

Healthcare Execs Face Federal Drug Charges in Landmark Telehealth Case

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In a first-of-its-kind prosecution, federal prosecutors have charged two healthcare executives with unlawfully distributing controlled substances, such as Adderall, through a telehealth website. These charges demonstrate the Department of Justice's intensified focus on enforcing federal controlled substances laws in the rapidly evolving digital health landscape.

The government bases the bulk of its controlled substances charges on two requirements of the Controlled Substance Act (CSA). First, that a controlled substance "must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." Second, the "corresponding responsibility" of a pharmacist not to knowingly fill an invalid prescription for controlled substances. The novelty of this case is that neither the doctors who issued the prescriptions nor the pharmacies that filled them have been charged. Instead, the defendants are charged with *causing* the doctors and pharmacists to violate the statute.

The defendants are Ruthia He, founder and CEO of Done Global Inc., and David Brody, clinical president of the closely related Done Health P.C. (collectively "Done").

The Alleged Scheme: How Done Did It

The indictment alleges that Done operated a subscription-based platform that provided easy access to ADHD medication in exchange for monthly fees. The alleged scheme took advantage of COVID-era waivers that allowed physicians to prescribe controlled substances without an in-person examination of the patient and in states in which they were not licensed to prescribe controlled substances. Done allegedly structured its platform intentionally to allow for quick and easy prescriptions and access to controlled medications.

The government alleges that defendants caused providers to write prescriptions that were not for a legitimate medical purpose in the usual course of the provider's professional practice by pressuring prescribers, limiting information made available to prescribers, mandating initial consultations to be less than 30 minutes long, and instituting a policy of no follow-up visits with an automatic refill program.

Defendants also allegedly spent tens of millions of dollars on deceptive social media advertisements targeting drug seekers. The operation continued even after learning of overdoses and deaths among Done subscribers.

Done's practices allegedly caused a tremendous amount of medically unnecessary, highly addictive controlled substances to be unlawfully distributed. The government alleges that since the start of the COVID-19 pandemic, Done made over \$100 million through its business model, which facilitated prescriptions of over 40 million pills of Adderall and other stimulants.

Not Done Yet: Novel Charges Could Set Precedent for Future Prosecutions

Two major post-pandemic Department of Justice priorities converge in this case: combatting telehealth fraud and stemming the tide of illegal distribution of prescription drugs by persons in the medical industry. Historically, unlawful prescription drug distribution has primarily focused on highly addictive opioids, while telehealth-related enforcement actions have focused on unlawful kickbacks and medical necessity issues related to fraudulent insurance claims. This unprecedented indictment brings these focal points together in a new way by charging telehealth executives with illegal distribution of prescription stimulants through telemedicine, potentially setting a precedent for future prosecutions.

The charges against He and Brody also highlight the growing scrutiny of online prescription services, particularly those dealing with controlled substances. As telehealth continues to expand, this case may serve as a warning to other digital health companies about the importance of regulatory compliance and ethical practices in prescribing medications online. Moreover, the government continues to scrutinize the business methods of COVID-era telehealth companies that utilized regulatory exemptions to provide services in ways that were previously prohibited.

This landmark indictment raises important questions about the balance between increasing access to mental health treatments and maintaining safeguards against prescription drug abuse. It also underscores the need for clear guidelines and oversight in the rapidly evolving telehealth industry.

As this case progresses, it will likely have far-reaching implications for the telehealth sector, potentially shaping future regulations and enforcement strategies. Healthcare executives, investors, and policymakers will be watching closely to understand how this case may impact the future of digital health services and online prescribing practices.

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