Hydroxycut - get ripped, or get ripped off??

An expose on the weight loss industry using Hydroxycut products as an example - fraud and ineffective regulation of supplements

Tag Words: Weight loss supplements, Hydroxycut, FDA, Ephedra, DSHEA, Weight loss industry fraud, supplement regulation in other countries

Authors: Alexandra Danel and Claudia Herreros with Julie Fagan, Ph.D

Summary

In the past twenty years obesity in America has become a major health care problem that has been increasing. The public spends $30 billion dollars a year on weight loss products and services. However, under the DSHEA, dietary supplements are not tested for their safety or effectiveness. Thus, only if the FDA receives reports is it required to show that the product is unsafe. Current solutions for removing unsafe products from the market take many years to accomplish and a lot of work. We propose that state legislators urge the federal government to regulate dietary supplements more effectively by requiring companies to prove safety and efficacy of their products prior to being marketed, make it mandatory that companies report all side effects of the product and expand the FDA’s recall authority. These changes will not cost the federal government much money and will insure a greater safety for consumers.

Video Link:
https://www.youtube.com/watch?v=iqOVvySb464

FDA and Dietary Supplement Regulation

(AD) Dietary supplements, which include weight loss products, were defined by Congress in the Dietary Supplement Health and Education Act of 1994 (DSHEA) as a “product taken by mouth that contains a dietary ingredient intended to supplement the diet.” These ingredients may include “vitamins, minerals, herbs or other botanicals, amino acids, and substances such as enzymes, organ tissues, glandulars, and metabolites.” Although they are found
in many forms, all of these products are dietary supplements and are under the general category of “foods,” not drugs. Therefore, they must be labeled specifically as a supplement.

Currently, the FDA regulates dietary supplements differently than it regulates conventional foods and drugs such as those over the counter and prescription medications. According to the DSHEA, which was signed into law by President Clinton, the manufacturers of dietary supplements are responsible for the safety of the products they introduce to the market. In addition, manufacturers are not obligated to register their products with the FDA or get their approval of the safety of the products they are selling. Before this law was put into place, dietary supplements were regulated the same way as other foods and drugs were, but the DSHEA amended the Federal Food, Drug and Cosmetic Act and changed the regulations of dietary supplement safety.

Under DSHEA, a manufacturer of a new dietary supplement is responsible to make sure that their product is safe for use, and any claims they make have substantial evidentiary support, and that their claims are not false or misleading. An exception applies when a “new ingredient” is introduced into a product, where a premarket review by the FDA is done to make sure it is safe, and is required under the DSHEA. Because there is not a list of dietary ingredients marketed before the DSHEA was put into law, manufacturers are responsible for determining if the ingredient they intend on using is new and if they find that the ingredient was used in a product before 1994, they must report which product is was used in. In 2007, the FDA created a CGMP, Current Good Manufacturing Practices to which producers of a new dietary supplement must adhere to. These regulations were made to make sure that the dietary supplements are of good quality and safe practices are used to produce them.

The FDA requires products that are intended to be sold to have certain information appearing on the label, such as a clear description of the product declaring it is a “supplement,” the name and address of the business of the manufacturer, packer or distributor, as well as a complete list of the ingredients in the product. The label must also include a nutrition label as a “Supplement Facts,” and any ingredient not included in that must be put in an “other ingredients” list. Every ingredient used in the making of the product must be on the label, including additives and processing aids such as colors, preservatives, gelatin or flavors. In addition, the FDA does not regulate the serving size for a dietary supplements, this is the responsibility of the manufacturer to make sure their product is safe for use.

Once a product is marketed, the FDA may then prove a product “unsafe” and remove it from the market or restricts its use. Those involved in the manufacturing, testing, quality control and distribution of a product must submit adverse reactions reported from consumers of their product to the FDA only if a new ingredient was used. The FDA may also receive reports directly from consumers or health care providers regarding the side effects associated with the use of a certain product. Only then, the FDA takes these reports, investigates them and identifies any detrimental effects that a product may posses and take necessary action against the potentially unsafe product. However, the reporting system is voluntary, so if a person experiences adverse reactions when using a certain product, he or she is not required to report it to the manufacturer of the product or to the FDA. There is also not a provision under any law of the FDA that requires a firm to disclose any information to the FDA or to consumers about the safety or benefits of their product. It is up to each business to disclose this information or not.
For a more general, less serious complaint about a certain product, one may contact the consumer complaint coordinator at their local FDA office.

The Federal Trade Commission (FTC) works under different regulations that the FDA does and it regulates the advertising of a product, including infomercials. The FTC and FDA, however, work closely to regulate marketing of a product.

**Fraud in the Weight Loss Industry**

To this day, a big problem with weight loss supplements, a dietary supplement, is fraud. The FDA website provides consumers with warnings and advice in using these products. First, the FDA warns consumers that some ingredients such as nutrients and plant compositions may be toxic and some ingredients may be harmful when taken for an extended period of time, when taken in high doses or when interacting with other drugs or foods. Some ingredients may also interact with certain conditions, so consulting with a doctor before taking such supplements is critical. Often, products claim that their products are natural or contain only herbal ingredients, but in fact they contain harmful ingredients that were not listed on the label and often times are illegal and have not been approved by the FDA. The website also cautions consumers of the fact that they have tested suspected unsafe weight loss products and have found 69 to be tainted and contain different ingredients such as prescription medications, seizure drugs, controlled substances and even drugs that are illegal in the US.

The FDA website also provides consumers with common misleading claims that the weight loss industry often uses. One common claim that these firms make is that their product works very fast without dieting or exercising. This is a scam and often times regular people dress up as doctors and appear on infomercials to make their claims seem more credible. Weight loss infomercials often include testimonials from people to show how effective their product is, but the FDA warns consumers that the scammers often alter their before and after pictures to showcase unrealistic results.

**History of Hydroxycut, a Weight Loss Supplement**

One of the most popular weight loss supplements at the time is a product called Hydroxycut. In 2008, the company reported that they had sold 9 million products that year, so they are widespread. The severe problems that this product has caused over the years, like many other dietary supplements including other weight loss supplements have, is caused by a lack of proper oversight and regulation of these products by the FDA.

In 2003, the manufacturer of the Hydroxycut products, MuscleTech Research and Development, Inc, was sued by the state of Missouri. Attorney General Jay Nixon charged the company with false advertising in a lawsuit, saying that their claims that the products were “clinically proven” and “fat burning” were false. The company’s own research even showed that compared to the placebo, the products had no efficacy. He also accused the manufacturer of using a “before” picture of a woman who has still not recovered from a recent pregnancy, so the results they tried to advertise were misleading. Nixon also said that the products did not have any adequate warnings about the possible serious adverse reactions, including death, of the main
active ingredient in the product at the time, Ephedra. MuscleTech denied any wrong doing and settle the case by paying $100,000.

Later that year, the New York Times reported that the creators of Hydroxycut hid internal studies showing that the products were ineffective, covered up evidence that it caused cardiac problems and even tampered with the documents used as evidence in the lawsuit.

Hydroxycut products are now owned by Iovative Health Sciences, Inc., and are reformulated to replace ephedra with copious amounts of caffeine in order to increase energy and reduce appetite. The company is still currently defending itself against the charges that the new formulated products still cause serious side effects. The cases reported to the FDA include liver damage, sometimes fatal, and other symptoms typically associated with caffeine overdose.

The FDA says that they have been receiving reports about adverse reactions to Hydroxycut products since 2000 and in 2004 when the company had already reformulated its products. The FDA claims that the company has gone through a number of reformulations and iterations, so the removal of ephedra did not seem to have mitigated the problems associated with the use of this product. The problem with the current Hydroxycut products is that the FDA is still unsure of which specific ingredient(s) are causing these health problems. In 2009, the FDA issued a warning about the use of Hydroxycut, and the company agreed to reformulate 14 of the 16 products. All 14 products have been recalled, and they all have a variety of ingredients, but not one specific ingredient that is common in all of them.

**History of the Banning of Ephedra**

Even with the banning of ephedra, it took years for the FDA to be able to take the dangerous products off the market. Ephedra refers to the plant Ephedra sinica and it has been used in Chinese medicine for over 5000 years for treating the common cold, the flu, hay fever and asthma. It contains ephedrine and pseudoephedrine, which stimulate the nervous system, increases heart rate and blood pressures and expands bronchial tubes, which helps with asthma symptoms. Ephedra also has a thermogenic effect which causes an increase in metabolism. This product was commonly used by athletes, although there was no precise evidence that it enhances performance. It has also been used for weight loss for many years, which studies show that it may cause short term minor weight loss, but no proof that the weight loss is actually maintain long term.

Studies show that there is a discrepancy between labeled dose and actual amount of ephedra in many weight loss supplements, often a significant amount. There have been 10 fold differences in the amount from lot to lot of the same brand. Adverse reactions associated with the use of this ingredient includes serious effects such as hyperthermia, insomnia, dehydration, severe skin reactions, seizures, heart attacks, stroke, irregular heartbeat or even death.

In 1997, the FDA responded to a copious amount of reports concerning the dangers of the use of Ephedra. A ban was proposed on products containing 8mg or more of ephedra and a better labeling system that includes warnings of serious side effects associated with the use of the product. In response to this, the Ephedra Education Council, created by the supplement industry attempted to oppose these charges and reported a study done by a private firm which claimed
ephedra was safe. They also tried to hide the publications which showed the discrepancies in the labeled doses and the actual amount of the ingredient in the weight loss products. At the same time, Metabolife, the manufacturers of a best selling supplement that contained ephedra at the time, received over 14,000 reports of adverse reactions, which were not reported to the FDA. Consequently, Michael J. Ellis, the co-founder of this company served six months in federal prison for failing to report the adverse reactions caused by the company’s products to the FDA. Between 1998 and 2000, the company spent $4 million dollars in order to fight against the regulation of ephedra in Texas. Because of this constant lobbying and because of the actions of Ephedra Education Council, the FDA ultimately withdrew their proposed restrictions and labeling adjustments in 2000.

That same year, the New England Journal of Medicine published many cases of sudden cardiac deaths and other severe adverse effects which occurred in mostly young adults using ephedra according to the dosages on the weight loss supplement labels. In 2002, in response to pressure from consumer advocacy groups and compelled by the Department of Justice, Metabolife turned over reports of their 15,000 ephedra adverse reaction reports. The FDA responded by running a meta-analysis of ephedra. The study found that the ingredient causes some weight loss, but no proof of long term weight loss of improvement of athletic performance. The study found that the use of ephedra showed severe gastrointestinal, psychiatric and nervous system side effects. Around the same time, a study from Annals of Internal Medicine found that “ephedra was 100 to 700 times more likely to cause a significant adverse reaction than other commonly used supplements such as kava or ginkgo bilboa.”

In December of 2004, the FDA indicated that it intends to ban any ephedra containing products and urged consumers to stop buying and using ephedra. Finally, in April of 2004, the FDA finally issued a ban on ephedra-containing supplements.

A supplement manufacturer, Nutraceutical Corporation managed to overturn the ban of ephedra in Utah, but the ruling was eventually appeal to the U.S. Court of Appeals for the Tenth Circuit in Denver, Colorado and the Appeals Court upheld the FDA ruling which banned the ingredient.

Ephedra played an important role in athletics as well. After the death of Korey Stringer, a Minnesota Vikings player, the US NFL banned players from using ephedra, after this product was found in Stringer’s locker and associated to his death. It is also banned by the NBA, International Olympic Committee and the World Anti-Doping Agency. Despite the years of fighting to ban this ingredient, ephedra is still commonly used by athletes. A survey of hockey college students was done in 2006 and found that almost half the players used ephedra in hopes to improve their athletic performance. Todd Sauerbrun, in fact, was suspended for the first month of the 2006 season of the NFL for using ephedra and testing positive for it. Also, Noriyuki Haga, a Japanese motorcycle racer, also used this ingredient, and was disqualified and banned from several races.

**Adverse Reactions: A Series of Case Studies**

(CH) Use of supplements and alternative drugs continue to thrive and should be of concern since many of the substances have unexplained and adverse medical consequences.
Although Hydroxycut was reformulated in 2009, there are still many concerns about the ingredients in the product and the pharmacodynamics and pharmacokinetic interactions these products present in the body. There are several case reports about the suspected side effects of the supplement and it is clear that more clinical data and research needs to be done before these products are put on the market for sale.

One of the rare and dangerous side effects that Hydroxycut has been linked to is hepatotoxicity; 23 cases of liver damage including on fatality and one liver transplant caused the FDA to issue a warning in 2009. After its reformulation, there are still cases of liver damage; it is obvious that the warning was not enough to protect consumers from this side effect. In one case a 19 year old with no significant past medical history presented with a 2-day history of fever, fatigue, myalgia and a rash over his lower extremities. The patient had started using Hydroxycut one week before to the presentation. Blood analysis revealed high levels of aspartate aminotransferase, alanine aminotransferase, alkaline phosphate and bilirubin; all indicative of compromise of liver function. Due to increasing bilirubin levels the patient was transferred to a different hospital for urgent liver transplant evaluation. Liver biopsy showed acute cholangitis; after treatment liver functions were restored 14 weeks after onset of presentation.

The key ingredient of Garcinia in the Hydroxycut preparation is Hydorxy Citric Acid (HCA) which has been associated with hepatocellular and cholestasic pattern of injury. The biopsy was suggestive of cholangitis which was likely secondary to drug medicated injury. Although causation is difficult to prove, the temporal relationship after exposure to Hydroxycut and improvement upon removal of the supplement plus absence of other etiologies would point to Hydroxycut being the most likely cause for hepatotoxicity in this patient.

Another ingredient which has been linked to acute liver injury is the green tea extract (Camellia sinesis) in other over-the-counter weight-loss herbal supplements. The patient in this case demonstrated multi-lobular necrosis which is a hallmark presentation of liver injury associated with this ingredient. The exact mechanism of hepatotoxicity induced by Hydroxycut is unknown. Possible hypothesis are allergic reactions or contamination of extract during production of the product. In all reported cases of acute liver injury induced by Hydroxycut, liver function was restored after cessation of the product.

In addition to Hepatotoxicity, there have also been other cases of patients presenting with life threatening conditions upon consumption of the product. The next case report is of atrial fibrillation that was potentially induced by Hydroxycut. A 63-year old obese female presented to the emergency department with a 48-hour history of right-hand side neck pain which worsened to chest pain and palpitations the night prior to admission. The patient had been taking Hydroxycut using the labeled dose for 2 weeks prior to presentation. The patient reported a less intense episode during a pervious trail of Hydroxycut 3 months before and did not seek medical attention because symptoms resolved 5 days after discontinuation of the product. Upon physical examination nothing was significant but when the EKG was examined there was a narrow QRS complex which was consistent with atrial fibrillation. The patient was treated and discharged after 3 days. The case scored an 8 on the Naranjo algorithm which translates into probable association between Hydroxycut and development of AF in this patient.
Hydroxycut has not been evaluated in clinical trials but individual components such as hydroxycitric acid (HCA) and EGCG, a green tea extract, have been studied with largely inconclusive results. In a study of HCA the change in body weight among patients receiving HCA was significantly lower than baseline but not different from subjects receiving placebo. There has recently been studies published that indicate that EGCG does not cause weight loss. In the patient with AF the EGCG is presumed to have caused the side effects in this patient. This ingredient is an antagonist of KCNA5, a pore-forming subunit of protein which is expressed in the human atria; EGCG prolongs the duration of atrial action potential. Prolonged AF is risky and patients with hypertension, diabetes and other cardiovascular diseases should avoid consuming dietary supplements with contain EGCG.

In another interesting case a 65-year old woman presented to her local hospital with a pounding headache which she described as “getting hit in the head with an axe.” The headache did not improve by taking over-the-counter medications and CT and MRI were normal at the time of admission. Upon questioning the patient reported taking Hydroxycut two weeks prior to her headache. Two days after admission she experienced leg weakness and visual disturbances; another MRI revealed areas of restricted diffusion consistent with acute infarcts in the cerebral artery in her right occipital lobe. The diagnosis of restricted cerebral vasoconstriction syndrome and the patient was treated accordingly. She was advised not to take Hydroxycut and at a follow-up appointment the patient demonstrated resolution.

The case demonstrated that although amphetamine-related weight loss supplements have been associated with RCVS, Hydroxycut had not been previously implicated. It is impossible to prove that Hydroxycut caused this condition but the temporal relationship between the presentation of symptoms and the initiation of the product in addition to the resolution after discontinuation implicates Hydroxycut as a causative agent. One hypothesis is that caffeine may have been the ingredient responsible for causing RCVS: the daily dose of Hydroxycut contains 400 mg of caffeine which is equivalent to four cups of coffee. In addition caffeine is known to cause cerebral vasoconstriction, even though it has not been implicated in reversible cerebral vasoconstriction syndrome. Other components in the formulation may have also contributed although none of the other components are known to cause vasoconstriction.

These are just some of the cases although there are many more where people experience adverse side effects that can presented during trails with Hydroxycut. These cases illustrate that although these drugs are advertised to be safe and effective that is not always the case. Many of the authors in these cases caution health care professionals to be alert to the possibility of these “safe and effective” drugs causing other problems. There is no clear evidence that these products actually cause weight loss. It is clear that there needs to be closer monitoring of patients taking weight loss supplements and tighter regulation from the government drug agencies is warranted.

**Paradigms for Management of Dietary Supplements**

The FDA has already taken several steps in order to improve the management of dietary supplements. In 2007 the FDA required mandatory adverse event reporting; this caused the reporting to increase three-fold from the previous years. For example, form January 2008 to October 2008 the FDA received 948 adverse event reports - compared to 298 reports received in the same time period the year before. It is evident that firms were withholding a large amount of
information from the FDA regarding their products and this shows that they will continue to do so until other regulatory measures are stated. The FDA is limited in the amount of information on the number and location of dietary supplements firms, the types of products that are available and has no information about the moderate and mild side effects. Even if the FDA determines that a product is unsafe, it is limited in its ability to remove the product from the market; it does not have sufficient recall authority and the process towards demonstrating the risk of the products is a difficult one. In addition, even though the FDA has taken several steps toward educating the consumers about dietary supplements, surveys and experts indicate that consumers have trouble understanding labels. This means that the consumer is put at a high risk due to confusion and unclear safety and efficacy of products.

Based on past experiences with Hydroxycut and other harmful weight loss supplements the United States should take a more precautionary approach that are used in other countries such as Japan and Canada. Canada requires that manufacturers be registered and obtain a product license; the application must include detailed information about the product, ingredients, intended uses, potency and evidence of safety and efficacy. Firms are required to report any serious adverse reactions associated with their product within 15 days and must provide information about mild and moderate reactions on an annual basis. In contrast to the United States, reporting is not required by the consumer and firms are not required to report moderate or mild reactions. Additionally, the products must be pre-approved before they are put on the market. In the Japan products are regulated on the basis of their product claims. There are two types of claims; Food and nutrient function claims for vitamins and minerals with established benefits. Food for Specified Health Uses claims require government approval for safety and efficacy prior to marketing a product which claims to have physiological effect on the body. To use this type of claim on a product a firm is required to provide the government with evidence supporting the physiological effect and safety of the product prior to marketing.

By looking at the ways in which other countries regulate their dietary supplements they can be used as a paradigm to regulate dietary supplements in the U.S. We have several recommendations that we believe will improve and protect consumers from the dangerous side effects of products such as Hydroxycut and other weight loss supplements like its kind.

**Our Recommendations**

(CH) First and foremost, we recommend that products should be evaluated for safety and efficacy prior to being marketed. Under DHESA, once a product is marketed, the FDA has a responsibility for showing that the product is “unsafe” before it can do anything to restrict the product’s use. We believe that it is irresponsible to wait until the product has caused harm to the consumer in order to do anything about it. As in the case of Hydroxycut, the product caused death, need for liver transplant and other effects before a warning was issued. In addition, the makers of the product removed the product themselves and reformulated it. However, we have provided plenty of evidence that even though the product was reformulated there are clearly still issues; not only are the ingredients like green tea extract and HCA proven to not cause weight loss but they may be harmful. For example, the green tea extract EGCG was a possible causative agent for atrial fibrillation in one patient.
The next recommendation is that the companies provide the FDA with information about the products they sell, the names of the products and the ingredients. The limited knowledge that the FDA has on these companies limits the ability of the FDA to adequately determine if a product is truly safe. Companies should be allowed to self-identify as dietary supplement firms and provide the FDA with all of the necessary information related to their product; such as new ingredients that they add to their products and provide evidence that these ingredients are truly safe for the consumer. Currently, if a dietary supplement is reformulated to include different ingredients or different amount of ingredients without renaming the products the FDA might not be aware of these changes. Providing the FDA with this information could help the agency analyze the adverse reports that they receive and be better equipped to protect the public.

In addition to this information about the product we believe that the companies should be required to report not only serious adverse effects but also moderate and mild effects. The FDA estimates that the number of reports is close to 50,000 each year\(^5\); however because companies are not required to report these there is clearly a large deficit. This is because many times consumers do not believe products to be unsafe because they are advertised otherwise, consumers fail to inform their physicians that they are consuming the product and the reporting process is rather difficult. The FDA is currently developing MedWatchPlus, a web-based portal that simplify the reporting process\(^5\). This is great because it would create a single portal for consumers, industry and practitioners to use. Requiring all adverse effects to be reported would provide the agency with more information that would be beneficial since there is only a sparse amount of scientific data available and since these products are not approved or tested before they are put on the market.

Lastly, we believe that the agency is limited in its ability to remove a product from the market once a safety concern has been identified and we believe that the FDA should be granted mandatory recall authority. Currently, the FDA can take several advisory actions; these actions include issuing the firm a warning, issuing consumer alerts, or issuing an advisory to the industry. Or the FDA can take administrative and judicial enforcement actions to remove the product from the market. These actions include working with companies on a voluntary product recall; about half of the recalls in 2007 were due to the presence of pharmaceutical ingredients in supplement products. They can detain or refuse the product if it is imported, pursue legal action against the firm or they can ban the ingredient. The FDA has banned one ingredient-ephedra almost 10 years after issuing an advisory; the FDA has not banned any other ingredient. However, in Hydroxycut no one ingredient was ever determined to have caused the health consequences and from all of the cases that were presented it is evident that the combination of all these ingredients could be responsible for causing these health effects. In addition, banning substances is a very difficult process; this is because the agency must establish adulteration under the significant or unreasonable risk standard\(^5\). This is further limited by lack of scientific research conducted on dietary supplements.

In conclusion, we believe that the growing dietary supplement industry and more specifically the weight loss supplement sector needs to be regulated. We believe that products like Hydroxycut can bring risk to the public and it is the responsibility of the government to protect consumer by making changes in the way that it handles dietary supplements. The past history of Hydroxycut in concert with the health effects that it caused in consumers after its reformulation raises some serious questions about it safety and efficacy. However, due to the
lack of scientific evidence we recommend several changes in the way that these types of products should be handled. Most importantly we believe that the products should be pre-approved before they are put on the market and that the FDA should have more authority when it comes to removing these products from the market if there are safety concerns. Countries like Canada and Japan have similar systems in place and these can serve as paradigms for the United States to follow. Overall, these changes can help protect consumers before they are exposed to these questionable dietary supplements and increase overall health in this country.

**Product Efficiency Investigation and Letter to the Legislator**

(CH) In order to bring about the recommendations that we suggested in our research, we believe that we needed to first investigate the effectiveness of Hydroxycut by contacting the company and inquiring about the clinical trials they have conducted. Secondly, we wrote a letter to our local legislator and demanded that they propose a bill to better regulate supplements and urge other states to do the same.

The first objective of our service project was to find out if the product was really effective in helping people lose weight. In order to do this we needed to know about the clinical trials that Hydroxycut has conducted and the reports that they generated. We contacted the number for product information on the label (appendix 1), however, when we called it was impossible to get into contact with a representative. The messages given the automatic operator instruct the consumer to go to the product website and find the necessary information there. The only information about the clinical trials provided on the website state that “Individuals used Hydroxycut with diet and exercise and have been remunerated. Average weight loss with key ingredients was 20.94 lbs. in one 12-week study and 16.50 lbs. in one 8-week study. All groups followed a calorie-reduced diet.” We then contacted Iovate Health Sciences instead where I was able to get into contact with one of the representatives. He said that the 12-week study published on their website was in a peer reviewed journal article, The Open Complimentary Medicine Journal. The Study was a randomized double-blind study conducted on 34-subjects. However, the interesting thing is that the study is not on Hydroxycut, it is only based on four ingredients in Hydroxycut. This means that although these ingredients may have been shown to be safe and effective in the study the other ingredients in Hydroxycut have not been proven to be safe and we do not know about how all these products interact with each other. The second 8-week study is not available to the public and is used only for government purposes.

We decided to figure out the product effectiveness from consumer reports. We took out reviews from a diet review website. The overall rating of Hydroxycut was 80% which means that 80% of people who tried it liked it. One consumer states Hydroxycut is a product that ‘really’ does work. However, the consumer was concerned about the effects that it can have on the liver an until the company have proved the product is safe it is not worth losing your life over. Another consumer wrote that the product made her feel dizzy and made her heart beat faster. Overall, there are many comments like this; some people state that they love the products, other state that they like it but are scared of side effects and some people post horror stories about what this product has done to them. It is obvious that real clinical trials conducted by an unbiased party need to be conducted. Even though consumer reviews show that the products do work...
showing that the products are safe could help boost company images and make consumers more comfortable using the products.

Secondly we decided to write a letter to the legislator for district 18 Senator Barbara Buono who is responsible for health and human services. In our letter we decided to talk about the issue with dietary supplements and make several recommendations about how dietary supplements should be regulated. We suggested that before products be put on the market the safety and efficacy should be tested and this should be the individual company’s responsibility so that the federal government does not spend money on this. We also stated that all reports of side effects should be reported to the FDA and not just adverse effects. In this manner, the FDA can have more information about a product and can keep track of the issues and safety concerns that it poses. Lastly, we recommended that the FDA’s recall authority should be expanded. If the FDA finds that a product is unsafe, there is no way that it can remove it from the market. The only thing that can be done is to issue warnings and ban an ingredient in the product. We urged our legislator to propose a bill that could take all of these recommendations into account and urge other states to do the same. One of the great things about our recommendations is that they do not cost anything so money is not an issue in this case.

After sending out our letter, we have not heard anything back at the moment. We believe that this could be because the particular legislator that we sent it to is too busy or one letter is not enough to really make an impact. There needs to be a large response from the public and mobilization in order to get a reaction out of the government. It is true that there is power in numbers and we wish that we had put together a petition and send that with our letter in order to get a greater response.

References:

7. “Nixon vs. Musletech.” Missouri Attorney General's office. Archived from the original on 2006-10-26, Circuit Court of the City of St. Louis, State of Missouri
10. “FDA Regulation of Nutritional Supplements,” www.fda.org

Appendices:

To: Senator Barbara Buono
Re: FDA Regulation of dietary supplements

Weight loss supplements, such as Hydroxycut, are considered a “dietary supplement” under the Dietary Supplement Health and Education Act of 1994 (DSHEA). Under this law, the manufacturers are responsible for the safety of the product and there is lack of proper oversight and regulation of these products by the FDA. In fact, when the FDA tried to ban ephedra in the past, a dangerous ingredient widely used in weight loss supplements and in athletes to improve performance and/or lose weight, it took 7 years to finally take it off the market due to lack of cooperation and resistance from different groups and manufacturers and due to lack of strong authority by the FDA.

It is clear that the weight loss industry is only interested in making money at the expense of the health of consumers. Metabolife, the manufacturers of a best selling supplement that contained ephedra at the time, received over 15,000 reports of adverse reactions, which were not reported to the FDA.

More proof that the weight loss industry is fraudulent is on the FDA website, which actually provides consumers with warnings of misleading claims that the weight loss industry often uses. One common claim that these firms make is that their product works very fast without dieting or exercising. These are a scam and often, regular people dress up as doctors and appear on infomercials to make their claims seem more credible. Weight loss infomercials often include testimonials from people to show how effective their product is, but the FDA warns consumers that the scammers often alter their before and after pictures to showcase unrealistic results.
The FDA says that they have been receiving reports about adverse reactions to Hydroxycut products since 2000 and in 2004 when the company had already reformulated its products. It is still unknown which specific ingredient or combination of ingredients is the culprit. This means that people are still using these products and experience serious side effects such as liver damage and death. It is unacceptable that these products are still sold to the consumers, considering their dangers.

During our research to investigate if Hydroxycut products are actually effective, we tried to inquire the company about their clinical trials. We dialed the phone number provided on the product label, but we were not able to get in touch with a representative. The only information provide about the clinical trials is “Individuals used Hydroxycut with diet and exercise and have been remunerated. Average weight loss with key ingredients was 20.94 lbs. in one 12-week study and 16.50 lbs. in one 8-week study. All groups followed a calorie-reduced diet.” Clearly, there is no scientific proof to back up the claims made by the manufacturers. Also, consumer reviews show that 80% are satisfied with the results of using this product, but most are uncomfortable using them and scared about the side effects and the fact that it has not been proven to be safe by the FDA.

We urge you to propose a bill that will mitigate the problems associated with the weight loss industry. We recommend a few small changes that will not cost the government a lot and that we believe will be truly effective in better regulating these products. We recommend that manufacturers be required to provide the FDA with substantial proof that their product is safe for use and publish their clinical trials. These clinical trials should also be available to the general public. This will avoid any product causing serious harm to consumers, since under the DSHEA the FDA can only try to take a product off the market after it proves to be unsafe. Next, manufacturers should be required to report not only serious side effects, but also moderate and mild effects.

A great concern in the FDA’s ability to regulate these products is that they are limited in the ability to remove a product from the market once there is a safety concern, so we want this bill to grant the FDA mandatory recall authority. A product should be able to be taken off the market until it is reformulated and proved to be safe again. Obviously, the FDA can mostly just issue warnings or pursue legal action against a certain company, so and more power to actually be able to ban an unsafe product should be given.

Thank you for your time and consideration.

Sincerely,
Alexandra Danel and Claudia Herreros