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# Food and Drug Administration Surveillance of the Role of Foreign Objects in Foodborne Injuries

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## Synopsis .....

*As part of its effort to assure a safe food supply, the Food and Drug Administration maintains a passive surveillance system for the reporting and followup of complaints related to food items. This surveillance system, called the Complaint Reporting System, records and investigates consumer complaints about the quality of a specific food item, its packaging, or unexpected effects following consumption of the food.*

*This study, relying on data gathered from the 2,726 reports of discovery of a foreign object in a*

*food item during fiscal year 1989, develops a profile of consumer complaints, focusing on those associated with resultant injury or illness.*

*Fourteen percent of all reported cases of foreign object exposure cited resultant illness or injury. The most common foreign object reported in food is glass, and the most common injury is a laceration or abrasion of soft tissues of the perioral area, including the throat. There was a disproportionate representation of children younger than age 3 years with documented illness or injury.*

*Only 3 percent of the complaints came from attending health professionals; 82 percent were self-reported. Practitioner awareness of the system is limited primarily because literature in this area is scant.*

*The collection and investigation of reports of foreign objects in food are important because such reports provide early warnings of potential problems with manufacturers' food items. Although data suggest that severe injury from foreign object ingestion is rare, continued monitoring is warranted. Health professionals are encouraged to report such injuries through the existing system.*

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**S**URVEILLANCE SYSTEMS at various levels of government exist in the United States to monitor the impact on public health of infectious diseases, chronic diseases, injuries, and adverse drug reactions. Although interest in the area of injury epidemiology has recently increased, remarkably few reports have focused on the role of food items as a cause of injury. Those few reports of foodborne injury that have been published generally have described injury from excessively heated or sharp food items (1-3).

As a component of its effort to assure a safe food supply, the Food and Drug Administration (FDA) of the Public Health Service maintains a passive surveillance system for the reporting and followup of complaints related to food items. This surveillance system, called the Complaint Reporting System, records and investigates consumer com-

plaints about the quality of a specific food item, its packaging, or unexpected effects following consumption of the food.

## Methods

The Complaint Reporting System is a passive surveillance system that receives complaints about food items from four sources—consumers who directly contact FDA, health or legal professionals reporting on behalf of consumers, local and State health departments, and trade or manufacturing groups. FDA's 21 field offices accept reports from the United States and Puerto Rico.

After receiving a consumer complaint, an FDA field investigator collects information on the complaint by letter, by telephone, or in person. Depending on the nature and severity of the com-

plaint, the investigator may visit the home of the complainant, examine or collect the food in question, interview attending health care professionals, or contact the manufacturer of the food. Details are collected regarding both the food and the illness or injury alleged to have occurred after consumption of the food.

An injury from a foreign object in food is defined as any injury that reportedly resulted from consumption of a food item containing a foreign object. A foreign object is defined as any extraneous object or material that is not a component of or related to the food in question (for example, glass, blades, bolts, nails, plastic, stones, and so on). Not included in this analysis are reports of suspected or confirmed tampering with food products, which are coded separately from injuries associated with food containing foreign objects.

We reviewed all complaints reported to the FDA Complaint Reporting System that occurred during fiscal year 1989 (October 1, 1988–September 30, 1989) that involved an illness or injury associated with a foreign object in food. Details abstracted from each report included information about the food, foreign objects, and the injury sustained. Where possible, we also reviewed medical records for those persons who were hospitalized or consulted a health professional for their injuries. Reporting rates of injury by foodborne foreign objects were calculated by geographic region, using 1988 U.S. Census population figures as the denominator.

## Results

A total of 10,923 complaints about food items consumed in fiscal year 1989 was reported to the FDA Complaint Reporting System. The largest single category of complaints involved the presence of foreign objects in food, accounting for 2,726 (25 percent) of all complaints. Of the 2,726 persons who reported a foreign object in their food, 387 (14 percent) also reported an injury or illness resulting from eating the food. Of the 387, 123 complainants (32 percent) reported consulting a health professional for the problem; 62 (50 percent) were attended to in a private office, 53 (43 percent) were treated in an emergency room, and 8 (7 percent) were hospitalized.

**Categories of foods implicated.** All 10,923 complaints were coded for specific type of food product involved (table 1). Of those 2,726 reports of foreign objects in food, the most common food

Table 1. Complaints reported to FDA during fiscal year 1989, categorized by food industry

Industry	Distribution of 10,923 complaints <sup>1</sup>		
	Number	Percent	Rank
Fruits .....	914	8.4	1
Vegetables .....	807	7.4	2
Soft drinks.....	791	7.2	3
Bakery .....	717	6.6	4
Fishery.....	587	5.4	5
Cereal.....	496	4.5	6
Infant foods.....	470	4.3	7
Chocolate and cocoa products ...	440	4.0	8

<sup>1</sup> Data not shown for rankings higher than 8.

Table 2. Complaints of foreign objects in food, reported to FDA in fiscal year 1989 and categorized by food industry

Industry	Distribution of 2,726 reports of foreign objects <sup>1</sup>		
	Number	Percent	Rank
Bakery .....	277	10.2	1
Soft drinks.....	228	8.4	2
Vegetables .....	226	8.3	3
Infant foods.....	187	6.9	4
Fruits .....	183	6.7	5
Cereal.....	180	6.6	6
Fishery.....	145	5.3	7
Chocolate and cocoa products ...	132	4.8	8

<sup>1</sup> Data not shown for rankings higher than 8.

Table 3. Confirmed reports of illness or injury caused by foreign objects in food received in complaints to FDA during fiscal year 1989 and categorized by food industry

Industry	Distribution of foreign object complaints from 123 confirmed cases of illness or injury <sup>1</sup>		
	Number	Percent	Rank
Soft drinks.....	23	18.7	1
Infant foods.....	19	15.4	2
Bakery .....	17	13.8	3
Chocolate and cocoa products ...	8	6.5	4
Fruits .....	8	6.5	4
Cereal.....	6	4.9	6
Vegetables .....	5	4.1	7
Fishery.....	4	3.3	8

<sup>1</sup> Data not shown for rankings higher than 8.

type implicated was bakery products with 277 complaints (10.2 percent) as shown in table 2.

Products involved in complaints about foreign objects from persons with illness or injuries who visited a health care professional are listed in table 3. Soft drinks had the highest number of associated complaints (23, or 19 percent); infant food was the next most common category, with 19 complaints (15 percent).

Table 4. Foreign objects in food cited in 123 confirmed cases of illness or injury reported to FDA during fiscal year 1989

Type of object	Number
Glass	48
Slime or scum	29
Metal	19
Plastic	8
Stone or rock	6
Capsule or crystals	6
Pit or shell	4
Wood	2
Paper	1

Table 5. Frequency of illness or injury<sup>1</sup> from 123 confirmed cases reported to FDA during fiscal year 1989

Nature of illness or injury	Number
Laceration or abrasion of soft tissues of perioral area, including throat	46
Gastrointestinal distress, including nausea, vomiting, or diarrhea	44
Damage to teeth, dental restorations, or prosthetic dental appliance	18
Choking or shortness of breath	5
Headache	4
Dizziness	3
Puffy face	2
Rash	2
Fever	2
Chest pain	1
Lost voice	1
Nose bleed	1
Collapsed lung	1
Seizure	1
Pain in arm and shoulders	1

<sup>1</sup>Each person may have more than 1 reported symptom.

**Nature and severity of injury or illness.** Table 4 lists the foreign objects present in foods eaten by the 123 persons who sustained a foodborne injury and sought professional health care. The most common physical complaint within this same group was damage to the perioral area, including cuts to the palate, gingiva, buccal mucosa, lips, or throat (table 5).

In an attempt to examine the severity of the associated illnesses or injuries, those 123 people who visited a physician or dentist were categorized by extent of treatment. Seventy-one persons were examined by the attending health professional and released with no treatment (58 percent). Only palliative treatment, such as debridement of superficial abrasions or dispensing of anti-emetic medication, was administered to another 19 persons (15 percent). Twenty-five patients required minor procedures such as outpatient removal of glass pieces from the mouth or throat, or dental treatment of either the hard or soft oral tissues (20 percent).

Eight people required hospital admission (7 percent).

Of these eight persons, three were infants being observed after ingesting glass pieces, and the others were adults who were admitted for examination and observation after exposure to foreign objects. One patient remained hospitalized until ingested staples were passed, and another was admitted overnight after experiencing shortness of breath following ingestion of a sharp foreign object. A 12-year-old girl stayed in the hospital overnight because she experienced nausea and headache after she consumed gum with an unusual texture. One patient with a history of a recent cerebrovascular accident was hospitalized 24 hours for observation of reported nausea and shortness of breath after ingesting an unknown semisolid mass in orange juice. One woman remained hospitalized for 7 days after a laceration to her tongue, although the symptoms she experienced, such as nausea, fever, and seizure, were judged by her physicians to be unrelated to ingestion of the foreign object. There were no reports of deaths from foreign object injury.

**Demographic information.** We examined the reports for the distribution of age and sex of the complainants and for secular trends in reporting. Of the 117 accounts of foreign objects causing injury or illness in which the sex of the consumer could be determined, 62 complainants (53 percent) were female and 55 (47 percent) were male. Of the 123 reports of documented injury or illness, 19 of the patients were children younger than age 3 years (15 percent). A count of the number of reports of foreign objects received in each month demonstrated no apparent pattern, with increases and decreases occurring randomly (see figure).

The frequency of reporting complaints varied by district, with a range of 1.8 complaints per million people residing in Puerto Rico to 20.8 complaints per million New York State residents in fiscal year 1989. The median incidence of complaints was 9.5 complaints per million, which was found in the area containing the States of Washington, Alaska, Montana, Idaho, and Oregon. No geographic pattern was evident.

The sources of complaints were examined for the 123 persons who had an illness or injury from foreign object exposure and who visited a health professional. Of these 123, 101 (82 percent) were self-reported, 16 (13 percent) were reported by the local health agency or police, 2 (2 percent) were from a trade source, and 4 (3 percent) were

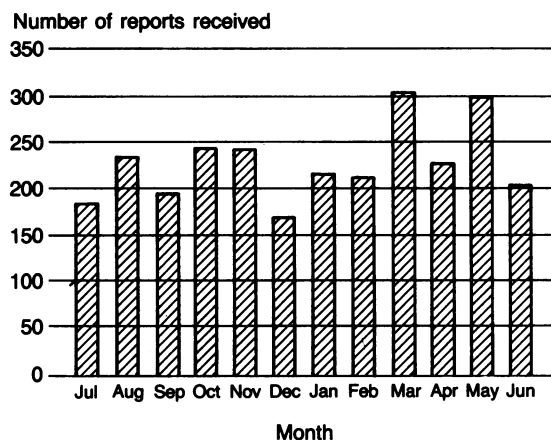
reported by health or legal professionals. Two of these four reports were generated by nurses on behalf of examining physicians, one was called in by a hospital laboratory supervisor, and one by a lawyer representing a complainant. Of the total 123 complainants who reported receiving medical care, 22 visited a dentist. No dental professionals were listed as the source of any report.

Two typical case reports of illness or injury resulting from exposure to a foreign object in food follow:

On May 4, 1989, a woman living in Arizona reported finding granular-sized pieces of glass in a chocolate-coated peanut candy bar that she purchased from a vending machine at her place of employment. She felt irritation in her throat and experienced stomach cramps 2 hours after the ingestion of the candy. She visited the emergency room of the community hospital and was examined there and released. She also stated that two other people with whom she was working discovered candy bars with what looked like glass in them; one of these candy bars was also recovered. Both candy bars were given to the police for examination, and the woman complainant requested that her attorney keep the candy bar in his possession. On May 5, 1989, the FDA investigator from the area field office visited the attorney and examined the candy. A piece of the suspect candy that contained the glass material was placed in vinegar, and the suspect material dissolved. The investigator concluded that although the candy contained hardened and potentially sharp material, it was not glass. The results were reported to the complainant and no further action was taken on the complaint.

A 20-month-old Asian girl was being fed by her mother from a glass jar containing commercially prepared strained turkey on February 14, 1989, at a friend's home in Florida. After feeding the child three-fourths of the turkey, the mother noticed large chunks of glass in the bottom of the jar. She called an ambulance and took the child to a nearby hospital. The child vomited blood on the way to the hospital and again 30 minutes later. The child was evaluated by a pediatrician and admitted to a hospital. An abdominal radiograph taken in the hospital revealed a foreign body present in the intestine. A specimen of fecal material collected on February 14, 1989, revealed an irregular fragment of glass measuring 1.1 X 0.6 X 0.3 centimeters. The following day, another radiograph of the area revealed no foreign bodies. Analysis of a stool specimen on February 15, 1989, revealed no foreign

Monthly reporting of foreign objects in food to FDA, fiscal year 1989



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bodies present. The refractive index of the glass in the stool matched the glass pieces found in the jar. However, that refractive index did not match the refractive index of the jar glass.

## Discussion

The Complaint Reporting System is the only surveillance system to our knowledge that systematically collects data on injuries linked to food. This system represents a way to detect foodborne injury, an entity not routinely detected by surveillance activities in many States. The results from our study suggest that, although the reports of foreign objects in food are common, the morbidity associated with such events is very low.

Because the system is passive in nature, it is complete only to the extent that voluntary reports enter it. The total of 2,726 foreign object complaints reported for fiscal year 1989 most likely underestimates the actual number of such occurrences. Unlike the FDA's Adverse Drug Reporting

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system, which mandates manufacturers' input and relies heavily on reports generated by health care practitioners, food complaint information is supplied almost exclusively by consumers (4). To increase the number and reliability of reports, health care providers should be made aware of the food surveillance system and encouraged to report foodborne injuries or illnesses that they treat. These may be reported to the nearest FDA District office or to Division of Emergency and Epidemiological Operations, Room 13-62, HFC-160, 5600 Fishers Lane, Rockville, MD 20857; telephone (301) 443-4667.

The breakdown of the complaint sources shows a very low rate of reporting by health professionals. A total of 123 people reported visiting a physician or dentist for examination or treatment of an illness or injury resulting from exposure to a foreign object in a food source. Two of these reports were generated by physicians and one by a hospital laboratory supervisor. None were reported by dentists.

Practitioner awareness of the system is limited primarily because literature in this area is scant. Although the most frequent site of foreign object injury in our series was the perioral region, we are not aware of any published reports elaborating a dentist's role in reporting trauma of this nature in any of the major dental journals. Likewise, a Medline search of the years 1980-90 provided only three references (1-3) to foodborne injury, two in the form of letters to a major medical journal.

Data obtained from a passive surveillance system based primarily on consumer-initiated reports are difficult to evaluate in terms of developing meaningful values for incidence, associations, and conclusions because of their intrinsic selection bias (5). The monitoring system provides FDA with a sample of consumer problems with the food supply; however, it is uncertain that this sample is representative of the actual distribution of the nature and severity of problems. This type of complaint

system tends to elicit a greater response when the perceived health consequences of the problem are more serious (6). One would expect those persons who experienced illness or injury to be more likely to initiate a report than those with no adverse outcome from the experience. Reports of illness or injury from foreign object exposure as a percentage of all reported foreign object exposures (14 percent) is, in all likelihood, an overestimate of the medical consequences of discovery of foreign objects.

The vast majority of the reports involving injury followed by a visit to a physician for children younger than age 3 years concerned reports of discovery of glass in jars of infant food products. The correspondence between consumers and manufacturers of the products in question conveys a strong desire on the part of the parents to make the manufacturers aware of the seriousness with which they view the problem. Both the severity of the injury and the difficulty in communicating with an infant or very young child often necessitate clinical examination and medical observation. The overrepresentation of this segment of the population (15 percent of reports compared with 5 percent of the U.S. population (7)) is probably due to the combination of potential seriousness of ingested glass, inability to communicate with an infant, and the highly protective parent-infant relationship.

Medical or mass media attention can stimulate reporting in a distorted manner, and this may be the case as incidents of tampering have become more serious and publicized in recent years (8). Although both unconfirmed and confirmed incidents of tampering are listed as separate categories for food complaints, a prevailing suspicion may nonetheless play a role in elevating the incidence of case reports of foreign object contamination. With increased safety sealing and other visible means to prevent food and drug tampering, food and drug safety is a concern about which consumers are constantly being reminded. Consumers may be more likely to report a foreign object, since discovery of a foreign object is perceived as a loss of product integrity that would warrant investigation.

The ranking of food industries by frequency of food complaints varies according to the type of complaints; reports from all sources, total complaints involving foreign objects, and verified reports of illness or injury from foreign objects were examined. It is interesting to note that soft drinks and infant foods occur with a low frequency in total food complaints and total foreign object complaints (4-8 percent). In foreign object com-

plaints with illness or injury followed by a medical examination, however, soft drinks (19 percent) and infant foods (15 percent) occur with significantly higher frequencies. Either the dangers of injury or illness are higher in these products than in the others reported because of some intrinsic danger, such as a high percentage of glass containers, or they are perceived as higher and therefore have a higher medical visit rate. Although fruits are the most commonly targeted food type for all complaints, they rank as fifth most common for foreign objects. This may indicate that fruits are more susceptible to other types of contamination and are not as likely to contain foreign objects as other foods. The fact that bakery items increase from the fourth most common among all complaints to the most common among foreign object complaints may reflect a tendency of baked goods to be contaminated with foreign objects in greater proportion to other types of adulteration.

These data are not adjusted for yearly per capita consumption of each food category listed. It is impossible to draw any conclusion about quality control in each food industry, since large numbers of complaints from a given industry may simply reflect the large overall consumption of that food group.

## Conclusion

The collection and investigation of reports of foreign objects in food are important because such reports provide early warnings of potential problems with manufactured food items, as rare as these events may be. During the course of many of the investigations of foreign objects, the manufacturers of the food, as well as the individual vendors involved, voluntarily initiated the removal of specific lots of the product as a precaution. As is the case with passive reporting systems, the number of reports as a percentage of the true incidence is low, compared with more active data gathering systems (8). In this investigation, one specific reason for this discrepancy is revealed by an examination of the sources of the complaints. Consumers, who are the primary source of complaints, are not solicited to submit reports concerning the quality of their food. The low percentage of reports from manufacturers reflects the lack of mandated manufacturer reporting, as was already discussed. In addition, the current investigation demonstrates the small number of reports of food-related injury or illness generated by health care providers.

Each of the 2,726 consumer complaints of for-

eign object injury or illness reported to FDA were fully investigated. Most people did not visit a health professional for the problem, and of those who did, a very small proportion required treatment other than minor outpatient care. Although data suggest that severe injury from foreign object ingestion is rare, continued monitoring is warranted. We encourage health professionals to report such injuries through the existing system.

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