GLP-1s and Health Justice: Equity as a Third Pillar of Drug Regulation
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I. Introduction

Glucagon-like peptide-1 (GLP-1) agonists, sold under brand names such as Ozempic and Wegovy, represent one of the most significant pharmaceutical innovations of the past decade.[1] Originally approved by the U.S. Food and Drug Administration (FDA) for the treatment of type 2 diabetes, these drugs quickly surged in popularity because of their weight loss effects, driving unprecedented demand and nationwide shortages.[2] This rapid rise in off-label use for obesity and cosmetic weight management has exposed deep inequities in the federal drug regulation system: although the FDA ensures that new drugs are safe and effective, the agency has no authority to ensure that these drugs are accessible or equitably distributed.

A structural limitation in the FDA's statutory framework lies at the root of this disparity. The Federal Food, Drug, and Cosmetic Act (FDCA) authorizes the FDA to evaluate drugs for safety and efficacy, but not for affordability or equitable access.[3] Once a drug enters the market, decisions regarding pricing and coverage fall to market forces and third-party payers, such as private insurers, state Medicaid programs, and Medicare, rather than the agency charged with protecting public health.[4] The result is a regulatory system that narrowly defines "public health," emphasizing scientific validation while overlooking the social conditions that determine whether approved medications reach the populations who need them most.

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[1] Magda Wojtara et al., *Glucagon-Like Peptide-1 Receptor Agonists for Chronic Weight Management*, Adv. Med. 9946924 (2023).

[2] U.S. Food & Drug Admin., *Ozempic (semaglutide) Prescribing Information* (2024); U.S. Food & Drug Admin., *Wegovy (semaglutide) Prescribing Information* (2024); *Yearslong Shortage of Popular Weight-Loss and Diabetes Drugs is Resolved, FDA says*, Associated Press (Feb. 21, 2025), https://apnews.com/article/wegovy-ozempic-obesity-diabetes-treatment-shortage-a5f94b1dd7449e15a17922f5503354d6.

[3] Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-399f (2021).

[4] Patricia Danzon, *Competition and Antitrust Issues in the Pharmaceutical Industry* (Uni. of Pa. Wharton Sch. 2014), https://faculty.wharton.upenn.edu/wp-content/uploads/2017/06/Competition-and-Antitrust-Issues-in-the-Pharmaceutical-IndustryFinal7.2.14.pdf

This article argues that the current two-pillar framework of drug regulation—safety and efficacy—is inadequate in a system where unequal access to approved therapies produces population-level health disparities. Using GLP-1s as a case study, this paper contends that equity should be recognized as a third pillar of drug regulation. Incorporating equity into the FDA's mission would bring drug regulation in alignment with contemporary public health demands and with the principles of health justice, which calls for dismantling structural barriers to health.[5]

The health justice framework provides the conceptual foundation for this argument. As articulated by scholars such as Emily Benfer and Lindsay Wiley, health justice treats health equity as a civil right and legal obligation.[6] From this perspective, the FDA's narrow statutory focus on safety and efficacy functions as a form of structural inequity, producing predictable hierarchies in access to life-changing treatments. Expanding the FDA's mandate, whether through administrative reform or interagency collaboration, would embed equity into the core of drug regulation, ensuring that medical innovation benefits the public broadly instead of solely those with economic privilege.[7]

This paper begins by examining the FDA's current structure and the statutory limits of its authority. It then identifies the systemic inequities this framework produces, including socioeconomic and racial disparities currently present in GLP-1 access, as well as the compounded effects of Medicare and Medicaid coverage restrictions. Next, the paper proposes administrative, interagency, and legislative reforms to embed equity into regulatory decision-making. Taken together, these analyses support the argument that the FDA cannot fulfill its

[5] U.S. Food and Drug Admin., *FDA's Commitment to Health Equity* (Health Equity Fact Sheet) (last visited Dec. 8, 2025).
[6] Emily A. Benfer, *Health Justice: A Framework (and Call to Action) for the Elimination of Health Inequity and Social Injustice*, 65 AM. U. R. Rev. 275, 283-84 (2015); Lindsay F. Wiley, *Health Law as Social Justice*, 24 Cornell J.L & Pub. Pol'y 47, 53-54 (2014).
[7] 21 U.S.C. § 393(b).

statutory duty to "protect and promote public health" unless equity becomes a foundational regulatory principle.[8]

II. The Status Quo: FDA's Current Regulatory Framework and the GLP-1 Case Study

A. The FDA's Statutory Foundation and Regulatory Pillars

The Federal Food, Drug, and Cosmetic Act (FDCA) establishes the FDA's authority over the approval, labeling, and marketing of drugs.[9] Under this statute, manufacturers must demonstrate that a drug is safe and effective for its intended use before it may enter interstate commerce.[10] Grounded in scientific evidence and clinical trial data, the FDA's evidentiary review is designed to protect the public from unsafe or fraudulent products.[11] However, the statute does not authorize the consideration of affordability, distributive impact, or social need. As Professors Rachel Sachs, W. Nicholson Price II, and Patricia Zettler observed, "Congress deliberately positioned the FDA as a scientific gatekeeper rather than a redistributor of health resources."[12] The FDA's mission statement reflects this orientation, instructing the agency to "protect the public health by ensuring that ... drugs are safe and effective" and to "promote the public health by promptly and efficiently reviewing clinical research."[13] This framing anchors the FDA's function on scientific outcomes, not on whether those outcomes are equitably realized across populations.

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[8] *Id.*
[9] 21 U.S.C. §§ 301-399f (2021).
[10] *Id.*
[11] U.S. Food and Drug Admin., *Drug Development Process*, https://www.fda.gov/patients/learn-about-drug-and-device-approvals/drug-development-process (last visited Dec. 10, 2025).
[12] Rachel E. Sachs, W. Nicholson Price II & Patricia J. Zettler, *Rethinking Innovation at the FDA*, 104 B.U. R. Rev. 513, 521 (2024).
[13] 21 U.S.C. § 393(b).

The Kefauver–Harris Drug Amendments of 1962 strengthened this gatekeeping function by requiring "substantial evidence" of safety and efficacy through "adequate and well-controlled investigations."[14] Enacted in the wake of the thalidomide tragedy, where thousands of infants were born with birth defects after a sedative was prescribed to pregnant women for morning sickness, these amendments established rigorous premarket review.[15] While these amendments strengthened the FDA's evidentiary standards, they also cemented a binary model: a drug is either "safe and effective" or it is not. This framework left no regulatory space for questions of cost, coverage, or distributional justice.

The Hatch–Waxman Act of 1984 (Drug Price Competition and Patent Term Restoration Act) introduced the Abbreviated New Drug Application (ANDA) process, permitting generic manufacturers to rely on brand-name safety and efficacy data.[16] This reform increased affordability through market competition rather than through equity-focused regulation. As Sachs observes, "coverage and reimbursement policies have become as important as FDA approval in determining who benefits from innovation."[17] Consequently, affordability and accessibility have become delegated to the market and to public and private payers, rather than incorporated into the FDA's conception of its public health mission. This framework is further strained by practices such as "evergreening," in which companies obtain additional patent on

[14] Kefauver-Harris Amendments, Pub. L. No. 87-781, 76 Stat. 780 (1962); 21 U.S.C. § 301 et seq.; See U.S. Food and Drug Admin., *FDA's 2025 ANDA prioritization pilot to support U.S. generic drug manufacturing and testing* (2025), https://www.fda.gov/drugs/drug-safety-and-availability/fda-announces-new-anda-prioritization-pilot-support-us-generic-drug-manufacturing-and-testing. This pilot demonstrates that the agency may incorporate broader policy considerations into review sequencing, even though such prioritization remains grounded in market-competition logic rather than distributive equity.

[15] James H. Kim & Anthony R. Scialli, *Thalidomide: The Tragedy of Birth Defects and the Effective Treatment of Disease*, 122 Toxicol. Sci. 1 (2011).

[16] Drug Price Competition and Patent Term Restoration Act, Pub. L. No 98-417, 98 Stat. 1585 (1984); U.S. Food and Drug Admin., *Abbreviated New Drug Application (ANDA)*, https://www.fda.gov/drugs/types-applications/abbreviated-new-drug-application-anda.

[17] Rachel E. Sachs, *Prizing Insurance: Prescription Drug Insurance as Innovation Incentive*, 30 Harv. J.L & Tech. 153, 157 (2016).

minor modifications—such as new formulations, delivery mechanisms, or dosing regimens—or strategically lists patents in the FDA's Orange Book to delay generic entry.[18] These practices extend market exclusivity beyond the period originally contemplated by Hatch–Waxman, rendering the statute's promise of competition-drive affordability incredibly dubious.[19]

Judicial interpretation has further reinforced this limited understanding of the FDA's mandate. Courts consistently defer to the FDA's judgment in drug-related matters, emphasizing that the agency's authority does not extend to issues of affordability or access. In *Association of American Physicians & Surgeons, Inc. v. U.S. Food & Drug Administration*, the court confirmed the broad discretion afforded to the FDA in regulating medical products while simultaneously highlighting the limits of its statutory role.[20] As a result, the FDA's two-pillar framework remains intact, even as contemporary disparities to access suggest that this model is no longer sufficient to achieve public health equity.

B. GLP-1 Drugs as a Case Study of Regulatory Limits

The approval and commercialization of GLP-1 drugs illustrates the limits of a system built for an earlier era of drug development. Ozempic (semaglutide) was approved for type 2 diabetes in 2017, while Wegovy—containing the same active ingredient at a higher-concentration—was approved for chronic weight management in 2021.[21] Both drugs satisfied the FDCA's safety and efficacy standards. However, once these drugs entered the market, the FDA's authority effectively ended. Because the agency does not regulate medical practice, physicians

[18] Roger Collier, *Drug Patents: The Evergreening Problem*, 185 Can. Med. Ass'n. J. E385 (2013).
[19] Timothy Bonis, Aaron S. Kesselheim, and Sean Tu, *Serial Patent Litigation: an Emerging Strategy to Delay Entry of Generic Competition*, 3 Health Aff. Sch. qxaf240 (2025), https://doi.org/10.1093/haschl/qxaf240.
[20] *Ass'n of Am. Physicians & Surgeons, Inc. v. U.S. Food & Drug Admin*., 226 F. Supp. 2d 204, 208 (D.D.C. 2002).
[21] U.S. Food & Drug Admin., supra note 2.

may prescribe drugs off-label, meaning for uses not approved by the FDA, including for non-medical or cosmetic weight loss.[22]

The dramatic rise in off-label GLP-1 use strained supply chains, producing nationwide shortages that disproportionately affected diabetic patients. These shortages were driven primarily by off-label prescribing that exceeded production capacity, as well as by the limited infrastructure of Novo Nordisk, a prominent diabetes drug manufacturer and a comparatively smaller pharmaceutical company.[23] While the FDA could not have prevented these supply constraints, the monitoring of drug distribution could have helped improve equitable access when new drugs enter the market. Newer GLP-1s from Eli Lilly, such as Mounjaro and Zepound, show that even companies with robust manufacturing infrastructure still face pricing and access challenges, highlighting the potential value of FDA equity oversight and regulatory guidance to reduce disparities in affordability and coverage.[24] The FDA's inability to mitigate these shortages or influence distribution outcomes underscores the regulatory blind spot between approval and access. Under the FDCA, the FDA governs premarket safety and labeling but lacks authority over pricing, supply allocation, or equitable availability.[25] This leaves access to become a function of market dynamics and insurance design rather than regulatory oversight, allowing wealth and insurance coverage to largely determine who can access these drugs.

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[22] *United States ex rel. Polansky v. Pfizer, Inc*., 822 F.3d 613 (2d Cir. 2016).
[23] Novo Nordisk, *Annual Report* (2024), https://www.novonordisk.com/content/dam/nncorp/global/en/investors/irmaterial/annual_report/2025/novo-nordisk-annual-report-2024.pdf; Novo Nordisk, *Annual Report* (2025), https://www.novonordisk.com/content/dam/nncorp/global/en/investors/irmaterial/annual_report/2026/novo-nordisk-annual-report-2025.pdf.
[24] U.S. Food & Drug Administration, *Mounjaro (tirzepatide) Prescribing Information* (2022); U.S. Food & Drug Admin., *Zepbound (tirzepatide) Prescribing Information* (2025); Fraiser Kansteiner, *After Novo and Lilly Resolved GLP-1 Shortages, Where Does the Compounding Industry Stand? Experts Weigh In*, Fierce Pharma (2025), https://www.fiercepharma.com/manufacturing/although-glp-1-access-questions-linger-compounded-versions-novo-and-lillys-obesity.
[25] 21 U.S.C. §§ 301-399f (2021).

Intellectual property (IP) enforcement and recent litigation further exacerbated the inequities that emerged during the GLP-1 shortage. As patients who could not obtain or afford branded semaglutide turned to compounded alternatives, Novo Nordisk initiated a broad litigation campaign against compounding pharmacies, alleging unfair competition and safety violations. In *Novo Nordisk, Inc. v. Brooksville Pharmacy, Inc.*, the court held that the company's state-law claims were preempted by the FDCA, but the broader legal landscape has continued to constrain access to compounded alternatives.[26] Recently, a federal district court upheld the FDA's removal of GLP-1 drugs from the drug shortage list—effectively ending legal compounding regardless of demand or ongoing affordability barriers.[27] The combined effect of IP enforcement, preemption doctrine, and FDA administrative actions has depleted access to lower-cost compounded formulations at precisely the moment many patients relied on them as their only viable option. This dynamic highlights how legal structures beyond the FDA's direct regulatory authority can nonetheless amplify inequities in drug access. [28]

III. The Problem: Socioeconomic Inequities and Structural Barriers

A. Socioeconomic Disparities in Drug Access

The rise of GLP-1 drugs has revealed longstanding inequities in the American drug distribution system. Although these medications have revolutionized treatment options for

[26] *Novo Nordisk, Inc. v. Brooksville Pharmacy, Inc*., 785 F. Supp. 3d 1123, 1132 (M.D. Fla. 2025).; See U.S. Food and Drug Admin. Press Announcement, *FDA Intends to Take Action Against Non-FDA-Approved GLP-1 Drugs* (Feb. 6, 2026), https://www.fda.gov/news-events/press-announcements/fda-intends-take-action-against-non-fda-approved-glp-1-drugs, expressing concerns about safety, quality, and unlawful marketing of compounded semaglutide products.

[27] Joseph Choi, *FDA's removal of Ozempic, Wegovy from drug shortage list upheld*, The Hill (June 18, 2025), https://thehill.com/policy/healthcare/5357358-fda-ozempic-wegovy-drug-shortage-list/.

[28] Shweta Kumar, *Compounding Inequities Through Drug IP and Unfair Competition*, 102 Geo. L.J. 371, 390 (2024).

diabetes and obesity, they have also become emblematic of a two-tiered system in which wealth and insurance coverage determine who benefits from therapeutic innovation.

Empirical data demonstrates these disparities. A 2025 study published in JAMA Health Forum found that Black, Hispanic, and Medicaid-insured patients were significantly less likely than white and privately insured patients to receive GLP-1 drugs despite comparable clinical eligibility.[29] The study also reported higher out-of-pocket costs for patients with public insurance, reflecting how income-based and racial inequities shape access to these weight-loss and metabolic therapies. Similarly, a Kaiser Family Foundation (KFF) analysis identified "cost, coverage, and equity" as the primary barriers to GLP-1 access, emphasizing how inconsistent insurance policies and cost-sharing policies exacerbate disparities.[30] These inequities persist because of the current U.S. drug regulatory policy structure, which prioritizes market efficiency over equitable distribution. When insurers decide whether a clinically effective drug will be covered, they essentially decide who will benefit from medical progress.

Media narratives have obscured the regulatory dimensions of this inequity. For example, a TIME article emphasized that Medicaid and Medicare "will not cover GLP-1 drugs for weight loss."[31] Meanwhile a Wall Street Journal editorial framed access debates in terms of whether Americans "need" weight-loss drugs, rather than questioning why public systems exclude them from coverage.[32] Such framing reinforces the idea that inequitable access results from individual

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[29] Ameet Sarpatwari et al., *Glucagon-Like Peptide-1 Receptor Agonist Order Fills and Out-of-Pocket Costs by Race, Ethnicity, and Indication*, JAMA Health F. (2025).
[30] Kaiser Family Foundation, *New Weight Loss Drugs Raise Issues of Coverage, Cost, Access and Equity* (2023).
[31] Alice Park, *Medicare Will Not Cover GLP-1 Drugs for Weight Loss*, TIME (Apr. 2025), https://time.com/7275495/medicare-glp-1-drugs-weight-loss/.
[32] *Americans Don't Need Ozempic to Cure Obesity*, Wall St. J. (Aug. 27, 2025), https://www.wsj.com/opinion/americans-dont-need-ozempic-to-cure-obesity-glp-1s-weight-loss-3ac9d401?gaa_at=eafs&gaa_n=AWEtsqd3OISpfjZjJRnVXoV8n3JgLncEXKX61kT52T_Df5QM0Cjgy6ig5uby6W_Bz1g%3D&gaa_ts=69a0fb6f&gaa_sig=NtxYcqZaqpyoXQSkXG6gvPuV7XWjGRQjMZHEnJOFuGDpTgEABF-cWFnuaqoId_hX3PkK5H7am_6b-gS2SF5H2w%3D%3D.

consumer decisions rather than structural policy design, masking the deeper legal and regulatory choices that restrict access.

B. Structural and Statutory Barriers

These inequities can be traced to federal statutes that place affordability and coverage questions outside the FDA's authority. The agency's statutory authority ends once a drug meets the safety and efficacy threshold, leaving affordability to private insurers, state Medicaid agencies, and Medicare policymakers.[33] This fragmented governance produces inequities in access through two primary mechanisms: Medicare's categorical exclusion of weight-loss drugs and state-by-state variation in Medicaid coverage.

Under Medicare Part D, the Social Security Act expressly excludes drugs "used for anorexia, weight loss, or weight gain" from coverage.[34] This provision reflects an outdated understanding of obesity as a lifestyle issue instead of a chronic disease with significant health consequences. As a result, elderly and disabled Medicare beneficiaries face barriers to accessing GLP-1s, even when drugs like Wegovy demonstrate clinically meaningful cardiovascular and metabolic benefits. Congressional analyses indicate that these exclusions persist largely because of projected federal costs rather than any clinical rationale.[35]

Medicaid's structure produces a different, but equally significant, inequity. Although states participate in the Medicaid Drug Rebate Program—which requires manufacturers to provide rebates to state Medicaid programs in exchange for coverage of their outpatient drugs—states retain discretion to exclude anti-obesity medications from their formularies.[36] Only thirteen

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[33] U.S. Department of Health and Human Services, *A Report in Response to the Executive Order on Lowering Prescription Drug Costs for Americans*, https://www.cms.gov/priorities/innovation/data-and-reports/2023/eo-rx-drug-cost-response-report.
[34] 42 U.S.C. § 1395w–102(e)(2)(A).
[35] Congressional Research Service, *Medicare Coverage of GLP-1 Drugs* (2024).
[36] 42 U.S.C. § 1396r–8.

states currently allow Medicaid to cover GLP-1s, while others, such as California and Massachusetts, have recently moved to exclude coverage even for qualifying conditions.[37] Budgetary concerns have shaped these decisions. The Congressional Budget Office has warned that expanding coverage for anti-obesity medications could substantially increase federal and state spending.[38] However, this argument fails to account for long-term health savings or principles of distributive fairness. Together, these statutory exclusions and fragmented coverage regimes reflect a deeper problem: the FDA's mission to "protect and promote the public health" cannot be fully realized if addressing affordability and distribution remains outside its purview.[39]

C. Consequences for the FDA's Public Health Mandate

Although the FDA's safety and efficacy framework prevents medical harm and ensures therapeutic benefit, it currently does little to address the social determinants that affect drug access. As GLP-1 shortages and coverage disparities have shown, inequitable distribution can undermine the agency's broad statutory mission. Section 393(b) of the FDCA directs the FDA to ensure that "drugs are safe, effective, and available," but "availability" has been narrowly interpreted to mean the presence of a product on the market, rather than meaningful accessibility across socioeconomic and demographic groups.[40] Under this narrower reading, a drug is considered "available" once approved and commercially marketed—even if cost, insurance design, or supply constraints render it functionally inaccessible to certain populations.

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[37] Natalie Muth, *States Are Walking Back Medicaid Coverage for GLP-1s*, MedPage Today (July 15, 2025), https://www.medpagetoday.com/opinion/second-opinions/116512; *How Lawmakers Are Expanding Coverage for GLP-1 Medications*, Pharmacy Times (Nov. 7, 2025), https://www.pharmacytimes.com/view/states-push-forward-on-insurance-mandates-for-glp-1-and-obesity-treatments.

[38] Congressional Budget Office, *How Would Authorizing Medicare to Cover Anti-Obesity Medications Affect the Federal Budget?* (2024).

[39] 21 U.S.C. § 393.

[40] *Id.*

By maintaining a regulatory structure that separates public health protection from distributive justice, the FDA inadvertently legitimizes inequitable outcomes. Wealthier and privately insured patients gain early and continuous access to breakthrough therapies, while low-income populations—who often disproportionately experience obesity and diabetes—remain excluded. The result is what might be described as "scientific legitimacy but social failure": a treatment that can reduce morbidity and mortality becomes another marker of health inequality.[41]

This gap stems from regulatory choices rooted in mid-century regulatory reform and persists because equity considerations fall outside the FDA's statutory authority.[42] The GLP-1 example illustrates that ensuring safety and efficacy alone is insufficient to achieve the FDA's mission to promote public health. Unless equity becomes a core consideration, the agency's mission will remain incomplete.

IV. The Solution

A. Reframing Through the Health Justice Framework

The health justice framework provides a theoretical foundation for integrating equity into U.S. drug regulation. Developed by scholars such as Emily Benfer and Lindsay Wiley, the framework conceptualizes equity as a legal obligation, necessary for constitutional and statutory commitments to public health.[43] Health justice frames health disparities as predictable outcomes of structural determinants—including statutory design, agency discretion, and regulatory priorities—rather than as individual or market failures. Instead of asking how marginalized

[41] Sachs, Price & Zettler, *Rethinking Innovation at the FDA*, supra note 12, at 520.
[42] Jorg Mahlich, Sybille Rious, and Matthiew Verry, *The Philosophy of Pharmaceutical Regulation—Paternalism or Freedom of Choice?*, Front. Med. (2023).
[43] Benfer, *Health Justice: A Framework*; supra note 6; Wiley, *Health Law as Social Justice*, supra note 6.

groups can navigate existing barriers, health justice asks how the regulatory system itself must change to produce equitable outcomes.

Applied to the FDA, this framework highlights the limits of a drug regulatory system centered on safety and efficacy. Although the FDA's statutory mission under 21 U.S.C. § 393(b) directs the agency to "protect and promote the public health," its existing regulatory tools primarily ensure the scientific integrity of medical products, not their accessibility.[44] The agency's traditional focus on safety and efficacy reflects a regulatory model rooted in mid-twentieth-century public health crises. While this model remains essential, it cannot address the distributive consequences of drug approval in a healthcare system where affordability and access are structurally unequal.

From a health justice perspective, inequitable access to GLP-1s is a regulatory failure. It reflects a statutory framework that neither requires nor empowers the FDA to consider how approved drugs are distributed across demographic, socioeconomic, and geographic lines. Reconceptualizing the FDA's mission requires understanding scientific validity and equitable access as interknit concepts. Clinical benefit is meaningless if the populations medically indicated for a treatment are unable to access it. Therefore, equity must function as a third regulatory pillar, alongside safety and efficacy, enabling the FDA to consider the real-world public health consequences of its decisions and bridge the gap between innovation and justice.

[44] 21 U.S.C. § 393(b).

B. Embedding Equity Within Existing FDA Authority

The FDA has substantial administrative discretion that can support the incorporation of equity considerations without new statutory mandates. Agencies routinely interpret broad statutory directives to address emerging policy challenges, and the FDA's authority to "promote public health" provides a legally grounded anchor for equity-oriented interpretations.[45] The FDA already conducts risk-benefit assessments, evaluates adverse events, reviews post-market data, and collects demographic data in clinical trials, demonstrating the agency's capacity to analyze complex, multi-factor outcomes beyond strict scientific efficacy.[46] Under the FDCA's broad directive to take "appropriate action on the marketing of regulated products," the FDA could incorporate equity impacts into its evaluation of clinical data and post-market conditions.

Scholars Christopher Morten and Amy Kapczynski have argued that expanding public disclosure of clinical and post-market data can enhance accountability and serve as a catalyst for equity-oriented policymaking.[47] Enhanced transparency in clinical trial demographics, post-approval utilization, and pricing or supply patterns could reveal inequities currently obscured by statutory and regulatory protections for confidential commercial information and trade secrets. This approach builds on the FDA's 2014 Action Plan to Enhance the Collection and Availability of Demographic Subgroup Data and extends the framework to include equity-focused post-market analysis.[48] As disclosure is already within the FDA's authority, this approach offers an administratively feasible means to promote equity even without congressional reform.

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[45] Erica N. White, *Overcoming the Major Questions Doctrine with Federal Public Health Authorities*, 18 Harv. L. & Pol'y Rev. 184 (2024), https://journals.law.harvard.edu/lpr/wp-content/uploads/sites/89/2024/08/18.1-MQD.pdf.
[46] U.S. Department of Health and Human Services & U.S. Food and Drug Admin., *Benefit-Risk Assessment for New Drug and Biological Products: Guidance for Industry* (Oct. 2023).
[47] Christopher Mortin & Amy Kapczynski, *The Data Regulatory, Rebooted: Why and How the FDA Can and Should Disclose Confidential Data on Prescription Drugs and Vaccines*, 109 Cal. L. Rev. 493, 496 (2021).
[48] U.S. Food & Drug Admin., *FDA Action Plan to Enhance the Collection and Availability of Demographic Subgroup Data* (2014).

a. Post-Market Equity Assessments

Post-market equity assessments offer a practical tool for the operationalization of equity into existing FDA processes. Operating analogously to environmental and health impact assessments under the National Environmental Policy Act (NEPA), the assessments would not alter the standards for drug approval. [49] Instead, they would require the FDA to evaluate the distributional impacts of approved drugs by examining: pricing and affordability trends; demographic utilization patterns; disparities between insured and uninsured patients; geographic or racial disparities in access; and the effects of shortages on clinically indicated populations.

These assessments would operate within the FDA's analytical and informational role. The agency would collect, standardize, and publish data, enhancing transparency without regulating medical practice, pricing, or insurance coverage. By creating a consistent mechanism for monitoring access patterns across insurers, manufacturers, and state programs, post-market assessments would reveal inequities that are currently obscured by inconsistent reporting across insurers, manufacturers, and states.

Over time, this increased transparency could inform legislative reforms and guide the Centers for Medicare & Medicaid Services (CMS), state Medicaid agencies, and Congress toward more equitable coverage frameworks. Public identification of disparities would strengthen the FDA's ability to "promote public health" by revealing the inequities that undermine that mission.[50]

[49] U.S. Food and Drug Admin., *Environmental Impact Review at Center for Drug Evaluation and Research*, (2025).
[50] 21 U.S.C. § 393(b).

b. Creation of a Public Health Equity Office

The FDA's existing Office of Minority Health and Health Equity (OMHHE) plays an important role in improving diversity in clinical research. However, its mandate is focused almost entirely on representation, not on distributional equity—that is, who ultimately receives approved drugs once they reach the market.[51] These are distinct problems: representation ensures that clinical trial generalizability, while distribution determines whether those populations can obtain the treatment post-approval. OMHHE's current structure does not authorize the office to evaluate supply shortages, price-driven exclusion, geographic disparities, or insurer practices. As a result, OMHHE is not positioned to implement equity considerations at the stages of approval, post-market oversight, or interagency coordination.[52]

A dedicated Public Health Equity Office would fill this institutional gap. Unlike OMHHE, this office's mandate would extend beyond representation to include: conducting post-market assessments; evaluating whether FDA actions disproportionately advantage or burden specific populations; integrating equity analysis into approval and post-market review processes; and serving as the FDA's liaison to CMS, Health Resources and Services Administration (HRSA), and other federal partners on equity initiatives. Institutionalizing equity analysis through a dedicated office would ensure systemic attention to distributional consequences across the agency, better aligning FDA decision-making with its statutory mission to promote public health.

Although establishing a Public Health Equity Office would be legally permissible as an internal organizational action under APA § 553(b)(A), its political feasibility remains uncertain. Recent efforts to expand equity-focused initiatives within federal agencies have encountered

[51] U.S. Food and Drug Admin., *About the Office of Minority Health and Health Equity* (2024).

partisan resistance, making new appropriations or explicit congressional endorsement unlikely in the near term.[53] Nonetheless, political environments evolve. In the interim, the FDA retains organizational authority to create such an office using existing appropriations and internal restructuring authority.

c. Administrative Law Considerations

Integrating equity into the FDA's regulatory processes raises administrative law considerations, particularly under the Administrative Procedure Act (APA). Any reform—whether introducing post-market equity assessments or creating a Public Health Equity Office—must operate within the APA's doctrinal limits. Under APA § 553, notice-and-comment procedures are required for legislative rules that carry the force of law.[54] However, §553(b)(A) exempts "interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice" from these requirements.[55] Most of the reforms proposed in this paper fall within these exemptions.

The creation of a Public Health Equity Office constitutes a rule of internal organization and therefore does not require notice and comment. Likewise, post-market equity assessments could be implemented through interpretive rules or policy statements, as they would guide the FDA's internal analysis without imposing binding obligations on regulated parties. Agencies regularly develop internal analytic frameworks, such as risk-benefit methodologies or disclosure policies, without formal rulemaking. Equity assessments would function similarly: informing the agency's understanding of public health consequences without directly regulating manufacturers, prescribers, or insurers.

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[53] Leadership Conference on Civil and Human Rights, *Trump's executive orders on diversity, equity, and inclusion, explained* (2025), https://civilrights.org/wp-content/uploads/2025/02/LDF-FactSheet-Anti-DEIA-EOs_202501.pdf
[54] 5 U.S.C. § 553
[55] 5 U.S.C. §553(b)(A)

If the FDA interprets its statutory mission to include consideration of distributional outcomes, that interpretation would itself qualify as an interpretive rule clarifying how the agency understands its duty to "protect and promote the public health" under 21 U.S.C § 393.[56] Although the Supreme Court has eliminated Chevron deference in *Loper Bright Enterprises v. Raimondo*, agencies retain authority to interpret broadly framed statutory mandates in the first instance, subject to judicial review.[57] When Congress has delegated expansive public health responsibilities, courts continue to recognize the agency's scientific and technical expertise in applying those mandates. The FDCA's directive to protect and promote public health provides a sufficiently broad statutory foundation to support equity-orientated interpretative guidance grounded in the statute's text.[58]

Critics may argue that incorporating distributive or social values into administrative decision-making inappropriately expands an agency's role, warning that such policy choices belong to Congress.[59] This concern is especially pronounced in drug regulation, where the FDA has long viewed its mission as primarily scientific rather than socioeconomic.[60]

The distinction between "science" and "values" is tenuous in this context. Decisions about clinical trial design, post-market surveillance, and data disclosure already reflect normative judgments about which risks matter and to whom. Moreover, equitable access to FDA-approved drugs is central to the FDA's statutory mandate. When life-changing medications such as GLP-

[56] 21 U.S.C. § 393(b)
[57] *Loper Bright Enterprises v. Raimondo*, 603 U.S. __ (2024)
[58] Benjamin M. Barczewski, *Chevron Deference: A Primer*, CRS Report No. R44954 (Jan. 3, 2023), https://www.congress.gov/crs-product/R44954.
[59] T. Scott Kelly, Scott R. McLaughlin, and Zachary V. Zagger, *Supreme Court Issues Landmark Decision Upending Deference to Federal Agencies*, Ogletree Deakins (June 28, 2024), https://ogletree.com/insights-resources/blog-posts/supreme-court-issues-landmark-decision-upending-deference-to-federal-agencies/; Richard J. Pierce Jr, *What Factors Can an Agency Consider in Making a Decision?* 2009 Mich. St. L. Rev. 67 (2009).
[60] Munveer Thind and Peter R. Kowey, *The Role of the Food and Drug Administration in Drug Development: On the Subject of Proarrhythmic Risk*, 11 J. Innov. Cardiac Rhythm Mgmt. 3958 (2020).

1s are disproportionately available to higher-income or well-insured populations, and clinically eligible patients are priced out or left behind during shortages, these inequities undermine the health outcomes the agency is tasked with protecting.

Integrating equity into the FDA's internal analytic framework ensures that the agency understands the real-world public health impact of its decisions. Administrative law provides a clear path: as long as equity measures are framed as non-binding interpretive or procedural rules guiding internal deliberation, the FDA may adopt them without initiating formal rulemaking. This approach respects statutory boundaries while acknowledging that access is essential to achieving public health in practice.

C. Interagency Coordination Between FDA and CMS

Integrating equity into drug regulation also requires coordination between the FDA and the Centers for Medicare & Medicaid Services (CMS), two federal agencies whose decisions jointly determine whether a drug is scientifically validated and whether it is accessible. Although both agencies operate within the Department of Health and Human Services (HHS), they serve distinct regulatory roles: the FDA evaluates scientific safety and efficacy, while CMS regulates coverage, reimbursement, and access through federal insurance programs.[61] Equity-oriented coordination would allow CMS to draw on FDA data about real-world use, shortages, and demographic disparities when making national coverage and payment decisions.

a. Existing FDA-CMS MOUs

The FDA and CMS already maintain a formal structure for interagency collaboration. In 2010, the agencies entered in Memorandum of Understanding (MOU) No. 225-10-0010 to "promote collaboration and enhance knowledge and efficiency by providing for the sharing of

[61] Alliance for Aging Research, *CMS Has the Legal Authority to Cover Anti-Obesity Medications (and Should): a Legal, Regulatory and Policy Assessment* (2024).

information and expertise between the Federal partners."[62] CMS has relied on this MOU when developing national coverage determinations for emerging technologies, incorporating FDA data on clinical performance and demographic representation into reimbursement decisions.[63] Subsequent MOUs reinforce this collaborative foundation: MOU No. 225-16-004 streamlines the categorization of investigational medical devices to support CMS's coverage decisions during clinical trials, while MOU No. 225-16-008 establishes coordination during public health emergencies involving medical countermeasures.[64]

These agreements demonstrate that the agencies already share data and expertise when doing so advances their missions. What is missing is an explicit equity orientation. Expanding the scope of existing MOUs to include equity-related data, such as demographic utilization patterns or shortage-related impacts, would better enable CMS to design more equitable coverage policies. Extending the current coordination model to include such data would not expand either agency's statutory authority; rather, it would operationalize the FDA's mandate to "promote public health" under 21 U.S.C. § 393 and support CMS's obligation under the Social Security Act to ensure equitable access to medically necessary care.[65]

b. Joint Equity Monitoring Programs

A joint equity monitoring program would enable the FDA and CMS to track and respond to access disparities that neither agency can address on its own. Such a program could integrate FDA post-market surveillance data with CMS claims and utilization data; identify racial, socioeconomic, geographic, or age-based disparities in real-world access to FDA-approved

[62] U.S. Food and Drug Admin., Memorandum of Understanding (MOU) No. 225-10-0010 (2010).
[63] Centers for Medicare & Medicaid Services, *Transforming Medicare Coverage: A New Medicare Coverage Pathways for Emerging Technologies and Revamped Evidence Development Framework (2023).*
[64] U.S. Food and Drug Admin., Memorandum of Understanding (MOU) No. 225-16-004 (2015); U.S. Food and Drug Admin., Memorandum of Understanding (MOU) No. 225-16-008 (2016).
[65] 42 C.F.R. pt. 400

drugs; publish annual reports identifying drugs with significant access disparities; recommend policy interventions to HHS or Congress when inequities undermine public health goals; and coordinate on reimbursement or formulary decisions for drugs with substantial equity concerns. This structure mirrors existing federal cross-agency models, such as FDA-CDC coordination on vaccine safety monitoring under the Vaccine Adverse Event Reporting System (VAERS).[66] A similar model focused on equity would provide a systemic and legally grounded mechanism to identify access gaps and guide federal response.

D. Future Directions: Legislative and Structural Reform

While immediate administrative reforms can enhance transparency and coordination in the short term, achieving meaningful equity in drug access ultimately requires statutory and structural modernization. Legislative action can provide the statutory mandate and resources necessary for sustained engagement with distributive equity.

a. FDCA Amendments

Congress could amend the Federal Food, Drug, and Cosmetic Act (FDCA) to explicitly incorporate equitable access into the FDA's public health mission, mirroring broader legislative trends in health equity observed in environmental and social policy. For instance, Congress could amend 21 U.S.C. § 393(b)(1), the provision driving how the FDA interprets its responsibility across the drug lifecycle.[67] Alternatively, a new statutory provision requiring the FDA to consider equity in drug review, approval, and post-market surveillance could be created. Such language would provide a statutory hook for integrating equity into the agency's core functions, formalizing the agency's responsibility to proactively identify and mitigate access barriers faced by historically underserved populations.

[66] Vaccine Adverse Event Reporting System (VAERS), U.S. Dep't of Health & Hum. Servs., https://vaers.hhs.gov/.
[67] 21 U.S.C. § 393(b)(1).

b. CMS Coverage Reform

Congress could also revisit Medicare and Medicaid coverage rules that contribute to access disparities. For Medicare, revising or removing the Part D exclusion regarding weight-loss medications would permit coverage of drugs with significant public health benefits. Similarly, Congress could standardize the treatment of anti-obesity medications across states or provide clearer federal guidance to reduce inequities stemming from state-by-state discretion. Congress could also direct CMS to integrate equity metrics into coverage determinations, aligning reimbursement policy with national public health goals.

c. IRA-Style Affordability Mechanisms

The Inflation Reduction Act (IRA) demonstrates Congressional willingness to embed affordability considerations into federal drug policy.[68] Extending negotiated pricing, inflation rebates, or reporting obligations to therapeutic classes such as GLP-1s would align federal financing structures with equitable access while simultaneously containing costs. Equity impact assessments could be incorporated into post-market evaluation of drugs subject to negotiated prices, providing a data-driven mechanism to measure whether affordability reforms reduce access disparities.[69] By integrating affordability with equity objectives, Congress could establish a policy framework that promotes both access and sustainability.

VI. Conclusion

The regulatory history of GLP-1s highlights both the strengths and limitations of the FDA's traditional two-pillar model. While the agency has succeeded in ensuring drug safety and efficacy, these achievements have been accompanied by major inequities in access. Safety and efficacy remain essential foundations, but without equity, they achieve only partial justice: a

[68] Inflation Reduction Act of 2022, Pub. L. No. 117-169, 136 Stat. 1818.
[69] *Id.*

drug that is safe and effective yet accessible mainly to wealthy or well-insured patients falls short of promoting public health in any meaningful way.

Embedding equity as a third pillar of drug regulation would better align the FDA's statutory mission with contemporary public health realities. Mechanisms such as post-market equity assessments, strengthened interagency collaboration, and eventual statutory amendments could help realize this vision. Applying a health justice framework transforms drug regulation from a system that merely approves medicines into one that ensures fair access to their benefits. To truly fulfill its public health mission, the FDA must ensure that safety, efficacy, and equity together guide what it means to promote public health.