# Compounding is the latest darling of telehealth and Big Tech, but is Silicon Valley prepared for the regulation that comes with it?

### *Takeaways*

- The COVID-19 pandemic accelerated key trends in the compounding industry
- Telehealth platforms have rapidly spread into the compounding space
- Big Tech has entered the pharmacy space and shaken up the compounding industry
- New entrants must appreciate the unique regulatory landscape of the compounding space

Compounded medications and the pharmacies that prepare them have long been at the forefront of innovation and health care management. Over the last year, however, the COVID-19 pandemic has accelerated trends that have been gaining traction in the compounding industry for some time, namely, telehealth and the entry of Big Tech and big data.

The compounding industry has changed in two key ways, by: (1) complementing the customized and personal care offered via telehealth platforms and (2) adapting to the entry of large name-brand tech companies. These trends will undoubtedly continue into the next year and beyond.

However, many of these new entrants to the compounding industry may not appreciate the rules and regulations that apply to compounded medication. Compounded medication occupies a unique space in the human and animal health care market and in the drug supply chain by satisfying patient treatment needs when a commercially available drug is unavailable or inappropriate for treatment. That unique space, however, comes with unique regulatory requirements.

Compounding pharmacies must comply with multiple layers of regulations, including portions of the federal Food, Drug & Cosmetic Act (FDCA), state statutes and regulations governing the practice of pharmacy, controlled substance regulations, and compounding standards developed by organizations like the U.S. Pharmacopeia (USP). Regulation is even more nuanced when it comes to compounding medication for animals. As new entrants try to make the most of rapidly changing technology and ever-evolving ways to deliver medical care to patients, it becomes increasingly important to stay apprised of state and federal regulations governing compounding.

## Telehealth expansion

Over the last several years, telehealth companies like Roman, Curology, Hims & Hers Health, and Dermacare, among many others, that offer prescription and over-the-counter medications typically through a subscription or membership program have rapidly expanded their presence in the compounding industry. Typically, these companies do so either by partnering with existing compounding pharmacies to prepare medications, or building their own in-house compounding pharmacies to meet patient need. This trend accelerated in 2020 as many telehealth companies capitalized on increased consumer demand during the COVID-19 pandemic not only for telehealth visits with medical professionals but also for tailored treatments comprising everything from skin creams, to erectile dysfunction treatments, acne medication, and hair loss treatments.

These tailored treatments are not possible without prescriptions for compounded medication from licensed medical professionals, and, as a result, telehealth companies have turned to the compounding industry to provide a conduit to meet patient need. However, even if these telehealth companies are not preparing the compounded medication themselves, they must be aware of the rules and regulations governing the practice of pharmacy and of compounding regulations. Failure to understand the industry could cause disruptions in service and scrutiny from regulators.

## Big Tech enters the pharmacy space

Several national and multinational e-commerce and technology businesses that had no prior involvement with human or animal health care have recently entered the pharmacy space with the goal of becoming big players in the industry. For example, a leading online pet store, Chewy, recently opened its own licensed compounding pharmacy. Likewise, Amazon recently launched its own digital pharmacy, Amazon Pharmacy, and Walmart has expanded its online pharmacy presence into specialty pharmacy services and pet health pharmacy services. It is likely only a matter of time before other e-commerce businesses enter the pharmacy and compounding spaces.

Many of these Big Tech entrants that operate on a national scale will need to ensure that they comply with federal law and state regulations governing the practice of pharmacy. They will need to navigate, among other things, online pharmacy laws, controlled substance regulations, and laws governing practitioner-patient relationships. Without a solid foundation in regulatory compliance, Big Tech will find itself at the mercy of state or federal regulators, which could result in significant damage to their pharmacy businesses.

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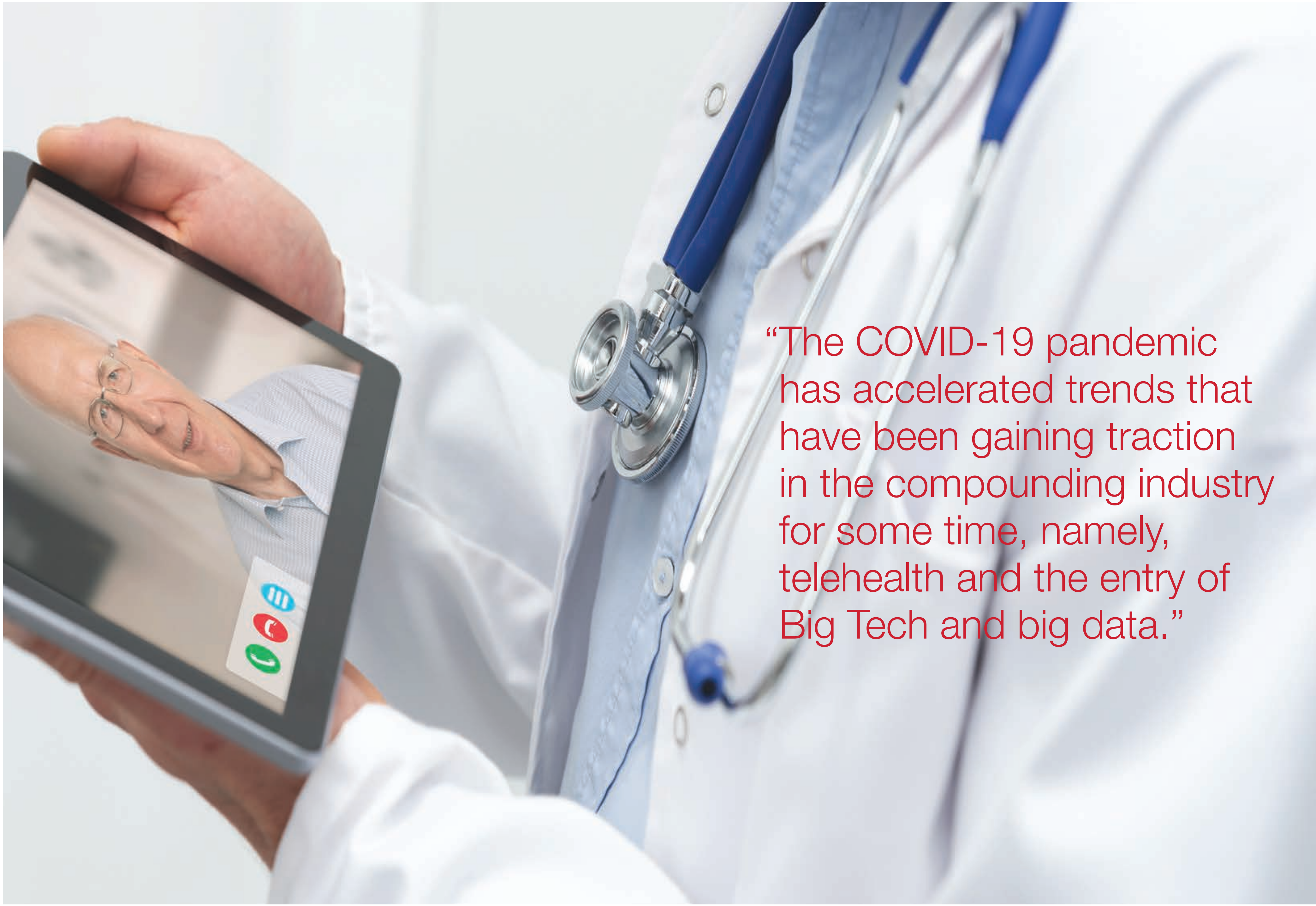

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## New entrants must understand the risks of wading into the compounding space

There are a lot of advantages to entering the compounding pharmacy space, including the ability to create customized medications without going through the U.S. Food and Drug Administration's (FDA's) costly new drug approval process and to avoid certain burdensome health care laws (as most compounding pharmacies do not accept or bill insurance). However, in 2012, New England Compounding Pharmacy was involved in a meningitis outbreak that was linked to 76 deaths. This incident made national headlines, and, since that time, compounding pharmacies across the country have faced increased federal and state regulatory scrutiny.

For example, in 2013, Congress amended the FDCA to recognize two types of compounding facilities: (1) traditional compounding pharmacies and (2) outsourcing facilities. Each type of facility has unique federal guidelines governing the circumstances and conditions under which it can compound medication. The FDA has published multiple guidance documents over the past several years reflecting its current thinking on compounded medications.

There are also 51 different sets of state regulations (including the District of Columbia) governing the practice of pharmacy and compounding. These state regulations are ever evolving and require constant tracking and review to ensure that compounders remain on top of changes. Certain states, like California and New Mexico, have even begun to impose their own compounding standards on compounded medication that are, in certain ways, more onerous than those recommended by the USP.

In addition, we are seeing state and federal regulators move to address the expansion of telehealth and online pharmacy practice into the compounding space. Over the past year alone, we have seen:

- Increased regulatory attention to compounders' responsibilities as it relates to telehealth and the need to ensure that appropriate patient–practitioner relationships exist, especially when those relationships may be established entirely by virtual means;
- Fewer geographic restrictions on where compounding pharmacies can dispense medications when the provider treated the patient via telehealth; and
- More state-specific and DEA-specific guidance, temporary waivers, and temporary rules setting out the regulators' current thinking on telehealth and compounding and providing insight into formal regulations yet to come.

Thus, whether a health care platform intends to partner with third-party compounding pharmacies or to bring compounding processes in-house, without a real appreciation for the regulatory space that compounding pharmacies occupy, these companies could find themselves on the wrong side of state and federal regulators.

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**Emily L. Hussey**
Counsel
Chicago

Emily L. Hussey is a counsel in the firm’s Life Sciences Health Industry Group. Her practice focuses on state and federal regulation of pharmaceutical products, animal drugs, medical devices and cosmetics with an emphasis on federal and state regulation of compounded human and animal drugs.

**Kelly J. Kearney**
Associate
Chicago

Kelly J. Kearney is an associate in the firm’s Life Sciences Health Industry Group. She focuses her practice on compounding pharmacy regulation and litigation where she provides strategic legal advice to businesses and individuals for compliance, transactional, and litigation matters.