

June 7, 2018

The Honorable Greg Walden
Chairman
U.S. House Committee on Energy and
Commerce
2185 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Kevin Brady
Chairman
U.S. House Committee on Ways and Means
1011 Longworth House Office Building
Washington, D.C. 20515

The Honorable Lamar Alexander
Chairman
U.S. Senate Committee on Health, Education,
Labor, and Pensions
455 Dirksen Senate Office Building
Washington, D.C. 20510

The Honorable Orrin Hatch
Chairman
U.S. Senate Committee on Finance
104 Hart Senate Office Building
Washington, D.C. 20510

The Honorable Frank Pallone
Ranking Member
U.S. House Committee on
Energy and Commerce
237 Cannon House Office Building
Washington, D.C. 20515

The Honorable Richard Neal
Ranking Member
U.S. House Committee on Ways and Means
341 Cannon House Office Building
Washington, D.C. 20515

The Honorable Patty Murray
Ranking Member
U.S. Senate Committee on Health, Education,
Labor, and Pensions
154 Russell Senate Office Building
Washington, D.C. 20510

The Honorable Ron Wyden
Ranking Member
U.S. Senate Committee on Finance
221 Dirksen Senate Office Building
Washington, D.C. 20510



Dear Chairman Walden, Ranking Member Pallone, Chairman Brady, Ranking Member Neal, Chairman Alexander, Ranking Member Murray, Chairman Hatch, and Ranking Member Wyden:

The Patient Quality of Life Coalition (PQLC) represent patients, health professionals, and health care systems, dedicated to improving quality of care and quality of life for all patients through increasing access to palliative care and maintaining access to appropriate pain management. We write today to make you aware of our policy priorities as you continue to consider legislation to address the opioid crisis. We understand that several bills have passed out of multiple committees recently that address these issues. As both houses of Congress consider these bills, we welcome the opportunity to share our perspective and work with you in this endeavor.

Pain management is an integral part of palliative care for many patients with serious illness.¹ These patients commonly experience pain due to their underlying illness(es) and sometimes the treatment itself, yet pain and other symptoms tend to be under-recognized and under-treated as part of regular

¹ "Serious illness" is defined as a health condition that carries a high risk of mortality and either negatively impacts a person's daily function or quality of life, or excessively strains their caregivers. See Kelley AS, Bollen-Lunds E. Identifying the Population with Serious Illness: The "Denominator" Challenge. J Palliat Med. 2017 Nov 10. doi: 10.1089/jpm.2017.0548.

care.² Poorly managed pain in this population can contribute to decreased productivity, poorer quality of life, increased health care utilization, and even increased mortality.³ Palliative care helps prevent and relieve pain by systematically screening and assessing for pain and other symptoms, tailoring pharmacological and other interventions to patients' individual circumstances (including medical history and stated goals of care), and carefully monitoring and adjusting treatment regimens as needed over the course of the illness.⁴

The PQLC is mindful of the serious and growing public health crisis caused by the inappropriate use of opioids, and support evidence-based efforts to reduce harm and adverse events associated with such misuse. At the same time, we want to make sure that public policies intended to reduce inappropriate use of opioids do not simultaneously create access barriers to pain management and symptom relief for patients suffering from diseases such as cancer, heart disease and Alzheimer's for whom opioids are medically indicated, and who are often times benefiting from such treatment.

We commend Congress for continuing to address the opioid crisis in a bi-partisan and transparent process that has included multiple hearings and opportunities for public input. We ask you to consider the following feedback as you continue this process.

Research and Innovation

Several of the bills considered by the relevant congressional committees have included increased funding and expanded agency authority to conduct research on better treating substance use disorder and pain, and finding new non-opioid treatments. Increasing research in these areas – particularly research at the National Institutes of Health (NIH) – is crucial to addressing the opioid crisis and improving the quality of life for the patients our organizations represent. We consider the goal of increasing research in this area to be one of our top priorities in any congressional action on opioids this year.

The PQLC strongly support the inclusion of the ACE Research Act (H.R. 5002/S.2406) in any final bill package. This bill increases the flexibility for the NIH to approve "high impact, cutting-edge projects" that address the opioids crisis more quickly and efficiently, including finding new, non-addictive pain treatments. We are supportive of increasing funding for research in these areas and increasing focus on finding new ways to treat pain – including new drugs as well as non-pharmacological treatments.

The PQLC also supports the inclusion of the Opioids and STOP Pain Initiative Act (H.R. 4733/S. 2260), which appropriates \$5 billion over five years for NIH-directed pain research. The bill authorizes the NIH to intensify and coordinate research into the understanding of pain, therapies for chronic pain, and alternatives to opioids for pain research. It also directs NIH to consider recommendations made by the Interagency Pain Research Coordinating Committee. We support any legislative efforts, including this one, to implement the Federal Pain Research Strategy, which includes research on novel drugs and non-pharmacological pain treatments, improved screening tools to help providers assess pain, national

² Wilkie DJ, and Ezenwa MO. Pain and symptom management in palliative care and at end of life. *Nurs Outlook*. 2012; 60(6):357-364. doi: 10.1016/j.outlook.2012.08.002. Available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3505611/pdf/nihms408159.pdf>

³ "Management of pain in older adults." *Geriatric Palliative Care*. Eds. Chai E, Meier DE, Morris J, and Goldhirsch S. New York: Oxford University Press, 2014. 159-169. Print.

⁴ Morrison LJ, and Morrison RS. Palliative care and pain management. *Med Clin N Am*. 2006; 90(5):983-1004. doi: 10.1016/j.mcna.2006.05.016. Retrieved from <https://www.ncbi.nlm.nih.gov/pubmed/16962853>

registries and research networks for diverse pain conditions, effective models for pain management and care delivery, and precision medicine methodology for preventing and treating pain.

Research that finds new treatments for pain or better methods for using existing pain treatments will help patients with serious illness better maintain their quality of life while dealing with debilitating symptoms like pain. It will also give healthcare professionals more options in treating their patients and will reduce reliance on pain treatment with opioids.

Restrictions on Patient Access to Opioids: Prescription Limits and Lock-In Policies

We recognize that policymakers at multiple levels of government are currently considering restrictions on opioid prescriptions. These restrictions include limits on dosage of opioids, limits on duration of an initial prescription, requirements that patients receive opioid prescriptions from a limited number (usually one) of prescribers, and requirements that patients use a limited number (usually one) of pharmacies to fill their opioid prescriptions. We note that H.R. 5808 and H.R. 5799, currently under consideration in the House Energy & Commerce Committee, require or strongly incentivize Medicaid programs to implement such restrictions.

As organizations representing seriously ill patients, many of whom require prescriptions that would trigger such restrictions, we are very concerned about the impact they would have on patient access to treatment. We believe these policies could impede or prevent access for certain patients who can benefit from opioids to treat their pain or other symptoms of serious illness and who take them safely. If Congress moves forward in consideration of these two bills or others establishing these restrictions, we urge your extreme caution. We recognize that the legislation passed by the Senate Health, Education, Labor and Pension Committee, the Opioid Crisis Response Act (S. 2680), requires HHS to release a study on the impact of federal and state laws and regulations that limit the length, quantity, or dosage of opioid prescriptions. We support the requirement for HHS to study these limits and their effects on patient access, and urge Congress and other policymakers to wait for the results of this study before further limiting access.

If you are to move forward with new opioid prescription limits, we ask you to provide exemptions for cancer, heart disease, Alzheimer's and other seriously ill patients. Such exemptions should follow these guiding principles:

- Include cancer patients in active treatment and cancer survivors who continue to receive treatment for pain because of the effects of cancer treatment or the cancer;
- Include patients receiving hospice care;
- Include other non-cancer patients experiencing pain or other symptoms related to a serious illness who are receiving, or would be eligible for, palliative care services;
- Be standardized in definition and application across all plans or programs affected by the policy;
- Be applied as early in the process as possible so that a patient who qualifies for an exemption will experience little or no disruption to treatment – and to minimize the time plans, prescribers and pharmacists must spend in resolving restrictions for patients who are ultimately exempted; and
- Be clearly explained and included in aggressive outreach and education efforts to prescribers so they can anticipate access challenges for their patients and proactively minimize these obstacles; and
- Include a clear and timely appeals process for patients that should be exempt but are not.

If Congress moves forward in considering H.R. 5808, H.R. 5799, or any other legislation that establishes prescription limits or lock-in policies for opioids, we urge you to provide these exemptions – and to not leave these details for the determination of regulators or states. Seriously ill patients need these protections to be a federal priority, and to be a consistent minimum standard across all states. For more guidance on such exemptions, please refer to the June 6 letter sent by the Patient Quality of Life Coalition to the U.S. Department of Health and Human Services, available at http://patientqualityoflife.org/wp-content/uploads/2018/06/PQLC-Memo-Exemption-Language-for-Opioid-Restrictions-05312018_FINAL-sent-to-HHS.pdf.

Increasing Quality Pain Management

We are pleased that several proposed bills under consideration in Congress take steps to provide better training for healthcare professionals in pain management. While it is important to focus on developing new treatments, we also know it is crucial that prescribers and other healthcare professionals working with patients in pain know how to most appropriately diagnose and treat that pain with the best evidence-based treatments and protocols.

The PQLC supports the re-authorization of the NIH Centers of Excellence in Pain Education (H.R. 5261), which provides coordination of the development, evaluation and distribution of pain management curriculum for health professional schools to improve how healthcare professionals are taught about pain and its treatment. We also support the re-authorization of the Health Resources and Services Administration's Program for Education and Training in Pain Care (S. 2680), which awards grants to entities to train health care professionals in pain care. We strongly support the authorization and funding of these programs, as we believe more clinicians need quality training in pain management. However, we also caution Congress not to shift the focus of these programs too much towards prevention and detection of addiction. As currently authorized, these programs serve a unique role in providing new resources to train clinicians in pain management, and programs should not be re-purposed to only focus on prevention of addiction or abuse and misuse of opioids.

We also recognize that Congress wants to take new steps to monitor opioid prescribing practices. The system to identify and communicate with 'outlier prescribers' proposed in S. 2920 and H.R. 5716 may help to identify prescribers who need more training or technical assistance in prescribing opioids, facilitate the delivery of that training and track improvements in outcomes. However, we urge Congress to carefully consider which prescribers should be exempt from any enforcement actions under this system – or which patients should be exempt from the outlier calculations for prescribers. While current versions of this bill exempt hospice and cancer patients in active treatment, we urge Congress to add exemptions that fully align with our recommendations for exemptions above, and include cancer survivors and other seriously ill patients.⁵ Flagging prescribers and enforcing additional training requirements on professionals who treat cancer patients, cancer survivors, and patients receiving palliative care would not be an efficient use of resources – especially considering that palliative care specialists have some of the most extensive training in pain management.

We also urge Congress to consider including bi-partisan legislation that addresses the proactive need to expand research in pain, palliative care and symptom management at the National Institutes of Health, and expand education and training of providers in the medical subspecialty of palliative care who are on the front lines of treating patients with serious illness. The Palliative Care Hospice Education and

⁵ See http://patientqualityoflife.org/wp-content/uploads/2018/06/PQLC-Memo-Exemption-Language-for-Opioid-Restrictions-05312018_FINAL-sent-to-HHS.pdf

Training Act (S. 693/H.R. 1676) has strong bi-partisan support in both chambers, and has been identified as legislation that includes balanced policy solutions that would positively impact care for patients with serious illness who live with pain and other symptoms due to a serious illness. We would welcome the opportunity to discuss the PCHETA legislation and its inclusion in a final legislative package.

Increasing Access to Opioid Alternatives

Just as increasing research on pain and new methods of pain management is important, it is also important that the U.S. Food and Drug Administration (FDA) continue to focus on bringing potential new and better treatments to market. Congress is considering several provisions that help FDA focus on developing non-opioid or non-addictive medical products intended to treat pain. The PQLC is supportive of this focus, as it will increase the options clinicians have in effectively treating their patient's symptoms, and hopefully lead to better outcomes for seriously ill patients.

The second step in increasing access to opioid alternatives is to ensure that existing and new alternatives to opioids (including non-pharmacological treatments) are covered by government and private insurance plans. Many patients are not able to use currently-available alternative treatments because they are not covered by insurance – or are covered at much higher costs – and therefore not affordable. S. 2911, which requires HHS to release guidance on mandatory and optional items and services that may be provided under a State Medicaid plan for non-opioid treatment and management of pain; and H.R. 5776, which requires HHS to review Medicare payments to adjust incentives for coverage of outpatient pain treatment and submit a report to Congress on the extent to which Medicare Advantage plans cover non-opioid treatments; are important steps towards expanding access to alternative pain treatments. If Congress proceeds with this type of legislation, we encourage you to ensure that any new or adjusted coverage be provided with cost-sharing that is no less burdensome than the cost-sharing for opioid treatments.

Continuing Support of Prescription Drug Monitoring Programs (PDMPs)

Several bills currently under consideration provide additional support to state Prescription Drug Monitoring Programs (PDMPs) (S. 2680 and H.R. 5812); require certain prescribers to use PDMPs (H.R. 5801). These programs collect data that can be used as a patient care tool, a tool to investigate drug diversion or insurance fraud, and an early warning system for drug shortages. PDMPs are important tools for health care, education, research, law enforcement and abuse prevention efforts. Our organizations support increased funding and coordination for these important and successful programs. The PQLC supports efforts to enhance PDMPs that are interoperable between states, have clear access requirements for physicians, allow physician access to patient prescription history, allow physician authorization to delegate practice monitoring responsibilities to office personnel, and have strong patient confidentiality protections.

Preventing Diversion and Misuse

Our organizations support several of the efforts currently being considered to prevent diversion of opioids or fraudulent prescribing. These include:

- Clarifying FDA's authority to require drug manufacturers to package certain drugs, including opioids, to allow a set treatment duration – for example, a “blister pack,” for patients who may only need a 3 or 7-day supply (S. 2680 and H.R. 5687);
- Clarifying FDA's authority to require manufacturers to provide patients a simple and safe way to dispose of leftover drugs as part of the drug's packaging, which may reduce the supply of unused medication available for diversion and make it easier for patients – or family members

of such patients who have passed away – to dispose of their unused medication in a convenient manner (S. 2680 and H.R. 5687);

- Allowing hospice care providers to safely and properly dispose of controlled substances for the deceased, by requiring the Drug Enforcement Agency (DEA) to issue regulations to specify how hospice programs should dispose of unneeded substances in the hospice care setting (S. 2680 and H.R. 5041); and
- Requiring all prescribing (S. 2460/H.R. 3528) and prior authorization (S. 2908, H.R. 5773 and H.R. 4841) processes in Medicare Parts C and D to be electronic.

As Congress considers these measures, our organizations welcome the opportunity to discuss our views with you. If you have any questions, please contact Keysha Brooks-Coley, Vice President, Federal Advocacy, American Cancer Society Cancer Action Network and Chair of the Patient Quality of Life Coalition, at 202-661-5720 or Keysha.Brooks-Coley@cancer.org.

Sincerely,

American Cancer Society Cancer Action Network
Cancer Support Community
Catholic Health Association of the US
Center to Advance Palliative Care
Lung Cancer Alliance
National Patient Advocate Foundation
Oncology Nursing Society
Pediatric Palliative Care Coalition
ResolutionCare Network
Supportive Care Coalition
Trinity Health