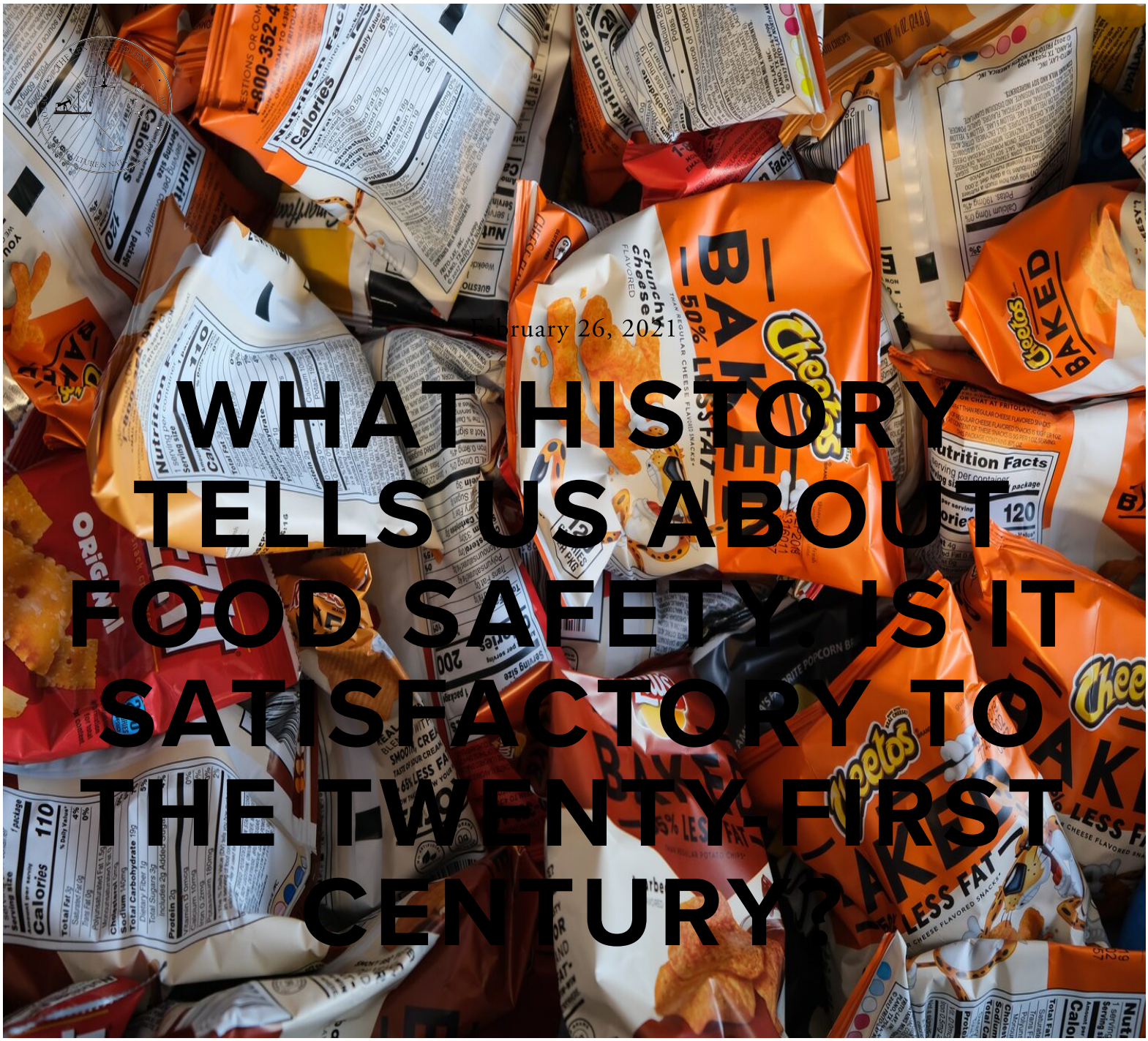


February 26, 2021

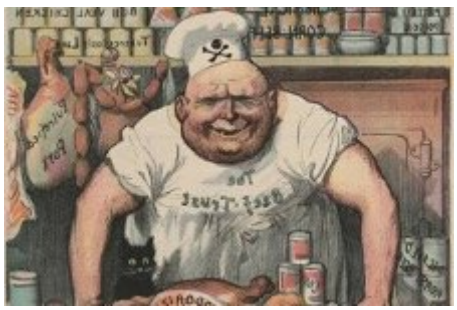
WHAT HISTORY TELLS US ABOUT FOOD SAFETY: IS IT SATISFACTORY TO THE TWENTY-FIRST CENTURY?

Impact! (/full-blog/category/Impact%21)

BY: ABIGAIL HARTGE

America has a long history centered around food safety, but interestingly, so does Kentucky. Although Dr. Harvey Wiley was born in Indiana, his mother was from Menifee County, Kentucky.[i] Wiley is more famously known as the Chief Enforcement Officer of the Pure Food and Drug Act.[ii] Wiley started as a chemist who analyzed food additives and studied how substituting additives comprised of inferior and cheaper adulterants cheated farmers and consumers.[iii] Dr. Wiley knew from his data analysis that American food manufacturers went utterly unchecked and products did not label their ingredients due to lack of government action.[iv] At the time, milk contained formaldehyde and canned foods used borax as an additive.[v] Wiley found these food ingredients had severe consequences impacting the safety and health of consumers.[vi] Desperate to implement change and prove the adverse long-term effects, he famously convinced men and women to be part of his studies.[vii] They were called the "poison squad."[viii] It was apparent to Dr. Wiley that if the public was made aware of the dangers, then the government would be left with no choice but to enact laws protecting consumers.[ix]

The Federal Food, Drug, and Cosmetic Act (FD&C Act) is the current prevailing law that is regulated by the Federal Drug Administration (FDA).[x] However, food labeling issues from long ago are compatible with the current twenty-first centuries' battles between big food businesses, government guardians, and consumer protection.[xi] This blog focuses on two lawsuits, similarly alleging the products in question cause substantial health risks, raising questions about the appropriate responses, remedies, and proper authority to regulate.



A 1906 cartoon from Puck magazine attacking the 'Beef Trust.'

For years, Ms. Donna Hayes from Jefferson County, Kentucky, used talcum powder products manufactured by Johnson & Johnson (J&J) and Colgate-Palmolive Company.[xii] Ms. Hayes regrettably passed away from mesothelioma.[xiii] Cynthia Hayes, the executrix of her estate, filed suit alleging these manufacturers' talcum powder products contain asbestos, that the asbestos caused

Ms. Hayes's death, and that J&J and Colgate were responsible for her death.[xiv] On appeal, three issues were reviewed. First, appellants argued that the jury's instructions were erroneous;[xv] second, that the trial court erred when it permitted J&J to bring forward testimony that characterized the use as "personal" from its corporate representative;[xvi] and finally, that the trial court decided to exclude evidence related to a scientific article Cynthia cited to in her allegations.[xvii] On January 29, 2021, the Kentucky Court of Appeals determined the trial court committed a reversible error concerning the trial's court decision to admit J&J's corporate representative's testimony.[xviii] The Court of Appeals also determined that the trial court did not err when it provided jury instructions or to exclude Cynthia's evidence.[xix]

Ms. Hayes's lawsuit is focused on product liability, which in Kentucky has a strict liability or negligence standard.[xx] This means that the manufacturer has a non-delegable duty to provide reasonably safe products when the product is foreseeably consumed.[xxi] The FDA currently relies on Congress to explicitly grant it the authority to regulate cosmetic ingredients and primarily relies on the producer to self-report its products' safety.[xxii] The FDA may lack the authority to order a producer to test for asbestos, despites its substantial risk, but what the FDA can do is perform independent research when its received complaints.[xxiii] The second lawsuit regards a food item that the FDA does regulate and has provided more consideration.

On December 4, 2020, the Ninth Circuit Court of Appeals concluded in *McGee v. S-L Snacks National* that the injuries alleged by McGee were insufficient and lacked standing, ultimately dismissing the case.[xxiv] McGee alleged economic injury because she believed she was purchasing a safe product when she was not.[xxv] She claimed a proximate physical injury due to the product increasing her cholesterol and insulin dysregulation,[xxvi] ultimately claiming that because of her consumption she has increased her future risk of disease. [xxvii] Although, S-L Snacks National is aware of the danger with trans fats, the company discloses this on their food labels.[xxviii] The court considered McGee's allegations and noted there is some support to her claim from the case of *Koronthaly v. L'O real, USA, Inc.*, a case in which the plaintiff won because trace amounts of lead were found in the manufacturer's product.[xxix] However, McGee did not provide medical evaluations to confirm her injuries cause by S-L Snacks National.[xxx]

J&J more recently has made headlines because of its talcum powder products, with roughly 16,000 lawsuits filed alleging that talcum powder products has a causal link to ovarian cancer and mesothelioma.[xxxi] The FDA also has made headlines because of their delayed response to the talcum powder products and lack of governmental guardianship.[xxxii] Since these newsworthy headlines, the FDA has focused its attention on testing talcum powder for asbestos and is predicted

to make its final finding determinations within the year.[xxxiii] As for trans fats, the FDA extended the deadline for producers to reformulate their product by 2021.[xxxiv] Currently, in the United States, several products from the FDA registry still contain trans fats.[xxxv]

Unfortunately, this is just two examples of why the FDA is necessary. Furthermore, it demonstrates why Dr. Wiley so fiercely advocated for food safety. From the very beginning, the food, drug, and cosmetic industry has never been a unitarian group. It resembles more of a polytheistic composition from various interest groups—all of whom encompass individuals, businesses, and politics. Reflecting historically, since America's industrialization, these issues seem to be cyclical.

There is a necessity for food, drug, and cosmetic items to be precisely labeled as lack of transparency can be dangerous. It is also the FDA's obligation to fulfill a governmental guardian role in order to protect the collective consumer. It is plausible to consider if listing health or ingredients has adequately sufficed. Labeling ingredients is a practice that predates the FDA, yet consumers are still facing vulnerabilities. While both litigants in the analyzed lawsuits were not incorrect about the injuries, what each litigant lacked was the necessary data to persuade the courts. Dr. Wiley proved consumers are safer when products have ingredient labels but further analysis questions whether or not ingredient labels are enough. With the FDA's over-reliance on cooperation of businesses to disclose information, more problems are foreseeable when disclosures are genuine yet faulty.

[i] Jack High & Clayton A. Coppin, *Wiley and the Whiskey Industry: Strategic Behavior in the Passage of the Pure Food Act*, 62 BUS. HIST. REV. 286, 292 (1988).

[ii] *Id.* at 286.

[iii] *Id.* at 294.

[iv] Tyler Moss, *The 19th-Century Swill Milk Scandal That Poisoned Infants With Whiskey Runoff*, Atlas Obscura (Nov. 27, 2017), https://www.atlasobscura.com/articles/swill-milk-scandal-new-york-city [https://perma.cc/HXZ8-A5FW].

[v] Jaya Saxena, *We Owe Food Regulation to a 19th-Century Chemist who Poisoned His Colleagues,* Eater (Jan. 28, 2020), https://www.eater.com/2020/1/28/21112258/pbs-the-poison-squad-documentary-food-regulation-history-deborah-blum-interview [https://perma.cc/S3RU-UEA3].

[vi] Deborah Blum, The Poison Squad: One Chemist's Single-Minded Crusade for Food Safety at the Turn of the Twentieth Century 19 (Penguin Press 2020).

[vii] Saxena, *supra* note v.

[viii] *Id.*

[ix] *Id.*

[x] *Id.*

[xi] *Id.*

[xii] *Hayes v. Colgate-Palmolive Co.,* No. 2019-CA-1343-MR, 2021 WL 298377, at *1 (Ky. Ct. App. Jan. 29, 2021).

[xiii] *Id.*

[xiv] *Id.*

[xv] *Id.*

[xvi] *Id.*

[xvii] *Id.*

[xviii] *Hayes*, 2021 WL 298377, at *8.

[xix] *Id.* at 2, 9.

[xx] *Id.* at 2

[xxi] *Id.*

[xxii] Lisa Girion & Chad Terhune, *FDA Bowed to Industry for Decades as Alarms were Sounded Over Talc,* Reuters (Dec. 3, 2019), https://www.reuters.com/investigates/special-report/usa-health-fda-talc/ [https://perma.cc/V5BC-YWBU].

[xxiii] Monique Richards, *FDA In Brief: FDA Releases Final Report of Talc-containing Cosmetic Products Tested for Asbestos*, FDA (Mar. 9, 2020), https://www.fda.gov/news-events/fda-brief/fda-brief-fda-releases-final-report-talc-containing-cosmetic-products-tested-asbestos [https://perma.cc/A64Z-MYEB].

[xxiv] *McGee v. S-L Snacks Nat'l*, 982 F.3d 700, 710 (9th Cir. 2020).

[xxv] *Id.* at 704.

[xxvi] *Id. at 708.*

[xxvii] *Id.* at 709.

[xxviii] *Id.* at 701.

[xxix] *Id.* at 707.

[xxx] *McGee*, 982 F.3d at 708.

[xxxi] Girion, *supra* note xxii.

[xxxii] *Id.*

[xxxiii] Richards, *supra* note xxiii.

[xxxiv] *Final Determination Regarding Partially Hydrogenated Oils (Removing Trans Fat)*, (May 18, 2018) https://www.fda.gov/food/food-additives-petitions/final-determination-regarding-partially-hydrogenated-oils-removing-trans-fat [https://perma.cc/K3TG-3M72].

[xxxv] *Food Additive Status List,* FDA (Oct. 24, 2019), https://www.fda.gov/food/food-additives-petitions/food-additive-status-list#additives [https://perma.cc/Y9U8-JSUJ].

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