

The Honorable Kathleen Sebelius
U.S. Department of Health and Human Services
200 Independence Ave. SW
Washington DC 20201



August 16, 2013

Dear Secretary Sebelius:

We have written to you on several previous occasions to share our concerns that the Food and Drug Administration (FDA) is unfairly competing with our small business by taking our ideas and duplicating our commercial food safety and food defense computer software.

In dismissing our concerns and closing the matter, both the Department of Health and Human Services (HHS) and the FDA have rebuffed repeated offers to share evidence of the gross plagiarism committed by the FDA.

Please find attached three enclosures. The first enclosure is an evaluation of my 2006 doctoral dissertation and the subsequent 2007 FDA Food Protection Plan. The evaluation demonstrates gross FDA plagiarism of my research in the FDA Food Protection Plan.

The second enclosure is an evaluation of the ideas contained in my 2007 patent disclosure (which is based on my doctoral dissertation) that have been plagiarized by the FDA.

The third enclosure provides twenty specific examples of FoodQuestTQ ideas that have been plagiarized by the FDA as they developed the FDA Food Protection Plan, Food Defense Plan Builder, the Mitigation Strategies Database, iRisk and the FREE-B food safety and food defense computer software tools.

In all of the previous letters we have written to you and other officials at HHS and FDA, we have repeatedly suggested that we have a meeting in order to resolve the very serious issues that have arisen here. Our requests to meet with you have gone unanswered.

We, of course, are concerned about the serious impact this matter has already had on our livelihoods but we are also equally concerned about the larger implications this situation can have on FDA's future research credibility and the motivation of small businesses to continue to invest in the research necessary to fuel innovation.

As we have consistently done from the beginning, we would like to again offer you the opportunity to meet with us to resolve this problem in a fair and equitable way that will not cause the American people to lose faith in the safety of the drugs, food and medical technology that we all rely on.

Sincerely,

A handwritten signature in black ink, appearing to read "John H. Hnatio".

John H. Hnatio, EdD, PhD
Chief Science Officer

Enc (3)