

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA**

INTERNATIONAL ASSOCIATION OF COLOR
MANUFACTURERS,

Plaintiff,

v.

Civil Action No.: 2:25-cv-00588

ARVIN SINGH, in his official capacity as
Cabinet Secretary of the West Virginia
Department of Health,

JUSTIN DAVIS, in his official capacity as Interim
Commissioner of West Virginia Bureau for Health,

L. PAUL HARDESTY, VICTOR L. GABRIEL,
F. SCOTT ROTRUCK, NANCY J. WHITE,
ROBERT W. DUNLEVY, CHRISTOPHER A.
STANSBURY, GREGORY F. WOOTEN,
CATHY L. C. JUSTICE, and DR. SARAH
ARMSTRONG TUCKER, in their official
capacities as members of the West Virginia State
Board of Education,

and

MICHELE L. BLATT, in her official capacity as
State Superintendent of Schools of West Virginia,

Defendants.

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiff, the International Association of Color Manufacturers (“IACM”), brings this Complaint to enjoin as unconstitutional West Virginia House Bill 2354 (“H.B. 2354”), codified as Sections 16-7-2,4 and 18-5D-3A of the West Virginia Code, which was signed into law earlier this year and took effect (in part) on August 1, 2025. In support of this action, IACM states as follows:

PRELIMINARY STATEMENT

1. West Virginia’s new law arbitrarily prohibits certain named synthetic color

additives¹—used to color food and beverage products—that the U.S. Food and Drug Administration (“FDA”) evaluated and certified as safe decades ago.

2. Color additives are comprehensively regulated in the U.S. and elsewhere throughout the world. In this country, as required by the 1960 Color Additive Amendments, the FDA conducted an extensive investigation into the synthetic color additives that H.B. 2354 targets. After a thorough review and testing process, the FDA approved seven synthetic colors as safe for use—including each of the colors West Virginia now bans.

3. The FDA is not alone. Other countries, global research institutions and foreign regulatory bodies that have studied these synthetic color additives and all have concluded that they can be safely used. None have found any merit to purported safety concerns in humans.

4. Against this backdrop, one would have imagined that if West Virginia were to suddenly ban color additives that were FDA-approved and used safely for decades, the Legislature would have done so (a) based on new, public, reliable scientific evidence (b) that would be reflected in a robust legislative record replete with findings of fact justifying such a ban.

5. Nothing of the sort occurred. The statute itself and the legislative record contain **no** evidence supporting West Virginia’s ban. Nor could they have, because none exists.

6. Instead, it appears that H.B. 2354 is part of a new pseudoscientific fad that seeks to up end decades-long settled science, entirely lacking in any justification. West Virginia merely decreed, without any attempted justification, that a handful of additives are inherently “poisonous and

¹ FD&C Red No. 40, FD&C Yellow No. 5, FD&C Yellow No. 6, FD&C Blue No. 1, FD&C Blue No. 2 and FD&C Green No. 3. H.B. 2354 prohibits a seventh color additive, FD&C Red No. 3. While IACM submits that H.B. 2354 is just as constitutionally unsound in banning FD&C Red No. 3 as in prohibiting the other named colors, the FDA has indicated it is removing its approval for this additive as of January of 2027, and IACM members already are discontinuing its use. Therefore, IACM has elected not to challenge the statute as to this particular color additive.

injurious.”

7. The West Virginia Legislature has acted unlawfully in several, independent respects.

8. By expressly naming and prohibiting the targeted color additives without any rational basis for finding that they are, in fact, unsafe in any way, H.B. 2354 violates the equal protection guarantees under the U.S. and West Virginia Constitutions.

9. H.B. 2354 also operates as an unconstitutional bill of attainder under both federal and state constitutions, singling out for prohibition and criminal sanction the named color additives without providing their manufacturers any opportunity to demonstrate that they are not harmful and thus not worthy of criminal penalties.

10. And, H.B. 2354 is so vague and ambiguous that it violates constitutional due process protections.

11. The Court should declare the law unconstitutional and enjoin its enforcement.

12. If the law is allowed to be enforced, IACM’s members—manufacturers of these color additives and manufacturers of products which utilize these additives—will suffer irreparable harm, both through the deprivations of their constitutional protections as well as the significant economic costs that the law will impose on them.

13. Through this action, the IACM seeks declaratory and injunctive relief to vindicate the constitutional rights of its members and prevent them from suffering the serious harms that, if enforced, H.B. 2354 will cause.

THE PARTIES

14. Plaintiff IACM is a not-for-profit corporation, incorporated in Washington, D.C., with its principal office located at 1101 17th Street, N.W., Suite 700 in Washington, D.C. IACM is a trade association which was originally founded in 1972 by color industry leaders as the Certified Color

Manufacturers Association, and IACM continues to be a strong voice in support of the safe use of color additives.

15. IACM is the only association representing the interests of the color additives industry, both natural and synthetics, as well as the color user community, on the state, national, and international levels. IACM's mission is to advance the interests of manufacturers, producers, and users in the color industry by demonstrating the safety of colors and promoting the industry's economic growth. IACM's members include color manufacturers, who manufacture color additives, including the seven colors named in H.B. 2354, as well as dozens of other colors.

16. Defendant Dr. Arvin Singh is the Cabinet Secretary for the West Virginia Department of Health.² Dr. Singh as the Cabinet Secretary is "the chief executive officer of that department and...is charged with the administration of this chapter." W. Va. Code § 16-1-3(e)(1). Dr. Singh as secretary is charged with, amongst other things, enforcement of H.B. 2354 and W. Va. Code §§ 16-7-3 and 4.

17. Defendant Justin Davis is the Interim Commissioner of the West Virginia Bureau for Health. Commissioner Davis as Commissioner for the Bureau for Public Health may be designated

² In 2023, the Legislature reorganized the Department of Health and Human Resources into three distinct departments: the West Virginia Department of Health, the West Virginia Department of Human Services, and the West Virginia Department of Health Facilities. *See* H.B. 2006 (eff. May 23, 2023). Under W. Va. Code § 5F-2-1a(f)

All programs, orders, determinations, rules, permits, grants, contracts, certificates, bonds, authorizations and privileges which have been issued, promulgated, made, granted or allowed to become pursuant to authority provided by this code to the Department of Health and Human Resources or the Secretary of that Department that are in effect on the dates of the creation of the new departments as provided in this section shall continue in effect according to their terms until modified, terminated, superseded, set aside or revoked by the department or secretary that assumes authority over the subject matter of the same under the provisions of this Act.

the state health officer.³ *See* W. Va. Code § 16-1-5. Commissioner Davis is the chief executive of the Bureau for Public Health and is tasked with, among other things, enforcing “all laws of this state concerning public health[,]” to “inspect and examine food, drink, and drugs offered for sale or public consumption[,] and “to make complaint or cause proceedings to be instituted against any person, corporation or other entity for the violation of any public health law” *See* W. Va. Code §§ 16-1-6(a)(2), (4) and (5). In addition, Commissioner Davis is charged with enforcement of H.B. 2354 and W. Va. Code § 16-7-3.

18. Defendants L. Paul Hardesty, Victor L. Gabriel, F. Scott Rotruck, Nancy J. White, Robert W. Dunlevy, Christopher A. Stansbury, Gregory F. Wooten, Cathy L. C. Justice, Dr. Sarah Armstrong Tucker (collectively the “Board Defendants”) are members of the West Virginia Board of Education and are vested with the “general supervision of the free schools of the State[.]” W. Va. Const. Article XII, § 2. Defendant Michele L. Blatt (together with the Board Defendants, the “State BOE Defendants”) is the State Superintendent of Schools, selected by the West Virginia Board of Education to serve as the chief school officer of the State. *Id.* The State BOE Defendants are responsible for establishing, implementing, and enforcing education standards for all facets of public education in West Virginia, including standards governing school nutrition programs operated by county boards of education throughout the State. *Id.*; *see also* W. Va. § 18-2-5; W. Va. Code § 18-5D-1-5, W.Va. C.S.R. § 126-86-1, *et seq.* As a result, the State BOE Defendants are responsible for ensuring that W. Va. Code § 18-5D-3A is enforced.

³ Pursuant to W. Va. Code § 16-2-2, “Commissioner” “means the Commissioner of the Bureau for Public health, who is the state health officer.” Further, pursuant to W. Va. Code § 30-3-4(5) “State health officer” “means the commissioner for the Bureau for Public Health or his or her designee, which officer or designee shall be a physician and shall act as secretary of the board and shall carry out any and all responsibilities assigned in this article to the secretary of the board.”

JURISDICTION AND VENUE

19. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1331, as the causes of action, at least in part, arise under the Constitution of the United States. This Court further has jurisdiction over this matter pursuant to 28 U.S.C. § 1343(a)(3), as this suit is intended to “redress the deprivation, under color of any State law, statute, ordinance, regulation, custom or usage, of any right, privilege or immunity secured by the Constitution of the United States or by any Act of Congress providing for equal rights of citizens or of all persons within the jurisdiction of the United States.” This Court has jurisdiction over the remaining causes of action pursuant to its supplemental jurisdiction provided by 28 U.S.C. § 1367(a).

20. The Declaratory Judgment Act provides that, in a case of actual controversy within its jurisdiction, a United States court may declare the rights and other legal relations of any interested party seeking such declaration. 28 U.S.C. § 2201(a).

21. This Court has authority to issue injunctive relief pursuant to 28 U.S.C. § 2202, and its inherent equitable powers to enjoin the actions of state officials if they contradict the federal Constitution or federal law. *Ex parte Young*, 209 U.S. 123, 159-60 (1908); *accord, e.g., Larson v. Domestic & Foreign Com. Corp.*, 337 U.S. 682, 689 (1949).

22. Venue in this district is proper pursuant to 28 U.S.C. § 1391(b)(2) because this action challenges a West Virginia law criminalizing the sale of some of IACM’s members’ products in this district, while calling into question their ability to sell other products and this district, accordingly directly restricting and restraining IACM’s members’ conduct.

23. Venue is also proper in this district because this is where Defendants perform their official duties and a substantial part of these events giving rise to these claims occurred. *See* 28 U.S.C. § 1391(b)(1).

24. Defendants do not possess immunity under the Eleventh Amendment of the United States Constitution because of their direct roles in enforcing the unconstitutional statute at issue.

STANDING

25. IACM has associational and representative standing to prosecute this action.

26. IACM's members would have standing to sue individually, in their own right. Enforcement of H.B. 2354 will cause IACM's members imminent, concrete, particularized injuries, including invasion of their legally protected interests, irreparable constitutional violations, compliance costs, potential civil and criminal penalties.

27. An exemplar IACM member, AmeriColor Corporation ("AmeriColor"), demonstrates the association's standing. AmeriColor is a family-owned and -operated company that manufactures food coloring products associated with the baking and sugar art industries. Founded in 1995, AmeriColor is based in California, but the products it supplies include the six challenged color additives and are currently sold in West Virginia. AmeriColor is confident in the safety of its color additive products and the FDA has regularly certified compliance of the manufactured batches of the subject color additives AmeriColor utilizes in its products as fully compliant with the FDA's color additive certification program standards. If H.B. 2354 is allowed to go into full effect, AmeriColor will be harmed in a variety of ways, including incurring unrecoverable costs such as compliance, developing and marketing alternatives, and costs associated with the uncertainty involved in whether any replacement products might also be deemed poisonous and injurious even though they, too, are safe pursuant to FDA requirements.

28. These injuries are certainly impending as H.B. 2354 became effective as to school nutrition programs on August 1, 2025, and will become generally effective throughout the state for all purchases and products on January 1, 2028.

29. These injuries are caused by Defendants, who are charged with enforcement of H.B. 2354, which presents coercive effect on IACM's members through its civil and criminal penalties.

30. These injuries can be redressed through the judicial relief sought herein to enjoin enforcement of H.B. 2354 and declare it constitutionally invalid.

31. Were each of IACM's members to file individual suits to pursue these claims, those suits would present an unnecessary undue burden on the Court when the Court can adjudicate the identical claims on behalf of all members.

32. IACM seeks no damages herein, only declaratory and injunctive relief. Accordingly, individual participation from IACM's members is not necessary because "the remedy, if granted, will inure to the benefit of those members of the association actually injured." *Warth v. Seldin*, 422 U.S. 490, 515 (1975).

33. The interests IACM seeks to protect through this action are germane to its purpose. IACM's mission is to advance the interests of manufacturers, producers, and users in the color additive industry by demonstrating the safety of color additives and promoting the industry's economic growth. H.B. 2354's declaration of the targeted color additives as "poisonous and injurious," and its ban of their use, directly threatens that mission.

RELEVANT FACTUAL AND LEGAL BACKGROUND

A. Color Additives and FDA Regulation

34. The FDCA defines a color additive as "a material which is a dye, pigment, or other substance ... and when added or applied to a food, drug, or cosmetic, or to the human body or any part thereof, is capable (alone or through reaction with other substance) of imparting color thereto." 21 U.S.C. § 321(t). Color additives can be derived from flowers, minerals, wood, and even insects, and have been used in food and beverages for thousands of years.

35. Color additives can be composed in a variety of ways, broadly falling into two categories: “natural” color additives and “synthetic” compositions. But this distinction is not always meaningful, because there are some color additives that are considered “natural” but that are produced through chemical synthesis.

36. Under FDA’s regulations, color additives are classified as either “certified” or “exempt from certification.” 21 U.S.C. § 379e(a)(1)(A). **Certified color additives** are synthetically produced (or human made), impart an intense, uniform color and blend easily to create a variety of hues. There are seven certified color additives approved for use in foods called “FD&C” color additives because they also may be used in foods, drugs and cosmetics. Color additives that are **exempt from certification** generally include dyes and pigments derived from a variety of sources such as vegetables, minerals, or animals, and may also be produced through chemical synthesis. Examples of exempt color additives include annatto extract (yellow), dehydrated beets (bluish-red to brown), caramel (yellow to tan), beta-carotene (yellow to orange), and grape skin extract (red or purple).

37. Whether a color additive is synthetic or natural has no bearing on its overall safety. All color additives, regardless of their classification, are subject to rigorous standards of safety prior to their approval for use in food. The FDA must find that the color is “safe,” meaning that there is “convincing evidence that establishes with reasonable certainty that no harm will result from the intended use of the color additive.” 21 C.F.R. § 70.3(i)

38. The six synthetic color additives that are the subject of this challenge are all FD&C colors which are safe and enjoy global approval. These six FD&C colors have been rigorously reviewed by leading authorities, for decades, including the FDA, the European Food Safety Authority (EFSA), Health Canada, and the Joint FAO/WHO Expert Committee on Food Additives (JECFA), all of which have found no causal link between FD&C color additives and adverse human health effects.

Despite some misconception to the contrary, these six FD&C colors remain approved and widely used in global markets, including the European Union, where any formulation differences are driven by consumer preference rather than legal mandates.

39. IACM strongly supports the continued safe use of all color additives, including FD&C color additives, which are among the most thoroughly studied and strictly regulated ingredients in the food supply. Color additives, regardless of source, play a critical role in ensuring product consistency, enhancing visual appeal, and maintaining consumer confidence in food and beverage products.

40. In the U.S., color additives must be approved by the FDA before they can be used in foods, drugs, or cosmetics, pursuant to the Federal Food, Drug, and Cosmetic Act, (the “FDCA”). 21 U.S.C. §§ 301 *et seq.*, 379(e).

41. The Color Additive Amendments of 1960, which are part of the FDCA, establish an elaborate system for regulation of color additives in the interests of safety. Pub. L. No. 86–618, 74 Stat. 397; 21 U.S.C. § 379(e).

42. Synthetic color additives, many which were already in use at the time of the Color Additive Amendments’ enactment were originally provisionally permitted (“listed”) for use for a finite term, but had to then be subject to a robust FDA review and approval for safety before they could be listed permanently in FDA’s regulations as safe color additives. These provisional listings could be extended by request, depending on the additive’s progress in meeting the color additive petition requirements described in the statute and implementing regulations.

43. In the wake of the Color Additive Amendments’ enactment, a group consisting of color additives manufacturers and users was formed called the Certified Color Industry Committee (“CCIC”). CCIC oversaw and submitted the five of the six subject color additive petitions for FD&C Blue No. 1, FD&C Blue No. 2, FD&C Green No. 3, FD&C Yellow No. 5 and FD&C Yellow No. 6 in

the mid-to-late 1960s after extensive discussions with the FDA. FD&C Red No. 40 was not included in this group because it was handled separately by Buffalo Color Company that owned a patent on its production (Buffalo Color later was purchased by Hilton-Davis) and was permanently listed by FDA in a separate action.

44. CCIC evolved into IACM's predecessor, the Certified Color Manufacturers Association ("CCMA") and served as the petitioner for these applications.

45. During the early-to-mid 1970's, CCMA engaged in extensive discussions with the FDA on the types of safety studies that would be required to demonstrate safety for each color additive. The discussions included a thorough review of the existing safety literature and other known related safety information. Reproduction studies (including teratology) were conducted on more than half a dozen color additives, though the FDA's primary focus was on potential toxicity and carcinogenicity. CCMA and FDA agreed that for Blue 1, Blue 2, Green 3, Yellow 5 and Yellow 6 lifetime toxicity/carcinogenicity feeding studies in rats and mice would be required to demonstrate safety, and for Red 3 these studies would be supplemented by a multi-generation reproduction study.

46. The toxicity/carcinogenicity study protocols were designed in collaboration between CCMA, its expert consultants, and FDA scientists. The laboratories performing the studies were selected in collaboration with the FDA.

47. The focus of the toxicity/carcinogenicity studies was detecting toxic and carcinogenic potential. The study protocols remain to this day state-of-the art study protocols and exceed the protocol requirements for studies conducted by the National Toxicology Program, among others.

48. The toxicity/carcinogenicity lifetime feeding studies in rats were designed for exposure up to 30 months and included in utero exposure, again to address carcinogenicity concerns. The colors were administered ad libitum in feed at dose levels up to 5% in several of the studies, which is a dietary

concentration that is far beyond current average human consumption. An interim sacrifice after one year was included in the rat studies. A variety of toxicological endpoints were incorporated into the studies including clinical chemistry endpoints to assess liver and kidney function. Behavioral observations were also included. There were also mouse studies which were similar to the rat studies in design and conduct but did not include in utero exposure and were two years in duration.

49. CCMA provided regular interim data from these studies to the FDA. Based on the FDA's evaluation of that interim data, consistent extensions of the provisional listings were granted for all six color additives until the studies were terminated.

50. All of the studies of the six challenged additives completed their designed duration – none were terminated early due to observed effects and all resulted in the FDA finding no safety concerns in humans.⁴

51. The process by which these colors became certified and permanently listed (“approved”) by the FDA, including federally mandated toxicity and carcinogenicity studies and comprehensive compliance measures, was unprecedented for a food ingredient at the time, and CCMA bore all the costs associated with these efforts.

⁴ These studies include the following publications in peer-reviewed scientific literature:
Borzelleca J.F. and Hallagan J.B. The safety and regulatory status of food, drug, and cosmetic color additives. In *Food Safety Evaluation*. Finley and Armstrong, Eds. American Chemical Society. Washington. 1992.
Borzelleca J.F., Depukat K. and Hallagan J.B. Lifetime toxicity/carcinogenicity studies of FD&C Blue No.1 in rats and mice. *Food and Chemical Toxicology*. 28, 221. 1990.
Borzelleca J.F. and Hallagan J.B. Multigeneration study of FD&C Red No.3 in Sprague-Dawley rats. *Food and Chemical Toxicology*. 28, 813. 1990.
Borzelleca J.F. and Hallagan J.B. A chronic toxicity/carcinogenicity study of FD&C Yellow No. 5 in rats. *Food and Chemical Toxicology*. 26, 179. 1988.
Borzelleca J.F. and Hallagan J.B. A chronic toxicity/carcinogenicity study of FD&C Yellow No. 5 in mice. *Food and Chemical Toxicology*. 26, 189. 1988.
Borzelleca J.F., Capen C.C. and Hallagan J.B. A chronic toxicity/carcinogenicity study of FD&C Red No. 3 in rats. *Food and Chemical Toxicology*. 25, 723. 1987.

52. As a result, today, a color additive may be used only after the FDA has published a regulation listing the additive for such uses as safe. Federal law defines “safe,” as meaning “that there is convincing evidence that establishes with reasonable certainty that no harm will result from the intended use of the color additive.” 21 CFR §§ 70.3(i), 70.42. The color additive in question must specifically satisfy (among other things) the requirements of what is referred to as the “Delaney Clause,” which prohibits the listing of any color additive “found . . . to induce cancer in man or animal.” 21 U.S.C. § 379(b)(5)(B).

53. Though there was a seventh synthetic additive that CCMA supported at that time, FD&C Red No. 3, the safety study conducted for that additive did show evidence of thyroid tumors in high-dose male rats. CCMA extensively investigated the observed thyroid effects and demonstrated through additional specialized studies that they were related to the color additive’s ability, because of its tetraiodo-fluorescein chemical structure, to interfere with rat thyroid hormone metabolism in a thresholded manner—a secondary mechanism. The FDA originally approved the petition for FD&C Red No. 3, as these results were only found in rats and were chemically distinguishable, such that the FDA at the time felt that the findings in rats had “limited relevance in humans,” but the FDA has since been forced to make a Delaney Clause finding, announcing that the additive will be delisted and its approval revoked in January of 2027. The change was not due to any new scientific findings or research, but rather due to a legal finding that the FDA lacks statutory discretion as a matter of law to opine that an additive does not present a risk of cancer in humans if the additive presents a known risk of cancer in animals, as FD&C Red No. 3 did to rats. Pertinently, the six color additives that H.B. 2354 targets do not have the same tetraiodo-fluorescein chemical structure of FD&C Red No. 3 that interfered with the rats’ thyroids and are therefore chemically distinguishable and not at risk of revocation on those grounds. None of these six additives have shown a risk to human health.

54. All six of the subject synthetic color additives banned by H.B. 2354 are safe and currently approved by the FDA for use in human food. 21 C.F.R. §§ 74.101, 74.102, 74.203, 74.303, 74.340, 74.704-706.⁵

55. These color additives remain among some of the most highly regulated food items under the FDCA.

56. The manufacturing methods and specifications for these color additives are codified in FDA's regulations and the batches produced by IACM's color manufacturing members are tested for conformity with the applicable regulatory specifications.

57. Once these color additives were approved for use by the FDA, the recipes for the respective color additives were codified as well to set forth composition and purity requirements.

58. The color additives then continue to be subject to scrutiny and monitoring by the FDA as a "certifiable" color additive. *See generally* 21 C.F.R. §§ 80.10-80.39. As a certified color, any batches of the color additive that are manufactured must be sampled and analyzed by FDA chemists to ensure that the codified recipe was followed such that the batch meets the requirements for composition and purity stated in the regulation. This requirement is to ensure that the batch does not contain impurities at levels that would pose a health concern.

59. Using an uncertified form of these color additives—deviating from the composition and purity requirements set forth in the regulation—renders the product adulterated in violation of the FDCA, and the FDA can take action against the product.

60. Once a batch is certified, the manufacturer must also keep records of how and to whom

⁵ The FDA has issued an order to "Revoke Authorization for the Use of Red Dye No. 3 in Food and Ingested Drugs," which will take effect on January 15, 2027 for foods and January 18, 2028 for drugs. However, FD&C Red No. 3 is chemically distinguishable from the other six banned colors. As noted previously, the IACM has decided not to challenge H.B. 2354's application as to Red 3.

the batch was distributed until the entire inventory for the batch has been used, and then maintain those records for at least two years thereafter. 21 C.F.R. § 80.39.

61. These certification requirements, wherein the batches are tested to ensure conformity with composition and purity, are unique to FD&C colors such as the ones expressly banned in H.B. 2354.

62. It bears emphasis that the FDA has no discretion here to allow the targeted color additives if they are potentially unsafe. *See Pub. Citizen v. Young*, 831 F.2d 1108, 1112 (D.C. Cir. 1987) (quoting 21 U.S.C. § 367(b)(5)(B)) (finding that for carcinogens, the FDA has no discretion, once a finding has been made that cancer is induced in man or animals, no matter how remote, the dye “shall be deemed unsafe, and shall not be listed.”).

B. West Virginia Enacts H.B. 2354

63. For decades, West Virginia has regulated the safety of its food products through various statutory provisions. Namely, West Virginia law prohibited the “adulteration” of food through West Virginia Code Section 16-7-1:

No person shall, within this State, manufacture for sale, offer for sale, or sell, any drug or article of food which is adulterated within the meaning of this article.

64. The code went on to define the meaning of the term “adulterated,” to inform what conduct the law prohibited:

Any drug or article of food shall be deemed to be adulterated within the meaning of this article . . .

(b)(7) if it contains any added substance or ingredients which are poisonous or injurious to the health;

W. Va. Code § 16-7-2.

65. Those who violated these provisions were subject to the enforcement and penalties set forth in Section 16-7-4 of the code:

Whoever, by himself or his agents, knowingly adulterates or causes to be adulterated any article of food or drug, or knowingly manufactures for sale, offers for sale, or sells, within this state, any article of food or drug which is adulterated within the meaning of this article, without making the same known to the buyer, shall be guilty of a misdemeanor, and, upon conviction thereof, shall be fined not exceeding five hundred dollars, or confined in jail not more than one year, or both, in the discretion of the court; and in addition to the penalties hereinbefore provided, he shall be adjudged to pay the cost and expense of analyzing such adulterated food or drug, as set forth in the certificate of the person making the analysis, not exceeding twenty-five dollars in any one case, which shall be included in the costs of such prosecution and taxed in favor of the state department of health or the West Virginia board of pharmacy, as the case may be; and if he be a registered pharmacist or assistant pharmacist, his name shall be stricken from the register. The adulterated article shall be forfeited and destroyed.

66. The state health officer and other enforcement agents were then empowered to take “specimens” for analysis to determine if a food product was adulterated.

It shall be the duty of a qualified chemist to test and analyze any such specimen, to record the result of his or her analysis among the records of the department, and to certify such findings to the state health officer, the West Virginia Board of Pharmacy, or to the county or municipal health officers, as the case may be. If the analysis indicates that the said food or drug is adulterated, a certificate of such result, sworn to by the person making the analysis, who shall also state in his or her certificate the reasonable cost and expense of such analysis, shall be prima facie evidence of such adulteration in any prosecution under this article.

W. Va. Code § 16-7-3.

67. Upon information and belief, when the state would test such specimens, they would not test for the presence of any of the color additives at all, let alone the additives at issue in this case, as those additives were not considered, and are not, “poisonous or injurious to the health,” as defined in Section 16-7-2.

68. However, earlier this year, legislators in West Virginia proposed an amendment to these code provisions, without any investigation, fact finding, or rational basis. H.B. 2354 was

sponsored by Delegates Adam Burkhammer, Ian T. Masters, David Elliott Pritt, Evan Worrell, Michael Hite, Margitta Mazzocchi, Eric Brooks, and Chuck Horst, on February 13, 2025. H.B. 2354's proffered purpose, at its inception, was to "prohibit[] the sale of any food product in the state that includes the dyes Red 3, Red 40, Yellow 5, Yellow 6, Blue 1, Blue 2[,] and Green 3."

69. H.B. 2354 had its first reading in the House of Delegates on February 24, 2025, and its second reading on February 27, 2025. H.B. 2354 proposed that the following language be added to the definition of "adulterated" in Section 16-7-2:

[I]f it contains any added substance or ingredients which are poisonous or injurious to the health, **including Red Dye 3, Red Dye 40, Yellow Dye 5, Yellow Dye 6, Blue Dye 1, Blue Dye 2[,] and Green Dye 3;**

2025R2924. This list of expressly banned substances includes seven synthetic FD&C color additives, including the six that IACM challenges herein which were then, and still are, codified as safe for the use in food by the FDA. 21 C.F.R. §§ 74.101, 74.102, 74.203, 74.340, 74.704-706.

70. On February 28, 2025, Delegate Worrell proposed a revision to the bill to add two preservatives to the explicit references to specific color additives to now be considered poisonous or injurious to health:

[I]f it contains any added substance or ingredients which are poisonous or injurious to the health, **including butylated hydroxyanisole, propylparaben, FD&C Blue No. 1, FD&C Blue No. 2, FD&C Green No. 3, FD&C Red No. 3, FD&C Red No. 40, FD&C Yellow No. 5, and FD&C Yellow No. 6;**

CS for HB 2354 at 2 (emphasis added). Among two other minor edits to the proposed bill, Delegate Worrell also proposed an additional section be added to the code by the proposed bill, which would be enacted as Section 18-5D-3A:

(a) Effective August 1, 2025, the following food additives shall be deemed unsafe and shall not be permitted as an ingredient in any meal served in a school nutrition program as set forth in this article:

- (1) Red Dye No. 3 (CAS Reg. No. 16423-68-0);
- (2) Red Dye No. 40 (CAS Reg. No. 25956-17-6);
- (3) Yellow Dye No. 5 (CAS Reg. No. 1934-21-0);
- (4) Yellow Dye No. 6 (CAS Reg. No. 2783-94-0);
- (5) Blue Dye No. 1 (CAS Reg. No. 3844-45-8);
- (6) Blue Dye No. 2 (CAS Reg. No. 860-22-0); and
- (7) Green Dye No. 3 (CAS Reg. No. 2353-45-9).

(b) An elementary, middle, or high school may permit the sale of food items that do not comply with this section as part of a school fundraising event if the sale of those items takes place off of and away from school premises or the sale of those items takes place on the school premises at least one-half hour after the end of the school day.

Eng. CS for HB 2354. Delegate Worrell's proposal carried by a vote of 93 to 5. The bill was then read a third time and passed by the West Virginia House in a vote of 93 to 5.

71. The bill was then introduced in the West Virginia Senate and read for the first time on March 3, 2025, followed by a second reading on March 4, 2025. On March 5, 2025, Senator Morris proposed a revision to the bill, by changing the effective date that the new language when Section 16-7-2 would go into effect from January 1, 2027 to January 1, 2028. Enr. CS for HB 2354. Senator Morris's proposal passed by a vote of 31 to 2, and the Senate passed the proposed bill by the same number of votes on the same date.

72. On March 13, 2025, the House of Delegates concurred with the Senate's amendment to the effective date for Section 16-7-2 by a vote of 79 to 17.

73. Delegate McGheehan then proposed an additional amendment, this time to Section 16-7-4, modifying the enforcement provisions for violation of the law as follows (in addition to changing the genders of various pronouns in the law):

(b) This section does not apply to any person who offers for sale. or sells. within this state. less than \$5,000, in aggregate, of adulterated food, per

month, when the food is adulterated by including of butylated hydroxyanisol, propylparaben, FD&C Blue No. 1, FD&C Blue No. 2, FD&C Green No. 3, FD&C Red No. 3, FD&C Red No. 40, FD&C Yellow No. 5, or FD&C Yellow No. 6.

HB2354 HFA McGeehan 3-13 #1, CR 3338. The amendment passed by a vote of 88 to 8.

74. On March 14, 2025, the Senate concurred with the House amendments by a vote of 26 to 4, passing the now final bill with the same number of votes.

75. In its final form, H.B. 2354 amends West Virginia Code Section 16-7-2 to summarily classify FD&C Blue No. 1, FD&C Blue No. 2, FD&C Green No. 3, FD&C Red No. 3, FD&C Red No. 40, FD&C Yellow No. 5, and FD&C Yellow No. 6 as “poisonous or injurious,” while inexplicably reversing decades of criminalization of the “adulteration” of food by excepting violators whose violation was the use of these color additives or chemicals in the sale of food products if their sales are under \$5,000 a month. W. Va. Code § 16-7-4. H.B. 2354 also enacts Section 18-5D-3A to prohibit use of the same colors from school nutrition programs effective August 1, 2025.

76. The West Virginia legislature intended to target these color additives—H.B. 2354’s stated purpose explicitly concedes this fact, with no reference to public health therein.

77. Throughout H.B. 2354’s journey to enactment, there was little debate on H.B. 2354, and none of the debate that occurred was scientific in nature. The only comment made by a legislator regarding scientific support for the bill referenced a since debunked health assessment from the California Environmental Protection Agency’s Office of Environmental Health Hazard Assessment about potential sensitivity to synthetic food dyes in children and whether those sensitivities may result in neurobehavioral issues. Critically, the assessment failed to establish a causal link between the dyes and neurobehavioral issues such that the California Department of Health itself determined it would

not use the assessment as a basis for its own interventions.⁶ Prior to the assessment, a myriad of other public health authorities found no casual link existed⁷, and, since the assessment was conducted, the FDA has opined there is no such causal link.⁸

78. Prior to H.B. 2354's enactment, Defendants had never taken the position that any of the seven colors were "poisonous or injurious" under the statute. None of IACM's members have been subject to any enforcement actions under West Virginia law because they are not poisonous or injurious.

79. The Legislature, recognizing that these products are not poisonous or injurious—as they would not need to be expressly enumerated in H.B. 2354 if they were as they would have already fallen within the existing language of the law—resorted to banning the color additives by name.

80. Governor Patrick Morrisey signed H.B. 2354 into law on March 24, 2025. The provisions banning the named color additives from school nutrition programs (Section 18-5D-3A) went into effect on August 1, 2025 with the broader ban on these color additives state-wide (Sections 16-7-2 and 16-7-4) effective on January 1, 2028.

81. The Secretary of the U.S. Department of Health and Human Services, Robert F. Kennedy, was present at H.B. 2354's signing on March 24, 2025, at which Governor Morrisey commented that the law made West Virginia the leader of "the Make America Healthy Again mission. . ." and thanked "the Legislature, HHS Secretary Robert Kennedy, and the entire Trump

⁶ Cal. Dept. of Pub. H., Response to Petition from the Center for Science in the Public Interest, et. al (Sept. 2024), available at www.cdph.ca.gov/Programs/OLS/CDPH%20Document%20Library/Response.pdf

⁷ See, e.g., Joint FAO/WHO Expert Committee on Food Additives (JECFA), Eighty-sixth Report (2019), Eighty-fourth Report (2017), and Eighty-second Report (2016)

⁸ FDA, "Color Additives Questions and Answers for Consumers" (Dec. 2023), available at <https://www.fda.gov/food/color-additives-information-consumers/color-additives-questions-and-answers-consumers>.

Administration for helping us launch this movement right here in West Virginia.” Notably, the FDA, which falls under Secretary Kennedy’s purview, has not changed its position on the six colors that are the subject of IACM’s suit, which are codified as “safe” by federal standards.

82. Despite its revised final stated purpose, this law will do little to improve public health. H.B. 2354 will only serve to place a severe strain on West Virginia’s food industry. American consumers deserve the choice to enjoy food and beverage products at various price points.

83. Removing FD&C color additives from school meals will not improve their nutritional profile or limit the number of processed foods offered. However, this law may make healthy options less appealing and will place additional burdens on schools already struggling to provide nutritious meals, complicating efforts to meet federal nutrition standards. Rather than improving health outcomes, H.B. 2354 will limit food choices, increase costs, and create unnecessary challenges for West Virginians.

84. H.B. 2354’s negative consequences for IACM’s members is equally apparent. When the law fully goes into effect, as enacted, if the state tests a product, and the analysis reveals a positive result for one of the banned color additives, then the manufacturer or seller of that product could be prosecuted for violating the law.

85. And, due to the prime facie nature of the test results being used in the prosecution under Section 16-7-3, there will be no process by which the accused can defend that the color additive is not in fact poisonous or injurious and is in fact safe. Thus, if IACM’s members run afoul of the statute, they will summarily be subject to the potential criminal and civil penalties, punishable by up to one year in prison.

86. Compliance will be costly and complex for producers, retailers, and distributors alike—some of whom may be forced to discontinue operations in the state. Restricting color additives ignores

scientific evidence and fails to consider the complex challenges of reformulation. Reformulating products is neither simple nor immediate, and the resulting supply disruptions will limit the availability of familiar grocery items, exacerbating food accessibility challenges, especially in rural areas.

87. Replacing FD&C color additives with naturally derived color alternatives is not a simple swap. IACM members already offer naturally derived color options that have been available to consumers for decades. However, overcoming all the challenges created by a nonscientific mandate, including production hurdles, technical limitations, supply chain restraints, uneven product results, higher costs, and regulatory inconsistencies, will take more than five years, if not an entire generation. Moreover, the development of any new color additives would need to follow FDA approval standards, which are robust, costly, and time consuming to establish.

88. Furthermore, this baseless legislative action intrudes upon the exclusive authority of the State Board of Education and the State BOE Defendants, with the Legislature substituting its judgment for their own. As Article XII, Section 2 of the West Virginia Constitution provides: “The general supervision of the free schools of the State shall be vested in the West Virginia board of education which shall perform such duties as may be prescribe by law.”

89. Pursuant to these general supervisory powers, the State BOE Defendants have obligations to establish, implement and enforce high quality education standards for all facets of public education in West Virginia, as well as a duty to ensure the complete executive delivery and maintenance of a “thorough and efficient system of free schools.”

90. As the Supreme Court of Appeals of West Virginia has recognized, general supervision “is not an axiomatic blend of words designed to fill the pages of our State Constitution, but it is a meaningful concept to the governance of schools and education in this state. Decisions that pertain to education must be faced by those who possess expertise in the educational area.” *W. Va. Bd. of Educ.*

v. Hechler, 180 W. Va. 451, 455, 376 S.E.2d 839, 843 (1988).

91. Indeed, this delegation of power from the citizens of West Virginia to the State Board of Education is unique, and “[u]nlike most other administrative agencies which are constituents of the executive branch, the Board enjoys a special standing because such a constitutional provision exists.” *Hechler*, 180 W. Va. at 455, 376 S.E.2d at 842.

92. As part of this constitutional duty to establish, implement and enforce standards for all facets of education in West Virginia, the State Board of Education is responsible for establishing standards governing school nutrition programs operated by county boards of education throughout the state. *See* W. Va. Code § 18-5D-3. Section 18-5D-3A unconstitutionally intrudes upon and co-opts educational policymaking—particularly school nutritional standards—that belongs solely to the State Board of Education under West Virginia’s constitutional framework.

93. By bypassing the WVBOE’s constitutional prerogative to supervise education and enact rules governing school nutrition, H.B. 2354 unconstitutionally encroaches on the Board’s exclusive authority under Article XII, Section 2 of the West Virginia Constitution.

CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF (COUNT I) **DECLARATORY/INJUNCTIVE RELIEF—EQUAL PROTECTION** *Fourteenth Amendment of the United States Constitution and* *Article III, Section 10 of the Constitution of West Virginia*

94. Plaintiff incorporates and repeats the allegations set forth in Paragraphs 1 through 93, above.

95. The Equal Protection Clause of the Fourteenth Amendment provides that: “[n]o State shall . . . deny to any person within its jurisdiction the equal protection of the laws.” U.S. Const. amend. XIV, § 1. The clause “does not take from the States all power of classification,” *Pers. Adm'r v. Feeney*, 442 U.S. 256, 271 (1979), but “keeps governmental decisionmakers from treating differently persons

who are in all relevant respects alike.” *Nordlinger v. Hahn*, 505 U.S. 1, 10 (1992).

96. Article III, Section 10 of the West Virginia Constitution provides that: “[n]o person shall be deprived of life, liberty, or property, without due process of law, and the judgment of his peers.”

97. “Equal protection of the law is implicated when a classification treats similarly situated persons in a disadvantageous manner.” *Israel v. West Virginia Secondary Sch. Activities Comm’n*, 182 W.Va. 454, 458, 388 S.E.2d 480, 484 (1989).

98. “To succeed on an equal protection claim, a plaintiff must first demonstrate that he has been treated differently from others with whom he is similarly situated and that the unequal treatment was the result of intentional or purposeful discrimination.” *Morrison v. Garraghty*, 239 F.3d 648, 654 (4th Cir. 2001). If the plaintiff makes this showing, “the court proceeds to determine whether the disparity in treatment can be justified under the requisite level of scrutiny.” *Id.*

99. If the subject law does not burden a suspect class or implicate a fundamental right, then rational basis review applies. *Pennell v. City of San Jose*, 485 U.S. 1, 14 (1988) (citing *New Orleans v. Dukes*, 427 U.S. 297, 303 (1976)).

100. Even under rational basis scrutiny, a classification system “must find some footing in the realities of the subject addressed by the legislation.” *Heller v. Doe*, 509 U.S. 312, 321 (1993). “The State may not rely on a classification whose relationship to an asserted goal is so attenuated as to render the distinction arbitrary or irrational.” *City of Cleburne, Tex. v. Cleburne Living Center*, 473 U.S. 432, 446-7 (1985).

101. H.B. 2354 treats the enumerated color additives differently from not only other color additives, but from all other ingredients which could be used to manufacture food products.

102. There is no health distinction between the expressly banned color additives and the

other color additives that IACM's members manufacture.

103. There is no rational basis for treating the expressly banned color additives differently than any other color additive, let alone any other ingredient.

104. The Legislature drew this distinction arbitrarily, without any findings of fact, and the legislative history fails to justify the distinction.

105. The Legislature's disparate treatment of these color additives, and thereby IACM's members, is irrational and arbitrary.

106. There is no "rational relationship between the disparity of treatment and [a] legitimate governmental purpose." *Veney v. Wyche*, 293 F.3d 726, 731 (4th Cir. 2002) (quoting *Heller*, 509 U.S. at 319–20).

107. H.B. 2354 accordingly denies IACM's members equal protection under the law and is unconstitutional.

SECOND CLAIM FOR RELIEF (COUNT II)
DECLARATORY/INJUNCTIVE RELIEF—BILL OF ATTAINDER
Article I, Section 10 of the United States Constitution and
Article III, Section 4 of the Constitution of West Virginia

108. Plaintiff incorporates and repeats the allegations set forth in Paragraphs 1 through 107, above.

109. Article I, Section 10 of the United States Constitution provides that: "[n]o State shall . . . pass any Bill of Attainder, ex post facto Law, or Law impairing the Obligation of Contracts, or grant any Title of Nobility." A bill of attainder is "a law that legislatively determines guilt and inflicts punishment upon an identifiable individual without provision of the protections of a judicial trial." *Nixon v. Administrator of General Services*, 433 U.S. 425, 468 (1977); *see also United States v. O'Brien*, 391 U.S. 367, 383, n. 30 (1968); *United States v. Lovett*, 328 U.S. 303 (1946).

110. Article III, Section 4 of the West Virginia Constitution also provides that "[n]o bill of

attainder, ex post facto law, or law impairing the obligation of a contract, shall be passed.” West Virginia’s prohibition of bills of attainder “follow[s] the contours set by the United States Supreme Court in construing the same prohibition in the Federal Constitution.” *Baker v. Civil Service Commission*, 161 W.Va. 666, 677, 245 S.E.2d 908, 914 (1978).

111. Accordingly, for legislation to comport with both the United States and West Virginia constitutions, “legislative bodies must accomplish their objectives by ‘rules of general applicability’ and ‘cannot specify the people upon whom the sanction it prescribes is to be levied.’” *Planned Parenthood of Cent. North Carolina v. Cansler*, 877 F.Supp.2d 310, 321 (M.D.N.C., 2012) (quoting *United States v. Brown*, 381 U.S. 437, 442 (1965)).

112. H.B. 2354 “singl[es] out” a group, manufacturers and users of the seven enumerated color additives, for “legislatively prescribed punishment.” *Communist Party of the United States v. Subversive Activities Control Board*, 367 U.S. 1, 86 (1961) (“The singling out of an individual for legislatively prescribed punishment constitutes an attainder whether the individual is called by name or described in terms of conduct which, because it is past conduct, operates only as a designation of particular persons.”).

113. H.B. 2354 imposes punishment, both penally and economically. Anyone who:

knowingly adulterates or causes to be adulterated any article of food or drug, or knowingly manufactures for sale, offers for sale, or sells, within this state, any article of food or drug which is adulterated within the meaning of this article, without making the same known to the buyer, shall be guilty of a misdemeanor, and, upon conviction thereof, shall be fined not exceeding \$500, or confined in jail not more than one year, or both, in the discretion of the court

W. Va. Code § 16-7-4(a).

114. H.B. 2354 imposes such punishments against the manufacturers of its enumerated colors, or manufacturers of products which utilize those color additives, without due process. W. Va. Code § 16-7-3 permits the government to, through chemical analysis, use any indicia of the presence

of one of the enumerated color additives as “prima facie evidence for prosecution.” Nor are manufacturers given the opportunity to defend the safety of the targeted color additives.

115. H.B. 2354 accordingly operates as an unconstitutional bill of attainder.

THIRD CLAIM FOR RELIEF (COUNT III)
DECLARATORY/INJUNCTIVE RELIEF—DUE PROCESS
Fourteenth Amendment of the United States Constitution

116. Plaintiff incorporates and repeats the allegations set forth in Paragraphs 1 through 115, above.

117. The Due Process Clause of the Fourteenth Amendment of the United States Constitution requires that “a fair warning . . . be given to the world in language that the common world would understand, of what the law intends to do if a certain line is passed.” *Bittner v. United States*, 598 U.S. 85, 102 (2023) (quoting *McBoyle v. United States*, 283 U.S. 25, 27 (1931)).

118. “It is a basic principle of due process that an enactment is void for vagueness if its prohibitions are not clearly defined.” *Grayned v. City of Rockford*, 408 U.S. 104, 108 (1972).

119. While the Constitution does not require “mathematical certainty from our language,” it does prohibit statutory language so unclear about prohibited conduct that it “may trap the innocent by not providing fair warning” or so standardless that it allows “arbitrary and discriminatory enforcement.” *Greenville Women's Clinic v. Comm’r, S.C. Dep’t of Health & Env’t*, 317 F.3d 357, 366 (4th Cir. 2002) (quoting *Grayned*, 408 U.S. at 108, 110).

120. “To survive a vagueness challenge, a statute must give a person of ordinary intelligence adequate notice of what conduct is prohibited and must include sufficient standards to prevent arbitrary and discriminatory enforcement.” *Manning v. Caldwell for City of Roanoke*, 930 F.3d 264, 272 (4th Cir. 2019) (en banc); *see also Hill v. Colorado*, 530 U.S. 703, 732 (2000) (noting a law is unconstitutionally vague if it “authorizes or even encourages arbitrary and discriminatory

enforcement.”).

121. The term “poisonous and injurious to health,” as used in W.Va. Code § 16-7-2, and as amended by H.B. 2354, is vague and undefined. In fact, the term “poisonous and injurious” is not defined anywhere in West Virginia law in any context.

122. As written, and particularly as amended by H.B. 2354, a person of ordinary intelligence—including IACM’s members—have no way of knowing whether their color additives that are not expressly enumerated by amendment—are violative of the law.

123. It is unclear by what criteria the West Virginia Legislature intends “poisonous and injurious” to be enforced both (1) in the existing language of W.Va. Code § 16-7-2, as the term is undefined; and (2) as the terms is rendered even more vague and confusing by only expressly enumerating examples of color additives which the FDA has already approved as “safe.”

124. The vague and undefined nature of the law invites arbitrary enforcement against unnamed color additives.

125. By failing to define the term “poisonous and injurious,” the law impermissibly disincentivizes the use of many ingredients that are and have been deemed safe by the FDA as a result because “[u]ncertain meanings inevitably lead citizens to ‘steer far wider of the unlawful zone’ than if the boundaries of the forbidden areas were clearly marked.” *Grayned*, 408 U.S. at 109; *see, e.g., W. Virginia Coal. Against Domestic Violence, Inc. v. Morrissey*, 689 F. Supp. 3d 272, 292 (S.D.W. Va. 2023) (finding provision facially void for vagueness in its failure to define “any action against” as the term “fails to provide a person of ordinary intelligence a reasonable opportunity to know and understand what is prohibited, so that he or she may act accordingly.”).

126. H.B. 2354’s imposition of criminal penalties requires more clarity than is provided by the text of the statute to comport with the due process.

127. H.B. 2354’s use of the term “poisonous and injurious” is so vague that the provision is constitutionally void and unenforceable.

PRAYER FOR RELIEF

Plaintiff IACM respectfully prays that this Court:

- a. Issue an order and judgment declaring that H.B. 2354, and/or the challenged provisions of H.B. 2354, violates the U.S. and West Virginia Constitutions, and is unenforceable;
- b. Enjoin, preliminarily and permanently, without security, the implementation and enforcement of H.B. 2354 against IACM’s members;
- c. Enjoin, preliminarily and permanently, the implementation and enforcement of H.B. 2354 as to the sale of color additives;
- d. Award IACM costs and reasonable attorneys’ fees, as appropriate; and
- e. Grant any other relief the Court finds just and appropriate.

Dated: October 3rd, 2025

Respectfully submitted,

/s/ Carte P. Goodwin

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