AP) — Anabolic steroids, the substances taken to help build muscle, are man-made versions of a male sex hormone called testosterone.

In children and teen-agers, steroids can make bones stop growing prematurely and prevent a child from reaching normal height, the U.S. Food and Drug Administration warned last year.

Health authorities also say steroids can cause breast enlargement in men, along with testicle shrinkage, impotence and enlarged prostate. In women, steroids have been linked to deepened voice, beard growth, baldness and breast diminution.

Steroid users of either gender may also show liver disorders and "roid rage," which is increased aggression and antisocial behavior. A study of steroid-taking athletes published earlier this year found mental problems ranging from deep depression to impulsive buying sprees and outbursts of violent rage.

Anabolic steroids are different from anti-inflammatory steroids, which are commonly used in medicine. Anabolic steroids also have some medically approved uses, such as treating certain types of anemia.



Topeka Capital-Journal Dec. 16, 88

Steroids usually obtained on black market, in gyms

By JOHN NELSON
AP sports writer

Most of the dangerous, muscle-building steroids used in the United States are obtained through the black market and less often from doctors prescribing the drug illegally, experts say.

Some of the drugs are manufactured in the United States, but most of them are smuggled into the country from places such as Mexico, where they are available over the counter.

"There are some little home labs where they're importing the drug and then printing up phony labels," Dr. Bob Goldman, chairman of the Amateur Athletic Union's medical committee, said Thursday. He said fake steroids from East Germany, Italy and France "are really hot now" among young users.

Drugs also come into the country with "athletes who travel overseas and come back to the states with suitcases filled," Goldman said.

"In terms of getting it from a physician, that's dropped off a lot because of litigation and changes in the repercussions," Goldman said.

While penalties have gotten stiffer in the United States for trafficking steroids, doctors also are more aware of dangerous possible side effects, such as liver cancer and heart disease.

A study by Pennsylvania State University assistant professor W.E. Buckley, released in today's Journal of the American Medical Association, shows that one in 15 high school senior boys have used anabolic steroids.

Although nearly half of those using steroids said it was to improve athletic performance, 26.7 percent of 3,403 surveyed said appearance was the main reason.

"The majority of steroids are consumed by individuals who are concerned by how they look — factory workers, lawyers, policemen and firemen — and there is even a smaller market now in kids," U.S. attorney Phillip Halpern told The New York Times in a copyright series of stories last month.

The annual black market in steroids is estimated at $100 million. Officials told the Times there were from five to 20 clandestine labs in the United States manufacturing steroids. The rest come from outside the country.

When Olympian David Jenkins was sentenced earlier this month in San Diego for steroid trafficking, it was estimated that the Mexican smuggling ring in which he was involved was responsible for up to 70 percent of the drug in the United States.

"I get them as young as 12, 13, 14 and 15," Goldman said. "That's the new group we see coming in strong. What do they watch Saturday morning on television? Cartoons. And what do they all look like? He-Man. They all look like gorillas."

Goldman, a former weightlifter, said the drugs often are obtained by young people at private gyms or in their own school locker rooms in much the same way they might obtain cocaine on the playground.

"Wherever somebody's going to weight train, there's a market," Goldman said. "Here's a typical scenario. There's one muscular guy in the gym, and he's been working for $5 an hour. Now, he suddenly sees he can make thousands by selling steroids.

"Some of the transactions go on right in the locker rooms at the schools, the transactions as well as the shooting up. The kids store the stuff in their lockers."

Goldman said a teen-age user "can get started for $10 or $20" with a small bottle of one of the cheaper steroids. "Then, once they get into it, they can be spending hundreds of dollars a month," he said.

The Times' series quoted authorities as saying major distribution points were body-building gyms and fitness centers, where steroids can be purchased directly or a connection can be made.

"The scary part is, here we have the finest product of this country — our young, aggressive people — and we're going to have an entire patient population developing diseases they never should have had in the next five to 10 years," Goldman said. "And they're our finest product."

STATE OF KANSAS

DEPARTMENT OF HEALTH AND ENVIRONMENT
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Mike Hayden, *Governor*

Stanley C. Grant, Ph.D., *Secretary*
Gary K. Hulett, Ph.D., *Under Secretary*

Testimony Presented to

Senate Public Health and Welfare Committee

By

Kansas Department of Health and Environment

Senate Bill No. 181

Background

Senate Bill No. 181 precludes prescription distribution or administration of anabolic steroids (AS) or human growth hormone (HGH) to adults, adolescents or children with the following exceptions:

1. As an accepted treatment of medical disease, e.g., adrenal insufficiency, leukemia, collagen disease, etc.

2. For children and adolescents, "1) initiation of delayed puberty, 2) growth promotion, 3) treatment of micropenis, 4) treatment of hypogonadism"[1]

The exceptions must be under the supervision of a physician licensed to practice medicine and surgery, who is knowledgeable about potential adverse side effects of the prescribed medication in adults, adolescents, and children.

Adverse effects of anabolic steroids are formidable. these include benign and malignant tumors of the liver, toxic hepatitis, oligospermia (decreased sperm production), testicular atrophy, virilization (masculinization) of females, decreased high density lipoproteins with increased risk of coronary artery disease, acne, severe psychologic problems and gynecomastia in males. The most serious long term effect of anabolic steroids in adolescent males is acceleration of maturation resulting in premature closure of the epiphysis (growth centers) of the long bones and decrease in ultimate height.

Offenses will fall under felony charges judged by repetition and severity of the offense.

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Issues

In a recent article of the Journal of the American Medical Association, the prevalence of use of anabolic steroids among male high school seniors was 6.6%. Over two thirds of the user group initiated use at age 16 or younger. Primary sources of anabolic steroids was 60% black market, 21% physician, pharmacist and veterinarian. The remaining was either by mail order catalogue or other means.[2] Physicians licensed to practice medicine and surgery should be the only source of anabolic steroids for prescriptions for accepted usage.

Section 1(a)(3) designating the limitation placed on the amount of tablets or cubic centimeters of anabolic steroid that may be possessed does not accomplish what it intends to achieve. No method of monitoring the amount, the possessor of the amount or by whom monitoring will be done is presented. The only legal use of anabolic steroids or human growth hormones by an individual will be by prescription written by a physician for a "valid medical purpose."

The intent of the bill coincides with almost all sports organizations, including the American College of Sports Medicine[3] and the American Academy of Pediatrics[4] which condemn the use of anabolic steriods and human growth hormones "by a person who is in good health."

Recommendation

The Kansas Department of Health and Environment supports the passage of S.B. 181 with the following change:

> Delete 1(a)(3) as unnecessary to accomplish the intent of the bill.

Presented by:

Charles Konigsberg, Jr., M.D., M.P.H.
Director, Division of Health
Kansas Department of Health and Environment

1. Moore, W.V., Anabolic Steroid Use in Adolescence, JAMA, 260:3484, 1988.

2. Buckley, W.E., Yesalis, C.E. et al, Estimated Prevalence of Anabolic Steroid Use Among Male High School Students, JAMA, 260:3441, 1988.

3. American College of Sports Medicine: Position Statement on the Use and Abuse of Anabolic/Androgenic Steroids in Sports. Med. Sci. Sports, 19:534, 1987.

4. Committee on Sports Medicine Anabolic Steroids and the Adolescent Athlete, Pediatrics 83:127, 1989.

State of Kansas

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Board of Healing Arts

TO: Senate Committee on Public Health & Welfare

FROM: Richard G. Gannon, Executive Director

DATE: February 20, 1989

RE: TESTIMONY ON SENATE BILL NO. 198

The process to register Respiratory Therapists started in 1986 as mandated by the Legislature.

In order for an applicant to become registered in Kansas, they must first pass an examination approved by the Board. This examination is the Certification for Entry Level Respiratory Practitioners and is given by the NBRC (National Board Respiratory Care) and is given three (3) times a year. The sites of the examination are Wichita and Kansas City, Missouri.

There are a total of 71 sites throughout and an applicant is allowed to sit for the examination at any of the seventy-one sites.

Within the Respiratory Therapy field there is more than one level of credentialing. All applicants are registered as Respiratory Care Practitioners.

The cost of the examination depends on the level of entry an ranges from $75.00 to $190.00.

Applicants must pass with a scaled score of 75 (seventy-five).

This bill amends 65-5509 to change the fee of examination from $100.00 to $250.00.

Thank you for the opportunity to appear in support of this bill.

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Attachment 6

9 RS 0984

SENATE BILL NO. ____

AN ACT concerning the discharge of voluntary patients under the treatment act for mentally ill persons; amending K.S.A. 1988 Supp. 59-2907 and repealing the existing section.

Be it enacted by the Legislature of the State of Kansas:

Section 1. K.S.A. 1988 Supp. 59-2907 is hereby amended to read as follows: 59-2907. (a) The head of a treatment facility shall discharge a voluntary patient within a reasonable time but not to exceed three days, excluding Saturdays, Sundays and legal holidays, after the receipt of such patient's written request for discharge.

(b) If the voluntary patient is a minor, the written request for discharge shall be made by the minor's parent or person in loco parentis unless ~~the minor made written application to become a voluntary patient on the minor's own behalf or unless the minor is 16 or more years of age~~ the minor is 14 or more years of age. ~~If~~ A minor 14 or more years of age ~~who has made written application to become a voluntary patient on the minor's own behalf and has requested~~ may request to be discharged from the treatment facility. A minor who has been admitted to a treatment facility as a voluntary patient upon the written application of the parent or person in loco parentis to such minor and who is ~~16~~ 14 or more years of age may request to be discharged from the treatment facility. The head of the treatment facility shall promptly inform the minor's parent or other person in loco parentis of ~~the~~ any such request.

(c) Nothing in this act shall prevent the head of the treatment facility or other person from filing an application for determination of mental illness with respect to a voluntary patient who is refusing reasonable treatment efforts and is likely to cause harm to self or others if discharged.

Sec. 2. K.S.A. 1988 Supp. 59-2907 is hereby repealed.

Sec. 3. This act shall take effect and be in force from and after its publication in the statute book.

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Attachment 7

9 RS 0981

_____ BILL NO. _____

By

AN ACT authorizing the secretary of social and rehabilitation services to sell and convey certain property currently being used as a workshop for the blind.

Be it enacted by the Legislature of the State of Kansas:

Section 1. The secretary of social and rehabilitation services is authorized to sell and convey or lease on behalf of the state of Kansas the following described real estate otherwise known as the Kansas City workshop for the blind and any personal property located on such premises:

A tract of land situated in the southwest quarter (SW 1/4) of the southeast quarter (SE 1/4) of section 28, township 10 south, range 25 east of the sixth principal meridian, in Wyandotte county, Kansas, bounded and described as follows: Beginning at a point in the south line of Sunshine Road (formerly White Eagle Road) as originally established 66 feet, that is 483 feet distant east, measured at right angles, from the north and south center line of said section 28; thence east along the south line of Sunshine Road as originally established 66 feet wide a distance of 183.0 feet; thence southeasterly along a straight line which forms an angle of 45 degrees 4 feet from east to south with said south line of Sunshine Road as originally established, a distance of 38.13 feet, more or less, to a point 693 feet distant east, measured at right angles, from said north and south center line of section 28; thence south along a straight line parallel with and 393 feet distant east, measured at right angles, from said north and south center line of section 28, a distance of 36.62 feet; thence southerly and southwesterly along a tangent curve to the right, having a radius of 340.0 feet, a distance of 400.59 feet, more or less, to a point 483 feet distant east, measured at

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right angles, from said north and south center line of section 28; thence north along a straight line parallel with and 483 feet distant east, measured at right angles, from said north and south center line of section 28, a distance of 376.95 feet, more or less, to the point of beginning; containing an area of 60,611 square feet, more or less; subject to all covenants, restrictions, rights, liens and claims that shall run with the land.

Sec. 2. The secretary may sell or lease such real estate or personal property for one dollar and other good and valuable consideration and without the necessity of appraisal, bid or publication.

Sec. 3. The proceeds from the sale or lease of any property under the provisions of this act, after deducting the expenses of such sale or lease, shall be paid into the state treasury to the credit of the state general fund.

Sec. 4. In the event that the real estate described in section 1 is not continuously used as a workshop for the blind for ten years from the date of sale, ownership of the real estate shall automatically revert back to the state of Kansas. The title to the real estate shall revert back to the state of Kansas immediately upon discovery that the property is being used for an unintended purpose at any time during the ten-year period.

Sec. 5. This act shall take effect and be in force from and after its publication in the statute book.