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WILL FSMA ADEQUATELY PROTECT THIS
NATION'S FOOD SUPPLY?

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Will FSMA Adequately Protect This Nation's Food Supply?

Randall K. Fields, CEO, Park City Group, Inc.

I. INTRODUCTION

Every year, 48 million Americans become sick; 128,000 are hospitalized, and 3,000 die due to foodborne diseases, according to data from the Centers for Disease Control and Prevention. The resulting food recalls can cost food companies millions of dollars in legal costs, judgments, man-hours and damage to their brands. In January 2011 Congress passed and President Obama signed into law the Food Safety Modernization Act (FSMA). FSMA gave the Food and Drug Administration (FDA) new powers to help prevent problems in the U.S. food supply before they occur, to better enforce food safety standards and to hold imported food to the same standards as domestic food. FDA is also mandated to establish a national food safety system in collaboration with state and local authorities that mandates participants in the food supply industry to implement “one forward, one back” tracking on the food that moves through their operations.¹ The central question is, is FSMA adequate, and if not, what else needs to be done?

The answer to the first part of the question is a resounding “no.” The U.S. food industry, as one might expect, fought back against FSMA while it was in Congress. Legislators wanted a national database for food and drug data, but the food industry was able to come away with the one forward, one back system. However, the industry may, as participants in the largest and most important supply chain on earth, have won the battle and lost the war. This paper will articulate how only a public-private national database of food and drug data will allow government and industry to remove one of the most important problems in food safety—time—while providing a system that has no substantial barriers to adoption.

A national database of food and drug data will not only save lives by eliminating time-consuming searches through companies’ one forward, one back databases, but it will also save money, both in terms of the implementation of the system and in terms of savings from recalls and legal actions. A system already exists that can address all these concerns and help provide the country with a safer food supply.

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POLICY RECOMMENDATIONS

FDA should:

- Establish a public-private national foods database that will allow instant, real-time access to tracking data for all products in the U.S. food supply.
- Ensure that the database is agnostic in terms of internal systems and communication.
- Ensure that the database is easy to use and affordable.

II. BACKGROUND

FSMA mandates that food companies maintain one forward, one back records on their food products. In other words, they are required to maintain records on where the food and/or ingredients in their facilities and warehouses came from and where they are headed. However, if companies adopt this as their recordkeeping standard, it will prove woefully inadequate. One forward, one back recordkeeping does not protect the consumer, the company or its brand. Time is everything when determining the source of food contamination. One forward, one back gives food companies a day or more to identify the sources of the food involved in a recall or investigation. However, each passing hour can mean more illnesses and death. In addition, without a costly physical audit, there is no ability to determine if the participants are actually maintaining records. When the records are needed, investigators may be met with blank stares or directed to stacks of unfiled papers, rather than the organized records that they need.

The risks associated with not following a higher level of food safety recordkeeping are great. The longer it takes to track and trace problems, the more it costs. Consider the following examples in which prompt identification of the source of the problem could have saved money:

- One lettuce head in New York that was contaminated with *Salmonella* forced a Maryland distributor to pay \$4,000 in labor costs to contact customers who had purchased their lettuce from the same farm.²
- In 2009, a recall of Peanut Corporation of America products cost the industry \$1 billion, according to testimony by the chief of the Georgia Peanut Commission given before Congress. CDC reported that the incident killed nine people and made nearly 700 ill in 46 states.³
- In 2008, Menu Foods paid more than \$24 million to settle over 100 lawsuits filed against it because the company imported Chinese pet food that was contaminated with melamine, a poison. This was on top of \$8 million already paid to settle earlier suits. In addition, the recall of the products cost the company \$65 million. The tainted pet food killed 4,000 cats and dogs.⁴

Some attorneys are making law suits against food companies a cornerstone of their practices. Bill Marler made a career by suing Jack-in-the-Box and Odwalla on behalf of victims of *E. coli* O157:H7 contamination in the 1990s. Marler says he handles 75 to 100 outbreaks at any given moment and even employs an epidemiologist on his staff. He says he has collected an astounding \$600 million in judgments and settlements from defendants.⁵

Another factor that influences this situation is the large amount of imported food in the U.S. food supply. Consider that in an April 2011 report the Government Accountability Office determined that more than 80 percent of all seafood sold in the U.S. was imported from foreign countries. Many of these countries have food safety standards far more lax than the U.S. Should a U.S. company stake its future on the food-handling practices of a foreign company, two or three steps up the food supply chain, about which it knows little or nothing? The same dilemma holds true for fruits and vegetables: a 2005 USDA report found that 16 percent of vegetables and 44 percent of fruit sold in the U.S. were imported.

Because so much is at risk, FSMA should be considered a starting point or baseline for retailers and food suppliers rather than the sum total of their food safety efforts. The players involved cannot afford to wait for government to react to events, draft regulations and then tell them what steps to take. The key tool in quickly identifying the source of foodborne illnesses is a national database of food and drug data that will provide participants with instant and up-to-the-minute information on every aspect of a product.

Unfortunately, rather than moving proactively toward achieving this goal, things are in limbo. Numerous competing technologies and standards are being introduced into the marketplace, such as the Produce Traceability Initiative and GS1 identifiers, while FDA runs trial balloons on a limited budget to best determine how to implement the regulations spelled out in FSMA. As in all cases of new technologies entering the marketplace, the players are reluctant to commit to any one

until a winner rises to the top. Early adopters who gamble on a technology will pay a higher price for implementation and may find themselves stuck with an obsolete system if their choice is not adopted industry-wide.

III. ISSUES IN DISPUTE

Time is a major component of risk when it comes to identifying the source of food contamination. Consider this scenario: Dozens of people become sick or die. It is determined they all ate melons from the same retail chain. Under the current system, the retailer would provide investigators with the sources of their melons, and a day later it is revealed the melons came from two different regional distributors. Each regional distributor is contacted, and dozens of farms that grew the melons are identified on a list after another day. However, the search also reveals that some of the melons were cut up and put into fruit salad, adding another dimension to the problem. Days have gone by, and no one is any closer to an answer.

Complicating this scenario is that each link in the food chain involved in tracking the contaminated melons back to their sources uses a different system to meet FDA's one forward, one back requirement. Differing data types, different modes of transmission, different levels of expertise in operating the system, differing food identifiers, hardware failures—all contribute to slowing down the investigative process. The truth is that the one forward, one back system is essentially manual. The investigators will be looking at different reports in different formats to piece together their puzzle.

A third flaw in the system is that some food companies have been reluctant to install adequate tracking systems because of cost and ease of use. Vendor A's system was more comprehensive but too expensive, so it was scrapped in favor of vendor B's less expensive, less user-friendly alternative. Training was too expensive for some companies, too, so employees might have received a manual or attended a two-hour webinar. When it comes time to use the system in an actual food safety emergency, employees find themselves stumbling through menu after menu and contacting customer service just to find out where their melons came from and where they went. The myriad of initiatives in produce, bakery, deli, seafood etc. all require different database changes that retailers must accommodate.

Who really believes, in this economic climate, that retailers will be able or willing to adopt all of these technologies?

IV. RESEARCH AND RESPONSE

A. **Establish a public-private national foods database that will allow instant, real-time access to tracking data for all products in the U.S. food supply.**

When companies rely on multiple systems spread across thousands of vendors, this approach is no better than the situation that existed before the passage of FSMA. The simple solution to all of these flaws in the current one forward, one back system is a national database of food and drug data. Such a system already exists. It is near-real-time. It works with all kinds of data and even paper documents. And it is both affordable and easy. A national food and drug data database would act as a "universal translator." Right now, there are too many food safety initiatives, various internal systems, different formats of data exchange and different communication protocols. Complicating things further is that there are too few technical resources, automated suppliers and dollars to spend. We need something now to bridge the gap, and allow all systems to seamlessly communicate with one another, and store the information for rapid outbreak analysis. In other words, we need a universal translator that enables each supply chain participant to communicate their information any way they want to a translator that will then keep that information and also forward it to any other member of the supply chain exactly the way they want

to receive it. Thus, each member of the supply chain only sends their information once, while the system sends it to as many receivers as necessary, each the way they want to receive it.

Synchronized commerce was invented more than 15 years ago, based on the concept of universal translation. Thousands of retail and supplier trading partners' data were synchronized, enabling them to execute reconciled electronic commerce without changing any systems or installing any hardware or software. The system was based on the use of existing standard electronic documents rather than requiring compliance with a single standard. Synchronized commerce requires the same type of tracking, tracing and validation for financial settlement between trading partners. The same kinds of information, stored in the same way, can be used for food safety.

With synchronization, each participant can identify items his way, and the national database translates the data into how others identify the same item. This reduces the burden for all participants—they provide the data once, and the database will translate it to all participants with which the supplier does commerce. The system can facilitate GS1 identifiers among other identifiers and translate seamlessly to any other. For participants with no electronic documents, the database would provide a scanning and manual data entry service.

In a national food and drug data database, there is no need to wander from retailer to distributor to supplier, wasting precious time as each generates its own reports on where its food came from and where it went. Because all the data are at one's fingertips in a national database, the information is literally seconds—not days—away. A complete, holistic picture is available at any given moment. The national food and drug safety database would function as a “system as a service” meaning it is always on, utilizing extensive backups and redundancies to avoid data loss and multiple ISP connections to ensure adequate bandwidth for large numbers of users. Bank-level security and other security measures would be utilized to ensure the safety of data.

Investigators would be able to quickly go to the farms suspected of selling contaminated produce and cut right to the heart of the matter, instead of playing detective and piecing together a patchwork of reports in a variety of formats, all using different identifiers. The database would use business rules-driven processes, including exception reporting for discrepancies or missing data, which causes alerts to be generated.

Summarizing, a national food and drug data database will answer the following questions in near-real-time:

- Where did it sell?
- By whom and when was it delivered to the retailer?
- Who produced it?
- Who produced the ingredients?
- What other products contain those ingredients from that producer?
- What other locations received products with that suspect ingredient?

B. Ensure that the database is agnostic in terms of internal systems and communication.

An impediment to the implementation of a national food data database is the variety of data formats and structures that any given company might be using currently in its recordkeeping. Given the range of technical sophistication of the thousands of companies that are in the food supply chain, it is unrealistic to expect each company to convert or upload its own data to a national database. By working with the database, companies of all sizes could simply send their existing electronic documents for conversion by any of variety of methods, electronic or physical (e.g., a mailed CD). The database would

then extract the necessary data from these documents, making the process painless and affordable for companies in the system. The database would use suppliers' and retailers' current B2B documents, including common industry identifiers and standards when available.

The steps for entering data into the proposed national food and drug data database are efficient and not labor-intensive:

1. Supplier and national food and drug data database exchange identifiers.
2. Retailer and database exchange identifiers.
3. Supplier will electronically transmit their deliveries to database. A document with traceability information is included.
4. Database will receive, process and save the data. The data are matched up with the retailer's identifiers. Delivery data are accessible by retailer (meets one forward, one back requirement in FSMA), and food source data are accessible by retailer (meets "one-back" criteria). The database provides tracing back (pedigree) as far as the retailer desires. All data are archived for two years.

A national database will make the full pedigree of food products available from farm to store, including:

- Location IDs
- Item IDs
- Supplier IDs
- Retailer IDs
- Quantities (units, cases, etc.)
- Delivery dates
- Shipment dates
- Batch number
- Lot number
- Expiration date
- Store IDs

For both retailer and supplier, the data are highly visible and traceable. Other types of information that could be stored in the database include house "supplier" food plans, certifications and import inspections. A Governance Committee consisting of representatives of all levels of the supply chain would ensure that the database only releases information consistent with liability and "need to know" concerns. A Science Committee would ensure that the "right" data consistent with the current science are being collected and stored.

Partners that have common industry identifiers would be able to use them, and others can still participate—no single standard is required. As new technologies are introduced the system would accept the information without the need for others in the supply chain to become "compliant" with a new standard. When a planned produce tracking initiative is in place, the system would accept any scanning data that are produced at each level without the need to change internal databases or make other changes. In short, as the regulations and technologies advance, the data that emerge can be accommodated in the system.

C. Ensure that the database is easy to use and affordable.

The cost to food companies to implement their own food safety database can be overwhelming. Adding yet another information system requires thousands of person-hours to spec, bid, award, install and train employees in addition to the actual cost of purchasing the system and paying regular maintenance fees. And even then, there is no guarantee that it will be compatible with other databases upstream or downstream in the food supply, short-circuiting the entire process.

In contrast, a national database would be affordable and easy. What is meant by “affordable” and “easy”? Affordable and easy means that there is no cost involved in changing a company’s internal systems, no need for them to change or add new hardware, and no need to adopt new standards of identification for their products. Unlike nearly all the competing solutions out there, an ideal solution would be a hosted, web-based solution, requiring minimal to no hardware and software installation and would be so inexpensive that no one could object to the cost.

Furthermore, the lower the cost to the participants, the lower the cost that will be passed on to the consumer. Each participant would pay a very small monthly subscription cost. That cost is estimated to range between \$25 and \$350 per month, depending on size.

Figure 1 provides a graphical analysis of the situation. Most solutions require hardware and software installations and the adoption of a single standard. They are firmly planted in quadrant II, expensive and hard. However, a national food and drug database would land square in quadrant IV, affordable and easy.

The ability to use any existing document, rather than creating and integrating new systems, results in lower costs for both retailers and suppliers. If someone has no electronic system, then paper can be scanned or the information manually entered into the system. When a third party develops a stand-alone solution for a company, that company’s investments costs are higher. Their partners’ investment costs are higher as they adapt to interface with multiple systems. Time required for acquisition, installation and training are higher, as are ongoing expenses. Meanwhile, scalability is reduced. The opposite holds true in the central database model. Investment by the company and its partners is low because they are paying a tiny percentage of the total cost of the national system, as are the time required for setup and ongoing expenses. Meanwhile, scalability is high due to the large size and expandability of a national-scale database system.

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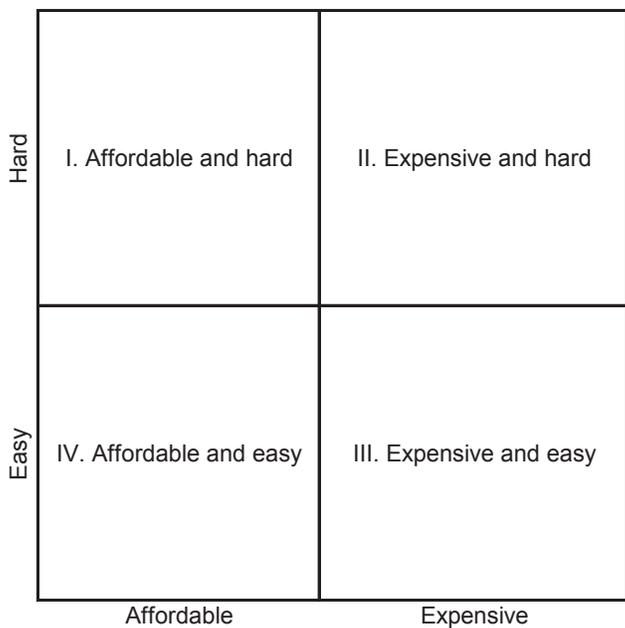


Figure 1. Affordability and ease of use diagram

V. IMPACT OF POLICY RECOMMENDATIONS

Implementing a national food and drug data database will accomplish two goals: reducing risk and saving money. Consumers deserve to know the food they eat won't kill them—at least not directly. But in a global food economy, it is difficult, if not impossible in some cases, for suppliers, retailers and government agencies to ensure that the food that reaches consumers' shelves is safe to eat.

At the same time, consumer perceptions and a company's branding mean everything in terms of its ability to compete in the marketplace. Famous brands have suffered for years after a recall due to the perception that the product is not safe for consumption. By quickly and accurately tracking food contamination to its sources using the global view provided by a national database, companies' hard-earned brands and reputations can be preserved, limiting costly and embarrassing recalls and potentially saving companies millions in settlements, judgments and legal fees. A national database of food and drug data meets these needs and more.

VI. CONCLUSION

A patchwork of conflicting databases that add cost and frustration to every supplier and retailer is not the solution. A centralized food database will allow every participant in the food supply access to information quickly and accurately and, in turn, make the food supply safer.

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