Affidavit of Truth: Food and Drug Administration

1. From 2002 through the summer of 2006, JOHN HNATIO conducted a major program of privately funded research at The George Washington University as part of his doctoral dissertation. The research identified a new way to think about risk management that included all critical infrastructures including the food supply. An addendum to the doctoral dissertation specifically addresses the food supply.
2. In 2003, John Hnatio filed an invention disclosure with the USPTO based on his research. In July 2007, a USPTO patent issued claiming priority to HNATIO’s original 2003 invention disclosure. The patent describes new methods for quantifying and projecting risk that can be applied across all critical infrastructures including the agricultural industry vertical.
3. In August 2006, JOHN HNATIO’s final doctoral dissertation was published by The George Washington University. The dissertation was registered as copyrighted material.
4. In November 2007, the FDA issued their “National Food Protection Plan,” that describes ideas contained in JOHN HNATIO’s doctoral dissertation and July 2007 USPTO patent.

1. Over the period 2006 to 2012, FDA officials received a series of proprietary briefings from John Hnatio concerning the development of food risk management tools based on his doctoral dissertation. These briefing materials contained trade secret information that Hnatio developed as he reduced his invention to practice and were marked proprietary.
2. On March 25, 2009, JOHN HNATIO submitted a proprietary unsolicited proposal to the FDA Joint Institute for Food Safety and Nutrition (JIFSAN) (Dr. Julianna Ruzzante) and the Center for Food Safety and Applied Nutrition (CFSAN) (Dr. Robert Buchanan) for the co-development of HNATIO’s patented food risk software. The plan contained trade secret information HNATIO developed as he reduced his invention to practice and was marked proprietary. The unsolicited proposal was rejected by JIFSAN and CIFSAN.
3. In December 2010, the FDA released their “iRisk,” food risk management tool that accomplishes the same purpose as HNATIO’s prior developed risk management software.
4. In April 2011, the FDA released their “Food Defense Mitigation Strategies Database,” food risk management tool that accomplishes the same purposes as HNATIO’s prior developed risk management software.
5. In June 2011, the FDA released their “Food Response Emergency Exercise Bundled or FREE-B,” food risk management tool that accomplishes the same purposes as HNATIO’s prior developed risk management software.
6. Battelle Memorial Institute in their role as a support contractor for FDA, facilitated a Military Interdepartmental Purchase Request (MIPR) from the Department of Defense Chemical Warfare/Chemical and Biological Defense Information Analysis Center (CBIAC) to direct, without competition, a pass through subcontract to a small company called Valbrae Technologies to produce FDA’s “Food Defense Plan Builder,” tool that accomplishes the same purposes as JOHN HNATIO’s prior developed risk management software.
7. During a well-attended webinar meeting held on October 2, 2012, Mr. Jody Menikheim, head of FDA’s Food Defense Team, stated that their “Food Defense Plan Builder,” tool accomplished the same purpose as JOHN HNATIO’s prior developed risk management software but was not as sophisticated.
8. On October 2, 2012, in the same meeting, JOHN HNATIO offered Mr. Menikheim and the FDA a $1.00 per year license for FDA employees to use HNATIO’s suite of computer tools if the FDA stopped competing directly with HNATIO.
9. The FDA publicly endorsed the brand name and products of Tyco Integrated Security Systems, a direct competitor of JOHN HNATIO, by allowing an FDA official to appear in an on-line marketing video produced by Tyco Integrated Systems. 5 C.F.R. Part 2635, sets forth the procedures that must be followed when a Federal agency endorses a private sector organization, products, or persons.
10. On December 12, 2012, the FDA held a food industry meeting at the Headquarters of the Grocery Manufacturer’s Association (GMA) in Washington, D.C., to obtain inputs on their new “Food Defense Plan Builder,” software tool. JOHN HNATIO was prohibited by the FDA from attending this meeting. FDA’s claim that no one but food processors would be allowed to attend to the meeting in order to avoid unfair competition was later proven false. Among the non-food processor attendees at the meeting included Tyco Integrated Security Systems, a direct competitor of JOHN HNATIO.
11. On May 18, 2013, the FDA released their “Food Defense Plan Builder,” food risk management tool that accomplishes the same purposes as JOHN HNATIO’s prior developed risk management software.
12. U.S. Government employees and their contractors used JOHN HNATIO’s trade secrets in the performance of their official U.S. Government work as a means of making personal profit. Personal profit to U.S. Government employees and their contractors took the form of offers of FDA employment, awards, bonuses, promotions and other forms of individual recognition for developing software tools that accomplish the same purposes as JOHN HNATIO’s prior developed risk management software.
13. U.S. Government employees engaged in a conflict of interest by failing to recuse themselves from investigating JOHN HNATIO’s allegations of fraud, waste and abuse that were being made directly against them. 5 C.F.R. Part 2635, Subpart A, General Provisions, specifically require employees of the U.S. Government to avoid appearances of, and never engage in, actual conflicts of interest. The Code of Ethics for Government Service (P.L. 96-303) states that such allegations should be referred to the Office of Inspector General for independent investigation.
14. U.S. Government employees engaged in the obstruction of justice by entering into an actual conflict of interest to conduct an investigation of their own alleged misconduct. FDA spoliated evidence to avoid the public release of evidence under Title 5 U.S.C. §552 (the Freedom of Information Act).
15. By competing directly with JOHN HNATIO, the U.S. Government has defined itself as an “entity engaged in commerce,” under Sherman Antitrust. Under Sherman Antitrust, an unlawful monopoly exists when only one entity controls the market for a product or service, and it has obtained that market power, not because its product or service is superior to others, but by suppressing competition with anticompetitive conduct. The FDA is engaging in anti-competitive conduct by developing software tools that accomplish the same purposes as JOHN HNATIO’s prior developed risk management software and giving them away for free. By FDA’s own admission the FDA food risk tools are not as sophisticated as JOHN HNATIO’s risk management software. By providing less sophisticated software to the food industry free of charge the FDA is lowering food safety standards, endangering the public health and safety and directly harming the consumer.
16. Affiant incorporates by reference a comprehensive report of investigation that includes a computer library of documentary evidence supporting each of individual statements of truth as set forth in paragraphs one (1) through nineteen (19), above. The report dated November 28, 2014, entitled, “The Case of FoodQuestTQ” and exhibits can be directly accessed on the World Wide Web at <http://www.jpgis.org>