

to the Assistant to the President for Homeland Security and Counterterrorism on the consideration and implementation of Panel recommendations concerning the SAP, including a rationale for failure to implement any recommendations.

(vi) The Panel shall be chartered for a period of 4 years subject to renewal through the interagency policy committee process led by the National Security Staff.

(b) To further assist the Secretaries of Health and Human Services and Agriculture and the Attorney General in implementing the policy set forth in sections 1, 4, 5, and 6 of this order, the National Science Advisory Board for Biosecurity shall provide technical advice and serve as a conduit for public consultation, as needed, on topics of relevance to the SAP.

SEC. 8. *Sharing of Select Agent Program Information.* (a) Consistent with applicable laws and regulations, the Secretaries of Health and Human Services and Agriculture and the Attorney General shall, no later than 6 months from the date of this order, develop a process and the criteria for making SAP information available to executive departments and agencies when such information is necessary for furthering a public health, safety, security, law enforcement, or national security mission.

(b) SAP information shall continue to be safeguarded properly and handled securely to minimize the risk of disclosing sensitive, personal, and other information protected by the Privacy Act, 5 U.S.C. 552a.

SEC. 9. *General Provisions.* (a) The National Security Staff shall, on a biennial basis, review the implementation and effectiveness of this order and refer to the interagency policy committee process any issues that require further deliberation or adjudication.

(b) Nothing in this order shall be construed to impair or otherwise affect the authority granted by law to a department or agency, or the head thereof, or functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(c) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(d) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

BARACK OBAMA.

[Reference to the National Security Staff deemed to be a reference to the National Security Council Staff, see Ex. Ord. No. 13657, set out as a note under section 3021 of Title 50, War and National Defense.]

### § 263. Preparation of biological products by Service

(a) The Service may prepare for its own use any product described in section 262 of this title and any product necessary to carrying out any of the purposes of section 241 of this title.

(b) The Service may prepare any product described in section 262 of this title for the use of other Federal departments or agencies, and public or private agencies and individuals engaged in work in the field of medicine when such product is not available from establishments licensed under such section.

(July 1, 1944, ch. 373, title III, § 352, 58 Stat. 703.)

#### Statutory Notes and Related Subsidiaries

##### CHANGE OF NAME

“Secretary of Health and Human Services” substituted for “Secretary of Health, Education, and Welfare” pursuant to section 509(b) of Pub. L. 96-88, which is classified to section 3508(b) of Title 20, Education.

#### Executive Documents

##### TRANSFER OF FUNCTIONS

Functions of Public Health Service, Surgeon General of Public Health Service, and all other officers and employees of Public Health Service, and functions of all agencies of or in Public Health Service transferred to Secretary of Health, Education, and Welfare by Reorg. Plan No. 3 of 1966, eff. June 25, 1966, 31 F.R. 8855, 80 Stat. 1610, set out as a note under section 202 of this title.

### § 263-1. Education on biological products

#### (a) Internet website

##### (1) In general

The Secretary may maintain and operate an internet website to provide educational materials for health care providers, patients, and caregivers, regarding the meaning of the terms, and the standards for review and licensing of, biological products, including biosimilar biological products and interchangeable biosimilar biological products.

##### (2) Content

Educational materials provided under paragraph (1) may include—

(A) explanations of key statutory and regulatory terms, including “biosimilar” and “interchangeable”, and clarification regarding the use of interchangeable biosimilar biological products;

(B) information related to development programs for biological products, including biosimilar biological products and interchangeable biosimilar biological products and relevant clinical considerations for prescribers, which may include, as appropriate and applicable, information related to the comparability of such biological products;

(C) an explanation of the process for reporting adverse events for biological products, including biosimilar biological products and interchangeable biosimilar biological products; and

(D) an explanation of the relationship between biosimilar biological products and interchangeable biosimilar biological products licensed under section 262(k) of this title and reference products (as defined in section 262(i) of this title), including the standards for review and licensing of each such type of biological product.

##### (3) Format

The educational materials provided under paragraph (1) may be—

(A) in formats such as webinars, continuing education modules, videos, fact sheets, infographics, stakeholder toolkits, or other formats as appropriate and applicable; and

(B) tailored for the unique needs of health care providers, patients, caregivers, and other audiences, as the Secretary determines appropriate.

##### (4) Other information

In addition to the information described in paragraph (2), the Secretary shall continue to publish—

(A) the action package of each biological product licensed under subsection (a) or (k) of section 262 of this title; or