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President's Corner

"As you may have heard, NASCIC operates by facilitating communication, sharing resources, and enhancing collaboration. To guide our efforts, we will reach out to our community at various times for their input. It is so important that we hear from a large portion of our community about their reality and what they want us to focus on as we try to make changes for all of us.

This kind of information not only helps NASCIC as a whole, but it can also help various member organizations and individuals with their focused efforts as well as partner organizations in their efforts."

- President, Kim Anderson-Erisman

Registration is open!

The next face-to-face NASCIC meeting will be held in Cleveland, Ohio on Sunday October 6, 2019.



The theme is 'COLLABORATING FOR CHANGE'. We have collectively been making great progress over the last year on our initial activities. We welcome members and non-members to come together and continue building our ability to collaborate across our community and across various stakeholders.

Full information about the meeting is on our [website](http://www.nasciconsortium.org/nascic-annual-meeting-2019).

New Project Engagement Database

NASCIC receives several projects requesting input or involvement from people living with SCI or their caregivers and family. As a step to begin to build our capacity, we have decided to start a database of people interested in helping with projects. If you are interested in participating in these projects, please complete this form via [this link](#). As we receive approved project requests, we will contact you with these opportunities. Be assured that your information will be kept safe as outside entities will not have access to this database. Thank you for your participation in our SCI community.

Reminder:

If you would like to help grow the membership of NASCIC, we welcome you to spread the word! Membership is free for all categories. To apply for membership all people have to do is

NASCIC Invited to Partner with FDA

The FDA division of the Center for Device and Radiological Health (CDRH) hosted their first Patient Engagement Town Hall meeting to kick-off the Patient & Caregiver Connection Program (PCC). NASCIC was one of fourteen organizations invited to be involved with the pilot program. During this test phase, we will work with the PCC program to help the program evolve to include more patient organizations.

Jeff Shuren, CDRH Center Director, introduced this meeting with opening remarks highlighting that safety & efficacy go hand-in-hand with technology innovation. *"They are a ying & yang,"* he described as patients need to be involved in the entire process. The Patient Preference Initiative began at CDRH around 2011 when the Center began studying patient benefit versus risk determinations. Five years later in 2016, the PCC became part of a strategic initiative to include increased transparency with the patient populations and a goal for 90% of the CDRH staff to directly interact with the patient populations that they cover.


Shuren also introduced two key recent activities. One is the creation of the Patient Advisory Committee which brings expertise from patient advocacy groups to advise CDRH. The first meeting was held in October 2017. Draft guidance on patient engagement with the FDA-CDRH will be issued by the end of 2019 for public comment. The second is the commencement of the PCC program. *"These efforts help us to understand the needs, wants, and desires of our primary customer,"* concluded Shuren.

The PCC was formed as an intentional and meaningful interaction with the patient population and the program is housed in the Office of Strategic Partnerships and Technology Innovation (OST). There are 3 goals to gain an understanding of:

- living with a specific disease or condition
- how medical devices are used for diagnosis, treatment, or management of a patient's disease or condition, and
- current issues or trends related to medical devices.

The operation of the program is a simple feedback loop between PCC and the involved organizations. The OST contacts the PCC representatives with areas that need a greater understanding, then CDRH will issue key questions to the involved organization. These questions are disseminated to their constituents to gain feedback and the results and ancillary commentary is looped back to CDRH.

During the PCC kick-off meeting, each of the 14 organizations gave a 3-minute introduction along with participating in panel discussions from the audience. The



lunch hour was open for a town hall interaction with representatives from a variety of offices within CDRH including review and compliance officers, research affiliates, and policy administrators. This is a step in the right direction to have our voice heard within the FDA and to engage with them directly. The NASCIC liaison will be Jen French and will report periodically on updates from the FDA and active communications with the agency.