

May 27, 2014

Ms. Sylvia Mathews-Burwell
Director
Office of Management and Budget
725 17th Street, NW
Washington, DC 20503



Dear Ms. Mathews-Burwell:

Congratulations on the recent decision of the Senate Finance Committee to forward your nomination to be the new Secretary of the Department of Health and Human Services to the full Senate for a confirmation vote. We are writing this letter in anticipation that you will be confirmed by the full Senate and to extend our very best wishes as you take on this new and important responsibility.

We are a small company that has fallen victim to the misappropriation of our patented ideas, copyrights and trade secrets by members of the Food Defense Team of the Food and Drug Administration (FDA). Employees of the Food Defense Team used our intellectual property to duplicate a number of our computer software tools. This resulted in the complete loss of our sales.

When we filed a complaint with the Small Business Administration (SBA) about our concerns, the FDA began a program of retaliation against us. The FDA has used their regulatory influence over the food industry as a means to silence and force us out of business. After we filed our complaint with the SBA's National Ombudsman for Small Business, the Department of Health and Human Services, Office of General Counsel (OGC), dismissed the matter forcing any resolution of the situation down the narrow legal pathway of a patent infringement lawsuit.

For a small company such as ours that has lost all of our sales, this does not represent a viable alternative for us because of the tremendous expense and long time frames involved in pursuing a law suit against the U.S. Government. The loss of sales we have suffered means that we do not have the money we must have to defend ourselves. So far, the Department of Health and Human Services has refused to discuss the possibility of working with us to find a fair solution to the situation.

As you assume your new position as the Secretary of the Department of Health and Human Services we respectfully request your help in finding a fair solution to the situation.

Please feel free to contact me if you have any questions and we will try to answer them. My telephone number appears below.

Respectfully yours,

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

John H. Hnatio, EdD, PhD
Chief Scientist

cc: Distribution list

Attachment (1): One Page Overview

Overview of FoodQuestTQ Matter

- FoodQuestTQ is a small company that builds risk management software to make the food we all eat safer.
 - The software tools built by FoodQuestTQ are based on the doctoral research, a subsequent patent and the trade secrets that were developed by one of the company's owners.
- In the fall of 2012, FoodQuestTQ learned that the Food and Drug Administration (FDA) plagiarized the doctoral research and stole the company's ideas to duplicate the food risk management software that FoodQuestTQ was already selling to the food industry.
- Because FoodQuestTQ could not afford to sue the federal government, they contacted the FDA and offered them a \$1/yr. license for the government to use their products if they would stop duplicating the company's products and giving them away for free.
 - The FDA never responded to the offer.
- To break the impasse, FoodQuestTQ filed a complaint with the National Ombudsman for Small Business in March 2013.
 - The matter was then elevated to the Office of General Counsel (OGC) in the Department of Health and Human Services (HHS).
 - In April 2013, OGC-HHS dismissed the matter stating that no laws were violated and alleging that FoodQuestTQ failed to cooperate in their investigation.
- FDA and HHS continue to blacklist FoodQuestTQ with the food industry as punishment for complaining to the National Ombudsman for Small Business.
 - In November of 2013 the National Ombudsman referred the matter to the Inspector General of the Department of Health and Human Services for investigation.
 - No investigation has been conducted.
- As of May 2014, FDA continues to provide the food industry with duplicates of our food protection software and continues to use their regulatory influence to blacklist our small company. With no sales for our products, FoodQuestTQ is being forced out of business.

Distribution:

Mr. Brian Castro, NOSB, SBA
Representative John Delaney, MD
Senator Chuck Grassley, IA
Ms. Margaret Hamburg, Commissioner, FDA
Representative Sam Graves, MO
Senator Mary Landrieu, LA
President Barack Obama, White House
Senator Pat Leahy, VT
Mr. Daniel Levinson, OIG-DHHS
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Senator Mark Warner, VA
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