

## **HYPOTHETICAL CASE STUDY 1.1: EMERGING SAFETY ISSUES CONCERNING FDA-REGULATED PRODUCTS.**

State and local public health authorities have been investigating an outbreak due to a foodborne pathogen. There are 18 illnesses primarily in one state with a few in a neighboring state. According to the human laboratory data, the same strain of pathogen caused all of the illnesses. One individual has died. The epidemiological investigation by the states found sandwiches and salads in common but no epidemiologic study is underway yet to implicate a specific food item.

### **Issues for Discussion:**

(Note: Because the purpose of the discussion is to elucidate the policy considerations that should be weighed in deciding whether changes to current practice, laws, or regulations are warranted, the issues should be discussed without regard for current practice, laws, or regulations.)

1. Should FDA communicate this outbreak to the public? If so, what should the agency say? Is there anything that should not be communicated?
2. Should knowledge of the specific pathogen causing the outbreak influence the agency's decision?
3. Should the population that may be potentially exposed to the pathogen affect whether, and when, a message should be communicated?
4. How should FDA effectively communicate to consumers as the investigation evolves and new information changes the picture?

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CDC informed FDA what the vehicle for the pathogen is. The states and FDA traced back the product to a common grower. The implicated product from the grower consists of only a portion of the market share for that product, but at this point, it is not known which specific harvesting periods or fields are implicated in the outbreak. Distribution of the product was limited to two states. One of those states issued a consumer warning advising consumers not to eat the implicated product at all. Consumers are confused about which products are implicated in the outbreak.

### **Issues for Discussion:**

(Note: Because the purpose of the discussion is to elucidate the policy considerations that should be weighed in deciding whether changes to current practice, laws, or regulations are warranted, the issues should be discussed without regard for current practice, laws, or regulations.)

1. Should FDA issue a consumer warning on the implicated product? What are the factors that should be considered in deciding whether to do so?
2. If FDA does issue such a warning, how should the agency respond to concerns that it told people not to eat some products (those not from the implicated field) that had no problems?