

AGENCY FOR INTERNATIONAL DEVELOPMENT
WASHINGTON, D.C. 20523

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MEMORANDUM

TO: MISSION HEALTH OFFICES

FROM: S&T/H/HSD, Rosalyn C. King *RAC*

SUBJECT: Drug Infrastructure Development and U.S. Public Health Service

The attached INVENTORY, prepared by the International Affairs Staff Office of Health Affairs of the Food and Drug Administration, is a listing of applicable functions by office of agencies of the U.S. Public Health Service (USPHS). It is provided so that missions might consider tapping these technical resources for development assistance in the design, implementation and evaluation of pharmaceutical components of health projects.

Staff of offices listed herein may be available for short-term consultancies of up to three months. In selected cases, and with prior approval, long-term consultancies may be arranged. As with the experience you may have had with CDC, travel and per diem costs are still the responsibility of the mission. These services can be accessed using a mission-funded Participating Agency Service Agreement (PASA) or Resources Support Service Agreement (RSSA).

The name, address, and telephone number of contact person of agencies listed in this INVENTORY are:

FOOD AND DRUG ADMINISTRATION (FDA)
Mr. John Lupien
International Affairs Staff
5600 Fishers Lane
Room 1147
Rockville, Maryland
(301) 443-4480

HEALTH RESOURCES AND SERVICES ADMINISTRATION (HRSA)
Mr. George Dines
International Health Affairs
5600 Fishers Lane
Room 1418
Rockville, Maryland
(301) 443-6151

CENTERS FOR DISEASE CONTROL (CDC)
Mr. Billy G. Griggs
Assistant Director for International Health
Bldg 1, Room 2122
Atlanta, Georgia 30333
(404) 329-3530

NATIONAL INSTITUTES OF HEALTH (NIH)
FOGARTY INTERNATIONAL CENTER
Mr. Jack Schmidt
International Coordination and Liaison Branch
Bldg 38A, Room 610
Bethesda, Maryland 20205
(301) 496-1415

HOW TO USE THE INVENTORY

It is suggested that you:

First, review the range of functions of the offices whose services might be needed and determine if the USPHS is the appropriate technical source.

Second, decide what kind of assistance is required (eg., needs assessment for strengthening the pharmaceutical component of projects, design of quality control laboratories, evaluation of essential drug policies.)

Third prepare a scope of work. If there is a question as to the appropriateness of USPHS, preparing a preliminary scope of work would be in order.

Fourth, send the scope of work (final or preliminary) to contact person at address listed. Be sure to include pertinent specifications such as proposed starting date, the length of time required, language requirements, etc. This may be sent via pouch or cable with pass through request to the contact person listed.

Fifth, discuss with the contact person the USPHS staff identified and the details of the arrangement.

Sixth, provide, if requested, background materials, project documents, etc. needed for the consultation.

It is suggested that sufficient lead time be assumed so that USPHS does not feel required to give a rapid, unsound response.

Attachment: INVENTORY

Clearances:

FDA/IAS/OHA:JLupien:Date:1/28/85

FDA/IAS/OHA:GMoy:Date: 1/28/85

S&T/H:AVanDusen:Date: MD 2-12-85

I N V E N T O R Y

DRUG INFRASTRUCTURE DEVELOPMENT
AND
ESSENTIAL DRUGS PROGRAMS

-APPLICABLE FUNCTIONS OF U.S. PUBLIC HEALTH SERVICE AGENCIES-

Prepared By
International Affairs Staff
Office of Health Affairs
U.S. Food and Drug Administration

June 1984

INVENTORY

DRUG INFRASTRUCTURE DEVELOPMENT AND ESSENTIAL DRUGS PROGRAMS

-APPLICABLE FUNCTIONS OF U.S. PUBLIC HEALTH SERVICE AGENCIES-

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**INVENTORY OF FUNCTIONS OF U.S. PUBLIC HEALTH SERVICE AGENCIES
APPLICABLE TO DRUG INFRASTRUCTURE DEVELOPMENT AND
ESSENTIAL DRUGS PROGRAMS**

Name of Public Health Service Agency/Unit and
Description of Expertise/Function

Application to Drug Infrastructure
Development and Essential Drugs Programs

I. FOOD AND DRUG ADMINISTRATION (FDA)

A. Center for Drugs and Biologics (CDB)

1. Office of the Director

Coordinates, directs, develops and monitors CDB programs, policies and activities; plans, develops and implements consumer and professional education and information activities; coordinates the international communications and assistance efforts and Foreign Visitor Program; manages advisory committee and consultant assistance.

Overall assessment of current national pharmaceutical policies and programs; determination of immediate and longer range needs with regard to program development; determination of infrastructure needed for implementation of proposed legislation, policies; providing information and education; development of an advisory capability.

2. Office of Drug Research and Review

Performs major functions related to the new drug approval process that includes review of pre-clinical data results, clinical protocols, results of clinical studies, and proposed labeling; evaluates manufacturing and laboratory methods; conducts medical evaluation of clinical experience following new drug approval.

New drug development for those countries or regions able to establish research capability; new drug approval process to allow assessment of locally needed drugs developed outside the country; approval process for assessment of locally needed drugs approved elsewhere for the purpose of detecting variations in safety and effectiveness due to nutritional, genetic and environmental factors.

a. Division of Drug Biology

Laboratory facility; provides pharmacology and toxicology information to the drug reviewing units; devises biological methods for study and analysis of drugs; plans and conducts research concerning optimum animal and biochemical systems for drug assay; performs bioassays to determine drug potency (including insulin testing); plans and conducts research to investigate the nature and properties of pharmacologically significant substances in biological systems drug metabolism, mechanisms and identity of adverse drug reactions, interactions between drugs and between drugs and environmental chemicals, neuroendocrine relationships, and effects of drugs on behavior.

New drug research and development.

b. Division of Drug Chemistry

Laboratory facility; provides information and advice on chemistry of drugs and methods of physicochemical identification of drugs; proposes and establishes specifications to standardize drugs and reference substances; validates New Drug Application analytical procedures; reviews field laboratory validation data.

New drug research and development; quality control through methods evaluation and refinement.

c. Center for Drug Analysis

Highly automated laboratory; tests drug samples obtained through surveillance programs; devises new automatic methods for rapid analysis of drug dosage forms; devises new methods and develops new equipment for the examination of individual drugs which present analytical problems; participates in various collaborative studies, for example, to test validity of proposed analytical methods.

Development of quality control through drug sample testing for those countries/regions able to consider automated laboratory systems.

3. Office of Biologics Research and Review

Similar to 2 above, but for biological products

a. Division of Biological Investigational New Drugs

Responsible for ensuring that investigations of new products are properly conducted; develops standards to assure safety, purity, potency, and efficacy of new products have been established prior to licensing.

New biological product development/approval process; on-site inspections of clinical or other facilities conducting pre-clinical or clinical studies on biological products.

b. Division of Product Certification

Reviews data for licensing biological products and their manufacturers; coordinates and assists in the review of labeling of biological products.

New biological product approval process.

c. Division of Blood and Blood Products

Laboratory facility; reviews applications and data to approve the use of products that have not been licensed; reviews data for licensing such products and their manufacturers; develops standards for blood and blood products; plans and conducts hepatitis research; plans and conducts research on the preparation, preservation, safety, purity, potency and efficacy of such products for therapeutic use; plans and conducts research on the immunological problems; tests diagnostic reagents employed in grouping and typing blood; participates in the inspection of manufacturers of such products.

New blood product development/approval process; ensuring quality control through research and testing under local conditions and manufacturer inspections.

d. Division of Virology

Laboratory facility; reviews applications and data to approve the use of viral and rickettsial products, interferons and other immune stimulants; reviews data for licensing such products and their manufacturers; plans and conducts research on the biology and pathogenesis of the major human pathogenic viruses, the immune response to infection and vaccination, and the role of interferon and its effects on immune responses; participates in the inspection of manufacturers of such products; serves as a tissue culture source for the Office of Biologics. WHO Collaborating Center on Yellow Fever.

New viral product development/approval process; ensuring quality control through research and testing under local conditions and manufacturer inspections.

e. Division of Bacterial Products

Laboratory facility; reviews applications and data to approve the use of products designed to prevent, treat, or mitigate bacterial, fungal, and allergenic diseases in humans; reviews data for licensing such products and their manufacturers; conducts research, on bacterial products; participates in the inspection of manufacturers of biological products. WHO Collaborating Center for Research on Pertussis Vaccine.

New bacterial product development/approval process; ensuring quality control through research and testing under local conditions and manufacturer inspections.

f. Division of Product Quality Control

Laboratory facility; performs sterility, safety, pyrogen and potency tests; performs safety, neurovirulence and potency tests utilizing nonhuman primates; conducts research to improve existing quality control tests and to develop appropriate assays for new products; coordinates the protocol review and product testing program; establishes and provides official U.S. reference standard preparations for quality assurance tests required by FDA regulations. WHO Collaborating Center for Research and Reference Services for Immunological Biological Products.

Development of quality control of biologics through sample testing and related research.

g. Division of Biochemistry and Biophysics

Laboratory facility; plans and conducts research on the chemistry and biology of vaccines and other biological products, impurities and/or unsuspected components of new products, the pathogenesis of infectious diseases caused by bacteria, rickettsia, viruses, and parasites, and immunologic processes which may lead to morphologic alteration; conducts interferon research projects and maintains state-of-the-art technology in amino acid analysis, carbohydrate analysis, Nuclear Magnetic Resonance Spectroscopy, Gas Chromatography, Mass Spectrometry, Cell Sorter and Electron Microscopy; participates in the inspection of manufacturers of biological products.

Biological product and technology research.

4. Office of Drug Standards

a. Division of Over-the-Counter (OTC) Evaluation

Coordinates development of monographs (define allowable ingredients, indications, dosages and labeling) for the marketing of OTC drugs; provides technical assistance in implementing final drug monographs; maintains a listing of all OTC active ingredients used in the U.S. and their proposed future marketing status.

Development of lists of essential drugs and drugs to be sold without prescription and distributed commercially.

b. Division of Drug Advertising and Labeling

Monitors and evaluates prescription drug promotional materials, advertisements, practices and related labeling; provides guidance and support in formulation of policy, regulations and advisory opinions in advertising and promotional labeling.

Regulation of drug promotion and labeling.

c. Division of Biopharmaceutics

Evaluates bioavailability and pharmacokinetic protocols and data for new and generic drugs; reviews factors that affect drug bioavailability; maintain listings of drugs requiring biopharmaceutic in vivo testing and dissolution testing.

Evaluation of national lists of essential drugs and drug quality control procedures.

d. Division of Generic Drug Monographs

Evaluates scientific data to determine approvability of generic drugs not requiring safety and efficacy data for approval; serves as primary source of information on current labeling, methods validation and establishment inspection reports for most generic drugs requiring approval; maintains a listing of drugs which can be approved without clinical trials.

Use and labeling of generic drugs.

5. Office of Compliance

a. Litigation and Recall Staff

Provides guidance and assistance with regard to legal Enforcement activities to ensure the safety and actions (seizures, recalls, prosecutions, effectiveness of drugs, injunctions); receives all requests for legal action consideration and assigns to appropriate compliance unit for evaluation; provides coordination and guidance and develops necessary additional support for all regulatory actions of CDB that are contested, including legal proceedings and administrative hearings.

b. Division of Drug Labeling Compliance

Provides regulatory advice on drug labeling compliance; evaluates reports from field inspector, including results from inspections, investigations, and recommendations for compliance actions; notifies firms regarding the status of their drugs under OTC and other drug monographs; directs FDA program that requires listing of drug products and manufacturers of drugs marketed in the U.S. WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce (drug approval status).

Development of an inventory of drug products and manufacturers. Enforcement activities to ensure compliance with labeling requirements.

c. Division of Drug Quality Compliance

Develops, coordinates, reviews and revises Current Good Manufacturing Practices (CGMP) regulations and other drug product quality regulations from a manufacturing standpoint; develops, approves, directs and monitors compliance programs with regard to standards for drug manufacturing.

Development of quality control through the enforcement of CGMP's and other drug product quality regulations concerning manufacturing.

d. Division of Drug Quality Evaluation

Uses specially developed drug product data information system to monitor and evaluate nationwide drug product quality; coordinates drug recalls related to drug product quality; develops/directs drug quality evaluation programs, including surveillance and mandatory and voluntary drug certification.

Ensuring drug product quality through enforcement of product specifications.

e. Division of Scientific Investigation

Assigns, directs, and coordinates inspections of sponsors and investigators of preclinical and clinical drug studies, institutional review boards and commercial clinical testing facilities in collaboration with FDA's field organization to assure that scientifically valid and accurate data are submitted in support of drug approvals; investigates and monitors the conduct of clinical research with regard to human drugs.

New drug approval process with regard to on-site inspections of clinical or other facilities conducting pre-clinical or clinical drug studies; ensuring human subject protection.

f. Division of Biological Product Compliance

Plans, develops and directs the regulatory compliance programs to assure the safety, purity, potency and efficacy of biological products; coordinates and conducts a nationwide inspection and sampling program; develops facts required to support legal actions concerning violative products; develops compliance and surveillance programs and standards (including regulations) covering the regulated biological industries.

Administrative activities for enforcement of quality control of biologics.

g. Division of Regulatory Affairs

Interprets the scope, applicability, and intent of laws enforced by FDA, and proposed and published regulations and policy statements for the Center. Initiates, develops, reviews, and/or approves all new and revised regulations and Federal Register notices for the Center. Develops guidelines setting forth administrative-legal procedures for applying new or changed authority regarding drugs and biologics and for new or revised regulations or regulatory policy in the Center.

Development and monitoring program of various field activities to ensure compliance with regulations and policies.

6. Office of Epidemiology and Biostatistics

a. Division of Drug and Biological Products Experience

Receives, evaluates, and disseminates information on adverse drug and biological products reactions; publishes adverse drug reaction alerts (ADR Highlights) and summaries of drug use and experience in the FDA Drug Bulletin. WHO Collaborating Center for Adverse Drug Reaction Monitoring.

Monitoring adverse drug and biological products reactions; development of adverse drug reaction reporting system; evaluation and dissemination of information on drug use and experience.

b. Division of Biometrics

Provides statistical and computational analysis to risk assessment and efficacy evaluations of drugs.

Risk assessment of drug utilization.

7. Office of Management

a. Division of Drug Information Systems Design

Designs, implements and monitors management and scientific/technical information systems for CDB; maintains FDA Chemical Structure File and designs systems for searches; establishes and monitors implementation of policies regarding all CDB automated data processing activities, such as planning, contracts, equipment, and procurement.

Development of information systems compatible with (scientific, medical, etc.) automated systems or establishment of automated systems for those countries with required resources.

b. Medical Library

Acquires, catalogues, and disseminates pharmaco-medical and scientific information for use by FDA scientists and administrators; serves as liaison with drug and other outside information centers, such as the National Library of Medicine; provides manual and automated services in support of compiling and disseminating medical/scientific information.

Establishment or improvement of medical/scientific library or information center.

B. Office of Regulatory Affairs/Executive Director of Regional Operations

1. Medical Product Quality Assurance Staff

Develops and maintains liaison with other government agencies procuring medical supplies under the Government-Wide Quality Assurance Program (GQAP) in which FDA assumes responsibility for quality assurance for drugs and medical devices; provides final approval authority for the acceptability of drug products and firms for procurement by purchasing agencies; manages FDA's firm profile system that provides current approval status of firms to market drugs and medical devices. WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce (GMP status).

Administrative activities for ensuring quality of currently approved safe and effective drugs and medical supplies.

2. Field/District Offices - Investigations Branches

Inspects establishments subject to laws and enforced by FDA; collects samples for analysis; performs field analyses; performs special investigations, including those required under the GQAP; investigates reports of adverse experience; performs premarket clearance investigations of drugs and devices; monitors recalls and performs follow-up activities; in the event of alleged non-compliance, determines appropriate action in liaison with U.S. attorneys and performs follow-up activities with U.S. Marshals.

Development of quality control programs through regulations manufacturer inspections, product sampling and laboratory analysis and subsequent enforcement action where necessary.

3. Field/District Offices - Laboratory Branches

Performs laboratory analysis of drug samples to assess compliance with laws and regulations and to identify potential problems or trends; provides expert advice and training with regard to laboratory techniques and technological developments to other Federal, State, and local agencies, foreign counterpart agencies, and industry.

Development of quality control programs through product sample testing.

C. Office of Health Affairs

1. Health Assessment Policy Staff

Provides guidance in establishing procedures for protection of human subjects involved in clinical testing and research; serves as locus for activities related to international drug scheduling conventions.

Development of procedures for assuring protection of human subjects in clinical trials; development of procedures for evaluating and scheduling drugs with abuse potential.

2. International Affairs Staff

Provides liaison and coordination of FDA international activities with other governmental and bilateral health organization. Develops, coordinates, and implements technical and regulatory assistance programs under bilateral and multilateral auspices.

Coordination with foreign and multilateral health and pharmaceutical related programs. Development of training courses, consultancy services, and specialized training in a broad range of areas related to essential drugs.

II. HEALTH RESOURCES AND SERVICES ADMINISTRATION (HRSA)

A. Office of Operations and Management/Division of Grants and Procurement Management

Material Management Branch/Perry Point Service and Supply Center

The HRSA Supply Service Center (SSC) at Perry Point, Maryland is the Department of Health and Human Services (DHHS) Medical Supply Depot which provides supply support to all DHHS activities and other federal agencies to include Job Corps, Peace Corps, diplomatic personnel and other authorized federally funded programs.

Development of the drug supply system including depot system of procurement, inventory management, storage and distribution.

The SSC buys, stores, controls and ships medical supplies to include drugs to these facilities. The SSC provides unit-of-use, patient-ready pre-packaged drugs in the customary prescribed quantities to enable health care providers to better serve the needs of their patient population

B. Indian Health Service/Office of Professional Standards and Evaluations/Division of Resource Coordination

Pharmacy Service of a Service Unit (Hospital, Clinic, etc.)

Provides all necessary pharmacy services including distribution of drugs to nursing stations and clinics, maintenance of drug stocks at proper levels, proper storage and labeling of drug stocks throughout the Service Unit and insuring that the drugs being used have not deteriorated nor in any manner become unfit for use; provides services and drugs to other facilities as necessary; consults with medical, nursing and other staff on improvements needed to provide a more efficient patient care delivery system; provides to patients primary care services for acute and chronic diseases using protocols approved by medical staff;

Selection of essential drugs; improvement of the drug supply system; ensuring the proper use of essential drugs by providing information and training to health care workers and patients; provides clinical training for pharmacists.

accomplishes patient consultation and drug therapy; apprises tribal patient consultation and drug therapy; apprises tribal representatives of current pharmacy practices and services available; provides members for appropriate committees including the Service Unit Pharmacy and Therapeutics Committee which is composed of physicians, pharmacists and other health professionals and which recommends policy on matters relating to the therapeutic use of drugs.

C. Office of the Administrator

Office of International Health Affairs

Serves as the HRSA focal point for policy guidance and program coordination relating to international health; provides staff advice to the Administrator on international health policies, programs and activities; maintains liaison with international institutions and organizations and other departments agencies on international health matters; arranges for international technical assistance in the health field at the request of other HRSA components; serves as the focal point in HRSA for relationships with international organizations, especially the World Health Organization (WHO) and the Pan American Health Organization (PAHO), and provides technical consultation to HRSA Offices and Bureaus; directs reimbursable participant training programs for the United Nations and WHO; provides HRSA components with information and reports as needed on international programs and activities, including unilateral, bilateral, and multilateral research in support of national health goals; establishes procedures for screening and approval of proposed international travel by HRSA personnel.

In countries with ongoing HRSA coordinated project -- ensuring coordinated multisectorial action (health, education, planning, etc.).

III. CENTERS FOR DISEASE CONTROL (CDC)

A. Office of the Director

Manages and directs the activities of CDC; provides liaison with other governmental agencies, international organizations, learning institutions, and other outside groups; coordinates, in collaboration with the PHS Office of International Health, international health activities relating to disease prevention and control.

Coordination of activities related to epidemiology of drug use in disease prevention and control.

B. Epidemiology Program Office

Serves as the focal point for the collection, analysis, and communication of basic surveillance information and consultation in epidemiology and surveillance within the Offices of the CDC, other Federal agencies, State and local health departments, international organizations and other nations; provides epidemiologists on request to other nations. Develops new and improved methods of communications using computers.

Collection of epidemiological information; design of computerized communications systems.

C. International Health Programs Office

1. Office of the Director

Provides liaison and coordination of CDC international health activities with other government agencies, international agencies, and bilateral health agencies; develops and implements on-site training for foreign nationals in technical and management aspects of health care delivery.

Coordination with other health and pharmaceutical related programs. Development of orientation for travelers to developing countries; development of training courses integrated with primary health care delivery.

2. Division of Evaluation and Research

Develops and tests surveillance methodologies and operations research to identify and quantify health status and disease problems and to solve identified medical and epidemiological problems in developing countries.

Experience working with the WHO Expanded Program of Immunization (EPI) and Diarrheal Disease Programs, and AID Combating Childhood Communicable Diseases (CCCD) Program using immunization, malaria control, and oral rehydration salts in Africa.

3. Division of Program Services

Implements programs to provide technical assistance to developing countries to reduce morbidity and mortality and to improve child health, including immunization and diarrheal disease control.

Experience with EPI and CCCD.

D. Laboratory Program Office

Develops and maintains a national data base and determines baseline information concerning health laboratory practice; promotes efficient and effective laboratory practice; identifies health laboratory problems and needs; administers a proficiency testing program, a national laboratory management, training and consultation program for States and other client groups; provides liaison between national and international health laboratory community and appropriate CDC programs.

Development and operation of health laboratory facilities and programs.

1. Office of the Director

Provides leadership and guidance on policy, program planning, program management, and operations of the Laboratory Program Office; interacts with public, private, academic and voluntary sectors of the health community to identify the problems and needs of the health laboratory community and provides consultation and assistance in the formulation of solutions.

Overall coordination and management of health laboratory programs.

2. Division of Laboratory Training and Consultation

Administers a national laboratory training program directed toward disseminating current laboratory technologies the laboratory community; provides scientific consultation and on-site scientific and safety review services to local, State, and Federal health laboratories; collaborates with international health agencies and governments by providing laboratory training and training materials for use in international health laboratory community; provides consultation in specialty areas such as tuberculosis, laboratory safety, radiation safety, educational methodology, and manpower development.

Resource for information, training, and consultancy services in public health laboratory practices.

a. Consultation and Educational Resources Branch

Conducts technical reviews and consults with State and other health laboratories and agencies in specialty areas of laboratory safety, radiation safety, mycobacteriology, and educational methodology to determine needs and render technical assistance directly or by referral; serves as a national resource in collecting and disseminating information on laboratory training and training materials; assists State and other health laboratories, international health organizations, universities, and professional associations with jointly planning and presenting field workshops, seminars and lectures in the same specialty areas.

Resource for information, training, and consultancy services in public health laboratory practices in specialty areas of laboratory and radiation safety, mycobacteriology, and educational methodology.

b. Laboratory Training Branch

Develops, organizes and presents laboratory training courses, lectures, seminars, workshops and bench training; assists State and other public health laboratories, international health organizations, universities, and professional associations with jointly planning and presenting field workshops, seminars and lectures in specialized areas including bacteriology, diagnostic immunology, mycology, parasitology, venereal disease, and virology.

Resource for training and training materials for public health laboratory methodology in specialty areas of bacteriology, diagnostic immunology, mycology, parasitology, venereal disease, and virology.

3. Division of Technology Evaluation and Assistance

Plans and conducts a national laboratory evaluation program; develops proficiency testing methodology and administers a proficiency testing program for licensed clinical laboratories, Federal, State, and local public health laboratories, and selected study groups.

Resource for performance evaluation of public health laboratories and for assistance based the results of performance evaluation activities.

a. Performance Evaluation Branch

Administers a performance evaluation program for licensed clinical laboratories, Federal, State, and local health laboratories, WHO and PAHO laboratories, and selected groups in areas such as cytology, diagnostic immunology, hematology and microbiology.

Resource for performance evaluation of public health laboratories.

b. Technical Assistance Branch

Develops and conducts laboratory assistance programs based on results of performance evaluation activities; consults with State public health laboratory directors and other members of the health laboratory community on changing technologies and means of evaluating laboratory performance; serves as the focal point for distribution of new and updated information on the state of technology with respect to quality control and good laboratory practices.

Resource for assistance based on performance evaluation of public health laboratories; resource for information on most recent advances in good laboratory practices.

E. Center for Prevention Services

1. Division of Immunization

Administers research and operational programs for the prevention and control of various preventable diseases.

Experience in use and epidemiology of live virus vaccine programs in the United States.

Maintains Monitoring System for Illness following Immunization (MSIFI), and Biologics Surveillance Program.

Adverse reaction monitoring system for public sector administered vaccines; computerized system of reporting data from manufacturers on total dose sold and storing of immunization assessments and reminders for revaccination.

2. Division of Venereal Disease Control

Administers research and operational programs for prevention and control of syphilis, gonorrhea, and other sexually transmitted diseases.

Technical assistance in drug distribution programs for control and treatment of these diseases.

F. Center for Environmental Health/Clinical Chemistry Division

Conducts and coordinates national and international programs to improve and standardize biochemical and immunochemical diagnostic procedures for the prevention and control of diseases.

Technical assistance in laboratory analysis programs and reagent evaluation.

G. Center for Health Promotion and Education/Division of Reproductive Health

Provides technical assistance to international, governmental, and non-governmental organizations on bilateral and multilateral research and demonstration projects, including surveys and assessments.

Resource for use of family planning pharmaceuticals.

H. Center for Infectious Diseases (CID)

1. Office of the Director

Coordinates the activities of the CID; provides liaison with other governmental agencies and international organizations including the World Health Organization.

Resource for activities on infectious disease control, including prevention and treatment.

2. Biological Products Program

Produces, evaluates, and distributes reference biological reagents; provides technical assistance to public health laboratories and research organizations.

Resource for diagnostic reagents and laboratory tests in disease control.

3. Sexually Transmitted Diseases Laboratory Program

Performs research and development on sexually diseases; provides reference diagnostic services for national and international health organizations, collaborates in development of immunizing agents.

Resource for diagnosis of sexually transmitted diseases.

4. Division of Bacterial Diseases

Conducts research on diagnosis, treatment, and control of bacterial diseases, technical assistance, and epidemic aid to national and international health organizations.

Resource for prevention and control of bacterial diseases.

5. Division of Mycotic Diseases

Conducts research and surveillance related to prevention, diagnosis, and control of actinomycotic and fungal diseases. WHO Collaborating Center for Mycotic Diseases.

Resource for diagnosis, prevention, treatment and control of mycotic diseases.

6. Division of Parasitic Diseases

Conducts surveillance investigations and studies of parasitic diseases; provides reference and drugs. diagnostic services; conducts laboratory studies of chemotherapy and immunology to develop effective methods for diagnosis, prevention, and control of parasitic diseases. WHO Collaborating Center for Host and Parasite Studies on Malaria.

Testing for blood chloroquine and other antimalarial testing for drug resistance to malaria; resource for diagnosis, prevention, and control of parasitic diseases.

7. Division of Vector-Borne Viral Diseases

Conducts surveillance, investigations, and studies of vector-borne viral diseases and plague to develop strategies for diagnosis, prevention, and control. WHO Collaborating Center for Arbovirus Reference and Research, WHO Collaborating Center for Research on Basic Principles of Insecticide Formulations, Chemical and Physical Methods.

Resource for drug and vaccine control of vector-borne viral diseases.

8. Division of Viral Diseases

Conducts surveillance, investigations, and studies of viral and rickettsial diseases, research on control strategies, reference/diagnostic services. WHO Collaborating Center for Reference and Research on Influenza, on Rabies, for Rickettsial Reference and Research, for Smallpox and other Pox Virus Infections, for Reference and Research (Enteroviruses), for Reference and Research (Respiratory Virus Diseases other than Influenza).

Resource for diagnostic testing of sera, for characterizing of field isolates in vaccination programs, and for strategies in the control of viral diseases.

9. Division of Hepatitis and Viral Enteritis

Conducts surveillance, investigations, and studies of viral hepatitis and gastroenteric diseases. WHO Collaborating Center for Reference and Research on Viral Hepatitis.

Resource for control of virally caused hepatitis and enteritis.

IV. NATIONAL INSTITUTES OF HEALTH (NIH)

A. Office of the Director

Provides leadership and direction to the programs and activities of the National Institutes of Health.

Development of policies relevant to specialized NIH components regarding a total drug development program.

1. Office of Medical Applications and Research

Provides technical and scientific information to the PHS's assessment program of biomedical technology; plans and conducts NIH Consensus Development conferences which include drug assessments.

Development of consensus statements on drug issues, including recommended drug regimens for specific health problems and contraindications for drug use.

2. Office for Protection from Research Risks

Establishes procedures governing the protection of human and animal subjects involved in NIH research; provides guidelines and policy on use of human and animal subjects involved in experimental and clinical trials of drugs, and the development of animal models for the testing of experimental drugs.

Development of procedures for assuring that human subjects in drug research are informed of potential adverse risk involving drug use.

B. National Cancer Institute (NCI)

Plans, conducts and coordinates a national program involving: (a) research on the detection, diagnosis, cause, prevention, treatment and palliation of cancers and on rehabilitation of the cancer patient; and (b) demonstration of the effectiveness of cancer control methods and techniques.

Development of policy guidance to programs in which chemotherapy is a component in clinical care; collection and dissemination of information on cancer control.

1. Division of Resources, Centers and Community Activities

Plans and conducts research, evaluation, demonstration, technology transfer, education and information dissemination programs to expedite the use of new information relevant to the prevention, detection, and diagnosis of cancer, and the pretreatment evaluation, treatment, rehabilitation, and the continuing care of cancer patients in the community and in cancer centers.

Support for professional and paraprofessional clinical education, research training, and continuing education.

2. Division of Cancer Treatment

Plans, directs, and coordinates an integrated program of intramural, extramural and clinical cancer treatment research as well as research conducted in cooperation with other Federal agencies with the objective of curing or controlling cancer in man by utilizing treatment modalities singly or in combination.

Administration of a total drug development program encompassing all phases from drug acquisition up to and including clinical trials; distribution of information and data on experimental and clinical studies related to cancer treatment to appropriate scientists and physicians.

3. Division of Cancer Cause and Prevention

Plans and directs a national program of laboratory, field and demographic research on the nature, history, cause and prevention of cancer.

Evaluation of mechanism of cancer caused by chemical, viral and environmental agents.

C. National Heart, Lung, and Blood Institute (NHLBI)

Plans and provides leadership for a national program in diseases of the heart, blood vessels, blood and lungs. Plans, conducts, fosters, and supports an integrated and coordinated program of research, investigations, clinical trials, and demonstrations related to the causes, prevention, methods of diagnosis, and treatment (including emergency medical treatment) of the heart, blood vessels, lungs, and blood diseases through research performed in its own laboratories, and through contracts and research grants to scientific institutions and to individuals.

Development and evaluation of drugs and devices relating to the prevention, treatment, and rehabilitation of heart, lung, and blood diseases; collection and dissemination of educational materials on appropriate drug use, with emphasis on disease prevention.

D. National Library of Medicine (NLM)

Plans and administers a national on-line biomedical information and retrieval system (MEDLINE). Plans, develops, and operates a national toxicology information system (TOXLINE). Develops and administers a program to organize and analyze published information on the effects of drugs and chemicals on man, and prepares special bibliographies and reports on that subject (CHEMLINE).

Collection, dissemination, and exchange of information important to the progress of medicine and health.

E. National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases (NIADDK)

Provides leadership for a national program in the four major disease categories of arthritis, musculoskeletal, and skin diseases; diabetes, endocrinology and metabolic diseases; kidney, urologic and hematologic diseases; and nutrition.

Development and evaluation of research in the four disease categories including clinical trials and their relation to prevention and treatment; collection and dissemination of education materials for health professionals and the lay public, with emphasis on disease prevention, including appropriate drug use.

F. National Institute of Allergy and Infectious Diseases (NIAID)

Conducts, fosters, and supports research and research training programs directed at finding the causes of and improved methods for diagnosing, treating, and preventing immunologic and infectious diseases.

Development and evaluation of specific disease control measures and solutions to infectious and immunological disease problems, including vaccine and drug development.

G. National Institute of Dental Research (NIDR)

Conducts, fosters, and supports research training in the causes, diagnosis, prevention, and cure of oral diseases and disorders.

Laboratory, clinical and field research aimed at specific dental problems; selection of essential drugs for oral diseases and disorders.

H. National Institute of Child Health and Human Development (NICHD)

Conducts, fosters, and supports biomedical and behavioral research through research grants, research contracts, and research performed in its own laboratories on child health, maternal health, problems of human development with special reference to mental retardation, and on family structure, the dynamics of human population, and the reproductive process.

Basic research on fertility and infertility interventions, and on vaccine and drug efficacy for preventing and treating major diseases in mothers and children.

I. National Institute of General Medical Sciences (NIGMS)

Supports research for a Pharmacological Sciences Program, including research on the chemistry of natural products.

Development of information on biological and chemical processes involved in the actions of therapeutic drugs and on the effects of synthesis of new drugs.

J. National Institute of Neurological and Communicative Disorders and Stroke (NINCDS)

Conducts, fosters and supports research and research training on cause- prevention, diagnosis and treatment of neurological, sensory, communicative, and muscle disorders.

Inter and extramural field research on neurological and communicative disorders and stroke.

K. National Eye Institute (NEI)

Cooperates and collaborates with professional, commercial, voluntary, and philanthropic organizations concerned with vision research and training, disease prevention and health promotion, and the special health problems of the visually impaired disable and blind.

Cooperation and collaboration with international organizations in basic and applied research including clinical trials related to natural history, cause, prevention, diagnosis and treatment of disorders of the eye and visual systems.

L. National Institute on Aging (NIA)

Conducts, fosters, and supports biomedical and behavioral research and training pertaining to the aging process and related health fields.

Epidemiological and behavioral studies on drug use in the elderly.

M. Division of Research Services (DRS)

Plans and promotes research on laboratory animal models; development and use of uniform international standards for research animals and information exchange on laboratory animal science.

Provides guidance on use of animals for drug research.

Administers biomedical engineering and instrumentation services.

Provides guidance and training on laboratory instrument use, maintenance and repair.

N. Clinical Center

Conducts clinical care research, including drug evaluation.

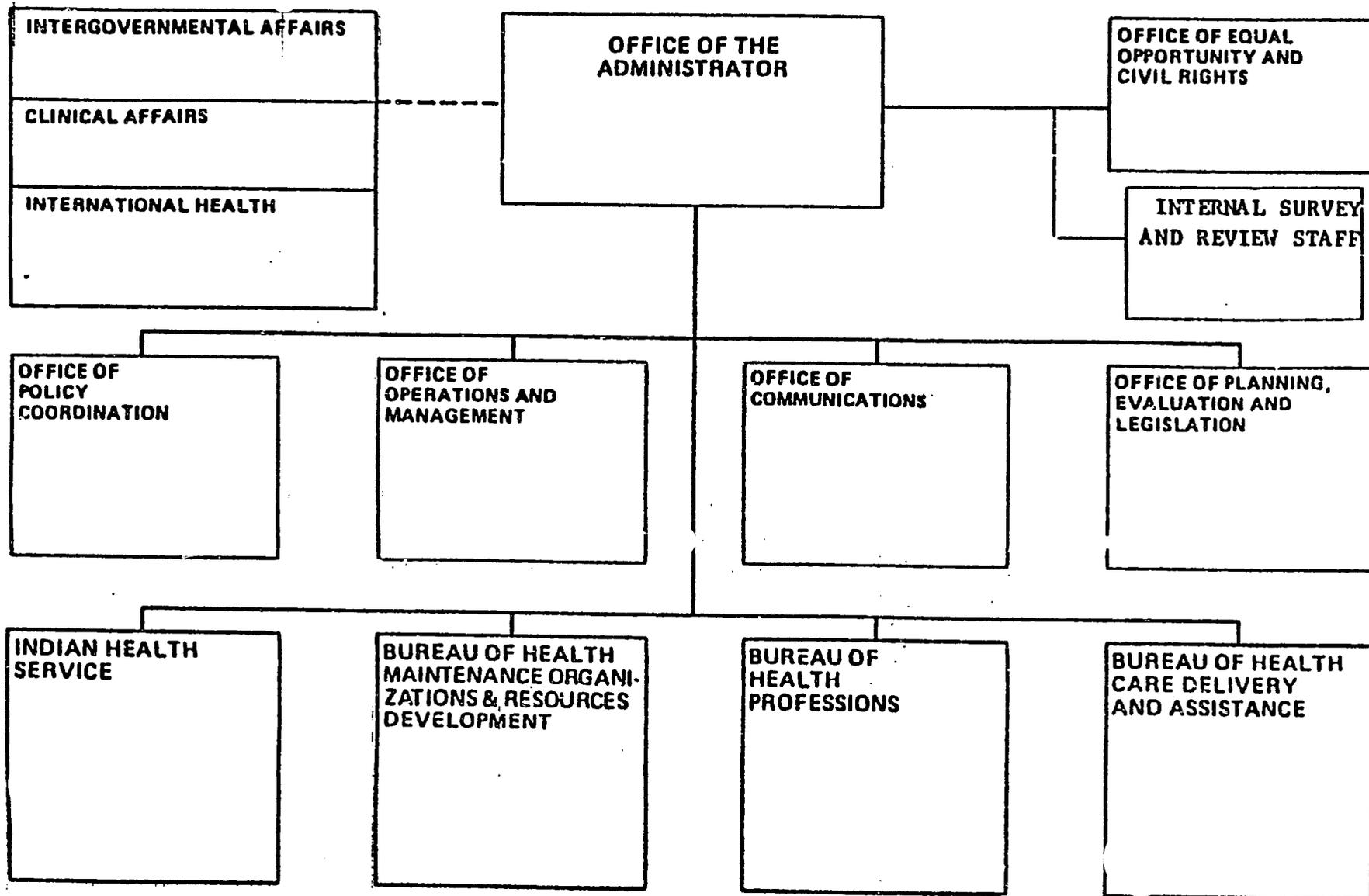
Establishment of patient facilities and services, other than physician care, for subjects under clinical investigation which includes administration of experimental chemotherapy.

O. Fogarty International Center (FIC)

Provides leadership to facilitate biomedical and behavioral research at the international level.

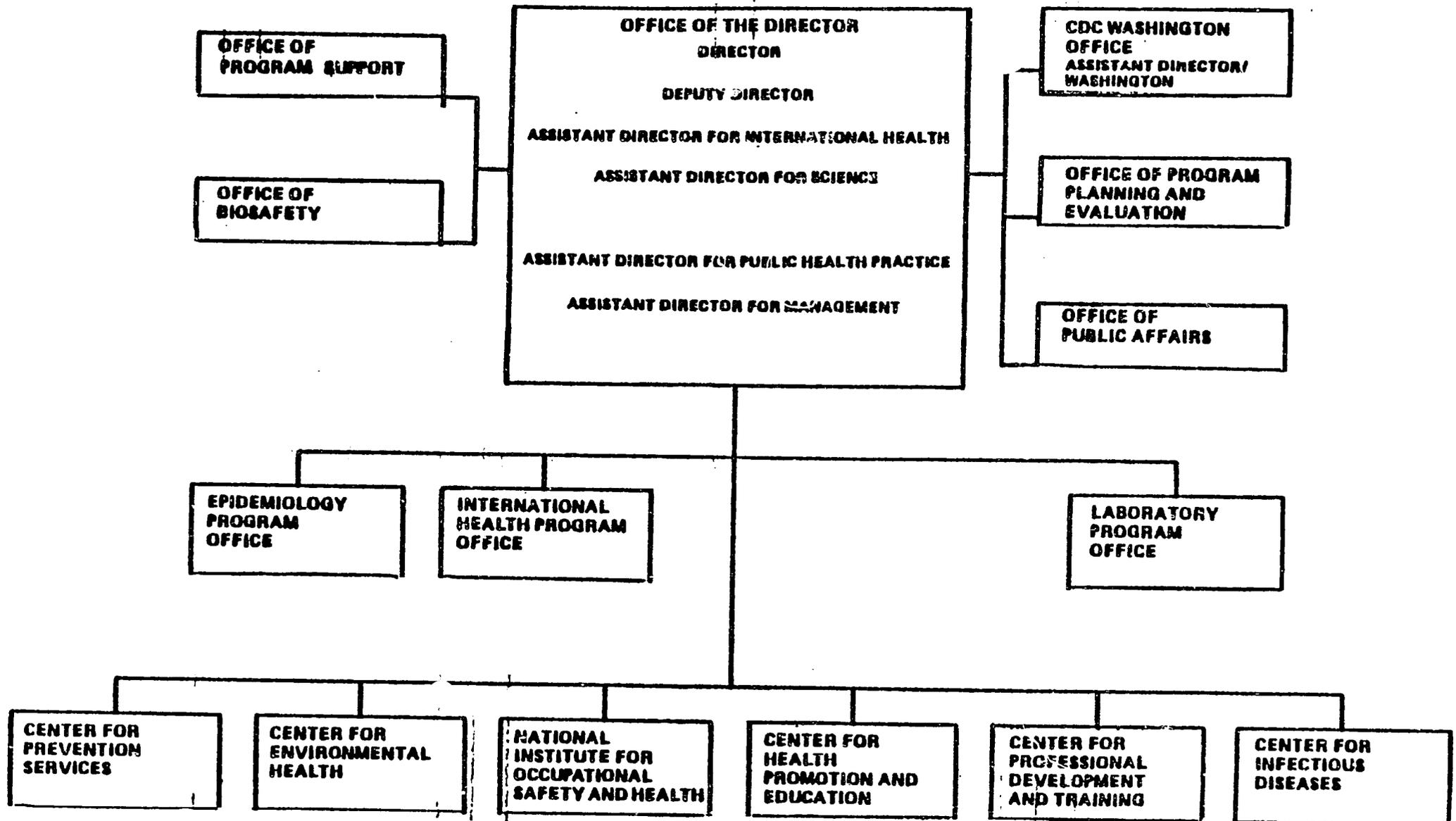
Provides international collaboration for NIH components and liaison with PHS agencies and international organizations on current and emerging international health issues; provides fellowships and administers visiting scientist program; develops and conducts international conferences on disease prevention and control.

**DEPARTMENT OF HEALTH & HUMAN SERVICES
PUBLIC HEALTH SERVICE
HEALTH RESOURCES AND SERVICES ADMINISTRATION**



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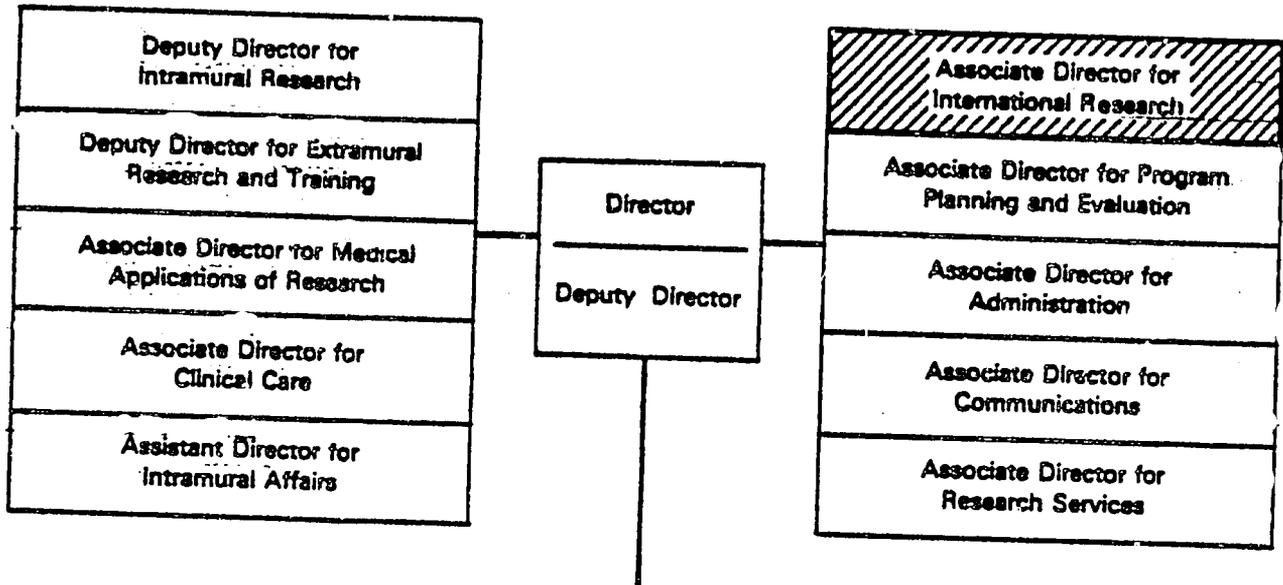
**DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
CENTERS FOR DISEASE CONTROL (HC)**



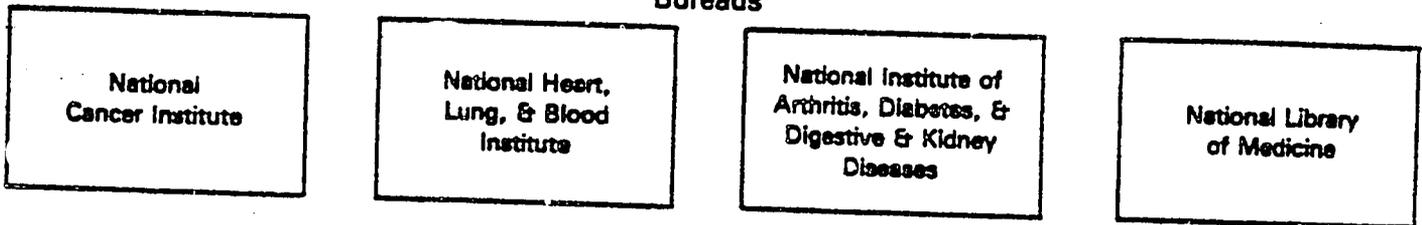
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NIH organization chart

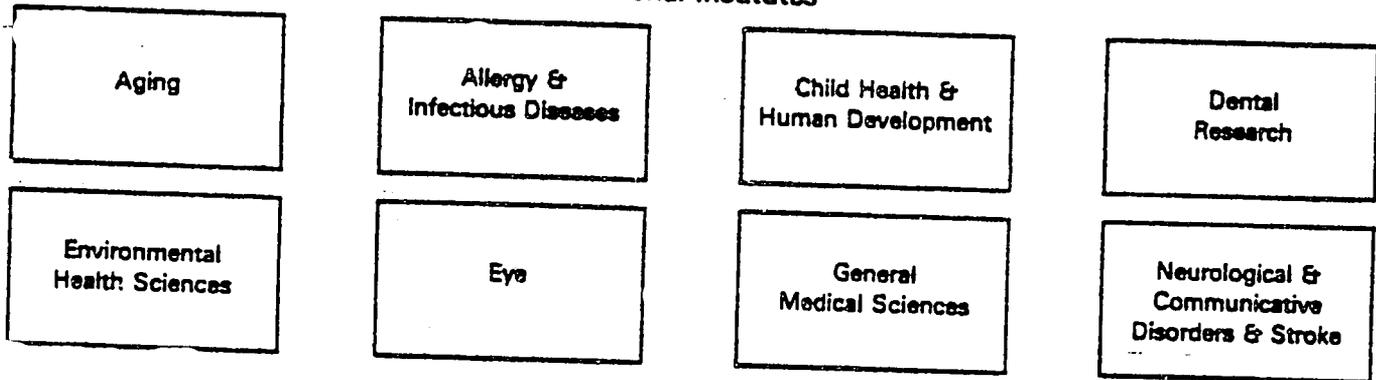
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PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH



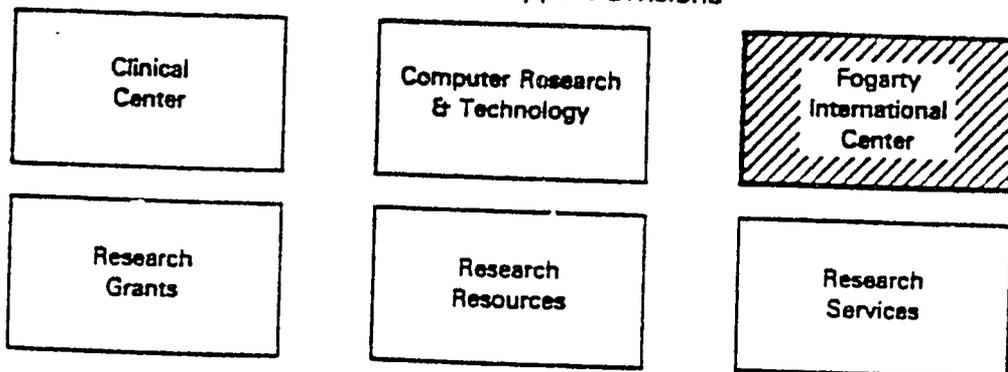
Bureaus



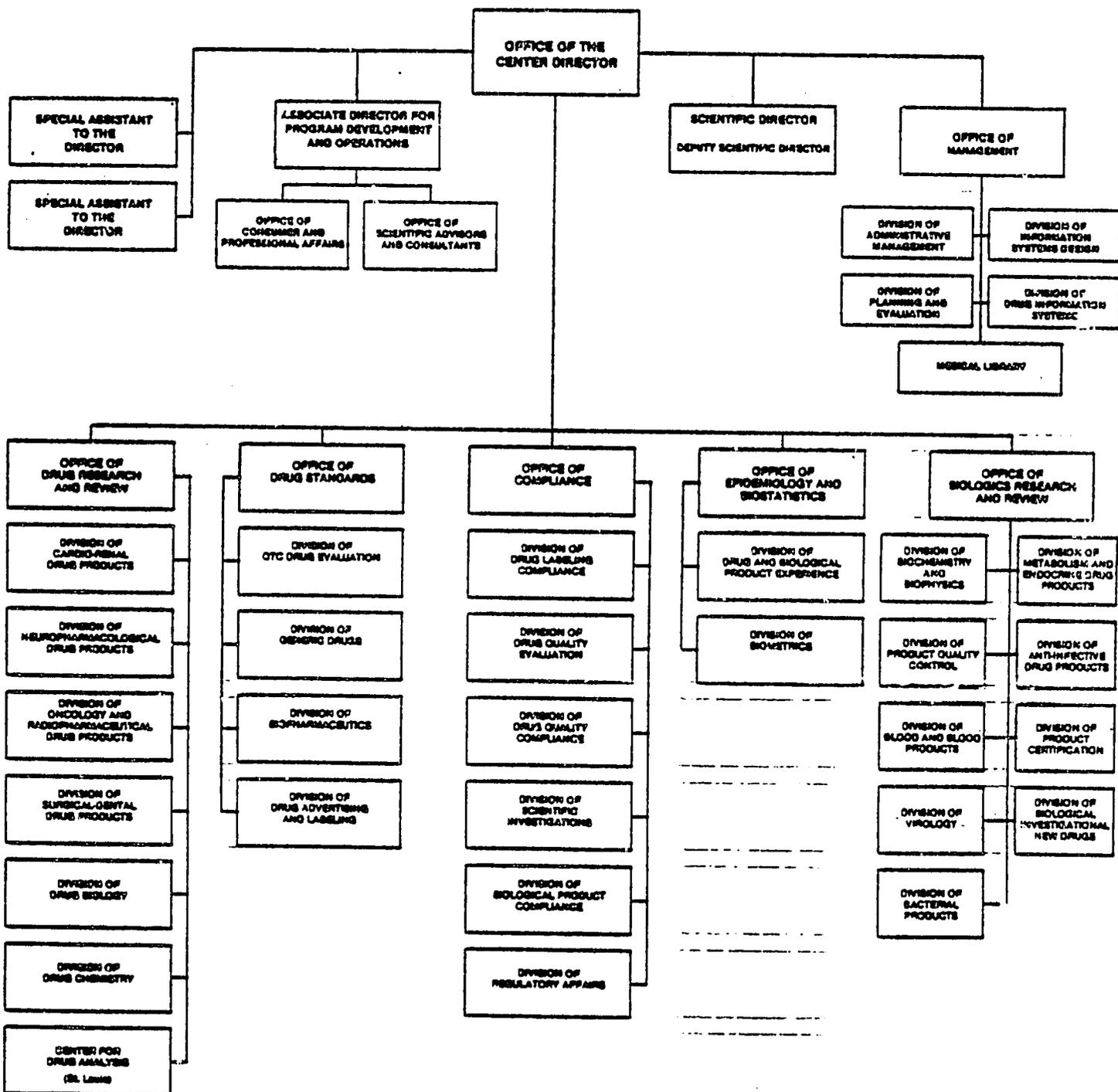
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