UNITED STATES GENERAL ACCOUNTING OFFICE
WASHINGTON, D.C. 20548

HUMAN RESOURCES
DIVISION

August 11, 1982

B-207247

The Honorable Richard S. Schweiker
The Secretary of Health and
Human Services

Dear Mr. Secretary:

Subject: Centers for Disease Control Should Charge Fees for Various Diagnostic Laboratory Services (GAO/HRD-82-70)

The Centers for Disease Control (CDC) should recover substantial amounts of incurred costs by imposing additional user charges for various diagnostic laboratory services that it provides to such non-Federal organizations as diagnostic product manufacturers and clinical laboratories as well as Federal agencies. These laboratory services include field testing of diagnostic products, evaluating lot samples of diagnostic reagents, providing reference reagents to manufacturers, evaluating the quality of diagnostic testing services provided by laboratories, and providing laboratory training services.

In fiscal year 1981, CDC collected about $550,000 from non-Federal organizations and Federal agencies for certain laboratory services it provided. We estimate that, in fiscal year 1981, using current legislative authority, CDC could have collected about $2.1 million in additional revenues from non-Federal organizations toward recovery of the $5.1 million in costs it incurred for providing such services to Federal and non-Federal entities. If CDC had not been restricted by another statute imposing a maximum fee on interstate laboratories, an additional estimated $650,000 could have been recovered.

Also, CDC could have sought additional reimbursements, amounting to $242,000, from other Federal agencies for which it provided certain of these same services. (See enc. I for detailed discussion of our findings.)

(102067)

OBJECTIVES, SCOPE, AND METHODOLOGY

The objective of our review was to determine the extent to which CDC should be recovering the costs of diagnostic laboratory services provided to non-Federal organizations and other Federal agencies.

Our review focused on certain CDC laboratory services that we believed provided special benefits to the clinical laboratory industry and on similar services provided to other Federal agencies. We reviewed

--the legislation, Federal policy statements, court decisions, and other related material dealing with Federal imposition of user charges and interagency reimbursements;

--the objectives of each of the laboratory services discussed in the report which are provided by CDC; and

--the nature and extent of services that users receive.

We obtained information on the material contained in our report from (1) CDC program documents and interviews with CDC headquarters officials in Atlanta, Georgia, (2) the Food and Drug Administration (FDA), (3) the College of American Pathologists, and (4) the Health Care Financing Administration.

To estimate the amounts that could be recovered through user fees, we obtained, but did not verify, laboratory diagnostic services' cost data for fiscal year 1981 from CDC headquarters. From information provided by CDC, we estimated the administrative costs CDC would incur in collecting the user charges discussed in the report.

Our review was conducted in accordance with the Comptroller General's "Standards for Audit of Governmental Organizations, Programs, Activities, and Functions."

USER CHARGES SHOULD BE IMPOSED AND INTERAGENCY REIMBURSEMENTS OBTAINED TO RECOVER COSTS

In fiscal year 1981, CDC collected about $79,000 from such non-Federal entities as hospitals and universities for laboratory training services and about $471,000 from other Federal agencies for diagnostic reagents and special laboratory evaluations. No charges were made for other laboratory services. We estimate that, under current legislative authority, CDC could have collected an additional $2.1 million in fiscal year 1981 by imposing

appropriate user charges on non-Federal entities. Another statute prevented the collection of an additional estimated $650,000 in user charges from interstate laboratories. An additional $242,000 in reimbursements could have been obtained for certain laboratory services that CDC provided to other Federal agencies.

With certain exceptions, user charges are to be imposed by Federal agencies to recover the costs of services that provide special benefits to non-Federal recipients above and beyond those accruing to the general public. Federal agencies are granted general authority to establish user charges for services provided to identifiable recipients under 31 U.S.C. 483a, commonly known as the User Charge Statute. The Office of Management and Budget (OMB) Circular A-25 provides Federal agencies more specific guidance as to when user charges should be imposed.

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 in the Economy Act (31 U.S.C. 686). The act provides for no exceptions to actual cost reimbursement.

Our estimates of revenue that could have been generated in fiscal year 1981 by imposing appropriate user charges to non-Federal concerns follow.

--$428,000 for field testing diagnostic products.

--$790,000 for evaluating lot samples of diagnostic reagents that had been classified by FDA for commercial use.

--$210,000 for providing reference reagents to manufacturers.

--$550,000 for evaluating (proficiency testing) and improving the quality of diagnostic testing services provided by public health and private clinical laboratories. (This income estimate excludes an estimated $650,000 in user charges which could not be imposed and collected from interstate clinical laboratories. The Clinical Laboratories Improvement Act (42 U.S.C. 263a) limits fees imposed on interstate laboratories to annual licensing fees of $125. Imposing fees based on CDC's total costs of proficiency testing would require that the act be amended to remove the fee limitation.)

--$74,000 in additional reimbursements to recover the full costs of providing laboratory training services to private industry and other nonpublic health entities. (Current CDC tuition rates reflect incomplete and outdated cost data.)

Also, CDC should have recovered from other Federal agencies an additional $165,000 for proficiency testing services and an additional $77,000 by charging full cost tuition rates for training Federal laboratory personnel.

While CDC has imposed or considered user charges for some of its laboratory services, it has generally opposed user charges for other services. CDC's general opposition to user charges is based primarily on its view that imposing charges for services may discourage user participation and impair program objectives.

CDC officials contend that the services for which CDC does not charge are not subject to user charge requirements because the ultimate beneficiary is the general public, even though initial benefits may accrue to organizations immediately receiving the services. We recognize that the decision of whether or not to charge users is one for the agency to make using the guidance provided in OMB Circular A-25. CDC has not exceeded its proper authority in making that decision. However, we continue to believe that CDC should charge a fee to certain types of users discussed in this report because they receive benefits above and beyond those accruing to the general public.

FAILURE TO RETURN USER CHARGE REVENUES TO CDC CITED AS A DISINCENTIVE TO COLLECT

The User Charge Statute and OMB Circular A-25 generally require that the revenues collected be paid into the Treasury as miscellaneous receipts rather than returned to an agency for program use. Several CDC officials told us that this requirement offers no incentive for CDC to impose user charges if revenues are not later available for program use. In fact, they pointed out that CDC would incur additional administrative costs in collecting the user charges which, in turn, would reduce the funds available for program operations.

OMB Circular A-25 provides guidance by which CDC can, if it desires, seek legislative authority to retain user charge revenues for program use. However, whether or not CDC is successful in obtaining legislative authority to retain other user charges, it should impose such charges.

RECOMMENDATIONS TO THE SECRETARY OF HHS

We recommend that you require the Director of CDC to impose user charges that will recover the total cost of laboratory services provided to non-Federal beneficiaries and other Federal agencies.

Specifically, we recommend that CDC be directed to

--charge laboratory product manufacturers for field testing laboratory diagnostic products;

--charge laboratory product manufacturers for evaluating lot samples of commercially available diagnostic reagents;

--charge laboratory product manufacturers for providing reference reagents;

--charge clinical laboratories, other than interstate laboratories, and Federal agencies for proficiency testing;

--adjust charges for laboratory training to reflect all current costs and later review and adjust such costs annually;

--charge Federal agencies for laboratory training; and

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

In addition, we recommend that you propose legislation to permit the recovery of total costs for licensing services, including proficiency testing, provided under the Clinical Laboratories Improvement Act.

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As you know, section 236 of the Legislative Reorganization Act of 1970 requires the head of a Federal agency to submit a written statement on actions taken on our recommendations to the House Committee on Government Operations and the Senate Committee on Governmental Affairs not later than 60 days after the date of the report and to the House and Senate Committees on Appropriations with the agency's first request for appropriations made more than 60 days after the date of the report.

We are sending copies of this report to the Chairmen of the four above-mentioned Committees, the House Committee on Energy and Commerce, and the Senate Committee on Labor and Human Resources. Copies are also being sent to the Directors of OMB and CDC.

We obtained comments from CDC officials on the matters discussed in this report and their views are recognized where appropriate.

We appreciate the cooperation and courtesy given our staff during this review and welcome the opportunity to discuss the above matters with you or your staff.

Sincerely yours,

Edward A Densmore

for Gregory J. Ahart
Director

Enclosure

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ABBREVIATIONS

CDC	Centers for Disease Control
FDA	Food and Drug Administration
GAO	General Accounting Office
HHS	Department of Health and Human Services
OMB	Office of Management and Budget

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CENTERS FOR DISEASE CONTROL SHOULD CHARGE FEES FOR VARIOUS DIAGNOSTIC LABORATORY SERVICES

The Centers for Disease Control (CDC) should recover substantial amounts of incurred costs by imposing additional user charges for various diagnostic laboratory services that it provides to such non-Federal organizations as diagnostic product manufacturers and clinical laboratories as well as Federal agencies.

In fiscal year 1981, CDC collected about $550,000 from non-Federal organizations and Federal agencies for the laboratory services it provided. In our opinion, under current legislation, CDC could have collected about $2.1 million in additional revenues from non-Federal organizations toward recovery of the $5.1 million in costs it incurred in fiscal year 1981 for providing such services to non-Federal and Federal entities. Conflicting statutes prevented the collection of an additional estimated $650,000 in user charges from interstate laboratories. Also, CDC could have sought additional reimbursements, amounting to $242,000, from other Federal agencies for which it provided certain of these same services.

BACKGROUND

CDC's mission is to assist State and local health authorities and other health-related organizations in (1) preventing the spread of communicable diseases, (2) protecting against other diseases or conditions amenable to reduction, (3) providing protection from certain environmental hazards, (4) improving occupational safety and health, and (5) otherwise promoting good health. CDC has broad legislative authority to engage in essentially any disease prevention and control activity that it deems necessary to protect and improve public health.

CDC offers an array of laboratory services under authority of the Public Health Service Act to aid in developing and applying diagnostic laboratory technology. The services are provided to Federal, State, and other public health agencies and to the clinical laboratory industry. Laboratory services provided by CDC include

--evaluating the industry's laboratory diagnostic products,

--evaluating commercially available laboratory diagnostic reagents,

--producing reference and diagnostic reagents and distributing them to industry and public agencies,

--conducting laboratory proficiency testing for public and private clinical laboratories and public health laboratories, and

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--providing training to public and private laboratory personnel.

With certain exceptions, user charges are to be imposed by Federal agencies to recover the actual cost of services which provide special benefits to identifiable non-Federal recipients above and beyond those which 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 recipients under 31 U.S.C. 483a, commonly known as the User Charge Statute. This statute states essentially that the Congress intends that certain services provided to identifiable non-Federal recipients be self-sustaining to the fullest extent possible and authorizes the head of each Federal agency to prescribe charges to recover the Government's costs for providing such services.

The Office of Management and Budget's (OMB's) 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 the 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.

Computations of costs for user charges and reimbursements from other Federal agencies must include all costs of providing a service. For user charges, OMB Circular A-25 provides specific cost computation requirements, covering both direct and indirect costs. The cost of providing the service must also be reviewed annually and charges adjusted as necessary. The OMB Circular

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states that costs shall be determined or estimated from the best available records in the agency and that new cost accounting systems will not be established solely for this purpose.

Two recent Federal court decisions have clarified what user charges may include. The U.S. Court of Appeals for the District of Columbia Circuit concluded that charges may include the full cost of providing a service even though the service may result in some incidental public benefit. Electronic Industries Association v. FCC, 554 F.2d 1109, 1115 (D.C. Cir. 1976). In another ruling, the U.S. Court of Appeals for the Fifth Circuit concluded that, when a service is provided to a private beneficiary, the agency may recover the service's full cost regardless of whether the service may also incidentally benefit the public and that there is no need to allocate the cost of providing the service between the recipient and the public. Mississippi Power and Light Company v. N.R.C., 601 F.2d 223 (5th Cir. 1979) cert. denied 444 U.S. 1102 (1980).

In setting or adjusting charges, agencies may make exceptions to the general policies when

--the cost of collecting the fee 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 a 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 in the Economy Act (31 U.S.C. 686). The act provides for no exceptions for cost reimbursement.

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 authority of the Economy Act are generally retained by the agency providing the services.

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USER CHARGES SHOULD BE IMPOSED AND INTERAGENCY REIMBURSEMENTS OBTAINED TO RECOVER COSTS

CDC should be recovering the full cost of diagnostic laboratory services which it provides to non-Federal organizations. For example, in fiscal year 1981, CDC could have collected about $2.1 million by imposing user charges on non-Federal recipients that receive special benefits beyond those accruing to the public at large. These laboratory services include (1) field testing diagnostic products, (2) evaluating commercially available diagnostic reagents, (3) providing reference reagents to manufacturers, (4) testing the proficiency of intrastate clinical laboratories, and (5) training laboratory personnel. Conflicting statutes prevented CDC from collecting an additional estimated $650,000 from interstate laboratories for proficiency testing services.

An additional $242,000 could have been obtained from Federal agencies by recovering the full costs associated with testing the proficiency of clinical laboratories and training Federal laboratory personnel.

The costs to collect both user charges and interagency reimbursements should also be recovered by CDC. These costs are discussed in this report, but are not included in the estimated amounts of additional revenues CDC could have collected in fiscal year 1981.

Field testing diagnostic products

CDC should charge for field testing diagnostic products because, in most cases, the service is performed at the manufacturers' requests and because the service helps make the manufacturers' products marketable.

Field testing involves evaluating such products as diagnostic kits for detecting certain diseases. The field tests, which provide information on the attributes and limitations of a prototype or a marketed product's capabilities, often lead to product improvements and help assure public confidence in the product. Commercial manufacturers often rely on information generated during CDC's field testing to support their claims of new products' capabilities when the products are submitted to the Food and Drug Administration's (FDA's) diagnostic device classification program. FDA submission is required for commercial marketing of such products.

CDC officials assert that field testing services, as well as other services discussed later, are exempt from user charge requirements because the services benefit the general public. More specifically, the officials claim exemption under the OMB Circular A-25 provision that no charge should be made for services when

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the identification of the ultimate beneficiary is obscure and the service can be primarily considered as benefiting broadly the general public.

We recognize that the decision of whether or not to charge user fees is one for the agency engaged in the activity to make. Consequently, CDC's decision to impose no charge on its users for the laboratory services discussed in this report is an appropriate exercise of its authority under OMB Circular A-25. However, we question the basis for CDC's decision. We continue to believe that CDC should charge user fees to the beneficiaries of CDC's field testing of diagnostic products and other diagnostic laboratory services because they receive special benefits beyond those accruing to the public at large.

We recognize that the public ultimately receives a benefit from CDC's field testing of diagnostic products or any other CDC service. In CDC's view, its purpose in providing such services is to improve the quality of these diagnostic laboratory services and eventually the overall quality of health care available to the general public. We don't dispute CDC's assessment of its agency function. Rather, we believe that charging specific identifiable recipients of special diagnostic laboratory service benefits is consistent with CDC's function and the provisions of OMB Circular A-25.

CDC claims support for its position in Federal court decisions concerning the User Charge Statute and OMB Circular A-25. CDC cites a case in which the court held, in part, that a regulatory agency could not impose fees on a manufacturer for testing the manufacturer's product beyond compliance with established standards to satisfy some additional, independent public interest. Electronic Industries Association v. FCC, 544 F.2d 1109, 1115 (D.C. Cir. 1976). In that case, a hypothetical example was presented in which a regulatory agency imposed a fee on a manufacturer in order to pay for agency tests that were not required by statute and that might not benefit the manufacturer at all. The tests were to serve some independent public interest. In our view, the situation at CDC is different because the manufacturers participate voluntarily with the expectation of benefiting directly.

CDC also relies on the position taken in Aeronautical Radio, Inc. v. U.S., 335 F.2d 304 (7th Cir. 1964), cert. denied 389 U.S. 966, as support for its determination to impose no charge. In that case the court held that in determining whether or not to establish a fee schedule, "each agency must weigh the policy of making its services 'self-sustaining' against the public policy considerations for which it [the agency] was formed." CDC believes that the public purpose for which it was formed--for the protection and promotion of public health--is best served by not establishing a fee schedule for products and services. The charging of fees

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would, in CDC's view, reduce participation in its programs and hinder its ability to accomplish objectives for the benefit of the public health.

We do not believe that the imposition of a user charge is inconsistent with CDC's mission of protecting and promoting public health. Further, the decision of whether user charges should be imposed should not, in our opinion, be made on the basis that the services ultimately benefit the public, but rather, on whether an identifiable user receives special benefits over and above those accruing to the public.

By field testing diagnostic products, CDC officials believe that CDC is able to stay abreast of changes in technology and to further improve evolving diagnostic products. Accordingly, CDC believes this service benefits the general public, and since CDC is usually given the products tested, the products tend to increase the overall knowledge and capabilities of CDC laboratories. CDC is concerned that, if manufacturers are not willing or able to reimburse CDC for these services, the benefits will be lost.

CDC's concern that manufacturers may not be willing to pay is questionable because other medical research institutions nationwide conduct similar field testing under contract with manufacturers and recover the cost of their services. For example, in 1980 CDC, in collaboration with five other research institutions, conducted field tests on a new automated clinical chemistry diagnostic device to determine its effectiveness. The resulting report endorsed the device and suggested ways to further improve it. The five non-Federal research institutions were reimbursed for the cost of their services while CDC was not.

In fiscal year 1981, 1,068 commercial products were reported by CDC as having been tested at manufacturers' requests at a total cost of $428,000, or an average cost of about $400 per product. CDC officials said that not all tests had been included in these figures because its reporting system for such tests will not be fully implemented until 1982.

We believe that the $428,000 could have been recovered by CDC through charges to manufacturers for its field testing services. The cost to collect these charges is estimated to be $28,600 annually, or about 7 percent of the estimated receipts.

Evaluating commercially available diagnostic reagents

In addition to field testing diagnostic products, CDC routinely evaluates lot samples of diagnostic reagents that have been classified by FDA for commercial use and are being mass produced by private manufacturers. CDC should charge for such routine evaluations of reagents because the evaluations are performed at

the manufacturers' requests and help assure user confidence in the manufacturers' products.

CDC evaluations of commercial reagents are based on CDC-developed performance specifications, and reagents that are inspected and approved are so identified. Reagents meeting CDC's recommended specifications are listed in a CDC monthly report by manufacturer and lot number. Clinical laboratories and interested manufacturers may request to be on the mailing list of the report, which has an international circulation of over 6,000 copies.

Manufacturers whose products meet CDC specifications may use, on the package or on literature that accompanies the evaluated lot, this statement: "Samples of this lot were tested by the Centers for Disease Control and found to meet CDC specifications."

Products that do not meet CDC specifications are not publicized, but the manufacturers are notified. CDC believes that publishing lists of products that fail CDC's evaluation would discourage voluntary participation. Instead, CDC tries to persuade manufacturers to take reagents not meeting recommended CDC specifications off the market, or CDC may assist manufacturers in further developing and improving their products.

CDC also publishes a list of commercial sources for various diagnostic reagents. The publication identifies manufacturers that submit their products to CDC for evaluation.

As in its field testing of diagnostic products, CDC does not charge for its evaluations of reagents because it believes that the services are exempt and that imposing charges could adversely affect the program. It believes that charging manufacturers for reagent evaluations may cause the manufacturers to stop participating in the program and that related public benefits would be lost.

The program has experienced a steady increase over the years and now includes more than 200 products produced by nearly 30 manufacturers. In 1981, CDC evaluated 2,261 reagent lots at a total cost of $790,000, or about $350 per lot tested. CDC should recover such costs. We estimated the cost to collect these charges to be $28,600 annually, or about 4 percent of the estimated revenues to be collected.

Providing reference reagents to manufacturers

Small quantities of reference reagents are distributed by CDC to product manufacturers and public health laboratories so that these entities can conduct their own comparative performance tests on commercially produced reagent lots. CDC should charge laboratory product manufacturers for the reference reagents it provides

because such reagents assist manufacturers in their product quality control efforts and, therefore, enhance the marketability of their products.

In addition to producing and distributing reference reagents, CDC also produces and distributes larger quantities of reagents used directly in diagnostic tests, such as in testing for Legionnaires disease. These reagents are not commercially available, or the commercial supply is unreliable. Quantities of reagents sufficient for diagnostic use are provided only to public health laboratories and other Federal agencies or are used in CDC's own laboratories. The reagents are provided in limited quantities to private industry for use as a reference reagent.

CDC's policy is to provide the reagents on a reimbursable basis to other Federal agencies (reimbursements totaled about $46,000 in fiscal year 1981) and at no charge to State, territorial, local, and international public health agencies, including the Department of Health and Human Services' (HHS') grantees. Commercial manufacturers are provided reference reagents at no charge.

Although not charging State and other public health agencies may be justified in view of the exceptions in OMB Circular A-25, CDC should charge manufacturers for reference reagents.

CDC program officials told us that charges have not been imposed on manufacturers because the program is designed to improve commercially available reagents for the public's benefit and is therefore exempt from user charge requirements. However, OMB Circular A-25 does permit charges for services which are provided to private beneficiaries, although the public derives some benefit. In January 1980, CDC proposed charging private industry for reagents but, according to CDC officials, the proposal was not adopted because HHS opposed CDC's proposal to retain the revenues for program use.

In fiscal year 1981, CDC distributed or used directly 84,242 units of reference and diagnostic reagents. The total cost to produce the reagents during fiscal year 1981 was about $1.5 million, or about $18 per unit. About 14 percent of the reagents were shipped to commercial manufacturers. We estimate that, if manufacturers were charged for reference reagents, CDC would recover about $210,000 annually. The cost to collect for reference reagents provided to manufacturers would be about $4,400 annually, or about 2 percent of the estimated revenues.

Testing the proficiency of clinical laboratories

Proficiency testing is used to evaluate and improve the quality of diagnostic testing services provided by clinical laboratories. CDC should recover the total cost of proficiency

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testing services provided to other Federal agencies and should charge clinical laboratories for proficiency testing because these services help individual laboratories identify and correct specific performance problems, and help assure user confidence in laboratory performance. To charge interstate laboratories, CDC must first seek remedial legislation. CDC also should recover the total cost of proficiency testing services provided to other Federal agencies.

CDC tests laboratories' proficiency by mailing test specimens to them. Initially only public health laboratories participated in CDC's proficiency testing, but over the years CDC has incorporated private and public clinical laboratories into the program. More than 2,400 laboratories now participate. The chart on page 10 provides statistical information on the laboratories participating in CDC's proficiency testing program.

Some clinical laboratories voluntarily participate, while others do so because of legal requirements. In 1967, CDC acquired a regulatory responsibility under the Clinical Laboratories Improvement Act, which mandated proficiency testing for interstate laboratories as part of a Federal licensing requirement. Through an interagency agreement, CDC has since turned over the issuance of licenses to the Health Care Financing Administration. CDC continues to conduct the proficiency testing. About 30 percent of the laboratories participating in CDC's proficiency testing program are interstate laboratories that participate for licensing purposes.

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Laboratories in CDC's Proficiency Testing Program
(as of February 1982)

Types	Number		Percent
Non-Federal clinical laboratories (note a):			
Interstate	804		
Intrastate	639		
Manufacturers	64		
Subtotal		1,507	61
Federal laboratories:			
Military	75		
Veterans Administration	56		
Indian Health	5		
U.S. Public Health Service	14		
Other	53		
Subtotal		203	8
Non-Federal public health laboratories:			
State	43		
Local	255		
Red Cross	8		
Forensic	43		
Subtotal		349	14
Reference laboratories (note b)		267	11
Foreign laboratories		88	4
Other laboratories		49	2
Total		2,463	100

a/Hospital laboratories (private, State, county, city, and university), independent clinical laboratories, and diagnostic product manufacturers.

b/Laboratories used for peer comparison in proficiency testing.

CDC officials generally oppose charging for proficiency testing partly because they consider the information obtained through the testing as vital to directing CDC's national laboratory improvement program. They contend that imposing charges would impair CDC's ability to solicit voluntary participation. As with other services, CDC maintains that its proficiency testing services ultimately benefit the public and are exempt from user charge requirements.

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CDC officials also believe that the licensing fee stipulated in the Clinical Laboratories Improvement Act places a legal limit on the charge CDC can impose on interstate laboratories. This act authorizes the Secretary of HHS to charge interstate laboratories an annual fee for licensing not to exceed $125. However, the Health Care Financing Administration has waived the licensing fee on the basis that the cost to collect the fee represents an unduly large part of fee receipts.

CDC officials said, and we agree, that the prescribed fee established by the Clinical Laboratories Improvement Act limits the charges which the Health Care Financing Administration or CDC could impose. However, neither the act's language nor its legislative history indicates a specific intent to modify the requirements of the User Charge Statute. Without such intent, agencies are required by OMB Circular A-25 to propose to OMB appropriate remedial legislation if there is an inconsistency between or among different legislative authorizations.

The total cost of operating the proficiency testing program in fiscal year 1981 was about $2 million, or about $800 per participating laboratory. As shown in the chart on page 10, 1,507 (or 61 percent) of the laboratories participating are non-Federal clinical laboratories. An additional 203, or 8 percent, of the laboratories participating are Federal laboratories.

We estimate that CDC would recover about 61 percent of the cost to provide proficiency testing, or $1.2 million annually based on fiscal year 1981 costs, if user charges were imposed on non-Federal clinical laboratories. However, about $650,000 of the $1.2 million cannot be collected until remedial legislation is enacted to correct the conflict between the Clinical Laboratories Improvement Act and the User Charge Statute. The cost to collect the charges is estimated to be about $30,400 annually, or 2.5 percent of the $1.2 million.

In addition to recovering proficiency testing costs from certain non-Federal entities, CDC should obtain full reimbursement for services to other Federal agencies. In fiscal year 1981, CDC recovered $425,000 from certain Federal agencies for the cost of special proficiency testing services, but it could have recovered an additional $165,000 from several other Federal agencies that also received services.

Training laboratory personnel

Unlike its practice of providing direct laboratory services without charge, CDC charges for its laboratory personnel training. However, because its cost data are incomplete and outdated, CDC is not recovering full costs from non-Federal agencies. Also, CDC is not requiring reimbursement from Federal agencies.

CDC provides certain laboratory training services at its headquarters primarily to meet the needs of State and local health departments. After fulfilling these obligations, services are made available to Federal agencies, international agencies, foreign governments, private industries, and universities. CDC charges tuition for employees of entities other than Federal, State, and local health agencies. CDC's total cost to provide laboratory training in fiscal year 1981 was about $420,000.

Because CDC had not used current and complete cost data in computing tuition, it recovered from users such as hospitals and universities, only about $79,000 of the $230,000 in recoverable training costs in fiscal year 1981. Although OMB Circular A-25 requires that costs be reviewed at least annually and rates be appropriately adjusted, CDC's rates had not been adjusted since October 1979 and they did not reflect all costs.

Tuition rates should include all direct and indirect costs, including a proportionate share of the agency's management and overhead costs. CDC's formula for computing its tuition does not include indirect costs, which amounted to an estimated 29.6 percent of direct costs in fiscal year 1981. Based on CDC's fiscal year 1981 costs, we estimate that CDC could have recovered an additional $74,000 annually from non-Federal sources if charges had been adjusted to reflect full costs.

In addition to using outdated and incomplete cost data, CDC is not recovering the cost of training employees of Federal agencies. In fiscal year 1981, 182 students (or 18 percent) participating in the CDC program were employees of other Federal agencies. Based on our calculations, CDC could have recovered an additional $77,000 if other Federal agencies had been charged actual costs as authorized by the Economy Act.

FAILURE TO RETURN USER CHARGE REVENUES TO CDC CITED AS DISINCENTIVE TO COLLECT

In addition to its philosophical opposition to user charges for various diagnostic laboratory services, CDC officials said that the requirement to return user charge revenues to the Treasury represents a disincentive for CDC to impose charges. However, under certain circumstances, OMB Circular A-25 permits a Federal agency to seek authority to retain user charges for program purposes.

The User Charge Statute and OMB Circular A-25 generally require that revenues collected be paid into the Treasury as miscellaneous receipts rather than returned for program use. Several CDC officials told us that this requirement offers CDC no incentive to impose user charges because the revenues are available for program use, and in fact, CDC would incur additional administrative costs collecting the user charges which would reduce the funds available for program operations. Legislation would be required for CDC to retain the user charge revenues it generates.

CDC has considered collecting and retaining user charges as a way to expand its production and distribution of diagnostic reagents. In January 1980 CDC proposed legislation for that purpose but, according to CDC officials, HHS rejected the proposal.

Regardless of overall program concerns that may reduce CDC's general incentive to impose user charges, CDC is providing services for which user charges should be charged. Whether user charge revenues should be retained for program use is a separate issue. CDC can seek authority to retain other user charges for program use through specific legislative proposals as provided for in OMB Circular A-25.

CONCLUSIONS

We believe that CDC should impose additional user charges to recover the costs of various diagnostic laboratory services provided to non-Federal organizations. While CDC collected about $550,000 from non-Federal organizations and Federal agencies for the laboratory services it provided in fiscal year 1981, we estimate that additional services costing about $3 million should have been subject to user charges.

We recognize that certain public benefits accrue from the CDC laboratory services discussed in this report. However, in certain situations, benefits also accrue to identifiable private entities 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 services provided.

RECOMMENDATIONS TO THE SECRETARY OF HHS

We recommend that the Secretary require the Director of CDC to impose user charges recovering the total cost of laboratory services provided to certain non-Federal beneficiaries and other Federal agencies.

Specifically, we recommend that CDC be directed to

--charge laboratory product manufacturers for field testing laboratory diagnostic products;

--charge laboratory product manufacturers for evaluating lot samples of commercially available diagnostic reagents;

--charge laboratory product manufacturers for providing reference reagents;

--charge clinical laboratories, other than interstate laboratories, and Federal agencies for proficiency testing;

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--adjust charges for laboratory training to reflect all costs and later review and adjust such costs annually;

--charge Federal agencies for laboratory training; and

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

In addition, the Secretary should propose legislation to permit the recovery of total costs for licensing services, including proficiency testing, provided under the Clinical Laboratories Improvement Act. This would eliminate the conflict between the Clinical Laboratories Improvement Act, which prescribes a maximum fee of $125 for licensing interstate laboratories, and the User Charge Statute, which requires recovery of the full costs of the services provided.