

Editorial

Analyze that Feces Before You Throw it into the Fan

The Echinacea hit the fan recently on the “60 Minutes” segment with Andrew Weil. Ed Bradley’s confrontation of Dr. Weil with adverse analysis of products recommended by the media-annointed alternative medicine spokesman is certain to raise a cry in many quarters.

Mr. Bradley displayed the analysis by two laboratories of echinacea products from three manufacturers. Company A’s echinacea was found to be 91 percent of label potency by the first laboratory and only 26 percent of label potency by the second laboratory. Both laboratories are recognized as experienced and qualified. Company B’s and C’s echinacea was found by both laboratories to be less than 50 percent of label claim. Did Congressman Henry Waxman, the most vocal critic of alternative medicine, wake up the next morning shouting, “There is a Santa Claus!”? Perhaps Congressmen dream of a Santa *Clause*. What does it all *really* mean?

Dr. Weil’s response to Mr. Bradley’s data was, “How do we get products we can feel comfortable with?” Added to that response might be, “When will we get *reproducible* laboratory procedures and standards?” I was not surprised whatsoever that one laboratory found 65 percent more “echinacea” than did the other laboratory in the same Company A product. It could be a difference in testing methods, reference standards, or, as Mr. Bradley implied, a poor product. In this case, the latter is likely. Encapsulating herbal extracts in softgels is a very exacting process, and it is very difficult to get a homogenous product. Interestingly enough, in 1985 I bought a bottle of a highly-touted *Lactobacillus acidophilus*, which the company claimed to have independently analyzed by the most reputable laboratory. I split the bottle’s contents in half, sending part to the very same laboratory in California and the other half to their sister branch in Illinois. Although they are the same company, with the same name, the samples came back with different results, neither of which was *Lactobacillus acidophilus*.

Some months ago I had a lengthy conversation with Dr. Jonathan Collin, publisher of the *Townsend Letter for Doctors and Patients*. He had called wanting my input on whether he/we should write an article about the lack of manufacturing quality control in the dietary supplement industry. The following is a brief synopsis of the quagmire we would be entering.

Dr. Collin suggested that more independent analysis was needed and that he liked to see companies that sent out products for analysis. I pointed out that the unscrupulous company would simply make up one bottle of perfect product and send it out for analysis. Independent analysis must be done from random samples obtained from the retail shelf.

The April 2000 issue (Vol. 5, No. 2) of this journal contained an original research article entitled, “The Effect of Bilberry Nutritional Supplementation on Night Visual Acuity and Contrast Sensitivity,” written by several researchers in the U.S. Navy. One of the researchers, Dr. John Laurent, requested that I provide the active and placebo for the study, which I did, utilizing Indena bilberry for the active. He

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contacted me soon after he received the materials and expressed his concern that an independent laboratory analysis showed the placebo contained a high amount of the active bilberry anthocyanin. I knew the placebo was synthetic food dye, so the mistake had to be flawed analysis. The analysis had been performed by one of the two reputable laboratories cited above. *In this industry* the accepted analytical method for bilberry is found at: <http://www.inanetwork.com/methods/index.html>, the site of the Institute for Nutraceutical Advancement. This method is utilized by most laboratories and involves pH-differential spectrophotometry, which measures the hue and intensity of the bilberry color. Unfortunately, it also will measure similarly colored dyes and show them as active constituents. The confusion had resulted because I did a good job in mixing three different food dyes to come up with a color close to bilberry. Further analysis revealed that, indeed, there was no activity in the placebo. Since some manufacturers of bilberry tablets routinely coat their product with a blue-colored coating for uniformity, laboratories can have their results affected when performing the standard test.

Over the last few years, I have spoken with a number of analytical laboratory directors as well as some members of the U.S.P. commission, which is attempting to set analytical standards for herbs. The problems are many-faceted and obviously more complex than simple food dye additives.

With all the studies of herbal supplement products that have been done over the decades, only one *active* has been absolutely proven, salicylic acid from willow bark. Many *markers*, which can be analyzed for, have been found, but have not been isolated and proven in studies to be *the* active.

In Europe, herbal products are invariably sold as single herbs in dosage form. In the United States, mixtures of herbs abound, making analysis of marker compounds a Herculean task. An accepted test for an individual herb, in many cases, will not be able to distinguish between similar markers in a compound product. These products will require much more complex testing, such as HPLC mass spectrophotometry, at a much greater cost. Even then, herbal ingredients will have variation in marker compounds, depending on which company extracted and manufactured them. The only absolute method for independent testing to be correct would be to test each ingredient that was actually utilized in the manufacture of the final dosage form, and then test them in the proper ratio claimed on the label to see if the markers match.

Analytical methods which will work on undiluted, individual ingredients may not work well on finished products containing other non-herbal ingredients or excipients. For instance, OPC (Pycnogenol) is generally tested by “Porters method,” another light absorption test method. This will work perfectly on the ingredient, but can fail on a finished dosage form that contains magnesium bound to certain organic acids. Herbs are not the only ingredients which need the correct analytical procedure to “get it right.” For example, Atomic Absorption (AA), the old mineral analysis standby, can accurately analyze calcium, magnesium, and

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potassium in their simple forms, such as carbonates or bicarbonates. Throw a little citric or malic acid in the beaker and the results can show significantly less of the mineral than is actually present. You need to utilize the more expensive Inductive Coupled Plasma (ICP) method to obtain the correct reading.

It seems that whenever “standards” are bandied about concerning “alternative” medicine products, that the word “herbal” always arises in the same context. There are more than “herbal” products sold by the dietary supplement industry. It would stand to reason that a strong indicator of a company’s quality may also be determined by the regular products it produces, which can be analyzed using existing, accepted methods. If the stated amount of vitamin C is not in their product, it is a good indication that problems lie elsewhere as well.

So, exactly who is going to test all these products and perform the most correct test possible? It will be years before there are agreed upon standards, markers, and testing methods from any “official” agency, such as the U.S.P. There are a few companies offering a “seal of approval,” however, testing is generally limited to a few herbal ingredients and costs are high.

Perhaps we need an Underwriters Laboratory or Kosher style system, where all companies pay a *reasonable* fee for random testing of a significant portion of their products and a random inspector with the thoroughness of a rabbi. The straightforward testing of substances such as vitamins, minerals, amino acids, and fatty acids could be easily done without controversy. *After the laboratory has purchased the product*, the testing of herbal products could be accomplished by notifying the manufacturer of the upcoming test and obtaining from them actual samples of the herbal ingredients utilized in the product. Although more involved, this would provide the ability to truly test the marker level of the herbal ingredient(s) and any additional ingredients which may affect the testing methodology.

Something must be done before the industry’s fifteen minutes of fame routinely becomes 60 Minutes of shame.

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Publisher