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Journal of the American Pharmacists Association

journal homepage: www.japha.org

A DOSE OF INSPIRATION

COVID-19 emergency responders in FDA's Center for Drug Evaluation and Research

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The U.S. Public Health Service Commissioned Corps, led by the Assistant Secretary for Health and operations overseen by the U.S. Surgeon General, is 1 of the 8 uniformed services and is the only uniformed service committed to protecting, promoting, and advancing the health and safety of the nation. The Commissioned Corps is a highly trained, fully deployable national asset to preserve public health and national security during national or global public health emergencies. Driven by a passion to serve the underserved, these officers fill essential public health leadership and clinical service roles with the nation's federal government agencies. As America's health responders, Commissioned Corps officers stand ready to deploy at a moment's notice to preserve public health and national security during national and global health emergencies. Commissioned Corps pharmacy officers in the Food and Drug Administration's (FDA) Center for Drug Evaluation and Research (CDER) are actively engaged in the novel coronavirus disease 2019 (COVID-19) response. Commissioned Corps pharmacy officers currently serve in "Incident Command System" positions such as Operations Section Chief and Planning Section Chief on CDER's official COVID-19 response task force. In these positions, they coordinate teams of subject-matter experts responding to urgent requests for information from federal government partners, including the Health and Human Services' Assistant Secretary for Preparedness and Response, Assistant Secretary for Health,

and Centers for Disease Control and Prevention. They assist in preparing CDER statements for the FDA commissioner and legislative briefings to keep stakeholders informed of COVID-19 response activities.

There are currently no approved drug products for the prevention or treatment of COVID-19. Commissioned Corps pharmacy officers are serving as emergency coordinators working directly with physicians of U.S. patients with COVID-19 to enable access to investigational drugs for treatment under emergency Investigational New Drug processes. These officers are on-call 24 hours, 7 days a week to ensure health care providers across the United States can access FDA staff at any time to facilitate the use of investigational drugs when the patients they are treating have exhausted all approved drug product options.

With the globalization of the pharmaceutical supply chain, FDA is tasked with closely monitoring events that could threaten the U.S. supply of drug products. As part of the COVID-19 emergency response, Commissioned Corps pharmacy officers within the CDER Drug Shortage Staff (DSS) are actively monitoring global drug supply chains to anticipate and mitigate any drug product shortages resulting from manufacturing disruptions from the outbreak. Drug shortage situations can negatively affect patient care and challenge the tools available to health care providers, making this proactive supply chain monitoring a critical component of FDA's emergency response. DSS maintains

frequent communication with manufacturers to help prevent drug shortages. As a resource for the public, FDA maintains a website for real-time information about drug shortages here: <https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm>.

Commissioned Corps pharmacy officers also engage in teams that identify and evaluate promising investigational drug products for the treatment or the prevention of COVID-19. To deliver the highest level of support for rapid product development, FDA provides scientific advice and regulatory guidance to facilitate the advancement of promising candidates.

During emerging infectious disease outbreaks, FDA must be vigilant to protect the public from fraudulent products falsely claiming to prevent or treat COVID-19. Commissioned Corps pharmacy officers contribute to FDA's task force dedicated to closely monitoring for fraudulent products and false product claims related to COVID-19. During public health emergencies, FDA is committed to identifying and taking regulatory action against products that mislead the public in the prevention or treatment of emerging infectious diseases.

Providing up-to-date information to the public is a critical component of emergency response. In CDER, Commissioned Corps pharmacy officers participate in FDA-wide communications teams charged with issuing key information for the public about the current outbreak. These officers developed a webpage that provides information

about treatment options, fraudulent products, and FDA's emergency response resources. This team also has Commissioned Corps pharmacy officers in the Division of Drug Information who answer direct questions from the public about COVID-19.

These examples provide a snapshot of the myriad of responsibilities and duties of Commissioned Corps pharmacy officers at FDA, in addition to the many FDA officers deployed to front lines, in responding to this global pandemic. These Commissioned Corps pharmacy officers work tirelessly during emergencies such as COVID-19 to complete the

mission: protecting public health by ensuring U.S. citizens have access to safe, effective, quality, and available drug products.

Acknowledgments

The authors gratefully acknowledge the many U.S. Public Health Service Commissioned Corps pharmacy officers for their FDA service to the COVID-19 outbreak response and the following officers for their contributions to this article: Captain Andrei Nabakowski, Captain Val Jensen, Captain Mary Kremzner, Captain Paras Patel, Captain

Ray Ford, Commander Larry Lim, Commander Rebecca McKinnon, Lieutenant Commander Lena Choe, Lieutenant Commander Carlos Gonzalez-Mercado, Lieutenant Commander Gayle Tuckett, and Lieutenant Renu Lal.

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