## PATIENT SAFETY BLOG

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## FDA Must Improve Monitoring of Food Safety

## January 11, 2012 by Patrick A. Malone

According to a report by the Department of Health and Human Services, every year 128,000 Americans are hospitalized and 3,000 die from food poisoning. The FDA is responsible for safeguarding the food supply and for inspecting food facilities. A recent study addressed concerns about the rigor of these inspections.

As reported on the FDA Law Blog, the report enumerated several "significant weaknesses" in oversight of food facilities inspected by state agencies under contract to the FDA.

They include:

- failure to ensure that the number of required inspections was completed;
- payment for incomplete inspections;
- · failure to ensure that all state inspections were properly classified and that all violations were remedied;
- failure to complete the required number of audits for one-third of the states and inconsistent follow-up on systemic problems.

Patrick A. Malone Patrick Malone & Associates, P.C. 1331 H Street N.W. Suite 902 Washington, DC 20005 pmalone@patrickmalonelaw.com www.patrickmalonelaw.com 202-742-1500 202-742-1515 (fax) The findings are important because in recent years state contractors have conducted most food facility inspections. Questions about the reliability of inspections and audits conducted by an agency other than the FDA have come from many quarters. Third-party auditors have taken the heat for several recent outbreaks of food-borne illness, such as the 2009 salmonella outbreak in a peanut processing facility.

Some such outbreaks have resulted in wrongful death lawsuits, including the listeriosis found in cantaloupes last year from which 30 people died.

As dire as the HHS report seems, the long-term effect on food safety is rosier once the FDA implements an accreditation system for third-party auditors authorized by the Food Safety Modernization Act (FSMA) enacted last year. That system focuses on imported food, but the FDA is interested in recognizing third-party certification programs generally.

As the report suggests, ultimate success is a matter of the FDA stepping up to answer the question "Who guards the guards?"

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