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FOOD & BEVERAGE

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FDA Flexes Its Muscles in Food Fights

Strategic risk and crisis management take center stage as criminalization of enforcement threatens companies and their executives

Warning: *Being a food company executive can be hazardous to your health. That's no joke. Food and beverage companies and their executives are being prosecuted like never before. The following discussion on this high-risk enforcement environment is drawn from a recent webinar, "Food Safety Crisis and Risk Management," conducted by a team from McGuireWoods and McGuireWoods Consulting. It has been edited for length and style.*

MCC: *Investigations, enforcement actions and litigation in the food and beverage sector have exploded in recent years, including criminal prosecutions. How did we get here?*

Spivey: The current trend is criminalization of what previously were handled as civil enforcement actions. Simply put, selling adulterated or misbranded food is a crime with implications to both companies and individuals. Any food that may be injurious to health is considered adulterated. That's common sense. What may not be quite as intuitive is that if a company packs or prepares food in unsanitary conditions, the food may be deemed adulterated whether or not it is contaminated. There is no requirement that the food actually cause injury or that it be contaminated, only that it be held, packed or prepared in conditions that could have caused contamination.

There is broad prosecutorial discretion in this area. Prosecutors look to product composition as well as manufacturing and shipping conditions. If a company does not comply with current Good Manufacturing Practices (cGMP), their food may be deemed adulterated. A violation is a misdemeanor if it's a first offense and there's no actual knowledge of the adulteration. A repeat offense is a felony for the company regardless of actual knowledge. It is a strict liability crime.

That's what has stunned the industry. Introduce adulterated product into the stream of commerce and it's an automatic misdemeanor regardless of whether there were bad actors or negligence. A company can exceed industry standards, implement and adhere



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—Angela M. Spivey

to all applicable cGMPs, and still be charged. If it's a repeat offense or there were bad actors, it's a felony. As we see more felony prosecutions, there will be a broad impact on the industry, including corporate structure changes to avoid felony prosecution resulting from multiple unrelated recalls occurring at distinct locations that happen to be owned by a single corporate entity.

MCC: *Individuals implicated criminally regardless of their knowledge or participation sounds chilling. What's the legal basis?*

Taylor: It's called the *Park* doctrine, which was, until recently, a little-known rule used on a limited basis to prosecute corporate officials without proof of actual knowledge of the offense. The U.S. Supreme Court first recognized the responsible corporate officer doctrine in 1943 in *U.S. v. Dotterweich*, but most people look to 1975's *U.S. v. Park*.

Mr. Park was the CEO of Acme, a national retail food chain with 36,000 employees, 874 retail outlets, and 12 warehouses. Rats and rat feces were found in two of the company's warehouses. The FDA warned Acme to clean it up. They didn't. When they found more they decided to prosecute Park even though there were no reported illnesses and no public harm. The Supreme Court ultimately held that corporate executives can be prosecuted for unintentional violations of food and drug laws by their companies. The Court said that purity of food is so important it warrants the highest standard of care, and that those exercising supervisory responsibility have a positive duty to insure that violations don't occur. It's a very broad doctrine.

After many dormant years, the *Park* doctrine has been revitalized. In 2010, a GAO report criticized lax criminal enforcement of corporate officers. The FDA then announced it would increase misdemeanor prosecutions of corporate officers. The FDA and DOJ implemented the change via their internal procedures, indicating they would consider factors such as the individual's position in the company and

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authority to correct or prevent the violation; knowledge of and actual participation in the violation; actual or potential harm to the public; a pattern of illegal behavior; failure to heed prior warnings; whether the violation is widespread; and whether it is serious.

Clearly, this is not something you're going to see any old time. There has to be a serious threat to the public.

MCC: *Didn't the Yates memo plow some of the same ground in the financial services context?*

Taylor: Yes. On September 9, 2015, Deputy Attorney General Sally Quillian Yates sent a seven-page memo to every DOJ division head and U.S. attorney prioritizing pursuit of criminal enforcement actions against individuals, particularly among the ranks of senior executives. The idea behind it was to drive compliance and accountability by making clear that DOJ is focused on actively pursuing cases against culpable individuals. It also applies leverage against companies by conditioning receipt of cooperation credit on their cooperating in the investigation of individuals. There should be absolutely no doubt in its wake that trends like increasing reliance on the *Park* doctrine and other responsible corporate officer doctrines are here to stay.

In a sense, the food and beverage industry has been a trendsetter on this issue. The FDA has, to a degree, thrown up a white flag and said it's easier to prosecute individuals after the fact than to regulate an industry proactively. If you don't police yourselves, here are the consequences.

MCC: *Although there was plenty of activity before it came along, the Food Safety Modernization Act (FSMA) of 2011 was something of a game changer for food safety. Tell us how.*

Neale: Before the FSMA you had consequences like requested recalls and seizure of product, but the drill was different. The worst that could happen was an appearance before the House Oversight Committee for an hour or two of grilling on live TV. But leading up to the FSMA, the FDA appeared at every hearing and asked for mandatory recall authority, which they got in 2011. They also got something else: All facilities holding produce or distributing food now had to register with the FDA.

That was a key development. Registration means paying a fee to fund the inspection process and essentially raising your hand and saying, "Here I am, come inspect me." And the FDA can summarily revoke registration. That means they can request the recall of a specific product, but also pull the plug on an entire facility's product – affected or unaffected— if they suspect a reasonable probability of serious adverse health consequences. This is a remarkable power that does not exist in any other industry of which I am aware.

But perhaps the biggest change didn't require a change in the law at all. That was the threat of criminal prosecution. The FDA's Office of Criminal Investigation (OCI) realized its best deterrent was a cliff. If you stepped too close, you ran the risk of falling (or being pushed) off – and absolutely nobody wanted to fall off. It became the tail that wags the dog in all outbreaks of food-borne illness. C-Suite executives are worried about insulation from potential criminal prosecution. That gives food safety professionals leverage they never had before.

MCC: *Let's talk about enforcement and the actual consequences of these trends. What can we learn from some of the specific cases?*

Spivey: We were involved for a short duration with the PCA (Peanut Corporation of America) investigation arising from a salmonella outbreak and nine deaths linked to a family-owned business in Georgia. This is perhaps the most publicized criminal prosecution in the food industry and definitely the harshest outcome. Three former executives were convicted, with the former owner found guilty of 57 felony counts and sentenced to 28 years in prison – tantamount to a life sentence for the 61-year-old. There was evidence of bad actors in the case, a congressional hearing with senators grilling PCA executives, President Obama openly criticizing the FDA, the FBI raiding the plant with guns drawn, and a 76-count indictment of four people, including a receptionist acquitted of all but one obstruction charge and still sentenced to five years in prison. These are the harshest penalties to date.

Taylor: The Jensen Farms case was lower profile but maybe even more important. It arose from a 2011 cantaloupe listeria outbreak linked to more than 30 deaths. There was no intentional wrongdoing, which makes this prosecution noteworthy. The executives were brought to their arraignment in shackles – very unusual for a misdemeanor. There had been prior problems with hygiene, but there were no specific allegations and no evidence they knew they were shipping tainted products. Facing six years in prison and \$1.5 million in fines, they pleaded guilty and were sentenced to six months' home detention, five years' probation and \$150,000 in restitution. That's not much compared to PCA, but that's serious punishment for misdemeanors with no evidence they knew what was going on or that the products were tainted.



The threat of criminal prosecution became the tail that wags the dog in all outbreaks of food-borne illness.

– James F. Neale

Neale: Then there's the Quality Egg case, another example of OCI's willingness to flex its criminal muscles. This was a salmonella outbreak involving billions of eggs and almost 2,000 confirmed illnesses but no deaths and no prior knowledge. We are squarely in misdemeanor territory, but the father and son who owned the egg empire were nonetheless sentenced to jail. It's on appeal to the Sixth Circuit, and it will be interesting to see what happens.

MCC: *If repeat offenses are felonies, why hasn't Chipotle been criminally charged?*

Neale: We know from recent public filings that Chipotle is under criminal investigation. Notably, this is an end user – a retail establishment – far down the supply chain. It's an entity that almost surely did not originate all of the problems it is having. It's true that Chipotle has had a number of problems, including

a salmonella outbreak, several E.coli outbreaks, and distinct norovirus outbreaks. What's remarkable, however, is that the U.S. Attorney initiated a grand jury investigation based on a norovirus outbreak almost assuredly brought into one restaurant by a sick employee – a virus that affected 200 people in a single California restaurant. We have never seen anything like that. It illustrates how a problem can mushroom into a federal criminal case.

MCC: *Let's talk about the crisis management aspects of these situations – how companies communicate about crises as opposed to how they respond to them.*

Hubbard: Both Chipotle and Blue Bell, the private ice cream company, have received extensive media coverage of tainted food and resulting illnesses. They've also become case studies in public relations of the right way and the wrong way to handle crisis communications.

Blue Bell has been widely praised for being quick, constant and honest in their communications. They talked about the problem, its cause and what they were doing to address it. They posted frequent updates on their website with specific actions they were taking, which is critical. The CEO released a video early on that explained the approach they were taking. They were willing to remove everything from the shelves. The communication team was tweeting constantly.

Most observers give Blue Bell credit for making it clear that they had two priorities: solve the problem and bring their customers back. They lived those priorities through the crisis. When they came back onto the shelves, they did it with positive and proactive media. They created a "Blue Bell's Back" hashtag, rolled out a new flavor each day, and hyped the fact that they were beyond the problem. We're new, we're better, we're back, and we want you with us! It was a strong effort.

Chipotle is getting credit now in the PR industry for some of their moves, but that follows some initial stumbles. Most recently, they took the unprecedented action of closing every U.S. restaurant to conduct food safety training for all employees. That was a brilliant PR move and a smart operational move. The CEO also went on NBC's Today Show and offered a sincere apology and said they would start getting things right. The problem was that he was talking as much about what they had been doing wrong as about the crisis itself. That's what happens when you get behind on communications, and it's part of what got Chipotle into so much trouble. They were harshly criticized for focusing on investors instead of customers, and for being smug about their commitment to sustainability and their "more rigorous standards for procuring and securing food." If that's the case, people asked, how did this happen? If you're going to make statements, you've got to live up to them or it will come back to bite you.

The other mistake Chipotle made was trying to explain the differences between E.coli and norovirus because they had different incidences at different restaurants. Consumers didn't want an education on health. They should have been focusing on their actions to solve the problem.

Another lesson from these cases concerns social media. It's not a megaphone; it's a conversation. Consumers, especially younger consumers, expect a personalized response. How a company responds online during moments of crisis can determine whether or not a brand bounces back.

For example, Hot Pockets did a recall, issued a press release and posted on Facebook, where readers expressed anger and fear. Hot Pockets reportedly has been sending those people cookie-cutter responses – a major mistake.

In contrast, Amy's Kitchen had a spinach recall and communicated about it on Facebook. Its representatives sent individualized responses to every single person who took the time to comment, and did the same on Twitter. That's how to use social media. You have to be all in.

MCC: *What's the relationship between strategic risk and crisis management? Or is it two ways of saying the same thing?*

Brackett: Strategic risk management and crisis management are distinct but closely related concepts. Strategic risk includes the design, implementation and modifica-

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Regulation and Litigation Test GCs

The key trends in the food and beverage industry, according to fellow corporate counsel

By Lizzy Duffy, Vice President / Acritas

Acritas' data reveals how buyers of legal services within the global food and beverage industry face unique challenges when managing the legal affairs of their businesses.

Regulation, Regulation, Regulation

One-third of senior corporate counsel in food and beverage organizations*, interviewed as part of Acritas' 2015 global Sharplegal survey, cite regulation as the key challenge facing the industry at this time.

For some, the "change in [the] regulatory positions of the government" creates challenges at home, while for other U.S. companies, it is the conflicting regulations abroad that make it difficult to do business globally, with one respondent saying, "It's hard to be a global company when you're facing different regulations of your product in different countries."

After the heavy regulatory burden, businesses are facing wider challenges.

Market Conditions Still Challenging

"Market volatility and supply availability" were a major concern for one U.S. GC we spoke with. Across the world, 24 percent of Sharplegal survey respondents told us that market conditions were the next most important major challenge facing the food and beverage industry, and along with low prices and supply and demand, they were in fact the second most mentioned set of challenges facing the U.S. and global market as a whole.

One assistant chief legal in the U.S. summed up the global market feeling by confirming that "the economy and level of consumer spending" remain their biggest challenge, adding "in the very affluent neighborhoods it is fine, but in a lot of the other middle-class neighborhoods, consumer spending is still very low."

North of the border, a Canadian GC provided more detail around the industry's anticipated market condition challenges, which included concerns about

"dealing with the variability of the price of commodities" as well as "exchange rate fluctuations." The same worries were mentioned as a main challenge facing a GC based in the U.S., who cited "global commodity pricing swings and U.S. dollar or Canadian dollar currency fluctuation."

Growing Litigation

An "increasing amount of litigation" was mentioned by more than double the proportion of senior corporate counsel working in food and beverage organizations compared with both the U.S. and global markets.

Litigation in the food and beverage sector is the third biggest challenge cited by legal departments around the world. U.S. survey respondents told us that they had general concerns about litigation on the back of the "changing regulatory landscape," as well as more specific challenges "involving claims and advertising, [and] also wage and hour type litigation."

Join the Debate

If you would like a detailed legal spend report on the food and beverage industry in the U.S. or globally (generated from data provided by your peers), then all you have to do is complete a short Sharplegal telephone interview with Acritas. Please email Deirdre Roddy at droddy@acritas.com or go to acritas.com/takepartinsharplegal2016 to register your interest to participate.

Acritas interviews over 2,300 senior corporate counsel across 50 countries every year for Sharplegal – the world's most comprehensive annual study of the global legal market.

*Based on the responses of 142 corporate counsel in organizations with revenues of \$50 million and above in the food and beverage sector who took part in Acritas' Sharplegal survey in 2015.

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tion of corporate ethics and compliance programs. This sits at the intersection of legal and business risk mitigation. It's important because the best way to prepare for and prevent crises is using risk analysis to put thoughtful compliance programs in place. If you manage strategic risk well, you will hopefully never have to engage in crisis management.

We all know what a crisis looks like from the outside. What companies often fail to consider ahead of time is what a crisis looks like from the inside. Crises tend to upset the assumptions companies, executives and employees have about what employees would or would not do in the normal course of business. They tend to be isolating and durable, and you can expect irrationality from markets, the press, customers, clients and suppliers.

In any crisis response you are going to be dealing with numerous factors and audiences, each vying for your attention and requiring urgency. Externally, you're going to engage with law enforcement and regulators, and you might even be hauled in front of Congress. You have to deal with traditional and now social media. If you're publicly traded, the investment community is going to focus intently on your response. We've talked about criminal exposure, but there's civil litigation exposure as well.

That's all common sense. What people can easily lose sight of are the internal audiences—from the board and management to the hourly worker—who can be equally as important as the external ones. It's important to figure ways to communicate to your employees in particular, to ease any anxieties, and to make them ambassadors for your brand.

People also lose sight of insurance considerations. You need to notify your carriers quickly because coverage typically does not start until they're notified.



Social media is not a megaphone; it's a conversation. Consumers expect a personalized response.

– Mark B. Hubbard

MCC: There's plenty to scare the daylight out of food and beverage companies. What about prevention? What steps can companies take to prepare for a crisis and mitigate the risks?

Brackett: Corporate communications are hugely important. Tone from the top matters to your brand and to how law enforcement and regulators are going to look at you. If you set the right tone and show good faith, you will be well positioned to tamp down law enforcement and regulatory enthusiasm for coming after you. If you're callow or dismissive, or anything other than forthcoming, you're going to throw gas on the fire.

On the front end, routine risk analysis is vitally important. Having policies, procedures and codes in place is all to the good, and you want to train your people and do contingency planning. Most people who've gone through a significant crisis will say that every plan made in advance goes out the window the moment a

crisis strikes. There's some truth to that, but contingency planning is still important. At a minimum, it will help you have a hierarchy of leadership and outside resources in place, so you know who to call in at the outset. With that in place you're ahead of the game.

We've also seen success with pre-crisis outreach. Some companies have a Darth Vader-type reputation, which is often not merited. Through outreach to local U.S. Attorney's offices and other law enforcement and regulators, you can help the government actors who would be scrutinizing the company during a crisis see that the company is part of the community and takes compliance seriously. When you can establish that kind of relationship and good faith, you position the company so that if concerns arise, rather than kicking down the door, they might call and sort it out.