RED FLAGS FOR RED 3: HOW THE OVERTURN OF *CHEVRON* WILL SHAPE AMERICA'S HEALTH

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INTRODUCTION

Synthetic food dye Red No. 3 is found in most of America's comfort food: cookies, candy, yogurts, frozen desserts,[1] and even vegetarian meats.[2] Although there is widespread use of FD&C Red No. 3 in food, most people do not realize this synthetic coloring is derived from petrochemicals[3]—that is, the same crude oil or natural gas used for fuel.[4] For over fifty years, the Food and Drug Administration (FDA) has accepted widespread use of various artificial food colorings, including FD&C Red No. 3,[5] making them among the most common ingredients in the foods and beverages Americans consume daily.[6]

FD&C Red No. 3 was first banned from cosmetics in 1990 and was approved for continued use in foods and ingestible drugs.[7] Despite well-established research linking FD&C Red No. 3 to cancer and a wealth of health issues, only recently has there been regulatory change. In October 2022, the Center for Science in the Public Interest (CSPI) petitioned the FDA to completely ban FD&C Red No. 3, arguing that its use violated the Federal Food, Drug, and Cosmetic Act (FDCA). Section 409(c)(1)(A) of the FDCA contains the Delaney Clause, which forbids the approval and use of food and color additives shown to cause cancer in humans or

* I would first like to thank God, for His blessings and guidance throughout this writing journey. Thank you to Professor Zoldan, Natalie Sullivan Baker, Allison Gilbert, and Breanna Norman for their support and advice throughout the writing process. Finally, thank you to my amazing family and friends for their patience and encouragement.

1. *FD&C Red No. 3*, U.S. FOOD & DRUG ADMIN. (Jan. 15, 2025), https://www.fda.gov/industry/color-additives/fdc-red-no-3.

2. *MorningStar Farms® Veggie Bacon Strips*, MORNINGSTAR FARMS, https://smartlabel.kelloggs.com/Product/Index/00028989971951#ingredients (last visited Mar. 10, 2026).

3. Aristo Vojdani & Charlene Vojdani, *Immune Reactivity to Food Coloring*, 21 ALT. THERAPIES IN HEALTH & MED. 52, 52 (2015).

4. Sarah Kobylewski & Michael F. Jacobson, *Toxicology of Food Dyes*, 18 INT'L J. OCCUPATIONAL & ENV'T HEALTH 220, 220 (2012).

5. *FD&C Red No. 3*, *supra* note 1.

6. Laura J. Stevens et al., *Amounts of Artificial Food Dyes and Added Sugars in Foods and Sweets Commonly Consumed by Children*, 54 CLINICAL PEDIATRICS 309, 309 (2015).

7. Adrienne Crezo, *Red 3: FDA Finally Bans Cancer-Causing Food Dye*, CTR. FOR SCI. IN THE PUB. INT. (Jan 15, 2025), https://www.cspinet.org/cspi-news/red-3-fda-finally-bans-cancer-causing-food-dye.

animals.[8] This provision has successfully banned synthetic food flavoring additives such as benzophenone, ethyl acrylate,[9] and the synthetic packaging material, styrene.[10] Despite studies linking FD&C Red No. 3 to cancer in male rats, the FDA continually upheld its use in food and ingestible pharmaceuticals.

At last, on January 16, 2025, the FDA put out an official order revoking FD&C Red No. 3 from food and ingestible drugs, to be in full effect in January 2027.[11] At first glance, this appears to be a step towards improving the health of America; however, the recent Supreme Court ruling in *Loper Bright Enterprise v. Raimondo* may potentially lead to a different outcome. The FDA Order implicates food manufacturing companies that have profited from selling products replete with FD&C Red No. 3.[12] These companies are likely to challenge the order, arguing for different interpretations of the Delaney Clause, particularly regarding whether it carves out an exception for color additives that only pose a minimal risk of cancer. Under *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*,[13] courts gave deference to administrative agencies when interpreting the meaning of an ambiguous statute.[14] However, in 2024 the U.S. Supreme Court overturned *Chevron*, holding that statutory interpretation belonged to the judiciary, not administrative agencies.[15] Accordingly, challenges to the FD&C Red. No. 3 revocation will involve a court's own statutory interpretation of the Delaney Clause, despite its unfamiliarity with the impact of synthetic dyes on human health.

The shift from agency to judicial statutory interpretation warrants a discussion on its possible impact on public health. Section I of this Comment first discusses the widespread use of FD&C Red No. 3 in food and the FDA's recent order repealing its use. Next, Section II reviews how a court under *Chevron* has interpreted the Delaney Clause. Section III explores how the judiciary may employ various methods of statutory interpretation in construing and applying the Delaney Clause. Finally, Section IV briefly discusses Trump's recent regulatory freeze and its potential impact on the FDA's current and future repeals.

I. BACKGROUND

The Standard American Diet (SAD) is characterized by calorically dense foods that are packed with sugar, sodium, saturated fats, and a plethora of food

8. 21 U.S.C. § 348(c)(3)(A) (1994); NAT'L RSCH. COUNCIL, *The Delaney Clause and Other Regulatory Actions*, *in* DIET, NUTRITION, & CANCER 219, 219 (1982).

9. Food Additive Regulations; Synthetic Flavoring Agents and Adjuvants, 83 Fed. Reg. 50490, 50502 (Oct. 9, 2018) (to be codified at 21 C.F.R. pts. 172, 177) [hereinafter Food Additive Regulations]; 21 C.F.R. § 177.2600 (2025).

10. Food Additive Regulations, *supra* note 9; 21 C.F.R. § 172.515.

11. Request to Revoke Color Additive Listing for Use of FD&C Red No. 3 in Food and Ingested Drugs, 90 Fed. Reg. 4628, 4633 (Jan. 16, 2025) (to be codified at 21 C.F.R. pt. 74) [hereinafter Request to Revoke]; 21 C.F.R. § 74.303.

12. 21 C.F.R. § 74.

13. Chevron U.S.A., Inc. v. Nat. Res. Def. Council, Inc., 467 U.S. 837, 843-44 (1984).

14. *Id.* at 866.

15. Loper Bright Enters. v. Raimondo, 603 U.S. 369, 412-13 (2024).

additives.[16] It is of no surprise that America is deemed one of the unhealthiest countries in the world.[17] The diet and lifestyle Americans follow have fueled the obesity epidemic and exacerbated the risk of early-onset cancer.[18] In fact, the American Cancer Society estimates that in 2024, over two million new cancer cases will be diagnosed in the United States, and over half a million lives will be lost.[19] Importantly, approximately 18% of preventable cancers are attributable to the cumulative effect of excessive body fat, unhealthy diets, lack of physical activity, and alcohol consumption.[20] While this may sound discouraging, about 840,000 cancer cases are preventable and controllable with only slight changes in food ingredients.[21]

Whilst Americans have been trusting the food industry to produce real and nourishing foods, companies have exploited this naivety by inconspicuously adding complex and unhealthy ingredients into foods. Although food packaging falls beyond the scope of this Comment, it is important to recognize that many people struggle reading food labels and ascertaining whether a food product is nutritious or completely detrimental to their health. This is aggravated by companies' use of chemicals that the general public has never heard of—i.e., emulsifiers listed as ethoxylated mono- and diglycerides or xanthan gum. The focus here is not on how a food label should be displayed, but rather what ingredients it should contain. The FDA is charged with taking regulatory action and barring the use of toxic ingredients in food. Given the alarming health statistics our country faces, this could be the key to reducing cancer rates.

A. Color Additives and FD&C Red No. 3

Imagine eating a bowl of grey Lucky Charms cereal or beige Skittles—not exactly appetizing. Color additives, which are dyes that impart vibrant hues, are used to transform these processed foods from bland and colorless to vibrant and visually appealing.[22] As such, color additives can be found in most candy, dressings, condiments, drinks, and snacks.[23] Color additives can either be naturally derived or synthetically made. Natural sources include paprika and saffron (red), turmeric (yellow/orange), and copper sulfate (blue),[24] while artificial additives "are

16. David Grotto & Elisa Zied, *The Standard American Diet and Its Relationship to the Health Status of Americans*, 25 NUTRITION CLINICAL PRAC. 603, 603 (2010).

17. *See id.* at 610.

18. *Cancer Facts & Figures 2024*, AM. CANCER SOC'Y 2 (2024), https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2024/2024-cancer-facts-and-figures-acs.pdf.

19. *Id.* at 1.

20. *Id.*

21. *Id.*

22. Ameena Batada & Michael F. Jacobson, *Prevalence of Artificial Food Colors in Grocery Store Products Marketed to Children*, 55 CLINICAL PEDIATRICS 1113, 1116 (2016).

23. *Id.*

24. *Color Additives in Food*, U.S. FOOD & DRUG ADMIN. (July 6, 2023), https://www.fda.gov/food/color-additives-information-consumers/color-additives-foods.

synthesized mainly from raw materials obtained from petroleum."[25] Foods that contain synthetic coloring have increased by 500%,[26] the most commonly used being FD&C Red Nos. 3 and 40, Blue 1, Yellow 5, and Yellow 6.[27]

The use of color additives is valuable to both consumers and producers. As consumers, color is the most important sensory cue in setting a person's expectations of taste and flavor.[28] As for the food industry, manufacturing companies capitalize on the use of artificial color additives by attracting consumers to their unnaturally bright, intense, and aesthetically appealing products.[29] As alluded to throughout this Comment, this tactical choice has led to damaging health consequences.

Erythrosine B, otherwise known as FD&C Red No. 3, was one of the most commonly used synthetic color additive, appearing in thousands of products sold in the United States.[30] It was approved for use in "junk foods" such as cereals, candy, flavored drinks, and baked goods,[31] as well as "healthy" products like baby food, dried fruit, and meal replacements.[32] Essentially, if the processed food is red, it most likely contains FD&C Red No. 3. The consumption of such a delicious color additive has come with a detrimental cost to human health.

The use of color additives is controlled and approved by the FDA.[33] Generally, the FDA "evaluates safety data to ensure that a color additive is safe for its intended purposes."[34] Unlike natural color additives, synthetic ones must be batch certified before they are approved for use.[35] This is a process in which the FDA evaluates the artificial dye's appearance, looks for the presence of any impurities,[36] and verifies that the dye conforms with the specifications listed in the regulation for that dye.[37] FD&C Red No. 3 first appeared in the Food Inspection

25. *Color Additives History*, U.S. FOOD & DRUG ADMIN. (Nov. 3, 2017), https://www.fda.gov/industry/color-additives/color-additives-history.

26. Vojdani & Vojdani, *supra* note 3, at 52.

27. Batada & Jacobson, *supra* note 22, at 1113.

28. Charles Spence, *On the Psychological Impact of Food Colour* 4 FLAVOUR 1, 1 (2015).

29. Maria Manuela Silva et al., *Food Colour Additives: A Synoptical Overview on Their Chemical Properties, Applications in Food Products, and Health Side Effects*, 11 FOODS 1, 18 (2022).

30. *See FoodData Central: Food Search*, U.S. DEP'T OF AGRIC., https://fdc.nal.usda.gov/food-search?type=Branded&query=&marketCountries=United%20States,Canada,New%20Zealand (last visited Mar. 10, 2026) (although search results vary depending on whether "Red. No. 3," "Erythrosine B," or "FD&C Red. No. 3" is searched, each query yields thousands of products. I believe this inconsistency reflects the lack of transparency with which companies disclose ingredients.).

31. *Is Red Dye 40 Safe?*, CLEVELAND CLINIC (Mar. 8, 2023), https://health.clevelandclinic.org/red-dye-40.

32. Diana L. Doell et al., *Exposure Estimate for FD&C Colour Additives for the US Population*, 33 FOOD ADDITIVES & CONTAMINANTS: PART A 782, 786 (May 2016).

33. *Color Additives in Food*, *supra* note 24.

34. *How Safe Are Color Additives?*, U.S. FOOD & DRUG ADMIN. (July 13, 2023), https://www.fda.gov/consumers/consumer-updates/how-safe-are-color-additives.

35. *Color Additives in Food*, *supra* note 24.

36. *Color Certification FAQs*, U.S. FOOD & DRUG ADMIN. (Mar. 2, 2022), https://www.fda.gov/industry/color-certification/color-certification-faqs.

37. *Id.*

Decision in 1907[38] and was permanently listed in 1969 as approved for use in food, drugs, and cosmetics.[39]

B. Revocation of FD&C Red No. 3

Section 21 U.S.C. § 348 is the body of law that governs color additives in food. The Delaney Clause, also known as the cancer clause, reads:

> **A color additive (i) shall be deemed unsafe, and shall not be listed**, for any use which will or may result in ingestion of all or part of such additive, **if the additive is found by the Secretary to induce cancer when ingested by man or animal**, or if it is found by the Secretary, after tests which are appropriate for the evaluation of the safety of additives for use in food, to induce cancer in man or animal, and
>
> (ii) shall be deemed unsafe, and shall not be listed, for any use which will not result in ingestion of any part of such additive, if, after tests which are appropriate for the evaluation of the safety of additives for such use, or after other relevant exposure of man or animal to such additive, it is found by the Secretary to induce cancer in man or animal.[40]

Thus, approval and use of any color additive is subject to the Delaney Clause. The meaning and stringent application of this provision have been the subject of much controversy.[41] Nonetheless, the FDA's understanding is if the Secretary finds it to induce cancer in humans or animals, the color additive is determined to be unsafe for consumption.[42] The currently approved FD&C synthetic color additives include Red 40, Citrus Red 2, Yellow 5 and Yellow 6, Blue 1 and Blue 2, Green 3, and Orange B.[43]

Another way a color additive can be repealed or added is by submitting a petition. Under 21 C.F.R. § 71, a person interested in the amendment of a current regulation may submit a petition accompanied by supporting data.[44] The burden is on the petitioner to show that the additive is safe, which the FDA will evaluate and

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38. *See Regulatory Status of Color Additives: FD&C Red No. 3*, U.S. FOOD AND DRUG ADMIN. (Feb. 6, 2026), https://hfpappexternal.fda.gov/scripts/fdcc/index.cfm?set=ColorAdditives&id=FDCRed3&sort=Sort_Unique_ID&order=ASC&startrow=1&type=basic&search=red%20no%2E%203.

39. 21 C.F.R §§ 74.303, 74.1303 (1969).

40. 21 U.S.C. § 379e(b)(5)(B) (1994) (emphasis added).

41. *See, e.g.*, Bruce S. Wilson, REGULATING PESTICIDES IN FOOD: THE DELANEY PARADOX (1987); Mansi Krishan et al., *A Regulatory Relic: After 60 Years of Research on Cancer Risk, the Delaney Clause Continues to Keep Us in the Past*, 433 TOXICOLOGY AND APPLIED PHARMACOLOGY 1, 5 (2021) (discussing the advances in technology which render the Delaney Clause outdated and in need of reconsideration).

42. *Id.*

43. *Color Additives Questions and Answers for Consumers*, U.S. FOOD & DRUG ADMIN. (Dec. 14, 2023), https://www.fda.gov/food/color-additives-information-consumers/color-additives-questions-and-answers-consumers.

44. 21 C.F.R. § 71.1.

either approve or deny.[45] The FDA evaluates this data, and if approved by its scientists, it will take appropriate action.[46]

In the late 1980s, studies emerged finding that high doses of this synthetic dye increased thyroid neoplasia, thereby causing thyroid cancer in male rats.[47] As a result, in 1990 the FDA terminated the listing of FD&C Red No. 3 in cosmetics and externally or topically applied drugs, but its use continued in food and ingestible drugs.[48] In 1992, scientists tried to ban the use of FD&C Red No. 3 in food and ingestible drugs based on the same studies but failed.[49] As such, the food and drug industry continued adding FD&C Red No. 3 color to food and ingestible drugs.

In October 2022, the Center for Science in the Public Interest petitioned the FDA to completely ban the use of FD&C Red No. 3.[50] In its petition, the CSPI argued that scientific data and prior FDA findings concluding that FD&C Red No. 3 causes cancer and mandated the revocation of this synthetic color additive from use in food and ingestible drugs.[51] CSPI relied on the Delaney Clause as well as case law interpreting the Delaney Clause to reach its conclusion that FD&C Red No. 3 is not safe for consumption.[52]

In reviewing the petition and accompanying comments, the FDA explained that its reason for banning FD&C Red No. 3 stems from two 1987 studies showing that the synthetic dye induces cancer in male rats.[53] Two toxicity/carcinogenetic studies were performed in 1987: one administering 0.0% to 1.0% dietary level of FD&C Red No. 3, named "original study," and another administering 0.0% and 4.0% dietary FD&C Red No. 3, named the "high-dose study."[54] The study discusses that when the rats were given doses of Red No. 3 *in utero*, or in the womb, there were no effects on the rats' health.[55] However, when administering a 4.0% dietary level of Red No. 3 to male rats, there was a statistically significant increase in the prevalence of thyroid follicular cell adenoma, otherwise known as a tumor in the thyroid gland.[56]

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45. *Id.*

46. *Id.*

47. J. F. Borzelleca et al., *Lifetime Toxicity/Carcinogenicity Study of FD&C Red No. 3 (Erythrosine) in Rats*, 25 FOOD CHEM. TOXICOLOGY 723, 726 (1987).

48. Termination of Provisional Listings of FD&C Red No. 3 for Use in Cosmetics and Externally Applied Drugs and of Lakes of FD&C Red No. 3 for All Uses, 55 Fed. Reg. 3516, 3518 (Feb. 1, 1990) (to be codified at 21 C.F.R. pts. 1, 2).

49. Revocation of the Permanent Listings for Use of FD&C Red. No. 3 in Food and Ingested Drugs, 57 Fed. Reg. 16742, 16742 (Apr. 27, 1992).

50. Petition to Revoke Color Additive Listing for Use of FD&C Red No. 3 in Food and Ingested Drugs 1 (Dep't of Health and Hum. Servs. Food & Drug Admin. Jan. 16, 2025), https://www.cspi.org/sites/default/files/2022-10/Red%203%20petition_24%20Oct%202022_FINAL%20%281%29.pdf [hereinafter CSPI Petition].

51. *Id.*

52. *Id.* at 2.

53. Request to Revoke, *supra* note 11, at 4630-32

54. Borzelleca et al., *supra* note 47, at 725.

55. *Id.* at 726.

56. *Id.*

The FDA assessed this data and noted that while the studies showed FD&C Red No. 3 to induce thyroid tumors in male rats, no such effect is likely for humans.[57] Nonetheless, the FDA was persuaded to repeal the use of FD&C Red No. 3 in food, concluding that "[d]espite its limited relevance to humans, the cumulative data and information show that high exposure to FD&C Red No. 3 induces thyroid tumors in male rats."[58] It is important to highlight the FDA's decision-making process in repealing FD&C Red No. 3. Despite its very limited risk to humans, the FDA cited back to the Delaney Clause which explicitly states that any color additive that is found "to induce cancer when ingested by man or animal" must be deemed unsafe and must not be listed for use.[59] Thus, compliance with the Delaney Clause mandated the repeal of FD&C Red No. 3.

As such, on January 16, 2025, the FDA promulgated an order "revoking the authorized uses in food and ingested drugs of FD&C Red No. 3 in the color additives regulation."[60] Beginning on January 15, 2027, FD&C Red No. 3 will no longer be listed as an approved synthetic color additive.[61]

II. INTERPRETATION OF THE DELANEY CLAUSE UNDER THE *CHEVRON* REGIME

When cases or controversies arise involving the interpretation and application of administrative statutes, the central question is which branch of government is best equipped to make that determination. This creates a tension between the judiciary's role in applying the law and the administrative agency's expertise in implementing it. In the 1984 landmark decision *Chevron U.S.A., Inc. v. Natural Resources Defense Council*, *Inc.*, the Supreme Court deferred to the agency's interpretation of statutes, recognizing its specialized knowledge and expertise in the field.[62] As a result of this trans-formative decision, courts were directed to refrain from imposing their own construction when faced with ambiguous statutes.[63] Thus, although the judiciary is typically tasked with legal interpretation, courts would have to set that aside and follow the agency's interpretation and apply it to the case at hand. This section examines the interpretation of the Delaney Clause within the framework of *Chevron's* two-step process.

A. Chevron*: The Landmark Decision*

In *Chevron U.S.A., Inc. v. Natural Resources Defense Council*, *Inc.,* the U.S. Supreme Court laid out a two-step process for evaluating statutes and granted substantial deference to the agency with expertise in the subject matter.[64] First, a

57. Request to Revoke, *supra* note 11, at 4631.
58. *Id.*
59. *Id.* at 4630.
60. *Id.* at 4628.
61. *Id.*
62. Chevron U.S.A., Inc. v. Nat. Res. Def. Council, Inc., 467 U.S. 837, 865-66 (1984).
63. *Id.*
64. *Id.* at 842.

court should address whether the statute at issue is clear or ambiguous.[65] If it is clear, meaning that "Congress has directly spoken to the precise question at issue," then a court should apply the statute as written and conclude its analysis.[66] However, if the statute is ambiguous, or if Congress has not directly spoken to the particular issue, then a court ought to defer to the administrative agency's "permissible construction of the statute."[67] The Supreme Court acknowledged the distinct roles of each federal branch, but also recognized that the judiciary lacks the proficiency and experience of the federal agency tasked with enforcing the statute.[68] As such, the Court delegated great authority to administrative agencies in interpreting the meaning of a statute, emphasizing that this meaning should be given great weight.[69]

B. Delaney Clause Under Chevron

Under the *Chevron* legal standard, the FDA had the flexibility of interpreting statutes when Congressional intent was not clear.[70] If the FDA's application was challenged in a judicial proceeding, a court would apply the *Chevron* two-step process.[71] Under this framework, the first question to ask is whether Congress's intent is clear or ambiguous.[72] Although the words of the Delaney Clause explicitly state that a color additive is deemed unsafe and ought not be listed "if [] found by the Secretary to induce cancer when ingested by man or animal,"[73] the current list of approved color additives does not necessarily reflect this intent.

For example, FD&C Red No. 40 has raised public concern for years for its detrimental health effects but is still deemed safe and is approved for use. While it is estimated that ninety-four percent of Americans over the age of two consume Red 40,[74] this color additive has not been evaluated for potential health risks since 1971[75] and is listed as an approved synthetic color additive.[76] The FDA continues to hold that Red 40 "may be safely used for coloring foods (including dietary supplements)" subject to the FDA's specifications and restrictions of use.[77]

Thus, the most prominent question that the Delaney Clause raises is whether there is a so-called "*de minimis* exception" to the cancer rule. In other words, if a color additive is shown to only have a slight probability of increasing the risk of

65. *Id.* at 842-43.
66. *Id.*
67. *Id.* at 843.
68. *Id.* at 865.
69. *Id.* at 844.
70. *Id.* at 843.
71. *Id.* at 842.
72. *Id.*
73. 21 U.S.C. § 379e(b)(5)(B) (1994).
74. Doell et al., *supra* note 32, at 790.
75. Brian Ronholm, *California Leads the Nation with First Ban on Six Harmful Food Dyes in School Food*, CONSUMER REPS. (Sep. 28, 2024), https://advocacy.consumerreports.org/press_release/california-leads-the-nation-with-first-ban-on-six-harmful-food-dyes-in-school-food/.
76. *Regulatory Status of Color Additives: FD&C Red No. 40*, *supra* note 38.
77. 21 C.F.R. § 74.340(c) (1996).

cancer in either man or animal, must the color additive be banned? Or, in the alternative, can the color additive still be deemed safe for consumption since the risk is almost negligible? The following two cases lay out the court's decision-making process and reasoning.

1. Public Citizen v. Young

In *Public Citizen v. Young*, the United States Court of Appeals for the District of Columbia Circuit held that the Delaney Clause was not subject to an implicit de minimis exception.[78] This case arose as a challenge to the FDA's approval of two synthetic color additives—FD&C Orange No. 17 and Red No. 19—despite evidence showing an increased the risk of cancer in laboratory animals.[79]

The Public Citizen Health Research Group argued the FDA did not have the authority to approve these color additives given that the Delaney Clause was a zero-tolerance policy and thus not subject to a de minimis exception.[80] On the other hand, FDA Commissioner Dr. Frank Young contended that the risk of cancer posed by Orange 17 and Red 19 were so trivial: Orange No. 17 had a risk of just one in nineteen billion and Red No. 19 had a risk of one in nine million.[81] The basis of this argument was that the Delaney Clause did have a de minimis exception permitting the FDA to overlook prevalences of cancer if they were negligible. Thus, although the FDA review panel did in fact find that these color additives "induce[] cancer when tested in laboratory animals," this evidence was so trivial and "the lifetime cancer risks of the substances extremely small."[82] This clearly demonstrates how, in interpreting the Delaney Clause, the FDA carved out an exception for risks of cancer that are so trivial and unlikely to cause lifetime risks.

The issue presented before the Court of Appeals was whether the FDA had the inherent authority to effectuate a de minimis exception.[83] Under *Chevron*, the court's first step in answering this question was to determine whether congressional intent was clear or ambiguous.[84] After evaluating the clause's legislative history, the court stated that legislative intent was clear: there is no de minimis exception, and "the [Delaney] clause was to operate automatically once the FDA squeezed the scientific trigger."[85] As such, there was no reason for the court to defer to the FDA's own construction of the statute. Rather, the court looked to the plain language of the statute. At the outset, the court stated, "[t]he natural—almost inescapable—reading of this language is that if the Secretary finds the additive to 'induce' cancer in animals, he must deny listing."[86] The court explained that once it is confirmed that a color additive is carcinogenic, the FDA

78. Pub. Citizen v. Young, 831 F.2d 1108, 1122 (D.C. Cir. 1987).
79. *Id.* at 1109.
80. *Id.* at 1109-10.
81. *Id.* at 1111.
82. *Id.* at 1110-11.
83. *Id.* at 1111.
84. Chevron U.S.A., Inc. v. Nat. Res. Def. Council, Inc., 467 U.S. 837, 842-43 (1984).
85. *Pub. Citizen*, 831 F.2d at 1117.
86. *Id.* at 1112.

has the obligation to disapprove of it.[87] Accordingly, the court found that "trivial" risks of cancer to laboratory animals associated with both FD&C Orange No. 17 and Red No. 19 were enough to trigger the Delaney Clause and ban their use in food.[88]

2. Les v. Reilly

In *Les v. Reilly*, the Court of Appeals for the Ninth Circuit similarly held that there was no exception to the Delaney Clause, and congressional intent clearly reflected this.[89] The issue in this case involved food pesticides rather than synthetic color additives. In *Les*, evidence showed that food pesticides benomyl, mancozeb, phosmet, and trifluralin induced cancer.[90] This did not stop the Environmental Protection Agency (EPA) from approving them.[91] The EPA interpreted the Delaney Clause as "permit[ting] concentrations of cancer-causing pesticide residues greater than that tolerated for raw foods so long as the particular substances posed only a 'de minimis' risk of actually causing cancer."[92] The issue before the court was whether the Delaney Clause did indeed carve out an exception for such minimal risks of cancer.[93] The Ninth Circuit Court disagreed with the EPA.[94] Like the Court in *Public Citizen*, the Court turned to legislative history and found that Congress had clearly intended such a rigid, zero-tolerance clause.[95] Thus, "once the finding of carcinogenicity is made, the EPA has no discretion."[96] Concluding that the language of the provision was "clear and mandatory,"[97] the EPA could not refuse to ban known carcinogens.[98] Since congressional intent was not ambiguous, the Ninth Circuit did not turn to the EPA's construction of the statute.

3. Synthesis

The courts in both *Public Citizen v. Young* and *Les v. Reilly* ended their analysis after addressing the first question of the *Chevron* framework. Since congressional intent was clear—the Delaney Clause was not subject to a de minimis exception—the courts had no need to subsequently defer to the administrative agency's construction of the clause. And, if the agency's construction was contrary to legislative intent, it was deemed void. However, if a court determined that Congress had not spoken directly to the de minimis issue,

87. *Id.* at 1121-22.
88. *Id.* at 1122.
89. Les v. Reilly, 968 F.2d 985, 986, 990 (9th Cir. 1992).
90. *Id.* at 987.
91. *Id.* at 988.
92. *Id.*
93. *Id.*
94. *Id.* at 986.
95. *Id.* at 989-90.
96. *Id.* at 988.
97. *Id.*
98. *Id.*

the court would then have deferred to the agency's construction of the statute. In the cases above, this would have permitted the FDA's approval of FD&C Orange No. 17 and Red 19, and the EPA's use of carcinogenic pesticides in food. As a result, these administrative agencies would have broad flexibility in applying the Delaney Clause without much oversight from the court.

C. Overturn of Chevron*:* Loper Bright Enterprises v. Raimondo

In January 2024, the U.S. Supreme Court overturned *Chevron* in the seminal case *Loper Bright Enterprises v. Raimondo*.[99] The Court rejected *Chevron*'s two-step framework, reaffirming that interpretation of the law is "the proper and peculiar province of the courts," rather than that of administrative agencies.[100] At issue before the Supreme Court was whether the National Marine Fisheries Service (NMFS) had the authority to require fishermen to pay for the costs of at-sea observers under the Magnuson-Stevens Act.[101] The Court addressed the forty-year-old deference doctrine under *Chevron* and overruled it, concluding that it was contrary to the Framers' intent and the fundamental principle of separation of powers.[102]

The Court articulated that the role of the Administrative Procedure Act (APA) was a "check upon administrators whose zeal might otherwise have carried them to excesses not contemplated in legislation creating their offices."[103] As such, moving forward, courts are to use their own judgment in deciding "all relevant questions of the law," whether clear or ambiguous, leaving no deference to an agency's interpretation of the statute.[104] No exception should be made merely because courts are confronted with statutory ambiguity arising from an executive agency. Moreover, the Court rejected the perception that agencies are equipped with more specialized expertise than the courts.[105] Courts, too, have this expertise. Thus, under current law, if congressional intent behind a statute is ambiguous, the judiciary will have to apply its own statutory construction.[106]

III. LEGAL ANALYSIS: INTERPRETATION OF THE DELANEY CLAUSE AFTER *LOPER BRIGHT ENTERPRISES*

With the overturn of *Chevron*, rather than deferring to the FDA for its interpretation of the Delaney Clause, courts will now use their independent judgment using various tools of statutory interpretation. This raises concern as to whether the judiciary is better equipped to be in charge of the American health and

99. Loper Bright Enters. v. Raimondo, 603 U.S. 369, 385 (2024).
100. *Id.*
101. *Id.* at 381.
102. *Id.* at 400-01.
103. United States v. Morton Salt Co., 338 U.S. 632, 644 (1950).
104. *Loper Bright Enters.*, 603 U.S. at 371; 5 U.S.C. § 706 (1946).
105. *Loper Bright Enters.,* 603 U.S. at 412.
106. *See, e.g.*, NLRB v. Hearst Publ'ns, Inc., 322 U.S. 111, 130-31 (1944), *overruled by* Nationwide Mut. Ins. Co. v. Darden, 503 U.S. 318 (1992).

food system in place of the Federal Food and Drug Administration itself. This may cause serious legal consequences because, unlike agency executives who are more familiar with the statute at issue and have issued regulations based on these statutes, judges are not "masters of the subject."[107]

It is important to note that *Loper Bright* does not overturn past cases that relied on *Chevron*. However, due to its recent enactment, disputes over the FDA's order revoking FD&C Red No. 3 will now be subject to a judicial court's own interpretation. As discussed, there are two competing arguments: (1) that the Delaney Clause includes a de minimis exception for color additives that pose a very minimal or negligible risk of cancer, and (2) that a minimal risk of cancer should have no bearing on whether a color additive is safe for human consumption.

Ultimately, this decision will rest with the courts. Under *Loper Bright,* a court will employ tools of statutory interpretation to decode the meaning of a statute and its applicability to a federal agency's rulemaking.[108] The most common interpretive tools judges may use are ordinary meaning, statutory context, canons of construction, and evidence of statutory implementation.[109] These tools of statutory interpretation, along with a prediction of a court's outcome, are discussed below.

A. Ordinary Meaning

If the meaning of a statute is not immediately clear, a court may first turn to its "'ordinary' or 'plain' meaning of the statutory text,"[110] unless the context of the statute suggests otherwise.[111] This method requires a court to focus on the literal text of a statute and interpreting it through the lens of dictionaries, books, or its usage in other areas of the law.[112] This method was employed by the court in *Public Citizen v. Young*, as the Court was faced with the meaning of the Delaney Clause.[113] The D.C. Circuit explained, "The natural—almost inescapable—reading of this language is that if the Secretary finds the additive to 'induce' cancer in animals, he must deny listing."[114] Accordingly, the court found the strict and clear meaning of inducing cancer required the FDA to ban the color additives in question.

Using this approach, it is evident that if the FDA is presented with evidence that FD&C Red No. 3 induces cancer in animals, its listing must be revoked. The plain meaning of the statute in no part suggests there to be an exception for evidence showing minimal or negligible risks of cancer. Additionally, the plain reading does not distinguish between studies linking an additive to cancer in

107. United States. v. Moore, 95 U.S. 760, 763 (1877).

108. *Loper Bright Enters.*, 603 U.S. at 400-01.

109. VALERIE C. BRANNON, CONG. RSCH. SERV., R45153, STATUTORY INTERPRETATION: THEORIES, TOOLS, AND TRENDS 2-3 (2023).

110. *Id.* at 21.

111. *E.g.*, Gonzales v. Carhart, 550 U.S. 124, 152 (2007) ("In interpreting statutory texts courts use the ordinary meaning of terms unless context requires a different result.").

112. BRANNON, *supra* note 109, at 22-23.

113. Pub. Citizen v. Young, 831 F.2d 1108, 1111-12 (D.C. Cir. 1987).

114. *Id.* at 1112.

animals or humans. Again, the statute reads "cancer when ingested by man or animal."[115] Most scientific studies are conducted on animals, rodents specifically, rather than humans.[116] This is due to various reasons such as safety, cost, biological similarities, and greater statistical data.[117] Moreover, the plain reading does not differentiate between cancer risks based on the concentration or course of time an additive is administered in a study. The 1987 studies compared the administration of Red No. 3 in low doses and high doses.[118] The results of the studies indicated that "there was no statistically significant increase in the incidence of adenomas in male rats at lower levels (up to 1.0% or 507 mg/kg day)."[119] The study further finds that these tumors were not found until the twenty-fourth month of administration.[120] This, however, does not change the analysis. The Delaney clause makes no mention of concentrations or date range.

The FDA also shares this perspective. In its order repealing FD&C Red No. 3, the FDA relied on two 1987 studies linking its use to toxicity and cancer in male rats.[121] The Administration stated that although the data is "of limited relevance to humans,"[122] the prevalence of thyroid tumors in rats is sufficient under the Delaney Clause.[123] The very slight risk of cancer did not change the FDA's conclusion.[124]

Under this approach, a court would likely enforce the repeal of FD&C Red No. 3. Although a court will not defer to the FDA's construction of the Delaney Clause, by applying the plain and ordinary meaning, it is likely to support the FDA's decision. A court may reasonably conclude that the plain meaning of the Delaney Clause requires any color additive which induces cancer in man or animal to be considered unsafe for human consumption. This bolsters the idea that whether Red No. 3 is shown to cause an increased risk of cancer in rats or humans, per the plain reading of the Delaney Clause, the distinction does not make a difference in the analysis. Since the studies found an increased risk of thyroid cancer in male rats when given Red No. 3 in high doses, a court may support its revocation.

B. Statutory Context

The next tool of statutory interpretation is statutory context. This method requires a court to look beyond the individual words of the statute and widen its scope of analysis.[125] Specifically, a court may consider other sections of the

115. 21 U.S.C. § 379e(b)(5)(B) (1938).

116. *Why Animal Research?*, STANFORD MED.: ANIMAL RSCH. AT STANFORD, https://med.stanford.edu/animalresearch/why-animal-research.html (last visited Mar. 10, 2026).

117. *Id.*

118. Borzelleca et al., *supra* note 47, at 723.

119. *Id.* at 731.

120. *Id.*

121. Request to Revoke, *supra* note 11, at 4631.

122. *Id.*

123. *Id.* at 4633.

124. *Id.*

125. BRANNON, *supra* note 109, at 25.

statute,[126] similar statutes in other areas of the law,[127] or the statute as a whole.[128] Depending on the court, judges may prefer this method over ordinary meaning. For instance, in *King v. Burwell*, the United States Supreme Court addressed the tension between the plain reading of a statute and its reading in context.[129] The Court found that a plain reading of the statute was too strict and would work contrary to its purpose.[130] The Court explained that when statutory text is ambiguous, it may be better able to decode its meaning by looking at the statute in context.[131] This would offer a court a broader understanding in light of policy and the purpose of the statute as a whole.[132]

The Delaney Clause is found in 21 U.S.C. § 379e, which regulates different aspects of regulating color additives.[133] Part (a) addresses that a color additive is deemed unsafe unless it conforms with its listing requirements, is batch certified, or is exempt from the certification process.[134] From this part alone, a court may find that FD&C Red No. 3 is safe for use. As a synthetic colorant, FD&C Red No. 3 undergoes the batch certification process, and there is no data indicating that it fails to conform with the listing requirements of 21 C.F.R. § 74.303.[135]

Part (b) dictates the listing of color additives and the Secretary's mechanism of approval.[136] It is the Secretary's duty to establish regulations for safe color additives and limit their use accordingly.[137] The Secretary must consider several factors such as consumption, cumulative effects, expert safety factors, and the availability of testing methods for the additive and its by-products.[138] Again, a court may find that low concentration of FD&C Red No. 3 for human consumption may reverse a finding that it is unsafe. Precisely, a scientific opinion estimates that the average adult intake ranges between 0.0031 mg/kg per body weight per day and 0.01 mg/kg per body weight per day, which is below the Accepted Daily Intake of 0.1 mg/kg per body weight per day.[139] Thus, such low consumption coupled with a minimal risk of cancer in male rats may lead a court to find FD&C Red No. 3 safe for consumption and thus may repeal the FDA's order.

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126. *E.g.*, NLRB v. SW Gen., Inc., 580 U.S. 288, 299-300 (2017).

127. *E.g.*, United States v. Marshall, 908 F.2d 1312, 1317 (7th Cir. 1990).

128. *E.g.*, FCC v. AT&T Inc., 562 U.S. 397, 407-08 (2011); Holder v. Hall, 512 U.S. 874, 883 (1994).

129. *See* King v. Burwell, 576 U.S. 473, 485-86 (2015).

130. *See id.* at 498.

131. *See e.g.*, *id.* at 497 ("In this instance, the context and structure of the Act compel us to depart from what would otherwise be the most natural reading of the pertinent statutory phrase.").

132. *Id.* at 492.

133. 21 U.S.C. § 379e (1994).

134. § 379e(a).

135. *Color Additives in Food*, *supra* note 24.

136. § 379e(b).

137. *Id.*

138. § 379e(b)(5)(A).

139. Eur. Food Safety Auth., *Scientific Opinion on the Re-evaluation of Erythrosine (E 127) as a Food Additive,* 9 EUR. FOOD SAFETY AUTH. J., Feb. 7, 2011, at 1, 11, https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2011.1854.

However, listed just below these factors is the infamous Delaney Clause, which stipulates that if a color additive is found to induce cancer in man or animals, it must be deemed unsafe for use. As a whole, 21 U.S.C. § 379e does not readily distinguish between what is safe as opposed to unsafe. Per Section (b)(5)(A), a Secretary will consider a multitude of factors to determine if the color additive is safe.[140] However, under Section (b)(5)(B), an additive is deemed unsafe if it induces cancer in man or animal.[141] Perhaps a color additive's safety lies on a spectrum; except once it is found to induce cancer, it is automatically deemed unsafe for consumption. The statute does not prescribe how a color additive is to be tested to determine whether it causes cancer. A plausible assumption is that, although the risk of cancer may be very minimal, once cancer is detected it is automatically unsafe. As such, a court may find that, though negligible, the risk of cancer in male rats caused by FD&C Red No. 3 is sufficient to deem it unsafe.

Language similar to the Delaney Clause is also found in FD&C Act § 409(c)(3).[142] This statute applies to the FDA's approval or denial of petitions regarding the use of food additives as a whole. It uses the same language: "no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal."[143] Once again, this Section prescribes that a food additive will be deemed unsafe if it induces cancer in man or animal. No further text asserts an exception for minimal risks of cancer or for risks of cancer only shown in animals.

Considering part (a) alone, a court may find FD&C Red No. 3 safe for consumption. However, under the statutory context approach, a court should turn to the statute as a whole. The statute makes a distinction for the procedure and outcome of a color additive that is safe and one that is unsafe: "safe" considers a multitude of factors, yet once there is a possibility of cancer, it is "unsafe." Since data shows a risk of cancer when ingested by laboratory animals, a court should find that Section (b)(5)(B), the Delaney Clause, directly applies and supports the FDA's repeal. Accordingly, the court's evaluation of the FDA's order under the *Loper Bright* ruling may not result in a different outcome than it would have under *Chevron*. A court may very well conclude the FDA made the right call by revoking FD&C Red No. 3.

C. Canons of Construction

Another tool of statutory interpretation is classified as the canons of construction, "which are presumptions about how courts ordinarily read statutes."[144] The last-antecedent canon has some overlap with ordinary meaning but focuses more on grammatical rules within the text.[145] For instance, this tool

140. § 379e(b)(5)(A).
141. § 379e(b)(5)(B).
142. § 348(c)(3)(A).
143. *Id.*
144. BRANNON, *supra* note 109, at i.
145. *Id.* at 29.

was previously used to determine the applicability of a criminal law statute based on commas used in a series of convictions.[146] This canon is not applicable for the Delaney Clause because there is no listing or series of factors within the clause.

Another canon is the rule against surplusage. It is a semantic canon that gives effect to each word or part of a statute.[147] In this manner, a statute should be interpreted in a way to avoid unnecessary repetition.[148] For example, in *Bailey v. United States*, the U.S. Supreme Court wrestled with whether a criminal law statute using both "carry" and "use" of a firearm had a purpose and whether those terms meant the same thing.[149] The Court assumed Congress had a reason for using two terms rather than one and thus treated both terms individually.[150]

Applying this reasoning to the Delaney Clause, it is first evident that man and animal each serve a separate purpose in the clause. If Congress wished to strictly rely on human studies, it would not have included the term "animal." Thus, a court should conclude that both human and animal studies should be taken into consideration to determine whether a color additive is deemed unsafe. Since the 1987 studies showed an increase of thyroid tumors in male rats, this alone may be sufficient to trigger the Delaney Clause. Moreover, the Delaney Clause uses one verb in relation to cancer: to induce. Again, if Congress wished to create a spectrum and differentiate between minimal and more prominent risks of cancer, it would have done so. Under the cannons of construction, a court will likely support the revocation of FD&C Red No. 3 as a permissible synthetic color additive.

D. Legislative History

If the statute does not answer the question before the court, the next tool of statutory interpretation a court may apply is legislative history.[151] The purpose is to determine congressional intent and apply the statute accordingly.[152] To do so, a court will primarily turn to Congress's deliberations over the course of its enactment.[153] As the Supreme Court explained in *Milner v. Department of the Navy*, legislative history is not employed to override clear congressional intent.[154] If there is "clear evidence of congressional intent…[the Court] will not take the opposite tack of allowing ambiguous legislative history to muddy clear statutory language."[155]

It is essential to first address the FDA's purpose and the history of food safety. As it is known today, the FDA is a federal agency within the U.S.

146. Lockhart v. United States, 577 U.S. 347, 349 (2016) (quoting 18 U.S.C. § 2252(b)(2)).
147. BRANNON, *supra* note 109, at 30-31; *see* Duncan v. Walker, 533 U.S. 167, 174 (2001).
148. BRANNON, *supra* note 109, at 31; *see, e.g.*, Colautti v. Franklin, 439 U.S. 379, 392 (1979).
149. Bailey v. United States, 516 U.S. 137, 146 (1995).
150. *Id.*
151. *See, e.g.*, Green v. Bock Laundry Mach. Co., 490 U.S. 504, 508-09 (1989).
152. BRANNON, *supra* note 109, at 40; s*ee, e.g.*, Mitchell v. Cohen, 333 U.S. 411, 418 (1948).
153. BRANNON, *supra* note 109, at 39.
154. Milner v. Dep't of the Navy, 562 U.S. 562, 572 (2011).
155. *Id.*

Department of Health and Human Services.[156] It is tasked with "protecting the public health…by ensuring the safety of [the] nation's food supply, cosmetics, and products that emit radiation."[157] The Food and Drug Administration operates as a component of the executive branch[158] while functioning under the authority of the legislative branch.[159] In addition to the legislature's power to tax,[160] spend,[161] and regulate interstate commerce,[162] Article I Section 8 of the U.S. Constitution grants Congress the broad authority to enact any law that is deemed necessary and proper to execute its functions.[163] As such, although the establishment of federal agencies is not explicitly mentioned in the Constitution, the legislative branch is recognized as having the implied authority to create and oversee these federal agencies.[164]

Prior to the establishment of the Food and Drug Administration, no health or safety standards were in place to guide the manufacturing or production of food. Increasing urbanization in the 18th and 19th centuries resulted in increasing unethical food production and unsupervised use of poisonous preservatives—lice was used as a brown sugar substitute and mercury as a coloring for chocolate.[165] Many of these practices were brought to light and sparked public concern for the lack of federal oversight.[166]

In 1906, President Roosevelt signed the Pure Food and Drug Act,[167] which made it unlawful to produce, sell, and transport misbranded and adulterated food.[168] This vested the Department of Agriculture's Bureau of Chemistry with the authority to examine food and determine compliance with federal guidelines.[169] In 1927, the non-regulatory research functions of what was then known as the Food, Drug, and Insecticide Organization were reorganized within the Department of

156. *HHS Agencies & Offices*, U.S. DEP'T OF HEALTH & HUM. SERVS. (Aug. 28, 2025), https://www.hhs.gov/about/agencies/hhs-agencies-and-offices/index.html.

157. *What We Do,* U.S. FOOD & DRUG ADMIN. (Nov. 21, 2023), https://www.fda.gov/about-fda/what-we-do.

158. *Health and Human Services Department*, FED. REG., https://www.federalregister.gov/agencies/health-and-human-services-department (last visited Mar. 10, 2026).

159. TODD GARVEY & SEAN M. STIFF, CONG. RSCH. SERV., R45442, CONGRESS'S AUTHORITY TO INFLUENCE AND CONTROL EXECUTIVE BRANCH AGENCIES 8 (2018).

160. *See* U.S. CONST. art. I, § 8, cl. 1; United States v. Sanchez, 340 U.S. 42, 42 (1950).

161. *See* U.S. CONST. art. I, § 8, cl. 1; South Dakota v. Dole, 483 U.S. 203, 207 (1987).

162. *See* U.S. CONST. art. I, § 8, cl. 3; NLRB v. Jones & Laughlin Steel Corp., 301 U.S. 1, 1-2 (1937).

163. *See* McCulloch v. Maryland, 17 U.S. 316, 324 (1819); Nat'l Fed'n of Indep. Bus. v. Sebelius, 567 U.S. 519, 537 (2012).

164. *See* Buckley v. Valeo, 424 U.S. 1, 138-39 (1976); Humphrey's Ex'r v. United States, 295 U.S. 602, 629 (1935).

165. Andrea T. Borchers et al., *The History and Contemporary Challenges of the US Food and Drug Administration*, 29 CLINICAL THERAPEUTICS 1, 4 (2007).

166. UPTON SINCLAIR, THE JUNGLE 162 (1905).

167. *Part I: The 1906 Food and Drugs Act and Its Enforcement*, U.S. FOOD & DRUG ADMIN. (Apr. 24, 2019), https://www.fda.gov/about-fda/changes-science-law-and-regulatory-authorities/part-i-1906-food-and-drugs-act-and-its-enforcement.

168. Wiley Act, Pub. L. No. 59-384, 34 Stat. 768 (1906).

169. *Id.* at 769.

Agriculture.[170] The FDA then obtained its name as the Food and Drug Administration in 1930.[171]

Despite the start of food regulation, America's health remained compromised. The Sulfanilamide Disaster unfolded as untested sulfanilamide was being prescribed, which led to numerous deaths across the country.[172] The incident revealed that more action and supervision were necessary. This pressured Congress to grant the FDA more regulatory oversight; further, under the 1938 Federal Food, Drug, and Cosmetics Act, the FDA was decisively authorized to establish standards of identity, quality, and quantity of foods, pharmaceuticals, and cosmetics.[173]

The Delaney Clause first appeared in the 1958 Amendment to the FDCA. It banned the use of carcinogenic food additives and operated as a zero-tolerance policy.[174] Complaints on the rigidity of this provision eventually lead an amendment in 1960 when the term "color additive" was defined for the first time.[175] Color additives were a distinct category separate from food additives with specific provisions that exclusively applied to them.[176] The Delaney Clause's food additive policy was maintained and extended to include color additives. It read, "A color additive…shall not be listed…if, after tests which are appropriate…it is found by the Secretary to induce cancer in man or animal."[177] Notably, provisions were also added permitting the use of color additives if the FDA determined them to be safe for general use.[178]

Congressman James Delaney, as chairman of the Select Committee to conduct investigations on the use of chemicals, pesticides, and insecticides in food, was the driver behind the Delaney Clause.[179] Despite new regulations guiding the production of food, cancer was an increasing and ongoing problem in the early 1950s, and Congressman James Delaney saw the need for intervention. The Delaney Clause was introduced in the House Bill and was accepted by the Senate.[180] The primary concern at the time was the use of a pesticide called Aramite which was then approved as a food additive.[181] Delaney proposed that no cancer-

170. John P. Swann, *FDA's Origin*, U.S. FOOD & DRUG ADMIN. (Feb. 1, 2018), https://www.fda.gov/about-fda/changes-science-law-and-regulatory-authorities/fdas-origin.

171. *Id.*

172. Carol Ballentine, *Sulfanilamide Disaster*, U.S. FOOD & DRUG ADMIN.: CONSUMER MAG. 1 (June 1981), https://www.fda.gov/files/about%20fda/published/The-Sulfanilamide-Disaster.pdf.

173. Federal Food, Drug, and Cosmetic Act, ch. 675, 52 Stat. 1040 (1938).

174. Food Additive Amendment of 1958, Pub. L. No. 85-929, 72 Stat. 1784, 1784-85 (1958) (codified as amended at 21 U.S.C. § 349).

175. Color Additive Amendments of 1960, Pub. L. No. 86-618, 74 Stat. 397, 397 (1960) (codified as amended at 21 U.S.C. §§ 342, 361).

176. *Id.* at 399-402.

177. *Id.* at 400.

178. *Id.* at 399.

179. *See Delaney, James Joseph*, BIOGRAPHICAL DIRECTORY OF THE U.S. CONG., https://bioguide.congress.gov/search/bio/D000211 (last visited Mar. 10, 2026).

180. Pub. Citizen v. Young, 831 F.2d 1108, 1113 (D.C. Cir. 1987).

181. Les v. Reilly, 968 F.2d 985, 989 (9th Cir. 1992).

inducing additive can be used in food, regardless of how minimal the risk.[182] His purpose was to prevent any cancer-inducing additive from ever entering the market. Delaney explicitly said "[t]he precedent established by the Aramite decision has opened the door, even if only a little, to the use of carcinogens in our foods. That door should be slammed shut and locked. That is the purpose of my anticarcinogen provision."[183] Congressman James Delaney felt compelled to pass this provision after experiencing the death of a relative due to cancer.[184] Delaney strongly advocated for this and recognized that "even a minute dose of a cancer-producing agent constitutes a serious health hazard."[185]

Delaney received support from Arthur Flemming, Secretary of Health, Education, and Welfare. Flemming stated that "[u]nless and until there is a sound scientific basis for the establishments of tolerances for carcinogens,…the Government has a duty to make clear…that it will do everything possible to put persons in a position where they will not unnecessarily be adding residues of carcinogens to their diet."[186] He added, "we simply have no basis on which such discretion could be exercised because no one can tell us with any assurance at all how to establish a safe dose of any cancer-producing substance."[187] Delaney received further support from cancer researcher William Hueper, who stated that he did "not believe that one could establish a safe dose of carcinogens" and added that the technology available at this time was not sufficient to determine what a safe dose of carcinogen would be.[188]

This part of legislative history and support illustrates the intent and purpose of the Delaney Clause. The clause is named after Congressman James Delaney himself, and it would be absurd to completely disregard his motives. Since Delaney had already rejected competing views over the possibility of a de minimis exception, so should the courts. It would be contrary to congressional intent to conclude that FD&C Red No. 3 is safe for consumption simply because the risk of cancer is so minimal or only relevant to animals. And as such, based on legislative history, a court may interpret the Delaney Clause as supporting the repeal of FD&C Red No. 3.

E. Evidence of Statute Implementation

Finally, a court may turn to evidence of statutory implementation. This method entails looking at how the statute has been applied by the agency coupled

182. *Food Additives: Hearing Before the H. Subcomm. on Health and Sci. of the H. Interstate and Foreign Com. Comm.,* 85th Cong., 497-98 (1958) (statement of James Delaney, Congressional Representative of New York).

183. *Id.* at 498.

184. John H. Weisburger, *The 37 Year History of the Delaney Clause*, 48 EXPERIMENTAL & TOXICOLOGIC PATHOLOGY 183, 183-84 (1996).

185. 106 CONG. REC. H14349-86, 14350 (daily ed. June 25, 1960) (statement of James Delaney).

186. H.R. REP. NO. 86-1761, at 12 (1960).

187. *Id.* at 13.

188. Michael Tortorello, *The Great Cranberry Scare of 1959*, THE NEW YORKER (Nov. 14, 2015), https://www.newyorker.com/tech/annals-of-technology/the-great-cranberry-scare.

with the judges' own understandings of how it should be implemented.[189] This tool is similar to the *Chevron* regime in that a court considers the administrative agency's way of executing the statute. There is a limitation, however, such that judges will also consider their own understandings even if contrary to the agency's practices.[190] Courts may likely substitute their own understandings in light of the statute's practical consequences.[191]

The FDA's application of the Delaney Clause has not been consistent. For instance, prior to resistance from the public, the FDA approved the listing of color additives Orange No. 17 and Red No. 19 despite evidence showing a link to cancer in laboratory animals.[192] FD&C Red No. 40 is another color additive that has generated considerable controversy.[193] Under current law, Red No. 40 is listed as an approved synthetic color additive for use in food, drugs, and cosmetics, so long as it undergoes batch certification and complies with the agency's limitations on use.[194] Multiple research studies continue to show that Red No. 40 accelerates tumor growth in mice,[195] yet the FDA has taken minimal action.

An examination of potential judicial understandings is warranted. Judges are pragmatic individuals who seek sound, policy-driven, and effective law. In terms of policy, two major players are to be considered: consumers and manufacturers. On one hand, there is a drive to make Americans healthier by reducing the risk of developing cancer, regardless of how negligible the risk is. On the other hand, a ban on any color additive that is linked, even negligibly, to cancer may harm big food manufacturers' revenue and the economy as a whole. At the moment, over half of America's food is processed.[196] The revenue of America's top ten food manufacturing companies ranges from 13.5 to 87 billion dollars.[197] Additionally, the limited availability and more costly alternative of using natural food colorants would increase the cost of production as well as sale prices. Thus, if a particular judge or court occupies a more capitalist mindset, the Delaney Clause may be interpreted to overlook data showing very minimal risks of cancer.

The outcome under this approach is unclear. A court may be troubled by the FDA's inconsistencies or may push for a less stringent and more practicable application of the statute. However, judges may also enforce the rigidity of the

189. BRANNON, *supra* note 109, at 45.

190. *Id.*

191. *Id.* at 47.

192. *See* Pub. Citizen v. Young, 831 F.2d 1108, 1110 (D.C. Cir. 1987) (displaying the case filed challenging the FDA's approval of Orange No. 17 and Red No. 19).

193. *See, e.g.*, Qi Zhang et al., *The Synthetic Food Dye, Red 40, Causes DNA Damage, Causes Colonic Inflammation, and Impacts the Microbiome in Mice*, 11 TOXICOLOGY REPORTS 221, 221 (2023).

194. 21 C.F.R. § 74.340 (2025).

195. SARAH KOBYLEWSKI & MICHAEL F. JACOBSON, FOOD DYES: A RAINBOW OF RISKS 30-31 (2010), https://www.cspi.org/sites/default/files/media/documents/resource/food-dyes-rainbow-of-risks.pdf.

196. Jenifer E. Clapp et al., *Changes in Serving Size, Calories, and Sodium Content in Processed Foods from 2009 to 2015*, 15 PREVENTING CHRONIC DISEASE, 2018, at 1, 1.

197. Kate Taylor, *These 10 Companies Control Everything You Buy*, BUS. INSIDER (Sep. 28, 2016, at 17:18 ET), https://www.businessinsider.com/10-companies-control-the-food-industry-2016-9.

clause in order to safeguard America's health. Accordingly, challenges to the revocation of FD&C Red No. 3 could go in either direction.

IV. FUTURE OF ADMINISTRATIVE AGENCIES REGULATIONS

Newly appointed President Trump has issued a Regulatory Freeze Executive Order effective on January 20, 2025.[198] His memorandum directs all federal agencies to cease issuing new regulations until a President-appointed agency head has reviewed and approved the rule; withdraw rules that have been sent to the Office of the Federal Register but not yet published; and postpone for 60 days rules that have already been published, but not yet implemented, and which raise substantial issues of fact, law, or policy.[199]

The FDA's order revoking FD&C Red No. 3 may be subject to this freeze. The repeal was published in January 2025 and falls within Trump's 60-day timeframe. Additionally, the removal of a color additive based on various interpretations of the Delaney Clause arguably poses a substantial question of law or policy. This could have positive or negative implications. Although it is uncertain who the President-appointed agency head will be, if the individual supports the FDA's reasoning and interpretation of the Delaney Clause, then the FDA's order would likely be unaffected. Still though, under *Loper Bright*, it would be subject to review by the courts. However, if the agency head chooses to revoke the FDA's order, this could put a halt on other synthetic color additives and the overall health of Americans. The only course of action now is to observe how things unfold.

CONCLUSION

Cancer rates are rising at an alarming pace, and the overall health of Americans continues to decline, creating a serious health concern for our nation. It is important to remember that we have a system designed to safeguard our well-being. This system must stand on the principles of justice and accountability and protect the health of the American people. In January 2025, the FDA took significant action by ordering the repeal of FD&C Red No. 3, one of the most widely used synthetic color additive, from food and ingested drugs. This was based on data linking the color additive to thyroid cancer in male rats. The Agency relied on the zero-tolerance Delaney Clause providing that any food or color additive found to induce cancer in animals or humans is deemed unsafe for consumption and must be removed from the FDA's listings. Though the color additive poses a very minimal risk of cancer in laboratory animals, this is sufficient to trigger the Delaney Clause and ban its use.

The doctrine outlined in *Chevron U.S.A., Inc. v. Natural Resources Defense Council*, *Inc.* prescribes a two-step framework for courts to analyze ambiguous statutes. First, courts would determine whether Congress had directly addressed

198. *Regulatory Freeze Pending Review*, THE WHITE HOUSE: PRESIDENTIAL ACTIONS (Jan. 20, 2025), https://www.whitehouse.gov/presidential-actions/2025/01/regulatory-freeze-pending-review.

199. *Id.*

the issue. If not, courts would defer to administrative agencies' construction of the statute and apply this interpretation to the issue before them. However, forty years later, the U.S. Supreme Court ruled that the judiciary will no longer give deference to administrative agencies when evaluating ambiguous statutes, despite agencies' greater familiarity with the subject matter. It is rather the duty of the courts, charged with interpreting the law, to implement various tools of statutory implementation and reach a reasonable conclusion. Thus, if challenges to the FDA's order arise, a court will no longer turn to the FDA's understandings of the Delaney Clause.

Taking into consideration the tools of statutory interpretation that a court may use in evaluating the Delaney Clause, the outcome may nevertheless be the same under both the *Chevron* doctrine and the newly held *Loper Bright* regime. The text of the clause, Congressman James Delaney's intent, and the statute's meaning in the context of other provisions seem to point towards one direction: if a color additive causes cancer in man or animal, it ought to be banned. With newly-elected President Donald Trump's regulatory freeze, the outcome of FD&C Red No. 3's revocation and other FDA regulations is unclear. Ultimately, it is the health of America that is at stake—neither the FDA, the judiciary, nor the President should interpret the strict Delaney Clause as anything but literal meaning: to outright ban any carcinogens from being added to food. However, with so many variables at play, only time will tell what lies ahead.