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FOOD & BEVERAGE LITIGATION UPDATE

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LEGISLATION, REGULATIONS AND STANDARDS

Support Sought for Citizen Petitions on Sugary Beverages Pending Before FDA

U.S. Reps. Raúl Grijalva (D-Ariz.), John Conyers (D-Mich.) and Lucille Roybal-Allard (D-Calif.) have circulated a request to their colleagues that they join a letter to Food and Drug Administration (FDA) Commissioner Margaret Hamburg asking that the agency take action on two citizen petitions, pending before the agency for some eight years, seeking a rule that sugary beverages "carry a rotating series of health messages on their labels in order to educate consumers on the health risks of sugar overconsumption." The first petition was filed in 2005 by the Center for Science in the Public Interest. *See "Ask the FDA to Review Petitions on Sugary Beverages,"* October 22, 2013.

FDA Seeks Stay in FSMA Rulemaking Litigation

The U.S. Food and Drug Administration (FDA), currently under a district court timeline for completing the implementing regulations required under the Food Safety Modernization Act (FSMA), has filed an emergency stay pending appeal before the Ninth Circuit Court of Appeals, arguing that the 16-day government shutdown in October makes compliance "not only unsound but impossible." *Ctr. for Food Safety v. Hamburg*, No. 13-16841 (9th Cir., filed October 18, 2013). Details about the district court's refusal to amend the deadlines appear in Issue 494 of this *Update*.

FDA specifically requests relief from the November 30 deadline for the publication of a proposed rule "addressing novel requirements for preventing the intentional adulteration of food." The agency claims that compliance would "threaten[] to waste scarce agency resources and risk[] results inconsistent with the public interest by requiring FDA to spend the next several weeks completing and publishing a proposal that does not take account of pertinent information." Further claiming that the district court "failed to apply governing legal principles and overstepped its authority," FDA also seeks an expedited oral argument date for its appeal of the lower court order. A motion for stay is pending before the district court.

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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.

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FSIS Issues New Guidance on Humane Handling Practices

The U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) has **developed** new guidance, titled "FSIS Compliance Guide for a Systematic Approach to the Humane Handling of Livestock," that outlines a set of practices for livestock slaughter establishments that support the Humane Methods of Slaughter Act.

Noting that the agency has taken "significant" measures during the past few years to strengthen its ability to enforce humane handling laws at livestock slaughter facilities nationwide, FSIS Administrator Al Almanza said that the guidance will assist facilities in "minimizing excitement, discomfort and accidental injury" of animals presented for slaughter.

FSIS has also reiterated its intent to better equip employees to prevent and respond to inhumane handling incidents by delivering "more practical, situation-based humane handling training to inspectors and veterinarians who verify and enforce humane handling requirements at [] livestock slaughter establishments." The training covers various realistic animal-handling scenarios that employees may encounter, including truck unloading, stunning and post-stunning, noted an FSIS statement. *See FSIS News Release,* October 23, 2013.

EFSA Issues Feed Additives Guidance on Renewal of Authorizations

The European Food Safety Authority's (EFSA) Panel on Additives and Products or Substances Used in Animal Feed (FEEDAP) has **issued** guidance to assist applicants "in the preparation and submission of technical dossiers for the renewal of the authorization of additives for use in animal nutrition." According to EFSA, EU regulations require applicants to renew feed additive authorizations every 10 years by submitting stand-alone dossiers that take into account "the most up-to-date scientific knowledge" as well as "the current scientific/methodological approaches." Although the information included in each dossier will depend on "the additive nature, the functional group, the substance itself, the target animals, and the conditions of use," the submission must enable regulators to assess the additive in question "based on the current state of knowledge" and to determine whether the additive complies with the "fundamental principles for the renewal of authorization."

"During the last years, the FEEDAP Panel has developed several guidance documents to assist applicants in the preparation and presentation of dossiers for the authorization of feed additives," notes the FEEDAP Panel, which developed the guidance after conducting a public consultation. "These guidance documents have been prepared mainly to help applicants in the preparation of technical dossiers for the authorization of new feed additives/new uses of a feed additive (Article 4), the reevaluation of feed additives already authorized (Article 10) or the modification of terms of an authorization (Article 13). However, no guidance has been developed so far to help applicants in the preparation of dossiers for the renewal of the authorization (Article 14)."

Mexican Government Approves Junk Food Tax

Mexico's lower house has reportedly approved a new fiscal package that would, among other things, tax high-calorie foods—such as chocolate, sweets, pudding, potato chips, and ice cream. The new tax, which complements a planned charge on sugar-sweetened beverages (SSBs) discussed in Issue 497 of this *Update,* is part of a broader package proposed by President Enrique Peña and is expected to pass in the Senate by the end of the October. According to news sources, the proposed legislation would tax high-calorie foods—defined as those providing 275 calories or more per 100 grams—at 5 percent of the ticketed price and chewing gum at 16 percent. The price of soft drinks would increase by about 8 cents per liter.

The move is supported by health experts who note that Mexico has one of the world's highest rates of obesity, reportedly surpassing the United States, and who applauded higher prices for chips, candy and other foods they deem unhealthy. Opponents, many of whom liken the effort to New York City Mayor Michael Bloomberg's so-called crusade to tax or limit SSB serving sizes, claim that it will negatively affect the business community, particularly mom-and-pop stores that rely on soft drink sales for their livelihoods. Other detractors observe that the items likely subject to the new taxes are those consumed by the poorest citizens, and they will pay disproportionately. *See Los Angeles Times,* October 18, 2013; *Chicago Tribune,* October 23, 2013.

India's Supreme Court Orders Checks on Carbonated Soft Drinks

India's Supreme Court has reportedly accepted a government scientific panel's finding that the chemical additives in soft drinks— e.g., artificial sweeteners, phosphoric acid, carbon dioxide, coloring agents, benzoic acid, and caffeine—are well within safety levels and do not pose a health hazard to citizens. According to a news source, the Union government insisted that the Food Supply and Standards Act, 2006, along with its rules and regulations, constituted a "vigorous regulatory regime and [was] being implemented meticulously."

At the same time, however, the court ordered the Food and Safety Standards Authority of India to monitor and conduct regular checks of all carbonated soft drinks sold in the country, indicating that the matter relates to citizens' fundamental right to life guaranteed under the Constitution. The order was passed by a bench composed of Justices K.S. Radhakrishnan and A.K. Sikri, who were hearing a public interest litigation (PIL) seeking the establishment of an independent panel to evaluate the harmful effects of soft drinks on human health, particularly on children. That PIL also called for a "regulatory regime" to monitor chemical additives in foods in India, including soft drinks, and to make it mandatory for soft-drink manufacturers to disclose contents on labels and include warnings about potential harmful effects. *See The Hindu Business Line,* October 22, 2013; *Economic Times,* October 23, 2013.

OEHHA Requests Comments on Changes to Advisory Board Member Qualifications

California EPA's Office of Environmental Health Hazard Assessment (OEHHA) has requested comments on proposed changes to the requirements pertaining to scientific experts appointed to Proposition 65 (Prop. 65) advisory committees by the governor. The proposed revisions would specify the expertise required—completion of a doctoral degree and research experience in an area of specialization, along with demonstrated "ongoing expertise in the conduct of advanced scientific work of relevance to the identification of carcinogenic chemicals [or "that pose reproductive or developmental hazards"] using generally accepted and scientifically valid principles and methodologies." The proposal would also remove certain financial disclosure provisions now redundant given the addition of advisory committee members to OEHHA's Conflict of Interest Code. Comments are requested by December 9, 2013.

LA City Council to Consider Ban on GM Seeds and Plants

Los Angeles city council members Paul Koretz and Mitch O'Farrell have reportedly introduced a motion that would call on the city attorney to "prepare and present an ordinance which would prohibit the growth of genetically modified (GM) crops within city limits. Specifically, the ordinance should prohibit each [of] the following practices related to the growing of GM crops within city limits: the planting of GM seeds; the sale of GM seeds by vendors; the sale of any seeds that could potentially be contaminated by other genetically modified organisms (GMOs); the sale of GM fruit trees and plants." The motion notes that 52 percent of "LA County residents voted in favor of Proposition 37, which would have required labeling on raw or processed genetically modified food products offered for sale to consumers." It also raises questions about the safety of consuming GM foods and risks to the environment, including honey bee colony collapse disorder. *See Huffington Post,* October 22, 2013.

LITIGATION

Cantaloupe Growers Sue Safety-Audit Company over *Listeria* Outbreak

Jensen Farms has filed a lawsuit against the company that hired the food-safety auditor who gave the cantaloupe grower a "superior" rating during a 2011 audit not long before the grower shipped fruit allegedly contaminated with *Listeria* to a distributor that required the cantaloupe to be certified by the auditor, giving rise to a nationwide outbreak that killed 33 people and hospitalized many others. *Jensen Farms v. Primus Group, Inc.*, No. n/a (Colo. Dist. Ct., filed October 15, 2013). The farm has since ceased operation, and the Jensen brothers have entered guilty pleas to charges of adulteration of food and aiding and abetting.

According to the complaint, a Primus auditor indicated in 2010 that the cleaning technology used at the farm could potentially contaminate cantaloupe because it

used re-circulating chlorinated water. The 2011 auditor, a different individual, was told about changes to the system made in response to the 2010 concerns, and Eric Jensen allegedly explained that the new washer/dryer system relied simply on the chlorination in city water. Despite this information and without warning that the new system created a hazard or risk of contamination, the auditor allegedly gave the grower a "superior" rating. The plaintiff claims that if it had failed the July 2011 audit, "and had its cantaloupes not been 'Primus Certified,' those cantaloupes would not have been sold by Jensen and distributed by Frontera as 'Primus Certified.'"

The complaint discusses the Food and Drug Administration (FDA) report, which identified the design of the conveyer system and removal of the hydrocooler, "conditions observed by Primus during its audit and passed as safe." It also notes that an FDA Center for Food Safety & Applied Nutrition senior advisor "opined that the Primus Labs subcontractor that conducted the pre-harvest inspection of Jensen Farms, and provided a 'superior', score of 96% for the audit upon which Jensen Farms relied, was seriously deficient in its inspection and findings."

Alleging negligence, breach of contract, negligent hire, negligent misrepresentation, and unfair and deceptive trade practices, the grower seeks damages for all damages incurred, including from civil lawsuits, the criminal charges and loss of the business, or to be incurred, costs, attorney's fees, interest, and treble damages. *See The Denver Post*, October 22, 2013.

Jack Daniel's Brings Trademark Infringement Lawsuit Against Whiskey Maker

According to a news source, Jack Daniel's Properties, Inc. has filed a trademark infringement action against the companies that produce and sell Popcorn Sutton's® Tennessee white whiskey. *Jack Daniels Props., Inc. v. J&M Concepts, LLC*, No. 13-1156 (U.S. Dist. Ct., M.D. Tenn., filed October 18, 2013). The whiskey is apparently named after an Appalachian moonshiner who killed himself rather than serve a federal sentence after he was convicted of offenses relating to moonshine production. The defendants purportedly sold their product first in mason jars, but then switched to bottles that allegedly copy Jack Daniel's bottle—"a square-shaped bottle with angled shoulders that house a signature and beveled corners, and labeling with a white-on black color scheme, filigree designs, and font style reminiscent of that of the Jack Daniel's trade dress," the complaint said. Alleging willful trademark infringement, deceptive trade, fraudulent misrepresentation, and unfair competition, the company seeks injunctive relief, disgorgement of unjust profits and damages. *See Courthouse News Service*, October 22, 2013.

Consumers Challenge "Unpasteurized" and "100% Raw" Juice Labels

New York and California residents have filed a putative nationwide class action against Hain Celestial Group, Inc., alleging that its fruit and vegetable juice products, labeled as "Unpasteurized" and "100% Raw" are false and misleading because the products undergo high pressure processing, "which neutralizes the benefits of

the live enzymes, probiotics, vitamins, proteins, and nutrients that would otherwise be retained in a raw and unpasteurized juice." *Stark v. Hain Celestial Group, Inc.*, No. 13-7246 (U.S. Dist. Ct., S.D.N.Y., filed October 15, 2013). The plaintiffs claim that they purchased a variety of these juices—"Red Juice," "Gold Juice," "Green Juice," "Yellow Juice," and "White Juice"—at a price premium, relying on representations that the products were, as labeled, able to deliver the nutritional benefits associated with a raw-food diet.

According to the plaintiffs, raw juice products have, at best, a 5-day shelf-life, while the defendants' products have a 30-day shelf-life, which is possible only with processing that purportedly "may inactivate enzymes and or alter the physical properties of the food material" and "may also cause greater levels of protein denaturation and other potential detrimental changes in food quality that could affect the appearance of and texture of food, compared to the unprocessed product." The plaintiffs also describe the "Manifreshto®" panel on the products' labels; it states, in part, "Juice should never be cooked. Cooking juice kills vitamins and live enzymes. Even 'flash' pasteurized means cooked." The plaintiffs contend that the processing the defendants have employed since "at least March 2012" also affects "the structure of the components responsible for nutrition and flavor." Attached to the complaint is the plaintiffs' July 2, 2013, notice and demand for corrective action addressed to the defendants.

In addition to seeking the certification of a nationwide class, the plaintiffs ask for the certification of California and New York subclasses. Alleging violation of the Magnuson-Moss Warranty Act, breach of express warranty and the implied warranty of merchantability, unjust enrichment/common law restitution, and violations of California's Consumers Legal Remedies Act, Unfair Competition Law and False Advertising law, as well as violation of New York's General Business Law (deceptive acts or practices), the plaintiffs seek declaratory and injunctive relief, compensatory and punitive damages, interest, restitution, attorney's fees, and costs.

Putative Class Claims Kefir and Lassi Products Misbranded with "Evaporated Cane Juice"

A California resident has filed a putative nationwide class action against Lifeway Foods, Inc., alleging that many of its kefir, lassi and frozen yogurt products are misbranded under federal law and the state's Sherman Law because they list as ingredients "Evaporated Cane Juice" or "Organic Cane Juice," terms that purportedly render the products illegal. *Figy v. Lifeway Foods, Inc.*, No. 13-4828 (U.S. Dist. Ct., N.D. Cal., San Francisco Div., filed October 17, 2013). The plaintiff avers that he and the class purchased these illegal products at a premium price and have sustained economic damages under the unlawful business acts and practices law. According to the complaint, the "unlawful sale of an illegal product is the only element necessary for the UCL claim. No reliance is necessary." The plaintiff requests restitution, injunctive relief, corrective action, attorney's fees, costs, and interest.

OTHER DEVELOPMENTS

Researchers Study Effects of Framing Childhood Obesity Messages

Communications and health policy researchers report that while perceptions about government interventions to address childhood obesity are correlated with political ideology, certain approaches to—or framing of—the childhood obesity message can affect whether conservatives accept the seriousness of the problem and are willing to (i) endorse responsibility beyond the individual, and (ii) support policy action. Sarah Gollust, et al., "Framing the Consequences of Childhood Obesity to Increase Public Support for Obesity Prevention Policy," *Research & Practice*, November 2013.

Their findings were based on two Web-based public opinion surveys. The first involved testing perceptions as to a series of common messages about the consequences of childhood obesity. And from those viewed as the strongest, the researchers selected four to use in the second study to assess beliefs about responsibility for addressing childhood obesity and support for policies intended to curb its incidence, including a tax on sugar-sweetened beverages, physical activity requirements in schools, restrictions on "junk" food marketing during children's TV programming, school-based surveillance, and prohibitions on toys in fast-food kids' meals. Messages about childhood obesity adversely affecting military readiness, long-term health consequences, health-care costs, and childhood bullying "significantly increased participants' perceptions of the seriousness of childhood obesity" and brought the views of conservatives more into line with those of liberals and moderates.

Still, conservatives were generally unlikely to assign responsibility to anyone other than parents or the children themselves. According to the authors, "although the military readiness frame did increase conservatives' assignment of responsibility to external actors, there was no corresponding decrease in their attribution of responsibility to parents." The authors caution that the studies had certain limitations because they were Internet-based, and they also suggest that care be taken in developing health promotion campaigns, because some messages about excessive weight in children may increase levels of stigma or the blame "Americans hold toward this stigmatized group."

MEDIA COVERAGE

NYT Highlights Growth in GM Yeast Applications

A recent *New York Times* article focused on advances in synthetic biology has claimed that the exponential growth in genetically modified (GM) yeast applications "could revolutionize the production of some of the most sought-after flavors and fragrances," including vanilla, saffron, patchouli, and stevia. According to the October 20, 2013, article, food, cosmetic and pharmaceutical companies seeking

plant extract alternatives are increasingly turning to GM yeast and other micro-organisms "cultured in huge industrial vats" to synthesize vanillin, valencene, nootkatone, and other chemicals as byproducts of the fermentation process. Proponents of this technique have not only argued that the yeast-made flavorings are less expensive to manufacture than their plant-based counterparts, but that the end result is a natural ingredient because it originates in a living organism.

"The need for natural is a key driver," said Ahmet Baydar, director of research and development at International Flavors and Fragrances, which reportedly hopes that yeast-made vanillin "will be attractive to food companies that want to label their products all-natural but do not want to pay the higher price for natural vanilla." In addition, investors have noted that synthetic biology could help stabilize volatile markets for key food and pharmaceutical components "subject to great swings in price and availability."

But GM yeast applications have also drawn criticism from traditional extract purveyors and environmental groups like Friends of the Earth, which has already petitioned ice cream makers to reject yeast-made vanillin. "Another issue is whether foods containing such ingredients will need to be labeled made from genetically modified organisms in countries that require such labeling," reports the *Times*. "The flavor companies say they do not think so because the yeast is considered a processing aid, not a source of the food. The United States does not require labeling, though there are legislative efforts in various states to do so."

SCIENTIFIC/TECHNICAL ITEMS

Law, Medicine & Pharma Professors Call for Probiotics Oversight

Noting the difficulty of classifying products with probiotics, defined as live microorganisms that have a beneficial effect when consumed in sufficient quantities, due to their varied marketing as foods, dietary supplements, medical foods, foods for special dietary use, or drugs, University of Maryland professors in law, medicine and pharmacy suggest ways that the Food and Drug Administration (FDA) could regulate them. D.E. Hoffmann, et al., "Probiotics: Finding the Right Regulatory Balance," *Science*, October 18, 2013. For example, probiotic products with drug claims "generally should be subject to the same rigorous requirements as other products making drug claims, including adequate and well-controlled investigations." They also recommend an abbreviated approval format for "probiotic foods, dietary supplements, and dietary ingredients for which there is adequate evidence of safety in the target population; approved food additives; and substances generally recognized as safe (GRAS)."

They further recommend that FDA "establish a monograph for probiotic foods and dietary supplements that could be modeled on that adopted in Canada for natural health products or FDA's monographs for OTC [over-the-counter] drugs." In Canada, "all probiotic natural health products require premarket assessment and licensing and must be supported by evidence of strain-specific safety and efficacy under recommended conditions of use. Compliance with the monograph requirements leads to expedited review of the application for marketing the product." While the authors recognize that foods and dietary supplements do not require premarket approval in the United States, they believe that, similar to OTC monographs, FDA probiotics monographs, specific to strains believed to be GRAS and effective for a particular benefit, "would list, among other things, active ingredients, acceptable product claims, labeling, and dosage. Ideally, a monograph would reduce the number of unsubstantiated probiotic claims and thereby help consumers make more informed decisions."

Soft Drink Consumption Allegedly Linked to Global Weight Gain

A recent study has allegedly concluded that soft drink consumption "is significantly linked to overweight, obesity and diabetes worldwide, including in low- and middle-income countries." Sanjay Basu, et al., "Relationship of Soft Drink Consumption to Global Overweight, Obesity, and Diabetes: A Cross-National Analysis of 75 Countries," *American Journal of Public Health,* November 2013. Relying on soft drink industry data obtained from the EuroMonitor Passport Global Market Information Database, researchers analyzed soft drink sale records for 79 countries from 1997 to 2010 that included per capita annual purchases of both imported and domestically-produced carbonated soft drinks. They also examined age-standardized overweight prevalence data obtained from the World Health Organization's Global Database on Body Mass Index, which reflects "the best available population-representative, survey-based estimates of the percentage of adults aged 20 years and older in each country who had a [BMI] of 25 kg/m^2 of greater."

After assessing "global trends and variation in soft drink consumption" as well as "the relationship between soft drink consumption and overweight, obesity, and diabetes prevalence," the study's authors reported that "soft drink consumption increased globally from 9.5 gallons per person per year in 1997 to 11.4 gallons in 2010." Based on these results, they noted that each 1 percent increase in soft drink consumption was associated with (i) an additional 4.8 overweight adults per 100 adults, (ii) an additional 2.3 obese adults per 100 adults, and (iii) an additional 0.3 adults with diabetes per 100 adults.

"Industry analysts suggest that soft drink consumption is expected to rise by 15.7% over the next 5 years in low- and middle-income countries and 9.5% worldwide," concludes the study. "To put the magnitude of the associations we found into perspective, this projected rise in soft drink consumption would correspond to an additional 2.3 billion adults who are overweight, 1.1 billion adults who are

obese, and 192 million new cases of diabetes worldwide over the next 5 years, with at least 60% of the burden falling on low- and middle-income countries."

In a related development, a second study has purportedly found that decreased consumption of sugar-sweetened beverages (SSBs) among U.S. adults is linked to improved biomarkers for chronic disease risk. Kerrie Hert, et al., "Decreased consumption of sugar-sweetened beverages improved selected biomarkers of chronic disease risk among U.S. adults: 1999-2010," *Nutrition Research,* October 2013. Relying on data from the National Health and Nutrition Examination Survey 1999-2010, University of North Dakota researchers noted that SSB consumption decreased during this time while (i) high-density lipoprotein (HDL) levels increased, (ii) low-density lipoprotein (LDL) levels decreased, and (iii) C-reactive protein (CRP)—a measure of inflammation—decreased. They also concluded that higher intakes of SSBs were associated with lower HDL and higher CRP.

"The correlations follow trend lines. The biomarkers improved over time as soda consumption declined. The overall conclusion to be drawn from this study is that it provides further evidence that drinking less sugary soda is a good idea," New York University Nutrition Professor Marion Nestle told *FoodNavigator-USA.com* in independent comments about the study. "This present study may have its own methodologic problems but its results are consistent with many other independently funded studies pointing in the same direction." *See FoodNavigator-USA.com,* October 25, 2013.

Study Examines Prevalence of Abnormal Prion Protein Linked to vCJD

Public Health England researchers have **reported** that the abnormal prion protein (PrP) linked to variant Creutzfeldt-Jakob Disease (vCJD)—the human form of bovine spongiform encephalopathy (BSE)—is potentially more prevalent than previously thought, raising concerns about the cross-contamination risks associated with blood, blood products and surgical instruments. Noel Gill, et al., "Prevalent abnormal prion protein in human appendixes after bovine spongiform encephalopathy epizootic: large scale survey," *British Medical Journal,* October 2013. After finding that 16 out of 32,411 appendix samples obtained between 2000 and 2012 tested positive for abnormal PrP, the study's authors estimated an overall prevalence of 493 per million population, nearly double the 237 per million point estimate measured in an earlier survey of appendixes. "Unlike in clinical cases of variant CJD, no particular age group or geographic region was affected, and no susceptible genotype was identified," according to a concurrent *BMJ* editorial.

The researchers noted, however, the growing discrepancy between "the prevalence of vCJD prions observed in the exposed population and the relatively small number of patients who have developed vCJD." In particular, they suggested that "the human transmission barrier for [BSE] may be high for clinical disease but substantially lower for peripheral lymphoreticular infection," adding that infection

of the central nervous system with vCJD prions "may greatly favor the methionine homozygous genotype, peripheral lymphoreticular infection may be much less selective, or even favor the valine homozygous genotype." To help answer these questions, the study recommends the development of a human blood screening test for abnormal PrP in addition to a survey of appendixes removed before the BSE outbreak started in the mid to late 1970s.

"It is important to note the presence of the abnormal protein in the appendix does not confirm an individual will develop vCJD," explained Bath University Professor David Brown, a former government advisor on BSE, in an October 15, 2013, *Independent* article. "As the authors themselves point out, the incidence of vCJD is very small in relation to those who were exposed to BSE. Therefore this result does not indicate one in 2,000 people carry vCJD, and it could just be down to people who carry the abnormal protein in their appendix… At most the report suggests a broad range of people could be carriers of a prion disease, which was suspected anyway."

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