



How GLP-1s Have Changed Compounding

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20 Years Ago, Compounders Were...

- All 503A (no section 503B in existence yet)
- Made up of hospitals, infusion pharmacies, and “mom and pop” community pharmacies
- Preparing mostly sterile-to-sterile CSPs OR nonsterile CNSPs
- Largely using manual / legacy methods to prepare a compound
- Commonly offering large formularies (hundreds to >1,000) at a practice site
- Preparing batch sizes often for N = 1 to 10 patients
- Seeing a mix of cash pay and some insurance
- No board certification in existence
- Less intense regulatory scrutiny



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What Events / Shifts Have Happened Since Then?

- 2012 NECC Tragedy → DQSA → Section 503B + Increased Regulatory Scrutiny of Compounding
- 2013 NABP Launches VPP Accreditation
- Mid 2010s-Present HCPs Became Social Media Influencers of Healthcare Products → Patients are interested in precision medicine and want to live well
- 2019 Healthcare Marketing on Social Media (e.g., Mucinex on TikTok) → consumerization of healthcare
- 2019 First BCSCP Class
- 2020 COVID-19 → telehealth use becomes mainstream + certain regulations relax (e.g., DEA CS)
- **2022-2025 Multiple GLP-1 National Drug Shortages** → 503As and 503Bs step up to assist patients in continuity of care
- 2022 AI Boom
- 2023 USP Updates → Increased quality expectations
- 2025 New US Administration → No added federal laws BUT FDA has been busy with Green List, HRT black box removal, and warnings on claims



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How Have GLP-1s Changed Compounding?

1. Public Awareness & Perception
2. Big Pharma's Response
3. Market Expansion & Evolution
4. Regulatory Landscape
5. Shift in the Business Model



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Public Awareness & Perception

- A [national poll](#) (1,222 U.S. adults, Feb 2025) found:
 - 42% of adults are familiar with pharmacy compounding.
 - 29% didn't know what compounding was, and another 29% were unsure what it means.
 - 87% correctly knew compounded medications must be prescribed by a licensed practitioner.
 - 79% of people who had used compounding pharmacies reported a positive experience.



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Public Awareness & Perception Has Evolved

- Public familiarity with compounding pharmacies is measurable. Many people now recognize compounding exists and what it generally involves.
- Among people who have used compounded medications, satisfaction rates are high.
- Compounded prescriptions are believed to constitute a [meaningful share](#) of overall prescriptions, across therapy areas.
- A significant knowledge gap remains on specifics of regulation or oversight.



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Big Pharma's Response

- Major manufacturers are paying closer attention: lawsuits, coordinated public messaging, and PR campaigns to shape perception.
 - [Litigation](#): MFR files lawsuits over GLP-1 copies.
 - [Litigation](#): MFR expands legal actions against telehealth/compounders.
 - [PR Messaging](#): MFR promotes 'healthy skepticism' toward compounded drugs.
 - [PR Messaging](#): MFR publicly criticizes compounded drug suppliers following ads.



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Big Pharma's Response

- Generic and specialty pharma companies are looking for new revenue streams.
 - Multiple industry [market reports forecast significant growth](#) in the compounding pharmacy market — e.g., from USD 14.7 billion in 2025 to USD 19.4 billion by 2030 at ~5.7 % CAGR — driven by personalized medicines, which pharma companies consider strategic.
 - Compounding pharmacies help meet unique patient needs and personalized medicine demand, which is increasingly [an area of strategic interest](#) for many healthcare and drug manufacturers exploring value beyond traditional blockbuster models.
 - Specialty drugs and pharmacy services continue to grow rapidly and attract investment from large healthcare/pharma sectors, indicating that adjacent services such as compounding and personalized dosing are in the orbit of broader pharmaceutical business models. This can be inferred from industry analysis showing high specialist demand and investment in specialty medicines (e.g., [Cardinal Health raising forecasts](#) due to specialty demand).



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Market Expansion & Evolution

- Hospital and home infusion compounding is still prevalent
- The GLP-1 shortage drew non-traditional players into compounding including venture capital firms, private equity investors, telehealth platforms, and entrepreneurs.
- Result: consolidation and bifurcation. There seem to be fewer “mom & pop” shops, and more large-scale compounders with professional infrastructure are emerging.



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Market Expansion & Evolution

- But within the market two new archetypes emerged:
 - Speed/marketing-led entrants optimizing for rapid growth.
 - Quality-focused entrants building for long-term scale or acquisition.
- Overall, industry quality standards rose as serious players invested in compliance and sustainability.



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Regulatory Landscape

- NABP's VPP inspection programs [gained traction](#) as states looked for consistency and shared oversight models.
- FDA unveiled a novel regulatory tool ([Green List](#)) aimed at clamping down on unsafe imports of active pharmaceutical ingredients (APIs) for GLP-1 (glucagon-like peptide-1) drugs.
- FDA issued [multiple warning letters](#) and enforcement actions related to promotional claims.



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What Does the Compounding Industry Look Like Now?

- A mix of 503A + 503B
- Made up of hospitals, infusion pharmacies, and community pharmacies
 - Ownership Models: independent, health-system aligned, VC- or PE-backed, & telehealth-integrated
- Still a lot of sterile-to-sterile CSPs, but a large increase in nonsterile-to-sterile CSPs and nonsterile CNSPs
- Processes bifurcated – some still using manual / legacy methods, others using semi/automation
- Less formulations offered at a practice site
- Often larger batch sizes prepared for a cohort of patients
- Cash pay
- BPS in sterile compounding
- Heightened regulatory scrutiny and enforcement



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Shift in the Business Model

- Post-GLP-1 and post-USP revisions, compounders are rationalizing their SKU lists and moving away from very large formularies.
- The new model emphasizes specialization, consistency, and high-quality production over endless customization.
- The result: fewer products*, but safer, more reliable ones, and a maturing industry identity.



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What's on the Horizon for the Industry?

- **Patients want convenient access to quality personalized medicines**
 - The source and quality of the ingredients used in compounding is important
 - Novel equipment can level up the reproducibility & reliability of the compounding process
 - A barbell approach to formulation offerings may be needed to meet both precision medicine and popular SKU expectations
- **Laws, regulations, and industry standards will continue to evolve**
- **Telehealth and AI are here to stay**
- **Claims of safety or efficacy cannot be made on compounds**
- **Clinical justification for a compound over an FDA approved product is important**



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