

# FOR RELEASE

March 29, 2022 | News

## Introducing Dr. Daniel Rastein, CassdermaRX and Castle IRB

See attached CASTLE IRB NEWSLETTER dated March 2022 Volume 2. This Release relates to our very own Dr. Daniel N. Rastien, PFD FDA IRB Program Coordinator, of whom we are so very proud.

In addition to being retained by the PFD team to coordinate the Institutional Review Board Sponsored by Advarra for the PFD/iOrthopedics INC new orthopedic Resilient Arthroplasty Device (RAD) referred to as 'iKnee', Dr. Rastein, MD, MPH is also the Founder & CEO of CassdermaRX, one of only four portfolio projects selected as meeting the exacting standards of PFD Capital Partners for the PFD Management Opportunity Fund 3001, LLC.

### ABOUT CASSDERMA RX

CassdermaRX is the developer of an innovative pharmaceutical-grade topical gel that supports the rapid regeneration of tissue for atrophic recalcitrant wounds. The gel is based on a patented formulation that uses a serum-free, nutrient-rich medium supplemented with a non-steroidal anabolic hormone to stimulate and support the growth of connective tissue originating from a wound bed and its peripheral walls.

Founded in 2020 to begin the process of bringing to market an innovative discovery in a curative wound healing topical product is a direct result of the decade-long work of Dr. Rastein.

As an educator and noted industry leader in healthcare and biomedical research, Dr. Rastein has been involved in designing the regulatory standards of numerous drugs and biomedical devices for cutting-edge manufacturing, research, medical, aerospace, and agriculture companies.

In 2010, Dr. Rastein became aware of an abandoned patent for a unique wound-care formulary. Because of his background in bioresearch, Dr. Rastein immediately saw how important the product that was described would be in presenting a game-changing shift for the treatment of chronic wound-care patients. During the next ten years, Dr. Rastein worked with a key group of formulary researchers, patent lawyers, and pharmaceutical marketing experts to take the concepts from the abandoned patent in order to secure the rights and revive the patent in order to bring this work from vision to reality.

Because of the dedication of Dr. Rastein and his team, a new patent was able to be granted providing four unique allowances, two for formulary and two for application methods, and so CassdermaRX was created to begin the next steps for regulatory approval.

The result of this effort is the CassdermaRX Wound Healing Hydrogel which is a first-of-its-kind topical agent that delivers vital nutrients directly to a wound site. It also provides a naturally occurring hormone that stimulates the growth of healthy cells at the wound site to promote the regeneration of connective tissues vital



## **ABOUT CASSDERMA RX, continued**

to the restoration of new skin and deep tissue to heal a variety of wound types including those from pressure wounds, diabetic ulcers, as well as burns and surgical wounds, which are some of the most difficult to cure.

CassdermaRX is now focused on moving the invention through the necessary Clinical Trials to gain an FDA Investigational New Drug Authorization that would allow it to begin human clinical trials.

## **About Castle IRB (the sponsor)**

Castle IRB is a premier institutional review board offering IRB review services in many areas of research, specializing in the genes, cell therapy and rare disease space.

## **What is an IRB?**

Institutional Review Boards, or IRBs, review research studies to ensure that they comply with applicable regulations, meet commonly accepted ethical standards, follow institutional policies, and adequately protect research participants.

## **What is its purpose?**

Under FDA regulations, an IRB is an appropriately constituted group that has been formally designated to review and monitor biomedical research involving human subjects. In accordance with FDA regulations, an IRB has the authority to approve, require modifications in (to secure approval), or disapprove research.

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# CASTLE IRB NEWSLETTER

March 2022

Volume 2



## Melissa Fink

Director of  
IRB Operations

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## MESSAGE FROM THE DIRECTOR OF IRB OPERATIONS

Greetings Castle IRB Members! It is hard to believe that we are nearly a quarter into 2022 already. This issue, I wanted to share some metrics on full board operations, and to give you a glimpse into the goals we've set for full board review operations this year.

As you can see by the IRB Meeting Metrics table below, volume is increasing, and to meet turnaround time (TAT) commitments to our clients, half of the meetings convened in Quarter 1 of 2022 were moved to a non-standing day. Given this, Castle will be starting off Q2 with adding a second standing meeting a week. Thank you all for sharing your availability for the selected time: Fridays, 10am-12pm Central. Those who indicated availability, please begin holding that time on your calendar beginning in April; as usual, invitations to attend any given meeting will come a week in advance.

Due to the increase in volume, we'll also be looking at adding Vice Chair roles to the Castle IRB committee to help chair meetings. We'll also be introducing additional tools and training targeting increased efficiency in how we operate and consistency in our reviews. Hopefully all changes that make our roles clearer as we each have a unique set of expertise to bring to reviews (more from our Chair Stephanie on that, below).

The first efficiency initiative we are taking up is related to IRB Meeting Minutes, and with this we need your help! Castle IRB is aiming to shorten the timeline from IRB Meeting to finalized minutes to 3 weeks. To accomplish this, we must shorten the timeframe for IRB Member review of draft minutes to 3 business days and request signatures on the final draft within 2 business days. Thank you all for your help with this goal!

We are experiencing 100% client satisfaction right now, and our network is growing. We appreciate your flexibility and help in refining and improving our full board operations as we grow!

IRB Meeting Metrics	2021	Q1 2022
Average Meetings per Month	2/month	3/month
# of Meetings held Weds versus Other	83% Weds, 17% Other	50% Weds, 50% Other
Average # of Agenda Items per Mtg	2.5	3

# MEMBER CORNER

## Spotlight: Daniel Rastein

### How did you start your career in clinical research?

My career in clinical research actually started in 2005 with pre-clinical research when I was assigned to make the research department at Cedars-Sinai Medical Center, "GLP." I was familiar with GCP – Good Clinical Practice from the human side, but I had no idea what GLP was, especially when I showed up for work in the vivarium! As you can imagine, the sights, sounds and smells were very different than the main medical center. Although shocked at first, being an animal lover, I quickly fell in love with the extreme caring nature of the dedicated staff and all of the rules and regulations to protect and reduce harm to the most vulnerable of our society. I used this strong foundation every day in ethical discussion in clinical research to this day. I also still give lectures on GLP (FDA, Good Laboratory Practice) to the research community.

### If you could trade places with anyone for a day, who would it be and why?

If I can go back in time, instead of trading places, I would love to shadow, assist and learn from Mother Teresa. She would seek out and approach the poorest and sickest people living in the slums and say "I love you and want to take care of you." This unconditional love and service towards mankind is definitely something that I aspire to.

### What's something about you (a fun fact) that not many people know?

I am part of the James Beard Foundation and strongly support their programs called, "Good Food For Good" - for food sustainability, educational scholarships and support of restaurants and their workers through these challenging times.

### What is the weirdest food you have eaten (or a favorite food)?

Being a "foodie" and always adding new spices to my collection and exploring different cultures, I was invited to try "something different" by my Korean friends and neighbor. I rushed over to their house all excited. Once seated, they placed in front of me a giant jar filled to the rim with soy sauce with a unique smell, called Gejang. I was a bit confused until they reached inside and pulled out a big raw whole crab. They thought that I would be deterred, but I dove right in. It was tasty once you get over the texture of the raw crab meat which was a little gelatinous and slimy. They were surprised as evidently, according to them, it is a "more advance food."

