

Washington, D.C. 20201

September 21, 2011

TO: Francis S. Collins, M.D., Ph.D.

Director

National Institutes of Health

FROM: /Daniel R. Levinson/

Inspector General

SUBJECT: Appropriations Funding for National Institute of Allergy and Infectious Diseases

Contract HHSN266-2006-00015C With NexBio, Inc. (A-03-10-03119)

The attached final report provides the results of our review of appropriations funding for National Institute of Allergy and Infectious Diseases contract HHSN266-2006-00015C with NexBio, Inc.

Section 8L of the Inspector General Act, 5 U.S.C. App., requires that the Office of Inspector General (OIG) post its publicly available reports on the OIG Web site. Accordingly, this report will be posted at http://oig.hhs.gov.

If you have any questions or comments about this report, please do not hesitate to call me, or your staff may contact Lori S. Pilcher, Assistant Inspector General for Grants, Internal Activities, and Information Technology Audits, at (202) 619-1175 or through email at Lori.Pilcher@oig.hhs.gov. We look forward to receiving your final management decision within 6 months. Please refer to report number A-03-10-03119 in all correspondence.

Attachment

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

APPROPRIATIONS FUNDING FOR NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES CONTRACT HHSN266-2006-00015C WITH NEXBIO, INC.



Daniel R. Levinson Inspector General

> September 2011 A-03-10-03119

Office of Inspector General

http://oig.hhs.gov

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OFFICE OF AUDIT SERVICES FINDINGS AND OPINIONS

The designation of financial or management practices as questionable, a recommendation for the disallowance of costs incurred or claimed, and any other conclusions and recommendations in this report represent the findings and opinions of OAS. Authorized officials of the HHS operating divisions will make final determination on these matters.

EXECUTIVE SUMMARY

BACKGROUND

The National Institute of Allergy and Infectious Diseases (NIAID) is 1 of 27 institutes and centers of the National Institutes of Health (NIH), an agency of the Department of Health and Human Services (HHS). The NIH Office of the Director sets policy and plans, manages, and coordinates NIH-wide programs and activities. Like all Federal agencies, NIAID is required to comply with appropriations statutes when acquiring supplies and services with appropriated funds.

An agency may obligate appropriations for goods and services when (1) the purpose of the obligation or expenditure is authorized, (2) the obligation occurs within the time limits for which the appropriation is available, and (3) the obligation and expenditure are within the amounts provided by Congress.

Federal statutes limit the purpose for which an agency may use appropriations to "the objects for which the appropriations were made except as otherwise provided by law" (31 U.S.C. § 1301(a)). Federal statutes also limit the time during which an appropriation is available. A fiscal year appropriation may be obligated only to meet a legitimate, or bona fide, need arising in, or in some cases arising prior to but continuing to exist in, the appropriation's period of availability (31 U.S.C. § 1502). Congress determines the amount of funding available to an agency for the purchase of goods and services by enacting appropriations. The Antideficiency Act prohibits an agency from obligating or expending those funds in advance of or in excess of an appropriation unless specifically authorized by law (31 U.S.C. § 1341(a)(1)).

The Comptroller General has held that "the question of whether to charge the appropriation current on the date the contract is made, or to charge funds current at the time the services are rendered, depends on whether the services are 'severable' or 'entire' [nonseverable]." When services are continuing and recurring, they are severable, and the agency must fund the contract with fiscal year appropriations from the year in which services are provided, unless otherwise authorized by statute. When services are for a single outcome or effort, they are nonseverable and therefore chargeable to the fiscal year in which the contract is awarded, even though performance may extend into subsequent fiscal years.

On September 29, 2006, NIAID awarded contract HHSN266-2006-00015C (the Contract), totaling \$49.8 million, to NexBio, Inc. (NexBio), in San Diego, California. The Contract requires NexBio to develop Fludase as a broad-spectrum therapeutic agent against influenza. We determined that the Contract is a nonseverable service contract because it represents a single undertaking and provides for a single outcome (to perform clinical testing and development of an antiviral influenza drug) at the conclusion of the 5-year contract.

From November 2008 through February 2009, an HHS internal review group called the "Tiger Team" assessed 176 HHS contracts, including 21 NIH contracts. The Contract was 1 of the 21 NIH contracts assessed. For 17 of the 21 contracts, the Tiger Team identified instances in which contract funding was not consistent with the current HHS Acquisition Regulation or

appropriations law. The Tiger Team report did not identify its concerns or quantify funding errors by contract.

OBJECTIVE

Our objective was to determine whether NIAID funded the Contract in compliance with the purpose, time, and amount requirements specified in appropriations statutes.

SUMMARY OF FINDINGS

NIAID funded the Contract in compliance with the purpose requirements of appropriations statutes. However, NIAID did not comply with the time requirements and may not have complied with the amount requirements specified in the statutes. NIAID funded only \$19.8 million of the \$49.8 million contract obligation with fiscal year 2006 appropriations. NIAID obligated a total of \$20.0 million in violation of the bona fide needs rule: \$10.0 million of fiscal year 2007 appropriated funds and \$10.0 million of fiscal year 2009 appropriated funds, and it planned to obligate funds appropriated for future years as well. Because the Contract was for nonseverable services, NIAID was required to record the full amount of the Contract using fiscal year 2006 appropriated funds. By not recording the full obligation using fiscal year 2006 appropriations, NIAID potentially violated the Antideficiency Act.

To remedy the bona fide needs rule violation, NIAID will need to deobligate the fiscal years 2007 and 2009 appropriations and any future-year appropriations obligated after our review. To remedy the potential Antideficiency Act violation, NIAID will need to record an obligation of \$30.0 million (\$49.8 million less \$19.8 million) using fiscal year 2006 appropriations. If NIAID does not have \$30.0 million of fiscal year 2006 appropriations available, it will violate the Antideficiency Act.

RECOMMENDATIONS

We recommend that NIAID:

- deobligate \$10.0 million of fiscal year 2007 funds,
- deobligate \$10.0 million of fiscal year 2009 funds,
- record the remaining \$30.0 million of the \$49.8 million contract obligation against fiscal year 2006 funds, and
- report an Antideficiency Act violation if fiscal year 2006 funds are not available.

NATIONAL INSTITUTES OF HEALTH COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, NIH concurred with the findings that the Contract is nonseverable and that it should have been funded at the time the Contract was awarded. NIH said that HHS would report the violation as required by 31 U.S.C. § 1351.

NIH did not address our recommendations to correct the improper funding for the first 4 years of the Contract. Until NIH makes these adjustments, HHS cannot report the correct amount of its Antideficiency Act violation. Therefore, we continue to recommend that NIH record the remaining \$30.0 million Contract obligation against fiscal year 2006 funds and deobligate funds appropriated for other years.

We have modified our recommendations to identify the funding adjustments necessary by fiscal year. NIH's comments are included in their entirety as the Appendix.

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NATIONAL INSTITUTES OF HEALTH COMMENTS

INTRODUCTION

BACKGROUND

The National Institute of Allergy and Infectious Diseases (NIAID) is 1 of 27 institutes and centers of the National Institutes of Health (NIH), an agency of the Department of Health and Human Services (HHS). The NIH Office of the Director sets policy and plans, manages, and coordinates NIH-wide programs and activities. Like all Federal agencies, NIAID is required to comply with appropriations statutes when acquiring supplies and services with appropriated funds.

Federal Appropriations Statutes

An agency may obligate appropriations for goods and services when (1) the purpose of the obligation or expenditure is authorized, (2) the obligation occurs within the time limits for which the appropriation is available, and (3) the obligation and expenditure are within the amounts provided by Congress.

Federal statutes limit the purpose for which an agency may use appropriations to "the objects for which the appropriations were made except as otherwise provided by law" (31 U.S.C. § 1301(a)). A fiscal year appropriation may be obligated only to meet a legitimate, or bona fide, need arising in, or in some cases arising prior to but continuing to exist in, the appropriation's period of availability (31 U.S.C. § 1502(a)). Unless otherwise specified in the appropriation, the period of availability for most funds is the fiscal year for which the appropriation is made.

Bona fide needs may involve transactions that cover more than 1 fiscal year, depending on the nature of the services involved: "The general rule is that the fiscal year appropriation current at the time the contract is made is chargeable with payments under the contract, although performance thereunder may extend into the ensuing fiscal year" (23 Comp. Gen. 370, 371 (1943)). Multiyear contracting authority provided by statute is an exception to the bona fide needs rule.

The Comptroller General has held that "the question of whether to charge the appropriation current on the date the contract is made, or to charge funds current at the time the services are rendered, depends on whether the services are 'severable' or 'entire' [nonseverable]." When services are continuing and recurring, they are severable, and the agency may fund the contract with separate subsequent fiscal year appropriations. A contract for a single outcome or effort is chargeable to the fiscal year in which it is awarded, even though its performance may extend into subsequent fiscal years. The Comptroller General has explicitly held that incremental funding (i.e., other than full funding) of nonseverable service contracts violates the bona fide needs rule (71 Comp. Gen. 428 (1992)).

Congress determines the amount of funding available to an agency by enacting appropriations to cover programs, projects, purchases, and services needed by the agency during the period for

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¹ As cited in GAO-04-261SP, Appropriations Law, Vol. I, p. 5-24.

² As cited in GAO-04-261SP, Appropriations Law, Vol. I, p. 5-23.

which the funds are made available. The Antideficiency Act prohibits an agency from obligating or expending funds in advance of or in excess of an appropriation unless specifically authorized by law (31 U.S.C. § 1341(a)(1)). The Antideficiency Act requires agencies to report violations to the President and to Congress, with a copy to the Comptroller General (31 U.S.C. § 1351). The Office of Management and Budget (OMB) Circular A-11, *Preparation, Submission and Execution of the Budget*, pt. 4, § 145, prescribes the methodology for this reporting.

National Institute of Allergy and Infectious Diseases Contract Award

On September 29, 2006, NIAID awarded contract HHSN266-2006-00015C (the Contract), totaling \$49.8 million, to NexBio, Inc. (NexBio), in San Diego, California. The Contract requires NexBio to develop Fludase³ as a broad-spectrum therapeutic agent against influenza. We determined that the Contract is a nonseverable service contract because it represents a single undertaking and provides for a single outcome (to perform clinical testing and development of an antiviral influenza drug) at the conclusion of the 5-year contract.

Departmental Review of National Institutes of Health Contracts

In 2008, HHS management formed an internal review group of program, contract, and financial personnel called the "Tiger Team." From November 2008 through February 2009, the Tiger Team assessed 176 HHS contracts, including 21 NIH contracts. The Contract was 1 of the 21 NIH contracts assessed. For 17 of the 21 contracts, the Tiger Team identified instances in which contract funding was not consistent with the current HHS Acquisition Regulation (HHSAR) or appropriations law. ⁴ The Tiger Team report did not identify its concerns or quantify funding errors by contract.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

Our objective was to determine whether NIAID funded the Contract in compliance with the purpose, time, and amount requirements specified in appropriations statutes.

Scope

We reviewed all obligations and payments made under the Contract during fiscal years 2006 through 2009. We did not review NIAID's internal controls because our objective did not require such a review.

We performed our fieldwork at NIAID in Bethesda, Maryland.

³ Fludase is an experimental antiviral drug for influenza.

⁴ Funding Multiple Year Contracts; Tiger Team Summary Report, July 29, 2009.

Methodology

To accomplish our objective, we:

- reviewed appropriations and acquisition laws and regulations and Contract requirements;
- reviewed the Tiger Team report;
- reviewed contract file documentation, including the statement of work, to determine the nature of the products or services to be provided; and
- analyzed funding documents and payment invoices to determine what appropriations were obligated, recorded, and expended.

We conducted this performance audit 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 objective.

FINDINGS AND RECOMMENDATIONS

NIAID funded the Contract in compliance with the purpose requirements of appropriations statutes. However, NIAID did not comply with the time requirements and may not have complied with the amount requirements specified in the statutes. NIAID funded only \$19.8 million of the \$49.8 million contract obligation with fiscal year 2006 appropriations. NIAID obligated a total of \$20.0 million in violation of the bona fide needs rule: \$10.0 million of fiscal year 2007 appropriated funds and \$10.0 million of fiscal year 2009 appropriated funds. It planned to obligate funds appropriated for future years as well. Because the Contract was for nonseverable services, NIAID was required to record the full amount of the Contract using fiscal year 2006 appropriated funds. By not recording the full obligation using fiscal year 2006 appropriations, NIAID potentially violated the Antideficiency Act.

To remedy the bona fide needs rule violation, NIAID will need to deobligate the fiscal years 2007 and 2009 appropriations and any future-year appropriations obligated after our review. To remedy the potential Antideficiency Act violation, NIAID will need to record an obligation of \$30.0 million (\$49.8 million less \$19.8 million) using fiscal year 2006 appropriations. If NIAID does not have \$30.0 million of fiscal year 2006 appropriations available, it will violate the Antideficiency Act.

FUNDING VIOLATIONS

Bona Fide Needs Rule Violation

Federal statutes limit the time for which an appropriation may be used. A fiscal year appropriation may be obligated only to meet a legitimate, or bona fide, need arising in, or in some cases arising prior to but continuing to exist in, the appropriation's period of availability (31 U.S.C. § 1502(a)). Bona fide needs may involve transactions that cover more than 1 fiscal

year, depending on the nature of the services involved. A contract for nonseverable services must reflect a bona fide need identified in the fiscal year in which the agency awards the contract, although the contract's performance may extend into subsequent fiscal years. Agencies must fully fund nonseverable service contracts by obligating funds representing the entire amount of the contract from appropriations available during the fiscal year in which the agency awards the contract.

In fiscal year 2006, NIAID awarded the 5-year nonseverable service Contract and incurred an obligation totaling \$49.8 million based on an existing bona fide need. However, NIAID recorded only \$19.8 million of the obligation with fiscal year 2006 appropriations. Subsequently, NIAID improperly recorded obligations totaling \$20.0 million: \$10.0 million using fiscal year 2007 funds and \$10.0 million using fiscal year 2009 funds. However, NIAID did not have a bona fide need in fiscal years 2007 and 2009. To remedy the violation, NIAID will need to deobligate the \$10.0 million fiscal year 2007 appropriation, the \$10.0 million fiscal year 2009 appropriation, and any future-year appropriations obligated after our review.

Potential Antideficiency Act Violation

Congress determines the amount of funding available to an agency by enacting appropriations to cover programs, projects, purchases, and services needed by the agency during the period for which the funds are made available. The Antideficiency Act prohibits the agency from obligating or expending any amount in advance of or in excess of an appropriation unless specifically authorized by law (31 U.S.C. § 1341(a)(1)). The Antideficiency Act requires agencies to report violations to the President and to Congress, with a copy to the Comptroller General (31 U.S.C. § 1351). OMB Circular A-11, *Preparation, Submission and Execution of the Budget*, pt. 4, § 145, prescribes the methodology for this reporting.

NIAID should have recorded the full fiscal year 2006 obligation for \$49.8 million at the time of the award of the Contract. Instead, NIAID recorded only \$19.8 million of the obligation with fiscal year 2006 appropriations. To remedy the potential Antideficiency Act violation, NIAID will need to record an obligation of \$30.0 million (\$49.8 million less \$19.8 million) using fiscal year 2006 appropriations. If NIAID does not have \$30.0 million of fiscal year 2006 appropriations available, it will violate the Antideficiency Act.

CAUSES OF FUNDING VIOLATIONS

Generally, the Tiger Team report attributed funding violations to:

- widespread misunderstanding of appropriations laws because of conflicting HHSAR guidance over the past 25 years;
- the use of incremental funding in ways that were not consistent with the current HHSAR and appropriations law; and
- the need for additional training and a broader understanding of appropriations law among acquisition, budget, and program staff.

The Tiger Team did not identify the specific reasons for funding violations for each contract reviewed. HHS management corrected the conflicting guidance in HHSAR 332.702(a) and reissued it on December 20, 2006, approximately 3 months after NIAID awarded the Contract.

RECOMMENDATIONS

We recommend that NIAID:

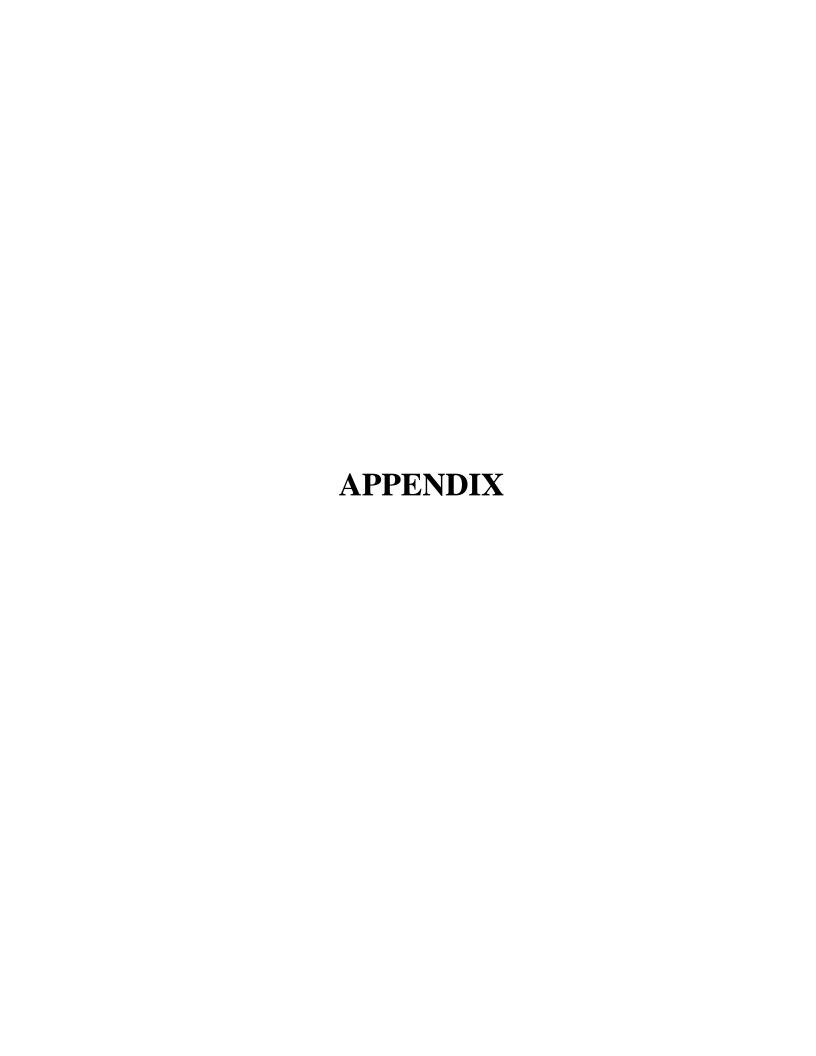
- deobligate \$10.0 million of fiscal year 2007 funds,
- deobligate \$10.0 million of fiscal year 2009 funds,
- record the remaining \$30.0 million of the \$49.8 million contract obligation against fiscal year 2006 funds, and
- report an Antideficiency Act violation if fiscal year 2006 funds are not available.

NATIONAL INSTITUTES OF HEALTH COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, NIH concurred with the findings that the Contract is nonseverable and that it should have been funded at the time it was awarded. NIH said that HHS would report the violation as required by 31 U.S.C. § 1351.

NIH did not address our recommendations to correct the improper funding for the first 4 years of the Contract. Until NIH makes these adjustments, HHS cannot report the correct amount of its Antideficiency Act violation. Therefore, we continue to recommend that NIH record the remaining \$30.0 million Contract obligation against fiscal year 2006 funds and deobligate funds appropriated for other years.

We have modified our recommendations to identify the funding adjustments necessary by fiscal year. NIH's comments are included in their entirety as the Appendix.





DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health Bethesda, Maryland 20892

JUN 1 7 2011

TO:

Daniel R. Levinson

Inspector General, HHS

FROM:

Director, National Institutes of Health

SUBJECT:

Response to Office of Inspector General Draft Report, Appropriations Funding

for National Institute of Allergy and Infectious Diseases Contract HHSN266-

2006-00015C With NexBio, Inc. (A-03-10-03119)

Attached are the National Institutes of Health's revised comments on the Office of Inspector General's draft report entitled, Appropriations Funding for National Institute of Allergy and Infectious Diseases Contract HHSN266-2006-00015C With NexBio, Inc. (A-03-10-03119).

We appreciate the opportunity to review and comment on this important topic. We have provided general comments that address the findings and recommendations in the draft report. Should you have questions or concerns regarding our comments, please contact Meredith Stein in the Office of Management Assessment at 301-402-8482.

Francis S. Collins, M.D., Ph.D.

Attachment

GENERAL COMMENTS ON THE DEPARTMENT OF HEALTH AND HUMAN SERVICES OFFICE OF INSPECTOR GENERAL DRAFT REPORT ENTITLED, APPROPRIATIONS FUNDING FOR NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES CONTRACT HHSN266-2006-00015C WITH NEXBIO, INC. (A-03-10-03119)

The National Institutes of Health (NIH) appreciates the review conducted by the Office of the Inspector General (OIG) and the opportunity to provide clarifications on this draft report. NIH respectfully submits the following comments:

Summary of OIG Findings:

- The National Institute of Allergy and Infectious Diseases (NIAID) did not comply with the time requirements and may not have complied with the amount requirements specified in the statutes. NIAID funded only \$19.8 million of the \$49.8 million contract obligation with fiscal year 2006 appropriations. NIAID obligated a total of \$20 million in violation of the bona fide needs rule: \$10 million of fiscal year 2007 appropriated funds and \$10 million of fiscal year 2009 appropriated funds, and it planned to obligate funds appropriated for future years as well.
- Because the contract was for nonseverable services, NIAID was required to record the full amount of the contract using fiscal year 2006 appropriated funds.

Summary of OIG Recommendations:

- NIAID should record the remaining \$30 million of the \$49.8 million contract obligation against fiscal year 2006 funds and deobligate funds appropriated for years other than fiscal year 2006.
- NIAID must report an Antideficiency Act violation if fiscal year 2006 funds are not available.

NIH Comments:

The NIH concurs that NIAID Contract HHSN266-2006-00015C is a nonseverable services contract and that under Federal appropriations law the contract should have been funded from the fiscal year current at the time the contract was awarded. The NIH concurs with OIG's findings as summarized above. Accordingly, NIH understands that the Department of Health and Human Services (HHS) will report the violation as required by 31 U.S.C. § 1351. NIH further understands that the HHS report will identify the proposed actions taken to correct the systemic problems within HHS which led to this and other violations.