U.S. GOVERNMENT ACCOUNTABILITY OFFICE

441 G St. N.W.
Washington, DC 20548

September 8, 2023

Congressional Requesters

Medical Advertising: Federal Oversight of Devices

Advertising of medical devices reaches consumers directly through various media, including broadcast, print, the internet, and social media platforms. The Food and Drug Administration (FDA) within the Department of Health and Human Services (HHS) and the Federal Trade Commission (FTC) have shared responsibility overseeing direct-to-consumer advertising of medical devices in the United States.[1] Medical devices include a broad range of products such as any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, or software intended to be used in the diagnosis or treatment of disease.[2] There are millions of medical devices on the market that can be sold over-the-counter (e.g., blood pressure monitors and fertility tracking mobile applications), with a prescription (e.g., contact lenses and dental aligners), or in accordance with other regulatory restrictions (e.g., cardiac pacemakers). Since 2009, we have placed FDA's oversight of medical products, including medical devices, on GAO's high-risk list.[3]

You asked us to review federal oversight and the effects of direct-to-consumer advertising of medical devices. This report describes (1) FDA's and FTC's oversight responsibilities for direct-to-consumer advertising of medical devices and (2) identified effects of direct-to-consumer advertising of medical devices.

To describe how FDA and FTC oversee direct-to-consumer advertising of medical devices, we reviewed documentation and interviewed agency officials to understand the agencies' oversight processes and activities related to direct-to-consumer advertising of medical devices. This includes how they coordinate with each other, and how they communicate with consumers and businesses. We also explored FDA data on adverse events and FTC data on consumer complaints to determine if they can be used to provide context for potential advertising issues related to medical devices. The FDA database is designed as part of the agency's post market surveillance effort for identifying potential safety issues. The FTC database is designed to

[1]The Federal Food, Drug, and Cosmetic Act in 1938 gave FDA regulatory authority over medical devices. See Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 331-397). The Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539 (1976) gave FDA new authorities, including premarket review and authority to impose restrictions on the sale, distribution or use of devices. Among other authorities, FDA is responsible for ensuring that devices introduced into interstate commerce are not misbranded, including that their labeling is not false or misleading. See e.g., 21 U.S.C. §§ 331(a) and 352(a). The FTC regulates advertising pursuant to its general statutory authority to govern unfair or deceptive acts or practices under the Federal Trade Commission Act. Specifically, section 5 of the Federal Trade Commission Act prohibits unfair or deceptive acts or practices in or affecting commerce and section 12 prohibits the false advertisement of food, drugs, devices, services, or cosmetics. See 15 U.S.C. §§ 45, 52.

[2]See 21 U.S.C. §321(h)(1); 15 U.S.C. § 55(d).

[3]See GAO, *High-Risk Series: Efforts Made to Achieve Progress Need to Be Maintained and Expanded to Fully Address All Areas,* GAO-23-106203 (Washington, D.C.: Apr. 20, 2023).

identify potential deceptive or unfair practices that harm consumers. Therefore, these databases could not be used to generate counts of adverse events or consumer complaints related to direct-to-consumer advertising of medical devices.

To describe the identified effects of direct-to-consumer advertising of medical devices, we reviewed documentation from FDA and FTC regarding the effects of direct-to-consumer advertising and conducted a literature search for studies that analyzed the effects of direct-to-consumer advertising of medical devices. To identify relevant studies, we searched various databases, such as EBSCO platform, JAMA Network, ProQuest platform, PubMed, and SCOPUS. We performed these searches to identify articles published from January 1997 to November 2022. In addition, we interviewed FDA and FTC officials and a selection of 11 external stakeholder groups representing consumers (three groups), patients (three groups), providers (three groups), and manufacturers (two groups) regarding the effects of direct-to-consumer advertising of medical devices, including any emerging issues on this topic and the agencies' planned actions for addressing them.[4] We selected 11 stakeholder groups by identifying groups that have focused on issues related to direct-to-consumer advertising, medical devices, and consumer protection. We determined that these groups have focused on issues related to direct-to-consumer advertising of medical devices by reviewing publicly available materials about these groups.

We conducted this performance audit from August 2022 to September 2023 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

FDA and FTC Oversight of Direct-to-Consumer Advertising of Medical Devices

FDA and FTC share roles and responsibilities for overseeing direct-to-consumer advertising of medical devices. Both agencies can take action against false or misleading advertising of medical devices in accordance with the agencies' respective statutory authorities. FDA and FTC also conduct outreach to businesses and consumers on the laws and regulations governing direct-to-consumer advertising of medical devices.

Agencies' Roles and Responsibilities for the Oversight of Direct-to-Consumer Advertising of Medical Devices

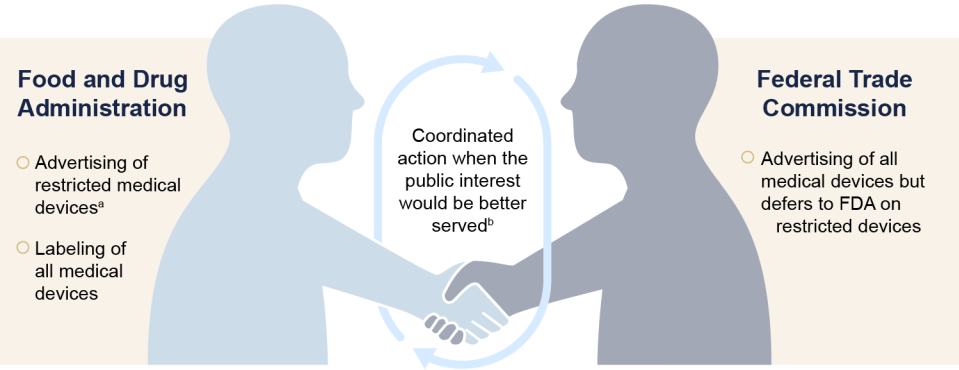
FDA and FTC follow the roles and responsibilities laid out in their 1971 memorandum of understanding for their respective oversight of direct-to-consumer advertising of medical devices and other regulated products, including foods, drugs, and cosmetics (see fig. 1).[5] The memorandum of understanding provides that FTC has primary responsibility regarding the truth or falsity of direct-to-consumer advertising, except to the extent the advertising involves prescription drugs. While the memorandum does not distinguish between different types of

[4]These stakeholder groups were: Advanced Medical Technology Association, American Association of Orthodontists, American Medical Association, American Optometric Association, Better Business Bureau, Medical Device Manufacturers Association, National Alliance for Hispanic Health, National Health Council, National Medical Association, Public Citizen, and Truth in Advertising. Concerns such as compliance with relevant laws and regulations other than those governing direct-to-consumer advertising and issues related to standard of care are outside the scope of this report.

[5]See Federal Trade Commission, *Memorandum of Understanding between the Federal Trade Commission and the Food and Drug Administration,* 36 Fed. Reg. 18,539 (May 1971).

medical devices, officials from both agencies stated that they consider restricted medical devices in the same way they consider prescription drugs with respect to regulating advertising. Restricted medical devices are devices designated by the Secretary of HHS as those that can only be sold (1) on oral or written authorization by a licensed practitioner or (2) under conditions specified by regulation in order to assure its safety and effectiveness.[6] The agencies have no other agreements in place related to roles and responsibilities for overseeing direct-to-consumer advertising of medical devices, according to agency officials.

Figure 1: Food and Drug Administration (FDA) and Federal Trade Commission (FTC) Oversight Responsibilities for Direct-to-Consumer Advertising of Medical Devices



Source: GAO analysis of FDA and FTC documentation and interviews with agency officials; GAO (illustrations). | GAO-23-106197

[a]Restricted medical devices are devices designated by the Secretary of Health and Human Services as those that can only be sold (1) on oral or written authorization by a licensed practitioner or (2) under conditions specified by regulation in order to assure its safety and effectiveness. 21 U.S.C. § 360j(e).

[b]The agencies can coordinate on enforcement actions or pursue separate proceedings. Generally, in these circumstances, FDA and FTC officials stated that FDA would review the products for compliance with FDA's requirements and FTC would review the advertising for truth or falsity.

FDA. FDA has primary responsibility for overseeing the truth or falsity of advertising for restricted medical devices, such as cardiac pacemakers and heart valves.[7] In addition, FDA has oversight responsibility to ensure that, among other things, the information on all medical device labeling is not false or misleading.[8]

- ***Advertising.*** Advertising is defined broadly to include traditional print and broadcast advertisements, infomercials, internet marketing, social media, press releases, and other materials.[9]

- ***Labeling.*** Labeling is defined as all labels—i.e., displays of written, printed, or graphic matter upon the immediate container of any article—and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers or (2)

[6]A device can be designated as a restricted medical device as a condition of approval of a premarket approval application or through rulemaking. See 21 U.S.C. §§ 360j(e), 360e(d)(1)(B)(ii). Prescription devices must also be sold on oral or written authorization by a licensed practitioner, but different regulations may apply. According to agency officials, not all prescription medical devices are restricted medical devices.

[7]See 21 U.S.C. § 352(q)(r).

[8]21 U.S.C. §§ 352(a); 331(a).

[9]See, e.g., GAO, *Memory Supplements: Clarifying FDA and FTC Roles Could Strengthen Oversight and Enhance Consumer Awareness,* GAO-17-416 (Washington, DC: May 16, 2017).

accompanying such article.[10] The FDA has interpreted accompanying materials to include posters, tags, pamphlets, circulars, booklets, brochures, instruction books, direction sheets, fillers, etc.[11]

FTC. FTC has primary responsibility for the truth or falsity of advertising for all devices that are not restricted, including most over-the-counter medical devices such as denture cleansers and pregnancy tests, and some prescription devices such as contact lenses and dental aligners. FTC officials stated that the agency also has responsibility for overseeing the truth or falsity of advertising for devices that are marketed without having completed FDA's pre-market regulatory process (also known as illegal devices). FTC officials stated that, while FTC is focused on the advertising of illegal medical devices, the agency has the authority to regulate the advertising of all medical devices.[12]

Examples of Enforcement Actions to Address Violations

In accordance with agency and regulatory policy, the Food and Drug Administration (FDA) and the Federal Trade Commission (FTC) have a number of enforcement actions that they may pursue in response to false or misleading advertising of medical devices. For example:

- **Warning letters.** The agencies may issue warning letters to notify businesses of violations and provide them an opportunity to take voluntary and prompt corrective action.
- **Civil monetary penalties.** In certain cases, the agencies may pursue civil monetary penalties, or fines, to businesses in violation of FDA and FTC laws and regulations.
- **Prosecution.** The agencies may conduct investigations of illegal activities involving medical devices and may pursue prosecution.

Source: GAO review of FDA and FTC documentation and interviews with agency officials. | GAO-23-106197

Joint. FDA and FTC officials stated that the agencies will coordinate on an as-needed basis to share direct-to-consumer advertising concerns and consumer complaints.

FDA and FTC Actions for Addressing Potential Violations with Direct-to-Consumer Advertising of Medical Devices

FDA and FTC have several tools and actions available to identify and address violations related to direct-to-consumer advertising of medical devices.

FDA. FDA's Regulatory Procedures Manual and internal process documents establish the agency's procedures to address regulatory and enforcement matters, including potential violations related to direct-to consumer advertising.[13] When confronted with a direct-to-consumer advertising issue, FDA officials stated that the agency generally looks for potential violations in the advertisement that fall under the agency's primary areas of authority (e.g., promoting an unapproved use of a medical device) and generally does not solely base an enforcement action on whether an advertisement was false or misleading.

FDA officials stated the agency may become aware of potential violations relating to direct-to-consumer advertising of medical devices while preparing for, or conducting, inspections for those devices already on the market by checking on a company's distribution or website, or through complaints submitted directly to FDA by individuals or competitors. If the potential violation involves a medical device other than a restricted device, such as an over-the-counter

[10]21 U.S.C. § 321(k)(m).

[11]See U.S. Department of Health and Human Services, Food and Drug Administration, *Labeling – Regulatory Requirements for Medical Devices,* FDA 89-4203 (Rockville, MD: Aug. 1989). See also 21 U.S.C. § 321(k) (definition of label); 21 U.S.C. § 321(m) (definition of labeling).

Both FDA and FTC can take actions in response to false or misleading labeling that are consistent with their respective statutory authorities. See 21 U.S.C. § 352; 15 U.S.C. § 45.

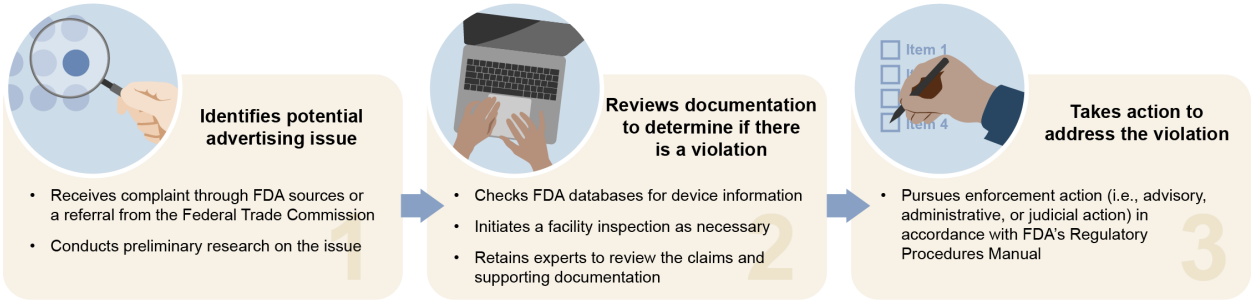
[12]See 15 U.S.C. §§ 45(a), 55(a).

[13]See Food and Drug Administration, *Regulatory Procedures Manual* (Feb. 2022).

medical device, FDA officials stated that staff may refer the issue to FTC and consult as needed on the matter.

- **Oversight process.** Once FDA becomes aware of potential violations relating to direct-to-consumer advertising of restricted devices, agency staff are responsible for investigating the concerns and taking appropriate action. FDA officials stated that the agency will often communicate directly with companies in an effort to achieve voluntary compliance. As appropriate, FDA staff may take enforcement actions in accordance with the processes outlined in the agency's Regulatory Procedures Manual (see fig. 2).[14]

Figure 2: Typical Steps Taken by the Food and Drug Administration (FDA) to Oversee False or Misleading Advertising Claims of Medical Devices



Source: GAO review of FDA documentation and interviews with agency officials; GAO (illustrations). | GAO-23-106197

- **Oversight actions.** According to agency officials, FDA initiates enforcement actions on a case-by-case basis and after weighing the agency's benefit and risk factors, including the likelihood and extent of harm to the public, the egregiousness of the conduct, and any special populations that are particularly affected by the practice.[15] FDA's Regulatory Procedures Manual outlines a number of enforcement actions that FDA may pursue. According to FDA officials, FDA took 255 enforcement actions between 2018 and 2022 related to medical device advertising issues.

- **Oversight challenges.** FDA officials stated that the agency has limited resources to actively monitor the volume of direct-to-consumer advertising. As a result, the agency considers the type and magnitude of benefits along with the severity and likelihood of harm when making enforcement decisions. FDA officials also stated that the agency encourages patient advocacy groups to report device advertisement concerns to FDA, while the agency focuses its efforts on the underlying issue in false or misleading advertisement cases, such as a company advertising its device for a medical use that has not been approved by the FDA.

FTC. FTC regulations specify the procedures that the agency must follow when carrying out its oversight responsibilities.[16] FTC officials stated that they may become aware of issues with direct-to-consumer advertising of medical devices via the FDA, complaints submitted by

[14]We use the term "enforcement action" to include advisory actions, such as warning letters, as well as administrative and judicial actions.

[15]See Food and Drug Administration, *Factors to Consider Regarding Benefit-Risk in Medical Device Product Availability, Compliance, and Enforcement Decisions,* FDA-2016-D-1495 (Rockville, MD: Dec. 2016).

[16]16 C.F.R. Parts 0 – 16.

consumers to the FTC's Consumer Sentinel Network, or from device manufacturers, who typically raise concerns about a competitor's activities.[17] FTC officials also stated that, on an ad hoc basis, the agency will conduct key word searches on social media platforms and search engines related to advertising trends that the agency is monitoring. FTC officials stated that complaints concerning medical devices within FDA's authority, such as those pertaining to the advertising of restricted devices, would be referred to the FDA.

- **Oversight process.** FTC staff are responsible for reviewing the medical device complaint and product claims to determine whether to open an investigation, according to FTC officials. This decision can depend on agency resources and priorities. If FTC investigates, and the device company is unable to provide scientific evidence in support of its advertising claims, FTC will typically attempt to negotiate a resolution with the company before bringing a case through an internal administrative process or through federal courts, officials told us (see fig. 3).[18]

Figure 3: Typical Steps Taken by the Federal Trade Commission (FTC) to Oversee False or Misleading Advertising Claims of Medical Devices

Source: GAO interviews with FTC officials; GAO (illustrations). | GAO-23-106197

- **Oversight actions.** These include investigation and litigation. FTC considers the potential for substantial injury to the public, including monetary injury and unwarranted health, safety, and privacy risks, when deciding whether to investigate and litigate potential advertising issues.[19] According to FTC officials, FTC took 67 public enforcement actions between 2018 and 2022 related to medical device advertising issues, including litigation, warning letters or cease and desist demands, and other investigations.

- **Oversight challenges.** FTC officials stated that the agency has limited resources and competing priorities for using them. As a result, the agency considers the extent of consumer injury, financial and physical, when determining how to allocate their resources. FTC officials also told us that the small size of many offending companies

[17]The Consumer Sentinel Network is FTC's online database of consumer reports about fraud, identity theft, and other consumer protection topics, including advertising complaints. FTC and its law enforcement partners can use information in the database to spot trends, identify questionable business practices and targets, and enforce the law.

[18]Before disseminating an advertisement, advertisers must have adequate substantiation for all objective product claims conveyed, expressly or by implications, to consumers acting reasonably. FTC guidance states that claims about the health benefits or safety of health-related products, including medical devices, require substantiation in the form of competent and reliable scientific evidence. Federal Trade Commission, *Health Products Compliance Guidance* (Dec. 2022).

[19]See Federal Trade Commission, *Strategic Plan for Fiscal Years 2022-2026* (Aug. 2022).

can make it difficult for FTC to track and locate a company to take appropriate action. For example, someone with a small amount of capital can start a business and set up a website to sell products online, and these companies can be located anywhere in the world.

Joint. In certain circumstances, the agencies will coordinate on enforcement actions, such as issuing joint warning letters. When the agencies initiate proceedings involving the same parties, FDA and FTC officials stated that FDA reviews the product to ensure it has undergone appropriate FDA regulatory processes and is otherwise in compliance with applicable FDA laws and regulations, and FTC reviews the advertising for truth or falsity. For example, during the COVID-19 pandemic, FDA and FTC worked together to send a joint warning letter to a company selling ceramic-grade magnets intended for use in the mitigation, prevention, treatment, diagnosis, or cure of COVID-19. They advised the company that the medical device was offered for sale and distribution in the U.S. without marketing approval, clearance, or authorization from FDA; and that the advertised treatment claims were not supported by competent and reliable scientific evidence.[20]

FDA and FTC Outreach to Businesses and Consumers on Direct-to-Consumer Advertising Rules

Both FDA and FTC conduct outreach to businesses and consumers to educate them on the rules governing direct-to-consumer advertising.

FDA. FDA has issued several draft guidance documents for businesses on its website, such as guidance on presenting risks associated with prescription drugs and medical devices in advertisements. For example, a June 2014 document described, among other things, how businesses should present medical device benefit and risk information within advertisements on social media platforms.[21] Once a year, FDA also convenes its Patient Engagement Advisory Committee to discuss patient-related issues, hear comments from members of the public, and advise FDA on topics such as agency guidance and policies and communication of device benefits and risks. For example, in October 2021, this committee met to discuss patient-focused communications during medical device recalls.

FTC. FTC has issued several guidance documents for businesses on its website, such as guidance on the advertising and promotion of health-related products, including medical devices. For example, a December 2022 document provides guidance from FTC staff on how to ensure that claims about the benefits and safety of health-related products are truthful, not misleading, and supported by science.[22] FTC also hosts events and issues blog posts, press releases, reports, and other content relating to health claims and advertising practices, which are posted on the agency's public website.[23] For example, along with the issuance of the

[20]See Food and Drug Administration and Federal Trade Commission, *Warning Letter–Durazo Medical Biomangetism and Neuro-Alignment, RE: Adulterated and Misbranded Products Related to Coronavirus 2019* (Aug. 19, 2020).

[21]Food and Drug Administration, *Guidance for Industry: Internet/Social Media Platforms with Character Space Limitations—Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices (draft)* (Rockville, MD: June 2014).

[22]Federal Trade Commission, *Health Products Compliance Guidance* (Dec. 2022).

[23]Federal Trade Commission, "Health Claims," *Federal Trade Commission website*, accessed Apr. 11, 2023, https://www.ftc.gov/news-events/topics/truth-advertising/health-claims.

December 2022 guidance, FTC also published a blog post on what is new and what is not in the updated guidance.

Joint. FDA and FTC have collaborated on several public education resources. For example, the agencies, in conjunction with the HHS Office of the National Coordinator for Health Information Technology and Office of Civil Rights, collaborated on an interactive, web-based tool to help the public navigate the laws and regulations related to mobile health applications, some of which are considered to be medical devices.[24] Examples of mobile health applications include apps that help consumers track fitness, diet, mood, sleep, and menstruation, among other things, and apps that contain consumer medical records or health insurance claims.

Selected Stakeholder Views of the Effects of Direct-to-Consumer Advertising of Medical Devices

Our literature search identified no studies that analyzed the effects of direct-to-consumer advertising of medical devices. However, 11 stakeholder groups we interviewed that represented consumers (three groups), patients (three groups), providers (three groups), and manufacturers (two groups) did identify varied effects of as well as concerns with direct-to-consumer advertising of medical devices (see text box). For example, five out of 11 stakeholder groups we interviewed stated that an advantage of direct-to-consumer advertising of medical devices is that it can provide additional information to consumers, and three groups stated that it can educate the consumer. Two groups told us that there are no advantages to this type of advertising.

In addition, seven of the 11 stakeholder groups we interviewed expressed general concerns associated with direct-to-consumer advertising of medical devices, as follows.

- Information in the advertisements may not be truthful (two groups).
- Advertisements do not contain adequate risk information (one group).
- Advertising can negatively affect the patient-physician relationship by interfering with the ability to arrive at the best treatment option (two groups).
- Advertisements can increase demand for the products, which can increase costs to the patient and the health care system or lead to uses that are not warranted (two groups).
- Target audience of some direct-to-consumer advertisements may be vulnerable, including those with medical conditions (two groups).
- Consumers can be harmed by the advertised devices (two groups).

[24]Federal Trade Commission, *Mobile Health App Interactive Tool* (Dec. 2022).

Selected Quotes from Stakeholder Interviews on the Effects of and Concerns with Direct-to-Consumer Advertising of Medical Devices

"Direct-to-consumer advertising is an important tool for educating and encouraging patients to speak with their physicians about products and treatments available to them, including a full discussion about risks and benefits." –Device Manufacturer Group

"Many of those in the targeted population may have complicated medical conditions…These consumers are particularly susceptible to direct-to-consumer ads using tricky, complicated language to claim that the product in question can treat or cure their particular condition." –Consumer Advocacy Group

Source: GAO interviews with stakeholder groups. | GAO-23-106197

Two of the 11 stakeholder groups we interviewed also expressed some concerns related to specific medical devices: contact lenses and dental aligners. While their concerns were not directly related to advertising, these two groups noted that some retailers of these devices may be distributing them without complying with relevant laws and regulations or adhering to a certain standard of care, among other concerns.

Three of the 11 stakeholder groups stated their organizations are more focused on direct-to-consumer advertising of prescription drugs than medical devices. Two stakeholder groups also noted possible future areas of concern when it comes to advertising of medical devices and prescription drugs, including the ease with which consumers can purchase medical products directly from an online advertisement. When we asked the agencies about this concern, FDA officials stated that drugs and devices have different regulatory frameworks with regard to advertising and, specifically with regard to devices, the agency would follow its procedures for addressing potential violations, including to the extent that this concern also involves false or misleading labeling or advertising. FTC officials noted that FTC may investigate such practices if the concerns regard the false or misleading advertising of medical devices, and will coordinate with FDA to investigate cases involving health claims.

Agency Comments

We provided a draft of this report to the Department of Health and Human Services' Food and Drug Administration and the Federal Trade Commission for review and comment. Both agencies provided technical comments, which we incorporated as appropriate.

We are sending copies of this report to the appropriate congressional committees, the Secretary of Health and Human Services, and the Chair of Federal Trade Commission. In addition, the report is available at no charge on the GAO website at http://www.gao.gov.

If you or your staff members have any questions about this report, please contact me at (202) 512-7114 or DeniganMacauleyM@gao.gov. Contact points for our offices of Congressional Relations and Public Affairs may be found on the last page of this report. Other key contributors to this report included Tom Conahan (Assistant Director), Xiaoyi Huang (Analyst-in-Charge), Emily Bippus, and Christina Liu Puentes. Additional assistance was provided by Sonia Chakrabarty, Laurie Pachter, Ethiene Salgado-Rodriguez, Jeffrey Tamburello, and Nicole Willis.

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