HR 2749 Increases Criminal Sanctions for Harmless Acts

Does HR 2749 authorize a 10 year jail sentence for paperwork violations or citing legitimate scientific research about a food or food supplement product? Some have disputed this. But the correct answer is yes.

The Alliance for Natural Health USA (ANH-USA) has disseminated materials citing concerns that the criminal penalties language in HR 2749 could be interpreted as applicable to recordkeeping violations thus providing for up to a 10 year prison sentence for administrative violations that do not result in harm or the threat of harm from "adulterated" products within the common sense meaning of the term. ANH-USA has also expressed concern that HR 2749 could provide up to a 10 year sentence for "misbranding" by citing health benefits on a product's label. Some organizations, however, read the legislation differently and do not believe criminal penalties are of concern for these types of violations. This memo is intended to lay out the specific language in black and white to respond to these concerns.

Specific relevant language from HR 2749:

SEC. 134. CRIMINAL PENALTIES.

Section 303(a) (21 U.S.C. 333) is amended--

(1) in paragraph (1), by striking `Any' and inserting `Except as provided in paragraph (2) or (3), any'; and

(2) by adding at the end the following:

(3) Notwithstanding paragraph (1), any person who knowingly violates paragraph (a), (b), (c), (k), or (v) of section 301 with respect to any food that is misbranded or adulterated shall be imprisoned for not more than 10 years or fined in accordance with title 18, United States Code, or both.'.

Relevant language interpreted:

An increase in criminal penalties from 3 years to 10 years is applicable if any person knowingly violates the below stated provisions with respect to any food that is misbranded or adulterated:

(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.

(b) The adulteration or misbranding of any food, drug, device, or cosmetic in interstate commerce.

(c) The receipt in interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.

(k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded.

(v) The introduction or delivery for introduction into interstate commerce of a dietary supplement that is unsafe under section 350b of this title.

□ A product is "misbranded" if a claim is made in the label which expressly or by implication characterizes the relationship of any nutrient...to a disease or health-related condition… 21 USC §343(r)(1)(B).

□ A product is "adulterated" if it is held under conditions that do not meet good manufacturing practice regulations (21 USC §342(g)(1). Recordkeeping violations constitute Good Manufacturing Practices violations (FD 07-3039 Final Sections 111.95(b), 111.75, 111.70, etc). For example, 111.95(b)(2) requires one to keep records of the qualifications of a supplier for the purposes of relying on a supplier's certificate of analysis.

- The definitions of "misbranded" and "adulterated" are quite detailed. A complete listing of the offenses which constitute misbranding and adulteration can be found under sections 402 and 403 of the Food Drug and Cosmetic Act, conveniently highlighted here: http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/FDCActChapterIVFood/default.htm.

- Good Manufacturing Practices can be found here: http://www.gpo.gov/fdsys/pkg/FR-2007-06-25/pdf/07-3039.pdf.

□ Section (v) above references section 350(b) and is concerned with new dietary ingredients specifically. If a new dietary ingredient, one that was not marketed prior to DSHEA, is introduced into commerce without FDA approval, without being "GRAS" (generally recognized as safe), and it is "unsafe" (which it would be by definition if it was not GRAS), then criminal penalties may apply.

"Knowingly" is a legal term meaning that a person must know, for example, under (a) above, that that he or she is introducing into interstate commerce a product that is adulterated or misbranded (as adulterated and misbranded are defined in the Food Drug and Cosmetic Act). In other words, a person must know that they are, for example, citing health benefits of a food or food supplement on their web site. The key here is that there is no accompanying requirement that harm could result as a consequence of the intended action for criminal sanctions to be applicable. Generally, an actor must know (intend) or deliberately close his or her mind to the risk (recklessness) that his or her action would result in harm suffered by the victim. The crime of battery, for example, requires the basic intent that the actor knew or should have known that his or her action would lead to harmful contact with the victim. In HR 2749, there is no requirement that any harm or threat of harm result from knowing violations.

Although it seems illogical, it appears from a plain interpretation of the language that as written, HR 2749 could provide criminal penalties of up to 10 years imprisonment, for example, for citing the science on the health benefits of a food or food supplement (misbranding). The application of criminal penalties to a recordkeeping violation such as the one highlighted above seems equally illogical; however, as written, criminal penalties could apply for not complying with new cumbersome recordkeeping requirements (adulteration). Practically speaking, it is doubtful a judge or jury would give a violator 10 years for recordkeeping violations; however, it is the threat of sanctions that will provide FDA unnecessary authority and a hammer that may be used to threaten and coerce companies engaging in activities of which FDA may not approve.