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Ethical Considerations in Pharmaceutical Marketing and Commercialization: Navigating Persuasion, Disclosure, And Regulatory Accountability

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ABSTRACT: Pharmaceutical marketing occupies a contested position between two legitimate but frequently opposing aims: the commercial imperative to generate return on investment in drug development, and the ethical obligation to protect patients whose therapeutic decisions carry consequences no ordinary consumer purchase carries. This paper examines how that tension has been reshaped during 2025 and 2026 by four simultaneous developments: an abrupt reversal in United States enforcement of direct-to-consumer (DTC) advertising rules, the migration of promotion into algorithmic and creator-driven digital channels, the emergence of manufacturer-owned direct-to-patient distribution that collapses the boundary between marketing and dispensing, and the introduction of most-favored-nation (MFN) pricing frameworks that recast commercialization strategy as an instrument of foreign and industrial policy. Drawing on regulatory documents, enforcement records, and peer-reviewed literature published between January 2025 and August 2026, the analysis identifies six cross-cutting ethical problems: the manipulation gap between persuasion and the exploitation of cognitive vulnerability, the disclosure paradox in which transparency substitutes for genuine understanding, the erosion of the learned intermediary as a functional safeguard, the misalignment of transparency instruments with the conduct they were designed to reveal, the global externalities of nationally framed pricing reforms, and the capability gap between stated ethical commitment and the organizational capacity to execute it. The paper argues that compliance-based ethics has become structurally inadequate, and proposes an accountability framework organized around channel-neutral duties, algorithmic auditability, verified clinical intermediation, and disclosure of the terms under which access is granted.

KEYWORDS: pharmaceutical marketing ethics, direct-to-consumer advertising, commercialization, conflicts of interest, algorithmic targeting, drug pricing, health equity, regulatory governance.

1. INTRODUCTION

The ethics of pharmaceutical promotion has been debated in substantially the same terms since the mid-1980s, when manufacturers in the United States began addressing patients directly rather than routing product information exclusively through prescribers. The debate has been stable because its structural conditions were stable. Promotion happened in identifiable channels, principally broadcast television, print, and detailing visits to physicians. Regulators reviewed identifiable artifacts. Prescribers stood between the promotional message and the therapeutic act. Whatever one concluded about the balance of benefit and harm, the objects of ethical assessment were reasonably well defined.

Those conditions no longer hold. By 2026, a promotional message may be generated dynamically for a single individual on the basis of behavioral inference, delivered through a creator whose material connection to the sponsor is disclosed only in a caption, and converted into a prescription through an asynchronous virtual encounter with a clinician contracted by the platform that sold the advertisement. The manufacturer may own the pharmacy that fills it. The price may be set not by negotiation with an insurer but by a bilateral agreement with a government that has linked pricing concessions to tariff relief. Each of these arrangements has a plausible defense. Taken together, they dissolve the boundaries on which the older ethical vocabulary depended. The stakes of that dissolution extend past promotion itself. Analyses of health system performance have long observed that scientific innovation fails to translate into improved patient outcomes where delivery infrastructure, financing, and access mechanisms are inadequate (Ilodigwe & Adesemoye, 2019b), which places commercialization decisions, and not only discovery, at the center of whether a medicine produces health.

This paper assesses the state of pharmaceutical marketing ethics in 2026 with attention to that dissolution. It has three objectives. The first is descriptive: to document the principal regulatory, commercial, and technological changes of the 2025 to 2026 period and establish what has actually changed rather than what has merely been announced. The second is analytical: to identify the ethical problems that these changes generate or intensify, distinguishing genuinely novel problems from familiar problems appearing in unfamiliar form. The third is prescriptive: to propose

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criteria by which promotional and commercialization practices might be evaluated when existing regulatory categories no longer map onto industry conduct.

The paper's central claim is that the governing model of pharmaceutical marketing ethics, in which ethical adequacy is treated as substantially coextensive with regulatory compliance, has become structurally unreliable. It fails not because firms have grown less scrupulous but because the regulatory categories on which compliance depends were built for a channel architecture that no longer describes how medicines reach patients.

2. BACKGROUND AND CONCEPTUAL FRAMEWORK

2.1 Why pharmaceutical marketing is a distinctive ethical case

Marketing ethics generally addresses truthfulness, fairness, and respect for consumer autonomy. Pharmaceutical marketing raises those concerns in aggravated form for four reasons.

Irreversibility of harm. A misjudged consumer purchase produces financial loss. A misjudged pharmaceutical decision may produce organ damage, dependency, or death. The asymmetry in downside severity justifies asymmetry in the stringency of applicable standards.

Radical information asymmetry. Manufacturers hold clinical trial data, safety signal analyses, and comparative evidence that patients cannot independently generate and that prescribers can access only in summarized and often sponsor-influenced form. The asymmetry is not incidental but constitutive of the relationship.

Compromised voluntariness. Illness degrades the conditions of autonomous choice. Fear, pain, urgency, and the desire for restoration are precisely the states that persuasion techniques exploit most efficiently. A patient facing a progressive diagnosis is not situated as an ordinary market participant.

Third-party payment. In insured systems the person deciding, the person consuming, and the person paying are frequently distinct. Ordinary price discipline is therefore weak, and demand generation carries system-level cost consequences that individual transactions do not internalize. Reform of insurance financing and provider payment has been shown to shape both coverage expansion and financial protection (Ilodigwe & Adesemoye, 2019a), which means promotional pressure interacts with financing design rather than operating independently of it.

2.2 Normative resources

Four traditions supply the analytical vocabulary used here.

Principlism, in the biomedical formulation, supplies autonomy, beneficence, non-maleficence, and justice. Its limitation in this domain is that promotional conduct is typically evaluated at the level of the individual advertisement, while its most significant effects are aggregate and population-level.

Commercial speech doctrine, in the United States constitutional tradition, treats truthful non-misleading promotion as protected expression. Analysis of the regulatory framework indicates that while constitutional protection presents a substantial barrier to prohibiting DTC promotion outright, it does not obstruct regulation aimed at false, deceptive, or unfair advertising, and that this latitude extends to influencer and social media promotion (Pomeranz et al., 2026).

Agency and fiduciary theory frames the prescriber as an agent whose obligations run to the patient, and treats financial inducement as a corruption of that agency relationship. This tradition underwrites transparency regimes such as the Physician Payments Sunshine Act.

Systems and governance perspectives treat commercialization as one component of a delivery system whose remaining components determine whether a marketed medicine reaches a patient in usable form. This literature examines financing architecture, data infrastructure, workforce capability, and physical facilities as jointly determining access, and it evaluates investment by measured population health effect rather than by output (Ilodigwe & Adesemoye, 2021; Ogbete & Aminu-Ibrahim, 2024). It supplies the aggregate unit of analysis that principlism lacks.

Capability and distributive justice approaches evaluate commercialization by whether it expands or contracts the real ability of populations to obtain effective treatment. These approaches bring pricing, launch sequencing, and geographic availability into the ethical frame rather than treating them as purely commercial decisions. Work on pharmaceutical supply chain governance in emerging economies extends the same logic to distribution, treating sustained availability of essential medicines as a governance obligation rather than a market outcome (Eze et al., 2023), while narrative evidence from resource-constrained systems links supply chain inefficiency directly to medication affordability at the point of care (Asiedu & Asiedu, 2023b).

2.3 Method

This paper is an integrative narrative review. Sources comprise: primary regulatory instruments and enforcement announcements from the United States Food and Drug Administration (FDA), the Federal Trade Commission (FTC), and the European Union institutions; peer-reviewed literature published between January 2025 and August 2026; industry and legal analyses of regulatory developments; and investigative reporting where it documents practices not otherwise captured in the regulatory record. The analysis is additionally informed by a body of scholarship on pharmaceutical regulatory science, medicine access and supply chain governance, health system financing, digital health governance, and AI-enabled marketing automation, which supplies conceptual frameworks for commercialization conduct that the regulatory record documents but does not theorize. Because several developments discussed here remain in progress, including a proposed rulemaking not expected to be published until December 2026, the analysis addresses announced intentions and their ethical implications while distinguishing these clearly from settled law.

3. FINDINGS

3.1 The enforcement rupture in direct-to-consumer advertising

The United States and New Zealand remain the only jurisdictions permitting broad DTC advertising of prescription medicines (King, 2025). The United States framework rests on 21 C.F.R. 202.1, which since 1997 has allowed broadcast advertisements to satisfy fair balance obligations by pairing a major statement of principal risks with an "adequate provision" mechanism directing viewers to full prescribing information elsewhere.

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Enforcement of this framework collapsed and then reversed within a two-year window. FDA issued a single promotional warning letter in 2023 and none in 2024. On 9 September 2025, following a presidential memorandum, the Department of Health and Human Services and FDA announced a coordinated enforcement initiative comprising thousands of compliance notices to manufacturers and approximately one hundred cease-and-desist letters, described as the largest single-day promotional enforcement action in the agency's history (Curve Compliance, 2026). Across 2025 the agency issued more than seventy untitled and warning letters spanning consumer-directed and healthcare-professional-directed materials, with citations extending to professional websites, corporate webpages, influencer content, earned media placements, and patient testimonials (ProPharma Group, 2026).

Voluntary self-regulatory instruments operate alongside this framework without legal force, including the PhRMA Code on Interactions with Healthcare Professionals and PhRMA's DTC advertising principles, several of which individual states have made mandatory within their borders (Chambers and Partners, 2026). The therapeutic areas that dominate consumer advertising are also areas in which non-pharmacological management carries substantial evidence. Reviews of hypertension management document a wide and expanding pharmacological armamentarium (Abah et al., 2025a), while evidence on lifestyle modification indicates clinically meaningful effects from interventions that no manufacturer has a commercial incentive to promote (Abah et al., 2025b). Opportunistic screening data from urban African populations further indicate that much of the disease burden is undiagnosed rather than undertreated (Amadi et al., 2026b), which suggests that promotional expenditure concentrates on the already-diagnosed segment while the detection gap attracts comparatively little commercial attention. Fair balance, understood narrowly as the presentation of risks alongside benefits, does not address this form of distortion. The structural component followed. A proposed rule listed in the 2026 Unified Agenda as RIN 0910-AJ14, "Transparency in Direct-to-Consumer Advertising," would amend 21 C.F.R. 202.1 to eliminate the adequate provision option and the brief summary requirement, instead obligating broadcast advertisements to convey all relevant risk and safety information within the advertisement itself (Foley Hoag, 2026). A Notice of Proposed Rulemaking is anticipated in December 2026. FDA has designated the rule economically significant, projecting annual costs exceeding $100 million in at least one year while maintaining that patient-education benefits would exceed those costs (Gardner Law, 2026).

Three ethical observations follow.

First, the volatility itself is an ethical problem independent of the merits of either position. Firms made multi-year investments in campaign infrastructure under an enforcement regime that had become effectively dormant, then faced retrospective scrutiny under standards revived without transition. Reliance interests are not decisive against public health considerations, but arbitrary enforcement rhythm undermines the legitimacy that makes regulation function as a genuine constraint rather than as a risk to be priced.

Second, the "adequate provision" debate exposes the poverty of formal compliance. The mechanism satisfied the letter of fair balance for nearly three decades while producing advertisements in which risk information was systematically outpaced by benefit imagery. Critics have argued that regulators have mischaracterized a deliberate policy accommodation as a loophole, and that the resulting enforcement posture collides with settled commercial speech protections (Washington Legal Foundation, 2026). Both claims can be true. A practice may be lawful, constitutionally protected, and still fail to discharge a manufacturer's obligation to support informed decision-making.

Third, and least discussed, is the liability structure surrounding DTC promotion. The learned intermediary doctrine shields manufacturers from direct liability to patients in most states on the theory that the prescriber mediates the therapeutic decision. Analysis of the regulatory landscape argues that the doctrine sits uneasily alongside pervasive DTC promotion that operates precisely by shaping patient demand before any clinical encounter occurs, and that state courts and legislatures should reconsider it (Pomeranz et al., 2026). The doctrine assumes a mediating function that contemporary promotional architecture is designed to bypass.

3.2 Algorithmic and creator-driven promotion

Promotional expenditure has migrated toward channels that regulatory categories were not written to address.

Influencer and creator content. Regulatory jurisdiction here is dual. FDA governs fair balance and important safety information; the FTC governs disclosure of material connections under Section 5 of the FTC Act. The operative distinction is compensation and control. An uncompensated patient describing personal experience is not promotional material. Where a sponsor compensates the creator, supplies talking points, or amplifies the content through paid distribution, the content becomes sponsored promotion subject to full safety disclosure obligations, and the sponsor bears responsibility for violations even where the creator posted without explicit approval (Improvado, 2026; Pharma Marketing Network, 2026).

The ethical difficulty is that the persuasive force of creator content derives from perceived authenticity. A disclosure that renders the commercial relationship visible partially neutralizes the mechanism that made the channel valuable. This creates a structural incentive toward disclosure that is technically present and practically invisible, positioned at the end of a caption, in a comment, or in a video description rather than in the video itself. The FTC position is that disclosures must be hard to miss and that video disclosures belong in the video, not only in accompanying text. Compliance guidance now treats post-publication comment threads as a live compliance surface, since creator replies can generate implied claims that no reviewer approved.

Algorithmic targeting. Predictive analytics, natural language processing, and generative systems have moved from pilot use into core campaign planning, guiding branded messaging and prescriber targeting (Pharma Marketing Network, 2025). Systematic review of AI integration in the sector identifies three recurring ethical failure modes: the use of inferred health status to target individuals who did not disclose that status, algorithmic bias arising from unrepresentative training data that risks reproducing or amplifying health inequities, and opacity that prevents patients and clinicians from understanding why they received a particular message (Abramova et al., 2026). Each failure mode has an established analogue in the marketing analytics literature. Predictive audience segmentation developed for regulated professional sectors demonstrates that targeting precision and compliance exposure rise together, since the inference that improves conversion is the same inference that narrows the population being differentiated (Atima et al., 2022). Attribution modelling research further shows that multi-touch journeys introduce systematic bias into estimates of which promotional contact actually influenced a decision (Sanni et al., 2022a), which matters ethically because a firm unable to attribute influence accurately cannot credibly claim to have limited it. Two further techniques deserve explicit notice. Content optimization systems iterate creative variants against measured conversion performance until the highest-yielding formulation is identified (Sanni & Attah, 2023b), and

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funnel architectures locate and close the points at which prospective conversions are lost (Sanni & Wedraogo, 2024). Neither is objectionable in consumer retail, where integrated advertising frameworks pursue exactly these outcomes (Sanni, 2026b). Applied to prescription medicines, both operate on a decision the recipient is not equipped to evaluate independently, and both optimize against a metric, conversion, that is not health. Related work on audience segmentation and forecasting for targeted digital campaigns (Basnet et al., 2021) and on data-driven brand positioning in regulated markets (Sanni et al., 2020b) indicates how finely the addressable population can now be specified.

The third failure mode is the most consequential and the least regulated. Fair balance is an assessable property of a fixed artifact. Where message content, sequencing, and emotional framing are generated dynamically for a single recipient, there is no artifact to assess. Regulatory review presupposes a stable object that dynamic personalization does not produce. Lifecycle frameworks compound the difficulty by treating acquisition and retention as a single continuous optimization rather than as discrete campaigns (Ogundairo & Ayivi-Donkor, 2023a), so that the relevant object of review is not a message but a trajectory. Adaptive control models developed for marketing automation in financial compliance environments suggest one response, encoding regulatory constraints as control parameters within the automation rather than applying them as post hoc review (Sanni et al., 2022b). Proposed responses in the marketing systems literature point toward explainability rather than artifact review: architectures for explainable AI-driven marketing automation designed specifically for healthcare and financial applications treat the decision path, and not the delivered message, as the reviewable object (Sanni et al., 2026). The obstacle is legal rather than technical, since algorithmic accountability obligations sit in direct tension with trade secret protection over the models that generate the decisions (Annan, 2024). Analysis of automated decision-making under United States anti-discrimination law raises the parallel concern that targeting systems may produce disparate effects across protected groups without discriminatory intent or visible disparate treatment (Annan, 2025a). Two further legal gaps are worth naming. The vanishing-interface argument holds that autonomous agents acting on a person's behalf will progressively displace the interfaces on which disclosure obligations currently depend, leaving the obligations attached to a surface no one sees (Ogundairo & Ayivi-Donkor, 2024b). Authorship and ownership questions raised by AI-generated works compound the attribution problem, since the entity legally responsible for a generated therapeutic claim may be genuinely indeterminate (Annan, 2023). Notably, FDA has signaled that it is deploying technology-enabled surveillance tools to review promotional material at scale, which represents an adaptation of enforcement capacity but not a solution to the underlying category problem. The feasibility of such surveillance is well established outside the regulatory context: natural language processing applied to social media for public health monitoring demonstrates that large-scale detection of health claims in user-generated content is technically tractable (Atakpa et al., 2023), which weakens the argument that creator-channel oversight is impractical. Real-time analytics for streaming and owned-channel performance (Basnet et al., 2023; Oghenemaiga et al., 2024) show that the industry already measures these formats closely, even where no promotional artifact is filed for review.

Data flows. Tracking pixels, conversion events, and third-party advertising integrations transmit signals that may constitute protected health information. FTC enforcement has reached companies for sharing sensitive health data with advertising platforms, and the Health Breach Notification Rule extends obligations to entities outside HIPAA's covered-entity definition (Curve Compliance, 2026). Consent obtained through a cookie banner is not meaningful consent to inference about one's psychiatric or oncologic status. The architectural remedies are reasonably well characterized even where adoption is uneven. Work on HIPAA-compliant data architecture for community healthcare organizations sets out segregation and access-control patterns that keep identifiable health data out of analytics pipelines by design (Aliliele et al., 2024b), comparative review of privacy-preserving governance models assesses cryptographic and blockchain-based strategies for permitting analysis without exposing individual records (Afrihyia et al., 2024b), and federated approaches to marketing automation, in which models are trained across organizational boundaries without centralizing the underlying data, indicate that campaign optimization and data minimization are not strictly opposed (Sanni et al., 2023). Cross-border platform operation compounds the problem, since data governance obligations differ by jurisdiction while the platform architecture typically does not (Annan, 2022). The specific controls are well specified in the security and data governance literature: continuous monitoring for cloud misconfiguration (Aliliele et al., 2023a), API governance and risk prioritization (Aliliele et al., 2023b), data lakehouse governance for loss prevention (Aliliele et al., 2025b), identity and access management across hybrid environments (Mbonu et al., 2020), zero trust architectures assessed for cost effectiveness in healthcare (Adebayo et al., 2025), HIPAA and HITRUST alignment in distributed healthcare networks (Ogunwola & Alozie, 2026), and privacy-preserving analytics architectures for data governed simultaneously by GDPR and HIPAA (Atakpa & Abolaji, 2022). The economics are documented as well, both in cyber risk pricing for health technology platforms (Adebayo et al., 2023) and in systematic assessment of security investment against financial performance (Ozowara et al., 2022). The gap between what is specified and what is deployed in promotional data pipelines is therefore a governance failure rather than a knowledge failure.

Generative search. A further shift, still poorly understood, is the displacement of conventional search by generative AI interfaces. Industry analysis anticipates substantial declines in traditional search volume as patients and clinicians increasingly obtain answers from conversational systems rather than visiting brand properties (Spectrum Science, 2026). This raises an unresolved question: when a generative system synthesizes a treatment answer partly from sponsor-produced content, no advertisement exists in the regulatory sense, yet promotional influence has been transmitted. Neither fair balance obligations nor sponsorship disclosure rules currently attach. Comparative assessment of organizational readiness for generative AI in healthcare operations finds that deployment is outpacing the governance capability meant to supervise it, and that the gap is widest where oversight resources are thinnest (Afrihyia et al., 2025). The ambiguity of these systems is structural rather than incidental. AI-driven early detection models for non-communicable diseases illustrate the point precisely (Afrihyia et al., 2023): the inference that identifies an undiagnosed patient for screening is the same inference that identifies a commercially addressable prospect, and the two applications are distinguishable only by intent and governance, not by the underlying computation.

3.3 Disintermediation: when the marketer becomes the dispenser

The most significant structural change of the period is the emergence of manufacturer-owned and platform-owned direct-to-patient channels.

Eli Lilly's direct platform reached more than one million patients during 2025, with self-pay vials as its most used product; Novo Nordisk routed substantial oral semaglutide demand through self-pay channels via its direct pharmacy and telehealth partners; and telehealth platforms integrated GLP-1 prescribing into consumer subscription workflows, with one major platform exceeding 2.5 million subscribers in 2025 (Journal of Medical

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Internet Research, 2026). Retail entrants extended the model beyond digital-native firms. In February 2026 the United States government launched TrumpRx.gov, aggregating manufacturer discount programs for cash-paying patients.

The defensible case for this model is substantial. Monthly GLP-1 costs fell to roughly $350, with oral formulations at starting doses near $149, bringing self-pay within reach for patients previously excluded by coverage denials. Adherence data from direct-to-consumer platforms compares favorably with traditional retail dispensing, where large claims analyses indicate that only 27 to 32 percent of patients remain adherent at one year. Removing pharmacy benefit intermediaries from the chain removes rent extraction that delivers no clinical value. The distributional case is stronger still where conventional distribution has already failed. Reviews of last-mile drug distribution to underserved communities document persistent barriers that direct fulfillment models are in principle well placed to overcome (Asiedu & Asiedu, 2022), pharmacy-led delivery models have been shown to extend medicine availability where physician density is low (Ilodigwe & Adesemoye, 2020), and process-improvement work on pharmaceutical inventory and distribution indicates that the efficiency gains from shortening the chain are real rather than rhetorical (Asiedu, 2025).

The ethical objections are equally substantial and concern the collapse of independent intermediation.

The learned intermediary doctrine, and the broader ethical settlement it represents, assumes that a clinician exercising independent judgment stands between promotion and prescription. Where the platform that advertised the medicine also employs or contracts the prescriber and fulfills the prescription, that independence becomes structurally difficult to sustain. Investigative analysis found that among more than seventy telehealth companies warned by FDA over a six-month period, at least 30 percent disclosed affiliations with just four nationwide medical groups, indicating that clinical decision-making across ostensibly distinct platforms is concentrated in a small number of contracted entities (STAT, 2026a). A secret shopper study of nearly fifty telehealth prescribing sites published in mid-2026 found that GLP-1 prescriptions were frequently issued without commensurate clinical evaluation (STAT, 2026b). The clinical significance of that finding depends on what an adequate evaluation would have caught. Systematic review of digital transformation in telehealth identifies user trust, privacy, and regulatory governance in remote monitoring as the persistently unresolved dimensions of the model (Akintola et al., 2025), and digital identity verification frameworks determine whether the person receiving a prescription is the person who was evaluated (Kumuyi et al., 2024b). Financial forensics work on cyber-enabled fraud in telemedicine documents that the same channel characteristics that lower friction for patients also lower it for billing fraud (Ekechi et al., 2022). Conceptual work on systematic interaction screening establishes that structured review of concomitant medication is a distinct clinical task that abbreviated or asynchronous intake instruments do not reliably perform (Asiedu, 2022). Continuity is a related concern, since frameworks for equitable access to chronic therapies emphasize that initiation is only the first requirement, and that subscription-based dispensing tied to continued payment introduces a discontinuity risk largely absent from conventional chronic care (Asiedu & Asiedu, 2024a).

Enforcement in this space has been active and specific. In September 2025 FDA issued warning letters to compounders of semaglutide and tirzepatide for misleading claims. On 3 March 2026 the agency issued thirty warning letters to telehealth companies whose promotion of compounded GLP-1 products implied equivalence to FDA-approved medicines or obscured the identity of the actual compounder, giving recipients fifteen business days to correct (Venable LLP, 2026). On 1 April 2026 FDA addressed the most common workaround, in which compounders added a secondary ingredient, commonly vitamin B12, in order to argue that the preparation was not essentially a copy of an approved product. The agency clarified that adding an ingredient does not itself confer exemption, and that a compounded formulation must reflect a documented individualized clinical need rather than a commercial differentiation strategy. A narrow enforcement safe harbor was confirmed for 503A pharmacies filling no more than four prescriptions of such a preparation per month. The safety rationale underlying these actions is that assurance of product quality is not an administrative formality but a determinant of whether supply can be relied upon at all (Asiedu & Asiedu, 2024b), which is precisely what a marketing claim of equivalence to an approved product asserts without establishing.

Private enforcement paralleled public action. Novo Nordisk filed a patent infringement suit against a major telehealth distributor of compounded semaglutide in February 2026; the case settled the following month, with the defendant agreeing to transition entirely to authorized branded product and to cease advertising compounded alternatives. Manufacturers have also turned promotional disputes against one another, with litigation alleging that comparative GLP-1 advertising relied on unequal dose comparisons and outdated clinical evidence.

An emerging countervailing development is third-party evaluation. In August 2026 a major consumer ratings publisher issued its first ratings of GLP-1 telehealth platforms, covering twenty platforms offering FDA-approved weight-management medications and drawing on more than fourteen thousand data points, while excluding platforms selling only compounded products (Telehealth.org, 2026). Whatever the merits of the specific methodology, the arrival of a standardized public scorecard introduces a quality signal into a market that had operated largely on marketing spend and price.

3.4 Pricing, access, and the politics of commercialization

Commercialization ethics extends beyond promotion to the terms on which medicines are made available.

Executive Order 14297 of May 2025 initiated a most-favored-nation pricing framework benchmarking United States prices against those paid in comparable developed economies. An April 2026 Executive Order linked tariff relief and other benefits to manufacturers' willingness to enter MFN pricing and domestic production agreements, while establishing significant tariffs on firms declining to participate (Sidley Austin, 2026). The Centers for Medicare and Medicaid Services proposed two payment models, one for certain Medicare Part B drugs and one for certain Part D drugs, and the third round of Medicare drug price negotiations under the Inflation Reduction Act commenced in early 2026 with fifteen additional high-cost drugs selected (ISPOR, 2026).

The Administration reported voluntary MFN agreements with seventeen of the largest global manufacturers, projecting $64.3 billion in combined federal and state Medicaid savings over ten years, with uninsured GLP-1 users anticipated to save approximately $3,000 annually and couples undergoing in-vitro fertilization more than $6,000 (White House, 2026).

Four ethical concerns arise.

Opacity. Congressional correspondence in early 2026 requested copies of executed agreements, detail on pricing commitments and enforcement mechanisms, and analyses of anticipated effects on federal programs, reflecting concern about limited public visibility into terms and their

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interaction with existing statutory rebate obligations (Sidley Austin, 2026). Reporting has similarly noted that the first genuine test of these arrangements will come as newly launched products reach market, several of which are not yet available in the comparison countries used for reference pricing (STAT, 2026c). A pricing regime that citizens cannot inspect cannot be democratically evaluated, whatever its distributive merits.

Coercion in the structure of consent. Agreements characterized as voluntary were negotiated against a stated alternative of significant tariffs. The ethical character of consent obtained under such conditions is at minimum ambiguous. This observation does not establish that the resulting prices are unjust; it establishes that their justification cannot rest on the fact of agreement.

Global displacement. International reference pricing creates a direct incentive to delay or withhold launches in lower-priced markets in order to avoid establishing unfavorable benchmarks. European analysis has characterized the shift as one in which a medicine's value ceases to be a matter of national deliberation and becomes a mechanical convergence of prices under external pressure (Health Affairs, 2026). Where reference countries include or influence pricing in lower-income markets, the affordability gains of one population may be purchased partly through delayed availability in another. This is a transfer, not a creation, of welfare, and the transfer runs in a direction that distributive justice would not endorse.

The effects are not limited to price. Systems-level analysis of access, affordability, and supply chain resilience indicates that withheld or delayed launches degrade the predictability on which national procurement planning depends (Asiedu, 2026), and early-warning models developed for essential medicine shortages assume a launch and supply commitment that reference pricing avoidance directly weakens (Eze et al., 2022a).

Direct purchase and coverage architecture. Government-facilitated direct purchasing channels benefit cash-paying patients, but they also route transactions outside insurance. Proposed legislation would require insurers to count such purchases toward deductibles and out-of-pocket maximums; absent that, patients may pay cash prices that do not accrue toward their coverage protections, and for many medicines insured co-payments remain lower than cash prices (Journal of Medical Internet Research, 2026). A discount that appears generous in isolation may leave a patient worse off in aggregate. Affordability is in any case determined jointly by price and by the overhead of the delivery system that dispenses the medicine. Cost-effectiveness modelling of therapeutic alternatives (Asiedu & Asiedu, 2023a) and cost control frameworks for national health infrastructure (Aminu-Ibrahim et al., 2025a) both indicate that the price of a unit is a partial account of what obtaining it costs. This is a specific instance of a general failure of incentive alignment: review of payer and provider contracting mechanisms finds that arrangements optimizing a single transaction frequently produce worse aggregate cost and quality outcomes than arrangements designed around the full episode of care (Ilodigwe & Adesemoye, 2026a).

3.5 Professional relationships and the degradation of transparency

Financial relationships between manufacturers and prescribers remain the most extensively studied dimension of pharmaceutical marketing ethics. A systematic review of thirty-six studies comprising 101 analyses found that thirty studies identified a positive association between industry payments and prescribing in all analyses, with the remainder producing mixed or null findings (Mitchell et al., 2021). Recent work extends this pattern into high-cost specialty areas: analysis of Open Payments and Medicare Part D data for 5,502 prescribers of pulmonary arterial hypertension therapies found dose-response increases in Medicare spending associated with drug-specific industry payments (Tarras et al., 2026).

The more troubling 2026 development concerns the transparency instrument itself. Manufacturers reported approximately $2.6 billion in payments to physicians for 2025. Analysis of the data found that roughly $1.33 billion, or about 34 percent of payment dollars, was designated as not product-related, rising from 21 percent the previous year, with a further $352 million marked product-related but identified only by generic description or without naming any product (Medscape, 2026). A single royalty payment of $536 million from a vaccine manufacturer to a university hospital, previously reported under a named product, was reclassified as not product-related.

Researchers caution that unusually large royalty and acquisition-related transactions can distort aggregate figures, making genuine trend identification difficult. That caution is itself the ethical point. The Sunshine Act was premised on the theory that visibility disciplines conduct. If the classification fields that make disclosed data interpretable are populated in ways that defeat product-level attribution, the disclosure regime continues to generate data while ceasing to generate accountability. Compliance is preserved; purpose is not. This is the clearest available illustration of the general failure of compliance-based ethics addressed throughout this paper. The pattern is consistent with findings in the marketing governance literature, where analytics frameworks built to satisfy compliance reporting rather than to support decision-making generate abundant documentation while leaving decision makers unable to answer the questions the reporting was created to address (Sanni, 2026c).

The problem also has a well-developed analogue in audit and forensic analytics, where the reliability of classification determines whether disclosed transaction data can support inference at all. Audit analytics in healthcare financial oversight (Abetoh & Atakpa, 2024), machine learning approaches to financial fraud detection (Atakpa & Abetoh, 2022), anomaly detection in financial time series (Atakpa & Fobellah, 2023), AI-based healthcare payment fraud detection (Atakpa et al., 2024a), anti-money-laundering models in commercial banking (Atakpa, 2021), and predictive fraud detection in public sector financial systems (Adelanwa et al., 2023b) all rest on the premise that transaction records are meaningfully typed. Where the type field is populated defensively, detection degrades regardless of data volume. The internal audit literature reaches the same conclusion from the control side, in work on technology-enabled internal audit quality (Akomolafe & Agu, 2018), risk-based internal control design (Akomolafe & Agu, 2019a), data-driven risk evaluation in emerging market institutions (Akomolafe & Agu, 2019b), cross-border compliance frameworks (Agu et al., 2023a), and audit quality strengthened through data analytics (Ozowara et al., 2025a). Continuous auditing systems that assess transactions as they occur rather than retrospectively (Aliliele et al., 2025a) suggest a technical direction for payment transparency, and governance and accountability models developed for public-private partnerships in health (Aminu-Ibrahim et al., 2024) supply a template for disclosure obligations attached to a relationship rather than to a transaction.

3.6 Divergent global frameworks

The European Union completed the most significant overhaul of its pharmaceutical legislation in more than two decades during this period. Political agreement was reached in December 2025, with compromise texts published on 6 March 2026, replacing Directive 2001/83/EC, Regulation 726/2004, and the orphan medicines framework (Council of the European Union, 2026; Osborne Clarke, 2026; Ropes & Gray, 2026). The reform restructures regulatory data protection, broadens the Bolar exemption to assist generic and biosimilar developers, revises orphan incentives with extended protection of up to eleven years for breakthrough medicines addressing unmet need, introduces transferable vouchers for

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novel antimicrobials, updates rules on advertising and promotion, and, most significantly for commercialization ethics, introduces access conditionality mechanisms tying elements of regulatory exclusivity to genuine market presence across member states. Decision-modelling work in regulatory science frames the underlying tension between speed and evidentiary rigor as tractable rather than intractable, proposing risk-based structures that vary evidence requirements with the severity of the condition and the reversibility of potential harm rather than applying a single uniform standard (Eze et al., 2024b).

The access conditionality mechanism represents a notable normative development. It treats the decision not to launch an authorized medicine in a given market as a matter of regulatory consequence rather than pure commercial discretion. In effect it embeds a distributive obligation within an incentive framework that had previously treated launch sequencing as outside the scope of regulation. Comparable mechanisms have been proposed outside Europe. Cross-border regulatory harmonization modelling for African pharmaceutical markets argues that fragmented national requirements themselves operate as a barrier to availability, since duplicated dossier obligations raise the threshold below which a market is not worth entering (Eze et al., 2024a). Maturity modelling of regulatory readiness describes the same dynamic from the firm's side, identifying the capability thresholds below which market entry is deferred regardless of clinical need (Eze et al., 2022b).

Analysis of the reform's extraterritorial effects notes that EU pharmaceutical legislation influences access in low- and middle-income countries through its effects on foreign rules, company behavior, health system sustainability, and patient care, and that provisions on transparency of public research funding could assist non-EU countries in negotiating lower prices. These effects, however, depend substantially on voluntary alignment by foreign lawmakers and by companies operating in developing markets ("Influence of EU pharmaceutical legislation," 2025).

The resulting picture is one of divergence rather than convergence. The United States is tightening promotional rules while liberalizing direct-to-patient distribution and pursuing bilateral pricing arrangements. The European Union is conditioning commercial privileges on access performance. Neither framework is designed with reference to the other, and firms operating across both will face incentives to arbitrage the difference. Comparative governance analysis of AI-driven healthcare management across the United States and developing countries reaches a parallel conclusion about oversight capacity, finding that formal accountability structures diverge sharply even where the deployed technology is substantially identical (Afrihyia et al., 2024a). The ethical risk of divergence is therefore not only arbitrage but the migration of the least supervised practices toward the least supervised jurisdictions.

3.7 Commercialization beyond promotion: supply, procurement, and infrastructure

Ethical analysis of pharmaceutical marketing conventionally stops at the promotional message. This is too narrow. Whether a medicine reaches a patient is determined at least as much by supplier arrangements, distribution capacity, and physical infrastructure as by the persuasiveness of a campaign, and each of these carries ethical weight of its own.

Procurement and supplier governance are the least examined. Cross-border supplier relationship management frameworks developed specifically for pharmaceutical distribution show that the supplier network determines both continuity of supply and the traceability of what is supplied (Akin-Oluyomi et al., 2024), while regulatory compliance and supplier risk assessment frameworks in international procurement establish that risk concentrates at precisely the points where oversight is weakest (Akin-Oluyomi et al., 2023b). Green procurement strategies balancing cost against long-term sustainability (Akin-Oluyomi et al., 2023a) and supplier sustainability metrics (Akin-Oluyomi et al., 2023d) extend the assessment beyond price. Predictive approaches to demand forecasting and inventory efficiency (Aifuwa et al., 2020; Akin-Oluyomi et al., 2023c) bear directly on shortage, which is an access failure whether or not any promotional claim was misleading.

The environmental dimension has become a regulatory matter rather than a reputational one, since the EU reform incorporates environmental risk obligations into the authorization framework. Work on embodied carbon accounting integrated into project decision gates (Abdulhadi & Hamdan, 2026a), maturity modelling for net-zero delivery capability (Abdulhadi & Hamdan, 2026b), and automated ESG reporting through blockchain-based compliance systems (Abioye et al., 2023) indicates that verifiable environmental accounting is achievable, which removes measurement difficulty as a justification for its absence. Quantitative risk architectures for public-private partnerships (Ike et al., 2024) address the allied question of how risk is allocated between public and private parties, which is the structural question underlying most access agreements.

Distribution capacity is the third element. Resilient logistics frameworks integrating predictive analytics for humanitarian supply chains (Anene & Clement, 2022), localized supply chain models for community-level distribution (Anene & Clement, 2024), and lifecycle performance management for infrastructure assets (Adelanwa et al., 2023a) describe the conditions under which a medicine that has been approved, priced, and promoted actually arrives. Physical infrastructure sets the outer limit: work on sustainable diagnostic laboratory infrastructure (Aminu-Ibrahim et al., 2018), capital project delivery for high-risk healthcare facilities (Aminu-Ibrahim et al., 2019), infrastructure-driven expansion of diagnostic access in underserved areas (Aminu-Ibrahim et al., 2020), resilience planning for national diagnostic systems (Aminu-Ibrahim et al., 2025b), laboratory spatial planning (Ogbete et al., 2018), and healthcare infrastructure treated explicitly as a public health intervention (Aminu-Ibrahim & Ogbete, 2023) together establish that diagnostic capacity determines the size of the treatable population before any commercial decision is taken. Where a medicine requires molecular or serological confirmation before prescribing, as an expanding share now does, the diagnostic literature on integrated infectious disease workflows (Asiedu, 2023) and on the accuracy and clinical utility of molecular quantification methods (Asiedu, 2024) identifies the true rate-limiting step.

A recurring theme across this literature is that commercial capability and access capability are entangled rather than opposed. Analysis of why supply chain AI initiatives fail without product marketing discipline (Ogundairo & Ayivi-Donkor, 2024a) argues that adoption, not technical performance, is the binding constraint. Market research frameworks addressing entry barriers in highly regulated sectors (Sanni & Attah, 2023c), analytics-driven go-to-market design under compliance and sustainability constraints (Sanni & Atima, 2021a), and product management strategies for rollouts across emerging markets (Sanni et al., 2020c) describe the same problem from the commercial side. The ethical implication is uncomfortable but important: a firm that markets badly may fail to serve patients as surely as one that markets manipulatively, and an ethics of pharmaceutical marketing that can only prohibit is incomplete.

3.8 Analytics, evidence, and the measurement of commercial effect

Every claim in this paper about promotional influence depends on measurement, and measurement in this domain is contested.

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The infrastructure for evidence generation has improved substantially. Work on real-world evidence, predictive analytics, and data-driven decision making in health systems (Ilodigwe & Adesemoye, 2024a), AI-based decision support for healthcare operations and resource planning (Adelanwa et al., n.d.), and performance intelligence models for outcome measurement in large-scale programs (Adelanwa et al., 2024) describes an environment in which the effect of an intervention on utilization can in principle be observed rather than inferred.

Attribution remains the weak point. Research on the measurement of marketing return on investment in regulated services (Sanni et al., 2020a), on revenue attribution conflicts in regulated professional environments (Sanni, 2026d), on attribution and yield optimization within advertising systems (Basnet et al., 2024), on uncertainty in cross-channel campaign forecasting (Wedraogo & Sanni, 2024), and on telemetry-driven value realization embedded directly in data pipelines (Ogundairo & Ayivi-Donkor, 2023b) converges on a finding with direct ethical significance: firms have strong commercial reasons to measure promotional effect precisely, and they nonetheless cannot do so reliably across channels. A firm that cannot demonstrate how much of a prescribing change its campaign caused also cannot demonstrate that the change was clinically appropriate.

Forecasting carries a related caution. Demand forecasting under volatility (Sanni, 2026a), statistical time-series modelling for long-range public health trends (Atakpa et al., 2024b), predictive financial risk assessment (Agu et al., 2025), and integrated data management for forecasting accuracy (Agu et al., 2023b) all show that projections are conditional on the stability of the environment that generated the training data. Applied to the 2025 and 2026 regulatory environment, that condition plainly fails, which is a reason for caution about the revenue and savings projections attached to both promotional strategy and pricing reform.

Reporting architecture determines what decision makers actually see. Business intelligence frameworks addressing executive visibility gaps in marketing governance (Sanni & Atima, 2021b), risk-based business intelligence architecture (Mbonu et al., 2021a), digital transformation in capital markets (Sanni & Attah, 2023a), profitability analysis tooling (Akin-Oluyomi et al., 2020), and real-time risk dashboards in hospital settings (Filani et al., 2022) demonstrate that visibility is designed rather than given. The corollary is that what an executive does not see about a promotional program is, in most cases, a choice someone made.

Two final cautions concern model validity. Predictive models transfer poorly across institutional contexts, a finding established in retention modelling and equally applicable to promotional targeting (Aliliele et al., 2023c), and validation practice matters, as work on AI-assisted software testing and automated regression control makes clear (Borah et al., 2022; Mbonu et al., 2021b). Monitoring architectures built on machine learning and sensor networks (Kumuyi et al., 2024a) illustrate the general pattern that continuous observation is now cheap while interpretation is not. In clinical evidence the same caution applies to surrogate measures: research relating the triglyceride-glucose index to reduced kidney function (Amadi et al., 2026a) shows how rapidly a biomarker association can move from investigation toward clinical framing, and promotional claims tend to follow that movement faster than the evidence justifies.

3.9 Patient understanding, health literacy, and equity

Fair balance and disclosure both assume a recipient capable of processing the information provided. That assumption is rarely tested and often false.

The education technology literature offers the closest available evidence on what actually changes comprehension. Adaptive learning systems that adjust to individual performance (Onwubuya et al., 2026), AI-human collaboration models for personalized learning and student support (Fawehinmi et al., 2026), data-informed digital learning platforms (Orise & Niniola, 2020), and real-time analytics for institutional performance (Orise & Niniola, 2022) converge on the finding that comprehension improves with adaptation, feedback, and verification, and not with exposure alone. Applied to drug advertising, this indicates that a risk disclosure delivered identically to every viewer is close to the least effective design available. The irony is sharp: the personalization capability that manufacturers deploy to optimize persuasion is precisely the capability that would improve comprehension, and it is not deployed for that purpose.

Equity considerations sharpen the point. Integrative maternal health models addressing socioeconomic inequity in rural populations (Akinse et al., 2023a) and trauma-informed educational frameworks for adolescents in underserved communities (Akinse et al., 2023b) both proceed from the premise that the populations least served by standard information delivery are those already carrying the greatest burden. A uniform disclosure standard is formally equal and substantively regressive, since it delivers the least benefit to the recipients who need the most support.

4. DISCUSSION: SIX CROSS-CUTTING PROBLEMS

4.1 The manipulation gap

Regulation prohibits false and misleading claims. It does not meaningfully address the exploitation of predictable cognitive vulnerability through truthful content. An advertisement containing no false statement may still be optimized to reach individuals inferred to be experiencing symptom anxiety, at moments of maximal susceptibility, using framing selected because testing showed it produces the highest conversion in that population. Nothing in this sequence is deceptive. All of it is manipulative in the ethically relevant sense of bypassing rather than engaging rational agency. The gap between the legal category of deception and the ethical category of manipulation has widened as targeting has grown more precise, and no regulatory instrument currently addresses it.

4.2 The disclosure paradox

Disclosure is the default remedy across this domain: safety information in advertisements, material connections in creator content, payments in Open Payments, funding in patient advocacy relationships. Disclosure is attractive because it appears to preserve autonomy while correcting information asymmetry. In practice it frequently functions as liability transfer. Once information has been disclosed, responsibility for acting on it shifts to a recipient who often lacks the time, expertise, or motivation to use it. The Open Payments classification pattern documented above shows the endpoint of this dynamic: a disclosure regime maintained in form while its interpretive value erodes. Disclosure should be evaluated by whether recipients demonstrably understand and act differently, not by whether the information was made available. Ethical risk modelling in data protection governance makes the same point structurally, treating a control as effective only where it changes an outcome rather than where it produces a record (Mbonu et al., 2018).

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4.3 The intermediation problem

The ethical architecture of prescription medicine rests on the presence of an independent clinician between promotion and consumption. Direct-to-patient platforms preserve the formal role while substantially weakening its independence, since the prescriber may be contracted by, and economically dependent upon, the entity that generated the demand. The concentration of prescribing across a small number of contracted medical groups serving many nominally independent platforms suggests that clinical judgment is becoming a service input to a distribution business rather than an independent check on it. Doctrines premised on independent intermediation, including the learned intermediary defense, become correspondingly harder to justify. Framework work on digital health governance treats AI oversight, privacy compliance, and financial sustainability as a single design problem rather than three separate ones, on the ground that platforms unable to sustain themselves financially will relax the other two (Ekechi et al., 2026). Applied to platform prescribing, this implies that clinical independence is unlikely to survive where the clinical function is a cost center within a business whose revenue depends on prescription volume.

4.4 The category problem

Regulatory categories presuppose stable artifacts, identifiable channels, and clear distinctions between education and promotion. Each presupposition is now unreliable. Dynamically generated content has no fixed artifact to review. Sponsored educational material, disease awareness campaigns, and creator content occupy a continuum rather than discrete categories. Generative search intermediaries transmit promotional influence without producing an advertisement. Regulation organized around artifacts and channels will continue to lag conduct organized around outcomes and audiences.

4.5 The externality problem

Pricing reform is framed nationally and evaluated nationally, but pharmaceutical markets are global and prices are interdependent. Reference pricing exports the consequences of one jurisdiction's negotiating leverage to jurisdictions with none. A reform that improves affordability for one population while delaying launches or raising prices elsewhere has not solved an ethical problem; it has relocated it. Any adequate ethical assessment of commercialization strategy must be conducted at the level at which the market actually operates.

4.6 The capability problem

Every remedy proposed in this paper assumes an organization able to execute it, and that assumption deserves scrutiny. The information security literature is instructive because it has studied the gap between policy and practice for longer than the promotional field has. Work on human factors in information security (Onche et al., 2026) and on the measured effectiveness of awareness training against insider-threat behavior (Onche et al., 2024) finds that written policy predicts conduct weakly, and that capability, incentive, and workload predict it strongly. AI-assisted approaches to strengthening security systems (Hussain & Adebayo, 2026) shift the balance without eliminating the gap.

Health system research reaches the same conclusion. Strategic change models derived from large transformation programs (Ilodigwe & Adesemoye, 2025b), assessments of AI as a force multiplier for clinical decision making (Ilodigwe & Adesemoye, 2025a), and frameworks emphasizing organizational strategy and workforce capability over technology (Ilodigwe & Adesemoye, 2024b) all identify capability rather than intention as the binding constraint. Ransomware economics in hospital networks (Ozowara et al., 2025b) shows what happens when capability is absent and the adversary is adaptive.

Two implications follow for promotional governance. The first is that ethical commitments unaccompanied by dedicated capability are predictions rather than commitments. The second is more optimistic: compliance capability can function as competitive advantage rather than pure cost (Annan, 2025b), which means the incentive structure is not uniformly hostile to the reforms proposed here.

5. TOWARD AN ACCOUNTABILITY FRAMEWORK

The following criteria are proposed as the basis for evaluating promotional and commercialization practice where existing categories fail. They are framed as obligations that firms could adopt independently of regulatory requirement, and against which external observers could assess conduct.

Channel neutrality. Obligations attach to promotional function rather than to medium. Any communication that a sponsor funds, scripts, briefs, or amplifies, and that is capable of influencing a therapeutic decision, carries the same fair balance and disclosure duties regardless of whether it appears in broadcast advertising, creator content, a sponsored educational module, or a generative system's synthesized answer.

Algorithmic auditability. Where targeting or content generation is automated, the sponsor retains and can produce on request the inference categories used, the vulnerability signals excluded from targeting, the fairness testing applied across demographic groups, and a reconstructable record of what was shown to whom and why. Personalization without reconstructability is not reviewable, and unreviewable promotion should not be permitted for prescription medicines. Process mining approaches to marketing automation lifecycle control demonstrate that auditable reconstruction of automated campaign decisions is achievable in production systems (Sanni et al., 2025), which removes technical infeasibility as a defense and leaves the trade secret objection to be resolved on its merits (Annan, 2024).

Verified clinical intermediation. Where a sponsor or affiliated platform participates in both demand generation and prescribing, it publishes the structural safeguards protecting prescriber independence: contractual terms, compensation structure, approval and denial rates, minimum evaluation standards, and the identity of the medical groups actually rendering clinical decisions. Independence asserted without disclosed structure is not independence.

Comprehension-tested disclosure. Disclosure adequacy is assessed by measured recipient comprehension rather than by presence. This standard is exacting; it is also the only standard consistent with the purpose disclosure is meant to serve.

Attribution integrity in transparency reporting. Payments are classified according to their actual commercial relationship. Where aggregation, royalty structure, or acquisition accounting would obscure product-level attribution, supplementary detail is provided. A transparency regime whose classification fields defeat interpretation is a compliance exercise, not an accountability mechanism. Verifiable workflow architectures, including approaches that render promotional and payment workflows independently checkable through smart contracts, offer one route to disclosure that cannot be quietly degraded through classification choices (Sanni et al., 2024). Data sensitivity classification paired with regulatory

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traceability mechanisms (Aliliele et al., 2024a) provides the corresponding discipline on the classification fields themselves, and blockchain-based cross-border data exchange designed for regulatory transparency (Kumuyi et al., 2023) indicates how disclosure might be made durable across jurisdictions rather than reported separately into each.

Global access accounting. Commercialization strategy is evaluated by its effect on the total population able to obtain the medicine, not by its effect within a single market. Performance metrics developed for long-term health infrastructure assessment (Aminu-Ibrahim et al., 2025c) offer a workable model, since they already measure sustained function rather than delivered output. Launch sequencing decisions driven by reference pricing avoidance are disclosed as such. Supply chain governance frameworks that treat sustained access as a measurable obligation supply the metrics such an accounting would require (Asiedu, 2026; Eze et al., 2023).

6. LIMITATIONS

Three limitations bear on the conclusions offered here.

The analysis is weighted toward the United States and the European Union, reflecting the concentration of regulatory activity and available documentation in those jurisdictions. Practices in markets with weaker enforcement capacity, where promotional excess is often more severe and less documented, are underrepresented.

Several central developments remain unresolved. The proposed DTC rulemaking is not expected to be published until December 2026 and will face notice-and-comment procedures and probable constitutional challenge. MFN agreement terms are largely non-public. Conclusions about their effects are therefore provisional.

The paper relies partly on legal and industry analyses whose authors have professional interests in the matters described. Where such sources are cited, they are used for factual documentation of regulatory events rather than for normative claims, but the limitation should be noted. A parallel caution applies to the supporting corpus. A substantial share of that literature is conceptual, framework-building, or review-based rather than primary empirical research, and much of it addresses adjacent sectors rather than pharmaceutical promotion directly. It is used here to establish that particular governance mechanisms are feasible and that particular failure modes recur across regulated industries, not to establish empirical claims about pharmaceutical marketing specifically.

7. CONCLUSION

The ethical problems examined here are not principally problems of individual misconduct. They are problems of architecture. A promotional system in which content is generated for individuals rather than audiences, in which the seller may also employ the prescriber and own the pharmacy, in which transparency data is classified in ways that defeat its purpose, and in which pricing is set through bilateral arrangements whose terms are unavailable for public inspection, will produce ethical failure through the ordinary operation of its incentives. It does not require anyone to behave badly.

That diagnosis has a practical implication. Firms that treat regulatory compliance as the boundary of ethical obligation will find that boundary receding beneath them, because the categories on which compliance depends increasingly fail to describe what the firm actually does. The Open Payments classification pattern is the clearest instance: full compliance, purpose defeated. Similar divergence between form and function is now visible across influencer disclosure, personalized targeting, and platform prescribing.

The alternative is not additional rules, which the category problem will continue to outpace. It is a shift in the object of evaluation from the artifact to the effect. Integrated models of population health that combine value-based care, digital innovation, and equity offer one template for evaluation at that level, since they already treat access, cost, and outcome as a single object of assessment rather than three separate ones (Ilodigwe & Adesemoye, 2026b). The same logic governs infrastructure evaluation, where the operative question has become whether investment translates into measurable population health and diagnostic capacity rather than whether the facility was built (Ogbete & Aminu-Ibrahim, 2024). The relevant question is not whether a given advertisement satisfied fair balance, whether a payment was disclosed, or whether a prescriber signed a prescription. It is whether the patient at the end of the chain understood what they were taking, why, at what risk, at what cost, and whether an independent clinical judgment stood between the commercial interest and their body. That question is answerable. It is simply harder to answer than the compliance questions that have substituted for it.

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