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Public Health Industrial Base (PHIB) Study
Bureau of Industry and Security
Office of Technology and Evaluation
U.S. Department of Commerce

Re: 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 (Docket No. BIS-2020-0034)

Dear Members of the U.S. Department of Commerce PHIB Study,

Vizient, Inc. appreciates the opportunity to respond to the U.S. Department of Commerce's Notice of Request for Public Comments on the Condition of the Public Health Industrial Base (PHIB) 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 (hereinafter, "RFI"). Vizient supports efforts to better understand the condition of the PHIB and to identify sound policies and actions to strengthen the PHIB.

Background

Vizient, Inc. provides solutions and services that improve the delivery of high-value care by aligning cost, quality and market performance for more than 50% of the nation's acute care providers, which includes 95% of the nation's academic medical centers, and more than 20% of ambulatory providers. Vizient provides expertise, analytics, and advisory services, as well as a contract portfolio that represents more than $100 billion in annual purchasing volume, to improve patient outcomes and lower costs. Headquartered in Irving, Texas, Vizient has offices throughout the United States.

Comments and Recommendations

Vizient offers the below answers in response to certain questions posed in the RFI that seek feedback on topics where Vizient has unique expertise or insights. As the Department of Commerce considers these and other responses in developing recommendations, we emphasize the importance of increasing transparency of the manufacturing supply chain as it will help stakeholders better understand the origination of pharmaceutical ingredients and, more broadly, support supply chain resiliency.

(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).
Vizient serves a critical role in the health care supply chain, leveraging data and the collective buying power of our members to achieve competitive pricing on health care services and supplies for our members. Both prior to and during the COVID-19 pandemic, Vizient has focused a significant amount of its sourcing, clinical and analytics expertise on improving the resiliency of the supply chain to sustain access to high quality, essential medications. As a result of our members and this degree of familiarity, Vizient can provide a perspective across many components of the pharmaceutical supply chain.

At present, the PHIB for pharmaceutical manufacturing has been and remains vulnerable to numerous disruptions, including quality deficiencies, natural disasters, limitations of raw materials, unanticipated business decisions and, obviously, pandemics. However, a lack of transparency regarding key manufacturing and sourcing steps exacerbates the harm that is already associated with any disruption source.

The extent of visibility into critical aspects of manufacturing remain obscure. As a result, it is extremely challenging for the market to know what elements of supply require additional investment and action to create validated redundancy. Until such time as there is greater clarity, it will remain nearly impossible to know which components of the supply chain require further reinforcement against potential threats. In addition, it will be similarly challenging to identify effective strategies to support sustained investments in a truly resilient infrastructure that consistently delivers high quality pharmaceuticals.

(ii) What policies and actions should the U.S. Government take to strengthen the PHIB in the United States?
Vizient encourages the U.S. Government to structure regulations and provide financial incentives regarding pharmaceutical manufacturing in a manner that strongly supports a market of high-quality medications whose supply has inherent and enduring resiliency to various disruptive forces. As stated previously in our comments, there is limited transparency regarding the quality and sustainability of manufacturing capacity in the U.S. Increased clarity is required so the market better understands the investment required to achieve this level of resiliency. If the requirements for high quality and redundant manufacturing capacity were better understood, the market could make more informed decisions that would ultimately lead to a strengthened PHIB.

(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.
The manufacturing supply chain is highly complicated and the overarching understanding of it is extremely limited. As a result, it is difficult to identify one or even a few areas of greatest

vulnerability. Prior to COVID-19, Vizient and the health care community have been involved in a two decades-long fight against the routine occurrence of drug shortages. In these two decades, we have witnessed shortages due to natural disasters (e.g. Hurricane Maria), manufacturing business decisions (e.g. vincristine[1]), and a multitude of quality issues and/or supply disruptions, including active pharmaceutical ingredients (API), vials and rubber stoppers, among many others. Any single disruption of the numerous components of a medication could render a critically essential drug product unavailable to providers and the patient populations they serve. In April 2019, Vizient identified that health systems spend an estimated $359M per year managing drug shortages, which results in additional 8.6M hours of labor per year.

Another critical vulnerability is the extent and speed with which manufacturing can respond to increased demand. At the onset of COVID-19, the initial fear across the healthcare landscape was that the infection in China would disrupt the flow of API, which could precipitate shortages later in the year. However, this did not take place as anticipated. Instead, the greatest threat faced by the supply channel was the extraordinary increase in demand for critical care-related medications. Fortunately, Vizient was able to assist our members in obtaining access to these products through our Essential Medications list and Novaplus Enhanced Supply strategies. However, it was a very close call and illustrates that neither the additional capacity nor the needed technologies or redundancies exist to expand production capability to align with the needs for events such as the COVID-19 pandemic. This inability to produce medications rapidly on a scale beyond routine use is a critical threat as well.

(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.
It is nearly impossible to accurately predict what challenge the next crisis or disaster may present. Therefore, the PHIB must be resilient against all these challenges. As we will discuss in the next response, Vizient has created its own Essential Medications list for hospitals and health systems and would be happy to speak with the appropriate parties about how this list might vary depending upon the nature of the threat or event.

(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

[1] *See* American Society of Health-System Pharmacists (ASHP). Current Drug Shortages: Vincristine Sulfate Injection. Last updated January 31, 2020, noting reasons for the shortage, "Pfizer had vincristine on shortage due to manufacturing delays and increased demand. They are the sole supplier of vincristine sulfate injection. There is a Dear Healthcare Professional letter available at https://www.fda.gov/media/131865/download" and "Teva discontinued Vincosar in early-July 2019", available at: https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=600&loginreturnUrl=SSOCheckOnly

dependent on foreign suppliers? In responding to this question, please address: a. whether 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?

Vizient is a healthcare performance improvement company and group purchasing organization. We do not take title to any medications. Instead, we work with distributors and manufacturers to support the cost-effective use of drugs. However, while we do not manufacture medications, we have increasingly required suppliers to disclose the manufacturing location and API origination point for essential medications contained with the Vizient Novaplus Enhanced supply strategy. Vizient began requiring the disclosure of manufacturing locations in 2018, subsequent to the experience with Hurricane Maria and, in 2019, began requiring information on API point of origination. In 2019, Vizient also began working with strategic suppliers to house 4 to 6 months of additional inventory for its members within domestic locations. Based on that information, the below table outlines how we presently characterize the top manufacturing and API origination points for contracted products.

Top Countries by Manufacturing Location/API Origination Point: Identified as a Result of March 2020 Contacted Supplier Survey

Manufacturing	API
US	US
India	Italy
Austria	China
Switzerland	India
Germany	Spain and Switzerland

Compared to the traditional narrative of most medications coming from China and/or India, we were intrigued to find a much larger domination of U.S. and European based manufacturing and API sourcing. Still, this analysis only includes a subset of medications. Also, there are many other components beyond the API that could have originated elsewhere. However, it *is* possible to source and manufacture medications in locations other than China and India. In addition, it is important to consider that many of the drug shortages we have faced over the last 20 years have been associated with quality problems and other manufacturing failures that have transpired here in the U.S. While U.S.-based manufacturing and sourcing has many qualities of merit, we are concerned it will be viewed as a substitute for validated, high quality pharmaceutical production overseas.

(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?

First, we would like to applaud the work of the Food and Drug Administration for publishing their list of Essential Medicines, Medical Countermeasures, and Critical Inputs. As mentioned previously, Vizient published its initial Essential Medications list in January 2020. That list has served to focus our Novaplus Enhanced Supply strategy to include 31 drugs, 151 National Drug Codes, and 53 million additional protected units of essential medications housed within the U.S. In order to begin rectifying the weaknesses of the existing PHIB, it is critically relevant to designate those products of greatest concern whether they be foreign or domestically produced.

Second, while Vizient does not directly manufacture medications, we are anecdotally aware that environmental regulations and the cost of domestic labor make foreign manufacturing strategies appear more desirable for pharmaceutical suppliers. As a result, evaluating these concerns for potential action would be appropriate steps for the government.

Still, as we have summarized above, domestic manufacturing does not guarantee high quality products. If the U.S. was able to implement a system of increased transparency and make objective measures of quality manufacturing available to end users, it is possible that the market could support greater investment in high quality, domestic manufacturing locations.

(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?

To foster private sector innovation, Vizient believes that the government should invest in new technologies, such as those used in continuing manufacturing processes, to overcome some of the manufacturing issues that have contributed to the last two decades of shortages.

Vizient also encourages the government to explore novel technologies that could greatly compress the time required to ramp up production as needed during circumstances such as a pandemic. It is critical the government identify and support innovative manufacturing solutions because current pharmaceutical manufacturing tends not to prioritize cultivating new, essential, critical care medications. As evidenced by the Vizient Essential Medications list, the vast majority of products that are identified as being of the greatest importance are those that have long since reached the end of their product exclusivities. Due to market needs and the desire to develop medications that are for chronic and specialty illnesses and generate larger returns on investment, fewer dollars are allocated to investigation of novel critical care therapeutics. Therefore, the medications that are essential today will likely remain essential in 20 years. Given there appear to be barriers to fund additional development for novel critical

care therapeutics (and/or if there is no viable remaining innovation to be realized), we must find new ways to manufacture legacy essential medications in a more efficient, more resilient manner.

(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?
As mentioned in section (vii), the principal focus of new drug development is on therapies for areas where treatment is lacking. Frequently, these therapies are for chronic and increasingly smaller disease states. There is limited funding for broadly used critical care drugs. As a result, the drugs of greatest importance for critical care and in disaster response scenarios remain the same. Therefore, additional research and development, particularly in improved manufacturing, would be critical to addressing the limitations of the essential medication supply chain.

(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?
Vizient appreciates this question, as we believe there is a need for greater transparency regarding the challenges confronting manufacturers in seeking and identifying skilled labor.

In addition, Vizient notes workforce challenges impacting the U.S. pandemic response extend beyond manufacturing challenges and reach the point of care. From a staffing perspective for hospitals and health systems, Vizient believes that there is a need to create fungibility of staffing across the country, especially given the ongoing shortage of registered nurses in the country which impeded the nation's ability to respond to the pandemic. In addition to addressing specific staffing needs, these concerns could also be addressed through interchangeability of licensure or broader licensure policies. Also, Vizient believes easing barriers to allow caregivers from abroad to enter the United States during times of massive surges and healthcare crises can help address staffing concerns.

Also, Vizient believes certain staffing challenges during natural disasters and pandemics could be overcome by establishing state or regional approaches to labor procurement to standardize rates and placement of staff according to objective measures. During the COVID-19 pandemic we have learned that each health care entity focused on its own needs, as opposed to considering consolidated needs within a region. Based on Vizient's work with the state of Arizona where we supported broader labor procurements efforts in the summer, during the winter surges our previous approach is again helping to strategically distribute staff to where they are needed most.

Lastly, again considering training, we believe establishing a workforce pool, such as registered nurses, that is able to deploy rapid just-in-time training on a variety of topics to quickly prepare other health care professionals (e.g., additional registered nurses) that may not have the

knowledge or skills to serve in unique, public health circumstances would help address workforce flexibility needs while maintaining patient safety.

(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?
The strategy Vizient has leveraged for success, both prior to and during COVID-19, has been our Novaplus Enhanced Supply. By partnering with manufacturers not only to meet current demand, but to create additional, domestically housed inventory for essential medications, Vizient has been able to create a more resilient supply chain for these products and mitigate shortages in the event of future supply disruptions. As stated above, the Novaplus Enhanced Supply strategy currently consists of 31 drugs, 151 National Drug Codes, and 53 million additional protected units of domestically housed essential medications. During the height of COVID-19, this strategy was responsible for bringing an additional 676,000 units of propofol to the market. Vizient has worked with the FDA, FEMA and others to share its unique data capabilities and insights to enable more accurate estimation of need for essential drugs and avert shortages before they occur. Vizient is willing to discuss further partnerships to expand the analytics infrastructure to monitor and predict demand for essential medications.

(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?
As stated above, due to the absence of significant investment in critical care drug development, the essential medications of today will likely be priority products going forward. Therefore, the relevance of these products to disaster and other high intensity care suggests that the demand for such products will remain consistent.

Vizient also reiterates the need to provide greater transparency in the supply chain to support stakeholder resiliency efforts.

(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?

1. Continue to focus on essential medications that create the greatest disruption of critical care during times of crisis.
2. Provide incentives to support the expansion of additional, functional and redundant manufacturing capabilities.
3. Increase the transparency of manufacturing including the availability of objective metrics to assess medication quality.

(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.
Over the last two decades of the drug shortages crisis, Vizient has periodically received reports of medications provided through the "gray market" with pedigrees of questionable quality. During the pandemic, Vizient's members have not indicated they received counterfeit drug products, and Vizient continues to maintain efforts to vet suppliers. Vizient remains supportive of the provision of the Drug Supply Chain Security Act to protect the integrity of the supply chain against counterfeit products.

We also encourage the Department of Commerce to review the written testimony that Vizient[2] provided to the Senate Committee on Finance regarding the reliability of the U.S. medical supply chain during the COVID-19 pandemic, including the issue of counterfeit PPE.

(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.
As a group purchasing organization, Vizient contracts with PPE suppliers. Several of Vizient's suppliers for different types of PPE manufacture products abroad and, to a smaller extent, some suppliers operate domestically. Various factors can impact access to different types of PPE, for example, as mask production increased, production of other types of PPE (e.g., medical gowns) continues to recover. As efforts are made to reduce foreign dependency and increase U.S. competitiveness, we believe it is critical that investments are also made in personnel, machinery upgrades, building expansions, and in-house raw material production.

Conclusion

Vizient appreciates the Department of Commerce's efforts to learn more about the change in the status of the PHIB and work to identify initiatives to strengthen the PHIB. Vizient would welcome the opportunity to further engage with the Department of Commerce as the PHIB Study evolves.

Vizient membership includes a wide variety of hospitals ranging from independent, community-based hospitals to large, integrated health care systems that serve acute and non-acute care needs. Additionally, many are specialized, including academic medical centers and pediatric facilities. Individually, our members are integral partners in their local communities, and many are ranked among the nation's top health care providers. In closing, on behalf of Vizient, I would like to thank the Department of Commerce for providing us the opportunity to comment on this important RFI. Please feel free to contact me or Jenna Stern at

[2] Vizient's Cathy Denning testified on behalf of Vizient. Cathy Denning, RN, MSN, is Vizient's Group SVP, Sourcing Operations, Analytics & Center of Excellence Vizient, Inc., https://newsroom.vizientinc.com/cathy-denning-rn-msn.htm

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Respectfully submitted,

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