The Supreme Court Decision on Federal Prescribing Rules for Controlled Substances

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The Supreme Court’s 2022 opinion overturning Roe v Wade overshadowed another decision with important implications for the practice of medicine. In the June 2022 Ruan v United States opinion, the Court provided much-needed clarity regarding when a physician can be subject to criminal conviction for writing improper prescriptions for controlled substances. By narrowing the scope of criminal liability, this decision will benefit both physicians and patients, especially patients seeking treatment for pain.

In Ruan v United States, the Court heard appeals by several physicians who were convicted for violating the Controlled Substances Act (CSA), a federal law aimed at counteracting the illicit drug trade. This law makes it a crime to dispense a wide range of drugs, or “controlled substances,” without a valid prescription. A physician who has registered with the US Drug Enforcement Administration can lawfully prescribe a drug, but only if that prescription is “issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.” In their appeal, the defendants in Ruan v United States argued the lower courts had wrongly allowed them to be convicted under the CSA without requiring proof that they had intentionally prescribed drugs in an unauthorized manner. The Supreme Court agreed, holding that convicting a physician for violating the CSA requires proving beyond a reasonable doubt that the physician knowingly or intentionally prescribed controlled substances without a legitimate medical purpose. The “beyond a reasonable doubt” standard for conviction requires that the jury must be virtually certain of the defendant’s guilt.

The purpose of the CSA’s regulations governing prescribing is to prevent physicians from using their prescribing powers to engage in drug trafficking; for example, by effectively selling prescriptions to individuals who misuse drugs. However, some courts have allowed physicians to be convicted simply for writing prescriptions that did not conform to prevailing professional standards. Under this approach, even if a physician prescribed drugs in a good faith effort to promote a patient’s well-being, the physician could be sentenced to prison if any of the prescriptions were outside “the usual course of professional practice.” In other words, although the Court had previously held that the CSA only “regulates medical practice insofar as it bars doctors from using their prescription-writing powers as a means to engage in illicit drug dealing and trafficking,” some courts have allowed physicians to be convicted under the Act for mere negligence—a lower legal standard that is much easier for prosecutors to satisfy.

This low threshold for conviction placed accused physicians in a tenuous position. When investigating a physician, federal prosecutors have engaged experts to scrutinize the physician’s patient records and identify prescriptions that, in the expert’s opinion, did not conform to the usual professional practice. Courts have not required these experts to practice in the same specialty as the accused physicians. The experts’ findings have often focused on record-keeping failures, putting physicians at risk of criminal conviction for failing to stay up to date on reporting requirements when prescribing controlled substances. Since each allegedly improper prescription constitutes a separate violation of the CSA, accused physicians could face millions of dollars in fines and decades in prison if convicted. Faced with such severe penalties and such a low standard for conviction, physicians could experience enormous pressure to plead guilty in exchange for lighter sentences.

This was deeply unfair to physicians, who could face draconian penalties without any evidence that they intended to engage in criminal activity. The risk was particularly acute for physicians who treat patients for pain. Identifying the “usual course of practice” for treating pain is especially challenging because patients’ experiences of pain and treatment needs are so varied. Moreover, although physicians are trained to trust their patients (and patient self-report is the standard approach for assessing pain), physicians could be convicted for failing to detect that their patients were misusing or diverting their prescribed drugs.

Even as some courts applied a low standard for convicting physicians for improper prescribing, the federal government repeatedly escalated its use of criminal law enforcement to prosecute prescribers. For example, in 2017, the US Department of Justice (DOJ) created multiple task forces charged with investigating and prosecuting prescribers of controlled substances. One DOJ unit tasked 12 federal prosecutors with focusing exclusively on investigating allegedly illicit opioid prescriptions. Another was created to “aggressively deploy and coordinate all available criminal and civil law enforcement tools” to “crack down” on unlawful opioid prescribers. In 2019 alone, these task forces charged scores of physicians with illegally prescribing opioids as...
part of what the DOJ described as the “biggest crackdown of its kind in US history.”

Physicians’ concerns about prosecution harmed patients in predictable ways. Faced with mounting scrutiny from state and federal law enforcement and a low standard for conviction, some physicians abruptly reduced or discontinued patients’ opioid prescriptions to protect themselves from legal liability, irrespective of their patients’ needs. Other physicians began refusing to treat patients for pain. In 2019, the US Food and Drug Administration reported it had received reports of patients who had experienced serious harm from having their opioid pain medications suddenly discontinued or rapidly decreased, including “serious withdrawal symptoms, uncontrolled pain, psychological distress, and suicide.” The statement further warned that sudden discontinuation or rapid tapering of these medications could cause patients to experience uncontrolled pain or withdrawal symptoms that could lead them to seek illicit opioids, such as heroin.

The Supreme Court’s decision in Ruan v United States represents a critical step toward remedying these problems. The Court categorically rejected the idea that physicians could be convicted as drug traffickers merely by showing they prescribed outside the usual course of practice, regardless of their intent. The Court observed that such a standard would “criminalize a broad range of apparently innocent conduct” and risk deterring physicians from using their best judgment to benefit patients. Accordingly, the Court concluded that to convict a physician for writing improper prescriptions, “the Government must prove beyond a reasonable doubt that the defendant knew that he or she was acting in an unauthorized manner or intended to do so.”

In other words, rather than simply showing that a physician’s prescriptions did not conform to professional standards, prosecutors must prove the physician intentionally wrote prescriptions without any legitimate medical purpose. The Court acknowledged that deviating from prevailing standards, such as prescribing pain medications for certain off-label uses or in unusually large doses, can be relevant in determining whether a physician intended to act unlawfully. But these practices should not establish criminal liability on their own. Rather, prosecutors must show other evidence of a physician’s intention to act as a drug trafficker, such as prescribing drugs with high potential for misuse without examining patients or charging patients according to the volume of drugs prescribed.

While this heightened standard should not impede prosecutions of physicians who operate so-called “pill mills,” the standard will provide significant protection to physicians who prescribe in good faith. As the Supreme Court has acknowledged, the purpose of the CSA is to prevent drug trafficking, not to regulate the quality of physicians’ prescribing practices. By limiting criminal prosecutions to physicians who intentionally prescribe drugs for improper purposes, the Ruan v United States decision leaves the regulation of medical practice to state licensing boards and the civil justice system. Physicians who harm patients through negligent prescribing practices can be held liable for damages through civil lawsuits. More importantly, state laws empower medical boards to set minimum practice standards and to ensure that physicians meet them. When a physician’s prescribing practices violate professional norms, a board can require additional continuing medical education or place limitations on the physician’s practice. For serious or continued problems, a board can suspend or revoke a physician’s license. Absent evidence that a physician intentionally prescribed drugs without a legitimate medical purpose, these measures are more appropriate responses to improper prescribing than sentencing the physician to years in prison.

The authority to prescribe drugs is a weighty responsibility for which physicians should be held accountable. Promoting responsible prescribing is essential to mitigating an opioid epidemic that continues to harm both patients and their communities. But there are better ways to address that problem than by prosecuting negligent physicians as drug traffickers. By narrowing the scope of criminal liability in favor of more constructive and effective approaches to promoting responsible prescribing, the Court’s decision in Ruan v United States can be a victory for physicians and patients alike.

ARTICLE INFORMATION
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