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URGENT

Dr. Elizabeth Yetley, U.S. Delegate, (CCNFSDU) FDA/CFSAN(HFS-830) 200 **C** street, S.W. Washington, D.C., 20204

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Dear Dr! Yetley:

I am a treating physician for hundreds of patients with toxic injury followed by chronic illness (resume enclosed). The process of chemical injury and the body's repair mechanisms produce numerous biochemical disturbances. These include nutritional deficiencies for which repletion is medically necessary based upon test results of deficiency. I have enclosed a manuscript describing some of these alterations. I recently quantified data on 30 new consecutive toxic injury patients for a scientific conference. Cobalamin (vitamin B12) was deficient m 79%: this is used in the repair and synthesis of myelin Antioxidant function was reduced 73%. Molybdenum was deficient in 43%: this is required for the conversion of organic sulfur compounds in the diet to sulfate for Phase II of detoxification. Glutathione (the body's most important intracellular antioxidant and a major Phase II detoxification agent) was deficient in 65%. 54% were deficient in three or more essential amino acids, with amino acids involved in Phase II detoxification being the most prevalent deficient. Cell membrane composition showed deficiency of anti-inflammatory essential fatty acids in 76%. Other nutritional deficiencies were common, and patients were treated based upon test results. All testing was conducted by CLIA appved laboratories.

These patients are intolerant to most medications, likely due to impaired detoxification as documented by challenge testing, using a CLIA approved laboratory. They typically experience significant side effects and fail to obtain symptom relief with the vast majority of pharmaceutical agents (which are petrochemical derivatives in large part). However, they consistently improve with repletion by supplementation of nutrients which have been documented as deficient on Restriction which would prevent physicians from prescribing medically necessary supplementation would lead to ongoing severe disability for such patients. It also constitutes unnecessary and unwanted interference in the doctor patient relationship and in the basic principles of medical ethics.