



DEPARTMENT OF COMMERCE

Bureau of Industry and Security

[Docket No. 201124-0316]

RIN 0694-XC068

Notice of Request for Public Comments on Condition of the Public Health Industrial Base and Recommend Policies and Actions to Strengthen the Public Health Industrial Base to Ensure Essential Medicines, Medical Countermeasures, and Critical Inputs Are Made in the United States

AGENCY: Bureau of Industry and Security, Office of Technology Evaluation, U.S. Department of Commerce.

ACTIONS: Notice of request for public comments.

SUMMARY: On August 6, 2020, President Trump issued an Executive order, *Combating Public Health Emergencies and Strengthening National Security by Ensuring Essential Medicines, Medical Countermeasures, and Critical Inputs Are Made in the United States*.

Among other directives, the EO directed that, by February 2, 2021, the Secretary of Commerce shall submit a report to the Director of the Office of Management and Budget, the Assistant to the President for National Security Affairs, the Director of the National Economic Council, and the Director of the Office of Trade and Manufacturing Policy, describing any change in the status of the Public Health Industrial Base (PHIB) and recommending initiatives to strengthen the PHIB. This notice requests comments from the public to assist the Department of Commerce

(referred to henceforth as “Commerce”) in preparing this report on the condition of the PHIB and recommending policies and actions to strengthen the PHIB.

DATES: The due date for filing comments is December 23, 2020.

ADDRESSES: *Submissions:* All written comments on the notice must be addressed to PHIB Study and filed through the Federal eRulemaking Portal: <http://www.regulations.gov>. To submit comments via <http://www.regulations.gov>, enter docket number BIS–2020–0034 on the home page and click “search.” The site will provide a search results page listing all documents associated with this docket. Find a reference to this notice and click on the link entitled “Comment Now!” (For further information on using <http://www.regulations.gov>, please consult the resources provided on the website by clicking on “How to Use This Site.”)

FOR FURTHER INFORMATION CONTACT: Jason Bolton at 202-482-5936 or via email Jason.Bolton@bis.doc.gov; PHIBstudy@bis.doc.gov.

SUPPLEMENTARY INFORMATION:

Background

On August 6, 2020, President Trump issued Executive Order 13944, *Combating Public Health Emergencies and Strengthening National Security by Ensuring Essential Medicines, Medical Countermeasures, and Critical Inputs Are Made in the United States* (EO 13944). Section 1 of EO 13944 stated that the United States must protect U.S. citizens, critical infrastructure, military forces, and the economy against outbreaks of emerging infectious diseases as well as chemical, biological, radiological, and nuclear (CBRN) threats. To achieve this, the United States must have a strong Public Health Industrial Base (PHIB) with resilient domestic supply chains for the Essential Medicines, Medical Countermeasures, and Critical Inputs deemed necessary for the United States. As defined in EO 13944, “Essential Medicines” are those Essential Medicines deemed necessary for the United States pursuant to section 3(c) of EO 13944; “Medical Countermeasures” means items that meet the definition of “qualified

countermeasure” in section 247d–6a(a)(2)(A) of title 42, United States Code; “qualified pandemic or epidemic product” in section 247d–6d(i)(7) of title 42, United States Code; “security countermeasure” in section 247d–6b(c)(1)(B) of title 42, United States Code; or personal protective equipment described in part 1910 of title 29, Code of Federal Regulations. Section 7 of EO 13944 contains the definitions of other terms that are applicable to this notice (e.g., “Active Pharmaceutical Ingredient,” “Advanced Manufacturing,” “API Starting Material,” “Critical Inputs,” “Finished Device,” “Finished Drug Product,” “Healthcare and Public Health Sector,” and “Qualifying Countries”). The definition of “produced in the United States” used in this notice is consistent with the definition of “produced in the United States” as used in Section 25.1 of the Federal Acquisition Regulation (FAR) *Buy American Act-Supplies* and in the FAR Clause 52.225-1.

Section 1 of EO 13944 directs that domestic supply chains must be capable of meeting national security requirements for responding to threats arising from CBRN threats and public health emergencies, including emerging infectious diseases such as COVID–19. The EO further states that it is critical that the United States reduce its dependence on foreign manufacturers for Essential Medicines, Medical Countermeasures, and Critical Inputs to ensure sufficient and reliable long-term domestic production of these products, minimize potential shortages, and mobilize our Nation’s PHIB to respond to these threats. The EO directed that the policy of the United States is to accelerate the development of cost-effective and efficient domestic production of Essential Medicines and Medical Countermeasures and to have adequate redundancy built into the domestic supply chain; ensure long-term demand for these items, and critical inputs that are produced in the United States; create, maintain, and maximize domestic production capabilities for these items that are essential to protect public safety and human health and to provide for the national defense; and combat the trafficking of these items, and critical inputs over e-commerce platforms and from third party online sellers involved in the government procurement process.

In EO 13994, the President directed the heads of Executive Branch agencies, including the Secretary of Commerce, to fulfill the stated policy objectives of the order. Under section 6, paragraph (b) (Reporting) of the EO, the Secretary is directed, by February 2, 2021 (within 180 days of the date of the August 6 order), to submit a report to the Director of the Office of Management and Budget (OMB), the Assistant to the President for National Security Affairs, the Director of the National Economic Council, and the Director of the Office of Trade and Manufacturing Policy, describing any change in the status of the Public Health Industrial Base and recommending initiatives to strengthen the Public Health Industrial Base.

This notice requests comments from the public to assist Commerce in preparing this report on the condition of the PHIB (“change in the status”) and recommending policies and actions (“initiatives”) to strengthen the PHIB.

As stated in section 6, paragraph (c) of EO 13944, to the maximum extent permitted by law, and with the redaction of any information protected by law from disclosure, Commerce’s report shall be published in the *Federal Register* and on the agency’s official website.

Definition of Public Health Industrial Base (PHIB)

As defined in EO 13944, “PHIB” means the facilities and associated workforces within the United States, including research and development facilities, which help produce Essential Medicines, Medical Countermeasures, and Critical Inputs for the Healthcare and Public Health Sector. The PHIB includes all entities domestically manufacturing or producing medical products, including medical devices, medical equipment, medical countermeasures, and medications, pharmaceutical products, and other products designed to improve patient outcomes. This includes the manufacturing of components and materials that are essential to create end-item medical products, as well as ancillary supplies and disposable consumable products.

For medical devices and medical equipment, the PHIB includes all components that, if replaced by an equivalent alternative component, would require an amendment to the final product’s 510(k) certification. For medications and pharmaceutical products, it includes drug

finishing (*i.e.*, fill-finish, tableting, or capsule formulation), as well as the active pharmaceutical ingredients (API) and the key starting materials that are used to make the API. For blood products and medical products derived from animals (such as porcine and bovine heparin), the PHIB includes all aspects of the extraction, processing and formulation supply chain. For vaccines and biologics, it includes research and development, as well as the production of all components of the end product without which the end product would be ineffective for its intended purpose.

The PHIB also includes the labor force necessary to conduct the manufacturing and supply chain operations described above. It does not include the ability of distributors to source medical products from foreign sources to distribute within the U.S. healthcare system.

Written Comments

Interested parties are invited to submit written comments, data, analyses, or information pertinent to the task of preparing this Commerce report pursuant to EO 13994 to the Department's Office of Technology Evaluation no later than December 23, 2020.

The Department is particularly interested in comments and information directed to the policy objectives listed in EO 13944 as they affect the U.S. PHIB including, but not limited to, the following:

- (i) What is the condition of the current U.S. PHIB? Commenters in responding to this question are encouraged to reference their position in the PHIB (*e.g.*, research and development facility, manufacturer, distributor, or consumer).
- (ii) What policies and actions should the U.S. Government take to strengthen the PHIB in the United States?
- (iii) What aspects or parts of the PHIB are most vulnerable during outbreaks of emerging infectious diseases?

a. How likely might such an event be, how much of an impact might it have in manufacturing operations, and what mitigation measures might be most effective in offsetting these impacts?

b. In responding to this question, commenters are encouraged to include any lessons learned from responding to COVID-19 or other historic pandemics, and the ramping up of U.S. capacity in various areas that did or did not occur to meet these challenges.

(iv) What aspects or parts of the PHIB are most vulnerable to chemical, biological, radiological, and nuclear (CBRN) events?

a. How likely might such an event be; how much might it impact manufacturing operations; and what mitigation measures might be most effective in offsetting these impacts.

b. In responding to this question, commenters are encouraged to include any lessons learned from responding to previous CBRN threats and the ramping up of U.S. capacity in various areas that did or did not occur to meet these challenges.

(v) For the Essential Medicines, Medical Countermeasures, and Critical Inputs with which your organization is involved under the PHIB, for what percentage of these items are you dependent on foreign suppliers? In responding to this question, please address:

a. whether or not there are foreign dependencies in any part of your supply chain for critical inputs (*e.g.*, active pharmaceutical ingredients (APIs)) or for finished products?

b. whether it would be possible to source these critical inputs and/or finished products from the United States, as well as how long you anticipate it would take to source these items from U.S. suppliers if your foreign supplier(s) was no longer available?

(vi) Are there any costs, regulatory or other factors that make it difficult or impossible to produce or source Essential Medicines, Medical Countermeasures, and/or Critical Inputs in the United States? In addressing this question, please also address:

a. any concerns that you may have regarding sourcing or producing these items in the United States, in contrast to sourcing or producing them outside the United States.

b. does your organization have mechanisms to determine whether Essential Medicines, Medical Countermeasures, and Critical Inputs are produced in the United States? What, if any, are the limitations to those mechanisms?

Commenters are encouraged to be as specific as possible in their comments regarding the particular issues that may exist. For example, an example of a regulatory provision accompanied by a specific example of how the provision hinders domestic production is more helpful to Commerce than a statement that the regulatory environment in the United States discourages domestic production.

c. how significant of a concern is “pricing” in being able to achieve maximum domestic production?

(vii) What is the U.S. Government doing or could do to foster private and public sector investment and innovation in the U.S. PHIB, including, for example, investments in upgrades to equipment, or the adoption of emerging technologies, and/or automation that would increase productivity and competitiveness. Should the U.S. Government do more to foster U.S. PHIB investment, particularly in automation and emerging technologies? If so, what policy actions should it undertake?

(viii) With respect to the U.S. PHIB, what are the challenges to investing in automation and other productivity-enhancing technologies in the United States as compared to moving operations abroad to lower-cost labor countries? Would increased investment in, or higher use of, more efficient and cost-effective automation and productivity enhancing

technologies affect your decisions to source all or some of your Essential Medicines, Medical Countermeasures, and Critical Inputs in the United States?

(ix) Briefly assess whether the amount of federal funds spent on U.S. PHIB research and development (R&D) is adequate; if not, specify why spending should be increased or decreased. Which types of R&D projects, if adequately funded, would have the most impact on the competitiveness of the U.S. PHIB supply chain?

(x) Briefly assess U.S. Federal procurement policy with respect to the U.S. PHIB and how it encourages or discourages investment in the PHIB. How should U.S. Federal procurement policy to make the PHIB more productive and more internationally competitive, as well as to encourage investment in automation and other emerging technologies?

(xi) What are the workforce challenges to strengthening the U.S. PHIB, and what are best practices or suggestions for how U.S. industry can overcome these challenges? What have you done to address these challenges? How might emerging technologies in the PHIB create new workforce training needs? Which skillsets will the job market most demand in the future?

(xii) How can the U.S. Government or the private sector help to accelerate the development of cost-effective and efficient domestic production of Essential Medicines and Medical Countermeasures and to have adequate redundancy built into the domestic supply chain for Essential Medicines, Medical Countermeasures, and Critical Inputs?

(xiii) What are the three most important things that can be done by the U.S. Government or the private sector to ensure long-term demand for the Essential Medicines, Medical Countermeasures, and Critical Inputs that are produced in the United States?

(xiv) What are the three most important things that can be done by the U.S. Government or the private sector to create, maintain, and maximize domestic production capabilities

for the Critical Inputs, Finished Drug Products, and Finished Devices that are essential to protect public safety and human health and to provide for the national defense?

(xv) How significant of a problem is trafficking of counterfeit Essential Medicines, Medical Countermeasures, and Critical Inputs over e-commerce platforms and from third party online vendors also involved in the U.S. Government procurement process? In responding to this question, commenters are encouraged to provide specific examples of how these practices may have undermined production in the United States, endangered U.S. citizens, or undermined the reliability of the U.S. supply chain.

(xvi) How great of a threat is cybercrime or malicious cyber activity to your organization and other organizations that you depend on as part of your supply chain for Essential Medicines, Medical Countermeasures, and Critical Inputs? In addressing this question, commenters are encouraged to provide specific examples of how cyber threats (*e.g.*, ransomware, distributed denial of service attacks (DDoS) and malware) have undermined production in the United States and the reliability of the U.S. supply chain for Essential Medicines, Medical Countermeasures, and Critical Inputs. How can the U.S. Government or the private sector strengthen the PHIB sector's ability to prevent, detect, and recover from malicious cyber activity? To what extent, if any, does dependence on foreign suppliers increase your organization's exposure to cybercrime or create additional burdens because of the complexities involved in dealing with different countries' laws on cyber issues?

(xvii) From your organization's perspective, how dependent is the U.S. supply chain on foreign suppliers for items for use in Personal Protective Equipment (PPE)? In addressing this question, please address whether there are specific factors that undermine U.S. competitiveness in this area and provide any recommendations that your organization may have for reducing foreign dependency and increasing U.S. competitiveness. In addressing this question, specify whether your organization produces, sells or uses PPE.

Requirements for Written Comments

The <http://www.regulations.gov> website allows users to provide comments by filling in a “Type Comment” field, or by attaching a document using an “Upload File” field. The Department prefers that comments be provided in an attached document. The Department prefers submissions in Microsoft Word (.doc files) or Adobe Acrobat (.pdf files). If the submission is in an application format other than Microsoft Word or Adobe Acrobat, please indicate the name of the application in the “Type Comment” field. Please do not attach separate cover letters to electronic submissions; rather, include any information that might appear in a cover letter within the comments. Similarly, to the extent possible, please include any exhibits, annexes, or other attachments in the same file, so that the submission consists of one file instead of multiple files. Comments will be placed in the docket and open to public inspection, unless a statement is filed justifying nondisclosure and referring to the specific legal authority claimed, and a non-confidential version of the submission is provided. Anyone submitting business confidential information should clearly identify the business confidential portion at the time of submission, file a statement justifying nondisclosure and referring to the specific legal authority claimed, and provide a non-confidential version of the submission. Comments may be viewed on <http://www.regulations.gov> by entering docket number BIS–2020–0034 in the search field on the home page.

All filers should name their files using the name of the person or entity submitting the comments. Communications from agencies of the United States Government will not be made available for public inspection.

Anyone submitting business confidential information should clearly identify the business confidential portion at the time of submission, file a statement justifying nondisclosure and referring to the specific legal authority claimed, and provide a non-confidential version of the submission. Guidance on submitting business confidential information is as follows: anyone

submitting business confidential information should clearly identify the business confidential portion at the time of submission, include a statement justifying nondisclosure and referring to the specific legal authority claimed with the submission, and provide a non-confidential version of the submission which will be placed in the public file on <http://www.regulations.gov>. For comments submitted electronically containing business confidential information, the file name of the business confidential version should begin with the characters “BC”. Any page containing business confidential information must be clearly marked “BUSINESS CONFIDENTIAL” on the top of that page. The non-confidential version must be clearly marked “PUBLIC”. The file name of the non-confidential version should begin with the character “P”. The “BC” and “P” should be followed by the name of the person or entity submitting the comments or rebuttal comments. If a public hearing is held in support of this investigation, a separate *Federal Register* notice will be published providing the date and information about the hearing.

The Bureau of Industry and Security does not maintain a separate public inspection facility. Requesters should first view the Bureau’s web page, which can be found at <https://efoia.bis.doc.gov/> (see “Electronic FOIA” heading). If requesters cannot access the website, they may call 202–482–0795 for assistance. The records related to this assessment are made accessible in accordance with the regulations published in part 4 of title 15 of the Code of Federal Regulations (15 CFR 4.1 through 4.11).

Matthew S. Borman,

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