

**2020 America’s Got Regulatory Science Talent Competitions
Presentation Abstracts & Student Biographies**

University of Maryland	
1st Place Team	“Brain Alliance” MeDevice: A mobile app that allows consumers to access and view information about FDA approved medical devices. This app will promote transparency and be easy for patients to use.
Team Members	Adaeze Amaefule, Breanna Owoo, Hannah Kim, and Sydney Yuen
FDA mentors	<ul style="list-style-type: none"> • Marlene Kim, PhD, Chemist, Division of Applied Regulatory Science, Office of Translational Science, Center for Drug Evaluation and Research, FDA • Meng Hu, PhD, CDER/OGD/ORS/Division of Quantitative Methods and Modeling, Office of Research and Standards, Office of Generic Drugs, Center for Drug Evaluation and Research, FDA
Presentation Abstract	The FDA regulates thousands of medical devices, ranging from everyday instruments such as thermometers, all the way to complex apparatuses such as implantable defibrillators. Given that medical devices are pervasive in both consumers’ and healthcare providers’ everyday lives, the focus of this project was to devise a way for everyone to easily access information regarding a medical device they may be using. MeDevice is a mobile app that allows consumers to access and view information about FDA-approved medical devices. Its purpose is to promote transparency of medical device information by streamlining all pertinent information, including use, precautions, recalls, warnings and more. MeDevice also ensures ease of adverse event reporting by including a direct link to the FDA MedWatch reporting system, which may improve post-market surveillance data and enhance real-world evidence. Whether it is a patient looking up information regarding their intrauterine device or a healthcare provider searching for different blood glucose meters to recommend to their patients, MeDevice is intended to provide clarity and satisfaction in knowing that the device being used is and continues to be the safest and most effective option based on the wealth of information the FDA puts forth in real-time.
Team Member Bios	
Adaeze Amaefule	Adaeze Amaefule is a second-year pharmacy student at the University of Maryland School of Pharmacy (UMSOP). She currently serves as the Director of National Engagement for the UMSOP Industry Pharmacists Organization (IPhO) chapter, and as the Secretary for the Student National Pharmaceutical Association (SNPhA). She previously conducted patient-centered outcomes research analyzing the role of pharmacists in medication management with the Center for Innovative Solutions at UMSOP. Currently, she is involved in health economics research regarding hepatocellular carcinoma with the Pharmaceutical Health Services Research (PHSR) department at UMSOP. She is interested in pursuing a career in the pharmaceutical industry after graduation.

Breanna Owoo	Breanna-Verissa Owoo is a second-year PharmD student at the University of Maryland School of Pharmacy (UMSOP) and is appointed as a Student Ambassador for the School of Pharmacy. She is heavily involved in the Student National Pharmaceutical Association (SNPhA) whose purpose she upholds, in serving the underserved. Breanna is also the National Representative for Christian Pharmacists Fellowship Intl (CPFI). Recently, she has had the opportunity to perform research regarding health economics outcomes, as it pertains to Hepatocellular Carcinoma. Breanna has a growing interest in clinical pharmacy management but is exploring her interests in the pharmaceutical industry.
Hannah Kim	Hannah Kim is a second-year student pharmacist attending the University of Maryland School of Pharmacy (UMSOP). She is currently the President-Elect of the Student Section of Maryland Public Health Association (SMdPHA) and Secretary of the Academy of Managed Care Pharmacy (AMCP). She also works as an infusion pharmacy intern at the Johns Hopkins Home Care Group. Hannah worked previously as an ORISE Fellow at the FDA, where she evaluated clinical pharmacology data regarding patients with hepatic impairment, and she has recently begun health economics and outcomes research regarding hepatocellular carcinoma under the Pharmaceutical Health Services Research (PHSR) department at UMSOP. She seeks to gain a post-graduate fellowship in regulatory or medical affairs and pursue a career in the pharmaceutical industry or regulatory field.
Sydney Yuen	Sydney Yuen is a second-year PharmD student at the University of Maryland School of Pharmacy (UMSOP). During her time at UMSOP, she has been actively involved as the Communication Vice President for the American Pharmacists Association Academy of Student Pharmacists (APhA-ASP), as well as secretary for the Student Section of the Maryland Public Health Association (SMdPHA). With an invested interest in public health outcomes and determination of cost-effective pharmaceutical treatments, she has begun research investigating hepatocellular carcinoma treatments through the lens of the patient experience. In the future, she hopes to pursue a career in medical affairs or regulatory science in the pharmaceutical industry or federal agency.

University of Maryland	
2nd Place Team	“Just (insul)in-case” Insulin: A jump-start to manufacturing biologics on demand in public health emergencies
Team Members	Karen Nguyen, Hanna Lefebo, Amanda Dinh, Anthonia Azubike, Andrew SyBing, and Jeffrey Banaszak
FDA mentor	Kimberly Maxfield, PhD, Policy Lead, Office of Clinical Pharmacology, Office of Translational Sciences, Center for Drug Evaluation and Research, FDA
Presentation Abstract	The U.S. has an extensive plan to combat public health emergencies, such as natural disasters. However, as seen through our current COVID-19 pandemic, there are gaps in our medication supply chain, leading to issues of cost, time, and transportation. Manufacturing “biologics on-demand” is a novel and unregulated method that uses cell-free systems to make almost any drug, at anytime, anywhere. We propose to leverage existing FDA policies to expedite the approval of emergency drug manufacturing, using insulin as a prototype for the implementation of the new manufacturing system. Such policies include Emergency Use Authorizations (EUAs), the Animal Rule, and Current Good Manufacturing Practices (cGMP). Our goal is to proactively save patients’ lives and improve national emergency preparedness through the implementation of novel manufacturing methods.
Team Member Bios	
Karen Nguyen	Karen Nguyen is a second-year pharmacy student at the University of Maryland, School of Pharmacy (UMSOP), and an incoming ORISE Fellow for the FDA. At the PAVE Center, her research aims to incorporate the patient voice into value assessment frameworks, through discrete choice experiments. She enjoys being active in the UMSOP community, through her roles with the Academy of Managed Care Pharmacy (AMCP) and the Student Government Association. She aims to combine her professional interests through the Pharmapreneurship Pathway, which includes managed care, marketing, market access, and serving minority populations. Additionally, she founded the largest Facebook group dedicated to connecting individuals passionate about pharmacy, especially in the Asian community.
Hanna Lefebo	Hanna Lefebo is a second-year pharmacy student at the University of Maryland, School of Pharmacy (UMSOP). She is interested in pursuing a career in pharmacy that focuses on population health and psychiatry. She has previously worked as a Pathways Intern in ORA at the FDA where she worked with compliance pharmacists and investigators to expand her knowledge of public health and regulatory compliance. She is currently highly involved with the College of Psychiatric and Neurologic Pharmacist (CPNP) where she builds her network and knowledge. She also works at The Johns Hopkins Hospital as a clinical intern and is currently working on a project on long acting antipsychotics with a clinical psychiatric pharmacist.

Amanda Dinh	Amanda Dinh is a second-year student at the University of Maryland School of Pharmacy (UMSOP). Her academic pathway is Pharmaceutical Industry with a focus on marketing. Currently, she is the Vice President (VP) of the school's Industry Pharmacist Organization (IPhO), which promotes the advancement of industry pharmacists and pharmacy students. As VP, she enjoys mentoring those who are planning to pursue a career in pharmacy and encouraging others to explore the various opportunities in industry. She also serves on the executive board of Kappa Psi, a pharmaceutical fraternity focused on leadership and service. Her interests are geared towards the advancement of future drug development in order to benefit the greater community.
Anthonia Azubike	Anthonia Azubike is a second-year pharmacy student at the University of Maryland, School of Pharmacy (UMSOP). She is very passionate about Novel drug development and improving the efficacy and safety of pharmaceutical products. Through her research, she hopes to evaluate different antineoplastic agents with a very strong interest in designing anti-cancer drugs with a good safety profile. She currently works as a Pharmacy intern at The Johns Hopkins Hospital. She is interested in a career that focuses on regulating the efficacy and safety of pharmaceutical products being utilized by patients.
Andrew SyBing	Andrew SyBing is a second-year student pharmacist at the University of Maryland School of Pharmacy (UMSOP) interested in pursuing a career in quantitative drug development. Pivoting from a bachelor's in chemical & biomolecular engineering, Andrew has regulatory experience at the Food and Drug Administration (FDA) in ensuring reviewer consistency through analyzing trends in various FDA approved products. Furthermore, he has experience in PK modeling in simulation and determining PK/PD profiles, dose-response relationships, and dosing regimens for various preclinical and early phase assets through working with UMSOP's Center for Translational Medicine (CTM). He hopes to expand his technical skills and drug development knowledge this Summer by participating in Pfizer's student worker program as a pharmacology intern investigating the pharmacologic profile of various blood disorders, and by pursuing a Masters in Pharmacometrics through the UMSOP dual degree program.
Jeffrey Banaszak	Jeffrey Banaszak is a second-year student pharmacist at the University of Maryland School of Pharmacy (UMSOP) interested in pursuing a career that increases patient access to new life-saving medications. Jeffrey also has an interest in understanding public health from the patient population level. As a board member of the university organization referred to as the Entrepreneurship and Innovation Network, Jeffrey hopes to leverage his passions to produce innovative and novel solutions to problems that exist within the pharmaceutical sector of the healthcare industry.

University of Maryland	
2nd Place Team	“RidRx” Phone app that allows easy access for safe medication disposal
Team Members	Anyen Fon, Hang Vo, Chidiogo Eke, and Olamide Olujohungbe
FDA mentor	Roberta Glass, MD, Senior Medical Officer, Division of Psychiatry, Center for Drug Evaluation and Research, FDA
Presentation Abstract	RIDRx is our solution to proper medication disposal. Lack of proper medication disposal creates many problems, from affecting public safety to drug diversion, and is a cause of the majority of childhood poisoning. The lack of correct medication disposal is not due to the lack of resources, but rather a problem of awareness. Thus, through the implementation of this app, we are centralizing all information concerning drug disposal, with the most current information; making it easy and accessible with one touch and, therefore, raising public awareness of safest ways to dispose of medications, at the nearest disposal locations, or from the comfort of one’s home. Future steps that can be implemented are also recommended.
Team Member Bios	
Anyen Fon	Anyen Fon is a second-year pharmacy student at the University of Maryland School of Pharmacy (UMB). Ms. Fon completed her undergraduate education at Prince George’s Community College (PGCC) where she obtained an Associate of Science in Computer Science. At UMB, Ms. Fon has served as an Alternate Delegate for the Student National Pharmaceutical Association (SNPhA) and is a current member of the Academy of Managed Care Pharmacy (AMCP). She has interests in Regulatory Science, Research, and the Pharmaceutical Industry. She enjoys spending time with family and serving the underserved both in Baltimore and at her local church.
Hang Vo	Hang Vo completed her undergraduate education at Montgomery College and obtained an Associate of Science in Environmental Science. She is currently a second-year pharmacy student at the University of Maryland School of Pharmacy. She is actively involved in American Pharmacist Association-Academy of Student Pharmacists (APhA), American College of Clinical Pharmacy (ACCP), American Society for Clinical Pathology (ASCP), Alpha Zeta Omega Professional Fraternity (AZO), and Rho Chi Society. She would love to pursue clinical pharmacy in cardiology. She has a special interest in geriatrics so she loves to volunteer at those events that promote geriatric health. She also loves baking and crocheting in her free time.
Chidiogo Eke	Chidiogo Eke Obtained a Doctor of Veterinary Medicine (DVM) degree from the University of Nigeria. She is currently enrolled in the University of Maryland Baltimore School of Pharmacy as a second-year student. A member of American Pharmacist Association-Academy of Student Pharmacists (APhA-ASP), Academy of Managed Care Pharmacy (AMCP) and Industry Pharmacists Organisation (IPhO). She is interested in Regulatory Science as well as Pharmaceutical industry and Research. She likes to volunteer in grassroot outreach programs in the Baltimore area and mentor junior pharmacy students.

Anyen Fon	Anyen Fon is a second-year pharmacy student at the University of Maryland School of Pharmacy (UMB). Ms. Fon completed her undergraduate education at Prince George's Community College (PGCC) where she obtained an Associate of Science in Computer Science. At UMB, Ms. Fon has served as an Alternate Delegate for the Student National Pharmaceutical Association (SNPhA) and is a current member of the Academy of Managed Care Pharmacy (AMCP). She has interests in Regulatory Science, Research, and the Pharmaceutical Industry. She enjoys spending time with family and serving the underserved both in Baltimore and at her local church.
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FDA Judges for Univ. Maryland event:

- Silvana Borges, M.D., Associate Director for Regulatory Science, Office of Neuroscience, OND, CDER, FDA
- Wayne Amchin, Regulatory Project Manager, Office of New Drugs, Office of Drug Evaluation I, CDER, FDA
- Alemayehu (Alex) Akalu, PharmD., Senior Staff Fellow, Oncology Program, Office of Hematology & Oncology Products, CDER, FDA

University of Rochester

1st Place Team	“My RWD” A process to provide individuals increased autonomy over their mobile health data.
Team Member	Sydney Simpson
Presentation Abstract	Pathogen outbreaks in food – like E. coli in romaine lettuce – are fairly common, but current methods to trace contamination through the food supply chain are labor intensive, time consuming, imprecise and often end in the disposal of safe produce. I propose using blockchain software, which is already commercially available and utilized for supply chains by some businesses, to record transactions involving nationally-distributed, high-risk produce (like romaine lettuce). Blockchain records each transaction, linking it to previous transactions and building digital a scaffold that can be easily traced- effectively decreasing traceback time from over a week to seconds. Under my proposal the FDA would either have access to these blockchain databases or sync the information into one database, allowing for fast and efficient tracebacks of contaminated produce.
Team Member Bio	
Sydney Simpson	Sydney Simpson will graduate from the University of Rochester in August with a PhD in Microbiology and Immunology, and an advanced certificate in Regulatory Science. While her thesis focuses on Platelet-HIV interactions during acute infection, Sydney is interested in pursuing a career in Science and Health Policy, and is particularly interested in infectious disease prevention and biosecurity. During her graduate career she has been involved in many organizations and is the President of the Graduate Student Society, and the Treasurer of the University of Rochester Science Policy Initiative.