Lagniappe: The Impact of Headache Disorders in America*

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The immense burden of headache disorders in America has been very rarely considered during the formal deliberations of Congress. On February 14, 2012, the Committee on Health, Education, Labor, and Pensions of the United States Senate held a public hearing on Pain in America: Exploring Challenges to Relief. During that hearing, Senator Bernard Sanders of Vermont entered into the Congressional Record testimony on the impact of headache disorders on behalf of the Alliance for Headache Disorders Advocacy.

Key words: headache disorder, National Institutes of Health

In compliance with a provision of the 2010 Patient Protection and Affordable Care Act (PPACA), the Secretary of the Department of Health and Human Services requested that the Institute of Medicine of the National Academies conduct a study “to assess the state of the science regarding pain research, care, and education and to make recommendations to advance the field.” In June 2011, the findings of this comprehensive study were issued as a consensus report: Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research. On February 14, 2012, this landmark study was the focus of a public hearing entitled Pain in America: Exploring Challenges to Relief held before the full Committee on Health, Education, Labor, and Pensions (HELP) of the United States Senate. During the course of that hearing, Senator Bernard Sanders of Vermont entered into the Congressional Record the following testimony on the impact of headache disorders in America on behalf of the Alliance for Headache Disorders Advocacy.

TESTIMONY

Chairman Harkin, Ranking Member Enzi, and Members of the HELP Committee:

Thank you very much for providing me with this valuable opportunity to discuss the impact of headache disorders in our country.

My name is Bob Shapiro. I am the President of the Alliance for Headache Disorders Advocacy, a coalition of 10 national and regional not-for-profit organizations advocating on behalf of Americans with disabling headache disorders. I am also a practicing physician, research scientist, and a Professor of Neurology at the University of Vermont College of Medicine.

Conflict of interest: The author reports no conflict of interest.

Headache: The Scope of the Problem.—Headache in America is a wholly misunderstood phenomenon. Half of Americans will experience some type of headache this year, and more than 90% of Americans will experience headache in their lifetimes. While mild headaches are a nearly universal human experience, their near ubiquity combined with a century of direct-to-consumer promotion of inexpensive over-the-counter analgesics has reinforced an impression that headaches are only a minor problem, except for those with a low tolerance for pain. This is profoundly mistaken.

In fact, headache is a symptom that is common to a broad category of neurological disorders. Chronic migraine, post-traumatic headache, chronic daily headache, cluster headache, and related disorders exact tremendous social, economic, and personal burdens that collectively comprise a smoldering and neglected major public health crisis. However, because of broad public familiarity with mild headaches and their near-absence of fatal complications, these incapacitating disorders are caught in a blind spot of public inattention. While they are highly prevalent, costly, and disabling, they are nonetheless stigmatized and dismissed.

First, some facts may be useful:

- Headache disorders result in more than $31 billion in annual US direct and indirect economic costs, exceeding the estimated annual US costs of epilepsy, asthma, and ovarian cancer combined. Furthermore, recent data suggest that total US costs because of headache disorders may actually be 3 times higher than previous estimates.
- Headache is the most common symptom of concussive or mild traumatic brain injuries. Among veterans of the Iraq/Afghanistan conflicts, 37% of servicemen and 57% of servicewomen reported ongoing migraine if there was a deployment history of concussive injury and any predeployment history of migraine. More than 500,000 concussions in the US are sustained annually by children playing tackle football.
- World Health Organization (WHO) data indicate that migraine is the 19th leading cause of life lived with disability and by itself results in more lost years of healthy life (“disability-adjusted life years”) in the US annually than multiple sclerosis, epilepsy, ovarian cancer, and tuberculosis combined.
- Almost 1 in 5 Americans (~60 million people) will experience an attack of some form of migraine this year. Fewer than half of these people have formally received this diagnosis.
- Seventy-five percent of adult Americans with episodic migraine are women, predominantly of child-bearing age; however, the very high prevalence of migraine overall means that it is not just a women’s disorder.
- Four percent of Americans have headaches of more than a 4-hour duration, at least 15 days per month, defined as “chronic daily headache.”
- Severe headaches disproportionately affect individuals with low income or limited education, as well as some minority groups, such as Native Americans.
- Cluster headache, a recurrent episodic disorder virtually unknown to the general public and typically unrecognized by physicians, is reputed to be the most severe pain that humans can experience. More than half of cluster headache sufferers have recurrent thoughts of suicide. It has a prevalence of approximately 1 in 1000 comparable with multiple sclerosis.
- Migraine with aura increases the risk of cardiovascular disease and is linked to more than 1500 deaths in the US annually even after all other known risk factors have been accounted for. Americans with migraine with aura or frequent migraine are also more than 3 times more likely to attempt suicide than those without migraine, irrespective of the presence of depression. Migraine is highly comorbid with depression, anxiety, asthma, epilepsy, substance abuse, obesity, and multiple other disorders that compound disability and suffering.

Health Care for Headache Disorders.—Given the broad scope and huge burden of headache disorders in America, what health care resources are arrayed to manage the problem? Unfortunately, headache disorders have historically been neglected by practicing
physicians. Early formulations of migraine described it as a psychiatric disorder or stigmatizing misbehavior particularly afflicting women of weak constitution but otherwise having no physical abnormalities. Such impressions have led generations of physicians to a well-entrenched dismissal of migraine as a nonserious malady of complainers.

Unsurprisingly, few doctors have chosen to care for patients with headaches. While headache is the primary clinical focus area for more than half of America’s 17,000 neurologists, a total of only 290 US physicians are certified by the United Council of Neurological Subspecialties (UCNS) as having specialty training in Headache Medicine. On average, there is only one UCNS certified US headache physician for 43,000 Americans with chronic daily headache or 200,000 Americans with migraine. A survey in 2004 found that most academic neurology departments in the US did not actually have a dedicated headache specialist on faculty and there are currently only 17 UCNS accredited fellowship programs in the US to train new headache specialists. With few academic mentors and clinical training program opportunities, the outlook for recruitment of new headache medicine providers and clinician-scientists is bleak. It would be inaccurate to say that organized medicine has abandoned headache patients; it never took them seriously to begin with.

An unintended consequence of recent healthcare reform presents a further potential threat to patient access to headache care. To promote primary and preventative care, the PPACA provides for incentive bonuses to cognitive care providers but only for those providers of particular primary care specialties. That is, under PPACA, incentives are only accorded to certain types of doctors rather than just to the type of medicine practiced. While headache care is very heavily weighted to cognitive over procedural care and headache medicine providers often provide primary or principal medical care, almost all headache medicine providers are ineligible for the PPACA incentives; 85% of UCNS certified headache providers are neurologists, and neurology is not a medical specialty cited under the provision. Furthermore, recent proposals to resolve the failed Medicare Sustainable Growth Rate reimbursement formula have included consideration of steep cuts to procedural medical specialties. In this case, neurologists would also be inappropriately grouped with surgeons rather than with internists for these purposes. Ineligibility for PPACA incentives, combined with imposition of significant Medicare reimbursement cuts, could render already financially tenuous headache care practices as unviable. Such an outcome would be especially problematic for patients with headache disorders because they often rely on headache providers for delivery of their primary or principal medical care.

Therapeutic options for headache disorders are few. Over the past 50 years, only one novel drug, sumatriptan, has been developed specifically for the acute treatment of migraine and subsequently approved following an FDA priority review. While the approval of sumatriptan in 1992 was a breakthrough, the drug does not work immediately, it is ineffective in 40% of attacks and a quarter of migraine patients, and it is contraindicated in many other patients with cardiovascular disease. Six “me-too drugs,” which are structurally and therapeutically similar to sumatriptan, were subsequently FDA-approved, but these have not substantially changed the landscape of available therapies. Moreover, sumatriptan remains expensive even though it is now available in generic form.

Opioid medications, which are a mainstay of therapy for acute pain conditions, have a very limited role in the care of recurrent headache disorders such as migraine. Opioids characteristically render other headache medications less effective, and their use in migraine significantly increases the risk for worsened attack severity and frequency. However, because of the relatively higher cost of triptans and generally inadequate knowledge of headache practice among both primary care providers and insurance carriers, 20% of US migraine patients must still rely on opioid and barbiturate medications for the acute treatment of attacks.

Four drugs are FDA-approved and marketed for the prevention of episodic migraine and one drug for the prevention of chronic migraine. All of these drugs were initially FDA-approved for other medical indications, all have significant potential side effects lim-
iting tolerability, none are curative, and many patients are not responsive to any of them.

**Research on Headache Disorders.**—Headache disorders research has never been adequately funded. Perhaps taking a cue from physicians, the National Institutes of Health (NIH) has also neglected headache disorders, and very limited funding for headache disorders research has been available through the Department of Defense, private philanthropies, or any other sources. In 2011, the NIH expended $21 million on all headache disorders research, comprising less than 0.07% of the overall budget. Moreover, NIH estimates an actual decline in such funding to $20 million through FY2013. While the NIH has sponsored at least 6 investigator conferences and “workshops” over the past 4 years to discuss the planning for headache disorder research, it has not issued any request for applications (RFAs) or other funding opportunities with funds set aside to prioritize the actual conduct of such research. In fact, only once has the NIH ever issued an RFA on migraine research; it funded a total of 4 grants in 2007 but did not appreciably increase overall funding for the disorder. The NIH has not funded a research grant on cluster headache in more than 25 years. Two NIH standing peer-review study sections each have one headache research scientist currently serving a 3-year term, although neither study section is otherwise focused on the review of headache disorders grant proposals.

In this climate of poor research funding and uncertain grant proposal review, few seasoned scientists have entered the headache field. Furthermore, promising early-stage scientists are often led by their academic mentors to consider this to be a dead-end career track, thereby exacerbating the shortage of investigators. Of 14,229 research presentations at the 2006 annual meeting of the Society for Neuroscience, only 22 were related to headache disorders. Over the past 35 years, the pre-eminent science journals *Nature* and *Science* have each published only one research report related to migraine. High-impact general medical journals publish almost 9 times as many articles on asthma as on migraine. Of the progress that has occurred in migraine research in the past 2 decades, a disproportionate number of seminal findings have emerged from non-US laboratories. For example, of the 8 genes for migraine susceptibility that have been identified to date, 7 of them were discovered by non-US investigative teams.

**Migraine and Epilepsy: Similar Disorders, Divergent Research Paths.**—Regarding the direct benefits to patients that can result from NIH research funding, an instructive comparison can be made between 2 highly similar disorders, migraine and epilepsy. Both are paroxysmal brain disorders that share in common some identified genes, brain events, and medications. They also often occur together in the same individuals. While both may be disabling, according to WHO data, migraine results in 3 times more lost years of healthy life as epilepsy annually in the US. Migraine is also far more prevalent and costly overall.

By contrast with migraine, however, the NIH has invested well in epilepsy research over the past 20 years. In 2011, NIH expenditures on epilepsy totaled $152 million vs $16 million for migraine. NIH epilepsy programs have included “benchmarks” initiative to guide new investigators and a remarkably successful, cost-effective and largely unsung, early-stage screening program to identify promising new drugs. The NIH also has a standing peer-review study section that is largely and specifically devoted to ensuring fair and informed review of epilepsy grant proposals. The returns on this investment for epilepsy have been impressive. Over the past 20 years, while FDA approvals for novel migraine drugs have languished, patients with epilepsy have benefited measurably by the FDA approval of 14 novel anti-seizure medications and even more drugs are in late-stage clinical trials.

The comparison between migraine and epilepsy drug approvals starkly underscores the pivotal role that NIH-funded fundamental and translational research plays in drug discovery. In the case of migraine, the pharmaceutical industry has simply not delivered on its own. The recent successes in epilepsy drug development offer the clear promise that with comparable NIH investigator-initiated research funding, fair and informed peer-review of grant proposals, and implementation of a robust NIH migraine drug screening program, multiple novel and effective therapies would emerge for patients with headache disorders.
A Way Forward for Americans With Headache Disorders.—The National Institute of Neurological Disorders and Stroke mission is “to reduce the burden of neurological disease.” This mission cannot be realized without addressing a major source of that burden: the untended crisis of Americans with disabling headache disorders. Moreover, the persistent neglect of such a large source of US disease burden indicates a lapse in NIH surveillance of sources of disease burden and a lack of a formal policy to take disease burden measures into consideration in prioritizing research funding. NIH must have a policy that ensures that any significant source of disease burden is never so grossly misaligned with the application of NIH resources in the future. We urge NIH to focus on the funding of innovative burden of illness research with the goal of developing measures that may guide public policy acceptable to a consensus of NIH stakeholders. Adoption of more objective criteria for the distribution of NIH funding, based in part on improved disease burden measures, should increase transparency, reduce the politicization of the NIH funding process overall, and ensure that all Americans are equitably benefiting from tax payer-funded research.

In the meantime, Americans with headache disorders warrant an NIH commitment of a magnitude at least equal to that currently directed towards alleviating epilepsy. We urge immediate and remedial attention to building NIH intramural and extramural programs for headache disorders research and to implementation of the recommendations of the NIH Headache Research Planning Meeting Report of October 2011, “Opportunities and Priorities for Headache Research.”

In particular, we believe that new NIH programs should include:

- The establishment of regional academic headache disorders research and care “centers of excellence” to train clinicians in headache medicine and clinician-scientists to pursue research in this area.

- Without adequate NIH-funded research and academic programs devoted to headache disorders, there will continue to be limited, or non-existent, institutional support in medical schools for the training of headache medicine clinicians and clinician-scientists.

- Major new and sustained set-aside funding of investigator-initiated fundamental and translational research on headache disorders, especially pertaining to identification of biomarkers and development of relevant models of disease.

To attract and retain quality investigators to this field, it is necessary to ensure that adequate funding sources will be sustained and that peer-review of grant proposals will be informed and fair.

- Establishment of a migraine drug screening program to foster early-stage development of novel and effective therapies.

Such a drug screening program could be implemented by extension of the established anticonvulsant screening program and might be mostly self-funded through modest fees assessed of pharmaceutical industry users and targeted to the foundation for the NIH.

To assure access to effective headache care for patients, we urge inclusion of headache specialty providers in the incentive reimbursements that will be accorded to primary health care providers in health care reform and also in the protections from cuts in reimbursements that may result from resolution of the Medicare sustainable growth rate formula.

Headache Patient Testimonies.—I conclude with the unedited voices of a few, among thousands, Americans who have recently provided comments on a petition urging Congressional attention to headache disorders (see also Appendix S1):

Michelle L. from Newport News, VA, writes:
I have not shut myself off from life, my head pain has shut life off from me. I would hate to see another person go through life as lonely and afraid as I am at this very moment.

Joyce W. from Glen Rock, NJ writes:
My father suffered from cluster migraines. In 1980, he chose to end his life at age 52 rather than live with these headaches any longer. 32 years later and there are still no good answers.
Gail B. from Mexico, MO writes:

18-22 days a month I am in bed with a migraine, and NO ONE can help me. NO clinic, no headache specialist and no neurologist. Lost my career, my marriage and my life. My son received a TBI from an IED in Iraq, he now suffers also but with memory loss, yet he’s deployable. Go figure.

Carrie S. from Charlotte, NC writes:

So many of us have to stop working and live on government aid because of headache disorder disabilities. With lack of education, funding for research, and new treatment options, we are have no other option than to continue living this way. Give the nation education, research funding, and new treatment options, and I guarantee that you will be shocked at how many Americans will benefit and be able to go back to work, thus paying back into the system. Help us so that we can help you.

Patricia D. from Highland, CA writes:

I have suffered with migraines since the age of 13. It has now been 34 years with no answers as to why I am getting them or a medicine that helps. Sad to say I have gotten a migraine every day of my life for numerous years. I am tired, depressed and have lost my joy. I have exhausted the help of 4 neurologists and 2 pain specialists in the past 10 years. I’ve left doctor appointments crying because I was told, “I have done all I can to help you. There is nothing left to try.” My family has spent thousands of dollars to try and help me because my insurance would not cover different treatments and medicines. I have tried to get into migraine trials but after they see all that I have tried and medicines I have taken they deny me. Unless you walk in the shoes of a chronic daily migraine sufferer, you cannot relate! No matter how much you try you will never understand what we go through. My prayers are out to all who suffer from debilitating headaches!

Sandy S. from Des Plaines, IL writes:

Signing this with a migraine, hoping someone we elected will listen to us for a change.

REFERENCES


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SUPPORTING INFORMATION

Additional Supporting Information may be found in the online version of this article:

Appendix S1.—Unedited public comments submitted to an online petition urging Congressional action on headache disorders and excerpted for inclusion in the testimony for before the US Senate Committee on Health, Education, Labor, and Pensions hearing on February 14, 2012.

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