



February 6, 2023

Robert Califf
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Gary Gensler
Chair
Securities and Exchange Commission
100 F Street, NE
Washington, DC 20549

Lina Khan
Chair
Federal Trade Commission
600 Pennsylvania Avenue, NW
Washington, DC 20580

Xavier Becerra
Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Merrick Garland
Attorney General
Department of Justice
950 Pennsylvania Avenue, NW
Washington, DC 20530

Dear Commissioner Califf, Chair Khan, Attorney General Garland, Chair Gensler, and Secretary Becerra:

On behalf of the American Academy of Family Physicians (AAFP), representing 127,600 family physicians and medical students across the country, I write to express our concerns regarding recent trends in direct-to-consumer (DTC) pharmaceutical advertising that promotes telehealth-only platforms, as well as potentially inappropriate and harmful prescribing practices being carried out by these virtual platforms.

The AAFP [supports](#) expanded use of telehealth and telemedicine as an appropriate and efficient means to enhance patient-physician collaborations, increase access to care, improve health outcomes by enabling timely care interventions, and decrease costs. In particular, the Academy strongly supports expanding access to behavioral health services delivered via telehealth, which has been shown to be an important tool to provide more equitable access to services and to increase treatment initiation due to decreased stigma.^{i,ii} We have supported policies to permanently facilitate virtual prescribing of [buprenorphine](#) for opioid use disorder treatment and generally allow access to [controlled substances](#) by telemedicine.

However, recent reports have indicated that the Drug Enforcement Administration (DEA) is concerned that some telehealth providers have abused pandemic waivers by overprescribing drugs. The DEA is reportedly investigating two platforms, Cerebral and Done, for allegedly overprescribing controlled substances used to treat attention-deficit hyperactivity disorder (ADHD). These “on-demand” telehealth platforms have been promoted directly to consumers via advertising from pharmaceutical companies, which encourage them to use these services to “speak with a doctor now” to obtain a prescription. Some integrated companies both sell pharmaceuticals and prescribe via their own

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R. Shawn Martin
Leawood, KS

telehealth platforms.

Patients using these platforms may not have received a thorough examination with a provider who was able to consider their comprehensive medical history to properly diagnose and prescribe an appropriate treatment. Now, many of these patients are experiencing fragmented care as some pharmacies, such as CVS and Walmart, stop filling prescriptions from these companies. Patients are reporting difficulty transitioning their care and accessing appropriate in-person services.ⁱⁱⁱ

In light of these developments and growing concerns from our members, we would like to share the AAFP's position on these practices.

Current [AAFP policy](#) supports efforts by manufacturers of prescription pharmaceuticals, nonprescription medications, health care devices, and health-related products and services to provide general health information to the public. At the same time, the Academy urges that any direct-to-consumer advertising of prescription drugs by pharmaceutical companies be based on disease state only, without mention of a specific drug by name. The AAFP also believes that the following conditions must be met, in order for DTC advertising to be acceptable:

- Information should be accurate, balanced, objective, and complete, not false or misleading, and should not promote unhealthy or unsafe practices.
- Patients must be provided with clear and accurate cost information on products, including compounded medications.
- If specific properties or indications are mentioned, then negative or adverse reactions and effects should likewise be mentioned, in a manner that is equitable in respect to time, font size, speed of information, etc., to ensure information is accessible and understood by the consumer.
- Advertisements should not promote the use of products that have addictive or abuse potential.
- If advertisements direct the consumer to a physician, referral should be to the consumer's family or personal physician. The AAFP considers it inappropriate and unethical for an advertiser to act as a referring agent, due to the consumer's lack of awareness of any potential conflict of interest associated with such a referral.

Our concerns extend to the practice of pharmaceutical advertising in electronic health records (EHRs) and patient portals, as well. While most EHR systems do not allow advertising, a small share may maintain partnerships with pharmaceutical companies and generate revenue through physician-directed advertising. This may inappropriately influence a physician's prescribing decisions or potentially jeopardize the privacy of a patient's personal health data. **The AAFP believes that it is inappropriate for pharmaceutical advertising of any kind to occur in EHRs, patient portals, and other digital point-of-care environments.**

In the current digital landscape, a patient may face a barrage of pharmaceutical advertisements in any given place when accessing care virtually: when they log in for a telehealth visit, send a message to their provider, or check their medical records.

The recent trends in pharmaceutical advertising directing consumers to specific telehealth platforms and the business relationships between these companies fail to meet many of the above conditions outlined in the Academy's policy. In some instances, integrated telehealth platforms like Hims have explicitly advertised off-label uses for certain medications to patients.^{iv} While

doctors are able to use their medical training and best judgment to prescribe medications for off-label use, it is illegal for pharmaceutical companies to do so in their advertising.^v

These arrangements also go against the AAFP's stated [position](#) that it is improper for physicians to receive payment from an entity, including non-monetary items of value, to induce or reward the generation of business by that entity. These companies appear to be putting revenue before patient safety by promoting potentially unnecessary, inappropriate, and harmful prescriptions.

As noted in our [Joint Principles of Telehealth Policy](#), **the Academy strongly believes that the permanent expansion of telehealth services should be done in a way that advances care continuity and the patient-physician relationship.** As noted earlier, many patients who initiated treatment through one of these telehealth platforms failed to receive comprehensive evaluations that considered their complete medical history or appropriate follow-up care. We are concerned that these companies have failed to execute responsible care coordination, which is necessary to ensure patient safety and continuity of care for the immediate condition being treated, and it is necessary for effective longitudinal care. Expanding telehealth services in isolation without any regard for previous physician-patient relationship, medical history, or the eventual need for a follow-up hands-on physical examination can undermine the basic principles of the medical home, increase fragmentation of care, and lead to the patient receiving suboptimal care.

Furthermore, these relationships between pharmaceutical companies and telehealth platforms raise concerns about the potential risks they may pose to patient data privacy and confidentiality. The AAFP has long [supported](#) policies that guarantee the appropriate security of protected health information while working to improve patients' access to their data. The Academy's [policy](#) is strongly supportive of making data reliably interoperable while maintaining patient confidentiality and the fundamental right to privacy. A confidential relationship between physician and patient is essential for the free flow of information necessary for sound medical care, and confidentiality of patient health data should continue to be a priority outside of the physician-patient relationship.

The AAFP has supported federal legislation to protect against the unwarranted and unconsented sale and transfer of personal and health information that exists outside of HIPAA. For example, we have previously [endorsed](#) the Health and Location Data Protection Act (S. 4408), which prohibits data brokers from selling and transferring customers' health and location data and requires the Federal Trade Commission to promulgate rules to implement and enforce these protections.

We appreciate your attention to this concerning issue. The AAFP looks forward to working with each of your agencies to protect patients and ensure they are receiving high-quality care, both virtually and in-person. Should you have any questions, please contact Erica Cischke, Director of Legislative and Regulatory Affairs at ecischke@aafp.org.

Sincerely,

A handwritten signature in black ink that reads "Sterling N. Ransone, Jr. MD FFAFP". The signature is written in a cursive, flowing style.

Sterling N. Ransone, Jr., MD, FFAFP
Board Chair, American Academy of Family Physicians

ⁱ Lingley-Pottie P., McGrath P.J. Telehealth: a child and family-friendly approach to mental health-care reform. *Journal of Telemedicine and Telecare*. 2008;14(5):225-226. doi:10.1258/jtt.2008.008001

ⁱⁱ Peterson, A.L., Mintz, J., Moring, J.C. *et al.* In-office, in-home, and telehealth cognitive processing therapy for posttraumatic stress disorder in veterans: a randomized clinical trial. *BMC Psychiatry* **22**, 41 (2022). <https://doi.org/10.1186/s12888-022-03699-4>

ⁱⁱⁱ Palmer K. "Telehealth patients are scrambling for in-person care amid crackdown on online controlled substances," *STAT News*. January 17, 2023. Accessed online at: <https://www.statnews.com/2023/01/17/adhd-drug-telehealth-done-cerebral-prescription-access/>

^{iv} Brown K.V, De Vynck G. "Hims built a \$1.6 billion online empire by pushing prescriptions," *Bloomberg*. October 30, 2020. Accessed online at: <https://www.bloomberg.com/news/features/2020-10-30/how-hims-built-an-online-prescription-drug-empire-on-outdated-oversight?leadSource=uverify%20wall>

^v U.S. Centers for Medicare and Medicaid Services, "Off-Label Pharmaceutical Marketing: How to Recognize and Report It." October 2015. Accessed online at: <https://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/Medicaid-Integrity-Education/Downloads/off-label-marketing-factsheet.pdf>