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Study of representative samples of the more commonly used anti-obesity proprietary preparations

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**A STUDY OF REPRESENTATIVE SAMPLES OF THE MORE
COMMONLY USED ANTI-OBESITY PROPRIETARY PREPARATIONS**

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**Submitted in Partial Fulfillment for the Degree of
Doctor of Medicine**

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INTRODUCTION

There is considerable amount of confusion in the medical literature as to the meaning and proper application of the term "proprietary medicine." It has been used, particularly by the laity and to a certain extent by the medical profession, interchangeably with such phrases as "patent medicine", "over-the-counter medicine", "trade-marked medicine", and "registered medicine."

The Second Edition of the Webster's New International Dictionary defines the first three phrases mentioned above in following way:

PROPRIETARY - made and marketed by a person or persons having the exclusive right to manufacture and sell such; as proprietary article, medicine, or food.

PATENT MEDICINE - a packaged medicine put up for immediate use by the public and protected by a patent. The package is labeled with the name of the medicine and carries directions for its use.

NOSTRUM - a medicine recommended by its preparer; especially, a medicine the ingredients of which are kept secret; a patent or quack medicine.

As to the phrase "exclusive right" incorporated in the above definition of the word "proprietary", the Court in a Minnesota case, *Tridje v. Haney* (1931) 184 Minn. 569, 239 NW. 611, (1) states that:

The word "proprietary" as applied to medicines implies that the compound has been prepared by a manufacturer according to his own formula, though it is not necessary for the formula to be the exclusive property of the maker or that the process be secret.

In another case (2), the California Court states that:

Strictly speaking, one may say that a patent medicine is only one that is protected by a patent. Also it is possible to say that a proprietary medicine is only one which is protected by a patent, for in no other way does a proprietor secure an exclusive right of property in its manufacture.

In the above mentioned definition of the word "nostrum", the Webster Dictionary clearly states that this word is or may be used synonymously with "patent" or "quack medicine." The indiscriminate application of the above terms and phrases is also evident throughout the voluminous literature on the subject of advertisement and sale of pharmaceutical products.

The pharmacist, however, appears to have solved the whole problem by adding two new abbreviations to his everyday vocabulary, i.e. "Rx", which refers to the drugs restricted to prescription sale, and "OTC", which denotes drugs that may be sold "over-the-counter without prescription." (3) Thus the term "OTC" is being used nowadays by both the pharmacist and the physician for proprietary drugs, for patent medicine, and, in short, for all those pharmaceutical products which are not required by the law to bear the label "Caution: Federal Law prohibits dispensing without prescription." These products include all medicines of secret or known composition which are advertised directly to the public for self-medication and purchased without the advice and often without the approval of the medical profession. It is believed that very few of these medicines "are actually registered as to ingredients and patented in the United States

Patent Office, . . . (although) . . . most of them are protected by trade names which become, through registration and usage, the property of the manufacturer or distributor." (4) The object of this paper is to study selected representatives of this particular group of drugs as they are used for self-medication against obesity.

THE OBJECTIVES OF THIS STUDY

The purpose of this paper is to evaluate the therapeutic effectiveness of certain representatives of the more commonly used anti-obesity proprietary preparations available on the market in terms of their ingredients and the claims made for them by the manufacturers and distributors.

The preparations studied were those commonly dispensed without prescription in most drug stores in Omaha. No literature was found to determine on a statistical basis which preparation is most popular at the present time. Furthermore, the popularity of these preparations and the volume sold fluctuate so much at any given period of time that no reliable statistical evaluation in this respect was possible. Nor was it possible to establish what product has been preferred by the public, say, during the last year, as the opinion of pharmacists in this respect varied considerably. My personal communication with several pharmacists in town revealed that they do not keep any preparation in the store unless there is a popular demand for it. Those preparations which are or appear to be out of public demand are promptly removed from the shelves.

A total of eleven preparations was studied. They were:

RDX
Melozets - Methylcellulose Wafers
Al Hin-One Capsules
Ayds
Regimen Tablets
Dietrite
Junex

Kessamin Tablets To Lose Weight
Metrecal
Mynex
Revlon Thin-Down

Particular attention was paid to the following:

1. **INGREDIENTS:** It was not always possible to ascertain the amount of each ingredient in the preparations. However, in most cases both the name and the dosage of constituent ingredients were obtained directly from the labeling and/or accompanying instructions.

2. **RECOMMENDED DOSAGE AND DIRECTIONS FOR USE:** This was obtained from the data furnished by the manufacturer or the distributor.

3. **PRICE:** This was taken from the label appearing on the preparation and was found to be identical in the drug stores in Omaha and Lincoln.

Representative samples of the listed preparations were selected and analyzed in detail in the following pages with respect to: a) Ingredients; b) Recommended dosage; c) Pharmacological properties; d) Therapeutic effectiveness of the recommended dosage; and e) The extent to which each preparation answers the claims of its manufacturer.

The remaining six preparations were included as a portion of this paper in the appendix.

R D X

INGREDIENTS:

Skim milk	Amount not given
Dextrose	" " "
Saccharin	" " "
Flavoring	
Ascorbic Acid	30 mgm per tablet

Protein	25%
Carbohydrate	60%
Fat	1%

RECOMMENDED DOSAGE:

One or two tablets before each meal.
Take also as desired between meals.

PRICE:

125 tablets - 6.5 oz., \$2.98

ADVERTISED:

Eat . . . and . . . Lose Fat with Clinically-Tested RDX
"Full-Stomach" Reducing Plan.

The RDX Plan lets you eat what you want, yet lose ugly
fat. It helps you reduce without strenuous
exercise or starvation diet . . .

RDX Tablets are primarily designed to help you curb
your craving for between-meal snacks and
avoid over-indulgence in rich, fattening
foods. They contain no dangerous drugs. . .
no hormones . . .

Depend upon RDX tablets to help you control your
temptation to overeat. Carry them with
you wherever you go.

MANUFACTURED BY: Pharmaceuticals, Inc., Newark, N. J.

Discussion

No direct quantitative data of the ingredients of this preparation have been furnished by the manufacturer. This makes the quantitative evaluation of this preparation an approximation at best.

The data furnished by the manufacturer are:

1. Total weight of 125 tablets -- 6.5 ounces
2. Relative amounts of protein, carbohydrate and fat
 - a. Protein -- 25%
 - b. Carbohydrate -- 60%
 - c. Fat -- 1%
3. Ascorbic Acid -- 30 mg.

The following information can be derived from the above-mentioned data.

1. Weight of each tablet in the metric system:
1 ounce -- 28.35 gm.
6.5 oz -- 185 gm. (weight of 125 tablets)
185 : 125 -- 1.48 gm. (1480 mg.) - (weight of each tablet)
2. The relative quantities of protein, carbohydrates and fat being given, the approximate amount of each ingredient per tablet will be:
 - a. Protein -- 370 mg.
 - b. Carbohydrate -- 888 mg.
 - c. Fat -- 15 mg.
 - d. Ascorbic acid -- 30 mg.
 - e. Saccharin and flavoring -- 177 mg.
3. In terms of caloric values (5):
 - a. Protein: $370 \times 5.6/1000 = 2.1$ Cal.
 - b. Carbohydrate: $888 \times 3.96/1000 = 3.5$ Cal.
 - c. Fat: $15 \times 9.5/1000 = 0.1$ Cal.
 - d. Ascorbic Acid - 0
 - e. Saccharin - 0

Total caloric value per tablet: 5.7

If a patient were to take 10 tablets per day, which is above the average according to the manufacturer's recommendation, he would be consuming:

- a. Protein: $370 \times 10 = 3.70$ gm. - 21 Cal.
- b. Carbohydrate: $888 \times 10 = 8.88$ gm - 35 Cal.
- c. Fat: $15 \times 10 = 0.10$ gm. - 1 Cal.

Total number of Calories consumed per day - 57

For this the patient would have to pay 29.8¢ per day. Now, the retail price on the skim milk is:

- a. Regular skim milk - 14¢ per quart
- b. Powdered skim milk - 8¢ per quart (6)

Each fluid quart (approx. 1000 cc.) will furnish the following amounts of:

- a. Protein - 35 gm.
- b. Carbohydrate - 51 gm.
- c. Fat - 1 gm.

Plus the following minerals and vitamins:

- d. Calcium - 1.230 gm.
- e. Phosphorus - 970 mg.
- f. Iron - 1 mg.
- g. Sodium - 520 mg.
- h. Potassium - 1500 mg.
- i. Vitamin B₁ - 0.4 mg.
- j. Vitamin B₂ - 1.8 mg.
- k. Nicotinic Acid - 1 mg.
- l. Ascorbic acid - 10 mg.

Hence, the patient can spend one half the price of 10 tablets per day and obtain approximately ten times the amount of ingredients contained in 10 tablets and, what is more, in about the same proportion too.

As to the saccharin, although its amount is not mentioned, assuming the dosage per tablet to be 30 mg.* , the total amount

* This is used as a substitute for an ordinary lump of sugar. (7)

consumed per day (10 tablets) will be 300 mgm. The retail price of saccharin in one-half grain tablets is 100 tablets 39¢ (6), i.e. 3250 mg. for 39¢, approximately 0.3¢ per tablet, or 3.5¢ per 10 tablets per day.

The retail price on Ascorbic Acid (6) is: Vit. C in 100 mg. tablets, 100 tablets \$2.00, or 2¢ per tablet (per 100 mg) and 6¢ per 300 mg. (10 tablets of RDX per day).

The total retail price of the ingredients per 10 tablets of RDX (daily dosage) will be:

Skim milk	1¢
Saccharin	3.5¢
Ascorbic Acid	6¢

or a total of 10.5¢

But the cost of the ingredients for the manufacturer must undoubtedly be much lower than that, because: 1) even the retail price on powdered skim milk is approximately one-half that of the fluid skim milk; 2) wholesale price must be much lower than the prices given for any of the above-mentioned ingredients (approximately 1/3 to 1/2 of the retail price). (6); 3) the manufacturer no doubt obtains these ingredients at a price which is only a fraction of the wholesale price offered to the retailer.

Basis for the Use of the Above Ingredients

SKIMMED MILK. It is true that skimmed milk is a valuable source of protein, vitamins and minerals. (9) All these constituents are indispensable in replacement therapy for obese patients on a low caloric diet who may not be taking the above ingredients

in an adequate amount. However, it is not clear what advantage is gained by consuming skimmed milk in the form of tablets.

SACCHARIN. This is a synthetic sweetening agent of benzene derivation whose chemical name is benzosulfimide (10) or ortho-sulfamidobenzoic acid. It is totally unrelated to carbohydrate sugars and has the following properties (8):

- a. It has no nutritional value and passes through the body unchanged; hence it is used in anti-obesity preparations as a substitute for sugar.
- b. It is non-toxic in quantities ordinarily used.
- c. Occasionally its peculiar taste may become repulsive and thus diminish appetite.

ASCORBIC ACID. This is essential for the proper formation of intercellular substance. Its level in skimmed milk is low.* The daily requirement of this vitamin is not definitely known. It is estimated that a dietary intake of 75 mg. daily for the adult person will more than adequately supply the necessary requirement. (11) It appears that the addition of this vitamin alone was for the substitutonal value in a restricted diet, as in doses recommended it can hardly be considered to have a diuretic and anti-edema effect.**

* 1 mg. per 100 gm. of skimmed milk. (7)

** See reference #8, p. 93.

Conclusion.

Here is a preparation whose principal values lie in the skimmed milk which can be obtained for less than 1¢ a day to satisfy the recommended dosage. The added saccharin has a questionable appetite depressant effect and, as a substitute for sugar, can be obtained at a fraction of the price which the patient has to pay for RDX. As for the Ascorbic Acid, it could easily be obtained in required amount by drinking a glass of the more palatable orange or lemon juice.* Yet here is how this preparation has been presented to the public and here is what the patient has been asked to believe.

1. Eat . . . and . . . lose Fat with Clinically-Tested RDX. "Full-Stomach" Reducing Plan . . .

2. The RDX Plan lets you eat what you want, yet lose ugly fat. It helps you reduce without strenuous exercise or starvation diet . . .

3. Depend upon RDX Tablets to help you control your temptation to overeat. Carry them with you wherever you go . . .

* Fresh orange or lemon juice contains approximately 60-70 mg. ascorbic acid per 100 cc., (8), p. 94.

MELOZETS
METHYLCELLULOSE WAFERS

INGREDIENTS:

Each wafer contains 1.5 gm. of methylcellulose in a wheat flour base together with sugars, salt and flavors.

Each wafer is equivalent to about 30 cal.

RECOMMENDED DOSAGE:

One or two wafers one-half hour before meals or when hungry.

Not more than eight wafers should be taken in any 24-hour period.

PRICE:

One-half pound -- \$1.35

ADVERTISED:

These pleasant tasting wafers offer an effective mechanical means of satisfying the feeling of hunger.

Melozets provide bulk . . . and help to satisfy the feeling of hunger that so frequently occurs.

MANUFACTURED BY: Merck, Sharp & Dohm.

Discussion

This preparation, which is marketed in the form of crackers, contains 1.5 gm. of methylcellulose in a wheat flour base. It also contains sugar, salt and various flavors the relative or actual amounts of which are not furnished by the manufacturer. The methylcellulose incorporated in this preparation has been described as having the following properties (8)*:

1. It is hydrophilic and turns into a colloidal solution when mixed with water. Hence, its use as a laxative and adjuvant for treatment of constipation (0.5 - 1.5 gm. 2 to 4 times a day).
2. It is inert, has no caloric value and is not absorbed from the digestive tract.
3. It expands in volume when moistened.

These properties have been claimed to produce a sensation of satiety and fullness without contributing any calories. This is presumably achieved by the swelling of the hydrophilic substance within the stomach. The bulk-laxative effect of this substance on the stomach, however, has not been evaluated on a scientific basis. In fact, the function of the stomach as a medium through which the total caloric intake is controlled has been questioned. (12) In spite of the claims of the manufacturer to the effect that "These pleasant tasting wafers offer an effective mechanical means of satisfying the

* p. 208

feeling of hunger", it has been found experimentally that when an inert or bulk producing substance is administered to rats along with their regular diet, this mixture has no lasting effect upon their total caloric intake. To compensate for dilution of their diet with such inert substances as kaolin, these animals increased the amount of their ingested food and thus maintained their usual caloric intake. (13) Furthermore, methylcellulose or its synthetic derivative carboxymethylcellulose is not entirely innocuous.*

1. It is contraindicated in ulcerative colitis. (8)
2. It should be administered in gradually reduced dosage. (14)
3. Due to the rapid absorption of water and swelling, these preparations have been reported to produce esophageal impaction (15, 16) and even fatal intestinal obstruction. (17)

* Sodium carboxymethylcellulose is a synthetic hydrophilic colloid and differs from methylcellulose in that it is insoluble in gastric juice. (14)

MULTI-VITAMIN AND MINERAL PREPARATIONS

Two preparations have been chosen for study: ALL-IN-ONE capsules and AYDS.

The amount of vitamins incorporated in the recommended daily dosages of these two preparations is as follows:

	<u>ALL-IN-ONE</u>	<u>AYDS</u>
Vitamin A		800 u
Thiamine (Vit. B-1)	2.304 mg.	333 u
Riboflavin (Vit. B-2)	2.880 mg.	1 mg.
Pyridoxine (Vit. B-6)	2.888 mg.	
Ascorbic Acid (Vit. C)	37.320 mg.	
Calcium Pantothenate	2.880 mg.	
Vitamin D	4.500 mg.	400 u
Niacinamide	14.400 mg.	

The value for each incorporated mineral ingredient could not be ascertained, as it was given either in percentage of "the normal requirement" or in combination with several minerals. The exact range of the daily minimal or maximal requirements of vitamins and nutrients has not been definitely established. (21) The values provided by the Food and Nutrition Board of the National Research Council are (20):

FOOD AND NUTRITION BOARD, NATIONAL RESEARCH COUNCIL
RECOMMENDED DAILY DIETARY ALLOWANCES, REVISED 1958

Designed for maintenance of good nutrition
of healthy persons in the United States

Age:	MEN (70 kg.)			WOMEN (58 kg.)		
	25	45	65	25	45	65
Calories	3200	3000	2550	2300	2200	1800
Protein	70	70	70	58	58	58
Calcium (gm.)	0.8	0.8	0.8	0.8	0.8	0.8
Iron (mg.)	10	10	10	12	12	12
Vitamin A (IU)	5000	5000	5000	5000	5000	5000
Thiamin (mg.)	1.6	1.5	1.3	1.2	1.1	1.0
Riboflavin (mg.)	1.8	1.8	1.8	1.5	1.5	1.5
Niacinamide (mg. equiv.)	21	20	18	17	17	17
Ascorbic Acid (mg.)	75	75	75	70	70	70
Vitamin D				Only in pregnant and lactating women		

Taking into consideration the fact that the safe range of therapeutic dosages of vitamins is approximately five to ten times that of the recommended daily allowance, it is safe to assume that the values of vitamins incorporated in the two preparations under consideration are innocuous even if the patient continues taking an adequate daily diet. (11)* On the other hand, if the patient were to follow a well balanced reducing diet, prescribed by a competent physician, there would be no need to supplement it by vitamins and/or minerals as it is very easy to prescribe a low calorie

* p. 512

diet which would incorporate adequate amounts of all essential nutrients. Hence, supplementation of even a reducing diet with vitamin pills or minerals is at best an unnecessary financial burden on the patient. (18) The only justification for use of such a supplementation to the diet in the case of obese patients subjecting themselves to self-medication is that by accepting the misleading advertisements of the manufacturers they deprive themselves of medical guidance and may easily subject themselves to an unbalanced diet lacking in essential nutrients. An adequate weight reducing diet easily supplies adequate amounts of vitamins and minerals. This is particularly true of vitamins A, C and D. It is only in certain exceptional situations that need for additional use of members of the B-complex group of vitamins may arise, as their concentration in reducing diets may be less than optimal. (19)

The two preparations mentioned above are presented with their ingredients on the following pages.

ALL-IN-ONE CAPSULES

INGREDIENTS:

Each capsule contains:

Ferric Pyrophosphate	11.4 mg.
Tricalcium Phosphate	121.23 mg.
Thiamine HCl	0.384 mg.
Calcium Pantothenate	0.48 mg.
Pyridoxine HCl	0.048 mg.
Methylcellulose 400 cps	121.32 mg.
Ascorbic Acid	6.22 mg.
Irradiated Yeast	0.75 mg.
Riboflavin	0.48 mg.
Niacinamide	2.40 mg.
Malt Diastase	25.00 mg.
Soy neutral protein	151.00 mg.

Percentage of minimum daily requirements supplied by eight capsules:

Iron	100%
Calcium	50%
Phosphorus	25%
Vitamin B-1	240%
Vitamin B-2	150%
Vitamin C	160%
Vitamin D	25%

plus

Niacinamide	19.2 mg.
Vitamin B-6	0.38 mg.
Calcium Panto- thenate	3.84 mg.

Each capsule contains 1/50 gr. of saccharin, a non-nutritive, artificial sweetener which should be used by persons who must restrict their intake of ordinary sweets.

1208 mg. of 89% protein material is added along with methylcellulose and digestive ferments.

DIRECTIONS FOR USE:

Two capsules 15 minutes before each meal, three times a day, and upon retiring.

PRICE: Open

ADVERTISED:

It's SO EASY TO BE SLIM.

Science now helps you take off your fat while you eat the foods you choose.

The amazing ALL-IN-ONE reducing plan has been planned by nutritional scientists to help you lose weight faster, safer, easier than you've ever dreamed possible. You no longer want to eat as much. You don't give up your favorite foods - you merely cut down. And you don't have to miss any meals either. Your appetite is controlled so that you naturally eat less at meal time, and by eating less you lose weight almost automatically. It's just as easy and simple as that.

MANUFACTURED BY: State Pharmacal Co., Chicago 1, Ill.

Discussion

Besides vitamins and minerals this preparation contains:

1. Methylcellulose, the properties of which have been described in connection with the MELOZETS METHYLCELLULOSE WAFERS (q. v.)

2. MALT DIASTASE* This is a diastatic ferment obtained from malt, the grain of barley. The therapeutic value of this ferment is questionable as its action is weak and unreliable. (8)*

3. SOY NEUTRAL PROTEIN. This is a protein whose biological value is markedly improved either by heat treatment or by the addition of methionine. (22); but no methionine has been added to this preparation. Hence, it is assumed that this substance has been added simply as a protein to the preparation presumably to increase its nutritional value.

In summary, this is a multi-vitamin and mineral preparation to which have been added protein, methylcellulose and a digestive ferment of questionable value.

* p. 54

AYDS

INGREDIENTS:

Ayds Candy contains:

Corn syrup
Sweetened condensed whole milk
Oleo and vegetable oil
Soya flour
Tricalcium phosphate
Powdered egg yolk
Powdered carrots
Salt
Iron phosphate (insoluble)
Lecithin
Non-fat milk solids
Sorbitol
Imitation and natural vanilla flavor

(Neither amount or proportion of above ingredients given.)

Vitamin D (Ergosterol)	400 USP units
Vitamin A	800 USP units
Vitamin B-1 (Thiamin)	333 USP units
Vitamin B-2 (Riboflavin)	1 mgm.
Calcium	175 mgm.
Iron	5 mgm.
Phosphorus	100 mgm.

One Ayds contains approx. 25 cal.

RECOMMENDED DOSAGE:

One or two Ayds 15 or 20 minutes before each meal

PRICE:

104 pieces, 1 lb. 8 oz. - \$3.25
208 pieces, \$5.50

ADVERTISED:

New England Clinic proves Ayds best reducing method in
Medical Test.

Ayds users lost 13.7 lbs. (average) . . . during 60-day test.
Some lost as much as 26 lbs. Only Ayds users had no "unplea-
sant side effects."

The Ayds Plan is recommended by eminent medical authorities. The combination of pure food vitamin rich ingredients in each Ayds candy helps quell hunger by naturally stimulating the blood sugar apparatus which helps control our appetite, at the same time satisfying the stomach's craving for food.

If one must reduce, it's wise to follow a way that agrees with Nature. Use Ayds. Eat sensibly. Reduce safely.

MANUFACTURED BY: Carlay Division, Dept. F, Company Corporation,
Batavia, Ill.

Discussion

This is in essence a vitamin and mineral candy. The amounts of the ingredients, except for the vitamins and part of the minerals incorporated in the preparation, are not furnished by the manufacturer. From the qualitative point of view, most of the ingredients used in this preparation are similar to those in any other candy. There is no way to tell whether any particular food substance has been given preference for its high satiety and low caloric values. No bulk producing or appetite depressant substance has been incorporated into this preparation. In short, this is a candy preparation fortified, so to speak, by vitamins and minerals which, according to the manufacturer, help one lose up to 26 lbs. within a period of two months.

REGIMEN TABLETS

INGREDIENTS:

In green tablets:

Vitamin D (irradiated yeast)
Vitamin B-1
Vitamin B-2
Vitamin B-6
Vitamin C
Niacinamide
Calcium Pantothenate
Diastase of Malt
Benzocaine

In yellow tablets:

Phenyl-Propanolamine HCl
Caffeine Alkaloid Anhydrous
Iron (Ferrous Sulfate)
Potassium Iodide
Copper (Cupric) Sulfate

In pink tablets:

Ammonium chloride

Total Contents: 156 tablets

36 coated pink
60 coated yellow
60 coated green

DIRECTIONS FOR USE:

For the first three days swallow 2 pink, 1 yellow tablet, and allow 1 green tablet to dissolve in your mouth, one-half hour before meals three times daily . . .

For the next seven days take only 1 yellow tablet and 1 green tablet about a half hour before each meal.

PRICE:

156 tablets, \$3.00

ADVERTISED:

A new dietary combination to satisfy hunger, remove excess water, control and inhibit appetite.

The Regimen Plan does most everything medical science can do to help you attain your goal . . .

As long as you have weight to lose follow the Regimen Plan and each week you will notice a weight loss that will delight you and please your friends and family . . .

Keep a supply of Regimen on hand by ordering your next package in advance. Order right now to be sure of losing as much weight as is necessary.

MANUFACTURED BY: Drug Research Corp., New York, N.Y.

Discussion

This preparation has been selected for analysis mainly because of phenylpropanolamine hydrochloride incorporated into it. This is essentially a multivitamin-mineral preparation plus phenylpropanolamine hydrochloride and ammonium chloride. The preparation is marketed in three kinds of tablets which are recommended to be taken together according to the directions supplied by the manufacturer. No dosage has been furnished.

The green tablets are composed of:

- a. A combination of water-soluble vitamins plus Vit. D;
- b. Diastase of malt, a diastatic ferment of questionable therapeutic value as discussed in ALL-IN-ONE CAPSULES (q.v.)
- c. Benzocaine (Ethyl Aminobenzoate) - This is a local anesthetic. It has also been used to relieve gastralgias of various etiologies with doubtful results. (31) Its inclusion here is presumably for the purpose of obtunding hunger pang.

The yellow tablets are composed of:

- a. Minerals
- b. Caffeine Alkaloid Anhydrous - this is used as a psychic, muscular and respiratory stimulant and also as a diuretic and cardiac tonic. The rationale for its use here is not apparent. The dosage of this drug is not known. Its excessive stimulation

of the higher centers precludes use of this drug for most purposes.*

(10)

c. Phenylpropanolamine Hydrochloride (Propadrine HCl) - this is a sympathomimetic amine with actions similar to those of ephedrine but it has a greater pressor activity and slightly less stimulant. The therapeutic indications for propadrine are essentially the same as those for ephedrine. It is predominantly used as a topical anti-congestant of mucous membranes and in 25 mg. capsules orally every 2 to 4 hours against asthma. It has, however, been widely used and exploited as an allegedly effective chemical ingredient of several widely advertised "no-diet" reducing nostrums without sufficient scientific evidence to support this claim. The dosage of this drug in the preparation under consideration has not been furnished by the manufacturer, but it is assumed to be 25 mg. per tablet. (32) This is approximately equivalent to the recommended dosage for asthma. In a study conducted for the purpose of evaluation of the effectiveness of propadrine as an anorexigenic agent (33), the conclusion reached was that "Phenylpropanolamine, when administered in recommended doses, and even in twice the supposedly therapeutic doses, failed to effect a statistically significant reduction in weight. The changes in weight associated with the ingestion of phenylpropanolamine were of approximately the same magnitude as those accompanying the ingestion of a placebo . . . "

* p. 272

Thus there appears to be no justification for the promiscuous use of a pharmacologic agent whose therapeutic effectiveness cannot be proved or justified. Here are some of the claims made for this 'wonder drug' (32):

" . . . It contains three active drugs necessary to perform the three most important functions of reducing. Each drug was tested by doctors in leading hospitals and clinics for safety and effectiveness. The results were so amazingly successful that they were published in leading medical journals so that other doctors might become acquainted with this outstanding discovery . . . "

"World's most fabulous reducing Regimen acts without fad difficulties, without ever going hungry, even without giving up your favorite foods."

"Amazing new wonder drug tablet for fat people. Works through the blood-stream, directly on the cause of your overweight."

The pink tablets contain only ammonium chloride. This is a diuretic drug and the rationale for its use here is based on the reduction in weight which ensues following depletion of edema fluid through diuresis. But the use of this drug is not without hazards and may be extremely dangerous in elderly individuals in whom the kidneys' ability to excrete a maximally acid urine and produce ammonia may be diminished. (10)*

* p. 414

CONCLUSIONS

Approximately one-hundred million dollars are spent annually for weight reducing purposes. (23) One writer estimates that 3% of the population of the United States are overweight (24), but this estimate seems far too low. These overweight persons comprise a disproportionately large percentage of the average medical office practice. It has been demonstrated that there is a specific relationship between longevity and body weight. The mortality of the obese person is between 14 and 86% above normal depending on the person's age and degree of obesity. (25) Obesity goes hand in hand with such chronic diseases as arteriosclerosis, hypertension, heart disease, diabetes mellitus and a host of degenerative diseases which incapacitate and shorten life.

It has been stated that obesity arises from a condition of positive energy balance. (26) However, the exact mechanism which leads to this imbalance is not known. Nobody has adequately explained the process which stimulates the desire to eat to such an extent that an individual will indulge in overeating even though this entails social ostracism, unflattering appearance and poor health. (27) Many physiological and psychological factors contribute to overeating. The therapeutic approach should vary on the basis of these contributing factors. One short scheme of classification lists these factors in the following way. (27)

1. Psychosocial and environmental factors:
 - a. Ordinary vicissitudes of daily life, e.g. domestic upsets, fatigue, boredom, economic worries.
 - b. Feeling of insecurity and guilt.
 - c. For relaxation.
 - d. For sexual motives.

2. Organic factors:
 - a. Organic diseases which restrict physical activity.
 - b. Feeling of tiredness and belief that food will restore energy lost.
 - c. Brain injury.
 - d. Adiposity following castration, cortisone administration and due to fat deposition associated with puberty, pregnancy, and the climacteric.
 - e. Nocturnal hyperphagia due to recurrent bouts of hyperglycemia during the night.
 - f. Inability of the tissues to metabolize carbohydrate beyond the pyruvic acid stage.

3. Constitutional factors:
 - a. Inheritance.
 - b. Metabolic disturbances.

Despite this variety of etiological factors underlying obesity and despite the seriousness of the problem involved, its treatment has often been slighted and considered simple enough to be handled by self-medication or by some business establishments as "beauty salons, physical culture institutes, manufacturers of exercise equipment and vibratory machines and drug houses who profit from the slimming aspirations of millions of persons by selling them worthless nostrums and for whom there is only one kind of obesity and that is 'easy weight reduction or your money back obesity.'" (3)

What is the price that the patient pays for such an approach to the problem of obesity?

1. These preparations are ineffective at best and toxic in certain cases.

2. They divert the patient's attention from his basic problem and cause loss of valuable time in seeking proper medical care. (29)

3. They cause considerable loss in terms of time and money.

4. Furthermore, the overall survey of these preparations shows that:

a. They are essentially shot-gun preparations of vitamins, minerals, bulking agents, confections, dried milk, etc.;

b. They are presented to the public as a panacea disregarding the underlying cause of obesity, the treatment of which in most instances might be more important than obesity itself;

c. Through misrepresentations and false advertisements, they defraud the credulous public and indirectly undermine their confidence in genuine pharmaceutical preparations.

The treatment of obesity is difficult even when a scientific approach to the problem is used. (28) This is further complicated by the fact that patients usually expect "miraculous changes in appearance" almost overnight. The overweight are, therefore, easy prey for the distributors of questionable preparations offered as specific anti-obesity drugs. (30)

We are faced with a disease exceedingly common in occurrence and extremely resistant to the treatment. It is associated with a high incidence of accompanying illnesses, such as diabetes, hypertension, cholelithiasis and a high mortality rate. An understanding of the factors involved in its development is a sine qua non of a proper approach to this problem. The treatment should be individualized and carried out by a sympathetic, understanding, and well-qualified physician.

ACKNOWLEDGEMENT

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A P P E N D I X

DIETRITE

INGREDIENTS:

Each 6 tablets contain:

Vitamin B-1 (Thiamin HCl)	3 mg.
Vitamin B-2 (Riboflavin)	6 mg.
Vitamin B-6 (Pyridoxine HCl)	0.6 mg.
Vitamin C (Ascorbic Acid)	180 mg.
Calcium Pantothenate	3 mg.
Niacinamide	30 mg.
A non-nutritive bulk concentrate	1800 mg.

As a dietary supplement, this product affords in each six tablets three times the minimum daily requirement of Vitamin B-1, three times this requirement of Vitamin B-2, and six times this requirement of Vitamin C.

DIRECTIONS FOR USE:

Two to four tablets (depending on appetite) with full glass of water, 30 minutes before each meal. May be used also as an aid to appease "between-meal" hunger.

ADVERTISED:

Supplies a sensation of bulk and tends to allay hunger in reduction diet in addition to supplying specified vitamins which may be lacking in reducing diets.

Reduce the sensible DIETRITE way . . . No special diet, no drugs, no massages . . .

PRICE:

126 tablets - \$3.00

DISTRIBUTED BY:

Vitamin Division, Dwarfies Corporation, Council Bluffs, Iowa.

JUNEX

INGREDIENTS:

Each red tablet contains:

Calcium (Tricalcium Phosphate)	116 mg.
Phosphorus (Tricalcium Phosphate)	60 mg.
Vitamin B-1 (Thiamin HCl)	1 mg.
Vitamin B-2 (Riboflavin)	1 mg.
Niacinamide	6 mg.
Calcium Pantothenate	1 mg.
Vitamin B-6 (Pyridoxin HCl)	0.1 mg.
Vitamin C (Ascorbic Acid)	16 mg.
Vitamin D	140 USP units
Diastase of malt	100 mg.
Iron (Ferrous Sulfate)	3.4 mg.
Iodine (Potassium Iodide)	0.1 mg.
Copper (Cupric Sulfate)	0.6 mg.
Manganese (Manganese Sulfate)	0.6 mg.
Zinc (Zinc Chloride)	0.6 mg.
Cobalt (Cobalt Sulfate)	0.06 mg.
Choline (Dihydrogen Citrate)	5 mg.
Methionine DL	6.5 mg.
Sodium Copper Chlorophyllin	4 mg.
Sodium Sucaryl	0.25 gr.

Each white tablet contains:

Methylcellulose	6 gr.
Calcium (Tricalcium Phosphate)	38 mg.
Phosphorus (Tricalcium Phosphate)	20 mg.

One red tablet and one white tablet three times a day provide the following percentages of the minimum adult daily requirement:

Iron	100%
Calcium	60%
Phosphorus	30%
Iodine	300%
Vitamin B-1	300%
Vitamin B-2	150%
Vitamin C	160%
Vitamin D	100%

DIRECTIONS FOR USE:

Take 1 white tablet and 1 red tablet one-half hour before each meal three times a day.

PRICE:

60 tablets (30 white tablets and 30 red tablets) - \$2.98

ADVERTISED:

Reducing the new sensible way . . . No diet to follow . . .

No drugs . . . No exercise . . .

Remember, you do not have to cut out any meals or your favorite foods, but results will be quicker if you cut down on sugar, sweets, fatty meats and an excessive amount of salt . .

DISTRIBUTED BY:

Junex Products, 430 West Grant Place, Chicago 14, Ill.

KESSAMIN TABLETS

INGREDIENTS:

One day's supply (12 tablets) contains:

Vitamin A	5000 units
Vitamin D (Irradiated yeast)	1000 units
Thiamin HCl (B-1)	1 mg.
Riboflavin (B-2)	2 mg.
Pyridoxin HCl (B-6)	0.5 mg.
Cobalamin (Vit. B-12 activity)	1 mcgm.
Ascorbic Acid (C)	30 mg.
Niacinamide	10 mg.
Dicalcium Phosphate	150 mg.
Ferrous Sulfate, dried	35 mg.
Pasteurized skimmed milk	4 gm.
Sodium Carboxy-methylcellulose	2 gm.

The recommended daily dose (12 tablets) will furnish the following proportions of the minimum daily adult requirement:

Vitamin A	125%
Vitamin D	250%
Vitamin B-1	100%
Vitamin B-2	100%
Vitamin C	100%
Iron	100%
Calcium	6%
Phosphorus	4%

DIRECTIONS FOR USE:

Three tablets one hour before each meal and three tablets before going to bed.

PRICE: (open)

ADVERTISED:

Kessamin tablets contain no harmful drugs. The bulking action of the Sodium Carboxy-methylcellulose helps to give a full feeling and thereby tends to reduce the urge to overeat . .

Kessamin . . . together with the Kessamin plan is guaranteed to reduce weight satisfactorily without the use of harmful drugs . . .

MANUFACTURED BY: McKesson & Robbins, Inc., New York, N.Y.

METRECAL

INGREDIENTS:

Metrecal is made from:

Non-fat milk solids
Soya flour
Whole milk solids
Sucrose
Starch
Corn oil
Coconut oil
Yeast
Flavoring
Minerals and Vitamins

Each one-half pound supplies:

Calories	900
Fat	20 gm.
Protein	70 gm.
Carbohydrate	110 gm.
Ash	14.5 gm.
Vitamins:	
A	5000 units
D	400 units
E	10 units
Thiamine (B-1)	2 mg.
Riboflavin (B-2)	3 mg.
Ascorbic Acid (C)	100 mg.
Niacinamide	15 mg.
Pyridoxine (B-6)	2 mg.
Folic Acid	0.50 mg.
Vitamin B-12	2 mcg.
Calcium Pantothenate	10 mg.
Minerals:	
Calcium	2.0 gm.
Phosphorus	1.8 gm.
Sodium	0.9 gm.
Potassium	3.5 gm.
Chloride	1.6 gm.
Iron	15.0 mg.
Manganese	2.0 mg.
Copper	1.5 mg.
Zinc	5.0 mg.
Iodine	150.0 mcg.

Caloric distribution:	
Protein	30.5%
Fat	19.5%
Carbohydrate	50.0%

RECOMMENDED USAGE:

One can of Metrecal powder mixed with a quart of water . . .
used as a total daily diet . . .

One glass of Metrecal beverage may be taken for each meal
and one at bedtime or the total quantity may be divided
into more or fewer servings throughout the day as desired.

PRICE:

3 cans, 24 oz. - \$3.25

ADVERTISED:

Medical trials of Metrecal powder, with a wide range of
patients, demonstrated effective results in weight con-
trol diets. Patients lost weight readily and rapidly ...
over one-half pound a day was the average loss in a
group of 100 patients . . . losses as high as 18 pounds
in 12 days were recorded. Doctors were especially im-
pressed with the way Metrecal satisfied patients' ap-
petite . . .

Metrecal not only provides effective weight loss within
a short period of time but also meets the nutritional
and psychological criteria of being convenient and easy
to follow, nutritionally complete and satisfying . . .

Metrecal alone . . . 900 measured calories . . . for
adequate nutrition with high satiety while losing weight

Metrecal introducing a new concept . . . for weight
control . . .

MANUFACTURED BY: Mead Johnson & Company, Evansville 21, Ind.

MYNEX

INGREDIENTS:

Two green tablets together contain:

Ferric Pyrophosphate	16 mg.
Tricalcium Phosphate	720 mg.
Diastase of Malt	100 mg.

Each maroon tablet contains:

Vitamin B-1	1 mg.
Vitamin B-2	1 mg.
Vitamin C	16 mg.
Niacinamide	6 mg.
Vitamin D	200 IU
Vitamin B-6	0.4 mg.
Calcium Pantothenate	2 mg.

RECOMMENDED DOSAGE:

Two green tablets one-half hour before each meal, three times a day. Take one maroon tablet soon after each meal.

Taken as directed, two green tablets and one maroon tablet three times a day provide the following percentages of the minimum daily requirements:

Iron Phosphate	100%
Tricalcium Phosphate	100%
Diastetic Malt Extract	50%
Thiamin HCl (B-1)	300%
Riboflavin (B-2)	150%
Ascorbic Acid (Vit. C)	160%
Vitamin D	100%

PRICE:

63 tablets - \$3.00

ADVERTISED:

The Mynex reducing plan contains no exercise, no massage.

Reduce with this safe easy Mynex plan . . .

MANUFACTURED BY: (Distributors) Marlene's, Inc., 349 W. Ontario St.,
Chicago 10, Ill.

REVLON THIN-DOWN

INGREDIENTS:

Three "THIN-DOWN" Tablets contain 75 mgs. of phenylpropano-
lamine hydrochloride together with:

Vitamin A Acetate	4000 units, MDAR	100%
Vitamin B-1 (Thiamine HCl)	1 mg.	" 100%
Vitamin B-2 (Riboflavin)	1.2 mg.	" 100%
Vitamin C (Ascorbic Acid)	30 mg.	" 100%
Vitamin D	400 units	" 100%
Vitamin B-6 (Pyridoxine HCl)	0.1 mg.	
Niacinamide	10 mg.	" 100%
Calcium Pantothenate	3 mg.	
Iron	10 mg.	" 100%
Iodine	0.1 mg.	" 100%
Cobalt	0.1 mg.	
Fluorine	0.15 mg.	
Manganese	0.1 mg.	
Molybdenum	0.5 mg.	
Zinc	1 mg.	
Magnesium	10 mg.	
Potassium	5 mg.	

DIRECTIONS FOR USE:

One tablet swallowed with water a half hour before each meal.

PRICE:

90 tablets - \$3.50

ADVERTISED:

Revlon's Thin-Down 'Formula for Beauty' can not only decrease your weight (in pounds and inches) but actually increase your vitality, energy, and give you an over-all beautiful feeling.

Thin-Down tablets help to exert the discipline needed to change a weight-gaining appetite to a weight-losing appetite . . .

Thin-Down tablets are not the usual candies or bulk stomach-fillers designed to "spoil your appetite." Thin-Down tablets contain a remarkable drug, used medically for overweight patients. The new drug . . . actually helps you lose your desire for fattening foods of all kinds, helps you form a

completely new eating habit -- the habit of eating for slim, young beauty, not flabby bulk . . . You'll find you feel like walking more, feel like playing more, feel like being a participant instead of a spectator . . .

Within a week, you'll feel peppier, more lithe and limber. Soon your face will wear a new glow, those flabby spare tires around your waist will start to disappear; your thighs and upper arms to thin down. You'll lose that bulky "middle-age" middle, which can make you look dumpy, and older than you are, no matter what your height or age. . .

MANUFACTURED BY:

Revlon Pharmacial Division.

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