Shook, Hardy & Bacon L.L.P.

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FOOD & BEVERAGE LITIGATION UPDATE

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LEGISLATION, REGULATIONS AND STANDARDS

FTC Conducts Workshop on Competition and Safety in Pet Meds Industry

The U.S. Federal Trade Commission (FTC) conducted a day-long workshop, October 2, 2012, "to examine competition and consumer protection issues in the pet medications industry." Currently pending before the House Subcommittee on Health, a bill (H.R. 1406) introduced in April 2011 by Representative Jim Matheson (D-Utah) would require FTC to issue rules mandating pet medication prescription portability, which could fundamentally change the way such products are sold in the United States. FTC seeks stakeholder input on issues that would affect a $7-billion-a-year industry and has extended the public comment period to November 1.

An early step in FTC's investigation, the workshop provided a forum for widely divergent views as veterinary professional advocates and representatives of the animal health industry addressed current practices limiting the distribution of pet medications and the potential impact of a change that would allow consumers to purchase the drugs from a full range of providers and retailers. According to veterinary representatives, (i) retaining the status quo ensures drug safety and efficacy, (ii) pet medication pricing is currently competitive, and (iii) prescription portability is already required under veterinary ethical rules and some state laws. They claimed that the proposed legislation was nothing more than "a solution in search of a problem."

Counsel for generic drug manufacturers asserted, to the contrary, that portable prescriptions were essential to the development of more competitive pricing. Online pharmacy representatives claimed that their primary concern involves an inability to acquire pet medications from the manufacturers and their consequent shortages, as opposed to lack of prescription portability. Compounding pharmacists agreed with that assessment, noting that an inability to obtain drugs from manufacturers limited their ability to compound drugs not otherwise available in the marketplace. Major retailers asserted that restricting distribution to veterinarians raises consumers' costs, creates a potential conflict of interest for the prescribing veterinarian and impairs convenience for "one-stop-shoppers" unable to purchase pet medications from retail pharmacies.

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The American Society for the Prevention of Cruelty to Animals took the view that prescription portability would reduce costs to consumers, thereby increasing animal health and encouraging pet adoption from shelters.

With much of the evidence cited in support of the workshop participants' positions anecdotal or speculative, FTC also turned to evidence from the contact lens industry, which has operated under similar prescription portability legislation since 2003. This evidence was also unavailing given acknowledgement from panelists about a lack of adequate empirical evidence whether contact lens portability resulted in increased safety risks to consumers or lower prices.

The public comment period provides an important vehicle for stakeholders to ensure that FTC is evaluating full and reliable evidence on these issues. The Commission has posted on its **Website** the hundreds of comments already received and will place workshop submissions and PowerPoints® there to help stakeholders identify specific points to address. Agency officials indicated that the comments could inform FTC's report on the matter and will be used by lawmakers and regulators as they develop further regulatory, legislative or enforcement responses. This report was prepared by Shook, Hardy & Bacon Attorney Scott DuPree who attended the hearing. Please contact him at **sdupree@shb.com**, or 816-474-6440, for further information or questions. *See FTC News Release*, September 19, 2012.

FTC Revises "Green Guides" for Environmental Marketing Claims

The Federal Trade Commission (FTC) has **revised** its Green Guides to "help marketers avoid making misleading environmental claims." According to FTC, the revisions reflect "hundreds of consumer and industry comments" and include changes to existing Guides "as well as new sections on the use of carbon offsets, 'green' certifications and seals, and renewable energy and renewable materials claims."

In particular, the updated guidance advises against "broad, unqualified claims that a product is 'environmentally friendly' or 'eco-friendly'" because such claims are "nearly impossible to substantiate." FTC has also warned marketers about the use of unqualified degradable claims for solid waste products and items destined for landfills, incinerators or recycling facilities, and clarified its guidelines for compostable, ozone, recyclable, recycled content, and source reduction claims. In addition, the Green Guides now offer new sections covering issues not anticipated in previous editions, such as (i) certifications and seals of approval, (ii) carbon offsets, (iii) "free-of" claims, (iv) "non-toxic" claims, (v) "made with renewable energy" claims, and (vi) "made with renewable materials" claims.

The Commission has noted, however, that the revised Green Guides do not address the terms "sustainable," "natural" or "organic," partly to avoid contra-

vening directives from other agencies. "The introduction of environmentally friendly products into the marketplace is a win for consumers who want to purchase greener products and producers who want to sell them," said FTC Chair Jon Leibowitz in an October 1, 2012, press release. "But this win-win can only occur if marketers' claims are truthful and substantiated. The FTC's changes to the Green Guides will level the playing field for honest business people and it is one reason why we had such broad support."

FDA Food Facilities Registration System Is Unavailable

While foreign and domestic food facilities, including farms, must renew their registrations with the Food and Drug Administration (FDA) beginning October 1, 2012, under the Food Safety Modernization Act, the agency is not accepting registration renewals at this time. Facilities required to be registered under the law are asked to check FDA's **Website** to learn when the system becomes available.

EU Publishes List of Authorized Flavorings for Food Use

The European Commission has **published** its list of flavoring substances authorized for use in foods. Effective October 22, 2012, Regulation EU 872/2012 provides a roster of more than 2,500 substances evaluated by the European Food Safety Authority (EFSA) and deemed safe for human food uses, while Regulation EU 873/2012 establishes transitional measures for other flavorings, such as those made from non-food sources, that are still under review. Flavoring substances not found on the list "will be banned after an 18-months phasing-out period."

To prepare the new regulations, EFSA's Scientific Panel on Food Contact Materials, Enzymes, Flavorings and Processing Aids (the CEF Panel) initially considered approximately 2,800 substances already on the EU market as well as 197 additions. Although the majority of substances reportedly did not present safety concerns, the CEF Panel recommended removing seven substances from commerce and asked for further data on 400 others. Industry can submit data on these pending applications before the deadlines established in the new list, which will apply as of April 22, 2013, and undergo annual updates.

"The Panel is extremely satisfied that this long-term program of work is now coming to fruition," CEF Panel Chair Iona Pratt said in an October 1, 2012, press release. "However, our job is not completely done yet. Besides the remaining substances for which data are required, EFSA also expects to receive a number of applications related to new flavorings, many of which are likely to be complex mixtures that may require a revised risk assessment approach."

EC Confirms That REACH Provides Best Framework for Nanomaterial Risk Management

The European Commission (EC) has concluded, in its second regulatory review on nanomaterials, that, while certain challenges continue to face those trying to assess their potential risks, the Registration, Evaluation, Authorisation and Restriction of Chemical Substances (REACH) "sets the best possible framework for the risk management of nanomaterials when they occur as substances or mixtures." Still, the EC acknowledges that "more specific requirements for nanomaterials within the framework have proven necessary," and thus it "envisages modification in some of the REACH Annexes and encourages ECHA [European Chemicals Agency] to further develop guidance for registrations after 2013."

REACH took effect in June 2007. Viewed as the strictest law regulating chemical substances to date, it requires all chemicals imported or produced in the European Union (EU) over a certain quantity to be registered and the manufacturers and importers to gather and report information about the chemicals' properties. The law's provisions will be phased in over 11 years.

The EC review reports that 11 million tonnes of nanomaterials, with a market value of about EUR 20 billion, are on the market globally. It further estimates that 300,000 to 400,000 EU jobs are directly linked to nanotechnology. According to the EC, "limited data exist on manufactured nanoparticles in the workplace and the environment" and "[d]etecting nanomaterials in complex matrices such as cosmetics, food, waste, soil, water or sludge is even more challenging." Yet, the EC continues to maintain that "the risk assessment paradigm used for the evaluation of standard food products is also appropriate for nanomaterial applications in the food and feed chain." It justifies applying REACH requirements to nanomaterials given their flexibility, stating "[m]any substances exist in different forms (solids, suspensions, powders, nanomaterials, etc.). Under REACH, different forms can be considered within a single registration of a substance. However, the registrant must ensure the safety of all included forms and provide adequate information to address the different forms in the registrations, including the chemical safety assessment and its conclusions."

Critics of the EC approach reportedly claimed that it was "dragging its feet" on nanomaterials regulation. Swedish MEP Carl Schlyter, a spokesperson for the Greens movement, said, "The Commission has dodged the key issue by comparing nanomaterials with normal substances on the sole basis that not all nanomaterials may be toxic." He also claimed, "It is highly misleading to suggest that the generic rules of REACH, designed for normal substances, are appropriate for nanomaterials, and contradictory to the calls for a case-by-case approach for the risk assessment of nanomaterials." *See Nanowerk News*, October 4, 2012.

LITIGATION

Court Dismisses POM Wonderful's Challenge to FTC Substantiation "Rule"

A federal court in the District of Columbia has dismissed the declaratory judgment action that POM Wonderful filed against the Federal Trade Commission (FTC) shortly before the Commission brought an enforcement action against the pomegranate product producer. *POM Wonderful LLC v. FTC*, No. 10-1539 (U.S. Dist. Ct., D.D.C., decided September 30, 2012). More information about the complaint and FTC's motion to dismiss appears in Issues **364** and **373** of this *Update*. According to the court, "[t]he balance of relevant factors counsels against exercising jurisdiction over this action."

Among other matters, the court found that (i) the declaratory judgment action would not fully resolve the parties' claims because they would "still have to litigate whether POM's health claims about its products were false, misleading, and unsubstantiated in violation of the FTC Act"; (ii) "other overlapping proceedings are pending" and POM can raise arguments in those proceedings that it has raised in the declaratory judgment action; and (iii) "granting declaratory relief would require the resolution of an anticipatory defense." As to the latter, the court determined that "[a]t least two of the four causes of action asserted in POM's declaratory judgment action are properly considered anticipatory defenses."

The court also observed that by filing its action just two weeks before FTC brought its enforcement action, POM "leaves the disfavored appearance that [it] hastily filed the instant case, in part, to secure tactical leverage from proceedings in this forum." The essence of POM's dismissed claims was that FTC had adopted new substantiation requirements, i.e., heightened scientific evidence and pre-approval from the Food and Drug Administration, without notice-and-comment proceedings, when it entered agreements setting forth these requirements with two companies "whose advertisements overstated their products' effect on disease prevention, mitigation, and treatment." The company will now have to litigate these claims in the enforcement action.

Court Refuses to Certify Wage and Overtime Class Action Against Steak N Shake

A federal court in Georgia has denied a request to certify a nationwide class of Steak N Shake hourly employees in a dispute over alleged violations of the Fair Labor Standards Act, finding that class members are not similarly situated to the named plaintiffs or to each other. *Beecher v. Steak N Shake Operations, Inc.*, No. 1:11-cv-04102-ODE (U.S. Dist. Ct., N.D. Ga., Atlanta Div., decided September 27, 2012). The putative class would have involved some 65,000 employees working in more than 400 corporate restaurants in five different U.S. regions. They alleged that restaurant managers were authorized to and

did in fact change time records in bad faith and thus did not compensate them for all of their work or paid them less than minimum wage.

According to the court, the evidence showed that restaurant managers had a number of legitimate reasons for altering time records. For example, if the clock in/clock out times did not correctly reflect the actual hours worked, changes would be made for payroll purposes, or if the reported tips were too low, upward adjustments could be made to avoid the need for a minimum wage differential payment. The court stated, "Even assuming, arguendo, that there exists a nationwide practice of reviewing and sometimes revising hours clocked in and out, and tips received, that is not enough glue to hold this proposed class together; neither is the fact that Defendant generally discourages managers from allowing overtime work. Defendant has not only explained why it does this, but Defendant has also come forward with the individual time records for Plaintiffs. Via these time records and related declarations, Defendant has undercut some of Plaintiffs' broad assertions that all hourly-paid employees were not properly compensated."

The court also noted that a class action would be unmanageable as it would involve "calling numerous supervisors from individual stores to attest to each and every change to an individual Plaintiff's payroll record" as well as "correction-by-correction mini-trials of more than 2 million corrections made to time and tip records of the putative class." Given the class size, lack of cohesion among claims and the plaintiffs' failure "to identify a nationwide policy or commonality among the proposed members," the court concluded that they failed to show that they and potential class members were similarly situated.

Court Again Rebuffs Nabisco's Challenge to Remand Motion

A federal court in California has denied Nabisco, Inc.'s request that it reconsider a previous ruling granting a motion to remand a consumer-fraud class action to state court for failing to satisfy the amount in controversy for diversity jurisdiction under the Class Action Fairness Act. *Garcia v. Nabisco, Inc.*, No. CV 12-04272-RGK (SSx) (U.S. Dist. Ct., C.D. Cal., decided September 26, 2012). Because the product targeted by the plaintiff, "Wheat Thins 100% Whole Grain" crackers, is no longer on the market, the court rejected an estimate of expenses that would be incurred, if the plaintiffs succeed, to reformulate product packaging for other newly formulated products, "which are not the subject matter of this action."

Animal Rights Group Sues Large-Scale Egg Producer

The Animal Legal Defense Fund (ALDF) has filed a putative class action against a large-scale, California-based egg producer alleging that it falsely represents that the eggs are laid by hens "raised in wide open spaces in Sonoma Valley." *ALDF v. Judy's Family Farm Organic Eggs*, No. n/a (Cal. Super. Ct., filed October

1, 2012). According to ALDF, the hens are actually "crammed in covered sheds with no outdoor access." The animal rights group alleges violations of California's Unfair Competition Law, False Advertising Law and Consumers Legal Remedies Act.

The organization cites Michael Pollan's *The Omnivore's Dilemma*, which discussed the defendant and its parent company, also named in the suit, as follows: "Who could begrudge a farmer named Judy $3.49 for a dozen organic eggs she presumably has to get up at dawn each morning to gather? Just how big and sophisticated an operation Petaluma Eggs really is I was never able to ascertain: The company was too concerned about biosecurity to let a visitor get past the office." The Cornucopia Institute, representing the interests of family farmers, claims on its Website that Petaluma Farms, selling its eggs under several brand names including Judy's Family Farm, has been granted a permanent exemption from its organic certifying agent from an outdoor access requirement on the basis of the threat of avian influenza.

Meanwhile, ALDF also recently filed a lawsuit in New York against the state agriculture department alleging that it has violated the state Agriculture and Markets Law "by allowing the ongoing sale of foie gras in the state of New York." *ALDF v. N.Y.S. Dep't of Agric. & Mkts.*, No. n/a (N.Y. Sup. Ct., filed September 25, 2012). Several foie gras producers were also reportedly named as defendants. According to ALDF, the law requires the department to prohibit the distribution of foie gras, which it contends is a product of the pathologically diseased livers of ducks and geese that have been force fed. *See ALDF Press Releases*, September 25 and October 1, 2012.

Class Action Against General Mills Claims GMOs Render Granola Bars Not Natural

A California resident has filed a putative class action against General Mills, Inc., alleging that its "100% Natural" labeling and advertising for products such as Nature Valley® Dark Chocolate Peanut Butter Crunchy Granola Bars are misleading because the products contain ingredients grown from genetically modified organisms (GMOs). *Rojas v. General Mills, Inc.*, No. 12-5099 (U.S. Dist. Ct., N.D. Cal., filed October 1, 2012). Contending that the soy, yellow corn flour, soy flour, and soy lecithin in the granola bars are GMO ingredients, the plaintiff does not request that the defendant provide a GMO disclosure; rather, he "only requests Defendant to remove the '100% NATURAL' labeling from its Product."

While the plaintiff's alleged harm is purely economic, i.e., he did not get the benefit of his bargain, he alleges that GMOs "pose a potential threat to consumers because medical research and scientific studies have yet to determine the long-term health effects of genetically engineered foods." He compares shoppers not wishing to consume GMOs with people who follow

restricted diets for religious or moral reasons or those who "physically cannot eat certain foods" due to allergies.

Seeking to certify a statewide class of consumers, the plaintiff alleges violations of California's Unfair Competition Law, False Advertising Law and Consumers Legal Remedies Act. He asks the court to enjoin the defendant from making product claims that violate these laws, and seeks restitution, disgorgement, actual and punitive damages, attorney's fees, costs, and interest.

Alleged *E. Coli* Injury Claims Filed in Canada

An Edmonton, Alberta, resident has filed a putative class action against a beef processor with operations in Alberta and Nebraska, alleging that he became severely ill from consuming the company's beef, which was recalled in September 2012 due to an *E. coli* outbreak. *Harrison v. XL Foods Inc.*, No. 1203-14727 (Can. Alta. Q.B., filed October 2, 2012).

Seeking to certify province-wide and nationwide classes of plaintiffs "who purchased and/or consumed the Recalled Products," the plaintiff alleges strict liability, breach of the Fair Trading Act, negligence, waiver of tort/disgorgement, and vicarious liability. He requests punitive and actual damages, as well as non-pecuniary general damages, pecuniary damages, disgorgement of revenues, attorney's fees, costs, and interest. He also seeks a declaration that the recalled products are contaminated.

According to news sources, plaintiff Matthew Harrison fell ill after eating allegedly contaminated steak, purchased at a Costco store, at a friend's house. He was purportedly hospitalized and missed a week's work. The Canadian Food Inspection Agency started warning the public and distributors about the allegedly tainted meat products on September 16, several weeks after the plaintiff consumed the product. Routine testing on September 4 reportedly showed a positive *E. coli* sample at the defendant's Alberta facility. The company has since recalled more than 1,500 meat products from major retailers; a number of illnesses have reportedly been linked to the company's beef products. *See CTVNews* and *Law360*, October 3, 2012.

OTHER DEVELOPMENTS

Transgenic Cow Raises Questions About FDA Approval Process

According to a recent report published in the *Proceedings of the National Academy of Sciences,* scientists have successfully engineered a transgenic dairy cow that produces milk with decreased levels of β-lactoglobulin (BLG), a major allergen which is not present in human milk. Anower Jabed, et al., "Targeted

microRNA expression in dairy cattle directs production of β-lactoglobulin-free, high-casein milk," *PNAS*, October 2012. After testing their hypothesis in a mouse model, New Zealand researchers apparently used a technique called RNA interference to effectively silence the gene responsible for expressing the BLG protein in cow's milk. The resulting transgenic calf reportedly yielded milk with "no detectable BLG protein" but "more than twice the level of the casein proteins that also normally occur in cow's milk."

"People have long looked into reducing this enigmatic protein, or completely knocking it out, because there has been no definitive function able to be assigned to it. So, we developed this scientific model to investigate the effect of knocking BLG protein out on the composition and functional properties of milk, and to determine whether the absence of BLG produces cow's milk that is hypoallergenic," said one of the study's authors in an October 2, 2012, AgResearch press release. "We now want to breed from Daisy and determine the milk composition and yield from a natural lactation. We also want to investigate the origin of Daisy's taillessness [sic], a rare congenital disease in cows."

Meanwhile, the report has prompted further public discussion about the Food and Drug Administration's (FDA's) plans to regulate genetically modified (GM) animals. As Rosie Mestel recounts in an October 1, 2012, *Los Angeles Times* article, the agency's delay on the first application for fast-growing Atlantic salmon created by AquaBounty Technologies "has had a chilling effect on animal biotech efforts" ranging from environmentally friendly pigs to poultry and livestock that would require fewer antibiotics or other medical interventions.

"The process for getting government approval to sell food derived from genetically engineered animals appears to be at a hopeless logjam," writes Mestel, citing many projects that have dried up or relocated for lack of both regulatory and financial support in the United States. Additional details about a coalition of industry and scientific groups concerned about FDA's progress on the AquaBounty salmon decision appear in Issue **404** of this *Update*.

Retired Military Leaders Say American Youth "Still Too Fat to Fight"

Mission: Readiness, a non-profit organization of senior retired military leaders, has issued a second **report** claiming that one in four young adults are still "too overweight to enlist." Titled "Still Too Fat to Fight," the latest report alleges that U.S. students "consume almost 400 billion calories from junk food sold at schools each year." It also cites data from the Robert Wood Johnson Foundation and Centers for Disease Control and Prevention suggesting that efforts to improve school nutrition in New York City, Philadelphia and other cities have led to decreased childhood obesity rates in those areas.

Building on its 2010 call-to-action, Mission: Readiness is urging schools and governments to consider limiting the sale of competitive foods in campus vending machines and cafeterias. "Removing the junk food from our schools should be part

of nationwide comprehensive action that involves parents, schools, and communities in helping students build stronger bodies with less excess fat," states the report, which calls on Congress to take bipartisan steps to ensure access to more nutritious, lower-fat, lower-calorie food at schools. "We need action to ensure that America's child obesity crisis does not become a national security crisis." Additional details about the first report appear in Issue 346 of this *Update*.

"BeeBots" Generate Buzz Worldwide

Researchers with the Universities of Sheffield and Sussex recently announced plans to build a computer model of the honey bee brain that would eventually pilot "an autonomous flying robot." According to an October 2, 2012, press release, the "Green Brain" project aims to produce a tiny flying robot able to sense and act like a live bee for applications ranging from mechanical pollination to search and rescue missions. To this end, Green Brain will rely on high-performance desktop computer processors known as GPU accelerators rather than more expensive supercomputer clusters.

"NVIDIA's GPU accelerators are an important part of the project, as they allow us to build faster models than ever before," said Thomas Nowotny from the University of Sussex's Centre for Computational Neuroscience and Robotics. "We expect that in many areas of science this technology will eventually replace the classic supercomputers we use today and pave the way for many future advances in autonomous flying robots. We also believe the computer modeling techniques we will be using will be widely useful to other brain modeling and computational neuroscience projects."

At the same time, scientists hope to provide insight into bees' highly-developed olfactory sense while advancing the field of artificial intelligence. "The development of an artificial brain is one of the greatest challenges in Artificial Intelligence," said University of Sheffield project leader James Marshall. "So far, researchers have typically studied brains such as those of rats, monkeys, and humans, but actually 'simpler' organisms such as social insects have surprisingly advanced cognitive abilities." *See i09.com,* October 2, 2012.

SCIENTIFIC/TECHNICAL ITEMS

New Study Examines Shared Neurobiology of Obesity and Addiction

A recent study examining the shared neurobiological substrates of obesity and addiction has concluded that "there are several identifiable circuits in the brain, whose dysfunctions uncover real and clinically meaningful parallels between the two disorders." N.H. Volkow, et al., "Obesity and addiction: neurobiological overlaps," *Obesity Reviews,* September 2012. According to the study's authors, "Drugs of abuse tap into the neuronal mechanisms that modulate the motivation to consume food, thus, it is not surprising that there is an overlap in the neuronal

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mechanisms implicated in the loss of control and overconsumption of food intake seen in obesity and in the compulsive intake of drugs seen in addiction."

In particular, the study considers brain dopamine (DA) pathways and their role in both obesity and addiction, cautioning that the current debate over "food addiction" often oversimplifies behavioral patterns involving environmental and biological factors. As a result, the authors seek to sidestep the debate by focusing on the neurobiological processes shared by obesity and addiction "that, when disrupted, can result in compulsive consumption and loss of control in a dimensional continuum."

The findings ultimately suggest that "it is the discrepancy between the expectation for the drug/food effects (conditioned responses) and the blunted reward experience that sustains the drug taking/food overconsumption behavior in an attempt to attain the expected reward." Individuals with disrupted brain DA pathways may thus experience (i) "an enhanced motivational value of the drug/food…at the expense of other reinforcers"; (ii) "an impaired ability to inhibit the intentional (goal-directed) actions triggered by the strong desire to take the drug/food…that result in compulsive food/drug taking"; and (iii) "enhanced stress and 'antireward reactivity' that results in impulsive drug taking to escape the aversive state."

"The picture that is emerging is that obesity, similar to drug addiction, appears to result from imbalanced processing in a range of regions implicated in reward/saliency, motivation/drive, emotion/stress reactivity, memory/conditioning, executive function/self-control and interoception, in addition to possible imbalances in the homeostatic regulation of food intake," concludes the study. Additional details about lead author Nora Volkow's work as director of the National Institute on Drug Abuse appear in Issues 106 and 233 of this *Update*.

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