Nutraceuticals—Pandora’s box?
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The term nutraceutical is not a legal term, but was coined in the 1980’s by a physician regarding oral compounds that were neither a nutrient or a pharmaceutical. The now defunct North American Veterinary Nutraceutical Council defined veterinary nutraceuticals as a non-drug substance in a purified or extracted form that is administered orally to provide agents for normal body function. Administering these products is done with the intention of improving the health and well-being of animals. Nutraceuticals are classified as dietary supplements and fall under the regulation of the Food and Drug Administration (FDA).

The Dietary Supplement Health and Education Act of 1994 mandated that the FDA regulate dietary supplements as food and not as a drug. A dietary supplement is a product taken by mouth that contains an ingredient intended to supplement the diet. As a dietary supplement, nutraceuticals include a wide variety of products including: vitamins, minerals, herbs or other botanicals, amino acids, enzymes, metabolites and organ or glandular tissues. Nutraceuticals can be produced as tablets, capsules, liquids, soft gels, gelcaps, or powders.

There are three categories of labeling claims: health claims, nutrient claims and structure/function claims. The manufacturer of the nutraceutical(s), the FDA or the Federal Trade Commission (in cases of advertising) are responsible for validating label claims. Manufacturers are allowed to make specific claims regarding health benefit(s) of their products, as long as there is adequate evidence to substantiate that those claims are not false or misleading. The label must include the following: a descriptive name of the product stating it is a supplement; the name and place of business of the manufacturer or distributor; a complete list of ingredients; and the net content of the product. The label must also include the following statement: “These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.” There are no rules regarding the amount of the nutrient in a serving size of a nutraceutical. In addition, manufacturers and distributors do not need FDA approval to sell nutraceuticals.

Products classified as a drug must be proven safe and effective before they are marketed to the public. Manufacturers of nutraceuticals and other dietary supplements are not required to prove safety or effectiveness of these products before marketing. The FDA is required to prove a dietary supplement is unsafe after it has been marketed before it will take action to limit or remove the product from the market. Unsafe nutraceuticals are brought to the FDA’s attention through the use of Adverse Events Reporting. Reportable events are classified as either ‘adverse’ - any health-related event associated with the use of a dietary supplement that is adverse - or ‘serious adverse event’ - any event associated with the supplement that results in death, a life-threatening experience, hospitalization, significant disability or incapacitation, congenital anomaly or birth defect or requires medical or surgical intervention to prevent one of these stated outcomes.

The perception of the public, however, is to view these products as entirely beneficial to health and in no way harmful to themselves or their animals. A tour of the World Wide Web will reinforce this idea. Phrases like: virtually no side effects; works with any other medication; safe; natural alternative; natural food based supplement; trusted by pet owners; empowered by nutraceuticals; natural benefits; pure and natural; improve health without giving actual medicines - lead the general public to believe there are no risks and all gains with the use of nutraceuticals.

The AVMA guidelines for complementary and alternative veterinary medicine (CAVM) include the use of veterinary nutraceutical therapy. This guideline states that although the quality of studies and reports pertaining to CAVM vary, it is the responsibility of the veterinarian to critically evaluate the literature and other sources of information regarding the use of these modalities. Veterinary recommendations for treatment with CAVM should only take place after a diagnosis is established. This diagnosis must be based on sound, accepted principles of veterinary medicine. The AVMA guidelines also state that recommendations based on CAVM modalities must be safe and effective and should be
based on available scientific knowledge and the medical judgment of the veterinarian. However, the guidelines do note that CAVM practices may differ from current scientific knowledge and what is routinely taught in veterinary curriculum.\(^5\)

Results of experiments using nutraceuticals are difficult to interpret due to small animal numbers, low repeatability and response to these compounds varies between individuals. In addition to individual variability, one must also take into account the age (immature vs. mature), the breed, the selection pressure placed on different breeds/species (performance animals vs. food production animals), the environment (temperate vs. tropical) and overall ration (ration storage, amount fed to each individual, macro and micro nutrient quality and ratio) when evaluating the effectiveness of a particular nutraceutical.\(^6\)

The lack of clear regulatory definitions in regards to the concentration of active ingredients and the presence of glycosidic and salt forms of these components in nutraceuticals allow for wide variability in the quality of the raw materials used to manufacture these products. Evaluations of 70 formulations of 25 different nutraceuticals revealed no nutraceutical showed consistently high quality. To the contrary, a number demonstrated consistently low quality. This wide variability in constituent quality was also noted when using whole food sources. These factors indicate that much closer regulation of the manufacture of nutraceuticals is required.\(^7\)

In summary, the use of nutraceuticals offers client animals an opportunity to achieve optimal health if given in the correct formulation and for precise circumstances. The difficulties in identifying what nutraceutical or combination of nutraceuticals would benefit an individual animal with a particular malady is fraught with minimal regulatory oversight of these products, limited scientific data, misrepresentation of information to the general public, and wide variability in the quality of these bioactive compounds.

**Some questions to ponder**

- One of Webster’s definitions of Pandora’s box is a complex situation fraught with problems and pitfalls. How can DVMs guide clients in the use of nutraceuticals given the fact that more and more people are ordering products from the internet?
- How can one identify the best brand of nutraceutical for an individual animal’s treatment?
- How does one evaluate the response to a nutraceutical?
- How long should an animal remain on a nutraceutical?
- At what stage of production (growth, breeding, pregnancy, lactation) should a nutraceutical be used or not used?
- How does one identify nutraceuticals that contain high bioavailable ingredients?
- How does one know if the quality of a particular nutraceutical is consistent from one lot to the next?
- What type of experimental design(s) would allow better evaluation of a nutraceutical for a particular syndrome like testicular degeneration?

**Keywords:** Nutraceutical, complementary and alternative veterinary medicine

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