2211 Sanders Road
Northbrook, Illinois 60062

October 13, 2015

Representative Anne Gonzales, Chair
House Health and Aging Committee
77 South High Street, 13th Floor
Columbus, Ohio 43215

RE: HB 248 (Sprague, Antonio) Abuse Deterrent Formulation Written Testimony

Dear Chairwoman Gonzales:

I write today to convey the opposition of CVS Health to House Bill 248 (Sprague, Antonio), a bill addressing Abuse Deterrent Formulation drugs (ADF). It is the opinion of my company that this legislation as currently drafted, while well intentioned, is not the best approach to dealing with the epidemic of prescription drug abuse in Ohio. It imposes an artificial barrier on individual patients' cost-sharing requirements for this one category of prescription drugs, shifting the true cost of these drugs to public and private payers and to employees who will ultimately have to pay higher premiums, while potentially creating unintended consequences of pushing people to utilize alternative drugs such as heroin. As a health care company we want to preserve the ability to utilize all the tools at our disposal to fight this epidemic, and support a more comprehensive approach that includes education, counseling, treatment, OARRS and law enforcement.

CVS Health is a pharmacy innovation and health care company comprised of retail pharmacies, a pharmacy benefit manager, retail based clinics and a specialty pharmacy division. We operate 321 stores and 60 Minute Clinics in Ohio. We employ over 7,000 Ohioans including 900 pharmacists and 152 Nurse Practitioners and contribute nearly $56,000,000 in state and municipal taxes. Our operations impacting Ohio resulted in 50,331,260 claims processed and 32,127,018 prescriptions filled in the state in 2014.

It should be stated from the outset that CVS Health shares in the national goal of reducing the abuse of opioids and other controlled prescription drugs. Patients with both temporary and chronic pain deserve safe and effective treatment to help to ease their suffering and we are committed to providing them with the very best care. It is our belief that public policy promoting only ADF opioids (1) is a one size fits all approach to drug abuse, (2) locks a market that, as noted by the FDA, is "rapidly evolving," into static coverage requirements, (3) does not prevent abuse or potential overdose, and (4) would do little to improve the opioid abuse problem in Ohio.

What is an Abuse-Deterrent Opioid Analgesic?

The Food and Drug Administration (FDA) has just recently issued draft guidance[1] on abuse-deterrent opioids to assist pharmaceutical manufacturers in creating formulations of opioids with abuse deterrent properties. It is worth noting that the FDA guidance explicitly recognizes that "abuse-deterrent properties are defined as those properties shown to meaningfully ***deter*** abuse, even if they do not fully ***prevent*** abuse." The document suggests that ADF formulations can currently be generally categorized as follows: Physical/Chemical Barrier: drugs with physical barriers that can prevent

[1] "Abuse-Deterrent Opioids – Evaluation and Labeling – Guidance for Industry"," April 2015; http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm334743.pdf

chewing, crushing, cutting, grating, or grinding of the dosage form. Dosage forms with chemical barriers should resist extraction of the opioid through use of common solvents including water, alcohol or other organic solvents.

- Agonist/antagonist combinations: An opioid antagonist is added to the formulation to interfere with the release of the opioid if the medication is taken in any other way than it was intended.
- Aversion: Substances are added to the dosage form to produce an unpleasant effect if the dosage form is manipulated prior to ingestion or if a higher dosage than directed is used.
- Delivery system: Alternative delivery systems such as a depot injectable or an implant that is more difficult to manipulate.
- Prodrug: Medication contains a prodrug that lacks opioid activity until it has been transformed in the gastrointestinal tract.
- Combination: 2 or more of the above methods can be combined to deter abuse.

Specific concerns about HB 248:

- The bill requires that insurers must cover ***all*** abuse deterrent formulations and may not impose dollar limits, copayments, deductibles, or coinsurance requirements that are less favorable to an insured that those of non-abuse deterrent formulations. This type of mandate or restriction interferes with the ability of health plans/PBMs to design an evidence-based pharmacy benefit that is also financially sustainable.
- Arbitrarily reduced cost-sharing, e.g., the legislation's limit of out-of-pocket cost per prescription to the generic copay for non-ADF formulations does not lower the overall cost of the prescription drug. Instead, it simply shifts those costs back to the health plan and ultimately to both the employers who sponsor the plans and employees who pay increased premiums.
- Reduced copays remove one incentive for patients to use medications at an appropriate quantity. With lower copay, patients who tend to overuse controlled substances will have one less barrier to obtaining additional medication. The legislation may have a significant fiscal impact on the state, but has no proven commensurate public health benefit. Legislation requiring the use of ADF formulations would increase expenditures for state employee and state Medicaid programs because no generics are currently available for any FDA-approved ADF opioid. The LSC Fiscal Note estimated at $11 million -$167 million based on 5% of current opioid prescriptions for the Ohio Medicaid program. Tennessee found dramatic increases\ in health insurance premiums for its residents. For the TN state government, the minimum cost increase was estimated at $11M in year one alone.[i] Similarly drafted bills in Utah and Illinois were rejected because of the projected costs incurred of $7.1 million with an additional $2.4 million cost to local governmentand $55 million, to the Department of Healthcare and Family Services of (Illinois's Medicaid Department).
- It makes the State of Ohio the determinant for therapy rather than relying on the professional judgment of doctors and pharmacists. Ultimately, they are responsible for determining the proper course of medication for a patient.
- Prior authorization allows for a comprehensive review of the patient, including weighing cost vs. clinical need, of an opioid deterrent formulation
- Under current Ohio law a physician can write "Dispense as Written" (DAW) on a prescription to require the drug be dispensed exactly as prescribed by the physician.

Specific concerns with ADFs

- While technological innovations have been developed to prevent opioid medications such as OxyContin from being crushed, dissolved, chewed, or cut, this does not prevent abuse and potential overdose because an individual can still ingest opioids as intended and continue to ingest increasing amounts of ADF opioid. The FDA refers to ingestion as the most common form of opioid abuse.
- According to the New England Journal of Medicine, after the introduction of an ADF of OxyContin, abusers significantly lowered their use of OxyContin, but increased use of other opioids, such as heroin.[ii] The authors concluded, "abuse-deterrent formulations may not be the 'magic bullets they hoped they would be in solving the growing problem of opioid abuse."
- One of the ADFs can address one lingering concern: All medications can be misused and abused if the user ingests medications that are not prescribed to them or ingests more tablets than prescribed, regardless of the technology. In other words, while the technology is intended to prevent the opioid medication from being crushed, dissolved, chewed or cut, it does not prevent a person from simply swallowing more pills. Furthermore, there are

ways to circumvent some of these ADFs. A simple Google search for “methods to crush Oxycontin” returns many posts and blogs on ways to circumvent the abuse deterrents in the formulation.

CVS Health is supportive of methods to help to deter drug abuse, and we recognize that abuse deterrent formulas can be a useful tool in this battle. However, requiring these formulations to be covered at the same copayment rate as cost effective generic products most likely will not greatly impact patient safety and decrease abuse.It will, however, hide the true cost of healthcare from the consumer. This legislation does not restrain the prices of medication. Instead, the legislation provides an artificial limit on a patient’s out-of pocket costs, while transferring the patient’s coinsurance responsibility to the payer, including state employee benefit programs and state Medicaid plans – with no proven public health benefit.

In conclusion, CVS Health will continue our partnership with the State of Ohio to address the serious issue of prescription drug abuse, and look forward to addressing the concerns we have outlined in an effort to find the best solution to fight this epidemic together.

Sincerely and Respectfully,

Erik M Woehrmann
Senior Director, Government Affairs
CVS Health

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[i] Tennessee General Assembly Fiscal Review Committee, “Fiscal Note: SB 993 - HB 1818,” April 1, 2011.
[ii] Cicero, T.J. and Surratt, H.L., “Effect of Abuse-Deterrent Formulation of OxyContin,” New England Journal of Medicine, July 12, 2012.