The Case FDA Already Answered:

Pill Appearance, Trade Dress Functionality, and the Patients Who Cannot Absorb a Change

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Abstract

In 2011 a commentator argued in a pharmacy journal that the Food and Drug Administration should standardize the appearance of bioequivalent medications, that judicial precedent had already made trade dress rights in a medicine's appearance nearly impossible to establish, and that formal agency recognition of appearance as functional would end most trade dress claims because functionality is the agency's question and not the courts'. In 2014 the agency answered in a medical journal. It conceded that changes in pill appearance contribute to patient non-compliance, then said that trade dress protections are extensive, that even color can constitute a defensible trademark, and that its options were therefore limited to guidance and surveillance. It assigned the remaining burden to the dispensing pharmacist. More than a decade later nothing has changed, and the agency's legal premise has not held up. This Article argues that the barrier the agency invoked does not exist, and that the agency's own materials prove it. Part 206 of Title 21 already forbids any solid oral dosage form from entering interstate commerce without a code imprint that, together with the product's size, shape, and color, permits unique identification, and the exemption list published alongside that rule contains six grounds, none of them intellectual property. The agency then issued guidance recommending that generic tablets closely approximate the size of the reference drug, for the stated purpose of patient compliance, and declined to say anything about color, the one attribute over which trade dress is litigated. Federal courts have meanwhile held pill appearance functional precisely because patients rely on it, which under settled doctrine defeats protection rather than establishing it, and a claim to trade dress in a pill's color additionally requires a showing of secondary meaning that prescription drugs are structurally unable to make, because the patient never sees the manufacturer's packaging. That the question keeps arriving as a trademark dispute between two firms, in which the patient appears only as evidence, is itself an argument for deciding it somewhere else. The Article then identifies the population the record does not count. For patients with persecutory-spectrum conditions and for older patients with cognitive impairment, an unannounced change in a pill's appearance is not an adherence variable. It is evidence, absorbed into a belief structure, and the disclosure the agency assigned to the pharmacist can recruit the person delivering it into the very system it was meant to disconfirm.

Keywords: disability law; ADA Title III; trade dress; functionality doctrine; generic substitution; FDA; medication adherence; persecutory delusion; reasonable modification; preemption.

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Contents

I. Introduction

A prescription is refilled every thirty days. The molecule does not change. The dose does not change. The pill changes, because the pharmacy's wholesaler contract moved to a different manufacturer, and that manufacturer's tablet is a different color, or a different shape, or both.

For most patients this is a moment of mild confusion, resolved or not resolved, and then forgotten. For some it is not. Patients rely on the appearance of their medication to confirm they are taking the right thing; in a national survey of patients taking chronic disease medications, seventy-two percent said so directly.[1] Among patients who had begun a generic cardiovascular medication after a heart attack, twenty-nine percent experienced a change in the shape or color of a pill within a year, and those changes were associated with substantially elevated odds of stopping the medication.[2]

This Article is not about that literature, which is now extensive and largely one-directional. It is about a legal claim the agency made in response to that literature, and about a population the literature does not count.

The legal claim came in December 2014, when two officials of the Food and Drug Administration published a reply in the same journal that had run the cardiovascular study.[3] The agency conceded that appearance changes can contribute to nonadherence. It described the mechanism accurately, noting that generic drugs make up nearly eighty-five percent of prescriptions dispensed and that patients will continue to experience appearance changes as economic forces drive product turnover in pharmacies and mail-order houses. And then it explained why it would not act. Trade dress protections, the agency said, are extensive; even color can constitute a defensible trademark; a requirement that generics match the reference

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1. Aaron S. Sarpatwari et al., *A Survey of Patients' Perceptions of Pill Appearance and Responses to Changes in Appearance for Four Chronic Disease Medications*, 34 J. Gen. Internal Med. 420 (2019).

2. Aaron S. Kesselheim, Katsiaryna Bykov & Jerry Avorn, *Burden of Changes in Pill Appearance for Patients Receiving Generic Cardiovascular Medications After Myocardial Infarction*, 161 Annals Internal Med. 96 (2014). Non-persistence was associated with color change at an adjusted odds ratio of 1.34 and with shape change at 1.66.

3. Kathleen Uhl & John R. Peters, *Burden of Changes in Generic Pill Appearance*, 161 Annals Internal Med. 839 (2014).

product in size, shape, and color could effectively eliminate the ability to market a generic product in many cases. Short of substantial changes in trade dress law, the agency concluded, it had two options: issue guidance and conduct surveys. The dispensing pharmacist, it observed, is currently responsible for explaining appearance differences to concerned patients.

That was not a novel question presented to the agency for the first time. Three years earlier, in a pharmacy journal, Alfred Engelberg had argued the opposite in some detail, and had argued it in terms the agency did not engage.[4] Judicial precedent, Engelberg wrote, had significantly restricted the circumstances in which a valid claim to trademark rights in the appearance of any product can exist, and industry practice in an era of mandated substitution had evolved so that valid trademark rights in the appearance of a medicine were highly unlikely ever to be established.[5] More pointedly, he identified whose question it was: formal recognition by the agency of the important functional role that product appearance plays in reducing patient anxiety and enhancing medication safety would bring an end to most trade dress claims, because it is ultimately up to the agency, and not the courts, to determine which attributes of a medicine play an important role in making drugs safe and efficacious.[6]

The argument of this Article is that Engelberg was right, that the agency's 2014 answer was wrong when it was written, and that it is now wrong in a way the agency can verify from its own rulebook without waiting for a court.

Part II sets out the record and the one empirical study that cuts the other way. Part III states the agency's position from its own publications. Part IV shows why the trade dress premise fails: as a matter of the agency's existing regulations and its own guidance, which already recommends appearance conformity in size while declining to reach color; as a matter of functionality doctrine, which federal courts have applied to prescription tablets repeatedly since 1980 and four times since March of 2025; as a matter of secondary meaning, which prescription

4. Alfred B. Engelberg, *The Case for Standardizing the Appearance of Bioequivalent Medications*, 17 J. Managed Care Pharmacy 321 (2011).

5. *Id.* at 322.

6. *Id.*

drugs are structurally unable to establish; and as a matter of institutional allocation, because the question keeps being decided in trademark suits between private firms. Part V explains why the manufacturers cannot be the answer, because federal preemption removes them from tort liability for labeling and design while leaving appearance outside the sameness duty, and because antitrust exposure prevents them from coordinating on their own. Part VI identifies the population for whom the agency's assigned remedy inverts rather than merely failing. Part VII sets out what remains for the individual patient under Title III of the Americans with Disabilities Act, and why the obligation belongs upstream of the counter. The Article closes with what the agency can do without any change in trade dress law at all.

II. The Record

The evidence that pill appearance matters to patients is fifteen years old, consistent, and largely one-directional. It is also, on the single population this Article is most concerned with, thinner than it looks.

A. The Empirical Base

The finding that patients rely on the appearance of their medication is not an inference drawn from adherence data. Patients report it directly. In a national survey of 814 respondents taking medications for four chronic conditions, 72 percent said they relied on pill appearance to ensure they were taking the correct medication, 72 percent wanted the same color on refill, 71 percent the same shape, and 75 percent the same size.[7] Twenty-one percent reported having thought at some point that they had received the wrong medication, and 8 percent reported adjusting how they took a medication in response to a change in its appearance, with lower-income respondents more likely to report the adjustment.[8] A later national survey by the same group found that about half of patients, 51 percent, had experienced an appearance change on a refill within the past year,

7. Sarpatwari et al., *supra* note 1.

8. *Id.*

and that of those, about half again, 53 percent, had experienced it two or more times.[9] This is not an occasional event.[10]

The behavioral consequence has been measured repeatedly. Among more than 60,000 patients initiating an antiepileptic drug, a change in pill color was associated with elevated odds of failing to refill.[11] Among patients starting generic cardiovascular medications after a myocardial infarction, both color and shape changes were associated with non-persistence, shape carrying the larger association.[12] A study of angiotensin receptor blockers found the association extended past the refill record to blood pressure control.[13] A mixed-methods systematic review of older patients found that those managing multiple medications use appearance to distinguish among them, and that similar-appearing products defeat that system.[14]

The synthesis of this literature reports an impact in seven of the ten studies it included, a significant association with persistence in three of the five that measured persistence, and a significant association with adherence in all three that measured adherence.[15]

B. The Study That Found Nothing

The single most on-point study in this literature found no effect. Examining 4,810 patients with schizophrenia in a Basque administrative database, researchers found that 26.9 percent were nonadherent by a medication possession ratio below eighty percent, that different brands of the same antipsychotic were dispensed to 8.5 percent of the cohort, and that, contrary to

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9. Rachel E. Barenie et al., *Preferences for and Experiences With Pill Appearance Changes: National Surveys of Patients and Pharmacists*, 26 Am. J. Managed Care 340 (2020).

10. The frequency figures are drawn from a secondary account of the survey and should be confirmed against the published article before submission.

11. Aaron S. Kesselheim, Alexander S. Misono & William H. Shrank, *Variations in Pill Appearance of Antiepileptic Drugs and the Risk of Nonadherence*, 173 JAMA Internal Med. 202 (2013).

12. Kesselheim, Bykov & Avorn, *supra* note 2.

13. *See* Blanca Lumbreras et al., *Impact of Changes in Pill Appearance in the Adherence to Angiotensin Receptor Blockers and in the Blood Pressure Levels*, 7 BMJ Open e012586 (2017).

14. *See* Rukhsana Shariff et al., *Does the Formulation of Oral Solid Dosage Forms Affect Acceptance and Adherence in Older Patients?*, 21 J. Am. Med. Directors Ass'n 1015 (2020).

15. Blanca Lumbreras, Javier Sanz-Valero & Rocío López-Pintor, *Impact of Variation in Pill/Package Appearance of Drugs on Patients' Behavior: A Systematic Review*, 18 J. Patient Safety 310 (2021).

their expectations, there was no significant association between an inconsistent appearance of prescribed antipsychotics and poorer adherence.[16]

The result is not answered by ignoring it, and this Article does not. It is answered by noticing what was measured. A medication possession ratio computed from dispensing records detects whether a prescription was filled on schedule. It does not detect what a patient believes about the pill, whom the patient suspects of having changed it, or what happens inside a household when a spouse offers a reassurance the patient does not accept. A patient may continue filling and swallowing a medication on a perfect schedule while the appearance change is absorbed into a persecutory belief structure and reorganizes around the person handing over the bottle. Nothing in a claims database can see that.

The systematic review of this literature reaches the same methodological point, observing that the divergence between its included studies and prior evidence may lie in the use of databases to assess persistence and adherence rather than the evaluation of data in individual patients, and noting a countervailing finding of a significant association between adherence and a potential change in the appearance of olanzapine, an antipsychotic.[17]

III. What the Agency Said

The agency's position on this subject is short, published, and unamended. It appears in a 2014 letter from two officials of the Food and Drug Administration, printed in the same journal that had run the cardiovascular study five months earlier.

The letter concedes the harm. The agency states that it realizes changes in pill appearance and packaging can contribute to patient non-compliance, and that it has published draft guidances

16. Unax Lertxundi et al., *Influence of an Inconsistent Appearance of Antipsychotics on Drug Adherence in Patients with Schizophrenia*, 97 Medicine e12990 (2018). The article carries an erratum correcting Figure 1, which does not alter the reported findings. *See* Erratum, 97 Medicine e13496 (2018).

17. Blanca Lumbreras, Javier Sanz-Valero & Rocío López-Pintor, *Impact of Variation in Pill/Package Appearance of Drugs on Patients' Behavior: A Systematic Review*, 18 J. Patient Safety 310 (2021).

addressing certain aspects of these concerns.[18] It describes the delivery mechanism accurately: generic drugs account for nearly 85 percent of prescriptions dispensed, and patients will continue to experience appearance changes as economic forces drive product turnover in pharmacies and mail-order houses.[19] It notes that the agency has published draft guidance addressing certain aspects of these concerns.[20]

It then states the limit. On the agency's account, as reported in the secondary literature, the legal protections for the characteristics of drug products known as trade dress are extensive, even color can constitute a defensible trademark, and given the breadth of those protections a requirement that a generic drug have the same or similar size, shape, and color as the reference drug could effectively eliminate the ability to market a generic product in many cases. The agency concluded that short of substantial changes in the legal protections for trade dress and trademark, it had two options, advising manufacturers through guidance documents and surveying approved generic products, and that the dispensing pharmacist is currently responsible for explaining these differences to concerned patients.[21]

That the sameness set stops short of appearance is not merely inferable from the regulations. The agency has said so in its own table. Writing in 2019 with the Director of the Office of Generic Drugs, the Director of the Office of Research and Standards set out what brand and generic drugs generally have the same and what they may have different. The first column lists active ingredient, route of administration, dosage form, strength, labeling, and conditions of use. The second lists inactive ingredients, formulation design, drug release mechanism,

18. Uhl & Peters, *supra* note 3. The authors identified themselves as the Acting Director of the Office of Generic Drugs and the Acting Director of the Office of Bioequivalence within that office, Center for Drug Evaluation and Research.

19. *Id.*

20. *Id.*

21. These passages are drawn from secondary accounts of the letter and have not been verified against the published text, which is behind a subscription. The concessions quoted in the preceding paragraph are verified. Nothing in the argument that follows depends on the paraphrased passages; the agency's position on its own authority is independently established in Part IV from its regulations and guidance.

manufacturing process, and product size, shape, or color.[22] Size, shape, and color sit in the column of things that may differ, alongside the manufacturing process. The agency is not describing a legal constraint. It is describing a design space it has left open.

Three features of that answer matter for what follows. It is a legal conclusion rather than a scientific one. It is offered as the reason for inaction, so if the conclusion fails the inaction has no stated ground. And it disposes of the residual harm by assigning it to a party who cannot cure it, which Part VI takes up.

IV. The Barrier Does Not Exist

The agency gave one reason for inaction. This Part offers three responses, in ascending order of how much the agency would have to concede to answer them. The first requires only that the agency read its own regulations. The second requires that it read the functionality cases. The third asks who was supposed to decide the question in the first place.

A. The Agency Already Regulates Appearance

The agency's 2014 position was that trade dress law confines it to guidance and surveys. That position is difficult to reconcile with a binding regulation the agency issued and enforces.

No drug product in solid oral dosage form may be introduced or delivered for introduction into interstate commerce unless it is clearly marked or imprinted with a code imprint that, in conjunction with the product's size, shape, and color, permits the unique identification of the drug product and the manufacturer or distributor of the product.[23] Size, shape, and color appear in the operative text, as components of the identification system the rule creates. A product that fails to comply may be deemed adulterated, misbranded, or an unapproved new drug.[24] Registrants must submit to the agency, for each drug subject to the imprinting requirements, the drug's size,

22. Robert Lionberger & Kathleen Uhl, *Generic Drugs: Expanding Possibilities for Clinical Pharmacology*, 105 Clinical Pharmacology & Therapeutics 278, 278 tbl.1 (2019). Uhl is the co-author of the 2014 letter.

23. 21 C.F.R. §206.10(a) (2026).

24. *Id.* §206.10(b).

shape, color, scoring, and code imprint, and that reporting obligation extends even to products the agency has exempted from imprinting.[25]

The agency has also decided which reasons excuse compliance with that appearance requirement. The exemption provision lists drugs used in clinical investigations, placebos designed to resemble the study drug, drugs used in bioequivalence studies, pharmacist-compounded prescriptions for an individual patient, radiopharmaceuticals, and products whose size, shape, or texture makes imprinting technologically infeasible; and it establishes a request procedure for products administered solely in controlled health care settings and never self-administered.[26] Trade dress does not appear on that list. Trademark does not appear on that list. Nothing on the list reaches a retail antipsychotic dispensed for self-administration at home.

An agency that requires appearance-based identification by rule, collects appearance data from every registrant, backs the requirement with adulteration and misbranding consequences, and publishes an exhaustive list of excuses that omits intellectual property is not an agency with no room to act on appearance.

There is a second and more pointed answer, and it comes from the guidance the 2014 letter itself invoked.

The agency issued that guidance in draft in December 2013 and finalized it in June 2015.[27] Its stated concern is that differences in size, shape, and other physical characteristics between a generic and its reference listed drug may affect patient compliance and acceptability of medication regimens or lead to medication errors. Its central recommendation is that a generic

25. 21 C.F.R. §207.49(a)(10) (2026) (requiring submission, "[f]or each drug that is subject to the imprinting requirements of part 206 of this chapter including products that are exempted under §206.7(b), the drug's size, shape, color, scoring, and code imprint (if any)").

26. 21 C.F.R. §206.7 (2026).

27. Size, Shape, and Other Physical Attributes of Generic Tablets and Capsules; Guidance for Industry; Availability, 80 Fed. Reg. 35366 (June 19, 2015) (Docket No. FDA-2013-N-1434); *see* Draft Guidance for Industry on Size, Shape, and Other Physical Attributes of Generic Tablets and Capsules; Availability, 78 Fed. Reg. 74130 (Dec. 10, 2013). The agency issued a revised final version in October 2022 under the same docket.

tablet or capsule closely approximate the size of the product it references, with numerical tolerances.

Three things follow.

First, the agency has already recommended appearance conformity between generic and brand. Not merely regulated appearance, which it does by rule under Part 206, but instructed generic manufacturers to make their products resemble the reference drug in a specific physical attribute, for the stated purpose of patient compliance. If trade dress law barred the agency from requiring that generics look like the reference product, it would bar the size recommendation on precisely the same reasoning. The agency has never explained why the argument that stops it at color does not stop it at size.

Second, the omission of color is the agency's own characterization, not an inference. The 2014 letter says the agency has published draft guidance addressing certain aspects of these concerns. Certain aspects is the agency's phrase. The aspects addressed are size and shape. The aspect not addressed is color, in the June 2015 final guidance and in the October 2022 revision alike, across eleven years and two rounds of public comment on the same docket. The letter does not say which aspects were left out or why, and the guidance does not say either.[28]

Third, the shape of the omission tracks the shape of the legal exposure. Size is the attribute over which trade dress claims are least often asserted. Color is the attribute over which they are most often asserted, and it is the attribute the agency identified as a source of patient confusion and then declined to address. The 2014 letter presents the boundary as one that trade dress law drew. The boundary the agency drew runs between the attribute nobody sues over and the attribute everyone sues over.

Two limits on this guidance should be stated, because they matter to what it can be asked to prove. It is not binding, and by its terms it applies only to new abbreviated applications rather than to approved products already on the market. Neither limit touches the point. A non-binding

28. Contemporaneous commentary reports that the agency had separately voiced concern about color differences between brand and generic products before the final guidance issued, and that the final guidance nonetheless omitted any color recommendation. That report has not been traced to a primary agency document and the point in the text does not rest on it.

recommendation is still an exercise of the authority the agency said trade dress law denied it, and the question here is not whether the guidance solves the problem but whether the agency believed itself powerless. It plainly did not.

B. Functionality Defeats the Claim

The agency's premise is that trade dress protection in pill appearance is extensive. The doctrine points the other way.

Trade dress protection does not extend to functional features. A product feature is functional, and cannot serve as a trademark, if it is essential to the use or purpose of the article or if it affects the cost or quality of the article.[29] Protection reaches only those incidental, arbitrary, or ornamental features that identify a product's source.[30] The threshold is lower than the word "essential" suggests. The Third Circuit has held that under both the statute and the case law, a feature's particular design is functional if it is useful, and that the existence of other workable designs is relevant evidence but not independently enough to make a design non-functional.[31] The same opinion sets out several ways functionality may be shown, among them direct evidence that a design makes a product work better, and, as strong evidence, that a product's marketer touts the feature's usefulness.[32]

A caution about the reach of that standard belongs here rather than in a footnote. The petition for certiorari in *Ezaki Glico* presented the question whether trade dress is functional if it is essential to the use or purpose of the article, as the petitioner contended the Supreme Court and nine circuits had held, or merely useful, as the Third Circuit held below. The Court denied review. The "useful" formulation is therefore the governing standard in the circuit that

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29. TrafFix Devices, Inc. v. Mktg. Displays, Inc., 532 U.S. 23, 32 (2001) (quoting Qualitex Co. v. Jacobson Prods. Co., 514 U.S. 159, 165 (1995), quoting Inwood Labs., Inc. v. Ives Labs., Inc., 456 U.S. 844, 850 n.10 (1982)), *quoted in* Shire US Inc. v. Barr Labs., Inc., 329 F.3d 348, 353 (3d Cir. 2003).

30. *Shire*, 329 F.3d at 353.

31. Ezaki Glico Kabushiki Kaisha v. Lotte Int'l Am. Corp., 986 F.3d 250, 259–60 (3d Cir.), *as amended* (Mar. 10, 2021), *cert. denied*, 142 S. Ct. 420 (2021). The opinion supersedes an earlier version reported at 977 F.3d 261 (3d Cir. 2020).

32. *Id.* at 259–60 (citing *TrafFix*, 532 U.S. at 29).

decided *Shire* and in which *Novadoz* was litigated, and it is contested elsewhere. The argument in this Part does not depend on it. The narrower *TrafFix* formulation reaches the same result for prescription tablets, because a feature on which patients depend to identify their medication is essential to the use of the article on any reading.

The Supreme Court has twice indicated where prescription pills sit on that line. In *Inwood* it recorded the trial court's finding that some patients commingle medications in a container and rely on color to differentiate one from another.[33] In *Qualitex*, discussing that finding, it observed that competitors might be free to copy the color of a medical pill where the color serves to identify the kind of medicine in addition to its source.[34] And Justice White, concurring in *Inwood*, put the point in clinical terms: for the patient-user the constancy of color and shape may be psychologically reassuring and therefore as medically beneficial as the drug itself.[35]

Lower courts applying the standard to prescription tablets have landed in the same place, and the posture matters. In *Shire*, the holder of trade dress in Adderall tablets sought a preliminary injunction against a generic competitor. The district court found that the plaintiff had not carried its burden of proving non-functionality, crediting expert testimony that patients with attention deficit disorder overuse visual cues, that color coding confers a substantial degree of clinical functionality during dose titration and adjustment, and that a generic's similar appearance enhances patient safety and compliance with the prescribed regimen. The Third Circuit affirmed the denial of the injunction.[36]

A federal district court took the question up three times in 2025, in the same case, and came out both ways. The litigation is worth setting out at length, because the two opinions together show a court working on a question it is not well positioned to answer, and because both of them credit the premise this Article rests on.

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33. *Inwood*, 456 U.S. at 853, 858 n.20.

34. *Qualitex*, 514 U.S. at 169, *quoted in Shire*, 329 F.3d at 357.

35. *Inwood*, 456 U.S. at 862 n.3 (White, J., concurring in the judgment), *quoted in Shire*, 329 F.3d at 358 n.21.

36. *Shire*, 329 F.3d at 353–55. The operative finding was that the plaintiff fell short of its burden to prove non-functionality on a preliminary injunction record, reviewed for abuse of discretion, rather than an adjudication that the trade dress was functional as a matter of law. The quoted characterizations of clinical utility are drawn from expert declarations the district court credited.

In March, the court granted preliminary relief on the trade dress claim, finding the size, shape, and color of Entresto likely non-functional.[37] The finding rested on the brand's own declaration that it was unaware of any functional reason why the lower doses needed to be smaller than the target dose, that the sizes could be made uniform without affecting efficacy, and that the selection of size and shape was based on a desire to differentiate the tablets from competitors' trade dresses.[38] Even so, the court credited the patient-side point without qualification: distinctive identifiers of medications can serve as useful visual cues for patients, particularly more vulnerable populations such as the elderly or others with comorbidities, and familiarity with a medication to be taken in seeming perpetuity has an element of functionality.[39] What it declined to accept was the extension, holding that the functionality doctrine cannot mean that any distinctive look and feel of a pill leaves generic brands free to copy it wholesale under the guise of ensuring that patients know what they are taking. The generic, the court observed, could have just picked different colors, or different shapes, or different sizes.[40]

In May, ruling on a motion to stay that injunction pending appeal, the same court reversed course on functionality and granted the stay.[41] The reasoning is the most complete judicial treatment of this question available, and it reaches color directly.

The court found the distinctions between doses, based on color-coding and size, likely functional because patients, physicians, and pharmacists rely on those distinctions to tell the three strengths apart, and because Entresto patients, like the Adderall patients in *Shire*, require initial titration and intermittent dosage adjustment.[42] On color specifically it drew the distinction this Article has been pressing. Although there may have been no functional reason to choose violet white, pale yellow, and light pink in the first instance, those colors, once chosen, come to represent to large numbers of those taking the drug not its source but its ingredients and their

37. Novartis AG v. Novadoz Pharms. LLC, No. 2:25-cv-00849 (D.N.J. Mar. 17, 2025) [hereinafter *Novadoz I*].
38. *Id.*
39. *Id.*
40. *Id.*
41. Novartis AG v. Novadoz Pharms. LLC, No. 2:25-cv-00849 (D.N.J. May 22, 2025) [hereinafter *Novadoz II*].
42. *Id.* (citing *Shire*, 329 F.3d at 354).

effects.[43] The court then set out the consequences, drawing on *Inwood*: many elderly patients associate color with therapeutic effect; some patients commingle medications in a container and rely on color to differentiate one from another; colors are of some help in identifying drugs in emergencies; and use of the same color for brand-name drugs and their generic equivalents helps avoid confusion on the part of those responsible for dispensing them.[44]

The conclusion it drew from that is the strongest statement of the point in the case law. Generic manufacturers that fail to mimic the reference drug's color scheme can suffer a significant disadvantage because the feature is essential to the use or purpose of the article or affects its cost or quality, and the problem is of particular significance for patient populations who suffer from chronic illnesses, regularly commingle medications, and depend on a drug product's visual appearance to distinguish their medications from one another.[45]

That formulation matters for a reason beyond its content. It finds essentiality, under the narrower *Inwood* and *Qualitex* standard, rather than mere usefulness under the Third Circuit's broader one. The argument in this Part therefore does not depend on the standard that was contested on certiorari in *Ezaki Glico*.

The same opinion closes the circuit between this Part and the last. The court established the functionality of tablet size and shape by relying on the agency's own physical attribute guidance, citing its findings that as many as forty percent of Americans have some difficulty swallowing tablets and capsules, that tablet size influences esophageal transit irrespective of patient factors, and that oval tablets may be easier to swallow than round tablets of the same weight.[46] The guidance the agency issued while declining to reach color is now being used by courts as evidence of functionality in the attributes it does reach.

In July, on a fuller record, the court denied a preliminary injunction outright and again found the appearance functional. Considering the full record, the court found the appearance of

43. *Id.* (quoting *Shire*, 329 F.3d at 358 n.20).

44. *Id.* (citing *Inwood*, 456 U.S. at 853).

45. *Id.* (quoting *Qualitex*, 514 U.S. at 169, quoting *Inwood*, 456 U.S. at 850 n.10).

46. *Id.* (citing the FDA Physical Attribute Guidance at 2–3).

the product functional, because elderly patients and patients with comorbidities, who make up many of the patients taking the drug, rely on visual cues to identify the effects of and distinguish their heart failure medication; and because those patients rely on overall appearance for visual continuity, which affects adherence, generic competitors would suffer a significant disadvantage if they could not mirror those features.[47] It held dosage coding by color and size functional on the same reasoning, because patients begin on lower doses and progress upward.[48] And it rejected the objection that other factors also affect adherence and that alternative appearances remain available, observing that the Supreme Court found functionality in *Inwood* on evidence that some patients commingle medications and rely on color to differentiate one from another, that a feature need not be functional for every consumer, and that the functionality bar is low.[49]

The same opinion draws the historical line Part IV has been assuming. Modern generic drugs must meet stringent federal standards, which the court said allays the trade dress policy concern about consumers relying on the overall look of a product to indicate quality; and drug color cases, quoting *Qualitex*, have more to do with public health policy regarding generic drug substitution than with trademark law. That alone, the court held, distinguishes pre-Hatch-Waxman trade dress cases from those that post-date it.[50]

The consequence is an inversion the 2014 letter does not account for. Trade dress protection weakens as clinical reliance strengthens, because clinical reliance is what makes a feature functional. The agency treated the clinical case for conformity and the legal obstacle to conformity as running against each other. They run together. Every additional finding that patients depend on pill appearance is an additional reason that appearance cannot be owned.

47. Novartis AG v. Novadoz Pharms. LLC, No. 2:25-cv-00849 (D.N.J. July 15, 2025) [hereinafter *Novadoz III*] (citing *Inwood*, 456 U.S. at 853, and *Qualitex*, 514 U.S. at 169).

48. *Id.*

49. *Id.*

50. *Id.* (quoting *Qualitex*, 514 U.S. at 169, and citing *Shire*, 329 F.3d at 355 n.14, 356 n.17).

1. What the Split Shows

The three rulings are not simply inconsistent, and the movement between them is instructive rather than embarrassing to the argument here.

Both the March and the May opinions credited that patients, and vulnerable patients especially, rely on the appearance of a medication they take indefinitely. The March opinion said so in terms while ruling for the brand. What divided the two was not whether appearance matters to patients but what follows from that fact in a trademark proceeding, and the March court's answer discloses the problem: the generic could have just picked different colors, or different shapes, or different sizes.

That instruction is the practice this Article addresses. A court applying trademark law correctly, on the record before it, directed a generic manufacturer to differentiate the appearance of a bioequivalent product from the reference drug, having just credited that patients rely on that appearance. Nothing in the doctrine gave the court anywhere else to go. Its task was to allocate a commercial interest between two firms, and the patient appeared in the case only as evidence.

The March finding also contains a concession the brand did not have to make. Novartis's own declaration was that no functional reason required the doses to differ in size, that the sizes could be made uniform without affecting efficacy, and that the selection was based on a desire to differentiate the tablets from competitors' trade dresses. The party best positioned to know said the appearance of its product was chosen to distinguish it from other firms' products, not to serve the patients taking it. That is the same account of industry practice given from the generic side, where appearance is selected arbitrarily to avoid litigation. Neither side selects appearance for the patient. Both have said so.

2. The Secondary Meaning Problem

Functionality is not the only obstacle to a trade dress claim in a pill's appearance, and it may not be the largest one. Color is not inherently distinctive. A producer claiming trade dress in the color of a product must establish secondary meaning, which requires showing that the

primary significance of the feature in the minds of the consuming public is not the product but the producer.[51]

Prescription pharmaceuticals are close to the worst possible category in which to make that showing, and the reason is structural rather than evidentiary. The consumer who would have to form the source association is the patient, and the patient never sees the manufacturer's packaging. The tablets arrive in an amber vial with a pharmacy label. Promotion runs to physicians, and extensive promotion to physicians does not establish that they have passed along to their patients any message as to source. The *Ives* court drew the conclusion directly: secondary meaning will perhaps be difficult to establish in those prescription drug cases where the patient never sees the manufacturer's packaging.[52]

The two obstacles compound rather than merely coexist. To the extent a color has come to mean something to the patient, what it means is the drug and its effects, not the firm that made it, which is what *Shire* described when it said colors come to represent to large numbers of those taking the drug not its source but its ingredients and their effects. That association is the functionality finding. It is also the failure of secondary meaning. The same fact defeats the claim twice, and it is the fact on which this Article's argument about patients rests.

3. The Condition the 1982 Cases Set

Before leaving functionality, one of the pre-Hatch-Waxman decisions deserves direct treatment, because it is the closest thing in the case law to a rejection of this Article's argument, and because of what it says.

In *Ciba-Geigy Corp. v. Bolar Pharmaceutical Co.* the brand-name holder obtained a preliminary injunction against a generic manufacturer that had copied its capsule's appearance. The generic defended on functionality, arguing that identical appearance spared patients the

51. *Ives*, 488 F. Supp. at 401 (quoting Kellogg Co. v. National Biscuit Co., 305 U.S. 111, 118 (1938)).
52. *Id.*

anxiety of receiving an unfamiliar pill. The court rejected the defense, and the language has been read since as disposing of the anxiety argument.[53]

Read in full, the holding is narrower and considerably more useful. The court rejected the anxiety defense on one evidentiary premise. Two physicians testified, one from each side, and both agreed that as soon as the situation is explained to the patient, which the court described as standard medical and pharmacy practice, the patient invariably accepts the explanation and the temporary anxiety is immediately dissipated. The court then stated the converse in terms: if the fears and anxieties of the patient could not be quelled by such an explanation, it may well be that a finding of functionality would be mandated.[54] Its supporting finding used the same qualifier: the fully informed patient can easily adjust to a new color scheme.[55]

So the 1982 court did not hold that pill appearance is non-functional. It held that pill appearance is non-functional so long as explanation works, and it identified the finding that would follow if explanation did not.

The premise was contestable when the court adopted it. Two years earlier, on the same question, a court in the Eastern District of New York had found capsule colors functional on testimony that pointed the other way. Many elderly patients associate the appearance of their medication with its therapeutic effect; there was testimony that some patients refuse to take equivalent drugs of a different color despite explanation of the equivalence by their doctors; and other patients eventually accept a differently appearing equivalent if their physician assures them the prescription was filled correctly, but are caused considerable anxiety and confusion by the change.[56]

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53. Ciba-Geigy Corp. v. Bolar Pharm. Co., 547 F. Supp. 1095 (D.N.J. 1982).

54. *Id.* at 1104.

55. *Id.* at 1108 n.11.

56. Ives Labs., Inc. v. Darby Drug Co., 488 F. Supp. 394, 398–99 (E.D.N.Y. 1980). The court stated flatly that "the colors are functional in several respects," and reasoned that where patients associate the drug with its therapeutic effect in that manner, insisting that the defendants use a different color would unjustifiably put them at a competitive disadvantage. *Id.* at 398. The subsequent history is long and does not disturb the findings relied on here. *See* Inwood Labs., Inc. v. Ives Labs., Inc., 456 U.S. 844, 853 (1982) (recounting the district court's functionality findings).

Set the two records side by side. In *Ciba-Geigy*, two physicians agreed that explanation invariably works. In *Ives*, the testimony was that some patients refuse despite explanation, and that others accept but are left anxious and confused. The *Ives* court also found that some patients commingle their drugs in a single container and then rely on the appearance of the drug to follow their doctors' instructions.[57] Note what that court did *not* rest on. It found the colors functional while separately holding that the plaintiff had failed to establish secondary meaning, observing that secondary meaning will perhaps be difficult to establish in prescription drug cases where the patient never sees the manufacturer's packaging.[58] The finding on patient reliance was therefore not doing work for a party that needed it to win on the whole case.

The uncertainty this line produces is itself an argument. Courts applying the same doctrine to drug appearance have reached opposite factual conclusions on materially similar questions: functional in *Ives* in 1980, non-functional in *Ciba-Geigy* in 1982, non-functional in March 2025 and functional in May 2025 in the same case before the same judge. That is not a criticism of any of those courts. It is what happens when a recurring question of pharmaceutical safety is resolved case by case, on records assembled by private litigants for commercial ends. It is the strongest available argument for the allocation this Article proposes in the next section.

Ciba-Geigy said that if the fears and anxieties of the patient could not be quelled by explanation, a finding of functionality may well be mandated. *Ives* is a finding, two years earlier, that for some patients they cannot. The condition was already satisfied in the case law when the 1982 court wrote the sentence.

Two developments since have made the premise still harder to sustain. The first is empirical. Explanation is not standard practice in the sense the court assumed. Eighty-six percent of patients say they want a pharmacist to tell them when a pill's appearance changes,

57. *Ives*, 488 F. Supp. at 398–99.

58. *Id.* at 401. The court's disposition was to dismiss the trade dress claim while enjoining one defendant's use of a particular name.

and thirty-seven percent recall ever being told.[59] The court's premise was that the fully informed patient adjusts easily. In roughly two thirds of cases the patient is not informed at all.

The second is the subject of Part VI, and the opinion itself marks it as unreached. The court's finding concerned temporary anxiety in a general patient population. It did not consider patients for whom an explanation is not a neutral input, and it did not consider what happens when the person offering the explanation is inside the framework the patient is using to interpret the change.

One further finding in the same opinion is worth carrying forward for a different reason. The court found that the vast majority of patients taking that medication do not or cannot identify it, or its source, by reference to the matter imprinted on the capsule, most such patients being over the age of sixty and unlikely to have sufficiently acute eyesight to detect the difference.[60] That is a judicial finding, made in 1982 by a court ruling for the brand, that imprint codes do not perform the identification function for older patients and that appearance does.

That periodization was identified outside the courts before it was adopted inside them.[61] One further fact confirms the point: the party whose products vary asserts no interest in the variation. Generic manufacturers select an appearance for each product individually and arbitrarily, to avoid expensive litigation with brand-name manufacturers claiming trademark rights in a medicine's appearance; they make no effort to associate their products' appearance with a source and have never asserted trade dress claims of their own.[62] The variation is litigation-avoidance behavior. It performs no trademark function for anyone.

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59. Sarpatwari et al., *supra* note 1.

60. *Ciba-Geigy*, 547 F. Supp. at 1102.

61. Engelberg, *supra* note 4 (dating the protective decisions to the period before the Hatch-Waxman Act and state substitution laws).

62. *Id.*

C. Who Decides

If the trade dress premise fails, one question remains: who is supposed to say so. The 2014 letter treats the answer as the courts and treats the agency as waiting on them. That has the allocation backwards, and the point was made to the agency before it wrote.

Formal recognition by the agency of the important functional role that product appearance plays in reducing patient anxiety and enhancing medication safety would bring an end to most trade dress claims, Engelberg wrote in 2011, because it is ultimately up to the agency, and not the courts, to determine which attributes of a medicine play an important role in making drugs safe and efficacious.[63]

That allocation is not a matter of preference. Functionality asks whether a feature is essential to the use or purpose of the article. For a prescription drug, the question of which attributes are essential to safe and effective use is the question the agency exists to answer, and it answers that question routinely in other contexts. A court assessing whether a tablet's color is functional is deciding a pharmaceutical safety question in a trademark proceeding, on whatever record two private litigants have chosen to build.

One further development bears on the weight the agency's own legal conclusion should carry. That conclusion construed the agency's authority in correspondence rather than through rulemaking, and it did so by resolving a question of trademark law, a body of law the agency does not administer. A reviewing court is no longer required to accept an agency's construction merely because the underlying statute admits of more than one reading. Courts must exercise their independent judgment in deciding whether an agency has acted within its statutory authority, and they need not, and under the Administrative Procedure Act may not, defer to an agency interpretation of the law simply because a statute is ambiguous.[64] The 2014 position is entitled to whatever persuasive force its reasoning earns, and the reasoning runs three sentences.

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63. Engelberg, *supra* note 4.

64. Loper Bright Enters. v. Raimondo, 603 U.S. 369, 412–13 (2024). The decision carries the heavy distinguishing traffic expected of a recent administrative-law landmark; nothing located disturbs the proposition cited here.

There is also a live admission available, and it is not merely rhetorical. Manufacturers of authorized generics market them on the ground that patient counseling may be streamlined because the product has the same taste, color, mouth feel, size, and shape as the innovator product. Engelberg observed in 2011 that a claim of commercial advantage resting on the functional value of appearance to patients forecloses any claim to trade dress rights in that appearance.[65] Third Circuit doctrine supplies the evidentiary basis for that observation: it is strong evidence of functionality that a product's marketer touts a feature's usefulness.[66] The industry says appearance matters clinically when it is selling, and that appearance is protectable branding when it is suing, and the first statement is admissible against the second.

V. Why the Manufacturers Cannot Be the Answer

A reader who accepts that appearance changes cause harm will look first to the companies that change the appearance. Federal preemption doctrine has closed that route, and the way it closed it locates the responsibility precisely.

Generic manufacturers operate under a federal duty of sameness. What must be the same is enumerated: the same active ingredient, the same route of administration, the same dosage form, the same strength, bioequivalence, and the same labeling as the reference listed drug.[67] Because a generic manufacturer cannot unilaterally change its labeling, state failure-to-warn claims against it are preempted.[68] Because it cannot unilaterally change its design, design defect claims are preempted as well.[69] The Fifth Circuit has read the duty of sameness to reach past the label itself, holding that a manufacturer seeking to avoid liability would have to take affirmative steps to alert consumers, doctors, or pharmacists of changes in the drug label, and that the duty of sameness prohibits generic manufacturers from taking such action unilaterally.

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65. Engelberg, *supra* note 4.
66. *Ezaki Glico*, 986 F.3d at 259–60.
67. *See* Mut. Pharm. Co. v. Bartlett, 570 U.S. 472, 476–77 (2013) (quoting 21 U.S.C. §§355(j)(2)(A)(ii)–(v)).
68. PLIVA, Inc. v. Mensing, 564 U.S. 604 (2011).
69. *Bartlett*, 570 U.S. at 486–87.

The reasoning was that a warning issued by the generic manufacturer but not the brand would inaccurately imply a therapeutic difference between the two and could therefore be impermissibly misleading.[70]

The scope of that holding is narrower than it first appears, and the narrowness runs in a useful direction. What the duty of sameness forecloses is unilateral communication about the drug label. A notice that the tablet now arrives in a different color is not a communication about the label, and it does not imply a therapeutic difference; an appearance change is the paradigm non-therapeutic difference. Nothing in *Morris* decides whether a manufacturer may tell a pharmacist that its tablet has changed shape, and the Article does not need it to. The point here is only that the label-and-design route to the manufacturers is closed.

Appearance is absent from every one of those holdings. It is not in the enumerated sameness set. The regulation defining sameness for purposes of a suitability petition lists active ingredients, dosage form, strength, route of administration, and conditions of use, and says nothing about color, shape, or size.[71] Neither Supreme Court decision reaches the question; each leaves open whether federal law requires or bars a change in a generic tablet's physical appearance.

The consequence is structural. The impossibility inquiry asks whether the private party could independently do under federal law what state law requires of it.[72] The Court applied that test through a specific mechanism: a party who cannot satisfy its state duties without the Federal Government's special permission and assistance, dependent on the exercise of judgment by a federal agency, cannot independently satisfy those duties for preemption purposes.[73] On appearance, unlike on labeling and design, that mechanism does not engage. The agency's own change-control regulation treats appearance-adjacent modifications as minor. The deletion or reduction of an ingredient intended to affect only the color of the drug product, and the addition

70. Morris v. PLIVA, Inc., 713 F.3d 774, 777 (5th Cir. 2013) (quoting PLIVA, Inc. v. Mensing, 564 U.S. 604 (2011)).

71. 21 C.F.R. §314.92 (2026).

72. *Mensing*, 564 U.S. at 620.

73. *Mensing*, 564 U.S. at 624.

or minor revision of a code imprint on a solid oral dosage form other than a modified release form, are both changes that need only be documented in the next annual report rather than approved in advance.[74] That is the treatment the agency gives to changes it regards as having minimal potential to adversely affect the identity, strength, quality, purity, or potency of the product.[75]

The regulation does not squarely classify a change to the tablet's own shape or size, and it addresses color only through the deletion or reduction of a color ingredient. What can be said with confidence is narrower than the strongest version of the point and sufficient for the argument: appearance is not among the attributes the statute requires to be the same, no preemption decision has held that appearance changes are federally compelled or federally forbidden, and the agency's change-control scheme treats the appearance-related changes it does address as minor rather than as major changes requiring prior approval. Appearance is therefore the attribute in this system least constrained by the federal duty of sameness and least reached by the preemption cases.

That does not make the manufacturers the solution. Engelberg identified why: absent leadership from the agency, generic manufacturers are unlikely to set industry standards on uniformity of appearance because of antitrust concerns that arise whenever competitors take joint action.[76] Coordination among competitors on a product attribute is precisely the conduct antitrust law scrutinizes. A federal requirement is not. The agency is the only actor that can produce uniformity without creating the problem, which returns the question to the party that said in 2014 that it could not act.

74. 21 C.F.R. §314.70(d)(2)(ii), (viii) (2026).

75. *Id.* §314.70(d)(1).

76. Engelberg, *supra* note 4, at 322.

VI. The Population the Record Does Not Count

The literature surveyed in Part II measures adherence. It asks whether a patient who receives an unfamiliar pill keeps taking the medication. That is the right question for most patients and the wrong question for some, and the ones for whom it is wrong have the most at stake.

A. Two Groups Inside One Class

Consider first an older patient managing several medications whose cognitive function is impaired. Brain function is an enumerated major life activity under the Americans with Disabilities Act, so an impairment substantially limiting it is a disability, and age-related cognitive impairment frequently qualifies.[77] For that patient, appearance is not a convenience. It is the working identification system, and the research on older patients confirms both that it is used that way and that similar-looking products defeat it.

Consider second a patient with a persecutory-spectrum condition. Schizophrenia and related disorders are disabilities under the same provision. For that patient the operative fact is not that appearance aids identification. It is that the condition consists, in substantial part, of a settled framework for interpreting unexplained changes in the environment as evidence that something is being done to them.

These are not two populations, one of which happens to overlap the statute. They are two groups within a single protected class, and this Article treats them that way.

B. Why Adherence Is the Wrong Measure

For the second group, a change in a pill's appearance is not a source of confusion to be resolved. It is data, and it enters a system already built to receive it.

On the leading cognitive account, persecutory delusions are threat beliefs, maintained not by a single deficit but by a set of interacting processes: worry, low self-confidence, intolerance

77. 42 U.S.C. §12102(1)(A), (2)(A)–(B).

of anxious affect, reasoning biases, and safety-seeking behaviour.[78] The relevant feature for present purposes is what that architecture does with new information. Reasoning biases prevent the processing of alternative explanations, and three quarters of patients with delusions do not report any alternative explanation for the events they cite as evidence.[79]

The distinction between confusion and absorption matters because the two produce different observable behaviour. Confusion produces a question, and then either an answer or a missed dose. Absorption into a persecutory framework produces neither. The patient may take the pill. The patient may take every pill on schedule for a year. What changes is not the dispensing record but the patient's account of who is doing what to them, and no measure computed from a pharmacy claims database can detect it. That is why the one study conducted on this population, using exactly that measure, found nothing, and why its null result does not answer the question raised here.

C. Why the Assigned Remedy Inverts

The agency's disposition of the residual harm was to observe that the dispensing pharmacist is responsible for explaining appearance differences to concerned patients. The survey evidence suggests this is not happening at scale: 86 percent of patients wanted a pharmacist to notify them about a change in appearance, and 37 percent recalled ever receiving such notification.[80]

The deeper objection is not that the explanation is rarely given. It is that for this population the explanation cannot do the work assigned to it, and can do harm instead. Three findings from the clinical literature bear on why.

1. The Explanation Is Disconfirmatory Evidence, and That Is the Problem

An explanation offered to a patient who suspects their medication has been tampered with is, in the terms of the field, disconfirmatory evidence. Two well-characterized reasoning biases govern

78. Daniel Freeman, *Persecutory Delusions: A Cognitive Perspective on Understanding and Treatment*, 3 Lancet Psychiatry 685 (2016).

79. *Id.* at 687.

80. Sarpatwari et al., *supra* note 1.

what happens to it. A bias against disconfirmatory evidence describes a thinking style readily dismissive of evidence contradicting a held belief, and jumping to conclusions describes strong conviction in an idea before much or any evidence has been gathered.[81] These are described as underlying mechanisms of paranoia and suspiciousness across the schizophrenia spectrum.[82]

The companion construct is belief flexibility, defined as a metacognitive process of thinking about one's own beliefs, changing them in light of reflection and evidence, and generating and considering alternatives.[83] In the largest study of its kind, 273 patients with delusions were assessed over twelve months. Forty-one percent held their delusions with 100 percent conviction, 50 percent showed the jumping-to-conclusions bias, and between 50 and 75 percent showed a lack of belief flexibility.[84]

The finding that matters most for a remedy built on explanation is the one about stability. Over the year, conviction declined slightly. The reasoning biases did not move. As the authors put it, an inflexible way of thinking or limited data gathering does not improve as the delusional conviction reduces; rather, they are enduring.[85] There is accordingly no window in the course of the illness during which a pharmacist's explanation can be expected to work better. The capacity the remedy presupposes is the capacity the condition impairs, and it is the part that does not remit.

2. The Explanation Is Ambiguous, and Ambiguity Resolves Toward Threat

A pharmacist saying that the manufacturer changed is not unambiguous information. It is a social communication about the patient's medication, delivered by a person with access to that medication, in answer to a question the patient did not necessarily ask.

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81. Thanh P. Le, Taylor L. Fedechko & Alex S. Cohen, *Stress and Cognitive Biases in Schizotypy: A Two-Site Study of Bias Against Disconfirmatory Evidence and Jumping to Conclusions*, 62 European Psychiatry 20, 20–21 (2019).

82. *Id.* at 21.

83. Suzanne Ho-wai So, Daniel Freeman & Graham Dunn, *Jumping to Conclusions, a Lack of Belief Flexibility and Delusional Conviction in Psychosis*, 121 J. Abnormal Psychol. 129, 130 (2012) (quoting Garety et al.).

84. *Id.* at 129, 133.

85. *Id.* at 136.

Interpretation bias describes how such ambiguity is resolved. Once an ambiguous stimulus has been attended and its possible meanings encoded, interpretation is the process that settles it into a single meaning.[86] A meta-analysis of twenty studies found negative interpretation bias associated with paranoia in clinical populations at a standardized mean difference of 1.01, and found that the bias increased with the severity of paranoid symptoms.[87]

That is the mechanism behind the observation this Part began with. The reassurance is not neutral information weighing against the belief. It is ambiguous social information, and for this population ambiguous social information resolves toward threat. The disclosure therefore has a direction, and the direction runs toward the person offering it.

3. What This Costs

The pharmacist is one instance. The more common one is a family member, because the person who collects the refill and hands over the bottle is usually not a clinician.

Put the three findings together. The explanation is disconfirmatory evidence entering a system that is characterized by resistance to disconfirmatory evidence. That resistance does not remit. And the explanation itself is ambiguous social information, of the kind that resolves toward threat in proportion to the severity of the paranoia. The result is that the agency's assigned remedy, applied to this population, can convert the two people the patient most needs into participants in the framework the treatment is trying to loosen.

Nonadherence is a principal driver of relapse in schizophrenia, and the relationships that sustain adherence are the ones this remedy spends. A regulatory scheme that permits appearance to vary and assigns the resulting explanation to the patient's closest relationships is drawing on those relationships to cover a defect in the product.

86. Antonella Trotta, Jung-Woo Kang & Daniel Ståhl, *Interpretation Bias in Paranoia: A Systematic Review and Meta-Analysis*, 9 Clinical Psychol. Sci. 3, 5 (2020).

87. *Id.* at 3.

D. The Discrimination Is in the Uniformity

None of this describes a manufacturer or a pharmacy treating a patient with a psychiatric disability differently from anyone else. The pill changes for everyone. The explanation, when offered, is offered to everyone in the same terms.

That is the point. The prohibition reaches methods of administration that have the effect of discriminating on the basis of disability, and effect is the operative word.[88] The governing test asks whether a facially neutral policy burdens the plaintiff in a manner different and greater than it burdens others.[89] A system that varies the appearance of medication and assigns notification as the remedy distributes a uniform practice across a population in which the practice does not land uniformly. For most patients the variation costs a moment. For a patient managing eight medications with impaired recall it costs the identification system. For a patient with a persecutory condition it costs a piece of the relationship that keeps them medicated. Identical treatment producing unequal enjoyment is the situation the effects provision exists to reach, and the fifteen-year record of this problem does not contain a single study designed to detect the version of it described here.

VII. What Remains at the Counter

A pharmacy is a place of public accommodation. The statute names it.[90] Coverage is therefore not in dispute, and the analysis begins where it ordinarily takes several pages to arrive.

The defense will begin with the inventory provision, which states that the ADA's public accommodations title does not require a public accommodation to alter its inventory to

88. 42 U.S.C. §12182(b)(1)(D)(i).

89. *See* Crowder v. Kitagawa, 81 F.3d 1480, 1484 (9th Cir. 1996) (Hawaii's quarantine of carnivorous animals, applied to guide dogs, effectively denied blind visitors meaningful access to state services); *see also* Payan v. Los Angeles Cmty. Coll. Dist., 11 F.4th 729, 738 (9th Cir. 2021) (relying on *Crowder* and *Choate* in holding disparate impact claims cognizable). Later applications have enforced the different-and-greater requirement strictly, which is the burden this Part accepts rather than avoids.

90. 42 U.S.C. §12181(7)(F).

include accessible or special goods that are designed for, or facilitate use by, individuals with disabilities.[91] That provision does not reach this claim, for two reasons.

First, it governs what must be stocked. It does not address the manner in which a retailer operates, or what it communicates about the goods it has chosen to stock.

Second, and more usefully, the same section imposes an affirmative obligation the defense does not usually quote. A public accommodation shall order accessible or special goods at the request of an individual with disabilities if, in the normal course of its operation, it makes special orders on request for unstocked goods, and if the goods can be obtained from a supplier with whom the public accommodation customarily does business.[92] Pharmacies special-order in the normal course of operation, and they order from wholesalers with whom they customarily do business. A request that a particular patient's refills be sourced consistently from one manufacturer is far closer to a special order than to an alteration of inventory. The regulation the defense leads with contains the answer to itself.

The substantive obligation is the reasonable modification provision, under which discrimination includes a failure to make reasonable modifications in policies, practices, or procedures when such modifications are necessary to afford goods and services to individuals with disabilities, unless the entity demonstrates that the modification would fundamentally alter their nature.[93] Running alongside it is the effects provision, which forbids an entity, directly or through contractual or other arrangements, from utilizing standards or criteria or methods of administration that have the effect of discriminating on the basis of disability.[94]

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91. 28 C.F.R. §36.307(a) (2026). The examples given are Brailled versions of books, books on audio cassette, closed-captioned video tapes, special sizes or lines of clothing, and special foods to meet particular dietary needs. *Id.* §36.307(c).

92. *Id.* §36.307(b).

93. 42 U.S.C. §12182(b)(2)(A)(ii).

94. *Id.* §12182(b)(1)(D)(i).

A. The Paternalism Trap

There is a structural oddity in this area worth stating plainly, because it explains why the remedy has to be an obligation to source consistently rather than a discretion exercised at the counter.

Suppose a pharmacist, told about a customer's condition, declines to dispense a substituted generic on the ground that the change would be bad for that particular patient. Whatever else that is, it is a refusal to provide a service on the basis of disability, and the statute does not treat good intentions as a defense. Congress identified overprotective rules and policies as a form of discrimination in the Act's findings, and the Supreme Court has read that finding as aimed at refusals to give an even break to classes of disabled people while claiming to act for their own good in reliance on untested and pretextual stereotypes.[95]

A defense based on risk to the individual is not categorically unavailable under the Act. *Echazabal* upheld a regulation permitting an employer to refuse to place a worker at risk to his own health, reasoning in part that the express provision addressing threats to others appeared in a statutory list of qualification standards that "may include" such a requirement, phrasing that pointed away from exclusive specification.[96] The public accommodations title is drafted differently. Its direct threat provision is not an item in an illustrative list of permissible standards; it is a standalone construction provision followed by a definition, and the definition states that the term means a significant risk to the health or safety of others.[97] The interpretive move that carried *Echazabal* is therefore not available on this text. The point should be made with the appropriate caution, because the underlying argument has lost once. The Ninth Circuit had reasoned that by specifying only threats to other individuals in the workplace, the statute made clear that threats to the disabled individual himself fell outside the defense, and that a contrary regulation would conflict with congressional policy against paternalism. The Supreme Court reversed.[98] What

95. Chevron U.S.A. Inc. v. Echazabal, 536 U.S. 73, 85 (2002) (citing 42 U.S.C. §12101(a)(5)).
96. *Id.* at 80–81 (construing 42 U.S.C. §12113(b)).
97. 42 U.S.C. §12182(b)(3).
98. *Echazabal*, 536 U.S. at 78–79 (describing the reasoning below), *rev'g* 226 F.3d 1063 (9th Cir. 2000).

distinguishes the public accommodations title is the drafting, not the policy, and no court has yet decided the question on that text.

Even where the defense is available, it is conditioned. The regulation *Echazabal* upheld survived because it required a particularized enquiry, a reasonable medical judgment relying on the most current medical knowledge or the best available objective evidence, and an individualized assessment of the person made after considering the imminence of the risk and the severity of the harm.[99] What the Court approved was a clinical determination. What it condemned was sham protection resting on stereotype.

A retail counter is not a place where the first can be performed. Which produces the structure this Article is describing. The only defense the law makes available to a seller who would withhold a product for the buyer's own good requires a clinical judgment the seller is not competent to make and does not make. Protective refusal therefore fails in practice, however well meant. And nothing in the same body of law obliges the seller to say anything at all. The result is a regime in which the solicitous act is unlawful and the silent one is not, and the patient harmed by the silence has no claim against the party who could most cheaply have prevented it.

That asymmetry is not an argument for licensing paternalism. Refusal is the wrong remedy and the disability rights tradition is right to forbid it; a patient is entitled to be sold what everyone else is sold. It is an argument that the obligation belongs on the other side of the transaction, as a duty to make the product consistent rather than a discretion to withhold it. Which returns the matter to the agency.

The reasonable modification framework supplies the individual half. A proprietor does not satisfy the statute by declining to consider a customer's account of a disability, and the obviousness of a disability is not a condition of the obligation.[100] A patient who tells a pharmacy that appearance consistency is necessary for them has made the request the statute contemplates, and the answer is measured against fundamental alteration, not convenience.

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99. *Echazabal*, 536 U.S. at 86.

100. Dudley v. Hannaford Bros. Co., 333 F.3d 299, 307–10 (1st Cir. 2003).

This Part concludes with a limit the Article should state rather than obscure. A pharmacy can source one patient's refills consistently. It cannot make manufacturers conform. Title III is an individual remedy for an individual patient, and the systemic problem is the agency's.

VIII. Conclusion

In May 2011 the agency was told, in print, that judicial precedent had made trade dress rights in a medicine's appearance nearly impossible to establish, that the appearance of a medication plays a functional role in reducing patient anxiety and enhancing medication safety, and that formal recognition of that fact by the agency would end most trade dress claims because functionality in a prescription drug is the agency's question. In December 2014 the agency answered that trade dress protections were too extensive to permit it to act, and that the pharmacist would explain.

Nothing about that answer has improved with time. The agency already forbids any solid oral dosage form from entering interstate commerce without a code imprint that, together with size, shape, and color, permits unique identification. It collects each product's size, shape, and color from every registrant, including for products it has exempted from imprinting. It has published the complete list of reasons excusing compliance with that appearance requirement, and intellectual property is not among them. Courts have held the appearance of prescription tablets functional, and have done so for the reason that makes the agency's position untenable: because patients rely on it. The preemption decisions that shield generic manufacturers from tort liability for labeling and design leave appearance untouched, so the manufacturers can change appearance and cannot be made to, and antitrust exposure means they will not coordinate to standardize it on their own. Every road runs back to the agency, and the agency's stated reason for standing still is a proposition of trademark law that was doubtful when written and is not tenable now.

What follows requires no legislation and no change in the law of trade dress. It requires the agency to say, in the exercise of an authority it has already used to regulate the appearance of every solid oral dosage form in the country, that the color, shape, and size of a prescription

medication are functional attributes of the product, and to require that bioequivalent products dispensed to the same patient look the same.

The fifteen-year record makes the case in terms of adherence, persistence, and blood pressure. This Article has argued that those measures understate the harm, because they were built to detect a patient who stops taking a medication and not a patient who keeps taking it while the pill becomes evidence of something else. For the patient whose condition consists of a framework for reading unexplained change as intent, the current arrangement produces a monthly test the patient cannot pass and that the people closest to them cannot help with, because the help sounds exactly like what they are afraid of. That patient is inside the protected class. Nobody has counted them, and the remedy the agency assigned makes their position worse.

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