american academy of pain management

Integrative pain management for optimal patient care

January 22, 2014

Representative Gene DiGirolamo
Chair, Human Services Committee
Pennsylvania House of Representatives
Harrisburg, Pennsylvania

RE: HR 544

Dear Representative DiGirolamo and Members of the Committee:

I am writing on behalf of the American Academy of Pain Management in opposition to House Resolution 544, which requests that the Attorney General investigate the proliferation of prescription opioid drugs and take other, related, actions based on the findings of that investigation. We are concerned that an investigation of this nature focuses too narrowly on the harms that can result from use of opioid analgesics, while ignoring the benefits experienced by thousands of Pennsylvanians who use them to treat moderate-to-severe pain. I believe that such an investigation, if coupled with an effort to recover financial damages as outlined in the bill, is likely to have a chilling effect on the use of prescription opioid analgesics, resulting in harm to those individuals.

The supporting background information presented in this resolution is challenging for me in a number of respects. First, it can be read to imply that manufacturers of opioid analgesics have engaged in a conspiracy to cause widespread addiction to their products as a means of creating huge profits. I do not believe this to be true. While there is no denying that addiction to prescription opioid analgesics is a significant public health problem, I believe this was an unforeseen and unintended consequence resulting from efforts to make effective pain treatment more readily available. Now that this unintended consequence has been identified, these manufacturers are taking steps to combat it, developing new abuse-deterrent formulations and creating robust educational programs about ways to prevent and treat prescription drug abuse. Indeed, some manufacturers now spend as much money on these educational programs as they do on educational programs promoting use of their products for pain relief. To punish these companies by demanding recovery of the costs associated with prescription drug abuse seems unnecessarily harsh.

I also note the statement that, "[b]etween 1977 and 2007, the distribution of prescription opioids has increased 627%". It is unclear if this refers to the entire country, or only to Pennsylvania, but I believe this number is deceptively large. First, due to the nature of compounding percentages (not unlike compound interest earned on a savings account), a 627% increase over the course of 30 years represents only an average annual increase of about 6.5%. Second, note that the situation in 1977 was one in which all types of pain, including the often-severe pain associated with terminal cancer, was massively undertreated, suggesting that some substantial increases were clearly warranted. In fact, recent studies have found that pain associated with cancer and its treatment is still under-managed! Additionally, in 1977, the long-acting opioid analgesics available to today's

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patients were not yet on the market; because of the relatively high doses of medication contained in these products, their introduction into the market produced a somewhat deceptive increase in reports of the amount of drug distributed. Suffice it to say, the shock value of a 627% increase is significantly diminished when these factors are considered.

Finally, I am unfamiliar with any data source that supports the contention that "[c]hronic, nonmedical use of prescription opioids has increased 75% since 2002". The National Survey on Drug Use and Health (NSDUH), conducted annually by the Substance Abuse and Mental Health Services Administration, part of the US Department of Health and Human Services, has extraordinarily different findings. Since the NSDUH began asking respondents about prescription pain relievers in 2002, the percentage of the population 12 years of age and older reporting that they have engaged in non-medical use has been essentially unchanged (regardless of whether the time frame queried is the past month, past year, or the respondent's lifetime).

None of this is to deny that abuse of prescription opioid analgesics is a significant public health issue. Clearly, it is such an issue, with deadly consequences for more than 16,000 Americans every year. However, it is not the only significant public health issue that must be considered here. According to the Institute of Medicine's 2011 report, *Relieving Pain in America*, chronic pain affects more than 100 million American adults, and costs our economy between $560 and $635 billion each year. The risk represented by HR 544 is that, in the zeal to ameliorate one public health issue, actions taken will cause another public health issue to worsen—and the latter issue already dwarfs the former in terms of both the number of people affected and the cost to society.

For a number of reasons outlined in the Institute of Medicine's report, healthcare providers have found themselves increasingly reliant on opioid analgesics to treat chronic pain. Shortcomings in medical education (both basic and continuing), lack of research, and poor reimbursement for non-pharmaceutical approaches to treating chronic pain, all have conspired to create a situation in which many healthcare providers feel they have no reasonable option but to prescribe opioid analgesics.

To be fair, then, I believe that any investigation into the misuse, abuse, and diversion of prescription opioid analgesics in Pennsylvania also should investigate the status of pain care in Pennsylvania. This investigation should examine the adequacy of pain management education in Pennsylvania's medical, nursing, and allied health training programs; whether there is an adequate supply of qualified healthcare providers available to provide high-quality pain care for everyone who needs it; the need for clinicians who provide non-pharmaceutical treatment for pain, such as psychologists, physical therapists, massage therapists, acupuncturists, etc., and the adequacy of reimbursement for those services; and what efforts might be undertaken to change detrimental cultural beliefs about pain and its management.

Based on this dually-focused investigation, the task force should be empowered to suggest balanced solutions that could potentially address both of these public health issues. Determining a solution before even beginning the investigation, as HR 544 does, is unwise, and suggests that the outcome of the investigation is already known. I believe that the experts appointed to a task force should be tasked with doing more than identifying supporting data for a pre-determined solution, and that such an approach is more likely to benefit all interested parties.

I am happy to discuss my concerns and suggestions with you if necessary. Please feel free to contact me by email at btwillman@aapainmanage.org, or by telephone at 209-533-9750, ext. 110.

About the Academy: The American Academy of Pain Management is the largest pain management organization in the nation and the only one that embraces an integrative model of care, which: is patient-centered; considers the whole person; encourages healthful lifestyle changes as part of the first line of treatment to restore wellness; is evidence-based; brings together all appropriate therapeutic approaches to reduce pain and achieve optimal health and healing; and, encourages a team approach.

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Prescription Drug Abuse

PhRMA
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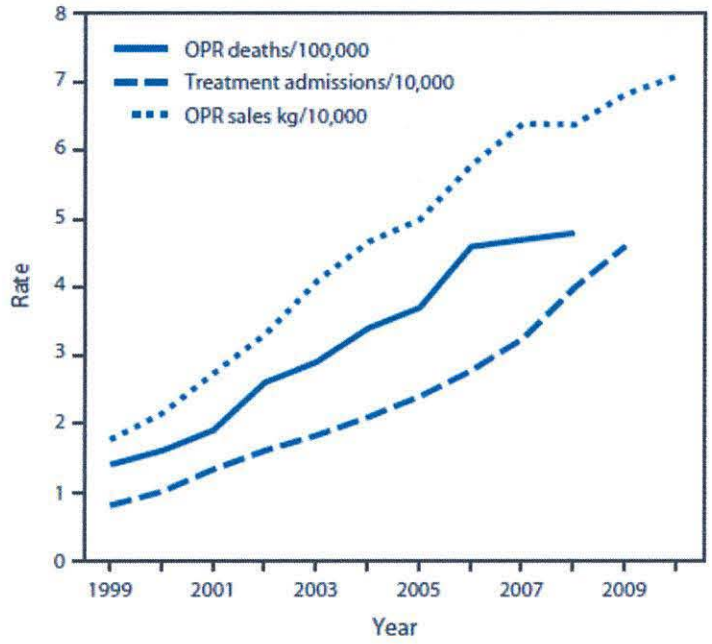
Overdose Deaths Involving Prescription Drugs

- CDC estimates that, in 2010, about 16,600 Americans died of overdoses involving prescription drugs
- Statistics are somewhat "squishy" due to reliance on death certificates
- These are usually called "prescription drug overdose deaths"
- Yet, previous CDC research suggests that about 75-80% of decedents used multiple drugs, not including alcohol, and that as many as 55-60% did not have a prescription for the drugs involved
- While explanations for increased deaths have been proposed, the real reasons remain to be clarified

How Do We Explain This?

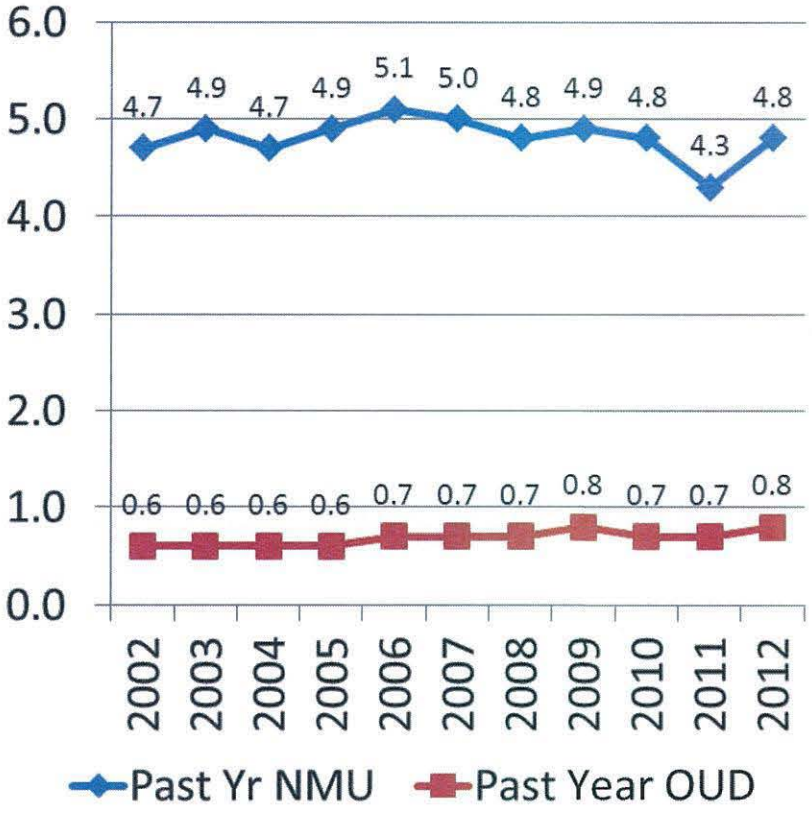
CDC graph of opioid sales, OD deaths, and treatment admissions

FIGURE 2. Rates* of opioid pain reliever (OPR) overdose death, OPR treatment admissions, and kilograms of OPR sold — United States, 1999–2010



* Age-adjusted rates per 100,000 population for OPR deaths, crude rates per 10,000 population for OPR abuse treatment admissions, and crude rates per 10,000 population for kilograms of OPR sold.

NSDUH data: Non-medical use, opioid use disorder rates in people ≥ 12 years old



Another CDC Observation

- Prescription opioids misused ≥ 200 days per year rose from 2.2/1000 in 2002-03 to 3.8/1000 in 2009-10 (74.6% increase)
- Increase was:
  - 105.3% among men
  - 81.0% among 26-34 year-olds
  - 134.6% among 35-49-year-olds
- This suggests that perhaps the greatest "bang for the buck" in reducing OD deaths might come from improving detection and treatment of people already misusing opioid analgesics
  - Speaks to need for increased training in techniques such as SBIRT
  - Suggests policy requiring such assessments might make sense

Jones CM : *Arch Intern Med* 2012:172(16):1265-7

Finally, What Does CDC Say?

- Prescription drug abuse:
  - 12.5 million non-medical users per year
  - $70-120 billion cost per year
  - 16,600 overdose deaths
  - "Prescription drug abuse, and related overdose deaths, is an epidemic"
- Chronic pain:
  - >100 million with chronic pain
  - $560-635 billion cost per year
  - Suicide risk doubled
  - " *crickets chirping*"
- If prescription drug abuse is an epidemic, then isn't chronic pain a pandemic?

Initiatives to Address Prescription Drug Abuse

- ONDCP: Plan includes the following:
  - Primary prevention
  - Early intervention
  - Increased access to treatment and support for recovery
  - Criminal justice reforms related to drug crimes
  - Improved information systems to analyze, assess, and manage the problem at the local level
- ASTHO: Presidential Challenge
- NGA: State Policy Academy
- Stated goal for both ONDCP and ASTHO: Reduce overdose deaths by 15% by 2015

Pharmacists' "Corresponding Responsibility"

- To be valid, controlled substance prescriptions have to be issued:
  - By an individual prescriber
  - For a legitimate medical purpose
  - Acting in the usual course of professional practice
- Pharmacists have a "corresponding responsibility"
  - This is never further defined
  - Pharmacists are taught that they have to verify legality and appropriateness of prescriptions
- This "corresponding responsibility" has become the basis for a new controversy

Pharmacists' "Corresponding Responsibility"

- Pharmacists and the chain drug stores that employ them have gotten a very clear message from DEA that they need to do more to ensure that prescriptions are appropriate
- Some chain drug stores have instituted new policies or toughened existing policies, resulting in much greater scrutiny of prescriptions
- Also results in many more phone calls to prescribers and many more patients having prescriptions denied at the pharmacy
- Prescribers are concerned that pharmacists are acting outside their scope of practice

Pharmacists' "Corresponding Responsibility"

- AMA House of Delegates passed a resolution protesting, in terms that were not especially conciliatory
- They are attempting to work with NACDS to resolve the issues
- There is an opportunity here for the profession of pharmacy to fill the void by defining what "corresponding responsibility" means, in behavioral terms, and by better defining scope of practice
- I believe they should be encouraged to work with NABP on a model policy

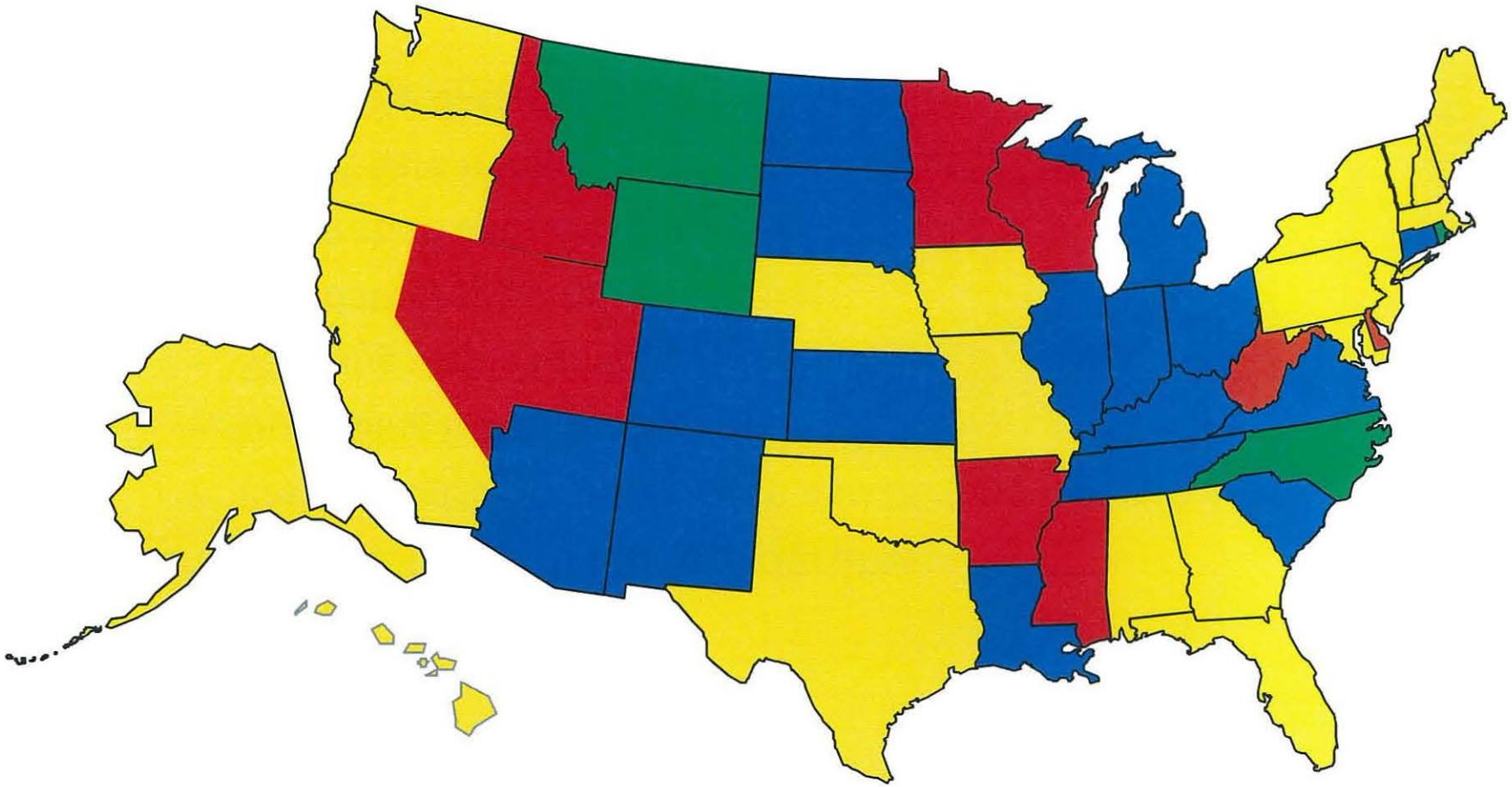
Wholesale Distributors

- Wholesale distributors also have gotten the message that they need to do more to detect possible "rogue" pharmacies and to act to control them
- Most have designed computer algorithms that detect outliers in terms of dispensing
- The most common response has been to summarily stop supplying the outlier pharmacies, without asking any questions
- This is essentially treating a screening measure as a diagnostic measure
- Results in some very good, specialized, pharmacies being affected without good reason

State Policy Issues

- Prescription monitoring programs:
  - Passing legislation in Missouri and DC (and Pennsylvania)
  - Upgrading features of programs
  - Securing stable funding
  - Mandatory registration and use
  - Integration with EHRs and HIEs
  - Use of data mining techniques to identify "bad actors"
  - Interstate data sharing

PMP Interconnect Status
October, 2013



Prescribing Guidelines

- States have been legislating the development of guidelines for prescribing of controlled substances, or, more often, opioid analgesics
- Most of the content of these guidelines is left to the regulatory process, but it is apparent that the general thought is that decreased prescribing will result in fewer OD deaths
- Mention is typically made of need to ensure adequate supplies for people with pain
- Unintended consequences, however, appear to include decreased access to medications

Prescribing Guidelines: Common Features

- Clear specification about:
  - Nature of history and physical
  - Documentation
  - Frequency of follow-up
  - Informed consent
  - Risk assessment
- Mandatory use of:
  - Prescription monitoring program
  - Urine drug tests
  - Patient-provider agreements ("contracts")
  - Written treatment plan

Prescribing Guidelines: Common Features and Unintended Consequences

- Threshold level of medication and/or duration of treatment, at which point something must happen
  - Documented re-evaluation of the treatment plan
  - Consultation with pain management specialist
- Unintended consequences:
  - Confusion about rules breeds anxiety among prescribers
  - Some reduce anxiety by ceasing to prescribe
  - Some use these rules as a scapegoat, while dropping people with chronic pain from their practices
  - Patients are unable to find other providers
- Unintended consequences documented in survey co-authored by Gary Franklin, in JABFM, (26):394-400.

Pain Clinic Regulation

- As a means of addressing "pill mills", policymakers seek to regulate pain clinics
- Pill mills are not pain clinics
  - What they do is already illegal
  - Suggests more of an enforcement problem than a problem with the law
- Pain clinics are now subjected to onerous and expensive new regulations
- Over-regulating pain clinics discourages the kind of care we need to foster

Pain Clinic Regulation: Unintended Consequences

- PCPs become frightened that they will unintentionally meet the criteria that define a pain clinic
- To avoid this, they drop patients using opioids and/or stop prescribing for some of these patients
- More and more patients are referred to pain specialists unnecessarily, making the specialists unavailable
- Some very experienced pain management providers are actually excluded from working in pain clinics because they are not board-certified

A New Resource for State Pain Policy Advocacy

- The State Pain Policy Advocacy Network is a project of the American Academy of Pain Management
- The purpose is to bring together disparate organizations with common interests, to advocate with one voice for good pain management policy
- **SPPAN's Mission:** To promote person-centered care for people affected by pain through advancing effective pain policy.

Why does SPPAN exist?

- State-level advocacy for good pain care policy has been fragmented, inconsistent.
- Collaboration is imperative to develop a coordinated effort to advance person-centered pain policy.
- Organizations lack staff, volunteer capacity to lead effective state pain policy efforts.
- SPPAN connects leaders and mobilizes action on the state level in the most effective way possible.

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STATE PAIN POLICY ADVOCACY NETWORK

SPPAN's unique role

- SPPAN tracks and analyzes all proposed pain policies; informs stakeholders
  - 800+ pieces of legislation, 250+ regulations
- SPPAN informs/supports advocates
- SPPAN convenes advocacy leaders around state-level policy issues for coordinated action

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Some SPPAN members

- Large organizations not focused on pain
  - AMA
  - American Osteopathic Association
  - American Academy of Family Physicians
  - American Pharmacists Association
  - American Cancer Society
- Major organizations focused on pain
  - American Society for Pain Management Nursing
  - National Fibromyalgia and Chronic Pain Association
  - US Pain Foundation
- Smaller state-based groups and individual advocates

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Examples of collaboration ahead

- 2014 Legislative agenda being developed with extensive stakeholder input
- New demonstration Medicaid waivers
- Prior authorization workgroup
- Florida project with Project Lazarus
- Patient advocacy committee

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How can I learn more?

Contact Amy Goldstein, Director, SPPAN
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Sign up for e-updates and
visit website at sppan.aapainmanage.org

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