Note from the Chair by Suzan Onel

I am pleased to announce the second issue of the ABA’s Food, Cosmetic, and Nutraceutical (“FCN”) newsletter. In this, our Winter 2014 issue, we lead off with a history of the origins of FSMA from Bill Marler, one of the founders of the food safety bar. Our second article is written by Vince Leone, a New York food industry insurance broker with decades of experience in guiding food industry clients in navigating complex insurance issues. Vince has set out a primer for food lawyers to use in reviewing contamination/recall coverage in the FSMA era. Our third article is Andrew Ittleman’s nuanced discussion of the complex relationship between the FDA and the FTC in the area of food labeling and food advertising compliance. The FCN Newsletter is intended to provide our members with perspectives and expert guidance from recognized and accomplished legal practitioners and from other professionals who serve our clients in the increasingly globalized food industry. We hope that over time our compilations will provide members with a library of sophisticated articles that expand and enhance their understanding of these complex and vital areas of regulation and compliance.

**Featured Guest Author**

**FSMA: The End of My 20-Year Law Practice? Let’s Hope So!**

by Bill Marler, Esq.

Bill Marler of Seattle’s Marler Clark law firm needs no introduction in the food law community. His FoodSafetyNews.com is required morning reading for lawyers, food scientists, and other industry professionals. His history, as seen from the trenches, is valuable background for an understanding of how the Food Safety Modernization Act (FSMA) happened. Mr. Marler’s comments on FSMA making food liability litigation extinct are, of course, tongue-in-cheek. Advances in genomic science now make pinpointing the etiology of foodborne illness increasingly precise. At the same time the extensive documentation, all discoverable, required by FSMA will create opportunities for technically-trained tort lawyers to hone their discovery skills. We expect to hear a good deal more from Bill Marler in the years to come. ~Charles Woodhouse

T’was the Friday before Christmas and all through the House – and Senate…

Perhaps an out of context fairytale is not how you expect me to start a discussion about the Food Safety Modernization Act (FSMA), or “Fizz Ma” to some. However, FSMA is a modern political tale that almost did not come true in the late days of 2010 in the nearly empty hallways and offices of congressional leadership. But, first I must digress.

Until January 1993 I had never given much thought to safe food. I assumed, like most Americans still do, that our food supply is, as our politicians always remind us, “the safest in the world.” Yet, standing in the ICU watching a young Jack in the Box outbreak victim struggle against a deadly toxin produced by
**Insurance Coverage & the Food Safety Modernization Act (FSMA)**

by Vincent Keane

Vincent Keane is a second generation commercial insurance broker who operates Capitol Risk Concepts, Ltd., A company started by his father 38 years ago. Capitol Risk Concepts is an insurance brokerage, known internationally as a food industry specialist, having shaped a number of proprietary insurance programs for food industry segments and clients. Vincent and Capitol Risk Concepts' staff strive to be on the cutting edge of the food industry, be it regulation, transportation, insurance, or technology. To learn more about Vincent or Capitol Risk Concepts visit [www.crclimited.com](http://www.crclimited.com)

As an insurance broker, specializing in the food industry, I can say, generally speaking, that the average food company has an insufficient understanding of how their business risks tie into their insurance portfolio. This situation is made all the more complex when food companies enter into sales contracts, containing enormous legal burdens, insured or not insured, with grocery store chains, wholesale buyers, etc. On top of these problems are the myriad of regulatory requirements, FSMA being the most recent, creating additional uncertainty for a food business.

Everyone wants to know whether there is insurance coverage to address the Food Safety Modernization Act (FSMA) requirements and, if so, which insurance policies will respond. In the market, today, there are a number of insurance policies that can respond to FSMA risks. When a contamination event occurs, there are several policies that a business should have in place to respond to such an event. They are the Comprehensive General Liability (CGL) policy, the Contamination/Recall policy and the Kidnap & Ransom policy.

*Cont’d as FSMA on p. 5.*

**Need for Regulatory Harmonization: How FDA & FTC’s Shared Jurisdiction Poses Problems for Labeling & Advertising Compliance**

by Andrew S. Ittleman, Esq. & Jessika A. Tuazon, Esq.

Andrew S. Ittleman, Esq. is a founding Partner of Fuerst, Ittleman, David, & Joseph, PL in Miami, Florida. He focuses his practice primarily in the areas of government regulation and litigation against government entities. He has represented companies in compliance issues related to the FTC, FDA, USDA, and CBP.

Jessika A. Tuazon, Esq. is an associate with the food, drug, and life sciences group at Fuerst, Ittleman, David, & Joseph, PL and focuses her practice on regulatory compliance related to FDA, FTC, USDA, and state agencies. She represents clients involved in, among others, the food, supplement, cosmetic, device, and drug industries.

The federal Food, Drug, and Cosmetics Act¹ (“FDCA”) authorizes the U.S. Food and Drug Administration (“FDA”) to regulate all foods, drugs, medical devices, and dietary supplements that enter into interstate commerce in the United States. The FDA’s regulatory responsibilities have expanded significantly over the past decade as a result of mounting legislative requirements, such as those set forth in the Food Safety Modernization Act² (“FSMA”) and the Food and Drug Administration Safety and Innovation Act³ (“FDASIA”). In addition to expanding the FDA’s jurisdiction, these laws have put pressure on the regulated industry to become increasingly familiar with the FDCA and the regulations promulgated by the FDA.

Unfortunately for industry, the laws and regulatory hurdles for bringing products to market do not begin and end with the FDA and FDCA. In addition to labeling regulations, products must comply with all laws regarding advertising and promotion. For the last 65 years, the FDA and U.S. Federal Trade Commission (“FTC”) have shared joint responsibility to regulate all

*Cont’d as FDA/FTC on p. 8.*
E. coli O157:H7, it was impossible to see food, certainly not hamburger, as safe.

In 1993 and through the congressional elections a few years later, a flurry of food safety ideas came from politicians until those ideas were crushed in the argument against trying to ensure that all Americans had health insurance and the elections that swept “The Contract with America” into office. Although the Jack in the Box E. coli outbreak, with nearly 700 ill and four children dead, outraged a nation and nearly brought the beef industry to its knees, without more ill and dead over a sustained period of time, memories faded and ideas for broad, substantive food safety changes were shelved.

The 1990s were not a complete food safety disaster, however. One act, thought at the time heretical, managed to slip through, but it certainly did so with much notice. In 1994, Mike Taylor, then head of USDA’s Food Safety Inspection Services (FSIS), stood before the seemingly all-powerful American Meat Institute (AMI) and announced in clear and simple language that ground beef could no longer be sold with the type of E. coli in it that caused the Jack in the Box catastrophe. The AMI, and others, sued FSIS to stop E. coli O157:H7 from becoming an adulterant.

Thanks to good lawyering, a wise court and the beef industry turning a loss into a win, however, our hamburger is safer today that at any time in the last two decades. In the 1990s, E. coli cases linked to ground beef accounted for most of my law firm’s revenue; today that is nearly zero. When my firm makes less money because there are fewer kids with kidney failure linked to hamburgers, that is a good thing.

But, as “hamburger disease” cases slowly died out, foodborne outbreaks were being linked to nearly everything else in the refrigerator and pantry – apple juice, lettuce, spinach, sprouts, peanut butter and cookie dough – sickening thousands and making headlines – and lawsuits. Some of the tainted products were mistakes in mass production, others locally grown, organic fare. As imports increased, so did food poisoning issues. We’ve seen outbreaks from hepatitis A in berries imported from South America to Listeria in fancy cheese imported from Italy. By 2006 it seemed that there was a foodborne illness outbreak a week, and with a different political wind blowing through the capital, food safety ideas once shelved were dusted off, and were being discussed once again.

By now, I had been in the food safety world for well over a decade and had taken much from the food industry on behalf of customers. I had money, and I made use of it to secure access to the offices of politicians to discuss “why it is a bad idea to have poisoned voters.” I also spent time speaking to the food industry around the world, asking it to “put me out of business.” It is funny how donations of money and the ending of my career were topics both groups enjoyed.

It was late 2006 and I was in Washington, D.C. for the – I cannot recall how many times. I had spent the morning shepherding clients to hearings to explain the devastation of being poisoned by food. I had a few moments to meet some Senate staffers on the ideas they had shelved over a decade ago, but felt now was the time to modernize food safety legislation for the first time in over 50 years. As I was escorted out a back door, I began the walk down a very long Senate office hallway. As I moved along towards the elevator at the far end, I nearly bumped into the somewhat new senator from Illinois as he and a staffer headed quickly to the same elevator. As we all walked in silence and waited for the same elevator, the youngish senator, who I had met a few years earlier at a fundraiser in Seattle, looked over at me. Perhaps he recognized me but most likely he did not. I smiled and introduced myself.

Over the next few years I gathered frequent flyer miles on the straight shot from Seattle to D.C.
Again, sometimes attending hearings with clients, sometimes meeting with congress members and senators, and even once testifying. I watched as the shelved food safety ideas of the 1990s came alive in committee rooms. By the summer of 2009, what was the House version of FSMA was passed overwhelmingly with both bipartisan support. Industry and consumers came together to work all sides of the aisles. FSMA headed to the Senate, where senators had already been working on a similar version of the groundbreaking legislation. And, then it stalled.

By now the fight over what to do about the near economic collapse of 2008, and the anger generated by the introduction and passage of the Affordable Care Act (a.k.a “Obamacare”) had left the Senate unable to agree on much of anything. In fact, that was true for most of D.C. Both the House version and the Senate version were going nowhere, as was any other meaningful legislation for that matter.

What little movement that was occurring in the Senate on food safety now centered on how to unwind many provisions so as to not potentially impact smaller and more local agriculture with those “damn food safety regulations.” Those actually concerned with being against “one size fits all” legislation merged with proponents of raw milk and other “any government is bad” groups to form what I described as the “Teat Party” as they tried to convince us that the “government was going to take over our backyard gardens.”

The 2010 midterms changed the political dynamic, swinging the House to another party. Although the Senate stayed the same, no significant legislation – let alone FSMA - moved. Finally, as fall moved to winter, the Senate passed its version of FSMA. A problem, however, was that what the Senate passed was supposedly constitutionally incorrect. The Senate-passed version had a clause inserted that required a charge for a re-inspection in certain circumstances. The House, which by the Constitution can set “taxes,” viewed this charge as a tax and “blue slipped” the Senate’s version, sending it back to the other side of Capitol Hill.

Over the next months, as senators eyed the exit door that is Christmas, FSMA competed with the “Dream Act,” “Don’t Ask, Don’t Tell” and other worthwhile legislative initiatives. I recall one trip to D.C. on a crowded elevator with young Hispanic merit scholars and muscle service members, thinking to myself that FSMA now was competing for the last weeks of 2010 with smart kids about to be deported and gay service members who fight for our freedom. I pushed myself to the back of the elevator.

By the Friday before Christmas I had spent the week urging senators from both parties to move FSMA back to the House before the recess. In the early afternoon of that Friday, I was sitting in the office of one senator, listening to a long description of what was either lactose intolerance or an aversion to gluten, when I was summoned to a meeting of top Senate staffers. As I was ushered into a meeting room, the Majority Leader’s office alarms went off – apparently a guy with a gun had tried to enter the Capitol. The door was promptly locked from the inside and we were all ordered to stay. After a few awkward moments when we all likely contemplated rather being somewhere else, we started talking about food safety.

The staffers all pointed to the lack of time left to move anything out of the Senate and back to the House for a vote and the logistical issues surrounding FSMA’s constitutional flaw. I left discouraged and took a late flight out of Dulles.

Ironically, as I pen this piece, I am sitting in the same chair where I received an email the following morning from one of the Senate staffers, telling me they had figured out how to get the Senate version of FSMA back to the House for a vote before Christmas. This time, when the bill passed the House it did so by a small majority (nearly 75 members had already left D.C. for vacation).
That “youngish senator” I had walked the hall with a few years previously signed the bill shortly thereafter. I have a signed copy of the bill on my wall.

Will FSMA end my law practice? Honestly, it is too early to tell. Most of the rules are still being written, being commented on or being implemented. Needed additional funding for food inspections has not been appropriated.

Many of you reading this article will be at the forefront of what FSMA will actually look like in practice. For those of you that have the baton of implementation, as you do your jobs remember that the kids I have represented in the last 20 years are much like the kids you go home to at night.

Yes, it is time to end my practice.

FSMA cont’d from p. 2.

The traditional Comprehensive General Liability (CGL) policy responds to both bodily injury and property damage arising from the incident. In recent years, the CGL has been heavily tested in the courts over the intent and extent of coverage provided by the property damage feature and the intent and meaning of the various policy exclusions. The conclusion from the court decisions appears to be that coverage depends on which legal jurisdiction you are in—no obvious clarity there. In our opinion, all the recent legal testing over the CGL coverage took place because the policyholder did not have a properly arranged insurance portfolio (e.g., Contamination/Recall policy) and they tried to “create” coverage after the fact.

The Contamination/Recall policy has become the coverage cornerstone, addressing the majority of risks, resulting from a contamination event. Unfortunately, these policies are not standardized. Coverage triggers, definitions, exclusions, warranties, and endorsements vary greatly and their intent is paramount in determining coverage adequacy.

An often overlooked insurance policy in a malicious contamination event is a Kidnap & Ransom policy which provides broader extortion coverage than the product extortion coverage found in the typical contamination/recall policy.

Now that the three basic policies have been identified, let’s look at how FSMA impacts them. In fact, in our opinion, FSMA has only materially changed one of the relevant insurance policies, Contamination/Recall. The FSMA feature that changed the Contamination/Recall policy was the “Mandatory Recall Authority” (MRA) provision under § 423 of FSMA. The important language to focus on is “a reasonable probability that an article of food…is adulterated under § 402 or misbranded under § 403(w) and the use of or exposure to such article will cause serious adverse health consequences or death to humans or animals.” It is also interesting to note that the Reportable Food Registry (RFR) under § 417 is also linked to the MRA and can play a role in a contamination event.

With the advent of the MRA, some insurers examined their coverage form and determined that their form did not cover an event caused by the MRA, unless the coverage trigger wording was enhanced. That is, before the MRA, only “actual” (provable by testing or other evidence) contamination events were covered.

For insurance purposes, the MRA created a new class of event, the “alleged” contamination, requiring only “a reasonable probability” of the existence of a contaminant in the goods. For example,
FDA could take an “environmental sample” from a process machine, find a contaminant, and declare that it is reasonably probable that the product that was processed through it became contaminated and, therefore, there is a reasonable probability that the finished product in the warehouse, resulting from the production run, is contaminated and must be destroyed. The response by some insurers was to alter the basic form or issue an endorsement, including what they call “Government Recall.” Not all the “Government Recall” coverage is the same and great care must be exercised in parsing the words to ensure a proper coverage response.

Before getting into more coverage details, it is important to understand a few things that should happen before analyzing insurance coverage. A lot of trouble, time, and expense can be saved by going through the following elements of the risk management process.

**Risk Identification**

In our estimation, there is a minimum of eighteen (18) basic loss costs that can arise out of a contamination event, regardless of whether there was an “actual” or “alleged” event, typically involving the CGL and the Contamination/Recall policies. Prospective policyholders seldom undergo a risk identification process. As a result, there is a lot of misconception and misunderstanding about what is covered by insurance, especially a Contamination/Recall policy. This condition is exacerbated by a minimal attention to or understanding of the risks assumed by them under a customer’s purchase and sale contract. These contracts create a substantial number of risks, some of which can be insured. Others are not. Seldom do prospective policyholders seek legal advice about these risks and, therefore, they constantly “bet the farm” to make the sale and do not know whether they are insured or not. This area is largely untapped by the legal profession.

The perils created for the policyholder through the transfer and/or assumption of risk through vendor contracts cannot be overstated here. These contracts are extremely one sided to the benefit of the buyer and, in most cases, the policyholder enters into a contract that can destroy their company (insurance coverage or not) with a single recall event.

**Risk Analysis & Quantification**

In performing the risk analysis and quantification, the two most important questions to be answered are, “Who gets the call in the chain of responsibility after having supplied the purported contaminated product?” and “Who pays for all the costs of a contamination event?”

In addition, a product seller not only needs to examine their own products and business operations but also the business operations and product quality of any supplier of ingredients, being introduced into the product sellers’ final end product (see Caudill Seed & Warehouse Co. v. Houston CAS Civil Action No. 3:10-CV-299-JHM, 835 F. Supp.2d 329 (2011)).

It is also important to consider that the business process does not necessarily follow the regulatory process and the RFR is a good case in point. Getting the regulatory and business processes sorted out plays a major role in analyzing and quantifying all the risks in a contamination event.

**Risk Transfer to an Insurer**

Once the risk analysis and quantification have been accomplished, two more things are important:

a) Know which risks are being transferred to an insurer for a premium
b) Know which risks have been retained or self-insured

For this exercise, we will focus on the accidental contamination risks transferred to an insurer.
Contamination/Recall Insurance

The Contamination/Recall policy is a unique coverage, incorporating quasi-legal liability provisions along with first party property and time element coverage. There are three basic coverage categories, Accidental Contamination, Malicious Product Tampering, and Product Extortion. When evaluating Accidental Contamination, attention must be paid to the coverage definitions and triggers for which there is no standardization.

Generally, there are several triggers that must be met for coverage to take effect. That is, an event, such as an accidental contamination, must, first, meet the policy definition and, second, bodily injury or property damage must ensue. For example, the defined event must take place and the second trigger, “consumption or use of the Named Insured's Contaminated Product(s)… has either resulted, or would result in…bodily injury and/or physical damage…” must also operate. Again, there is no standardization and the defined events vary as does the verbiage surrounding the results of consumption or use.

Assuming that both triggers have been met, one can look to coverage and limits to determine what will be paid and to whom. The majority of those loss costs (excluding bodily injury and property damage covered by the CGL policy) can be paid by the various coverage provisions, which will be described below. It should be noted that coverage provisions vary by insurer and some provisions may have to be added by endorsement.

**Direct Product Damage:** Coverage for the policyholder’s contaminated product, either in the warehouse or in the field, which is usually the largest loss cost in an event. Some policies may only cover product in the field. Coverage is often incorporated into “Recall Expenses” in a policy.

**Recall Expenses:** They are usually defined in the policy and some policies limit coverage. Typically, they represent the smaller loss costs in an event.

**Publicity:** Coverage is not always in the basic policy. When it is, care must be taken to understand its limitations. Perhaps, the most important feature of this coverage is that it can result from “an actual or alleged contamination, where the Named Insured's Product(s) and the Named Insured must be specifically named.”

**Lost Gross Profit/Extra Expense:** These are the most overlooked of all the coverage and can be the largest loss cost. If the policyholder loses an account, due to the event, this pays for a year or more of LGP. For many food businesses, a large account could represent from 10% to 50% of total revenue. Extra Expense can come into play when it is important to have another processor assume the processing role and costs exceed the normal costs of the policyholder.

**Rehabilitation Expenses:** This coverage pays for brand rehabilitation in the market. It is important to some but, for the most part, it just barely makes the radar of the typical policyholder.

**Crisis Response/ Consultant Expenses:** Coverage for these expenses can be very important and largely address the costs involving specialist attorneys and public relations/crisis response specialists.

**Customer Recall Costs:** While this coverage is available in the policy, it seldom comes into play, since nearly all the recall costs are borne by the company responsible for the contaminated product.
Customer Lost Gross Profit: This is similar to LGP above, except it applies to a customer. It can be a substantial loss cost under certain circumstances. Cases of where payments have been made under this coverage have been rare.

Application: This is a vital piece of the coverage puzzle. In some cases, it is part of the policy and/or only the products identified within it are covered—both limitations.

Conclusion

This is a limited treatise on a very technical, varying and evolving type of coverage. In summary, yes, insurance products do exist that respond to the new FSMA regulations but none of them do so completely. In order to ensure that recall/contamination coverage (including FSMA) is effective, the risk management process must take place, including a thorough analysis of all customer purchase and sale contracts (an income stream we have found largely underutilized by attorneys).

Nevertheless, without risk analysis and management taking place, effective coverage will always be gamble…even if the “appropriate” insurance policy is in place.

FDA/FTC cont’d from p. 2.

information disseminated to consumers about foods, drugs, medical devices, and dietary supplements. Under this arrangement, the FDA and FTC have agreed to work collaboratively to further the “common objective of preventing injury and deception of the consumer.”

Even though the FDA and FTC have a collaborative relationship, their powers are not derived from the same source. The FDA is authorized to promulgate and enforce regulations for product labeling under the FDCA, and the FTC is empowered to regulate marketing and advertising pursuant to the Federal Trade Commission Act (“FTC Act”). “Labeling” is defined in the FDCA as “all labels and other written, printed, or graphic matter (1) upon any article or any of its container or wrappers, or (2) accompanying such article.” The FTC has interpreted “advertising” as all promotional materials for a product, including websites, print advertisements, commercials, and other similar media.

Importantly, neither the FDA nor the FTC has formally adopted the other agency’s definitions or standards. Thus, despite their agreement to work together, the two agencies may rely on separate laws, definitions, and policies when carrying out their respective duties. The FDA and FTC’s reliance on separate statutes in regulating the same products has created difficulties for industry. For many members of industry, this regulatory landscape can be confusing because the agencies have not provided any clear guidance as to how either agency applies specific policies and standards of the other, nor how the two Acts can be reconciled in practice.

How Shared Jurisdiction Has Changed How the FDA and FTC Regulate Products

Over the last decade, Congress has pushed the FDA and FTC to take their collaborative efforts even further. For example, Congress has required the FDA and FTC to form “working groups” to facilitate the sharing of marketing information between agencies. This increased interagency cooperation has led to noticeable changes in the way the FDA and FTC approach enforcement actions. For instance, the FDA and FTC now use one another’s standards and policies to support findings of violative behavior. Likewise, the FDA has issued Warning Letters requiring alleged violators to respond to the FTC regarding the promotion of unapproved products.
For example, on February 1, 2011, the FDA issued a Warning Letter to Tennessee Scientific, Inc., a dietary supplement manufacturer, alleging that certain claims on the company’s website constituted unauthorized disease claims. According to the FDA, the use of such claims on dietary supplement products rendered them unapproved drugs. In addition to challenging the product’s labeling, the FDA’s Warning Letter cited Tennessee Scientific for violating the FTC’s advertising standards:

In addition, it is unlawful under the FTC Act, 15 U.S.C. § 41 et seq., to advertise that a product can prevent, treat, or cure human disease unless you possess competent and reliable scientific evidence, including, when appropriate, well-controlled human clinical studies, substantiating the claims are true at the time they are made. […] More generally, to make or exaggerate such claims, whether directly or indirectly, through the use of a product name, website name, metatags, or other means, without rigorous scientific evidence sufficient to substantiate the claims, violates the FTC Act.

Based on its findings, the FDA requested Tennessee Scientific to provide the FTC with a response regarding any possible violations of the FTC Act.

Similarly, the FTC has incorporated FDA standards into its enforcement of false or misleading advertising. For example, the FTC has required alleged violators to, as a condition of settlement, obtain FDA approval prior to continuing to advertise and market a particular product. In 2011, the FTC entered into a settlement agreement with Chemical Free Solutions LLC and Dave Glassel (collectively “Cedarcide Defendants”) regarding allegedly false and unsubstantiated claims about a product’s ability to kill or repel bed bugs. As a condition of the settlement, the FTC required the Cedarcide Defendants to obtain FDA approval of a new drug application or demonstrate compliance with an existing over-the-counter (“OTC”) drug monograph prior to marketing or selling the product in the United States.

These examples demonstrate how the FDA and FTC have coordinated their enforcement efforts when regulating companies whose products appear to violate labeling and advertising rules. While this collaboration can be effective, in other instances this shared jurisdiction has proven to create more confusion than clarity for industry. In some cases, the collaborative relationship between the FDA and FTC has actually blurred the jurisdictional lines between the two agencies. As a result, industry now has the difficult task of trying to accurately identify where one agency’s jurisdiction ends and the other agency’s jurisdiction begins. This task becomes exceptionally difficult when one agency fails to acknowledge the other’s regulatory categories, as discussed more fully in the example below. Because it is unclear which standards apply in these situations, industry is often forced to make educated guesses about product labeling and advertising.

**Example: The FDA and FTC’s Overlapping Jurisdiction Creates Confusion for Medical Food Manufacturers**

Unfortunately for some, such as members of the medical foods industry, understanding how to comply with both FDA and FTC standards may prove to be a difficult task. A “medical food” is a “food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation.” This lesser-known subcategory of foods has grown into a multi-billion dollar industry that is gaining in popularity worldwide.
The FDA has promulgated regulations and policies governing the regulation of medical foods. Medical foods have different labeling requirements than dietary supplements and ordinary foods, and are exempted from the nutrient content claims under the Nutrition Labeling and Education Act of 1990. The FDA has not provided industry with clear guidance on the scientific standard required to substantiate claims for product labeling. However, the FDA explained in a Federal Register notice that the level of scientific evidence required to support medical food claims “clearly” falls “somewhere between” drugs and conventional foods. Therefore, “medical foods are foods as defined in the [FDCA] and are subject to the general food safety and labeling requirements of the [FDCA],” but do not have to undergo premarket review or approval by FDA and individual medical food products do not have to be registered with FDA.

The FTC, on the other hand, has stayed silent in its acknowledgement of medical foods. Despite having jurisdictional authority to regulate the advertising of medical foods, the FTC has not explicitly adopted or recognized the FDA’s standard or definition. Similarly, the FTC has issued guidance documents regarding advertising for drugs, dietary supplements and foods, but has never provided the medical food industry with any information on how to advertise medical foods in compliance with the FTC Act.

Recently, the FTC reiterated that it is not required to accept the FDA’s standards or policies when pursuing enforcement action. Instead, the FTC maintains that it is unencumbered from applying the FTC Act as a one-size-fits-all standard for all products. The FTC based its position upon *Bristol-Myers Co. v. FTC*, wherein the Second Circuit held that “the FTC’s action should proceed unencumbered by inferences about what the FDA would (or would not) do if it pursued similar action.” The U.S. District Court for the Northern District of California supported the FTC’s position, explaining that whether or not a product is recognized as a medical food by the FDA has no bearing on the FTC’s ability to determine when a product’s advertising violates the FTC Act because “the degree of regulation [the products] would be subjected to by the FDA simply is not relevant.”

The FTC’s apparent lack of recognition of medical foods as a statutorily defined category of products poses a major hurdle for industry members seeking to bring their products into compliance with both the FDCA and FTC Act. Because the FTC does not appear to acknowledge or recognize Congress’s definition of medical foods or the FDA’s policies regarding the substantiation required for medical food claims, it remains possible for the FTC to challenge a medical food’s FDA-compliant labeling and advertising as violating the FTC Act. Under this blurry regulatory regime, medical food manufacturers face significant business and financial risks. In order to manage these potential liabilities, the medical food industry should take great caution when making decisions regarding the marketing and promotion of their products.

**What Does This Mean? How Can Industry Comply with FDA and FTC Requirements?**

The FDA and FTC’s collaboration has introduced uncertainty into the regulatory framework for labeling and advertising of foods, drugs, medical devices, and dietary supplements. As demonstrated in the FDA’s Warning Letter to Tennessee Scientific and the FTC’s consent agreement with the Cedarcide Defendants, the FDA and FTC appear to work together when doing so suits both agencies’ objectives. However, because the agencies are not bound to accept the other’s definitions and standards, either agency can focus exclusively on its own statute while
conveniently ignoring those belonging to others. This sort of inconsistency creates confusing and, at times, conflicting regulatory philosophies. Consequently, industry has difficulty understanding which standards apply and how to conform their products according.

In order for industry to gain a better understanding of how to operate within this regulatory framework, we submit that the FDA and FTC should provide some clarity regarding the use of definitions, standards, and policies across the two agencies. Until the FDA and FTC clarify how the FDA’s labeling regulations and FTC’s advertising regulations can be harmonized, if at all, members of industry should strive to develop marketing strategies that would survive heightened agency scrutiny. In order to do so, companies should study all applicable FDA and FTC regulations and informal policies. By becoming familiar with the FDA and FTC’s shared jurisdiction, members of industry will be better equipped to anticipate the regulatory risks associated with marketing foods, drugs, medical devices, dietary supplements, medical foods, and cosmetics.

Furthermore, members of industry should exercise caution when developing product claims or proposed advertising statements, especially those appearing on easily searchable websites or other related social media. As discussed above, the FDA and FTC have shown no signs of slowing down their cooperative efforts to take action against companies that violate the FDCA and FTC Act. Accordingly, members of industry should also be prepared to defend against any FDA or FTC enforcement actions, and should keep in mind the potential consequences of defending against such challenges.

**FDA/FTC Footnotes:**
5. Id.
7. Food, Drug and Cosmetic Act (FDCA) sections 201(k) and (m) (21 U.S.C. 321(k) and (m)).
9. 2009 Omnibus Appropriations Act, Pub. L. 111–8 (2009). Furthermore, the FTC Bureau of Consumer Protection Director David Vladeck stated that it is a goal to “enhance the enforcement efforts of both agencies.” Consequently, industry should expect “increase[d] [interagency] coordination with respect to strategic planning and case selection.” FTC Bureau Director David Vladeck, Remarks at Council for Responsible Nutrition, Annual Symposium for the Dietary Supplement Industry (Oct. 22, 2009).
11. FTC, Marketers of Unproven Bed Bug and Head Lice Treatments Settle FTC Charges.
12. FTC Cases and Proceedings, Springtech 77376, LLC, also doing business as Cedarcide.com, et al.
20. See Bristol-Myers Co. v. F.T.C., 738 F.2d 554, 559 (2d Cir. 1984)(holding that FDA regulations were not relevant in case brought under FTC Act because “[n]ot only is a different regulatory scheme involved, but generally speaking the FDA is concerned only with evaluating absolute safety and efficacy, and not with the questions of comparative safety and efficacy that arise in OTC drug advertising”); see also Thompson Med. Co. v. FTC, 791 F.2d 189 (D.C. Cir. 1986).
Publish Your Paper in the FCN Committee Newsletter!

We, the editors of the FCN Committee Newsletter, would like to invite all Committee members to contribute a piece for the upcoming Spring and Summer editions of the Newsletter. Below are some ideas for topics but please feel free to submit papers based on cases and topics that are currently of interest to you in the areas of food, cosmetics, and nutraceuticals.

- FDA regulation of cosmetics moving into 2014 and beyond. What are the regulatory trends and what issues will affect industry in the upcoming year and beyond as FDA takes a greater interest in cosmetic manufacturing practices and imported goods?
- Food, cosmetic, and nutraceuticals advertising. Given some interesting decisions and legal activity in the area of advertising this year, how should clients be advised when crafting advertising for their products?
- The role of third-party auditors in a comprehensive food safety plan and a cost-benefit analysis as well as the relation to insurance and liability issues.
- The relationship between the Article 9 Security Interests of lenders to food companies and FDA’s mandatory recall and administrative detention authority under the FSMA. What are the concerns of counsel for lenders during a serious (Class I or Class II) recall?
- FDA Draft Guidance for Industry: Frequently Asked Questions About Medical Foods; Second Edition. What does this recently issued guidance document mean for the medical food industry?
- A discussion of FDA’s February proposal, Draft Approach for Designating High-Risk Foods (Sec. 204 of FSMA).

We anticipate that the Spring issue of the Newsletter will be published in June, 2014 and we request that articles be submitted before then. Articles should be approximately 1,500-2,000 words. If you are interested in contributing please email us: Kelly Lightfoot at KLightfoot@fuerstlaw.com and Charley Woodhouse at cfw@regulatory-food-science.com.

Visit the Section of Science & Technology Law: Food, Cosmetics and Nutraceuticals Website!

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View our FCN Digests, including current news and events in the areas of food, cosmetics, and nutraceuticals.
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Food, Cosmetics, and Nutraceuticals Website
http://apps.americanbar.org/dch/committee.cfm?com=ST103010
About the Editors

**Charles F. Woodhouse** is an Attorney and Partner, in the law firm of Woodhouse Shanahan PA. Charles is admitted to the Bars of Pennsylvania, Florida, and the District of Columbia. Charles earned his BA at Dartmouth, MBA at Wharton (University of Pennsylvania), JD at Rutgers, and his Graduate Certificate in International Food Law & Regulation and MS Food Safety at Michigan State. His MS Food Safety thesis at MSU received MSU's 2011 Mather Food Safety Award.

He is Adjunct Professor of Law at MSU College of Law and will be teaching Regulation of US Food Imports for the 2014 Fall Semester in the LLM, MJ, and MS Food Law and Food Sciences programs. His business career includes being a founding shareholder of Marine Harvest International (salmon, shrimp, and other fin-fish aquaculture) and service as its president during its years as a publicly traded company on the American Stock Exchange. Since 1999, Charles has devoted his full time to his law practice which specializes in regulatory matters affecting the seafood and produce industries which together account for nearly 50% of all Food Safety incidents in the USA and the EU. His Food Law Blog may be found at www.food-label-compliance.com and his law firm’s website is www.seafood-and-produce-law.com and he can be contacted by email at cfw@regulatory-food-science.com.

Charles divides his year between Scanno (Aquila) Italy, Atlanta, Georgia, and Cedar Key, Florida. His law practice includes European Union Food Industry Regulatory Compliance with a particular focus on EU Food Labeling Regulation.

**Kelly L. Lightfoot** is an attorney with the Food, Drug, and Life Sciences Practice Group at Fuerst, Ittleman, David, & Joseph, PL in Miami, Florida. Kelly focuses her practice in the areas of food and drug law, assisting clients with regulatory and legal compliance issues involving the U.S. Food and Drug Administration (FDA), the Federal Trade Commission (FTC), and other federal, state and local authorities. Kelly is originally from Columbus, Ohio and earned her bachelor's degree in English from The Ohio State University and received her JD from Cleveland-Marshall College of Law.

Kelly has extensive experience representing clients in various federally regulated industries, including the medical device, food, dietary supplement, cosmetic, veterinary products, over-the-counter drug, and human cells, tissues, and cellular and tissue-based products (HCT/Ps) industries. She has assisted clients with product development, formulation, manufacture, importation and exportation, distribution, and marketing.

Kelly has authored and co-authored articles in various publications on the topics of dietary supplements, conventional foods, veterinary drugs, and medical device regulation. She advises clients on food, supplement, and cosmetic labels and labeling, advertising, social media, formulation, and manufacturing in compliance with FDA and FTC regulations and policies. Kelly can be reached by email at klightfoot@fuerstlaw.com.