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CDC Draft Opioid Guidelines Ignite Controversy

New draft guidelines from the Centers for Disease Control and Prevention (CDC) aimed at reducing opioid abuse and addiction have triggered a backlash from pain management experts, many of whom see the guidelines as being nothing short of misguided.

In their attempt to mitigate the real risks and dangers of addiction, critics allege that the new guidelines will cause real harm to a significant subset of chronic pain patients for whom opioids do not pose a threat, and who often do not have any other options to treat their pain.

Moreover, the CDC has been criticized for a perception of secrecy and collusion with special interests surrounding the draft guidelines. These perceptions are fueled by the fact that the draft guidelines were made public for only an hour and a half in mid-September, during a webinar, followed by a 48-hour window in which to send comments by email; as well as by the fact that the webinar in question was well attended by nonprofits focused on fighting addiction, insurers and pharmacies, and poorly attended by advocates of chronic pain patients.

One nonprofit in particular, Physicians for Responsible Opioid Prescribing (PROP), has drawn much of the ire in the ongoing debate, as several key members of PROP are also members of CDC groups that will have a lot of influence over the final guidelines.

Abrogating Patient-Centered Care

At the heart of the criticisms of the draft guidelines lies the charge that they favor the interests of payors over those of patients. That's the position maintained by Terri Lewis, PhD, an expert in rehabilitation administration. Dr. Lewis also has experience with chronic pain in two generations of her fa mily, with her son having inherited a problem with chronic back pain from her father. She has been closely following the debate over opioid prescribing, as well as the development of the draft guidelines, as a matter of both professional and personal interest.

"To me, [the draft guidelines] read as a risk mitigation strategy for physicians and providers, and not as a risk mitigation strategy for patients," Dr. Lewis said. "If they were, we wouldn't be using an addiction model."

As Dr. Lewis sees it, the draft guidelines, which include provisions for urine testing and limit the total number of opioids that can be prescribed to a single patient, do not leave room for pain patients to make decisions about their own treatment. Rather, she said, the guidelines start from the presumption that every chronic pain patient is a potential opioid addict.

"The difference between a patient in chronic pain and a person who is addicted is, with addiction, we expect a cure," Dr. Lewis said. "We expect the patient will recover to the point that they can maintain some cured state—even if they're on methadone; the goal is to integrate them back into society.

"That doesn't happen with chronic pain," she continued. "Chronic pain is progressive. It's associated with a multisystem injury to the body, and it's not going to be cured. So what we want to do is give that person the most optimal tools, in spite of what has happened to them. It's a big difference in approach."

Asking the Wrong Questions

Dr. Lewis also criticized the "one size fits all approach" toward pain patients taken by the draft guidelines, a criticism that has been echoed by others in the pain management community. Among those who share her concern is Lynn R. Webster, MD, a past president of the American Academy of Pain Medicine, and a *Pain Medicine News* editorial board member.

"The focus should not be on whether opioids should be used or not—the focus should be on what a person in pain needs," Dr. Webster said. "There should be a risk–benefit analysis for every treatment, and that's what should decide whether opioids are prescribed or not. You can't paint every person with the same brush.

“We have two national crises, and only one is being addressed by the CDC,” Dr. Webster continued. “We need to address the opioid problem, but we cannot ignore the larger problem of people in pain, which affects many more people.”

Dr. Webster also objected strongly to the inclusion of payors in the development of the draft guidelines, calling it the “most egregious error” in their conception.

“That’d be equivalent to having pharmaceutical companies making opioid guidelines,” he said. “It’s all about money.

“I would hope the CDC would be above that, that they’d be most interested in helping patients, whether they have the disease of addiction or the disease of chronic pain,” Dr. Webster added. “I don’t believe these guidelines do that.”

Regulation Without Representation

Dr. Webster also expressed frustration that the guidelines were developed without significant input from the pain management community or from chronic pain sufferers, a concern shared by Jeffrey Fudin, BS, PharmD.

Dr. Fudin, the founder and chair of Professionals for Rational Opioid Monitoring and Pharmacotherapy, a multidisciplinary group that advocates for “clinician education, proactive risk stratification and appropriate therapeutic monitoring” when it comes to opioids, said the pain community is irate at the way in which the CDC has handled the development of these draft guidelines.

“I’ve been working with several groups in the background to respond; the U.S. Pain Foundation sent in a response, and their letter had a number of organizations signed on it,” Dr. Fudin said. “So the pain community is outraged.

“But the problem is, you have all these patients who are indigent,” he continued. “They just don’t have the wherewithal to rise up against a government agency, or a group like PROP, that’s working 24/7 trying to take opioids away from patients in need.

“And the professionals, we’re spending our time taking care of patients,” he added. “So it’s difficult for us to sit down at the end of the day, day after day, and fight this battle.”

Dr. Fudin raised the question of where advocates for the stringent draft guidelines are receiving funding for their efforts, and echoed Dr. Webster’s concerns about conflicts of interest.

“One group that was on the CDC webinar was CVS—they own a huge, huge PBM [pharmacy benefit manager],” he said. “Don’t you think that’s a conflict of interest? They don’t want to pay for long-term extended-release opioids. It’d cost them a fortune.”

Dr. Fudin sharply criticized what he called a lack of balance in parties that the CDC included in the webinar sharing the guidelines.

“It was done in a secret way. There was not a panel of experts, [and] it was not fairly balanced,” he said. “They should have had pharmacists with expertise in pain management, doctors with expertise in pain management; they also should have had medical doctors well versed in substance abuse; they should have had clinical psychologists, public health people; and they should have had patient advocacy groups.”

Giving the chronic pain community only 48 hours to respond to the guidelines, Dr. Fudin said, was “cruel,” adding that people with chronic pain ought to have been given more time to respond, not less.

“I’m just disappointed in the CDC,” he concluded. “What they did was ethically, medically, professionally and morally wrong.”

Conspiracy Theories?

As to the role of PROP in the formulation of the draft guidelines, Andrew Kolodny, MD, PROP’s founder and current executive director, dismissed suggestions that PROP has played a behind-the-scenes role in drafting the guidelines as “fearmongering.” Dr. Kolodny, chair of psychiatry at Maimonides Medical Center in New York City, is also the chief medical officer of Phoenix House, a nonprofit dedicated to treating addiction.

He also rejected the perception that PROP, through its advocacy, seeks to restrict access to opioids. “That might be how the [pharmaceutical] industry sees it, and it might be how pain patients who are on opioids, and who think opioids are helping them, would see it, but we’re not trying to restrict access,” he said.

“Our advocacy is focused on the [FDA], to better regulate the way in which these products are promoted,” Dr. Kolodny added, “and to prevent pharmaceutical companies from marketing opioids for conditions for which they may not be appropriate.” He added that PROP also seeks to promote more cautious prescribing of opioids, through the education of clinicians.

Dr. Kolodny is adamant that PROP had no direct role in drafting the guidelines, but also said that it’s “not a coincidence” that several PROP members are on CDC panels that helped to develop the guidelines. (These include PROP’s president Jane Ballantyne, MD, professor of

anesthesiology and pain medicine at the University of Washington, in Seattle, and its vice president, Gary Franklin, MD, a research professor of environmental and occupational health sciences, also at the University of Washington, both of whom were in the "Core Expert" group involved with the draft guidelines.)

Rather, he said, "If you're looking for the leading experts who don't have conflicts of interest [with opioid manufacturers], you would wind up working with people from PROP, because the leading experts are either on our board, are our members or have worked closely with us."

Conflicting Priorities

However, Dr. Fudin pointed out that Dr. Kolodny himself is not, nor does he claim to be, an expert in chronic pain. Nevertheless, Dr. Kolodny attributes much of the benefits that patients perceive from opioids in treating chronic pain to opioid addiction—the approach that Dr. Lewis criticized in the draft guidelines.

"When you have a hammer, everything looks like a nail," Dr. Lewis said.

Dr. Kolodny pointed out that many experts in pain management are opposed to using opioids to treat chronic pain, including Richard Rosenquist, MD, chairman of pain management at Cleveland Clinic. Dr. Rosenquist has published his stance on the Cleveland Clinic's website (http://consultqd.clevelandclinic.org/2015/02/opioids-for-chronic-pain-2/#.VghfzURGR_8.twitter), but could not be reached for comment.

Dr. Webster agreed that opioids are not ideal, but maintains that until better treatments are developed—an effort that he believes will require something on the scale of the Manhattan Project—depriving patients who need opioids to manage chronic pain is not the solution.

"There are people in pain who benefit from opioids long term," he said. "There are probably millions of people today in this country who have been on opioid therapy for years, if not decades, without serious adverse effects, who believe it's made them more functional and increased their quality of life. Why would we ignore that?"

CDC Response

On Oct. 6, in response to criticism from patient advocacy groups, the CDC announced that it will revise the draft guidelines, reported Pat Anson of *Pain News Network*. The agency stated that it is still on track to publish the guidelines in January 2016.

—Ajai Raj

Pain and Addiction: The Horns of a True Dilemma

At its heart, the controversy over the Centers for Disease Control and Prevention draft guidelines for opioid prescribing reflects the difficulty of meeting the conflicting needs of two very different patient populations: chronic pain patients and opioid addicts. The battle over the guidelines is only the most recent expression of this struggle in the policymaking arena.


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Other policy initiatives that have pitted the needs of addicts—and, arguably, law enforcement—against those of chronic pain patients include pill mill laws and prescription drug monitoring programs, both of which went into effect in Florida in 2010. These initiatives, which aim to restrict the flow of opioids into the black market, appear to have succeeded at their stated goal of reducing opioid overdoses in that state.

However, the state also saw a spike in heroin overdoses during that same year. Critics of these measures, including Jeffrey Fudin, BS, PharmD, in the accompanying article, point out that they also make it more difficult, if not outright impossible, for chronic pain patients to receive the medicine they need to function in daily life.

Chris Nuland, PA, an attorney and lobbyist who represents the Florida Public Health Association, stands behind the pill mill law and prescription drug monitoring programs, but acknowledges the validity of criticisms such as those leveled by Dr. Fudin.

“Because of the law, and because of the FDA’s crackdown on pharmacies that indiscriminately fill what I would call bad prescriptions, pharmacies have become increasingly reluctant to fill opioid prescriptions, and many patients have had difficulty obtaining their medication,” Mr. Nuland said. “In fact, the Florida Medical Association and the pharmacies recently met to address those problems, which everyone concedes are true problems.”

Asked how the problem of addiction could be addressed more effectively, Mr. Nuland laughed.

“That’s a great question. We don’t know,” Mr. Nuland said. “And by ‘we,’ I mean the legislators, the health care lobbyists and everyone else.

“We do understand the need to address [the issue of addiction] at its base,” Mr. Nuland elaborated. “One option that’s out there is needle exchange programs, which would give the state or health care professionals the opportunity to deal with the addict at the source.”

In the meantime, Mr. Nuland said, “what we are working on is ensuring that the ‘legitimate’ pain patient is able to obtain their own medically necessary medications.”

—A.R.