REPORT BY THE U.S.

# General Accounting Office

## Centers For Disease Control Should Discontinue Certain Diagnostic Tests And Charge For Others

The Centers for Disease Control (CDC) performed reference diagnostic tests on 103,000 specimens in fiscal year 1981 for public health agencies, private health care providers, clinical laboratories, and Federal agencies at a cost of about $6.1 million.

CDC's specimen screening procedures need improvement. GAO estimates that 46 percent of the specimens tested by CDC, at a cost of about $1.9 million, were unnecessarily conducted. These specimens should have been, but were not, initially tested in commercial or State laboratories. An additional 13 percent of the remaining specimens were tested without any information concerning patient condition or ongoing treatment. Such information is necessary to determine the need for CDC's specialized testing and to provide meaningful test results.

User charges of $3.3 million could have been recovered from private health care providers and clinical laboratories. An additional $662,000 in reimbursements from Federal agencies could have been sought by CDC.



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WASHINGTON, D.C. 20548

HUMAN RESOURCES
DIVISION

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The Honorable Orrin G. Hatch
Chairman, Committee on Labor
and Human Resources
United States Senate

The Honorable Henry A. Waxman
Chairman, Subcommittee on
Health and the Environment
Committee on Energy and Commerce
House of Representatives

In accordance with your March 26, 1982, request, we have prepared this report on the Centers for Disease Control's laboratory diagnostic testing services program. In general, we believe that there are opportunities to improve program management and assure more efficient and economical use of the agency's resources.

The report contains specific recommendations to the Secretary of Health and Human Services regarding (1) the need to improve and enforce diagnostic specimen screening procedures and (2) the recovery of the total cost of laboratory diagnostic testing services provided to private beneficiaries and other Federal agencies.

As arranged with your offices, unless you publicly announce its contents earlier, we plan no further distribution of this report until 5 days from the date of the report. At that time we will send copies to interested parties and make copies available to others upon request.

Philip A. Bernstein
Director

REPORT BY THE
GENERAL ACCOUNTING OFFICE

# CENTERS FOR DISEASE CONTROL SHOULD DISCONTINUE CERTAIN DIAGNOSTIC TESTS AND CHARGE FOR OTHERS

## D I G E S T

As part of its broad mission of assisting Federal, State, and local health authorities and other health-related organizations, the Centers for Disease Control (CDC) offers a backup, or reference, laboratory diagnostic testing service. In fiscal year 1981, CDC performed tests on about 103,000 reference diagnostic specimens at a cost of about $6.1 million.

This report was prepared at the request of the Chairmen of the Senate Committee on Labor and Human Resources and the Subcommittee on Health and the Environment, House Committee on Energy and Commerce, because of their expressed interest in opportunities to improve CDC's management of its laboratory diagnostic testing services program and assure more efficient and economical use of resources. (See pp. 1 and 2.)

### CERTAIN SPECIMEN TESTING UNNECESSARILY PERFORMED INITIALLY BY CDC

CDC's diagnostic testing service is supposed to be a resource of final resort for testing specimens. Specimens sent to CDC are normally referred through State laboratories, which are to refer only those specimens which need CDC's testing. (See p. 6.)

GAO's analysis of a statistically valid sample of 400 specimen records, supplemented by information from CDC personnel and representatives of hospitals, physicians, and independent clinical laboratories, showed that 46 percent of the diagnostic specimens tested at CDC in fiscal year 1981 were not, but should have been, tested initially by commercial and/or State laboratories. GAO estimates the cost of that unnecessary testing by CDC to be about $1.9 million. (See p. 7.)

Officials at State public health laboratories and at CDC generally assume that prior testing, if commercially available, is being performed. However, specimens are not screened to make that determination. CDC laboratory personnel told GAO that they generally test any specimen they receive that is suitable for testing. Many CDC laboratory personnel realize tests are being performed that should be performed elsewhere but maintained that it is easier to do the tests than to screen and reject requests. (See p. 10.)

Most of the 25 health care providers and 2 clinical laboratories visited by GAO said that they requested commercially available tests from State or CDC laboratories because CDC and many States perform the tests without charge. Further, they indicated that, although getting test results from CDC through the State takes longer than getting results from commercial laboratories, time is not usually a critical factor when such specimens are submitted to CDC. (See p. 10.)

ESSENTIAL PATIENT INFORMATION NOT PROVIDED TO CDC

In varying degrees, request forms accompanying the specimens sent to CDC for testing lacked information CDC considers necessary to determine the need for CDC testing and to provide meaningful test results. To illustrate, excluding specimens that could have been tested elsewhere, 13 percent of the remaining specimens in GAO's sample were not accompanied by any information on the patient's signs and symptoms, related illness, ongoing treatment, or epidemiologic implications. However, CDC laboratory personnel assume the tests they perform are needed and the test results are useful. (See pp. 8 and 11.)

According to various CDC and State laboratory personnel, when CDC accepts and tests specimens without adequate accompanying information, several adverse effects may result. For example,

--more elaborate or less precisely focused tests may be performed than would have been suggested by a patient's signs and symptoms, related illnesses, current treatment, etc.;

--opportunities may be missed to provide certain specimen requesters with diagnostic information that may be important to the diagnosis and treatment of particular patient diseases;

--opportunities may be missed to acquire information that is of epidemiologic significance; and

--tests may be performed for research or other purposes not essential for patient care. (See p. 9.)

## USER CHARGES SHOULD BE IMPOSED ON CERTAIN RECIPIENTS AND ADDITIONAL INTERAGENCY REIMBURSEMENTS SHOULD BE OBTAINED

In accordance with the User Charge Statute (31 U.S.C. 9701) and Office of Management and Budget guidance, CDC should be recovering the full cost of diagnostic testing services that it provides to private health care providers and clinical laboratories. In addition, the Economy Act (31 U.S.C. 1535) requires CDC to obtain reimbursement for the services provided to other Federal agencies. (See pp. 14 and 15.)

In fiscal year 1981, CDC collected no fees from private health care providers and clinical laboratories and only about $30,000 from the Veterans Administration for laboratory diagnostic services. Excluding the estimated cost of tests which should have been performed elsewhere, GAO estimates that in fiscal year 1981 CDC could have collected about $3.3 million in user charges from private health care providers and clinical laboratories and an additional $662,000 from the Veterans Administration, Department of Defense, and other Federal agencies. (See pp. 15 to 17.)

## RECOMMENDATIONS

GAO is making several recommendations to the Secretary of Health and Human Services directed toward having CDC (1) avoid performing laboratory diagnostic tests that should be performed elsewhere, (2) obtain information needed to determine the need for CDC's specialized testing and to provide meaningful test results, and (3) recover the cost of its services. (See pp. 13 and 17.)

## AGENCY COMMENTS

The Department of Health and Human Services agreed with some recommendations contained in the report, but disagreed that fees for testing services should be imposed on certain beneficiaries. (See pp. 19 to 25.)

# Contents

## ABBREVIATIONS

| | |
|---|---|
| CDC | Centers for Disease Control |
| GAO | General Accounting Office |
| HHS | Department of Health and Human Services |
| OMB | Office of Management and Budget |

# CHAPTER 1

## INTRODUCTION

In a March 26, 1982, letter, the Chairmen of the Senate Committee on Labor and Human Resources and the Subcommittee on Health and the Environment, House Committee on Energy and Commerce, expressed interest in our ongoing review of the Centers for Disease Control's (CDC's) laboratory diagnostic testing services program and requested that we report to them on opportunities to improve program management and assure more efficient and economical use of resources. (See app. I.) We had previously identified opportunities to recover the costs of certain laboratory services that CDC provides to Federal agencies and to non-Federal entities.[1]

### BACKGROUND

Within the Nation's health care delivery system, there are about 100,000 private clinical laboratories that examine specimens and provide diagnosis, prevention, or treatment information. The majority of the clinical laboratories are operated as part of individual or group physician practices. However, about 13,000 hospitals and independent laboratories provide diagnostic testing services to physicians, of which about 900 accept specimens on an interstate basis. Private clinical laboratories perform an estimated 10 billion tests annually for which they charge about $18 billion.

State and local public health agencies provide laboratory diagnostic tests as a part of their overall public health responsibilities. Many of the tests they perform are available commercially. These laboratories perform tests on an estimated 23 million specimens annually at an estimated cost of over $100 million although their testing capabilities vary.

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[1]On August 11, 1982, we issued a report entitled, "Centers for Disease Control Should Charge Fees for Various Diagnostic Laboratory Services" (GAO/HRD-82-70). The report discussed the need for CDC to collect user charges from non-Federal entities and to be reimbursed by other Federal agencies for five laboratory testing, evaluation, and training services. It excluded the issue of collecting fees for CDC's diagnostic laboratory specimen testing services because we saw a need to first perform an analysis of the necessity for certain of those services.

As part of its broad mission of assisting Federal, State, and local health authorities and other health-related organizations, CDC offers a backup, or reference, laboratory diagnostic testing service. CDC's reference testing is conducted by its Center for Infectious Diseases. In fiscal year 1981, CDC performed tests on about 103,000 reference diagnostic specimens at a cost of about $6.1 million.

## OBJECTIVES, SCOPE, AND METHODOLOGY

The objectives of our review were to determine if, and to what extent, CDC

- --performed tests of diagnostic specimens that initially should have been tested elsewhere,
- --tested specimens that were not accompanied by related patient information CDC considers necessary for justifying and appropriately conducting the tests, and
- --recovered the costs of testing services provided to non-Federal entities and to other Federal agencies.

Our review was performed in accordance with generally accepted government auditing standards and focused on CDC's laboratory diagnostic testing services that provide reference testing to public health laboratories, private health care providers, and private clinical laboratories. Throughout our review, we considered

- --the objectives of CDC's laboratory diagnostic testing services,
- --the nature and extent of testing services that users receive,
- --the availability of diagnostic testing services in the private sector and in State public health laboratories, and
- --legislation, Federal policy statements, court decisions, and other related material dealing with Federal imposition of user charges and interagency reimbursements.

We obtained the material contained in this report from (1) CDC program documents, a CDC automated data base, and interviews with CDC headquarters officials and laboratory personnel in Atlanta, Georgia; (2) 7 State public health laboratories; (3) 25 private health care providers; and (4) 8 interstate clinical laboratories.

After excluding specimens sent to CDC for proficiency testing, special research projects, or epidemiologic aid, we selected a statistically valid sample of 400 specimen records from CDC's remaining fiscal year 1981 automated data base of about 103,000 specimen records.[2] We used the sample to

--quantify the extent to which CDC was testing specimens that should have been tested elsewhere and the extent to which it was testing specimens without necessary accompanying patient information and

--project user charge receipts and interagency reimbursements.

We defined as unnecessary those tests CDC performed on specimens that should have been, but were not, initially tested by commercial and/or State laboratories. An unknown number of the specimens, had they been initially tested elsewhere and depending on the results, might have subsequently required testing by CDC. We made no determinations concerning the medical necessity for any test.

We compared published lists of diagnostic tests offered by CDC, State public health, and commercial laboratories to identify commonly performed tests. Those tests covered 37 diseases. (See app. II.) Subsequently, we identified from the sample specimen records at CDC the tests that could have been done elsewhere but had not been attempted before referral to CDC.

To confirm our analysis of specimen records, we also

--had the appropriate CDC laboratory unit review our interpretation of sample specimen records,

--had the seven State public laboratories in California, Florida, Georgia, Illinois, North Carolina, Tennessee, and Texas, which collectively account for 37 percent of the specimens CDC received in 1981, review all of our sample specimen records which originated from their States to determine whether State records would show evidence that prior test results, if any, warranted additional testing by CDC, and

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[2]A sample size of 400 from the total population of 103,000 results in the following sample attributes.

| | |
|---|---|
| --Confidence level, two sided | 95 percent |
| --Precision | 5 percent |

--had a total of 25 private practitioners and hospitals, and 2 clinical laboratories, judgmentally selected from the submitters identified in our sample, review specimen records for tests which they requested from CDC. In total, 42 specimen records, representing 23 percent of the 182 specimens we classified as unnecessary, were reviewed to further verify that prior testing had not been performed and that information did not exist to otherwise justify CDC's testing.

Because visiting a statistically valid random sample of States, practitioners, hospitals, and clinical laboratories was impractical, we selected for visit a more geographically concentrated number in the seven States mentioned above. Specimens from these States represented a significant portion of the specimens in our sample. We considered such a selection reasonable because results of initial specimen record analysis at CDC indicated a distribution of unnecessary tests among the States roughly proportionate to their share of total specimens submitted to CDC. (App. III shows, by State, CDC's total reference diagnostic specimen workload in fiscal year 1981 and our total specimen sample, including specimens unnecessarily tested.)

To estimate the cost of specimens unnecessarily tested by CDC, we used CDC's estimates of costs per specimen for performing specific tests and projected the cost using our sample results. We did not verify CDC's cost data.

To identify specimens sent to CDC but not accompanied by patient information CDC had said was necessary, we

--determined from CDC records and confirmed with CDC laboratory personnel that certain information was considered essential,

--reviewed specimen records for the presence of necessary information, and

--confirmed with the appropriate CDC laboratory unit that no other information on the specimens was available at CDC.

To estimate the amounts that could be recovered through user charges and interagency reimbursements, we obtained from CDC, but did not verify, reference diagnostic testing cost data for fiscal year 1981. We reduced that amount by the proportion of specimens unnecessarily tested by CDC (specimens that could have been tested elsewhere). Only that portion of the total costs attributable to services provided to private health care

providers and clinical laboratories were considered to be recoverable user charges. From information provided by CDC, we estimated the administrative costs CDC would incur in collecting the user charges discussed in the report but did not include this cost in the estimated user charge receipts.

# CHAPTER 2

# CDC SHOULD DISCONTINUE TESTING SOME SPECIMENS AND SHOULD OBTAIN ESSENTIAL SPECIMEN INFORMATION

CDC should discontinue performing for public health agencies, private health care providers, and clinical laboratories diagnostic tests that should be, at least initially, done elsewhere. In addition, when performing requested diagnostic tests, CDC should obtain from the requester sufficient related information to determine the need for CDC testing and to provide meaningful test results. To discontinue testing specimens that can be tested elsewhere and to otherwise better manage the use of its testing resources, CDC must better screen test specimens. CDC has taken certain corrective steps, but additional actions are needed.

## CDC POLICIES ON PROVIDING REFERENCE DIAGNOSTIC TESTING SERVICES

In providing reference diagnostic testing services, CDC's policy is to avoid providing services that are available elsewhere and to give special emphasis to uncommon, exotic, or imported diseases or to disease outbreaks with known or suspected epidemiologic significances. Specimens most likely to yield positive results and those from cases judged to be of public health importance are to be given highest priority. To adhere to that policy, CDC offers reference testing services to State and other public health laboratories and through States to private health care providers and clinical laboratories. Some direct submissions to CDC, bypassing a State laboratory, are permissible but are to occur only with the knowledge and consent of the State public health laboratory director.

CDC also emphasizes the importance of having the specimen accompanied by relevant information to determine the need for CDC testing as well as to provide meaningful test results. CDC's policy requires that each specimen submitted for testing be accompanied by a completed form which calls for, among other things, name and age of patient, source of specimen, disease or agent suspected, a brief clinical history, and the tentative identification of the microorganism involved, if available.

## UNNECESSARY TESTING AND INADEQUATELY DOCUMENTED REQUESTS FOR TESTING WIDESPREAD

Analyses of 400 sample specimen records and further inquiry showed that 46 percent of the specimens were unnecessarily tested by CDC because they could have been, but were not, initially tested by commercial or State laboratories. We estimate that the cost of unnecessary testing by CDC was about $1.9 million in fiscal year 1981. Most of the remaining specimens were not accompanied by all the specimen information CDC said it needed to determine the need for CDC testing and to provide the most meaningful test results.

### Specimens that should have been tested elsewhere

Our analysis of randomly selected specimen records, discussions with CDC laboratory personnel, and information obtained from hospitals, physicians, and interstate clinical laboratories showed that 182, or about 46 percent, of the sample specimens tested in CDC laboratories in fiscal year 1981 should have been tested, at least initially, in commercial or State laboratories. There were no accompanying indications that prior testing had been done or attempted and no adequate justification was presented for asking CDC to perform the tests.

As projected from our sample, the more frequently occurring tests by CDC that could have been done commercially included

--10,100 specimens for amebiasis (an intestinal parasitic disease),

--7,000 specimens, each tested for blastomycosis, coccidioidomycosis, and histoplasmosis (three fungal infections),

--5,700 specimens for cryptococcosis (a fungal infection),

--4,600 specimens for toxoplasmosis (a parasitic disease), and

--3,900 specimens for aspergillosis (a fungal infection).

Testing for toxoplasmosis more specifically illustrates unnecessary testing in CDC laboratories. Initial testing for the disease is commercially available, and many State laboratories also offer it. CDC routinely performs the initial test on any specimen it receives but can also perform a more sophisticated

test that provides more definitive information. Normally, such further testing is necessary only for those specimens with positive initial test results that are accompanied by certain other diagnostic information.

Forms accompanying 18 of the 23 toxoplasmosis specimens in our sample contained no indication that the initial test had been performed prior to referral to CDC. Of the 18, only 3 had positive results. CDC performed the more sophisticated test on those three, but CDC laboratory personnel said that the more sophisticated test was not justified by specimen information the requester provided.

Interviews with original submitters and State officials confirmed that the commercially available initial toxoplasmosis testing was not being performed prior to referral to CDC. For example, the Florida State laboratory, which can perform the initial test, was neither performing it nor requiring that it be done commercially. Instead Florida routinely referred specimens to CDC when submitters requested the more sophisticated test. Florida officials said that, since CDC routinely performs the initial test, they saw no need to perform it or to require that the original submitter have it performed commercially. However, specimens with negative results would not normally have required referral to CDC if available commercial or State tests had been done.

Specimens not accompanied by necessary information

In addition to testing specimens that could have been tested commercially or in State laboratories, CDC tested specimens that were not accompanied by necessary information concerning patient condition and treatment. According to CDC officials, information about the patient, such as signs and symptoms and any associated illness or ongoing treatment, along with information about the specimens, such as any prior test results, is necessary for determining the need to use CDC's limited reference testing resources and is important if CDC is to provide meaningful test results. Such information is requested on forms provided by CDC for use by the State in submitting specimens to CDC for diagnostic testings.

In varying degrees, most records accompanying our sample specimens lacked such information. Excluding the specimens that could have been tested in commercial or State laboratories, 97 percent of the remaining specimens in our sample were not accompanied by all such patient information as signs and symptoms, related illnesses, treatment information, and epidemiologic information. Thirteen percent of these specimens were not

accompanied by any patient condition or ongoing treatment information.

As projected from our sample, the more frequently occurring types of information requested but not provided by the requesters included about

--47,000 specimens tested without any "treatment" information,

--44,800 specimens tested without any "associated illness" information,

--44,200 specimens tested without any epidemiologic information, and

--19,100 specimens tested without any "signs and symptoms" information.

Specimens that were submitted to CDC without such information called for testing such diseases as Legionnaires' (a pneumonia type disease) and schistosomiasis, toxocara, and ascaris (parasitic diseases). According to various CDC and State laboratory personnel, when CDC accepts and tests such specimens without the necessary accompanying information, there may be several adverse effects. For example:

--More elaborate or less precisely focused tests may be performed than would have been suggested by the patient's signs and symptoms, related illnesses, current treatments, etc.

--Opportunities may be missed to give certain specimen submitters diagnostic information that is not requested but that may be important to the diagnosis and treatment of their particular patients. This should be particularly true if CDC is concentrating on uncommon, exotic, or imported diseases.

--Opportunities may be missed to acquire information that is of epidemiologic significance. In a June 1981 memorandum, one CDC official pointed out that, "There is no charge for our services and, therefore, the Center must receive something of value for its labor; that 'something' is relevant (specimen) information. In most cases the epidemiological significance of this information has more public health importance than the test itself and testing performed without the proper information is a waste of the Centers' time and of minimal value to anyone."

--Tests may be performed for some purposes other than reference diagnosis, such as responding to medical university students who submitted specimens for research purposes.

## NEED FOR BETTER SPECIMEN REFERRAL AND SCREENING PROCEDURES

CDC's performance of tests which should have been conducted elsewhere and its testing of specimens not accompanied by pertinent patient information has been due to weaknesses in its specimen screening procedures. CDC has recently taken some steps to improve both procedure design and enforcement, but additional actions are needed.

### Screening for commercially available tests

CDC specimen referral procedures generally require all specimens to come through State public laboratories for initial screening. CDC officials said they rely on States to screen out specimens that do not need testing by CDC. However, CDC screening criteria have excluded any specific requirement for ensuring that available tests are performed before specimens are referred to CDC.

Officials at the seven State public health laboratories and at CDC said they (1) assume testing, if available, is being performed prior to referral and (2) have not specifically screened specimens to make that determination. Most State officials said they generally refer a specimen to CDC if the original submitter's specimen was suitable for testing and if the State does not offer the test. Likewise, CDC laboratory personnel said they generally test any specimen they receive that is suitable for testing. Many CDC laboratory personnel said that they realize tests are being performed that should be initially performed elsewhere but that it was easier to do the tests than to screen and reject requests.

Although some health care providers we contacted said they were unaware that tests they were obtaining from CDC were commercially available, most said they requested such tests from State or CDC laboratories because CDC and many States perform the tests without charge. They explained further that getting test results from CDC through the State takes longer than getting results from commercial testing but that time is not a critical factor in most cases since such tests are usually done for confirmation of their clinical diagnoses. When a more immediate response is important, they generally send specimens to private laboratories.

Since early 1981, CDC has been working to improve specimen screening and to otherwise make more efficient use of its diagnostic testing resources. For example, CDC has discontinued several tests, published criteria designed to restrict certain other tests, and most recently published revised specimen referral procedures to help assure that commercially available tests are performed before specimens are referred to CDC. In general, the new referral procedures emphasize that CDC does not provide routine diagnostic testing services. More specific requirements for prior testing are prescribed for parasitology tests and for a few virology tests. However, according to CDC officials, CDC has not yet begun to enforce the new referral requirements because of resistance from States and from private health care providers. Still, CDC officials believe that they have made significant overall progress and point to total specimen workload reductions of about 10 percent annually since 1980.

## Collecting essential specimen information

States are not requesting the specimen information CDC needs, and private health care providers are not inclined to provide it. States are supposed to complete CDC's specimen information form when referring specimens, but all the seven States we visited collect specimen information on State forms that do not request sufficient information from providers for the States to complete CDC's form. Some private health care providers said that they would provide the information if requested, but most said that CDC's form would be too time consuming to complete and believe that a physician's request for a test should be enough justification.

State officials and CDC laboratory personnel said they assume that the tests performed by either the State or CDC are needed and that the test results are useful. As stated earlier, CDC laboratory personnel said that it is generally easier to perform the tests than to reject them for inadequate justifications.

CDC's recently revised referral procedures include greater emphasis on providing complete specimen information, stating that the absence of necessary information may result in the specimen being discarded or returned. CDC officials said that, due to the need to redesign the specimen information form and resistance from States and private health care providers, this policy is not yet being enforced except when, due to lack of information, CDC cannot determine what test is being requested.

Eliminating or controlling direct submissions

CDC, contrary to its policies, is accepting some reference specimens directly from private health care providers without State involvement. CDC's procedures call for submissions through the appropriate State laboratory unless bypassing the State laboratory is authorized by both CDC and the State. About 10 percent of the specimens in our sample were submitted directly to CDC by private health care providers. From within the seven States we visited, about 50 percent of our sample specimens that were submitted directly to CDC were submitted without State authorization. Among the sample specimens submitted directly, about 43 percent could have been tested commercially and thus should not have been tested initially by CDC.

Again, testing for toxoplasmosis illustrates the problem. Prior to taking our sample, we had identified more than 100 toxoplasmosis specimens originating from Georgia in fiscal year 1981 which bypassed the State laboratory without State authorization. Georgia's laboratory tests for toxoplasmosis and, as previously discussed, CDC offers a more sophisticated test which is generally needed only when the initial test is positive. Test results of only 2 of the 100 Georgia specimens were positive, indicating that 98 of the specimens did not need testing by CDC. Georgia State laboratory officials said that one reason for many direct submissions to CDC is that the State charges for its testing while CDC does not.

A long-standing special arrangement CDC has had with Mount Sinai Hospital in Chicago represents another direct submission problem. CDC annually accepts about 500 specimens taken from missionaries returning from overseas. CDC routinely performs the initial testing for a number of parasitic diseases on these specimens; yet the hospital, other private laboratories, and the Illinois public health laboratory can perform those tests. Illinois officials said that the State had authorized this arrangement when CDC originally needed the specimens for certain research. CDC officials explained that, because of the established routine of performing the tests, they continued to accept the specimens after the related research need no longer existed.

Officials from all the seven States we visited said that unauthorized direct submissions to CDC are a problem that only CDC can correct since the specimens bypass the States. In its revised referral procedures, CDC has reemphasized its policy on direct submissions but, at the time of our review, had not started enforcing it.

## CONCLUSIONS

CDC has performed routine testing of diagnostic specimens that could be tested elsewhere. Additionally, CDC has not obtained necessary information to justify and most effectively complete the tests that it does perform.

Such unnecessary testing and testing without adequate information has occurred basically because CDC's specimen screening procedures are inadequate. CDC has taken some actions to correct the problems of unnecessary testing and inadequate information, but additional actions are needed.

## RECOMMENDATIONS TO THE SECRETARY OF HEALTH AND HUMAN SERVICES

We recommend that the Secretary require the Director of CDC to improve and enforce diagnostic specimen screening procedures.

More specifically, we recommend that CDC be directed to prepare, and maintain on a continuing basis, a list of diagnostic tests which it and commercial or State laboratories can perform. Such a list would be used during specimen screening at the State and CDC laboratory levels to identify those specimens which should be tested initially at a commercial or State laboratory rather than CDC.

Also, in view of CDC's emphasis on the importance of having a specimen accompanied by relevant information needed to determine the need for CDC testing as well as to provide meaningful test results, we recommend that CDC not accept specimens for testing that are not accompanied by all available information requested on the forms provided by CDC for use in submitting specimens.

Finally, we recommend that CDC not accept specimens for testing which are submitted directly from private health care providers and clinical laboratories unless such submissions are authorized by both CDC and the State laboratory.

# CHAPTER 3

# CDC SHOULD CHARGE FEES FOR CERTAIN DIAGNOSTIC TESTING SERVICES

CDC should be recovering the full cost of diagnostic testing services which it provides to private industry and to other Federal agencies. Excluding the estimated cost of unnecessary tests, CDC could have collected about $3.3 million in user charges from private health care providers and clinical laboratories and about $662,000 in additional reimbursements from Federal agencies for diagnostic testing services it provided in fiscal year 1981. The cost to collect both user charges and interagency reimbursements should also be recovered by CDC.

## FEDERAL POLICY CALLS FOR USER CHARGES AND INTERAGENCY REIMBURSEMENTS

With certain exceptions, user charges are to be imposed by Federal agencies for services that benefit identifiable non-Federal recipients above and beyond any benefits that accrue to the general public. Also, agencies are to be reimbursed for the actual cost of services provided to other Federal agencies.

Federal agencies are granted general authority to establish user charges for services provided to identifiable non-Federal recipients under 31 U.S.C. 9701, commonly known as the User Charge Statute. Essentially, the statute states that certain services provided to non-Federal recipients should be self-sustaining to the fullest extent possible and authorizes the head of each Federal agency to prescribe charges to recover the Government's cost for providing such services.

Office of Management and Budget (OMB) Circular A-25 interprets and implements the User Charge Statute. The OMB Circular states that:

> --A charge, which recovers the full cost to the Federal Government, should be imposed for a service (or privilege) which provides special benefits to an identifiable recipient above and beyond those which accrue to the general public. A charge should be imposed when a service (1) enables the beneficiary to obtain more immediate or substantial gains or values (not necessarily monetary) than those which accrue to the general public, (2) provides business stability or assures public confidence in the business activity of the beneficiary, or (3) is performed at the recipient's request and is above and beyond the services regularly received by other members of the same industry or group or by the general public.

--A charge should not be imposed for a service when the identity of the ultimate beneficiary is obscure and the service can be primarily considered as broadly benefiting the general public.

The Circular provides further that, in setting or adjusting charges, agencies may make exceptions to the general policies when

--the cost of collecting the fees would be an unduly large part of the receipts from the service;

--furnishing the service free is an appropriate courtesy to a foreign country or international organization, or comparable fees are set on a reciprocal basis with a foreign country;

--the recipient is engaged in a nonprofit activity designed for public safety, health, or welfare; or

--payment of the full fee by a State or local government or nonprofit group would not be in the program's interest.

In addition to collecting user charges from non-Federal entities, agencies are required to obtain reimbursement for the actual cost of services provided to other Federal agencies, as prescribed by the Economy Act (31 U.S.C. 1535).

OMB Circular A-25 requires that user charge revenues be returned to the Treasury as miscellaneous receipts. However, the Circular allows an agency to seek legislative authority to retain user charge revenues for its own use under certain circumstances. Funds received by one Federal agency from another agency for services provided under the Economy Act are generally retained by the agency providing the services.

## CDC'S DIAGNOSTIC TESTING SERVICES MEET COST RECOVERY REQUIREMENTS

Under provisions of OMB Circular A-25, CDC should charge for the diagnostic testing services it provides to private entities. Charging is appropriate because test results are intended to provide beneficial diagnostic information to identifiable private recipients. CDC should also be reimbursed for testing services provided to other Federal agencies, as prescribed by the Economy Act.

CDC provides diagnostic testing services, at no charge, to various non-Federal entities, including State and other non-Federal public health agencies, private health care providers,

and private clinical laboratories. CDC clearly should charge private health care providers and clinical laboratories. Although not charging State and other non-Federal public health agencies may be justified in view of the exceptions in OMB Circular A-25, CDC is responsible for determining the extent to which other non-Federal recipients should be charged.

CDC program officials told us that charges have not been imposed on non-Federal entities because CDC is providing backup diagnostic testing, not otherwise available, for the general public's benefit. They said that such service is exempt from user charge requirements. More specifically, the officials claim exemption under the OMB Circular provision that no charge should be made for services when the identification of the ultimate beneficiary is obscure and the service can be primarily considered as broadly benefiting the general public.

In CDC's view its purpose in providing such services is to make testing services available to the general public. We do not dispute CDC's assessment of its function, and we recognize that the public ultimately receives a benefit from CDC's testing services. We believe, however, that CDC should charge user fees to the identifiable private health care providers and clinical laboratories that receive its diagnostic testing services because they receive special benefits beyond those accruing to the public at large. Those recipients gain requested diagnostic information that is intended to be of benefit in compensable individual patient treatment. We believe therefore that charging user fees to specific identifiable recipients of special diagnostic services is consistent with CDC's function and with the provisions of OMB Circular A-25.

CDC could have recovered an estimated $3.3 million in user charges for the reference diagnostic services it provided to private health care providers and clinical laboratories in fiscal year 1981. That estimate is derived from projecting our sample results and using cost data provided by CDC. Excluding the 46 percent of our sample found to be unnecessarily tested and another 3 percent of our sample specimens not tested by CDC for various reasons, the remaining specimens tested by CDC were conducted for

--private health care providers and clinical laboratories (33 percent),

--other Federal agencies (8 percent),

--State and local governments or other entities providing public health services (7 percent), and

--submitters whose identities were not reported to CDC (3 percent).

The $3.3 million which could have been recovered from private health care providers and clinical laboratories is more than 33 percent of the $6.1 million CDC expended for reference diagnostic services because, according to CDC data, the tests we considered to be unnecessary tended to be less expensive to perform. Consequently, the remaining tests, including those tests conducted for private health care providers and clinical laboratories, represented a disproportionally larger share of the overall costs. The cost to collect reference diagnostic services provided to private entities would be $69,000 annually, or about 2 percent of the estimated revenues.

In addition to recovering testing costs from non-Federal entities, CDC should obtain full reimbursement for services provided to other Federal agencies as prescribed by the Economy Act. The act provides for no exceptions. In fiscal year 1981, CDC recovered about $30,000 from the Veterans Administration (VA) but could have recovered an additional $662,000 from VA, the Department of Defense, and other Federal agencies that received testing services.

## CONCLUSIONS

We believe that CDC's reference diagnostic testing services meet Federal cost recovery requirements. Based on CDC's fiscal year 1981 workload, and excluding those specimens that were unnecessarily tested, we estimate that CDC could collect about $3.3 million annually for the cost of testing services provided to private health care providers and clinical laboratories.

We recognize that certain public benefits accrue from CDC's testing services. However, in certain situations, benefits also accrue to identifiable private health care providers and clinical laboratories which are above and beyond those accruing to the general public. In these situations, the User Charge Statute provides for the collection of the full costs of the services provided.

CDC could have also recovered an additional $662,000 from other Federal agencies during fiscal year 1981.

## RECOMMENDATIONS TO THE SECRETARY OF HEALTH AND HUMAN SERVICES

We recommend that the Secretary require the Director of CDC to recover the total cost of laboratory diagnostic testing

services provided to private beneficiaries and other Federal agencies and to determine the extent to which other non-Federal agencies should be charged. More specifically, we recommend that CDC be directed to

--charge private health care providers and private clinical laboratories for diagnostic testing,

--determine the extent to which other non-Federal recipients of CDC's testing services should be charged by applying the provisions of the User Charge Statute and OMB Circular A-25, and

--charge all Federal agencies for diagnostic testing.

## CHAPTER 4

## AGENCY COMMENTS AND OUR EVALUATION

In a March 15, 1983, letter, the Department of Health and Human Services (HHS) provided comments on a draft of this report. (See app. IV.) HHS agreed with some recommendations contained in the report, but disagreed that fees for testing services should be imposed on certain beneficiaries.

### SCREENING PROCEDURES FOR DIAGNOSTIC SPECIMENS SUBMITTED TO CDC

In commenting on our report, HHS concurred with our recommendation that CDC improve and enforce its diagnostic specimen screening procedures, and said that this is an ongoing activity. HHS said that high priority had been given to this effort since a CDC reorganization in December 1980. HHS indicated that CDC distributed guidelines to the States in February 1983 for their use in screening submissions of specimens to CDC. These guidelines include a justification checklist that must be completed by the State before specimens can be accepted for testing at CDC. HHS attributed the declining trend, evidenced since 1979, in specimen workload to CDC's revised acceptance criteria.

We recognized in the report (see p. 10) that CDC had initiated steps to reduce unnecessary diagnostic testing. As stated in the report, however, CDC's revised referral procedures were not being enforced due to resistance from States and private health care providers.

The February 1983 guidelines formalized the policy and procedures which CDC had attempted to implement since 1981, but was not enforcing at the time of our review. Although CDC's justification checklist is an improvement, it will not, by itself, ensure improvement in CDC's specimen screening procedures. For example, previous laboratory results, if any, are now required with specimen submissions, but there is no requirement for evidence to be submitted with the specimen showing that attempts were made to have specimens tested at other sources before submitting them to CDC.

Reductions in the number of specimens unnecessarily tested will result only if CDC personnel comply with the revised guidelines and checklist.

While HHS cited the downward trend in specimens submitted to CDC to support its belief that CDC's specimen screening was effective, it failed to speak to the fact that

--CDC tested all specimens received that were suitable for testing,

--State laboratories send to CDC for testing all specimens that they do not test themselves, and

--an estimated 46 percent of the tests performed by CDC should have been, but were not, tested elsewhere.

HHS concurred, with reservations, with our recommendation that CDC prepare, and maintain on a continuing basis, a list of diagnostic tests which it and commercial or State laboratories can perform. In this regard, HHS believes that unnecessary diagnostic tests using commercially available reagents (chemical substances needed to conduct certain tests) should not be performed at CDC. However, HHS points out that emphasis must be placed on why the tests are being requested rather than whether they can be performed commercially. According to HHS, CDC does not accept specimens for routine diagnostic testing when commercial reagents are available. Specimens will be accepted, however, if it is suspected that they involve a cluster of infections or meet a public health need. In HHS' view, only a list of commercial reagents is necessary and only if the maintenance of this list is consistent with available resources.

We do not agree that maintaining a list of commercially available reagents is adequate. During our review, we found that various commercial and State laboratories produce their own reagents that may or may not be commercially available and that tests were being performed using reagents that CDC said were not commercially available. Additionally, many tests do not require reagents. For example, direct microscopy examinations do not generally require reagents. Thus, we believe that CDC should maintain lists of tests available from commercial and State laboratories to assure that it does not perform unnecessary tests. We believe that preparing and maintaining a list of available tests is necessary for CDC screening purposes and can be accomplished with minimal, if any, additional resources. In fact, the interstate and State laboratories we visited maintained lists of the tests they performed.

Further, while we agree that emphasis should be placed on why tests are being requested, information to answer this question is frequently unavailable at CDC. For example, we found that of the 182 of the 400 sample specimens which we determined could have been initially tested elsewhere, none had prior test results, only 8 had treatment information, 20 had epidemiologic information, 30 had signs and symptoms, 38 had associated illness information, 46 had the date of illness onset, and 134 had the date the specimen was taken.

HHS' statement that CDC does not accept specimens for routine diagnostic testing is contrary to what we found in our analysis of 400 randomly selected specimens. As discussed in chapter 2, our analysis of the 400 specimens indicated that 46 percent of the specimens submitted to CDC in fiscal year 1981 for reference diagnostic testing should have been, but were not, tested initially in a commercial or State laboratory.

In commenting further on this recommendation, HHS expressed concern with our estimate that 46 percent of the specimens tested by CDC, at a cost of about $1.9 million, in fiscal year 1982 were unnecessarily conducted. HHS said that:

--A wide variety of laboratory tests can be performed for each of the 37 diseases used in our analysis.

--The availability and reliability of tests from commercial and State laboratories for the diseases used in our analysis varies considerably and change over time.

--Requests for reference diagnostic services which do not indicate that previous tests were performed can mean that (1) the tests that were available to the sender were not appropriate for the particular disease, (2) no tests were available at the time laboratory information was needed, or (3) CDC and States are collaborating in an investigation.

Our analysis took the above factors into consideration. As discussed in our report, we did not conclude that tests could have been done elsewhere after merely identifying commonly performed tests for 37 diseases which CDC, State public health, and commercial laboratories can perform. To confirm that 182 sample specimens could have been initially tested elsewhere, we provided CDC with copies of available CDC specimen records to confirm that information on prior testing was not shown in these records. CDC laboratory officials could neither determine from these records whether previous testing had been performed, nor explain why the specimens were submitted to CDC. We confirmed that prior testing could have been, but was not, performed by having State laboratory officials in seven States, and clinical laboratories and health care providers in those States who originally submitted the specimens, review CDC's records and their own for selected specimens. Finally, we excluded those specimens submitted to CDC for proficiency testing, special projects, or epidemiologic aid before selecting our sample specimens.

## OBTAINING ESSENTIAL SPECIMEN INFORMATION

HHS agreed that CDC should not accept specimens for testing that are not accompanied by all available information requested on the CDC form. However, HHS said that CDC never intended that all the information requested on the present form be provided and indicated that CDC was (1) developing a simplified version of the specimen form to make the information needs more apparent and (2) making related changes in computer software.

CDC's recently issued guidelines for acceptance of reference diagnostic specimens indicate what specimen information is "required," "useful," or may be provided based on the submitter's judgment of the relevance of the information. We believe the simplified form being developed should be designed so that it can be used (1) for screening purposes and (2) to provide needed information about the specimen, the test requested, or the patient.

HHS agreed that CDC should not accept specimens for testing which are submitted directly from private health care providers and clinical laboratories except for previously arranged collaborative work with CDC scientists or when a delay would be harmful to the patient. HHS said that this is CDC's present policy.

This direct submission policy was CDC's policy during 1981 but, as discussed in chapter 2, we estimate that 10 percent of the specimens submitted in 1981 were submitted directly from private health care providers or clinical laboratories but did not fit into either of the exception categories cited by HHS.

## CHARGING FEES FOR CERTAIN DIAGNOSTIC TESTING SERVICES

HHS disagreed with our recommendations to (1) charge private health care providers and private clinical laboratories for diagnostic testing and (2) determine the extent to which other non-Federal recipients of CDC's testing services should be charged. In regard to the first recommendation, HHS indicated that it would not be practical or cost effective to implement this recommendation. HHS stated that the latter recommendation concerned an issue which had been previously explored and it concluded that the provisions of the User Charge Statute and OMB Circular A-25 do not apply to CDC activities.

We believe the implementation of these recommendations is practical, cost effective, and consistent with the provisions of the User Charge Statute and implementing guidance to agencies contained in OMB Circular A-25.

In commenting on its belief that collecting user charges would not be practical or cost effective, HHS said

> "GAO projects that 33 percent of specimens tested by CDC were submitted by private health care providers and clinical laboratories. CDC's computer records, however, show that this total should be 7 percent. Further, at least half of these include specimens submitted by collaborating scientists for epidemiologic or laboratory research studies * * *."

HHS stated also that

> "With well over 90 percent of specimens shipped to CDC by the States and other authorized institutions, it is neither possible nor desirable to charge private health care providers and private clinical laboratories for reference diagnostic testing."

HHS stated further that its new guidelines

> "should reduce significantly the already small percentage of specimens from private providers and clinical laboratories. Although the previous percentage was small, it represented a large number of providers and laboratories, and the extensiveness of billing would render charging impractical and not cost effective."

HHS has apparently misinterpreted the data in our draft report. Based on our sample, we estimate that about 70 percent of CDC's workload was submitted by private health care providers and clinical laboratories, after excluding those tests submitted for epidemiologic or laboratory research studies. As discussed earlier, much of what was submitted should not have been tested at CDC because prior testing, though available, had not been performed. The 33 percent used by GAO represents that portion of CDC's total workload that was appropriately tested by CDC, and for which a fee should have been charged. After excluding unnecessary tests, the submissions by private health care providers and clinical laboratories represent about 65 percent of the workload appropriately sent to CDC. The 7 percent referred to by HHS is, in fact, the percentage of the total workload that CDC's computer records show were submitted directly to CDC by private providers and laboratories. This, however, excludes submissions from private providers and laboratories that were channeled to CDC through the States. The 33 percent we used included both. To do otherwise, would understate both the use made of CDC by these providers and laboratories and the potential user fee collections.

As discussed on page 15 of our report, OMB Circular A-25 sets the criteria for judging the cost effectiveness of collecting charges. The Circular states that an agency may make an exception to charging user fees when the cost of collection would be an unduly large part of the receipts. CDC has estimated that the cost to collect charges for diagnostic testing would be about $69,000 annually, or 2 percent of the estimated receipts. Two percent is not an unduly large part of the estimated receipts.

As discussed in chapter 3 of our report, we believe that the provisions of the User Charge Statute and the implementing guidance to agencies contained in OMB Circular A-25 apply to CDC activities. More specifically, we believe the Director of CDC should recover the total cost of laboratory diagnostic testing services provided to identifiable private health care providers and clinical laboratories because they receive special benefits beyond those accruing to the public at large. These groups use CDC's test results, provided at no charge, in compensable individual patient treatment.

HHS agreed that CDC should charge other Federal agencies for diagnostic services except for specimens submitted as part of a collaborative study. However, HHS said that our report overstated the amount that could be collected from other Federal agencies. Among the factors questioned by HHS were the number of specimens tested for Federal agencies by CDC and the costs per specimen test, which vary depending on the complexity of the tests.

Regarding the issue of cost recovery, the difference in the amounts cited by us ($662,000) and HHS ($272,647) is attributable to our use of the direct and indirect costs of the specific tests performed and HHS' use of the average cost of all tests. To demonstrate the order of magnitude of the potential cost recoveries, we originally used CDC's average direct and indirect costs. At an audit closeout meeting with CDC officials in January 1983, they objected to the use of average costs and provided cost data for each type of test conducted. We used these data in the draft report submitted to HHS for review and comment. HHS' lower estimate of potential cost recoveries results from the use of the average cost of all tests. Our review indicated, however, that Federal agencies tended to request complex tests that had higher unit costs. If HHS had included recoveries from Public Health Service clinics, as we advocate, the amount to be recovered using average costs increases from $272,647 to $387,280. However, since the costs of specific tests are known, we believe they should be used and, based on the specific tests performed in 1981, could have resulted in recoveries of about $662,000.

In conclusion, HHS said that we did not place a dollar value on or measure the benefits of CDC's diagnostic testing program to the Federal Government and the general public and did not consider the cost to the Government should the program change. Descriptions of several special research projects were provided to illustrate these benefits. HHS stated also that CDC's reference diagnostic services provided only incidental benefits to identifiable recipients above and beyond those which accrue to the general public.

We recognize the achievements cited and that the public ultimately may benefit from CDC's testing services. However, as stated previously all specimens associated with projects similar to those cited by HHS were excluded during our analyses and projections relating to CDC's reference diagnostic testing program. Additionally, CDC laboratory personnel said that specimens received through CDC's reference testing services generally are not useful in research. We question, therefore, HHS' assumption that charging fees for testing specimens that were unsolicited and unrelated to ongoing research programs will adversely affect CDC's program and mission.

APPENDIX I



United States Senate
COMMITTEE ON LABOR AND
HUMAN RESOURCES
WASHINGTON, D.C. 20510

March 26, 1982

Mr. Charles Bowsher
Comptroller General of the United
States
United States General Accounting Office
Washington, D. C. 20458

Dear Mr. Bowsher:

The Senate Committee on Labor and Human Resources and the House Subcommittee on Health and Environment have maintained a continuing interest in your staff's efforts to identify weaknesses in Federal programs to improve operations at the Centers for Disease Control (CDC). Periodic briefings to our Committee staffs on this matter by representatives of your office have assisted us in this regard.

In late February, your staff told us that they had identified a number of management weaknesses involving CDC's laboratory diagnostic services program. These weaknesses were identified during an ongoing audit which addresses CDC's opportunity to recover the costs of services provided to certain manufacturers, clinical laboratories, and private health care providers.

If further inquiry by your staff into CDC's laboratory diagnostic services program substantiates the information developed to date, opportunities will exist for CDC to improve the management of this program, and assure more efficient and economical use of its resources. Therefore, we encourage your staff to continue its review of the CDC's laboratory diagnostic services program and request that we be provided a report on the results of your review.

The Committee staffs remain available to discuss this overall subject area.

Sincerely,

Orrin G. Hatch
Chairman, Committee on Labor
and Human Resources

Henry A. Waxman
Chairman, Subcommittee on Health
and the Environment

OGH:HAW:dtb

## DISEASES FOR WHICH CDC, STATE PUBLIC HEALTH, AND PRIVATE LABORATORIES OFFER TESTS

### Bacterial Diseases

- Brucellosis
- Gonorrhea
- Leptospirosis
- Salmonellosis
- Shigellosis
- Streptococcal
- Syphilis
- Tuberculosis
- Tularemia
- Tetanus
- Diphtheria
- Meningitis

### Fungal Diseases

- Aspergillosis
- Blastomycosis
- Candidiasis
- Coccidioidomycosis
- Cryptococcosis
- Histoplasmosis
- Sporotrichosis

### Parasitic Diseases

- Amebiasis
- Malaria
- Toxoplasmosis
- Echinococcosis
- Trichinosis

### Viral Diseases

- Influenza type A,B,C
- Mumps
- Mycoplasma Pneumoniae
- Respiratory syncytial
- Herpes virus
- Rubella
- Rubeola (measles)
- Q fever
- Typhus
- Rocky Mountain Spotted Fever
- Hepatitis A
- Hepatitis B
- Hepatitis Be

## CDC'S TOTAL SPECIMEN WORKLOAD AND GAO'S SAMPLE SPECIMEN RESULTS BY STATE

(FISCAL YEAR 1981)

| State: | CDC specimen workload | | GAO specimen sample | | | |
|---|---|---|---|---|---|---|
| | Number | Percent | Number | Percent of GAO total sample | Number of unnecessary tests | Percent of GAO total sample |
| Alabama | 1,796 | 1.74 | 11 | 2.75 | 3 | 0.75 |
| Alaska | 1,100 | 1.07 | 2 | 0.50 | 0 | 0.00 |
| Arizona | 1,703 | 1.65 | 8 | 2.00 | 4 | 1.00 |
| Arkansas | 791 | 0.77 | 4 | 1.00 | 0 | 0.00 |
| California * | 5,708 | 5.53 | 19 | 4.75 | 11 | 2.75 |
| Colorado | 2,753 | 2.67 | 10 | 2.50 | 5 | 1.25 |
| Connecticut | 2,655 | 2.57 | 6 | 1.50 | 5 | 1.25 |
| Delaware | 233 | 0.23 | 0 | 0.00 | 0 | 0.00 |
| District of Columbia | 1,270 | 1.23 | 4 | 1.00 | 1 | 0.25 |
| Florida * | 5,332 | 5.17 | 18 | 4.50 | 11 | 2.75 |
| Georgia * | 9,232 | 8.95 | 39 | 9.75 | 17 | 4.25 |
| Hawaii | 1,021 | 0.99 | 6 | 1.50 | 2 | 0.50 |
| Idaho | 752 | 0.73 | 2 | 0.50 | 2 | 0.50 |
| Illinois * | 6,561 | 6.36 | 30 | 7.50 | 17 | 4.25 |
| Indiana | 1,311 | 1.27 | 4 | 1.00 | 0 | 0.00 |
| Iowa | 1,366 | 1.32 | 4 | 1.00 | 1 | 0.25 |
| Kansas | 1,763 | 1.71 | 9 | 2.25 | 5 | 1.25 |
| Kentucky | 1,099 | 1.07 | 3 | 0.75 | 1 | 0.25 |
| Louisiana | 1,364 | 1.32 | 6 | 1.50 | 3 | 0.75 |
| Maine | 518 | 0.50 | 3 | 0.75 | 1 | 0.25 |
| Maryland | 2,165 | 2.10 | 9 | 2.25 | 6 | 1.50 |
| Massachusetts | 2,711 | 2.63 | 8 | 2.00 | 1 | 0.25 |
| Michigan | 1,427 | 1.38 | 9 | 2.25 | 6 | 1.50 |
| Minnesota | 1,863 | 1.81 | 10 | 2.50 | 1 | 0.25 |
| Mississippi | 1,444 | 1.40 | 6 | 1.50 | 6 | 1.50 |

*States visited by GAO.



APPENDIX III

| State: | CDC specimen workload | | GAO specimen sample | | | |
|---|---|---|---|---|---|---|
| | Number | Percent | Number | Percent of GAO total sample | Number of unnecessary tests | Percent of GAO total sample |
| Missouri | 2,787 | 2.70 | 9 | 2.25 | 2 | 0.50 |
| Montana | 477 | 0.46 | 1 | 0.25 | 1 | 0.25 |
| Nebraska | 522 | 0.51 | 1 | 0.25 | 0 | 0.00 |
| Nevada | 415 | 0.40 | 6 | 1.50 | 1 | 0.25 |
| New Hampshire | 700 | 0.68 | 1 | 0.25 | 0 | 0.00 |
| New Jersey | 2,495 | 2.42 | 7 | 1.75 | 4 | 1.00 |
| New Mexico | 625 | 0.61 | 5 | 1.25 | 2 | 0.50 |
| New York | 3,033 | 2.94 | 9 | 2.25 | 5 | 1.25 |
| North Carolina* | 3,600 | 3.49 | 22 | 5.50 | 10 | 2.50 |
| North Dakota | 595 | 0.58 | 2 | 0.50 | 1 | 0.25 |
| Ohio | 1,174 | 1.14 | 1 | 0.25 | 1 | 0.25 |
| Oklahoma | 1,930 | 1.87 | 9 | 2.25 | 3 | 0.75 |
| Oregon | 1,262 | 1.22 | 6 | 1.50 | 0 | 0.00 |
| Pennsylvania | 2,061 | 2.00 | 5 | 1.25 | 2 | 0.50 |
| Rhode Island | 419 | 0.41 | 0 | 0.00 | 0 | 0.00 |
| South Carolina | 1,160 | 1.12 | 3 | 0.75 | 2 | 0.50 |
| South Dakota | 1,578 | 1.53 | 3 | 0.75 | 2 | 0.50 |
| Tennessee* | 4,393 | 4.26 | 18 | 4.50 | 12 | 3.00 |
| Texas* | 3,097 | 3.00 | 12 | 3.00 | 5 | 1.25 |
| Utah | 588 | 0.57 | 1 | 0.25 | 1 | 0.25 |
| Vermont | 377 | 0.37 | 1 | 0.25 | 0 | 0.00 |
| Virginia | 2,224 | 2.16 | 9 | 2.25 | 5 | 1.25 |
| Washington | 1,700 | 1.65 | 8 | 2.00 | 4 | 1.00 |
| West Virginia | 855 | 0.83 | 1 | 0.25 | 1 | 0.25 |
| Wisconsin | 960 | 0.93 | 9 | 2.25 | 4 | 1.00 |
| Wyoming | 188 | 0.18 | 0 | 0.00 | 0 | 0.00 |
| International | 5,733 | 5.56 | 19 | 4.75 | 5 | 1.25 |
| Total | a/102,886 | 99.76 | 400 | 100.0 | 182 | 45.50 |

a/This figure does not include 248 specimens tested by CDC, but not by its Center for Infectious Diseases.

*States visited by GAO.



APPENDIX III

DEPARTMENT OF HEALTH & HUMAN SERVICES Office of Inspector General

MAR 14 1983

Mr. Philip A. Bernstein
Director, Human Resources
Division
United States General
Accounting Office
Washington, D.C. 20548

Dear Mr. Bernstein:

The Secretary asked that I respond to your request for our comments on your draft of a proposed report "Centers for Disease Control Should Discontinue Certain Diagnostic Tests and Charge for Others." The enclosed comments represent the tentative position of the Department and are subject to reevaluation when the final version of this report is received.

We appreciate the opportunity to comment on this draft report before its publication.

Sincerely yours,

Richard P. Kusserow
Inspector General

Enclosure

APPENDIX IV

## COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES ON THE GENERAL ACCOUNTING OFFICE'S DRAFT REPORT "CENTERS FOR DISEASE CONTROL SHOULD DISCONTINUE CERTAIN DIAGNOSTIC TESTS AND CHARGE FOR OTHERS," DATED JANUARY 26, 1983

### GENERAL COMMENTS

The Centers for Disease Control's (CDC) Reference Diagnostic Services program, discussed by this General Accounting Office (GAO) report, exists to provide a foundation for a successful nationwide program for preventing and controlling infectious diseases. As discussed in our comments to the GAO recommendations which follow, certain of GAO conclusions are based on stale data or erroneous data interpretations.

For clarity, we have organized the individual recommendations and our responses around GAO's three principal conclusions.

A. CDC accepts and tests specimens unnecessarily.

B. Many tests are performed without information available regarding the patient's condition or ongoing treatment.

C. Certain user charges should be recovered.

### GAO CONCLUSIONS:

### A. CDC SHOULD DISCONTINUE TESTING SOME SPECIMENS, B. CDC SHOULD OBTAIN ESSENTIAL SPECIMEN INFORMATION

#### GAO Recommendation

1) --We recommend that the Secretary require the Director of CDC to improve and enforce diagnostic specimen screening procedures.

#### Department Comment

We concur; this is an ongoing activity. The improvement and enforcement of diagnostic screening specimen procedures is an ongoing process and one which has been given high priority One of the stated purposes of the CDC reorganization in December 1980 was to provide more efficient integration of laboratory and epidemiologic activities. Significant changes have occurred--beginning before the inception of the GAO study--which are not reflected in this report.

In February 1981, an ad hoc advisory group was convened to review priorities for CDC's newly formed Center for Infectious Diseases (CID), including an evaluation of reference diagnostic service policy. In April 1981, the Director of CID met with the Association of State and Territorial Public Health Laboratory Directors (ASTPHLD) and informed them of (1) the recommendations of the advisory group, (2) CDC's plans for developing acceptance criteria for specimens, and (3) certain services that were being discontinued. Revised draft guidelines were presented to ASTPHLD in April 1982 and sent to all State Health Department Laboratory Directors for review and comment in May 1982. During this period, the Director of CID visited nine representative State laboratories to discuss reference diagnostic service policies. Modifications were made in the guidelines in response to State comments and noncompliance notifications were extended until publication of the final guidelines. The guidelines, including a justification check list that must be completed by the State before specimens can be accepted at CDC, were distributed in February 1983.

The number of specimens submitted to CDC for reference diagnostic testing has been decreasing since 1979 and dropping significantly since 1981--a trend resulting from CDC's revised acceptance criteria.

CDC's revised acceptance criteria reflect the six overall priorities CDC established in collaboration with the States for provision of reference diagnostic services.

a. Clinical specimens to aid in the diagnosis of life-threatening, unusual, or exotic infectious diseases.

b. Cultures and/or paired serum specimens, or tissues or histologic specimens, from patients suspected of having unusual or rarely encountered infectious diseases.

c. Cultures or serum specimens obtained from patients who have infectious diseases that occur only sporadically or who are involved in an outbreak due to an organism for which testing reagents are not commercially or widely available.

d. Organisms that (1) cannot be identified, (2) are isolated from normally sterile anatomic sites, or (3) are isolated repeatedly from one or more sites of the same patient or group of patients.

APPENDIX IV

e. Organisms that have atypical phenotypic characteristics, do not appear to be "usual" pathogens, or are associated with nosocomial (hospital acquired) infections.

f. Serum specimens or cultures that are clinically important and are sent to CID for confirmation because the results in State laboratories were bizarre or difficult to interpret, or difficulties were encountered with the reagents used.

As indicated, these priorities for services were under development prior to initiation of the GAO evaluation and have been distributed to all States along with complete guidelines for submission of specimens.

GAO Recommendation

2) --More specifically, we recommend that CDC be directed to prepare, and maintain on a continuing basis, a listing of diagnostic tests which it and commercial or State laboratories can perform. Such a listing would be used during specimen screening at the State and CDC laboratory levels to identify those specimens which should be tested initially at a commercial or State laboratory rather than CDC.

Department Comment

We concur with certain reservations. As indicated above, one of the six criteria used by CDC to accept specimens for testing specifies that specimens are for diseases for which reagents are not commercially or widely available. In this regard, we concur that unnecessary diagnostic tests utilizing commercially available reagents should not be performed at CDC--and as consistent with available resources we will maintain a listing of those reagents in commercial use for determining whether CDC testing is necessary. Nevertheless, emphasis must be placed on why the tests are being requested, not whether the tests can be performed commercially. CDC does not accept specimens for routine diagnostic tests for which reagents are available. They will be accepted, however, if it is suspected that the specimens involve a cluster of infections or meet a public health need. Requests by the States for tests in a disease outbreak often involve a battery of tests, some of which may be available commercially. As noted previously, a completed justification checkoff is now being required for each specimen and will make it possible to confirm the purpose or reason for sending the specimen to CDC.

Consistent with available resources, CDC will maintain a list of commercial reagents. However, we have certain reservations. Manufacturers frequently advertise reagents well in advance of their availability, or they may be withdrawn without notice. Offer of a manufacturer to sell also does not mean acceptance by all laboratories. Time is required for laboratories to develop confidence in a reagent. A delay of several years is common before reagents are accepted as being reliable. We provide training and technical assistance to State and other laboratories to expedite the acceptance of new technology. Routine reference services are terminated when it appears that a new technology is sufficiently diffused and accepted.

We have reservations too with the GAO estimate that 46 percent of the specimens tested by CDC, at a cost of about $1.9 million, were unnecessarily conducted. GAO also states that these specimens should have been, but were not, tested initially in commercial or State laboratories. GAO's methods for calculating the "46 percent" and the "about $1.9 million" are not apparent. Pages 4 and 5 of the GAO draft report state, "We compared published lists of diagnostic tests offered by CDC, State public health, and commercial laboratories to identify commonly performed tests. Those tests covered 37 diseases. (see App. II). Subsequently, we identified from the sample records at CDC the tests which could have been done elsewhere but which had not been attempted prior to referral to CDC."

With respect to the 46 percentage figure, it should be noted that:

a. A wide variety of laboratory tests can be performed for each of the 37 diseases in the GAO comparison table. The tests range from generic isolate identifications and serologies to specific and definitive isolate identifications and immunological procedures. Private laboratories that offer tests for the diseases listed usually perform the generic tests. State laboratories offer more definitive tests; CDC's tests are the most definitive.

b. The availability of these tests in private and State laboratories varies considerably and changes over time.

c. Commercial reagents of reliable quality are not consistently available for all of the diseases listed.

APPENDIX IV

d. Requests for reference diagnostic services which do not indicate that previous tests were performed for these diseases can mean that (1) the tests that were available to the sender were not appropriate for the particular disease--a test available only at CDC was necessary to provide adequate and appropriate information, (2) no tests were available at the time laboratory information was needed, or (3) CDC and States are collaborating in an investigation.

GAO Recommendation

3) --Also, in view of CDC's emphasis on the importance of having a specimen accompanied by relevant information needed to determine the need for CDC testing as well as to provide meaningful test results, we recommend that CDC not accept specimens for testing that are not accompanied by all available information requested on the forms provided by CDC for use in submitting specimens.

Department Comment

We concur. The CDC guidelines for acceptance of reference diagnostic services specimens clearly outline the minimum information required for each type of specimen. Filling in every blank on the present information form was never intended; specific information is required for certain specimens. To make these needs more apparent, a simplified version of the reference diagnostic services request form is under development. Changes in computer software related to these format changes will take about 1 year to complete.

GAO Recommendation

4) --Finally, we recommend that CDC not accept specimens for testing which are submitted directly from private health care providers and clinical laboratories unless such submissions are authorized by both CDC and the State laboratory.

Department Comment

We concur. This is the present CDC policy. The only exceptions to this policy are instances where (1) previous arrangements have been made with investigators to collaborate on projects with CDC scientists, or (2) delaying tests would be harmful to the patient. In the former instance, specimens are processed upon receipt. In the latter instance, specimens are processed after determination that time and circumstance do not permit return to the State; the submitter is informed of proper procedures for the future. Where there are problem areas, the State is informed.

GAO CONCLUSIONS:

C. CDC SHOULD CHARGE FEES FOR CERTAIN DIAGNOSTIC TESTING SERVICES

GAO Recommendation

We recommend that the Secretary require the Director of CDC to recover the total cost of laboratory diagnostic testing services provided to private beneficiaries and other Federal agencies, and to determine the extent to which other non-Federal agencies should be charged. More specifically, we recommend that CDC be directed to:

1) --Charge private health care providers and private clinical laboratories for diagnostic testing.

Department Comment

For several reasons, we do not believe it would be practical or cost-effective to implement this recommendation.

GAO projects that 33 percent of specimens tested by CDC were submitted by private health care providers and clinical laboratories. CDC's computer records, however, show that this total should be 7 percent. Further, at least half of these include specimens submitted by collaborating scientists for epidemiologic or laboratory research studies (an exception permitted under present CDC policy discussed earlier). As explained by the GAO report, the procedure for sending specimens to CDC is through the State health department laboratories where a prior determination is made to perform the tests in that laboratory and/or send them to CDC according to stated policies and priorities. CDC constantly attempts to make the logistics of this service foolproof, but recognizes that on occasion some specimens will be sent to and accepted by CDC without having gone through the States. A completely foolproof system may not be achievable.

With well over 90 percent of specimens shipped to CDC by the States and other authorized institutions, it is neither possible nor desirable to charge private health care providers and private clinical laboratories for reference diagnostic testing. Further, State and Federal Governments share responsibility to provide these types of reference services in the interest of the Nation's health. We will ask States to remind physicians and laboratories that specimens should be submitted to the State laboratory which will obtain the assistance of CDC if it is necessary. As previously stated, CDC has recently distributed a new manual providing guidance (including criteria) to States for submission of specimens. These guidelines should reduce significantly the already

small percentage of specimens from private providers and clinical laboratories. Although the previous percentage was small, it represented a large number of providers and laboratories, and the extensiveness of billing would render charging impractical and not cost effective.

GAO Recommendation

2) --Determine the extent to which other non-Federal recipients of CDC's testing services should be charged by applying the provisions of the User Charge Statute and OMB Circular A-25.

Department Comment

This area has been well-explored by the Department. Non-Federal recipients of CDC's testing services include State and local health departments, collaborating researchers, ministries of health of foreign countries, and international health organizations. All of these recipients are seeking CDC's assistance in the investigation, control, and prevention of infectious diseases of public health importance. These are within the scope of CDC's responsibilities.

The diagnosis, therapy, and other medical management strategies for individual patients may be based on CDC's laboratory results. The successful treatment of infectious diseases precludes the transmission of disease to other persons and terminates the cost of continued illness; therefore, it is a prevention measure. CDC laboratory services that are available elsewhere may be provided to CDC constituents to (a) confirm a previous laboratory result in an atypical or unusual illness, (b) assess the accuracy of routine results from a local laboratory, or (c) determine the reliability of reagents and/or test methods.

The applicability of OMB Circular A-25 in such circumstances has been thoroughly discussed in the Department's response to the GAO letter report "Centers for Disease Control Should Charge Fees for Various Diagnostic Laboratory Services."

GAO Recommendation

3) --Charge all Federal agencies for diagnostic testing.

Department Comment

We concur. We presently charge the Veterans' Administration for reference diagnostic testing services and will charge all other Federal agencies, except for specimens submitted as part of a collaborative study. Current charges will be

updated to collect the actual costs. The direct cost for various services range from a few dollars to over one hundred dollars per specimen depending on the complexity of the tests used. Because Federal laboratories are very few in number, the same argument relative to the cost effectiveness and practicality of billing, discussed for private providers and clinical laboratories, do not apply.

The GAO analysis overstates the amount that could be collected from other Federal agencies--"CDC could have also recovered an additional $662,000 from other Federal agencies during fiscal year 1981."

For other Federal agencies the GAO calculation is 103,000 x 8% = 8,240 specimens. Thus, the cost per specimen would be $662,000 : 8,240 = $80.34 per specimen. The CDC computer record for FY 1981 shows 5,801 specimens tested for other Federal agencies. Using the same method as GAO for calculating total CDC costs, the CDC specimen costs are $47/specimen for a total cost of $272,647 (5,801 x $47).

To conclude our comments in the section on charging user fees, we wish to point out that the GAO report does not include the dollar value and the benefits of the reference diagnostic services to the Federal Government and the general public. GAO concentrates on demonstrating how much money might be generated and does not consider the costs to the Government should its program be changed. For example, a partial list of benefits accrued in FY 1981 (without direct costs) through the program for only 1981 includes:

--Conducted a pneumococcal vaccine efficacy study including submission of specimens from all States. By combined laboratory testing, patient clinical information, and epidemiologic investigation CDC was able to show that the polyvalent pneumoccocal vaccine was not as efficacious as initially anticipated and that the incidence of pneumococcal disease in essentially all age groups remained unchanged.

--Developed surveillance systems for:

a. Newly emerging diseases such as Toxic Shock Syndrome, Lyme disease, and Entovirus 70 conjunctivitis to enable CDC to respond appropriately to public health emergencies and program planning.

b. Specific disease agents such as the recently described Vibrios-associated with diarrheal and systemic disease and the unclassified Coryne Bacteriaceae (known as the JK group) as important agents responsible for systemic infections in compromised patients. These "new" groups and others are seen as emerging groups of pathogens with broad disease implications, many of which (diagnosis, therapy, and prevention) are within CDC's mission.

APPENDIX IV

c. Antiobiotic resistance patterns that frequently serve as the initial signal of the emergence of bacterial strain resistance to the antibiotic of choice, e.g., the appearance of gonococcal strains resistant to spectinomycin (the antibiotic of choice for treating gonorrhea caused by penicillin resistant strains) and the increased rate of isolation of methicillin resistant strains of Staph. aureau in nosocomial infections. With early recognition of newly developing drug resistance, CDC is able to respond more quickly and efficiently with short term intervention and long range prevention strategies.

--Recognized for the first time a problem with epidemic typhus in the United States.

--Evaluated previously developed test for detection of botulinal toxin in stool specimens.

--Permitted detection of first case of influenza for the ensuing "flu" season.

--Recognized rapid growing mycobacterial species involved in nosocomial infections following cardiac surgery.

--Published in approximately 50 research publications, data on improved or new tests, characteristics of microorganisms, antibiotic sensitivities, importation of diseases, and unusual manifestations of diseases.

The Federal policy described in the User Charge Statute and OMB Circular A-25, grants general authority to Federal agencies to establish user charges for services where appropriate--services which provide special benefits to an identifiable recipient above and beyond those which accrue to the general public. The reference diagnostic services provided by CDC do not:

--Provide special benefits to an identifiable recipient beyond those which accrue to the general public.

--Enable the beneficiary to obtain more immediate or substantial gains or values than those which accrue to the general public.

--Provide business stability or assure public confidence in the business activity of the beneficiary.

--Provide services at the recipient's request above and beyond the services available to the general public. Services are provided at the request of States, other health organizations, and other Federal agencies--these organizations provide their services (and pass along the results of CDC's) to the general public.

APPENDIX IV

In responding to this report and in previous discussion with GAO, CDC has attempted to demonstrate that these reference diagnostic testing services primarily benefit the general public and that the benefit to the private recipient is incidental.

We do agree as prescribed by the Economy Act (31 U.S.C. 1535), to obtain reimbursement for the actual costs of services provided to other Federal agencies when these services are not part of a cooperative research project.

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