

President's Message

Michael Koren, MD, CPI, FAPCR

President, APCR



Thank you for the honor to serve as the President of the APCR Board of Trustees for the past year. I deeply appreciate the work of the Board and the many active members who have helped our organization get stronger. APCR pursues the unique mission - applicable to all medical specialties

- of serving and promoting members who participate in the various aspects of generating and disseminating evidence based medicine. In a world divided in so many ways, projecting the message of core principles that unite physicians across specialties can be challenging. Nonetheless, we have made great strides this year to bring together a wonderful group of physicians who care about the intellectual beauty and power of data driven decision-making. I feel privileged to have seen how a group of clinical investigators, pharmaceutical physicians, academics, consultants and folks with government backgrounds can work together harmoniously for the benefit of patients and our profession.

I hope as many of you as possible will join us at our [annual meeting](#) at the University of North Florida in Jacksonville on Nov 2nd and 3rd. For those of you who cannot attend, there will be a conference call available (866-200-5786; Conf. ID 5685316). Among the many items on our agenda, I will pass the torch of leadership to Dr. Cara East who will

serve as our next president. I could not be more excited about her ascension. Dr. East is a highly accomplished academic cardiologist. She will bring a leadership style of smarts and persistence that will serve APCR well.

We have set a busy agenda for our annual meeting and upcoming year. Items that Dr. East and the Board will tackle include starting new chapters of APCR for medical trainees and Latin American physicians. We also hope to launch an initiative for a service that matches studies with investigators. Stay tuned for details!

I will continue on the Board and help complete the work we have started addressing the conundrum of high drug prices. As you know, the cost of pharmaceuticals and other therapeutics has become a subject of intense public policy and political debate amongst many constituencies. APCR has identified this controversy as a topic for analysis and solution-based discussion. Over the past 18 months, we have discussed this issue at various meetings of our members and invitees. We will reveal a draft of a whitepaper, or as I like to call it, a physician "toolbox", on the topic at our annual meeting. With membership feedback, we will finalize the whitepaper by the end of the year. I hope that APCR's input into the conundrum of high drug prices will help as many patients as possible receive costly cutting-edge therapies at the best possible prices without damaging the enterprise that has so successfully produced the innovations.

Finally, please join me in congratulating the ten physicians who became Fellows of the Academy of Physicians in Clinical Research (FAPCR) this past year. Conferring candidates with such sterling credentials to enter the ranks of our Fellowship pleases me and fills me with confidence that our leadership as an organization and individuals will move forward medicine and public health.

Congratulations to the newest APCR Fellows:

- Edward Geary, MD, FAPCR
- Pablo Jimenez, MD, FAPCR
- Martin Kankam, MD, FAPCR
- Greg Koski, MD, FAPCR
- Marshall Nash, MD, FAPCR
- Nicholas Sarlis, MD, FAPCR
- Joseph Stauffer, DO, FAPCR
- Leonard Weather, MD, FAPCR
- Steven Weinstein, MD, FAPCR

APCR thanks CRN Clinical Research Network, LLC and its members for their support.



Membership Update

Renew Your APCR Membership Today!

Set the stage for a successful and productive 2019 by renewing your Academy of Physicians in Clinical Research (APCR) annual membership! Pay online today. It's fast, easy and safe!

Updating your profile is simple! Just follow these three steps:

- Go to apcrnet.org/profile
- Log in with your username and password
- Update your member profile

Stay Connected

APCR has an interactive website that incorporates many members-only features such as latest news and updates, member directory, career portal and more. You can also view your member account and keep your contact information up-to-date. Please feel free to email webmaster@apcr.net for assistance, or membership@apcr.net for login information.

Be sure to 'like' us on Facebook and follow us on Twitter and LinkedIn to stay up-to-date on important news and upcoming events.

Also, be sure to 'share' and 'retweet' our posts to share information with your friends, colleagues and patients!



facebook.com/AcademyPCR



twitter.com/AcademyPCR



linkedin.com/company/academy-of-physicians-in-clinical-research



More Membership Value Than Ever Before!

Career enhancement through discounted educational opportunities

- Exclusive industry job postings
- 30% discount to the latest clinical trials through SCRIIP
- Fellow designation opportunity
- Networking opportunities with industry professionals
- Discounted registration to annual meeting with opportunities to earn CME
- Be part of the collective voice for physicians in clinical research

apcrnet.org

Be sure to pay your MEMBERSHIP DUES to continue to receive all of these amazing benefits!

APCR
Academy of Physicians
in Clinical Research

Education Update

Gutting Drug Patents Puts Lives at Risk

The [National Review](#) recently published Peter Rheinstein, MD's op-ed explaining how proposed federal legislation could threaten the discovery of future cures. The Medicare Negotiation and Competitive Licensing Act would enable the government to allow competing pharmaceutical firms to copy medicines still under patent – without the patent-holder's consent. The threat of "compulsory licenses" would be a tool to force drug manufacturers to agree to lower their prices to whatever level the government considers reasonable.

Dr. Rheinstein's op-ed describes his

own experience developing cancer diagnostics and therapeutics. He worked at one of the many startups made possible by the Bayh-Dole Act. This 1980 law allows scientists initially funded by government grants to retain rights to the intellectual property they create. They can then use those rights to obtain funding for the clinical research necessary to bring their inventions from bench to bedside.

Dr. Rheinstein reminds us that securing investor funding for new drug research is a competitive process. Any possible investment – not just in the health and medical fields – that could yield a greater return threatens drug discovery. The threat of "compulsory licenses" reduces

the potential return from investment in that research.

APCR's upcoming Annual Meeting includes a comprehensive look at drug pricing issues. Assuring a fair price for producers and consumers, as well as other stakeholders, underpins not only America's ability to make drugs available to patients today, but also America's continued ability to make drugs available for the diseases of tomorrow.

The op-ed may be viewed at <https://www.nationalreview.com/2018/10/gutting-drug-patents-puts-lives-at-risk>. Dr. Rheinstein is an APCR Board Member and Past President. He represents APCR in the American Medical Association House of Delegates.

APCR Members First to Pilot New Educational Offerings

APCR announced a new collaboration with AudioEducatе and Rockpointe earlier this year. The pilot programs discuss the origins of medical ethics, regulations of informed consent and best practices for implementation in research practices.

Accessing the programs is as easy as using any other Alexa skill through Amazon or an app on your smartphone or tablet.

The activities were designed to be both quick and convenient to learners who like on demand technology and

want to access education at their convenience. What is different about the AudioEducatе platform from a standard podcast, webcast or online program is that Alexa interacts with you during the activity.

APCR President, Dr. Michael Koren said "I'm excited to have participated in this collaboration with AudioEducatе. This platform will enable our organization to deliver important educational content to our members and position APCR to be a leader with this new technology."

For more information about accessing these programs, contact us at audioeducate@apcrnet.org.

Updates in Advocacy

APCR would like to remind its membership that Resolutions and Reports submitted for the November House of Delegates meeting are posted online at <https://www.ama-assn.org/about/business-ama-house-delegates-2018-interim-meeting>. The AMA updates these postings as new items are received.

APCR members may be interested in reviewing Resolution 901 – Support for Preregistration in Biomedical Research. The Resolution, from the Medical Student Section, seeks AMA support to require pre-registration of clinical trials in order

to mitigate publication bias and improve the reproducibility of biomedical research. Some of the information that the Resolution seeks is available at <https://clinicaltrials.gov> and most medical journals will not publish results from clinical trials that have not been preregistered (<http://www.icmje.org/about-icmje/faqs/clinical-trials-registration>).

Preregistration of trials is also required by the Food and Drug Administration Amendments Act of 2007. To stay informed of APCR advocacy efforts and issues impacting clinical research, visit apcrnet.org.

Member Spotlight



Dr. Greg Koski, PhD, MD, discusses career influences, the rewards of clinical research and the benefits of being part of the Academy of Physicians in Clinical Research

What is your current role?

I am the CEO and Co-founder of Alliance for Clinical Research Excellence and Safety (ACRES).

What is the best part of your occupation?

I get to work with people all over the world who are committed to achieving excellence in clinical research.

How did you become interested in clinical research?

When I was a kid my grandmother came down with an untreatable brain tumor and they offered her an opportunity to participate in a clinical trial. She did not survive, but she had a period of 6 months of lucidity where she got to say goodbye to friends and loved ones. I was impressed that through research there was an opportunity to improve the lives of people. I was hooked at that point. I have been involved in research in some way since I was a junior in high school.

How did you become involved with the APCR?

In 2001, when I was the Director of the Office for Human Research Protections (OHRP), I was approached by several groups who were interested in extending certification to principal investigators. These organizations included ACRP, AAPP, and DIA. As the director of OHRP I felt strongly about the professional certification of investigators, so I encouraged their efforts. I worked with the three organizations over a period of 5 years to come together and create APPI, that was aligned with ACRP. They worked together for several years and then APCR was formed as the successor. I was involved in every step along the way and am proud that I was able to do so.

Explain how you benefit from being a member and/or fellow of the APCR.

Being a member of APCR provides an opportunity for me to represent the organization and its goals in a variety of settings around the world that foster greater acceptance, and awareness, of clinical research. This is a needed step forward to establish the quality of clinical research and the needed role of the physician investigator.

What would you like to see occur in the field of clinical research (i.e., scientific advances, greater awareness of the field, etc.) during your career?

For the last 9 years ACRES, along with 150 strategic allies around the world, have been working on an integrated system for improving

quality, safety and efficiency in the conduct of clinical research and ways to apply the knowledge gained more effectively in improving healthcare and quality of life for everyone. I want to see this work come to a fruitful conclusion in the interest of people all over the world.

What are your hobbies outside of the office?

I am an avid sailor. Three years ago, I bought my current vessel the Veneeni (a Lord Nelson 41 Blue Water Cruiser) that I will be sailing all over the world. When I am on land I will be pursuing my other hobbies of hiking, backpacking, cycling and eating good food.

What is something surprising that most people do not know about you?

I am pretty open person, but what many don't know is if I had pursued another career path, or taken the opportunity, I would have been a musician. I look forward to pursuing this interest and becoming a singer/songwriter in the vein of Kris Kristofferson.

Is there anything else you would like to mention?

It has been an extraordinary experience to meet people from every aspect of the clinical research field, including people from healthcare, ethics and regulatory areas. This includes the sponsors, CRO's and all the various vendors I have met during this decade of systems building that is now coming to a successful conclusion. I have met extraordinary people, and my life has been blessed to be part of this.