

# What You Need To Know: Over the Counter Slimming Products – Their Rationality and Legality

J K Candlish

## INTRODUCTION

In Singapore, no doubt as in other countries<sup>(1)</sup>, the slimming industry must be of considerable size. In response to well-founded warnings from government agencies and the medical profession about the health risks of obesity, as well as to allow the pursuit of self-esteem, numerous advertisements for spas and exercise centres appear in the newspapers and magazines, offering various programmes for slimming. Pharmacies and health food shops are replete with a large variety of capsules containing substances which claim to promote weight loss. In addition, there is a certain amount of direct selling by late night television, and it is also possible to purchase through the Internet. Doctors and health professionals in addition to patients and well subjects (all potential recommenders or purchasers, or both) will be concerned to understand the rationale for the marketing of these obesity "cures" in order to assess their possible efficacy – indeed to decide on whether they are worth buying at all. Often, suppliers either on the labels, in attached pamphlets, or in advertising, try to explain how their products work, if only, in the briefest manner. The present paper offers comments on these explanations, using biochemical or metabolic reasoning. It is hoped that such comments will help in making informed choices, if indeed it appears that any of the products have value.

## SLIMMING AIDS

**Chitosan** is sold under a variety of proprietary names, sometimes in the pure form, sometimes with a starch excipient, and sometimes in combination with other substances as listed below. It is a derivative of chitin, the material from crab and prawn shells, and can also be produced by fungi. Chemically it is described as a 1,4 glycosidically linked polymer of 2-amino-2-deoxy-D-glucopyranose. It appears to form gels in the gastrointestinal tract which bind lipids; this is logical in the chemical sense as after acidification in the stomach, it will enter the duodenum as a positively charged entity with the potential to attract fatty acids electrostatically. However the substance seems to be effective with triglyceride, which has no charge, so that some sort of coacervation (encapsulation by the chitosan gels) may be operating. Most of the trials have been conducted with animals<sup>(2)</sup>. These show a reduction in serum cholesterol; this would of course follow if the

substance renders fat, especially saturated fat, unavailable for absorption in the gastrointestinal tract. Clinical trials however are hard to detect, but one in Japan, showed that chitosan at a dose of 3 – 6 g per day for 2 weeks reduced total cholesterol and increased high density lipoprotein cholesterol<sup>(3)</sup>. The fibre has a number of other biological effects which will not be discussed here, but it might be noted that the acid-swollen fibre is very bulky and might well induce satiety. It seems promising, but further human trials would be welcome.

## Guar gum

Gums are branched carbohydrate polymers, soluble in water and known to reduce postprandial hyperglycaemia if taken with a meal<sup>(4)</sup>. They claim to promote slimming by producing satiety. On first principles, this may be correct but once again there is no record of any recent clinical trial.

## Hydroxycitric acid

Hydroxycitric acid can readily be inferred as a derivative of citric acid, which will recall the Krebs cycle, but is however not involved in the relevant mechanism. Hydroxycitric acid is found naturally in the fruit of *Garcinia cambogia*, the Malabar tamarind. The theory of its application involves the process of fatty acid synthesis which requires the export of acetyl coenzyme A from the mitochondria into the cytosol of the adipocyte via the synthesis of citrate. Hydroxycitric acid is a competitive inhibitor of citrate synthase. The author has only been able to locate one clinical trial, which failed to show any benefit of 1.5 mg for 12 weeks over controls<sup>(5)</sup>.

## Chromium picolinate

This is a vehicle for the assimilation of chromium – the picolinate merely chelates it. Chromium has long been known to be essential for the activity of insulin, in that it increases insulin sensitivity and decreases circulating insulin<sup>(6)</sup>. Since resistance to insulin is commonly thought of as a cause of obesity, it is not surprising that chromium has an effect on body composition. About 14 trials have been held with daily intakes of 200 to 400 µg of chromium picolinate per day, over 6 to 48 weeks. Many of them involved simultaneous exercise regimes; of which 3 involved sedentary subjects, two showed an increase in lean

Department of Biochemistry  
Faculty of Medicine  
National University of  
Singapore  
10 Kent Ridge Road  
Singapore 119260

J K Candlish, PhD, LLM  
Associate Professor

body mass and the others, no effect. The last trial however, involved simultaneous administration of fibre and caffeine. It is in the opinion of the most recent reviewer<sup>(6)</sup>, that the effect of chromium is likely to be small compared to exercise and a well balanced diet.

### **Carnitine**

Carnitine, which is usually stated on labels to be a "fat burner", is an amino acid synthesised in the liver from lysine and methionine but is not in itself found in proteins. It is also found in meat and dairy products. Its role is to transport acyl groups across the mitochondrial membrane so that they can be oxidised. The idea therefore is to tilt the balance in favour of fat oxidation rather than synthesis. Once there is sufficient carnitine in the cell to saturate the enzyme, carnitine acyl transferase (which is a substrate), there is no way that extra carnitine could accelerate fatty acid oxidation. It can only be argued to be a slimming substance for an obese person unable to obtain adequate amounts in the diet or by synthesis. Of course this can happen; the clearest example is probably in severe liver impairment or alcoholic cirrhosis. But in this situation, the patient has problems more urgent than the shedding of a few pounds of fat. In respect of the "well" obese, there is a built-in contradiction in that better fed they are, the more they are likely to have adequate carnitine supply and synthesis, and so the less likely they are to need supplements. Clinical trials on the treatment of the obese with carnitine seem to be entirely lacking.

### **Conjugated linoleic acid**

Linoleic acid *simpliciter* is one of the essential fatty acids technically described as C18: 2, n6, ie. it has two double bonds, by implication, since that is the normal pattern, three carbon atoms apart, in conjugated linoleic acid however, although also C 18 with 2 double bonds, these double bonds are only two carbons apart, hence it is "conjugated" in the sense the word is used in organic chemistry. It is not a single substance in that the conjugated double bonds may be variously disposed. It occurs in meat and dairy products and is generated by the intestinal flora of ruminants. In farm animals, conjugated linoleic acid appears to increase feed efficiency, ie. they eat less, and they have decreased body fat<sup>(7)</sup>. Human trials are only now in train, and their results are being anticipated.

### **Lipotropic factors**

It was found many years ago that fatty livers in rats can be prevented by feeding a number of substances such as choline, methionine, and betaine. These are precursors of phospholipids. Fatty livers occur when there is some deficiency in the export of triglyceride and cholesterol from the liver; these are packaged into lipoproteins which need *inter alia* phospholipids for their integrity. So the idea is that somehow these substances mobilise triglyceride. Unfortunately, a fatty liver can contribute only negligibly to weight gain, and there is no evidence as far as the author knows, that lipotropic substances are necessary for the removal of triglyceride from adipose tissue elsewhere. This is the role of hormone sensitive lipase, which releases

fatty acids to be taken up by serum albumin. If anything, lipotropic substances would facilitate the removal of triglyceride from the liver, as very low density lipoprotein, towards the peripheral deposits. Moreover the results of the studies in rats have never been duplicated in man. Certainly, alcohol induced steatosis might well be alleviated by lipotropic substances like betaine<sup>(8)</sup> but again this is not directly relevant to obesity.

### **Fucus**

This is an extract of a seaweed *Fucus vesiculosus* or bladderwrack. It is included in some herbal teas. It contains alginic acid, a polymer of mannuronic acid, and iodine (18 – 95 mg/100 g according to one volume devoted to folk medicine<sup>(9)</sup>). Thus the theory is that it will promote thyroxine synthesis and speed up metabolism. One preparation is sold as skin patches of 5 mg extract. Retailers do not explain how the polysaccharide, which claims to be an active ingredient, or iodine for that matter, can penetrate the epidermis, and 5 mg extract only contains 5 µg iodine unless it is concentrated in some way. A clinical trial is mentioned in the promotional literature, but without citation, or the affiliation of the investigator, one Dr R J Barr. A search of Medline, International Pharmaceutical Abstracts and Biomedical Collection III failed to detect this individual, who is depicted as a person of some gravitas with a stethoscope round his neck.

### **Herbal teas**

There is a large variety of these, with various mixtures on the market which include senna, dandelion, marshmallow, ginseng, chickweed, fennel and many others. Some seem to be derived from Chinese medicine, some from Western 'folk' beliefs. It is difficult to evaluate them, except that some like dandelion leaf are thought to produce the illusion of weight loss by diuresis and some, like senna, are well known laxatives. There was a prolonged controversy in the *Straits Times* in late 1997 on the safety of herbal medicines and Mr Wu Tuck Seng, President, Pharmaceutical Society of Singapore<sup>(10)</sup> warned of their potential problems. Whereas their efficacy for weight loss, except via water elimination, is doubtful, they are thought to contain substances like carcinogens which may be harmful or, as one group of authors puts it "the quantity and consumption over a long period of time is of major concern"<sup>(11)</sup>.

### **Pantothenic acid**

The rationale for including this in slimming preparations is that it is a component of coenzyme A, which is necessary for fatty acid catabolism. Thus the balance between fat synthesis and oxidation might be tipped in the direction of oxidation if pantothenic acid supply could be made optimal. There is however no evidence that it fails to be optimal in the otherwise well obese. One clinical trial which was reported rather informally, claims its efficacy when given in doses of 10 g per day, but the administration was accompanied by a diet of 1000 cal [sic] per day, which is simple starvation by any standards<sup>(12)</sup>.

### Amino acids

Labels often contain amino acids, usually arginine, in their listing. The rationale for this is that arginine stimulates growth hormone secretion in most (not all) subjects. Since growth hormone, which of course tends to promote the maintenance of lean mass at the expense of fat, is mainly secreted during the first few hours of sleep, these products usually claim to slim the buyer while he/she sleeps. But the effect, if it exists, has not been shown to be significant in a recognisable trial in human subjects.

This does not exhaust the list, and a further paper would be needed to evaluate such imaginative products as "body countouring" creams and gels. Newer promotions will come on the market, such as fat substitutes, lipase inhibitors, leptin and melanocyte stimulating hormone inhibitors. Most of them are likely to be restricted by prescription in the first instance. As with over the counter versions, it will be the long term effects which will be most difficult to evaluate.

### LEGAL ASPECTS

In the absence of well designed human trials, there is no evidence for the value of most of these preparations. How is it that they can be freely sold over the counter and even stridently advertise? The regulatory regime which might cover them is complicated. *A priori*, a substance taken by mouth, might be a food or a drug, but there are legislative exemptions from regulation of some substances which might initially be considered to be drugs, including most of the slimming preparations. However there are catch-all sections in the Medicines Act (SS 54 and 55)<sup>(13)</sup> which empower the Minister, in the interests of the public, to consider any substance sold to be a medicinal product and therefore to bring it back under its provisions.

There are two aspects to retailing, namely labelling and advertising, and by the Medicines (Medical Advertisements) Regulations<sup>(14)</sup>, there must be a permit for advertising medicinal products. By the Medicines (Advertisement and Sale) Act<sup>(15)</sup> reference to a number of diseases and conditions must not be made in advertisements; the list does not however include obesity. Nonetheless, by S 52 of the Medicines Act, the Minister may ban a medical advertisement containing language likely to mislead the public.

Albeit that unscrupulous claims might escape the letter of the regulations (although not the discretionary provisions under SS 52, 54 and 55 of the Medicines Act), there is a separate corpus of law in respect of consumer protection. By the Consumer Protection (Trade Descriptions and Safety Requirements) Act<sup>(16)</sup> S 4, "any person who in the course of a trade or business ... applies a false trade description to any goods shall be guilty of an offence". Crucially in this context, description includes a statement of "fitness for purpose" [(S 2(1) (d)]. There can be a fine or imprisonment or both for breach. Indeed all of the aforementioned acts and regulations hold criminal penalties; they are enforced by designated government authorities in the public interest<sup>(17)</sup>. In contrast, the provisions of the Sale of

Goods Act<sup>(18)</sup>, S 14<sup>(2)</sup> allow, in a civil action, application for damages from a supplier of goods which do not conform to merchantable quality, that is, fit for the purpose bought. This would seem to offer a vehicle for redress if slimming preparations, after purchase, turn out to be useless. Nonetheless, however fatuous might be a six-month course of a slimming aid costing say a few hundred dollars, it would take a brave consumer to sue a commercial concern for the recovery of this amount. If any harm or loss were to accrue from taking the slimming aid, there would of course be the basis for an action in negligence but this is even more chancy against a powerful corporation. The public must surely rely on the vigilance of the authorities and the criminalisation of administrative law. Finally, as in other countries, we have an Advertising Standards Authority to whom complaints may be made – obviously in the context of advertising, not selling. The Authority will look into a complaint and if accepted as justifiable, it will advise the advertiser to cancel or modify the offending item. It appears that the advertiser invariably complies with this "advice", to avoid a complaint by the Authority, (an arm of the Consumers' Association of Singapore, therefore not a government body but "an institution of a public character") to the Minister, who as stated above, has wide powers to intervene.

### REFERENCES

1. Popkin BM, Doak CM. The obesity epidemic is a worldwide phenomenon *Nut Rev* 1998; 56:106-14.
2. Koide SS. Chitin-chitosan: properties, benefits and risks. *Nut Res* 1998; 18:1091-101.
3. Maezaki Y, Tsuji K, Nakagawa Y. Hypocholesterolaemic effect of chitosan in adult males. *Biosci Biotech Biochem* 1993; 57:1439-44.
4. Jenkins DJA, Wolever TMS, Hockaday TDR, Leeds AR, Howart R, et al. Treatment of diabetes with guar gum. *Lancet* 1997; 2:779.
5. Heymsfield SB, Allison DB, Vasselli JR. *Garcinia cambogia* (hydroxycitric acid) as a potential antiobesity agent. *JAMA* 1998; 280:1596-600.
6. Anderson RA. Effects of chromium on body composition and weight loss *Nut Rev* 1998; 56:266-70.
7. Cook ME, Pariza MW. United States Patent 5,430,066, 4 July 1995.
8. Barak AJ, Beckenhauer HC, Bodakhsh S, Tuma DJ. Effect of betaine in reversing alcoholic steatosis. *Alc Clin Exptl Res* 1997; 21:1100-2.
9. Kenner D, Requena Y. *Botanical Medicine*. Paradigm Publications, Brookline, Mass, 1996, p 162.
10. *Straits Times*, 5th Dec 1997. (Mr Wu has also explained the attitude of pharmacists inter alia to herbal cures in a letter to the Singapore Medical Journal, 1983; 39:N8).
11. Manteiga R, Park DL, Ali SS. Risks associated with the consumption of herbal teas. *Rev Envir Contamination Toxicol* 1997; 150:1-30.
12. Leung LH. Pantothenic acid as a weight reducing agent: fasting without hunger, weakness and ketosis. *Med Hypotheses* 1995; 44:403-5.
13. Cap 176, 1985 Rev Ed.
14. Cap 176, Rg 2, 1990 Ed.
15. Cap 177, 1985 Rev Ed.
16. Cap 53, 1985 Rev Ed.
17. The statutes also include a number of defences which will not be considered here.
18. This is the UK Sale of Goods Act, 1979, retained in Singapore law by the Application of English Law Act, 1993.