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BY ELECTRONIC DELIVERY

The Honorable Patty Murray
Chairwoman
U.S. Senate Health, Education, Labor and Pensions Committee
428 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Richard Burr
Ranking Member
U.S. Senate Health, Education, Labor and Pensions Committee
428 Dirksen Senate Office Building
Washington, DC 20510

Dear Chairwoman Murray and Ranking Member Burr:

As the leading trade association representing manufacturers of medical imaging equipment, radiopharmaceuticals, contrast media, and focused ultrasound therapeutic devices, the Medical Imaging & Technology Alliance (MITA) welcomes the opportunity to share feedback on the *PREVENT Pandemics Act*.

Medical imaging technologies play an essential role in health care infrastructure and have been invaluable to the care pathways of evaluating, staging, managing, and effectively treating patients with COVID-19[1]. Given the power of medical imaging to quickly and non-invasively evaluate anatomy and physiological processes, we anticipate medical imaging playing a crucial role in any future public health emergencies, including pandemics.

The ongoing COVID-19 pandemic has challenged all sectors of society and resulted in many lessons learned -that we trust will inform decisions concerning preparation for future pandemics and other large scale public health emergencies. The medical imaging manufacturing industry stands ready to partner with Congress and other stakeholders to ensure that the United States is prepared to best respond to future pandemics.

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[1] https://www.covid19treatmentguidelines.nih.gov/overview/clinical-spectrum/

We offer the following recommendations and feedback on your proposal for strengthening our pandemic preparedness:

Feedback on Title IV—Modernizing and Strengthening the Supply Chain for Vital Medical Products

To ensure healthcare providers can meet escalated demand for medical imaging services during future pandemics, as well as in the event of any future public health emergencies, we strongly recommend the specific inclusion of imaging technologies in the Strategic National Stockpile (SNS). Industry stands ready to meet the increase in demand for our technologies, such as point-of-care-ultrasound systems whose portability and versatility was used during the COVID-19 pandemic to assess patients and provide real-time information. Access to these kinds of technologies allows for high quality imaging and diagnostic capabilities in any care-setting.

We recommend that the SNS list of items deemed critical to pandemic response be expanded to include at a minimum:

- Replacement parts and associated accessories for capital medical equipment to ensure ongoing functioning of devices
- Ultrasound systems, including point of care ultrasound systems
- Mobile X-Ray systems
- Contrast and associated contrast injection systems

In the event of a future pandemic—whether respiratory, or not—these technologies would also play a crucial role in triaging, diagnosing, staging, and treatment monitoring given their ability to quickly and non-invasively assess anatomy and physiological processes. As such, we recommend inclusion of a sufficient supply of medical imaging technologies in the SNS. A selection of literature on the value of imaging technologies during the COVID-19 pandemic can be found in the appendix below.

Given that emergence of new pandemics is unpredictable and that many medical products have established shelf-lives or expiration dates, processes should be in place to ensure that products in the SNS are available for use and are not beyond established shelf-life or expiration date. Planning processes should also be in place to replace products in the SNS before expiration or end of shelf-life.

Section 406 should be modified to allow for any company to compete for a government contract on at least a quarterly basis to provide necessary imaging equipment for the SNS, including the required servicing to maintain its readiness. The Department of Veterans Affairs uses a process where there are three acquisitions/competitions a year and then also an emergency "buy," process. Adopting a similar process for the SNS creates an ongoing, "warm," process that would also be able to immediately "scale," in the event of a crisis. Also, having a process that allows for three acquisition periods a year for imaging equipment for the SNS creates an automatic three times a year evaluation process of the readiness and capacity of the existing imaging equipment in the SNS. Establishing a predictable three times a year procurement process, will ensure a ready supply of technologies in the stockpile. This will be advantageous for future public health emergencies, enabling quick deployment to meet localized need.

MITA is encouraged to see recognition of ensuring SNS technologies and countermeasures are in working condition and undergoing appropriate maintenance services (Sec. 403) so they can be deployed immediately in a future public health emergency. When servicing and maintaining medical devices, the goal is to return the device to the safety and performance specifications established by the original equipment manufacturer (OEM), and to meet its original intended use. We recommend clearly defining

"working condition or usable" in this section as meeting these OEM safety and performance specifications.

MITA commends the Committee for addressing the need for better coordination and instructions regarding the process by which states can access the imaging equipment in the SNS (Section 404) as well as developing their own processes and procedures for creating state based SNSs (Section 410). During the initial weeks of the COVID 19 pandemic, it was very chaotic for hospitals and healthcare providers seeking access to imaging equipment using Federal resources. This was not the experience of MITA members with other countries, where those countries were procuring imaging equipment on behalf of their healthcare systems. Providing specific guidance and training for state department health officials as well as state and local associations and organizations of healthcare providers per the proposed section 404 will be very helpful for future pandemics. MITA would recommend the Committee modify the requirement for meetings in Section 404 to at least twice a year, versus annually to ensure that as personnel changes happen, the training is not lost at the state or local level.

MITA would also request that imaging equipment be specially included in the pilot program for State SNS, which as currently drafted only mentions medical supplies. Because most pandemics will require imaging equipment to address the healthcare needs, MITA asks that it be included as an eligible category.

Feedback on Title V—Enhancing Development and Combating Shortages of Medical Products

Supply chain challenges and product and component shortages have had widespread effects on the medical device industry over the course of the COVID-19 pandemic. Similar challenges can be expected in the event of future public health emergencies. We look forward to working with Congress and other stakeholders to develop policies that will mitigate the impact of future supply chain issues resulting from pandemic conditions. Regarding the provisions of the PREVENT Pandemics Act, we offer the following feedback:

- Sec. 505—Facilitating the use of real world evidence (RWE)
    - MITA supports the use of RWE and believes that FDA should accept this kind of evidence to support regulatory decision making
- Sec. 507—Increasing EUA decision transparency
    - It is unclear if this new authority is needed. Medical device manufacturers and FDA are already required to disclose this information.
- Sec. 508—Improving FDA guidance and communication:
    - MITA supports policies that will bring greater clarity to FDA guidance development and implementation
- Sec. 509- GAO study and report on hiring challenges at FDA:
    - MITA supports this study and hopes that it can lead to policies that enhance FDA hiring, recruitment, and retention
- Sec. 511- Ensuring registration of foreign drug/device manufacturers
    - It is unclear what problem this section would be solving given that foreign manufacturers are already required to register with FDA
- Sec. 515- Strengthening medical device supply chains & Sec. 516—Preventing medical device shortages
    - It is unclear how these sections would actually help mitigate shortages and supply chain issues. Manufacturers already develop risk management plans and have highly sophisticated supply chain operations.

    - These sections are very broad and would seemingly cover most or all medical devices—including those not related to pandemics or other PHEs, creating burdensome new requirements for manufacturers.
    - It is unclear how the information gathered from shortage notifications would be used by FDA and of what value it would be. Managing complex supply chain issues is outside of the FDA's expertise and jurisdiction.
    - The Agency can help industry address these challenges via other routes, including via enforcement discretion and other policies, outlined below
- Sec 517- Remote records assessments for medical devices
    - It is unclear that additional authority is needed in this area

Additional Recommendations

1. **Streamline FDA regulatory requirements for applicable medical imaging devices**

During the COVID-19 pandemic, FDA has issued numerous guidance documents and Emergency Use Authorizations (EUAs) to enable efficient delivery of essential medical technologies. This included a guidance specifically for medical imaging devices. The rapid development and issuance of these policies is commendable, but they lagged the initial onset of the pandemic, in some cases by months. We believe FDA should include the following policies to rapidly streamline delivery of medical imaging technologies to where they are most needed in their best practices report, including:

- Temporarily prioritizing review and clearance of medical imaging devices which play a role in the care pathway of the applicable disease, as recommended in Section 503 to expedite review of countermeasures
- Expediting issuance of accession numbers for 510(k) cleared products being imported to address a pandemic
- Granting manufacturers greater flexibility for static to mobile conversions for 510(k) cleared medical imaging systems under the expectation of escalated demand and urgent need in new temporary emergency hospitals (e.g. greater flexibility in design verification/validation documentation related to the conversion)
- Temporarily granting greater flexibility for use of alternate components and in supplier qualification in order to meet increased demand or to meet shortages resulting from supply chain disruptions arising from pandemic conditions
- Assessing the impact of facility and importation customs inspections on timely delivery of medical imaging devices and potentially postpone inspections until the pandemic has abated
- Participate in and support cross government coordination to meet demand for medical imaging devices in severely affected areas and facilitate movement of personnel providing service to these medical devices

In developing these policies, FDA should also be explicit concerning the process for handling products cleared under these policies once the public health emergency has ended. This will enable medical imaging device manufacturers to make informed decisions about their regulatory responsibilities post-pandemic.

2. **Establish processes to maintain continuity of non-pandemic medical care**

In addition to the role that medical imaging has played in COVID-19, our technologies are also part of the non-emergent medical procedures that patients have had to delay due to the pandemic. These include

procedures that are essential for the screening and diagnosis of numerous other medical conditions, in addition to the staging of disease progression and assessment of treatment effectiveness.

During the COVID-19 pandemic, beneficiary access to annual or non-urgent imaging exams has been severely impaired. Recent reports indicate that utilization of medical imaging procedures has dropped by 50% or more[2] and routine cancer screenings were down by as much as 94% in March 2020[3]. It is unclear what the continued effects of the pandemic will be on patient access to medical imaging and what impact to public health will result from drastically lower rates of imaging and screening. We are seeing major challenges for providers seeking to manage pent-up demand for overdue care and for patients seeking to ensure all necessary imaging exams get rescheduled and performed.

Implementing processes to facilitate continuity of care for non-pandemic cases will help to obvert any public health issues arising from missed imaging services. We recommend that in the future, incentives be created for providers to meet pent-up demand for healthcare services that a communications program be created to ensure patients understand when it is safe to return to normal care. We further recommend that policymakers, medical specialty societies, and medical technology manufacturers collaborate on development and dissemination of sterilization/disinfection protocols which facilitate continued operation of medical facilities.

3. **Implement consistent caseload reporting metrics**

Medical device manufacturers seeking to deliver product to meet pandemic-level demand need nationwide clear, consistent caseload reporting metrics to understand where care is most needed. Currently, individual healthcare facilities or localities are using their own metrics to assess capacity. These metrics are often not comparable across facilities or jurisdictions, creating confusion as to where demand is most urgent. Establishing a clear, consistent reporting framework will enable healthcare providers, government officials, and medical technology manufacturers to make informed decisions about where to direct resources.

4. **Provide additional research funding for the value of imaging to pandemic disease**

The medical imaging industry saw an uptick in demand for its products as healthcare providers sought to tackle COVID-19. Our technologies have played an important role in the COVID-19 care pathway, enabling clinicians to make informed decisions about how best to treat patients. Similarly, we anticipate medical imaging playing a valuable role in any future pandemic given its ability to quickly and non-invasively assess anatomy and physiological processes.

In order that clinical guidelines and appropriateness criteria can be rolled out as quickly as possible in the future, we recommend that research funding be specifically earmarked for determining the role for and value of imaging in pandemics and other large-scale public health events.

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[2] https://www.auntminnie.com/index.aspx?sec=sup&sub=imc&pag=dis&ItemID=128819
[3] https://www.statnews.com/2020/05/04/cancer-screenings-drop-coronavirus-pandemic-epic/

We look forward to working with Congress to prepare for the next pandemic. If you have any questions, please contact Holly Grosholz, Senior Manager, Government Relations, at hgrosholz@medicalimaging.org or 703-841-3228.

Sincerely,

Patrick Hope
Executive Director, MITA

MITA is the collective voice of medical imaging equipment and radiopharmaceutical manufacturers, innovators and product developers. It represents companies whose sales comprise more than 90 percent of the global market for medical imaging technology. These technologies include: magnetic resonance imaging (MRI), medical X-Ray equipment, computed tomography (CT) scanners, ultrasound, nuclear imaging, radiopharmaceuticals, and imaging information systems. Advancements in medical imaging are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. The industry is extremely important to American healthcare and noted for its continual drive for innovation, fast-as-possible product introduction cycles, complex technologies, and multifaceted supply chains. Individually and collectively, these attributes result in unique concerns as the industry strives toward the goal of providing patients with the safest, most advanced medical imaging currently available.