799 9th Street NW
Suite 210
Washington, DC 20001

T (202) 354-2600
vizientinc.com

March 16, 2020

The Honorable Michael R. Pence
Vice President of the United States
1600 Pennsylvania Avenue, NW
Washington, DC 20501

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independent Avenue, SW
Washington, DC 20201

Re: Strategies to Avoid Healthcare Supply Chain Disruption Secondary to COVID-19 Pandemic

Dear Mr. Vice President and Administrator Verma,

Thank you again for the opportunity to join you both at the White House Coronavirus Task Force hospital provider-focused meeting on March 11. I appreciate your specific questions regarding strategies to mitigate supply chain disruption as our nation's healthcare providers work to treat and care for patients in their communities. As a follow up to our conversation, I want to share with you the below recommendations to address supply and pharmacy access and availability issues due to COVID-19. Vizient appreciates the President's prioritization of this issue demonstrated most recently in the national emergency declaration, collaboration with private companies and related emergency orders.

Vizient believes the following recommendations will help providers more effectively address the acute issues that are today leading to disruption and shortage.

Supply and Personal Protective Equipment (PPE) strategies

1. Better distribute existing product

- Require retailers like Amazon, Home Depot to take down all PPE for sale and redirect inventory to the healthcare delivery system.
- Fly PPE to the United States from foreign sites of manufacture – container ships are taking too long. Also, speed customs approval of incoming product.
- Require PPE manufactures to prioritize healthcare demand (versus other industries).

- Ease transportation and fire protection restrictions on the movement of hand sanitizer and 70% isopropyl alcohol. Temporarily lifting this restriction would streamline and expedite access.
- Going forward, work with industry to develop a national model for manufacturers and distributors to initiate and define allocation protocols during times of national emergency.

2. Repurpose available product and leverage alternatives

- Evaluate whether the FDA can extend useful life for expired supply if there is no flaw in product.
- Redirect PPE from veterinarian use, dental use and any setting where it is not a necessity to the healthcare delivery system.
- Evaluate whether PPE such as facial protection, gowns, gloves, etc. used in other industries (e.g., manufacturing, chemicals, labs, etc.) can be repurposed for use in the healthcare setting (similar to the temporary approval of off-label use of NIOSH industrial grade masks).
- Provide guidance on what providers can do to locally reprocess PPE, invest in sterilization machines so PPE (including N-95 masks) can be reused instead of thrown away, and approve sterilization for single use devices such as eye shields or glasses.
- Allow for sharing of opened products between health systems and forgive the “own use” contract language on PPE items.

3. Implement strategies to increase manufacturing capacity

- Increase labor pool (by increasing incentives, national guard, etc.): Suppliers tell us that they are having difficulty finding workers to staff their manufacturing plants. As an example, we know one major supplier who is trying to increase production operations from 5 days to 7 days but cannot access the labor necessary to do so.
- Ensure all product manufactured in the United States stays in the United States.
- Work in collaboration with PPE suppliers to standardize production to the most quickly produced PPE types. For example, instead of making ten different exam glove types make one.
- Work in collaboration with PPE suppliers to reduce the production of non-PPE products (being mindful not to cause shortage of other supplies deemed critical) at PPE manufacturing locations in order to increase output.
- Work in collaboration with PPE suppliers to reduce production of non-PPE products (being mindful not to cause shortage of other supplies deemed critical) that use the same materials used for PPE.
- Evaluate deploying “pop-up” factories, using clothing / textile manufacturers to help with production.
- Consider financial or tax incentives to drive an increase in finished goods, an increase in shifts and/or an increase in additional manufacturing lines. This can include strategies like capital investment protection to reduce risk. This is important for PPE but also for products such as ventilators, oxygen tanks and infusion pumps.

– Nasal swabs that work with testing systems are critical and are on significant back order. Consider working with major manufacturers on strategies to increase capacity and expedite shipping. Consider expediting approval of alternative swabs.

4. Price gouging enforcement

– Publicize consequences and publicly enforce price gouging related to PPE and other critical products and supply; evaluate whether these penalties can be increased during times of national emergency.
– Support above with federal oversight in addition to state attorney general offices.

Pharmacy strategies

1. Empower the FDA to demand weekly volume reports from manufacturers regarding active pharmaceutical ingredient (API) and finished dosage form availability

– Under the current framework, FDA (and by extension the healthcare marketplace) has very limited insight into the origination point for API (including redundancy of supply) and other components of finished dosage forms (e.g. excipients, raw materials, vial stoppers, etc.).
– Manufacturers should be compelled to provide this information on a routine and timely basis so FDA can monitor in real-time any anticipated disruptions and implement other actions as appropriate.
– Manufacturers should also be compelled to disclose their plans regarding supply chain manufacturing redundancy strategies to avoid disruptions and drug shortages.
– To the extent possible, FDA should share this information with the healthcare marketplace including public disclosure of the reason for the shortage (lack of API availability, manufacturing issue, etc).

2. Prioritize approval of pending applications for "essential"[1] medications subject to shortage

– For critical medications where supply is either impaired or at high risk of disruption, the FDA can prioritize the approval of any pending applications, such as abbreviated new drug applications.
– Expedite approval of non-US pharmaceuticals for importation if necessary due to severe supply constraint.

[1] Vizient, Inc. (2020). Essential medications for high quality patient care, available at: https://www.vizientinc.com/-/media/Documents/SitecorePublishingDocuments/Public/VZT_EssentialMedications_Winter2020.pdf

- While FDA has been granted authority to prioritize approval actions for products with supply limitations to address shortages, it is unclear whether and how FDA is currently utilizing these authorities.

3. Eliminate on an interim basis any filing fees associated with abbreviated new drug applications filed for short and/or at risk drugs

- While generic medications are much less expensive to develop and manufacture than novel new drugs, even relatively small investments (like filing fees) can create a burden for certain manufacturers.
- During circumstances such as this one, suspension of fees associated with the filing of applications for essential drugs could encourage the creation of additional manufacturing capacity.

4. Expedite FDA action at manufacturing locations/API sources awaiting approval

- Support the FDA in expediting the review and approval of manufacturing locations that are awaiting evaluation. If all pending review actions could be prioritized and expedited, where appropriate, it would enable the expansion of manufacturing capacity.
- Given the FDA's present limitation in evaluating Chinese manufacturing locations, those resources should be redirected to evaluate domestic or other manufacturing and supply facilities where travel is not restricted.

5. Ensure FDA has adequate resources/funding to expedite the approval or expand the access to investigational drugs that would be used in the treatment of COVID-19

- A significant amount of concern about COVID-19 is the absence of a fully licensed vaccine or treatment alternative. Many investigational agents are currently under evaluation for us. We ask the federal government to provide any resources needed by FDA or any other agencies to expedite approval, as appropriate, or expand/expedite compassionate use programs.

6. Provide the Drug Enforcement Administration (DEA) the support needed to adjust aggregate production quotas (APQ) of controlled substances

- Similar to the support request for FDA, there could be an opportunity to support the DEA so that the agency can respond to any requested changes in APQ as rapidly as possible.
- While it's important to monitor and control APQs as part of the comprehensive strategy to limit and avoid drug diversion and opioid misuse, injectable opioids are a critical component of inpatient and critical care that pose access issues, which are expected to worsen during this pandemic.
- Given the anticipated higher demand for many critical inpatient drugs due to increases in hospitalization, we encourage removing barriers that prevent adequate supply of these medications being readily available to providers and patients.

7. Consider temporary suspension of exclusivity for sole sourced essential medications that are in short supply

- If an essential medication is currently protected from competition due to market exclusivity but is unable to meet market demand, the government could consider a temporary suspension of that exclusivity, if other suppliers would be able to provide product through an expedited approval mechanism.
- When the manufacturer of the sole source product has recovered durable supply capacity, the exclusivity could be reinstituted.

8. Delay enforcement of Unapproved Drug Initiative actions and 503B compounding activity

- As Vizient has recently noted[2], the Unapproved Drug Initiative, while needed and well intentioned, has inadvertently impacted healthcare providers by increasing the relative price of important medications, particularly when remaining "unapproved" products are required to exit the market.
- During this period, the FDA may want to consider not requiring "unapproved" drugs to leave the market until overall supply chain stability improves.
- Vizient fully supports the FDA's activities to promote and preserve the supply chain of safe and effective pharmaceuticals. Therefore, if there is a manufacturing issue with a 503B compounding pharmacy that jeopardizes patient safety, we absolutely want FDA to take the appropriate actions regardless of any external circumstances. However, we would also ask that FDA exercise its discretion in any 503B enforcement activities where a delay would not create a greater risk to patient safety.

9. Provide additional Federal Trade Commission (FTC) funding/support to monitor and investigate any pharmaceutical price gouging

- Throughout our experience with drug shortages of many products, we have seen examples of situations where secondary distributors/"gray" market participants offer pharmaceuticals in limited supply at greatly inflated and exorbitant prices.
- We would encourage the federal government through FTC to increase its vigilance for such actions. We also ask for a streamlined process for healthcare providers and others to notify FTC of such actions.

---

[2] Vizient, Inc. (2020). Financial Consequences of Good Intentions, available at: https://newsroom.vizientinc.com/sites/vha.newshq.businesswire.com/files/doc_library/file/UDI_Analysis_US_Market_Spend_FINAL_022420.pdf.

10. Provide incentives to support investigation of extended dating for essential medications

- We would ask the federal government to provide the necessary resource support for FDA to authorize, where appropriate, extending dating for essential medications during this period of supply uncertainty.
- We also encourage the government to provide financial incentives as appropriate to manufacturers to provide any additional data needed to make the determination of product quality beyond the original expiration date limit.

Again, Vizient is deeply appreciative of the opportunity to support the Administration's efforts to identify and employ mitigation activities during this trying time. Supply chain disruption is a significant challenge for health care providers, and we thank the administration's attention to avert shortages secondary to COVID-19. We remain available to answer any questions related to these recommendations and/or discuss other potential solutions to prevent further supply chain disruption. Please do not hesitate to reach me by email at byron.jobe@vizientinc.com or by phone at 972-830-0750. We look forward to working with you to protect the health of our nation and we thank you for your leadership.

Respectfully,

Byron Jobe
President and CEO
Vizient