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### When You Can't Watch What You Eat: Examining the FDA's Recall Process for Food Allergies

Jacob Passy

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## **TITLE: When You Can't Watch What You Eat: Examining the FDA's Recall Process for Food Allergies**

Written by Jacob Passy

Stefani Bush's friend believed she was being thoughtful.

Getting together at the Bush's suburban Lowell, Mass., home for an evening playing board games, the friend swung by a Hannaford Supermarket and scooped up store-baked cookies to share.

Stefani Bush set out the oatmeal raisin cookies – but not without first checking the package's ingredients. That's because she and her two young children suffer from food allergies, particularly to nuts. The label passed her inspection: no nuts listed. Everyone dug into the food, including Bush's son Will.

But Bush's husband took a bite and noticed something was not right. He tasted walnuts. What ensued were frantic phone calls to a doctor and worries as 11-year-old Will began to show signs of a reaction.

The panicked mom shuddered, "I thought, 'I almost just killed my son.'"

The label was wrong. The incident led Hannaford, a major New England grocery chain, to recall all packages of those kinds of cookies, but not before Will and potentially other allergy sufferers were exposed to the mislabeled goods.

That's not unusual. Each year, the government oversees several hundred of food items that are recalled off the nation's supermarket shelves for food allergy-related reasons. From cheeses to chocolate, salmon to seaweed, pistachios to plums. It is part of a national effort to protect the more than 7 million Americans who suffer from food allergies, especially children.

A CUNY News Service investigation examining US Food and Drug Administration records shows that, after food-borne pathogens like salmonella and listeria, the biggest reason in the nation for recalling food is because of allergies, and most of the time these products pose a risk to public health. Between January 2010 and September 2014, there were 546 recalls sparked by allergy concerns.

One of the main sources of these allergy-related recalls are supermarkets. Whole Foods, Trader Joe's, Kroger, Hannaford and other major chains account for about a fifth of all food recalls. Indeed, the top three individual companies with recalls are all supermarket chains.

These recalls stem from the way supermarkets make their branded goods, according to records and interviews with experts. Sometimes the problematic goods are manufactured by outside companies contracted by grocers to make cans and boxes

of food and brand them with a supermarket's logo. Other times supermarkets try baking or preparing foods at individual stores, and quality control falls short.

At the same time, the nation's regulatory system for recalls suffers from shortfalls.

Sometimes, grocery stores never notify federal regulators about products they quietly pull off their shelves, making it harder for consumers to know about possible dangers.

In addition, records show that many recalls come too late, after goods are already past their sell by dates and should no longer be available for sale or recommended for people to eat.

That happened with the Hannaford cookies. By the time the supermarket announced its recall, it was two days after the sell by date for some of the baked goods, at which time supermarkets likely would have pulled the product off its shelves.

"Do we have a ways to go? Honestly we do," said Steve Taylor, co-director of the Food Allergy Research and Resource Program, a food industry-funded consortium at the University of Nebraska. "There's some companies that are doing great, there are a few that are doing next to nothing and there's other companies that could improve."

### **SUBHEAD: WHY RECALLS HAPPEN**

Most of the time, the reason for allergy-related recalls is because labels do not show what's really in the product. Companies also sometimes fail to list all the ingredients in a product. That was the case with the cookies at the Bush house. A mistake in processing meant walnuts were put into dough later baked at the supermarket. Other times, food is cross-contaminated, tainted by ingredients used in the same facility to make a different product.

What's on those labels is important, according to experts, advocates and regulators.

"Reading ingredient labels is one of the cornerstones of food allergy management," said according to James R. Baker, Jr., chief executive and chief medical officer of the advocacy nonprofit Food Allergy Research & Education Inc. "Families and individuals managing food allergies depend on accurate labels to help them make informed choices, avoid reactions and stay safe."

That is the line of defense that Bush took before giving cookies to her children at the May 2013 gathering.

Exposure to mislabeled foods can pose dangers to public health. FDA records show that 60 percent of recalls happen because of a risk that these products "will cause serious adverse health consequences or death." Despite efforts like recalls, food allergies send more than 80 people each day this nation to a hospital emergency room, totaling to [30,000 visits annually](#), and, tragically, 150 deaths.

Children are especially susceptible [since one of every 20](#) children suffers from food allergies.

The Bush family was fortunate. Will previously had gone into anaphylactic shock, a severe and potentially fatal reaction. That happened when he touched a candy bar that included almonds. Before the night with the cookies, Will had never eaten walnuts.

The scared parents watched Will sleep through the night, ready to call 911 and inject him his EpiPen, a medication containing epinephrine that can abate severe reactions. Will suffered nausea and itchiness; the symptoms never worsened.

Hannaford Supermarkets declined to comment on the specific incident, but company spokesperson Eric Blom did say that Hannaford “[works] closely with vendors, food safety experts and regulators to ensure that all the products we sell are safe.”

### **SUBHEAD: SUPERMARKETS STRUGGLE WITH SAFETY**

The Hannaford recall was one of four related to allergies in the past four and a half years at the chain. It was one of many major supermarket brands whose goods were subject to recalls.

During that time, Whole Foods Markets posted the most of all grocers, with at least 18 recalls to its name, more than twice as many as runner-ups. Those include Wegman’s, Price Chopper and Kroger, each with at least seven recalls.

Among the roughly 300 different brands involved in recalls stemming from allergies since 2010, at least 17 percent of recalls involve products that supermarkets make and put on their own shelves.

Whole Foods recalled products like coffeecakes, chicken wraps, pimiento cheese and tom yum soup.

The company said the recalls are in part because the company has high standards, trains employees to be aware of how to properly prepare foods, and goes “well beyond the competition when it comes to providing shoppers with information.”

Whole Foods said another reason for its number of recalls is that it makes more prepared food than most other grocers. Records show almost all the recalled products were ones made in-house.

But in two cases, it had hired an outside company to make food and put the Whole Foods label on it.

In the supermarket industry, that is not unusual. Many food manufacturing companies hire themselves out to supermarkets, offering to make products and put a grocery chain’s label on the can or box.

These outside manufacturers are subject to the same rules as any food maker, and supermarkets are responsible for what they sell under their brand.

“Grocery stores, because they’re selling packaged food, they have to follow the same labeling practices as a big commercial facility,” Taylor said. “A big a company like Nabisco would have dedicated lines for Oreo cookies because they sell so many of them, so the chances that they’re going to have problems with undeclared allergens are close to zero in the first place.”

But he said, risks can be greater with supermarket food producers because, instead of food facilities dedicated to one line of products, they often make a variety of goods. That means the risk for cross-contamination may be greater because they have to clean to remove traces of allergy causing ingredients, and that is difficult.

In addition, outside manufacturers may contract out to several different supermarket chains at a time, complicating recalls because the same product could bear the label of different companies.

That happened in 2012, with Mission Foods, which produces Mexican offerings. It made a taco dinner package with a label that did not list milk as an ingredient. The package was sold in 22 states, but under different brands. In all, about a dozen different grocery store chains needed to recall tacos under their name, including Kroger, Winn-Dixie and Food Lion.

Grocers also often mix ingredients and make their own offerings in stores. That poses risks because these are often in smaller kitchens used to make a variety of goods, and these too need to be cleaned to remove traces of ingredients that may cause allergies, a difficult process.

Whole Foods cited that as a reason for its recalls, saying in a statement, “it’s not possible to make a 100 percent guarantee that those products have not come in contact with allergens in our kitchens because they are not dedicated, allergen-free facilities.”

Taylor said there are additional difficulties facing grocers that bake goods. FDA records show those account for about 25 percent of all allergy-related recalls, the single largest line of products in allergy-related recalls.

The reason is how bakeries are cleaned. Taylor described how, generally, lots of water is used to clean equipment. But because damp conditions could lead to mold in baked goods, dry cleaning methods are used in bakeries, and these are much less effective in removing traces of allergy-causing ingredients.

### **SUBHEAD: WHEN RECALLS COME TOO LATE**

To make matters worse, government records show many recalls happen too late, often coming after suggested expiration dates. These go by different names, such as

“use by,” “sell by” or “best by” dates. The dates are often not legally binding, but used by supermarkets to know when to pull products off shelves, or suggest to consumers that the goods should be consumed in that time span.

A CUNY News Service analysis of FDA recalls shows that at least 34 out of the 160 allergy-related recalls since 2010 that included the recall was announced after products should have been pulled off shelves anyway because they were past expiration dates.

That means many products were not recalled until well after their shelf life. The result is that there is far greater potential that someone has already eaten a product that poses a potential of triggering an allergic reaction. The recall is not cutting off the time that the goods are for sale.

This analysis is based FDA and company press releases issued in conjunction with recalls. There are likely more cases where the expiration dates were not listed in a press release. Government recall data does not track expiration dates.

Among the recalls that happen too late was the one for the oatmeal raisin cookies served at the Bush house. The sell-by date for those cookies was May 4. The recall did not occur until May 6.

A reason for delays is partly because supermarkets take time conducting laboratory tests analyzing products to check whether they are tainted.

Marianna Naum, an FDA spokeswoman, said there are many reasons why recalls may take so much time. "The timing of a recall depends on when the firm finds or receives word of the problem."

Taylor said the FDA is quick to approve recalls, taking usually a day or two, but that companies may do extensive testing before seeking a recall, and that takes time.

### **SUBHEAD: THE PREVALENCE OF UNREPORTED RECALLS**

Not every product that may pose an allergy threat is recalled.

Brooklyn mom Heidi Bayer found this out the hard way. She has a teenage daughter allergic to milk, eggs, wheat, and tree nuts, among other foods. A couple of years ago, Bayer gave her daughter a store-bought treat: candy made by Vermont Nut Free Chocolates.

But after biting into the candy bar, the girl started suffering from anaphylactic shock. She sent off remaining parts of the product to a lab, where testing proved it included milk.

When she called the company, in part to seek a recall, she said the company told her she should have also checked the company's website/read the label more closely. If she had done so, Bayer would have seen that while it was listed as "dairy free," the list of ingredients noted the bar "may contain" milk. The company cited that as the reason it would not recall the product.

"We have never claimed to have completely dairy free products available and we correctly label all products that leave our facility so the consumer can make an informed decision on whether or not to consume the product," said Mark Elvidge,

founder and CEO of Vermont Nut Free Chocolates. “Many consumers who have only a mild allergy or sensitivity to dairy do well with our dark chocolate items. We do not recommend any of our dark chocolate items to those who are more severely allergic to dairy or have dietary needs to strictly avoid it.”

“All of our label statements indicate that dairy ingredients are present, may be present or could have some level of presence where warranted,” said Mark Elvidge, founder and CEO of Vermont Nut Free Chocolates. “

To Bayer, though, the “may contain” warning was a lie. “It contains milk,” she said. “You can’t say your dark chocolate doesn’t have milk in it.”

The FDA maintains that advisory statements, such as a “may contain” warning, do not necessarily provide enough support to refrain from recalling a product.

“If a product contains a major food allergen as an ingredient but doesn’t declare it on the label appropriately, the food is misbranded,” said FDA spokesperson Marianna Naum. “[The] FDA considers any advisory statements in determining the classification of the recall, but doesn’t consider the advisory statement to be a replacement for appropriate ingredient labeling or producing the product using good manufacturing practices.”

Recalls under FDA oversight happen because of a 2004 federal law that more tightly regulated how the food industry listed ingredients to help allergy sufferers.

Before the law, said Dr. Scott Sicherer of the Jaffe Food Allergy Institute at Mount Sinai Medical Center, many food companies complicated their ingredients lists by using scientific synonyms such as “casein” for milk or “albumen” for eggs. Sometimes a full ingredients list wouldn’t even be provided.

The law requires that any food product that contains a major allergen has to list this ingredient in plain English on its packaging. The major allergens are those that considered the “top eight”: peanuts, tree nuts, milk, eggs, soy, fish, shellfish, and wheat.

“I teach families how to read labels and that they need to read labels every time they are buying food,” Sicherer noted.

But not every product that may pose an allergy threat is recalled.

In suburban Boston last year, Nancy Park bought a box of chocolate-chip cookies for her two children. Her son took a bite and soon started to break out in hives. The supermarket later admitted it failed to list that the cookies it made contained tree nuts. It blamed the problem stemmed from a mixup as tried new products.

It also said that because the product did not involve goods sold at a wide number of stores, it did not seek a government-overseen recall, but instead posted notices at its supermarkets about the problem.

“The investigation at the store concluded that one package was mislabeled, the one purchased by the customer,” said Jo Natale, vice president of media relations for Wegmans. “All other packages were labeled correctly.”

In situations like these, companies can choose to initiate a recall without the FDA’s guidance, meaning some go unreported by the agency. An FDA spokesperson said that the watchdog group does not track cases in which recalls are not reported.

“If the FDA learns of a recall during an inspection of a firm that was not reported to the FDA, the FDA will evaluate the firm’s recall and corrective action during the inspection,” Naum said.

This dynamic of recall reporting is one of the many facets of the FDA’s authority that was addressed by the Food Safety Modernization Act (FSMA). Today, the FDA has mandatory recall power, meaning it can demand that a product be pulled from shelves.

The scope of a recall depends on a company’s ability to determine at what point in the production process an error occurred, which led to the undeclared allergen.

Seattle lawyer Bill Marler said he had a client whose child had an allergic to undeclared milk in an energy bar. The company, which Marler declined to name, decided against instituting a recall.

“There wasn’t a recall because they were able to figure out that there was a glitch in production and that only a really small amount of the product was ever produced,” Marler said.

When many people think of a recall, they picture something massive – but in reality, recalls vary greatly in size and scope. In fairness, sizeable recalls do occur, such as a recall of Walmart brand trail mix that affected 19 states and involved over 330,000 packages of the product. On the other end of the spectrum, recalls can be quite small. A recall by McClure’s Pies and Salads in November 2011 involved just nine coconut pies that were sold in four states.

Regardless of the size of the recall, Marler said companies should be public about problems. “Transparency is an important way of making people accountable for what they do or don’t do.”

### **SUBHEAD: THE FUTURE OF FOOD AND ALLERGIES**

The FDA relies on companies to inspect their facilities for ingredients that could trigger allergies. It looks for companies to initiate recalls when it learns about a problem. Most recalls overseen by the government are performed by companies voluntarily.

As part of that approach, the government has few inspectors checking food-processing plants. “There’s thousands of food processing facilities out there across the country. The number of FDA inspectors only working on food is a limited group of



people who police a very large industry, so you've got to rely on the industry to some degree to do a responsible job on its own," said Taylor.

Some companies have gone further than what is required by federal rules. Snack bar maker Zego Snacks, for instance, has every batch of its products tested for allergens to back its claim that its products are free of the most common ingredients that trigger allergic reactions. Every product has a QR code that can be scanned so customers can see the test results.

The FDA is considering whether to change the way it oversees foods tainted with ingredients that could trigger allergies.

One such measure is moving to eliminate labels that use the phrase "may contain." Taylor believes that phrase causes some people to become confused about whether certain ingredients really are in what they are eating. The proposal would instead require companies to test products to make certain they don't go beyond certain thresholds, such as 10 parts per million, of a given allergen. If tests show greater concentrations, then labels would have to list the ingredient.

However some advocates oppose such changes. Currently federal rules essentially call for a zero-threshold, meaning no traces of the allergen are found in a product, which is designed to protect those most susceptible to severe allergic reactions. Food Allergy Research & Education, an advocate that has pushed for regulations to help those who suffer from allergies, wrote to the FDA recently, "the very idea of thresholds ... seems contrary to the medical advice food allergic individuals and families have received from their doctors."

FARE said it would want to see scientific evidence that a lower threshold could still protect those most susceptible to reactions, and it would want requirements that companies must use clear methods to analyze products.

The FDA said researchers are working on this subject, and the agency is talking with industry and advocates about any changes.