WRITTEN TESTIMONY
to
DRUG FORMULARY COMMISSION
DEPARTMENT OF PUBLIC HEALTH
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First let me thank the commission for accepting this testimony.

As an addiction medicine physician I have four main concerns about the impact of creating a limited formulary for long-acting opioid medications, requiring pharmacies to switch medications to a single preferred brand, and increasing the barriers for providers of pain medications to access medications that are not included in top-tier or first line formulary notes.

Addiction is about the person, not the substance. Opioid addiction is a chronic relapsing brain disease characterized by behavioral maladaptation to tolerance and avoidance of withdrawal. It is often characterized by 3 primary characteristics: loss of control of use of a substance with attendant decrease in meeting familial or vocational responsibilities or engaging in usual social, recreational, or spiritual pursuits; compulsive use or craving of the substance; and continued use despite known adverse consequences. Treatment, that involves rehabilitative behavioral counseling and medication assisted therapy saves lives. There is general agreement that three factors come together to produce addiction in an individual: genetic predisposition, environmental access and individual resilience.

1) The promise of reducing availability of certain long-acting opioids to alter the environment and make addiction more difficult may be overstated for patients who are already addicted..

> Current epidemiologic studies suggest that as access to prescription medication is significantly limited, people with substance use disorders move to illicit drugs, primarily, (currently,) heroin. The underground economy that supports illicit drug manufacturing then produces other substances, which augment opioid effect, the most common current medication being non-prescription fentanyl.
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> Tamper resistant medications, while valuable with naïve patients, do not provide significant change in the environments that support addiction once substance use disorder becomes fulminant. For opioid addicted people obtaining drugs becomes a full time occupation with significant collaborative intelligence – often communicated via social media and the internet –devoted to promoting means to disable the tamper resistant methods utilized to produce safer medications.

2) A formulary must have an accessible, effective exception process or it may abrogate pharmacokinetic evidenced-based care, impede care to a vulnerable population and increase addiction.

a) Evolving personalized medicine which allows utilization of genetic tools to determine medications most effective for pain care may be crippled by rigid formulary restrictions

Pseudo-addiction is a condition in which patients receive pain medication of insufficient strength, inappropriate duration, or inadequate bioavailability to manage their pain. Pseudo-addicted patients may violate pain contracts, hoard medication, request early refills, demand known branded medications and otherwise express drug misuse behaviors because their pain is inadequately managed.

Pseudo-addiction may occur as disease progresses, or it may be rooted in genetic differences involving pharmaco-kinetic or pharmaco-dynamic features of specific medications in particular individuals. Without rigorous screening, careful behavioral health engagement, and meaningful use of available science, to appropriately manage pain, desperate pseudo-addiction often becomes actual addiction. The promise of pharmacogenetics is to best define specific individualized treatment.

Personalized medicine is just at the margin of individualizing best option for pain care for primary medication. Required pharmacologic substitution with associated questions of standardized therapeutic equivalence, bioavailability, and chemical similarity of alternate compounds undermines the effectiveness of this approach.

b) Epidemiologically addiction has been demonstrated to have a strong genetic component. as yet poorly articulated scientifically, with a single treatment strongly based in a known allele.

In the absence of better evidence base, current management of severe chronic pain in a patient at risk for or diagnosed with substance use disorder, often requires delicate and complex trial-and-error utilization of opioids with specific particular concerns about adverse reactions and unintended effects. A rigid formulary may preclude success with prescription medication and trigger or retrigger illicit drug use in a genetically susceptible individual.

3) The formulary must include a delivery system that decreases barriers to care. Increasing barriers to obtaining needed pain medication promotes suffering and undermines the resilience of otherwise vulnerable people to remain in recovery.

The current prior authorization process to obtain opioids is cumbersome, inefficient, non-standardized and erratic and appears to augment health inequities. Impoverished patients, and patients in neighborhoods with significant criminal activity report particular difficulty obtaining prescribed

opioids. Reliance on electronic health records to resolve these issues appears utopian, in the environments where people most at risk for addiction are found. Substituting structural difficulties to prescribing for meaningful provider-pharmacy-patient engagement and education can only produce frustration and attempts at work-arounds needed protection.

Anecdotally, many addicted patients currently in treatment report turning or returning to illicit drugs when unable to acquire prescribed medications in a timely fashion

4) Finally, the new formulary must avoid advancing a perception of increased barriers to obtaining needed opioid medication for pain control or it may disrupt public health efforts to encourage appropriate disposal of unused medications and promote hoarding.

Many thanks for allowing me to participate in this very important and opportune discussion.