Shook, Hardy & Bacon L.L.P.

ISSUE 474 | MARCH 8, 2013

FOOD & BEVERAGE LITIGATION UPDATE

CONTENTS

LEGISLATION, REGULATIONS AND STANDARDS

FDA Issues Draft Guidance on Veterinary Drug Residues in Food

The Food and Drug Administration (FDA) has announced the availability of revised draft guidance related to the evaluation and safety of veterinary drug residues in human food. Both sets of guidance are part of the agency's efforts under the Registration of Veterinary Medicinal Products to harmonize technical requirements for the approval of veterinary medical products in the European Union, Japan and the United States.

The guidance titled "Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: General Approach to Establish a Microbiological Acceptable Daily Intake (ADI)" offers a plan for assessing "the human food safety of residues from veterinary antimicrobial drugs with regard to effects on the human intestinal flora." To this end, the guidance (i) "outline[s] the steps in determining the need for establishing a microbiological [ADI]"; (ii) "recommend[s] test systems and methods for determining no-observable adverse effect concentrations (NOAECS) and no-observable effect concentrations (NOAELs) for the endpoints of health concern"; and (iii) "recommend[s] a procedure to derive a microbiological ADI." The agency will accept comments on the revisions at any time.

FDA has also issued draft guidance titled "Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Genotoxicity Testing," which revises previous recommendations concerning "a second test to evaluate the potential of a chemical to produce chromosomal effects." Under the draft guidance, tests to determine whether this potential exists can now take three forms: (i) "an in vitro chromosomal aberrations test using metaphase analysis"; (ii) "an in vitro mammalian cell micronucleus test"; or (iii) "a mouse lymphoma test." The agency will accept comments on the draft guidance until May 6, 2013. *See Federal Register*, March 5, 2013.

Shook, Hardy & Bacon L.L.P.

FOOD & BEVERAGE LITIGATION UPDATE

ISSUE 474 | MARCH 8, 2013

SHB offers expert, efficient and innovative representation to clients targeted by food lawyers and regulators. We know that the successful resolution of food-related matters requires a comprehensive strategy developed in partnership with our clients.

For additional information on SHB's Agribusiness & Food Safety capabilities, please contact

Mark Anstoetter
816-474-6550
manstoetter@shb.com

or

Madeleine McDonough
816-474-6550
202-783-8400
mmcdonough@shb.com

If you have questions about this issue of the Update, or would like to receive supporting documentation, please contact Mary Boyd (mboyd@shb.com) or Dale Walker (dwalker@shb.com); 816-474-6550.

FDA Rule Targets Substances Approved for Use in Meat and Poultry Production

The Food Safety and Inspection Service (FSIS) has issued a final rule, effective May 6, 2013, that amends federal meat and poultry products inspection regulations to remove sodium benzoate, sodium propionate and benzoic acid from the list of substances prohibited for use in meat or poultry products.

According to FSIS, after considering the comments and petitions it received, as well as confirming that the Food and Drug Administration (FDA) had no objections to the safety of the substances, the agency has determined "that sodium benzoate, sodium propionate, and benzoic acid, under the conditions proposed in the petitions, are both safe and suitable for use as antimicrobial agents in certain RTE [ready-to-eat] meat and poultry products."

FSIS said that new uses of these substances in meat or poultry products will continue to be approved by FDA for safety and by FSIS for suitability. *See Federal Register,* March 7, 2013.

FDA Seeks Comments on Pilot Projects to Improve Supply Chain Product Tracing

The Food and Drug Administration (FDA) has released for public comment a report on pilot projects established under the Food Safety Modernization Act (FSMA) "with the food industry to explore and evaluate methods for rapid and effective tracking and tracing of foods." The report includes the recommendations of the Institute of Food Technologies, the agency's project partner, on improving tracking and tracing of food, and FDA will use public comments on those recommendations in finalizing its report to Congress on the matter. Electronic or written comments are requested by April 4, 2013. *See Federal Register*, March 5, 2013.

FDA Responds to Concerns About Piecemeal Release of Proposed FSMA Rules

According to a news source, the Food and Drug Administration (FDA), which has released for public comment just two of five major proposed rules to implement the Food Safety Modernization Act (FSMA), will allow the public to comment on all of them once they have all been made available. FDA spokesperson Shelly Burgess said, "We have received some feedback regarding this and FDA will adjust the comment periods to allow the opportunity for the public to comment as a package." Thus, no comment period will close until all five rules have been published. Information about the initial proposals appears in Issue 466 of this *Update. See Law360*, March 5, 2013.

FDA Reopens Comment Period for BSE-Related Rule

The Food and Drug Administration (FDA) has reopened the comment period for its 2005 interim final rule on the "Use of Materials Derived From Cattle

in Human Food and Cosmetics," which prohibited the use of certain cow components to prevent the potential risk of bovine spongiform encephalopathy (BSE) in human food and cosmetics. The interim final rule stated that a cow's small intestine was safe for use in human food and cosmetics provided the distal ileum was removed. According to the agency, new scientific data confirms the presence of low levels of BSE in other parts of the cow's intestine, including the proximal ileum. Interested parties can comment on the new studies until May 13, 2013. *See Federal Register,* March 4, 2013.

EFSA and EMA to Assess Phenylbutazone Health Risk

The European Food Safety Authority (EFSA) and European Medicines Agency (EMA) have **agreed** to conduct a health risk assessment of phenylbutazone after officials reportedly discovered the anti-inflammatory drug "in a small number of horse carcasses intended for the food chain." According to a March 7, 2013, news release, the European Commission requested the assessment as part of an EU-wide investigation into beef contaminated with horsemeat.

"[U]sed sparingly in human medicine for the treatment of severe inflammatory conditions where no other treatment is considered suitable," phenylbutazone is also approved for veterinary use but only in non-food producing animals such as dogs and sport horses. EFSA thus considers the drug a contaminant in food and will work with EMA to determine whether residues found in horsemeat pose any health risks to consumers. To this end, the agencies will consider "both the risk posed from consumption of the horsemeat itself as well as that arising from other products illegally contaminated with horsemeat," and will present scientific advice on the matter to the European Commission by April 5, 2013.

EFSA Announces Follow-Up Meeting on Aspartame Consultation

The European Food Safety Authority (EFSA) has **announced** an April 9, 2013, scientific meeting to discuss its draft opinion on the re-evaluation of aspartame (E951). Issued by the agency's Scientific Panel on Food Additives and Nutrient Sources Added to Food (ANS Panel), the re-evaluation declined to revise the current Acceptable Daily Intake (ADI) for aspartame after concluding that the substance and its breakdown products "pose no toxicity concern for consumers at current levels of exposure." Additional details about this conclusion appear in Issue **466** of this *Update*.

The follow-up meeting seeks to clarify any comments received during the draft opinion's consultation period, which ended February 15. Before adopting its final opinion on aspartame, the ANS Panel will take into account these responses and meeting discussions, as well as issue a separate report that outlines these proceedings. EFSA has asked "scientific experts in the field of food safety and parties who have contributed to the public consultation" to register for the conference by March 25.

Ontario Report Calls for Changes in Food Environment

A panel commissioned by Ontario's Ministry of Health and Long-Term Care has issued a March 2013 report outlining a three-part strategy designed to curb rising childhood obesity rates by supporting families, changing the food environment and creating healthy communities. Titled "No Time to Wait: The Healthy Kids Strategy," the report specifically recommends, among other things, that regulators (i) "ban the marketing of high-calorie, low-nutrient foods, beverages and snacks to children under age 12"; (ii) "ban point-of-sale promotions and displays of high-calorie, low-nutrient foods and beverages in retail settings, beginning with sugar-sweetened beverages"; (iii) "require all restaurants, including fast food outlets and retail grocery stores, to list the calories in each item on their menus and to make this information visible on menu boards"; and (iv) "develop a single standard guideline for food and beverages served or sold where children play and learn."

"Ontario is at a tipping point," concluded the Healthy Kids Panel, which has requested a commitment of at least C$80 million per year to reduce childhood obesity. "If we delay, we run the risk of more aggressive measures in the future."

GMO Labeling Legislation Proceeds in Vermont Legislature

Vermont's House Agriculture Committee has reportedly passed by an 8-3 vote legislation (H.112) that would require producers to label raw agricultural and processed food products that are genetically engineered. Milk, meat and ready-to-eat foods would be exempt from the labeling. The bill now moves to the House Judiciary Committee for consideration.

If passed, the legislation would evidently take effect 18 months after at least two other states adopt similar proposals, or 24 months after its passage in Vermont—whichever comes first. Previous versions of GMO labeling bills introduced in Vermont in 2011 and 2012 were defeated. *See Addison County Independent*, March 4, 2013.

Chicago Council Committee Defers Vote on Energy Drink Ban

During a hearing to discuss a prohibition on energy drinks in the city, a Chicago City Council committee reportedly decided to further consider the matter at a later date before taking a vote. The proposed ordinances include one introduced in January 2013 by Alderman Edward Burke that would prohibit the sale of drinks with 180 or more milligrams of caffeine and containing the alleged stimulants taurine or guarana. Committee Chair George Cardenas and Alderman William Burns previously introduced another proposal that would prohibit the sale of energy drinks to anyone younger than age 21. Details about Burke's proposal appear in Issue 468 of this Update. *See Chicago Tribune,* March 6, 2013; *TimeNewsFeed.com,* March 7, 2013.

Healthier Offerings Mandated for Seattle Vending Machines on City Property

The Seattle City Council has unanimously adopted a **bill** requiring 50 percent of the food and beverage offerings in vending machines operated on city property to be those deemed "healthier" and "healthiest" as defined by Public Health Seattle & King County's "King County Healthy Vending Guidelines."

According to the guidelines, "healthier" items include baked potato chips, frozen fruit juice bars, whole grain crackers, and pretzels, while the "healthiest" category includes fresh or dehydrated fruit and vegetables, whole grain cereals, low-fat popcorn, unsalted nuts or seeds, and fat-free or low-fat plain yogurt. *See Q13Fox.com,* March 4, 2013.

Meanwhile, Oregon state legislators have proposed **legislation** (H.B. 3403) that would establish nutritional requirements for the food and beverage offerings in vending machines in public buildings. Among other things, the proposal would limit vended items to those not containing (i) more than 200 calories per package; (ii) more than 35 percent of total calories from fat (not applicable to snacks consisting of nuts or seeds only); (iii) more than 35 percent of total calories from sugars; and (iv) any *trans* fat.

LITIGATION

Federal Jury Finds No Infringement in Tortilla Chip Dispute

According to news sources, a federal jury in Texas has determined that Ralcorp Holdings, which makes bowl-shaped tortilla chips sold as store brands, did not violate trademarks or infringe patents on an allegedly similar product made by Frito-Lay and sold as TOSTITOS SCOOPS!®. *Frito-Lay N. Am., Inc. v. Medallion Foods, Inc.*, No. 12-00074 (U.S. Dist. Ct., E.D. Tex., Sherman Div., decided March 1, 2013). Additional information about the lawsuit can be found in Issue **427** of this *Update*. Frito-Lay had sought an order requiring that the defendant cease making BOWLZ® and CUPZ® chips and $4.5 million in damages. *See Businessweek*, March 4, 2013; *The Kansas City Star*, March 5, 2013.

Chemical Industry Trade Association Challenges Proposed Prop. 65 Listing for BPA

The American Chemistry Council (ACC) has filed a complaint for declaratory and injunctive relief in a California state court against California EPA's Office of Environmental Health Hazard Assessment (OEHHA), which in January 2013 proposed listing the chemical bisphenol A (BPA) as a reproductive toxicant under the Safe Drinking Water and Toxic Enforcement Act of 1986 (Prop. 65). *ACC v. OEHHA*, No. n/a (Cal. Super. Ct., Sacramento Cnty., filed March 1, 2013). Further details about OEHHA's proposed BPA listing appear in Issue **468** of this *Update*.

According to ACC, the agency's scientific advisory panel, relying on the same document that OEHHA claims supports the listing—the National Toxicology Program's Center for the Evaluation of Risks to Human Reproduction (NTP-CERHR) Monograph on the Potential Human Reproductive and Developmental Effects of Bisphenol A—unanimously concluded in July 2009 that BPA does not satisfy the criteria for listing developmental toxicants under Prop. 65. NTP-CERHR apparently concluded that "the possibility that bisphenol A may alter human development cannot be dismissed" and that "studies in laboratory animals provide only limited evidence for adverse effects on development and more research is needed to better understand their implications for human health." ACC contends that this is insufficient evidence of reproductive toxicity.

ACC claims that the proposed listing constitutes an abuse of discretion and represents the only time OEHHA has ever "attempted to overrule a decision by the DART-IC [Developmental and Reproductive Toxicant Identification Committee] not to list a chemical by relying on *precisely the same evidence and science that the DART-IC found to be insufficient*." While ACC acknowledges that the maximum allowable dose level for BPA that OEHHA has proposed is likely not exceeded by any product containing the chemical, the trade group cites the immediate and detrimental effects on manufacturer, retailer and consumer behavior in Canada and other states when BPA regulatory action was proposed.

In this regard, ACC states, "Failure to enjoin OEHHA from listing BPA will create scientifically unwarranted and spurious fears among an unsuspecting public, result in an imminent and irreversible de-selection by consumers and retailers (among others) of products containing PBA, which products provide important health and safety benefits without fully equivalent substitutes, and cost millions of dollars in losses among manufacturers, distributors, retailers, farmers, and the economy in general."

Noting that the chemical is used in a wide range of products in addition to food-contact material, such as syringes, dialyzers, eyeglass lenses, sports safety equipment, cell phones, computers, hair dryers, automobiles, toys, and industrial flooring, ACC claims that listing BPA "without evidence of adverse effects in humans at any conceivable dose" would have immediate, serious and adverse effect on the public and the industry. ACC contends that it has submitted comments throughout administrative proceedings involving BPA in California and has thus "exhausted all available administrative remedies, or is excused from further exhausting them based on the doctrines of futility, irreparable harm, and the administrative agency's lack of jurisdiction to proceed further." It seeks a declaration that the proposed listing of BPA is contrary to California law and temporary, preliminary and permanent injunctions to stop OEHHA from taking any further action in the matter.

Gourmet Beverage and Neutraceutical Company Claims Trade Secrets Misappropriated

A company that makes and sells a proprietary blend of purported "wellness" herbs as part of its line of gourmet coffee, teas and hot chocolates has sued one of its former independent business owners/operators (IBOs) alleging, among other matters, disparagement, breach of a confidential performance agreement and non-competition clause, and the misappropriation of trade secrets. *SereniGy Global, Inc. v. Mendoza*, No. 13-08243CA04 (Cir. Ct., 11th Cir., Dade Cnty., Fla., filed March 6, 2013).

According to the complaint, the company relies on a network of IBOs to market and advertise its products and signed a performance agreement with the defendant to do so in March 2012. By October, the company allegedly "received information that Defendant had been making slanderous, derogatory and disparaging remarks about Plaintiff and its CEO in violation" of the agreement, was "divulging confidential information to a third-party," and "had been disloyal and involved in moral turpitude by advising another IBO to attempt to extort $300,000.00 from the Plaintiff's CEO." After the company terminated the defendant's IBO status, he allegedly "continued to violate the non-compete provisions of the terminated Performance Agreement." The company claims that despite sending a cease and desist letter to the defendant in February 2013, he "continues to intentionally and maliciously engage in the non-compete and anti-raiding activities in violation of the Performance Agreement."

Alleging breach of contract, breach of fiduciary duty, misappropriation of trade secrets, restraint of trade, tortious interference with contracts, and commercial disparagement, the company seeks in excess of $7 million in compensatory damages and $21 million in punitive damages. It claims to have created a "massive consumer demand" worldwide for its beverage and neutraceutical products containing ganoderma, "known for thousands of years to be associated with wellness, energy, longevity and balance." The substance is apparently derived from mushrooms.

Discredited Resveratrol Researcher Sues UConn for Wrongful Termination

A scientist who was accused of falsifying data in research on the purported health benefits of red wine has reportedly sued the University of Connecticut, claiming that it wrongfully dismissed him and violated his civil rights in doing so. *Das v. Univ. of Conn. Bd. of Trustees*, No. 13-6039748 (Conn. Super. Ct., Hartford, filed March 5, 2013).

Dipak Das alleges that he was not allowed to introduce exhibits and testimony or to cross-examine witnesses during his five-day dismissal hearing, the culmination of an investigation that apparently found that he had fabricated and falsified data. He also alleges that the university notified 11 scientific

journals before the investigative report on which the termination was based had been completed to advise them that he had "committed research misconduct," and that the university did this "as a means of coercing the plaintiff into settling by harming his reputation and standing in the scientific community."

According to a news source, Das became famous for research on the purported health benefits of natural ingredients, including the resveratrol in red wine. It was thought to promote longevity in laboratory animals. Das apparently demands reinstatement with tenure, lost wages and benefits, restoration of $1.5 million in National Institutes of Health funding, and an order for the university to rescind the notification of research misconduct. *See Courthouse News Service*, March 7, 2013.

OTHER DEVELOPMENTS

Public Health Researchers Advocate Food Marketing Regulations to Curb Obesity in Canada

A recent article published in the *Journal of Public Policy* has **recommended** "a national regulatory system prohibiting commercial marketing of foods and beverages to children" as part of an effort to curb rising obesity rates in Canada. Kim Raine, et al., "Restricting marketing to children: Consensus on policy interventions to address obesity," *Journal of Public Policy,* February 2013. Building on a consensus conference held in April 2011 by the Alberta Policy Coalition for Chronic Disease Prevention, the article's authors lay out a policy framework for evaluating "the political environment, evidence, issues, and challenges of placing restrictions on the marketing of unhealthy foods and beverages."

In particular, they describe the industry-sponsored Children's Food and Beverage Advertising Initiative as "insufficient," noting that in addition to TV advertising, marketers have increasingly adopted new media—"the Internet, adver-gaming, mobile messaging, and viral marketing"—that do not fall under current standards. As a result, the article urges the Canadian government to ban "*all commercial marketing of foods and beverages* to children under 18 years of age," as well as "set minimum standards, assure monitoring of compliance, and impose penalties for non-compliance." It also calls on regulators to expand the definition of marketing to include "*all media through which children are or can be targeted*" and create "*an independent body responsible for monitoring compliance.*"

"Lessons learned from tobacco control suggest the need for broad social change in environments and policy," write the authors. "Policies can create environments that make healthy choices easier and create opportunities to achieve healthy weights, but choosing among potential interventions poses a challenge to decision makers… Delaying remedial interventions because effectiveness is yet to be established makes little sense from a policy perspective as we need to avert future harm."

IOM Issues Workshop Summary on Trends in Food and Beverage Marketing to Children

The Institute of Medicine (IOM) has issued a pre-publication **summary** of its workshop "New Challenges and Opportunities for Change in Food Marketing to Children and Youth." Conducted by IOM's Standing Committee on Childhood Obesity Prevention, the November 5, 2012, workshop featured "presentations and discussion on contemporary trends in marketing of foods and beverages to children and youth and the implications of those trends for obesity prevention." According to IOM, "[t]he childhood obesity epidemic is an urgent public health problem, and it will continue to take a substantial toll on the health of Americans. The most recent data show that almost a third of U.S. children and adolescents are overweight or obese."

PHA Issues Report on Childhood Obesity

A non-profit focusing on childhood obesity has issued its first annual progress **report** on private sector commitments to address the issue. According to the Partnership for a Healthier America (PHA), nearly 3 million children "got moving in 2012," more than 8,000 "new physical activity opportunities became available for kids in 2012," dozens of new or renovated grocery stores opened in or near "food deserts" making healthier food available to more than half-a-million "low-access individuals," and "$18 million has been spent in the last 18 months in financing for new retail channels and innovative food distribution programs." *See PHA Press Release*, March 7, 2013.

IATP Webinar to Feature Anti-Sugar Crusader Robert Lustig

The Institute for Agriculture and Trade Policy (IATP) has announced a March 18, 2013, **Webinar** to discuss how "America's sweet-laden diet is helping drive obesity and chronic metabolic disease." Titled "Sickly Sweet: The Science and Policy of Fructose Overconsumption in America," the Webinar will reportedly be led by Robert Lustig, a specialist in neuroendocrinology at the UCSF School of Medicine who has garnered attention in national venues such as *The New York Times* for comparing sugar to a poison and linking it to metabolic dysfunction, cardiovascular disease, diabetes, liver cancer, and other non-communicable diseases.

NYC Department of Health Highlights Gaps in Potassium Labeling

A research letter published February 25, 2013, in *JAMA Internal Medicine* claims that less than 10 percent of surveyed packaged food products provided information about potassium content on their nutrition facts panels (NFPs). Noting that under current Food and Drug Administration (FDA) policy the disclosure of potassium levels is optional, researchers with New York City's Department of Health and Mental Hygiene apparently examined the labels of 6,560 products culled from a database created in 2009 for the National Salt Reduction Initiative. Their findings evidently revealed that "most packaged food products do not include potassium

content on the NFP" despite concerns that some consumers may need to monitor their intake of the electrolyte.

In particular, the study found that in almost one-half of the 61 food categories identified in the database, "potassium content was available for less than 1% of products." It also identified the five categories—"vegetable juice; seasoned processed potatoes; instant hot cereal; French toast, pancakes and waffles; and major main entrée sauce"—in which potassium levels were provided for more than one-half of the products, which ranged from 0 to 920 mg per serving. Based on these results, the authors expressed concern that items with high levels of potassium did not appear more likely to offer this information when compared to products with relatively low levels.

"The lack of potassium information on the NFP presents a problem for patients and consumers trying to make informed decisions when purchasing foods, particularly those motivated to minimize their risk of cardiovascular disease and those for whom potassium intake must be restricted," opine the letter's signatories who, in addition to calling for the creation of "a publicly accessible, product-specific nutrition database of packaged food products," urge FDA to consider requiring potassium content and percent daily value on labels when it overhauls NFP guidelines. "Providing this important information to consumers, patients, and researchers would allow a more detailed understanding of the food supply, which would complement existing strategies to improve population nutritional intake," the letter concludes.

Monster Energy Briefs Reporters on Expert Findings in Maryland Teen's Death

During a recent press conference, counsel for Monster Energy reportedly addressed claims made in a wrongful death lawsuit filed against the company by the parents of a Maryland teenager who allegedly died after consuming the company's energy drink. The company's experts have apparently reviewed the medical records in the case and determined that "there is no medical, scientific or factual evidence to support the Maryland medical examiner's report of 'caffeine toxicity' or that Ms. Fournier's consumption of two Monster Energy Drinks 24 hours apart contributed to, let alone was the cause of her untimely death."

Apparently, no blood tests were conducted to confirm the examiner's finding, and the 14-year-old had pre-existing conditions—an enlarged heart, a vascular form of connective tissue disease, mitral valve prolapse, and myocardial fibrosis—that purportedly increased her risk of cardiac arrest and sudden death.

The company was apparently motivated to call the press conference after a Chicago alderman cited the teen's death to justify a proposal that the city ban energy drinks. Additional information about that initiative appears elsewhere in this *Update*. Meanwhile, the plaintiffs' attorney reportedly indicated that other symptoms of caffeine toxicity were in the record. He said, "We have our experts and they have their experts [and] it's not appropriate . . . to litigate the case in the media." *See NBC News* and *Reuters*, March 4, 2013.

MEDIA COVERAGE

Sunstein Focuses on the Nanny State in Book Review

According to Law Professor and former White House Office of Information and Regulatory Affairs Administrator Cass Sunstein, a new book addresses the intersection of recent findings on human behavior with the paternalism many Americans equate with "big government" regulations, such as New York City's restrictions on the size of sugar-sweetened beverages. Sarah Conly's *Against Autonomy: Justifying Coercive Paternalism* contends that John Stuart Mill was wrong about the competence of human beings to know what is good for themselves and thus government's consequent lack of legitimacy to coerce people to prevent harm to themselves. "We are too fat, we are too much in debt, and we save too little for the future," she states, insisting "that coercion should not be ruled out of bounds."

Sunstein sums up Conly's approach to paternalism by noting the four criteria she would require to justify government coercion: the activity "must genuinely be opposed to people's long-term ends as judged by people themselves," the "measures must be effective rather than futile," "the benefits must exceed the costs," and "the measure in question must be more effective than the reasonable alternatives." Conly apparently approves of New York's ban on *trans* fats under her criteria, while remaining ambivalent about Mayor Michael Bloomberg's (D) effort to persuade the U.S. Department of Agriculture "to authorize a ban on the use of food stamps to buy soda." Sunstein contends that her "argument is careful, provocative, and novel, and it is a fundamental challenge to Mill and the many people who follow him. But it is in less severe tension with current practices than it might seem. A degree of paternalism is built into the workings of the modern regulatory state."

He concludes, "Conly convincingly argues that behavioral findings raise significant questions about Mill's harm principle. When people are imposing serious risks on themselves, it is not enough to celebrate freedom of choice and ignore the consequences. What is needed is a better understanding of the causes and magnitude of those risks, and a careful assessment of what kind of responses would do more good than harm." *See The New York Review of Books*, March 7, 2013.

SCIENTIFIC/TECHNICAL ITEMS

Salt Consumption Allegedly Linked to Autoimmune Disorders

Two groups of researchers have allegedly provided evidence that sodium induces the differentiation of CD4 T cells responsible for immune responses, thereby raising concerns about the role of salt intake in autoimmune disorders. Both published in *Nature,* the two studies in question suggested that "a high-salt diet can enhance the differentiation of a class of immune cells called T_H17 cells, and exacerbate disease in a mouse model of multiple sclerosis called experimental autoimmune encephalitis (EAE)," according to a concurrent news item. In addition, the authors

apparently found that mice lacking serum glucocorticoid kinase 1 (SGK1), which plays a role in EAE, had reduced neuropathy and some protection from a high-salt diet.

In particular, the first study examined how increased sodium chloride concentrations *in vivo* "markedly boost the induction of murine and human T_H17 cells," purportedly showing that the T_H17 cells generated under these conditions "display a highly pathogenic and stable phenotype characterized by upregulation of the pro-inflammatory cytokines GM-CSF, TNF-α and IL-2." Markus Kleinewietfeld, et al., "Sodium chloride drives autoimmune disease by the induction of pathogenic T_H17 cells," *Nature,* March 2013. Taken with the knowledge that "mice fed a high-salt diet develop a more severe form of EAE," these results evidently persuaded the authors that "increased dietary salt intake might represent an environmental risk factor for the development of autoimmune diseases through the induction of pathogenic T_H17 cells."

Meanwhile, the second study on the induction of pathogenic T_H17 cells focused on SGK1's role "in regulating IL-23R expression and stabilizing the T_H17 cell phenotype by deactivation of mouse Foxol, a direct repressor of IL-23R expression." Chuan Wu, et al., "Induction of pathogenic T_H17 cells by inducible salt-sensing kinase SGK1," *Nature,* March 2013. Although "the precise molecular mechanism by which IL-23 sustains the T_H17 response and induces pathogenic effector functions" remains unknown, the authors reported that "a modest increase in salt concentration induces SGK1 expression, promotes IL-23R expression and enhances T_H17 cell differentiation *in vitro* and *in vivo,* accelerating the development of autoimmunity."

Despite these initial findings, the *Nature* news item summarizing the two studies ultimately concluded that dietary salt is just one environmental factor associated with pathogenic T_H17 cell development. "So, although these are exciting and provocative data, it is clearly premature—as also pointed out by both sets of authors—to state that dietary salt influences autoimmune disease in people, and that this is mediated by T-cell-induced production of IL-17," write the article's authors. "However, the work should spur investigation of tangible links between diet and autoimmune disease in people."

Study Points to Maternal Diet's Purported Role in Creating "Junk Food Junkies"

A recent animal study has concluded that exposing rats to a perinatal "junk-food" (JF) diet "results in early desensitization of the opioid system which may explain the increased preference for junk food in these offspring." Jessica Gugusheff, et al., "A maternal 'junk-food' diet reduces sensitivity to the opioid antagonist naloxone in offspring postweaning," *The FASEB Journal,* March 2013. Relying on previous research, University of Adelaide scientists apparently surmised that the offspring of dams fed a cafeteria diet would exhibit an increased preference for "palatable" foods thanks to "changes in the μ-opioid receptor expression within the mesolimbic reward pathway."

After the offspring of JF dams were weaned, the study analyzed RNA isolated from the nucleus accumbens (NAc) and ventral tegmental area (VTA) of their brains, in addition to examining how they responded to injections of the opioid antagonist naloxone, which suppresses fat and sugar intake by blocking opioid signaling. According to the results, "exposure to a maternal cafeteria diet during pregnancy and lactation is associated with altered expression of the μ-opioid receptor expression in both the VTA and NAc at weaning in a region- and sex-specific manner, demonstrating for the first time that the effects of perinatal JF exposure on the opioid system are already present immediately following the exposure." The study author's also noted that when compared with a control group, naloxone treatment "was less effective at reducing the intake of the cafeteria diet in offspring exposed to the same diet during the perinatal period, consistent with a reduced sensitivity to opioids in these offspring."

"This work has provided novel insights into a potential mechanism through which maternal JF consumption increases the preference for junk food in offspring," concludes the study. "A better understanding of this mechanism is crucial if we are to develop possible strategies for intervention and becomes increasingly important in view of the rapidly rising rates of both childhood and adult obesity."

"This study shows that addiction to junk food is true addiction," added *The FASEB Journal's* editor-in-chief, Gerald Weissmann, in a February 28, 2013, press release. "Junk food engages the same body chemistry as opium, morphine or heroin. Sad to say, junk food during pregnancy turns the kids into junk food junkies."

OFFICE LOCATIONS

Geneva, Switzerland
+41-22-787-2000
Houston, Texas
+1-713-227-8008
Irvine, California
+1-949-475-1500
Kansas City, Missouri
+1-816-474-6550
London, England
+44-207-332-4500
Miami, Florida
+1-305-358-5171
Philadelphia, Pennsylvania
+1-215-278-2555
San Francisco, California
+1-415-544-1900
Tampa, Florida
+1-813-202-7100
Washington, D.C.
+1-202-783-8400