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Hospitalized Patients Are Civilian Casualties in the Government's War on Opioids

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A recent story by Pauline Bartolone in the Los Angeles Times draws attention to some under-reported civilian casualties in the government's war on opioids: hospitalized patients in severe pain, in need of painkillers. Hospitals across the country are facing shortages of injectable morphine, fentanyl, and Dilaudid (hydromorphone). As a result, trauma patients, post-surgical patients, and hospitalized cancer patients frequently go undertreated for excruciating pain.

Hospitals, including the ones in which I practice general surgery, are working hard to ameliorate the situation by asking medical staff to use prescription opioid pills such as oxycodone and OxyContin instead of injectables, when possible. But many patients are unable to take oral medication due to their acute illness or post-operative condition. In those cases, we are often asked to use injectable acetaminophen, muscle relaxants, or non-steroidal anti-inflammatory agents. But many times those drugs fail to give adequate relief to these patients—which is why they are not the first line of drugs we use.

The shortage is uneven across the country. Some hospitals are feeling the shortage worse than others. According to the American Society of Anesthesiologists, the shortage is so severe in some hospitals that elective surgeries—such as gallbladder and hernia operations—have been postponed.

Some hospitals have resorted to asking nursing staff to manually combine smaller-dose vials of morphine or other injectable opioids that remain in-stock as a replacement for the out-of-stock larger dose vials. Dose-equivalents of different IV opioids vary and are difficult to accurately calculate. This increases the risk of human error and places patients at risk for overdose, as was explained in a letter to the U.S. Drug Enforcement Administration by representatives of the American Hospital Association, American Society of Anesthesiologists, American Society of Clinical Oncology, American Society of Health-System Pharmacists, and the Institute for Safe Medication Practices. The letter asked the DEA to adjust its quota on the manufacture of opioids to help mitigate the shortage.

As part of the effort to address the opioid overdose crisis—which is really a fentanyl and heroin overdose crisis—the DEA, which sets national manufacturing quotas for opioids, ordered a 25 percent reduction in 2017 and another 20 percent reduction this year.

National shortages of drugs are not confined to injectable opioids. Over the years, various drugs in common use have gone on national "back-order" and health care practitioners have had to develop workarounds. The causes of these recurring shortages, not unique to the US, are complex and multifactorial.

For example, regulations and market forces have led to consolidation in the pharmaceutical industry and, for some drugs, have reduced the number of manufacturers to just one or two. Reimbursements to manufacturers of generics by Medicare and other third parties have reduced profit margins to levels that, in some cases, have caused manufacturers to leave the market.

The Food and Drug Administration also plays a major role. FDA regulations of manufacturing facilities add to costs and sometimes lead to temporary plant closures in order remediate the findings of FDA inspections. According to testimony given to Congress in 2011 by Scott Gottlieb (now the FDA Commissioner), many of the FDA's drug production safety policies are outdated and inflexible: "…The FDA and the manufacturers often don't understand the drug-production processes well enough to detect the root cause of problems. Instead of calling for targeted fixes of troubled plants, the agency has often required manufacturers to undertake costly, general upgrades to facilities. As a result, in 2010, product quality issues – and the subsequent regulatory actions taken by FDA to address these problems – were involved in 42% of the drug shortages."

In February 2017, an FDA inspection found significant violations in Pfizer's McPherson, KS manufacturing facility, where injectable opioids are manufactured, which was followed by a cutback in production at that plant in June 2017. Pfizer controls roughly 60 percent of the injectable opioid market. This production cutback has played a major role in the current injectable opioid shortage.

Another factor is the FDA's generic drug approval process. While Commissioner Gottlieb is committed to streamlining the process, it has been historically slow with large backlogs in applications. The median time to approval in 2016 was 47 months.

Also, disruption in the production supply chain—sometimes by natural disasters such as Hurricane Maria in Puerto Rico—can lead to temporary shortages, although this has not been a factor in the present opioid shortage.

But the above elements already existed before the DEA decided to help "fix" the opioid overdose problem. The DEA's decision to make deep cuts in the national quota for opioid production only exacerbates the situation. The DEA made the quota determinations based upon the fatal conceit (an attribute of all central planning) that the agency can know how many opioids will satisfy the needs of this nation of 325 million people. Ms. Bartolone quotes the agency as saying, "DEA must balance the production of what is needed for legitimate use against the production of an excessive amount of these potentially harmful substances."

Non-US injectable opioid manufacturers have received numerous requests to relieve the shortage but importing heavily regulated narcotics from other countries is complicated and difficult, requiring federal approval.

To address the alarming and steadily rising rate of overdose deaths, policymakers seem intent on reducing the prescription and supply of opioids by doctors to patients. Failing to recognize that the deaths are the result of nonmedical users accessing dangerous and potentially tainted drugs in a black market caused by drug prohibition, they charge full speed ahead, blinders tightly fastened. Patients in pain—and the doctors who want to help them—are the collateral damage in this futile war.

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