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503B outsourcing facilities

An opportunity for pharmaceutical manufacturers

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Introduction

With rising patient volumes and new therapeutic options in areas such as oncology and immunology, the market for sterile injectable drugs is expanding. Increasingly, hospitals are using ready-to-administer (RTA) dosage forms—prefilled syringes and premixed bags, for example—to improve the quality of medication administration and reduce costs. These factors, in turn, are raising demand for compounded medications.

The Food and Drug Administration (FDA) created 503B legislation as part of the Drug Quality and Security Act of 2013 (DQSA), designating 503B-compliant facilities (registered 503B "outsourcing facilities") as the only entities permitted to sell compounded medications to a range of healthcare providers in large batches, beyond patient-specific prescriptions. Since then, 503B businesses ('503Bs') have grown steadily, diverting hospital-channel revenue from traditional pharmaceutical manufacturers. In addition, because 503Bs circumvent traditional channels, pharmaceutical manufacturers have less visibility into medication use, hampering their ability to keep up with changing market conditions.

We believe that pharmaceutical manufacturers not only can defend against 503Bs, but also can turn the 503B market into an opportunity. In this paper, we lay out the argument for why pharmaceutical companies should consider entering the 503B business through acquisition, building in-house 503B capacity, or partnerships.

The creation and growth of 503Bs

The 503B legislation grew out of a need for greater regulatory oversight and patient safety standards within the compounding pharmacy market, while still meeting clinical needs not being met by approved drugs. Compounding pharmacies have traditionally served patients who require modifications to FDA-approved medications for various reasons, such as drug allergies and administration requirements (e.g., inability to swallow a pill). These pharmacies have also provided drugs in times of shortage, formulating from raw active pharmaceutical ingredients (API), and have repacked drugs into RTA forms not available with FDA-approved products.

Historically, compounding pharmacies faced less-stringent regulations than pharmaceutical manufacturers. For example, they were not required to comply with the FDA's Current Good Manufacturing Practices (CGMP). Compounding pharmacies also lacked requirements related to standard product labeling or prescribing information for safe use.[1] Several highly publicized incidents concerning the quality of compounded medications brought the sector to the regulatory forefront. The most infamous was a meningitis outbreak in 2012 from drugs compounded by the New England Compounding Center that led to the death of more than 100 patients.[2]

To increase regulatory oversight and improve quality standards for compounding pharmacies, the FDA created 503B legislation as a part of the DQSA. Also called outsourcing facilities, 503B compounding pharmacies are similar to traditional ('503A') compounding pharmacies but are allowed to compound medications in larger quantities, beyond just patient-specific prescriptions, for sale to providers (e.g., hospitals and clinics).

In addition to registering and functioning as an outsourcing facility, regulations require that 503Bs report to the FDA twice a year on the products they compound, adhere to CGMP requirements, and receive FDA facility inspections, according to a risk-based schedule.

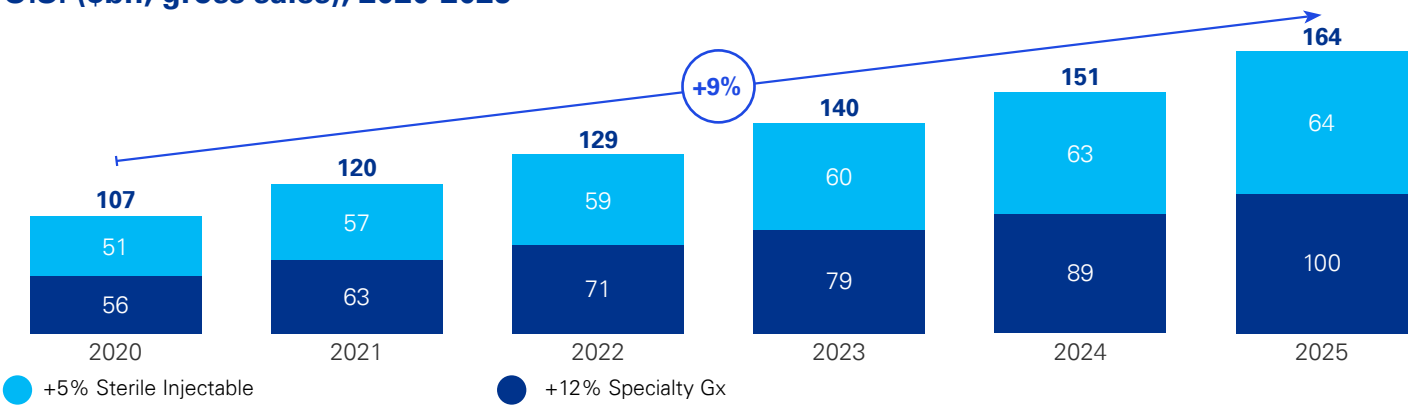
Continued hospital cost pressures, hospital concerns over liability for compounding errors, and growth in specialty and sterile injectable therapeutics (Exhibit 1) have all helped drive the 503B markets for compounded medications. Some hospital systems source as much as 10 percent to 20 percent of sterile injectable drug volumes from 503Bs.[3]

[1] Source: Jennifer Gudeman, Michael Jozwiakowski, John Chollet, and Michael Randell, "Potential Risks of Pharmacy Compounding," Drugs in R&D, March 23, 2013

[2] Source: Walter F. Roche Jr., "Number deaths caused by the 2012 fungal meningitis outbreak underreported," Nashville Tennessean, December 31, 2018.

[3] Source: KPMG LLP health system interviews and analysis.

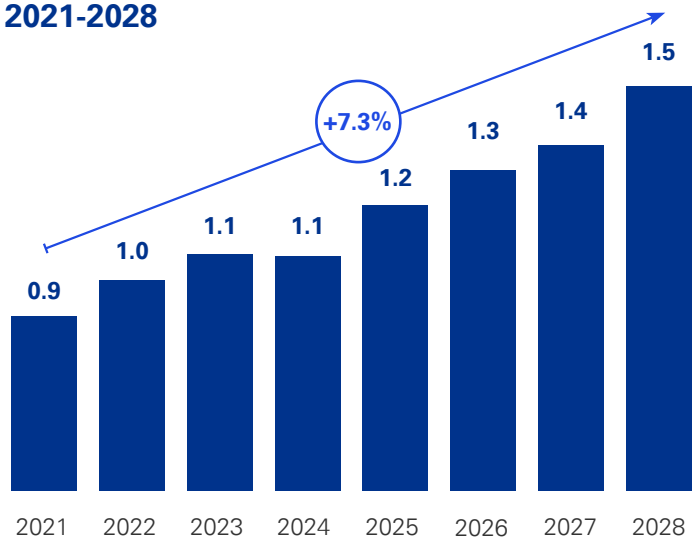
Exhibit 1. Specialty and sterile injectables markets are driving 503B growth in U.S. ($bn, gross sales), 2020-2025



Source: IQVIA

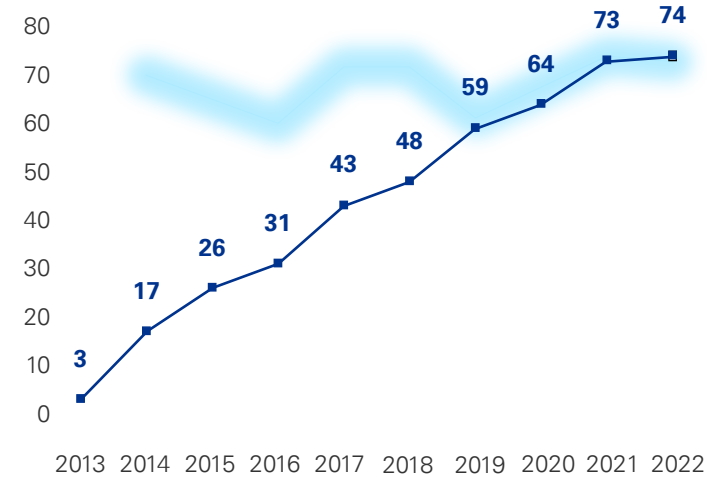
The U.S. 503B compounding pharmacies market, estimated at approximately $920 million in 2021, is expected to grow to approximately $1.5 billion by 2028, according to Coherent Market Insights,[4] a compound annual growth rate of 7.3 percent (Exhibit 2). In parallel, the number of registered 503B outsourcing facilities has remained relatively stable since 2014; however, FDA data signals a dynamic 503B landscape, with only 20 of the 71 entities registered in 2014 (3 first registered in 2013 plus 17 first registered in 2014) still registered in 2022.

Exhibit 2. 503B market in U.S. ($bn), 2021-2028



Source: Coherent Market Insights.

Exhibit 3. Number of 503B outsourcing facilities, 2013-2022



Source: KPMG interviews and analysis.

Source: FDA.

Private-equity (PE) firms and pharmaceutical manufacturers are showing increasing interest in the 503B market. In January 2022, Hikma became the first traditional pharmaceutical manufacturer to announce plans to expand into the 503B sector and build 503B capabilities nationwide. Its move followed the announcement in September 2021 by Premier, Inc. and 11 of its partner health systems to acquire a minority stake in Exela Pharma Sciences, a 503B. They join PE firms such as Bain Capital and Vistria Group that have made significant investments in 503Bs QuVa Pharma and SCA Pharma, respectively.

[4] Source: "U.S. 503B Compounding Pharmacies Market to Surpass US$1508.1Million by 2028; Owing to rise in geriatric population, Says Coherent Market Insights (CMI)," Coherent Market Insights, June 25, 2021.

The case for a greater 503B role for pharma

The challenges from the rise of 503Bs for traditional pharmaceutical manufacturers are twofold. First, 503Bs are driving erosion in manufacturers' hospital-channel revenues. Second, pharmaceutical manufacturers have limited visibility to what goes on in the 503B marketplace. Traditional industry sources (such as IQVIA, Evaluate, and others) have limited coverage of the 503B channel, making it difficult for manufacturers to estimate demand.

Still, we believe pharmaceutical manufacturers have clear advantages over existing 503Bs that can help defend against further share erosion and allow them to exploit key 503B market growth opportunities. Consider these factors working in manufacturers' favor:

01

Robust quality infrastructure

Pharmaceutical manufacturers have more robust quality management systems in place than 503Bs, with the capabilities to go beyond CGMP. This can enable manufacturers to take advantage of whitespace opportunities where hospitals' quality concerns may limit their 503B channel purchasing today.

02

Greater sourcing capabilities

Pharmaceutical manufacturers often procure (and sometimes manufacture) API volumes greater than those of 503Bs. This provides manufacturers with significant scale efficiencies beyond those of 503Bs. Pharmaceutical manufacturers can also utilize their broader supplier networks to better anticipate and navigate shortages and minimize disruptions.

03

Additional scale efficiencies

Beyond procurement efficiencies, pharmaceutical manufacturers can leverage greater enterprise scale efficiencies across areas such as technology, sales, and marketing to improve 503B cost profile.

Entry into 503B markets can yield additional benefits for pharmaceutical manufacturers, as follows:

01

Deeper channel relationships:

503B offerings can enable pharmaceutical manufacturers to strengthen hospital-customer relationships and expand direct supply agreements. Expanding these agreements can help strengthen pharmaceutical manufacturers' channel power and negotiating leverage with value-chain intermediaries, including but not limited to wholesalers and hospital group purchasing organizations.

02

Improved data:

Closer hospital relationships can also help pharmaceutical manufacturers better read hospital demand signals, including the clinical use of RTAs and other compounded medications. This improved data visibility can help pharmaceutical manufacturers mitigate risks of shortages and optimize portfolios to better meet hospital drug needs.

03

Portfolio efficiencies:

Compounding allows for dose form customization without the costs associated with approving and maintaining an FDA-approved stock keeping unit (SKU). Having 503B capabilities can help manufacturers manage SKU proliferation by supplementing market demand with compounding and leveraging improved hospital demand data to limit abbreviated new drug application filings to products with the greatest commercial viability. This has the potential to reduce portfolio complexity and yield significant associated operational cost savings.

Pharmaceutical manufacturers, however, will need to remain agile while identifying and implementing 503B-related strategies. An effective response would include:

503B market impact assessment:

Assess the anticipated impact of 503B markets on pharmaceutical manufacturers' existing portfolio and pipeline. Leverage deep knowledge and experience in the 503B compounding pharmacy space to identify portfolio risks and understand synergy opportunities. A good starting point would be to understand overlap between existing portfolio and pipeline products and the products currently produced by 503Bs (Exhibit 4).

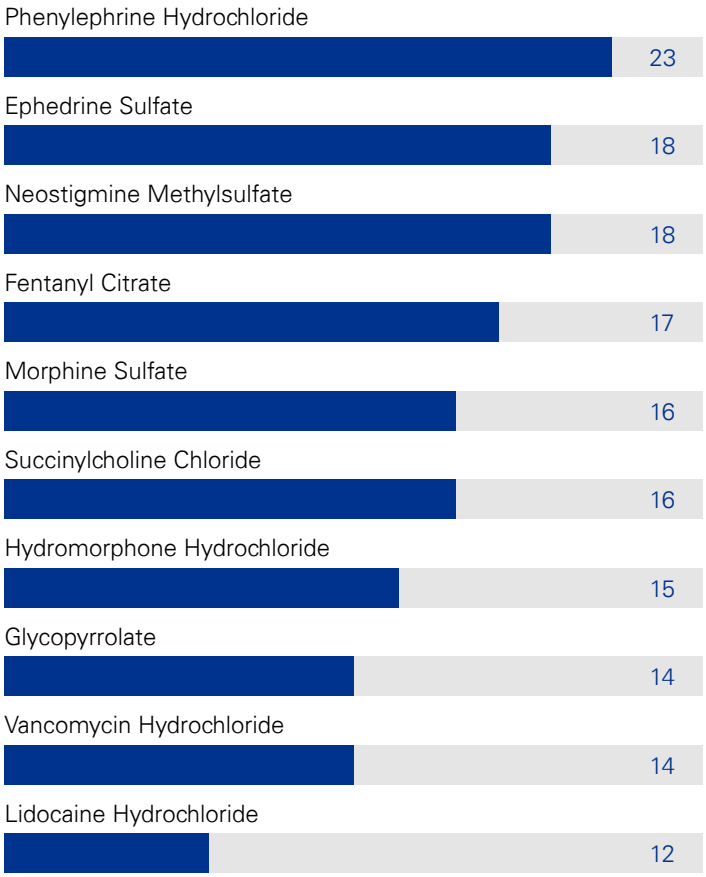
503B strategic options development:

Identify and define strategies to benefit from growth and defend share positions in 503B markets, accounting for the dynamic 503B regulatory environment. Strategies may include but are not limited to developing 503B capabilities organically or through mergers, acquisitions, and partnerships.

Execution of 503B strategy:

Leverage a full suite of strategic planning, transaction, and operational transformation services from external advisers for execution of the targeted 503B market strategies.

Exhibit 4. Top 10 APIs by the number of 503Bs commercializing products with the listed API[5]



Source: FDA

How KPMG can help

KPMG has significant 503B market and regulatory knowledge, and the experience, tools, and capabilities to help your organization optimize a strategic response to evolving 503B market conditions. More specifically, we can:

- Utilize leading proprietary and third-party data sources to underpin 503B market impact assessments.
- Tap our robust organization of professionals to gain primary research insight directly with leaders in compounding pharmacy markets.
- Bring to bear our capabilities as a global transaction advisory leader to gather market insights at deal speed.
- Leverage our global team of more than 4,000 dedicated life sciences strategy, regulatory, transaction, and implementation professionals for actionable insights anchored in extensive market knowledge and experience.

[5] Based on 47 unique 503B outsourcing facility entities.

Authors

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Rajesh is a principal in the KPMG Life Sciences Solution team and focuses on quality and regulatory services. He serves life sciences organizations in solving their most pressing quality, regulatory, and operational challenges across the entire value chain. For more than 25 years, Rajesh has led transformational engagements in support of regulatory, quality, supply chain, and manufacturing operations for leading pharmaceutical and medical device companies. He is passionate about evaluating and monitoring total cost of quality, quality metrics, and quality management maturity by leveraging emerging and disruptive technologies, such as predictive analytics, machine learning, cognitive, and context-aware computing, among others.

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This content outlines initial considerations meriting further consultation with life sciences organizations, healthcare organizations, clinicians, and legal advisors to explore feasibility and risks.

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