PAIN CARE COALITION

A National Coalition for Responsible Pain Care

American Academy of Pain Medicine • American Pain Society
American Society of Anesthesiologists

To: Steering Committee
Pain Care Coalition

Cc: Executive Directors

From: Bob Saner, Washington Counsel

Date: August, 2015

Re: **Status Report – 2nd Quarter 2015**

ORGANIZATIONAL ITEMS:

The PCC Steering Committee last met in Washington in November of last year. It met by conference call on April 20th, 2015 and discussed the development of PCC comments on the draft National Pain Strategy. Comments were subsequently developed and submitted in May. An in-person meeting of the Steering Committee will likely be held in Washington on November 4, 2015..

ADVOCACY ITEMS:

Issue: NIH Funding for Pain Research

Description: The PCC works to develop Congressional support for pain research at the NIH. This includes building legislative awareness and support for NIH infrastructure, including the Pain Consortium and the Interagency Pain Research Coordinating Committee ("IPRCC"), education of legislators about the current inadequacy of pain research funding, and cultivating champions for increasing the "pain research pie" at NIH. Cultivation of lasting constituent relationships with key legislators is a primary goal.

Status: Ongoing

Timeframe: Ongoing

Recent Activity: While done through AAPM in connection with its Annual Meeting in Washington, and not technically as a PCC-sponsored activity, AAPM President Sean Mackey, Steering Committee member Dan Carr, AAPM Executive Director Phil Saigh and I visited health staff in a number of Congressional offices on March 18, 2015. All visits

included some discussion of NIH funding, and advocacy materials previously developed by the PCC were used in support.

Offices visited included:

Senator Diane Feinstein (D-CA), Member Senate Appropriations Committee,

Senator Orrin Hatch (R-UT), Member Senate HELP Committee, longtime NIH supporter and pain advocate,

Senator Mark Kirk (R-IL), Member Senate HELP and Senate Appropriations Committees,

Senator Elizabeth Warren (R-MA), Member Senate HELP Committee,

Senator Ed Markey (D-MA), longtime NIH supporter, particularly during his career in the House, and

Representative Joseph Kennedy (D-MA), Member House Energy and Commerce Committee (Health Subcommittee).

Work on NIH appropriations measures for FY 2016 is beginning in both houses, but as with last year, it seems likely that the "end game" is more likely to be another Continuing Resolution, making it unlikely that NIH will see a significant increase in funding for next year. The NIH reauthorization bill (HR 6—"21st Century Cures Act"), has now passed the House on a solid bi-partisan basis. It includes a boost to NIH funding of $2 Billion/year over 5 years. The Senate HELP Committee is beginning to work on comparable legislation, and movement there is predicted by year-end. The PCC did not engage with the House sponsors on this massive bill, but the issues have clarified somewhat and there may be an opportunity to engage with the Senate before the process is completed. I will be making recommendations on that topic separately in the near future.

The PCC's advocacy for more pain research specifically has been hampered somewhat by the delay in development of a "gaps" analysis by the IPRRC. However, NIH has signaled its continuing intention to develop that analysis, both through the FY 2016 budget submission for NIH, and most recently by reference in the draft National Pain Strategy. It now appears that the IPRCC is embarking on the development of a National Pain Research Strategy, as a companion to the National Pain Strategy. This is likely to be a very positive effort, with involvement by many PCC related individuals as was the case with the NPS, but it is also likely to further extend the timeframe before we will have a "gaps-like" case statement to take to the Hill.

NOTE: In addition to Hill visits specifically focused on NIH research funding, research is a constant theme of PCC communications, whether on the Hill, to regulators, or with other advocacy groups.

Issue: Reauthorization of NASPER Prescription Drug Monitoring Program

Description: Legislative authorization for the NASPER grant program, enacted in 2005, has expired. Efforts to reauthorize it in the 112th and 113th Congresses, which the PCC supported, were not successful.

Rep. Ed Whitfield (R-KY), who championed reauthorization efforts in the last Congress, circulated a **discussion draft** of a bill in January which the Steering Committee reviewed. While the substantive changes to the law (and to Mr. Whitfield's bill last year) were deemed satisfactory, the draft did not include a new multi-year funding authorization. Rep. Whitfield's staff assured us that the funding provisions would be worked out. As a result, PCC Chair Rathmell sent Rep. Whitfield a letter indicating PCC support for his draft if funding authorization was adequately resolved.

On March 26th Rep. Whitfield did introduce his bill, co-sponsored again by Rep. Frank Pallone (D-NJ), as **H.R. 1725**. The bill now contains a five year funding authorization of $10,000,000 per year for FY2016-2020. This compares favorably to $7,000,000 per year in last year's version. H.R.1725 also includes a new provision, not in either last year's version or the January draft this year, requiring HHS to coordinate its implementation of NASPER with PMP efforts at the Department of Justice so as to avoid duplication of effort and funding.

S. 480, another free-standing bill to reauthorize NASPER, was introduced in the Senate in mid-February by **Senator Jean Shaheen (D-NH)**, with Senator Patrick Toomey (R-PA) as lead co-sponsor. This version is based on Senator Shaheen's bill from the 113th Congress, and differs slightly from the Whitfield bill in the House. It also authorizes funding at the $7 Million per year level, not the increased $10 Million in H.R. 1725.

NASPER reauthorization is also included in **S. 636**, a more complicated bill introduced by **Senator Tom Udall (D-NM)**. The NASPER provisions of the Udall bill mirror most of those in Whitfield and Shaheen, but also include others not found in the other two, including mandated use of PMPs by prescribers, stronger provisions on interoperability, and provisions specific to methadone.

The Udall bill also includes other abuse and addiction provisions not included in Whitfield or Shaheen and largely unrelated to NASPER. Among them are: (1) mandatory prescriber education tied to DEA licensure, a proposal which the PCC has declined to support in past legislative proposals, (2) a pilot project to develop standardized peer review of prescribing practices, (3) new grant programs for training and screening projects to identify and intervene in situations of suspect abuse, (4) grants to encourage states to expand prescribing authority for APNs and PAs, (5) an FDA review of Naloxone classification (prescription vs. "behind the counter"), (6) two GAO reports, and (7) amendments to the Controlled Substance Act provisions dealing with medication-assisted treatment for addiction.

Status: The House Committee on Energy and Commerce included NASPER in a January hearing, based on the January draft of the Whitfield bill. In late July, the full Committee reported the bill out without opposition and without amendment. It now awaits scheduling for Floor action in the House.

The two Senate bills were referred to the Senate HELP Committee, which has taken no action yet with respect to either.

Recent Activity: As noted above**,** the PCC supported the Whitfield bill in the last Congress, and the January draft, subject to seeing the funding provision. The PCC endorsed H. R. 1725 in a letter to Rep. Whitfield in late May, and sent another letter to all members of the House Energy and Commerce Committee in July, urging them to co-sponsor the measure. The PCC also endorsed Senator Shaheen's bill in the last Congress but has not taken a position yet on her new bill. The PCC has taken no position yet on the Udall bill.

MONITORING AND REPORTING ITEMS:

Issue: Prescription Drug Abuse and Diversion

Description: Congressional activity on this topic continues. Bills tracked by the PCC in the last Congress all died in December, but the number and variety of bills introduced in this Session continues to grow. Even the lengthy list below excludes several bills that relate less to pain care and more to FDA drug approval processes (e.g. abuse deterrent products) or limit themselves to addiction treatment/mental health measures ("back-end of the problem" bills).

Except for NASPER reauthorization, the PCC has not taken formal positions with respect to these various proposals. It did, however, update late last year its 2011 position paper on abuse and diversion, and that is made available to Congressional offices from time to time.

Among the pending bills which the PCC monitors:

H. R. 471 and S. 483—"Ensuring Patient Access and Effective Drug Enforcement Act"

Lead sponsors: Rep. Tom Marino (R-PA)
Rep. Marsha Blackburn (R-TN)
Senator Orin Hatch (R-UT)
Senator Sheldon Whitehouse (D-RI)

Summary: This bill mirrors one that passed the House but not the Senate in the last Congress. It would amend the CSA to make it harder for the DEA to suspend or revoke a registration without first giving the registrant notice and an opportunity to submit a corrective action plan. It also requires a report from HHS, in cooperation with other agencies, on how law enforcement efforts affect patient access to medications, and how collaboration between public agencies and private stakeholders can be improved to better serve both patients and prevention of abuse and diversion.

Status: The House bill was jointly referred to the Committees on Energy and Commerce and Judiciary. It was handled by Commerce with Judiciary having no objections, and thus no separate consideration of it. It subsequently passed the House in April. Both the Senate bill and the House-passed bill are now pending in the Senate Judiciary Committee.

H. R. 1021—"Protecting the Integrity of Medicare Act

Lead Sponsors: Rep. Kevin Brady (R-TX)
Rep. Jim McDermott (D-WA)

Summary: This Medicare "fraud and abuse" bill had one provision of interest to the PCC. Section 12 of the bill would have authorized Medicare Part D drug plan sponsors to establish patient--prescriber "lock-in" programs. Pursuant to these programs, certain identified at-risk beneficiaries would be assigned to specific physicians who alone would be able to write prescriptions for designated drugs at high potential for abuse and addiction.

Status: The bill moved rapidly through the House Ways and Means Committee and went to the House Rules Committee where it was considered for addition, and some portions were added, to **H.R. 2**, the Medicare "SGR Fix" legislation. However, Section 12 from the Brady bill was not among them, so it is not in the final SGR bill that has now passed both Houses, and been signed into law by the President. I suspect we will see this provision again, or something like it, in some other context. Section 12 was based in part on a Part D "lock-in" proposal introduced as separate legislation in the last Congress by Rep Gus Bilirakis (R-FL). There was no counterpart Senate bill, but there were similar proposals for Medicaid drug "lock-in" arrangements advanced by several Senators in previous years.

Rep. Bilirakis did reintroduce his "lock-in" bill separately on May 13, 2015 as **H. R. 2298**. It was referred to both Energy and Commerce and Ways and Means. It was subsequently rolled into (with only technical changes) **HR 6**, the 21st Century Cures bill which has now passed the House.

On July 30, 2015, Senator Pat Toomey (R-PA) introduced a "lock-in bill in the Senate, **S. 1913**. Text of the bill was not yet available in early August, but based on a summary of it, it appears to be similar to if not identical with the Bilirakis version. S. 1913 was referred to the Senate Finance Committee of which Senator Toomey and two co-sponsors of the bill are members. (See also **S. 1431** below)

S. 524 and H. R. 953—"Comprehensive Addiction and Recovery Act"

Lead sponsors: Senator Sheldon Whitehouse (D-RI)
Senator Rob Portman (R-OH)
Senator Kelly Ayotte (R-NH)
Rep. James Sensenbrenner (R-WI)

Summary: This is very ambitious legislation with provisions dealing with (1) prescribing guidelines, (2) naloxone promotion, (3) abuse prevention, (4) addiction treatment, (5) law enforcement training on addiction and overdose prevention, (6) judicial and correctional reforms, and (7) drug disposal, as well as others. It focuses heavily on opioids and heroin but many of its provisions deal with substance abuse

generally. The principle provision of likely interest to the PCC is Section 101 which would establish a "Pain Management Best Practices Inter-Agency Task Force." The Task Force would consist of designated Federal officials and experts from the private sector. It would be charged with developing best practices for pain management including prescribing of pain medications. The resulting best practices would be widely disseminated, but the legislation would not make them mandatory.

Status: The bills have been referred to the Judiciary Committees in both Houses. No action has been taken.

Note: There are many similarities between S. 524/H.R. 963 and the ongoing efforts within HHS to confront opioid-related overdose and addiction issues. See the announcement from Secretary Burwell on March 26th at the link below.

http://www.hhs.gov/news/press/2015pres/03/20150326a.html

S. 636—"Increasing the Safety of Prescription Drug use Act"

Lead sponsors: Senator Tom Udall (D-NM)
Senator Al Franken (D-MN)

(See discussion of Udall bill under NASPER above)

S. 707 and H. R. 1821—"Opioid Overdose Protection Act"

Lead sponsors: Senator Ed Markey (D-MA)
Senator Kelly Ayotte (R-NH)
Rep. Richard Neal (D-MA)
Rep. Frank Guinta (R-NH),

Summary: This bill would provide a limited shield from liability to civil suit for ordinary negligence in situations involving emergency administration of naloxone and other overdose response medications. Prescribers would be eligible for the shield if they have prescribed or provided the drug to an individual at risk of overdose, or to a caregiver, if the individual or caregiver has received training in opioid overdose response. Similarly, the individual administering the medication in a response situation would be protected.

Status: S. 707 was referred to the Senate Judiciary Committee, which has taken no action on the bill. H.R. 1821 is pending in the House Judiciary Committee with no action taken.

S. 799 and H. R. 1462—"Protecting Our Infants Act"

Lead Sponsors: Senator Mitch McConnell (R-KY)

Senator Robert Casey (D-PA)
Rep. Katherine Clark (D-MA)
Rep. Steve Stivers (R-OH)

Summary: This measure is designed to improve prevention and treatment of neonatal opioid abuse and neonatal abstinence syndrome. Components include (1) an AHRQ assessment and report on causes and risks, treatment options, appropriate use of opioids during pregnancy and several other aspects of the problem, (2) an HHS strategy to address research and service program gaps, and (3) CDC support to the states to improve data collection and public health surveillance on the problem.

Status: The House bill referred to the Energy and Commerce Committee, marked-up the bill in both Subcommittee and Full committee in late July, moving it in tandem with the House NASPER bill, and readying it for Floor action in the House. The Senate version was referred to the HELP Committee which has taken no action on it.

S. 1134—"Heroin and Prescription Opioid Abuse Prevention,Education and Enforcement Act"

Lead Sponsors: Senator Kelly Ayotte (R-NH)
Senator Joe Donnelly (D-IN)

Summary: This bill would do two things of particular interest to the PCC. First, it would create an HHS-led task force comprised of both public and private sector representatives, to develop "best practices" for both pain management and opioid prescribing, along with a strategy for their dissemination. The resulting guidelines would not be mandatory. This feature of S. 1134 is taken from the Whitehouse bill, S. 524, of which Senator Ayotte was a co-sponsor.

Second, it would provide for the first time a statutory authorization for the Hal Rogers PMP grant program, heretofore supported only by language in appropriations bills. The authorization would be for five years at $9 Million per year. This feature of the bill appears to be competitive with rather than complementary to the Whitfield and Shaheen NASPER reauthorization bills.

The bill would also authorize a public education campaign and a naloxone distribution grant program.

Status: The bill is pending in the Senate Judiciary Committee.

S. 1392—"Safer Prescribing of Controlled Substances Act"

Lead Sponsor: Senator Ed Markey (D-MA)

Summary: This is a "rifle shot" measure requiring mandatory professional education for physicians and other prescribers as a condition of DEA registration

and renewal. HHS/SAMHSA would be responsible for approving training programs, both in-person and online, that would satisfy the requirement. Programs would need to cover pain management "best practices," prescribing guidelines, substance abuse diagnosis and treatment, and medication adherence/diversion strategies. The bill does not specify a minimum number of hours, or a mandatory frequency of training, nor does it identify specific professional societies whose training programs would be considered acceptable for these purposes.

Status: The bill has been referred to the Senate HELP Committee.

(See also S. 1431 below)

S. 1431—"Prescription Drug Abuse Prevention and Treatment Act"

Lead Sponsors: Senator Joe Manchin (D-WVA)
Senator Angus King (I-ME)
Senator Shelley Moore Capito (R-WVA)

Summary: This is a complicated bill with multiple parts, several of which have similarities to other proposals in either the House or Senate. Of particular interest to the PCC are (1) provisions requiring mandatory prescriber training as a condition of DEA registration or renewal; (2) AHRQ development of drug abuse related quality measures for use in various provider settings; and (3) a Medicare Part D prescriber and pharmacy "lock-in" program similar to those introduced in the House. Other features in the bill relate to consumer education, opioid treatment programs, and an "opioid death registry."

The Manchin bill's approach to mandatory training differs considerably from that in the Markey bill, S. 1392. First, it would require 12 hours of training every 3 years; second, it would entail education on addiction detection/intervention (SBIRT) and treatment of opioid dependent patients as well as pain management; and third, it enumerates professional societies that would be eligible to deliver the training. AAPM, ABPM, APS and ASIPP are all listed in the bill, but ASA is not.

Status: The various provisions of this bill cut across multiple Senate Committee lines of jurisdiction. Interestingly, at this point it has been referred only to the Finance Committee, which would have jurisdiction only over the Medicare Part D lock-in section.

S. 1654—"Overdose Prevention Act" and **H. R. 2850—"Stop Overdose Stat Act of 2015"**

Lead Sponsors: Senator Jack Reed (D-NH)
Rep. Donna Edwards (D-MD)

Summary: These companion bills were introduced on June 23, 2015 with substantial bi-partisan co-sponsorship in both Houses. They are basically Naloxone promotion measures, and would authorize new funding through SAMHSA to

support state and local efforts to make Naloxone more widely available, and train patients, family members, and first responders on its use. The bills would also authorize yet another HHS task force to look at overdose prevention strategies, and encourage more NIDA research on overdose prevention. I believe these bills were originally developed and promoted by the Harm Reduction Coalition.

Status: The Senate bill was referred to the HELP Committee and the House bill to energy and Commerce. Neither Committee has taken any action at this time.

H. R. 1628—"Veterans Pain Management Improvement Act"

Lead Sponsors: Rep. Ron Kind (D-WI)
Rep. Lee Zeldin (R-NY)

Summary: This bill would establish new Pain Management Boards in each regional VA "VISN" (Veterans Integrated Service Network). The Boards would be appointed by the VA Secretary and be interdisciplinary, with representatives from pain medicine, addiction psychiatry and psychopharmacology, primary care, psychology, and social work. Patient and family representatives would also be included. The Boards would be charged with (1) development of patient-specific treatment recommendations and (2) more general best practices for management of patients with "complex clinical pain." Requests for Board recommendations could be initiated by VA patients, their families, their physicians or other VA facility employees. The bill also calls for annual reporting from the Boards to the HQ office of the VA, and a one-time report (2105) to the Veterans' Affairs Committees of the House and Senate.

Status: H.R. 1628 is pending in the Health Subcommittee of the House Veterans' Affairs Committee.

S. 1641—"Jason Simcakoski Memorial Opioid Safety Act"

Lead Sponsors: Senator Tammy Baldwin (D-WI)
Senator Shelley Moore Capito (R-WV)

Summary: This bill is another Veterans Health initiative, like the Kind bill above, but much more comprehensive. Several features of the bill are appealing insofar as they would raise the priority of pain management issues in the VA, and expose them to routine Congressional oversight, somewhat consistent with part of what the PCC hoped to achieve with the Veterans Pain Care Act seven years ago. At the same time, it is very far-reaching and in some respects so focused on opioid prescribing and the dangers inherent therein as to raise concerns about impeding access to opioid therapy where indicated. Features of particular interest to the PCC include: (1) a requirement to update the joint VA/DoD guidelines for Management of Opioid Therapy for Chronic Pain, using CDC "safe prescribing" guidelines still under development and very prescriptive guidance within the VA system on issues of patient safety and abuse deterrence; (2) enhanced prescriber training throughout

the VA system on both pain management and safe opioid use. (The training requirements are very prescriptive with respect to content, but not couched in terms of the number of hours or frequency. They are also to be implemented through the existing VA Interdisciplinary Chronic Pain Management Team Training Program, which is probably a positive.); (3) establishment of pain management teams at every VA medical facility, but no specifics with respect to the credentials of team members or whether physician's would function as team leaders; (4) better tracking of opioid use throughout the VA system using the real-time VA EHR ; (5) expanded use of PMPs by VA personnel; (6) expanded availability of and training on opioid antagonists throughout the VA system; (7) a new oversight group on pain management and opioid therapy within the Health Executive Committee of the Joint VA/DoD Executive Committee; (8) new Pain Management Boards within each VA "VISN" network (similar to Kind bill above); (9) a major GAO report on opioid prescribing within the VA and ongoing reports to Congress on the same; and (10) expanded use of complementary and integrative health throughout the VA (this provision is not pain specific, but is likely included as an alternative to opioid therapy).

Status: S. 1641 was referred to the Senate Committee on Veterans' Affairs which has taken no action on it as of this time. The bill does have a growing list of co-sponsors including several who have been active on the same issues in other contexts (e.g. Manchin, Markey and Brown).

H. R. 2463 –DOJ Grants for Drug Disposal Site

Lead Sponsors: Rep. Ami Bera (D-CA)
Rep. Phil Roe (R-TN)

Summary This measure, characterized as the "DROP Act," would authorize demonstration grants for creation or expansion of drug disposal programs. Eligible grantees would include, among others, states, local governments, drug distributors, hospitals and pharmacies. Grants would be for a two-year period and capped at $250,000. A major purpose of the grants would be to test programs that could be replicated on a large scale.

Status: Referred to both House Judiciary and Energy and Commerce Committees. No action taken.

For further information, contact Bob Saner at 202-466-6550 or rsaner@ppsv.com.