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Drugs and the Third World:

Stanozolol Toxicity and Unethical Marketing in Malaysia and the Third World

CONSUMERS' ASSOCIATION OF PENANG

151

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CONSUMERS' ASSOCIATION OF PENANG

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PREFACE

Stanozolol, an anabolic steroid drug, is generally used medically in androgen therapy in males as well as females. However, it can lead to serious disturbances in growth and sexual development when given to children. A notable side effect of stanozolol use is weight gain.

In Malaysia, stanozolol is promoted as an appetite stimulant for children. This is in direct contradiction with the warning by the American Medical Association that anabolic steroids should not be used to stimulate growth in children who are small but otherwise normal and healthy. In the US, the stanozolol product Winstrol is found to be very toxic and prescribed for only the narrowest indications. It is obvious that drug companies are employing double standards in marketing their drugs in Malaysia and other Third World countries as compared to developed countries.

This report hopes to throw more light on the dangers of stanozolol, as well as to alert consumers to the unethical marketing practices of the pharmaceutical companies.

CAP urges the Ministry of Health to ban the use of stanozolol in order to safeguard the health of all Malaysian consumers, particularly the children.

S M Mohd Idris, JP
President
Consumers' Association of Penang
July 1986

Update

This report was presented to the Ministry of Health, Malaysia, in July 1986. On 5 October 1986, the Director of Health, Tan Sri Abdul Khalid, announced that stanozolol, together with six other drugs, has been banned in Malaysia. Manufacturers and distributors would be given three months' grace to withdraw all products containing stanozolol from the market.

CHAPTER 1

INTRODUCTION

Many unnecessary pharmaceutical drugs which are banned or severely restricted in developed countries are still being widely marketed and used in developing countries.

From a study conducted by CAP on the anabolic steroid drug, stanozolol, it has been found that this drug is being marketed widely in Malaysia as an appetite stimulant for children. Stanozolol should be used only for treating aplastic anaemia, senile and post-menopausal osteoporosis and in pituitary dwarfism.

The *Drug Index for Malaysia and Singapore (DIMS)* shows one brand of stanozolol, Winstrol, which CAP managed to purchase over the counter although it is supposed to be a Group C Poison. Our study found that there are double standards in the marketing of this drug preparation in Malaysia and other developing countries as compared to the USA and UK.

According to *The Medical Letter,* an independent non-profit publication on drugs and therapeutics in the US, Winstrol (the only stanozolol preparation marketed in

the US) is considered too toxic for all but the narrowest indications. Besides this, in 1973, the American Medical Association warned that anabolic steroids (like Winstrol) should not be used to stimulate growth in children who are small but otherwise normal and healthy. However in Malaysia, this drug is still being promoted as an appetite stimulant for children.

Clearly some drug companies are taking advantage of the fact that local monitoring and surveillance of drugs are inadequate and hardly existent. The double standards practised by drug companies in marketing their drugs in Malaysia and other Third World countries can lead to wrong drug prescription and drug use.

Developing countries like Malaysia which already have limited funds available for the provision of adequate primary health care should not be spending money on unnecessary drugs. CAP therefore calls upon the Ministry of Health to ban the use of stanozolol, for the safety and health of Malaysian consumers.

CHAPTER 2

STANOZOLOL: INN (International Nonproprietary Name Selected By WHO)

Stanozolol is an anabolic steroid which is a derivative of testosterone*. Testosterone and its derivatives are used medically in androgen therapy in males and females and as anabolic agents (agents that aid in the building and repairing of body tissues).

In the male, androgen therapy may be employed as substitution therapy for testosterone deficiency. Deficiency states such as the male climacteric impotence (due to androgen deficiency), delayed puberty, hypogonadism and any other condition in which testosterone is deficient or absent may respond to androgen therapy.

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* Testosterone is a natural male steroid hormone produced by the testes. Steroid hormones are chemicals which control the development and maintenance of reproductive organs in the body. There is now a synthetic preparation available. (Parish 1976: 206).

In the female, androgen therapy may be used as part of the chemotherapeutic management of inoperable carcinoma of the breast in those who are more than one year but less than five years past menopause. Postpartum breast engorgement and pain in the non-nursing mother may also be relieved with androgens. Anabolic hormones, which are closely related to or derived from testosterone, may be useful in creating a positive nitrogen balance. Patients in a debilitated state may benefit from androgen therapy; however, diet and general health measures should also be considered and should accompany androgen therapy.

Anabolic hormones may also be used in the treatment of osteoporosis, certain types of anaemia, metastatic breast cancer, and the reversal of nitrogen loss that may occur during corticosteroid therapy.

(1) Adverse Effects of Androgen Therapy

In the adult male, adverse effects are minimal when the optimum dose is administered. Sodium and water retention may occur. In the prepubertal male, precocious sexual development may occur and require the discontinuation of therapy.

In the female, masculinizing effects (deepening of voice, facial hair, male-pattern baldness, etc) frequently occur when androgens are administered for long periods of time. These effects are usually irreversible, even when the drug is promtply discontinued after the development of masculinizing features. These adverse drug effects do

not usually occur when androgens are used briefly to treat post-partum breast engorgement.

Oedema (water retention) and jaundice may be seen in both sexes during androgen administration. There may also be an elevation of serum electrolytes (calcium, sodium, potassium and chlorides) as well as changes in other laboratory tests and studies (Scherer 1982: 154).

In failure of growth in children, especially if hypogonadal, androgens may occasionally be useful, but may promote premature epiphyseal fusion. Although they can cause jaundice, they may relieve the itching associated with jaundice. In combination with oestrogens, they may help in the treatment of post-menopausal disorders (Girdwood 1979: 430).

Muscular development is enhanced by anabolic agents and they have been used to promote the performance of athletes, especially females: this use is contrary to the international and most national rules of sports (Bowman, et al, 1980: 206).

Stanozolol has been effective for increasing haemoglobin levels in some patients with aplastic (congenital and idiopathic) anaemia (*Physicians' Desk Reference* 1983: 2140). It is probably effective as adjunctive but not primary therapy in senile and post-menopausal osteoporosis (Ibid). In pituitary dwarfism it may be used with care (Ibid).

(2) Caution and Warnings

Stanozolol is contraindicated in men with cancer of the prostate or breast (*Martindale* 28th ed: 1436). It should be avoided in pregnancy since virilisation of the female foetus has been reported. Its use should also be avoided in patients with nephrosis (Ibid). It should be used cautiously in patients with circulatory failure, renal or hepatic dysfunction, epilepsy, or migraine, which would be aggravated by fluid retention (Ibid).

Given for prolonged periods, it can cause jaundice (Ibid: 1426). Stanozolol lowers total testosterone by actions at both pituitary and hepatic levels (Small, et al, 1984: 21, 49-55).

Anabolic steroids are known to cause a variety of changes in plasma protein levels (Barbosa, et al, 1971: 388-398; Laurell, et al, 1979: 719-725). Stanozolol can lower the level of three important hormone-binding plasma proteins - TBG, DBG (γ Globulins) and SHBG (β Globulins).

(3) Adverse Reactions

These include increase in nitrogen retention and skeletal weight, sodium and water retention oedema, increased vascularity of the skin, hypercalcaemia (excess of calcium in the blood), and increased bone growth (*Martindale* 28th ed: 1436). Large and repeated doses in early puberty may cause closure of the epiphysis (a piece of bone separated from a long bone on early life by cartilage but later

becoming a part of the larger bone. It is at this cartilaginous joint that growth in length of the bone occurs) and stop linear growth (Ibid). Elderly males may become overstimulated (Ibid).

In women stanozolol leads to suppression of ovarian activity and menstruation, produces male pattern hirsutism (abnormal hairiness), causes deepening of the voice, atrophy of the breasts (wasting away or diminution in size of the breasts) and endometrial tissue, acne and hypertrophy (morbid enlargement or overgrowth) of the clitoris, increases libido (sexual drive) and suppresses lactation (Ibid).

In men large doses suppress spermatogenesis and cause degenerative changes in the seminiferous tubules (small tubes producing or carrying semen) (Ibid). Hepatic carcinomas have developed in some patients given the drug for prolonged periods (Ibid).

(4) Dosage

The recommended dosage is 6 mg (three tablets) daily in divided doses (*Physicians' Desk Reference* 1983: 2140).

The recommended daily dosage for children is:

Children under 6 years - ½ tablet (1 mg) twice daily.
Children 6-12 years - 1 tablet (2 mg) thrice daily (Ibid).

(5) Studies

The effects of orally-administered stanozolol, 5 mg twice

daily, on fibrinolysis, coagulation and on various haematological and biochemical parameters were studied in 16 healthy adults, eight males and eight females. There is good evidence that stanozolol produces some degree of fibrinolytic enhancement in both healthy adults and patients with various forms of vascular disease associated with fibrinolytic impairment (Kluft, et al, 1984: 157-164).

More specific effects of stanozolol are a reduction of plasma fibrinogen and an increase of plasma plasminogen, CI-inactivator and antithrombin III (Ibid).

The only stanozolol preparation marketed in the US is Winstrol by Winthrop. According to *The Medical Letter* (Vol 15 No 6, 16/3/73) an independent non-profit publication on drugs and therapeutics in the US, Winstrol is considered too toxic for all but the narrowest indications (cf Ledogar 1975: 27). Winthrop's entry on Winstrol in the 1983 edition of the *Physicians' Desk Reference* states that it can lead to serious disturbances of growth and sexual development when given to children. Premature stunting of growth can occur, as can premature enlargement of the penis and increased frequency of erections in boys. In girls, increase in body hair, male pattern baldness, deepening of the voice and clitoral enlargement can occur. In girls, 'These changes are usually irreversible even after prompt discontinuance of therapy' (*Physicians' Desk Reference* 1983: 2140). According to *The Medical Letter* 'every child who takes the drug in the recommended dosage for a long enough period of time will demonstrate these

effects' (cf Ledogar 1975: 28).

Stanozolol is not listed in the generic index in the *Monthly Index of Medical Specialities (MIMS)* Australia (Oct-Nov 1979 Vol 16 No 6).

In *MIMS* UK (January 1980 Vol 22 No 1), there is one preparation containing stanozolol, namely Stromba (Izal), which is used in 'Debilitating diseases, post-menopausal, senile or corticosteroid-induced osteoporosis; acute renal failure' with Contraindications in 'prostatic carcinoma and pregnancy'. Special Precautions warn against its use in 'impaired cardiac and renal function'. In bold lettering is stated that Stromba is 'Not recommended for children'.

CHAPTER 3

DRUG PROMOTION AND MARKETING IN THIRD WORLD COUNTRIES

In 1973, the American Medical Association warned that anabolic steroids (like Winstrol) 'should not be used to stimulate growth in children who are small but otherwise normal and healthy' (Ledogar 1975: 28).

According to Robert Ledogar, in Latin America, Winthrop was promoting Winstrol 'widely as (among other things) an appetite stimulant for underweight children' (Ibid).

In Mexico, he came across a drug compendium based on company-supplied information which was distributed to doctors, recommending Winstrol 'in states in which weight gain in children and adults is necessary, for loss of appetite no matter what the cause, for beneficial action to increase strength, interest, and general well-being ...' (Ibid).

In Brazil, he found boxes of Winstrol tablets which carried the statement that 'in states of appetite loss and malnutrition (Winstrol) stimulates appetite and improves protein anabolism (protein build up)' (Ibid: 28-29). In the drug inserts, 'thinness' and 'alterations in nutrition

and growth in children' were added, as well as many other indications (Ibid).

There was also a Winstrol paediatric preparation for children marketed in Brazil which was recommended for, among other things, appetite loss, malnutrition, and thinness, specifying 'alterations in nutrition and growth in children of pre-school age' (Ibid).

In the Dominican Republic he found that Winstrol was recommended for use in eight wide ranging conditions. One of them is 'non-malignant chronic diseases (renal, cardiovascular, gastrointestinal, arthritic or chronic infections)'. Another is 'retardation of growth in children' (Ibid).

In 1975, Dr Milton Silverman also found wide discrepancies of information on Winstrol by Winthrop in the countries in Central and South America (Silverman 1976: 53, 59). In Mexico, Central America, Ecuador, Columbia and Brazil it was promoted for the treatment of cirrhosis and chronic hepatitis; as supportive therapy in both chronic and acute illness in Mexico, Central America, Ecuador and Columbia; and for convalescent, pre-operative and post-operative care in Mexico, Central America, Ecuador, Columbia, Brazil and Argentina (Ibid). He also found that adverse reactions like growth stunting in children, increase in body hair, deepening of the voice and menstrual irregularities in females were mentioned in Mexico and Brazil. In Brazil there was also premature sexual development in young males. In Central America and Argentina, increase in body hair,

deepening of the voice and menstrual irregularities in females were disclosed. In Ecuador and Columbia none of the adverse reactions listed above were listed (Ibid: 53, 60).

In 1979, Bill Breckon of *The Listener* found Winthrop selling Winstrol suspension in Colombo, Sri Lanka (*The Listener* 6/9/79: 290-292). He also found that under 'demonstrated beneficial effects' in the Winstrol leaflet it concentrated solely on the trial use of Winstrol in promoting the growth of convalescing children between 1½ and 6½ years of age. No other trial use was quoted (Ibid). Winstrol suspension is not marketed in the US and according to Wilfred Lionel, Associate Professor of Pharmacology at Colombo University and Secretary of Sri Lanka's drug control committee, this was certainly a paediatric preparation (Ibid).

CHAPTER 4

DRUG INFORMATION AND BRANDS SOLD IN MALAYSIA

In Malaysia, doctors obtain information on stanozolol from three major sources. They are:

a) The *Drug Index for Malaysia and Singapore (DIMS)*. *DIMS* is a quarterly publication on ethical medicines available in Malaysia and Singapore. It is prepared by the pharmaceutical companies and distributed free to doctors in both countries.

b) Drug advertisements and brochures which are distributed free to doctors by drug company detailmen.

c) Drug inserts which come together with the drugs when they are purchased. The insert gives information on the use of the drug, the dangers and the precautions to be taken when the drug is used. The instructions and information on the drug insert are provided by the company which markets its particular brand product.

(1) *DIMS* Information

DIMS (January 1982 Vol 11 No 1) lists only one preparation for stanozolol: Winstrol tablet, manufactured by Winthrop/

Sterling. The contents consist solely of stanozolol. It is a Group C Poison, which means that according to the law, it can be dispensed by a pharmacist with entry in the Prescription Book. Apart from this there are no restrictions on the use of this drug. However, CAP staff were able to buy it over the counter without even so much as an entry in the Prescription Book!

(2) Warnings and Contraindications: Inadequate Information

Under Contraindications is listed:

'Cancer of the breast or prostate in males.
Cancer of breast in some females. Pregnancy, nephrosis, nephrotic phase of nephritis.'

It must be noted that the information provided is extremely skimpy. Although it is contraindicated in pregnancy, no mention is made of the fact that it should be avoided by nursing mothers.

(3) Indications Given

Besides the lack of information on adverse effects and contraindications, the information given on indications is also insufficient. The drug is indicated for 'patients with reduced protein synthesis or excessive breakdown of proteins'.

Winstrol tablets, containing stanozolol, which were bought over the counter without entry in the Prescription Book.

(4) Dosages

The dosages for adults and children are listed as follows:

'Adults:	1 tablet three times daily
Children:	2-6 years : ½ tablet twice daily
	6-12 years: 1 tablet twice daily'

The amount of stanozolol in each tablet is not listed.

CHAPTER 5

DRUG INFORMATION INSERT FOR WINSTROL

In the drug insert given with the drug in Malaysia, Winthrop describes the action of Winstrol in the following terms:

'Winstrol therapy leads to improvement in appetite, increased vigor and sense of well-being and notable gains in weight. In children it has been observed that Winstrol also produces a rapid increase in linear height without accelerating bone maturation.'

It is recommended for use 'in all conditions with reduced protein synthesis or excessive breakdown of proteins; children and adolescents with retarded growth or underweight; patients convalescing from acute illnesses; patients with gastrointestinal disorders that interfere with normal metabolism; to reduce catabolic breakdown of the tissue in patients with kidney disease; for patients with arthritis or osteoporosis to counteract catabolic effects of prolonged steroid therapy; for patients with decubitus ulcers; for pre- and post-operative care'. In all, there are eight wide ranging conditions for which Winstrol is recommended.

Under 'Side Effects and Precautions' Winthrop states that 'prolonged administration of Winstrol has produced mild hirsutism or voice change. In occasional patients, the menstrual periods have become milder and shorter. All these side effects are reversible with reducing or suspending medication' (See Appendix).

Winthrop does not state in its drug insert that the 'mild hirsutism or voice change' refers to young girls, and the side effects which are 'reversible' is in direct contra-indication to its information in the *Physicians' Desk Reference* where it states: 'In females, hirsutism, male pattern baldness, deepening of the voice, and clitoral enlargement have occurred. These changes are usually irreversible even after prompt discontinuance of therapy.' There is no mention that the drug given for prolonged periods can cause jaundice. Nowhere under this section in the drug insert is it stated that Winstrol can lead to premature stunting of growth in children, premature enlargement of the penis and increased frequency of erections in boys, male pattern baldness and clitoral enlargement in girls over a prolonged period.

Winstrol in its information to doctors in Malaysia not only deliberately leaves out important information and plays down the dangers of the drug, it has been shown to deliberately misinform users as well. In promoting its Winstrol product, Winthrop has also included a wide range of conditions for which the drug can be used, unlike in the US, where it is only used for aplastic anaemia, pituitary dwarfism and as supplementary treatment in senile and post-menopausal osteoporosis.

CHAPTER 6

CONCLUSION

This report has attempted to make a case for the need to remove all stanozolol preparations from the market.

Stanozolol is a drug which has been found to have many undesirable side effects. Its promotion as an appetite stimulant for children should not be continued as the many side effects resulting from its use show. It would be worthwhile to quote once more the opinion voiced by the American Medical Association when it said that anabolic steroids (like Winstrol) should not be used to stimulate growth in children who are small but otherwise normal and healthy.

It has been found that the drug company promoting this drug preparation has been practising double standards in its marketing of Winstrol in Third World countries as compared to developed countries. For instance in Latin America in 1974, Winthrop was promoting Winstrol as an appetite stimulant for underweight children. This was also the case in countries like Brazil, the Dominican Republic and Sri Lanka.

The drug company is also irresponsibly promoting its

product in Malaysia. Whereas in the *Physicians' Desk Reference* Winthrop's entry on Winstrol states that it can lead to serious disturbances of growth and sexual development when given to children, in Malaysia the drug insert for Winstrol states that Winstrol therapy leads to improvement in appetite, increased vigour and sense of well-being and notable gains in weight.

Drug companies cannot be allowed to promote such a dangerous drug for unnecessary conditions like appetite stimulation! This kind of promotion can lead to irrational drug prescription and drug use and to needless injury. From the above it can be seen that drug companies have been indulging in most unethical aggressive double-standard marketing of their drugs.

CAP strongly urges the Ministry of Health to recall this drug preparation from the market for the safety and health of Malaysian consumers. The Ministry of Health should immediately withold the sale of the drug until proper labelling is carried out by Winthrop. It should also warn all doctors as soon as possible of the dangers of the drug, and the limited conditions of its use.

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APPENDIX
DRUG INFORMATION INSERT FOR WINSTROL

WINSTROL

REGISTERED TRADEMARK

BRAND OF STANOZOLOL

Stimulates protein synthesis in anorexia, weight loss and inanition

DESCRIPTION: It has long been recognized that hormones, particularly androgens, exert a positive influence on anabolic activity and play a major role in stimulating growth and positive nitrogen balance, especially in adolescents. However, the use of androgens as an aid to stimulating protein synthesis has been limited in women because of the undesirable masculinizing effects.

Winstrol is 17β-hydroxy-17α-methylandrostano (3,2-c) pyrazole, a new heterocyclic steroid with marked anabolic but weak androgenic activity. When administered orally in animals, Winstrol was found to have about thirty times the anabolic activity and one-fourth the androgenic activity of methyltestosterone.

ACTION: Winstrol increases the retention of nitrogen and minerals, reverses tissue depleting processes and promotes better utilization of dietary protein. Winstrol therapy leads to improvement in appetite increased vigor and sense of well-being and notable gains in weight. In Children it has been observed that Winstrol also produces a rapid increase in linear height without accelerating bone maturation.

INDICATIONS: Winstrol stimulates the appetite and promotes protein synthesis in all conditions characterized by negative nitrogen balance whether due to insufficient absorption or inadequate protein synthesis or to excessive breakdown of proteins.

Winstrol is indicated in all conditions with reduced protein synthesis or excessive breakdown of proteins: children and adolescents with retarded growth or underweight; patients convalescing from acute illnesses; patients with gastrointestinal disorders that interfere with normal metabolism; to reduce catabolic breakdown of the tissue in patients with kidney disease; for patients with arthritis or osteoporosis to counteract catabolic effects of prolonged steroid therapy; for patients with decubitus ulcers; for pre- and post-operative care.

DOSAGE: The suggested initial dose for adults is 1 tablet (2 mg.) three times daily just before or with meals. Although smaller doses produce a response in some patients, consistently better

continued next page

results have been obtained with a daily dose of 6 mg. Higher doses have been employed but, as a rule, have not improved the results significantly.

The dosage for children should be adjusted according to age, as follows: 1 tablet daily or ½ tablet twice daily for children under 6 years, and 1 tablet twice daily for children from 6 to 12.

For young women who appear particularly susceptible to the androgenic effects of the drug, 1 tablet twice daily appears adequate for long-term administration. If this amount does not produce the desired results, the dosage may be raised to 1 tablet three times daily.

To obtain the maximal therapeutic effect, a well balanced diet should accompany the administration of Winstrol.

SIDE EFFECTS AND PRECAUTIONS: Winstrol is well tolerated, particularly when the tablets are taken shortly before or with meals. As is the case with other anabolic steroids, prolonged administration of Winstrol has produced mild hirsutism or voice change. In occasional patients, the menstrual periods have become milder and shorter. All these side effects are reversible with reducing or suspending medication. Patients with impaired cardiac and renal function should be watched closely during treatment because of the possibility of retention of sodium and water. A reversible abnormality in the bromsulphalein reaction has been observed with Winstrol as with all other anabolic steroids currently available.

Although Winstrol has been employed in patients with cancer of the prostate, its mild androgenic activity is considered by some investigators to be a contraindication.

Neither Winstrol nor any other agent with any detectable androgenic activity should be used in the pregnant patient.

HOW SUPPLIED: Winstrol is available as scored tablets of 2 mg., for easy administration of half-tablet doses to children.

WINTHROP PRODUCTS INC.
New York, N.Y., U.S.A.

89022-503

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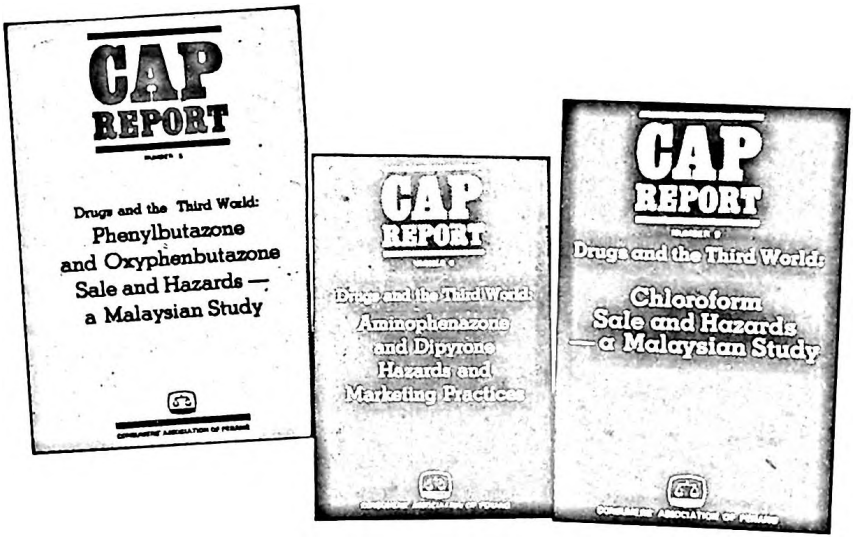

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** Besides stanozolol, these drugs were also banned by the Malaysian government a few months after the reports were presented to the Ministry of Health.*

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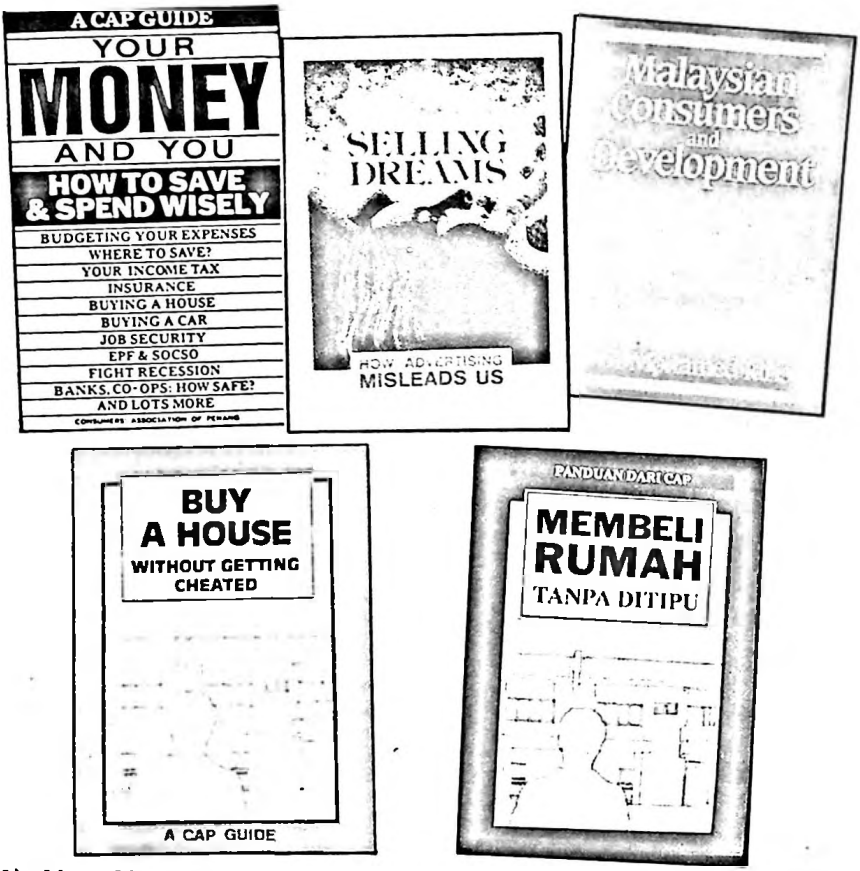

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Drugs and the Third World:

Stanozolol Toxicity and Unethical Marketing in Malaysia and the Third World

Stanozolol is an anabolic steroid drug being marketed in the Third World and in Malaysia as an appetite stimulant for children. In the US, however, the drug is considered very toxic and is not recommended for stimulating growth in children who are small but otherwise normal and healthy.

This report reveals the dangers of stanozolol to children, as well as the double standards employed by drug companies in promoting this drug in developing countries. It calls for a ban on the drug in Malaysia.

In October 1986, a few months after CAP sent this report to the Malaysian Ministry of Health, the government banned the sale of stanozolol in Malaysia.

The Consumers' Association of Penang (CAP) is a non-profit making organisation which fights for the rights and interests of Malaysian consumers through research, educational and representational activities.

The issues it takes up include the fulfilment of basic needs (food, nutrition, health, housing, transport, etc.), food and product safety, environmental pollution and problems, the rational use of resources, specific problems of women, and business malpractices.

This is part of a series of CAP Reports aimed at providing the public with the results of some of the important areas of CAP's activities. It is hoped that this series will generate public interest and awareness, and help to contribute towards a better life for Malaysians.

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