From the Editor: OPIOIDS AND US: Designed to fail

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AIDS, the Vietnam War, whatever your preferred scale for measuring horrific events, the numbers from the opioid crisis are as grave or worse. And, once again, it is the young who are dying. How we got to this point is an unbelievable story of corporate greed, government incompetence, regulatory commission overreach, and, unfortunately, physician ignorance.

Every one of us has contributed to this tragedy, and most of us still do. There are some easy first steps surgeons can take, but first let’s review the mistakes made that drove our country into addiction.

In 1995, as their patent on MS Contin was set to expire, Purdue Pharma gained Food and Drug Administration approval for OxyContin (“contin” is pharma talk for continuous). At this time, opioids generally were considered to be dangerous and mainly prescribed for cancer or end-of-life patients. Purdue representatives began an aggressive marketing campaign to break out of this niche. They were aided in this pursuit by the FDA, which wrote in the package insert that iatrogenic addiction was rare and the delayed absorption of OxyContin “is believed to reduce the abuse liability of a drug.” These statements were made without the backing of any clinical trials. But with an on-label statement of reduced addiction risk, representatives could sell OxyContin based on a diminished potential for abuse.

In addition to oncologists, the drug was now marketed to rheumatologists, primary care physicians, and surgeons. OxyContin, therefore, broke through the cancer barrier and became one of the most widely prescribed painkillers in the United States. While generating billions in profits, OxyContin also would become one of the most abused drugs in history.

There were several issues with OxyContin that led to its widespread misuse. The preparation contained up to 160 mg of oxycodone per pill, 16 times more than the strongest Percocet formulary. The tablet also could easily be crushed, overcoming the delayed-release formulation. Because of the FDA insert, sales representatives were free to report an addiction risk of less than 1%, which they did. Widely.

But what science backed this claim? The study referenced was not a study at all. The citation was a one-paragraph, five-sentence letter to the editor published by the New England Journal of Medicine in 1980. In it, the authors briefly described their experience with inpatient opioid therapy. No reference was made to outpatient opioid prescriptions. Still, this letter has been scientifically cited more than 600 times, with a spike starting in 1995, the year OxyContin was released. Even as thousands of Americans were dying each year from opioid use, the “study” continued to be offered.
as proof of a low risk of addiction. As recently as 2014, the letter was cited in the journal OncoTargets and Therapy to support the statement, “In reality, medical opioid addiction is very rare.”

Maybe if we knew our history we could avoid repeating it. Previously, the drug diacetylmorphine was introduced as a safe, nonaddictive substitute for morphine by Bayer Pharmaceutical in the late 1890s. Diacetylmorphine is better known by its trademarked name, Heroin.

In 1996, the American Pain Society and the American Academy of Pain Medicine formed a committee to issue a joint statement that advocated opioid use for chronic pain and again stating a low risk of addiction. The committee was chaired by J. David Haddox, DDS, MD, a paid speaker (and later executive) for Purdue Pharma. The American Pain Society also launched a campaign to treat pain more aggressively. “Pain is the fifth vital sign” became a far-reaching strategy, which was adopted by the Department of Veterans Affairs and, ultimately, nearly every hospital in the country. The campaign was so successful that, in 2001, the Joint Commission required hospitals to:

- Assess pain in every patient.
- Record the results.
- Provide treatment for the pain.
- Reassess the effectiveness of the treatment.
- Teach staff how to manage pain.

The Joint Commission is not alone in creating opioid-friendly regulations. The Hospital Consumer Assessment of Healthcare Providers and Systems surveys patients after hospital stays. Several of the questions include pain management. One asks the patient whether the hospital staff did “everything they could” to assist with the patient’s pain. The satisfaction scores from these surveys are directly tied to hospital payments.

In 1998, the Federation of State Medical Boards published a statement reassuring doctors that they would not be punished for prescribing even large amounts of opioids if it were in the course of medical treatment. In 2004, the FSMB went further, stating that medical boards should consider “undertreatment of pain” to be a “departure from an acceptable standard of practice,” suggesting that state medical boards should sanction doctors who undertreated pain. According to a report by Catan et al. in the Wall Street Journal, this policy was drawn up with help from Dr. Haddox, who is now a senior executive with Purdue. The FSMB also would later disclose nearly $2 million in funding from opioid manufacturers.

These regulatory groups created widespread legal and financial pressure for doctors to diagnose and quickly treat pain in every patient. But what resources did we have to do this swiftly and effectively? Opioid prescriptions soared. There were 116 million opioid prescriptions issued in 1999; by 2013, it was 207 million. Annually, there are now more opioid prescriptions filled in the United States than there are people. Overdose deaths rose 500% between 1999 and 2016. Last year, there were more than 42,000 opioid-related mortalities in the United States. Like an untended fire, the crisis now spreads unabated.

What about vascular surgeons? Few of us prescribe OxyContin. Surely the 30 Percocets we give out after surgery are safe? In reality, Percocet contains oxycodone, the same opioid found in OxyContin, and therefore, carries a high risk of addiction. Norco, Vicodin, and Lortab all contain the opioid hydrocodone. Some studies have shown a higher risk of addiction with oxycodone, but all opioids carry a significant danger of abuse and dependence. As surgeons, we came into this crisis with little or no training. This made us susceptible to bad science, bad-faith marketing, and bad ideas from regulatory commissions. Most of us learned how to prescribe postop opioids during the “hidden curriculum” of our third and fourth years of medical school: In other words, the residents taught us. Much like learning sex education on the streets, your mileage may vary. It is no wonder that a 2016 JAMA Internal Medicine news release found that simply having surgery was a risk factor for developing an opioid addiction. Surgeons don’t have an evidence-based plan to treat postoperative pain with opioids. About 6.5% of patients are still taking “postop” opioids 3-6 months after minor surgery; the numbers are about the same for major surgery (5.9%). Therefore, it is unlikely that pain is driving this chronic use.

Richard J. Barth Jr., MD, of Dartmouth-Hitchcock Medical Center in Lebanon, N.H., has studied opioid use following
surgery extensively. He found there is a wide variety in surgeons’ opioid-prescribing habits and most of us overprescribe. In one study, 72% of the prescribed pills after surgery were not taken. He recommends the following guideline for opioid prescriptions after inpatient surgical procedures: If the patient took no opioids the day before discharge, no script is needed. For patients taking 1-3 pills the day before discharge, 15 pills are given; and for those taking 4 or more pills, a script for 30 is given.

As vascular surgeons, we must break out of our bubble and address our contributions to this crisis. It is past time to look at our own habits. Overprescribing is dangerous; the excess pills often are found by abusers, sold, or used recreationally by others in the household. Some patients take all of the pills simply because that is what the doctor prescribed; to the patient, he or she is merely following the doctor’s orders, and therefore not engaging in a risky behavior.

As vascular surgeons, there are several steps we can take immediately to reduce our contributions to the opioid epidemic and protect our patients:

- Always use the lowest effective dose of opioids and dramatically reduce the number of pills in your postop scripts. Fewer than 15 pills will cover most surgeries we perform.
- New data show that acetaminophen combined with ibuprofen works better for acute pain than acetaminophen combined with an opioid. Increase your use of nonnarcotic pain medications.
- Counsel your patients on the risk of addiction. If you plan to issue a script with only a few pills or nonnarcotics, let them know why in advance.
- Use caution when prescribing opioids to patients with anxiety or depression. The risk of addiction is much higher in these patients because of the anxiolytic and antidepressant qualities that opioids have.
- Avoid opioids in patients taking benzodiazepines, which can exacerbate the risk of respiratory depression and death.
- Help patients safely dispose of unused opioids.
- Use drug-monitoring programs whenever available.
- Use opioids for acute pain only. We do not have the training to manage long-term use.

Meanwhile, OxyContin still is available and sold exclusively by Purdue Pharma. Before its patent expired, Purdue altered the formulation to make it harder to abuse when crushing the tablets. They then lobbied the FDA to block generic production of the original formula because it was “unsafe.” Though Purdue (under Mundipharma) now markets this original version in South America, Europe, and Asia.

Many lawsuits have been brought against Purdue. Even with such high-profile lawyers as Rudy Giuliani and Eric Holder, Purdue has paid more than $600 million in fines and pleaded guilty to marketing OxyContin with “the intent to defraud or mislead.” Three Purdue executives have pleaded guilty to criminal misdemeanor charges.

In 2015, the FDA approved marketing OxyContin to children as young as age 11 years.

To address their role in the opioid crisis, the Joint Commission issued a statement on April 18, 2016. It was not a master class in self-awareness; the statement claimed that it is a “misconception” that Joint Commission standards pushed doctors to prescribe opioids. Yet, according to a Class Action complaint (Kenova v. JCAHO), in a 2001 monograph published by the Joint Commission (and funded by Purdue Pharma), they wrote “Some clinicians have inaccurate and exaggerated concerns about addiction, tolerance, and risk of death. This attitude prevails despite the fact that there is no evidence that addiction is a significant issue when persons are given opioids for pain control.”

In 2016, the AMA passed a resolution to drop pain as a vital sign. They also urged the Joint Commission to stop requiring hospitals to ask patients about the quality of their pain care. The American College of Surgeons has started an education initiative to help surgeons and patients learn about opioids and surgery (funded by Pacira Pharmaceuticals, makers of EXPAREL, an injectable long-lasting local anesthetic). In a March 2016 statement in the New England Journal of Medicine, Centers for Disease Control and Prevention representatives said of opioids “We know of no other medication routinely used for a nonfatal condition that kills patients so frequently.” As vascular surgeons, we are long overdue for a self-assessment. It is now time to change our practices and habits to help end this
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national addiction. 

Resources

5. www.jointcommission.org/joint_commission_statement_on_pain_management

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