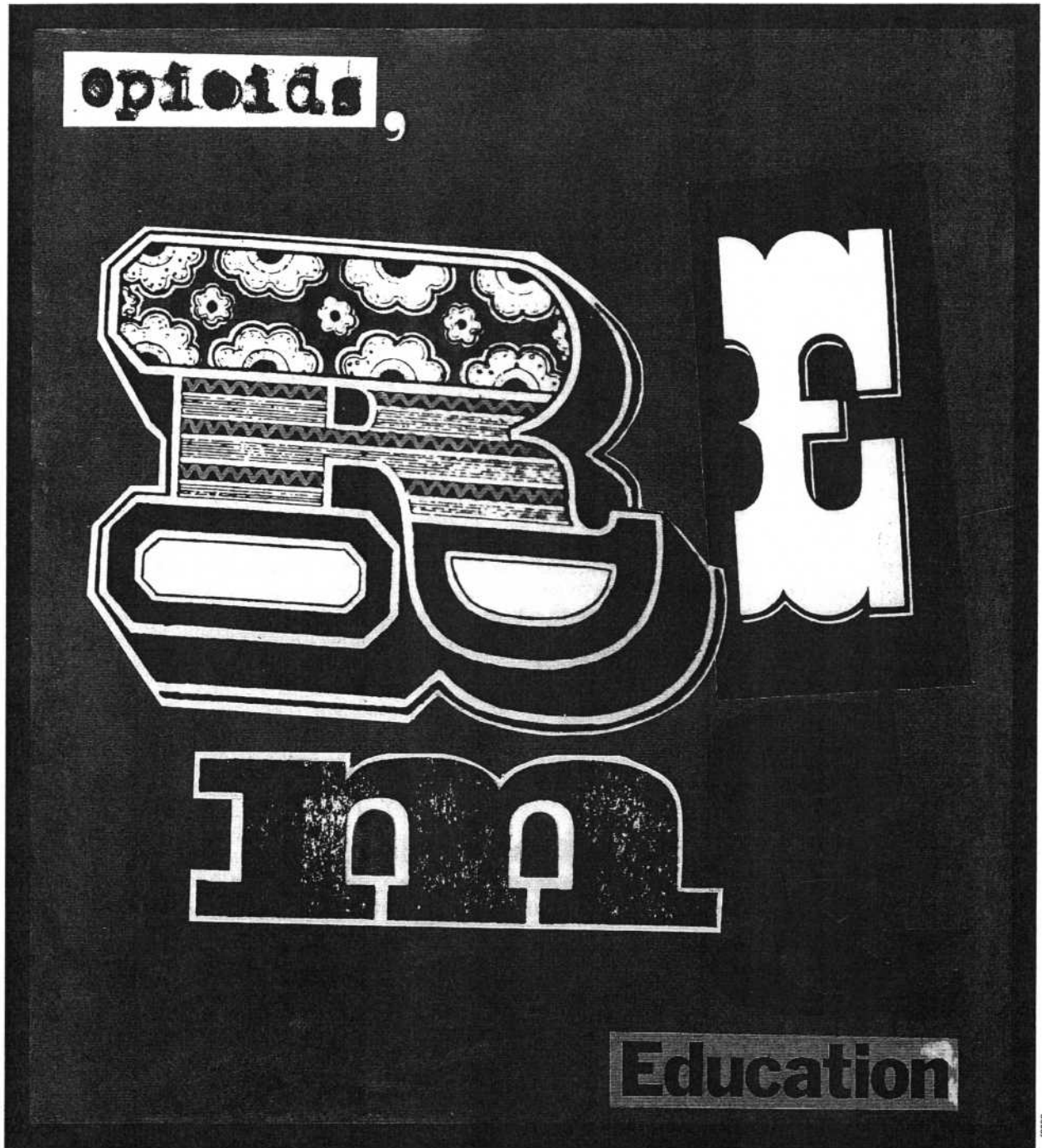


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PAINVIEW

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Avoid the Dangers of Opioid Painkillers and Gain Control Over Chronic Pain

BY BETH DARNELL, PHD REVIEWED BY HOLLY CASTER

EDITOR'S NOTE

AS THIS ISSUE OF *Painview* reaches your desk, the ASPE is finalizing the agenda for the most extensive Pain Educators Forum in the organization's history, to be presented at the PAINWeek National Conference in Las Vegas this September. If you've not already done so, now is an excellent—and cost-effective—time to go to www.painweek.org and register yourself and your colleagues at discounted rates for PAINWeek 2014. We look forward to seeing all of our members on September 2!

Our cover story for this edition of *Painview* is authored by ASPE board member Kevin Zacharoff, MD, FACIP, FACPE, FAAP. *Opioids, REMS & Education* explores the question of how, or even whether, education can make a difference in the safe and effective use of opioid analgesics for chronic pain, through a review of the implementation and anticipated effects of the FDA's REMS mandate for ER/LA opioids.

Complementing this discussion is a perspective on the changing legal and political environment attending opioid pain therapy, contributed by PAINWeek faculty member Stephen Ziegler, PhD, JD. In *Pain and the Politics of Hydrocodone* he notes that public policy with respect to opioid prescribing has fallen victim to the pendulum swing away from proactive pain management to fixation with misuse, abuse, and diversion.

Painview editorial staff member Holly Caster reviews *Less Pain, Fewer Pills: Avoid the*

Dangers of Opioid Painkillers and Gain Control Over Chronic Pain by Beth Darnell, PhD, a book and resource practitioners may want to consider for their patients in pain. It's a timely addition to the pain pharmacotherapy discussion. Through an exploration of the complex sensory and emotional contributors to pain, Dr. Darnell offers insight into therapeutic approaches to pain management that lessen reliance on medication alone.

What motivates a busy healthcare practitioner to become a CPE? A new feature premiering in this issue of *Painview* is the certified pain educator profile. We've asked Kathryn Schopmeyer, PT, DPT, CPE, what prompted her to join the ASPE and pursue the CPE credential. We hope her answers will enlighten—and encourage—you!

Finally, in his contribution *Physician Assistants and Pain Management*, PAINWeek faculty member Jeremy Adler, MS, PA-C, details how and why PAs are uniquely positioned to help bring the potential of multidisciplinary pain management from concept to reality.

We thank our editorial contributors for their efforts on behalf of this edition of *Painview*, and we extend an invitation to all of you, as pain educators, to participate in the content of upcoming issues.

Contact me with your thoughts and ideas at editor@paineducators.org. —KEITH DEMPSTER

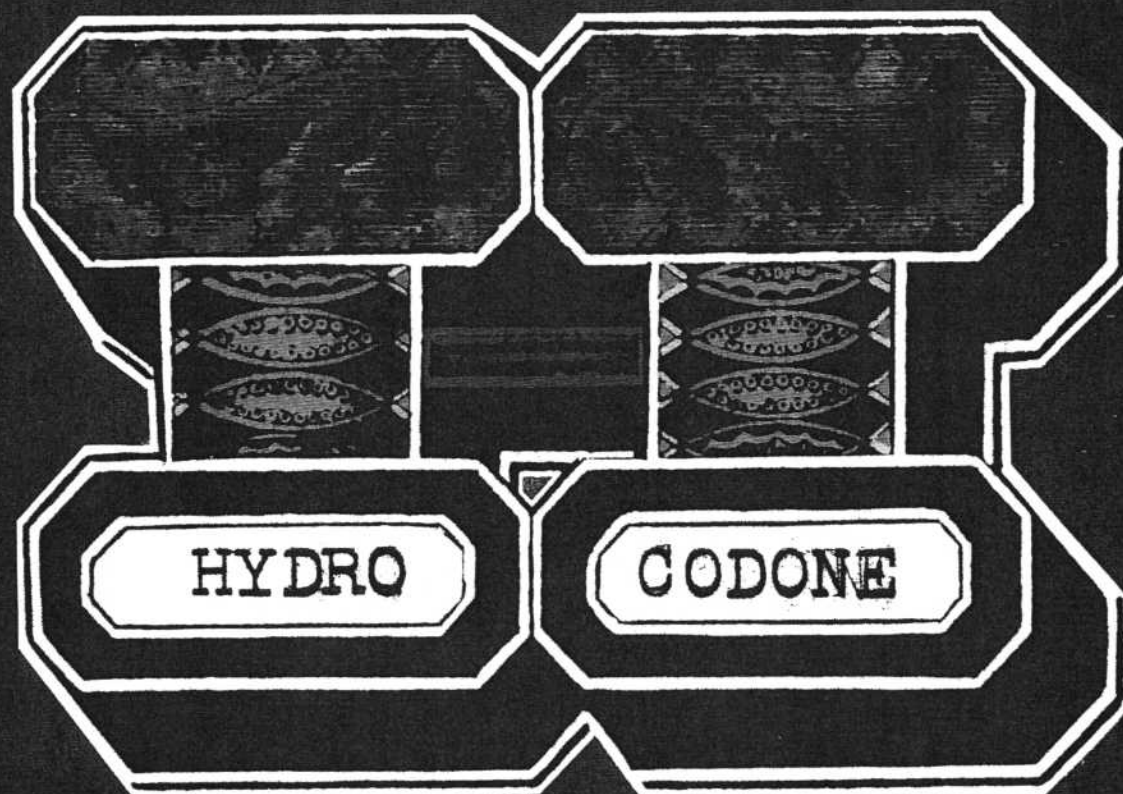
NEW CPEs

Brian Strang, PharmD, CPE

Jaskaran Singh, PharmD, BCPS, MBA, CPE

Emily Davies, PharmD, CPE

PAIN AND THE POLITICS OF



by Stephen J. Ziegler PhD, JD

THE US FOOD AND DRUG ADMINISTRATION (FDA) recently announced its recommendation to the US Department of Health and Human Services (HHS) that hydrocodone combination products be reclassified and moved from Schedule III to the more restrictive Schedule II of the federal Controlled Substances Act. While such a broad-sweeping change was considered by many in the pain community to defy common sense, one should never underestimate the power of politics and political theater in legal and regulatory decision-making. Notwithstanding this recent move by the FDA, hope for balanced policies still remains. And while the powerful play in this political theater goes on, the following commentary offers ways practitioners and patients may contribute a verse.



UNDERTREATED PAIN VS PRESCRIPTION DRUG ABUSE: A ZERO-SUM POLITICAL GAME?

UNDERTREATED PAIN HAS BECOME A major public health problem, and the Institute of Medicine has estimated that over 100 million Americans suffer from chronic pain. Reasons for its undertreatment stem from multiple barriers to its relief. For instance, patients may be unable to afford their health care or prescriptions (financial barriers); they may not want to be perceived as complainers or diverters, or become addicted (personal barriers); they may have their own biases about pain and its treatment (personal and cultural barriers); their healthcare provider may lack adequate knowledge, hold mistaken beliefs, or have a bias against opioids (medical barriers); the institution involved may prohibit the dispensing or prescribing of opioids (institutional barriers); or government created policies may exist that either negatively influence prescribing or create patient access problems (legal and regulatory barriers).¹

While the use of opioids in acute and chronic pain is well established, prescription drug abuse remains a significant problem. The Centers for Disease Control and Prevention was one of the first federal health agencies to raise concerns that the increase in injury and unintentional overdose death rate was attributed to the increase in opioid availability or prescribing.² Political pressure on elected officials to do something about the increase in morbidity and mortality associated with prescription drugs resulted in a variety of responses including, but not limited to congressional hearings involving pharmaceutical corporations; investigations of persons and organizations who had received funding from the pharmaceutical industry; new laws intended to eliminate pill mills; and increased funding for prescription monitoring programs.² Pressure was also exerted on the FDA to require: 1) mandatory education of prescribers pursuant to REMS (Risk Evaluation and Mitigation Strategy)²; 2) label changes for extended-release/long-acting opioids³; and 3) the rescheduling of hydrocodone combination products, moving them from their existing Schedule III under the federal Controlled Substances Act to the more restrictive Schedule II.⁴

While efforts by patient advocacy groups and others have increased awareness about the many barriers to the treatment of pain, the policy pendulum continues to swing away from the center and remains focused, if not fixated, on preventing prescription drug abuse and its harms. Instead of seeking to strike a balance between ensuring access and preventing abuse, recent political efforts have come at the expense of patients.² To many, the recent decision by the FDA to recommend the up-scheduling of all hydrocodone combination products defies common sense or is at least inconsistent with earlier statements. When we consider the relationship between a federal agency and Congress, however, it makes perfect political sense.

CONGRESS AND THE FDA: A PARENT-CHILD RELATIONSHIP

ALTHOUGH FEDERAL REGULATORY AGENCIES SUCH as the FDA have executive authority, they are actually created through congressional legislation and are subject to congressional oversight. Federal agencies are expected to fill in the details flowing from broad legislative mandates. Like any child, they do have some independence. For instance, while the agency cannot act outside of its delegated authority, Congress cannot micromanage the agency's affairs to the point of requiring congressional approval of every new agency rule or regulation. When Congress seeks to retain such power, it often amounts to an unconstitutional legislative veto, an action which violates the separation of powers by effectively passing a law without executive signature or veto.⁵

For some time, it appeared that the FDA was willing and able to maintain its independence and balance the need to ensure patient access to needed pharmaceuticals against the need to reduce abuse—and to resist political pressure in the process. For instance, the FDA rejected its own REMS advisory panel that called for mandatory education of prescribers out of concern that it would be burdensome on healthcare providers and create barriers to patient access.⁶ So, when a subsequent FDA advisory panel recommended the up-scheduling of all hydrocodone combination products, it seemed reasonable that the FDA would resist the call, especially in light of the negative impact it would have. After all, up until that time, Congress was unable to pass, let alone vote out of committee, the Safe Prescribing Act of 2013, an act which sought to amend the federal Controlled Substances Act and place any drug containing hydrocodone in Schedule II.⁷

But despite the FDA's earlier stance to maintain balance, and its earlier rejection of its own advisory boards out of concern for patient access, *and* the failure of Congress to pass legislation related to hydrocodone combination products, the FDA did a turnabout and announced it would recommend to HHS that hydrocodone combination products be reclassified and moved from Schedule III to the more restrictive Schedule II of the federal Controlled Substances Act.⁴

POLITICAL WINDS AND HYDRAULIC PRESSURE ON PUBLIC OFFICIALS

WHILE IT CERTAINLY SEEMS THAT the FDA made a decision based more in politics than science, the reality remains that no government agency is truly independent and must always remain aware of the direction and force of the prevailing political winds. The FDA is certainly not the first agency to succumb to such pressure, even when Congress lacks a consistent message or is unable to pass its own laws.

“The current anti-opioid political climate may eventually lead to a new **McCarthyism**—an **Opioid McCarthyism** where anyone who voices support for the use of opioids runs the risk of being labeled a drug pusher, a biased pharmaceutical funding recipient, or a mouthpiece for the pharmaceutical industry.”

For instance, several years ago a US Senator and US Representative sent a joint letter to the Drug Enforcement Administration (DEA) on a matter involving physician-assisted suicide. Their letter expressed opposition to the use of controlled substances to facilitate an assisted death, even if the procedure was authorized by state law. The letter closed by stating that: “Clearly Congress would have a serious concern were any federal agency to construe the intentional prescribing of lethal drugs for suicide as a legitimate medical practice.”⁸ Although these representatives were only 2 out of 535 elected officials in Congress, and Congress was not as unified as the letter writers described, these 2 elected officials also happened to be the chairs of their respective judiciary committees—committees which engaged in agency oversight and budgeting. Not surprisingly, the DEA agreed with them.

But regulatory agencies and Congress are not the only ones who can make bad decisions under pressure; our own courts have a long history of making errors, as stated by former United States Supreme Court Justice Oliver Wendell Holmes, Jr:

Great cases like hard cases make bad law... because of some accident of immediate overwhelming interest which appeals to the feelings and distorts the judgment. These immediate interests exercise a kind of hydraulic pressure which makes what previously was clear seem doubtful, and before which even well settled principles of law will bend.⁹

One likely explanation for many of the knee-jerk reactions we have seen in matters involving opioids stems from the fact that prescription drug abuse and unintentional death are emotional issues with powerful narratives. Stories involving the tragic loss of loved ones from prescription drug abuse not only make for compelling testimony; they can, at times, become the essence of political theater and be exploited to further an agenda or open a

policy window of opportunity.¹⁰ Those unwilling to use the tragedy of others for their own ends may nevertheless feel compelled to do something, even if it comes at the expense of legitimate pain patients. In fact, the current anti-opioid political climate may eventually lead to a new McCarthyism—an Opioid McCarthyism where anyone who voices support for the use of opioids runs the risk of being labeled a drug pusher, a biased pharmaceutical funding recipient,¹¹ or a mouthpiece for the pharmaceutical industry. Perhaps now is the time to rebut these critics and make our voices heard in a positive way?

CONCLUSION AND RECOMMENDATIONS

THE FDA'S DECISION TO RECOMMEND the up-scheduling of *all* hydrocodone combination products is a broad-sweeping action that will undoubtedly create access problems and inflict more pain on an already marginalized group of patients in a never-ending drug war. Efforts to reduce the morbidity and mortality associated with prescription drug abuse must be advanced, but these efforts must not ignore the plight of legitimate pain patients and the positive role that prescription drugs have in reducing pain and improving function. Fortunately, patients and healthcare providers can advance the creation of good public policy by making positive contributions to the debate. This can be accomplished with a minimal amount of effort by making their voices heard through their professional and advocacy organizations; through open comment periods whenever new rules and regulations are proposed¹²; by calling and writing their elected officials; or reaching out to pain organizations, such as the American Academy of Pain Management, who have developed a state pain policy advocacy network, which helps people get informed, stay connected, and take action.¹³ The powerful political play goes on, and indeed you may contribute a verse. ■

Stephen J. Ziegler, PhD, JD, is an associate professor of public policy, Indiana University-Purdue University, Fort Wayne, Indiana.

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