

Congress of the United States

Washington, DC 20510

December 6, 2021

The Honorable Gene L. Dodaro
Comptroller General of the United States
U.S. Government Accountability Office
441 G Street, N.W.
Washington, D.C. 20548

Dear Comptroller General Dodaro:

We write to request that the Government Accountability Office (GAO) conduct a study of the federal regulation of Direct-To-Consumer (DTC) advertising practices for prescription medical products. Within the federal government, the Federal Trade Commission (FTC) is responsible for protecting consumers and competition and has, for example, issued a Contact Lens rule to lay out consumers' rights to shop around when buying contact lenses. The Food and Drug Administration (FDA) is responsible for the safety and efficacy of medical products and tracking adverse events related to medical products. Additionally, companies are required to submit promotional materials to the FDA for review once they are being used in the marketing of a drug and can take action if the agency finds that a drug advertisement or other promotion is false or misleading.¹

In recent years, there has been an increase in companies marketing prescription medical products directly to consumers via television, social media, and internet advertising. A previous survey of healthcare providers conducted by the FDA found DTC advertising presented both benefits and challenges to the doctor-patient relationship.² While products advertised directly to consumers have the potential to increase convenience and lower costs to consumers, concerns have also been raised about reports of poor quality or adverse events related to these products. Additionally, some DTC products allow consumers to bypass evaluation or supervision by a healthcare provider entirely, which may be appropriate for some products and not for others. Two instances that provide an example of recent issues within this industry, having aroused repeated complaints and calls for each company to be investigated by the Federal Trade Commission and Food & Drug Administration:

- A mail-order orthodontics company that does not require typical in-person orthodontic visits faces allegations that they violated prescription labeling requirements established under the Federal Food, Drug and Cosmetic Act (FFDCA) and endangered consumers by not taking sufficient diagnostic steps prior to selling their orthodontic aligners, which has the potential to lead to long-term dental damage.^{3 4}

¹ <https://www.fda.gov/drugs/special-features/manufacturers-mouth-your-ears-direct-consumer-advertising>

² *Id.*

³ Griffith, Erin, and Peter Eavis. "This Company Says It Will Fix Your Smile. It May Shush You If It Doesn't." *The New York Times*, January 21, 2020. <https://www.nytimes.com/2020/01/21/technology/smiledirectclub-smile-nda.html>.

- An online distributor of contact lenses is accused of using older materials and switching prescribed lenses for other brands, which doctors allege affect the safety of the lenses. Advocacy groups and other complaints further allege that the company skirts existing prescription verification requirements under the FTC's Contact Lens Rule.^{5 6}

The rise of internet marketing and the push toward a DTC model of healthcare delivery represents a major change within our healthcare system. We are concerned that with the rapid growth of DTC advertising, appropriate regulatory oversight may be falling behind.

A GAO study into the ongoing practices and current regulatory oversight by federal agencies of these activities would provide valuable insight to guide potential regulatory and legislative action, if needed, in the future.

For these reasons, we request that the GAO review the practice of DTC advertising of medical products to consumers. Specifically, we would like you to examine the following:

1. What are the known advantages and concerns of marketing medical products that require prescriptions or other provider evaluation, such as contact lenses, directly to consumers?
2. What actions are federal agencies, such as the FDA and the FTC, taking to address any identified concerns?
3. Are there limitations to FDA or FTC's ability to enforce existing laws and regulations governing DTC advertising of prescription medical products and, if so, what are those limitations?

A GAO review of these issues will be an important step toward protecting consumers and towards mitigating any potential medical or public health harms that may arise from these marketing practices.

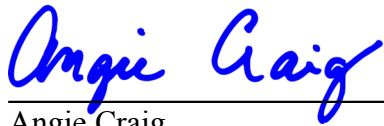
Thank you for considering this request.

Sincerely,

⁴ Appleby, Julie, and Victoria Knight. "In-Home Teeth Straightening Can Save Thousands. But Brace Yourself for the Risks." The LA Times, January 23, 2020. <https://www.latimes.com/business/story/2020-01-23/teeth-straightening-boom>.

⁵ Maheshwari, Sapna. "Contact Lens Start-Up, Big on Social Media, May Be Bad for Eyes, Doctors Say." The New York Times, July 21, 2019. <https://www.nytimes.com/2019/07/21/business/media/hubble-contact-lens.html>.

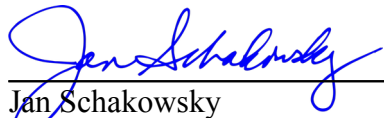
⁶ Griswold, Alison. "Contact Lens Startup Hubble Sold Lenses with a Fake Prescription from a Made-up Doctor." Quartz, December 14, 2017. Griffith, Erin, and Peter Eavis. "This Company Says It Will Fix Your Smile. It May Shush You If It Doesn't." The New York Times, January 21, 2020. <https://www.nytimes.com/2020/01/21/technology/smiledirectclub-smile-nda.html>.



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Member of Congress



Jan Schakowsky
Member of Congress



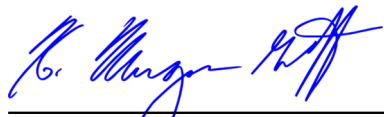
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Member of Congress



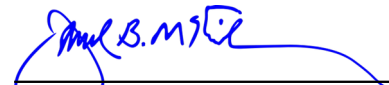
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