

June 15, 2020

Stephen M. Hahn, M.D.
Commissioner, Food and Drug Administration
White Oak Building One
10903 New Hampshire Avenue; Room 2217
Silver Spring, MD 20993

Francis S. Collins, M.D., Ph.D.
Director, National Institutes of Health
Building 1, Room 126
1 Center Drive
Bethesda, MD 20892

Dear Dr. Hahn and Dr. Collins:

As organizations that represent patients, families and clinicians that are collectively very engaged and invested in improving treatments for pain, we are writing to you to encourage you to make the development and availability of treatments for pain – and particularly non-addictive options – a high priority within your agencies. Specifically, we urge you to expeditiously and effectively move forward with the various provision of the SUPPORT Act.

As you are aware, treatment of pain – both acute and chronic – is an ongoing challenge for patients and clinicians, and is a multifaceted challenge because there are many different types of pain; and many different diseases and conditions that can produce acute and chronic pain. For example, the pain from migraine, cluster headache, endometriosis, osteoarthritis, low back pain (both muscular or neuropathic in origin), and acute injuries or medical procedures/surgeries are all different, and each type of pain may require different medicines and treatment plans.

Other factors that complicate the clinical treatment of pain are patients' and clinicians' wide-ranging expectations about pain; how treatments have evolved over the years; and of course, the greater use of opioid medicines to treat pain and the resulting epidemic of opioid use disorder.

We would also like to note, that one of the goals of treating acute pain is to prevent it from becoming chronic pain. While that is not always possible, how pain is initially treated – and the range of options for patients and clinicians – should be a consideration for your agencies' regulatory and research agenda and priorities.

Those are factors that we urge the FDA and NIH to consider in your work, and in your work with your Public Health Service and private sector colleagues, partners, and collaborators. And we greatly appreciate the work the agency has [done so far in implementing the SUPPORT Act](#) and addressing the country's opioid epidemic, including being very [supportive of developing non-addictive drugs to treat pain](#).

As part of your agencies' work to implement the SUPPORT Act, we urge you to keep front-of-mind those factors that require individualization of treatment for pain, including genetic, sex and age differences. Those factors – along with the different types of pain from different conditions – are important to the people we represent and educate, and need to be prioritized as you conduct research, and evaluate new treatment options and approaches for acute and chronic pain.

That is why we believe the FDA should make the provisions of the SUPPORT ACT directing the agency to gather public input to inform and guide its actions a top priority. We greatly appreciate that the FDA held a [public meeting in September 2019](#), but would encourage the agency to do more public meetings such as that one, as well as more focused or regional events – possibly on sub-topics, or related to specific populations or areas of concern – since stakeholder input will provide crucial perspectives for the agency and its private sector partners for the critical mission of developing non-addictive pain therapies. Information from patients and clinicians will help the FDA work with product developers and researchers to provide greater clarity and predictability about research activities and approval requirements. As history has clearly shown in other areas, providing clear guidelines is crucial for expediting development and review while upholding FDA's appropriately high standards.

Similarly, we urge the NIH to make implementing section 7042 of the SUPPORT Act a priority to help clinicians and researchers individualize treatment plans and options.

We have also noted that since the enactment of the SUPPORT Act, Congress has continued to focus on treatment of pain, and how to prevent opioid use disorder and the misuse of opioid medicines, while also recognizing that opioids may be appropriate for certain patients when alternatives are inappropriate or contraindicated. For example, the Senate Appropriations Committee issued a report encouraging FDA to continue making those issues a priority and focus on developing non-addictive pain treatments. And as you are aware, the President's 2021 Budget Proposal includes provisions for both the FDA and NIH to continue/expand this work – including the NIH's Helping Addiction Long-term (HEAL) initiative.

In conclusion, we are ready to help you in those efforts, and as groups that recognize the need for better treatments for pain – particularly non-opioid/non-addictive treatment options – we have been engaged in education and awareness for patients through a variety of activities ranging from publications, meetings and on-line resources. (This letter's Addendum contains a list of some resources our organizations have created through meetings and patient-focused research.)

We appreciate the magnitude of the tasks facing the agencies, but given the long-term importance of the needs for better pain treatments, we urge the FDA and NIH to appropriately prioritize work in this area. We believe that the FDA and NIH – working with patient stakeholders, clinicians, researchers, and treatment developers – can meet the needs of patients, clinicians and the country. Therefore, we specifically recommend that the FDA convene at least three public meetings (virtually or in person as appropriate) in the next 18 months.

We look forward to working with you on these critical areas since individual and collective efforts will both improve treatment for pain and address our nation's opioid epidemic, and appreciate your consideration of our concerns and perspectives. For questions about these matters, please contact any of the representatives from our organizations.

Thank you for your ongoing attention and good work to promote better treatment of pain and more options for patients and clinicians.

Alliance for Aging Research

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Alliance for Headache Disorders Advocacy

- Katie MacDonald, Executive Director (info@allianceforheadacheadvocacy.org) 802-734-7598

American Autoimmune Related Diseases Association

- Randall Rutta, President & CEO (randallrutta@aarda.org) 202-997-0909

American Behcet's Disease Association

- Mirta Avila Santos, MD, Executive Director (mavilasantos@behcets.com)

American Chronic Pain Association

- Penny Cowan, Founder & CEO (pcowan@theacpa.org) 916-652-8191

American Medical Women's Association

- Theresa Rohr-Kirchgraber, MD, FACP, FAMWA, President, 2015-2016 and Chair, Advocacy Committee (Trohrkir@iu.edu) and Eliza Lo Chin, MD, MPH, Executive Director (ElizaChin_md@yahoo.com or associatedirector@amwa-doc.org) 510-326-5395

American Society for Pain Management Nursing

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Amputee Coalition

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Arthritis Foundation

- Anna Hyde Vice President of Advocacy and Access (ahyde@arthritis.org) 202-843-0105

Association of Migraine Disorders

- Alicia Torborg, PMP, Executive Director (alicia@migrainedisorders.org) 401-269-9119

Caregiver Action Network

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Coalition For Headache And Migraine Patients (CHAMP)

- Kevin Lenaburg, Executive Director (Kevin.Lenaburg@headachemigraine.org)

For Grace: Women In Pain

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Global Healthy Living Foundation

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Headache and Migraine Policy Forum

- Lindsay Videnieks, Executive Director (lindsay@headachemigraineforum.org)

HealthyWomen

- Beth Battaglino, RN, CEO (beth@healthywomen.org) 732-241-5030; Monica Mallampalli, PhD, Senior Advisor for Scientific and Strategic Initiatives (monica@healthywomen.org) 410-963-1261; or Michael D. Miller, MD, Senior Policy Advisor (mdmiller@healthywomen.org) 617-285-0084

Lupus Foundation of America

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Men's Health Network

- Ana Tomšić, MPH, CHES, Vice President (Ana@menshealthnetwork.org) 202-543-6461 Ext. 106

Mental Health America

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Miles for Migraines

- Shirley Kessel, Executive Director (shirley@milesformigraine.org) 215-880-1150

The Myositis Association

- Mary McGowan, Executive Director (McGowan@myositis.org) 703-553-2631

National Alliance for Caregiving

- C. Grace Whiting, J.D., President and CEO (grace@caregiving.org) 202-918-1016

National Caucus and Center on Black Aging

- Karyne Jones, President & CEO (kjones@ncba-aging.org) 202-637-8400

National Council for Behavioral Health

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The National Grange

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National Hispanic Council in Aging

- Yanira Cruz, DrPH, MPH, President & CEO (ycruz@nhcoa.org) 202-347-9733

National Minority Quality Forum

- Gretchen C. Wartman, Vice President for Policy and Program (gwartman@nmqf.org) 202-223-7563

National Osteoporosis Foundation

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National Pain Advocacy Center

- Kate Nicholson, President (kate@katemnicholson.com) 901-409-9480

Osteoarthritis Action Alliance

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The Relapsing Polychondritis Foundation

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Sepsis Alliance

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Veterans Health Council

- Artie Shelton, M.D., Colonel, USA (Ret.), Director (ashelton@vva.org) 301-523-4312

Addendum – Patient Perspective Resources about Pain and Pain Treatments

- The **American Medical Women’s Association** notes that there are many sex and gender differences in pain, opioid use and opioid addiction:
 - Pain, nociceptive pathways, and pain expression differ in women and men
 - Women are more likely than men to develop conditions that can lead to chronic pain
 - Women are more likely than men to be prescribed the combination of opioids and benzodiazepines.
 - In comparison to men, women become addicted when taking lower doses of opioids for shorter periods of time (telescoping)
 - Women are more likely than men to have multiple prescribers of opioids and use of multiple pharmacies.
 - The rate of increase in opioid overdose-related deaths is higher in women than among men.
 - Mental health conditions that impact pain, and may lead to opioid use, are more common in women, but are still underdiagnosed.
 - Women are more likely than men to be victims of intimate partner violence, which can lead to chronic pain syndromes [and/or mental health issues](#) that [can](#) result in opioid misuse.
 - Older women who fall and present with injuries are more likely than men in similar situations to have had a recent opioid prescription.
- The **Amputee Coalition**
 - More than 2 million Americans live with limb loss, and another 28 million are at risk to lose a limb.
 - Everyone who loses a limb loss experiences post-surgical pain, with approximately 185,000 amputation surgeries occurring every year in the United States.
 - More than 80 percent of people with limb loss suffer from chronic pain.
- The **Arthritis Foundation’s** [A Mandate For Action](#) report published in February 2020 highlights key points from a patient-reported outcomes survey that identifies pain as one of the core challenges facing by people with arthritis, with 100% of respondents reporting pain in the last 7 days, and 92% reporting that it interfered with their day-to-day activities.
- The **Association of Migraine Disorders**
 - Migraine disease burden is highest among women of all ages. Estimated 40% of women will experience migraine during their lifetime.
 - To enable more clinicians to treat migraine and become aware of the many treatment options, AMD has developed the Migraine Toolbox: A Practical Approach to Diagnosis and Treatment ([MyCME.com](#)).

- **For Grace** collaborated with the *National Pain Report* in 2014 to conduct a survey with women in chronic pain to better understand their concerns and experience: [Women In Pain Survey Results](#)
- **Headache and Migraine Policy Forum**
 - Migraine is a major and underappreciated US public health problem
 - 47 million Americans will have attacks this year¹
 - 5 million Americans with migraine will have 10 or more days with headache per month²
 - Migraine is the 2nd leading cause of US disability¹
 - There are more than 1.2 million US Emergency Department visits for migraine annually³
 - Opioids are not indicated for the treatment of migraine⁴
 - Opioids are generally poorly effective for relieving migraine pain⁵
 - Opioids may increase frequency and severity of migraine attacks⁶
 - Opioid prescriptions for migraine present an avoidable risk for opioid use disorders
 - Opioids are nonetheless widely prescribed for migraine
 - Only a third of primary care providers are aware that opioids can worsen migraine⁷
 - 59% of US Emergency Department visits for migraine include opioid treatments²
 - 16% of Americans with migraine are active opioid users⁸
- **HealthyWomen** held a [Chronic Pain Summit](#) in July 2019, and the [key findings](#) from that event included:
 - 70% of chronic pain patients are women.
 - Women's life expectancy is reduced by one year for every 10 years spent with chronic pain.
 - Women with chronic pain are more likely to be treated with prescription pain relievers, like opioids, and at higher doses and for longer periods, than are men, putting women at greater risk for developing opioid use disorder.
 - While some research has addressed sex differences in pain management, perception and pain threshold, this progress has not translated to improved pain treatment for women (see [Sex Differences in Pain Response Matter](#))
 - Sleep loss increases pain sensitivity and is a major risk factor for developing chronic pain, especially in women.
- **HealthyWomen** worked with the Legal Action Center in 2018 to create a Toolkit of resources for [Strengthening Families and Communities by Improving Access to Treatment for Substance Use Disorder](#).

- **The National Alliance for Caregiving**

- Health care providers and policymakers are often unaware of the impact of caregiver strain on the role that a caregiver might play in the delivery of a therapy or care plan. Research has demonstrated time and time again that family caregivers, due to psychological distress, may overstate a patient's level of pain and in many cases the family caregiver may have greater distress than even the patient because of seeing the person in their care in pain.⁹ Fear about the use of pain medication on the part of a patient and their family caregiver can be a barrier to effective pain management.¹⁰ It is imperative to the health of people living with pain, and those who care for them, to have a wide range of treatment options that can enable shared and supported-decision making.

¹ GBD 2016 Headache Collaborators. Global, regional, and national burden of migraine and tension-type headache, 1990-2016: a systematic analysis for the Global Burden of Disease Study 2016. *Lancet Neurol.* 2018;17:954-976. <http://ihmeuw.org/50g6>

² Blumenfeld AM, Varon SF, Wilcox TK, Buse DC, Kawata AK, Manack A, Goadsby PJ, Lipton RB. Disability, HRQoL and resource use among chronic and episodic migraineurs: results from the International Burden of Migraine Study (IBMS). *Cephalalgia.* 2011;31:301-15. <https://www.ncbi.nlm.nih.gov/pubmed/20813784>

³ Friedman BW, West J, Vinson DR, Minen MT, Restivo A, Gallagher EJ. Current management of migraine in US emergency departments: an analysis of the National Hospital Ambulatory Medical Care Survey. *Cephalalgia.* 2015;35:301-9. <https://www.ncbi.nlm.nih.gov/pubmed/24948146>

⁴ Loder E, Weizenbaum E, Frishberg B, Silberstein S; American Headache Society Choosing Wisely Task Force. Choosing wisely in headache medicine: the American Headache Society's list of five things physicians and patients should question. *Headache.* 2013;53:1651-9. <https://www.ncbi.nlm.nih.gov/pubmed/24266337>

⁵ Tepper SJ. Opioids should not be used in migraine. *Headache.* 2012;52 Suppl 1:30-4. <https://www.ncbi.nlm.nih.gov/pubmed/22540203>

⁶ Thorlund K, Sun-Edelstein C, Druyts E, Kanters S, Ebrahim S, Bhambri R, Ramos E, Mills EJ, Lanteri-Minet M, Tepper S. Risk of medication overuse headache across classes of treatments for acute migraine. *J Headache Pain.* 2016;17:107. <https://www.ncbi.nlm.nih.gov/pubmed/27882516>

⁷ Minen MT, Loder E, Tishler L, Silbersweig D. Migraine diagnosis and treatment: A knowledge and needs assessment among primary care providers. *Cephalalgia.* 2016;36:358-70. <https://www.ncbi.nlm.nih.gov/pubmed/26122646>

⁸ Buse DC, Pearlman SH, Reed ML, Serrano D, Ng-Mak DS, Lipton RB. Opioid use and dependence among persons with migraine: results of the AMPP study. *Headache.* 2012;52:18-36. <https://www.ncbi.nlm.nih.gov/pubmed/22268775>

⁹ See, e.g., Yeager KA, Miaskowski C, Dibble SL, Wallhagen M. Differences in pain knowledge and perception of the pain experience between outpatients with cancer and their family caregivers. *Oncology Nursing Forum.* 1995 Sep;22(8):1235-1241 at <https://europepmc.org/article/MED/8532548>.

¹⁰ Valeberg, Berit Taraldsen PhD, RN; Miaskowski, Christine PhD, RN, FAAN; Paul, Steven M. PhD; Rustøen, Tone PhD, RN Comparison of Oncology Patients' and Their Family Caregivers' Attitudes and Concerns Toward Pain and Pain Management, *Cancer Nursing*: July/August 2016 - Volume 39 - Issue 4 - p 328-334 doi: 10.1097/NCC.0000000000000319, at https://cdn.journals.lww.com/cancernursingonline/Abstract/2016/07000/Comparison_of_Oncology_Patients_and_Their_Family.10.aspx