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Editorial
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The FDA and Racism against North American Indians

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Editorial

In 1958, the Delaney Clause was enacted which prohibits the use of food additives known to cause cancer in people or animals. However, several additives are still used and are generally recognized as safe due to a long history of use, even though these additives may cause cancer. For instance, sodium nitrite is known to cause cancer in humans and is widely used as an additive in cured meats [1].

The FDA used the Delaney Clause to outlaw sassafras tea and other products made from *Sassafras albidum* in 1960 [2]. This was based on data that showed safrole, a constituent of sassafras root bark, causes cancer in laboratory animals [3]. There is also evidence that sassafras contains molecules that prevent cancer [4]. Sassafras was not always a food additive, but was the main or only food in several preparations, such as sassafras tea. In addition, sassafras tea and other preparations had been used since Pilgrim times and were generally recognized as safe. American Indians have used sassafras for thousands of years and taught early settlers how to use sassafras [5,6]. The FDA announced that sassafras may increase liver cancer in humans, especially in children who drank sassafras tea or root beer [2].

Several food additives are used as spices and contain safrole. This includes cinnamon, nutmeg, cloves, cocoa, mace and black pepper [7]. These spices and flavoring agents are generally recognized as safe.

Of course banning sassafras devastated the market for root beer and other sassafras containing foods. Many companies found other products to make root beer from. Safrole free sassafras products were also produced and are still sold today. The FDA continues to enforce the ban on sassafras products that contain safrole. There is also some concern that illicit drugs may be synthesized from safrole.

As of 2021, there is no evidence that sassafras tea or other sassafras based foods cause cancer in humans. Since the FDA banned sassafras tea, the incidence of liver cancer has increased steadily [8]. If sassafras were an important human liver carcinogen, banning sassafras should have decreased the incidence of liver cancer. The incidence of liver cancer has decreased recently due to the introduction of hepatitis C treatments [8].

Sassafras tea was banned which had a major impact on the health food industry. In 1962, the Kefauver Harris amendments were enacted requiring clinical trials to prove efficacy and safety of all drugs. Based on this law, the FDA banned all plant medicines that were derived from North American Indian traditions. These medicines had not been tested in clinical trials, despite a long history of successful clinical use for some of these medicines such as yerba santa (*Eriodictyon californicum*) and gum plant (*Grindelia camporum*) [9]. This had a major impact on Pharmacies since many Pharmacies had previously sold several products based on American Indian traditions. One of the few plant medicines that continued to be FDA approved was digitalis from the European plants *Digitalis lanata* and *Digitalis purpurea*. These plants had been used in the US since the 1600s and were well known to be toxic. Digitalis gave rise to the saying "If the disease does not kill you, the Doctor will." The FDA continues to ban North American Indian plant medicines, except elder berry and Echinacea that were tested in clinical trials in Europe. This is de facto racism against North American Indian traditions.

Our country is being devastated by the over use of pain medicines. About 70,000 people die yearly from opioids and 55,000 from non-steroidal anti-inflammatory agents [10,11]. More effective and less toxic agents are available that come from North American Indian traditions [12]. Pain medicines that cure chronic pain are also available from North American Indian traditions [13]. These medicines could be tested in clinical trials and have the potential to save the lives of 125,000 or more people yearly. The FDA has declined applications to do clinical trials with two such medicines

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citing potential safety issues as the basis for refusal, despite a long history of safe and effective use of these medicines [9]. The racist policies of the FDA are resulting in the deaths of about 125,000 people yearly.

References

1. Xie T, Zhao Y, Chen L, Zhu Z, Hu Y, Yuan Y. Long-term exposure to sodium nitrite and risk of esophageal carcinoma: A cohort study for 30 years. Dis Esophagus. 2011;24(1):30-2.
2. US Food Unit Bars Safrol Flavoring. New York Times, December 2, 1960.
3. Segelman A, Segelman F, Karliner J, Sofia D. Sassafras and herb tea potential health hazards. JAMA. 1976;236(5):477.
4. Lunz K, Stappen I. Back to the roots an overview of the chemical composition and bioactivity of selected root essential oils. Molecules. 2021;26(11):3155.
5. Moerman D. Native American Medicinal Plants an Ethnobotanical Dictionary. Portland, Timber Press. 2009.
6. Perlmutter J, Cogan R, Wiseman M. Treatment of atopic dermatitis, dermatophytes, and syphilis by Indigenous peoples prior to 1850. J Cutan Med Surg. 2021.
7. Heikes D. SFE with GC and MS determination of safrole and related alkyl benzenes in sassafras teas. J Chromatogr Sci. 1994;32(7):253-8.
8. Petrick J, Florio A, Loomba R, McGlynn K. Have incidence rates of liver cancer peaked in the United States? Cancer. 2020;126(13):3151-5.
9. Adams J, Wong M, Villasenor E. Healing with medicinal plants of the west cultural and scientific basis for their use Fourth edition. La Crescenta, Abedus Press. 2020.
10. Adams J. Chronic pain can it be cured? J Pharm Drug Devel. 2017;4:105-8.
11. Drug Overdose Deaths in the U.S. Up 30% in 2020.
12. Adams J, Wang X. Control of pain with topical plant medicines. Asian Pacific J Tropical Biomed. 2015;5(4):268-73.
13. Adams J. Chronic pain two cures. OBM Integ Comp Med. 2018;3(4).