In a just published perspective piece in The New England Journal of Medicine, U.S. Food and Drug Administration (FDA) Commissioner Scott Gottlieb, M.D. outlines with colleagues the multi-prong approach the agency is using to combat the complex issue that is misuse and abuse of opioids while detailing surveillance measures already underway to detect rapidly the next wave of drug abuse. Among this so-called proactive pharmacovigilance plan is employing a social media “listening platform” that monitors opioid conversation traffic in traditional and other sites or forums that are publicly available. When alternative substances are mentioned, the data mining deepens.

With a goal of heading off escalation before problems are crises, this measure is a departure from the status quo reactive nature of prior policies. Hoping to intervene earlier and course correct before such issues become a more tragic and costly burden, the FDA would like to determine shifting trends and act upon the unexpected consequences well-intended, but often problematic restrictive policies can create. It is likely they are referencing as an example the pressure imposed on OxyContin manufacturers years ago to make an abuse-deterrent version of the addictive opioid. People were misusing, abusing and diverting the prescription drug - from not taking it as intended to crushing it up to snort and inject. When the abuse-deterrent form made this process more difficult by congealing when mashed up, people grew impatient and hastened their entry into the street drug market. Heroin rates soared.

Instead of opioids that are at the very least subject to dose dependence and quality control, people sought even more dangerous illicit substances now laced with higher potency, lethal fentanyl and other unknown contaminants.
Striking the balance between preserving appropriate, therapeutic use of prescription medications and curbing abuse is a daunting task. It appears the FDA recognizes the need for understanding the complicated social framework that drives these dynamic patterns, but chasing trends can often be the band-aid, not the cure.

Make no mistake, harm reduction is an important path forward in saving lives but routinely performs better with comprehensive care when informed by such influences like psychosocial, clinical status and epidemiological factors. The FDA group touches upon this and highlights its relevance in this opinion article[2]. But, until these topics share the discussion stage more meaningfully and substantially, we will not make a dent in breaking the cycle of addiction. The pill will change, but the outcomes won’t.

The conversation needs to involve active efforts to decipher why our culture of multi-drug abuse is so prevalent, how to impact attitudes on the hazards of prescription sharing and our propensity for self-medicating, make rehabilitation and re-entry programs more family-centric since we know adverse childhood experiences like chronic, extreme toxic stress when untreated can lead to adult dysfunction. With escalating rates of untoward effects on children (and adults) with this current opioid wave, we need to emphasize helping those addicted get rehab and other services that secure and stabilize their futures while also helping others never get addicted (see here[3] and here[4]).

Fully grasping the social determinants of health along with the FDA’s current analysis will likely allow us to make the greatest strides in long-term gains. Their preliminary work already reveals, which isn’t necessarily a revelation, gabapentinoid (e.g. used for seizures, neuropathic pain) scripts are on the rise and concern is being raised over possible abuse due to the changing behavior of opioid prescribing. Their sights are also set on Kratom and over-the-counter (OTC) loperamide.

Whether it is this spate of opioid difficulties, cold and cough suppressant misuse or abuse, or the latest ADHD drug call burden to U.S. Poison Control Centers[5], what I like to call substitution syndrome is a common ill of the human condition. The sooner we properly diagnosis it, approach it from a multidisciplinary perspective and accept its complex nature, the sooner we can be successful in treating it. The FDA leadership seems to get that, which is a promising start. Whether they can regulate to cure is another topic altogether.
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