Recent Developments in Food and Drug Law
Leading Lawyers on Dealing with Increased Enforcement, Keeping Up-To-Date with FDA Requirements, and Developing Compliance Practices

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Staying in Compliance with the New Food and Drug Laws in a Changing Legal Environment

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Introduction

The food and drug industry is constantly facing new challenges with the amending and implementation of new laws and the changes in enforcement of existing laws by new government administration. These challenges have become greater with the most recent economic times and the requirements for companies to expand to survive, market their products differently to distinguish products from competitors, and participate in Internet and social networking to help better communicate with consumers to market products.

All of these issues place a burden on a company to ensure it is complying with the current laws and the laws to be enforced or utilized by the various government agencies and/or plaintiff’s counsel. A company can best prepare itself for the legal actions that may ensue by being proactive in its business model approach and allowing itself to have the proper protocols in place to allow it to adjust to industry, scientific, social, and legal trends. A company that self-examines its operations and takes a lead in ensuring compliance with the law can maintain the confidence of the public and consumers and thrive in all economic times, even during an event that negatively affects the industry.

Implementation and Enforcement of Food and Drug Safety Laws

The Food and Drug Administration’s (FDA) implementation and enforcement of the Food Safety Modernization Act (FSMA) is presently a key concern for food and drug industry attorneys and their clients. It is unknown how the FSMA will be implemented and whether the FDA will have sufficient resources to enforce it, together with existing laws such as the Food, Drug, and Cosmetic Act (FDCA). A major source of uncertainty lies in the application of the FSMA to foreign suppliers of raw materials into the United States. Outbreaks of E. coli, salmonella, and other food-borne illnesses, and the commensurate public outcry, generate opportunities for an increasing amount of governmental involvement, which is followed by governmental attempts to create regulations aimed at preventing further outbreaks of such illnesses, and imposing liability on the parties responsible for such outbreaks and greater burden on the food industry.
Whether the government will criminally prosecute any of the offenders under the FSMA or FDCA remains to be seen. The original version of the FSMA included language to enhance the criminal culpability for food law violations to a felony, but in the final bill any violation of the act is classified as a misdemeanor.\(^1\) It is also unclear whether the government will prosecute individual defendants as opposed to pursuing only the corporate entities. In 1975, the US Supreme Court decided the case of *United States v. Park*, 421 U.S. 658 (U.S.Md. 1975), which affirmed the government’s ability to seek a misdemeanor conviction against corporate officials for violations of the FDCA. This form of prosecution is referred to as the “*Park* doctrine.”

Within the last year, the FDA deputy chief counsel for litigation and the Department of Justice (DOJ) have reaffirmed their intention to prosecute cases under the *Park* doctrine, and criteria for such prosecutions was released to the public in February 2011. When applying the *Park* doctrine, the government can prosecute a corporate official based solely upon his or her position of responsibility within the company. The *Park* doctrine does not require that the corporate official have any direct knowledge of the company’s violations. Rather, the prosecution needs only establish that the official was employed in a supervisory capacity to be able to implement remedies or guidelines to prevent the violations of federal law. The FDA and DOJ are making strong statements about their intent to pursue aggressive prosecution for violations of the FDCA and the FSMA. Nevertheless, even one of the worst outbreaks of food-borne illnesses in recent times, involving Peanut Corporation of America, did not result in officer or employee indictment.

The government has taken a clear position on criminal liability in the context of pharmaceutical company violations that starkly contrasts with its relative inaction on the food regulation front. The FDA has been working with the Drug Enforcement Agency (DEA) to bring many aggressive prosecutions against pharmaceutical companies and pharmacies accused of “pushing” OxyContin and other Class One and Class Two narcotics and painkillers. The FDA and DEA have brought criminal and civil forfeiture cases against pharmaceutical offenders on a nationwide scale, and the FDA and DOJ have aggressively prosecuted pharmaceutical company officers.

\(^1\) Pending legislation reinstates the felony culpability level for violating the FSMA.
Recently, an in-house counsel came under fire for alleged wrongs in responding to an FDA inquiry.²

**Recent FDA Enforcement Actions**

In several recent enforcement actions, the FDA has entered food or pharmaceutical facilities and seized raw materials or food products due to evidence of violations of the FDCA. For instance, in the course of one of its investigations within the past year, the FDA³ filed a verified complaint that revealed that US marshals seized food products based upon evidence of rat infestation. The FDA also investigated a company that had been making health claim representations relating to a juice drink product and eventually had the US Marshal’s Office seize that product as well, as a result of the product’s unapproved marketing claims. The unapproved marketing claims exposed the product to being labeled a “misbranded drug.” If a company makes a claim that its product will help, heal, or prevent an ailment, that product will then be within the purview of the FDA. Simply put, before a company makes statements claiming that its product helps cure injuries, diseases, or ailments, it needs to have authorization or approval by the FDA. The company must be able to substantiate and prove its health claims before it can market the claim on a product label.

Over the last two years, the FDA has undertaken several major enforcement actions on the basis of marketing and labeling claims concerning health benefits. For example, the manufacturer of Cheerios was investigated by the FDA for its claims that the cereal had certain health benefits, because the FDA asserted that the company’s health claims would essentially categorize Cheerios as a drug rather than a food. Similarly, Kellogg’s was advertising that eating its shredded wheat cereal would help improve children’s attention spans in school. The FDA again determined that these health benefit claims would be more appropriate for a nutritional supplement or a drug product.

In fact, a number of class actions are being brought by plaintiff’s lawyers to the effect that some food companies are making misleading claims and are

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² Prosecution failed in this case.
³ Through the US Attorney’s Office.
not complying with FDA labeling laws, as in the case of some yogurt companies that have been touting the health benefits of probiotic ingredients in their yogurt products. For example, Dannon recently agreed to a significant settlement with the Federal Trade Commission (FTC) because of certain claims on its yogurt products that the FTC and FDA deemed health benefit claims rather than simple food product advertising. The FTC concluded, without any admissions by Dannon, that the studies and research relied upon by Dannon did not substantiate the claims it was making in its advertising, and thus Dannon paid a $21 million settlement.

For companies in the food industry, labeling issues are an increasing concern. The FDA has always actively engaged drug companies in enforcement actions, but until recently its interest in food companies has been low. The FDA’s recent partnership with other federal agencies has created a more aggressive enforcement regime with respect to labeling and advertising in the food industry as well.

Budget Constraints Impacting Food and Drug Law Enforcement

At the same time the FDA and the government are threatening more prosecution, the economic downturn has affected enforcement actions in this area, as the government has not been able to provide the FDA with the type of budget the agency believes is necessary to enforce the food and drug laws. Even prior to the enactment of the FSMA, the FDA had plenty of laws at its disposal to enforce its regulations—but in many cases, effective enforcement comes down to having enough staff members to go out and inspect facilities. Due to government budget constraints, the FDA never seems to receive the funding it requests from Congress for its budget to fully enforce the laws that are on the books. The FSMA has created even more laws, which required the FDA to request additional funds to allow it to employ sufficient personnel to enforce the new laws. However, that request was denied.

Over the last few years, America’s food companies have been fighting for a smaller share of the market because people are buying less expensive food. This has led more corporate marketing departments to attempt to distinguish their products from those of their competitors, in some cases by making broad claims about a product’s greater health benefit or other
advantage. As a result, the number of potential FTC and FDA enforcement actions have increased as well.

**Technology and Social Media’s Impact on Food and Drug Law**

Social media has created new and different crisis management issues for many food and pharmaceutical companies. If, for instance, there is a food poisoning outbreak or other defect with a product, such as a foreign object in food packaging, social media and blogging sites have made it possible for the public to receive instant and constant updates on the product and personal accounts of consumer problems. Therefore, it is important for food and pharmaceutical companies to designate staff to track the company’s image on the Internet, so the company can conduct proper crisis management if necessary.

New technology has also impacted this area. For instance, new developments in nanotechnology are making it possible for food companies to add vitamins and other nutritional substances to their products to potentially increase the products’ health benefits. The FDA will have to determine whether the addition of such nutrients can truly be considered a “health benefit” or a “drug,” and if said additives are drugs, whether the food product should be regulated as a drug.

**FDA Guidance Regarding the New Food and Drug Laws**

Fortunately for food and drug lawyers and their clients, the FDA is providing advisory memorandums on many of the new laws in this area, including information about the FSMA and how the agency is going to enforce it. Timetables demonstrate when the FDA will be issuing further guidance on the FSMA and what actions it is going to define as being necessary to comply with the foreign food verification process.

Ultimately, however, the FDA tends to provide reactive rather than proactive guidance. For instance, in March 2010, the FDA commissioner first issued a number of warning letters to individual food companies based upon what she perceived as improper labeling practices, and later sent a letter to the entire food industry warning that the FDA was concerned about these labeling issues and would start issuing warnings and taking
actions based on the labeling concerns. In November 2010, the lead enforcement counsel for the FDA stated that federal prosecution in this area will be possible, and that the FDA is going to take very aggressive action in relation to any wrongful conduct, which was evident from select prosecution within the industry.

In most cases, rather than providing positive guidance or recommendations, the FDA will typically inform a specific company that it does not approve of certain actions, and through the FDA’s actions against that company the entire industry is placed on notice about a particular issue. Within the last year, the most obvious example was the reaction by the FDA to caffeinated alcohol products. Rather than providing guidance within the specific industry and working with the companies involved, the FDA issued a warning that necessitated immediate industry response without guidance from the agency.

Another example is the FDA sending numerous warning letters to food companies regarding health benefit claims on packaging. It was imperative that all food companies review all the FDA warning letters to determine what the FDA deems inappropriate. The wave of warning letters sent by the FDA for food claims required all food industry counsel to advise clients to review all labeling to ensure compliance with the then-current position of the FDA. If food companies did not review their health benefit claims after the FDA warning letters were posted on the FDA website, the FDA would view this conduct as ignoring the concerns of the FDA.

The Role of State Agencies in Enforcement Actions

The role of state agencies in food and drug industry enforcement actions largely depends upon the individual state and how active its agencies want to be. Some states have a very active agency equivalent to the FDA that supervises the food and drug companies in the state, specifically food storage facilities. The state of Minnesota’s agencies have been a leading force in the science of determining the source of many food-borne outbreaks, including outbreaks that did not begin or even occur in Minnesota. Unfortunately, there are negative examples of state agencies as well. The FDA outsourced its inspection obligations with respect to peanut products manufactured by the Peanut Corporation of America, and as a result, those inspections have tended to be a bit more relaxed than standard FDA inspections. Some of the inspections were not unbiased and
thorough, leading many experts to criticize the role of state and local agencies in the area of food inspection. Consequently, there has been a call for more third-party, unbiased reviews and involvement in this area.

Some states are also more proactive than others when it comes to food inspections. For instance, state regulatory agencies in Florida are very active with respect to protecting the state’s citrus crops, because citrus fruit is one of Florida’s primary exports. Conversely, state agencies in Florida are not as active when it comes to manufacturing inspections, because the state does not have the manpower to perform those inspections and any omissions in that area will not cause the same harm to the state’s economy.

**Proactive Responses to FDA Law Enforcement Investigations**

If a food or pharmaceutical industry client is facing an FDA investigation, there are always concerns regarding a criminal prosecution and indictment. Once an indictment is public against a particular corporate officer or director, he or she will most likely be placed on leave or lose his or her job. Often the general public will not know about a criminal investigation of a company’s officers and directors taking place behind the scenes. Also, the public typically does not understand the difference between a criminal investigation and an indictment—and typically, the public’s perception is that if the government issues an indictment, the indicted party is guilty. The negative effect of the indictment on the individual and company reputation will prevail even despite an acquittal.

Therefore, once a client knows he or she is being investigated by the FDA, he or she needs to start conducting a risk evaluation with regard to the situation (i.e., is it better to be proactive and assist the government in understanding the officer’s or director’s position and business decisions, or should the company allow the government to draw its own conclusions). If the government disagrees with the business decisions, the officer or director needs to demonstrate that the perceived wrongdoing was just bad business, and not criminal in nature. Conversely, if a client has no rational basis to either convince or argue with the government about why the officer or company chose such a business decision, it may be better to remain silent and avoid assisting the government in its case. The risk evaluation has to be performed with full
knowledge of all applicable facts and early in the investigation stage, as this evaluation will dictate the strategy and often the outcome of the investigation. In many cases, a company has to pay for the expense of an FDA investigation, in addition to any penalties ultimately imposed. For example, in February 2011, Tyson was charged with violating the Foreign Corrupt Practices Act (FCPA) for bribing Mexican officials for passing inspections. The government alleges that Tyson was able to export its chickens from Mexico more efficiently and earn higher profits, which gave the company an unfair market advantage—and therefore, it was violating the FCPA. The government obtained $4 million in the settlement. Ultimately, the cost for the company in terms of self-reporting, conducting an internal investigation, and implementing the necessary compliance program costs well more than the fine itself.

Indeed, the biggest impact an FDA investigation tends to have on a company is the cost of internal investigations to determine what type of violation actually occurred, and the costs of implementing a compliance program to prevent the situation from happening again. If the company or an employee is indicted, there are also attorney costs with respect to defending these cases, but the reputational harm and corresponding financial losses resulting from an FDA investigation and indictment are often irreparable.

**Common Enforcement Actions and Penalties for Food and Drug Law Violations**

Currently, the most commonly enforced violations with this administration pertain to labeling, branding, and marketing issues. Looking ahead, the industry is likely to see a greater emphasis on inspections ensuring safer food products and determining whether a food product has been adulterated. According to the FDCA, adulteration occurs when the final product is not what was intended or marketed to the public. Adulteration occurs when a product contains E. coli, salmonella, or foreign object contamination. If the FDA receives its requested funding, it will have the ability to conduct the inspections requested by the FSMA, implement the foreign verification process, and aggressively enforce violations of the FDCA and FSMA. At the same time, the government will continue to pursue companies for mislabeling and FCPA issues, as it did recently with
Kraft and its acquisition of Cadbury, because those cases tend to have a higher settlement value. Kraft, similar to many large food companies, has expanded its market share by acquiring other food companies. In the case of Kraft, it is under investigation for acquisition liability for alleged bribery violations by Cadbury employees in India. Thus, Kraft could ultimately be financially responsible for the alleged violations of Cadbury employees in India prior to Kraft’s acquiring the company. This new prosecution on acquisition liability demonstrates why due diligence is so important not only from a daily operational standpoint, but also when examining the operations of a company that may be purchased.

Most FDCA violators are merely subject to fines. However, there can be misdemeanor criminal components to these cases, and if an officer, director, or manufacturer is proven to have knowingly violated the law and has previous misdemeanors on their record, they can be charged with a felony. A felony charge can result in more than five years of incarceration, while a misdemeanor charge can result in one year of incarceration. In most cases, a violator’s punishment consists of some combination of house arrest—usually for six months—and then probation. With that said, a chief financial officer or supervisor could be incarcerated for allowing a financial benefit that violates the FCPA. A chief operation officer or plant manager can be jailed if it is established that he or she knew the company was producing adulterated, contaminated products. Consequently, the threat of incarceration is often used to instill fear in individuals who work in these industries to induce cooperation with FDA investigations.

At the same time, the government understands the value of fining corporations and impacting balance sheets to set an example and discourage other potential violators. Again, the cost of defending a government investigation is very high, as are the fines a company may be facing. Recall the $4 million Tyson settlement for FCPA violations and bribery, and the $21 million Dannon and FTC settlement. Both civil and criminal penalties are being utilized to prevent companies from violating the law.

**Key Compliance Challenges for Food and Drug Clients**

Pharmaceutical companies will continue to have the greatest compliance issues in the years to come, primarily because they regularly have labeling,
regulatory, patent, and FCPA issues related to manufacturing and selling drugs around the world. Fortunately, pharmaceutical companies also tend to better understand these issues, and they are able to weigh the risks and benefits of their actions because traditionally these companies have been exposed to FDA and FTC investigations for so many years.

Conversely, food companies tend to have the most difficulties with FDA compliance, particularly fast-growing companies, small “mom-and-pop” companies, and regional manufacturers that are suddenly facing compliance issues under the FSMA that they never faced in the past. For instance, a small company that receives sugar from overseas as a raw material is going to have to ensure compliance with the foreign verification process and the FSMA, and confirm that its suppliers are in compliance with the law. Unfortunately, the expense of such a compliance program may be too high for many small companies. Generally speaking, food companies are far behind pharmaceutical companies in terms of understanding how and why they need compliance programs, and they may not have the budget to do so.

**Helping Clients Develop Compliance Programs: Keeping Track of Current Issues**

When assisting a client in developing a compliance program, it is imperative to determine two things at the outset: first, what the company has experienced in the past that has caused problems, and second, what is transpiring in the client’s industry that will be the focus and strategy of a government investigation. For example, with respect to the recent food poisoning outbreak in Europe, blame was placed on both Dutch and German crops. In response, when working with a US company, it was first determined whether the company should continue to import any sprouts or other such products from Europe. The company needed to establish what types of products might cause similar problems for its production of food (i.e., either a raw material the company is utilizing in the United States, or other raw materials imported from Europe that the company imported for production in the United States). The company then developed an addendum to the client’s compliance program to set forth how it will deal proactively with the outbreak and ensure that the raw materials the client imports pass stringent industry compliance standards. If the company could not have created that
assurance, the company would have conducted additional testing on raw materials to ensure its food products are safe and unadulterated.

Consequently, general counsel for food and pharmaceutical companies need to track the industry trends and developing issues to determine how the company can avoid the same issues, and then transition the company’s compliance program to ensure it will not encounter similar problems. The company’s compliance program must also have a contingency plan for unavoidable problems.

At the same time, counsel needs to keep abreast of all new laws and regulations within the food and pharmaceutical industry. For example, clients in today’s food industry need to confirm that their foreign suppliers will be both FSMA and FCPA compliant. It is important to examine the parameters of the client’s current compliance program and adjust it to reflect the climate of the industry. This entails keeping an eye on new government investigations and/or food contamination outbreaks.

Most important, however, is the issue of actually administering and enforcing a compliance program. If a company has a document establishing a compliance program but nobody observes it, the government will not consider that to be an effective compliance program and may consider the company’s actions to be reckless, thereby enhancing its penalties and obligations to the public. On the other hand, if a company has a compliance program in place and is doing everything it can to uphold the program, then even if something falls through the cracks, it is likely to be viewed as a negligence issue or unavoidable occurrence.

Overseeing Compliance and Utilizing Outside Resources

Every company within the food or pharmaceutical industry should have someone within its general counsel’s office who handles compliance and works within both the legal and operational framework. That individual cannot be an “ivory tower” lawyer who simply tells everyone what they should do. Rather, he or she has to be someone who understands what is necessary in implementing a compliance program from a legal standpoint, and must be able to interact and work with the company’s plant managers,
chief operating officer, and regional managers to administer the compliance program and effectively implement the program. He or she has to be someone who can work with people and say, in effect, “This is what we have to do and how we can do it.” He or she also has to help the company understand that compliance is necessary and not just a worthless document in a file cabinet. As stated above, in most cases, having a compliance program that is ignored is worse than having no compliance program at all.

Therefore, a good compliance counselor can educate management on why they need to do certain things, and work with the people on the floor, including the plant managers, in terms of implementing the program. They must also listen to the plant managers when they say, “We cannot comply with this rule, but we can do it in another manner,” and if there is a better way, the counselor should modify the compliance plan accordingly.

The resources an attorney can use in this effort may include his or her own knowledge, any resources from his or her own experience, and reviews of past investigations by the FDA, the FTC, the US Department of Agriculture (USDA), and local agencies. This will allow counsel to determine what those government agencies are actually enforcing and in what manner. These resources should be used as guidelines in properly developing a compliance plan.

In addition, it is imperative to work with good lawyers and law firms that are familiar with these issues and understand the business world. It is easy to find a lawyer who can give legal advice, but it is imperative to consult with a lawyer who understands the operations of a business and how the law applies to that business. No administrative rule or statute applies to all businesses equally. Each business has to adapt or work with the law. That is why it is important to work with lawyers who truly understand how a particular business operates, why it operates, and the best manner for that business to comply with the law based upon its business operations.

Accordingly, there should be a good relationship between a company’s general counsel and outside counsel, and that outside counsel needs to understand the company’s business, the issues it faces, and how to position the client to avoid any violations and adopt the best compliance practices.
Internal Audits of Compliance Practices

Similarly, it goes without saying that clients must conduct random auditing of their products as they are prepared for distribution and randomly audit the supply chain and protocol the company has in place. This allows the company to make certain its products are safe and secure for public consumption. Likewise, random audits should be conducted with respect to labeling and marketing practices, and ensuring the company’s compliance programs for the FDCA, FSMA, and FCPA are current and effectively implemented. The marketing and legal departments are likely to battle back and forth. The legal department will want everything to be perfect in this area, while marketing will want as much latitude as possible. Therefore, it is important to have someone who can review the end product after those two parties have resolved their differences and give an unbiased opinion. In fact, a company can avoid costs and fines in the long run if it hires outside counsel to examine the plant and its marketing materials, and provide an opinion as to the compliance status of the company. This compliance strategy leads to better decisions about the safety practices, labeling, and marketing the company is using.

Future Developments in Food and Drug Law Enforcement and Compliance

With respect to future developments in food and drug law enforcement, much depends, as previously noted, on whether the FDA has enough funding for enforcement. Most likely, the industry will face more FTC involvement in this area. At the present time, there are increasing numbers of enforcement actions consuming the resources of the US attorney’s offices, particularly involving the new laws protecting whistleblowers. The US attorneys are handling these enforcement actions in addition to the normal civil and criminal case docket. Therefore, when the FDA or FTC approaches a US attorney and says, “We need to educate you on food and drug law,” it is most likely because the office does not have the staffing or resources for additional enforcement.

If the DOJ discovers that a local food company is violating the FCPA, and the DOJ believes it can likely recover $10 million in fines and penalties, the
local US attorney’s office will most likely agree to moving the prosecution forward. Local offices have budgets and other fiscal responsibilities to consider. On the other hand, if the DOJ tells the US attorney’s office, “We have a case involving misdemeanor violations for adulterated food, and we need one of your prosecutors to take that case,” the scenario is not likely to pique the local US attorney’s interest. Ultimately, if the government wants the food and pharmaceutical industries to take enforcement seriously, it will need to supply the funding to support that enforcement, similar to recent developments in the health care industry.

The Importance of Obtaining Outside Advice

It is always best for pharmaceutical companies to have outside legal advice. Many senior and general counsel jobs depend upon maximizing litigation results, ensuring the company is in compliance, and/or walking the company line. Some general counsel are in a position where they can be forward and advise management that the company should change corporate conduct despite the bottom line, because in the long run it will be best for the company. The best examples of this currently are having a proper FCPA compliance program implemented and conducting constant review of marketing language and campaigns prior to public release. Unfortunately, in many cases, general and senior counsel are part of the corporate culture or do not yet command the respect to convince the board of directors or management that it is better to be proactive than reactive to industry issues and new regulations and laws.

When working with outside consulting firms, auditors, and/or counsel who can give unbiased advice and opinions on compliance and litigation strategies, the general or senior counsel can use this advice to support his or her statements to the board or management. Of course, there may be cases where outside counsel will tell the general counsel what general counsel wants to hear to obtain more work from the company. That is why it is important to have access to outside consultants and counsel with a truly unbiased, third-party opinion. Therefore, it is a good idea for companies in the food and pharmaceutical industries to retain a firm with which they do not have a continuing relationship. Not only does such a resource enable a general counsel to review the weaknesses in the
company or compliance program, but it also provides a defense in litigation or an investigation. The company can utilize this outside advice to its benefit by explaining that it relied upon an outside, unbiased opinion of counsel in making a difficult business decision.

Three Key Pointers for Food and Drug Law Attorneys

To succeed in this practice area, a food and drug law attorney should be aware that there is a lot of scientific knowledge involved in this field. In fact, when starting out as an attorney in the food industry, counsel may not realize the importance of the detailed scientific aspects of the practice. As one progresses in his or her representation of companies, he or she will quickly learn that a working knowledge of the science of food, insects, illnesses, and all of the scientific components of bacteria, such as E. coli and salmonella, are imperative in defending a food-borne illness, foreign object, or defective device case. Having such knowledge allows counsel to interact with experts in the field, properly cross-examine the opposition’s experts, or evaluate the skill, knowledge, and suitability of potential experts. Counsel may never have the same level of knowledge as the expert or even the client, but it is necessary to have an in-depth knowledge and understanding of the science in this area.

Secondly, it is important to listen to the client in terms of what they believe is the best compliance strategy, and always be honest with the client if as counsel you do not agree. Always saying “yes” to the client is not in its best interest, and if you are not careful, the client may eventually come back and say, “You told me it was good to do this, and I did it, and now I am in trouble.” Therefore, it is best for counsel to be honest with the client, even if the client does not want to hear the negative opinion.

Finally, if as counsel one encounters an issue he or she does not understand, one must consult with someone who does. It is always troubling to be retained to defend a government investigation case and realize the company utilized inappropriate counsel lacking the requisite knowledge to competently defend the case. In these situations, more time is spent correcting previous errors and bad advice than correcting the legal issue or working on the government investigation. Therefore, if counsel is
working in an area that is not in his or her area of expertise, consult someone else who has this knowledge or team up for the specific matter. Simply stated, it is important to understand that there are segments of expertise within every industry, and counsel should always defer to those lawyers who possess the specifics within the legal field and the industry.

**Conclusion**

The food and drug industry is ever evolving, and it is imperative for professionals within the industry to maintain the most current knowledge of trends and industry standards. This not only includes the legal aspect of the industry, but the scientific and now the social aspects as well. The current industry trends must be evaluated carefully before a company concludes that it wishes to follow the trends. Some social media trends are beneficial, while other aspects can expose the company to greater liability. With all of the changes within the industry, it is essential that a company have good corporate governance, which necessitates proper quality assurance, ethical business practices, a compliance program that not only promotes these theories but actually implements them, and then strong general counsel to ensure its application.

Every company wants to strive to be perfect, but this goal is very high and, with so many outside factors playing a role, it is rarely obtainable. Thus, for companies within the food and drug industry, which now interact internationally, it is best for a company to be proactive and have the proper response protocols in place so, if and when an outbreak or faulty product becomes an issue or a company learns of improper behavior of a foreign agent, the company can react timely rather than having to establish the proper response and then react. With the unknown application and enforcement of the FDA and the FDCA and FSMA, it is necessary to be reviewing industry actions and reactions by the FDA, FTC, and DOJ so the company can do its best to ensure compliance within the law.

**Key Takeaways**

- Developing an FDA compliance program for a client requires discovering two things: first, what they have done in the past that has not worked or caused problems, and second, what is
transpiring in the client’s industry. A general counsel for a food or pharmaceutical company needs to follow the problems that have been occurring in the client’s industry, determine how the client company deals with such issues, and then transition the client’s compliance programs to make sure they will not face such problems in the future.

• Understanding what is necessary for implementing a compliance program from a legal standpoint is important, but you must also be able to interact and work with the company’s plant managers, the chief operating officer, and the regional managers to make sure the client’s compliance program is actually being implemented and is working effectively.

• Having scientific knowledge makes you more effective when cross-examining experts or determining whether your experts are the best experts for litigation. You will never have the same level of knowledge as your expert or client, but it is valuable to have some knowledge and understanding of the science in this area.

• Listen to the client in terms of what they believe is the best compliance strategy, and always be honest with the client if you do not agree. Always saying “yes” to the client is not in their best interest. Also, if you run into an issue you do not understand, consult with an expert who does.

Related Resources


Staying in Compliance with the New Food and Drug Laws…

GuidanceDocuments/FoodDefenseandEmergencyResponse/ucm 078978.htm

- **Guidance for Industry and Rules**, FDA (September 1, 2011), www.fda.gov/Food/FoodSafety/FSMA/ucm253380.htm
- **Seven Salmonella cases in Minnesota linked to multistate egg recall**, MINNESOTA DEPARTMENT OF HEALTH (August 16, 2010), www.health.state.mn.us/news/pressrel/2010/salmonella081610.htm
- **SEC investigating Kraft for corruption in India**, REUTERS (March 5, 2011), www.reuters.com/article/2011/03/05/us-kraft-investigation-idUSTRE7241JQ20110305

Brian E. Dickerson is a partner with Roetzel & Andress. He focuses his practice on the areas of complex litigation and regulatory matters, defending clients against government actions, administrative proceedings, and parallel civil proceedings. He litigates complex fraud cases, including bank, mortgage, securities, procurement, and health care fraud, as well as Foreign Corrupt Practices Act matters in all state and federal courts. He regularly conducts internal investigations for clients to ensure compliance with federal and state laws.

Mr. Dickerson’s defense practice involves the representation of clients throughout the United States in civil, regulatory, and criminal matters related to government procurement, compliance, and litigation. His representation has involved officers and directors, physicians, hospitals, financial institutions, household good companies, food companies, as well as Fortune 500 companies in matters related to or initiated by the Food and Drug Administration, the Department of Justice, federal governmental agencies, state regulatory agencies, and private and class action plaintiffs in federal and state courts. He has defended clients in such matters in Florida, Ohio, Illinois, the District of Columbia, New York, Illinois, Tennessee, Colorado, Georgia, Texas, Arizona, California, Nevada, Utah, Indiana, and Virginia.

Mr. Dickerson’s Food and Drug Administration representation also involves the representation of international, national, and local food manufacturers, farmers, suppliers,
and distribution companies, national and local restaurants, and international consumer goods manufacturers and suppliers, throughout the United States. This representation focuses on design and manufacturer product defects, recalls, foodborne illness outbreaks, and governmental agency investigations into the manufacturing and distribution process.
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