



THE DELANEY CLAUSE:

How it Impacts Regulatory Policy & Pathways to Change

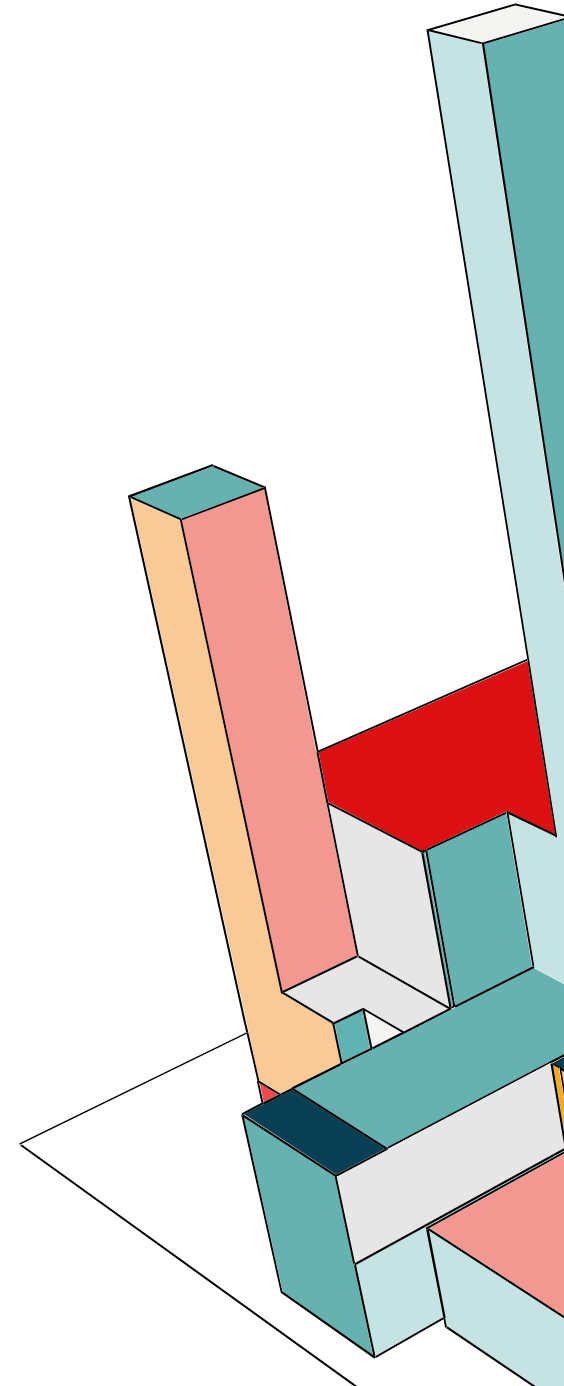
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IACM Global Color Conference

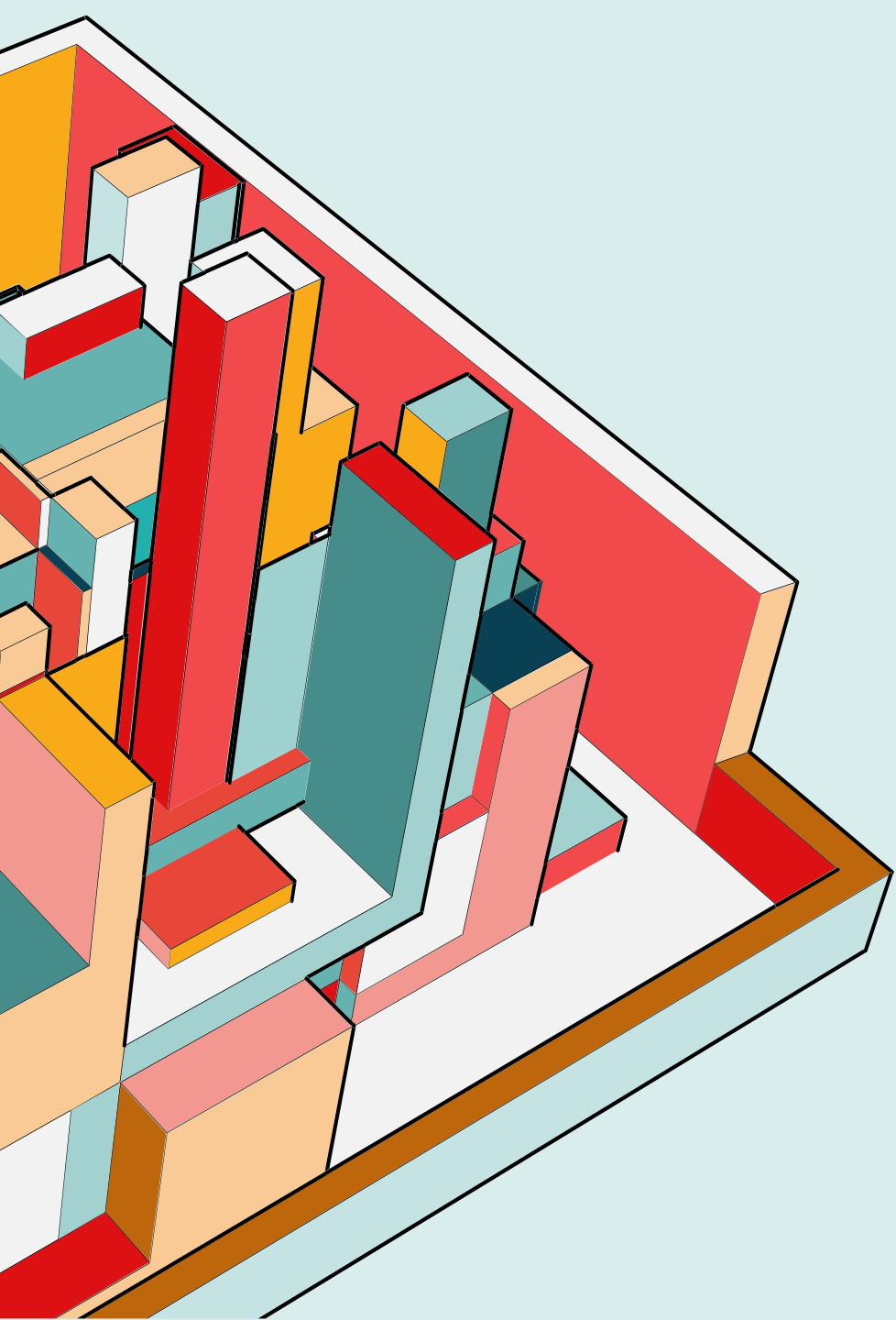
ROADMAP

- Introduction to the Delaney Clause
- FDA's Application of the Delaney Clause
- Any route to change?





A little history first...



THE DELANEY CLAUSE

Why was it introduced?



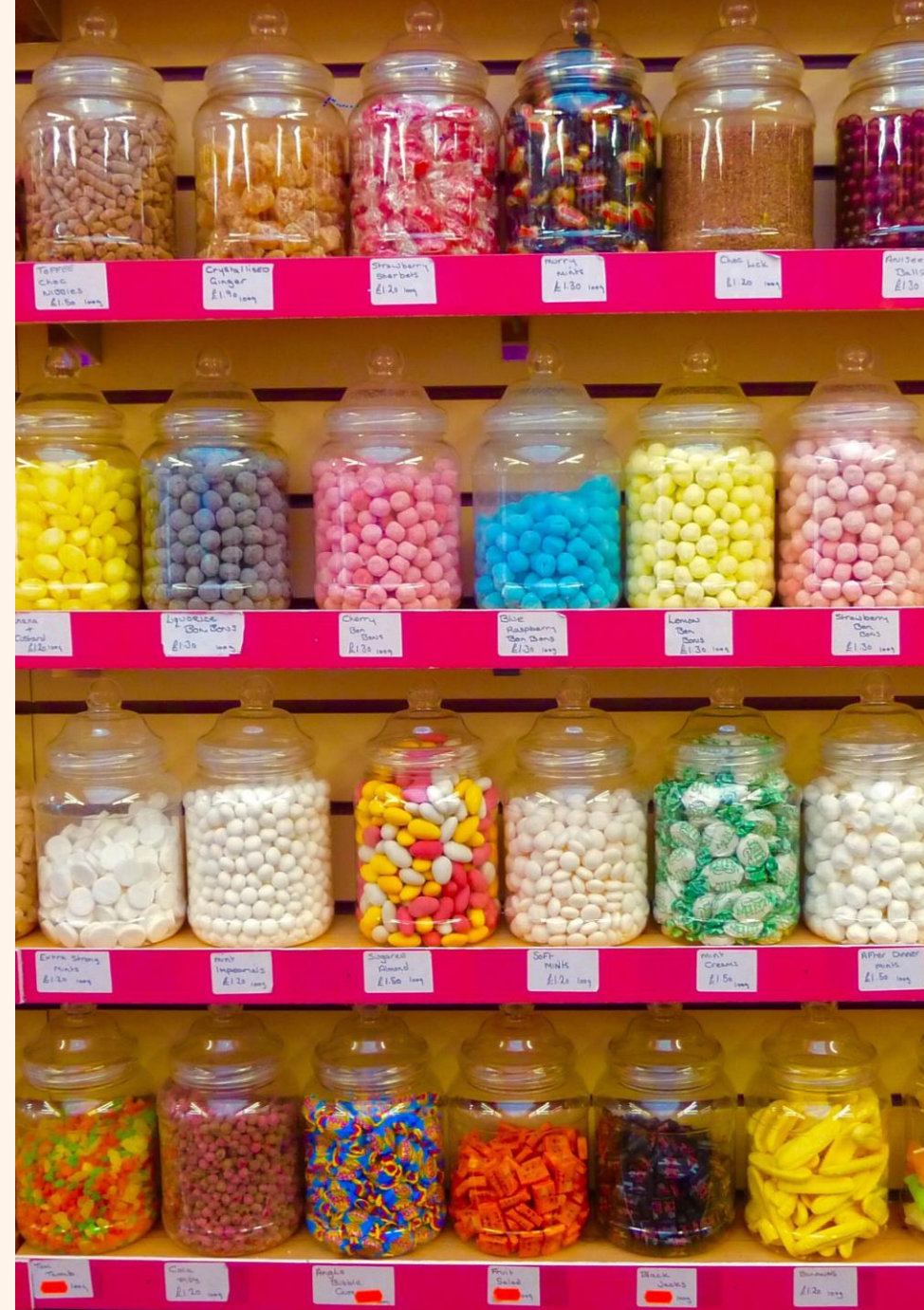
THE LANGUAGE OF THE COLOR ADDITIVE DELANEY CLAUSE

“A color additive shall be deemed unsafe...if the additive 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 additives for use in food, to induce cancer in man or animal, or...after other relevant exposure of man or animal to such additive is found...to induce cancer in man or animal.”

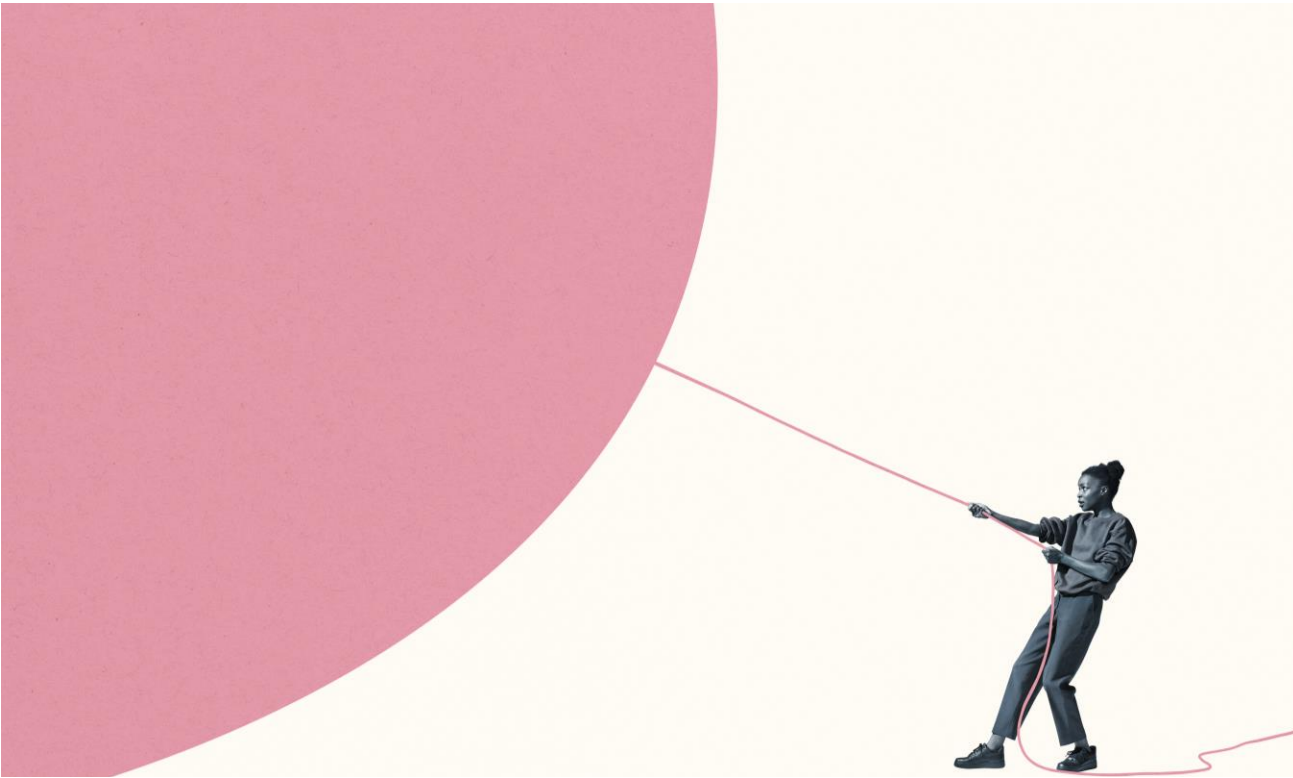
21 U.S.C. §379e(b)(5)(B)

SAFETY AS THE BASIS

But a reflection of the state of science from its time



APPLICATION OF THE DELANEY CLAUSE

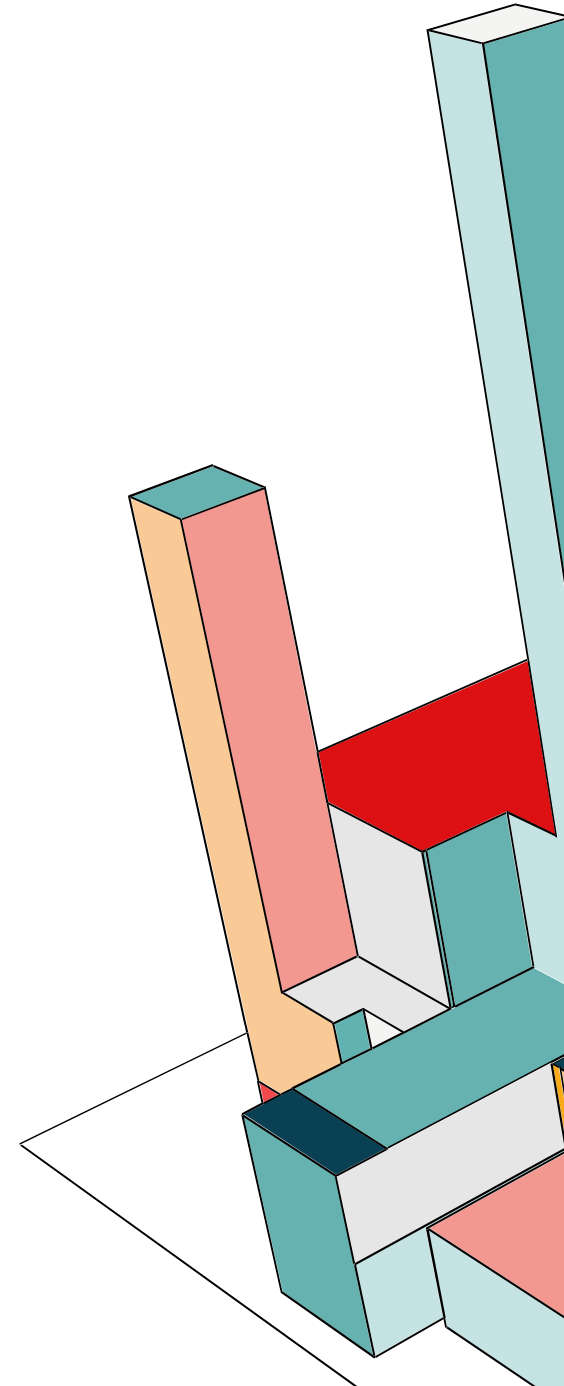


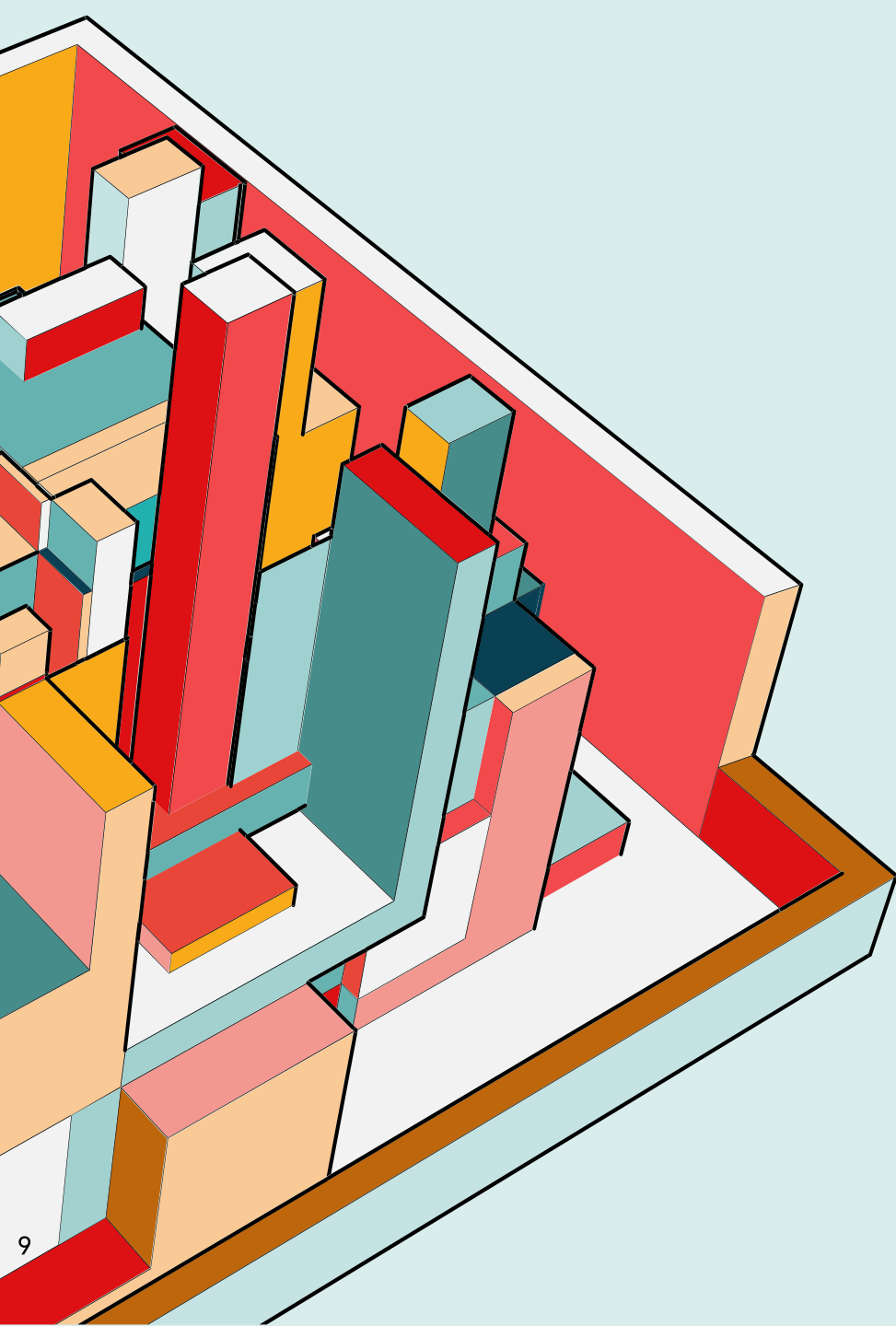
- Limited use as enforcement tool
- Impact of judicial precedent



ARE THERE INTERPRETATIVE GUARDRAILS TO THE DELANEY CLAUSE?

- Reminder - CAA Delaney says: "A color additive shall be deemed unsafe...if the additive 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 additives for use in food, to induce cancer in man or animal, or...after other relevant exposure of man or animal to such additive is found...to induce cancer in man or animal."





**WILL THE DELANEY
CLAUSE WILL BE
STRICTLY APPLIED
BY FDA?**



IS MEANINGFUL CHANGE POSSIBLE?

- FDA's post-market food chemical assessment program
- U.S. Supreme Court decision in *Loper* and loss of *Chevron* deference
- Statutory change the only pathway?

FINAL TAKEAWAYS

1. FDA likely to apply Delaney only when it has to but will likely apply it strictly
2. Meaningful change to Delaney will require statutory change
3. U.S. Supreme Court decision in *Loper* and loss of *Chevron* deference could create interesting judicial review opportunity but beware...
4. The food additive and color additive Delaney Clauses will continue to be weaponized by NGOs



THANK YOU

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International Association of Color Manufacturers

