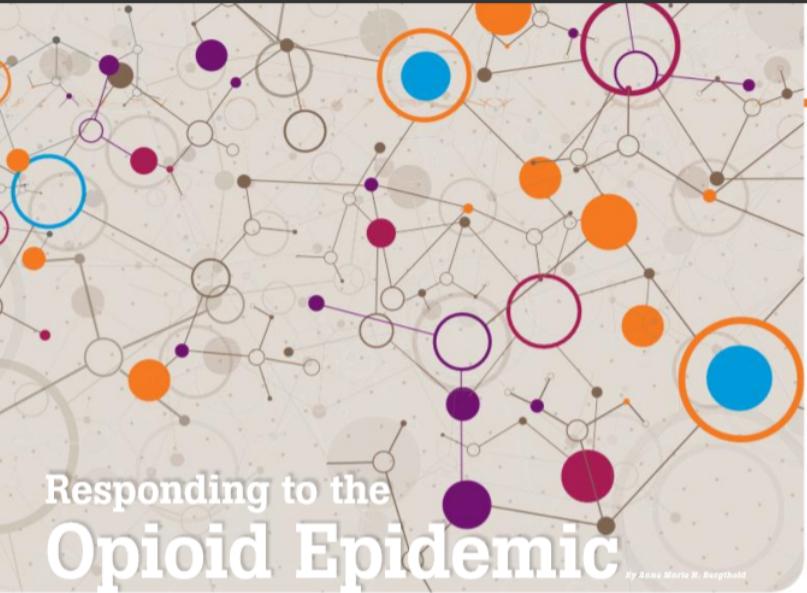


UPDATE:

Since this just-published article was researched by editorial staff at **University of the Pacific's Thomas J. Long School of Pharmacy and Health** for **INTERACTIONS** magazine, the California Health Care Foundation has awarded a second opioid grant to Health Plan of San Joaquin (HPSJ) and local partners San Joaquin General Hospital and Community Medical Centers, this time for implementation.

Please see below, "From the Perspective of a Health Care Provider," for comments by HPSJ Clinical Pharmacist **Kristen Tokunaga**, UOP 2015, PharmD.

"Responding to the Opioid Epidemic" (University of the Pacific - INTERACTIONS Magazine, Feb. 2017): https://issuu.com/pacific_pahs/docs/interactions_2016 → pages 10-11



Responding to the Opioid Epidemic

By Anne Marie W. Berghoff

From the Perspective of a Pharmaceutical Scientist

In May 2016, the Food and Drug Administration (FDA) announced it had approved Probuphine, the first implantable drug to deliver long-lasting medication to treat opioid dependency. "I invented it; I initially came up with the idea," said **Rajesh "Raj" Patel '87**, PhD, vice president of manufacturing and process development at Titan Pharmaceuticals, based in South San Francisco. Speaking with pride and gratitude, Dr. Patel shares that he had the opportunity to be involved in the complete development cycle.

"There are very few people who get the opportunity to take their patents to the market," Dr. Patel said. "I was lucky enough to work on my patent all the way from the beginning up to production. I worked with different teams on pre-clinical studies, clinical studies, regulatory filings and the approval process. I was also involved in setting up the manufacturing."

Recipients of Probuphine will have four matchstick-sized rods containing the drug inserted into their upper arm. The rods are removed after the six-month treatment period. If required, additional implants are administered for another six months. At this time, in order to determine the correct dosage for the individual, patients start the course of treatment in tablet form. Dr. Patel asserts that implantable drugs are changing the treatment paradigm. There are several clear advantages to having this drug available in implantable form, including that the drug cannot be resold illegally or accidentally ingested. Additionally, by making the drug implantable, patients cannot intentionally or unintentionally deviate from the treatment plan for six months. "We anticipate it will reduce the relapse rate," Dr. Patel said. "The FDA believes it is going to help patients get control of their lives. They don't have to make a daily decision. They know that they are committed to the treatment plan."

Dr. Patel strongly urges health care providers and pharmacists to discuss the risks of taking an opioid with their patients. "People need to start understanding that this is an epidemic," Dr. Patel said. "Without everyone's help and support we can't

get this epidemic under control." He believes that health care providers should emphasize that these pain killers should only be used sparingly. His advice is to tell patients to only take this medication when they really need it.

While a student at Pacific, Dr. Patel was a graduate assistant to **Ravindra Vasavada**, PhD, professor emeritus of pharmaceuticals. Dr. Patel explains that Dr. Vasavada challenged his graduate students to pursue research that they were passionate about and to think outside the box. "He encouraged students to go out and find a project that they were interested in," Dr. Patel said. It was this mindset of challenging the status quo when approaching the development of pharmaceuticals that set Dr. Patel on the path to developing Probuphine. Dr. Patel started working on the development of an implantable drug to combat opioid dependency in tablet form had been approved in Europe, but was not available in the United States until 2003 when a similar drug was approved by the FDA. Without Dr. Patel's forward thinking and innovative approach to research, which was fostered at Pacific, Probuphine would not be available today.

Dr. Vasavada congratulated his former student. "You have made a magnificent and timely invention," Dr. Vasavada said. "The enormity and scope of this achievement will sink in only gradually. As you already know, opioid addiction has reached epidemic proportions. Your invention will provide a meaningful option for the first time to those patients and an incalculable benefit to society as a whole. I am so happy your hard work and patience have paid off."

From the Perspective of a Pharmacist Attorney

The dramatic increase in opioid dependency has captured the attention of both health care professionals and lawmakers. "Efforts by lawmakers come down to decreasing the supply side and decreasing access to opioids in general," said **Tony J. Park '86**, PharmD, JD. As of July 1, 2016, it is mandatory for all health care practitioners to register for access to the Controlled Substance Utilization Review and Evaluation System (CURES 2.D), California's Prescription Drug Monitoring Program, which is overseen by the California Department of Justice. He believes that adherence to the legislation concerning the utilization of CURES will result in a dramatic decrease in the number of controlled substances that are dispensed in California.

Although pharmacists are not mandated by statute or regulation to review a patient's CURES report before dispensing a prescription, there are strong incentives for pharmacists to do so. According to Dr. Park, the California State Board

By the Numbers

In "Current State of Opioid Therapy and Abuse," **Laxmaiah Manchikanti, MD, Adam M. Kaye '95, PharmD, FASCP, FCPA** and **Alan D. Kaye, MD, PhD, DABA, DABPM, DABIPP**, share the sobering statistics which underscore the prevalence of opioid abuse in the United States.

4,680% Increase of opioid misuse between 1996 and 2011	80% Up to 80 percent of heroin users first took prescription opioids
28,647 Number of deaths involving opioids in 2014 (triple the number in 2000) and representing 61 percent of all drug overdose deaths	\$86 billion Estimated total cost of prescription opioid abuse in the United States including workplace, health care and criminal justice expenditures
90% More than 90 percent of patients who receive a prescription opioid overdose continue to be prescribed opioids, usually by the same prescriber	

Red Flags of Opioid Abuse

Tony J. Park '86, PharmD, JD strongly recommends that pharmacists review the guidelines outlined in the case summary of Board of Pharmacy Case No. 38022 "In the Matter of the Accusation Against Pacific Pharmacy, Thang Tran" for practical advice on how they can identify patients who have become dependent on opioids. Red flags may include:

- Irregularities on the face of the prescription
- Nervous patient demeanor
- Age or presentation of patient (e.g., youthful patients seeking chronic pain medication)
- Cash payments
- Requests for early refills of prescription
- Prescriptions written for an unusually large quantity of drugs
- Prescriptions written for potentially duplicative drugs
- Initial prescriptions written for stronger opiates (e.g., OxyContin 80mg)
- Long distances traveled from the patient's home to the prescriber's office or pharmacy
- Prescriptions that are written outside of the prescriber's medical specialty
- Prescriptions for medications with no logical connection to diagnosis or treatment

of Pharmacy set legal precedent in 2013¹ that now requires pharmacists to conduct a reasonable inquiry in the presence of certain red flag indicators suggesting that a controlled substance prescription may not have been ordered pursuant to a legitimate medical purpose. Checking CURES is one such measure. Dr. Park explains that failure to conduct a reasonable inquiry could result in the pharmacist violating their corresponding responsibility before dispensing a controlled substance, as well as an agency determination of unprofessional conduct, and even civil tort negligence. "I believe reviewing CURES data has now become a standard of practice," Dr. Park said. He believes the Board views CURES as a crucial component of due diligence that should be standard operating procedure before dispensing any controlled substances.

Pharmacists can also utilize CURES to protect their licenses. It can be used as a record to corroborate that they met their corresponding responsibility and performed the requisite reasonable inquiry before dispensing a controlled substance. For example, a pharmacist can attach a printed record of a patient's CURES report to the dispensing record to show that they performed a reasonable inquiry in the presence of certain red flags and that their decision to dispense the controlled substance was based upon the contents of the CURES report available at the time of dispensing².

Dr. Park emphasizes that the only way to turn the tide of the opioid epidemic is through interdisciplinary collaboration. Lawmakers, patients, pharmacists and other health care

professionals must all work together. He notes that while lawmakers can take steps to limit the availability of prescription opioids, it is critical that health care professionals redefine the way Americans think about prescription opioids.

¹ www.pharmacy.ca.gov/enforcement/prescribedental
² According to Dr. Park, there is a lag time between any given controlled substance dispensing activity and its appearance on CURES, which can vary from a few days to a few weeks.

From the Perspective of a Health Care Provider

Improved coordination of standardized care following best practices will prevent inappropriate "doctor shopping" and minimize access to unsafe doses of opioids."

To help curb this growing epidemic, pharmacists and other health care providers must educate themselves on ways they can identify, respond to and prevent opioid dependency. "We are now actively promoting clinician education on safe prescribing practices, including discouraging initiation of chronic high-dose opioids, encouraging regular use of drug monitoring tools such as Controlled Substance Utilization Review and Evaluation System and providing training for medication-assisted treatment for addiction, as well as overdose management," Dr. Tokunaga said. She believes that pharmacists have a responsibility to ensure that patients are well-informed. "We must take the extra time to counsel our patients on the potential risks," she said. "No matter where you are in your education or career, it is never too early or too late to learn about how you can help with the opioid crisis. It will literally take a village to end this epidemic. Both health care providers and community providers have a role and responsibility to contribute."

Have you been prescribed an opioid?

Recommendations from a Pharmacist

"Discuss in detail the risks and benefits with your provider before starting opioids. If you both decide on the need to use opioids, make sure to learn thoroughly when and how to use them, when not to use them and reasons why you should use them as sparingly as possible. In many cases, using the lowest effective dose for the shortest amount of time is a good rule to keep in mind."

- **Kristen Tokunaga '15**, PharmD, clinical pharmacist

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