I support passage of Senate Bill 163 as a concerned stakeholder and practicing physician. In my role as a pain medicine physician, I am confronted with balancing medical decisions with those made by insurance carriers on a daily basis. This is a source of great frustration, costly to my practice, and worrisome for its potential medical liability. I would like to detail some of my observations and add my opinion to this issue after working for 20 years in three (3) specialties: internal medicine, anesthesiology, and pain medicine.

1. **Fail-first is not the ideal approach.**
   - **a)** FDA approved meds for a given diagnosis often are not covered or may be non-formulary, thus requiring the use of a generic, non- FDA approved med for the same diagnosis. Many fail-first options are not supported by Randomized Controlled Trials (RCT)—considered the gold standard for authoritative research-- but rather consensus driven. One has to wonder why medical policies differ in the medications they favor and choose for fail-first. Aren't they reading the same literature?
   - **b)** Documentation of medication failure as required by insurance companies is onerous; this seems purposeful and meant to discourage physician appeals. One can not assume that a treating physician has access to prior therapy documentation. Yet a patient's verbal report is deemed insufficient to justify an authorization. This is particularly worrisome when a patient reports side effects but documentation is unavailable. This can result in prescribing a medication, against your better judgment, which the patient may not even take, and delaying appropriate treatment until their next office visit. All this before first-fail criteria are satisfied—and after exposing that patient to unnecessary risk.
   - **c)** Medication simplification is an often overlooked benefit of medication consolidation. Fail-first policies ignore this advantage. During a physician's clinical review process the ability to substitute 2-3 medications for a single alternative should be seen as cost-effective and therapeutically preferred. If the incidence of drug-drug interactions and poly-pharmacy can be reduced with a non-preferred alternative, then a rational, commonsensical fail-first policy should support it.
   - **d)** Copayments and deductibles are another strategy used by insurance payers to discourage utilization of prescribed, non-preferred medications. Without addressing this issue, any fail-first protocol is meaningless; it provides a simple and effective barrier to use.
   - **e)** I believe that prescribing a medication for an FDA-approved indication should bypass the fail-first process.

2. **There is an epidemic of prescription drug abuse. Controlled access is safe access.**
   - **a)** Abuse deterrent pain medications are typically not available in generic formulations. Those that are do not always use the same delivery systems, nor are they required

to. When addiction or a history of high risk abuse is present, prescribers should be allowed to utilize the formulations they deem necessary to insure patient safety and compliance.

b) Online pharmacies selling purportedly brand name products are a multi-billion dollar scam that threatens the safety of patients. This alternative is being used by an aging patient population due to economic constraints. There is simply no way to regulate this practice other than to create easier and affordable access to similar medications through insurance carriers regionally. I have seen fail-first drive this behavior in some of my patients.

c) Patients unable to afford medications or those not covered by their insurer have turned to family, friends, and "the street" to find prescription drugs—and will take their illegal equivalents out of desperation. Or perhaps worse yet, suffer in silence.

3. **Therapeutic equivalency is a fallacy.**

a) Great care and attention needs to be taken when using the terms "pharmaceutical equivalents", "pharmaceutical alternatives", and "therapeutic equivalents" since even pharmaceutical alternatives made by the same manufacturer can include differences in tablet/capsule and immediate/long-acting formulations—thus bioequivalence is unknown and testing for it not-required. An example might be the various formulations available for fentanyl patches, which have documented differences in bioavailability and hence clinical efficacy.

b) Medical Necessity should be an allowed bypass of fail-first and made a part of this bill. A bill that does not emphasize and support the medical decision making prerogative of the prescriber allows insurance carriers to practice medicine without any accountability.

Respectfully submitted,

Carl C Balog, MD, DABPM, FIPP