



Spring Semester 2019

Presented by Sickle Cell Community Consortium
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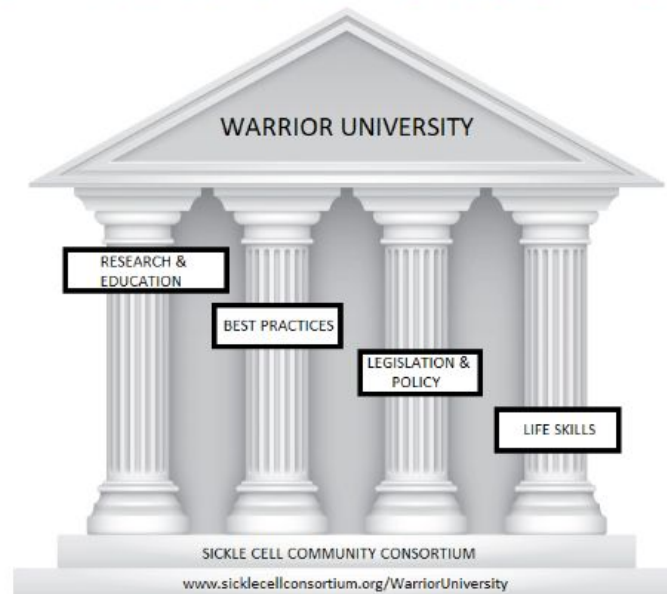
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WARRIOR UNIVERSITY

Warrior University is an online webinar curriculum series that will focus on patient and provider education, advocacy training, Consortium Speakers Bureau sign-up and certification, and best practices for sickle cell community-based organizations (to include grant writing, social media education and digital literacy, event planning, etc.). All current classes, presentations and workshops are classified into four warrior university pillars:

- Disease Education – This pillar focuses on existing sickle cell disease education. Classes will include courses and workshops as part of the Expert Patient Series. Advances level courses will require completion of prerequisite courses (or prerequisite exemption approval).
- Community-Based Organization/Certified Advocate Training & Best Practices – This pillar encompasses classes and workshops designed to provide training in expert advocacy and non-profit best practices. Courses include public speaking, grant writing, fundraising, etc.
- Research, Legislation & Policy – This pillar contains courses designed to keep sickle cell patients and caregivers up-to-date on the legislative and administrative policies of importance to the sickle cell community.
- Life Skills – This pillar will include courses designed to ensure that rare disease patients have the knowledge and skill set to live their best life.

FOUR PILLARS OF WARRIOR UNIVERSITY



FDA Patient Engagement Series: OVERVIEW

The Sickle Cell Consortium is excited to present the [Course Name] Webinar series as part of *Warrior University*. This [Course Name] Webinar series was developed to provide an in-depth understanding of the process for sickle cell patients, caregivers, and community-based organizations to become involved with, and influence the decisions of, the US Federal Food and Drug Administration. Together with Global Blood Therapeutics, we will provide the foundation for broadening patient/caregiver engagement.

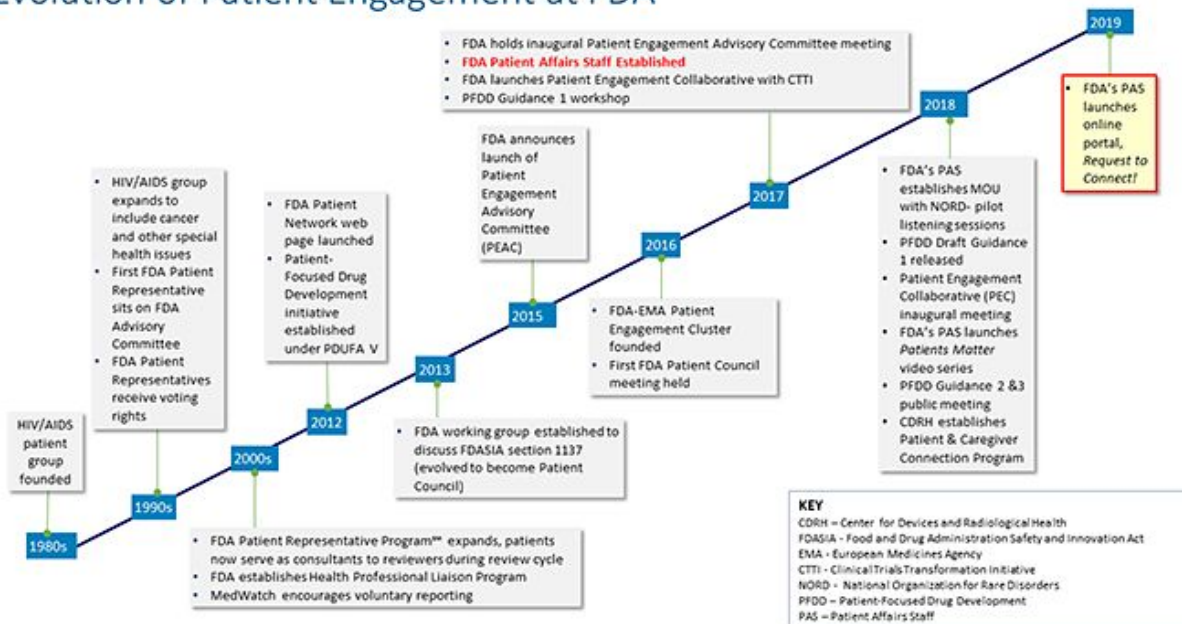
Rationale

The FDA has a difficult task when it comes to evaluating and approving new and innovative medical products.

Individual patients may experience the effects of diseases and therapies differently and each individual patient has a unique perspective about treatments or diagnostic procedures that differ from those perspectives of other patients or of their healthcare provider. The FDA has included the patient perspective in FDA Advisory Committee meetings since 1991.

Patients and Caregivers can get involved with the FDA in multiple ways. To learn more visit [here](#).

Evolution of Patient Engagement at FDA



CURRICULUM

WEBINAR COURSE: FDA Patient Engagement Series

The learning sessions in FDA Patient Engagement Series are designed to promote patient and caregiver engagement with the FDA. With a basic understanding of FDA engagement, these sessions will help attendees learn how to take the hands-on knowledge gained and use it to become involved with the FDA Patient Engagement Collaborate, the FDA Patient Council, serve on FDA Patient Panels, and more.

**April 2, 2019 | 7 PM EST | [REGISTER](#) |
Mr. James Valentine**

SESSION 1: Why Get Involved with the FDA?

- Regular and sustained patient advocacy with the FDA is important because:
 - Helps FDA understand the impact of sickle cell
 - Used in the approval decisions to balance benefits and risks of new therapies
 - FDA wants and solicits patient input into their processes.

**April 9, 2019 | 7 PM EST | [REGISTER](#) |
Dr. Lakiea Bailey**

SESSION 2: Developing and Advocacy Resume

- What is an advocacy resume?
- Why is it important to build an advocacy resume?
- How to create an advocacy resume?

**April 16, 2019 | 7 PM EST | [REGISTER](#) |
Mr. James Valentine**

SESSION 3: How to get involved with FDA?

- There are many ways the FDA solicits input from patients including product specific and context setting opportunities.
- Key ways to get involved include: acting as a patient representative, participating in listening sessions and focus group sessions.
- Helpful tips make it easier to take next steps and engage with the FDA.

PRESENTERS



James Valentine

James Valentine assists medical product industry and patient advocacy organization clients in a wide range of regulatory matters, including new drug and biologic development and approval issues. Mr. Valentine also works with clients on clinical trials operations and compliance matters.

Before joining the firm in 2014, Mr. Valentine worked in FDA's Office of Health and Constituent Affairs (previously Office of Special Health Issues) where he facilitated patient input in benefit-risk decision-making and served as a liaison to stakeholders on a wide range of regulatory policy issues. Mr. Valentine administered the FDA Patient Representative Program, facilitated stakeholder consultations during the reauthorization of PDUFA and MDUFA, helped launch the Patient-Focused Drug Development program, and developed the FDA Patient Network.

Mr. Valentine also worked at the Center for Drug Evaluation and Research (CDER) Office of Regulatory Policy where he coordinated the implementation of the medical gases certification scheme that was established in FDASIA and handled a variety of postmarket safety issues including REMS and safety labeling changes.



Dr. Lakiea Bailey

Dr. Lakiea Bailey is a sickle cell disease advocate, educator and research scientist. Diagnosed with sickle cell disease at age three, she has become a passionate advocate for those living with rare diseases and is committed to serving as a voice of encouragement and empowerment within the sickle cell community. Despite the devastating symptoms of sickle cell, Dr. Bailey was determined to complete her educational goals, earning a Bachelor degree in Biochemistry and Molecular Biology in 2001 and a Doctorate degree in Molecular Hematology and Regenerative Medicine in 2012. During the course of her education, Dr. Bailey was named a Southern Regional Education Board (SREB) Doctoral Scholar, was the recipient of multiple honors and awards, including the Fisher Scientific Award for Overall Excellence in Biomedical Research, the Medical College of Georgia Alumni Association Award, the Georgia Regents University Leadership Award and was inducted in the Alpha Upsilon Phi honor society. Dr. Bailey is the Executive Director of the Sickle Cell Community Consortium, a coordinated network of sickle cell disease community-based organizations throughout the United States, a contract consultant with bluebird bio, has served on patient panels, a disease expert with Pfizer, Novartis, FDA, NHLBI and sits on the Research Advisory Board for the Foundation for Sickle Cell Disease Research.