Review Article ISSN 2835-6276

American Journal of Medical and Clinical Research & Reviews

The FDA is Talking When They Should Be Listening – Part 2

Richard A Lawhern PhD, and Pat Irving RN

*Correspondence: Richard A Lawhern

Received: 25 Aug 2025; Accepted: 30 Aug 2025; Published: 05 Sep 2025

Citation: Richard A Lawhern. The FDA is Talking When They Should Be Listening – Part 2. AJMCRR. 2025; 4(9): 1-3.

On August 27, 2025, the US Food and Drug Administration in collaboration with the Reagan-Udall Foundation, held a public meeting from 2:00 to 5:00 PM, on "Demand Forecasting for Controlled Substances." The meeting was conducted as a hybrid (in-person and virtual) event to explore methods and challenges in estimating medical, scientific, and reserve stock needs for what are called "Schedule I and II" controlled substances. Three aspects of demand forecasting were addressed:

- Methods and processes for forecasting demand
- Effects of misuse and diversion (during which I personally spoke)
- Impact of under- or over-estimation of demand (Monty Goddard)

Public input to this session was remarkable for several reasons. Among the 26 comments offered, not one that I heard suggested that the FDA has been doing a good job – or even knows *how* to do a good job. Several patient speakers related that entirely unjustified FDA restrictions on availability of opioid pain relievers are destroying the lives of millions, including their own.

Three of us on the Speakers' Bureau of the National Campaign to Protect People in Pain were among those allowed to offer three-minute presentations by Zoom ™ session.

- Pat Irving, RN, spoke to the urgent need for accounting for impacts in greatly reduced availability of desperately needed opioid analgesics in local pharmacies, directly caused by injunctive relief provisions of the National Opioid Settlement. She advocated for outright recall and repudiation of those provisions based on their horrendous impact on patients and their clinicians.
- Monty Goddard began his presentation in the third area of the conference with, "Let me begin by stating the obvious, **underestimation of demand results in harm to patients**." He then pointed out FDA's failure to acknowledge **the reality** that shortages of pain medications have existed for several years. These shortages have doomed their efforts to predict future demand, or to ameliorate ongoing shortages. He emphasized the American Society of Health-System Pharmacists (ASHP) has been capturing **the reality** of the shortages for the last several years, and that the FDA must do the same.

In my three minutes, I offered the following:

"I am Richard A Lawhern, Ph.D. As a healthcare

educator and nationally known subject matter expert on policy for regulation of pain medicine, I have 28 years' experience and over 300 published papers. I teach guideline-informed best practices to clinicians in courses accredited by the Postgraduate Institute for Medicine. From this background, I will support and expand on themes sounded here by several others.

"I must go much further than some others in this session. I would assert that members of this FDA panel are in fact accessories to one of the largest healthcare frauds in US history. They are also entirely aware of what I am about to say because I and my colleagues briefed them in July 2024.

"As I wrote in December 2024 on KevinMD -- America's most widely read and cited healthcare newsletter -- "The FDA is Talking When They Should Be Listening".

"It is time to challenge the entire concept of "Risk Estimation and Mitigation Strategies" that incorporate draconian limitations on patient access to safe and effective pain relief. We know beyond any possible contradiction that opioid analgesics prescribed in an ongoing doctor-patient relationship are both safe and effective!

"Specific support for this reality is as follows:

1. Risk of treatment-related substance use disorder or overdose is less than one patient per thousand patients who are treated by a doctor with prescription opioid analgesics (34 million plus patients - Gabriel Brat et al, 2018).
2. In rare cases where a drug overdose, suicide attempt, or successful suicide occurs in over a million patients treated with prescription opioids, mental health factors are six to twenty-four times more significant as predictors of short-term risk, versus prescription of opioid pain relievers as such (STORM Model, Jennifer Oliva, et al, 2018).
3. Forty years of data published by CDC and the Veterans Administration demonstrates beyond any doubt that there is no relationship between rates of opioid prescribing and either accidental drug overdose deaths or hospital admissions for overdose treatment (Hawry Jalal et al, Science, 2018, Aubry and Carr Frontiers in Pain Medicine 2021).
4. Over-prescribing of opioid pain relievers to pain patients has never been a dominant cause of accidental drug overdose and isn't now. Our "crisis" is caused by illegal drugs circulating in street markets -- illegal fentanyl, cocaine or methamphetamine, compounded by alcohol. Street markets are almost totally unknown to patients with regular health insurance who are treated adequately for pain.

"FDA bureaucrats live in glass houses. It is time to break the glass and let in the light!

In the hours immediately following the FDA meeting, I received several notes of congratulation from patients and clinicians. One in-person attendee at the meeting observed that "the regulators in the room were riveted." What remains to be seen is whether the regulators care enough for the horrendous consequences of their own misdirection, to actually change anything in US public health policy for the treatment of severe pain.

Notes:

Richard A. Lawhern PhD is a frequent contributor

to peer reviewed journals. He has authored or co-authored over 300 papers and articles in clinical and mass media venues.

Pat Irving, RN is a former National patient safety educator once affiliated with the Kaiser Permanente insurance system.

Monty Goddard is a patient advocate who has been active in educating State Boards concerning the need to educate clinicians and pharmacists on improved guidelines in patient pain care.