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Title: FDA Regulations of Herbal Supplements

Introduced by: Joseph M. Beals, MD, for the Wayne County Delegation

Original Author: Joseph M. Beals, MD

Referred to: Reference Committee E

House Action: **AMEND**

Whereas, 40 percent of adults take herbal supplements, and

Whereas, in 1994, the Dietary Supplement and Health Education Act (DSHEA) dictated that supplements do not have to be approved by the United States Food and Drug Administration (FDA) and are presumed safe. However, there are numerous examples of their use causing adverse health outcomes such as:

- a. Silicate renal stones are becoming a human disease for the first time due to high levels of silicate in herbal products.
- b. St John's Wart, via its ability to induce cytochrome P450 CYP3A4 can decrease therapeutic levels of cyclosporine, HAART (Anti-Retroviral Treatment Against HIV, a combination of different classes of medication) and others.
- c. The FDA looked into banning ephedra in the mid 90's due to a dangerous side effect profile. However, using the protections of the DSHEA and political connections, herbal medicine suppliers avoided being banned until after numerous fatalities and the death of a celebrity baseball player in 2003.
- d. DMAA (Methylhexanamine) is an ephedra-like alpha antagonist found in workout supplements after the ban of ephedra. Though DMAA was biologically nearly identical to ephedra with a similar side effect profile it was not banned and was responsible for numerous deaths before the FDA could convince retailers to remove it from sale.
- e. Herbal erectile dysfunction products have a high frequency of adulteration with sildenafil or chemically modified sildenafil.
- f. Herbal weight loss agents have a high rate of intentional adulteration with Meridia, the now banned prescription weight loss medication.
- g. Other herbal medications, especially ayurvedic medications, have a high rate of heavy metal contamination which is a known cause of renal and neural toxicity.
- h. Some herbal medications can have unexpected side effects. For example, after ingesting a weight loss tea that contained the herb aristolochia, over 100 women in Belgium developed renal failure from aristolochia and later had high rates of renal and ureteral cancer.
- i. Aristolochia contaminated the food supply in southeast Europe and caused an endemic form of renal failure called Balkan nephropathy.
- j. The same herb, aristolochia, was also commonly used as an arthritis treatment in Taiwan. Taiwan has the highest rate of genitourinary cancer in the world but this plummeted after aristolochia was banned; therefore be it

48 RESOLVED: That MSMS supports the American Medical Association's existing policy on
49 Dietary Supplements and Herbal Remedies (150.954).

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52 WAYS AND MEANS COMMITTEE FISCAL NOTE: NONE