

Compounding's Reckoning: What Him Getting Smacked by FDA Tells Us About Healthcare's Gray Markets

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Abstract

The FDA's February 2025 warning letter to Hims represents a pivotal moment in digital health's ongoing dance with regulatory boundaries. This enforcement act targeting the company's compounded semaglutide offerings, illuminates fundamental tensions in healthcare innovation: the collision between patient access demands, regulatory frameworks designed for different eras, and venture-backed business models that thrive in ambiguity. The case offers insights into:

- Compounding pharmacy economics and the legal frameworks governing patient-specific medication preparation
- GLP-1 market dynamics worth \$100B+ annually and the gray markets that emerge around branded scarcity
- Regulatory arbitrage strategies that actually work versus those that don't
- What happens when companies build material revenue streams in contested regulatory spaces
- The timing of Novo Nordisk's simultaneous lawsuit and FDA enforcement
- How Super Bowl advertising spend intersected with regulatory collapse
- Stock market reactions to regulatory risk materialization

For investors and operators in digital health, this situation provides a masterclass distinguishing between calculated risk-taking and structural vulnerability, understanding how regulatory moats can evaporate overnight, and recognizing that market timing depends more on bureaucratic inertia than sustainable competitive advantage.

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The Warning Letter That Surprised Nobody

When FDA dropped its warning letter on Hims in early February 2025, the market reacted with the enthusiasm of someone discovering water is wet. The company's stock took a predictable hit, analysts scrambled to revise models, and the chorus "we always knew this was coming" started immediately. Which is interesting, because if everyone actually knew this was coming, the billion-dollar compounded GLP-1 market probably should not have materialized in the first place.

The warning letter itself reads like regulatory Mad Libs. FDA takes issue with Hims marketing compounded semaglutide products without approved new drug applications. The agency notes that these products don't meet the conditions for compounding under Section 503A of the Federal Food, Drug, and Cosmetic Act. There's hand-wringing about patient safety, concerns about product quality, and usual regulatory throat-clearing about how compounding is supposed to work for individual patient needs rather than mass distribution. Fox Business reported that Hims would discontinue its oral compounded semaglutide offering as a direct result, which tells you everything about how seriously the company took FDA's concern once enforcement became real rather than theoretical.

But the interesting part is not what FDA said. FDA says stuff all the time. The interesting part is when they chose to say it, who they chose to say it to, and what it reveals about the sustainability of building venture-scale businesses in regulatory zones. The timing was exquisite in its awfulness for Hims. The company had just committed to a Super Bowl advertising slot, one of the most expensive media buys in existence, promoting their weight loss offerings. The ad was already in production, the media spend already committed, and the brand messaging already locked in around democratizing access to treatments that rich people use to live longer.

Hims was pulling down meaningful revenue from these products. Not side-hustle money. Not proof-of-concept pilot programs. Real, material, model-moving revenue that analysts cared about and investors underwrote. The company had built infrastructure, supply chains, marketing machines, and customer acquisition funnels all oriented around delivering compounded GLP-1s at price points that made traditional pharmaceutical distribution look like a Renaissance fair. Yahoo Finance reported the stock crashed on the FDA announcement, with shares plummeting as investors suddenly remembered that regulatory risk is not just boilerplate language in the disclosures section.

And now FDA shows up suggesting that maybe, just maybe, using compounding pharmacies to mass-produce alternatives to blockbuster drugs was not quite what Congress had in mind when they created carve-outs for patient-specific preparatory medicines. The timing matters enormously. Novo Nordisk announced in late 2022

Wegovy shortages had been resolved. FDA maintains a drug shortage database, and when brand manufacturers can meet demand, the legal justification for compounding those drugs evaporates like morning dew. Compounding pharmacies exist in federal law to fill gaps, to customize medications for patients with specific needs, to provide alternatives when commercial products are unavailable. They do not exist to provide generic-ish alternatives to drugs that happen to be expensive but are otherwise readily available.

Except that is exactly what happened, at scale, with hundreds of millions in capital backing the effort. The disconnect between what compounding law was designed for and what it was being used for was so obvious that anyone pretending to be surprised by FDA enforcement was either lying or had not read the relevant statutes. But venture capital has a remarkable ability to convince itself that regulatory risk is someone else's problem, especially when growth metrics look good and exit time seems achievable before enforcement materializes.

How Compounding Became a Billion-Dollar Loophole

Compounding pharmacies have been around forever, doing the kind of work that made sense before pharmaceutical manufacturing became industrialized. Need a friendly liquid version of a tablet medication? Compounding pharmacy. Allergic to a specific inactive ingredient in a commercial formulation? Compounding pharmacy. Need a specific dosage strength that doesn't exist in marketed products? You get the idea. This was unglamorous, necessary work that served real patient needs in ways that mass manufacturing could not address.

The regulatory framework reflects this history. Section 503A of the Food, Drug, and Cosmetic Act provides a pathway for traditional compounding, allowing pharmacies to prepare patient-specific medications without going through the full FDA approval process. Section 503B created outsourcing facilities that could do larger-scale compounding under more stringent oversight. Both frameworks assume compounding serves a fundamentally different function than manufacturing. Both frameworks

assume demand is patient-specific and limited. Both frameworks were written by venture capital discovered that “patient-specific” is a pretty elastic concept if you squint hard enough and have lawyers willing to write memos supporting aggressive interpretations.

The business model that emerged over the last few years was clever in its simplicity and transparent in its regulatory vulnerability. GLP-1 drugs like Wegovy and Ozempic were experiencing massive demand driven by weight loss applications that far exceeded their initial diabetes-focused indications. Prices were high, running a thousand bucks a month for commercially insured patients paying out of pocket. Supply was constrained, with FDA’s drug shortage database listing semaglutide products as unavailable for extended periods. And compounding pharmacies could produce semaglutide for a fraction of the cost, selling it to patients at price points that felt accessible but still generated healthy margins for everyone involved in the distribution chain.

Enter the digital health platforms. Companies like Hims recognized they could leverage telemedicine infrastructure that connected patients to prescribers and compounding pharmacies, creating vertically integrated distribution networks that delivered \$100s to customers at two hundred to three hundred bucks monthly instead of twelve hundred. The patient experience was frictionless in ways that traditional pharmacy interactions are decidedly not. Sign up online, talk to a provider via video or asynchronous messaging, get a prescription, receive your medication in the mail. No insurance headaches, no prior authorizations, no fighting with pharmacy benefit managers about whether weight loss constitutes medical necessity for a drug approved for exactly that indication but somehow still subject to coverage denials.

For customers priced out of brand-name options or unable to access them through insurance, this felt like democratization of healthcare. For investors, it looked like a massive TAM with strong unit economics and customer acquisition channels that could scale without the friction of traditional healthcare delivery models. For companies building these platforms, revenue scaled beautifully because the underlying regulatory arbitrage was simple: as long as FDA listed semaglutide as being in shortage, compounding was legally defensible under existing frameworks.

And as long as each prescription could be justified as patient-specific with some minimal documentation showing individualized medical decision-making, the market distribution model occupied a gray zone rather than obvious black-letter violation.

The economics worked because compounding pharmacies could source active pharmaceutical ingredients cheaply, formulate them at scale while maintaining the legal fiction of patient-specific preparation, and distribute through digital platforms that handled customer acquisition and fulfillment logistics. Gross margins on these products could exceed seventy percent once operations reached scale. Customer acquisition costs were high but justifiable given lifetime value assumptions that hinged on continuous monthly subscriptions and cross-selling opportunities into other product lines. The playbook borrowed from every other DTC subscription business, except instead of selling razors or vitamins, you were selling peptides that required reconstitution and subcutaneous injection.

Nobody with any understanding of FDA should have been surprised that the agency would eventually show up. The question was always when, not if. And what would trigger enforcement. The optimistic view among operators in this space was that enforcement capacity was limited, that the patient benefit was real enough to create political complications for aggressive crackdowns, and that by the time enforcement materialized the companies would have diversified revenue streams or achieved other milestones that made early-stage regulatory risk worthwhile. The pessimistic view was that the agency was watching the whole thing develop and would drop the hammer as soon as the political and legal justification for tolerance disappeared.

The shortage resolution provided exactly that justification. Once Novo Nordisk could no longer meet market demand, FDA's tolerance for mass-market compounding evaporated. The agency started signaling through guidance updates and public statements that compounding semaglutide was only appropriate in narrow circumstances. And yet companies like Hims kept scaling distribution anyway, FDA moved from signals to enforcement.

The GLP-1 Gold Rush and Its Inevitable Hangover

The semaglutide shortage created a gold rush mentality that attracted capital well beyond what traditional compounding economics could support. Investors poured money into telehealth platforms, compounding pharmacies expanded production capacity, and a whole ecosystem emerged around delivering cheaper GLP-1s to a market that seemed infinitely large and infinitely willing to pay for access to drugs that promised significant weight loss with relatively tolerable side effect profiles.

The numbers were genuinely staggering in ways that made ignoring regulatory risk seem almost rational. Novo Nordisk's semaglutide products were generating tens of billions in annual revenue globally. Eli Lilly's tirzepatide products were on similar trajectories. Analysts projected the global GLP-1 market could hit one hundred billion dollars annually within a few years, driven by expanding indications, growing patient awareness, and accumulating clinical evidence for benefits beyond glucose control and weight loss. And the compounders were capturing a slice by offering functionally similar products at seventy-five to eighty percent discounts to list prices.

From a patient access perspective, this made sense in ways that exposed fundamental brokenness in pharmaceutical pricing and distribution. Obesity affects over forty percent of American adults. Type 2 diabetes affects another ten to twelve percent. Novo and Lilly could not manufacture enough product to meet demand even if every patient could afford list prices, which they obviously could not. Insurance coverage was spotty at best, with many plans excluding weight loss drugs categorically despite FDA approval for exactly that indication. Employers were adding GLP-1s to formulary exclusion lists because covering them would blow up pharmacy budgets. Medicare was prohibited by law from covering weight loss drugs. The traditional pharmaceutical access model was failing spectacularly, and compounders were filling the gap in ways that served real patient needs.

From a business model perspective, this was rocket fuel for valuations and venture funding. Companies could point to massive addressable markets, demonstrate strong demand signals through customer acquisition metrics and retention curves, show

compelling unit economics with gross margins that would make software investors jealous, and argue they were solving a real access problem that traditional pharmaceutical distribution was incapable of addressing. The regulatory risk was acknowledged but treated as manageable and deferrable. Sure, FDA might eventually crack down, but then the companies would have diversified revenue streams, built brand equity, established customer relationships that could be monetized through other products and hopefully exited or gone public at valuations that made early risk-taking worthwhile for everyone involved.

From a regulatory perspective, this was a nightmare unfolding in slow motion while FDA tried to figure out how to respond without creating worse patient access problems. The agency watched compounding pharmacies distribute semaglutide to thousands of patients monthly through telehealth platforms that looked nothing like traditional pharmacy practice. The patient-specific preparation requirement was being honored in letter but not spirit, with templated prescriptions and minimal individualization beyond dosing adjustments. Prescribers were often affiliated directly with the platforms, raising questions about whether medical judgment was truly independent or whether prescribing was driven by platform economics and patient demand. Quality control at compounding facilities was variable at best, with no requirement to prove bioequivalence to FDA-approved products and no systematic oversight of manufacturing processes.

And then Novo Nordisk resolved its manufacturing constraints. The company invested billions in production capacity, optimized supply chains, built new facilities and by late 2024 could meet market demand for Wegovy. Which meant FDA's drug shortage database no longer listed semaglutide products as unavailable. Which removed the legal foundation for mass compounding evaporated overnight. The entire business model of compounded GLP-1 distribution depended on shortage conditions that no longer existed, and everyone in the ecosystem knew it.

FDA did not immediately shut everything down because abrupt enforcement would have stranded thousands of patients mid-treatment and created its own access crisis. They signaled. They issued statements reminding stakeholders that compounding is only appropriate when drugs are in shortage or when patient-specific needs cannot

met by commercial products. They updated guidance documents. They gave the industry time to adjust and transition patients to approved products. But when companies like Hims kept scaling compounded semaglutide distribution even as shortages resolved, treating FDA's signals as suggestions rather than warnings, the agency's patience ran out.

The warning letter to Hims was the inevitable consequence of a regulatory game of chicken that the company was never going to win. Hims bet it could continue operating in the gray zone even after the justification for being there disappeared, presumably calculating that FDA enforcement would be slow enough that they could extract value before consequences materialized. FDA bet that public enforcement action against a high-profile player would send a message to the broader market that the tolerance period was over. Both were probably right, but only one of them had the power to impose consequences.

What Hims Actually Built and Why It Mattered

Hims deserves credit for execution even if the regulatory strategy was questionable and the ultimate outcome predictable. The company built a genuinely differentiated telehealth platform that combined provider networks, pharmacy infrastructure, customer acquisition machinery, and fulfillment logistics into an integrated system that worked remarkably well for patients. Their approach to men's and women's health products addressed real market gaps in areas where traditional healthcare delivery was awkward, expensive, or inaccessible due to social stigma or structural barriers.

The compounded GLP-1 offering was a natural extension of this model once you accepted the regulatory risk. Hims already had provider networks that could write prescriptions. They already had relationships with compounding pharmacies that could fulfill orders. They already had customer acquisition channels optimized for DTC health products with strong performance marketing capabilities. Adding

semaglutide was operationally straightforward and addressed massive unmet demand in a patient population that was highly motivated and willing to pay out of pocket.

What made Hims interesting from a business perspective was how they thought about customer relationships beyond individual transactions. This was not just a utilitarian pharmacy model focused on dispensing and forgetting. They were building ongoing relationships with customers around broader health and wellness needs, creating a platform that could sell multiple products over time to the same customer base. A GLP-1 customer might also use hair loss products, erectile dysfunction medication, skincare treatments, or other offerings in the Hims portfolio. Cross-selling opportunities were real and demonstrable in the data. Lifetime value calculation could justify aggressive customer acquisition spending that would look insane for single-product businesses.

The company also understood brand building in ways that traditional telehealth players did not, creating marketing that felt culturally relevant rather than clinical. Hims created a consumer brand with actual resonance beyond functional benefits. It was just a utilitarian service for accessing prescriptions. Their marketing felt modern and accessible. Their product design was thoughtful. They made healthcare consumption feel normal rather than clinical or shameful, which matters enormously for conditions that carry social stigma.

From an investor standpoint, Hims demonstrated that you could build a large, fast-growing healthcare business without dealing with insurance companies and all the associated complexity. The DTC cash-pay model avoided claims processing, prior authorizations, and reimbursement negotiations. Customers paid directly, margins were transparent, and revenue was predictable. This was compelling to investors exhausted by the complexity of traditional healthcare business models and the dysfunction of insurance reimbursement.

The problem was that a meaningful chunk of this promising business was built on regulatory sand that anyone could see was unstable. The compounded GLP-1 revenue was material enough that losing it would hurt growth projections and force downward revisions to financial models. But more importantly, it raised questions about

management judgment and risk assessment that went beyond this specific product line. Did leadership genuinely believe compounding was a durable long-term strategy? Or was this a calculated bet that they could capture enough value before FDA shut things down that it was worth the risk of building material revenue on an unstable foundation?

For operators building similar businesses, Hims provides a case study in both opportunity and caution. The opportunity is that digital health platforms can genuinely improve access and patient experience in meaningful ways, solving real problems that traditional delivery models fail to address. The caution is that building material revenue streams in contested regulatory spaces creates structural vulnerabilities that are hard to diversify away from, and that regulatory risk can materialize faster and more completely than optimistic projections assume.

Novo Nordisk Brings Out the Lawyers

Just to make sure Hims understood that their regulatory problems were not theoretical or distant, Novo Nordisk filed a lawsuit in early February 2025 targeting the company's compounded semaglutide offerings. USA Today reported on the lawsuit, which alleged patent infringement and unfair competition. The timing was not coincidental. Novo filed after FDA removed semaglutide from the shortage list and while the agency was preparing enforcement actions against compounders.

The lawsuit added a second front to Hims' regulatory battle, demonstrating that the company was not just facing FDA enforcement but also intellectual property challenges from the brand manufacturer. Novo has aggressively protected its GLP-1 franchise through patents covering not just the molecule but also formulations, dosing regimens, and delivery mechanisms. The company was not going to sit quietly while compounders eroded their market share using legal frameworks designed for completely different purposes.

From Novo's perspective, the compounding exception was being abused at scale to create what amounted to an unauthorized generic market for their blockbuster compound. The company invested billions in R and D to develop semaglutide, navigated ext

clinical trials to prove safety and efficacy, built manufacturing infrastructure to produce the drug at scale, and obtained FDA approval through the proper regulatory pathways. Watching compounders distribute functionally similar products without any of those investments or regulatory requirements was understandably frustrating.

The lawsuit strategy was smart because it created pressure independent of FDA enforcement. Even if FDA moved slowly or faced political resistance to aggressive enforcement, Novo could pursue civil litigation that would impose costs on compounders and create legal risk that investors would have to factor into valuations. Patent litigation is expensive and time-consuming. The discovery process alone would be burdensome for a company like Hims trying to scale operations and manage multiple product lines.

For Hims, fighting on two fronts simultaneously was untenable. Defending against FDA enforcement while also litigating with Novo over patent claims and unfair competition would consume management attention and resources that could be deployed elsewhere. The rational response was to exit the compounded semaglutide business entirely, which is exactly what they did.

The broader implication is that compounders were not just facing regulatory risk from FDA but also intellectual property risk from brand manufacturers. The combination made the business model fundamentally unstable once shortage conditions resolved. Any investor who underwrote continued growth in compounded GLP-1s after shortages ended was either ignoring obvious risks or betting on a very specific scenario where FDA and brand manufacturers both chose not to enforce rights aggressively.

The Super Bowl Ad That Aged Like Milk

In what might be the most expensive example of unfortunate timing in recent marketing history, Hims ran a Super Bowl ad just days after FDA enforcement became public. USA Today's Ad Meter covered the commercial, which focused on the wealth health gap and how rich people live longer because they can access treatments that average people cannot afford. The messaging was about democratizing access to

healthcare innovations, making expensive therapies available to broader populations through direct-to-consumer models.

The ad was well-produced and the message resonated with legitimate concerns about healthcare inequality and access barriers. But running it while simultaneously shutting down the exact product line that exemplified this mission created cognitive dissonance that was hard to ignore. Hims was spending millions on a Super Bowl promoting access to weight loss treatments at the same moment they were discontinuing their compounded semaglutide offerings under regulatory pressure.

The timing was particularly brutal because Super Bowl advertising is committed months in advance. The ad was probably conceptualized and produced before the FDA warning letter, locked in before Novo filed its lawsuit, and too far into the buying process to pull without eating massive cancellation costs. So Hims ran the ad while knowing that a core piece of the product portfolio it was meant to promote was being discontinued.

From a brand perspective, this created confusion. Customers who saw the Super Bowl ad and visited the Hims website looking for cheap semaglutide would discover it was no longer available. The disconnect between the brand promise in the advertisement and the product reality on the website was stark. Marketing spend that should have driven customer acquisition instead drove awareness of a product that no longer existed.

The Super Bowl ad also crystallized questions about what Hims' value proposition actually was once compounded GLP-1s were gone. The company still had other product lines and could still claim to improve access for conditions like hair loss and erectile dysfunction. But the marquee offering that generated the most buzz and probably the most revenue growth was off the table. What was left was a solid but not exciting DTC health platform competing in more crowded categories.

For investors, the Super Bowl ad spending right as the business model was collapsing raised questions about capital allocation and strategic judgment. Spending eight figures on a Super Bowl spot is a major commitment that should reflect confidence in the business trajectory. Doing it while core revenue streams were being shut down

regulators suggested either very bad timing or very poor communication between different parts of the organization about the severity of regulatory threats.

The contrast between the ad's message about democratizing healthcare and the reality of shutting down cheap drug access under pressure from FDA and brand manufacturers also highlighted tensions inherent in the DTC health model. The companies position themselves as disruptors making healthcare more accessible, but they are ultimately subject to the same regulatory frameworks as everyone else. When those frameworks impose constraints, the disruption narrative runs into the wall of regulatory authority.

The Regulatory Tightrope Nobody Wants to Discuss

Healthcare innovation lives in the space between what is clearly legal, clearly illegal, and nobody knows for sure. The best entrepreneurs figure out how to operate in that middle zone long enough to either prove their model works and get regulations updated, or build enough value that regulatory risk becomes someone else's problem through acquisition or public market distribution. The worst entrepreneurs ignore regulatory risk entirely and get blindsided when enforcement materializes.

Compounding was always in that middle zone, but the zone was narrower than the companies operating there wanted to admit. The laws are old, written before digital distribution existed and before anyone imagined using compounding to compete with blockbuster drugs. The regulatory framework was not designed for telehealth platforms shipping thousands of prescriptions monthly to customers nationwide. Enforcement is inconsistent and often reactive rather than proactive, creating gaps that entrepreneurs can exploit if they are willing to accept the risk.

But there are patterns in how FDA thinks about these situations that investors and operators need to understand if they want to make intelligent bets rather than blind gambles. The agency cares enormously about whether companies are operating in good faith within the spirit of regulations versus cynically exploiting loopholes. It cares about patient safety risks, especially when quality control is variable and

products are being distributed at scale without the oversight that approved drug receive. They care about whether enforcement would harm patients more than h them, which creates political constraints on aggressive crackdowns. And they ca about industry behavior, because if everyone starts doing something sketchy, the policy question shifts from edge cases to systemic issues requiring broader regul response.

Hims was operating in good faith in the sense that they were not hiding what the were doing. This was not some backroom operation running under FDA's radar. were publicly marketing compounded semaglutide, touting it in investor presentations, building it into financial models, and treating it as a core part of t growth story. The bet was that FDA would tolerate this because patient benefit v clear, shortage conditions provided legal cover, and the agency had limited enforcement resources to go after every compounding pharmacy.

The problem is that once shortage conditions resolved, the good faith argument apart. Continuing to mass-distribute compounded semaglutide when brand prod were available was no longer defensible as filling a gap in patient access. It was j competing with approved products using a regulatory carve-out designed for completely different purposes. FDA could not credibly maintain that this was appropriate use of compounding exceptions without gutting the entire framework that distinguishes compounding from manufacturing.

FDA has shown repeatedly that they will tolerate a lot of gray-zone activity if pa harm is low and companies are not actively thumbing their nose at the agency. T will even sometimes work with companies to find regulatory pathways that allow innovation to continue, creating new frameworks when old ones don't fit emergi business models. But when companies keep pushing after FDA has signaled that party is over, enforcement becomes inevitable because the agency's credibility depends on eventually following through on warnings.

The warning letter language is formulaic but the substance is serious. FDA is tel Hims that their compounding practices violate federal law. The agency is deman corrective actions and responses. And while warning letters do not carry immedi

legal penalties, they create a record that makes future enforcement much easier if companies do not comply. The warning letter is the last step before consent decrees, injunctions, and potentially criminal referrals for egregious violations.

For Hims, the rational response was exactly what they did. Discontinue the product, issue statements about patient safety and regulatory compliance, take the revenue and move on. The alternative was escalating enforcement that could threaten the entire business through injunctions, consent decrees, or worse. For other companies in similar positions, the message is clear. If you built material revenue in regulatory gray zones, start planning your exit strategy now before FDA makes the decision for you.

Market Implications and What Breaks Next

The Hims enforcement creates ripple effects across digital health in ways that extend well beyond compounding pharmacies and GLP-1 distribution. The broader lesson is about how FDA is thinking about digital distribution of healthcare products and services, particularly when those models challenge traditional pharmaceutical economics or distribution channels that have existed for decades.

Compounding pharmacies that scaled up infrastructure and staffing for GLP-1 demand now face serious questions about their business models and revenue sustainability. Many invested in expanded facilities, hired additional pharmacist technicians, built relationships with telehealth platforms, and constructed entire business operations predicated on ongoing demand for compounded semaglutide and tirzepatide. If FDA systematically enforces against compounded GLP-1 distribution across the industry rather than just making an example of Hims, a whole segment of the compounding pharmacy industry faces revenue collapse and potential closure.

The telehealth platforms that partnered with compounders are scrambling to replace revenue and rebuild growth narratives for investors. Some are pivoting to other product lines where regulatory risk is lower. Some are exploring whether they can facilitate access to brand GLP-1s through traditional distribution channels and

patient assistance programs. Some are probably going to die because their entire proposition was built around cheap GLP-1 access and there is no obvious Plan B generates comparable unit economics or market excitement.

There are also questions about what other regulatory gray zones might face similar scrutiny now that FDA has demonstrated willingness to enforce against high-profile digital health companies. Ketamine therapy for depression has become a substantial telehealth business despite questions about appropriate use, patient selection, and oversight of prescribing practices. Testosterone prescribing through DTC platforms operates in spaces where FDA and DEA have complicated and sometimes contradictory views about appropriate medical use versus performance enhancement. Abortion medication access via telehealth involves state law complexities on top of federal regulation and political dynamics that make enforcement unpredictable.

The pattern of building venture-scale businesses in areas where regulations are ambiguous or unevenly enforced is not unique to compounding. Digital health is full of companies operating in gray zones, betting that growth and patient benefit will outweigh regulatory risk or that enforcement will be too slow to matter before they are achieved. The Hims situation demonstrates that this bet does not always work and that when it fails the consequences are swift and material.

For FDA, the Hims enforcement signals a potential shift toward more active oversight of digital health distribution models. The agency spent years trying to figure out how to think about digital health without stifling innovation, recognizing that heavy-handed enforcement could prevent genuinely beneficial models from emerging. That period of studied patience may be ending as the agency gains confidence in distinguishing between innovation that deserves accommodation and regulatory arbitrage that deserves enforcement.

When companies treat regulatory ambiguity as permission rather than caution, FDA responds by removing the ambiguity, usually in ways that favor established players over disruptors. The pharmaceutical industry is paying close attention to the Hims situation because compounding presented a genuine competitive threat. If digital platforms could distribute functional equivalents of blockbuster drugs at massive

discounts using compounding as legal cover, the entire pharmaceutical business model faces pressure and the value of FDA approval diminishes.

Brand manufacturers want FDA enforcement to make clear that compounding is a generic pathway and that the investments required to develop and approve new drugs are protected by regulatory frameworks that prevent cheap copies from undermining market exclusivity. They have significant resources to push FDA in that direction through lobbying, litigation, and other forms of pressure. And they have legitimate concerns that if compounding is allowed to function as a de facto generic pathway, incentives for pharmaceutical innovation are weakened.

From a market structure perspective, cheap compounded GLP-1s were starting to create pricing pressure that would have been difficult for Novo and Lilly to ignore. If patients had reliable access to two hundred fifty dollar monthly alternatives, the companies would have faced hard questions from policymakers and payers about why their brand products cost five times as much. Resolving shortages and triggering FDA enforcement against compounders neatly eliminates that pricing pressure before it becomes a serious problem threatening the economic model of blockbuster drug development.

The Investor Calculus on Regulatory Risk

The challenge for healthcare investors is figuring out how to underwrite regulatory risk in ways that are intellectually honest rather than wishful thinking disguised as due diligence. Every pitch deck acknowledges regulatory risk in the standard risk disclosures section. Every diligence process includes legal review and regulatory analysis. And yet companies keep building material businesses in spaces where the regulatory foundation is obviously shaky and the durability is questionable to anyone willing to think critically about enforcement probabilities.

Part of this is incentive alignment throughout the venture ecosystem. Founders want to build big companies fast because that is what generates venture returns and acquisition interest. Early investors want growth that supports markups in subsequent rounds and eventual exits at attractive multiples. Later investors inh

positions and need to believe the story or write down their investments. Board members want to see momentum. Nobody has incentives perfectly aligned with success, so, this regulatory risk is actually unsurvivable and we should shut this down before building more revenue on an unstable foundation.

But there are frameworks for thinking about regulatory risk that can separate calculated bets from structural problems. The key questions are about durability, replaceability, and exit timing.

Durability asks whether the regulatory arbitrage can persist long enough to matter in building a business rather than just extracting short-term value. Compounding worked as long as shortages existed and FDA chose to tolerate mass distribution through telehealth platforms. Once shortages resolved, durability was zero because the legal justification evaporated. Companies that understood this could plan accordingly and either diversify revenue streams or structure cap tables and exit strategies around the expectation that compounded GLP-1 revenue would disappear. Companies that pretended durability was indefinite or that regulatory enforcement was unlikely set themselves up for exactly what happened to Hims.

Replaceability asks whether the revenue from regulatory gray zones can be replaced with more durable alternatives once enforcement materializes. If a company builds brand equity, customer relationships, and infrastructure using compounded GLP-1s as the initial wedge, can they transition to other products and services that generate comparable economics? Hims arguably yes, because their platform supports multiple product lines across men's and women's health. A company that only does compounded GLP-1s with no other revenue streams has no replacement revenue available and is just dead when enforcement happens.

Exit timing asks whether investors can realize returns before regulatory risk materializes. This is the most cynical but also most honest framing of how venture capital often approaches regulatory risk in practice. If you invest in a company exploiting regulatory ambiguity, your returns depend on either getting acquired before enforcement or going public and achieving liquidity before the bottom falls out. The Hims public investors who bought after the company scaled compounded

GLP-1 revenue are now holding losses as the stock crashed on FDA enforcement early investors who got liquidity through earlier financings or the IPO probably fine on a return basis.

The harder question is about what this means for healthcare innovation more broadly. The best healthcare companies often do operate in gray zones because that is where unmet needs live. Regulation is slow, updated infrequently, and often lags behind technology capabilities and patient expectations. Patient needs are immediate and do not wait for regulatory frameworks to catch up. Entrepreneurs who wait for perfect regulatory clarity never build anything because by the time clarity arrives someone else has already captured the market.

But there is a meaningful difference between operating in gray zones while working toward regulatory clarity versus building entire business models on the assumption that gray zones are permanent. The former is innovation that pushes boundaries and engages with regulators to create appropriate frameworks. The latter is regulatory arbitrage disguised as innovation, exploiting temporary gaps without any plan for how to operate sustainably once gaps close.

For the Hims situation specifically, the lesson is not that compounding was doomed from the start or that the company was foolish to pursue the opportunity. The lesson is that once the justification for compounding disappeared with shortage resolution and FDA signaled enforcement was coming, continuing to scale distribution was a bet that depended on FDA either not following through or enforcement being so slow that it did not matter for near-term financial performance. That bet failed, predictably, because FDA's credibility required following through and because other manufacturers like Novo added pressure through litigation.

Looking forward, digital health companies need to think much harder about what happens when regulatory patience runs out. FDA has shown they will tolerate a certain amount of risk in the name of innovation and patient access, especially when enforcement would cause its own patient harm by disrupting access to beneficial services. But tolerance has limits. And when those limits are reached, companies either adapt quickly or fail.

serious consequences that can include not just warning letters but injunctions, consent decrees, criminal referrals, and complete business model collapse.

The compounding gold rush is over. The question now is what other regulatory arbitrages are living on borrowed time, and whether the companies built on those arbitrages have enough runway to evolve before their time runs out. For investor discipline is separating companies that are genuinely solving durable problems from those that are just capturing value while regulatory inertia lasts. The difference matters more than pitch decks usually acknowledge and more than diligence processes often surface.



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