Approved 3-29-89
Date

MINUTES OF THE HOUSE COMMITTEE ON PUBLIC HEALTH AND WELFARE.

The meeting was called to order by Marvin L. Littlejohn
Chairperson at

1:30 a.m./p.m. on March 22, 1989 in room 423-S of the Capitol.

All members were present except:

Committee staff present:

Emalene Correll, Research
Bill Wolff, Research
Norman Furse, Revisor
Sue Hill, Committee Secretary

Conferees appearing before the committee:

Dennis Priest, (speaking for John Alquist) Income Maintenance Medical Services, Department of SRS
Ester Wolf, Secretary of Department on Aging
Mark Intermill, Kansas Coalition on Aging
Robert C. Guthrie, Alzheimers Association, (Printed testimony only)
Frank Lawler, Chairman Ks. State AARP Legislative Committee (Printed testimony only)
Richard Gannon, State Board Healing Arts
Tom Hitchcock, Kansas Board of Pharmacy
Chip Wheelen, Kansas Medical Society
Dr. Charles Konigsberg, Director/Division of Health/Ks. Department of Health/Environment
Kyle Smith, Assistant Attorney General/ Division of K.B.I.

Chairman called meeting to order and invited testimony to begin on bills to be heard this date. **SB 15, Sub. for SB 181, SB 287, SB 293.**

HEARINGS BEGAN ON SB 15.

Dennis Priest, speaking in behalf of John Alquist, Department of SRS, (Income Maintenance Medical Services, (Attachment No. 1). He highlighted differences between state and federal law in regard to division of assets, noting as the federal law takes effect October 1, 1989, the states are mandated to adopt its provisions, SB 15 seeks to suspend the State's current division law. The bill also allows for this suspension to be automatically lifted if the federal provisions do not take effect in accordance with medicare legislation. He detailed provisions on transfer of property, i.e., application only to persons receiving long term institutional care or home-community based services; 30 month time period in which transfers can affect eligibility; permits only transfers of the home to a spouse or to certain children or siblings of recipient. He noted the provisions regarding division of assets and permitting the federal law to pre-empt the state law will be beneficial to clients. Use of the suspension measure he noted was agreed upon by Senate Public Health/Welfare Committee,Revisor of Statutes,Departments on Aging, SRS. They support SB 15. He answered numerous questions, i.e., yes,SB 15 will allow for a smooth transition; yes, we recommend the bill be passed in its entirety; yes, there is a possibility the federal law might not go into effect as planned.

HEARINGS CONTINUED ON SB 15:--

Ester Wolf, Secretary of Department on Aging, noted their Department has given high priority to working on the Division of Assets, and with Federal Regulations. They are in full support of SB 15. She introduced Ms. Claire McCurdy who will continue to track the progress of this type of legislation. (Ms. McCurdy is Attorney for Department On Aging.

Mark Intermill, Kansas Coalition on Aging, (Attachment No. 2), spoke in support of SB 15 as amended by the Senate Public Health/Welfare Committee. He noted their Association was in opposition to the bill as originally drafted, because it meant that Kansans would have to depend solely on the Medicare Catastrophic Coverage Act for spousal impoverishment protection. The amendment in the Senate has the effect of suspending the division of assets law, rather than repealing it. Suspension removes the potential conflict with federal law, and assures spousal impoverishment protection will be available to Kansans whose spouses reside in a nursing home. We believe this is an appropriate course of action, he said, and support SB 15 as amended.

Noted: (Attachment No. 3), Robert Guthrie, Alzheimers Association had presented printed testimony only as he was unable to attend meeting. (Attachment No.4), from Frank Lawler, Chairman Kansas State AARP Legislative Committee offered printed testimony only as well.

HEARINGS CLOSED ON SB 15.

HEARINGS BEGAN ON SUBSTITUTE FOR SB 181.

Richard Gannon, Executive Director of Ks. Board of Healing Arts, (Attachment No. 5), offered support to SB 181. He noted the uncontrolled and harmful use of anabolic steroids, particularly among young athletes, is an increasing hazard to the health of our young Kansans, and has caused great concern. He noted three examples of anabolic steroids, i.e., Anavar, Anadrol, and Winstrol. He explained side effects of these drugs, and drew attention to hand-out, i.e., product information giving data on drug use, adverse reactions, safety information; also a lengthy article from Sports Illustrated which indicates activities of a young athlete in Ohio and his use of steroids which had perhaps lead to his death. He stated statistics on the growing problem of underground sales of these drugs, and asked that SB 181 be approved favorably so that our State can send a message to those who peddle these drugs unlawfully will pay a high penalty. He answered numerous questions, i.e., our licensees are very concerned as these drugs are being sold by gyms, and other sources, they are not being abused by physician over prescribing them; 4 or 5 other states have put these drugs on the Controlled Substance List.

Tom Hitchcock, Executive Secretary, Kansas Board of Pharmacy, (Attachment No. 6), noted the misuse and abuse of anabolic steroids is a large problem in Kansas. His testimony indicates specifics in deaths and severe health disorders being caused by misuse of these drugs. He urged the passage of SB 181, as an effort to curb this problem. He noted a technical error, (spelling) on Page 3, line 115, should be Stanozolol.

Chip Wheelen, Kansas Medical Society, (Attachment No. 7), spoke in support of SB 181, noting the bill will also allow for the continuing of prescribing steroids in cases where it is beneficial for certain medical treatments. He noted the bill provides penalties for those in violation, and asked for favorable passage.

MINUTES OF THE HOUSE COMMITTEE ON PUBLIC HEALTH AND WELFARE,

room 423-S, Statehouse, at 1:30 a.m./p.m. on March 22, 1989.

HEARINGS CONTINUED ON SUB-SB 181:

Dr. Charles Konigsberg, Director, Division of Health/Department of, Division of Health/ Department of Health/Environment, (Attachment No. 8), highlighted the exceptions of use of anabolic steroids under which a licensed physician must supervise such use. He detailed adverse effects of use of anabolic steroids, cited specifics on prevalence of use by high school males. Primary source of supply to these youngsters was 60% by black market, 21% by physician, pharmacist, and veterinarian. The remaining 19% was obtained by mail order catalog/or other unspecified means. He noted many sports related organizations including American College of Sports Medicine/American Academy of Pediatrics condemn the use of anabolic steroids "by a person who is in good health". He noted their Department is in support of SB 181.
Kyle Smith, Assistant Attorney General, Division of K.B.I., noted they have had their hands tied by controlling the abuse of these drugs since they are not on the Controlled Susbstance List. With SB 181 passed, they will be more effective in controlling black-market and illegal sale to young athletes. We need to send the message to kids about the ramifications that can be caused by the misuse of anabolic steroids.

HEARINGS CLOSED ON SUB. SB 181.

HEARINGS BEGAN ON SB 287.

Richard Gannon, Executive Director, Bd. Healing Arts, (Attachment No.9) explained rationale for SB 287. It was noted the need to process and issue temporary educational licensure to physicians coming to Kansas to obtain specialized training from our Accredited State Institutions or Affiliates. Kansas is proud to have the caliber of physicians that can share their State of the Art expertise. It was noted that the very top of the medical profession come to Dr. Joseph Galichia with the
Institute for Clinical Research, (Cardiovascular Group) who teaches techniques to individuals coming from all over the World. He noted with SB 287, Board will be able to streamline their process. He answered numerous questions, i.e., yes, the public will be protected; yes, these physicians must be fully licensed; yes, they monitor carefully those from other countries whose standards might be lower than American requirements. There was lengthy discussion in regard to "accredited medical education programs", and perhaps some language in the bill is more restrictive than the Board had intended. It was noted that medical technology is World Wide anymore, these learning sessions are an exchange of extremely complicated medical procedures. There was discussion in regard to coverage for liability.

Chip Wheelen, Kansas Medical Society noted short term liability coverage for visiting physicians is available.

HEARINGS CLOSED ON SB 287.

HEARINGS BEGAN ON SB 293.

Tom Hitchcock, Executive Director, Kansas Board of Pharmacy, (Attachment No. 10) spoke to support of SB 293, noting it was technical in nature, i.e., correct spelling of names of drugs, correct typographical errors, properly alphabetize names of drugs; list correctly new drugs, with all such action described in detail in his testimony. He noted with this accomplished, it will bring the bill into uniformity. He answered questions, i.e., they are continually having to list new drugs and this could/should be done each year.

It was noted that Sub. SB 181 relating to controlled substances and SB 293 could be combined if that is the wish of the committee.

MINUTES OF THE HOUSE COMMITTEE ON PUBLIC HEALTH AND WELFARE,

room 423-S Statehouse, at 1:30 ~~a.m./~~p.m. on March 22, 1989

HEARINGS CONTINUED ON SB 293:----

Kyle Smith, Assistant Attorney General, Division of K.B.I., stated Mr. Hitchcock and his Department have worked long and hard and are attempting to maintain a current list on controlled substances. He noted with these changes proposed, and a proper list being maintained, it will make their job a bit easier.

HEARING CLOSED ON SB 293.

Rep. Amos made motion to approve committee minutes of March 15th and March 20th as written, seconded by Rep. Weimer. Motion carried.

Chair noted action will be taken on Monday on bills heard this date.

Meeting adjourned.

GUEST REGISTER

HOUSE PUBLIC HEALTH AND WELFARE COMMITTEE

Date March 22, 1989

Name	Organization	Address
Kyle Smith	Atty. Gen. - KBI	Topeka, KS
Chip Wheelen	Ks Medical Society	Topeka
[illegible]	Bd of Healing Arts	"
Larry Buening	Bd of Healing Arts	Topeka
Charles Konigsberg, M.D.	KDHE	Topeka
Bob Williams	Ks Pharmacist's Assoc	Topeka
Tom Hitchcock	Bd of Pharmacy	"
KEITH R. LANDIS	CHRISTIAN SCIENCE COMMITTEE ON PUBLICATION FOR KANSAS	"
Jacque Oakes	PA	Topeka
Willynda Holmes	leg. asst.	Topeka
Barbara Joseph	AP	
OREN DOUGHERTY	ELI LILLY AND COMPANY	
Mark Intermill	KCOA	Topeka
Esther V Wolf	KDoAging	Topeka
Claire McCurdy	Aging	Topeka
Virginia McGrath	UPI	"
Anne Smith	Hein & Ebert	Topeka

Dennis Present testimony SRS

Department of Social and Rehabilitation Services

Winston Barton - Secretary

Statement regarding: Senate Bill No. 15

Title: An act relating to public assistance; relating to determination of persons eligible for assistance.

Purpose: The bill primarily accomplishes 2 purposes. First, it suspends the State's division of assets law effective September 30, 1989 based on implementation of similar federal provisions which were included in the Medicare Catastrophic Coverage Act of 1988. Second, it repeals sections of state statute regarding transfer of property in the public and medical assistance programs as specific federal transfer provisions were written into Medicaid law also as a result of the Medicare Catastrophic Coverage Act of 1988.

Background: In regards to the division of assets provisions within the bill, a federal division of assets policy was contained within the Medicare Catastropohic Coverage Act of 1988. This policy for the most part parallels the State's division of assets law which took effect on May 1, 1988. The primary differences between the state and federal law are in regards to the division limits and rights of the recipient and include the following:

1. A higher resource division limit is contained in the federal law ($60,000 maximum vs. $50,000 maximum under State policy). In addition, under the federal law, the $12,000 minimum division level can be increased up to $60,000.

2. A higher income division limit is contained in the federal law (122% of the federal poverty level for 1989 or $815/month vs. $781/month under State policy). In addition, the federal law raises the income limit to 133% of poverty on July 1, 1991 and to 150% of poverty on July 1, 1992.

3. A higher income division cap is contained in the federal law ($1500/month maximum vs. $1250/month maximum under State policy).

4. An additional income allowance is provided under federal law for other dependents, including children, who live with the community spouse (the State law has no such provision).

5. A fair hearing process is established under federal law if either spouse is dissatisfied with the resource or income division determination (not clear under State law).

6. There is no requirement for notices of intent or interspousal agreements to divide under the federal law (State law mandates these).

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The remaining provisions of the federal and state laws are similar in nature.

As the federal law takes effect on October 1, 1989 and States are mandated to adopt its provisions, Senate Bill No. 15 seeks to suspend the State's current division law. The bill also allows for this suspension to be automatically

lifted if the federal provisions do not take effect in accordance with the Medicare legislation, thus allowing the agency to revert back to the State provisions.

In regards to the transfer of property provisions within the bill, the Medicare Catastrophic Coverage Act made several fundamental changes in the Medicaid transfer policy which resulted in the need to modify state statute in this area. The transfer policy allows for a period of ineligibility if an individual disposes of a resource for less than fair market value. Those changes include:

1. Application of the transfer provisions only to persons who are receiving long term institutional care or home-and community based services (HCBS). Thus, if a person who is living independently gives away all of his or her resources, a penalty would no longer be applied unless he or she were to go into long term care within the 30 month period described below.

   Current state statute would apply a penalty regardless of the person's living arrangement.

2. A set 30 month time period in which transfers can affect eligibility. Persons who dispose of resources for less than fair market value in a 30 month period before or after the date they enter long term care can be penalized for up to 30 months.

   Current state statute looks at and penalizes such transfers up to 24 months from the date of transfer if the transfer was for less than $12,000 and, based on state regulation, up to 5 years if the transfer was for $12,000 or more.

3. Permits only transfers of the home to a spouse or to certain children or siblings of the recipient and transfers to the community spouse under the federal division of assets law without penalty.

   Current state regulations would permit transfers of all exempted resources (including the home) without penalty regardless of who they are transferred to as well as transfers under the State division of assets law.

Senate Bill No. 15 deletes from statute all provisions regarding transfer of property effective July 1, 1989 as the federal law is mandatory and will supersede State law for Medicaid purposes. In addition, the bill eliminates state transfer provisions for the cash assistance as well as the medical assistance programs. Thus, although transfers occurring in regards to Medicaid eligibility will be reviewed under the above federal policy, they will no longer affect eligibility in the cash programs.

This additional change was done based on the Department's recommendation that the transfer policy be applied only to the Medicaid program and no longer to either the Aid to Families With Dependent Children (AFDC) or the General Assistance (GA) program. There were several reasons for making this change. First, with the new federal requirements in the Medicaid program, the Department would be faced with implementing 2 separate and conflicting transfer provisions in its cash and medical programs. Second, the transfer policy in the AFDC and

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GA programs is an optional one and is not mandated under federal law. Third, and most important, the transfer policy is rarely applied in the cash programs as most cash eligible clients do not have any substantive resources to transfer to begin with. Most transfers which occur and may be subject to penalty are those done to qualify for medical assistance, particularly long term care.

Effect of Passage: The provisions regarding division of assets and permitting the federal law to pre-empt the state law will be beneficial to clients. The federal provisions are felt to be more liberal on the whole and may result in an increase in eligible clients over the next few years. The provisions especially allow for greater protection of the community spouse both in terms of income and resources.

The new federal provisions will affect the agency in several ways. Policies and procedures will need to be altered and field staff trained on the differences. Other administrative changes will also need to be made in terms of regulations, outreach materials, federal reporting, state plan amendments, forms, etc. Expenditures are not expected to substantially increase for FY 1990 but will probably increase in future fiscal years especially as the higher income levels under the federal law take effect.

Community agencies and other state departments, particularly the Department on Aging, will be impacted as well. The new policies and procedures will need to be analyzed and reviewed and outreach efforts and materials will need to be revised to reflect the new guidelines. Both SRS and the Department on Aging will need to work together on a coordinated strategy to convey to the public why this action is being taken and the benefits of the federal law.

In regards to the transfer of property provisions, a small number of cash assistance clients may be benefited by the elimination of transfer penalties. From the Medicaid side, certain clients may be benefited by the elimination of transfer penalties for persons who remain in independent living. Those who need long term care may also be benefited by the shortened look back and penalty period of 30 months (vs. up to 5 years under current State policy). Others may be disadvantaged by the more restrictive policy on what resources may be transferred without penalty.

From the Department's standpoint, the new federal law will somewhat simplify current transfer policy because of its limited application and consolidation of the penalty periods. Policies and procedures will need to be revised and field staff retrained. As with the division of assets impact, other administrative changes will be necessary. The changes are not expected to have any discernable fiscal impact. As earlier described, few transfer penalties have been applied in the cash programs so that elimination of this policy should result in only a minimal increase in expenditures. The same is felt to be true regarding the federal changes on the Medicaid side. Although the period of ineligibility is capped at 30 months and applies only to persons in long term care settings, most transfer penalties which occur under present State law are within this period of time and most of the transfers generally take place as a result of placement into long term care.

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pg 3
3-22-9

Recommendations: In regards to the portions of the bill dealing with the suspension of the State's division of assets law, the Department supports the action being taken. While the initial version of S.B. 15 sought to repeal the division law, that version raised a number of concerns among the groups and individuals who helped create the current law. As a result, members of the Senate Public Health and Welfare Committee along with the Revisor of Statutes and representatives from the Department on Aging and SRS met and agreed upon use of the suspension measure rather than a total repeal of the State law. Such action keeps the division law on the books so that if the federal provisions are later rescinded, the State will be able to reimplement the State provisions without the need for further legislative action and without the potential for gaps in coverage.

The Department also supports the provisions of the bill regarding transfer of property. This action is needed to allow the Department to comply with the new federal provision which is already in effect.

John W. Alquest
Commissioner, Income Maintenance
and Medical Services
296-6750

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3-22-9

Testimony on Senate Bill 15
Senate Public Health and Welfare Committee
March 21, 1989
Presented by Mark Intermill
For the Kansas Coalition on Aging

My name is Mark Intermill. I am the Director of the Kansas Coalition on Aging. I appreciate the opportunity to appear before the committee this morning to express the support of KCOA for SB 15, as amended by the Senate Public Health & Welfare Committee.

KCOA opposed SB 15 as it was originally drafted. In its original form, SB 15 would have repealed the Kansas division of assets law as of September 30, 1989, the date when the spousal impoverishment protection provisions of the Medicare Catastrophic Coverage Act are scheduled to take effect. The rationale for repealing the law was to remove a section of Kansas law which was redundant and may have been in conflict with federal law.

We opposed repeal of the division of assets law because it would have meant that Kansans would have to depend solely on the Medicare Catastrophic Coverage Act for spousal impoverishment protection. There are currently two bills before Congress which would have the effect of delaying or precluding the implementation of the Medicare Catastrophic Coverage Act. If Kansas' division of assets law is repealed and subsequent to repeal, the Medicare Catastrophic Coverage Act were repealed, Kansans would have been left without protections against spousal impoverishment.

The action taken in the Senate has the effect of suspending the division of assets law rather than repealing it. Suspension removes the potential conflict with federal law, and assures that spousal impoverishment protection will be available to Kansans whose spouses reside in a nursing home. We believe that suspension of the Kansas law is an appropriate course of action and support SB 15, as amended by the Senate Public Health & Welfare Committee.

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attm. # 2
3-22-9

ALZHEIMER'S ASSOCIATION
Someone to Stand By You.

DATE: March 16, 1989

TO: Members House Public Health & Welfare Committee

FROM: Marcene Grimes, Executive Director, Topeka Chapter

RE: Senate Bill 15

Attached please find a copy of the testimony presented by Robert C. Guthrie to the Senate Public Health and Welfare Committee on January 18 in opposition to repeal of the Kansas Division of Assets law.

Mr. Guthrie had to leave town and will be unable to appear at your hearings March 21 and 22. He asked me to convey his satisfaction with the amendments to Senate Bill 15 which provide for "suspension" of the Kansas law in lieu of repeal, for reasons expressed in his written testimony.

The forthcoming issue of our Chapter's quarterly newsletter expresses our organization's satisfaction with this way of handling the issue and we sincerely hope you will agree.

P&A W
Attm #3
3-22-9

SENATE PUBLIC HEALTH AND WELFARE COMMITTEE
SENATOR ROY M. EHRLICH, CHAIRPERSON
TESTIMONY OF ROBERT C. GUTHRIE, TOPEKA, KANSAS
SENATE BILL NO. 15 - RE: PROPOSAL NO. 39
JANUARY 18, 1989

QUALIFICATIONS

My name is Robert C. Guthrie of Topeka, Kansas. I speak in opposition to Senate Bill No. 15. My brief remarks are made as a member of The Kansas Alzheimer's Disease Task Force of 1985 and a member and past president of the Alzheimer's Disease Association, Topeka Chapter. During the 1987 and 1988 Sessions of the Legislature, I testified several times before this Committee and the House of Representative Judiciary Committee. I am a retired Senior Vice President and Director of Bank IV, Topeka, formerly The First National Bank of Topeka. Preceding my banking career, I graduated from the University of Kansas with a B. S. degree in Finance.

PERSONAL EXPERIENCE

My own personal experience has been to witness, since 1982, the slow, irreversible organic disease diagnosed as Alzheimer's, slowly incapacitating my bright, talented wife. She is now in The Skilled Care Nursing unit of Aldergate Village Health Care Center here in Topeka. The point I wish to emphasize today is that throughout my service on the State Alzheimer's Task Force and as a member of the Alzheimer's Association, Topeka Chapter, I talked to many spouses and family members who saw themselves being spent into poverty. The despair brought about by this, plus the grief of the long terminal illness of a loved one was devastating. My pride in seeing Kansas be a leader in adopting legislation like Senate Bill No. 264 was considerable. The Bill passed through the Legislature without dissent.

PRESENT SITUATION

That the Kansas Division of Assets and Income Law might be repealed because Congress later passed the Medicare Catastrophic Protection Act, which also contains provisions to ease the burden of spousal impoverishment, is causing considerable worry and stress among older Kansans facing financial impoverishment. The Governor, in his State of the State Message on January 9, 1989 said that "We have been aggressive in our attempts to preserve access to the kind of health care that our citizens deserve. A major accomplishment in this regard is last year's passage of a Division of Assets Law." Quoting further Governor Hayden said "Prior to enactment of the Division of Assets Law, older Kansans were faced with the threat of seeing their life savings disappear when a spouse fell victim to a catastrophic illness.

P&W
Attm #3
3-22-9

This situation has changed. To date more than 400 Kansans and their families have been helped by the Division of Assets initiative. Older Kansans can now be assured that poverty need not accompany a long term illness."

CONCLUSION

The Alzheimer's Disease Association, Topeka Chapter, knows that Senate Bill No. 15 embodies protective language. Repeal of K.S.A. 1988 Supp. 39-785 through 39-790 would be void if the Federal Act and payments thereunder did not commence for the calendar quarters beginning September 30, 1989, the date of repeal of the Kansas Legislation. But the Federal Act might become effective and later be amended or repealed. Based on news releases, there is growing sentiment in the Congress to amend or repeal the Federal Act.

The Kansans for whom I speak cannot see any need to rush the repeal of Senate Bill No. 264. This Kansas Session will be over before we know what Congress may do. How can Kansas members of the Legislature respond to their constituents should the benefits of Senate Bill No. 264 be allowed to slip away?

Thank You.

Robert C. Guthrie
3000 West 19th St.
Topeka, Kansas 66604

P&W
attm #3
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3-22-9

KANSAS STATE LEGISLATIVE COMMITTEE

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TESTIMONY

REGARDING SENATE BILL NO. 0015
KANSAS STATE LEGISLATIVE COMMITTEE OF AARP
March 22, 1989

After studying the original SB-15 and the Interim Committee's conclusions and recommendations, AARP's State Legislative Committee presented to the Senate Public Health and Welfare Committee testimony which opposed the original intent to repeal the Kansas Division of Assets law.

The principal objections of AARP's State Legislative Committee rested upon our concern for the very unstable situation in Congress relative to the Catastrophic Care Act. Legislation had been prepared calling for the repeal of the Act and other members of congress were readying amendments to the Act. Under these conditions it did not seem timely to repeal the Kansas Division of Assets law, thereby leaving concerned Kansans with nothing more than hope. Also, we question whether there was any publics awareness of our legislature's plans to repeal the Kansas law as we felt it was very likely such knowledge would foster considerable citizen concern. The Kansas act was viewed as the answer to many Kansans fears for their future. It was an act that offered benefits not just for the elderly couples but for their immediate and extended family.

AARP's State Legislative Committee now feels that the amended bill "to suspend rather than repeal the Kansas statute" relieves our original concerns. However, the State Legislative Committee reserves its final decision, dependent upon the concurrence of the House Committee on Public Health and Welfare to also agree to suspend and not to repeal the existing Kansas statute which provides for the division of assets and resources until the provisions of the federal act becomes operative in Kansas and hopefully with maximum benefits.

Frank Lawler, Chairman

PN&C attm #4 3-22-9

State of Kansas

Office of
RICHARD G. GANNON, EXECUTIVE DIRECTOR
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Board of Healing Arts

TO: House Committee on Public Health & Welfare

FROM: Richard G. Gannon, Executive Director

DATE: March 21, 1989

RE: SENATE BILL NO. 181

Thank you for the opportunity to appear before you and express the strong support of the Board of Healing Arts for Substitute for SB No. 181. As you will be able to determine, technical expertise for this testimony has been provided by several licensees and Board members who have profound concern for the potential for harm caused by the illicit use of anabolic steroids.

The uncontrolled and harmful use of anabolic steroids, particularly 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 misused.

There are a few specified medical uses for these drugs, as described in the attached pages from the Physicians' Desk Reference for Anavar, Anadrol, and Winstrol, these three being examples of anabolic steroids. However, these are such specialized and unusual situations that many physicians want an endocrinologist or a hematologist to prescribe them.

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Attm #5
3-22-9

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 significant 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 prematurely 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 <u>amazing</u> to realize how relatively inexpensive and available these drugs are to the young of our State.

Although fatalities have been poorly publicized, the attached article from the February 20, 1989, issue of <u>Sports Illustrated</u>, widely shows the sad death of an young athlete who used steroids.

I realize that listing anabolic steroids as Schedule IV controlled substances and providing specific penalties for their unlawful possession, sale and distribution will not totally alleviate their use any more than such laws have eliminated heroin, PCP and cocaine use. However, it will send a message to those that peddle these dangerous drugs to our young people that if they are caught there will be a heavy price to pay. Therefore, the Board urges passage of Substitute for SB No. 181.

I am happy to answer any questions you might have.

RGG:LTB:sl

Attachments - 2

PHW
attm #5
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88 PDR

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

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

...PPLIED

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

...50 mg 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-

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

... Federal law prohibits dispensing without pre-

AO5446-7

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

...PHYLLIN™ Tablets ℞

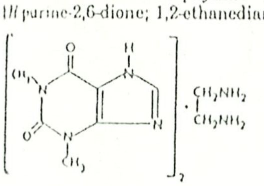
...[...lin]

...

...PTION

... tablet 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 ... ethylenediamine. Aminophylline is white or slightly ... granules or powder, having a slight ammoniacal ... bitter taste.

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



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

...

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

...IONS 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 ... 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... 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-... severe asthmatic episodes in certain sus-... The overall prevalence of sulfite sensitivity ... population is unknown and probably low. Sul-fite 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.

AO5230-9

Shown in Product Identification Section, page 429

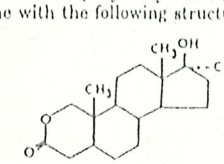
ANAVAR® ℞

[*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

PH&W #5893 3-22-9

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* [illegible] 0.25 mg per kilogram or 0.12 mg per pound of [illegible] This may be repeated intermittently as [illegible] indicated.

HOW SUPPLIED

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

Federal law prohibits dispensing without [illegible]

Shown in Product Identification Section

CALAN® Tablets
[*cal'an*]
(verapamil hydrochloride)

PRODUCT OVERVIEW

KEY FACTS

Calan, a calcium ion antagonist, exerts its [illegible] effects by modulating the influx of ionic calcium [illegible] cell membrane of the arterial smooth muscle [illegible] conductile and contractile myocardial cells. Calan [illegible] myocardial oxygen supply, reduces myocardial [illegible] sumption, and is a potent inhibitor of coronary [illegible] making it an effective antianginal agent. By [illegible] influx of calcium, Calan prolongs the effective [illegible] period within the AV node and slows AV [illegible] rate-related manner, thereby slowing the ventricular [illegible] patients with chronic atrial flutter or fibrillation [illegible] erts antihypertensive effects by decreasing peripheral [illegible] lar resistance, usually without orthostatic decrease [illegible] pressure or reflex tachycardia.

MAJOR USES

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

SAFETY INFORMATION

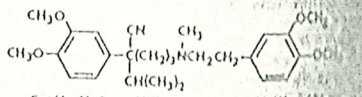
See complete safety information set forth below.

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 120 mg of verapamil hydrochloride.

The structural formula of verapamil HCl is



$C_{27}H_{38}N_2O_4 \cdot HCl$ M.W. 491

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] tically free of odor, with a bitter taste. It is soluble [illegible] chloroform, and methanol. Verapamil HCl is [illegible] related to other cardioactive drugs.

Inactive ingredients include cellulose, corn [illegible] hydroxypropyl cellulose, hydroxypropyl methylcellulose [illegible] iron oxide, lactose, magnesium stearate, polyethylene [illegible] talc, and titanium dioxide.

CLINICAL PHARMACOLOGY

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

Mechanism of action

Angina: The precise mechanism of action of Calan [illegible] antianginal agent remains to be fully determined, but [illegible] cludes 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 induced by [illegible] 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

...A-PEEL

...ION
...EEL is a wafer skin protectant containing the ... hydrophilic polymer—to provide moisture ... molecular weight synthetic rubber poly... elasticity and strength; low molecular ... rubber polymers—to provide adhesion to ... karaya gum powder—to provide adhesion to ...

...IONS AND USAGE
...A-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 ... occurrence of decubitus ulcers. SWEEN-A-PEEL ... effective when incorporated into a decubitus ... procedure.

...INDICATIONS
...ivity to any components of the preparation.

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

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

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

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

...N CREAM...
...
... Cream

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

...TIONS 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 ... Also apply to folds of skin subject to perspi... to dry or cracked skin and to pressure sensi... For ostomy care, apply a small amount on peristo... protection before attaching appliance. This re... and improves adhesion.

...RAINDICATIONS
...tivity to any components of the preparation.

...UTIONS AND ADVERSE REACTIONS
...al Use Only. Avoid contact with eyes. SWEEN ... by oral ingestion and is not considered a ... or skin irritant under normal use conditions.

...E AND ADMINISTRATION
... as required.

...SUPPLIED
... tubes, 2 oz. and 9 oz. jars; 3 oz. pump.

...N PREP...
...
... Barrier Film

...IPTION
... a medicated, liquid skin barrier which con... (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).

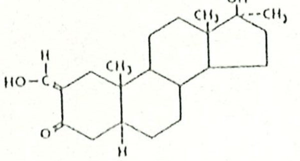
Syntex (F.P.) Inc.
HUMACAO, PUERTO RICO 00661

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 testes.

INDICATIONS AND USAGE
ANADROL-50 is indicated in the treatment of anemias 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 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 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

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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 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.
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-metayl-, 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 dysmenorrhea. In dysmenorrheic patients, the drug reduc... level of pros... in the uterus, which correlates with a reduction in... quency and severity of uterine contractions. Anal... tion has been shown by such measures as reduction... intensity scores, increase in pain relief scores, de... number of patients requiring additional analges... tion, and delay in time for required remedication... gesic effect has been found to last for up to 7 hours.
The drug was studied in patients with rheumatoid... osteoarthritis, ankylosing spondylitis, tendinitis... tis, and acute gout. It is not a corticosteroid. Improv... patients treated for rheumatoid arthritis has been... strated by a reduction in joint swelling, a reduction... reduction in duration of morning stiffness, a red... disease activity as assessed by both the investigat... tient, and by increased mobility as demonstrated by... tion in walking time.
In patients with osteoarthritis, the therapeutic ... drug has been shown by a reduction in joint pain... ness, an increase in range of motion in knee joints... mobility as demonstrated by a reduction in walk... and improvement in capacity to perform activit... living impaired by the disease.
In clinical studies in patients with rheumatoid ar... osteoarthritis, the drug has been shown to be com... aspirin and indomethacin in controlling the afore... measures of disease activity, but the frequency and... of the milder gastrointestinal adverse effects (n... pepsia, heartburn) and nervous system adverse e... tus, dizziness, lightheadedness) were less than in... aspirin- and indomethacin-treated patients. It is... whether the drug causes less peptic ulceration th...
In patients with ankylosing spondylitis, the drug ... shown to decrease night pain, morning stiffness... rest. In double-blind studies the drug was shown... fective as aspirin, but with fewer side effects.
In patients with acute gout, a favorable respon... was shown by significant clearing of inflammat... (e.g., decrease in swelling, heat) within 24-48 hours... as by relief of pain and tenderness.
The drug may be used safely in combination with... and/or corticosteroids; however, in controlled clin... when added to the regimen of patients receiving... oids it did not appear to cause greater improve... that seen with corticosteroids alone. Whether th... be used in conjunction with partially effective... costeroid for a "steroid-sparing" effect has ... quately studied. When added to the regimen of ... ceiving gold salts, the drug did result in greater... ment. Its use in combination with salicylates is... mended because data are inadequate to demo... the drug produces greater improvement over th... with aspirin alone. Further, there is some evide... rin increases the rate of excretion of the drug.
Generally, improvement due to the drug has not ... to be dependent on age, sex, severity or duratio...
In ^{51}Cr blood loss and gastroscopy studies with ... teers, daily administration of 1100 mg of ANA... proxen sodium) has been demonstrated to cause... significantly less gastric bleeding and erosion th... of aspirin.

INDICATIONS AND USAGE

ANAPROX (naproxen sodium) is indicated in ... mild to moderate pain and for the treatment of ... menorrhea.
It is also indicated for the treatment of rheumato... osteoarthritis, ankylosing spondylitis, tendinit... tis, and acute gout.

CONTRAINDICATIONS

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

WARNINGS

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

#5 Ogi 3-22-9

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 ([illegible] °F).

Distributed by Winthrop Breon Laboratories
Division of Sterling Drug Inc. New York, NY 10016
Manufactured by [illegible] Sterling Pharmaceuticals Inc.
Barceloneta, Puerto Rico 00617

TW 275-I

TRANCOPAL® ℞

brand of chlormezanone
Non-[illegible] Antianxiety Agent

DESCRIPTION

TRANCOPAL, brand of chlormezanone, is [2-(p-Chloro[illegible]]-3-methyl-4H-1,3-thiazin-4-one 1,1-di-oxide], 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® ℞

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 [illegible] the testes.

WINSTROL has been found to increase low-density lipo[illegible]teins and decrease high-density lipoproteins. These cha[illegible] are not associated with any increase in total cholester[illegible] triglyceride levels and revert to normal on discontinua[illegible] treatment.

Hereditary angioedema (HAE) is an autosomal dom[illegible] disorder caused by a deficient or nonfunctional C1 est[illegible] inhibitor (C1 INH) and clinically characterized by episo[illegible] swelling of the face, extremities, genitalia, bowel wall, [illegible] upper respiratory tract.

In small scale clinical studies, stanozolol was effecti[illegible] controlling the frequency and severity of attacks of [illegible] edema and in increasing serum levels of C1 INH and C[illegible] WINSTROL is not effective in stopping HAE attacks [illegible] they are under way. The effect of WINSTROL on incre[illegible] serum levels of C1 INH and C4 may be related to an incr[illegible] in protein anabolism.

INDICATIONS AND USAGE

Hereditary Angioedema. WINSTROL is indicated prophyl[illegible]tically to decrease the frequency and severity of attack[illegible] angioedema.

CONTRAINDICATIONS

The use of WINSTROL is contraindicated in the followi[illegible]

1. Male patients with carcinoma of the breast, or with kn[illegible] or suspected carcinoma of the prostate.
2. Carcinoma of the breast in females with hypercalc[illegible] androgenic anabolic steroids may stimulate oste[illegible] resorption of bone.
3. Nephrosis or the nephrotic phase of nephritis.
4. WINSTROL can cause fetal harm when administered [illegible] pregnant woman.

WINSTROL is contraindicated in women who are or [illegible] become pregnant. If this drug is used during pregnancy, [illegible] the patient becomes pregnant while taking this drug, [illegible] patient should be apprised of the potential hazard to th[illegible] tus.

WARNINGS

PELIOSIS HEPATIS, A CONDITION IN WHICH LIVER AND SOMETIMES SPLENIC TISSUE IS RE-PLACED WITH BLOOD-FILLED CYSTS, HAS BEEN REPORTED IN PATIENTS RECEIVING ANDRO-GENIC ANABOLIC STEROID THERAPY. THESE CYSTS ARE SOMETIMES PRESENT WITH MINI-MAL HEPATIC DYSFUNCTION, BUT AT OTHER TIMES THEY HAVE BEEN ASSOCIATED WITH LIVER FAILURE. THEY ARE OFTEN NOT RECOG-NIZED UNTIL LIFE-THREATENING LIVER FAIL-URE OR INTRA-ABDOMINAL HEMORRHAGE DE-VELOPS. WITHDRAWAL OF DRUG USUALLY RE-SULTS IN COMPLETE DISAPPEARANCE OF LE-SIONS.

LIVER CELL TUMORS ARE ALSO REPORTED. MOST OFTEN THESE TUMORS ARE BENIGN AND ANDROGEN-DEPENDENT, BUT FATAL MALIG-NANT TUMORS HAVE BEEN REPORTED. WITH-DRAWAL OF DRUG OFTEN RESULTS IN REGRES-SION OR CESSATION OF PROGRESSION OF THE TUMOR. HOWEVER, HEPATIC TUMORS ASSOCI-ATED WITH ANDROGENS OR ANABOLIC STE-ROIDS 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 ATHERO-SCLEROSIS ARE SEEN IN PATIENTS TREATED WITH ANDROGENS AND ANABOLIC STEROIDS. THESE CHANGES INCLUDE DECREASED HIGH-DENSITY LIPOPROTEIN AND SOMETIMES IN-CREASED LOW-DENSITY LIPOPROTEIN. THE CHANGES MAY BE VERY MARKED AND COULD HAVE A SERIOUS IMPACT ON THE RISK OF ATH-EROSCLEROSIS AND CORONARY ARTERY DIS-EASE.

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 deter-mined. 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 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 card[illegible]

#5 P97 3-22-9

hepatic disease. Concomitant administration of
nal cortical steroids or ACTH may add to the edema.
atric male patients treated with androgenic anabolic
oids may be at an increased risk for the development of
static hypertrophy and prostatic carcinoma.
hildren, anabolic steroid treatment may accelerate bone
uration without producing compensatory gain in linear
wth. This adverse effect may result in compromised adult
ture. 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
d hand every six months.
abolic steroids have not been shown to enhance athletic
ility.

PRECAUTIONS

General.
abolic steroids may cause suppression of clotting factors
V, VII, and X, and an increase in prothrombin time.
men 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
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
of estrogens. Menstrual irregularities may also occur.
e 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 andro-

ult or Adolescent Males. Too frequent or persistent erections of the penis, appearance or aggravation of acne.
omen. Hoarseness, acne, changes in menstrual periods, or
re hair on the face.
Patients. Any nausea, vomiting, changes in skin color, or
le 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).
cause of the hepatotoxicity associated with the use of 17-alpha-alkylated androgens, liver function tests should be
tained periodically.
iodic (every 6 months) x-ray examinations of bone age
ould be made during treatment of prepubertal patients to
termine the rate of bone maturation and the effects of androgenic anabolic steroid therapy on the epiphyseal centers.
common with other anabolic steroids, WINSTROL, brand
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
rdiovascular risk factors. Serum lipids and high-density
lipoprotein cholesterol should be determined periodically.
moglobin and hematocrit should be checked periodically
r polycythemia in patients who are receiving high doses of
abolic steroids.
Drug Interaction. Anabolic steroids may increase sensitivity
anticoagulants; therefore, dosage of an anticoagulant may
ve to be decreased in order to maintain the prothrombin
e 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
d 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-
ing properties of WINSTROL, brand of stanozolol tab-
s 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 in-
sed the ano-genital distance in rat fetuses, indicative of a
masculinizing effect. WINSTROL prevented pregnancy
n given orally to rats from the 1st to the 21st day of gesta-

Teratogenic effects or congenital malformation were ob-
ved in offspring of rabbits given 0.5 mg/day, 1.0 mg/day,
day of WINSTROL from the 8th through the 16th
pregnancy, nor were there any adverse effects on the
of pregnancy at these dose levels.
tumors have been associated with prolonged use of
genic anabolic steroids (see WARNINGS section).
patients treated with anabolics may be at an in-
sed risk for prostate hypertrophy and prostatic carci-

Pregnancy Category X. See CONTRAINDICATIONS sec-

Nursing Mothers. It is not known whether anabolic steroids
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. (1/4 gr.)	Ⓒ
268	Phenobarbital Tablet 30 mg. (1/2 gr.)	Ⓒ
269	Phenobarbital Tablet 100 mg. (1 1/2 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. (1/2 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.	

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HE'S A PISTOL

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JOHN'S JACKSON

MEMORIES

OLYMPIC MARATHON

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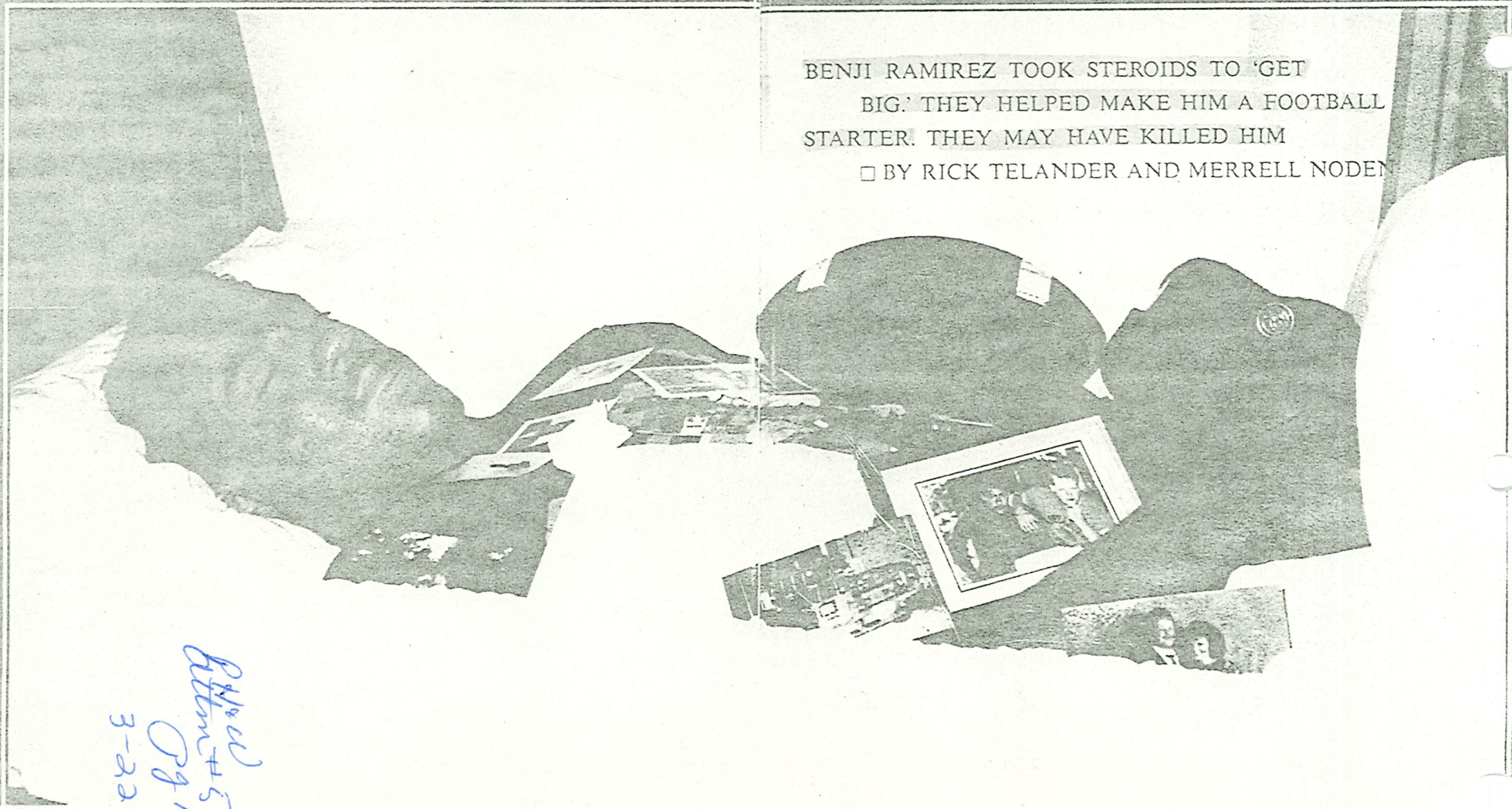
The DEATH *of an* ATHLETE

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



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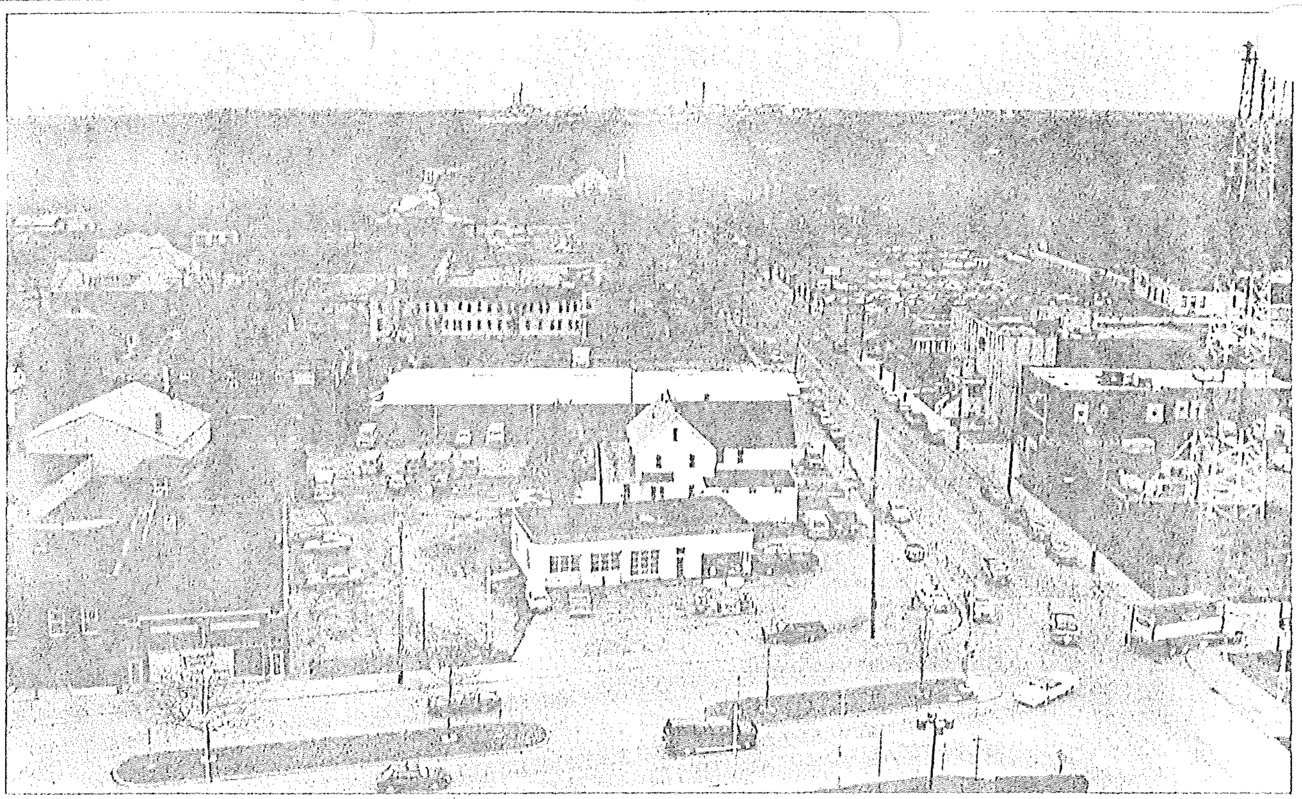

Physical fitness is one of the few growth businesses in Ashtabula, which has been devastated by the loss of several manufacturing companies.

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.

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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.

"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."

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."

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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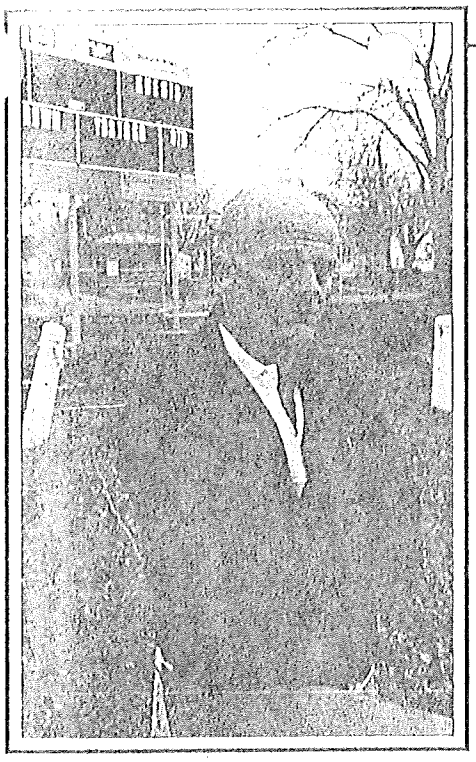


Orr admitted his ignorance of the signs of steroid use.

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."

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.

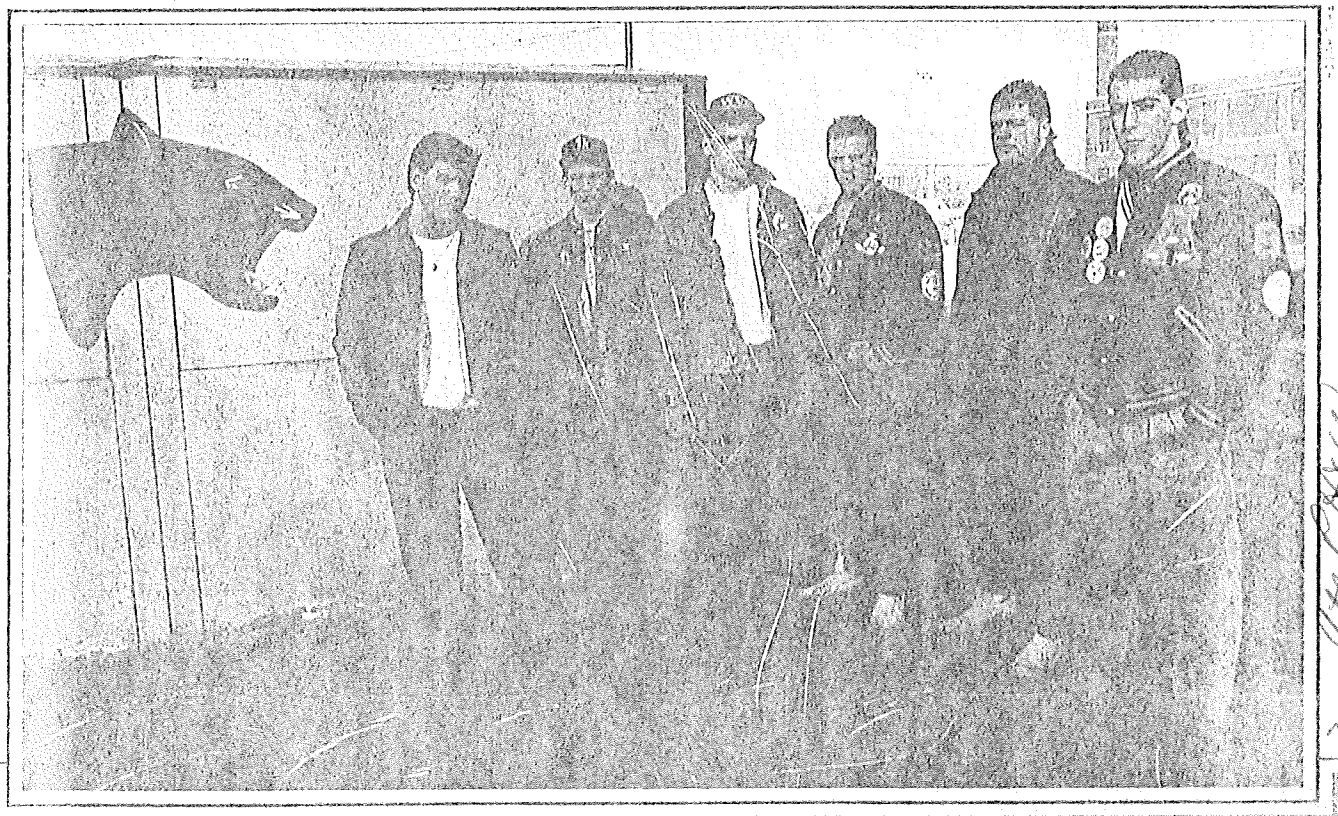
He now works at the Zip-Zap Brushless Car Wash in Ashtabula and says he's happy just to be alive, a notion he tried to impress on Ramirez several years ago when Ramirez approached him about taking steroids. "I was in training," says Wells, "and he said, 'Man, you're huge!' I said, 'Yeah, but a couple 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 to ask 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

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



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."

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.

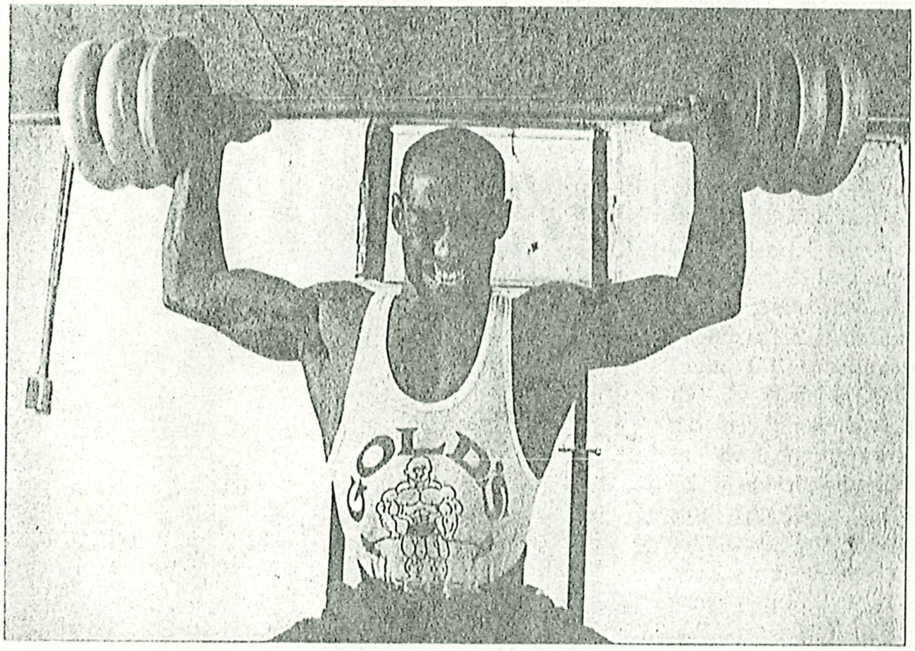
But Ramirez *was* using steroids. Sometimes, according to Morris, he would even shoot the drugs on game days, hoping for a rush that would carry over into the game. Morris went into Ramirez's bedroom the night after his death and found a used syringe in an old shoe in a wastebasket. "The cap was on the 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,



CARL SKALAK

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

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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.

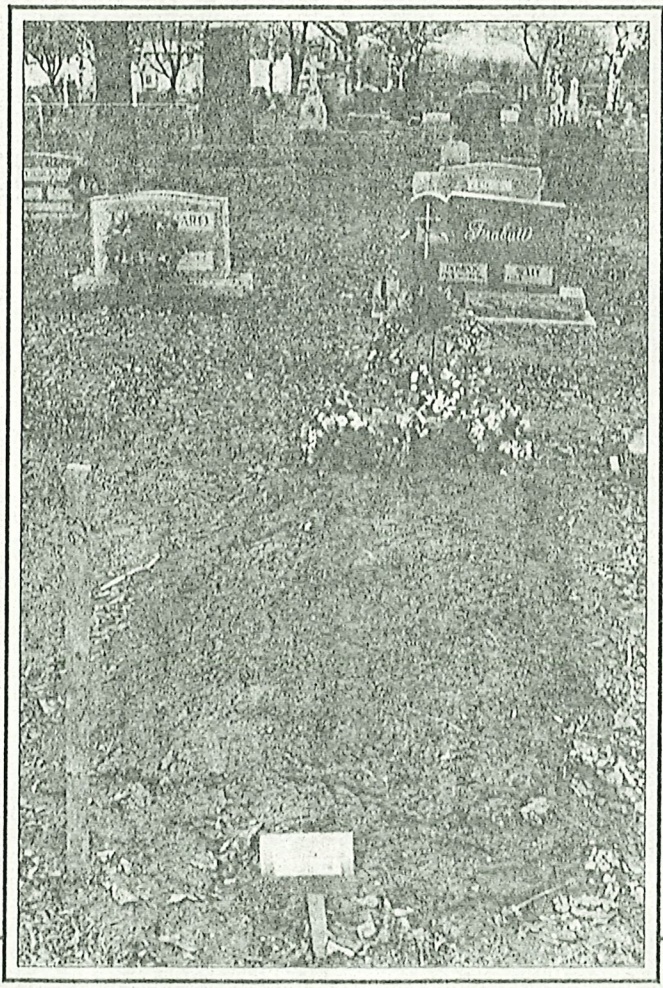
"All girls freak over bodies," says Gage. "I remember Benji saying he was starting to get the girls. Girls would say, 'Benji, you're getting big,' and he liked that. He liked the results."

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.



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Kansas State Board of Pharmacy

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STATE OF KANSAS

MIKE HAYDEN
GOVERNOR

SENATE BILL 181

HOUSE PUBLIC HEALTH AND WELFARE COMMITTEE

1:30 P.M. - March 22, 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 as 4 years ago, 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 steriods for 3 years.
2. Two heart attack deaths of athletes with no prior history of heart trouble but a strong history of steriod 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 anabolic steroids in Kansas.

Thank you.

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

March 22, 1989

TO: House Public Health and Welfare Committee

FROM: Kansas Medical Society

SUBJECT: Substitute for Senate Bill 181

The Kansas Medical Society appreciates this opportunity to express our support for the provisions of Sub. SB 181. The abuse of anabolic steroids is a problem that appears to be worsening and demands a response in the form of public policy. Medical researchers continue to discover harmful side affects of prolonged used 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.

It is important to keep in mind, however, that there remain a few medical uses for anabolic steroids. Prescription of such medication is usually done by a pediatric endocrinologist who has diagnosed a unique glandular disfunction in a child. Anabolic steroids are also used, on occasion, to reverse the effects of severe osteoporosis. The medical dictionary defines anabolic steroids as any of a group of synthetic derivatives of testosterone, which are used clinically to promote growth and repair of body tissues.

The provisions of Sub. SB 181 would allow physicians to prescribe anabolic steroids in those few instances when such medication would be appropriate. At the same time, the bill would impose penalties on anyone who might abuse anabolic steroids. For these reasons, we respectfully request that you recommend Sub. SB 181 for passage. Thank you for considering our comments.

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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

House Public Health and Welfare Committee

By

Kansas Department of Health and Environment

Senate Bill No. 181

Background

Senate Bill No. 181 proposes to preclude the prescription, distribution or administration of anabolic steroids, or human growth hormone, 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, and 4) treatment of hypogonadism."

The bill would require that these exceptions be supervised by a physician licensed to practice medicine and surgery, and who is knowledgeable about potential adverse side effects of the prescribed medication in adults, adolescents, and children.

Adverse effects of anabolic steroids are formidable, and include benign and malignant tumors of the liver, toxic hepatitis, decreased sperm production, testicular atrophy, masculinization of females, and severe psychological problems. The most serious long-term effect in adolescent males is premature closure of the growth centers of the long bones, thereby decreasing ultimate height.

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 supply was 60% black market, and 21% physician, pharmacist and veterinarian.

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The remainder obtained the drug by mail order catalog and other unspecified means.

Section 1(a)(3) designates the limitation placed on the amount of tablets or cubic centimeters of anabolic steroid that may be possessed. However, the intended purpose is not accomplished. The bill fails to specify the method of monitoring the amount, the possessor of the amount, or by whom monitoring will be done. The only legal use of anabolic steroids by an individual should be by an individual possessing a prescription for a "valid medical purpose," signed by a physician.

The intent of this bill is consistent with the recommendation of many sports-related organizations including the American College of Sports Medicine and the American Academy of Pediatrics. Both organizations condemn the use of anabolic steroids and human growth hormones "by a person who is in good health."

Recommendation

The Kansas Department of Health and Environment supports the passage of SB 181 with the deletion of Section 1(a)(3).

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.

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State of Kansas

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Board of Healing Arts

TO: House Committee on Public Health and Welfare

FROM: Richard G. Gannon, Executive Director

DATE: March 20, 1989

RE: SENATE BILL NO. 287

Mr. Chairman and members of the Committee, thank you very much for the opportunity to appear before you and submit testimony on behalf of this bill. This bill was requested by the State Board of Healing Arts to be introduced and passed the Senate with no amendments.

This bill seeks the creation of new authority to process and issue temporary educational licensure to physicians wishing to come to this State in order to obtain specialized training from accredited state institutions or their authorized affiliates.

For many years Kansas medical institutions have pioneered or participated in new methodologies of health care. As this leadership has become recognized nationwide, increasing numbers of physicians from across the country have sought training here. When the volume of such physicians was relatively small, the requirement for their completion of the comprehensive medical license application posed few problems or delays.

It has now become clear that a more expedited review process is needed -- possibly one which mirrors the approach used in temporary licensing of Visiting Professors. In the Visiting Professor example, physicians from other states are invited to Kansas to train our health care professionals (i.e. imported expertise). The reverse of this is achieved under SB 287, that being Kansas health care professionals providing training to physicians from other states.

SB 187 would facilitate the sharing of Kansas medical expertise.

Using present procedures of application, visiting physicians must undergo the extensive application process for full licensure, much the same as a physician who wishes to obtain licensure for a private practice, not an education for a few days or weeks. The

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Board requires the individual to submit copies of diploma and transcripts and also for their medical school to complete a section of the application that requires the school seal. The physician must also have all states in which he has ever held a license, currently or not, complete a verification form to the Board. If an individual has been licensed in several states this can take six to eight weeks to complete. This has, as a result, sometimes discouraged physicians from coming to Kansas for training experiences. When this occurs, they choose to go to other states with application processes more favorable to achieve their goals.

As indicated above, SB 287 offers a method of streamlining the application process, while retaining the basic safeguards necessary to ensure that the state will not lay itself open for possible future fraud or abuse.

Under SB 287, physicians seeking temporary licensure for educational purposes would be experienced in the related fields or procedures within which they seek further training. They would also be a practicing physician in good standing and not only be capable of securing coverage under the state's stabilization fund program, but also must obtain insurance in accordance with the Health Care Provider Insurance Availability Act.

All applicants must make application based upon their desire to participate in an approved continuing medical education program offered by the University of Kansas School of Medicine or one of its authorized affiliate sites/institutions. Further, the Board itself will continue to review such applications, affording this new process continued oversight and monitoring.

This type of training would allow Kansas to increasingly become recognized as an innovative, progressive state relative to state of the art health care, thus attracting high quality physicians for training.

Approval of SB 287 will encourage new opportunities in health care for the State of Kansas.

Thank you very much for the opportunity to appear before you today. If you have any questions, I would be happy to respond.

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Kansas State Board of Pharmacy

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STATE OF KANSAS

MIKE HAYDEN
GOVERNOR

SENATE BILL 293

HOUSE PUBLIC HEALTH & WELFARE COMMITTEE

1:30 P.M. - March 22, 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 293.

The changes requested in this bill would:

1) move from another location in the same schedule to list the drug in proper alphabetical order (two such changes);

2) make a corrective change in the four digit code to conform with the DEA controlled substance assigned code number (eight such corrections);

3) correct typographical errors (twelve such corrections);

4) move to the proper alphabetical order plus correction of the DEA controlled substance assigned code number (five such changes);

5) slot into the controlled substances schedule of Kansas such products that are listed in the DEA controlled substances listing (fifteen such changes);

6) correct such terminology to coincide with the federal listing (one such correction);

7) slot in verbage to coincide with federal listing (one such addition).

The above listed changes in the Kansas Controlled Substances Act will bring the Act into uniformity and conformity with the federal listing of controlled substances. These changes will enable the control of both legal and illegal distribution of such products.

The Board respectfully requests the passage of SB 293.

Thank you.

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