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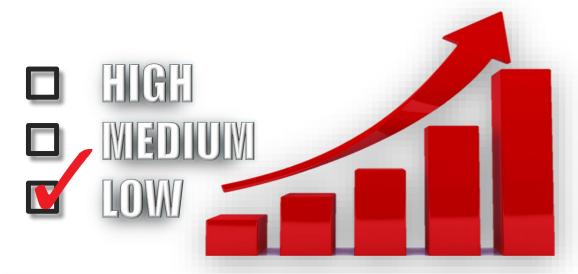
#### When the Government Comes Knocking:

How Pathogens in a Food Facility Can Lead to Criminal Charges





### WHAT IS THE RISK THAT YOUR COMPANY WILL BE INVOLVED IN A RECALL IN THE NEXT 24 MONTHS?





















#### THE THEME OF EVOLVING INDUSTRY EXPOSURE





#### THE FOOD SAFETY REVOLUTION





#### **NEW FOOD SAFETY STANDARDS**





#### MANDATORY REPORTING AND PULSENET





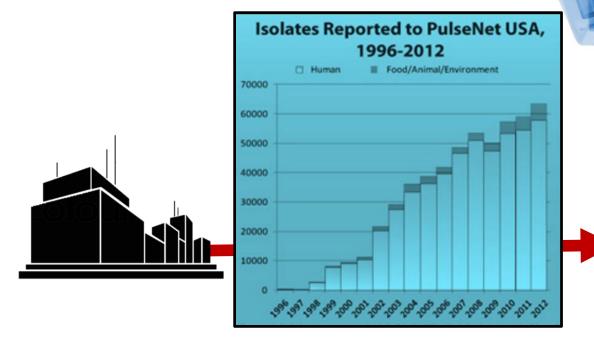
#### **REPORTABLE FOOD REGISTRY**







### >1,000,000 UNSOLVED ILLNESSES







#### THE GOVERNMENT'S RESPONSE



OVERHAUL THE SAFTEY OF THE U.S. FOOD SUPPLY



#### FOOD SAFETY MODERNIZATION ACT

**RULES AND REGULATIONS** 





### THE WAR ON PATHOGENS



In the 1990s, following a high profile foodborne illness outbreak on the West Coast, the national in the 1990s, honoring a high prome roodcorne lineac outbreak on one west coals, the national government implemented a system of mandatory reporting for healthcare providers whenever a government repairmented a system or transmitty reporting to transmitter provides with the construction of consumer was cultured parsine for a nonaparine limits, for Hearty one declares, in each or sheek each; the government has conducted testing to identify the specific genetic DNA strain of the microorganism. ting government has consistent resting to identify the agencinc general. Little Strange or sine resting general making people sick, and then uploaded the DNA signature into a national database called Puberket, While making propies six, and then uprisoned the unit-signature into a national distance concernments, retrieved this system has allowed the government to solve many high profile outbreaks over the last 20 years. tion bytem not access the government of some ranky right profits determine over the tast of years (lighting consumers sickness by a pathogen sharing a common DNA strain to a single food product), the verseng commenters screenised by a partitiogen amorning a common wireh satem to a singler total grounds, the vast majority of foodborne illnesses uploaded into the FulseNet database remain unsolved. What this view inagonity or topological summoves upplicated into the russener, parabolic technic unsource, verait tips means is that there are a large number of food companies that have been unknowingly processing and means is used there are a sarge number or neon companies shad share seem unancoming processing, distributing foods that are contaminated with pathogens and are making American consumers sick. FDA Response and Criminalization of Foodborne Illness

With the passage of the Food Safety Modernization Act (ISMA), the Food and Drug Administration From one-pressing in the Front Salety Industrial Control of the national food supply and to decrease the (TDA) was directed by Congress to overhaul the safety of the national food supply and to decrease the NUMER WITH SHOP UNIFORM TO OFFICIARE THE SHIPTY OF THE RESIDENCE OUT OF THE SHIPTY AND TO SHIPTY AND THE SHIPTY AND TO SHIPTY AND THE numerica on recuterative nationals and businesses, affect one must be aligned by resources command outsit not agency has been working to finalize new regulations requiring food companies to develop comprehensive agency riss incen working to timine enew regulations is equiving from conspanies to develop consprenensive written food safety programs. In additional to these offerts, FDA has also become increasingly aggressive written 100d safety programs. In accitional to those enterts, have not use occurring his description of the segment activities. The agency has also adopted a number of policy initiatives which reate additional and unprecedented tisk and exposure for all food companies.

Within the next five years, FDA will visit and inspect every food facility in the nation. To facilitate WRITIN THE BEXT TITLE YEARS, MAR best your and displact severy room secrety in one nations. To make these
its goal of preventing the distribution of confaminated footh, FDA's new policy is to conduct extensive as goal or prevening the distribution of contraminates roots, it is a new printy of to communications of the providing the conducting these visits, the neconstruction from the property of the contract of the contra agenty with execution instances regardless aware-execute, consecting more train a numerous sempons from event food facility and their testing those samples for pathogens such as Listeria Monocytogenes of Solinonella. No company will be immune from this sampling or scrutiny.

If the FDA finds a positive sample, FDA will immediately compare the DRA from that sample it the FLPR times a positive sampae, FLPA will immediately compare the LPRA from that sample against the Puberlet Databases. If the DNA matches a strain that made someone sick during the last 20 against the Pubernet Listabuse. If the Livin matches a satellit that make someone such owing the last av-years, the FDA will presume that the litness [or, illnesses) were caused by a product distributed from that reads, the rate was proported true, the senses for, relationed worst embouring a product unconsensed trues that facility, and may require the company to initiate a recall and likely cease operations until the facility, and may require the company to intrace a recall and takety cesse operations durative contamination is isolated and eliminated. In addition, because the company's products caused an illness, CONSERVATION TO INCUSED AND COMMUNICACE. OR ADMINISTRAÇÃO PROCESSOR ON COMPANY S PRODUCTS CARDOU AN INTESS. FOR WIll Barneth (see part of its new policy initiatives) a criminal investigation in cooperation of the U.S. Department of Austice against the company, seeking all emails, documents and records relating in any way. outpartness or anxion against the company, seeking an email, occurrents and records relating in any way to the plant operations and safety of the product. Under FDA legal standards, when a foodbornia library. THE PROPERTY OF THE PROPERTY AND ARREST OF THE PROPERTY. THE PROPERTY SHAPE STATES AND ARREST ARREST ARREST AND ARREST ARREST ARREST ARREST ARREST ARREST AND ARREST ARREST ARREST ARREST ARREST ARREST ARREST ARREST ARREST tenuts, a company energative or manager can use coarages sammany, even strongs to or ane out not solve they were selling a contaminated product. Each change carries up to a \$250,000 fine and a year in prison.



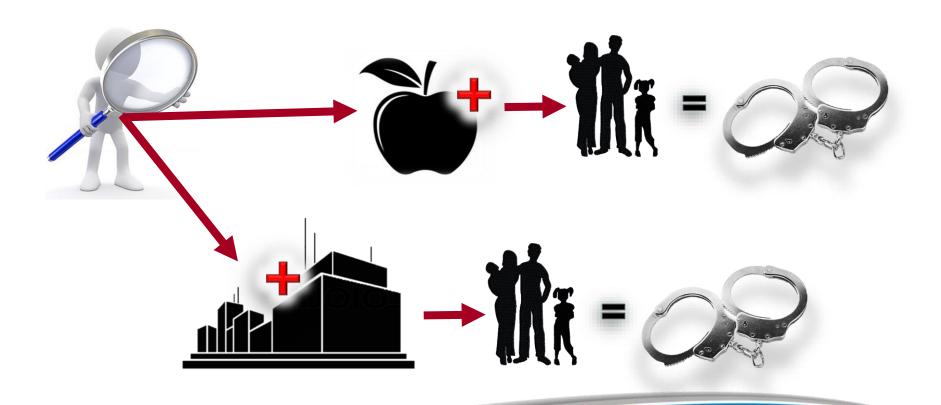
#### THE HUMAN ILLNESS STANDARD





#### THE FDA "SWAB-A-THON"







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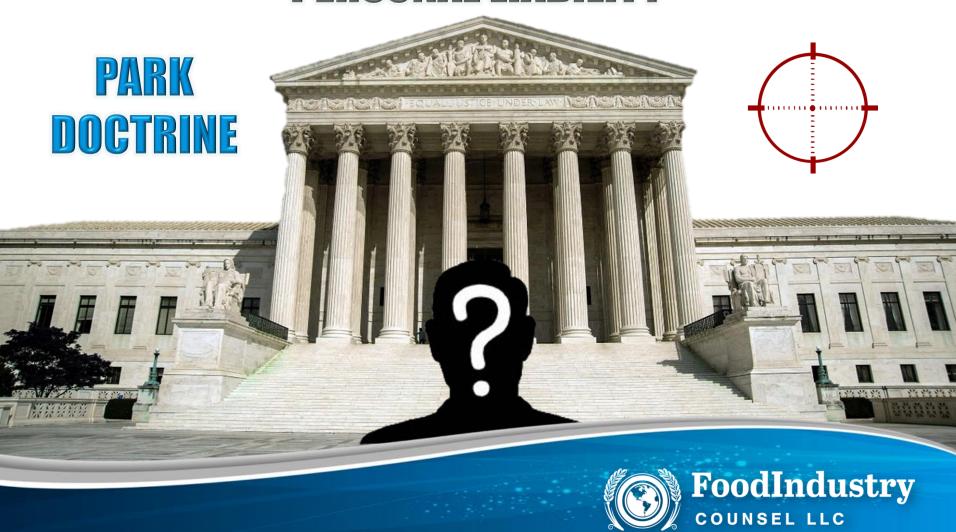












### PARK DOCTRINE

- (1) You are aware of a condition that could lead to product contamination;
  - (2) you are in a position to correct or eliminate the condition; and (3) you fail to correct or eliminate the condition.

MISDEMEANOR CHARGE



\$250,000 1 YEAR IN PRISON



#### WHAT MATTERS MOST TO FDA / DOJP





#### WHAT MATTERS MOST TO FDA / DOJP













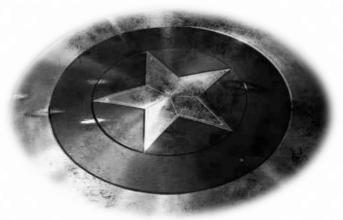








### WHAT CAN INDUSTRY DO TO PROTECT ITSELF?







# "PLAY FDA FOR A DAY" CONDUCT MICROBIOLOGICAL PROFILING OF ZONE 3 AND ZONE 4 AREAS





### **KNOW ITS SUPPLIERS**





#### KNOW ITSELF



HOW ARE YOU SAMPLING?
WHEN ARE YOU SAMPLING?
WHERE ARE YOU SAMPLING?



#### **KNOW ITSELF**



"ROOT CAUSE" V. "ROOT SOURCE"



#### REVIEW THE FDA INSPECTION CHECKLIST



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#### FDA INSPECTION CHECKLIST

What to do Before, During, and After Your Next FDA Inspection

#### INTRODUCTION

Food Industry Counsel, LLC is pleased to provide you with the most comprehensive and useful IDA Inspection Checklist available. With the passage of the Food Safety Modernization Act (FSMA), the Food and Drug Administration (FDA) was given the mission of overhauling the safety of the nation's food supply. The new FSMA regulations written by FDA are now coming into effect, and the agency is now aggressively enforcing its new rules during routine inspections. Within the coming years, FDA investigators will conduct an onsite inspection of every food facility in the U.S.<sup>1</sup>

Here are FDA's new enforcement priorities during routine unannounced inspections:

 To carefully critique each company's written food safety programs and verification records to ensure they are compliant with the new FSMA requirements;

(2) To conduct extensive Zone 1, Zone 2, Zone 3 and Zone 4 microbiological sampling inside all food facilities to find evidence of pathogenic contamination;

(3) To require recalls if the percentage of FDA samples testing positive for Listeria Monocytogenes, Salmonella or other pathogens exceeds FDA thresholds;

(4) To compare the DNA fingerprints of any pathogens found in the facility against the >1,000,000 human isolates stored in the CDC's PulseNet database to identify any matches, and then require food product recalls if any matches are found; and

(5) To initiate broader investigations, including criminal investigations, against food companies whose products are found to have caused human illness.

Against this backdrop, all companies should begin taking steps to prepare for their next FDA inspection. Companies can use the following checklists to ensure that they have completed the needed preparations before the FDA investigators arrive, to help effectively navigate the inspection process once the inspection is underway, and to appropriately respond to any FDA criticisms once the FDA inspection concludes.

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<sup>&</sup>lt;sup>1</sup> The FDA employees performing these routine onsite inspections are not referred to as "FDA Inspectors," but rather as "FDA Investigators." The concern with this terminology is that some FDA Investigators may be more inclined to find violations since their title presumes, in advance of any facility visit, that violations have already occurred.

#### SUPPLIER CONTRACTS AND RECALL INSURANCE





#### **READY TO EAT**





#### **READY TO PREPARE**



#### RECONDITIONING







#### **WORDS TO LIVE BY**

#### WHAT WOULD 12 JURORS THINK?





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