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Report to Congressional Requesters

March 1996

FDA LABORATORIES

Magnitude of Benefits Associated With Consolidation Is Questionable

GAO
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United States
General Accounting Office
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Health, Education, and
Human Services Division

B-270022

March 19, 1996

The Honorable Paul Sarbanes
United States Senate

The Honorable John J. LaFalce
The Honorable Bill Paxon
The Honorable Jack Quinn
House of Representatives

To protect consumers from unsafe, ineffective, and mislabeled products, the Food and Drug Administration's (FDA) Office of Regulatory Affairs (ORA) tests thousands of products annually in its laboratories for possible violations of federal laws. The operating costs for ORA's 18 field laboratories in fiscal year 1995 were about $17 million.

Because ORA officials believe that many of the office's laboratory facilities are old, need costly repairs, and do not meet the needs for conducting regulatory science in the future, ORA developed a 20-year plan to consolidate its field laboratories. As illustrated in table 1, the plan calls for closing several laboratories and building new ones, resulting in five "mega-labs" and four special-purpose labs.

Table 1: FDA's Current and Proposed Laboratory Structure

Current laboratory structure	Proposed laboratory structure
Multipurpose labs	**Multipurpose mega-labs**
Atlanta, Ga.	Atlanta, Ga. (expansion of current facility)
Baltimore, Md.	Jefferson, Ark. (new facility)
Buffalo, N.Y.	New York, N.Y. (new facility)
Chicago, Ill.	Seattle, Wash.
Dallas, Tex.	**Special-purpose Labs**
Denver, Colo.	Cincinnati, Ohio
Detroit, Mich.	Philadelphia, Pa.
Kansas City, Mo.	San Juan, P.R.
Minneapolis, Minn.	Winchester, Mass.
New York, N.Y.	
New Orleans, La.	
Los Angeles, Cal.	
San Francisco, Cal.	
Seattle, Wash.	
Multi- and special-purpose labs[a]	
Cincinnati, Ohio	
Philadelphia, Pa.	
San Juan, P.R.	
Winchester, Mass.	

[a]These labs have a specialty focus such as forensic chemistry in addition to multipurpose functions.

On the basis of your concerns, we reviewed ORA's consolidation plan, focusing on (1) projected cost savings, (2) projected operational efficiencies, and (3) site selection criteria. To complete our work, we reviewed agency procedures and data on the consolidation plan, analyzed the assumptions in the plan, and discussed the plan with key officials at FDA headquarters and selected field locations. See appendix I for more details on our work scope and methodology.

Results in Brief

While FDA's decision to consolidate its 18 laboratories and create 5 multipurpose mega-labs and 4 special-purpose labs could yield efficiencies, we found that the documentation and estimates of the benefits resulting from consolidation are questionable.

ORA projected that its 20-year consolidation plan would result in cost savings of about $91 million over the life of the plan. More specifically, ORA's cost estimates projected that the consolidation plan would cost $950 million over 20 years—about a 10-percent savings over the alternative of replacing existing labs. However, ORA made certain assumptions that may have inflated the replacement option cost. Moreover, current FDA workload data, which are the only efficiency measures presented by ORA, indicate that medium-sized labs (about 50 analysts per lab) are more efficient and effective than existing larger labs (about 100 analysts per lab).

In selecting sites for its mega-labs, ORA did little analysis of the relative efficiency of alternative sites. For example, ORA placed less emphasis on such factors as proximity to ports of entry and quantity of nearby food and other relevant businesses for its site selections. Instead, ORA's site selection decisions were based mainly on where it thought it would receive congressional funding approval.

Background

ORA, under the direction of the Associate Commissioner for Regulatory Affairs, is responsible for carrying out FDA's mission to ensure that foods, cosmetics, and medical products are safe, effective, and properly promoted and labeled.[1] ORA provides a central point to which headquarters officials can turn for field support services. It also exercises direct line authority over field operations, which are generally divided into four branches: investigations, laboratory, compliance, and administrative management. Product sampling and analyses are conducted primarily in the field by ORA's 21 district offices. Each office is headed by a district director responsible for operations.

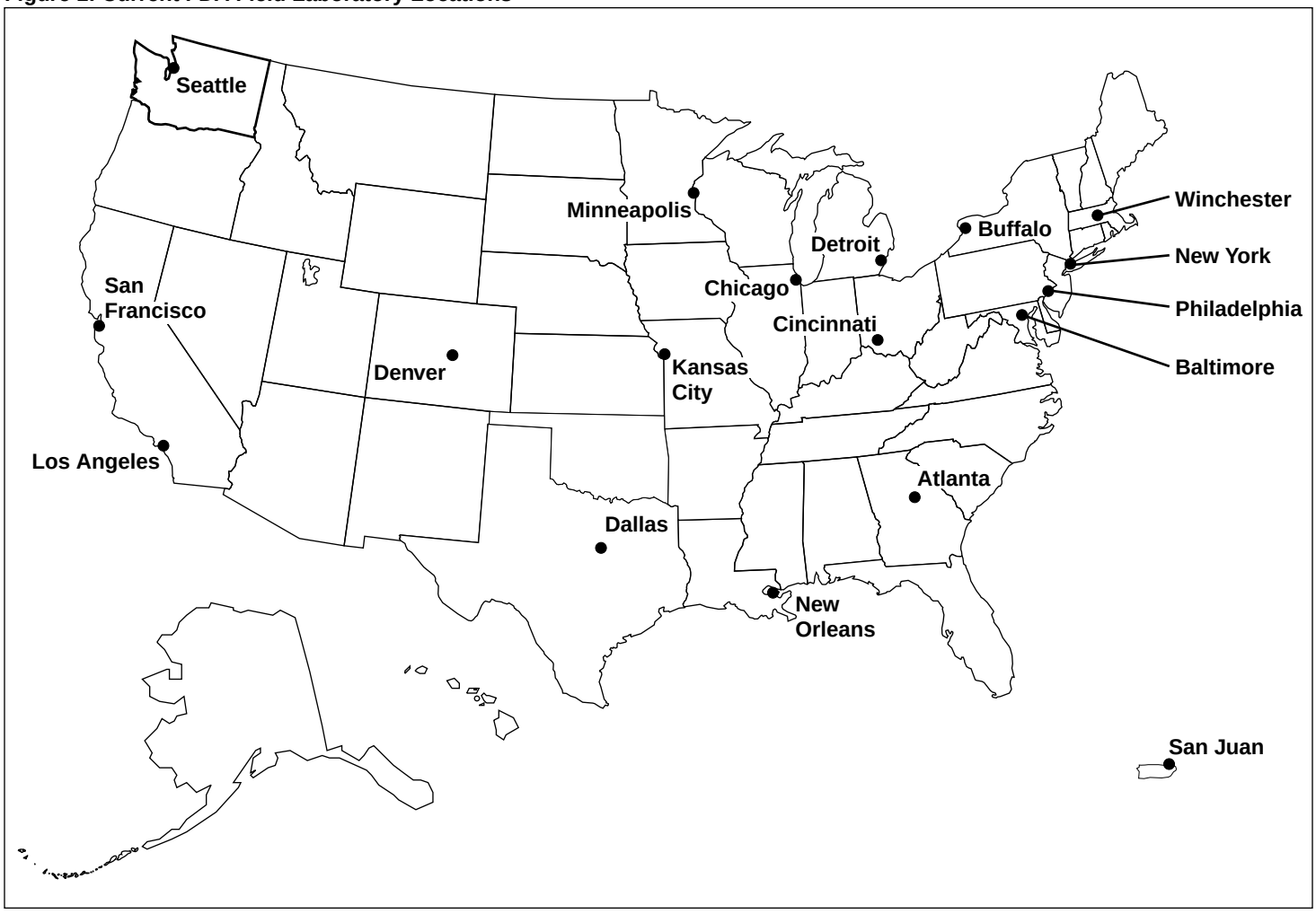
ORA's laboratories play a major role in protecting consumers from unsafe, ineffective, and mislabeled products. They provide a scientific base to support ORA enforcement and regulatory activity. The laboratories test thousands of product samples annually for possible violations of federal laws.

Current Structure Includes 18 Laboratories

ORA operates 18 field laboratories nationwide, including 1 in Puerto Rico, which FDA either owns or leases from the commercial sector or from the General Services Administration (GSA). (See fig. 1.)

[1]FDA derives its authority from the Federal Food, Drug, and Cosmetic Act of 1938, as amended (21 U.S.C. 301).

Figure 1: Current FDA Field Laboratory Locations



The laboratories, which are collocated with district offices, provide two program functions: (1) surveillance and compliance and (2) research. Surveillance and compliance functions are conducted by investigators and laboratory analysts who inspect and investigate domestic establishments and imports; sample, collect, and analyze products; monitor compliance with existing regulations; initiate legal actions when health hazards are detected; and respond to crises, such as consumer tampering. Enforcement decisions are supported by research activities, such as identifying potential health hazards and developing efficient and effective laboratory testing methods.

ORA spends about $17 million per year, excluding salaries, to operate its laboratories. The field locations employ about 650 operating personnel—which include chemists, microbiologists, entomologists, research analysts, engineers, and physicists—and about 275 support personnel.

ORA's Restructuring Plan—ORA 21

ORA refers to the plan for the proposed laboratory structure as ORA 21. According to ORA management, the plan is designed to be a flexible blueprint for the future, allowing for changes to be made as necessary, with a 20-year implementation period extending to the year 2014.

The laboratory structure under the plan includes the following:

- five mega-labs located in New York City, New York; Atlanta, Georgia; Los Angeles, California; Seattle, Washington; and Jefferson, Arkansas, which will be expected to perform all laboratory functions; and
- four special-purpose laboratories located in Winchester, Massachusetts (radionuclide analysis and engineering center); Cincinnati, Ohio (forensic chemistry center); Philadelphia, Pennsylvania (drug analysis center); and San Juan, Puerto Rico (drug analysis center).

Table 2 shows the expected laboratory closures and their scheduled closing dates.

Table 2: Expected Laboratory Closures and Dates

Laboratories	Closing date
Buffalo	1997
Chicago	1997
New Orleans	1998
Baltimore	1999
Dallas	2000
Detroit	2000
Minneapolis	2000
Denver	2010
Kansas City	2014
San Francisco	2014

History and Rationale for Consolidation

ORA was led to consider laboratory alternatives when it decided that many of its once state-of-the-art field laboratories built in the 1960s had become

obsolete. Over the years, FDA management has considered several options for replacing these facilities, from one-for-one replacement to consolidation.

In a 1986 consolidation plan, FDA proposed closing five laboratories to reduce the total capacity of its field laboratory system by about one-third.[2] In the early 1990s, ORA considered one-for-one replacement of these labs. For example, in 1991 and 1992, ORA had planned to construct new labs in New York and Baltimore, respectively. However, changes to the government's policy in 1992 precluded FDA from using GSA's federal building fund to acquire new construction projects. This caused ORA to reconsider its overall restructuring strategy. Accordingly, when ORA senior staff met in January 1993, they decided to examine how to most effectively and efficiently meet ORA's laboratory needs for the 21st century.

To accomplish this, ORA established the Working Analysts' Advisory Group (WAAG) in the summer of 1993 and the Laboratory Directors' Steering Committee in the fall of 1993. The members of these groups included laboratory analysts and directors, a field science adviser, and a representative of FDA's Division of Field Science. Also, during a strategic planning meeting in October 1993, the Associate Commissioner for Regulatory Affairs requested that the Regional Food and Drug Director for the Pacific Region develop an options paper to change ORA's field organizational alignment, including the laboratory structure, by the year 2004.

To evaluate the current field laboratory structure and to suggest modifications to it, the two committees assessed many issues, including positive and negative aspects of the current laboratories and other factors relevant to the selection of laboratory locations.

The two groups presented their recommendations to ORA senior staff. WAAG recommended that the 18 laboratories remain open and receive adequate funding support, while the Laboratory Directors' Steering Committee recommended that the 18 laboratories be reduced to 13. The committee noted, however, that it had recommended closing some laboratories because the field structure was overwhelmed with work due to overall staff attrition. According to one committee member, if FDA had adequately

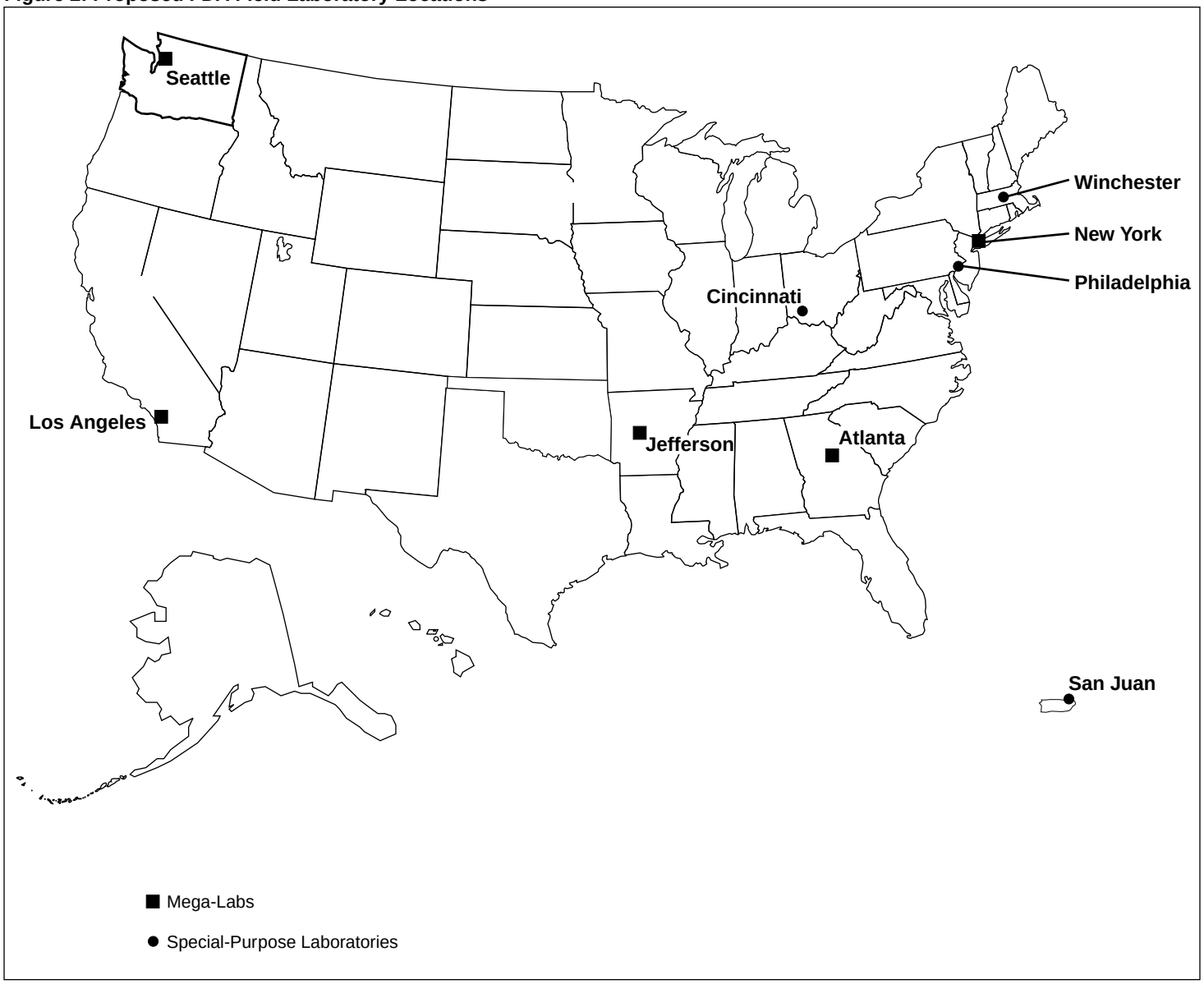
[2]GAO was asked to review FDA's 1986 proposal. GAO issued its report, Food and Drug Administration: Insufficient Planning for Field Laboratory Consolidation Decisions (GAO/HRD-88-21, Dec. 4, 1987), in 1987, concluding that FDA's criteria were limited and did not adequately address whether FDA could meet its current and future laboratory needs if the five laboratories were closed or whether cost-effective alternatives to closure were available to reduce its capacity.

staffed each laboratory, the committee would not have recommended certain ones for closure.

In December 1993, the Director for the Pacific Region issued the options paper, "Reorganizations of ORA for the 21st Century." The paper presented five options for restructuring the field laboratories. The options ranged from maintaining the status quo to restructuring using various consolidation options. The recommendations made by WAAG and the Steering Committee were incorporated into the paper's options and presented to ORA senior management before an ORA senior staff meeting in January 1994.

Participants in the ORA senior staff meeting discussed and reviewed each option and reached a consensus to consolidate the laboratories by creating five multipurpose mega-labs and four special-purpose labs. (See fig. 2.)

Figure 2: Proposed FDA Field Laboratory Locations



Projected Cost Savings May Be Overstated

ORA's analysis showed that its consolidation option saved money compared with continuing with the present structure by replacing labs when current leases expire. However, we found that ORA made assumptions that may have inflated the projected costs of replacing several laboratories.

Consolidation Versus One-for-One Replacement

ORA compared the costs of two options—consolidating laboratories as proposed (ORA 21) and replacing all laboratories as their leases expire. The replacement option assumes using leased property; the consolidation plan envisions that three of the mega-lab facilities (in Los Angeles, Seattle, and Jefferson, Arkansas) would be government owned. The costs estimated for consolidating versus replacing all the laboratories were about $950 million and $1.041 billion, respectively. Using these figures, ORA projected that the savings from its consolidation plan would be about $91 millon over a 20-year period.

ORA's assumption that it would have to lease space to replace existing laboratories was based on the federal budgetary process. Under budget score-keeping rules, outlays are generally scored on a cash basis when they occur. Therefore, the full construction cost must be appropriated in 1 year, and FDA believed that it could not compete for such funds given HHS' budget constraints. As we have pointed out previously, the federal government has often entered into leases to satisfy long-term space needs even though GSA analyses have showed leases to be more costly in the long run than ownership.[3]

Space and Staffing Requirements for Replacing Labs May Be Overstated

Under its most recently revised replacement analysis (July 1995), ORA appears to have overstated the space requirement for some laboratories and the staff requirements for two proposed laboratories. Such overstatements would increase the cost estimate for replacing laboratories and, thus, increase the comparative estimated savings from consolidation.

For the new facilities, ORA estimated laboratory space per analyst at 650 square feet and office space per nonanalyst at 230 square feet. (According to a GSA official, GSA considers occupied office space of about 153 square feet to be standard, but no standard exists for laboratory space.) ORA's consolidated space estimates, however, exceed all of ORA's existing laboratories' space amounts. For example, ORA's three newest laboratories—in Kansas City, San Francisco, and Seattle—currently operate with much less laboratory space per analyst. According to regional officials and laboratory analysts, the San Francisco facility, with 369 square feet per analyst, is state-of-the-art, and the Kansas City and Seattle laboratories, with 411 and 344 square feet per analyst, respectively, were similarly characterized in a 1994 FDA Division of Field Science report.

[3](Budget Issues: Budget Scorekeeping for Acquisition of Federal Buildings (GAO/T-AIMD-94-189, Sept. 20, 1994).

Also, the Atlanta laboratory, a multipurpose lab, currently has 33,654 square feet of laboratory, light industrial, and general storage space and 92 analysts on board with a capacity for 100. ORA had originally planned to expand this laboratory by 20,000 additional square feet for 60 additional analysts or about 333 square feet per analyst. However, after we questioned this estimate, ORA revised it, increasing it to 39,000 square feet (650 square feet per 60 additional analysts). Even using ORA's revised estimate of 39,000 square feet, the Atlanta laboratory would have only about 450 square feet per analyst for its expected total capacity after expansion.

If the cost estimates for to-be-leased space were based more on the amount of space in ORA's newer laboratories, the estimated costs of replacing laboratories would be significantly less than ORA has projected. Even if the estimates were based on the projected space for the Atlanta mega-lab after expansion, they would be about $2.2 million less per year than ORA has calculated. ORA feels justified in basing space requirements on 650 square feet per analyst and supplied us with a September 12, 1995, outside consultant's analysis performed after completion of our audit work. Although the consultant supported ORA's space requirement, this amount of space is nevertheless significantly greater than that being proposed for mega-labs in Atlanta and Seattle. Furthermore, ORA could not explain how and why existing space requirements in its newest laboratories (in San Francisco and Kansas) and in its proposed Atlanta and Seattle mega-labs are inadequate.

ORA also overestimated the staffing requirements for new laboratories in New York and Los Angeles under its replacement option. Instead of basing its estimates on the current staff size of these two laboratories—115 and 48, respectively—FDA used the mega-lab staff size of 189 analysts for New York and 75 analysts for Los Angeles. Thus, ORA came up with the same costs for the New York and Los Angeles facilities under both its replacement and consolidation options. Because the facilities' costs under the replacement option were not estimated on the basis of a smaller staff size, the resulting cost estimate for replacing the laboratories is overstated by about $2.5 million annually.

Operational Efficiency Gains From Consolidation Are Questionable

ORA believes that its consolidation plan would achieve certain benefits and efficiencies. Although we recognize that almost any restructuring could have some positive impact on operations, existing ORA evidence appears to contradict its claims that mega-labs will improve operations, supervisory/analyst ratios, and utilization of laboratory equipment. ORA's claims that its equipment and labs are obsolete are also questionable.

The operational efficiencies that ORA expects to gain through its consolidation plan include

- achieving a critical mass (50 or more analysts) in each lab,
- decreasing the number of mid-level managers,
- redeploying some supervisory staff to operations,
- decreasing support work required of operational staff,
- increasing efficient use of equipment, and
- being able to do shift work.

Efficiency of Medium-Sized Labs Versus Large Labs

FDA believes that efficiency involves many factors in addition to timeliness, such as overall costs per operations, staff, equipment, expertise available and utilized, accomplishments/outcomes from each sample tested, and customer service/responsiveness. However, FDA provided us evaluations of its laboratories based only on the factor of timeliness.

Current FDA timeliness statistics do not show that large laboratories are more efficient. In fact, FDA's fiscal year 1994 Sample Timeframe Report (which depicts each laboratory's timeliness in conducting analyses) showed that six out of seven medium-sized laboratories (33 to 50 analysts) were more timely than the two largest labs (New York and Atlanta). ORA officials in headquarters and in the field could not provide any explanation to contradict the data showing that its medium-sized laboratories were more timely or otherwise more efficient. In fact, WAAG and most ORA staff in the field that we spoke with stated that on the basis of their work experience an ideal laboratory size for efficiency is about 50 analysts. The Lab Directors' Steering Committee report also stated that a lab size of 50 to 75 analysts is ideal.

Supervisory/Analyst Ratio in Larger Labs Not Better Than in Most Other Labs

ORA's claim that larger labs would improve the supervisory/analyst ratio is also unsubstantiated. Data show that the supervisory/analyst ratio in ORA's two largest labs (in New York and Atlanta) with 115 and 92 analysts, respectively, is not better than in most of the other labs. For example, for

at least the last 2 years, the labs in Atlanta and New York have generally had supervisory ratios of 1 to 7 and 1 to 8, respectively. Only the lab in Chicago (with a ratio of 1 to 6) has had a worse supervisory ratio than the labs in New York and Atlanta.

Claims of Obsolete Equipment and Facilities Questionable

In August 1994, the FDA Commissioner stated that many labs had obsolete physical plants and analytical tools. Our work, however, raises questions about FDA's assessment. For example, the older labs (about 30 years old), referred to as "Rayfield buildings," are all similarly designed, brick facilities that appear to be structurally sound. The Atlanta laboratory site, in fact, includes a 1960 Rayfield building and an addition that was built in 1985. ORA wants to expand this site into a mega-lab.

WAAG also performed an evaluation of the existing labs. It concluded that the Rayfield buildings (in Atlanta, Baltimore, Buffalo, Cincinnati, Dallas, Detroit, and Minneapolis) generally are in good shape; however, some need renovation and/or additional space. With the expenditure of some funds for these purposes, these laboratories could be expected to continue to serve for approximately another 10 years. Most of the older facilities and some of the more modern facilities have three main problems: (1) insufficient or inoperative heating, ventilation, and air conditioning systems; (2) inoperable or insufficient exhaust hood capacity; and (3) insufficient space for employees or instrumentation.

WAAG provided the following possible solutions for the three problems. It suggested that (1) insufficient or inoperative heating, ventilation, and air conditioning systems be corrected by installing booster fans and remotely controlled baffles in existing air systems; (2) inoperable or insufficient hood capacity may be solved by using smaller tabletop exhaust systems, good housekeeping practices, and modified hoods to accept moveable lab benches so that heavy or complicated equipment set-ups in the hoods may be removed when not in use; and (3) additional space for analysts and instrumentation may be found if labs implemented good housekeeping practices. In commenting on a draft of this report, HHS argued against using what it considers a stop-gap measure to continue occupation in current facilities for a few more years.

Beyond the condition of the labs, the consensus of the analysts we spoke with is that present equipment is generally state-of-the-art. Analysts at several sites we visited told us that they do not know of more current equipment that is needed in their laboratories. FDA, on the other hand,

commented that a large percentage of field laboratory equipment is scheduled for replacement on the basis of purchase dates in accordance with the widely recognized Department of Veterans Affairs schedule of scientific equipment life expectancy. However, FDA has not demonstrated that its laboratories lack state-of-the-art equipment given its current facility capability. Furthermore, ORA provided us no support for how equipment needs would differ in the future.

One benefit of consolidation asserted by ORA was more intensive use of laboratory equipment. However, ORA did not provide evidence to refute assertions by analysts that cross-utilization of equipment is not always a viable option because instruments must be specially calibrated for particular samples.

Closures May Adversely Affect FDA's Analytical Staff

In addition to possibly overestimating the cost savings and efficiencies to be realized by consolidation, ORA may have underestimated this option's adverse impact on laboratory efficiency. For example, some analysts in the field believe that consolidation would result in a significant loss of experienced analysts.

Although ORA estimated that 75 percent of the analytical staff in labs scheduled for closure would relocate to other FDA facilities, it did not perform any analysis to support this estimate. We questioned this figure in a 1987 report[4] when ORA previously used it in a proposed laboratory consolidation effort. ORA said that it used the relocation rate of 75 percent because it did not want to appear to understate the relocation costs. If a large percentage of analysts would not relocate, ORA's operations could be adversely affected until new analysts are trained.

Site Selections Not Based on Recognized Criteria

To guide ORA in its site selection process, WAAG—at management's request—developed and prioritized a set of criteria for consideration, recognizing that meeting each criterion might be impossible. In addition, ORA management developed its own criteria. However, ORA appears to have based site selection mainly on the availability of construction funds or congressional indications that such funds would be available for specific sites.

WAAG's criteria included quality-of-life issues, such as transportation, housing, population density, crime, and the merit of area schools; and

[4]Food and Drug Administration (GAO/HRD-88-21, Dec. 4, 1987).

construction feasibility issues, such as costs and available land for building new or expanding existing facilities. WAAG's criteria also included projected workload distribution and the existing infrastructure to support the laboratories, such as commercial labs, workforce demographics, local universities, FDA investigation branches, and other government agencies.

ORA management considered these criteria but developed a somewhat narrower set of criteria, which included geographic dispersion (two laboratories on each coast and one centrally located), quantity of commercial establishments in the area, major shipping ports of entry, and availability of FDA-owned land.

We found, however, that the proposed mega-lab sites in New York, Los Angeles, and Jefferson do not meet many of the criteria established by WAAG and ORA. For example, the Jefferson site lacks such factors as proximity to ports of entry and quantity of nearby food and other relevant businesses. Instead, ORA appears to have placed more emphasis on the availability of funding in selecting the site locations. For the Los Angeles and Jefferson sites, the Congress has provided funds for architectural and engineering design work, with the expectation that subsequent construction funds would become available. Congressional action authorized construction funds to build a laboratory at the New York site, which committed FDA to this location. (See app. II.)

Conclusions

ORA believes laboratory consolidation is necessary to meet its pressing need to streamline and improve operations. Although consolidation may achieve efficiencies, the evidence ORA provided to us appears to have overstated the magnitude of the future benefits. For example, ORA may have overestimated its costs for replacing several labs. Also, ORA overestimated the staffing requirements for new laboratories in New York and Los Angeles under its replacement option. Such inflated replacement cost figures raise questions about ORA's estimated cost savings from ORA 21. Further, ORA's existing evidence appears to contradict its claims that the mega-labs will improve operational efficiencies.

These and other issues raised in this report suggest that FDA should revisit its plan to consolidate its regulatory laboratories.

Recommendation

We recommend that the Commissioner of FDA review the restructuring plan to determine whether ORA adequately weighed the benefits of consolidation relative to other alternatives.

Agency Comments

HHS commented that it shared our interest in having accurate and appropriate information upon which to base critical decisions about current and future laboratory facility needs. However, HHS believes that any further analysis would not satisfy the basic and compelling need to reduce operations costs where possible. Thus, the Department disagreed with our report. Specifically, it believes that (1) ORA's cost estimates (based on a space requirement of 650 square feet per analyst) are appropriate, (2) consolidation will result in efficient ORA operations, (3) the site selection for its mega-labs was based on reasonable criteria, and (4) its current equipment and facilities are obsolete.

We found that ORA (1) has not demonstrated why existing space requirements in its newest facilities (which are significantly less than 650 square feet per analyst) are inadequate; (2) does not have adequate measurable data to support its claim that consolidation would achieve certain benefits and efficiencies; (3) appears to have based site selection mainly on the availability of construction funds or congressional indications that such funds would be available; and (4) has not demonstrated that its laboratories lack state-of-the-art equipment because of its current facility capability or that its schedule to replace equipment would differ if ORA consolidated its labs. We are not questioning whether consolidation should occur but are reporting that documentation of the bases for ORA's decisions is lacking.

We have incorporated the agency's specific comments in this report where appropriate. A copy of the agency's full response and our rebuttal appear in appendix II.

We are sending copies of this report to interested congressional committees, the Secretary of Health and Human Services, the Commissioner of FDA, and other interested parties.

This report was prepared by Barry Tice, Assistant Director; Robert Wychulis; and Cameo Zola. Please call Mr. Tice at (202) 512-4552 if you or your staff have any questions about this report.

Sarah F. Jaggar
Director
Health Financing and
Public Health Issues

Contents

Abbreviations

FDA	Food and Drug Administration
GSA	General Services Administration
HHS	Department of Health and Human Services
NCTR	National Center for Toxicological Research
ORA	Office of Regulatory Affairs
WAAG	Working Analysts' Advisory Group

Scope and Methodology

We performed our work at FDA headquarters in Rockville, Maryland, and visited FDA laboratories in Buffalo, Baltimore, and San Francisco. We also reviewed videotapes of the Los Angeles, Seattle, Dallas, and New Orleans laboratories. We reviewed agency procedures and data governing its plan to restructure field laboratory facilities. During our review, ORA provided us three different cost savings estimates. The initial cost estimate was dated December 22, 1994, followed by revised estimates on May 26 and July 5, 1995. The cost data were presented for two restructuring options: (1) consolidating from 18 to 9 laboratories and (2) replacing every lab when current leases expire.

We discussed ORA's plan with key ORA officials in headquarters and at the sites we visited. In addition, we discussed selected data with GSA headquarters and field representatives. During our visits to the three field laboratories, we held group meetings with analysts and inspection/compliance personnel. Also, we met with import brokers in Baltimore and Tampa.

We conducted our work between October 1994 and November 1995 in accordance with generally accepted government auditing standards.

Comments From the Department of Health and Human Services and Our Evaluation

Note: GAO comments supplementing those in the report text appear at the end of this appendix.

DEPARTMENT OF HEALTH & HUMAN SERVICES Office of Inspector General

Washington, D.C. 20201

NOV 7 1995

Mr. Mark V. Nadel
Associate Director, National
and Public Health Issues
United States General
Accounting Office
Washington, D.C. 20548

Dear Mr. Nadel:

Enclosed are the Department's comments on your draft report, "Food and Drug Administration: Data To Justify Consolidating Its Field Laboratories is Lacking." The comments represent the tentative position of the Department and are subject to reevaluation when the final version of this report is received.

The Department appreciates the opportunity to comment on this draft report before its publication.

Sincerely,

June Gibbs Brown
Inspector General

Enclosure

The Office of Inspector General (OIG) is transmitting the Department's response to this draft report in our capacity as the Department's designated focal point and coordinator for General Accounting Office reports. The OIG has not conducted an independent assessment of these comments and therefore expresses no opinion on them.

COMMENTS ON THE DRAFT GAO REPORT ENTITLED, "FOOD AND DRUG ADMINISTRATION: Data To Justify Consolidating Its Field Laboratories is Lacking" (GAO/HEHS 95-249)

See comment 1.

As a general comment, the Department shares with the General Accounting Office (GAO) a common interest in having accurate and appropriate information upon which to base critical decisions regarding current and future laboratory facility needs. However, we believe that the draft report is not valid. We believe the report should fully address the history of FDA's efforts to manage its facility costs effectively, the practicalities of budget constraints, shrinking staff, capital acquisition procedures, and the role of the Congress with respect to acquiring facilities. We are also concerned that information provided to GAO by the Food and Drug Administration (FDA) to resolve issues raised in the exit conference was not included in the draft report.

See comment 1.

The FDA supplied an historical review of FDA Field laboratories from 1907 to the present. This review shows that, prior to the 1994 Laboratory Consolidation Plan (LCP), FDA had reviewed its overall organization and its laboratory operations in the 1970s and again in the 1980s. In both studies, FDA reached the conclusion that it would be necessary to operate with fewer laboratories in the future because of significant budget constraints, a growing workload resulting from new mandates, increasing national and international trade, and new technology that requires FDA to consolidate its resources and use them more effectively. The 1973 House Appropriations testimony called for six regional labs, and the 1986 plan recommended nine laboratories. Furthermore, both of the studies done in the past 20 years proposed that laboratories in Buffalo, Chicago, New Orleans, and Cincinnati be restructured or closed to contain growth in facility costs. In 1986, FDA had every intention of consolidating laboratories (for many of the reasons that are still valid), but was prevented from doing so by congressional action. The report's conclusion that FDA management formulated the strategic plan without proper study is amply refuted by the more than 20 years of effort that have been devoted to exploring the laboratory consolidation problem.

See comment 1.

The Office of Regulatory Affairs (ORA) senior managers were well aware of the previous studies and their conclusions when the 1994 assessment was undertaken. FDA managers recognized a pressing need to streamline operations, and concluded that laboratory consolidation would be necessary and could be done without eroding FDA's ability to carry out its mission.

The GAO draft report states that FDA has pursued a one-for-one replacement of older facilities until recently. Under currently prevailing circumstances, FDA has been compelled to pursue this course of action to adequately house its analytical functions.

Clearly, with aging facilities, whose leases have expired or soon will, and imposed restrictions on consolidation, FDA has been forced to replace facilities or refurbish them when that has been the only option. Consequently, many labs have been repaired frequently with stop-gap measures to keep them operational and meeting at least minimum standards.

The report does not suggest a more acceptable model for effective and efficient operations in the future that would consider the pressing need to contain costs while maintaining a high level of productivity and efficiency. Nor does it recognize the compelling need to continue to fulfill FDA's mission in the face of ever-increasing worldwide trade in FDA-regulated products; advances in science and technology that require up-to-date scientists, equipment and facilities; and the added responsibilities given to FDA by the Congress.

See comment 2.

It appears that GAO relied heavily on the report issued by FDA's Working Analysts' Advisory Group (WAAG). This group was convened as part of ORA's managers' effort to gain thoughtful input to solutions of resource and facility problems facing FDA. They were asked to advise FDA management on laboratory consolidation issues.

See comment 2.

We believe that the WAAG report does not deal with hard issues. The WAAG did not recommend any alternatives to the current structure. Furthermore, the criteria used by the WAAG were heavily weighted toward employee perceived quality-of-life issues rather than mission issues. The WAAG report recommended that FDA retain its current 18 labs, fully staffing and supporting them. The Department believes that the currently prevailing budgetary and political climate indicates the current laboratory network will not be viable for the future. Budget allocations would be better utilized and provide a stronger field structure with fewer laboratories to support.

See comment 2.

ORA managers have the responsibility for making such decisions, and they also have the expertise to take a broad view of the field resources (facilities and staff) for the future and determine in an objective manner the best network for the future. They all have had extensive field experience as investigators or analysts or both in multiple districts and regions as well as planning and managing complex activities requiring objective analyses.

The LCP will consolidate the present complement of 18 laboratories into 9, a move consistent with both the Administration's and Congress' streamlining and cost saving initiatives. GAO's concerns that the consolidation plan lacks supporting data regarding (1) projected cost savings, (2) projected efficiencies and measured impact on operations, and (3) site selection criteria will be addressed more fully below.

PROJECTED COST SAVINGS CALCULATIONS

Now on p. 3.

1. **"...ORA's projected cost savings from replacing all existing facilities may have been substantially overstated as these estimates were based on inflated estimates of laboratory space needs."** (page 2)

See comment 3.
Now on pp. 3,8,9,10.

This statement is not correct. The report repeatedly challenges FDA's cost calculations and asserts that FDA's estimates of laboratory space needs are inflated. (Most notably on pages 2, 7, and 9). GAO apparently based its estimates of FDA's laboratory space needs on a miscalculation of the space that will be available in the Southeast Regional Laboratory (SRL) when renovations are completed. As shown in FDA's July 5, 1995 submission, GAO includes a table labeled Housing Plan for Seven FDA Laboratories, the Atlanta laboratory expansion space requested was 39,000 sq. ft., not 20,000 sq. ft. as reported on page 9 of the draft report. The requested additional 39,000 sq. ft. of laboratory space will house 60 additional personnel who will be transferred from closing laboratories in Cincinnati, Baltimore and New Orleans. GAO understated the additional space that will be available in Atlanta by roughly half. With the expansion, the Atlanta laboratory will conform to FDA's planning module of 650 sq. ft. per analyst.

Now on p. 10.

See comment 4.

This "per analyst" estimate is "fully loaded," in that it incorporates space for necessary support operations such as storage and glass washing facilities. Further, on July 19, 1995 FDA offered supporting documentation for the 650 sq. ft. module, and cited two recent General Services Administration (GSA) Architectural and Engineering (A&E) studies, one done a few years ago by the 3DI firm, for FDA laboratory space in Los Angeles, and the other done when FDA was considering moving the Baltimore district office to a new location within the Baltimore area. Those A&E studies called for 694 sq. ft. per person and 724 sq. ft. per person, respectively, based on planned staffing at the time of the study. GSA has confirmed that there is no established standard for laboratory space and that the tenant agencies document their own needs for laboratory facilities.

See comment 4.

Based on discussions regarding GAO's concern about the validity of FDA's projected space requirements, and to provide an objective, realistic analysis of space requirements for new laboratories, FDA contracted with The Kling-Lindquist Partnership (TKLP), an architecture, engineering and interior design firm, to review the LCP and determine current space requirements for new laboratories based on comparable construction throughout the scientific community. TKLP's report, entitled "Review of FDA/ORA Field Laboratory Space Planning Factors", September 12, 1995, reviewed designs for nine recently-completed major new laboratories, including some constructed for the FDA-regulated industry such as the Glaxo RTP Research Center (1991) and

government laboratories such as the National Institutes of Health's Silvio Conte Building (1993). TKLP also reviewed plans for facilities not yet constructed such as FDA's planned Arkansas Regional Laboratory (1994-1995). The TKLP review found that labs doing only chemical analyses ranged in size from 245 sq. ft. per analyst to 430 sq. ft. per analyst (340 sq. ft. median); biology labs ranged from 260 sq. ft. per analyst to 450 sq. ft. per analyst (340 sq. ft. median); and multi-purpose analytical testing/processing labs such as FDA's field laboratories ranged from 400 sq. ft. per analyst to 800 sq. ft. per analyst (650 sq. ft. median). These figures agree with the 650 sq. ft. per analyst figure FDA uses for estimating the costs for new laboratory space. This study was provided to GAO on September 12, 1995.

See comment 4.

Since the draft report was received for comment, the Army Corps of Engineers, which is handling the Los Angeles facility acquisition for FDA, has independently completed an assessment of laboratory space requirements based on staffing and programmatic functions for that facility. They have determined that 50,500 sq. ft. is required to house 75 employees, a per employee average of 673 sq. ft. This independent assessment done by Sherlock, Smith & Adams, Inc. further supports FDA's use of 650 sq. ft. per analyst as an appropriate planning figure.

See comment 4.

On September 1, 1995, as requested by GAO evaluators, FDA also provided data showing the space per analyst for each of FDA's three newest field laboratories; Kansas City, San Francisco, and Seattle. The following table demonstrates that, at the time of first occupancy, the space per analyst in two of the three laboratories was in excess of FDA's current planning module of 650 sq. ft. per analyst. The third was somewhat lower but still significantly higher than the 360 sq. ft. per analyst used by GAO.

LABORATORY SPACE (GSA RENT BILLS) VERSUS
LABORATORY STAFFING AT TIME OF INITIAL OCCUPANCY

(Reflects "pure" lab space **PLUS** support space)

LAB	DATE SF-81 ISSUED	SQUARE FEET (SQ. FT.) PER LABORATORY	STAFFING	SQ. FT. PER PERSON
K.C.	Dec 1987	24,655	30	822
SEATTLE	June 1985	17,375	26	668
SAN FRAN	June 1991	25,821	52	497

See comment 4.

Clearly, the space figure (360 sq. ft. per analyst) used by GAO would not meet current standards for efficiently operated FDA and other similar laboratories because it would not provide for adequate laboratory support operations such as reagent storage; loading docks; sample storage and accountability; animal housing, feeding and sanitation; and bottle washing. Nor would it provide space for analysts to work away from the analytical station when not engaged in actual test procedures.

Now on p. 8.

2. **"ORA's cost comparison methodology contained weaknesses that raise doubts about the accuracy of its estimates."** (page 7)

See comment 5.

We disagree. After discussions with GAO auditors on cost comparison methodology, FDA twice recalculated the projected costs using GAO's suggestions. These analyses were provided to GAO. All three projected significant cost savings over the 20-year life of the LCP. The final revision projected $90 million in savings over 20 years if the laboratories are consolidated using FDA-owned property whenever possible. Also at GAO's suggestion, the final revision provided to GAO on July 5, 1995 reflected annual rent projections based on documented values for construction costs, associated rent derivations, and lab casework and bench cost estimates. These cost factors were adjusted for local market conditions. One example of the savings to be realized by consolidation is the Buffalo laboratory facility, which GAO acknowledged to be in poor condition. The Buffalo cost calculations have been provided to GAO.

3. **"In determining costs of the replacement option, ORA did not consider construction and government ownership as alternatives for replacing facilities...."** (page 8)

See comment 6.

FDA compared the cost of acquiring and operating 9 laboratories against the cost of replacing currently leased facilities and operating 18 laboratories. That cost comparison assumes FDA would continue to lease space for laboratories that presently are in leased space. GAO faults FDA's cost savings figure because we did not also compare construction and ownership costs as a way of replacing all leased laboratories. The simple fact, however, is that funds would not be available to replace all of the closing leased laboratories with government-owned facilities. Recent Office of Management and Budget directives have required that new construction and land purchase be fully funded in one fiscal year. FDA managers realistically assessed the likelihood of successfully competing with other FDA and Department programs for the required funds and elected to pursue a less costly approach, namely, that proposed in the LCP. We submit that management experience and their knowledge of the overriding need to balance the Federal budget made it unnecessary to expend the resources required to cost-out nonviable alternatives.

See comment 6.

Significantly, FDA did consider the important cost-effective advantage of Government-owned facilities in deciding where laboratories would be located. FDA's criteria strongly favored FDA-ownership and direct Federal construction as a cost-effective measure. FDA carefully considered Government ownership in recommending sites for its multipurpose or megalabs and specialty labs. The projected consolidated facilities in Los Angeles, Arkansas, and Seattle are Government-owned, as are facilities in Philadelphia, Winchester, and San Juan. Overall, six of the nine future laboratories are Government-owned. FDA incorporated the savings derived from direct Federal construction and ownership into the consolidation plan.

4. **"...ORA did not do any assessment to determine the cost of renovating its existing laboratories."** (page 8)

See comment 7.

FDA primarily considered its mission and how best to facilitate it in developing the LCP. FDA subsequently considered the condition and potential renovation or expansion of each existing facility as a part of its deliberations. Factors such as 1) the need to contain the growth of facility budgets; 2) prevalence of FDA-regulated industry; 3) volume of imported FDA-regulated products; and 4) concern for employee safety dictated that certain current facilities and locations, e.g. Buffalo, New Orleans, Detroit, Chicago, etc., would not have a high priority for replacement. Consequently a site-by-site renovation or direct construction assessment was not considered necessary.

See comment 7.

FDA's strategic plan is an effort to build a strong, long-term network to enable FDA to sustain scientific expertise and investigations into the next century. Renovating 1960's constructed facilities is not a long-term solution for achieving the cost savings needed. As GAO noted with respect to FDA's calculations of the costs associated with retaining the full complement of 18 laboratories, yearly rental costs add significantly to the over-all cost of housing laboratories. Renovating existing laboratories would not alleviate the need to pay rent, since all of the laboratories scheduled for closure are rented facilities.

See comment 7.

GAO discounted FDA's concerns about the safety of the areas surrounding some of FDA's laboratories and the general condition of current facilities. In June 5 and September 1, 1995 submissions to GAO, FDA documented that areas such as the Los Angeles and Chicago laboratory locations are unsafe. FDA also provided documentation showing the long history of physical plant deficiencies at the New Orleans and Baltimore facilities. GAO, itself, reported that Buffalo has had numerous facility deficiencies as well. These factors clearly demonstrate that renovation at these sites would not be feasible and should not be considered.

See comment 7.

Furthermore, the decision to renovate does not reside with FDA alone. Changes to existing leased space, particularly major changes, are dependent upon the owner's willingness to expend the money required to meet FDA's requirements. The leases on most of FDA's laboratories are expiring within the next 5 years. FDA, in conjunction with GSA, would be required to hold open bidding to allow any interested parties the opportunity to provide facilities meeting FDA specifications. Based on FDA's recent history with the process, it is unlikely that the current lessors would ultimately prevail, making a move necessary anyway. As the TKLP report indicates, renovation of old laboratories to meet current standards generally is more costly than new construction. It also results in less usable space than that in current facilities because of the need to provide more safety measures, such as separate storage for hazardous wastes and solvents and space outside the work stations for analysts to work when not actively engaged in a scientific procedure.

See comment 7.

Finally, renovation of current facilities often restricts improving the quality of the overall facility. In Baltimore, for example, hazardous waste and solvent storage areas are inadequate to meet today's fire safety codes. Additional contiguous space is unavailable to rectify this situation, thereby requiring expansion to adjacent land if the building is renovated. Renovation, in summary, is not generally an acceptable alternative to new construction for meeting or attaining 1995 facility design, safety, and program requirements. In a few cases renovation of rented facilities may be the option of choice

under specific circumstances, i.e., when the facility permits flexibility and FDA has a cooperative working relationship with the landlord such as that in Atlanta. Each facility must be evaluated in light of its own unique situation. Examples of renovation to produce future laboratories are Philadelphia and San Juan, both Government-owned facilities, that FDA plans to renovate to accommodate human drug testing laboratories.

See comment 7.

As mentioned above, TKLP compared costs for renovating two existing buildings at FDA's National Center for Toxicological Research (NCTR) site in Arkansas, for use as a field laboratory with the cost for new construction at the same site (which is FDA-owned). Their conclusion was that renovation was more costly and produced less net usable space for operations. The difference in cost was $38 million (renovation) versus $35 million (new construction).

EFFICIENCY AND IMPACT ON OPERATIONS

1. **...It (FDA) has not demonstrated that the resulting configuration (from laboratory consolidation) would perform scientific analyses and regulatory activities more effectively or efficiently than it does now."** (page 2)

Now on p. 3.

See comment 8.

The goal always has been, at a minimum, to perform at the same level of effectiveness while saving resources and establishing a laboratory network which will thrive over the next 20 years and not simply find the least expensive approach. This translates into taking advantage of the opportunity to make better use of equipment, save rent and maintenance on currently underutilized facilities, and aggregate analysts with like skills to ensure that work will not go undone because an analyst is unavailable. We believe FDA has demonstrated that operations will continue at a high efficiency rate, but at lower cost to FDA.

See comment 8.

As GAO was informed, FDA currently ships samples from all districts to distant laboratories for analysis, which is a standard operating procedure for FDA. Shipment of samples, therefore, is not a factor that would reduce the efficiency of the megalabs, nor can the need for collaboration be a factor. This point will be further discussed below. GAO was further informed that 21 analysts have VOLUNTARILY moved in anticipation of their "home" laboratory closing. We believe this is a good indication that there will be few problems associated with the availability of analysts in the megalabs. GAO also was informed that approximately 40 percent of FDA analysts are eligible for retirement. Probably many of these analysts will not choose to move, but will retire. This will afford FDA an opportunity to fill the resulting vacancies at a megalab rather than in one of the current laboratories that will be closing. These and other

factors suggest that efficiency will not be affected by consolidation.

See comment 9.

Furthermore, in reaching its conclusion, GAO did not appropriately use the FDA laboratory time frame reports for 1993-1994 as the basis for stating that FDA has not demonstrated that the proposed laboratory configuration would perform scientific analyses more effectively or efficiently than FDA does now. The time frames are used for work planning purposes and as goals for individual labs and the field as a whole to achieve on an average basis. The time frames do not measure the efficiency of either individual analysts or individual laboratories. As discussed on numerous occasions with GAO's evaluators, meeting time frames is only one factor in determining the efficiency and effectiveness of a laboratory operation. Other factors include the mix of analyses performed by a particular laboratory, cost, equipment utilization, appropriate prioritization of competing demands, etc. FDA does not agree that efficiency can be measured by time frame reports alone. Efficiency is the sum of overall costs per operations, staff, equipment, timeliness, expertise available and utilized, accomplishments/outcomes for each sample tested, customer service/responsiveness, etc. FDA provided GAO (May 17, 1995) with an explanation of time frame reports and their purpose.

2. "OPERATIONAL EFFICIENCIES FROM CONSOLIDATION (are) UNSUBSTANTIATED, Medium-Size Labs (are) More Efficient Than Large Labs, Supervisory/Analyst Ratio in Larger Labs (are) Not Better Than (in) Most Other Labs, (and) Savings From Better Utilization of Equipment (are) Unlikely." (Page 11)

Now on p. 11.

See comment 10.

We disagree. While it is impossible to present evidence of their performance before the laboratories are established, FDA has an accurate model of future megalab operations in its SRL, which services FDA districts from Louisiana to North Carolina. This laboratory consistently meets the established time frames for completing analyses. It also has a large enough cadre of analysts to allow uninterrupted operations on a day-to-day basis and to meet any extraordinary demands that arise. The SRL services several districts, providing team collaboration as required, rapid sample analysis turn-around, and a full range of analytical capabilities.

See comment 10.

Furthermore, a laboratory cannot provide uninterrupted service to the districts for 365 days a year with as few as one experienced analyst in a program area. A laboratory must have a cadre of experienced staff to maintain uninterrupted laboratory capability. With 18 laboratories, and experienced staff located at each, FDA must stretch the work load to provide mission-oriented, meaningful work at each. However, stretching resources simply because a lab exists and personnel have been trained is

inefficient and requires that each facility be equipped to perform all tests required by the program it services. FDA's current laboratory network has numerous laboratories where programs are staffed by a single analyst. The WAAG report recommended retaining all 18 laboratories and fully staffing them. The laboratory directors stated that staffing ideally should be between 50 and 75 analysts. FDA would require an analytical staff of 900, more than the current number of analysts, to staff 18 labs at this level. ORA is shrinking in size, not growing. Therefore, FDA would be required to consolidate laboratories, even to staff all the remaining labs with at least 50 people.

3. **"(The) IMPACT OF CONSOLIDATION ON FDA's OPERATIONS HAS NOT BEEN ADEQUATELY ADDRESSED, (S)ome analysts...believe consolidation will result in a significant loss of experienced analysts...."** (page 14)

Now on p. 13.

See comment 8.

FDA looses experienced analysts each year through retirement. FDA's workforce demographics, resulting from hiring initiatives of the 1960s and 1970s, indicate that the workforce will have a significant turnover in the next 5 years. GAO was provided with demographic information concerning FDA's current laboratory staff. Approximately 40 percent of the laboratory staff will be eligible for retirement from 1997 to 2000, which coincides with laboratory closures and personnel transfers. The laboratory consolidation effort will impact 240 personnel through the year 2000 and an additional 180 personnel by the year 2014. To retain experienced analysts, FDA is offering lateral transfers to laboratory locations of the analysts' preferences. In Fiscal Year (FY) 1995, 21 analysts from closing laboratories voluntarily took advantage of this offer. This is a positive indication that FDA will maintain expertise within its workforce. Nonetheless, with the projected retirements, FDA will need to recruit and train new analysts regardless of the fate of the consolidation plan. The consolidation plan will allow FDA to recruit, train and place personnel where they are needed.

4. **"...collaboration among analysts and inspection and compliance personnel would be compromised....The Team Concept Could Be Adversely Affected"** (page 14)

See comment 11.

FDA disagrees. In streamlining operations, FDA has and will continue to establish teams to conduct business more effectively. These teams may or may not be collocated. FDA currently has teams with members from different districts who collaborate on a daily basis in planning inspections, sample collections, etc. For instance, pesticide coordination teams were established in 1988 to provide day-to-day planning between investigators, compliance officers, and servicing laboratories. Most often, one laboratory within a region services two or three district pesticide operations. These teams function successfully without

being collocated. Most of their interaction is by conference calls and electronic data transmission, but as necessary, the teams get together for inspections and other activities. Effective drug inspection teams have been formed using members from the Los Angeles and Seattle district offices. The drug investigations teams include analysts from the Seattle district laboratory who provide technical assistance and investigators from throughout the Pacific region. Furthermore, the foreign drug inspection cadre matches investigators and analysts from around the country based on the technical expertise required. Often the cadre members meet for the first time as they embark on their inspection.

5. **"ORA estimates that 75 percent of the analytical staff in offices scheduled for closure will relocate to other facilities. ORA, however, did not perform any analysis to support this estimate. We questioned this figure in our 1988 report when ORA previously used it in a proposed laboratory consolidation effort."** (page 15)

Now on p. 13 .

See comment 12.

In planning for consolidation it is necessary to project that some percentage of the current staff will move to the megalabs. Whether that number is 75 percent or any other arbitrarily selected number makes little difference if the cost for relocating employees is not so understated that the resultant overall cost savings are inflated. FDA used the 75 percent figure as an upper estimate to ensure that cost projections did not understate the cost of consolidation. A lower estimate would, indeed, project greater savings from restructuring. However, two events requiring transfers of laboratory personnel confirm that the 75 percent is a reasonable estimate for planning purposes. When the Centers for Disease Control and Prevention laboratories were consolidated from Phoenix, Arizona to Atlanta, Georgia, approximately 75 percent of the scientific staff transferred. Likewise, the Center for Food Safety and Applied Nutrition's training facility in Cincinnati was closed and nearly 75 percent of the analysts transferred to headquarters. As stated above, we do not expect that laboratory consolidation will have an adverse affect on laboratory operations even if fewer than 75 percent of the analysts transfer. (See above for expected turnover from retirements.)

6. **"(The) Supervisory/Analyst Ratio in Larger Labs (is) Not Better Than (those in) Most Other Labs.** (page 12)

Now on p. 11.

This is an accurate statement for the current time. However, GAO should recognize that achieving the organizational management/employee goals will be done over a period of time through attrition, targeted replacements, reassignments, etc. ORA is committed, as is all FDA, to reduce middle management to reach a targeted supervisory ratio with a corresponding reduction in personnel costs. The current supervisory ratio in FDA

laboratories is not reflective of the mandate to improve the supervisor/employee ratio, which FDA endorses.

We do not expect the mandated ratios to be met in each laboratory during FY 1996, as the LCP will be implemented beginning in 1997. This means that, in the interim, some of the laboratories may have exceptionally high ratios while others have low ratios. When the megalabs are fully operational, this anomaly of transition will be corrected as necessary. Through training in team building and in managing personal growth, we are undertaking to prepare our staff for this organizational and cultural change.

SELECTION CRITERIA

1. **"...we found little evidence that ORA considered established criteria, such as quantity of commercial establishments in the area and major shipping ports of entry, in selecting the sites for its five mega-labs."** (page 2)

Now on p. 3.

See comment 13.

This statement is not correct as evidenced by the proposed locations of the megalabs. Three of the five are located in major port cities with large import operations and heavy concentrations of FDA-regulated industry. Another will be located in the heartland on federally owned property to service domestic production. The fifth will be FDA's Southeast Regional Laboratory which currently services three districts, including the Florida district with major import operations in Miami, Tampa, and Jacksonville.

See comment 13.

In the December 1994 briefing for GAO evaluators, FDA stated that the need to consider consolidation arose for a number of reasons, including the need to stretch FDA field resources to cover more responsibilities; funding for FDA field operations is static or being reduced; the concern about the Federal Government budget deficit makes it unlikely that FDA will have significant monies for renovating and maintaining facilities for the foreseeable future; and many of FDA's current facilities are in need of major repairs/renovations, have leases that will expire in the next few years, and are in unsafe locations. Furthermore, FDA freely acknowledged that the criteria used for determining which laboratories to retain, which to close, and where new laboratory capability would be appropriate were not captured in meeting notes or subsequent reports. However, they are well-established, and have been generally accepted as valid by FDA management through the many iterations of laboratory planning. The criteria include:

1. reduce facilities costs while preserving regulatory science services;

2. take advantage of federally-owned land and direct Federal construction whenever possible;

3. consolidate programs and equipment for improved efficiency and effectiveness;

4. expect loss of analytical expertise through retirement (more than 50 percent of the current laboratory personnel are eligible for retirement between 1997 and 2000;

5. locate laboratories near major clusters of FDA-regulated industry and major ports of entry;

6. consider the condition of the current laboratories, which must be in good repair, have ample room to meet current standards of safety and performance, accommodate the full range of equipment required for a regulatory laboratory as well as a full complement of analysts and support staff;

7. move employees from locations of public safety concern, e.g. Chicago, Los Angeles

8. identify those facilities having authorized prospectuses; and

9. consider the expiration dates for current leases and the relationship between FDA and the current lessor.

See comment 13.

FDA senior managers not only considered the factors GAO mentioned, they also considered the criteria used by the WAAG and the Laboratory Directors' Steering Committee. Using the objective criteria listed above, ORA concluded that reducing the number of facilities would provide savings which could be redirected to maintaining programs which otherwise would sustain losses.

See comment 13.

Interestingly, the report is not consistent regarding whether or not FDA used objective criteria to determine the future status of the laboratories. On the one hand, GAO states that there is little evidence that such criteria were used. On the other hand, the report faults FDA managers for substituting the objective criteria of "...geographic dispersion...quantity of commercial establishments in the area, major shipping ports of entry, and availability of FDA-owned land." for the criteria used by the WAAG.

See comment 13.

However, the WAAG proposal was based on criteria that primarily addressed the quality-of-life issues employees would experience in making their individual decisions regarding relocation. Consequently, the WAAG proposed only one scenario; retain all current laboratories in the same cities where they are currently located. They offered no alternatives that would address changing program requirements, resource constraints, and reduced

staffing. The WAAG criteria do not consider the full complement of management issues such as budget, staffing levels, and basic infrastructure components for the day-to-day operations of the organization.

2. **"The WAAG criteria were based primarily on each location's conduciveness to recruiting and retaining qualified analysts and on the costs associated with leasing and building new facilities."** (page 16)

See comment 14.

This statement implies that FDA managers did not consider staff recruiting and retention to be important. To the contrary, FDA is very concerned about maintaining its record for recruiting and retaining highly qualified analysts. Throughout the past 30 years FDA has had no difficulty in recruiting or retaining qualified analysts at any field location, even those in unsafe areas and other areas perceived to be undesirable by many. Moreover, the National Center for Toxicological Research which is perceived by some to be isolated, receives numerous inquiries/curriculum vitae for post-doctoral or sabbatical opportunities and full time employment. Furthermore, FDA retains scientific personnel equally well in all its field locations. These statements are supported by the retirement eligibility information provided earlier, i.e. nearly 40 percent of current staff are eligible for retirement, having served most, if not all, their careers with FDA. The average length of service for FDA's field laboratory staff ranges from 9 to 23 years per laboratory.

CONDITION OF EQUIPMENT AND FACILITIES

1. **"... the FDA Commissioner stated that many labs were obsolete in terms of their physical plants and their analytical tools. Based on our visits to three laboratories and our observation of video tapes of several other labs we question the Commissioner's assessment."** (page 13)

See comment 15.

GAO accepted their own cursory observations and the comments of analysts, who are not responsible for maintaining buildings and assuring that equipment is up-to-date and in good repair, as evidence that FDA laboratories are in acceptable condition. Yet the report states that "...we (GAO) did not independently assess the quality of equipment." On the other hand, the report does not discuss documentation submitted by FDA management.

See comment 15.

FDA provided an equipment inventory data summary showing that a large percentage of field laboratory equipment is scheduled for replacement based upon purchase dates and the widely-recognized Department of Veterans Affairs (DVA) schedule of scientific equipment life expectancy. The DVA schedule has been used Government-wide as a model for determining when laboratory

equipment needs to be replaced. For example, using the DVA life expectancy schedule, gas chromatographs have a life expectancy of 7 years, electrophoresis equipment has a life expectancy of 10 years, and centrifuges have a life expectancy of 10 years, etc. ORA has an equipment performance system (EPS) inventory of over $40 million in capital equipment which is tracked for replacement purposes. Based on the life expectancies and a 3 percent inflation factor, ORA projects its capital equipment replacement costs for each FY budget submission. In FY 94, ORA estimated more than $23.4 million would be required to replace all capital equipment scheduled for replacement in that fiscal year alone. This represents 2,515 discrete equipment items from a total inventory of 3,915 items (64 percent), which is a significant proportion of replaceable, obsolete or potentially inoperable equipment. Furthermore, FDA did not have the funds to replace most of the equipment identified as having met or exceeded its life expectancy. The outdated equipment is, therefore still in use, but on borrowed time.

See comment 15.

Additionally, to remain current with industry innovations and assessment techniques and to validate our scientific data, FDA must acquire new technology to meet the requirements of the respective program areas. Each fiscal year, FDA laboratories submit equipment requests to replace inoperable, obsolete equipment. In FY 95, ORA's laboratories submitted more than $5 million in equipment requests, 60 percent or $3 million of which was to replace current equipment.

See comment 15.

Lastly, FDA has taken measures to effect savings on equipment costs through laboratory specialization. Two examples of such specialization are New Orleans and Cincinnati, where FDA has been able to use automated testing equipment to reduce the burden on staff.

See comment 15.
Now on p. 12.

The annual field laboratory request for replacement equipment and the statement by analysts (page 13) are clearly contradictory. FDA's managers must rely on the record of budget requests for replacement and new equipment as a basis for determining potential cost savings to be realized by consolidation.

Now on p. 12 .

See comment 16.

2. **"Most of the older facilities and some of the more modern facilities have three main problems:**

1) insufficient or inoperative heating, ventilation and air conditioning systems;

2) inoperable or insufficient exhaust hood capacity, and

3) insufficient space for employees and/or instrumentation." (page 14)

This statement contradicts previous statements in the draft report, for example, "The older labs (about 30 years old), referred to as Rayfield buildings, which are all similar in design, are well constructed brick facilities and appear to be structurally sound." (page 13). Either FDA facilities do suffer from the deficiencies cited here or they do not. FDA is fully aware that many of its facilities are in poor condition that argues against using the stop-gap measures suggested by some analysts to continue occupation for a few more years.

See comment 17.

3. **"...the Atlanta lab is a Rayfield building that has been occupied by FDA since 1963."** (page 13)

This statement is not accurate. Atlanta's current facility complex is composed of two distinct buildings: 1) a 1960 Rayfield building with 14,505 sq. ft. of laboratory space and 16,500 sq. ft. of office and support space; and 2) an annex that was added in 1985 totalling 13,120 additional sq. ft. of laboratory space and 18,000 sq. ft. for office and support space. Furthermore, Atlanta's facility condition is superior based on the excellent landlord/tenant relationship which affords prompt attention to and resolution of facility maintenance problems.

See comment 18.

4. **"One lab director at a Rayfield building told us (GAO) that the buildings are sound and an engineer had advised him that there is sufficient space in the ceiling area for additional ducts or electrical work if needed."** (page 13)

We question the wisdom of basing a report of this nature on comments rather than documented maintenance and repair costs and the evident crowding in some laboratories. FDA utilizes professional engineering analyses based on current and projected program requirements in determining whether a facility will or will not meet standards or conditions. Additionally, the decision to proceed must also be cost-effective.

Now on p. 12 .

See comment 19.

5. **"The WAAG performed an evaluation of the existing labs. With the expenditure of some funds, these laboratories could be expected to continue to serve for approximately another 10 years."** (page 13)

The WAAG assessment was not a professional, technical evaluation of existing facility conditions as FDA official assessments must be. Furthermore, we disagree that housekeeping can provide sufficient space to meet FDA's needs. Nor does the "solution" noted above address the need to reduce the cost of renting so many facilities. FDA's primary reason for consolidating laboratories is to free up money to use for program activities rather than rent. Extending the life of the current facilities beyond their lease expiration dates is neither practical nor, in most cases, possible for the many reasons discussed previously in these comments.

GAO RECOMMENDATION

We recommend that before ORA begins to implement its plan and closes its laboratories, the Secretary of Health and Human Services (HHS) direct the Commissioner of FDA to modify its cost-benefit analysis to include other alternatives such as cost to construct laboratories versus lease, refurbishing existing laboratories, and retrofitting other existing buildings. In addition, when considering any major changes to its laboratory configuration, ORA should either (1) incorporate the criteria established be its Working Analysts Advisory Group or make clear what criteria it is using and why and (2) use explicit measures of operational effectiveness and efficiency.

See comment 20.

DEPARTMENT COMMENT

We do not concur. As demonstrated above, the Laboratory Consolidation Plan adopted by FDA and augmented by further analyses at the request of GAO is based on sound principles and thoroughly addresses the issues confronting FDA over the next several years. As stated above, the alternatives suggested by the recommendation are not viable for the most part. The leases on the facilities in question will expire over the next 20 years, making them unavailable for FDA use. Whether FDA stays in the same geographical vicinity or not, significant changes will be required and at a significant cost. FDA's plan is phased to coincide with lease expirations to prevent unnecessary disruption to both employees and operations. Furthermore, the alternatives that GAO recommends be analyzed do not satisfy the basic and compelling need to reduce operations costs where possible. Therefore, we do not believe it is prudent to do an analysis of these alternatives.

See comment 20.

It should be noted that at least one other Federal Agency is also consolidating laboratories to effect the cost savings necessary to comply with Government-wide budget reduction mandates. The Environmental Protection Agency (EPA) issued a report by the MITRE Center for Environment, Resources and Space in May, 1994, ("Assessment of the Scientific and Technical Laboratories and facilities of the U.S. Environmental Protection Agency" Contract No.68D40003) which concluded in part, "... (T)here are opportunities for EPA to improve the efficiency and effectiveness of its operations through management options. The changes that appear reasonable to MITRE to eliminate the apparent duplications of facilities and equipment and to increase the disciplinary strengths of the human resource base are:

* Consolidation of laboratories in the Office of Prevention, Pesticides and Toxic Substances and the two laboratories under the Office of Radiation and Indoor Air

* Realigning and consolidating ... laboratories in the manner of the Carnegie Commission option

* Reducing the number of laboratories within the regional offices through consolidation to a few laboratories with national service focus."

See comment 21.

We also disagree with the implication that the WAAG criteria be used as a primary factor in developing FDA's future laboratory network. As we have discussed, the WAAG criteria do not address the fundamental hard issues of how and where to reduce costs in order to better serve the public in times of decreasing funding, shrinking staff, and increasing responsibilities.

See comment 22.

In conclusion, the Department believes that FDA has undertaken consolidation measures to produce efficiencies necessary for operation in the future. FDA's current field network structure coupled with the poor condition of some laboratory facilities conclusively show that FDA field operations must change to gain efficiencies and make better utilization of resources including personnel, equipment, and facilities.

The following are GAO's comments on the Department of Health and Human Services' letter dated November 7, 1995.

GAO Comments

1. Contrary to the agency's comments, our report recognizes FDA's past efforts to consolidate its field laboratories. In addition, we also note that in our 1987 report we criticized FDA's 1986 consolidation plan because its criteria were limited and did not adequately address whether FDA could meet its current and future laboratory needs. More importantly, our current report does not dispute FDA's decision to consolidate, but questions the magnitude of benefits FDA associates with its planned consolidation.

2. We disagree with the agency that we placed undue reliance on the WAAG or the Laboratory Directors' Steering Committee reports. These were the only groups chartered by ORA to evaluate the current field laboratory structure and to suggest modifications. ORA's management also provided the groups' reports to us in support of its plan.

On many occasions, we sought additional input from ORA regarding its needs assessment for its field laboratories. We asked for any long-range or strategic plan that described FDA's workload expectations, including such data as future staffing needs, trends in compliance/inspection activities, shifts in port utilization, and possible changes in laboratory work resulting from new mandates. ORA provided no such data to us. Instead, ORA officials continuously told us that ORA's future laboratory plans were based on the current analyst workforce and an estimated 25-percent increase for expansion.

3. Although the agency takes exception to our interpretation of its laboratory space projections, we still believe that they may be overstated. On June 5, 1995, ORA had reported to us that it had completed and submitted to GSA a proposal to modify the Atlanta laboratory for an additional 20,000 square feet. As we stated in this report, ORA provided revised cost estimates in July 1995 for several of its laboratories, including changing the requirements for expanding the Atlanta lab to 39,000 square feet. Even with the larger space estimate for Atlanta, the overall space in Atlanta at full capacity would only be about 450 square feet per analyst, significantly less than 650 square feet as stated above.

4. We have acknowledged in our report ORA's September 12, 1995, consultant's report. Our concern with the requirement of 650 square feet

per analyst is, however, that it significantly exceeds the amount of space being proposed for mega-labs in Atlanta and Seattle and relatively new laboratory space occupied in San Francisco (1994) and Kansas City (1991). ORA has not provided us any explanation of why existing space in its newest facilities (San Francisco and Kansas City) and its proposed mega-labs in Atlanta and Seattle is inadequate.

According to data that ORA provided to us, the Kansas City, Seattle, and San Francisco laboratories have an analyst capacity of 60, 65, and 70, respectively. Using the laboratory square footage figures in the table in HHS' letter, the square footage per analyst is significantly less than that stated by FDA when considering the capacity for which these laboratories were built. For example, the San Francisco laboratory, FDA's newest lab, has only 369 square feet per analyst.

5. We have noted in our report that ORA's latest attempt (July 1995) at estimating lease costs for several of its laboratories was methodologically better than its previous two efforts. However, two issues we raised—(1) whether using a space requirement of 650 square feet per analyst is excessive and (2) ORA's overestimating the size of the New York and Los Angeles laboratories under its replacement option—continue to raise questions about ORA's projected 20-year savings.

As we demonstrated in this report, if ORA used a square footage per analyst requirement based on its proposed Atlanta laboratory (including using ORA's highest expansion figure), the cost for replacing six laboratories may be overstated by about $2.2 million per year. In addition, by overestimating the size of the Los Angeles and New York laboratories in its replacement costs, ORA may have overestimated the cost of these facilities by about $2.5 million annually.

6. We recognize FDA's concern about successfully competing for funds within the Department and have expanded FDA's concerns and views about this issue in the final report. We revised the report also to acknowledge the constraints of the budgetary process.

7. After considering the agency's comments, we deleted our discussion in the final report on renovation and its implications for offsetting any savings FDA sees from its laboratory consolidation plan.

8. We believe that losing as many as 40 percent of ORA's analysts is a significant factor that could adversely affect operations. This is especially

true if many analysts leave at the same time, which is usually the case when sites close. ORA's effectiveness could be weakened as a result until new analysts are trained.

9. We agree that efficiencies can be measured by many factors in addition to timeliness. However, as we point out in our report, FDA provided us evaluations of its laboratories based only on the factor of timeliness.

10. We were asked to look at the analysis FDA had to support its mega-lab site selections. FDA provided us with documentation for obtaining such planned operational efficiencies. We expected that such documentation would include analyses and projections of current and future workload/resource needs. Throughout our review, ORA never provided us any data suggesting that it lacked needed analysts of any type in any of its laboratories. Nor did ORA provide any analysis showing problems with its ability to analyze certain samples. In addition, during our review and discussions with headquarters and field officials, ORA never provided any explanation to contradict the data showing that medium-sized laboratories were more timely or otherwise more efficient.

11. Although consolidation may make implementation of the team concept more difficult, we recognize FDA's commitment to making it work and have deleted the reference to the team concept in the final report.

12. On page 8 of its comments, the Department states that about 40 percent of FDA's analysts are eligible for retirement and probably many of them will retire rather than move. As stated earlier, we believe that many analysts leaving at the same time could adversely affect operations at least in the short term.

13. Our report clearly points out that WAAG had developed comprehensive criteria to guide ORA in selecting possible sites for laboratory location and that ORA's management developed a somewhat narrower set of criteria.

WAAG's criteria for site selection included, in addition to quality-of-life issues, all the issues included in ORA's management's criteria. HHS' comments expand the set of criteria that ORA previously provided us. HHS has maintained that ORA considered WAAG's criteria along with the listed criteria in its comments. However, no evidence exists on how ORA considered any set of criteria. ORA appears to have based site selection mainly on the availability of construction funds or congressional indications that such funds would be available for specific sites.

14. We were only pointing out one element of WAAG's comprehensive criteria. We were not implying that FDA managers were not concerned with staff recruiting and retention.

15. The documentation provided to us by FDA dealt with its schedule to replace equipment. This action may occur whether ORA consolidates its labs or not. As we discuss in this report, we recognize that certain equipment will need to be replaced. However, FDA has not demonstrated that its laboratories lack state-of-the-art equipment because of its current laboratory facility capability. Furthermore, ORA provided us no evidence to show how these equipment needs would differ in the future. In addition, because overall staffing is not expected to decline as a result of ORA's consolidation plan and ORA has not demonstrated whether or how economies of scale can be realized with equipment usage, we question how consolidation would improve equipment resources.

16. While we recognize that some of ORA's laboratories have certain deficiencies, this does not mean that the laboratories are structurally unsound. Thus, we do not believe this to be contradictory.

17. We changed this reference to the Atlanta facility to reflect the clarification of dates noted.

18. We deleted this reference in the final report due to its anecdotal nature.

19. We have recognized the agency's concerns in the final report.

20. Since we did not review the laboratory consolidation efforts of the Environmental Protection Agency, we cannot comment on the relevance of MITRE's analyses to FDA's consolidation plans. Furthermore, we are not asserting that FDA should not consolidate its laboratories. Rather we question whether FDA has adequately weighed the benefits of consolidation relative to other alternatives. We have revised our recommendation in the final report to better reflect this concern.

21. HHS has maintained that ORA considered WAAG's criteria along with the listed criteria provided in its comments. However, no evidence exists on how ORA considered any set of criteria. ORA appears to have based site selection mainly on the availability of construction funds or congressional indications that such funds would be available for specific sites.

22. Our work does not suggest one laboratory field structure or alternative to be better than that proposed by FDA. It does point out, however, that FDA may have overstated the projected monetary and efficiency gains of its proposed laboratory consolidations.

Rationales for Proposed New Laboratories in New York, California, and Arkansas

In the last few years, FDA has selected Queens, New York; Jefferson, Arkansas; and Los Angeles, California as sites for new laboratories. This appendix gives an overview of the rationales for those site selections.

Selection of the Queens, New York, Site Made by the Congress

FDA's current New York lab is located in a 75-year-old GSA-owned warehouse building in Brooklyn. FDA moved its laboratory into the facility in 1964 when space was renovated on the seventh floor to provide 37,000 square feet of laboratory space. Because of the structure and age of the facility, GSA has decided not to support any major renovations to the building to improve the quality of the laboratory.

To replace the aging New York facility, a site was selected in Queens, New York, in 1991 before the ORA 21 plan. ORA officials told us that FDA had no choice in selecting this site because the House Committee on Public Works and Transportation and the Senate Committee on Environment and Public Works passed resolutions that authorized leasing funds for the Queens site facility at $7.875 million for a period of 20 years. ORA officials told us that FDA was congressionally mandated to use this site; thus, no other site was considered with the advent of ORA 21.

ORA did not pursue other alternatives to replace its Brooklyn facility and may not be able to objectively justify the new location. One ORA headquarters official told us that the Queens site is not the best choice for a mega-lab on the East Coast. Similar views were expressed in a May 1994 report by the Committee on Appropriations' surveys and investigations staff, which stated, "Other plans in process may also be ill-advised such as the acquisition of a new facility in Queens, New York, for regulatory analysis...."

This planned facility is by far the most expensive of the five proposed mega-labs with an estimated leasing cost for 1999 through 2014 of over $200 million.

Rationale for a New Mega-Lab in Jefferson, Arkansas, Questionable

Construction of a facility in Jefferson, Arkansas, is scheduled for completion in 1999 at a cost of about $38 million. In fiscal year 1994, $2.5 million was approved for an architectural and engineering design for the Jefferson facility.

The number of analysts expected for the site is between 140 and 150. According to ORA officials, the primary reason for selecting the Jefferson

site is because FDA owns land at its National Center for Toxicological Research (NCTR). FDA would then own the newly constructed facility permanently.

It appears, however, that FDA was influenced by other factors. For example, a December 1993 ORA options paper stated,

"Within the State of Arkansas there has been almost continuous, high-level political activity to build up NCTR and it's [sic] environs to stimulate the State's economy. A set of unique events has moved that effort to a higher plane.

This presents FDA with what is probably a one time opportunity to make a significant expansion in our use of the remnants of the initial structures. Given this set of circumstances, the Commissioner asked Deputy Commissioner for Operations and the Associate Commissioner for Regulatory Affairs, if ORA wanted to (be a player) in the efforts to identify new, and maybe better, things we could do there. They answered yes, as a matter of principle, without having developed a clear picture as to what that would be."

The justification for the proposed mega-lab in Jefferson does not meet even ORA's limited criteria. Jefferson is clearly not a port of entry into the country, nor is it an area that has a large number of commercial industries. Also, the largest nearby city—Little Rock (about 50 miles away)—is not among the top cities for air traffic, which makes the Jefferson site less accessible for the shipment of samples.

Several WAAG members and other ORA staff told us that they strongly opposed the selection of this site. WAAG's analysis concluded, "An ORA regulatory facility at NCTR would not adequately meet the criteria for an effective field laboratory that services the public on a day-to-day basis." Several analysts told us that they have several concerns about the Jefferson site, such as accessibility to a major airport, the availability of good schools and universities, and recruitment and retention of qualified analysts. Staff also questioned the logic of building a new laboratory in Jefferson when an existing facility in Kansas City, Missouri, a bordering state, was just built in 1992 and has a capacity for 60 analysts.

Rationale for the Los Angeles Site Questionable

The Los Angeles laboratory is crowded, with little room for instrumentation or people. Also, the lab is located in a relatively unsafe area with limited parking. FDA is currently investing about $1 million to renovate the facility, including converting office space to additional laboratory space.

ORA plans to construct its new mega-lab at the University of California in the Irvine area, where it has purchased land. The construction costs are estimated at about $40 million, and the facility is expected to accommodate up to about 75 analysts with an expansion potential to 125 analysts. FDA was appropriated $10 million for purchasing the land and for architectural and engineering design work.

Officials at another ORA lab in California—the San Francisco lab—told us that while a lab may be justified in the Los Angeles area because of the large number of imports and commercial industries, San Francisco should have been considered as a mega-lab alternative. The lab, occupied in 1994, accommodates 50 analysts and has a capacity for 70 analysts. The state-of-the-art facility is located in Alameda, California, and is one of several office complexes in a pleasant area with plenty of free parking. According to ORA's San Francisco staff person responsible for overseeing the San Francisco site renovation, an identical adjacent unoccupied office building could be converted to a laboratory for about $10 to $15 million. This is considerably less then the estimated $40 million in construction costs for a new Los Angeles facility.

ORA officials told us that San Francisco was not considered as a site for a mega-lab and, as part of ORA 21, would be closed in 2014. The only explanation provided was that funds were made available for Los Angeles from the Congress for the land and architectural and engineering design work.

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