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Herbs and the FDA: Current Regulation, Problems and Suggestions for Change

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Herbal products are an extremely profitable segment of the U.S. dietary supplement industry. In 2000, American consumers spent about \$591 million on herbal products.¹ Herbs are used as weight loss aids, cold and allergy treatments, analgesics, and treatments for psychiatric disorders such as depression and anxiety.² They are also used as treatments for more serious conditions including asthma, diabetes, endometriosis and heart disease.³ It seems that no matter what ailment a person has, there is a putative herbal treatment for it.

In 1994, largely because of American consumers' growing interest in alternative medicine (including herbs), Congress passed the Dietary Supplement Health and Education Act of 1994 (DSHEA).⁴ DSHEA amended certain portions of the federal Food, Drug and Cosmetic Act dealing with dietary supplements.⁵ Under DSHEA, manufacturers of dietary supplements such as herbs are not required to obtain premarket approval by the FDA before making their products available to consumers.⁶ Instead, the FDA bears the burden for showing a product is unsafe before it can take action to regulate its use.⁷ DSHEA also includes provisions allowing manufacturers of dietary supplements to make certain statements about the supplement's effects on the health and overall well-being of the consumer.⁸ While the manufacturer must have substantiation for these statements, they are not required to have them evaluated by the FDA before using them for marketing purposes.⁹

¹Bob Calandra, *Are Herbs Good Medicine?* WebMD Medical News, (May 14, 2001) <<http://my.webmd.com/content/article/1668.51113>> (citing statistic from the American Botanical Council).

²See generally James A. Duke, *The Green Pharmacy* (St. Martin's Paperbacks 1998) (1997) (providing an extensive overview of a number of medicinal herbs and the conditions that they can be expected to treat).

³*Id.*

⁴Dietary Supplement Health and Education Act of 1994, 103 P.L. 417, 108 Stat. 4325 (hereinafter "DSHEA").

⁵Food, Drug and Cosmetic Act of 1938 (codified in scattered sections of 21 U.S.C.).

⁶DSHEA, Section 4. This section will be explored in more detail later in this paper.

⁷*Id.* See also U.S. Food and Drug Administration Center for Food Safety and Applied Nutrition, *Overview of Dietary Supplements* (January 3, 2001) <<http://www.cfsan.fda.gov/~dms/ds-oview.html>> (interpreting and commenting on the relevant provisions of DSHEA).

⁸DSHEA, Section 6. The specific details of this section will be discussed later in this paper.

⁹*Id.* See also U.S. Food and Drug Administration Center for Food Safety and Applied Nutrition, Office of Nutritional Products, Labeling and Dietary Supplements, *Claims that Can be Made for Conventional Foods and Dietary Supplements* (revised October 2001) <www.cfsan.fda.gov/~dms/hcliams.html> (discussing the kinds of claims that manufacturers can make under DSHEA).

Under DSHEA, then, manufacturers of herbal products have a great deal of latitude in the kinds of products they are allowed to market and the ways in which they are allowed to market them. Unfortunately, this latitude can have harmful, and even deadly, consequences when herbal products that are unsafe are allowed into the market with little, if any, FDA regulation.¹⁰ In this paper, I will discuss the current treatment of herbal products under DSHEA and describe some of the risks of herbal products. I will also talk about current FDA responses to these risks and provide some suggestions for ways in which the federal government could better protect consumers by regulating the marketing of herbal products.

DSHEA and the Federal Regulation of Herbal Supplements

According to Section 3 of DSHEA, products containing herbs that are “intended to supplement the diet” are considered to be dietary supplements. As such, they are subject to all of the provisions in DSHEA that govern the safety and marketing of supplements.

The first relevant section of DSHEA is Section Four. Section Four lists four reasons that a supplement could be

¹⁰One example of a harmful herb is ephedra, which may cause serious side effects such as psychosis, mood disorders, an increase in blood pressure, heart attack or stroke. See, e.g., Peggy Peck, *Asian Herb Ma Huang May Trigger Psychosis, Mood Disorders: Potent Supplement Also Spikes Blood Pressure*, WebMD Medical News (February 20, 2000) <<http://webmd.lycos.com/content/article/1728.55214>> (discussing several side effects of ephedra); see also Ori Twersky, *More Reports Link Ephedra to Severe Side Effects But its Future and Real Risk Factors Remain Uncertain*, WebMD Medical News (March 31, 2000) <<http://my.webmd.com/content/article/1728.56154>> (talking about physical side effects of ephedra and providing an analysis of proposed FDA regulations). Ephedra will be discussed in more detail later in this paper.

considered to be adulterated, and thus subject to FDA regulation. These reasons are:

1. The supplement poses a “significant or unreasonable risk of illness or injury” when used according to directions given on the label or, when there are no directions given on the label, used in an “ordinary” way;
2. The supplement contains a new ingredient that cannot be shown to be safe;
3. The Secretary declares the supplement poses an “imminent hazard to public health or safety”; or
4. The supplement contains “poisonous or unsanitary” ingredients pursuant to Section 402(a)(1) of the Food, Drug and Cosmetic Act of 1938.

Section Four also provides that the burden of showing that a product is adulterated, and thus subject to regulation, falls on the FDA. Because the manufacturers do not have the burden of proving their products are unadulterated (and thus safe for consumption), the FDA cannot require any kind of premarket approval for herbal products. Therefore, unless the FDA can demonstrate that an herbal product meets one of the four criteria listed above, the product can remain on the market even if consumers or scientists raise concerns about the product’s safety.

The second relevant section of DSHEA is Section Six. Section Six lists the kinds of claims that supplement manufacturers can put on product labels or promotional materials. According to Section Six, acceptable statements are ones which:

1. Claim a “benefit related to a classical nutrient deficiency disease and disclos(e) the prevalence of such disease in the United States”;
2. “Describ(e) the role of a nutrient or dietary ingredient intended to affect the structure or function in humans;”
3. “Characteriz(e) the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function;” or
4. “describ(e) general well-being from consumption of a nutrient or dietary ingredient.

Section Six also states that manufacturers cannot make these statements unless they “have substantiation that such statement is truthful and not misleading.” Section Six does not provide for any kind of FDA review of these statements prior to their use, or any FDA review of the evidence supporting the statements. It does, however, require the manufacturer to include a disclaimer that the statement has not been evaluated by the FDA.¹¹ Section 6 also provides that manufacturers cannot make statements that suggest the supplement can “diagnose, mitigate, treat, cure or prevent” disease.¹²

Under these provisions of DSHEA, companies have a great deal of freedom to manufacture and distribute a variety of herbal supplements without first showing that they are safe or effective.¹³ They also have the authority to make a broad range of statements about the physical effects of herbs on consumers. Since there is no premarket approval requirement, the FDA’s hands are tied unless they can conclusively demonstrate that the products meet one of the definitions of adulterated supplements under Section Four. Because the burden is on the FDA to prove that products are unsafe or health statements are deceptive, manufacturers can aggressively market products that may pose health risks to consumers. This possibility is explored in detail in the next section of this paper.

Potential Health Risks Associated with Herbal Products

¹¹For more detail on this subject, see U.S. Food and Drug Administration Center for Food Safety and Applied Nutrition, Office of Nutritional Products, Labeling and Dietary Supplements, *Claims that Can be Made for Conventional Foods and Dietary Supplements* (revised October 2001) <www.cfsan.fda.gov/~dms/hcclaims.html> (providing an extensive overview of the kinds of claims that are allowed by DSHEA).

¹²While manufacturers are not free to make such claims, third parties are. My research turned up a number of websites (and books) that promoted the use of various herbs as treatments for particular diseases or conditions. See, e.g., James A. Duke, *The Green Pharmacy* (St. Martin’s Paperbacks 1998) (1997), MotherNature.com (providing a database including information on various herbs and the health conditions that they can be used to treat).

¹³The effectiveness issue, of course, raises the question of potential economic harm to customers from supplements that are ineffective or that fail to live up to the statements on their labels. This is a very real concern, but it would require an entirely separate paper to discuss it adequately. For that reason, the arguments in this paper are limited to the possibility of physical harm to consumers rather than economic harm.

Since DSHEA was passed in 1994, use of dietary supplements by American consumers has almost doubled.¹⁴ Unfortunately, when it comes to herbal remedies, “natural” or “popular” does not always mean “safe.” There are a number of herbal products that can have severely deleterious effects on the health of consumers. Ephedra (otherwise known as ma huang), for instance, has been linked to several incidents of severe illness and even death in consumers who have taken the herb.¹⁵

Ephedra is an herb that is commonly marketed as a weight-loss aid or energy enhancer.¹⁶ Between 1994 and 1997, the FDA reported a total of 37 deaths and 800 medical and psychiatric complications that it attributed to use of products containing ephedra.¹⁷ Last year, the FDA released 273 more reports (received between June 1997 and March 1999) of very serious side effects that were reportedly related to ephedra use.¹⁸ They included high blood pressure, stroke and heart attack.¹⁹ Other, less serious side effects that ephedra may cause are insomnia, jitteriness, dry mouth, and restlessness.²⁰ Some researchers also believe that there may be a link between ephedra use and psychiatric disorders such as psychosis.²¹

Ephedra isn't the only herbal dietary supplement that can endanger the health of consumers. CNN's website contains an article that states that members of a class of herbs known as the Aristolochia species have been linked to cancer and severe kidney damage in users.²² Echinacea, an herb that is marketed as an immune system

¹⁴Andrew Postman, *Sip your Way Thin and Other Diet Lies*, SELF, March 2002 at 172.

¹⁵Ori Twersky, *More Reports Link Ephedra to Severe Side Effects But its Future and Real Risk Factors Remain Uncertain*, WebMD Medical News (March 31, 2000) <<http://my.webmd.com/content/article/1728.56154>>

¹⁶Indeed, many very popular over-the-counter diet aids contain ephedra. Andrew Postman, *Sip your Way Thin and Other Diet Lies*, SELF, March 2002 at 172.

¹⁷Peggy Peck, *Asian Herb Ma Huang May Trigger Psychosis, Mood Disorders: Potent Supplement Also Spikes Blood Pressure*, WebMD Medical News (February 20, 2000) <<http://webmd.lycos.com/content/article/1728.55214>>

¹⁸Ori Twersky, *More Reports Link Ephedra to Severe Side Effects But its Future and Real Risk Factors Remain Uncertain*, WebMD Medical News (March 31, 2000) <<http://my.webmd.com/content/article/1728.56154>>

¹⁹*Id.*

²⁰According to manufacturers, some of these side effects may be temporary and may discontinue with long-term use of products containing ephedra. *Id.*

²¹Peggy Peck, *Asian Herb Ma Huang May Trigger Psychosis, Mood Disorders: Potent Supplement Also Spikes Blood Pressure*, WebMD Medical News (February 20, 2000) <<http://webmd.lycos.com/content/article/1728.55214>> (reporting on a journal study in which researchers note two incidences of psychosis that occurred (in previously healthy young men) after use of ephedra supplements).

²²Herb in Weight-Loss Pill Causes Cancer, Damages Kidneys, Researchers Report (June 8, 2000)

stimulant, may cause liver damage.²³ Kava-kava, an herbal sedative and sleep aid, can cause muscle spasms and tremors.²⁴ While herbs may be natural, they are certainly not free from side effects or potential health risks.

Another major problem with herbal preparations is that they can have serious risks when used in combination with other herbs or over-the-counter or prescription medications. Herbal sedatives, such as kava-kava and valerian, can lead to over-sedation when used in conjunction with other herbal sedatives or prescription central nervous system depressants.²⁵ Herbal antidepressants, such as St. John's Wort, could lead to adverse side effects when used in conjunction with prescription antidepressants.²⁶ St. John's Wort may also interfere with the absorption of some prescription medications, such as oral contraceptives and digoxin, potentially decreasing the effectiveness of these medications.²⁷ The possibility of herb-drug interactions is made more serious by the fact that some consumers don't seem to view dietary supplements, including herbs, as medications and therefore may not report their use to health care practitioners.²⁸ This can increase the likelihood that a doctor will unknowingly prescribe medication that may interact badly with an herbal supplement a patient is taking.

Unfortunately, because herbal products are considered to be supplements, there is little that the government can do to regulate their use or ensure their safety. The next section of this paper explores the existing ways in which the federal government could regulate the use of herbal supplements, and makes some suggestions as to how the government could better ensure the safety of consumers who use herbal supplements.

<<http://www.cnn.com/2000/HEALTH/alternative/06/08/herbal.dangers/>>

²³Deborah Angell, *Herbals in Your Life...Herb and Drug Interactions*, Ohio State University Extension Fact Sheet <http://ohioline.osu.edu/hyg-fact/5000/5406.html> (visited February 23, 2002).

²⁴*Id.*

²⁵*Id.*

²⁶*Id.*

²⁷*Id.*

²⁸Deborah Paddison, *Dangerous Liasons*, VIGOR (Spring 2001) <www.vigormagazine.com/lib/fit/fit-DangerousLiasons.htm> (stating that most patients who use herbal supplements don't bother to report their use to their doctors).

Current Forms of Federal Regulation and Suggestions for Change

While DSHEA severely limits the ways in which the FDA can regulate herbal supplements, there are still some avenues open to them when they feel that an herbal supplement is posing a serious risk to consumers. Section Four of DSHEA allows the FDA to take action to remove a supplement from the market when they feel it is adulterated (e.g. when it poses an “unreasonable risk” to consumers or when it is an “imminent hazard to public health or safety.”) Theoretically, this means that the FDA could place a ban on or enact regulations governing the use of certain supplements that it feels are unsafe.²⁹

One problem with placing the burden of proof on the FDA is that it is already an overburdened agency with limited regulatory and investigative resources. Given these limitations, it would be very difficult (if not impossible) for the FDA to monitor and collect evidence on every supplement that could be a danger. One source reports that of the approximately 20,000 dietary supplements on the market today, only 46 have “reportedly been reviewed by the (FDA) for safety.”³⁰ Therefore, it is possible that it could take some time for the FDA to even become aware of potential health risks stemming from use of a supplement.

Even after the FDA becomes aware of problems with a supplement, it has an uphill battle to fight before it can regulate the supplement. Because the burden of proving a supplement is unsafe falls to the FDA, a supplement can remain on the market until the FDA can conclusively show that it is unsafe. In practice, this often means that supplements can remain available to consumers long after there is evidence that they are unsafe. As one example

²⁹The FDA does occasionally exercise this power. After reports of negative side effects associated with the Aristolochia family, the FDA banned its importation into the U.S. *Herb in Weight-Loss Pill Causes Cancer, Damages Kidneys, Researchers Report* (June 8, 2000) <<http://www.cnn.com/2000/HEALTH/alternative/06/08/herbal.dangers/>>

³⁰Andrew Postman, *Sip your Way Thin and Other Diet Lies*, SELF, March 2002 at 172-173. Please note that, according to this article, the FDA has refused to confirm these statistics.

of this problem, the FDA has wanted to place limits on the use of ephedra for several years but has not yet done so.³¹ One reason that they have failed to place such limits was a report issued by the General Accounting Office in which they concluded that “additional evidence” was needed before the FDA could place limits on the dosage and duration of use of ephedra.³² It is not impossible for the FDA to regulate a supplement under the current regime, but it is extremely difficult.

There are things that the FDA can do to try to protect consumers from unsafe supplements that fall short of regulation. They can issue advisories and health warnings stating that certain supplements or ingredients in supplements are unsafe.³³ One problem with these advisories is that they may not reach all consumers. As *Self* magazine points out, “when was the last time you checked the FDA website before purchasing an herbal product?”³⁴

Another problem is the extent to which supplement manufacturers are allowed to aggressively advertise their products. Because Section Six allows companies to make statements about how their supplements impact the human body, they can make strong, appealing statements about how their products will have a positive impact on consumers’ health and appearance. Ads for weight-loss products containing ephedra often contain statements about how the product will cause fast weight loss and drastic changes in appearance with little effort on the part of the consumer.³⁵ When these ads do contain some form of disclaimer, it tends to be in very small type at the very bottom of the page.³⁶ These disclaimers are often ineffective in reaching consumers because most consumers don’t read the small print in these ads; instead, they are influenced by the photos and headlines promising fast,

³¹Ori Twersky, *More Reports Link Ephedra to Severe Side Effects But its Future and Real Risk Factors Remain Uncertain*, WebMD Medical News (March 31, 2000) <<http://my.webmd.com/content/article/1728.56154>>

³²Id.

³³There are many examples of such advisories on the FDA website at <<http://www.fda.gov>>.

³⁴Andrew Postman, *Sip your Way Thin and Other Diet Lies*, SELF, March 2002 at 173.

³⁵Ads such as this can be found in many magazines. An example is the advertisement for Hydroxycut in the March 2002 issue of SELF.

³⁶Some companies do include voluntary disclaimers in order to shield themselves from liability in the event of negative side effects. Andrew Postman, *Sip your Way Thin and Other Diet Lies*, SELF, March 2002 at 173.

drastic results.³⁷ If consumers ignore even disclaimers directly attached to the advertisements, it is probably unrealistic to expect that they will be influenced by warnings posted on the FDA website.

Based on this information, it appears that the current tools that FDA has for regulating herbal supplements are not sufficient to prevent consumers from using potentially harmful products. Given this, it seems like it would be prudent for the government to take steps to expand FDA's authority so that it can better protect supplement users.³⁸ One way in which the government could accomplish this goal is by reclassifying supplements as drugs, and treating them accordingly.

Arguably, supplements already are being marketed as drugs. The Food, Drug and Cosmetic Act of 1938 defines a drug as an article that is "intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals" or that is "intended to affect the structure or any function of the body of man or other animals."³⁹ As discussed earlier in this paper, many herbal supplements are used for medicinal purposes, which would seem to place them within the first part of the definition of a drug. Those that are not being used for medicinal purposes, such as weight-loss agents, are clearly intended to affect the structure or function of the body. It appears from this definition that most herbal supplements could easily be considered drugs rather than dietary supplements.

Having the government reclassify herbal remedies as drugs rather than supplements would have some immediate and positive effects on the government's ability to regulate them. First, and most importantly, the FDA could require supplement manufacturers to get premarket approval before they would be able to sell their supplements to consumers.⁴⁰ Requiring premarket approval would shift the burden to manufacturers to prove that their drugs were

³⁷Id.

³⁸The FDA alone would not have the authority to implement these new steps; doing so would likely require Congressional authority.

³⁹21 U.S.C. § 321(g)(1)

⁴⁰21 U.S.C. §355 requires any manufacturer hoping to market a "new drug" to file an application with the FDA.

safe, rather than leaving it to the FDA to prove that the drugs were not safe.⁴¹ If the supplement manufacturers could not show that the drugs were safe, they would not be allowed to release them into the market. If the supplement manufacturers could demonstrate that their products were safe, then consumers would be allowed to continue using them.⁴² By requiring premarket approval, and thus restricting the sale of dangerous herbal supplements, the FDA could help prevent the potentially deadly side effects that those supplements can cause. Second, treating herbal supplements as drugs instead of dietary supplements would give the FDA the authority to allow distribution of certain supplements by prescription only, while maintaining over-the-counter availability of others.⁴³ This would allow FDA to limit the distribution of dangerous supplements while ensuring consumers still have access to ones that are safer. It would also help ensure that consumers' health care practitioners would know what supplements they were using, thus helping to guard against potentially dangerous interactions.

If the government doesn't want to take the broad step of switching herbal remedies from supplement to drug status, there are other, more limited steps they could consider that might minimize the risks of supplement use by consumers. First, the government could place stronger restrictions on the kinds of claims that manufacturers could make in their supplement ads. One simple way in which the FDA could limit these statements is by requiring manufacturers to disclose the evidence that they have to support their statements. This would ensure that consumers would receive only correct information, and would help better inform them about their supplement choices.

Second, the government could give the FDA the authority to require stronger disclaimers on herbal products that are believed to be unsafe.⁴⁴ These disclaimers could list the potential side effects of an herbal supplement as well

⁴¹See *id.* for a discussion of the requirements of manufacturers who are submitting a new drug application.

⁴²The FDA would also have discretion to not require new drug applications from manufacturers whose supplements are generally recognized by scientific experts to be safe and effective, because such supplements would not meet the definition of "new drug" under 21 U.S.C. § 321(p)(1). This discretion is contingent on the supplement's (or a supplement with a similar composition) having been previously used by consumers. 21 U.S.C. § 321(p)(2).

⁴³21 U.S.C. 353(b)(1)(C) allows drugs to be limited to prescription status, and 21 U.S.C. 353(b)(3) allows the FDA to switch some drugs to over-the-counter status by regulation.

⁴⁴The FDA already has the authority to order these kinds of disclaimers for prescription drugs under 21 U.S.C. § 352(n).

as any contraindications for its use, and would provide consumers with more complete information about whether a supplement is safe for them to use. This would ensure that consumers would at least have all of the relevant information before they made a decision about whether or not to take a particular supplement.

Conclusion

Herbal supplements can be beneficial to consumers, but they also can cause serious side effects and potentially dangerous conditions. Under the current regulatory regime, the FDA can do little to protect consumers from these health risks. By taking certain steps, however, the government could provide the FDA with tools to more reliably oversee the safety of herbal supplements. This greater FDA oversight would help ensure that American consumers could enjoy the benefits of herbal supplements while avoiding the risks.

The FDA can also require manufacturers to place warnings about potential dangers to consumers under certain conditions of use on the labels of both prescription and over-the-counter drugs under 21 U.S.C. § 352(f).