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Doctor driven problem or doctor driven solution?

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The opioid crisis has been called "doctor driven;"[1] however, this judgment fails to consider numerous complicating and interacting factors that are not easily resolved. Pain is highly prevalent: More than half of US adults have experienced recent pain, while close to 10 percent of them suffer pain that is severe, bothersome, and persistent.[2] Persistent pain changes the neurobiology of the person who experiences it and sets in motion a spiral of adverse effects.[3] Pain limits function, worsens sleep, contributes to mental-health difficulties (eg, depression, anxiety), and degrades the quality of work, family, and social relationships. Available treatments are inadequate, pain advocacy lacks a strong voice, and research into pain mechanisms and safer, more effective treatments is insufficient to meet the burden. Spending on primary pain research has hovered near only 1 percent of the budget of the National Institutes of Health for well over a decade now.[3,4] Comprehensive interdisciplinary care has the best evidence and safety profile for chronic pain;[4] however, non-pharmacologic alternatives such as physical therapy, massage, yoga, acupuncture, and cognitive-behavioral therapy are unavailable or unaffordable for many, particularly in view of diminishing interdisciplinary programs in the United States and inadequate or absent insurance coverage.[5,6]

A culture of blame in regard to the opioid crisis exacerbates the difficulty of finding solutions that will serve all needs and that prioritize considerations relevant to the vulnerable addicted and pain populations. The Centers for Disease Control and Prevention (CDC), state law-making and regulatory bodies, and some practitioners have sought or implemented limits to opioid prescription quantities, dose, and duration of opioid therapy with the goal of reducing patients' opioid exposure along with the supply available for diversion and abuse.[7-9] It is appropriate to ensure that opioid prescriptions match the clinical indication in terms of dose and duration of therapy. Yet the US Food and Drug Administration (FDA) challenged the purported science behind uniform duration and dosage limits on opioid therapy, citing evidence that patients vary genetically in response to medication.[7] Regardless, supply-reduction policies are spreading,[10] although access to recommended non-opioid alternatives for severe pain remain out-of-reach for many patients. For some patients with pain conditions that are severe and lifelong, opioid analgesics are necessary, even though fraught with potential for adverse effects.

Certainly, there is no single, simple solution to the prescription drug crisis. One area in which all interested stakeholders and factions may agree is that once an opioid has been prescribed, it should be as safe as science and public policy can make it. A plan to reduce harm from medical and nonmedical consumption of opioids includes several components, including the issuance of prescribing guidelines,[8,9,11-13] greater use of prescription drug-monitoring programs (PDMPs) to identify patients who are obtaining unauthorized prescription medications, physician and patient education regarding the evidence-based risks and benefits of opioid therapy, insurance reform, both public and private, wider access with reduced stigma to opioid-use disorder treatment, and research into newer, safer therapies, including opioids with abuse-deterrent properties. None of these policies is likely to work in isolation but should be implemented simultaneously.

In recognition that curbing the opioid crisis will require a multifaceted, public-health approach, the FDA encourages expedited research to develop abuse-deterrent opioids (ADOs).[14] The FDA has issued guidance to industry containing recommendations for structuring trials to demonstrate abuse deterrence.[15] In addition, the agency has strengthened regulatory hurdles for new products without abuse-deterrent properties and issued a draft guidance to facilitate the development of generic ADOs.[14]

In defining terms, the FDA states that abuse is the intentional, non-therapeutic use of a drug product or substance, even once, to achieve a desirable psychological or physiological effect.[15] This is distinct from *misuse*, which is defined as the intentional therapeutic use of a drug product in an inappropriate way. The term abuse-deterrent properties refers to properties that deter or slow abuse, not fully prevent it.

Numerous abuse-deterrent technologies are currently available or in development. No ADO can prevent all forms of overuse and abuse. Overdose by ingesting too many pills may still occur, but technology is being developed to address this method of abuse. Only when ADOs replace the majority of earlier formulations can the public-health impact be fully known, with the allowance specified by the FDA that some non ADOs should remain available for certain settings such as hospice care in which injectable opioids are indicated.[15]

As use of therapeutic opioids has increased, so too have adverse societal consequences related to misuse and abuse involving medical and nonmedical opioids. Although imperfect, current ADO technology may provide incremental benefit to society. If permitted by the payers, ADOs can be one "science driven" solution.

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