

## **Your Generics & Biosimilars Industry**



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Robert Gaines Jr., PharmD, MBA is Senior Director of Sciences and Regulatory Affairs at the Association for Accessible Medicines. supporting the development and oversight of AAM's Sciences and Regulatory Affairs initiatives. Prior to joining AAM, Robert spent 15 years working at the Food and Drug Administration, serving in various roles across offices in the Center for Drug Evaluation and Research (CDER). In his most recent FDA position, Deputy Director for the Office of Program and Regulatory Operations within the Office of Pharmaceutical Quality (OPQ), he led an office of more than 100 employees responsible for providing the project management function for OPQ's quality assessment of all drug application types. Robert also completed a distinguished 20year career as a Commissioned Officer in the United States Public Health Service. retiring with the rank of Captain. During that time, he served as a pharmacist and deployed numerous times in various leadership roles for disaster and pandemicrelated responses.

Robert holds a PharmD from Howard University and an MBA from Trident University.



