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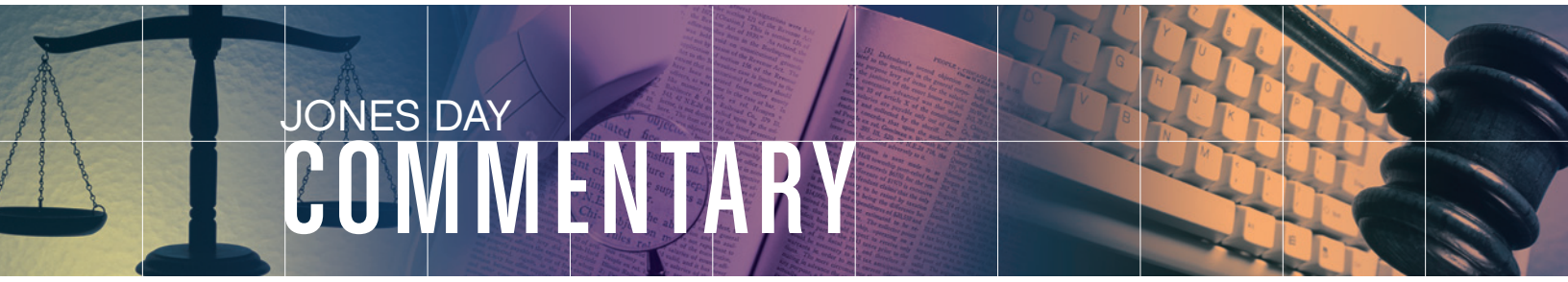

THE FDA FOOD SAFETY MODERNIZATION ACT: TACKLING THE FDA'S ABILITY TO PREVENT, DETECT, AND RESPOND TO FOODBORNE ILLNESS OUTBREAKS

After a tumultuous trip through Congress, President Obama signed the FDA Food Safety Modernization Act on January 4, 2011. The law is the first overhaul of the country's food safety legislation since the Federal Food, Drug, and Cosmetic Act was passed in 1938 and focuses on three major areas of improvement to the nation's food safety program. The first area speaks to improving the nation's ability to prevent food safety problems. The second focuses on improving the country's ability to detect and respond when foodborne illness outbreaks occur. Finally, the third area addresses strengthening the requirements for imported foods.

Through these three major areas, the Act places requirements and grants new authority to the Department of Health and Human Services and the Food and Drug Administration ("FDA"). However, the law specifically does not include food items regulated by the Department of Agriculture. Thus, the Act does not address the safety of meat, poultry, or processed eggs.

The Senate initiated and passed the Act in its current form in November 2010. The Senate-originated bill, however, violated the Constitution's "Origination Clause" because it included fee provisions. To overcome the procedural error, the House attached the Senate's version of the food safety legislation to an omnibus appropriations measure. However, the Senate refused to take up the measure, stalling the food safety legislation even longer. Determined to pass the legislation, the Senate, on December 19, 2010, avoided the Constitutional roadblock by amending a shell House bill with the language of the Senate's food safety bill and sending it back to the House. The House voted to accept the changes to the House shell bill on December 21, 2010, clearing the bill for the White House.

In regards to the first major area concerning the prevention of food hazards, the legislation sets up a hazard analysis and control program. The new program requires food facilities that manufacture, process, package, and handle food, such as factories and warehouses, to analyze and control their own hazards. These requirements would not apply to farms, restaurants, other retail food establishments, non-profit food establishments in which food is prepared for or served directly to the consumer, or fishing vessels. In response to the numerous produce-related outbreaks, the legislation also sets minimum science-based standards for the produce industry. The Department of Health and Human Services and the Department of Homeland Security are also given tools to address intentionally introduced hazards through vulnerability assessments and a National Agriculture and Food Defense Strategy.

Within the second area involving the government's ability to respond to food outbreaks, the new legislation increases the FDA's inspection capabilities by increasing the number of required inspections to be prioritized based on the risk posed. The new legislation also addresses the need for coordinated and integrated laboratory methods to better detect contaminants around the country as well as improved surveillance of contaminants nationwide by the CDC. The Secretary of the Department of Health and Human Services is also tasked with improving the ability of the government to track and trace food as it flows through the supply chain. The law includes stronger recordkeeping requirements for food facilities and a national tracing system. The new legislation provides for states, localities, and tribes to work with the federal government in a coordinated fashion to prevent and respond to outbreaks. This includes training, grant programs, and the creation of resource centers.

A large concern is that food imported into the United States does not meet the food safety standards outlined for domestic food producers. As a result, the new legislation places higher standards on importers of food as well as on foreign food facilities. Under the new legislation, importers must verify and possibly certify their foreign suppliers. The new legislation also gives the government the power to aid foreign governments in improving their food safety programs. This aid is through government-to-government support and the U.S. recognition of bodies that accredit third-party auditors of foreign food facilities.

In addition to the three major areas described above, there are a number of specific provisions in the new law that give the federal government additional powers in the protection of food safety. One potentially far-reaching new provision is the mandatory recall authority. The previous law allowed for voluntary recalls only. Under this new authority, the federal government now has the power to order a facility to stop distributing a contaminated product after it refused to voluntarily recall the product and had the opportunity for an informal hearing.

Another important new provision that will aid in the detection and prevention of foodborne illness is a strong whistleblower provision. This provision prohibits the discrimination and discharge of an employee who identifies, reports, or refuses to participate in a violation of the above regulations. The provision allows the employee to file a complaint and provides for a government investigation of that complaint.

Throughout the 234 pages of the Act, there is a consistent focus on not burdening small businesses and agricultural producers. "Very small businesses" and "small businesses," as to be defined by the Department of Health and Human Services in subsequent regulations, will be exempt from many of the new requirements. In addition, for a number of provisions, the Secretary is required to issue a small entity compliance guide to help small entities comply with the requirements of that provision. Finally, very small businesses and small businesses do not have to begin complying with a number of regulations promulgated under the new law until one year and two years, respectively, after promulgation.

Similarly, farms are given certain exemptions and flexibilities under the Act. Farms that sell more produce directly to consumers or retail food establishments than to other buyers and sell less than $500,000 annually are exempt from the minimum safety standards for produce. Some farms are also exempt from the strenuous recordkeeping requirements intended to help the government trace food as it flows through the supply chain. Food packaged and produced on a farm has only minimal recordkeeping requirements if "the

packaging of the food maintains the integrity of the product and prevents subsequent contamination or adulteration" and the labeling of the product includes complete business contact information for the farm. If a farm sells food directly to a consumer, it does not have to maintain any records. If a farm sells food directly to a grocery store, the store must "maintain records documenting the farm that was the source of the food." In this context, "sale of food" is when "food is produced on a farm" and "sale is made by the owner, operator, or agent in charge." The Secretary of the Department of Health and Human Services has the ability to revoke these exemptions if the farm or small business is involved with an outbreak.

As outlined above, the new law makes great strides toward protecting food safety with new industry-based standards and a mandatory recall authority. However, the law will come with substantial new burdens and uncertainties. The largest burden will likely be felt by mid-sized businesses. Larger food facilities probably already have some form of hazard analysis and control program in place and are already strictly monitoring the safety of the food they produce. Small businesses will likely be exempted from most of the requirements. It is the mid-sized businesses that will have to pay for the increased monitoring, recordkeeping, and inspection requirements included in the new Act. The Act is also accompanied by many general uncertainties for all food facilities and farms. The new requirements and government authorities will not really be fleshed out until the FDA issues the regulations required under the new law. Thus, producers will not know the true extent of their responsibilities and costs under the new law for months, maybe years, down the road when all the regulations are written and promulgated.

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