United States Government Accountability Office

GAO

Testimony

Before the Subcommittee on Health, Committee on Energy and Commerce, House of Representatives

For Release on Delivery
Expected at 10:00 a.m. EDT
Tuesday, May 22, 2007

PEDIATRIC DRUG RESEARCH

The Study and Labeling of Drugs for Pediatric Use under the Best Pharmaceuticals for Children Act

Statement of Marcia Crosse
Director, Health Care

May 22, 2007

PEDIATRIC DRUG RESEARCH

The Study and Labeling of Drugs for Pediatric Use under the Best Pharmaceuticals for Children Act

GAO Accountability · Integrity · Reliability

Highlights

Highlights of GAO-07-898T, a testimony before the Subcommittee on Health, Committee on Energy and Commerce, House of Representatives

Why GAO Did This Study

About two-thirds of drugs that are prescribed for children have not been studied and labeled for pediatric use, placing children at risk of being exposed to ineffective treatment or incorrect dosing. The Best Pharmaceuticals for Children Act (BPCA), enacted in 2002, encourages the manufacturers, or sponsors, of drugs that still have marketing exclusivity—that is, are on-patent—to conduct pediatric drug studies, as requested by the Food and Drug Administration (FDA). If they do so, FDA may extend for 6 months the period during which no equivalent generic drugs can be marketed. This is referred to as pediatric exclusivity. BPCA also provides for the study of off-patent drugs.

GAO was asked to testify on the study and labeling of drugs for pediatric use under BPCA. This testimony is based on *Pediatric Drug Research: Studies Conducted under Best Pharmaceuticals for Children Act*, GAO-07-557 (Mar. 22, 2007). GAO assessed (1) the extent to which pediatric drug studies were being conducted under BPCA for on-patent drugs, (2) the extent to which pediatric drug studies were being conducted under BPCA for off-patent drugs, and (3) the impact of BPCA on the labeling of drugs for pediatric use and the process by which the labeling was changed. GAO examined data about the drugs for which FDA requested studies under BPCA from 2002 through 2005 and interviewed relevant federal officials.

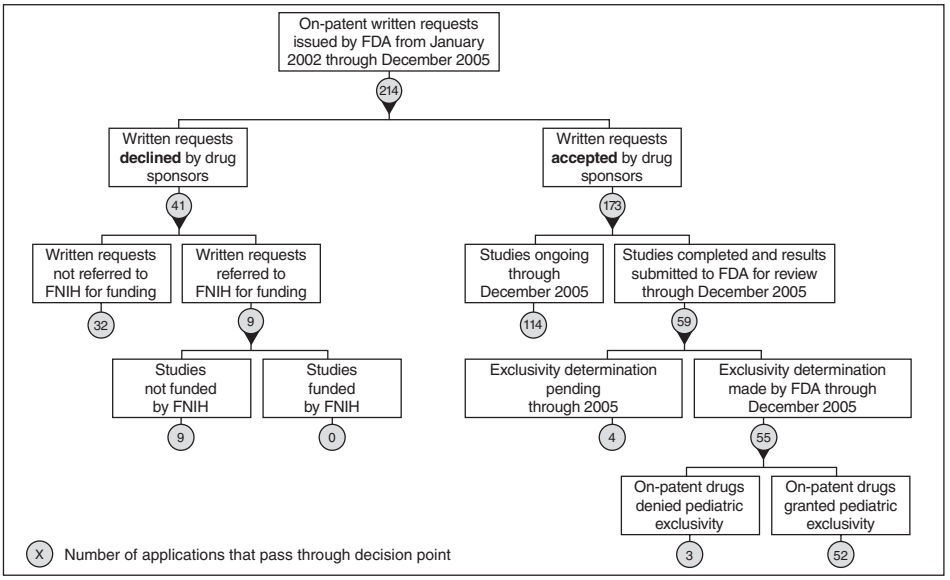
www.gao.gov/cgi-bin/getrpt?GAO-07-898T.

To view the full product, including the scope and methodology, click on the link above. For more information, contact Marcia Crosse at (202) 512-7119 or crossem@gao.gov.

What GAO Found

Drug sponsors have initiated pediatric drug studies for most of the on-patent drugs for which FDA has requested such studies under BPCA, but no drugs were studied when sponsors declined these requests. Sponsors agreed to 173 of the 214 written requests for pediatric studies of on-patent drugs. In cases where drug sponsors decline to study the drugs, BPCA provides for FDA to refer the study of these drugs to the Foundation for the National Institutes of Health (FNIH), a nonprofit corporation. FNIH had not funded studies for any of the nine drugs that FDA referred as of December 2005.

Written Requests Issued under BPCA for the Study of On-Patent Drugs (2002-2005)



Source: GAO.

Few off-patent drugs identified by the National Institutes of Health (NIH) that need to be studied for pediatric use have been studied. BPCA provides for NIH to fund studies when drug sponsors decline written requests for off-patent drugs. While 40 such off-patent drugs were identified by 2005, FDA had issued written requests for 16. One written request was accepted by the drug sponsor. Of the remaining 15, NIH funded studies for 7 through December 2005.

Most drugs granted pediatric exclusivity under BPCA (about 87 percent) had labeling changes—often because the pediatric drug studies found that children may have been exposed to ineffective drugs, ineffective dosing, overdosing, or previously unknown side effects. However, the process for approving labeling changes was often lengthy. For 18 drugs that required labeling changes (about 40 percent), it took from 238 to 1,055 days for information to be reviewed and labeling changes to be approved.

Mr. Chairman and Members of the Subcommittee:

Although children suffer from many of the same diseases as adults and are often treated with the same drugs, only about one-third of the drugs that are prescribed for children have been studied and labeled for pediatric use.[1] This has placed children taking drugs for which there have not been adequate pediatric drug studies at risk of being exposed to ineffective treatment or receiving incorrect dosing. In order to encourage the study of more drugs for pediatric use,[2] Congress passed the Best Pharmaceuticals for Children Act (BPCA) in 2002 to provide marketing incentives to drug sponsors for conducting pediatric drug studies.[3] Drug sponsors (typically drug manufacturers) may obtain 6 months of additional market exclusivity for drugs on which they have conducted pediatric studies in accordance with pertinent law and regulations.[4] This market exclusivity is known as pediatric exclusivity. When a drug has market exclusivity, it is protected from competition for a limited period; for example, the Food and Drug Administration (FDA) is prohibited from approving a generic copy for marketing.[5] Generally, pediatric exclusivity can only be granted to those drugs that are on-patent—that is, those that still have market

[1]The drug "label" refers to written, printed, or graphic material placed on the drug container while drug "labeling" is much broader and includes all labels and other written, printed, or graphic materials on any container, wrapper, or materials accompanying the drug. 21 U.S.C. § 321(k), (m).

[2]FDA generally defines the pediatric population covered under BPCA as children from birth to 16 years old, though studies have included children as old as 18.

[3]Provisions regarding pediatric studies of drugs are generally codified at 21 U.S.C. § 355a. Pub. L. No. 107-109, 115 Stat. 1408. The market exclusivity provisions of BPCA will sunset on October 1, 2007.

[4]The value of 6 months additional marketing exclusivity is difficult to assess and depends on a number of factors for which data are not available. However, a recent study estimated that for some drugs, the benefit of 6 months of marketing exclusivity was quite large, while for others the return the drug sponsor received for pediatric exclusivity was less than the cost of the studies. See Jennifer S. Li, et al., "Economic Return of Clinical Trials Performed Under the Pediatric Exclusivity Program," *JAMA*, vol. 297, no. 5 (2007).

[5]Drug sponsors can obtain additional market exclusivity or patent protection for drugs protected by patents, drugs designed to treat rare diseases, drugs consisting of new chemical entities, and already-marketed drugs approved for new uses. *See*, *for example*, 21 U.S.C. §§ 355(j)(5)(F)(ii), (iii); 21 C.F.R. § 314.108 (2006). Pediatric exclusivity under BPCA attaches to an existing listed patent or any existing market exclusivity held by the drug sponsor.

exclusivity[6]—and for which FDA has issued a written request for pediatric drug studies.[7] However, FDA can also request pediatric drug studies for off-patent drugs—drugs for which the patent or market exclusivity has expired. BPCA also included provisions designed to provide for the study of both on-patent and off-patent drugs that drug sponsors have declined to study.

When FDA determines that a drug may provide health benefits to children, it may issue a written request to the drug sponsor to conduct pediatric drug studies on that drug. When a drug sponsor accepts a written request and conducts studies, FDA reviews the report from the pediatric drug studies to determine whether to grant pediatric exclusivity to the drug. If FDA is satisfied that the studies have been conducted and reported properly, the drug in question may receive additional market exclusivity. FDA also reviews these pediatric drug study reports to see if the drug requires labeling changes.

BPCA provides for pediatric drug studies when the drug sponsor declines the written request. First, if a drug sponsor declines a written request from FDA to study an on-patent drug, BPCA provides for FDA to refer the drug to the Foundation for the National Institutes of Health (FNIH), which can fund the study if funds are available.[8] Sponsors cannot receive pediatric exclusivity for on-patent drugs that drug sponsors decline to study. Second, BPCA provides for the funding of the study of off-patent drugs by the National Institutes of Health (NIH), which, in consultation with FDA and experts in pediatric research, identifies off-patent drugs that need to be studied for pediatric use.

My remarks today provide an overview of the study and proper labeling of drugs for pediatric use under BPCA. I will focus on (1) the extent to which pediatric drug studies were being conducted under BPCA for on-patent drugs, (2) the extent to which pediatric drug studies were being conducted

[6]For purposes of this statement, we refer to drugs that have patent protection or market exclusivity as on-patent and those whose patent protection or marketing exclusivity has ended as off-patent. This is the same terminology typically used by government agencies to describe the exclusivity status of a drug under BPCA.

[7]FDA is responsible for issuing written requests for pediatric studies, determining whether a drug merits pediatric exclusivity as a result of those studies, and all steps in between.

[8]FNIH is an independent, nonprofit corporation. The majority of funds that FNIH receives are from the private sector. Only a portion of these funds are available for FNIH to award to researchers to conduct studies related to BPCA.

under BPCA for off-patent drugs, and (3) the impact of BPCA on the labeling of drugs for pediatric use and the process by which the labeling was changed. My remarks are based upon our report assessing the effect of BPCA on pediatric drug studies and labeling.[9]

In carrying out the work for our report, we collected and analyzed a variety of data from FDA, NIH, and FNIH about written requests and pediatric studies for both on- and off-patent drugs from January 2002 through December 2005. Our work focused on actions regarding these drugs prior to 2006. To evaluate the impact of BPCA on the labeling of drugs for pediatric use and the process by which labeling was changed, we reviewed summaries of the labeling changes for drugs studied from the enactment of BPCA through 2005. In addition, to assist with our review in general, we interviewed officials from FDA, NIH, and FNIH. The work done for this statement was performed from September 2005 through March 2007 in accordance with generally accepted government auditing standards.

In summary, most of the on-patent drugs for which FDA requested pediatric drug studies under BPCA were being studied, but no studies resulted when the requests were declined by drug sponsors. Drug sponsors agreed to study 173 of the 214 on-patent drugs (81 percent) for which FDA issued written requests for pediatric drug studies from January 2002 through December 2005. Drug sponsors completed pediatric drug studies for 59 of the 173 accepted written requests—studies for the remaining 114 written requests were ongoing—and FDA made a pediatric exclusivity determination for 55 of those through December 2005. Of those 55 written requests, 52 (95 percent) resulted in FDA granting pediatric exclusivity. In addition, of the 41 on-patent drugs that drug sponsors declined to study, FDA referred 9 to FNIH, which had not funded the study of any, as of December 2005.

Few of the off-patent drugs identified by NIH as in need of study for pediatric use have been studied. By 2005, NIH had identified 40 off-patent drugs it recommended be studied for pediatric use. Through 2005, FDA issued written requests for 16 of these drugs, and all but one of these written requests were declined by drug sponsors. NIH funded pediatric

[9]GAO, *Pediatric Drug Research: Studies Conducted under Best Pharmaceuticals for Children Act*, GAO-07-557 (Washington, D.C.: Mar. 22, 2007).

drugs studies for 7 of the remaining 15 written requests declined by drug sponsors through December 2005.

Almost all the drugs that have been granted pediatric exclusivity under BPCA—about 87 percent—have had important labeling changes as a result of pediatric drug studies conducted under BPCA, but the process for reviewing the study results and making these changes can be lengthy. The labeling of drugs was often changed because the pediatric drug studies revealed that children may have been exposed to ineffective drugs, ineffective dosing, overdosing, or previously unknown side effects. The review process took from 238 to 1,055 days when FDA required additional information to support changes in the drug labeling.

Background

BPCA was enacted on January 4, 2002, to encourage drug sponsors to conduct pediatric drug studies.[10] BPCA allows FDA to grant drug sponsors pediatric exclusivity—6 months of additional market exclusivity—in exchange for conducting and reporting on pediatric drug studies. BPCA also provides mechanisms for pediatric drug studies that drug sponsors decline to conduct.

BPCA Process

The process for initiating pediatric drug studies under BPCA formally begins when FDA issues a written request to a drug sponsor to conduct pediatric drug studies for a particular drug. When a drug sponsor accepts the written request and completes the pediatric drug studies, it submits to FDA reports describing the studies and the study results. BPCA specifies

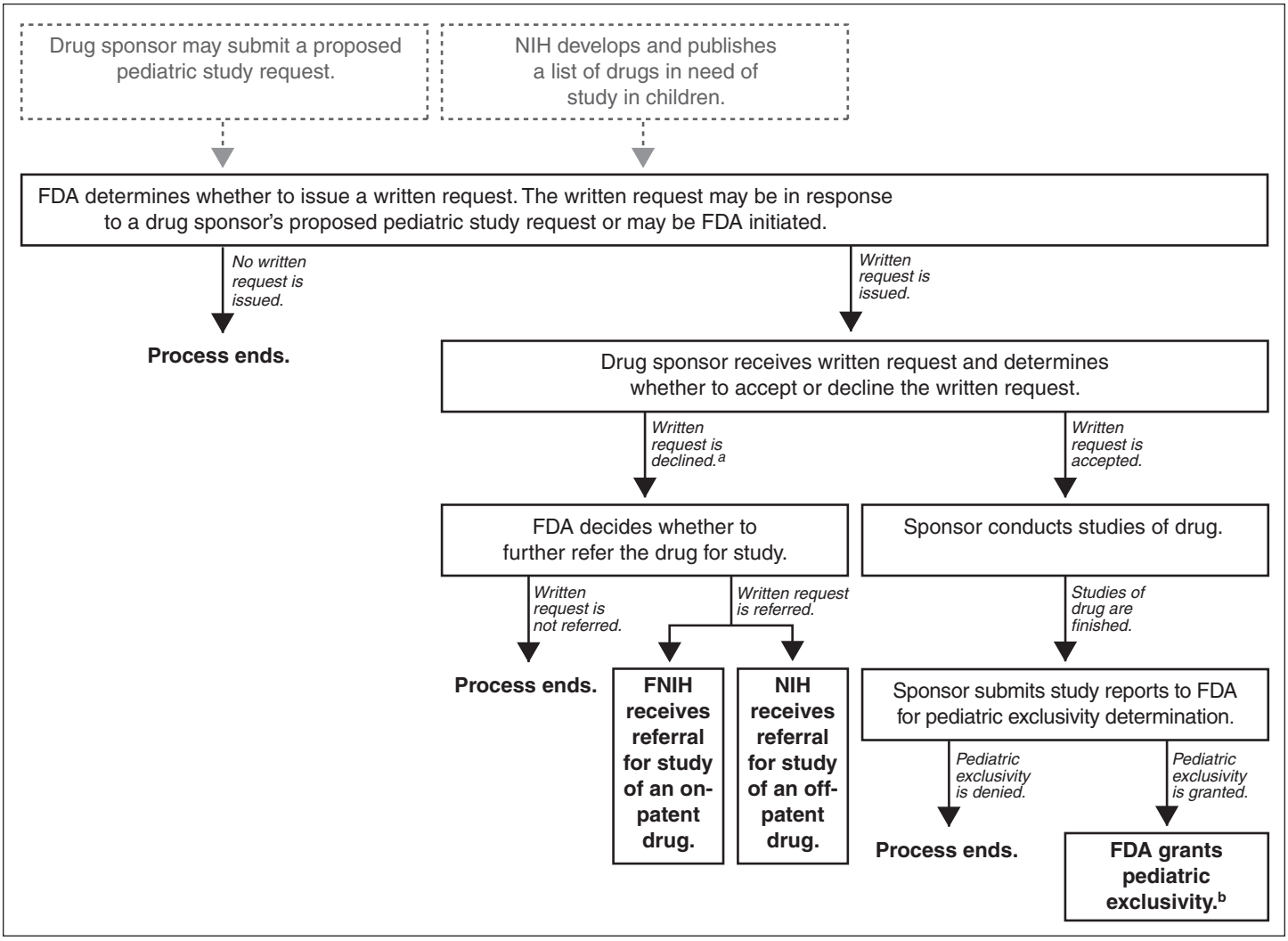
[10]BPCA reauthorized and enhanced the pediatric exclusivity provisions of the Food and Drug Administration Modernization Act of 1997 (FDAMA), Pub. L. No. 105-115, 111 Stat. 2296, which first established incentives for conducting pediatric drug studies—in the form of additional market exclusivity—and whose pediatric exclusivity provisions expired on January 1, 2002. We previously described how FDAMA was responsible for an increase in pediatric drug studies. GAO, *Pediatric Drug Research: Substantial Increase in Studies of Drug for Children, But Some Challenges Remain*, GAO-01-705T (Washington, D.C.: May 8, 2001).

that FDA generally has 90 days to review the study reports to determine whether the pediatric drug studies met the conditions outlined in the written request.[11] If FDA determines that the pediatric drug studies conducted by the drug sponsor were responsive to the written request, it will grant a drug pediatric exclusivity regardless of the study findings.[12] Figure 1 illustrates the process under BPCA.

[11]Under certain circumstances, FDA could have only 60 days to review the study report to determine pediatric exclusivity. However, FDA officials told us that under BPCA, this has never happened. Otherwise, FDA has 90 days to determine if the studies fairly respond to the written request, were conducted in accordance with commonly accepted scientific principles and protocols, and were properly submitted.

[12]Pediatric exclusivity applies to all approved uses of the drug, not just those studied in children. Therefore, if the studies find that the drug is not safe for use by children, the drug will still receive pediatric exclusivity and therefore extended market exclusivity for the adult uses of the drug.

Figure 1: BPCA Process



Source: GAO.

[a]If a drug sponsor of an off-patent drug does not respond to FDA's written request within 30 days, the written request is considered declined. Pediatric exclusivity is not granted to drugs where the drug sponsor declined the written request.

[b]FDA has granted pediatric exclusivity in response to written requests for on-patent drugs only. Under certain circumstances FDA could grant pediatric exclusivity in response to a written request for an off-patent drug.

BPCA Provisions for Pediatric Drug Studies Declined by Drug Sponsors

BPCA includes two provisions to further the study of drugs when drug sponsors decline written requests. FDA cannot extend pediatric exclusivity in response to written requests for any drugs for which the drug sponsors declined to conduct the requested pediatric drug studies.

First, when drug sponsors decline written requests for studies of on-patent drugs, BPCA provides for FDA to refer the study of those drugs to FNIH for funding. FNIH, which is a nonprofit corporation and independent of NIH, supports the mission of NIH and advances research by linking private sector donors and partners to NIH programs. FNIH and NIH collaborate to fund certain projects. As of December 2005, FNIH had raised $4.13 million to fund pediatric drug studies under BPCA.

Second, to further the study of off-patent drugs, NIH—in consultation with FDA and experts in pediatric research—develops a list of drugs, including off-patent drugs, which the agency believes need to be studied in children. NIH lists these drugs annually in the *Federal Register*. FDA may issue written requests for those drugs on the list that it determines to be most in need of study. If the drug sponsor declines or fails to respond to the written request, NIH can contract for, and fund, the pediatric drug studies. Drug sponsors generally decline written requests for off-patent drugs because the financial incentives are considerably limited.

Making Labeling Changes under BPCA for On-Patent Drugs

Pediatric drug studies often reveal new information about the safety or effectiveness of a drug, which could indicate the need for a change to its labeling. Generally, the labeling includes important information for health care providers, including proper uses of the drug, proper dosing, and possible adverse events that could result from taking the drug. FDA may determine that the drug is not approved for use by children, which would then be reflected in any labeling changes.

The agency refers to its review to determine the need for labeling changes as its scientific review. BPCA specifies that study results submitted as a supplemental new drug application—which, according to FDA officials, most are—are subject to FDA's general performance goals for a scientific

review, which in this case is 180 days.[13] FDA's process for reviewing study results submitted under BPCA for consideration of labeling changes is not unique to BPCA. FDA's action can include approving the application, determining that the application is approvable, or determining that the application is not approvable. A determination that an application is approvable may require that drug sponsors conduct additional analyses. Each time FDA takes action on the application, a review cycle is ended.

Drug Sponsors Agreed to Study the Majority of On-Patent Drugs with Written Requests under BPCA, but No Studies Were Conducted When Drug Sponsors Declined the Written Requests

Most of the on-patent drugs for which FDA requested pediatric drug studies under BPCA were being studied, but no studies have resulted when the requests were declined by drug sponsors. From January 2002 through December 2005, FDA issued 214 written requests for on-patent drugs to be studied under BPCA, and drug sponsors agreed to conduct pediatric drug studies for 173 (81 percent) of those.[14] The remaining 41 written requests were declined. Of these 41, FDA referred 9 written requests to FNIH for funding and FNIH had not funded any of those studies as of December 2005.

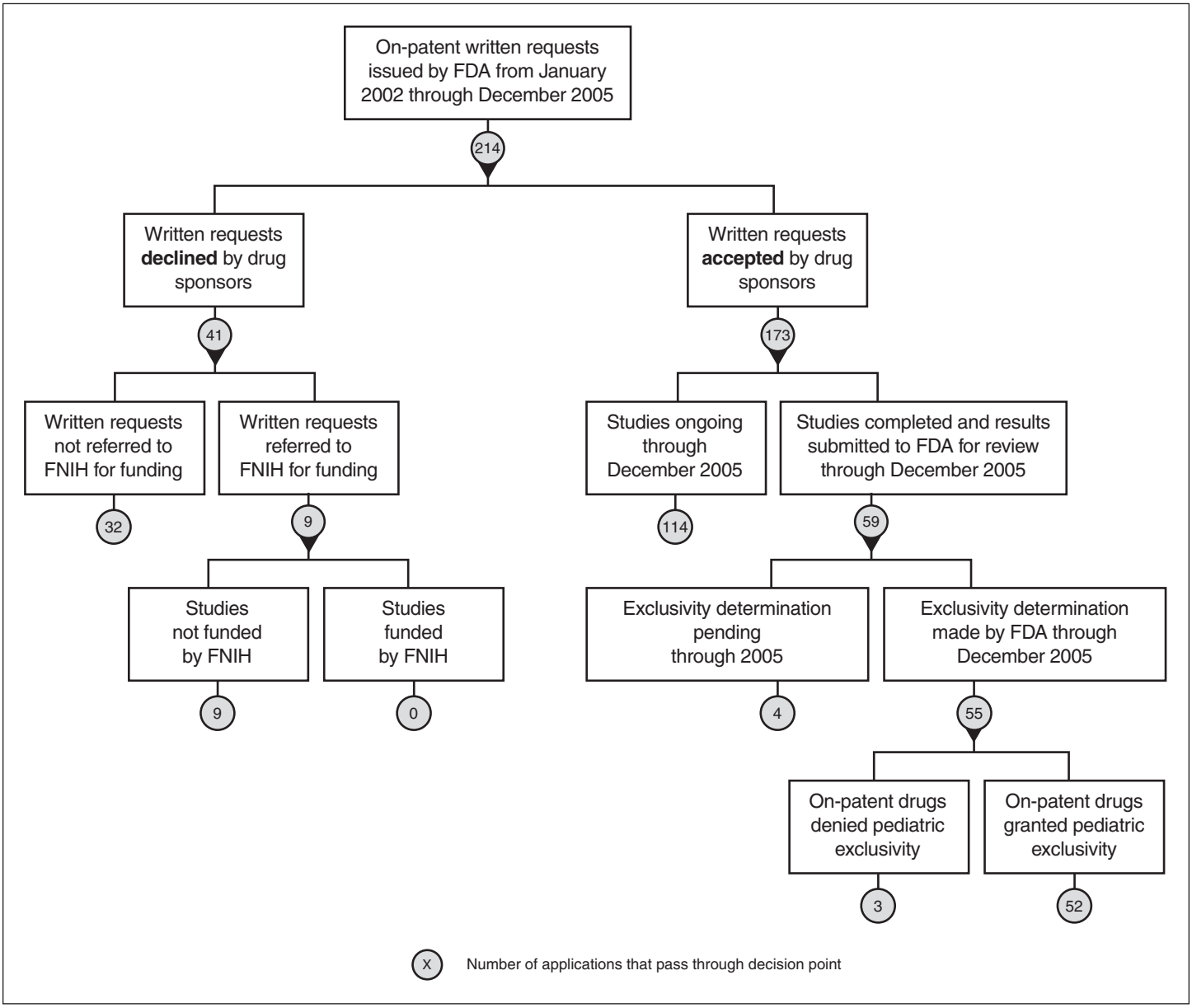
[13]Most drugs studied under BPCA have previously been approved for marketing in the United States, so a supplement to the original "new drug application" is submitted. BPCA requires that supplemental new drug applications submitted by drug sponsors be treated as "priority supplements." FDA's goal is to take action on priority supplements within 180 days. If the drug studied under BPCA was not previously approved for marketing in the United States, the application would be submitted as a new drug application. FDA has a performance goal to review nonpriority new drug applications in 10 months.

[14]Some drugs have two written requests for a variety of reasons. In some cases, FDA may have requested that the drug sponsor study the effects of the drug on different diseases. In other cases, there could be two written requests for the same drug, issued to different drug sponsors for different dosage forms of the drug. In addition, FDA told us that the specified time period for studies to be completed elapsed for some written requests before the completion of studies, and the agency issued new written requests. In all of these situations, we counted each of these written requests separately. Therefore, there are more written requests than there are unique drugs with written requests. Of the 214 written requests issued by FDA, 68 were written requests first issued under BPCA. The remaining 146 written requests were originally issued under FDAMA and reissued under BPCA because drug sponsors had not responded to the written requests or completed the requested pediatric drug studies at the time that BPCA went into effect.

Drug sponsors completed pediatric drug studies for 59 of the 173 accepted written requests—studies for the remaining 114 written requests were ongoing—and FDA made pediatric exclusivity determinations for 55 of those through December 2005.[15] Of those 55 written requests, 52 (95 percent) resulted in FDA granting pediatric exclusivity. Figure 2 shows the status of written requests issued under BPCA for the study of on-patent drugs, from January 2002 through December 2005.

[15]FDA had not completed its review of the study results to determine exclusivity prior to December 2005 for the remaining four drugs.

Figure 2: Status of Written Requests Issued under BPCA for the Study of On-Patent Drugs, from January 2002 through December 2005



Source: GAO.

Note: Written requests issued from January 2002 through December 2005 include new written requests issued under BPCA combined with written requests originally issued under FDAMA but reissued under BPCA.

Drugs were studied under BPCA for their safety and effectiveness in treating children for a wide range of diseases, including some that are common—such as asthma and allergies— and serious or life threatening in children—such as cancer, HIV, and hypertension. We found that the drugs studied under BPCA represented more than 17 broad categories of disease. The category that had the most drugs studied under BPCA was cancer, with 28 drugs. In addition, there were 26 drugs studied for neurological and psychiatric disorders, 19 for endocrine and metabolic disorders, 18 related to cardiovascular disease—including drugs related to hypertension—and 17 related to viral infections. Analyses of two national databases shows that about half of the 10 most frequently prescribed drugs for children were studied under BPCA.

Through December 2005, drug sponsors declined written requests issued under BPCA for 41 on-patent drugs. FDA referred 9 of these 41 written requests (22 percent) to FNIH for funding,[16] but as of December 2005, FNIH had not funded the study of any of these drugs.[17] NIH has estimated that the cost of studying these 9 drugs would exceed $43 million, but FNIH had raised only $4.13 million for pediatric drug studies under BPCA.

Few Off-Patent Drugs Have Been Studied under BPCA

Few off-patent drugs identified by NIH as in need of study for pediatric use have been studied. By 2005, NIH had identified 40 off-patent drugs that it believed should be studied for pediatric use. Through 2005, FDA issued written requests for 16 of these drugs. All but 1 of these written requests were declined by drug sponsors. NIH funded pediatric drug studies for 7 of the remaining 15 written requests declined by drug sponsors through December 2005.

[16]When a drug sponsor of an on-patent drug declines a written request, the agency must determine if there is a continuing need for information relating to the use of the drug in children. Reasons that FDA has concluded that there is not a continuing need include the drug was not yet approved, some part of the study was being performed by the drug sponsor or another party, the drug's patent ended, the risk-benefit assessment shifted, safe alternative therapies were already on the market even though the agency had issued the written request in hope of obtaining additional valuable information, another drug may have been approved or may soon be approved with a better safety record, or there is minimal use of the drug by children.

[17]In April 2006, FNIH agreed to allocate all $4.13 million it had raised for pediatric drug studies under BPCA to fund half of the cost to study one on-patent day—baclofen. NIH expects the cost of the study of baclofen to be about $7.8 million over three years and NIH agreed to cover the costs of the study that exceed the contribution from FNIH. Because FNIH has committed all of its BPCA funds to the study of baclofen, there are no resources left for FNIH to fund the study of any other drugs.

NIH provided several reasons why it has not pursued the study of some off-patent drugs that drug sponsors declined to study. Concerns about the incidence of the disease that the drugs were developed to treat, the feasibility of study design, drug safety, and changes in the drugs' patent status have caused the agency to reconsider the merit of studying some of the drugs it identified as important for study in children.[18] For example, in one case NIH issued a request for proposals to study a drug but received no responses. In other cases, NIH is awaiting consultation with pediatric experts to determine the potential for study.

Further, NIH has not received appropriations specifically for funding pediatric drug studies under BPCA. NIH anticipates spending an estimated $52.5 million for pediatric drug studies associated with 7 written requests issued by FDA from January 2002 through December 2005.[19]

Most Drugs Granted Pediatric Exclusivity under BPCA Had Labeling Changes, but the Process for Making Changes Was Sometimes Lengthy

Most drugs that have been granted pediatric exclusivity under BPCA—about 87 percent—have had labeling changes as a result of the pediatric drug studies conducted under BPCA. Pediatric drug studies conducted under BPCA showed that children may have been exposed to ineffective drugs, ineffective dosing, overdosing, or side effects that were previously unknown. However, the process for reviewing study results and completing labeling changes was sometimes lengthy, particularly when FDA required additional information from drug sponsors to support the changes.

Of the 52 drugs studied and granted pediatric exclusivity under BPCA from January 2002 through December 2005, 45 (about 87 percent) had labeling changes as a result of the pediatric drug studies. In addition, 3 other drugs had labeling changes prior to FDA making a decision on granting pediatric exclusivity. FDA officials said that the pediatric drug studies conducted up to that time provided important safety information that should be reflected in the labeling without waiting until the full study results were submitted or pediatric exclusivity determined.

[18]Since its inception, no drug has been removed from the list published in the *Federal Register*, regardless of the feasibility or likelihood of it being studied.

[19]The costs reported by NIH are estimates, which may change during the course of the studies.

Pediatric drug studies conducted under BPCA have shown that the way that some drugs were being administered to children potentially exposed them to an ineffective therapy, ineffective dosing, overdosing, or previously unknown side effects—including some that affect growth and development. The labeling for these drugs was changed to reflect these study results. For example, studies of the drug Sumatriptan, which is used to treat migraines, showed that there was no benefit derived from this drug when it was used in children. There were also certain serious adverse events associated with its use in children, such as vision loss and stroke, so the labeling was changed to reflect that the drug is not recommended for children under 18 years old.

Other drugs have had labeling changes indicating that the drugs may be used safely and effectively by children in certain dosages or forms. Typically, this resulted in the drug labeling being changed to indicate that the drug was approved for use by children younger than those for whom it had previously been approved. In other cases, the changes reflected a new formulation of a drug, such as a syrup that was developed for pediatric use, or new directions for preparing the drug for pediatric use were identified in the pediatric drug studies conducted under BPCA.

Although FDA generally completed its first scientific review of study results—including consideration of labeling changes—within its 180-day goal, the process for completing the review, including obtaining sufficient information to support and approve labeling changes, sometimes took longer. For the 45 drugs granted pediatric exclusivity that had labeling changes, it took an average of almost 9 months after study results were first submitted to FDA for the sponsor to submit and the agency to review all of the information it required and approve labeling changes. For 13 drugs (about 29 percent), FDA completed this scientific review process and approved labeling changes within 180 days. It took from 181 to 187 days for the scientific review process to be completed and labeling changes to be approved for 14 drugs (about 31 percent). For the remaining 18 drugs (about 40 percent), FDA took from 238 to 1,055 days to complete the scientific review process and approve labeling changes. For 7 of those drugs, it took more than a year to complete the scientific review process and approve labeling changes.

While the first scientific reviews were generally completed within 180 days, it took 238 days or more for 18 drugs.[20] For those 18 drugs, FDA determined that it needed additional information from the drug sponsors in order to be able to approve the drugs for pediatric use. This often required that the drug sponsor conduct additional analyses or pediatric drug studies. FDA officials said they could not approve any changes to drug labeling until the drug sponsor provided this information. Drug sponsors sometimes took as long as 1 year to gather the additional necessary data and respond to FDA's request.[21]

Mr. Chairman, this concludes my prepared remarks. I would be pleased to respond to any questions that you or other members of the Subcommittee may have.

For further information regarding this testimony, please contact Marcia Crosse at (202) 512-7119 or crossem@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this testimony. Thomas Conahan, Assistant Director; Carolyn Feis Korman; and Cathleen Hamann made key contributions to this statement.

[20]FDA considers itself in conformance with its review goals even though the entire process often took longer than 180 days.

[21]BPCA provides a dispute resolution process that FDA can use to resolve disagreements with drug sponsors regarding labeling of on-patent drugs where the only remaining issue concerns the labeling. FDA officials said they have never used this process because labeling has never been the only unresolved issue for those drugs for which the review period exceeded 180 days. Agency officials told us that reminding the drug sponsors that such a process exists has motivated drug sponsors to complete labeling change negotiations by reaching agreement with FDA.

GAO's Mission

The Government Accountability Office, the audit, evaluation and investigative arm of Congress, exists to support Congress in meeting its constitutional responsibilities and to help improve the performance and accountability of the federal government for the American people. GAO examines the use of public funds; evaluates federal programs and policies; and provides analyses, recommendations, and other assistance to help Congress make informed oversight, policy, and funding decisions. GAO's commitment to good government is reflected in its core values of accountability, integrity, and reliability.

Obtaining Copies of GAO Reports and Testimony

The fastest and easiest way to obtain copies of GAO documents at no cost is through GAO's Web site (www.gao.gov). Each weekday, GAO posts newly released reports, testimony, and correspondence on its Web site. To have GAO e-mail you a list of newly posted products every afternoon, go to www.gao.gov and select "Subscribe to Updates."

Order by Mail or Phone

The first copy of each printed report is free. Additional copies are $2 each. A check or money order should be made out to the Superintendent of Documents. GAO also accepts VISA and Mastercard. Orders for 100 or more copies mailed to a single address are discounted 25 percent. Orders should be sent to:

U.S. Government Accountability Office
441 G Street NW, Room LM
Washington, D.C. 20548

To order by Phone: Voice: (202) 512-6000
TDD: (202) 512-2537
Fax: (202) 512-6061

To Report Fraud, Waste, and Abuse in Federal Programs

Contact:

Web site: www.gao.gov/fraudnet/fraudnet.htm
E-mail: fraudnet@gao.gov
Automated answering system: (800) 424-5454 or (202) 512-7470

Congressional Relations

Gloria Jarmon, Managing Director, JarmonG@gao.gov (202) 512-4400
U.S. Government Accountability Office, 441 G Street NW, Room 7125
Washington, D.C. 20548

Public Affairs

Paul Anderson, Managing Director, AndersonP1@gao.gov (202) 512-4800
U.S. Government Accountability Office, 441 G Street NW, Room 7149
Washington, D.C. 20548