Committee on Oversight and Government Reform
2157 Rayburn House Office Building,
Washington, DC 20515

reporttoogr@mail.house.gov

Date:

Dear Committee Member,

The Food and Drug Administration needs oversight right now. The FDA has deliberately altered the meaning of the Dietary Supplement Health and Education Act of 1994 (DSHEA). Because of the dictates of this non-elected government agency, I can no longer buy dietary supplements made by BioAnue Laboratories Inc. My health is suffering and I need these products now!

July 2014, in Rochelle, Georgia, BioAnue Laboratories Inc., the owner and her husband were forced to stop selling and manufacturing dietary supplements. Why? The products were magically transformed into drugs, not because of the ingredients—those were all on the dietary supplement list—but rather because of words on an educational website which were used to describe how the nutrients worked inside the human body.

Congress wrote that one of the purposes of DSHEA was, "[A]ssuring the consumers the freedom to use the supplements of their choice;" (DSHEA, pg. 6, lines 16-18) " [C]onsumers should be empowered to make choices about preventive health care programs based on data from scientific studies of health benefits related to particular dietary supplements;" (DSHEA, pg. 2, lines 22-26).

"[A]lthough the Federal Government should take swift action against products that are unsafe or adulterated, the Federal Government should not take any actions to impose regulatory barriers limiting or slowing the flow of safe products and needed information to consumers; dietary supplements are safe within a broad range of intake, and safety problems with the supplements are relatively rare;" (DSHEA, pg. 4, lines 17-25)

Congress also specified that, "[T]he burden of proof is on the Food and Drug Administration to prove that a product is unsafe before it can be removed from the marketplace;" (DSHEA, pg. 5, lines 24-25 & pg. 6, lines 1-2)

The FDA did **not** show BioAnue's dietary supplements to be unsafe. BioAnue did not have *even a single customer complaint with the Better Business Bureau*. Federal Judge Marc T. Treadwell acted unlawfully by issuing an injunction against BioAnue Laboratories Inc. when there was no evidence that the products had harmed anyone. The FDA complained about product names and

Kelly Raber's articles but did not show the products to be unsafe. The DOJ never proved the Tumorx, BioAnue, or Mender trademark supplement brands to be harmful to the consumer. This unlawful injunction must be stopped, BioAnue's compliance must be honestly reviewed, and I must be allowed to buy the dietary supplements that have improved my health in the past!

On behalf of my family, my friends, and myself, I am demanding that you investigate the Federal Judge, the FDA, and the DOJ to see if they are following DSHEA. Specifically, I demand a review of the case involving BioAnue Laboratories Inc., Gloria Raber and Kelly Raber (Civil action no. 5:13-CV-188). I also want to know why the DOJ will not accept the review of the independent expert hired by BioAnue—steps taken by BioAnue to follow the judge's ruling.

The FDA and DOJ are not looking out for me and my family's best interest or health. They are hindering my health and happiness by not permitting BioAnue to re-open even after they proved their compliance with the injunction-- an injunction that not once proved their products to be unsafe!

Respectfully,

(name)

(address)

My Experience with BioAnue & TumorX products: