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October 1, 2015

Eric Sheehan, Chair
Drug Formulary Commission
Interim Bureau Director, Bureau of Health Care Safety and Quality
Massachusetts Department of Public Health
Bureau of Health Care Safety and Quality
99 Chauncy St., 11th Floor
Boston, MA 02111

Re: Drug Formulary Commission Testimony.

Dear Mr. Sheehan

On behalf of the Massachusetts Independent Pharmacists Association, and our members who operate community pharmacies across the Commonwealth of Massachusetts, we would like to thank you for the opportunity to provide the following testimony;

We understand that Chapter 258 of the Acts of 2014 tasks the Drug Formulary Commission to consider the development of a drug formulary of substitutions for schedule II and schedule III opiates to address the public health epidemic that the Commonwealth of Massachusetts is experiencing with opiate use and abuse.

As community pharmacists we routinely see the devastating impact of this crisis and the damage it causes to individuals involved as well as their families. Not only do we see the impact in the patients we serve, many of our members have been personally impacted as victim of robberies by individuals seeking to obtain opiates illegally. In Massachusetts the number of robberies of pharmacies for opiates increased by 93% from 2012 to 2013. Although the number has decreased in 2014 and 2015 all too often our members find themselves looking down the barrel of a gun being held by an individual addicted to opioids. As you can imagine this is a traumatic experience for many and one they never imagined they would have to endure. Because of this we welcome the day when opioids are no longer needed for treatment or those that are used have abuse deterrent properties that prevent individuals from abusing them. Unfortunately this day has not come yet.

Substitution with Abuse-Deterrent Products

We understand the Commission is considering a therapeutic substitution with an abuse-deterrent product when a non abuse-deterrent product is prescribed. We support therapeutic substitution with these medications when they have a significant advantage over non abuse-deterrent products. Unfortunately this situation does not exist today. While we have some abuse-deterrent products

available, they provide little advantage in preventing abuse. These products make it more difficult (but not impossible) to abuse by snorting or injecting however they do not prevent abuse by oral consumption (taking more than prescribed) or by smoking. Individuals seeking to abuse these medications have demonstrated they are very resourceful in overcoming the abuse-deterrent properties of currently available products. Given the increase cost of these products and the limited benefit in reducing abuse, we do not feel therapeutic substitution with these products is justified at this time.

We are not alone in our view of currently available abuse-deterrent products. The Physicians for Responsible Opioid Prescribing recently provided the testimony below;

On April 2, 2015 PROP issued the following comment in response to FDA's announcement that newly released long-acting opioids will be required to be formulated with abuse deterrence:
Statement by Dr. Jane Ballantyne, President of Physicians for Responsible Opioid Prescribing, on FDA's abuse-deterrent opioids industry guidance document:

"Formulating opioid medications so that they are less easy to abuse will go some way towards reducing abuse, misuse, accidental overdose and death when these occur as a result of tampering with prescription opioids. But making formulations difficult to tamper with does not make their active ingredient less addictive, nor do abuse deterrent formulations prevent tampering for the most determined of those already afflicted by the disease of addiction."

Health insurance plans in Massachusetts also have an incentive to use abuse-deterrent products. When their members abuse medication they are often paying for the product through the individual's insurance benefit and they then are often paying for treatment for opioid abuse. The fact that no insurer currently encourages the prescribing of these products is evidence of the minimal abuse-deterrent benefit.

Substitution with non Abuse-Deterrent Products

We understand the Commission is considering a therapeutic substitution with a non abuse-deterrent product when a non abuse-deterrent product that is highly abused is prescribed. We find no evidence that this type of substitution will reduce opioid abuse. As stated above individuals who seek to abuse opioids will find a way to do so no matter what is prescribed.

General comments on the development of a drug formulary for substitution

As stated above health plans already have incentives to promote the use of the most cost-effective products in the treatment of covered individuals. The Pharmacy and Therapeutics Committees of these health insurance plans routinely consider how to achieve these goals. We rely on this system to ensure appropriate treatment for every other medical condition and we find no evidence that this system is not working to promote the use of the most cost-effective opioid medication.

If the Commission authorizes a therapeutic substitution it may not have any effect as health plans can implement a number of policies to discourage the use of these medications. In addition, a therapeutic substitution formulary approved by the Commonwealth of Massachusetts may not apply to plans that are regulated by the federal government such as Medicare D and self-insured ERISA plans. This could create a very confusing and unworkable situation where the ability to substitute would depend on the

health insurance plan and the information that would be required to determine this is not readily accessible by the pharmacist at the time of dispensing.

We are concerned that the approval of a therapeutic substitution for opioids may increase the abuse of these products by giving prescribers and patients a false sense of security on the products substituted. Prescribers and patients need to be reminded that all opioids regardless of their abuse-deterrent properties are dangerous and highly addictive drugs that should only be used when appropriate. This policy may obscure this important message

We are concerned that the approval of a therapeutic substitution for opioids could reduce the financial incentive for pharmaceutical manufacturers to develop more effective abuse-deterrent products. If the current products with only limited abuse deterrent benefits are routinely substituted, what incentives will pharmaceutical manufacturers have to develop more effective products?

We are concerned about communication needed to get all parties in the health care system to have a uniform understanding regarding this activity. The efforts that will be needed to accomplish this should not be underestimated.

We are concerned about the ability of pharmacies to communicate therapeutic substitution activities electronically to prescribers and when submitting claims to insurers. Currently the standards for electronic communication between prescribers and dispensers and between dispensers and insurers do not capture this type of activity. These standards are developed nationally and the process to change the standards to allow for this type of activity will be long and cumbersome.

Given the other components of Chapter 258 of the Acts of 2014 that will have a positive impact on the opioid epidemic and the above issues that are will render a formulary of substitutions for opiates ineffective, we recommend that the Commission work cooperatively with health plans when they determine the increased use of a particular product can impact opioid drug abuse instead of creating a mandatory therapeutic substitution formulary.

Comments on the mechanism of a drug formulary for substitution

If the Commission allows the therapeutic substitution for opioids the substitution should be automatic similar the substitution of generic equivalents. We strongly oppose any requirement for additional communication between the pharmacist and prescriber before such a substitution is made as this will delay therapy in situations where immediate therapy is needed. In addition, pharmacies are not paid more to dispense opioid medications despite the fact they there are already significant administrative costs to dispense these medication. Additional requirements will only exacerbate this situation and provide additional incentives for the pharmacy not to carry the product.

If the Commission allows the therapeutic substitution for opioids the prescriber should be able to communicate when the therapeutic substitution is not appropriate. We recommend the notation that is currently used to prevent the substitution of generic equivalents (writing “No Substitution on the prescription) be used. We also recommend that the pharmacist be able to override the therapeutic substitution if the product is not available, the product is not covered by the patient’s insurance plan, or if they believe the substitution is not appropriate for any reason. Once again we strongly oppose any requirement for additional communication between the pharmacist and prescriber in these situations.

If the Commission allows the therapeutic substitution for opioids the substitution should be noted on the prescription label produced by the pharmacy. The notation should be similar to that used when a generic equivalent is substituted. We recommend the phrase Therapeutic Substitution (or T.S.) for the "product prescribed" where the product prescribed is the brand or generic name of the product written on the prescription. When pharmacies substitute with a generic equivalent this phrase is usually placed on the prescription label underneath the actual product dispensed. Pharmacies may not have the ability to put the therapeutic substitution notation in the same area of the prescription label. Many will need to place the phrase where they put directions for the patient. The Commission should ensure pharmacies have the flexibility to put the phrase anywhere on the label. Additionally if this type of substitution is allowed pharmacies should have no additional documentation requirements.

If the Commission allows the therapeutic substitution for opioids the substitution of a Schedule II medication in place of a Schedule III medication should not be considered as federal law for these two schedule are different and could lead to prescriptions that violate federal law.

If the Commission allows the therapeutic substitution for opioids there needs to be a comprehensive review of current laws, regulations, and policies to ensure conflicts are not created. Additionally if this substitution is required we recommend that both prescribers and dispenser be absolved of any liability associated with the substitution.

We would like to thank you for the opportunity to present this testimony. If you have any questions regarding this testimony, please do not hesitate to contact me.

Sincerely,

Todd Brown MHP, R.Ph.
Executive Director