Shook, Hardy & Bacon L.L.P.

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FOOD & BEVERAGE LITIGATION UPDATE

CONTENTS

LEGISLATIONS, REGULATIONS AND STANDARDS

Markey Requests FTC Investigation of Energy-Drink Claims

U.S. Rep. Edward Markey (D-Mass.) has written a November 30, 2012, letter to Federal Trade Commission (FTC) Chair Jon Leibowitz asking the agency to investigate advertising claims made by energy-drink manufacturers. Alarmed by recent media reports allegedly linking products such as 5-Hour Energy® to consumer deaths, Markey notes that many energy drinks "are sold as dietary supplements" that do not fall under Food and Drug Administration (FDA) rules for caffeine content or labeling, and do not require FDA approval before going on the market.

"As you know, the FTC has in the past successfully investigated and took action against claims made by alcohol-containing energy drinks found to be engaging in unsafe, deceptive marketing claims," writes Markey, who has also asked FTC to describe its coordination with FDA and other federal agencies. "I believe an investigation into energy drinks that do not contain alcohol and are often targeted at children may be warranted at this time." Additional details about FDA reports on 5-Hour Energy® appear in Issue 462 of this *Update*.

Meanwhile, the Center for Science in the Public Interest (CSPI) has criticized a Web advertisement created by 5-Hour Energy® manufacturer Living Essentials, LLC that allegedly quotes CSPI Executive Director Michael Jacobson as saying, "Overdoing caffeine alone is actually pretty difficult to do. Someone would have to make an effort to consume 40 or so 200-milligram tablets." According to a December 4, 2012, letter by CSPI's attorneys, the advertisement in question obtained the quote from a *Time* magazine interview and used it to suggest that "Dr. Jacobson believes that your product is safe."

"Dr. Jacobson and CSPI most certainly do not believe that 5-Hour Energy is necessarily safe at the dosages that may be consumed, as your video suggest," opines CSPI, which claims that Living Essentials misrepresented Jacobson's views and infringed on his "right of publicity under state statutes and common law." The consumer group has also accused the manufacturer

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of using Jacobson's statements for promotion without written permission, infringing on CSPI's marks and damaging the group's reputation. "In addition," continues the letter, "the use of CSPI's marks as described constitutes false advertising in violation of the Lanham Act, as the video does not reflect CSPI's view about 5-Hour Energy."

Living Essentials has since responded to the claims by removing the video from its Website "while the company 'research[es] the legal issues further.'" *See CSPI Press Release,* December 6, 2012.

FDA to Revise Tolerances for Residues of New Animal Drugs in Food

The Food and Drug Administration (FDA) has **issued** a proposed rule that would update tolerances "for residues of approved and conditionally approved new animal drugs in food by standardizing, simplifying, and clarifying the determination standards and codification style." According to FDA, the regulations describing how to set animal drug tolerances for human food are not uniform, do not provide all relevant information, and "no longer accurately reflect current regulatory science."

"For example, the regulations provide the ADI [acceptable daily intake] and safe concentrations for some, but not all, drugs," states the proposed rule. "In addition, the regulations list some tolerances as being for 'negligible' residue, and others as 'no residue,' 'zero' or 'not required,' but they do not explain what these important terms mean. The proposed rule addresses these inconsistencies by simplifying and standardizing the determination standards and codification style and by adding definitions for key terms." FDA will accept comments on the proposal until March 5, 2013. *See Federal Register,* December 5, 2012.

FDA Considers Revoking Standards of Identity for Artificially Sweetened Fruit Spreads

The Food and Drug Administration (FDA) has **proposed** revoking "the standards of identity for artificially sweetened jelly, preserves and jam," concluding that these standards "are both obsolete and unnecessary in light of [] regulations for food named by use of a nutrient content claim and a standardized term." Responding to a citizen petition submitted by the International Jelly and Preserve Association (IJPA), the proposed rule notes that standards implemented in 1959 for fruit spreads containing nonnutritive sweeteners (NNSs) only provided for the use of saccharin, sodium saccharin, calcium saccharin, or any combination thereof (21 CFR 150.140 and 150.160). These standards did not include other NNSs approved for food use since 1959, although FDA later established under the Federal Food, Drug and Cosmetic Act a general standard of identity for foods named by a nutrient content claim such as "low calorie" or "sugar free" "in conjunction with a standardized food term," e.g., "low calorie grape jelly."

FDA has "tentatively" agreed with IJPA that these later regulations make the 1959 standards of identity for artificially sweetened fruit spreads obsolete. According to IJPA, the general standard of identify for foods named by a nutrient content claim "provide fruit spread manufacturers with sufficient flexibility to use newer, intense [NNSs] in lieu of traditional nutritive sweeteners." The association also argued that "nutrient content terms (e.g. 'low calorie')… better communicate to the customer the benefit of the use of [NNSs] than does the term 'artificially sweetened,' which is required to appear on the labels of products manufactured in conformity with §§ 150.141 and 150.161." FDA has therefore concluded that revoking the standards for artificially sweetened fruit spreads "would promote honesty and fair dealing in the interest of consumers," and has requested comments on the matter by March 4, 2013. *See Federal Register*, December 4, 2012.

FDA Issues Final Food Irradiation Rules

The Food and Drug Administration (FDA) has issued final rules amending food additive regulations pertaining to the use of ionizing radiation in the production, processing and handling of **meat** and **poultry** products. Promulgated at the request of the U.S. Department of Agriculture, the rules took effect on November 30, 2012. FDA requests written objections or requests for a hearing by December 31.

The meat-product irradiation amendment would "provide for the safe use of a 4.5 kilogray (kGy) maximum absorbed dose of ionizing radiation to treat unrefrigerated (as well as refrigerated) uncooked meat, meat byproducts, and certain meat food products to reduce levels of foodborne pathogens and extend shelf life." The poultry-irradiation amendment would "increase the maximum dose of ionizing radiation permitted in the treatment of poultry products, to include specific language intended to clarify the poultry products covered by the regulations, and to remove the limitation that any packaging used during irradiation of poultry shall not include oxygen." *See Federal Register,* November 30, 2012.

Health Canada Approves Stevia for Tabletop and Food Use

Health Canada has **issued** a notice of modification adding steviol glycosides derived from the stevia plant to its list of permitted sweeteners. After concluding a technical consultation published on July 31, 2012, in response to three separate food additive submissions, Health Canada has evidently agreed that "available data support the safety and efficacy of steviol glycosides when used as described."

The revised list of permitted sweeteners authorizes the use of steviol glycosides as a tabletop sweetener and as a food additive in a number of food categories, including those pertaining to breakfast cereals, confections, nut

and peanut spreads, fruit spreads, sauces, beverages, baking mixes, desserts, chewing gum, and condiments. Health Canada has directed food labeling questions about the use of common names for steviol glycosides, such as "purified stevia extract" and "stevia leaf extracts," to the Canadian Food Inspection Agency.

Mexican Lawmaker Floats Chewing Gum Tax Proposal

A Mexican lawmaker has proposed a 50-percent tax on chewing gum. According to news sources, Institutional Revolutionary Party Deputy Juan Manuel Diez Francos claims such a tax could fund efforts to clean up the gum discarded in various public venues. Mexico is apparently the second largest consumer of gum behind the United States—citizens chew an average of 2.5 pieces daily. A similar proposal is currently being sought in Northern Ireland for the same reasons. *See VOXXI* November 28, 2012.

Peru Imposes 10-Year Ban on GMO Foods

Peru has passed a law that prohibits genetically modified organisms (GMOs) from being imported, produced or used anywhere within the country for the next 10 years. The law, which was approved by President Ollanta Humala last year and took effect last week, is aimed at preserving Peru's agricultural diversity, preventing cross-pollination and supporting local farmers. According to news sources, GMOs threaten the country's heritage plant species, including several varieties of colorful corn, which are becoming increasingly popular export commodities. Violating the law will result in a maximum fine of 10,000 UIT tax units, which is about 36.5 million soles ($14 million). The goods can also be seized and destroyed. *See Andean Air Mail & Peruvian Times,* November 17, 2012.

LITIGATION

Alleged Infringing Farmer Files SCOTUS Merits Brief on Patent Exhaustion

Indiana farmer Vernon Bowman claims in his U.S. Supreme Court merits brief that the Federal Circuit Court of Appeals, which ruled that he infringed patents by planting second-generation genetically modified (GM) seeds, has "significantly curtailed the patent-exhaustion defense" by refusing to "hold Monsanto's patent rights exhausted with respect to the seeds Bowman purchased from [a] grain elevator." *Bowman v. Monsanto Co.*, No. 11-796 (U.S., petitioner's brief filed December 3, 2012).

The U.S. Supreme Court agreed to review whether "the Federal Circuit erred by (1) refusing to find patent exhaustion in patented seeds even after an authorized sale, and by (2) creating an exception to the doctrine of patent exhaustion for self-replicating technologies." Additional information about the

dispute appears in Issue 434 of this *Update*.

The allegedly infringing seeds that Bowman planted as a second crop were purchased in a commodity grain mix from a grain elevator. Such mixes can, according to Bowman, "be dirty, containing a relatively high content of debris, seeds from other crops, and weeds . . . [Their] mixed, impure character makes it largely unsuitable for planting, except where a farmer requires low-cost seeds to balance the risks associated with late-season plantings." His crop "turned out to be resistant to Round Up [sic] related chemicals," thus making them plants containing the traits Monsanto has patented. Accordingly, Monsanto sued him for patent infringement.

When Monsanto sells its Roundup Ready® seeds to farmers, they agree by contract to certain limitations on their use, including planting a commercial crop for just one season, not supplying the seed to any other person for planting, and not saving any crop produced from the seed for replanting. According to Bowman, Monsanto enforces the restrictions in these agreements through patent-infringement suits, and the company has recovered some $23 million in 136 lawsuits against 400 farmers and 23 small-farm businesses since 2010. Monsanto apparently allows farmers to sell the progeny of their first-generation seeds to grain elevators in unrestricted sales and authorizes grain elevators to resell progeny seeds as part of the mixed commodity grain available to the public. Still, the company "asserts a right to sue purchasers of commodity seeds for patent infringement when they use those seeds for planting."

The Federal Circuit ruled that patent exhaustion does not apply to an "expressly conditional sale," or one in which post-sale restrictions are imposed on the purchaser. It also affirmed the district court's conclusion that "[n]o unconditional sale of the Roundup Ready® trait occurred because the farmers could not convey to grain dealers what they did not possess themselves." Bowman contends that "this reasoning fails to recognize that exhaustion has only one requirement—an authorized sale. Whether a licensee or the patentee makes the sale, if it is authorized, it triggers exhaustion, and the item sold passes outside the protection of the Patent Act."

The Federal Circuit also reasoned "that even if exhaustion applied to the seeds purchased as a commodity from a grain elevator, Bowman infringed Monsanto's patents because his use of the commodity seeds for planting constituted an impermissible 'making' of the invention. In this argument, the Federal Circuit likened the use of commodity seeds for planting to impermissible 'reconstruction' of the invention." Bowman argues that planting seeds is nothing like reconstruction and the Federal Circuit has extended the patent monopoly by judicial decision beyond the terms of the patent grant—action within Congress's exclusive jurisdiction. He contends, "By authorizing the sale of patented seeds, Monsanto has authorized the sale of a product that can

be used for practicing the patents and therefore has parted with all ability to restrict such use under the patent laws."

Bowman further argues that (i) "Congress has provided no exception to the exhaustion doctrine for seeds, let alone any other self-replicating technology," and (ii) "[p]atentees of self-replicating technologies have adequate contractual remedies to protect their interests in the use and resale of these technologies." He concludes by assuring the Court that a ruling in his favor would not "eviscerate" Monsanto's patent rights because "commodity grain does not directly compete with first-generation seeds given the mixed, impure character of commodity grain. A farmer buying commodity grain for planting cannot sell his progeny in competition with Monsanto given its mixed character and unknown ancestry."

GAP Lawsuit Seeks FDA Data on Use of Animal Antibiotics

The Government Accountability Project (GAP) has filed a lawsuit under the Freedom of Information Act (FOIA) against the Food and Drug Administration (FDA), alleging that the agency has wrongfully withheld information requested about the use of anti-microbial drugs in food-producing animals. ***GAP v. FDA*, No. 12-1954 (U.S. Dist. Ct., D.C., filed December 5, 2012)**. GAP requests an order requiring FDA to make the requested information available within 10 working days and further seeks costs and attorney's fees.

According to the complaint, GAP sought information in February 2011 about anti-microbial drugs collected from animal-drug sponsors under 21 U.S.C. § 360b. While FDA produced, as requested, educational and outreach materials that assist drug sponsors in fulfilling their reported duties, it withheld (i) "FDA's data for use of anti-microbial drugs in food-producing animals in 2009 as broken down by container size, strength, and dosage form"; and (ii) "FDA's data for use of anti-microbial drugs in food-producing animals in 2009 as broken down by class of animal." FDA relied on FOIA exemption 4 to withhold responsive material. GAP contends that the requested information "does not concern, and disclosure of the information would not reveal, any commercially valuable plan, formula, process, or device used for the making, preparing, compounding, or processing of any trade commodities."

GAP is a non-profit organization whose mission is to "promote corporate and government accountability by protecting whistleblowers, advancing occupational free speech, and empowering citizen activists."

Federal Court Allows Securities Fraud Claims to Proceed Against Diamond Foods

A federal court in California has determined that Diamond Foods' investors adequately pleaded knowledge, or *scienter*, on the part of the company and individual senior officers to allow putative class claims against them for false

and misleading statements in violation of federal securities laws to proceed. *In re Diamond Foods, Inc., Securities Litig.*, No. C11-05386 WHA (U.S. Dist. Ct., N.D. Cal., order entered November 30, 2012). The court also dismissed claims filed against the company's auditor, finding insufficient allegations to raise a strong inference of *scienter*, but allowed the plaintiffs to amend their complaint to cure its deficiencies.

The litigation arises from events occurring in 2010-2012, when Diamond was attempting to purchase the Pringles brand of snack chips from P&G. The company allegedly manipulated prices paid to walnut growers during those years and failed to properly account for the payments, resulting in what appeared to be an inflated value for its shares. When the irregularities came to light, Diamond's stock apparently plummeted nearly 37 percent. Citing witness statements and conflicting company statements to investors, the press and growers, the court found sufficient evidence at the motion-to-dismiss stage to support the plaintiffs' *scienter* allegations. The court found that *scienter* was neither negated by the individual defendants' failure to sell their stock during the class period nor by unqualified audit opinions provided by the company's outside auditor.

Putative Class Claims Curtailed in Coconut Water Consumer-Fraud Action

A federal court in California has granted in part the summary judgment motion filed by a coconut water company facing allegations that it overstates the magnesium and sodium content of its "O.N.E." product and falsely claims that it is a good source of electrolytes. *Vital v. One World Co., LLC*, No. SACV 12-00314-CJC(MLGx) (U.S. Dist. Ct., C.D. Cal., S. Div., order entered November 30, 2012).

The court dismissed all claims based on a study that allegedly found lower levels of magnesium and sodium than allowed by Food and Drug Administration (FDA) regulations when a product is claimed to be a "good source" of such nutrients. According to the court, the plaintiffs failed to show that the study was conducted under FDA's § 101.9(g) methodology and would thus impose more stringent requirements on the defendant than federal law.

The court allowed the plaintiffs to pursue claims that the product is falsely marketed as a "good source of electrolytes," because the product labels themselves show that the coconut water is a good source of just one electrolyte under FDA regulations. The court could not conclude that the practice was not deceptive as a matter of law because "[t]he phrase 'good source' of 'electrolytes' implies that O.N.E. is a 'good source' of more than one electrolyte. Therefore, the fact that the label makes a number of additional claims about potassium is not sufficient. A reasonable consumer might still believe that O.N.E. is a good source of at least one other electrolyte."

Malicious Prosecution Suit Filed Against Attorneys by 5-Hour Energy® Company May Proceed

In an unpublished decision, a California appeals court has determined that Innovation Ventures, LLC, the parent company which makes 5-Hour Energy®, may proceed with a malicious prosecution action against Howard Rubinstein and other consumer-fraud attorneys in connection with a putative class action filed against the company in 2010 on behalf of a woman, Vi Nguyen, whose claims about the product apparently changed during her deposition, leading to the suit's voluntary dismissal with prejudice. *Innovation Ventures, LLC v. Rubinstein*, No. G046242 (Cal. Ct. App., 4th Dist., decided November 29, 2012) (unpublished).

The court noted that the underlying consumer-fraud complaint referred in a number of places to the named plaintiff as "he" and that the named plaintiff did not believe she had ever seen the complaint or she would have corrected these references. She also apparently had never seen the attorneys of record "and had just met Rubinstein the day before her deposition." The court found that the underlying litigation was without merit, based on discrepancies in the evidence and the lawsuit's voluntary dismissal before a second round of depositions. The court also found that Innovation satisfied its prima facie case as to malice citing, among other matters, its counsel's declaration in opposition to the anti-SLAPP motions filed by Nguyen and her attorneys.

The declaration "described a telephone conversation in which Rubinstein 'offered to sell "protection" to Innovation unrelated to the merits of the claims he and Hewell intended to pursue on . . . Nguyen's behalf. Specifically, . . . Rubinstein represented that Innovation's . . . payment would vary based on the level of "protection" against his lawsuits that Innovation . . . desired to obtain. He said that the geographic scope of his promise to desist from filing lawsuits and the coverage of Innovation['s] . . . product line would depend on how much Innovation . . . was willing to pay him.'"

The court dismissed the malicious prosecution claims filed against Nguyen, finding insufficient evidence of malice on her part.

Challengers Seek Expedited Argument on NYC Large-Size Soda Ban

Soft drink manufacturers and restaurateurs have reportedly requested that the court re-schedule oral arguments in their challenge to a New York City prohibition on the sale of sweetened beverages in sizes that exceed 16 ounces. *N.Y. Statewide Coal. of Hispanic Chambers of Commerce v. NYC Dept. of Health & Mental Hygiene*, No. 653584/2012 (N.Y. Sup. Ct., N.Y. Cnty., filed October 12, 2012). Additional details about the case appear in Issue **458** of this *Update*. According to a news source, the industry interests seek oral argument before January 2013, claiming it will take up to three months to "retool" their operations to comply with the new requirements, which will take effect in March 2013, if upheld by the court. City attorneys have apparently decided not to oppose the request, noting that

everyone's interest will be served if the matter is "resolved sooner rather than later." *See Reuters*, December 5. 2012.

Arbitrator Orders May 2013 Deadline for U.S. COOL Rules to Comply with WTO Ruling

A World Trade Organization (WTO) arbitrator has **determined** that the United States must conform its country-of-origin-labeling (COOL) rules in accordance with an earlier ruling by May 23, 2013, finding that 10 months was a reasonable time for implementation. Additional details about the dispute, which involved a challenge brought by Canada and Mexico over 2008 COOL provisions for beef and pork products, appear in Issue **446** of this *Update*.

According to a news source, the labeling program has sharply reduced U.S. imports of Canadian pigs and cattle, because it purportedly raised U.S. packers' costs by requiring them to segregate imported animals from U.S. livestock. COOL supporters contend that such labeling provides consumers with important information about food origins. Canada's International Trade Minister Ed Fast and Agriculture Minister Gerry Ritz reportedly said, "We are particularly pleased that the arbitrator determined a reasonable period of time close to that proposed by Canada and Mexico, as opposed to the much longer period suggested by the United States."

While WTO's July 2012 ruling allows the United States to continue to require country-of-origin labels, according to U.S. trade officials, the program must be altered to ensure that it does not impermissibly interfere with trade. A spokesperson for the U.S. trade representative said, "The United States remains committed to ensuring that consumers are provided with information about the origin of beef and pork products they buy at the retail level. We intend to bring the COOL requirements into compliance within the period of time established by the arbitrator, and we will continue to work with USDA, Congress, and interested stakeholders in order to do so." *See Chicago Tribune*, December 4, 2012.

OTHER DEVELOPMENTS

Food Fight for Nickelodeon

In the ongoing battle over whether the government should regulate food ads targeting children, the Food Marketing Workgroup (FMW), a coalition of more than 80 health groups and nutritionists, is putting pressure on Nickelodeon and its parent company, Viacom, to adopt nutrition guidelines for foods marketed to children, particularly foods that license Nickelodeon characters such as SpongeBob SquarePants and Dora the Explorer.

More than 55 health organizations and 30 prominent nutritionists, physicians and other experts signed a December 3, 2012, **letter** to Nickelodeon and Viacom

urging them to implement stronger nutrition standards for the foods marketed to kids on Viacom's various channels and that bear images of its characters.

The group notes that although Viacom has taken some small steps in the right direction, it lags behind other children's entertainment companies such as The Walt Disney Co. and ION Television, which have adopted comprehensive policies that apply nutrition standards to all their marketing to kids. The FMW writes that "As the number one entertainment company for children, Nickelodeon has enormous influence over children's food choices and thus their lifelong habits and health. At a minimum, Nickelodeon should meet the food industry's own baseline and join the Council for Better Business Bureaus' Children's Food and Beverage Advertising Initiative," a self-regulatory group that promotes a baseline set of standards for food marketing to young children. "Even better, Nickelodeon could show leadership by working towards implementing the Interagency Working Group [IWG] food marketing guidelines." IWG is a federal task force that has proposed draft non-binding standards.

Danish Councils Establish Database to Identify Products Containing Nanomaterials

The Danish Consumer Council and Danish Ecological Council, in conjunction with the Department of Environmental Engineering at the Technical University of Denmark, have reportedly developed a database intended to help consumers identify products that may contain nanomaterials. The database evidently includes a description of each nanotechnology involved; rates of purported exposure risks to professional end-users, consumers and the environment; and potential hazards to human health and the environment by means of color coding. Food packaging materials are said to have incorporated nanoparticles to prolong shelf life and control microbial agents in packaged foods.

Danish Ecological Council chemical expert Lone Mikkelsen reportedly said, "We are concerned that . . . too many nanomaterials are introduced to the market, before we know the full effects on humans and the environment." Consumers will apparently be able to search the database to see if a certain product contains nanomaterials or is marketed as a "nano" product and then decide whether to purchase it. According to a news source, the database currently contains information about more than 1,200 products. *See Special Chem*, December 4, 2012; *ENEWSPF*, December 7, 2012.

SCIENTIFIC/TECHNICAL ITEMS

Brain Imaging Study Focuses on Food Logos

Researchers with the University of Missouri-Kansas City and University of Kansas Medical Center have used functional magnetic resonance imaging (fMRI) to map brain responses to food logos in obese and healthy-weight children. Amanda Bruce, et al., "Brain Responses to Food Logos in Obese and Health Weight Children,"

Journal of Pediatrics, November 2012. According to the study, 10 healthy-weight children and 10 obese children completed "self-report measures of self-control" and then underwent fMRI while viewing 60 food and 60 nonfood logos.

The results purportedly indicated that, when viewing food logos, "obese children showed significantly less brain activation than the healthy weight children in regions associated with cognitive control." Obese children also apparently demonstrated "greater activation in reward regions when shown food logos compared with baseline blurred images," although the researchers "did not find significantly greater brain activation in the OFC [orbitofrontal cortex] or ventral striatum, which have been identified in pervious food motivation neuroimaging studies."

"This study provides preliminary evidence that obese children may be more vulnerable to the effects of food advertising," said the study's lead author in a November 30, 2012, press release. "One of the keys to improving health-related decision-making may be found in the ability to improve self-control." Additional details about the researchers' neuroimaging work appear in Issue 455 of this *Update.*

Animal Study Implicates Nonnutritive Sweeteners in Weight Gain

A recent study has reportedly suggested that compared with sucrose, some nonnutritive sweeteners (NNSs) induce greater weight gain in Wistar rats. Fernanda de Matos Feijó, et al., "Saccharin and aspartame, compared with sucrose, induce greater weight gain in Wistar rats, at similar total caloric intake levels," *Appetite,* November 2012. After feeding 29 male rats a free chow diet and yogurt sweetened with sucrose, saccharin or aspartame over the course of 12 weeks, Brazilian researchers found that "addition of either saccharin or aspartame to yogurt resulted in increased weight gain compared to addition of sucrose," even though total caloric intake was similar among groups.

"Although saccharin and aspartame promoted relatively fewer calories from yogurt intake when compared to sucrose, increases in calories from chow intake effectively compensated for decreases in calories from yogurt, in such a way that there was a similar total caloric intake among all groups after the 12-week period of the experiment," concluded the researchers, who speculated that the weight gain involved a decrease in energy expenditure or an increase in fluid retention. "However, it was surprising to find that the NNSs were able to induce weight gain without an increase in total caloric intake, suggesting that other mechanisms such as decreased caloric expenditure may occur after NNS use."

Research Examines Role of High-Sugar Diet in Tumor Growth

A recent study has purportedly found that "high levels of glucose in the diet of mice with cancer is linked to increased expression of mutant p53 genes," raising questions about the effect of a high-sugar diet on tumor growth. Olga Catalina Rodriguez, et al., "Dietary downregulation of mutant p53 levels via glucose restriction: Mechanisms and implications for tumor therapy," *Cell Cycle,* November 2012.

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According to a concurrent Georgetown University Medical Center (GUMC) press release, normal p53 acts as a tumor suppressor but mutant p53 acts as an oncogene, with high levels of expression "linked to cancer aggressiveness, resistance to therapy, worse outcomes and even relapse after therapy."

The five-year study apparently examined how glucose restriction (GR) affected autophagy—the degradation of dysfunctional proteins—in cultured cells and tumor growth in animal models. The first experiments not only suggested that GR helped eliminate p53 mutant proteins via autophagy, but that transgenic mice fed a low-glucose diet showed "a significant decrease in the amount of mutant p53 protein in their tissues, compared to mice fed with a high carbohydrate diet." A second set of experiments allegedly determined that in mice engineered with human lung cancer cells, a low-carbohydrate diet effectively blocked tumor growth, "but only when the tumors expressed the mutant p53 protein that could be degraded by autophagy."

"This series of studies helps establish the mechanisms of why a low carbohydrate diet slows tumor growth. Glucose restriction triggers autophagy, a critical process for clearing the cell of detrimental, potentially damaging proteins or cellular debris that can eventually destroy the entire cancer cell. We believe that this process works more efficiently when mutant p53 is not around," the lead author was quoted as saying. "Various types of dietetic interventions have been shown to affect cancer growth, but no one had ever shown, before this study, that the amount of carbohydrates could affect the expression of mutant p53."

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