



Washington Metropolitan Society of Health System Pharmacists Newsletter

June 2020
Volume 3

WMSHP Executive Board

President

Vaiyapuri Subramaniam, PharmD

President Elect

Ashok Ramalingam, PhD

Immediate Past President

Sadhna Khatri, PharmD

Treasurer

Opeoluwa Fagbemi, PharmD

Secretary

Tina Patel, PharmD

Board Members

Jamila Jordan, PharmD

John Quinn, RPh. M.S.

Delegates

Michelle Eby, PharmD

Kit Wong, PharmD

Meenakshi Shelat, PharmD, BCOP

Editors

Tiffany Tseng, PharmD

John Quinn, R.Ph. M.S.

WMSHP website:

www.wmshp.org



Highlights of the WMSHP Virtual Educational Programs in June 2020

**Meenakshi Shelat, PharmD,
BCOP**

**Co-Vice Chair, WMSHP
Programming Committee,
ASHP Alternate Delegate**

Message from the WMSHP President

During this public health crisis of the COVID-19 pandemic, we are reminded of pharmacists providing patient care services at the front lines. The WMSHP continues to ensure its members of updated educational programs in a virtual format through continuing education (CE) sessions and applicable pharmacist resources shared in this newsletter and the *Drug Information section* on its website homepage. On page 1 of this newsletter is a comprehensive article on “*Highlights of the WMSHP Virtual Educational Programs in June 2020*,” that begins with WMSHP’s launching of its first virtual educational and CE program on June 11, 2020. On page 3, is an informative article on emergency use authorization (EUA) titled “*Emergency Use Authorizations (EUA) – Initial Development, Comparisons (NDA and IND), and Current Applications*” that exemplifies one of FDA’s tools to make available important medical products during the COVID-19 pandemic.

In an effort to continue staying engaged with our diverse WMSHP memberships’ needs under the dedicated direction of Vaiyapuri Subramaniam, PharmD, MS, we collaborated with Lana Konigsberg, PharmD, Senior Medical Science Liaison in the area of cardiovascular medicine for Sanofi and volunteer speakers to provide relevant continuing education (CE) in a virtual format to ensure the safety as well as educational opportunities for our members. For our first virtual session on June 11th, Dr. Konigsberg presented on “The 2019 Focused Update for the Management of Patients with Atrial Fibrillation,” which was an interesting pre-symposium that spurred an excellent live discussion virtually. Dhakrit Rungkitwattanukul, PharmD, BCPS, who is a Clinical Assistant Professor at the Howard University College of Pharmacy, presented on “Medication Safety and Issues during COVID-19 Treatment.”

**See page 2 – WMSHP Virtual
Education**

WMSHP Virtual Education

Dr. Rungkitwattanakul's CE program could not have been more relevant as many of us and clinicians globally are asking how to safely treat patients who are having signs and symptoms and/or admitted and screened positive for Covid-19 at a time where definitive studies for therapies are still ongoing. He presented recent data from within the US and globally. We look forward to continuing to provide virtual educational and CE sessions. Our next programs will be on June 24th and July 8th. On June 24th, James E. Cummins, Jr., Ph.D. of the Preclinical Microbicide and Prevention Research Branch from the NIH will be presenting on "Understanding the COVID-19 Pandemic: Epidemiology, Basic Science, Drug Targets and Therapeutic Options;" also with a pre-symposium by Dr. Konigsberg at 6 pm on "RecordAF: Registry on Cardiac Rhythm Disorders Assessing the Control of Atrial Fibrillation." Online registration through survey monkey is available with payment if applicable and is available on the WMSHP website. The event is free for WMSHP members and the cost for non-members is \$5. **The due date for registration for the July 24th CE is June 19th for everyone.** Please look out for the July 8th program announcement. We look forward to continuing this virtual format and providing relevant CE for our society. Acknowledgments and many thanks to the WMSHP Program, Membership, and Communication Committees. Feel free to contact us if you know dynamic speakers who would like to present at an upcoming event and if you would like to be involved with WMSHP!



Tiffany Tseng has been a WMSHP member since 2019. She received her PharmD from the University of Florida and has served in clinical research for 6+ years within the VHA, NIH, a CRO, and an independent consulting company based in DC.



**Meenakshi Shelat, PharmD, BCOP
Co-Vice Chair, WMSHP Programming
Committee, ASHP Alternate Delegate**

Presidents Message

Related to the article are new updates referenced in the *Drug Information* section in the WMSHP website on resources with search links to address, manage and mitigate COVID-19 transmission to educate patients and the public. As part of WMSHP's strategic plans to reach out with students at local pharmacy schools, we are pleased to have an article in the *Students Corner* of this newsletter contributed by a 4th year PharmD candidate at the Howard University College of Pharmacy (CoP) on "A *Student's Perspective: Positivity During These High-Pressure Times.*" The article provides examples of optimism and a positive perspective taken to adjust to a virtual classroom setting and how the College of Pharmacy utilized technology platforms that facilitated to guide its students.

The ASHP which is WMSHP's parent national organization, is working with its partner pharmacy organizations on joint recommendations to U.S. national agencies to empower pharmacists to effectively support COVID-19 initiatives that can help to ensure patients obtain needed treatments.

See page 8

Emergency Use Authorizations (EUA) – Initial Development, Comparisons (NDA and IND), and Current Applications

By Tiffany Tseng, PharmD

What is an EUA and how was it developed?

The emergency use authorization (EUA) has been one of several tools that the FDA has been using to help make important medical products available more quickly during the COVID-19 pandemic. A comprehensive EUA program was initially established by the Project Bioshield Act of 2004, subsequent to the events of September 11, 2001 and anthrax postal attacks, which amended section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) to allow the FDA to facilitate availability and unapproved uses of Medical Countermeasures (MCMs) to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by chemical, biological, radiological, and nuclear (CBRN) threat agents when there are no adequate, approved, and available alternatives. This authority is separate and distinct from the use of a medical product under an investigational application (i.e., Investigational New Drug Application (IND) or Investigational Device Exemption (IDE)), which prior to the act, was the sole mechanism for making unapproved products available in an emergency. The [Pandemic and All-Hazards Preparedness Reauthorization Act of 2013](#) (PAHPRA), the [21st Century Cures Act](#) of 2016, and [Public Law 115-92](#) of 2017 further amended Section 564 of the FD&C. Section 564(b)(5) also states that FDA's authorization of an emergency use of an unapproved product or unapproved use of an approved product does not authorize a delay in their review or other consideration of any pending application. If an EUA remains in effect for more than one year, FDA must provide the sponsor written explanation of obstacles to approval and specific actions to be taken by FDA and the sponsor to overcome them.

What does an EUA require?

Before the FDA may issue an EUA, the Health and Human Services (HHS) Secretary must declare that circumstances exist justifying the authorization, which typically involves a determination by the Secretary of Homeland Security, the Secretary of Defense, or the Secretary of HHS that there is, or a significant potential for, an emergency (including public health) involving a CBRN agent, attributed disease or condition, or material threat sufficient to affect national security.

After the HHS Secretary's EUA declaration, and feasible and appropriate consultations (i.e., with the Assistant Secretary for Preparedness and Response [ASPR], the Director of the National Institutes of Health [NIH], and the Director of CDC), FDA may issue an EUA if the following four statutory criteria are met: (1) serious or life-threatening disease or condition: the CBRN agent(s) referred to in the HHS Secretary's EUA declaration must be capable of causing a serious or life-threatening disease or condition; (2) evidence of effectiveness: the medicinal product considered for an EUA should demonstrate that it "may be effective" to prevent, diagnose, or treat serious or life-threatening diseases or conditions that can be caused by a CBRN agent; (3) risk-benefit analysis: the known and potential benefits of the product, when used to diagnose, prevent, or treat the identified disease or condition, outweigh the known and potential risks of the product; (4) no alternatives: there must be no adequate, approved, and available alternative to the candidate product for diagnosing, preventing, or treating the disease or condition.

How do the requirements of an EUA compare with those of an NDA or IND?

The EUA requires a lower level of evidence of potential effectiveness ("may be effective" standard) than the "effectiveness" standard that FDA uses for product approvals such as for a New Drug Application (NDA) and is assessed by the FDA on a case-by-case basis using a risk-benefit analysis, based on the totality of scientific evidence available. Such evidence available for FDA consideration may include, but is not limited to, results of domestic and foreign clinical trials, *in vivo* efficacy data from animal models, and *in vitro* data, with assessment of the quality and quantity of the available evidence.

How do the requirements of an EUA compare with those of an NDA or IND? (continued)

An IND similarly requires evidence that the drug “may be effective” for its intended use in its intended population (21 CFR 312.320(a)(3)(ii)), however in comparison to the EUA which is built on a public health model, the IND mechanism is built on a clinical research model with more administratively burdensome requirements including Institutional Review Board (IRB) approval of the investigational protocol, documented informed consent from all patients, and substantial record keeping. And despite the expanded access treatment IND having been established by the FDA in 1987 as a specific regulatory category of INDs to allow more extensive use of an investigational product for treatment of life-threatening or serious diseases, the clinical study nature and administrative requirements still render the IND to fall short in comparison to the EUA in providing the needed flexibility for effective use in national emergency situations, such as a universal vaccination campaign against a life-threatening infectious disease. Also, the amount, type, and quality of evidence available to support an EUA may not always be the same as that required for expanded access, IDEs, or humanitarian device exemptions under the FD&C Act and FDA regulations, depending on the specific product and circumstances of risk and benefits.

What EUAs have been issued during the pandemic?

On January 31, 2020, the HHS Secretary issued a declaration of a public health emergency related to COVID-19 and mobilized the Operating Divisions of HHS. On February 4, 2020, the HHS Secretary additionally determined pursuant to his authority under section 564 of the FD&C Act that the public health emergency involving the virus that causes COVID-19 has a significant potential to affect national security or the health and security of United States citizens living abroad. On the basis of this determination, the Secretary then declared that circumstances exist justifying the authorization of emergency use of: in vitro diagnostics for detection and/or diagnosis of the virus that causes COVID-19 ([February 4, 2020](#)); medical devices, including alternative products used as medical devices ([March 24, 2020](#)), and drugs and biological products ([March 27, 2020](#)) during the COVID-19 pandemic. As of June 17, 2020, the FDA has authorized 139 [tests](#) (including 118 molecular tests, 20 antibody tests, and 1 antigen test) and 3 (previously 4) [drugs](#) under EUAs. On June 15, 2020, [the FDA revoked the EUA for chloroquine and hydroxychloroquine](#) previously issued on March 28, 2020 as legal criteria for issuing such an EUA are no longer met and the known potential benefits of chloroquine and hydroxychloroquine no longer outweigh the known and potential risks (i.e., serious cardiac adverse events and other potential serious side effects) for their authorized use.

On May 1, 2020, the FDA issued an [EUA for remdesivir](#), Gilead’s intravenous direct acting antiviral drug, originally developed for Ebola, for hospitalized patients with severe COVID-19 based on preliminary clinical trial results indicating that the drug accelerated recovery. Severe COVID-19 is defined as patients with an oxygen saturation (SpO₂) ≤ 94% on room air, requiring supplemental oxygen, mechanical ventilation, or extracorporeal membrane oxygenation (ECMO), a heart-lung bypass machine. Publicly available Fact Sheets for [Healthcare Providers](#) and [Patients and Parent/Caregivers](#) as well as [Frequently Asked Questions on the EUA for Remdesivir for Certain Hospitalized Patients](#) accompany the EUA. On May 3, 2020, the federal government accepted from Gilead Sciences, Inc. a donation of the investigational drug remdesivir (606,840 vials enough to treat ~78,000 hospitalized COVID-19 US patients) and had fully allocated the original donation as of May 29, 2020. The [Office of the Assistant Secretary for Preparedness and Response \(ASPR\)](#) within the HHS has been working with Gilead Sciences, Inc., partners in state health departments, and the Trump Administration on the equitable and efficient distribution of donated remdesivir to healthcare providers, especially in light of its expanding global demand with drug approvals in Japan and the United Kingdom, focusing on the areas of the country hardest hit by the pandemic, with the goal of reaching as many patients as possible across all states and territories. On May 18, Gilead Sciences, Inc. committed to donating an additional 333,160 remdesivir vials expected to be delivered in early June. Hospitals were requested to submit data into the [HHS TeleTracking database](#) by June 8 so that HHS could allocate additional donated remdesivir to state health departments based on hospital need, with distributions scheduled for June 15 and June 29. Remdesivir is also being allocated for distribution within the healthcare systems of the Department of Defense, the Veterans Health Administration, and the Indian Health Service. Nevertheless, as the government orchestrates distribution of donated remdesivir, clinical trials under an IND remains the primary way to access remdesivir to generate critical data that inform the appropriate use of this investigational medicine. Per [Gilead](#), expanded access emergency treatment requests can be considered only when enrollment in a clinical trial is not a feasible option.

References

FDA. Coronavirus (COVID-19) Update: FDA Revokes Emergency Use Authorization for Chloroquine and Hydroxychloroquine. June 15, 2020. https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-revokes-emergency-use-authorization-chloroquine-and?utm_campaign=FDA%20Revokes%20Emergency%20Use%20Authorization%20for%20Chloroquine%20and%20Hydroxychloroquine&utm_medium=email&utm_source=Eloqua

FDA. Emergency Use Authorization. May 29, 2020. <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>.

FDA. Emergency Use Authorization of Medical Products and Related Authorities. Guidance for Industry and Other Stakeholders. January 2017. <https://www.fda.gov/media/97321/download>

FDA. Emergency Use Authorization for emergency use of remdesivir for the treatment of hospitalized 2019 coronavirus disease (COVID-19) patients. May 1, 2020. <https://www.fda.gov/media/137564/download>

FDA. Expanded Access to Investigational Drugs for Treatment Use – Questions and Answers. Guidance for Industry. June 2016. Updated October 2017. <https://www.fda.gov/media/85675/download>

FDA. Fact Sheet for Health Care Providers Emergency Use Authorization of Remdesivir (GS-5734). <https://www.fda.gov/media/137566/download>

FDA. Fact Sheet for Patients and Parent/Caregivers. Emergency Use Authorization (EUA) Of Remdesivir For Coronavirus Disease 2019 (COVID-19). <https://www.fda.gov/media/137565/download>

FDA. Frequently Asked Questions on the Emergency use Authorization for Remdesivir for Certain Hospitalized COVID-19 Patients. May 29, 2020. <https://www.fda.gov/media/137574/download>

FDA. Institutional Review Board (IRB) Review of Individual Patient Expanded Access Requests for Investigational Drugs and Biological Products During the COVID-19 Public Health Emergency. Guidance for IRBs and Clinical Investigators. June 2020. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/institutional-review-board-irb-review-individual-patient-expanded-access-requests-investigational>

Gilead. Emergency treatment with remdesivir. <https://rdvcu.gilead.com/>

Gilead. Working to Supply Remdesivir for COVID-19. <https://www.gilead.com/purpose/advancing-global-health/covid-19/working-to-supply-remdesivir-for-covid-19>

Nightingale SL, Prasher JM, Simonson S. Emergency Use Authorization (EUA) to Enable Use of Needed Products in Civilian and Military Emergencies, United States. *Emerging Infectious Diseases*. 2007;13(7):1046-1051. doi: 10.3201/eid1307.061188

PHE. ASPR's Portfolio of COVID-19 Medical Countermeasures under Investigation. Reviewed June 9, 2020. <https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Pages/remdesivir.aspx>

Secretary of Health and Human Services Alex M. Azar II, Determination that a Public Health Emergency Exists. (Jan. 31, 2020, renewed April 21, 2020), *available at* <https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx>.



WMSHP members enjoy a lecture, dinner and discussions with their colleagues at Positano Ristorante in Bethesda in 2019

Student Corner



Kodilorah Okoye, Pharm D student

A Student's Perspective: Positivity During These High-Pressure Times By Kodilorah Okoye Howard University College of Pharmacy

My name is Kodilorah Okoye and I am a rising 4th year Doctor of Pharmacy Candidate at the Howard University College of Pharmacy. In mid-March this year, the Coronavirus pandemic disrupted my everyday academic routine which primarily consisted of school, work, and studying. I was instructed to no longer return to campus as the entire university would be transitioning to 'remote learning'. On the one hand, I was relieved that my university put my health and safety first and I was also looking forward to a slower-paced lifestyle.

See next page

Student Corner Cont.

On the other hand, concern consumed me as I consider myself to be a collaborative and auditory learner who relies heavily on in-person lectures and studying regularly with groups. As an executive board member of various campus organizations, I also questioned how we would host events and keep members engaged.

I left the college campus to quarantine with my parents. My family home is in a very small rural town in Carroll County, Maryland that is distinctly quiet and serene. One would assume that these conditions would create the perfect study environment. Instead, I found that the slow pace made me lazy and that the fast pace of the District of Columbia had been integral in motivating me each day. Adjusting to living with my parents also had its challenges. On top of studying for my rigorous program, I had to incorporate my new normal of daily life which included household chores such as cooking and cleaning. On top of that, Carroll County was hit hard with COVID-19 cases. So, while my Doctor of Pharmacy degree program continued with full speed and intensity, I found myself having to limit social media and local news as COVID-19 was affecting people I knew and places I was very familiar with.

As I started finding ways to cope given the challenges brought about by COVID-19, the entire nation has had to come to reckon with the longstanding issues of systemic racism towards Black Americans. The challenges of systemic racism are ones that I have become conditioned to deal with, but the graphic nature of the most recent incidences, the civil unrest, and protests seen across the United States is something that I haven't experienced in my lifetime. The need to find time to balance my own mental/spiritual well-being, be present for the communities that need me, and remain responsive to my academic program has been all-consuming and, at times, difficult.

While this has been a very challenging experience for me, I am aware that these difficulties are being felt by many students across the nation. For a lot of us, the effects of the pandemic and the current social justice crisis has negatively impacted us in many ways. Additionally, some students have had to navigate additional challenges including disruption of their normal academic schedule, a lack of access to reliable internet, or even returning to a difficult home life and situation. Given that, I would like to share some of the positive experiences that I have observed during this period.

1. Due to the transition to a virtual classroom experience I am sure that our professors received a larger-than-normal volume of emails than they have ever received before. However, professors have made themselves available to be reached and even meet with students outside of their regularly scheduled "office hours".
2. I was still able to study in groups! My study group coordinated meetings using Google Hangouts and tutoring sessions were hosted using Zoom.
3. Regarding the different organizations I am involved with, the show went on. Guest speakers were open and willing to present to students virtually, so we were able to conduct webinars and get valuable content out to our community.

4. Furthermore, we were able to utilize the technology provided and we successfully completed our Objective Structured Clinical Examination (OSCE) virtually. The virtual experience was just as effective and valuable for me as it normally was in person.

5. Lastly, I was able to take advantage of discounted or free resources for students offered by organizations, like Coursera, Kaplan, and Harvard, to sharpen their abilities during this period.

I am very fortunate that the Howard University's College of Pharmacy quickly ushered in all the necessary technology platforms for a virtual classroom setting. This is a very uncertain time as a student, and I am trying to be as adaptable as possible. Through this experience, I have learned that I am resilient in the face of adversity. I am optimistic about the future, and I believe that I will be able to be successful in this program no matter what challenges may come next!

Presidents message from page 2

The recommendations include policy areas to address authorization to test, treat, and immunize; workforce and workplace issues; drug shortages and continuity of care; and reimbursement for services and removal of barriers. The recommendations build on ASHP's positions for expanded scope of practice and payment for COVID-19 testing and treatment.

WMSHP gratefully acknowledges all its members for their support of its programs.

Please use the society website (www.wmshp.org) for your needs.

Thank you and stay safe.

Sincerely,

Puri

Vaiyapuri Subramaniam, PharmD, MS, FASHP, FASCP, FCP