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American Society of Anesthesiologists

Volume 85 ■ Number 3 ■ March 2021
asamonitor.org

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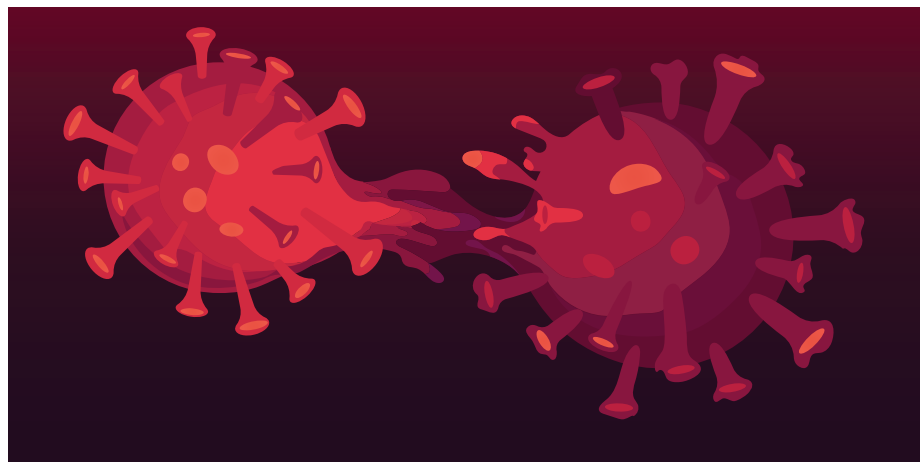
The Emerging Threat of SARS-CoV-2 Variants



Richard Simoneaux **Steven L. Shafer, MD**
Editor-in-Chief

The progress of SARS-CoV-2 has been marked by the emergence of several different genetic variants. In a recent Viewpoint article in JAMA, Lauring and Hodcroft discuss the history and background of SARS-CoV-2 variants (JAMA January 2021).

Many variants substitute one amino acid for another in the "spike protein" – the spike on the outside of the virus that makes it look like a WWII underwater mine. These variants are typically named by the substitution, using single letter names for the amino acids. For example, the SARS-CoV-2 variant D614G substitutes glycine (G) for aspartate (D) in position 614. The D614G variant emerged last spring, simultaneously appearing across several geographic regions. Rapid spread is strong evidence of a survival advantage, such as greater infectiousness, ability to evade antibodies, or reduced lethality. In the case of D614G, the primary benefit was a substantial increase in infectiousness (*Science* 2020;370:1464-8).

In early November 2020, outbreaks of COVID-19 associated with mink farms were observed in the Netherlands and Denmark. Among the mutations noted there were many instances of isolated sequences having a Y453F mutation (tyrosine replaced by phenylalanine at position 453) in the receptor-binding domain (RBD) of the spike protein. This variant helps the virus escape neutralizing antibodies (*bioRxiv* November 2020). It has since spread to patients in

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Exploring the Purdue Pharma Settlement and the Opioid Epidemic

Gordon Glantz

With lawsuits piling up against drug companies believed complicit in the opioid crisis, a major precedent was set in November 2020 when Purdue Pharma was ordered to pay an $8.3 billion settlement.

The order from Judge Robert Drain, who described the ruling as a "critical building block" to resolve mounting lawsuits against the company, capped off a federal investigation of programs that offered incentives to physicians and an electronic health records company for driving opioid prescriptions.

Purdue Pharma – owned by the Sackler family since 1952 (when it was known as Purdue-Frederick) – agreed to plead guilty to three felony criminal counts of wrongdoing.

According to The Washington Post, Purdue – with headquarters in Stamford,

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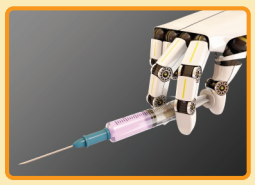

SPECIAL SECTION

Our Future: Deskilled or Super-Skilled? 23-27

Guest Editor: Uday Jain, BSEE, MD, PhD, FASA

Reducing Postoperative Delirium with Intraoperative Processed EEG

Jacqueline M. Leung, MD, MPH **Daniel J. Cole, MD, FASA**

Postoperative delirium is a geriatric syndrome associated with prolonged hospital length of stay and worsened functional and cognitive status after hospital discharge. Despite its prevalence, its pathophysiology is incompletely understood. Delirium is a complex interplay between patient vulnerability and precipitating factors. Although surgery is not a prerequisite for the occurrence of delirium, the prevalence of postoperative delirium after major surgery in the older patients is high, ranging from 10%-60% (*Psychiatr Clin North Am* 1996;19:429-48). Understanding the pathophysiology of postoperative delirium may also lend insight into revealing the mechanism underlying neurodegeneration such as Alzheimer's Disease, as postoperative delirium typically occurs in patients with prior cognitive impairment.

Given the powerful effects of general anesthetics on the brain and the numerous medications surgical patients are exposed to during and after surgery, some have hypothesized that anesthetics may be toxic to the brain, manifested as adverse postoperative cognitive changes, including delirium. Specifically, are we often "overdosing" our patients and unnecessarily exposing them to the potential adverse effects of general anesthetics?

Recent advances in anesthesia research have focused on neurotoxicity and neu-

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PERIODICALS

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Purdue Pharma

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Connecticut – has earned more than $30 billion since the opioid OxyContin arrived on the market in 1996.

Moreover, according to reports, a congressional panel zeroed in on the profits made by the Sackler family during the opioid crisis, noting that the family withdrew more than $10 billion from the company.

David and Kathe Sackler are descendants of two of the three Sackler brothers who originally bought the company.

With the knowledge that individual family members could still face charges, David Sackler offered this on December 17, 2020:

"I want to express my family's deep sadness about the opioid crisis. OxyContin is a medicine that Purdue intended to help people, and it has helped and continues to help millions of Americans."

The Sacklers faced heated questioning from the House Oversight Committee about how much they knew about the addictive nature of opioids when they encouraged sales of the company's blockbuster drug OxyContin. Purdue chief executive Craig Landau also testified.

The proceedings were held virtually due to the coronavirus pandemic. To put the issue in perspective, the death toll from COVID-19 is expected to reach 400,000 by the end of January. The opioid crisis, by comparison, has claimed the lives of an estimated 450,000 in the last two decades, approximately one in every 700 Americans.

"I have tried to figure out if there's anything I could have done differently knowing what I knew then, not what I know now," Kathe Sackler responded when asked about any feelings of remorse. "I have to say there is nothing I can find that I would have done differently."

As part of the settlement deal, the Sacklers proposed reorganizing Purdue Pharma as a public trust, which would redirect future profits to funding drug rehabilitation and other addiction-related recovery programs. Some members of Congress have strongly objected to this measure, preferring instead for the business to be shut down.

Reda Tolba, MD

Reda Tolba, MD, the Chairman of the Pain Management Department of the Cleveland Clinic in Abu Dhabi, was among the experts *ASA Monitor* queried for input on both the Purdue Pharma settlement and the ongoing crisis.

Gordon Glantz is a contributing writer.

"Both physicians and pharmaceutical companies have a shared responsibility to deliver safe and effective products to patients," said Dr. Tolba. "There remains a subset of patients who succeed with opioids, but this is certainly not the majority who present to my practice."

"Complications with analgesic therapies have heightened our attention to ensuring we are delivering safe and effective therapeutics to patients with challenging pain diagnoses," continued Dr. Tolba.

Vanila M. Singh, MD, MACM

To dig deeper into this complicated situation, the *ASA Monitor* spoke with Vanila M. Singh, MD, MACM, an Associate Professor of Anesthesiology, Perioperative and Pain Medicine at Stanford University. Dr. Singh was CMO to the Office of the Assistant Secretary for Health at the U.S. Department of Health and Human Services Medical from 2017 through 2019. She has also formerly held the positions of Chairperson of the Best Practices Inter-Agency Pain Management Task Force from the CARA act of 2016 and Acting Regional Health Administrator for the western United States. Dr. Singh is also the Vice Chairperson of the National Physicians Council and was a 2014 candidate for the U.S. House of Representatives.

ASA Monitor: Is the public trust solution going far enough?

Dr. Singh: "I will defer to the judge and other stakeholders on the case of the Purdue Pharma settlement. I do, however, remain concerned about the negative impact that Purdue's actions have had on the medical use of opioids in general."

Dr. Singh pointed to the "big hit" that legal opioids have taken, causing a ripple effect with patients forced off medications because of what she described as "the big pendulum swinging from one extreme to another."

"What is truly needed in the clinical environment, when it comes to pain medicine, is a nuanced understanding of an individual patient's needs rather than blanket statements made of all patients," she said. "Risk assessment of a certain clinical situation is vital, as people differ in their own medical conditions and in how they respond to a treatment due to different environmental and biopsychosocial aspects of their care."

Dr. Singh believes these safeguards need to be in place to identify those who are not good candidates for opioids or other treatments, as it is "a major part of what clinical medicine is all about," as opposed to a "one-size-fits-all" approach that lacks thought and understanding.

She concluded: "Stakeholders who are intent on the punitive aspects of Purdue's actions have been unwilling to accept that there is a time and a place for opioids, as well as non-opioids, and non-pharmaceutical treatments. The answer to solving the addiction issues is not to take away medications from those who have clinical benefit who have not had any issues with opioid misuse. We can be, and must be, more nuanced about it while we continue to put resources into the mechanisms of complex pain to find better treatments."

ASA Monitor: How do you believe the situation should be handled?

Dr. Singh: "The situation should be to provide more resources to clinical doctors to better serve their patient population with acute and chronic pain, including more time and improved access to treatments while also doing that for patients who have SUD (substance use disorder), or who are at greater risk for SUD. It is also important to distinguish between the two patient populations."

ASA Monitor: When used correctly, opioids are highly effective pain management medications; is this negative publicity surrounding opioid misuse going to raise skepticism among patients prescribed an opioid who could benefit from one, but now might want to avoid this treatment?

Dr. Singh: "The illicit drug crisis, which is currently the primary issue related to drug overdose and substance use disorder, has stigmatized the use and prescription of opioids in general, and has adversely impacted the ability to make clinical decisions regarding treatment and the provider-patient alliance."

Dr. Singh said this trend is "doing great harm to the known fact that opioids, in many instances and specific clinical situations, present a medical treatment option for patients."

She cited what she called an "individualized patient-centered approach" to pain medicine that accounts for the patient's underlying medical conditions and will "expedite them to a full medical recovery."

ASA Monitor: Has the opioid epidemic influenced the way you practice?

Dr. Singh: "There is no doubt that the drug epidemic has affected the way that clinicians have practiced – both through improved awareness but, often times, also through fear of repercussions or misunderstood clinical situations."

Dr. Singh sees the legislation of medicine as a "slippery slope" and is calling on state medical boards, the DEA, state legislatures and those who shape federal health policy to allow for clinical practitioners to still be able to use individual judgement while supporting and providing resources to identify patients who are not candidates for opioids. This could be done, she asserts, through prescription drug monitoring programs, lab testing, adequate patient time with doctors, and other initiatives. ■

We Want to Hear From You

What are your thoughts on this topic? The *ASA Monitor* welcomes your Letters to the Editor. Please submit all letters to **ASAMonitor@asahq.org.**