

Informal Note for: Elizabeth Dickinson

From: John Hnatio

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For many years prior to my retirement from government service, I had the great privilege of serving in senior positions in both the Executive and Legislative Branches of our government where I dealt directly with technology transfer issues and the vital relationship between the government and industry in achieving national objectives. For example, I was the leader of the technology transfer program for the nuclear weapons program that included all ten of the national laboratories where I oversaw billions of dollars of cooperative work between the government and the private sector. I also served as a loaned Executive from the White House to the Senate to spearhead efforts to strengthen the defense industrial base and promote greater cooperation between government and industry. Suffice it to say that I have "lived and breathed this stuff" for well over 30 years.

Based on my significant expertise in this area, there may be several specific aspects of this situation that you may wish to explore directly with the FDA Food Defense Team before we have the opportunity to meet.

First and foremost, is the requirement that federal employees protect and keep as confidential proprietary commercial information provided to them by the private sector. In all of our interactions with the FDA Food Defense Team we clearly advised them whenever we were sharing proprietary commercial information. In addition, all of the proprietary commercial information we provided to the FDA Food Defense Team was clearly marked as containing proprietary information. The FDA Food Defense Team used this proprietary information and other publicly available descriptions of our product to duplicate three of our products.

Second, are the numerous laws and statutes that dictate when the government can and cannot internally "build" products. Here the rules are very clear. Among these important rules is a documented "build-no build" determination by a government agency based on the notion that the activity involved is an "inherently government function." While the authority to regulate the food industry certainly is an inherently government function, food defense and food safety undertakings to assist the food industry implement and comply with those regulations are not. Rather, they represent a shared responsibility between the government and the private sector. The FDA Food Defense Team did not make a good faith "build-no build" determination before they decided to duplicate our products.

Another important government determination requires that no government agency or its subcontractors, including Battelle Memorial Institute in this case, be permitted to compete with the private sector. Here the rules are also very clear. Before and as part of any funding decision by a federal agency to contract with a Federally Funded Research and Development Center (FFRDC) the agency must make a "compete-no compete" determination. This requires that each federal agency systematically consider and reach a considered determination that the activity they are funding will not compete with the same, similar or better product offering that is already available in industry. In many federal

agencies this responsibility is shared by the Head Contracting Official and is basis to the procurement process. The FDA Food Defense Team did not make a good faith “compete-no compete” determination before they decided to duplicate our products.

There are several other issues that raise serious concerns about the integrity of the FDA Food Defense Team’s actions that are disturbing that their supervisors should be made aware of.

On October 6, 2012, we briefed the FDA Food Defense Team. During that briefing we attempted to discourage them from pursuing a course of action that would only result in a waste of taxpayer dollars to duplicate pre-existing commercial products. At that meeting, we offered the FDA Food Defense Team a one dollar a year license to use our tools for all FDA personnel across the Food and Agricultural industry vertical. The FDA Food Defense Team never responded to our offer. But they did tell us that our company’s products were far better than the ones that the FDA was developing under their contract with Battelle Memorial Institute.

In December 2012, we were invited by the Grocery Manufacturer’s Association (GMA) to attend an FDA Food Defense Team sponsored workshop. Before the meeting we were told by the FDA Food Defense Team that the principal purpose of the workshop was to discuss the use of a food defense targeting tool originally developed by the military Special Forces that has been converted by the FDA Food Defense Team for use by food facilities. After speaking personally with a member of the FDA Food Defense Team about the “true purpose” of the meeting, FoodQuestTQ created a web based survey to reach out to industry to obtain their inputs on the usefulness of the FDA targeting tool.

Just days before the scheduled Food Defense Team sponsored workshop at GMA, we published an article giving the preliminary results of the industry survey. The results of the survey raised serious questions about the utility of the FDA targeting tool by industry. This article received very significant notoriety within the FDA Food Defense Team as evidenced by the fact that the FoodQuestTQ article was “opened” for reading and further distribution by the leader of the FDA Food Defense Team more than 40 times.

A few days before the FDA Food Defense Team sponsored workshop was scheduled to take place on December 12, 2012, we were provided with a copy of the FDA Food Defense Team agenda for the workshop by GMA. We realized at this time that the Food Defense Team intentionally misled us about the true purpose of the workshop. The agenda made it clear that the real purpose of the workshop was for the FDA Food Defense Team to demonstrate and receive inputs from the food industry on the FDA’s new Food Defense Plan Builder tool. A representative of Battelle Memorial Institute wrote the company an e-mail stating that the FDA Food Defense Team industry workshop to demonstrate their new Food Defense Plan Builder tool could only be attended by food processing companies.

Late in the evening of December 11, 2012, we were informed by GMA that the FDA had prohibited our company from attending the following day’s workshop to demonstrate our FoodQuestTQ food defense plan builder tool (known as Food Defense Architect). The GMA advised us that the FDA Food Defense Team prohibited us from attending the workshop because they (the FDA Food Defense Team) did not want to give our company any unfair competitive advantage. After the workshop, we were able to

verify that we were again misled by the FDA Food Defense Team when we found that attendees at the workshop included many other non-food processing companies including competing software companies.

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