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November 22, 2020

Via Electronic Submission

Advisory Committee on Immunization Practices
Centers for Disease Control and Prevention
National Center for Immunization and Respiratory Diseases
1600 Clifton Road NE
MS-H24-8
Atlanta, GA 30329

Re: November 23, 2020 Meeting, Docket No. CDC-2020-0117

Dear Members of the Advisory Committee:

On behalf of the Advanced Medical Technology Association (AdvaMed) members, I write to provide comments concerning the equitable allocation of COVID-19 vaccine and request that the Committee consider certain aspects of the medical device industry workforce in the development of allocation guidance. AdvaMed is a trade association representing the world's leading innovators and manufacturers of medical devices, diagnostic products, digital health technologies, and health information systems. We are committed to ensuring patient access to life-saving and life-enhancing devices and other advanced medical technologies in the most appropriate settings, including innovative devices, medical applications, and diagnostic tests to support the care of patients with COVID-19. In vitro diagnostics companies, with a range of COVID-19 diagnostics and serological tests, have been working with vaccine manufacturers during clinical trials and will continue to serve an important role as vaccination begins and for as long as COVID-19 is a great threat to patients and public health.

The COVID-19 pandemic has had devastating impacts across the globe. The effect of the virus on the daily lives of individuals, patients, healthcare, and essential workers has been staggering. Even more dramatic are the disparate impacts of COVID-19 on populations and communities of color and other socioeconomically disadvantaged populations. AdvaMed has been actively engaged in assessing the medical device industry's role and responsibility in addressing healthcare disparities within the context of COVID-19 and more broadly. We appreciate and commend the Committee for its work in ensuring that any COVID-19 vaccine allocation plan takes these disparities into account.

As we move closer towards the approval of a COVID-19 vaccine, there must be a transparent and equitable plan for how patients access vaccinations and how that priority is determined. AdvaMed endorses the foundational principles utilized in the National Academies of Sciences,

Engineering, and Medicine Framework for Equitable Allocation of COVID-19 Vaccine ("NAS Framework")—the maximization of benefits, equal regard, mitigation of health inequities, fairness, evidence-based decision-making, and transparency.[1] We also strongly support the recommended prioritization schema based on the four identified risk-based allocation criteria—the risk of acquiring infection, risk of severe morbidity and mortality, risk of negative social impact, and risk of transmitting the disease to others.[2]

As the Committee evaluates and develops recommendations concerning the allocation of COVID-19 vaccines, AdvaMed would be grateful for guidance concerning medical device industry clinical field and manufacturing personnel, who are recognized in the U.S. Department of Homeland Security Cybersecurity & Infrastructure Security Agency (CISA) Guidance[3] as essential critical infrastructure healthcare workers. More specifically, guidance on determining and confirming eligibility for these essential workers to be vaccinated under appropriate allocation phases would help to ensure their health and safety as they endeavor to maintain patient access to needed technology.

Health Care Industry Representatives (HCIR)

Medical device company representatives are also referred to as Health Care Industry Representatives ("HCIRs"). They are often required to be present in patient care settings to provide technical support concerning the safe and effective application of surgical products

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1 National Academies of Sciences, Engineering, and Medicine. 2020. *Framework for Equitable Allocation of COVID-19 Vaccine*. Washington, DC: The National Academies Press. https://doi.org/10.17226/25917.

2 *I.d.*

3 U.S. Department of Homeland Security Cybersecurity & Infrastructure Security Agency, *Guidance on the Essential Critical Infrastructure Workforce: Ensuring Community and National Resilience in COVID-19 Response Version 4.0*, Aug. 18, 2020, available at https://www.cisa.gov/sites/default/files/publications/Version_4.0_CISA_Guidance_on_Essential_Critical_Infrastructure_Workers_FINAL%20AUG%2018v3.pdf (Under "Healthcare / Public Health," "Vendors and suppliers" and "workers at manufacturers" are specified:

> Vendors and suppliers (e.g. imaging, pharmacy, oxygen services, durable medical equipment, etc.).
>
> Workers at manufacturers (including biotechnology companies and those companies that have shifted production to medical supplies), materials and parts suppliers, technicians, logistics and warehouse operators, printers, packagers, distributors of medical products and equipment (including third party logistics providers, and those who test and repair), personal protective equipment (PPE), isolation barriers, medical gases, pharmaceuticals (including materials used in radioactive drugs), dietary supplements, commercial health products, blood and blood products, vaccines, testing materials, laboratory supplies, cleaning, sanitizing, disinfecting or sterilization supplies

and technologies.[4] In addition to this technical assistance function, HCIRs "may be involved in the remote calibration or adjustment of medical devices (for example, pacemakers, laser technology) to the surgeons' and manufacturers' specifications."[5] Generally, HCIRs must meet certain hospital supplier credentialing requirements to access certain areas of a hospital at the request of a healthcare provider. These credentialing requirements include documentation of vaccinations (or titers showing immunity) for Influenza, Tetanus, Diphtheria, Pertussis, Measles, Mumps, Varicella, and Hepatitis B.[6] It is also worth noting that the *American National Standard for Supplier Credentialing in Healthcare* was recently updated to include appropriate Personal Protective Equipment (PPE) use in healthcare provider facilities and a new section concerning Novel Viruses/Communicable Illness.[7] HCIRs are not contractors of the hospital; instead, they are employed or retained by medical device companies. This dynamic may complicate a vaccine administrator's ability to identify and flag HCIRs for prioritized vaccine allocation or to determine and confirm whether an HCIR meets the eligibility requirements for a particular phase of vaccination.

With regard to high-risk health workers identified for allocation Phase 1a of the NAS Framework, AdvaMed endorses the NAS Consensus Study statement that "access should not be defined by professional title, but rather by an individual's actual risk of exposure to COVID-19."[8] Consistent with that approach, certain medical device company representatives/ HCIRs

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4 See Association of periOperative Registered Nurses (AORN), Position Statement on the Role of the Health Care Industry Representative in Perioperative Settings, May 28, 2020, available at https://aornjournal.onlinelibrary.wiley.com/doi/full/10.1002/aorn.13065.

5 American College of Surgeons (ACS). Revised Statement on Health Care Industry Representatives in the Operating Room, October 1, 2016, available at https://www.facs.org/about-acs/statements/91-industry-reps-in-or.

6 *See* American National Standard for Supplier Credentialing in Healthcare, ANSI/NEMA SC 1-2019, Contents and Scope available at https://webstore.ansi.org/preview-pages/NEMA/preview_ANSI+NEMA+SC+1-2019.pdf

7 See MITA and C4UHC Press Release, available at https://www.medicalimaging.org/wp-content/uploads/2020/05/20.05.05-Final_MITA-Credentialing-Standard-Release-DRAFT.docx-CLEAN-002-copy-1.pdf

8 National Academies of Sciences, Engineering, and Medicine. 2020. *Framework for Equitable Allocation of COVID-19 Vaccine.* (p. 107) Washington, DC: The National Academies Press. https://doi.org/10.17226/25917. ("The first phase includes a "jumpstart" phase: Phase 1a. Included in Phase 1a would be "frontline" health workers—health professionals who are involved in direct patient care, as well as those working in transport, environmental services, or other health care facility services—who risk exposure to bodily fluids or aerosols. Under conditions of such scarcity, access should not be defined by professional title, but rather by an individual's actual risk of exposure to COVID-19. The rationale for including "frontline" health workers in the first phase is manifold: their contact with patients with SARS-CoV-2 (despite the use of PPE, which can be limited in some settings); the fact that they work in an essential industry, but may be precluded from performing their professional duties if they are exposed or infected; and the reality that many such

have an exposure risk to COVID-19 positive patients or their tissues, cells, or biofluids during their work to provide technical support for, calibrate, service, or repair medical devices (including diagnostics). HCIRs required by health care facilities or their job requirements to wear respirators and eye/face protection due to SARS CoV-2 exposure risk should be included among the Phase 1a allocation for High-Risk Health Workers. Some HCIRs support procedures/equipment/technology in the operating room or procedural suite and are required to be present during urgent, non-elective procedures (e.g., trauma, transplant, cardiac) and other medically necessary procedures (e.g., joint replacement). During the pandemic, hospitals have instituted additional COVID-19 access requirements for HCIRs. For example, some hospitals required HCIRs to undergo respirator fit testing and training so that HCIRs will be able to utilize hospital-issued respirators during procedures that these HCIRs support. During crisis capacity operations, some hospitals have required that HCIRs bring in their own respirators and other PPE for the procedures that they support, including gloves, gowns, and face shields. During the current PPE shortage, distributors of NIOSH-approved N95 respirators allocate nearly all of their supply to hospital purchasers. The best-case scenario for medical device manufacturers is to procure non-NIOSH-approved filtering facepieces that have FDA emergency use authorization for use as a respirator during this public health emergency. In these cases, although both the hospital staff and HCIR are in similar proximity to aerosol-generating procedures, some HCIRs do not have equivalent PPE relative to the hospital staff. This dynamic should elevate the prioritization of these HCIRs relative to other high-risk health workers who have access to NIOSH-approved PPE.

Importantly, HCIRs generally work across multiple health care facilities. Some HCIRs cover numerous hospital systems in a region and support procedures in multiple institutions per day. Vaccinating these HCIRs during Phase 1a would decrease the risk for these HCIRs to become vectors between institutions.

Medical Device Manufacturing/Distribution Personnel

Medical device industry personnel that are physically involved in manufacturing and distributing medical devices and diagnostics should be included among the Phase 2 allocation for Critical Workers in High-Risk Settings. The specialized and environmentally sensitive nature of manufacturing medical devices limits the ability of medical device manufacturers to increase the physical distance between some manufacturing personnel. These are critical workers who are essential to manufacturing and distributing medical devices and diagnostics integral to the treatment of COVID-19 and other patients and are at substantially higher risk of exposure due to their inability to physically distance.

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workers are potentially important nodes in onward transmission networks, given that many who are in low-wage jobs may also contribute to further transmission due to living in crowded, often multi-generational living situations where social distancing is unrealistic.")

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We believe that state health authorities and vaccine administrators would welcome the Committee's guidance on determining and confirming the eligibility of Health Care Industry Representatives (HCIRs) and medical device manufacturing and distribution personnel. We believe that an attestation by an HCIR's employer on company letterhead concerning the nature of their work and exposure risk should be sufficient to confirm eligibility for the HCIR for vaccination during Phase 1a. If additional documentation is required from the health care facilities that the HCIR supports, a centralized approach with a standard form or direction concerning the specified elements required of supporting documentation would greatly help to minimize the administrative burden on health care facilities and clinicians. For medical device industry manufacturing and distribution personnel, an employer attestation on company letterhead concerning the nature of the individual's work should be sufficient documentation to confirm vaccination eligibility during Phase 2.

AdvaMed appreciates the opportunity to provide these comments and looks forward to supporting the Committee to further a transparent and equitable allocation of COVID-19 vaccines. Thank you in advance for your consideration of the above. We would be pleased to discuss these issues in greater detail at your convenience. Please do not hesitate to contact me at (202) 783-8700 or tchang@advamed.org with any questions.

Sincerely,

/s/
Terry Chang, MD, JD