LETTERS

REGARDING THE REGULATION OF DIETARY SUPPLEMENTS

The recent commentary by Starr[1] contained factual errors and outdated references that do not reflect current regulations pertaining to dietary supplements in the United States. I would like to address a few inaccuracies.

The Current Good Manufacturing Practices (cGMPs) regulation[2] is mandatory for all manufacturers of dietary supplements. The commentary stated that dietary supplement cGMPs "remain nonbinding on the manufacturer." However, the author cited a Food and Drug Administration (FDA) inspection checklist for cosmetics, an entirely different category of FDA-regulated products.[3] Second, compliance with cGMPs for dietary supplements is required by law; any dietary supplement is adulterated unless manufactured in a cGMP compliant facility.[4] The author also stated that "manufacturers are reticent to adopt the FDA cGMP guidelines for botanical supplements," using a 2003 reference that predates the FDA's implementation of cGMPs in 2007.[5]

The FDA fully assesses safety data for new dietary ingredients (NDIs). The author contended that FDA's draft guidance on NDI notifications "allow manufacturers to cherry-pick favorable results to submit to FDA." This is simply not true. The FDA has stated that premarket NDI notifications should include objective summaries of all available human and animal toxicological information (both published and unpublished safety studies) and any other information relevant to the safety assessment of the NDI.[6] Furthermore, the FDA conducts an independent literature review to ensure that all available evidence is assessed.

The author incorrectly classified androstenedione as a dietary supplement when, in fact, the FDA banned androstenedione more than 10 years ago.[7] Furthermore, the Anabolic Steroid Control Act of 2004[8] named androstenedione a controlled substance, and both the Drug Enforcement Agency and FDA have authority to take criminal action against those who might try to sell steroids masquerading as supplements. Moreover, poison control center data were confused with reports of adverse events as statistics cited were old and prior to the enactment of mandatory adverse event reporting for dietary supplements in 2006.[9] Finally, the statement, "Manufacturers are not required to confirm the identity of all ingredients supplied to them. . ." is directly refuted by the cGMPs themselves, which require confirmation of dietary ingredient identity,[10] along with confirmation of strength, purity, quality, and composition.

It is troubling to find numerous errors in the published commentary as dietary supplements are important in the public health conversation but are largely misunderstood. This letter is intended to clarify some of the misinformation and hopefully initiate a balanced dialogue surrounding the regulation of dietary supplements in the United States. ■

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STARR RESPONDS

The author thanks MacKay, Senior Vice President, Scientific & Regulatory Affairs for the Council for Responsible Nutrition (CRN), for his interest in the article and contribution to the discussion on dietary supplement regulation in the United States. CRN is a powerful lobbyist