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Position Paper Regarding HCG Injections Along with a Very Low Calorie Diet for Weight Loss

The "HCG Diet" has become popular over the last few years due to the accessibility of the Internet and advertising by clinics that perform the protocol. I've read ATW Simeons protocol "Pounds and Inches: a New Approach to Obesity" several times. The paper is intriguing in terms of Simeons' theories about weight gain and the role of hypothalamic dysfunction in prevention of weight loss. It's also bold – Simeons claims that the protocol is easy to follow and uniformly effective in suppressing appetite, elevating mood, and enabling "abnormal", stubborn fat to be lost. He also states that HCG resets the hypothalamus to prevent lost weight from being regained. "Pounds and Inches" is available from several sources on the Internet. If you're interested, you can order a copy of Simeons' paper describing his protocol published in 1954 from the *Lancet*.[1]

HCG or "human chorionic gonadotropin" is a hormone produced during pregnancy. It's also produced by tumors in women (hydatidiform mole) and men (testicular cancer). HCG injections are used medically since part of its molecular structure mimics luteinizing hormone (LH). HCG injections (in dosages ranging from 1000 to 2000 units, 2-3 times per week) are used to increase testosterone production in men with low testosterone who want to preserve fertility. HCG injections (5,000 to 10,000 units) are sometimes used in women to induce ovulation.

Simeons protocol uses minute dosages of HCG (125 units), 6-7 days per week for 23 to 40 days, along with a very low calorie (VLC) diet of 500 calories per day. Since HCG does share some of its molecular structure with LH and thyroid stimulating hormone (TSH), theoretically, it may increase testosterone production, ovulation and progesterone production, or release of thyroid hormone. It may also cause excess stimulation of the ovary and ovarian cysts. However, the dosage used is very small and these effects are unlikely. A VLC diet (with or without HCG) can precipitate gallstones (since it's very low in fat), and may cause symptoms of toxicity (since fat tissue stores toxins).

Research regarding HCG injections and weight loss is nearly all negative. In other words, most trials where patients received either HCG injections or placebo and followed identical VLC diets, show no difference in amount of weight lost, type of weight lost, hunger level, or mood. A summary of published studies follows this paper.

No study that I've read has looked at long-term maintenance of weight lost with the HCG protocol. Randomized controlled trials of VLC diets show a large variation in regain of initial weight loss percentage. Participants in these trial regained 7-122% of initial weight lost by one year, and 26-121% by 5 years.[2] Active follow-up weight maintenance programs that include behavior therapy, nutritional education, and exercise are more effective at improving weight maintenance.

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[1] Simeons AT. The action of chorionic gonadotrophin in the obese. *Lancet.* 1954 Nov 6;267(6845):946-7.
[2] Saris W. Very-low-calorie diets and sustained weight loss. *Obesity Research.* 2001;Suppl 4:295S-301S.

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It would be worthwhile to perform a clinical trial to see if participants following the HCG protocol are more successful at maintaining weight loss than VLC diet alone. Simeons claims patients who follow his protocol maintain weight loss 60-70% of the time, although I don't think he published data to back up this claim.

I've spoken to many patients who've followed the HCG protocol with great success – they've lost significant amounts of weight, claim not to have been hungry, and had an increased sense of well-being. Many of these people have sustained their weight loss, many have not. I've personally gone through Simeons protocol, documenting all calories consumed as well as calories burned (by wearing a Bodybugg®). I also measured my fat and muscle percentage before and after the diet using bioelectrical impedance analysis. I lost 12 pounds and 4% body fat during the 23 day protocol. I was extremely hungry throughout the entire protocol, although I did exercise every day. Some proponents of the protocol recommend not exercising, although this seems like bad advice given the overwhelming health benefits of regular exercise. I've also undergone a VLC diet, documenting all calories consumed and burned, without using HCG injections. I lost a similar percentage of excess weight.

My position on the HCG protocol for weight loss is that I do not think it's harmful. I also don't think it has any effect over placebo. I do not discount the power of any placebo. The placebo response is really a measure of the power of the self-healing ability. Many people are willing to follow a VLC diet if they inject themselves or take oral HCG since they believe the HCG will suppress their appetite and help them lose weight. I do believe that physicians who perform this protocol should disclose the negative research regarding HCG benefits to patients. I also believe it is ignorant of them at best, and unethical at worst, to prescribe a substance and oftentimes, charge high fees, for a product or protocol that is a placebo.

Note that since 1975, the FDA requires the following information to be given with any HCG advertised or promoted for weight loss:

> HCG has not been demonstrated to be effective adjunctive therapy in the treatment of obesity. There is no substantial evidence that it increases weight loss beyond that resulting from caloric restriction, that it causes a more attractive or "normal" distribution of fat, or that it decreases the hunger and discomfort associated with calorie-restricted diets.

If you are interested in following the HCG protocol, I think you should be informed about the research regarding HCG and weight loss. You should also make sure your physician is aware of your current health status before you follow any VLC diet, and that causes of abnormal weight gain (e.g., hypothyroidism, hypogonadism, Cushing's, and other endocrine problems) have been ruled out. Before going on any VLC diet, I'd also recommend undergoing a detox program that supports Phase I and Phase II liver function. Make sure you don't have pre-existing gallstones, liver, or kidney disease. If you're using insulin for diabetes management, you must make sure your dosage is adjusted based on blood sugar levels, and that you don't develop ketoacidosis, which can be fatal.

If you do undergo a VLC diet (with our without HCG) you owe it to yourself to **change the factors that caused you to become overweight in the first place:** improve your overall diet

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and nutrition knowledge, honestly evaluate causes of emotional eating, decrease stress, and increase exercise frequency and intensity—otherwise, the chance of you gaining back the weight you've lost is nearly 100%.

I welcome comments or questions regarding my position. In addition, if you're aware of any research using the HCG protocol that I have not listed here, or if you believe my conclusions are incorrect, please contact me: drretzler@hormonesynergy.com.

Kathryn Retzler, ND

Summary of Research and Articles RE: HCG Injections & VLC Diet for Weight Loss

Note: Dr. Simeons does not state that HCG alone accomplishes weight loss; rather, he states patients treated with HCG will not be hungry or tired, will lose a different kind of weight ("abnormal fat" that is difficult to lose), and will experience an increased sense of well-being. He also claims that weight lost is unlikely to be regained ("60-70%" of patients keep weight off) due to a resetting of the hypothalamus.

Positive Papers:

Asher W, Harper H. Effect of human chorionic gonadotrophin on weight loss, hunger, and feeling of well-being. *Am J Clin Nutr.* 1973;26(2):211-8.

This study is a well-designed, randomized, double-blind trial of 40 women receiving HCG or placebo at an HCG treatment clinic (Harold Harper, MD). All followed a 500 to 550 kcal diet; 20 received 125 IU HCG six days per week for 6 weeks (36 injections); 20 received placebo injections six days per week (36 injections). Mean age of the HCG group was 37.8 years; placebo group 38.4 years. Results: Mean weight loss (HCG: 19.96 +/- 1.63 lbs; placebo: 11.05 +/- 1.29 lbs) and percentage of starting weight lost (HCG: 11.47%; placebo: 6.77%) were greater in the HCG group than the placebo group. Fourteen patients lost 15 lbs or more in the HCG group; 5 lost 15 lbs or more in the placebo group.

Hunger was decreased (HCG: 76.6% of daily responses indicated little or no hunger; placebo group 48.7% of daily responses indicated little or no hunger). Feeling of well being was greater in the HCG group (HCG: 86.5% indicated they felt "good" to "excellent"; placebo: 70% said they felt "good" to "excellent"). Blood pressure was not significantly different between the two groups. Interestingly, Dr. Harper's patients who received placebo injections lost more weight on average than either the HCG or placebo patients of 4 other physicians. The authors concluded, "Therefore, HCG used in a casual program of weight reduction, as it is often used in a general practice, is of no value," meaning that the very low calorie diet is the critical element leading to weight loss.

Gusman H. Chorionic gonadotropin in obesity. Further clinical observations. *Am J Clin Nutr*. 1969;22:686.

This paper is not a study but rather an article regarding Dr. Gusman's personal success treating "well over 2,500 patients of both sexes, aged 15 to 75" with Simeons' HCG protocol. Gusman studied with A.T.W. Simeons at his clinic in Rome. In this article, Gusman discusses Simeons'

concept of obesity, namely, that it is a "definite metabolic disorder, much as is diabetes, caused by a breakdown of a regulating mechanism located in the...hypothalamus." He call this "the fat-regulating center."

Gusman explains that fat cells in the obese differ from normal fat cells in that they're more numerous and larger. These "overstuffed" fat cells metabolize glucose less efficiently than normal fat cells. *Normal* fat tissue serves two functions: structural material (to protect organs and blood vessels) and fuel storage. *Abnormal* fat tissue is also a potential reserve for fuel, but is not immediately available in nutritional emergencies. Only after the normal fat reserves are exhausted will the body use abnormal fat. Severe calorie restriction leads to exhaustion of normal fat reserves before abnormal fat is used, and the patient will be weak and hungry "while the ugly fat deposits – of which he originally wished to rid himself – have hardly been reduced. At this point, the patient often becomes depressed and frustrated, and the diet is abandoned."

The only type of "nutritional emergency" where all types of fat cells are immediately useable is during pregnancy. Simeons suggests it's HCG that brings about changes in the hypothalamus preventing obesity during pregnancy.

Gusman compiled records from 450 of his patients receiving either 3 or 6 week treatment. He makes the following observations: 1) 90% of patients were able to reduce their weight, 2) 60-70% reached their desired normal weight, 3) "a majority" claimed this regiment was the easiest and most successful to follow, 4) "many" who regained some or all of their weight claimed they kept their weight off longer than previously, and didn't mind returning for treatment, 5)"nearly all patients" experienced "euphoria" in spite of marked low intake of food, and 6) the markedly obese had the most satisfying results.

Lebon P. Treatment of overweight patients with chorionic gonadotropin. *J Am Geriat Soc.* 1966;14:116.

Lebon P. Action of chorionic gonadotrophin in the obese. *Lancet.* 1961;2:268.

Simeons AT. The action of chorionic gonadotrophin in the obese. *Lancet.* 1954 Nov 6;267(6845):946-7.

Stuart C. The action of chorionic gonadotophin in the obese. *Lancet.* 1961;278(7196):268-9.

Negative studies:

Bosch B, Venter I, Stewart RI, et al. Human chorionic gonadotrophin and weight loss. A double-blind, placebo-controlled trial. *S Afr Med J.* 1990;77(4):185-9.

This study was a double-blind, placebo-controlled trial comparing HCG injections with placebo for weight loss. 40 obese women (body mass index greater than 30 kg/m2) were placed on the same diet supplying 5,000 kJ per day and received daily injections of saline or HCG, 6 days a week for 6 weeks. A psychological profile, hunger level, body circumferences, fasting blood sample, and food records were obtained at the start and end of the study, while body weight was measured weekly. Results: Subjects receiving HCG injections showed no advantages over those on placebo in respect to any of the variables recorded. Furthermore, weight loss on the diet was similar to that on severely restricted intake. The authors conclude, "There is no rationale for the use of HCG injections in the treatment of obesity."

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Craig L, Ray R, Waxler S, et al. Chorionic gonadotropin in the treatment of obese women. *Am J Clin Nutr.* 1963;12:230-234.

This study was a double-blind, placebo-controlled trial evaluating the effectiveness of the Simeon method using HCG vs. placebo, and a 550 calorie per day diet. 20 obese women were treated for forty days. Results: all subjects but one lost weight, but the losses were small and not uniform, suggesting varied adherence to the diet. The basal metabolic rate was increased in four HCG subjects and two control subjects.

Greenway FL, Bray GA. Human chorionic gonadotrophin (HCG) in the treatment of obesity: a critical assessment of the Simeons method. *West J Med.* 1977;127(6);461-3.

This study was a double-blind, placebo control trial using HCG injections or placebo to test weight loss, hunger level, mood, and localized (spot) reduction while adhering to a VLC diet. Results: Weight loss was identical between the two groups, and there was no evidence for differential effects on hunger, mood or localized body measurements. The authors conclude, "Placebo injections, therefore, appear to be as effective as HCG in the treatment of obesity."

Lijesen S, Theeuwen I, Assendelft W, et al. The effect of human chorionic gonadotropin (HCG) in the treatment of obesity by means of the Simeons therapy: a criteria-based meta-analysis. *Br J Clin Pharmacol* 1995;40:237-243.

This paper was a meta-analysis of eight uncontrolled and 16 controlled trials measuring the effect of HCG in the treatment of obesity. The trials were scored for quality and methods (based on four main categories: study population, interventions, measurement of effect, and data presentation and analysis) and the main conclusion of author(s) with regard to weight-loss, fat-redistribution, hunger, and feeling of well-being. Methodological scores ranged from 16 to 73 points (maximum score 100), suggesting that most studies were of poor methodological quality. Of the 12 studies scoring 50 or more points, one reported that HCG was a useful adjunct. The studies scoring 50 or more points were all controlled. The authors concluded, "that there is no scientific evidence that HCG is effective in the treatment of obesity; it does not bring about weight-loss or fat-redistribution, nor does it reduce hunger or induce a feeling of well-being."

Miller R, Schneiderman LJ. A clinical study of the use of human chorionic gonadotrophin in weight reduction. *J Fam Pract* 1977 Mar;4(3):554-8.

This study was a double-blind, crossover trial using saline or HCG injections, along with a VLC diet. There was also no significant difference in mood, hunger, or missed injections, and no apparent difference in adherence to diet when the two agents were compared. In contrast, a significant difference was found in the ability of subjects to lose weight in the first four weeks of the study in contrast with the second four weeks, no matter which agent was used. Thus, the initiation of a new therapeutic program, even using an inert agent, has a temporary benefit--a manifestation both of placebo effect and the Hawthorne effect.

Rabe T, Richter S, Kiesel L, Runnebaum B. [Risk-benefit analysis of a hCG-500 kcal reducing diet (cura romana) in females]. *Geburtshilfe Frauenheilkd.* 1987 May;47(5):297-307.

The British physician A.T.W. Simeons described in 1954 a new method for dieting. He combined a reduction diet (500 kcal per day) with daily injections of the pregnancy hormone human chorionic gonadotropin (hCG) (125 IU i.m.). According to Simeons the patient should not lose more weight during a 4-to-6 weeks' diet than without hCG, but the injections should facilitate to maintain the diet and to lose body weight at specific parts of the body (e.g. hip, belly, thigh). After

the first publication various studies conducted with male and female patients analyzed the efficacy of the "Cura romana". 10 of these studies showed positive and another 10 studies negative results with regard to hCG-related weight reduction. Two of these studies with positive results were double-blind studies (hCG vs. placebo). Most of them were reports on therapeutical experiences and were not controlled studies. According to these reports the body proportions normalized and the feeling of hunger was tolerable. Four out of 10 studies with negative results were controlled studies (hCG vs. control without hCG), whereas 6 were double-blind studies. These studies showed a significant weight reduction during dieting, but no differences between treatment groups in respect to body weight, body proportions and feeling of hunger. One of them is the only German study conducted by Rabe et al. in 1981 in which 82 randomised premenopausal volunteers had been dieting either with hCG or without hCG injections. In recent publications describing mostly well-documented double-blind studies, authors largely reject hCG administration in dieting. Supporters of the hCG diet must prove the efficacy of this method in controlled studies according to the German Drug Law. Until then the opinion of the German steroid toxicology panel is still valid, that hCG is ineffective in dieting and should not be used.

Shetty KR, Kalkhoff RK. Human chorionic gonadotropin (HCG) treatment of obesity. *Arch Intern Med.* 1977 Feb;137(2):151-5.

This study compared six hospitalized obese women given 125 IU of human chorionic gonadotropin (HCG) intramuscularly daily for 30 days with five obese women who received injections of dilutent only (placebo). Patients consumed identical, 500-calorie per day diets for the same period. Although the number of patients was small, the study is significant since patient diets and all injections were monitored closely in a hospital setting. Results: Mean weight loss in the HCG-treated group was nearly identical to that achieved by women given the placebo. Reduction of triceps skinfold thickness or circumferential body measurements of the chest, waist, hips, and thighs were not different. Patterns of change of a variety of plasma and urine substrates, electrolytes, and hormones were similar in the two groups and consistent with semistarvation and weight loss. The authors concluded," These results indicate that HCG has no effects on chemical and hormonal parameters measured and offers no advantage over calorie restriction in promoting weight loss."

Stein MR, Julis RE, Peck CC, et al. Ineffectiveness of human chorionic gonadotrophin in weight reduction: a double blind study. *Am J Clin Nutr.* 1976;29(0):940-8.

This study was a well-designed, randomized, double-blind trial of 51 women receiving HCG or placebo for 32 days (28 injections), along with a 500 to 550 kcal/day diet. The study was designed to duplicate the Asher-Harper study (above). Each patient was given the same diet (the one prescribed in the Asher-Harper study), was weighed daily Monday through Saturday and was counseled by one of the investigators who administered the injections. Results: There was no statistically significant difference in the means of the two groups in number of injections received, weight loss (HCG: 15.79 lbs; placebo: 15.52 lbs), percent of weight loss (HCG: 9.48%; placebo: 9.25%), hip and waist circumference, weight loss per injections, or in hunger ratings. The authors concluded, "HCG does not appear to enhance the effectiveness of a rigidly imposed regimen for weight reduction."

Young RL, Fuchs RJ, Woltjen MJ. Chorionic gonadotrophin in weight control. A double-blind crossover study. *JAMA.* 1976;236(22):2495.

202 patients participated in a double-blind, randomized, cross-over study of the effectiveness of human chorionic gonadotropin (HCG) vs. placebo in a weight reduction program. Serial measurements were made of weight, skin-fold thickness, dropout rates, reasons for dropping out,

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and patient subjective response. Results: There was no statistically significant difference between those receiving HCG vs. placebo during any phase of this study.

An additional interesting study:

Sohar E. A forty-day-550 calorie diet in the treatment of obese outpatients. *Am J Clin Nutr.* 1959;7:514-518.

The purpose of this paper was to present a method of producing rapid weight reduction in obese patients. This study looked at forty-five patients who started fifty-three courses of 550-calorie diet, consisting of two meals prescribed in detail. Patients were told what to eat (Simeon diet) and were not told calorie content. 39 patients were given HCG injections (125 units), 14 others received daily injections of saline. Patients were told that weight reduction would be due to the diet but that injections would help curb appetite. The authors assumed from the start that HCG was ineffective in terms of weight reduction. Injections were given for "psychological reasons only" since patients were assured they would curb appetite.

The authors state that the diet Simeon prescribed is successful because average daily weight loss is high due to the very low calories consumed. Patients are more likely to stick to the diet due to time limitation – i.e., they know the diet will only last 40 days. They state that "the vast majority of patients are willing to suffer for forty days for the reward of losing the predicted and attainable amount of 20 pounds." The author also surmises that success is due to the fact that food is prescribed, not calories. This eliminates the estimating that usually goes on with calorie counting. In other words, most patients do not weigh or measure food and do not record calories properly. Sohar recommends not advising patients in terms of calories, but to prescribe meals in detail.

Another reason Sohar gives for success of the diet is that only two meals per day are prescribed; therefore, contact with food is minimized. Lastly, activity level is unrestricted, "enabling all obese people, most of whom are housewives, to reduce." Sohar points out that his paper, as well as Simeon's work, proves that obese patients can lead a normal life performing moderate work on 500 to 600 calories per day.