NIH HEAL Initiative Must Focus on Headache Disorders to Reduce Opioid Prescribing and Disease Burden

● *The extraordinary burden of headache disorders.*

- **Migraine is the 2nd leading cause of all global disability [1].**
- **1 in 7 Americans will experience a migraine attack this year [2].**
- **Migraine with aura is associated with a 20% increased risk of mortality over 5 years [3].**
- **Cluster headache is widely reputed to be the most severe pain that humans can experience.**

● *Headache disorders are a major path to prescription opioid use disorders.*

- **Opioid use can *worsen* migraine frequency and severity [4].**
- **Evidence-based guidelines uniformly recommend *avoiding* opioids for headache disorders.**
  - **Yet, 59% of Americans seeking care for migraine in US Emergency Departments receive opioids [5].**
  - **Yet, 16% of Americans with migraine are active opioid users [6].**

● *Headache disorders are <u>not</u> just another group of pain disorders.*

- **Mutations in 9 different genes strongly increase migraine susceptibility, but <u>none</u> is linked to any other pain disorders [7].**
- **17 prescription drugs are FDA-approved for migraine or cluster headache, but <u>none</u> is FDA-approved for any other pain disorders [8].**
- **Headache disorders often disable *without* headache e.g. heightened sensation, vertigo, nausea, cognitive symptoms.**

● *NIH has neglected research on headache disorders.*

- **Headache disorders are the *least* funded NIH research area among the most burdensome US diseases [9].**
- **Migraine contributes 46% of the US disability burden due to neurological diseases and stroke, but migraine research comprises just 0.6% of all NINDS extramural funding [2, 10].**
- **NINDS research funding on headache disorders dropped 30% between 2013 and 2017 [10].**

● *To reduce opioids and burden, the HEAL Initiative must focus research on headache disorders.*

- **Congress appropriated $500M/year (FY18, FY19) for NIH opioid & pain research (*HEAL Initiative*).**
- **NIH issued focused HEAL Initiative RFAs to expand research on back pain and hemodialysis pain.**
- **NIH must now also issue focused HEAL Initiative RFAs to expand research on headache disorders.**

<u>Please Co-Sign the Dear Colleague letter for</u>

<u>FY2020 LHHS Appropriations Report Language for Headache Disorders</u>

- ***Isaac Loeb (isaac.loeb@mail.house.gov)*** ***for Representative Peter Welch***

Alliance for Headache Disorders Advocacy

Alliance for Patient Access
American Academy of Neurology
American Headache Society
Clusterbusters
Cluster Headache Support Group
Headache Cooperative of New England
Headache Cooperative of the Pacific
Migraine Research Foundation
Miles for Migraine Races
National Headache Foundation
Runnin' for Research
Southern Headache Society

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Proposed FY2020 LHHS Appropriations Report Language

"The Committee recognizes (1) that migraine is the 2nd leading cause of global disability, but that NIH funding for migraine research is strongly incommensurate with this burden, and (2) that migraine and other headache disorders are poorly responsive to opioids, but that these drugs are often inappropriately prescribed for these diseases. Under the HEAL Initiative, the NIH has recently issued Funding Opportunity Announcements that focus specifically on increasing research on back pain and hemodialysis-related pain. The Committee strongly urges the Director of NIH to issue a similar focused group of Requests for Applications to fund fundamental, translational, and clinical research on headache disorders, including migraine, post-traumatic headache, the trigeminal autonomic cephalalgias, and intracranial hypo/hypertension."

Citations:

1. GBD 2016. Global, regional, and national incidence, prevalence, and years lived with disability for 328 diseases and injuries for 195 countries, 1990-2016: a systematic analysis for the Global Burden of Disease Study 2016. *Lancet* 2017;390:1211-59.

2. Global Burden of Disease study, 2016, http://ihmeuw.org/43cn

3. Mamoud AN, et al. Migraine and the risk of cardiovascular and cerebrovascular events: a meta-analysis of 16 cohort studies including 1,152,407 subjects. *BMJ Open* 2018;8:e020498

4. Bigal ME, Lipton RB. Excessive acute migraine medication use and migraine progression. *Neurology*. 2008;71:1821-8.

5. Friedman BW, et al. Current management of migraine in US emergency departments: an analysis of the National Hospital Ambulatory Medical Care Survey. *Cephalalgia* 2015;35:301-9.

6. Buse DC, et al. Opioid use and dependence among persons with migraine: results of the AMPP study. *Headache*. 2012;52:18-36.

7. Monogenic migraine susceptibility genes, not associated with other pain disorders:
CACNA1A, ATP1A2, SCN1A, KCNK18, PRRT2, CSNK1D, TREX1, NOTCH3, COL4A1

8. Prescription drugs FDA-approved for migraine and/or cluster headache, but not FDA-approved for any other pain disorder: propranolol, timolol, divalproex sodium, topiramate, onabotulintoxina, erenumab, fremanezumab, galcanezumab, methysergide, sumatriptan, naratriptan, rizatriptan, zolmitriptan, almotriptan, eletriptan, frovatriptan, dihydroergotamine

9. https://report.nih.gov/info_disease_burden.aspx

10. https://report.nih.gov/categorical_spending.aspx