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Market Update

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2023 COMPOUNDING PHARMACY: **HOW USP 800, SEMAGLUTIDE, AND COMPETITIVE FORCES WILL SHAPE THE INDUSTRY**

This year is a dynamic and fast paced one for compounding pharmacy M&A. Early in the year, unpredictability in the broader economy created challenges for transactions and Semaglutide created a boom for sellers but pause for buyers. However, as the year progressed, anxiety dissipated, and buyers resumed their acquisition mandates. Last but not least, the constant pressure of changing regulatory standards continued to bring owners to the marketplace seeking exits and partnerships. Altogether 2023 will go down as one of the busiest M&A years in recent history for compounding pharmacy. This article covers three major influences on M&A activity in compounding pharmacy throughout the year and discusses their long-term impacts on the industry: USP 800, Semaglutide, and Competitive Forces.

USP 800

Consistent with history, there is always a compliance and/or regulatory storm looming in the compounding space, and USP 800 is the "soup de jour". For the past few years, compounding grappled with the MOU (which is still brewing at the FDA. It will simply morph into a new form.) and now the USP 800 standard is the next opponent in the ring for many compounding pharmacies. Some states and their respective boards of pharmacy already started enforcing the new standard while other states are lagging in adoption enforcement and are vaguely directing pharmacies to research thechapterthemselves and independently prep their business for a future inspection.

How does USP 800 impact M&A transactions? The answer is: it depends. Generally, buyers evaluate the geographic location of the pharmacy and conduct diligence on the regional board. Based on their indings, they may seek to make an allocation for potential USP 800 upgrades in the future. Of course, this is not the case if a seller is carving out certain assets of the business, so it's important to recognize the objective of the sale, at the inception of the transaction. Many times, owners already researched the necessary upgrades for USP 800 and drafted drawings, received price quotes, and applied for permits. This proactive approach simplifies transaction negotiations and both parties can review the documents together to settle on an appropriate course of action, if any.

> *"In the first six months of 2023, sales of Ozempic and Wegovy rose by 58% and 363%, respectively."* [2]

SEMAGLUTIDE AND GLP-1S

Called the biggest business event of 2023, Semaglutide, Wegovy and Tirzepatide (combined, referred to in this article as simply, "Semaglutide". Intentionally omitting retatrutide) arrived on

the weight loss stage and created tsunami size waves. Surging 300% over 3 years, practitioners wrote over 9 million prescriptions for Ozempic and Wegovy during the 4th Quarter of 2022[1]. Estimates for 2023 are much higher since the drug found its way onto the FDA's shortage list and patient awareness has increased exponentially. This medication possesses the power to reshape the entire economy, more than AI by an order of magnitude and future impacts on the compounding industry are immeasurable, irrespective of the drug's time spent on the shortage list.

Not all Semaglutide effects are tailwinds, there are headwinds as well. There has been a lot of buzz around the legal implications of dispensing the drug but the general sentiments around those counterpoints are moot while it remains on the shortage list. The recent legal claims against compounding pharmacies by Novo Nordisk et. al. are essentially baseless and APC commented on the matter in a recently released statement. However, after the drug is removed from the shortage list, the landscape will change dramatically. Compounding medications during a shortage is not foreign to this segment of pharmacy, rather it's part of the core, but in an M&A transaction, the perceived legal implications and future unpredictability can give buyers pause.

As a result, in 2022 and early 2023, profits from Semaglutide did not exactly enhance pharmacy valuations. But, as we approach 2024, many buyers now view the therapy through a different lens and are willing to recognize its value. Although often calculated differently than other legacy f ormulations, it's unrealistic to disassociate the collateral benefits realized from new practitioners and patients seeking this medication. Acquirers are therefore utilizing varying valuation methodologies for the drug revenue. Some acquirers will experience more synergies than others and use a particular methodology. While, other buyers are developing their own formulations and strategies for when the drug is removed from the shortage list (assuming that happens at some point) and may use a very different valuation methodology. Consequently, it's critical for a seller to conduct discussions with multiple prospective partners before selecting one.

COMPETITIVE FORCES

Compounding pharmacy consolidators are growing in number. Their strategies are crystallizing, and they are gaining strength and experience in the industry. Private equity, strategic buyers, and an increasing number of independents are making acquisitions. Of the thousands of independent compounding pharmacies, there are hundreds of potential targets and transactions range in structure from “file buys” (purchase only the scripts and not the entire business) to “buy & operate” recapitalizations (purchase part of the business and the owner stays on for a period of time) to 100% exits (owner walks away). Each buyer brings different pros and cons to a seller. One buyer may realize more synergies than another, yet another may have a greater need for a particular geographic or therapy profile. It’s essential that sellers flush out their ideal buyer through confidential marketplace assessments and speak with several acquirers to maximize their position in the marketplace.

As consolidating pharmacies increase in size and expand their reach, they become more alike than different. In a crowded industry like compounding pharmacy, differentiation will grow more challenging as brands become more similar[3]. As a result, consumers will increasingly base purchase decisions on price. Larger brands therefore seek to position themselves based on products and services, tailoring their activities to serve a particular customer population. Savvy acquirers incorporate a strategy that understands trade-offs in competition and their strategic mandates include carefully choosing what not to do, staying true to their differentiating competencies. Consequently, as time passes, we will see these acquirers concentrate their strategies on deepening an existing position rather than broadening and risk compromising it.

In the next 5 years the compounding pharmacy space is going to look much different than it does today, both in terms of service to customers and the players providing that service. Larger strategics, will continue to hone their powerful sales tactics and garner market share via acquisitive geographic expansion, lending powerful advantages over smaller independents. These competitive dynamics, among others will squeeze independents and the urgency to exit will increase. Regulatory organizations will continue to make business more challenging and smaller businesses that do not seek out partnerships will experience a downward pull on their growth. So much pull, that valuations may decline for certain companies as new compliance requirements make businesses look less attractive in the evolving marketplace. Even further, pharmacies may disintermediate as technology and telehealth streamline access to patients. Any competitive niche a seller can carve out today dramatically influences the value and opportunities available when they go to market tomorrow. Entertaining only one buyer is a mistake, especially as more players enter the sector, each bringing different advantages to a potential partnership.

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