

Attachment 1: Regulation Authorizing Data Collection- Public Health Service Act and
Food Safety Modernization Act

Public Health Service Act

TITLE 42 > CHAPTER 6A > SUBCHAPTER II > Part A > § 241

§ 241. Research and investigations generally

(a) Authority of Secretary

The Secretary shall conduct in the Service, and encourage, cooperate with, and render assistance to other appropriate public authorities, scientific institutions, and scientists in the conduct of, and promote the coordination of, research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and impairments of man, including water purification, sewage treatment, and pollution of lakes and streams. In carrying out the foregoing the Secretary is authorized to—

- (1)** collect and make available through publications and other appropriate means, information as to, and the practical application of, such research and other activities;
- (2)** make available research facilities of the Service to appropriate public authorities, and to health officials and scientists engaged in special study;
- (3)** make grants-in-aid to universities, hospitals, laboratories, and other public or private institutions, and to individuals for such research projects as are recommended by the advisory council to the entity of the Department supporting such projects and make, upon recommendation of the advisory council to the appropriate entity of the Department, grants-in-aid to public or nonprofit universities, hospitals, laboratories, and other institutions for the general support of their research;
- (4)** secure from time to time and for such periods as he deems advisable, the assistance and advice of experts, scholars, and consultants from the United States or abroad;
- (5)** for purposes of study, admit and treat at institutions, hospitals, and stations of the Service, persons not otherwise eligible for such treatment;
- (6)** make available, to health officials, scientists, and appropriate public and other nonprofit institutions and organizations, technical advice and assistance on the application of statistical methods to experiments, studies, and surveys in health and medical fields;
- (7)** enter into contracts, including contracts for research in accordance with and subject to the provisions of law applicable to contracts entered into by the military departments under sections 2353 and 2354 of title 10, except that determination, approval, and certification required thereby shall be by the Secretary of Health and Human Services; and
- (8)** adopt, upon recommendations of the advisory councils to the appropriate entities of the Department or, with respect to mental health, the National Advisory Mental Health Council, such additional means as the Secretary considers necessary or appropriate to carry out the purposes of this section.

The Secretary may make available to individuals and entities, for biomedical and behavioral research, substances and living organisms. Such substances and organisms shall

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be made available under such terms and conditions (including payment for them) as the Secretary determines appropriate.

(b) Testing for carcinogenicity, teratogenicity, mutagenicity, and other harmful biological effects; consultation

(1) The Secretary shall conduct and may support through grants and contracts studies and testing of substances for carcinogenicity, teratogenicity, mutagenicity, and other harmful biological effects. In carrying out this paragraph, the Secretary shall consult with entities of the Federal Government, outside of the Department of Health and Human Services, engaged in comparable activities. The Secretary, upon request of such an entity and under appropriate arrangements for the payment of expenses, may conduct for such entity studies and testing of substances for carcinogenicity, teratogenicity, mutagenicity, and other harmful biological effects.

(2)

(A) The Secretary shall establish a comprehensive program of research into the biological effects of low-level ionizing radiation under which program the Secretary shall conduct such research and may support such research by others through grants and contracts.

(B) The Secretary shall conduct a comprehensive review of Federal programs of research on the biological effects of ionizing radiation.

(3) The Secretary shall conduct and may support through grants and contracts research and studies on human nutrition, with particular emphasis on the role of nutrition in the prevention and treatment of disease and on the maintenance and promotion of health, and programs for the dissemination of information respecting human nutrition to health professionals and the public. In carrying out activities under this paragraph, the Secretary shall provide for the coordination of such of these activities as are performed by the different divisions within the Department of Health and Human Services and shall consult with entities of the Federal Government, outside of the Department of Health and Human Services, engaged in comparable activities. The Secretary, upon request of such an entity and under appropriate arrangements for the payment of expenses, may conduct and support such activities for such entity.

(4) The Secretary shall publish a biennial report which contains—

(A) a list of all substances

(i) which either are known to be carcinogens or may reasonably be anticipated to be carcinogens and

(ii) to which a significant number of persons residing in the United States are exposed;

(B) information concerning the nature of such exposure and the estimated number of persons exposed to such substances;

(C) a statement identifying

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(i) each substance contained in the list under subparagraph (A) for which no effluent, ambient, or exposure standard has been established by a Federal agency, and

(ii) for each effluent, ambient, or exposure standard established by a Federal agency with respect to a substance contained in the list under subparagraph (A), the extent to which, on the basis of available medical, scientific, or other data, such standard, and the implementation of such standard by the agency, decreases the risk to public health from exposure to the substance; and

(D) a description of (i) each request received during the year involved—

(I) from a Federal agency outside the Department of Health and Human Services for the Secretary, or

(II) from an entity within the Department of Health and Human Services to any other entity within the Department,

to conduct research into, or testing for, the carcinogenicity of substances or to provide information described in clause (ii) of subparagraph (C), and (ii) how the Secretary and each such other entity, respectively, have responded to each such request.

(5) The authority of the Secretary to enter into any contract for the conduct of any study, testing, program, research, or review, or assessment under this subsection shall be effective for any fiscal year only to such extent or in such amounts as are provided in advance in appropriation Acts.

(c) Diseases not significantly occurring in United States

The Secretary may conduct biomedical research, directly or through grants or contracts, for the identification, control, treatment, and prevention of diseases (including tropical diseases) which do not occur to a significant extent in the United States.

(d) Protection of privacy of individuals who are research subjects

The Secretary may authorize persons engaged in biomedical, behavioral, clinical, or other research (including research on mental health, including research on the use and effect of alcohol and other psychoactive drugs) to protect the privacy of individuals who are the subject of such research by withholding from all persons not connected with the conduct of such research the names or other identifying characteristics of such individuals. Persons so authorized to protect the privacy of such individuals may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals.

Food Safety Modernization Act (FSMA)

SEC. 205. <<NOTE: 21 USC 2224.>> SURVEILLANCE.

(a) Definition of Foodborne Illness Outbreak.--In this Act, the term "foodborne illness outbreak" means the occurrence of 2 or more cases of a similar illness resulting from the ingestion of a certain food.

(b) Foodborne Illness Surveillance Systems.--

(1) In general.--The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall enhance foodborne illness surveillance systems to improve the collection, analysis, reporting, and usefulness of data on foodborne illnesses by--

(A) coordinating Federal, State and local foodborne illness surveillance systems, including complaint systems, and increasing participation in national networks of public health and food regulatory agencies and laboratories;

(B) facilitating sharing of surveillance information on a more timely basis among governmental agencies, including the Food and Drug Administration, the Department of Agriculture, the Department of Homeland Security, and State and local agencies, and with the public;

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(C) developing improved epidemiological tools for obtaining quality exposure data and microbiological methods for classifying cases;

(D) augmenting such systems to improve attribution of a foodborne illness outbreak to a specific food;

(E) expanding capacity of such systems, including working toward automatic electronic searches, for implementation of identification practices, including fingerprinting strategies, for foodborne infectious agents, in order to identify new or rarely documented causes of foodborne illness and submit standardized information to a centralized database;

(F) allowing timely public access to aggregated, de-identified surveillance data;

(G) at least annually, publishing current reports on findings from such systems;

(H) establishing a flexible mechanism for rapidly initiating scientific research by academic institutions;

(I) integrating foodborne illness surveillance systems and data with other biosurveillance and public health situational awareness capabilities at the Federal, State, and local levels, including by sharing foodborne illness surveillance data with the National Biosurveillance Integration Center; and

(J) other activities as determined appropriate by the Secretary.

(2) Working group.--The Secretary shall support and maintain a diverse working group of experts and stakeholders from Federal, State, and local food safety and health agencies, the food and food testing industries, consumer organizations, and academia. <<NOTE: Deadline. Reports. Recommendations.>> Such working group shall provide the Secretary, through at least annual meetings of the working group and an annual public report, advice and recommendations on an ongoing and regular basis regarding the

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improvement of foodborne illness surveillance and implementation of this section, including advice and recommendations on--

- (A) the priority needs of regulatory agencies, the food industry, and consumers for information and analysis on foodborne illness and its causes;
- (B) opportunities to improve the effectiveness of initiatives at the Federal, State, and local levels, including coordination and integration of activities among Federal agencies, and between the Federal, State, and local levels of government;
- (C) improvement in the timeliness and depth of access by regulatory and health agencies, the food industry, academic researchers, and consumers to foodborne illness aggregated, de-identified surveillance data collected by government agencies at all levels, including data compiled by the Centers for Disease Control and Prevention;
- (D) key barriers at Federal, State, and local levels to improving foodborne illness surveillance and the utility of such surveillance for preventing foodborne illness;
- (E) the capabilities needed for establishing automatic electronic searches of surveillance data; and
- (F) specific actions to reduce barriers to improvement, implement the working group's recommendations, and [[Page 124 STAT. 3939]] achieve the purposes of this section, with measurable objectives and timelines, and identification of resource and staffing needs.

(3) Authorization of appropriations.--To carry out the activities described in paragraph (1), there is authorized to be appropriated \$24,000,000 for each fiscal years 2011 through 2015.

(c) Improving Food Safety and Defense Capacity at the State and Local Level.--

(1) In general. <<NOTE: Strategies.>> --The Secretary shall develop and implement strategies to leverage and enhance the food safety and defense capacities of State and local agencies in order to achieve the following goals:

- (A) Improve foodborne illness outbreak response and containment.
- (B) Accelerate foodborne illness surveillance and outbreak investigation, including rapid shipment of clinical isolates from clinical laboratories to appropriate State laboratories, and conducting more standardized illness outbreak interviews.
- (C) Strengthen the capacity of State and local agencies to carry out inspections and enforce safety standards.
- (D) Improve the effectiveness of Federal, State, and local partnerships to coordinate food safety and defense resources and reduce the incidence of foodborne illness.
- (E) Share information on a timely basis among public health and food regulatory agencies, with the food industry, with health care providers, and with the public.
- (F) Strengthen the capacity of State and local agencies to achieve the goals described in section 108.

(2) Review. <<NOTE: Deadline.>> --In developing of the strategies required by paragraph (1), the Secretary shall, not later than 1 year after the date of enactment of the FDA Food Safety Modernization Act, complete a review of State and local capacities, and needs for enhancement, which may include a survey with respect to--

- (A) staffing levels and expertise available to perform food safety and defense functions;
- (B) laboratory capacity to support surveillance, outbreak response, inspection, and enforcement activities;
- (C) information systems to support data management and sharing of food safety and

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defense information among State and local agencies and with counterparts at the Federal level; and

(D) other State and local activities and needs as determined appropriate by the Secretary.

(d) Food Safety Capacity Building Grants.--Section 317R(b) of the Public Health Service Act (42 U.S.C. 247b-20(b)) is amended--

(1) by striking "2002" and inserting "2010"; and

(2) by striking "2003 through 2006" and inserting "2011 through 2015".