

GAO

Testimony

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PRESCRIPTION DRUGS

Trends in FDA's Oversight of Direct-to-Consumer Advertising

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Highlights

Highlights of [GAO-08-758T](#), a testimony before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, House of Representatives

Why GAO Did This Study

The Food and Drug Administration (FDA) is responsible for overseeing direct-to-consumer (DTC) advertising of prescription drugs, which includes a range of media, such as television, magazines, and the Internet. If FDA identifies a violation of laws or regulations in a DTC advertising material, the agency may issue a regulatory letter asking the drug company to take specific actions. In 2002, GAO reported on delays in FDA's issuance of regulatory letters.

GAO was asked to discuss trends in FDA's oversight of DTC advertising and the actions FDA has taken when it identifies violations. This statement is based on GAO's 2006 report, *Prescription Drugs: Improvements Needed in FDA's Oversight of Direct-to-Consumer Advertising*, [GAO-07-54](#) (November 16, 2006). In this statement, GAO discusses the (1) DTC advertising materials FDA reviews, (2) FDA's process for issuing regulatory letters citing DTC advertising materials and the number of letters issued, and (3) the effectiveness of FDA's regulatory letters at limiting the dissemination of false or misleading DTC advertising.

For its 2006 report, GAO examined FDA data on the advertising materials the agency received and reviewed the regulatory letters it issued citing prescription drug promotion from 1997 through 2005. For this statement, GAO also reviewed data from FDA to update selected information from the 2006 report.

To view the full product, including the scope and methodology, click on [GAO-08-758T](#). For more information, contact Marcia Crosse, (202) 512-7114, crosse@gao.gov.

PRESCRIPTION DRUGS

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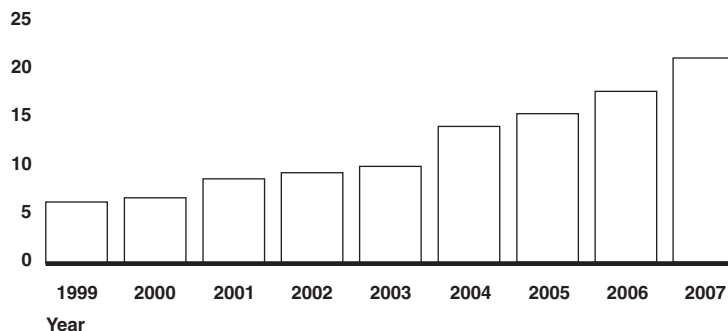
What GAO Found

Since 1999, FDA has received a steadily increasing number of advertising materials directed to consumers. In 2006, GAO found that FDA reviewed a small portion of the DTC materials it received, and the agency could not ensure that it was identifying for review the materials it considered to be highest priority. While FDA officials told GAO that the agency prioritized the review of materials that had the greatest potential to negatively affect public health, the agency had not documented criteria to make this prioritization. GAO recommended that FDA document and systematically apply criteria for prioritizing its reviews of DTC advertising materials. In May 2008, FDA indicated that it had documented criteria to prioritize reviews. However, FDA still does not systematically apply its criteria to all of the DTC materials it receives. Furthermore, GAO noted in its 2006 report that FDA could not determine whether a particular material had been reviewed. GAO recommended in that report that the agency track which DTC materials had been reviewed. FDA officials indicated to GAO in May 2008 that the agency still did not track this information. As a result, the agency cannot ensure that it is identifying and reviewing the highest-priority materials.

GAO found in 2006 that, since a 2002 policy change requiring legal review of all draft regulatory letters, FDA's process for drafting and issuing letters was taking longer and the agency was issuing fewer letters per year. FDA officials told GAO that the policy change contributed to the lengthened review.

In 2006, GAO found that the effectiveness of FDA's regulatory letters at halting the dissemination of violative DTC materials had been limited. By the time the agency issued regulatory letters, drug companies had already discontinued use of more than half of the violative advertising materials identified in each letter. In addition, FDA's issuance of regulatory letters had not always prevented drug companies from later disseminating similar violative materials for the same drugs.

Number of Materials Directed to Consumers Submitted to FDA, 1999 through 2007
Numbers in thousands



Source: GAO analysis of FDA data.

Note: Totals include final DTC materials, Internet materials—some of which may be directed to medical professionals—and materials designed to be given to consumers by medical professionals.

Mr. Chairman and Members of the Subcommittee:

I am pleased to be here today as you examine the practice of direct-to-consumer (DTC) advertising of prescription drugs, which includes a range of media, such as television, magazines, and the Internet. The Department of Health and Human Services' (HHS) Food and Drug Administration (FDA) regulates the promotion and advertising of prescription drugs, including DTC materials, to ensure they are not false or misleading and otherwise comply with applicable laws and regulations. This oversight function is carried out by FDA's Division of Drug Marketing, Advertising, and Communications (DDMAC). Recently, you have raised concerns regarding potentially misleading DTC advertising for several drugs.

FDA regulations require that drug companies submit final DTC advertising materials to FDA at the time they are first disseminated to the public.¹ In addition, although generally not required to do so, drug companies may voluntarily submit draft versions of DTC advertising materials to FDA for advisory comments.^{2,3} If FDA identifies a violation in a disseminated DTC advertisement, such as a false or misleading safety or effectiveness claim, the agency may issue a regulatory letter. In these letters, FDA asks drug companies to take specific actions, such as stopping the dissemination of the advertisement and, if FDA finds the violation to be particularly serious, running another advertisement to correct misleading impressions left by the violative advertisement. DDMAC drafts these regulatory letters, which are then reviewed and approved by the agency's Office of Chief Counsel (OCC). In October 2002, we reported on delays in FDA's issuance of these regulatory letters and recommended that the agency take action to reduce the amount of time for internal review of draft regulatory letters citing

¹21 C.F.R. § 314.81(b)(3)(i)(2007).

²21 C.F.R. § 202.1(j)(4)(2007). The FDA Amendments Act of 2007 provided FDA with new authorities related to the oversight of DTC advertising. The Act, among other things, authorizes FDA to require the submission of any draft television drug advertisement for review up to 45 days before it is scheduled to be disseminated. See Pub. L. No. 110-85, § 901(d)(2), 121 Stat. 823, 939 (2007), *codified* at 21 U.S.C. § 353b.

³The Pharmaceutical Research and Manufacturers of America (PhRMA) issued guidance effective January 2006 that states that “[drug] companies should submit all new DTC television drug advertisements to the FDA before releasing these advertisements for broadcast.” *PhRMA Guiding Principles: Direct to Consumer Advertisements about Prescription Medicines* (Washington, D.C.: PhRMA, November 2005), <http://www.phrma.org/files/DTCGuidingprinciples.pdf> (accessed Apr. 29, 2008).

violations in DTC materials.⁴ In response to our recommendation, FDA agreed to take steps to reduce the time to issue regulatory letters.

My remarks today are primarily based on our November 2006 report on trends in FDA's oversight of DTC advertising and the actions it took when it identified a violation in a disseminated DTC advertisement.⁵ Today, I will discuss (1) the DTC advertising materials FDA reviews, (2) FDA's process for issuing regulatory letters citing DTC advertising materials and the number of letters issued, and (3) the effectiveness of FDA's regulatory letters at limiting the dissemination of false or misleading DTC advertising.

For our November 2006 report, to examine the DTC advertising materials that FDA reviewed, we obtained data from FDA on the number and type of advertising materials that it received and reviewed from 1997 through 2005. To examine FDA's process for issuing regulatory letters that cited violative DTC advertising materials and the number of such letters that FDA issued, we reviewed all regulatory letters issued by FDA from 1997 through 2005. To examine the effectiveness of these regulatory letters, we reviewed their content to identify violations cited; we did not evaluate the appropriateness or legal sufficiency of these letters. In addition, we obtained information from FDA about the timeliness of the letters issued in 2004 and 2005 and drug companies' compliance with any corrective action requested by FDA. For this statement, we reviewed data from FDA to update selected information from our 2006 report. We shared the updated facts contained in this statement with FDA officials. They provided technical comments which we incorporated as appropriate. We conducted the work for our November report from January 2006 through November 2006 and for this statement from April 2008 through May 2008. We conducted all of our work 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.

⁴GAO, *Prescription Drugs: FDA Oversight of Direct-to-Consumer Advertising Has Limitations*, GAO-03-177 (Washington, D.C.: Oct. 28, 2002).

⁵GAO, *Prescription Drugs: Improvements Needed in FDA's Oversight of Direct-to-Consumer Advertising*, GAO-07-54 (Washington, D.C.: Nov. 16, 2006).

In summary, in our 2006 report we found that FDA reviewed a small portion of the DTC materials it received, and the agency could not ensure that it identified for review the materials it considered to be highest priority. We found that the number of final DTC materials FDA received each year had almost doubled from 2002 through 2005. Since 2006, the number of materials received by FDA has continued to increase. While FDA officials told us that the agency prioritized the review of materials that had the greatest potential to negatively affect public health, we found that the agency had not documented criteria to make this prioritization. Rather, FDA officials identified informal criteria that reviewers considered when identifying materials for review. We recommended that FDA document and systematically apply criteria for prioritizing its reviews of DTC advertising materials. We also noted in our 2006 report that FDA could not determine whether a particular material had been reviewed. Therefore, we recommended in our 2006 report that the agency track which DTC materials have been reviewed. In May 2008, FDA informed us that it now had documented criteria to prioritize reviews. However, FDA still does not systematically apply its criteria to all of the DTC materials it receives to determine which are highest priority for review. FDA officials also indicated to us in May 2008 that the agency still does not track whether a particular material has been reviewed. As a result, the agency cannot ensure that it is identifying and reviewing the highest-priority materials.

Since a 2002 policy change requiring internal legal review of all draft regulatory letters, FDA's process for drafting and issuing letters has taken longer and the agency issued fewer letters per year. Prior to this policy change, from 1997 through 2001, it took FDA an average of 2 weeks to issue a letter. After the change, from 2002 through 2005, once the agency began drafting a regulatory letter for violative DTC materials, it took an average of 4 months to issue the letter. In 2006 and 2007, the time increased to an average of over 5 months. FDA officials told us that the policy change contributed to the lengthened review by creating additional levels of review and making it necessary for the DDMAC reviewers who draft the regulatory letters to do substantially more work to prepare for and respond to comments from OCC. After the policy change, FDA issued about half as many regulatory letters that cited violative DTC advertisements per year—between 8 and 11 letters annually from 2002 through 2005, compared with 15 to 25 letters annually from 1997 through 2001. FDA issued 4 such letters in 2006 and 2 in 2007. FDA officials told us that the agency issued letters only for the violative DTC materials that it considered the most serious and most likely to negatively affect consumers' health.

At the time of our 2006 report, we found that the effectiveness of FDA's regulatory letters at halting the dissemination of violative DTC materials had been limited. FDA issued 19 such regulatory letters from 2004 through 2005. On average, it issued these letters 8 months after the violative materials were first disseminated. By the time these regulatory letters were issued, drug companies had already discontinued more than half of the violative advertisements. Generally, companies complied with FDA requests to remove cited materials that were still being disseminated, and those companies requested to issue corrective materials did so, but not until 5 months or more after the regulatory letter was issued. FDA's issuance of regulatory letters did not always prevent drug companies from later disseminating similar violative materials for the same drugs. We found that of the 89 drugs for which FDA cited violative DTC materials from 1997 through 2005, 25 drugs had DTC materials cited in more than one regulatory letter, sometimes for similar types of violations. Delays in issuing regulatory letters limit FDA's effectiveness in overseeing DTC advertising and in reducing consumers' exposure to false and misleading advertising.

Background

FDA regulates the content of all prescription drug advertising, whether directed to consumers or medical professionals. Advertising that is targeted to consumers includes both DTC and "consumer-directed" materials. DTC advertising includes, for example, broadcast advertisements (such as those on television and radio), print advertisements (such as those in magazines and newspapers), and Internet advertisements (such as consumer advertising on drug companies' Web sites). In contrast, consumer-directed advertisements are designed to be given by medical professionals to consumers and include, for example, patient brochures provided in doctors' offices.

Advertising materials must contain a "true statement" of information including a brief summary of side effects, contraindications, and the effectiveness of the drug.⁶ To meet this requirement, advertising materials must not be false or misleading, must present a fair balance of the risks and benefits of the drug, and must present any facts that are material to the use of the drug or claims made in the advertising. With the exception

⁶21 C.F.R. § 202.1(e)(1),(2)(2007). Those advertising materials that call attention to the name of the drug but do not include indication or dosage recommendations for use of the drug are exempt from these brief summary requirements.

of broadcast advertisements, materials must present all of the risks described in the drug's approved labeling. Broadcast materials may present only the major side effects and contraindications, provided the materials make "adequate provision" to give consumers access to the information in the drug's approved or permitted package labeling.⁷

Within FDA, DDMAC is responsible for implementing the laws and regulations that apply to prescription drug advertising. In March 2002, DDMAC created a DTC Review Group, which is responsible for oversight of advertising materials that are directed to consumers. As of May 2008, the group had a total of two group leaders, seven reviewers, and two social scientists. This group's responsibilities include reviewing final DTC materials and reviewing and providing advisory comments on draft DTC materials. The group also monitors television, magazines, and consumer advertising on drug companies' Web sites to identify advertising materials that were not submitted to FDA at the time they were first disseminated and reviews advertising materials cited in complaints submitted by competitors, consumers, and others.

Once submitted to FDA, final and draft DTC advertising materials are distributed to a DTC reviewer. For final materials, if the reviewer identifies a concern, the agency determines whether it represents a violation and merits a regulatory letter. For draft materials submitted by drug companies, FDA may provide the drug company with advisory comments to consider before the materials are disseminated to consumers if, for example, the reviewers identify claims in materials that could violate applicable laws and regulations.

If FDA identifies violations in disseminated DTC materials, the agency may issue two types of regulatory letters—either a "warning letter" or an "untitled letter." Warning letters are typically issued for violations that may lead FDA to pursue additional enforcement actions if not corrected; untitled letters are issued for violations that do not meet this threshold. Both types of letters cite the type of violation identified in the company's

⁷FDA published draft guidance for DTC broadcast advertisements in 1997, and final guidance in 1999, that described an approach drug companies could use to meet the regulatory requirement for making adequate provision of key information. The outlined approach provides that drug companies disseminate complete information included in a drug's approved package labeling through alternative sources, such as a toll-free number and a drug company Web site. See FDA, *Guidance for Industry: Consumer-Directed Broadcast Advertisements* (Rockville, Md.: Aug. 1999).

advertising material, request that the company submit a written response to FDA within 14 days, and request that the company take specific actions. Untitled letters request that companies stop disseminating the cited advertising materials and other advertising materials with the same or similar claims. Warning letters further request that the company issue advertising materials to correct the misleading impressions left by the violative advertising materials.⁸ The draft regulatory letters are subsequently reviewed by officials in DDMAC, FDA's Office of Medical Policy (which oversees DDMAC), and OCC. FDA has stated that it instituted OCC review for the purpose of promoting voluntary compliance by ensuring that drug companies that receive a regulatory letter understand that the letter has undergone legal review and the agency is prepared to go to court if necessary.⁹

FDA Reviewed a Small Portion of DTC Materials and Could Not Ensure It Was Reviewing the Highest-Priority Materials

As of 2006, FDA reviewed a small portion of the increasingly large number of DTC materials it received. FDA attempted to target available resources by focusing its reviews on the DTC advertising materials that had the greatest potential to negatively affect public health, but the agency did not document criteria for prioritizing the materials it received for review. Agency reviewers considered several informal criteria when prioritizing the materials, but these were not systematically applied and the agency did not document if a particular DTC material was reviewed. As a result, the agency could not ensure that it was identifying or reviewing the materials that were the highest priority.

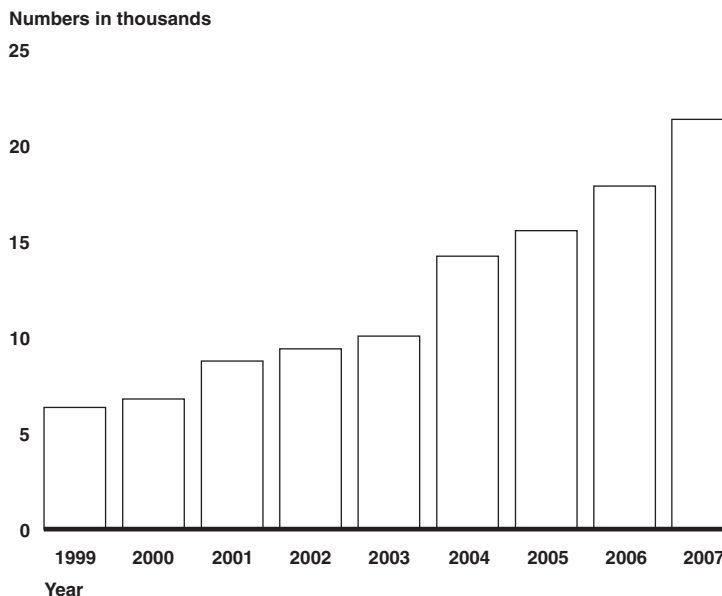
FDA officials told us at the time of our 2006 report that the agency received substantially more final and draft materials than the DTC Review Group could review. In 2005, FDA received 4,600 final DTC materials

⁸While FDA does not have explicit authority to require companies to act upon these letters, if the companies continue to violate applicable laws or regulations, the agency has other administrative and judicial enforcement avenues that could encourage compliance or result in the product being taken off the market. For example, FDA, through the Department of Justice, may seek additional remedies in the courts resulting in the seizure of drugs deemed to be misbranded because their advertising is false or misleading. With the enactment of the FDA Amendments Act of 2007, FDA was also authorized to assess civil monetary penalties. Pub. L. No. 110-85, § 901(d)(4), 121 Stat. 823, 940-942 (2007), *codified* at 21 U.S.C. § 333(g).

⁹See [GAO-03-177](#), 32.

(excluding Internet materials) and 6,168 final Internet materials.¹⁰ FDA also received 4,690 final consumer-directed materials—such as brochures given to consumers by medical professionals. FDA received a steadily increasing number of final materials from 1999 through 2005. We found that, in 2006 and 2007, the total number of final DTC, Internet, and consumer-directed materials FDA received continued to increase.¹¹ (See fig. 1.)

Figure 1: Number of Final DTC, Internet, and Consumer-Directed Materials Submitted to FDA, 1999 through 2007



Source: GAO analysis of FDA data.

¹⁰FDA's count of submitted materials did not distinguish between Internet materials targeted to consumers and those targeted to medical professionals. However, FDA officials told us that most Internet materials, such as drug companies' Web sites, include both a consumer and a professional component.

¹¹We could not determine whether there had been a similar increase in the number of draft DTC materials FDA received because the agency did not track this information.

FDA officials estimated that reviewers spent the majority of their time reviewing and commenting on draft materials. However, we were unable to determine the number of final or draft materials FDA reviewed, because FDA did not track this information. In the case of final and draft broadcast materials, FDA officials told us that the DTC group reviewed all of the materials it received; in 2005, it received 337 final and 146 draft broadcast materials. However, FDA did not document whether these or other materials it received had been reviewed. As a result, FDA could not determine how many materials it reviewed in a given year. We recommended in our 2006 report that the agency track which DTC materials had been reviewed. FDA officials indicated to us in May 2008 that the agency still did not track this information.

At the time of our 2006 report, FDA officials identified informal criteria that the agency used to prioritize its reviews. FDA officials told us that, to target available resources, the agency prioritized the review of the DTC advertising materials that had the greatest potential to negatively affect public health. We recommended that FDA document its criteria for prioritizing its reviews of DTC advertising materials. FDA informed us in May 2008 that it now has documented criteria to prioritize reviews. For example, its first priority is to review materials with “egregious” violations, such as those identified through complaints. In addition, FDA places a high priority on reviewing television advertising materials. FDA officials also told us that the agency places a high priority on reviewing draft materials because they provide the agency with an opportunity to identify problems and ask drug companies to correct them before the materials are disseminated to consumers.

We reported in 2006 that FDA did not systematically apply its criteria for prioritizing reviews to all of the materials that it received. Specifically, we found in 2006 that, at the time FDA received the materials, it recorded information about the drug being advertised and the type of material being submitted but did not screen the DTC materials to identify those that met its various informal criteria. FDA officials told us that the agency did identify all final and draft broadcast materials that it received, but it did not have a system for identifying any other high-priority materials. Absent such a system for all materials, FDA relied on each of the reviewers—in consultation with other DDMAC officials—to be aware of the materials that had been submitted and to accurately apply the criteria to determine the specific materials to review. This created the potential for reviewers to miss materials that the agency would consider to be a high priority for review. Furthermore, because FDA did not track information on its reviews, the agency could not determine whether a particular material had

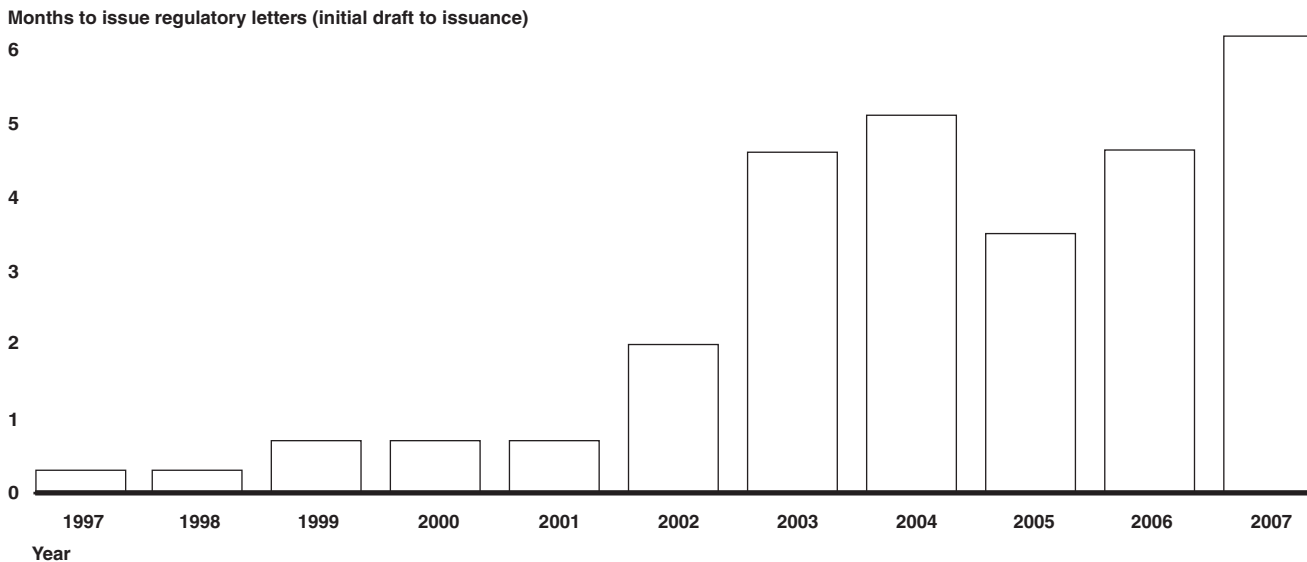
been reviewed. As a result, the agency could not ensure that it identified and reviewed the highest-priority materials. We recommended that the agency systematically screen the DTC materials it received against its criteria to identify those that are the highest priority for review. As of May 2008, FDA still did not have such a process.

After the 2002 Policy Change, FDA's Process for Issuing Regulatory Letters Took Longer and the Number of Letters Issued Declined

In 2006 we reported that, after the 2002 policy change requiring legal review by OCC of all draft regulatory letters, the agency's process for drafting and issuing letters citing violative DTC materials had stretched to several months and FDA had issued fewer regulatory letters per year. As a result of the policy change, draft regulatory letters received additional levels of review and the DTC reviewers who drafted the letters did substantially more work to prepare for and respond to comments resulting from review by OCC. FDA officials told us that the agency issued letters for only the violative DTC materials that it considered the most serious and most likely to negatively affect consumers' health.

Once FDA identified a violation in a DTC advertising material and determined that it merited a regulatory letter, FDA took several months to draft and issue a letter. For letters issued from 2002 through 2005, once DDMAC began drafting the letter for violative DTC materials it took an average of about 4 months to issue the letter. The length of this process varied substantially across these regulatory letters—one letter took around 3 weeks from drafting to issuance, while another took almost 19 months. In comparison, for regulatory letters issued from 1997 through 2001, it took an average of 2 weeks from drafting to issuance. We recommended in 2002 that the agency reduce the amount of time to draft and issue letters and the agency agreed. We found in 2006, however, that the review time had increased and we again urged the agency to issue the letters more quickly. In 2006 and 2007, it took an average of more than 5 months from drafting to issuance. One letter took less than 2 months to issue while another took about 11 months. (See fig. 2 for the average months from 1997 through 2007.)

Figure 2: Average Months to Issue Regulatory Letters Citing Violative DTC Materials, 1997 through 2007



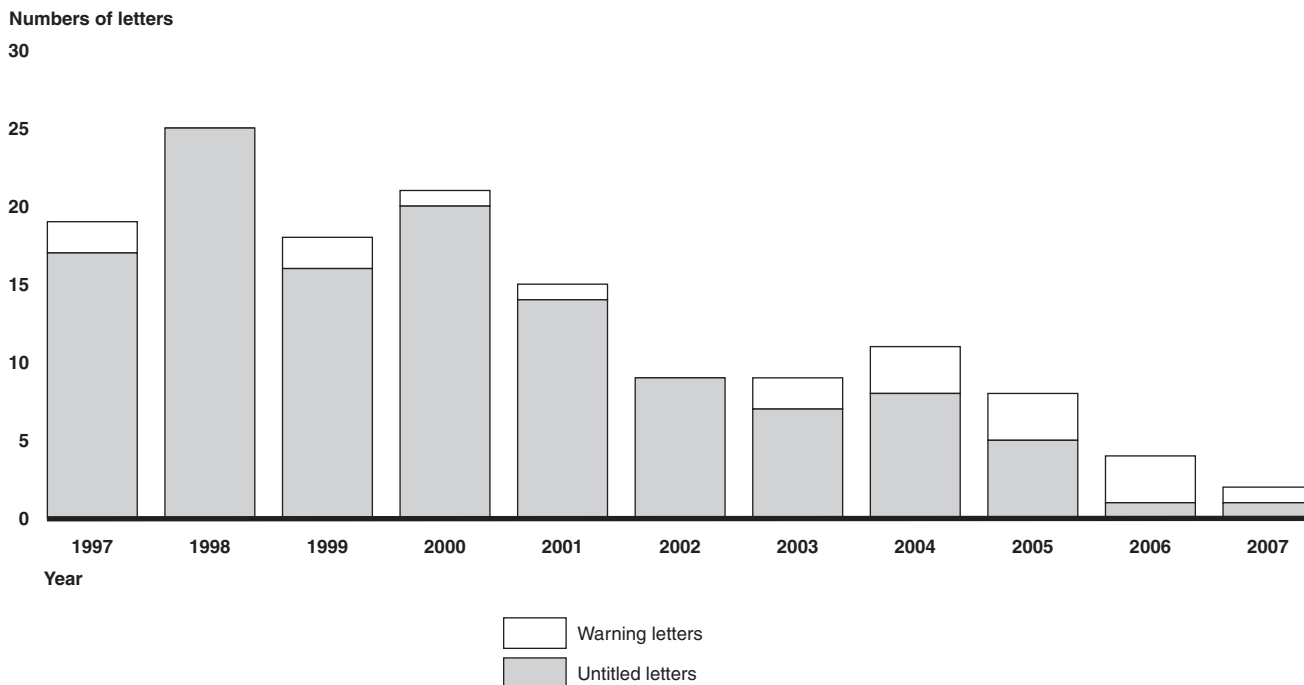
Source: GAO analysis of FDA documents.

Note: For each letter, we determined the number of months from the date on which a reviewer first began drafting a regulatory letter to the date the letter was issued. FDA does not track the date a violation was identified or the date it was determined that the violation merited a regulatory letter.

The primary factor that contributed to the increase in the length of FDA’s process for issuing regulatory letters was the additional work that resulted from the 2002 policy change. All DDMAC regulatory letters were reviewed by both OCC staff and OCC’s Chief Counsel. In addition to the time required of OCC, DDMAC officials told us that the policy change created the need for substantially more work on their part to prepare the necessary documentation for legal review. After meeting with OCC and revising the draft regulatory letter to reflect the comments from OCC, DDMAC would formally submit a draft letter to OCC for legal review and approval. OCC often required additional revisions before it would concur that a letter was legally supportable and could be issued. While OCC officials told us that the office had given regulatory letters that cited violative DTC materials higher priority than other types of regulatory letters, their review of DDMAC’s draft regulatory letters was a small portion of their other responsibilities and had to be balanced with other requests, such as the examination of legal issues surrounding the approval of a new drug. Recently, FDA informed us that it now allows some steps to be eliminated—if deemed unnecessary for a particular letter—in an attempt to make the legal review process more efficient.

The number of regulatory letters FDA issued per year for violative DTC materials decreased after the 2002 policy change lengthened the agency’s process for issuing letters. From 2002 to 2005, the agency issued between 8 and 11 regulatory letters per year that cited DTC materials. Prior to the policy change, from 1997 through 2001, FDA issued between 15 and 25 letters citing DTC materials per year. An FDA official told us that both the lengthened review time resulting from the 2002 policy change and staff turnover within the DTC Review Group contributed to the decline in the number of issued regulatory letters. More recently, we found that the number of letters issued that cite DTC materials has continued to decline—FDA issued 4 letters in 2006 and 2 letters in 2007. (See fig. 3 for the number of letters issued from 1997 through 2007.)

Figure 3: Number of Regulatory Letters FDA Issued That Cited DTC Advertising Materials, 1997 through 2007



Source: GAO analysis of FDA regulatory letters.

Although the total number of regulatory letters FDA issued for violative DTC materials has decreased, the agency has issued in recent years proportionately more warning letters—which cite violations FDA considers to be more serious. Historically, almost all of the regulatory letters that FDA issued for DTC materials were untitled letters for less serious violations. From 1997 through 2001, FDA issued 98 regulatory letters citing DTC advertising materials, 6 of which were warning letters. From 2002 through 2005, 8 of the 37 regulatory letters were warning letters. Of the 6 letters FDA issued for DTC materials in 2006 and 2007, 4 were warning letters.

FDA regulatory letters may cite more than one DTC material or type of violation for a given drug. Of the 19 regulatory letters FDA issued from 2004 through 2005, 7 cited more than 1 DTC material, for a total of 31 different materials. These 31 materials appeared in a range of media, including television, radio, print, direct mail, and the Internet. Further, FDA identified multiple violations in 21 of the 31 DTC materials cited in the letters. The most commonly cited violations related to a failure of the material to accurately communicate information about the safety of the drug. The letters also often cited materials for overstating the effectiveness of the drug or using misleading comparative claims. Of the 6 regulatory letters FDA issued in 2006 or 2007 that cited DTC materials, 2 cited more than 1 DTC material and all identified multiple violations in each of the cited materials.

For our 2006 report, FDA officials told us, that the agency issued regulatory letters for DTC materials that it believed were the most likely to negatively affect consumers and that it did not act on all of the concerns that its reviewers identified. For example, they said the agency may be more likely to issue a letter when a false or misleading material was broadly disseminated. When reviewers had concerns about DTC materials, they discussed them with others in DDMAC and may have met with OCC and medical officers in FDA's Office of New Drugs to determine whether a regulatory letter was warranted. However, because FDA did not document decisions made at the various stages of its review process about whether to pursue a violation, officials were unable to provide us with an estimate of the number of materials about which concerns were raised but the agency did not issue a letter.

Effectiveness of FDA Regulatory Letters at Halting Dissemination of Violative DTC Materials Was Limited

At the time of our 2006 report, we found that FDA regulatory letters were limited in their effectiveness at halting the dissemination of false and misleading DTC advertising materials. We found that, from 2004 through 2005, FDA issued regulatory letters an average of about 8 months after the violative DTC materials they cited were first disseminated, by which time more than half of the materials had already been discontinued. Although drug companies complied with FDA's requests to create materials to correct the misimpressions left by the cited materials, these corrections were not disseminated until 5 months or more after FDA issued the regulatory letter. Furthermore, FDA's regulatory letters did not always prevent drug companies from later disseminating similar violative materials for the same drugs.

Because of the length of time it took FDA to issue these letters, violative advertisements were often disseminated for several months before the letters were issued. From 2004 through 2005, FDA issued regulatory letters citing DTC materials an average of about 8 months after the violative materials were first disseminated. FDA issued one letter less than 1 month after the material was first disseminated, while another letter took over 3 years. The cited materials were usually disseminated for 3 or more months, and of the 31 violative DTC materials cited in these letters, 16 were no longer being disseminated by the time the letter was issued. On average, these letters were issued more than 4 months after the drug company stopped disseminating these materials and therefore had no effect on their dissemination. For the 14 DTC materials that were still in use when FDA issued the letter, the drug companies complied with FDA's request to stop disseminating the violative materials. However, by the time the letters were issued, these 14 materials had been disseminated for an average of about 7 months.¹²

As requested by FDA in the regulatory letters, drug companies often identified and stopped disseminating other materials with claims similar to those in the violative materials. For 18 of the 19 regulatory letters issued from 2004 through 2005, the drug companies indicated to FDA that they had either identified additional similar materials or that they were reviewing all materials to ensure compliance. In addition to halting materials directed to consumers, companies responding to 11 letters also

¹²For one violative advertising material, we were unable to determine from FDA's files when the violative advertising material ended.

stopped disseminating materials with similar claims that were targeted directly to medical professionals.

Drug companies disseminated the corrective advertising materials requested in FDA warning letters, but took 5 months or more to do so. In each of the six warning letters FDA issued in 2004 and 2005 that cited DTC materials, the agency asked the drug company to disseminate truthful, nonmisleading, and complete corrective messages about the issues discussed in the regulatory letter to the audiences that received the violative promotional materials. In each case, the drug company complied with this request by disseminating corrective advertising materials. For the six warning letters FDA issued in 2004 and 2005 that cited DTC materials, the corrective advertising materials were initially disseminated more than 5 to almost 12 months after FDA issued the letter. For example, for one allergy medication, the violative advertisements ran from April through October 2004, FDA issued the regulatory letter in April 2005, and the corrective advertisement was not issued until January 2006.

FDA regulatory letters did not always prevent the same drug companies from later disseminating violative DTC materials for the same drug, sometimes using the same or similar claims. From 1997 through 2005, FDA issued regulatory letters for violative DTC materials used to promote 89 different drugs. Of these 89 drugs, 25 had DTC materials that FDA cited in more than one regulatory letter, and one drug had DTC materials cited in eight regulatory letters.¹³ For 15 of the 25 drugs, FDA cited similar broad categories of violations in multiple regulatory letters. For example, FDA issued regulatory letters citing DTC materials for a particular drug in 2000 and again in 2005 for “overstating the effectiveness of the drug.” For 4 of the 15 drugs, FDA cited the same specific violative claim for the same drug in more than one regulatory letter. For example, in 1999 FDA cited a DTC direct mail piece for failing to convey important information about the limitations of the studies used to approve the promoted drug. In 2001, FDA cited a DTC broadcast advertisement for the same drug for failing to include that same information.

¹³In 2006 and 2007, FDA issued 6 letters for drugs that had not previously been cited in regulatory letters. As of April 2008, the agency had issued one regulatory letter for a drug that had been cited in 2 previous regulatory letters.

Concluding Observations

Given substantial growth in the number of DTC advertising materials submitted to FDA in recent years, FDA's role in limiting the dissemination of false or misleading advertising to the American public has become increasingly important. Fulfilling this responsibility requires that the agency, among other things, review those DTC advertising materials that are highest priority and take timely action to limit the dissemination of those that are false or misleading. We found in 2006 that FDA did not have a complete and systematic process for tracking and prioritizing all materials that it received for review. FDA's development of documented criteria to prioritize reviews is a step in the right direction. However, as we recommended in 2006, we believe that FDA should take the next step of systematically applying those criteria to the DTC materials it receives to determine which are highest priority for review. While the agency said that it would require vastly increased staff to systematically screen materials, we found in 2006 that FDA already has most of the information it would need to do so. Finally, despite FDA agreeing in 2002 that it is important to issue regulatory letters more quickly, the amount of time it takes to draft and issue letters has continued to lengthen. We believe that delays in issuing regulatory letters limit FDA's effectiveness in overseeing DTC advertising and in reducing consumers' exposure to false and misleading advertising.

Mr. Chairman, this completes my prepared statement. I would be happy to respond to any questions you or the other members of the subcommittee may have at this time.

Contacts and Acknowledgments

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