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Patient-Focused Drug Development on Chronic Pain

Comments from the American Academy of Pain Medicine

Docket FDA-2018-N-1621

The American Academy of Pain Medicine (AAPM) is writing on behalf of patients who live with chronic pain and whose voices have gone increasingly unrecognized. The leaders of AAPM applaud the FDA for taking steps to rectify this oversight with its July meeting and call for public comment to hear more perspectives on living with intractable, chronic pain.¹ Patients testified as to their harsh experiences in July, and the FDA listened. We stand with these patients and echo the concern that efforts to curb the opioid crisis have inadvertently led policymakers and payers to marginalize the needs of people with pain.

We at AAPM recognize that the United States is experiencing a serious drug crisis driven, in part, by prescription opioid prescribing patterns.² We are also concerned that efforts to prevent harm through prescribing reductions have brought unintended consequences for people with few other treatment options. Many patients tell of being forced to taper off opioids, even if they have been adherent to and functional on their medical therapy for years.^{3,4} In most instances, these patients are prescribed opioids because there are no other pain relief options that are effective, affordable, or covered by major insurances. Leaders of AAPM believe solutions to address the opioid crisis should encompass the needs millions of Americans with disabling pain.

One such solution would be to create incentives for industry to develop safer and more effective analgesics. Eventually, the opioids being prescribed today must be replaced either by new mu agonists with less potential for serious adverse effects or with non-mu molecules with effective analgesic properties and no rewarding properties. Accomplishing such scientific research goals will require nurturing useful collaborations and facilitating a variety of public and private partnerships. Several small companies have promising molecules, putatively as potent in delivering analgesia as opioids, designed to reduce or eliminate rewarding properties. We believe the FDA should create incentives to facilitate the development of these molecules.

We also urge the FDA to exercise its influence on payers, including the Centers for Medicare & Medicaid Services, to provide coverage and reimbursement for evidence-based alternatives to opioids for chronic pain (e.g., cognitive-behavioral therapy, interdisciplinary pain programs) and to require parity in mental health and substance-abuse treatment. Unfortunately, these treatments and other innovative solutions for the treatment of pain are not readily adopted by the payer community. As Schatman highlighted, the

United States lags behind other industrialized nations in the number of accredited interdisciplinary pain programs, which dropped from 210 in 1998 to 84 in 2005.⁵ Since then, the number of accredited programs has continued to drop with the payer community's unwillingness to cover such programs.⁶ Moreover, the correlation between mental illness and prescription drug abuse is well established in patients who are prescribed opioids for chronic pain.⁷⁻⁹

We at AAPM believe that the country needs a new national focus to eliminate pain as the No. 1 healthcare problem in America. To be clear, we are calling for a "cultural transformation" as described by the Institute of Medicine in its 2011 report on the state of pain¹⁰ and further elucidated in the National Pain Strategy.¹¹ Part of this transformation centers on a new approach to funding. In 2016, the Comprehensive Addiction and Recovery Act (CARA) was passed.¹² The act authorized more than \$181 million per year to fight the opioid crisis. Since it can be argued that the opioid crisis evolved because of limited treatment and coverage options for treating pain, it would be logical that there should be a similar if not greater investment in finding solutions for pain. And yet the United States has failed to meet the needs of pain research that is commiserate with the magnitude of the problem.

Another piece of the transformation—a change in mindset—would acknowledge the failures of a public policy that elevates enforcement at the expense of public education in seeking to halt the spread of prescription drug abuse. It is past time to devote greater resources for research and education to address the pain problem in the United States. Without that transformation at the cultural and societal level in our attitudes toward pain, solutions to end the opioid crisis cannot succeed.

Stopping the harm from prescription drug abuse requires adequate funding for new non-addictive analgesics, reimbursement for alternative care and substance abuse treatment, and a fresh mindset that says law enforcement is not the only answer. We advocate for raising pain patients into the light of compassion and formulating good scientific partnerships to address their needs.

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About AAPM

The American Academy of Pain Medicine is the premier medical association for pain physicians and their treatment teams with some 2,000 members. Now in its 35th year of service, the Academy's mission is to advance and promote the full spectrum of multidisciplinary pain care, education, advocacy, and research to improve function and quality of life for people in pain. Information is available on the Academy's website at painmed.org.

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