Statement PhRMA

In Opposition of Alaska House Bill 53
March 26, 2013

Position: PhRMA opposes HB 53, which would create an undue burden on Alaskans who need pain treatment and interferes with the relationship between the patient and the primary care provider.

The Pharmaceutical Research and Manufacturers of America (PhRMA) is a voluntary, nonprofit association that represents the country's leading pharmaceutical research and biotechnology companies, which are devoted to inventing medications that allow patients to live longer, healthier and more productive lives. PhRMA companies are leading the way in the search for new cures and treatments. Since 2000, PhRMA member companies have invested over $500 billion in the search for new treatments and cures, including an estimated $49.5 billion in 2011 alone.

PhRMA appreciates the opportunity to provide comments about Alaska House Bill 53. PhRMA shares the concerns about the growing non-medical use of prescription drugs. People who abuse prescription drugs get them from multiple sources. According to a 2011 Government Accountability Office (GAO) report,[1] controlled substances can be diverted in a variety of ways from illegal or improper prescribing, prescription forgery, pharmacy thefts, or "doctor shopping" and can occur through illegal sales of controlled substances through internet pharmacies or pain clinics.[2] PhRMA believes that all participants in the drug manufacturing and distribution system must participate in the efforts to reduce the abuse of prescription drugs, especially because the majority of the medicines dispensed in the classes of most commonly-abused drugs are generic medicines.[3] There is not a single, easy solution and it requires shared accountability and partnership among all stakeholders in order to develop strategies to reduce the prevalence of prescription drug abuse.

While the intent of the legislation is to reduce non-medical use of pain medicines, it will likely create unintended consequences for patients and healthcare providers in Alaska. Less than two years ago, Washington State passed similar legislation to House Bill 53 (WAC 246-918-800). According to anecdotal reports and media articles, patients in Washington are now having difficulty accessing pain treatment and some are forced to drive several hours in order to access it, if they are even able to receive it at all.

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[1] GAO, Prescription Drug Control: DEA Has Enhanced Efforts to Combat Diversion, but Could Better Assess and Report Program Results, No. GAO-11-744 (2011).

[2] "According to the DEA, from fiscal years 2006 through 2009, rogue Internet pharmacies were a major source of this problem." *Id.* at 2. *See also* Prescription Drug Diversion: Combating the Scourge, Hearing Before the Subcomm. on Commerce, Manufacturing and Trade of the H. Comm. on Energy and Commerce, 112th Cong. 2 (2012) (statement of Joseph T. Rannazzisi, Deputy Assistant Administrator, DEA).

[3] Within the categories of most abused medicines as identified by the National Institute on Drug Abuse, an estimated 91% of prescriptions at the retail level were for generic medicines with only 9% of the prescriptions at the retail level for brand name medicines in calendar year 2011, based on PhRMA analysis of retail claims data from IMS Vector One National Audit (VONA), February 27, 2012. VONA aggregates data received from more than half of all retail pharmacies nationwide, representing nearly half of all retail prescriptions dispensed, but does not include mail-order prescriptions or prescriptions dispensed by long-term care pharmacies.

HB 53 would add an unnecessary burden for the patient who would be required to seek out a pain care specialist, of which there are few in Alaska. According to the American Academy of Pain Management, there are only seventeen pain specialists in the state and most of them are concentrated in the Anchorage region. Given the rural nature of Alaska, it is not easy for patients to access primary care in some areas, let alone particular specialists. In addition, patients who are suffering from chronic pain or a condition that requires pain treatment must usually rely upon family members, caregivers or friends to coordinate their care, transport them and even pick up their medications. These loved ones often have to sacrifice vacation days or take off days from work, not to mention a loss in income, in order to help the patient. HB 53 only adds to the complexity for these patients, and their families, to access the treatments and care that they need in a timely manner.

By requiring a third person or "gatekeeper" to prescribe medications at a certain dose, this legislation creates a barrier between the patient and their provider. Healthcare prescribers such as nurse practitioners, physician assistants, and physicians may not have the specific education or training set out in the legislation, but they have many years of education, training and expertise that allow them to safely prescribe medications to their patients on a daily basis. Moreover, they are in the best position to be familiar with their patient and that patient's clinical situation, including the patient's history, medication regimen and whether they are likely to consistently take their medications as prescribed. Requiring a third person to provide a consultation before a patient can receive treatment that their healthcare provider feels is necessary further delays access to needed medications and could create more fragmented or uncoordinated care.

PhRMA supports effective treatment, which requires access to, as well as compliance with, the prescribed regimen. Maximizing the potential for medicines to improve health depends upon people seeking, receiving, and following through on recommended care. More specifically, realizing the full value of medicines depends on appropriate medication use: being prescribed the right medicine at a dose and regularity to achieve the desired clinical effects and taking the medicine as prescribed consistently for the time required.

PhRMA has taken many steps to reduce the abuse of prescription medicine and to develop treatments for those who become addicted to medicines or other substances.

Drug Development: One task that is uniquely a responsibility of the companies engaged in the research to develop new treatments is the development of treatments for addiction. A recent PhRMA report indicates that in 2012 there were 26 medicines in development to treat addiction. Of those, 7 are intended to treat opioid addiction, 7 to treat cocaine addition, 4 to treat alcohol abuse, and 2 are for general drug dependence.

In addition, PhRMA member companies are going above and beyond by investing in innovative technology and developing abuse deterrent formulations of both new and existing drugs, formulations that can greatly reduce the potential for abuse because of the technology. Six abuse deterrent formulations have been approved by the FDA and are on the market, while 15 are in development as of December of 2012. FDA has recently issued guidance for manufacturers interested in developing and conducting studies of abuse deterrent formulations of either existing or new medicines.

Prescription Drug Monitoring Programs: As part of the solution to combat prescription drug abuse and misuse, PhRMA supports the use of Prescription Drug Monitoring Programs (PDMPs) and encourages both program enhancements and continued evaluations of effectiveness. Important improvements in the PDMP process include interstate interoperability where states can share data with each other through "real time" access to the data for providers and pharmacists. Data that is two weeks or older is not as useful in detecting

doctor-shopping as data that is "real time."

Education Programs for Prescribers and the Public: PhRMA believes that it is important for prescribers to be aware of the risks of addiction to medicines and to alert patients about those risks. In addition, prescribers need to know how to assess whether a patient poses a risk for addiction, and how to work with such patients to limit that risk. HB 53 states that a consultation is needed for patients who require 120 milligrams or more of an opiate. However, a "one-size-fits-all" approach is not supported in scientific literature or medical experts. Patients have many different characteristics and there are other variables that may require different doses from other patients. Establishing an arbitrary threshold fails to address the real issue. Experts have developed treatment guidelines and patient agreements that are specifically designed to address the risk of addiction, but prescribers may not know about those options, or may not have the time within the insurers' payment structures to work closely with patients. Therefore, education about the possibility of addiction and how to work with patients to prevent addiction would be much more beneficial.

It is also important for patients, and their family members, to be aware of the risks posed by abuse of prescription drugs, including the risk of an overdose or of addiction. PhRMA has worked with several groups over the past few years to develop educational programs. Most recently, PhRMA helped sponsor and provide content for DRUGFREE.org Medicine Abuse Awareness Project, which helps educate parents, grandparents and caregivers about the dangers and consequences if medications are misused and abused, as well as specific tips as to how to raise this topic with your child. Research has shown that kids are 50 percent less likely to abuse medication if a parent has talked to them about the risks of this behavior. Some other industry-sponsored educational programs have focused on a specific age group, such as teens, college students, adults, and seniors. In Washington State, PhRMA worked with Washington Health Foundation to educate college students on college campuses throughout the state about prescription drug abuse. And most recently, PhRMA is part of the National Governors' Association (NGA) Prescription Drug Abuse Academy, a seven-state, one year pilot where states are working with the NGA to create a tailored action plan to support specific policies to reduce the prevalence of drug abuse.

PhRMA's overall message on prescription drug abuse includes the following:

- Take your medicine EXACTLY as prescribed by your healthcare provider
- Do not share your medications with anyone
- Store it appropriately
- Dispose of it properly through household trash unless otherwise indicated on the label

Treatment Programs: There are treatment programs for addiction, but they are expensive, often have long waiting lists, and are often not supported by insurers or state programs. PhRMA believes that it is important for states to look at the scope of treatment programs available and whether there are ways to improve access to treatments.

In summary, PhRMA does not believe that creating access barriers or unnecessary restrictions for patients who need pain treatment is the answer to reducing prescription drug abuse and instead, will likely create unintended consequences. Rather, efforts that focus on education of patients and healthcare providers to prevent this behavior would be more effective. **For all of these reasons, PhRMA opposes HB 53.**