Statement to the FDA on homeopathy, April 20-21, at FDA White Oak campus, Bethesda, MD.

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Time requested: 5 minutes
Discussion topics: Patient attitudes towards products labeled as homeopathic.
The adequacy of information patients have to make informed decisions about products labeled as homeopathic.

Statement:

I am Janine Jagger, President of the Familial Mediterranean Fever Foundation. I am also Professor of Medicine at the University of Virginia School of Medicine. The FMF Foundation represents patients with a genetic inflammatory disease that, if untreated, involves extreme pain in various forms. FMF is life-threatening for certain patients who develop amyloidosis. Amyloidosis can be fatal but is preventable with treatment. The discovery of colchicine (Latin: colchicum autumnale) as an effective anti-inflammatory treatment for FMF which was introduced in 1972, has saved thousands of lives of FMF patients worldwide and has dramatically eased the suffering from extreme forms of pain. Colchicine remains the gold-standard treatment for FMF worldwide and is so specific to FMF pathology that a positive response to it is still the single criteria that confirms a diagnosis of FMF. Let me state clearly that the efficacy of colchicine has been unequivocally established in multiple trials and scientific studies. The dosage and drug interactions and safety parameters have been well established in the peer reviewed medical literature.

Unfortunately, over-the-counter (OTC) homeopathic products sold in the U.S. pose a serious threat to patients with FMF. Over-the-counter homeopathic products labeled “colchicum autumnale” in pill form are sold in the U.S. in health food stores and online. There are multiple products available with various homeopathic dilutions of “colchicum autumnale” indicated under “active ingredients” on the label. The various dilutions found on these products include 6C, 9C, 12C, 15C, 30C, 200CK, 1M, 10M, 4X, 6X, 15X, 30X. All of these dilutions according to homeopathic theory are purported to have different therapeutic effects.

FMF patients see these products in health food stores and believe that because the label says “colchicum autumnale” that these products are an OTC form of colchicine, when in fact there is no therapeutic colchicine in these preparations. Clearly the individuals who purchase homeopathic colchicine do not know that 1) they are foregoing colchicine treatment by taking a homeopathic

preparation of “colchicum autumnale,” and 2) homeopathic theory is based on “like treats like” such that conforming to the tenets of homeopathy an anti-inflammatory substance is the opposite of the substance that would treat an inflammatory condition. Clearly, these products are not being purchased because patients understand and are conforming to the theory of homeopathy. They see a product with a name on the label and assume they are buying that product.

FMF patients must be informed with an explicit label warning of the danger of substituting homeopathic “colchicum autumnale” for FDA regulated colchicine. There is a complacency about the consequences when consumers take “nothing” in place of a drug that has been proven effective, because it is believed that “nothing” has no side effects and no toxic dose. But I wish to make it clear in the case of FMF, a genetic inflammatory disease, that substituting “nothing” for prescription colchicine is very serious in that the patient is deprived of a well documented, effective and life saving therapy. When an FMF patient chooses homeopathic “colchicum autumnale” over colchicine they replace an effective treatment with a deceptive illusion of treatment.

The purveyors of homeopathic products depend on the ignorance of consumers to maximize sales. When consumers do not understand the homeopathic theory that “like treats like” they simply select products by the name on the label. In this regard the consumer is truly being duped. For some there may be no medical harm beyond the inherent deception, but for others, taking “nothing” in place of an effective, well-documented treatment carries the risk of substantial harm and consumers need protection from that harm.