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Testimony Before the General Law Committee
HB 484 AA Prohibiting Generic Substitution for Tamper Resistant Drug Formulations
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Good afternoon Senator Doyle, Representative Baram and members of the General Law Committee. My name is Carrie Rand-Anastasiades and I am the Executive Director of the CT Association of Community Pharmacies, a trade association representing chains such as Walgreens, Rite Aid and Big Y to name a few. I am here to testify in opposition to HB 5484 An Act Prohibiting Generic Substitution for Tamper Resistant Drug Formularies.

Pharmacist substitution of brand name drugs with FDA-approved, therapeutically equivalent drugs saves money for patients, employers, and insurance carriers. It is a legal and well-established practice throughout the country. Prescribers, when issuing prescriptions to patients, indicate whether a pharmacist may engage in generic substitution. Prescribers retain the ultimate authority in this matter.

Throughout the country, legislation has been introduced to create obstacles to the existing generic substitution practices for brand name opioid tamper resistant formulations ("TRF"). These bills would prevent pharmacists from substituting brand name opioid TRF products with generically equivalent alternatives unless the pharmacist first obtains additional consents from both the prescriber and the patient. Such a requirement would unnecessarily increase state costs and complicate patient access to medication.

Prescribers already retain the ultimate authority as to whether or not pharmacists can substitute a brand name product with a therapeutically equivalent generic. Current statute ensures that prescribers retain ultimate authority over whether or not a prescribed drug can be substituted with a generic equivalent. A prescriber's decision on this point is clearly articulated to the dispensing pharmacist on the face of the prescription. Layering on special requirements to the existing laws that would require pharmacists to obtain additional written and signed consent from the prescriber for brand name opioid TRF products would be redundant; prescribers *already* make the determination on whether or not generic substitution is permitted at the point of issuing a prescription.

Imposing special requirements for brand name opioid TRF products would complicate patient access to medication. Redundant requirements that ultimately reaffirm prescribers' earlier choices will result in unnecessary delays in patient care. More often than not, pharmacists will be unable to reach prescribers who are otherwise busy treating patients, and will have to wait hours or days for a response. Such delays are both an inconvenience to patients and impediments to the timely delivery of patient care.

Additionally, many third party insurers limit the number of brand name drugs they cover although physicians are not always aware of a patient's formulary. Forcing the substitution of a medication that is not covered by an insurer would cause further complications and delays for the patient, including the possibility of waiting for a new prescription to be written. Currently, there are only a few opioids on the market that incorporate "tamper resistant technology." All of these drugs are more expensive brand products, making it less likely that these drugs will be on many insurers' formularies.

This legislation will increase state health care costs. Because brand name drugs are significantly more expensive than generic drugs, state health program such as Medicaid generally require pharmacists to dispense more cost effective generically equivalent products unless the prescriber indicates that a brand product is medically necessary. Legislation that would make it more difficult for pharmacists to engage in generic substitution for TRF products would ultimately impose a significant fiscal impact to the state. Notably, the Tennessee Medicaid agency estimated that this type of legislation would increase state expenditures by $11,873,100.

States should not act ahead of FDA on this matter. FDA has only recently issued draft guidance on TRF opioid products (referred to by FDA as "abuse deterrent formulations") which outline the process for brand companies to seek approval from FDA to add abuse deterrent claims to their labels. More data is needed in order to evaluate the effectiveness of the new TRF products at deterring drug abuse. Notably, in issuing the draft guidance, FDA has opted to continue to allow for generic, non-abuse deterrent products to remain on the market and has not yet made any special determinations for these products. Considering that FDA's work in this area is ongoing, enacting laws at this time that limit substitution of TRF products would not only be premature, but could also potentially conflict with standards or guidance developed by FDA on this subject.