

## **The FDA, Medical Foods and Patents**

More than a year ago, a prominent physician approached me about assisting him in the manufacture of a nutrient product. He questioned whether it should be marketed as a “medical food” or as a “dietary supplement.” My response was to urge caution relative to the former, as I believed then – and still do – that eventually FDA will reign in those products now being creatively marketed as “medical foods,” but which are wholly outside the confines of the regulatory definition for such products. Contrary to what those companies who are pounding out tons of sales of “medical foods” would have us believe, federal law is quite specific about what constitutes an actual “medical food.” 21 C.F.R. Section 101.9(j)(8) exempts true “medical foods” from food and dietary supplement labeling regulations. Question: Which of the several concoctions masquerading as medical foods now on the market qualify under Section 101.9(j)(8) as a “food which is formulated to be consumed or administered under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation?” Answer: None. This labeling exemption – one of a small handful – was crafted to allow a physician to formulate a specialty food for a patient with “limited or impaired capacity to ingest, digest, absorb, or metabolize ordinary foodstuffs or nutrients.” Every company who markets its proprietary “medical food” on the shelves of health-food stores – by creating a truck-size loophole in a regulation where none rightfully exists – puts in jeopardy the ability of legitimate food and supplement companies to manufacture and market needed products for a small portion of the patient population – the “orphan drug” equivalent of a food if you will.

Segue to: The “tangled web we weave” department. It is sometimes interesting how an FDA action can have a rippling effect. The big government spider, content in the center of its web, presently has under consideration a health claim petition for a widely used dietary supplement, phosphatidylserine (PS). Said petition was made under the double-edged language of the Dietary Supplement Health and Education Act of 1994 (DSHEA), which requires application to the FDA for labeled health claims. Included in DSHEA is the cut-off date of October 15, 1994, before which an in-use product or ingredient is “grandfathered” as a dietary supplement. By definition, a product or ingredient sold before that date is deemed to be a dietary supplement.