

From: CDER Center Director

Sent: Monday, September 22, 2014 12:22 PM

To: FDA-CDER-wide

Subject: Bob Rappaport to Receive 2015 John and Emma Bonica Public Service Award;
Retiring after 20 Years of Service

Importance: High

CDER Staff:

I am delighted to inform you that Bob Rappaport, M.D., will receive the 2015 John and Emma Bonica Public Service Award.

Given annually by the American Pain Society (APS), this award honors outstanding contributions to the field of pain through public education, public service, and other efforts to further knowledge about pain. The award is named for the late John Bonica, who was an anesthesiologist and a leading force in the pain treatment movement, and his wife, Emma.

As director of the Division of Anesthesia, Analgesia, and Addiction Products (DAAAP), Office of New Drugs, Bob leads a large team to oversee the investigation, development, approval, continued safety, and safe use of drug products to treat pain and addiction disorders, as well as drug products used in the setting of clinical anesthesia.

His significant contributions have made a positive impact that will benefit many people for years to come. Just last year, Bob received the Agency's Lifetime Achievement Award for his contributions to the anesthesia, analgesia, and addiction fields by accelerating the discovery and development of new drugs with improved efficacy and safety. Bob has demonstrated a superior and enduring commitment to these fields, the Agency, and public health.

The John and Emma Bonica Public Service award will be presented to Bob on May 14, 2015 at the APS 34th Annual Scientific Meeting.

Please join me in extending congratulations to Bob for this well-deserved honor!

Retirement

Bob's latest award is coming at an opportune time. After 20 years of dedicated service to FDA and the American public, Bob will retire on September 30.

Prior to joining FDA, he was on faculty at the George Washington University School of Medicine and Health Sciences. Bob came to FDA in 1994 as a medical officer in the former Division of Neuropharmacologic Drug Products. After three years, he joined the Division of Anesthetics, Critical Care, and Addiction Drug Products as a team leader before becoming director of the current DAAAP 11 years ago. Bob is board certified in neurology and sleep medicine.

As the director overseeing addiction product review, Bob has been a powerful force driving innovation and important initiatives. He has also faced many challenges, most significantly in the area of opioid drug products. Opioids are powerful drugs that can provide significant relief when prescribed appropriately for people in pain. They also pose a risk of abuse, misuse, and overdose. Bob and his staff have worked diligently over the past decade to balance these two competing concerns, taking to heart the diverse opinions and strong feelings on both sides.

As part of this work, they have:

- Partnered with other federal agencies and the White House's Office of National Drug Control Policy
- Increased and clarified the warning information contained in the opioid class labels
- Created the Extended-release and Long-acting (ER/LA) Opioids Risk Evaluation and Mitigation Strategy, which took about three years, working with many different offices within FDA
- Held multiple public meetings to hear from diverse stakeholders
- Developed studies to better understand how effective and safe opioids are in long-term use in order to expand the limited amount of data available beyond 12 weeks of use
- Continued efforts to encourage and assist in the development of abuse-deterrent opioid formulations, including writing the recently published draft guidance for industry in collaboration with the Office of Surveillance and Epidemiology, the Controlled Substances Staff, the Office of Regulatory Policy, the Office of the Chief Council, and the Center Director's Office

Other Partnerships and Developments

Another challenge Bob faced as DAAAP director was the need for refined drug development pathways for the drugs in DAAAP. As a result of a history of organizational changes in the area of pain drugs, he and his staff sought a better understanding of what the right trial design should be for efficacy for these drug classes.

To improve the way these drugs are developed and to make new products in these classes available sooner, Bob is credited for implementing Analgesic, Anesthetic, and Addiction Clinical Trial Translations, Innovations, Opportunities, and Networks ([ACTTION](#)) – a public-private partnership under the Agency's Critical Path Initiative. ACTTION was initially created to advance the field of analgesic clinical trial design, but has since been expanded to include sedation, addiction, and peripheral neuropathy.

Bob also led the development of another public-private partnership, also under the Critical Path Initiative, to address the concerns regarding the neurotoxicity seen in juvenile animals, including

primates, exposed to general anesthetics and sedation drugs. As there is still uncertainty regarding risk to children who are exposed to these drugs, Bob led the creation of the public-private partnership called [SmartTots](#). This partnership brings together thought leaders who can do the research needed to understand the risk for children and to raise the money needed to do this research.

In addition, Bob and his staff completed a draft guidance for industry on the development of analgesic drug products, a significant challenge that required they not only learn how to develop and study analgesic drugs, but also work to understand related issues such as abuse liability, pediatric pain, and analgesic treatment – and how to address them.

Lasting Legacy

Many of us came to depend on and deeply value Bob's leadership, knowledge, and insight. He has served the Agency with distinction and professionalism. Bob leaves with us two decades of committed service that reflect his passion for serving others and for having the best interest of patients at heart. It's easy to see that he puts others first and has not backed down in his commitment to provide safe and effective medicines to those who need them.

His work in the areas of anesthesia, analgesia, and addiction drug review will continue to make a lasting impact at FDA. I am certain he will be remembered here and spoken of with respect, admiration, and gratitude for all that he has done. Please join me in wishing Bob a warm farewell as he looks forward to enjoying retirement.

With Bob's departure, Sharon Hertz will serve as acting director, DAAAP.

Janet Woodcock