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H. 723 introduced to curb over-prescription of opioid medications in Vermont

By **Press Release**
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News Release — Rep. Linda Joy Sullivan
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Vermont Representative Linda Joy Sullivan (Democrat, Bennington-Rutland) announced today the introduction of legislation seeking to stimulate industry-wide self-regulation by and among pharmaceutical manufacturers, physicians, and physician-affiliated hospitals and healthcare entities to curb the over-prescription of opioid medications in Vermont.

Sullivan was joined by over 20 other Legislators from both parties in co-sponsoring the legislation.

The bill, H.723, would through the creation of a new private cause of action make all providers associated with the care of individual patients legally accountable for injuries shown to have been caused by violations of standards governing the prescription of opioids already existing under Vermont regulations.

This proposed legislation would engraft into Vermont statute law the core of what are now largely advisory physician/provider guidelines promulgated by the Vermont Department of Health relating to the prescription of opioids. Violation of what will become new statutory standards of care would, when shown to have contributed to and caused an opioid addiction and associated injury, permit the commencement of a private cause of action against physicians and healthcare providers associated with the patient's care (and potentially even to manufacturers). The standards would not displace or supersede any of the existing rules and guidelines promulgated by the Department of Health.

The Problem:

The dramatic increase in the last 20 years in the prescription of opioid pain relievers ("OPR") has led directly to a 9-fold increase in the numbers of persons suffering opioid addiction, has spawned a huge market for illegal non-prescription substitutes such as heroin and has contributed to the frightening opioid death rates associated with what the U.S. Centers for Disease Control and Prevention has called the "worst drug overdose epidemic in U.S. history." "The correlation between opioid sales, OPR-related overdose deaths and treatment seeking for opioid addiction is striking." A. Kolodny, D.T. Courtwright, C.S. Hwang, P. Kreiner, J.L. Eadie, T.W. Cark and G.C. Alexander. 2015. The Prescription Opioid and Heroin Crisis: A Public Health Approach to an Epidemic of Addiction. The rate of opioid addiction in Europe is a fraction of that experienced in the United States. There is significant evidence that the opioid epidemic in the United States has its roots first in marketing efforts by the pharmaceutical industry and second in the development of prescription-writing practices among U.S. physicians that are far less conservative than those followed in other parts of the world.

The bill seeks to encourage an industry-wide, self-policing solution to a crisis contributed to by the pharma / healthcare industry in the United States that to this day profits from enormously high US prescription rates and accompanying medically-assisted treatment protocols for those patients in recovery.

Elements of the Proposed Legislation:

The proposed Act would first adopt in statutory form core provisions of Rules 5 and 6.4 of the existing Vermont Rules Governing the Prescribing of Opioids for Pain (e.g., maximum dosage and durational limits for initial and subsequent prescriptions, and required re-evaluations of long term prescriptions for chronic care) and would adopt the essence of Rule 6 of the Vermont Prescription Monitoring system, requiring prescribers to check the system before prescribing opioids.

Creation of a Private Cause of Action:

The Act would permit a person aggrieved of violations of Vermont opioid prescription standards to commence a law suit for actual or statutory damages. Individual patients have had difficulties prevailing in negligence suits across the United States, in large part due to the difficulty in proving that "prescription malpractice" in fact caused the patient's later addiction and injury. The burden of proving causation would under the Act remain on the person bringing the law suit. However, in cases where there has shown to have been repeat violations of the standard, a rebuttable presumption of causation would be established, requiring the prescriber to demonstrate that the inappropriate prescription practices did not result in addiction or to legal injury to the patient.

The Act would provide that:

1. Any person who demonstrates that he or she has subsequently, and as a proximate result of a physician/provider's violation of one or more of the Act's objective standards, developed an opioid dependency resulting in injury to that person, would be entitled to pursue a private cause of action. There would a three-year statute of limitations from the date of the physician's violation.

2. In the event that a physician/provider is shown to have committed two or more violations of those standards, a rebuttal presumption would exist that the prescription malpracticewas the cause of the injury

3. In the event that there are three or more violations of the statute involving the same patient, exemplary (or "punitive") damages could be awarded.

4. In the event that the action involves four or more violations committed by a physician in a 12-month period that involved the prescription, as to each violation, an opioid identified as produced and distributed by an individual pharmaceutical manufacturer, thatmanufacturer would be deemed liable jointly and severally liable without fault for the actual damages shown to have resulted.

5. In all cases, the physician's employer and other affiliated entities (hospital, clinic,Accountable Care Organization ("ACO"), practice group etc.) would be jointly and severally responsible in any such action to the same extent as the physician.

The Need for Vicarious Liability and Manufacturer Strict Liability:

Most common law employers are legally, or vicariously, responsible for the misdeeds of their employees. A healthcare entity may be responsible directly for damages caused by its physician employee. The proposed Act would extend this concept of respondeat superior to care entities beyond common-law employers with which the physician / prescriber has an ownership interest in or other professional (patient-related) affiliation. That is, hospitals, practice groups, ACOs, clinics and other healthcare entities responsible in whole or in part for the care of the patient would also be legally responsible for the injuries caused by "prescription malpractice." This provision of the Act is intended to promote internally within the healthcare industry collaborative, self-policing opioid prescription writing processes, protocols and training initiatives.

The Act would also impose liability on pharmaceutical companies without fault, provided that there are shown to have been four predicate violations involving the patient and a specific manufacturer-produced opioid within a 12-month period. While the pharmaceutical manufacturer may not have had actual knowledge of the inappropriate prescription practices, the Act is predicated on the concept that pharmaceutical manufacturers have immensely profited from the uptick in opioid prescription practices knowing that the distribution of their products was subject to inappropriate practices and excessive prescription-writing by individual prescribers. As such, the proposed Act would impose a form of "enterprise liability" based on a manufacturer's having put into the stream of commerce — and into the control of a reasonable foreseeable class of negligent prescribers – a dangerous instrumentality.

Representative Sullivan acknowledged, "While this proposal is going to be opposed by manyhealthcare providers, we're suffering an industry-created crisis that requires an industry-wide fix. We cannot continue to defer entirely to decisions made by individual physicians without some level of accountability within the healthcare industry as a whole."

Sullivan emphasized that the prospect of liability at the entity level should encourage true internal industry oversight of individual prescribers. "The imperative to 'heal thyself,' can't be limited to physicians. By imposing industry-wide accountability we might finally achieve meaningful prescription-writing protocols and internal safeguards and reviews."

Sullivan added, "Remember, we would not be creating new standards. Vermont's Department of Health has already adopted the standards on which a patient could seek to recover damages." Sullivan also downplayed the likelihood of an onslaught of frivolous litigation. "A former patient would still have to charge and prove that he or she was injured because of the physician's violations – given the nature of addiction that will in many cases be difficult and attorneys already have an obligation to certify that the allegations of injury and causation are made in good faith. However, the operation of a rebuttable presumption where there have been repeat violations, and the ability of a claimant to be awarded statutory damages, should permit greater access to the courts. That alone will provide a true incentive for practitioners to address this crisis in a meaningful – and truly effective — way."

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