

COMPETITION BY THE FOOD AND DRUG ADMINISTRATION WITH SMALL BUSINESS

The parties: FoodQuestTQ LLC, a small business with offices situated at 4720 Hayward Drive, Frederick, Maryland, 21702, and the Food and Drug Administration (FDA) with offices situated 10903 New Hampshire Avenue, Silver Spring, Maryland, 20993.

FOODQUESTTQ LLC CONTACT INFORMATION

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BACKGROUND

Projectioneering LLC is a small Frederick, Maryland-based company working with two other Frederick Maryland-based companies, ThoughtQuest LLC and FoodQuest LLC. Projectioneering LLC owns the intellectual property used by both ThoughtQuest LLC and FoodQuest LLC. ThoughtQuest LLC was created in 2008 for the purpose of supporting the start-up of companies across different industry verticals using the intellectual property owned by Projectioneering LLC. From 2008 to 2012, ThoughtQuest LLC reduced the Projectioneering LLC owned patent to practice for the food and agricultural fields of use. In early 2012, FoodQuestTQ LLC was established to commercially sell a suite of computer software tools across the food industry vertical that are based on the Projectioneering LLC patent.

SUMMARY

FoodQuestTQ LLC has filed a complaint with the Office of Small Business Advocacy and the Small Business Ombudsman. The complaint is based on three inextricably intertwined prohibited actions that the company alleges have been taken against them by the Food and Drug Administration, namely:

1. FQTQ allegations of unlawful FDA competition with FQTQ under statutes and governmental procedures including, but not limited to, the FAIR Act and OMB-Circular A-76, respectively;
2. The alleged FDA theft of Trade Secrets and proprietary information from ThoughtQuest LLC, FoodQuest LLC and Projectioneering LLC, in violation of Title 18 U.S.C. and other statutes, and;

3. Projectioneering LLC and FQTQ allegations that FDA has infringed on Projectioneering LLC owned patent: The Complexity Systems Management Method, Patent No.: US 8,103,601 B2 in violation of Title 18 U.S.C. and other statutes.

Until December 2012, the FoodQuestTQ LLC employed five people. In January 2013, faced with the continuing prospect of direct government competition that interfered with their commercial sales, FoodQuestTQ was unable to obtain an essential operating loan it required to stay in business. In December 2012, the company was forced to lay off all of its employees because of lagging sales resulting from the public release of similar products by the FDA.

This document describes the events leading up to and surrounding the actions allegedly taken by the Food and Drug Administration (FDA) to duplicate products that were already developed and for commercial sale by FoodQuestTQ LLC.

CASE DESCRIPTION

Over the period of the past three years representatives of ThoughtQuest LLC and FoodQuestTQ LLC have met extensively with FDA employees and shared with them information regarding the reduction of their patented technology for commercial use/sale to the food industry.

The information provided to FDA personnel was clearly marked as containing industry proprietary information. In addition, ThoughtQuest LLC and FoodQuestTQ LLC principals state that FDA employees they spoke with were verbally advised that the information being shared with them was proprietary and contained ThoughtQuest LLC and FoodQuestTQ LLC business proprietary and trade secret information.

In September 2012, FoodQuestTQ LLC principals became concerned that the FDA was, unbeknownst to them, taking their business proprietary and trade secret information to duplicate their products, under a contract with Battelle Memorial Institute.

In late October 2012, under pressure to avoid direct competition with the FDA that would put them out of business, FoodQuestTQ LLC, with the permission of their Board of Directors, offered the FDA a \$1/yr. license to use their technology. FDA officials did not respond to the FoodQuestTQ LLC offer.

FDA and their contractor, Battelle Memorial Institute, continue to deploy products free of charge to the food industry that duplicate the products that were already developed and being commercially sold by FoodQuestTQ LLC.

The FDA actions have severely impacted FoodQuestTQ LLC sales. In early December 2012 when they were no longer able to meet payroll FoodQuestTQ LLC was forced to lay off all of their company's employees.

In January 2013, based on continuing competition by the FDA resulting in poor sales of their products, FoodQuestTQ LLC was denied a critical operating loan they needed to stay in business.

TIMELINE OF EVENTS LEADING TO THE LAYOFF OF FOODQUESTTQ PRINCIPALS AND EMPLOYEES

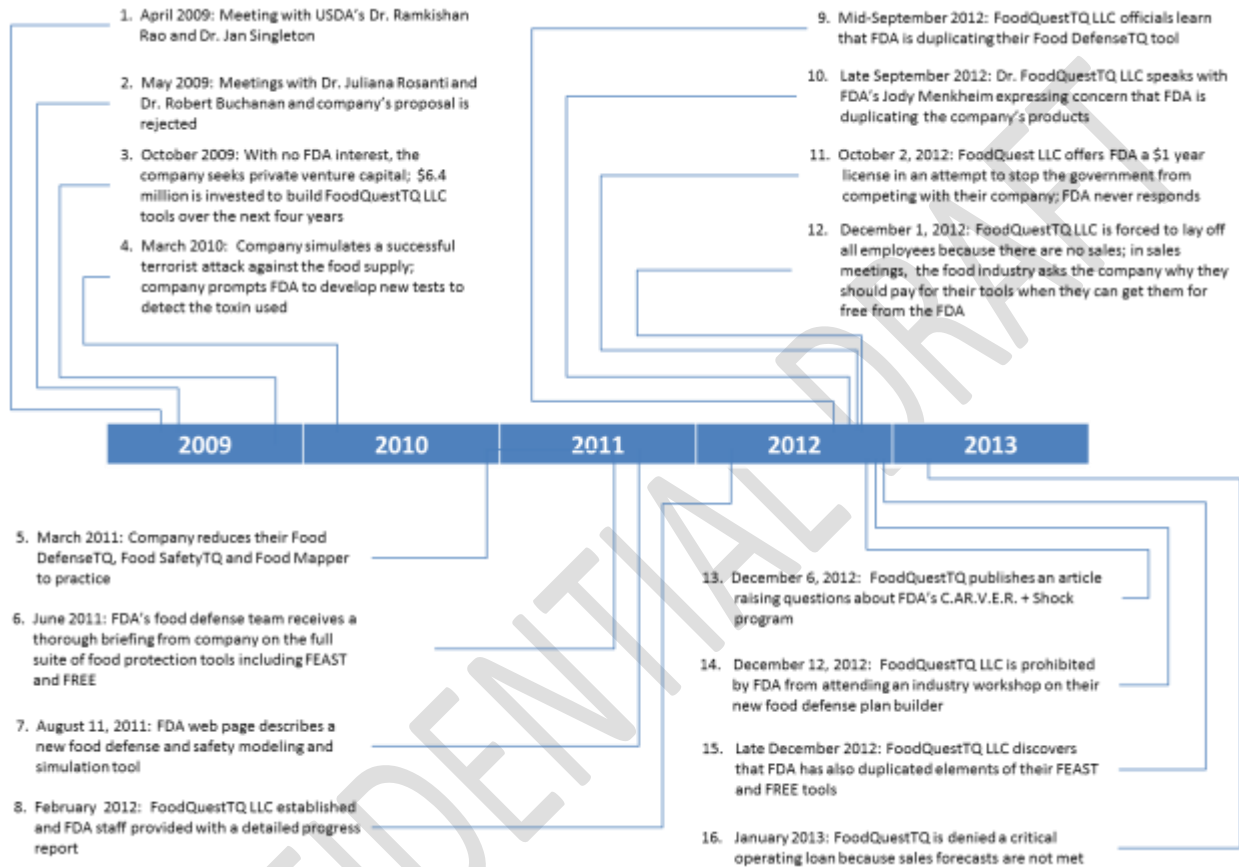


Figure 1: Timeline of FoodQuestTQ LLC and FDA Activities

1. In April 2009, representatives of ThoughtQuest LLC first contacted the U.S. Department of Agriculture (USDA). They met with Drs. Ramkishan Rao and Jan Singleton who were senior leaders at the U.S. Department of Agriculture's, National Institute of Food and Agriculture (NIFA). The purpose of the meeting was to forge a public-private partnership to make the food supply safer. ThoughtQuest LLC representatives shared their scientific breakthroughs, proprietary technology, and business plans for creating a safer food supply. Drs. Rao and Singleton were highly supportive of ThoughtQuest LLC's efforts. After the meeting, the company had follow-on meetings with Dr. Jeannette Thurston and other members of the USDA staff at NIFA to share their progress.

2. In May 2009, ThoughtQuest LLC representatives had their first contact with FDA when they met with Dr. Juliana Rosanti at the Joint Institute for Safety and Nutrition (JIFSAN). Their objective was to explore the possibility of a joint project with JIFSAN using their patent to make the food supply safer; this led to a second meeting with Dr. Robert Buchanan, the head of the University of Maryland's Center for Food Safety and Nutrition (CIFSAN). Dr. Buchanan was a retired FDA senior food safety official and still serves as a senior scientific advisor to the FDA. At that time, Dr. Leanne Jackson, current head of the FDA's Food Defense Team was on the staff of CIFSAN.¹ As a result of these meetings, ThoughtQuest LLC representatives were asked to submit a detailed proposal to Dr. Buchanan describing their patent, scientific breakthroughs, technology tools, and business plans for creating a safer food supply. The proposal was clearly marked as containing proprietary information. The proposal was subsequently rejected by Dr. Buchanan.

Note: Over the next three and a half years, the company continued to maintain very close contacts with both the USDA and FDA as they developed their products. The company briefed USDA and FDA officials on every step of their scientific and technological progress. They hoped that, at some point, USDA and FDA would join them in the public-private partnership they originally envisioned to improve the safety of the food supply based on the company's new science and technology innovations.

3. In October 2009, when the FDA showed no apparent interest in their patent and supporting technology, ThoughtQuest LLC sought venture capital. In addition to the \$3.5 million invested by the two principals of ThoughtQuest LLC, the company received an additional \$2.9 million in venture capital over the next four years to build and commercially deploy their suite of computer software tools to help the food industry prevent and improve responses to accidental and intentional food poisonings.
4. In 2010, ThoughtQuest LLC was asked by a large global food manufacturer to use their patent and technology to simulate a worst case terrorist attack using a biological agent against one of their major food product lines. The goal was to "bring down the company." Based on this tasking, ThoughtQuest LLC was able to scientifically simulate the successful take down of the company as a result of terrorists introducing a particular toxic agent into their product. The simulation was highly successful because no effective laboratory test existed at that time for detecting the presence of the agent that was used to poison the particular product. With the permission of the company involved, ThoughtQuest LLC representatives closely coordinated the results of the simulation and the methodology they used with Dr. Reginald Bennet and other officials at the FDA in

order to prompt the development of specific laboratory and field tests that would detect the deadly agent.

5. By early 2011, ThoughtQuest TQ LLC personnel reduced three of their products to practice and began commercial sales of their Food DefenseTQ, Food SafetyTQ and Food Mapper tools.
6. In June 2011, Mr. Menkhiem, a senior member of the FDA food defense team, and his food defense staff were given a comprehensive briefing and demonstration of the entire suite of ThoughtQuest LLC software tools that were being commercially sold or under development for commercial sale. The presentation included a demonstration of the Food Response and Emergency Evaluation (FREE) tool and the Food Event Analysis and Evaluation (FEAST) tools. Over the coming months, the company maintained close contact with Mr. Menkheim to give him periodic updates on their progress.
7. On August 11, 2012, Mr. David Park, then Principal Scientist of FoodQuestTQ LLC came across an official FDA website that described a new FDA tool for modeling and simulating food defense and food safety scenarios.

Note: As further discussed below, in late December 2012, Dr. Hnatio conducted a detailed review of the FDA website to discover that the FDA had duplicated the elements of two of FoodQuestTQ tools—the Food Event and Analysis Simulation Tool (FEAST) and the Food Response and Emergency Evaluation (FREE) tool. The FDA slightly modified the name of their new tool from the original FoodQuestTQ commercial name of FREE to the new FDA name “FREE-B.”

8. In early February 2012, Projectioneering LLC and ThoughtQuest LLC stood up a new company called FoodQuestTQ LLC that would assume responsibility for the further development and sales of their computer software tools across the food industry.

Also, Mr. Menkheim and his staff were provided with a detailed progress briefing and proprietary documents that included both business confidential and trade secret information describing the industry uses of the FoodQuestTQ LLC tools, the system architecture and the algorithms supporting the FoodQuestTQ tools. All this information was clearly marked as containing company proprietary information.

9. In mid-September 2012, FoodQuestTQ LLC officials learned for the first time, that the FDA had been working with Battelle Memorial Institute to build their own food defense

plan builder to compete directly with the FoodQuestTQ LLC's existing Food DefenseTQ product. This situation prompted Dr. John Hnatio, the Chief Science Officer of FoodQuestTQ, to call Mr. Menkheim to express his concerns that FDA was developing a product that already existed. Mr. Menkheim explained that FDA was not competing with FoodQuestTQ LLC had because the food defense plan builder tool being built by the FDA was not nearly as sophisticated as the FoodQuestTQ tools.

10. In late September 2012, Dr. Hnatio had another telephone another conversation with Mr. Menkheim and asked him specifically about the nature and purpose of an upcoming FDA sponsored workshop on FDA's new food defense plan builder tool scheduled to be held on December 12, 2012. Mr. Menkheim told Dr. Hnatio that the principal purpose of the upcoming meeting was to discuss a terrorist targeting tool known as C.A.R.V.E.R. + Shock. He advised that FDA's food defense planner was being developed in order to make it easier for industry to use C.A.R.V.E.R. + Shock.ⁱⁱ
11. The next interaction between FoodQuestTQ LLC and the FDA took place on October 2, 2012, when a "go-to-meeting" webinar was held. During the webinar, FoodQuestTQ LLC FDA staff updated Dr. Menkheim and his staff on the company's continued progress to upgrade their suite of computer software tools. Particular attention was given to the use of the company's Food DefenseTQ tool as the way to build food defense plan. A more advanced tool known as Food Defense Architect that would make it even easier for food companies to develop their own food defense plans was also demonstrated.

During the webinar, FoodQuestTQ again raised their concerns that FDA was building a food defense planner tool to compete with FoodQuestTQ LLC's existing Food DefenseTQ and Food Architect products. To avoid any potential conflict with FDA that could adversely impact their business, FoodQuestTQ LLC offered the FDA a license to use their technology across the food vertical for \$1/yr. Prior to the webinar, FoodQuestTQ officials met with a member of their Board of Directors, Mr. Joe Welty, to discuss the FDA's actions and received permission to offer the \$1/yr. license in order to avoid direct competition by the FDA. During the webinar, Mr. Menkheim advised that he could not make such a decision but would take the matter to his FDA bosses. FDA never responded to FoodQuestTQ LLC on the matter.

12. On December 1, 2012, when sales failed to materialize for FoodQuestTQ LLC's Food DefenseTQ and Food Defense Architect line of food defense tools, the company was forced to lay off all of their employees including the two founders of the company. Without pay, FoodQuestTQ LLC principals continued to prepare for the December 12,

2012, industry workshop on C.A.R.V.E.R. + Shock and the FDA's new food defense builder tool. The company developed an internet survey to ask the food industry how effective the FDA's C.A.R.V.E.R. + Shock approach was to them in protecting the food supply.

13. On December 6, 2012, Dr. Hnatio of FoodQuestTQ LLC published an article on the potential dangers of using C.A.R.V.E.R. + Shock as a counter-terrorist assessment tool. The article shared the preliminary results of the FoodQuestTQ survey. The results were mixed with a majority of respondents raising questions about the utility of C.A.R.V.E.R. + Shock. The C.A.R.V.E.R. + Shock article written by Dr. Hnatio was a matter of very significant interest throughout the FDA. For example, the web based software used to conduct the survey indicates that Dr. Leanne Jackson, (the former CIFSAN official referenced in entry 2. Above) who is now in charge of FDA's Food Defense Oversight Team, opened the article for review and/or further distribution over 40 times. It is noted that C.A.R.V.E.R. + Shock is a major \$13 million funding line item for Dr. Jackson's office.
14. The December 12th 2012, FDA sponsored industry workshop was hosted by the Grocery Manufacturer's Association (GMA) at their Headquarters building in Washington, D.C. Mr. Warren Stone, Senior Director of Science Policy coordinated the meeting. At FoodQuestTQ's request, Mr. Stone allowed for a 20 minute slot on the workshop agenda for FoodQuestTQ to demonstrate their food defense plan builder tool that was already commercially available to the food industry.

From e-mails sent to us by Mr. Stone as he coordinated the FDA workshop, we first learned that FDA was working under a multi-million dollar contract to help the FDA develop their food defense plan builder. We found the name of Mr. Colin Barthel, who is the Battelle Memorial technical manager for FDA's food defense mission. FoodQuestTQ LLC tried repeatedly to reach Mr. Barthel to discuss our concerns that Battelle Memorial Institute may be using the company's intellectual property to duplicate their products for use by the FDA. After repeated attempts to reach Mr. Barthel by e-mail and telephone to discuss the situation, FoodQuestTQ LLC finally received an abrupt e-mail from him stating he would not speak with them and that the FDA sponsored workshop on December 12th 2012 was strictly limited to food processors. Mr. Barthel referred FoodQuestTQ LLC back to the FDA's Food Defense Oversight Team to discuss any concerns.

On the evening December 11, 2012, FoodQuestTQ LLC principals were notified by Mr. Stone that FDA had specifically disinvited any ThoughtQuest LLC (now FoodQuestTQ

LLC) personnel from participating in the FDA industry workshop to be held at GMA Headquarters the following day. Mr. Stone was told by the FDA that they did not want to give any preference or any endorsement to one commercial product over any other. FoodQuestTQ LLC was prohibited by the FDA from attending the workshop.

FoodQuestTQ LLC did, however, independently brief a few of the remaining food industry participants late in the day after the FDA sponsored workshop for industry was over and FDA officials had left the building. When FoodQuestTQ LLC officials signed into the conference room where they were going to demonstrate their products, they saw the attendee list of companies that participated in the earlier FDA sponsored industry workshop. The list included numerous companies that were not food processors but, in fact, competitors of FoodQuestTQ LLC, such as Tyco Integrated Systems.

15. In late December 2012, FoodQuestTQ LLC's concerns about the FDA action to prohibit their attendance at the FDA industry workshop caused them to go back and conduct a review of their work with FDA. It was at this time Dr. Hnatio took a closer look at Mr. Park's earlier reference (August 2011) to an FDA web site on modeling, simulation and responses to food defense and food safety emergencies. When Dr. Hnatio fully explored the FDA web page he discovered that the FDA had duplicated elements of their FEAST and FREE tools. Unbeknownst to FoodQuestTQ LLC, the FDA had slightly modified the name of the FDA tool from the FoodQuestTQ LLC's commercial name of FREE to the new government FDA name of "FREE-B."

Note: During the preceding months, prior to learning about the actions of the FDA to compete with them, company officials were befuddled as to why their sales projections were not being met. They could not figure out why their products were not selling. It was not until after the FDA industry workshop that they began to receive direct feedback from food processing companies. In these sales meetings, industry asked FoodQuestTQ LLC why they should buy their products when the FDA was providing the same thing for free.

16. In January 2013, FoodQuestTQ LLC was denied a vital investor loan to continue operations. During the period from September 2012 through January 2013, FoodQuestTQ LLC was in critical negotiations to obtain an operating loan from their investors. In early October 2012, as the evidence mounted that FDA and Battelle Memorial Institute were duplicating their products and as sales were failing to materialize, FoodQuestTQ LLC principals were left with no option but to inform their Board of Directors of the situation. The news that FDA was spending millions of dollars under a contract with Battelle Memorial Institute to duplicate FoodQuestTQ's products

and poor sales raised the risk of future investment by their investors to an unacceptably high level. In early January 2013, their request for an operating loan was denied.

CURRENT STATUS

In January 2013, representatives of FoodQuestTQ LLC contacted members of Congress to request their assistance in obtaining a meeting with Ms. Elizabeth Dickinson, Chief Counsel at the Food and Drug Administration. Company officials felt that if Ms. Dickinson was made personally aware of the circumstances she would quickly act to correct the situation. At this time, the matter has become tied up in legal maneuvering by the FDA. Company officials still have not been allowed to personally meet with Ms. Dickinson. This is a matter of great concern to FoodQuestTQ LLC since the owners of the business and all employees had to be laid off without pay several months ago and the company cannot afford to pay the attorney's fees required to fight a long protracted legal battle with the FDA.

In February and March 2013, the inventor of the Projectioneering LLC owned patent undertook a comprehensive review of the FDA web site to identify any possible activities where the FDA had infringed on the Projectioneering LLC patent (The Complexity Systems Management Method, Patent No.: US 8,103,601 B2.) The inventor identified five FDA products that accomplished the same or similar functions as the Projectioneering LLC patent and FoodQuestTQ software tools that were already or were in the final process of being made ready for commercial sale before they were duplicated by the FDA. A subsequent technical crosswalk of the five duplicate FDA products against each of the 20 claims and 101 objects of the Projectioneering LLC patent demonstrates flagrant infringement by the FDA.

PRINCIPAL ISSUES

1. FOOD AND DRUG ADMINISTRATION USE OF CONFIDENTIAL FOODQUESTTQ LLC BUSINESS AND PRODUCT INFORMATION

Over a period of approximately three years FoodQuestTQ LLC met extensively with FDA employees and provided them with detailed briefings which included the proprietary and trade secret information relating to the reduction of their patent for commercial sale to the food industry. All proprietary information shared with FDA employees was clearly marked as containing industry proprietary information. In addition, FoodQuestTQ principals verbally advised the FDA employees they shared any proprietary information with that the information they were sharing required protection pursuant to the Code of Federal Regulations (48 CFR 27.402) and other government statutes.

Note: Title 18 USC 1905 applies to disclosure by a government employee of any information provided to the government by a company or other nongovernment organization, if the provider of the information identified it as proprietary or as being provided to the government in confidence. The penalty is mandatory removal from office (termination of employment), and the offender may be fined not more than \$1,000 and imprisoned not more than one year.

Specific legal statutes and portions of the Federal Acquisition Regulations that pertain to the protection of commercially owned proprietary information include:

- Title 18 USC 1831–39 - Protection of Trade Secrets [Chapter 90].
- Title 18 USC 1905 – Disclosure of Confidential Information.
- Title 41 USC 423 – Procurement Integrity.
- Title 5 CFR 734 – Employee Responsibilities and Conduct.
- FAR 3.104-1 – Procurement Integrity, General (48 CFR).
- FAR 27.4 – Rights in Data and Copyrights (48 CFR).
- FAR 52.215-12 – Restriction on Disclosure and Use of Data (48 CFR).
- FAR 52.227-14 – Rights in Data (48 CFR).ⁱⁱⁱ

2. FOOD AND DRUG ADMINISTRATION COMPETITION WITH FOODQUESTQ LLC

The government is precluded under the FAIR Act from competing with the private sector whenever the same or better products can be procured from industry. FQTTQ offered the FDA Food Defense Team a \$1/yr. license to use FoodQuestTQ LLC technology in order to avoid unfair competition by the government. FDA never responded to the offer. Based on proprietary business information provided to them, FDA was fully aware that the products they were developing with Battelle Memorial Institute were already developed and being commercially sold by FoodQuestTQ LLC.

Efforts to make the food supply safer are a shared responsibility between the government and the private sector and non-regulatory activities have never been considered an inherently government function. A simple Google search of food safety and food defense, identifies literally hundreds of “hits” with private sector companies doing everything from consulting, risk assessments, third party audits in support of FDA’s governmental regulatory compliance responsibilities. The FDA itself promotes the use third party private sector companies to assure the quality of food safety and food defense at food operations all across the food supply.

The FDA actions in this case also raise questions regarding the Agency's compliance with OMB Circular A-76. This document (and other statutes) specifically restrict government agencies and federally funded research and development organizations such as Battelle Memorial Institute from directly competing with the private sector.

3. THE IMPACT OF THE FOOD AND DRUG ADMINISTRATION POLICY AND ACTIONS ON SMALL BUSINESSES GENERALLY

FoodQuestTQ LLC is only one of millions of small businesses in America that provide the innovation required to solve national challenges. The nation depends on small businesses and the entrepreneurs who risk everything to create them. The jobs the nation must create to keep people employed are generated by small businesses like FoodQuestTQ LLC. Much of the innovation that the nation and our government must have to solve national problems comes from small businesses like FoodQuestTQ LLC. By competing with small businesses like FoodQuestTQ LLC and forcing them out of business, the FDA risks losing the genius and innovation the nation desperately needs to solve the country's food protection and food safety problems.

ⁱ See: <http://www.linkedin.com/pub/leeanne-jackson/19/920/718>

ⁱⁱ Note: C.A.R.V.E.R. + Shock was developed by the military special forces to plan attacks against the critical infrastructures of the enemy. In the aftermath of 9-11, FDA attempted to convert the tool for civilian use by the food industry with mixed results. Currently, the pursuit of C.A.R.V.E.R. + Shock is a continuing \$13 million dollar FDA budget line item.

ⁱⁱⁱ http://www.wrc.noaa.gov/wrso/security_guide/propriet.htm