#MillionsMissing USA Protest Demands for ME

On May 25, 2016, and again on September 27, 2016, at the #MillionsMissing USA demonstrations, Myalgic Encephalomyelitis (ME) patients and families, advocacy organizations and individual activists call for the US Department of Health and Human Services and its agencies -- especially the NIH and the CDC -- to implement the following list of demands.

Our goal is to give the 1 to 2.5 million[i] disabled American patients with ME (sometimes referred to as Chronic Fatigue Syndrome or CFS) their lives back, and to prevent even more children, teens, young adults and adults from joining the ranks of the millions who are already missing -- missing from their careers, schools, social lives and families due to the debilitating symptoms of the disease. Millions of dollars are also missing from ME research, and millions of medical providers are missing out on proper clinical training to diagnose and help patients manage this devastating illness.

For ME patients and their families, we demand:

1. **Increased Funding and Program Investments**
   $250 million in funding and program investments, commensurate with the disease burden

2. **Clinical Trials**
   Clinical trials to secure medical treatments for ME

3. **Increased Accessibility and Quality of Clinical Care**
   Improve access to and quality of clinical care through appropriate medical education and growing the pool of knowledgeable ME specialists

4. **A Serious and Urgently Executed Commitment**
   HHS leadership, oversight and a serious commitment to urgently address ME

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Rationale and Details for the #MillionsMissing ME Protest Demands

For ME patients and their families, we demand:

1. Funding and Program Investments, Commensurate with the Disease Burden

The NIH must dedicate funding and program investments for ME commensurate with the disease burden, and they must do this without continued delay, as patients have already been waiting three decades.

Rationale

Thirty years of neglect by the NIH, combined with a stigma toward this disease, has resulted in insufficient and erroneous research as well as uninvolved academic researchers and pharmaceutical companies.[ii] To address these problems, and save lives, the NIH must immediately implement an aggressive set of investments to substantially ramp up its funding and program commitments over the next 3-5 years, using definitions such as the Canadian Consensus Criteria and the ME International Consensus Criteria.

Details

To finally have NIH funding and investments commensurate with disease burden, our demand is to increase the paltry $7M per year currently allotted to ME[iii] to the more equitable amount of $250M. This new program of investments must be developed and executed in collaboration with ME research experts, clinicians and patients, and must include:

- Funding five regional ME Centers of Excellence, each with a research/clinical trial component and also a clinical care component to address the current crisis.
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- Funding multiple requests for applications (RFAs) for ME over the next three years, for a total of at least $10M the first year, $20M the second year and $25M the third year.

- A significant increase in funding for investigator-initiated extramural research (including hypothesis-generating research), as well as a commitment of intramural staff focused on ME research.

- Funding a research network that will collaborate in the development and execution of an ME research strategy.

- The use of research case definitions such as the Canadian Consensus Criteria and the ME International Consensus Criteria that best describe this disease. The Fukuda definition should not be used to select ME cohorts because it does not require core features of the disease.

- Funding an outreach plan to engage major academic centers and pharmaceutical and biotech companies in ME research and drug development.

2. Clinical Trials to Secure Medical Treatments for ME

Health and Human Services (HHS) must fund and incentivize ME clinical trials to secure medical treatments for ME. This must be done with great haste, as patients are missing out on their lives and losing their lives to this disease.

Rationale

After thirty years, there is still not one Food and Drug Administration (FDA)-approved medication for the disease. An estimated one-quarter of ME patients are severely ill, meaning at least two hundred and fifty thousand patients are unable to leave their homes or bed, many for decades. With no FDA-approved treatments available to them, they have little hope of ever improving. To address this situation, HHS must fund and incentivize clinical trials in the following manner:

Details

- We demand the NIH immediately partner with the FDA to address the key obstacles to moving clinical trials forward. NIH must also actively incentivize pharmaceutical and biotech industries so that at least five accelerated clinical trials of medications are conducted over the next five years. The goal must be getting at least two FDA-approved medications on the market for ME patients in the next five years. Proposed medications include Ampligen,[iv] Rituxan[v] and antiviral medications,[vi] all drugs that have been in trials already and have been successfully used to treat ME patients.

- The clinical trials must include severely ill, homebound patients, and must be overseen by an advisory team of ME specialists and researchers who best know the needs of this patient population.

3. Increased Accessibility and Quality of Clinical Care

HHS must address the clinical care crisis by establishing clinical care centers and proactively growing the pool of ME disease experts. Further, the Centers for Disease Control and Prevention (CDC) must immediately discard its erroneous and outdated information related to ME and replace it with accurate medical education and clinical guidelines, based on the most recent scientific information and the practices of ME experts, and preapproved by a panel of recognized disease experts.

Rationale

The U.S. has a crisis in clinical care for ME patients because clinical guidance includes erroneous and harmful information. No medical specialty has accepted responsibility for ME, and the handful of disease experts are geographically distant and have long waiting lists. Further, many disease experts are reaching the ends of their careers, magnifying the crisis. HHS must take

proactive steps to address this crisis by quickly growing the pool of disease experts. It must also stop disseminating scientifically invalid and medically unethical information that misleads doctors on the nature of the disease and as a result, can hurt patients. In its place, CDC must provide clinical guidance based on information authored by disease experts.

Details

Growing the pool of disease experts: To address the lack of disease experts, HHS must add a clinical care component to the Centers of Excellence being planned by the NIH and also take additional proactive steps to grow the pool of knowledgeable disease experts and gain the commitment of medical specialties to learn about this disease and treat patients with ME.

Medical Education: The IOM Report stated that ME is not a psychological disease, yet much of the influential research on ME has focused on psychological factors.[vii] A 2015 NIH Pathways to Prevention (P2P) Report called for the retirement of the Oxford case definition[viii] because it is overly broad and includes people with other conditions including mental illness. Yet CDC still uses statements and references based on psychogenic theories and the Oxford case definition in its current guidance. Other medical education providers do the same because CDC does. Such guidance encourages an unethical focus on psychological factors and treatments, such as GET and CBT that puts ME patients at significant risk of harm. To address this situation, the CDC must issue new ME medical education and clinical guidelines in the following manner:

- The CDC must immediately revise their ME medical education and clinical guidelines to replace erroneous and outdated information with updated, correct information based on the 2014 IACFS/ME Primer[ix] the 2012 ME-ICC Primer,[x] and the IOM report, supplemented with the August 2015 recommendations from the CFS Advisory Committee.

- All medical education content must be approved by recognized ME expert clinicians, researchers and patients before publication.

- The CDC must actively reach out to the larger medical community and to medical education providers to disseminate this updated content while simultaneously removing the erroneous information and material.

4. HHS Leadership, Oversight and a Serious Commitment to Urgently Address ME

HHS must demonstrate a serious commitment to ME commensurate with the severity and prevalence of the disease. This commitment must specifically remove all internal HHS impediments to achieving rapid progress and must be implemented with the full and open collaboration of, and accountability to, ME experts and patients.

Rationale

HHS's lack of leadership and commitment to ME for the past thirty years has resulted in the neglect of a serious neurological disease and the abandonment of 1 to 2.5 million disabled Americans. HHS's neglect has stalled research and drug development; disincentivized academic centers and pharmaceutical companies; and led to disbelieving medical providers, which has, in turn, resulted in a stigmatization of patients and abysmal, often harmful, clinical care.[xi] HHS's short-sighted policies and unilateral actions have destroyed the scientific and medical infrastructure for ME that could have advanced research and proper care for patients.[xii] HHS must now act with a commitment, focus and sense of urgency regarding all aspects of its response to this disease in order to remedy the situation, as patients are losing their lives to this disease, many having spent years, even decades, too weak to function. In doing so, HHS's decision-making process can no longer take place behind closed doors; HHS plans for ME must be developed and executed in conjunction with those who intimately know the disease: ME experts and patients.

Details

- HHS Leadership, Oversight and Commitment
  To ensure rapid progress, HHS must immediately accept the CFSAC Aug. 2015 recommendation of appointing a "senior-level cross-agency leader ("czar") with the authority, position and fiscal responsibility required to coordinate, develop, implement, and monitor a broad strategic cross-agency response to this disease through open and collaborative engagement of both internal and external stakeholders."[xiii] The plan must be fast-tracked and must include long-term goals and milestones, as well as criteria for measuring progress. The currently established Trans-NIH ME Working Group does not address these needs, as it has no coordination of a cross-agency strategic response. That response must address not only research, but also drug development, epidemiology, medical education, access and quality of medical care and public awareness.

- NIH Leadership, Oversight and Commitment
  Given the multi-systemic nature of ME, it is crucial that each relevant Institute within the NIH must immediately put forth its own publicly-stated strategic and financial commitments and goals. To ensure coordination across the Institutes and to make rapid progress on an NIH research strategy, the Trans-NIH ME Working Group must continue. Finally, to ensure we make fast progress in the context of the NIH's organizational structure, ME must be assigned to an NIH Institute right away. Given ME's clear neurological dysfunction, the disease must be placed in the National Institute of Neurological Disorders and Stroke (NINDS) as recommended by CFSAC.[xiv]

- CDC Leadership, Oversight and Commitment
  To demonstrate their serious commitment to urgently address ME, the CDC must restore the ME budget which was eliminated in their 2017 budget justification submitted to Congress.[xv] Additionally, the CDC must provide funds to conduct epidemiological studies to reassess prevalence, prognosis and risk factors. In doing so, the CDC must use the

Canadian Consensus Criteria, as does the NIH in its current intramural study. Further, the CDC must implement a mechanism to ensure that a panel of recognized disease experts are involved in final decision making on all aspects of the CDC's efforts related to ME.

Closing Note: These demands were originally issued for the May 25, 2016 MillionsMissing demonstrations. Minor revisions were made to the demands in November 2016 to reflect community input on the definition, the primer, the name, and the need for improvements in clinical care.

Contact

To learn more, please contact info@MEAction.net

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[i] Institute of Medicine of the National Academies. "Beyond Myalgic Encephalomyelitis/Chronic Fatigue Syndrome: Redefining an Illness." Institute of Medicine of the National Academies. Final report May 2015. http://www.iom.edu/Reports/2015/ME-CFS.aspx

[ii] Institute of Medicine of the National Academies. "Beyond Myalgic Encephalomyelitis/Chronic Fatigue Syndrome: Redefining an Illness." Institute of Medicine of the National Academies. Final report May 2015. http://www.iom.edu/Reports/2015/ME-CFS.aspx; 2015 Pathways to Prevention Report http://prevention.nih.gov/docs/programs/mecfs/ODP-P2P-MECFS-FinalReport.pdf

[iii] NIH Funding for Research by Disease. https://report.nih.gov/categorical_spending.aspx
The estimate of $250M is based on comparing funding to the funding of diseases of similar disease burden. For instance, the IOM report stated that ME patients are more impaired than those with MS and yet, in 2015, multiple sclerosis received $94M for an estimated prevalence of 400,000 (based on information from Cleveland Clinic). If spending were equivalent to prevalence and disease burden as estimated by level of impairment, spending would be roughly $250M a year.

[iv] Mitchell WM, "Efficacy of rintatolimod in the treatment of chronic fatigue syndrome/ myalgic encephalomyelitis (cuffs/me)." *Expert Review of Clinical Pharmacology*. April 2016. http://www.ncbi.nlm.nih.gov/pubmed/27045557

[v] Fluge O, Bruland O, Risa K, Storstein A, Kristoffersen EK, Sapkota D, Næss H, Dahl O, Nyland H, Mella O. "Benefit from B-Lymphocyte Depletion Using the Anti-CD20 Antibody Rituximab in Chronic Fatigue Syndrome. A Double-Blind and Placebo-Controlled Study." *Plos One* Oct 2011; 6(10): e26358. http://dx.doi.org/10.1371/journal.pone.0026358

[vi] Montoya M, Kogelnik A, Bhangoo M, Lunn M, Flamand L, Merrihew, Watt T, Kubo J, Paik J, Desa M. "Randomized Clinical Trial to Evaluate the Efficacy and Safety of Valganciclovir in a Subset of Patients With Chronic Fatigue Syndrome." *Journal of Medical Virology* August 19, 2013. 85:2101–2109 http://dx.doi.org/10.1002/jmv.23713

[vii] Institute of Medicine of the National Academies. "Beyond Myalgic Encephalomyelitis/Chronic Fatigue Syndrome: Redefining an Illness." Institute of Medicine of the National Academies. Final report May 2015. http://www.iom.edu/Reports/2015/ME-CFS.aspx

[viii] 2015 Pathways to Prevention Report - Page 16
https://prevention.nih.gov/docs/programs/mecfs/ODP-P2P-MECFS-FinalReport.pdf

[ix] International Association for Chronic Fatigue Syndrome/Myalgic Encephalomyelitis. "Chronic Fatigue Syndrome Myalgic Encephalomyelitis: A Primer for Clinical Practitioners 2014 Edition." 2012, revised 2014. http://iacfsme.org/portals/0/pdf/Primer_Post_2014_conference.pdf

[x] 2012 ME-ICC Primer http://www.hetalternatief.org/ICC%20primer%202012.pdf

[xi] Institute of Medicine of the National Academies. "Beyond Myalgic Encephalomyelitis/Chronic Fatigue Syndrome: Redefining an Illness." Institute of Medicine of the National Academies. Final report May 2015. http://www.iom.edu/Reports/2015/ME-CFS.aspx Page 1-3, 15-16, 27-31.

[xii] U.S. National Institutes of Health. Office of Disease Prevention. "Pathways to Prevention Workshop: Advancing the Research on Myalgic Encephalomyelitis/Chronic Fatigue Syndrome. December 9-10, 2014. Executive Summary." National Institutes of Health. Office of Disease Prevention. Final Report June 16, 2015. http://prevention.nih.gov/docs/programs/mecfs/ODP-P2P-MECFS-FinalReport.pdf
The lack of funding and the stigma toward the disease have discouraged researchers from investigating the disease. The P2P noted, "With a relatively small number of researchers in the field and finite resources, partnerships across institutions are needed to advance the research and develop new scientists."

[xiii] U.S. Department of Health and Human Services CFS Advisory Committee. Advisory Committee Meeting Recommendations. August 18-19, 2015. Last accessed September 12, 2015. http://www.hhs.gov/advcomcfs/recommendations/2015-08-18-19-recommendations.pdf

[xiv] U.S. Department of Health and Human Services CFS Advisory Committee. Advisory Committee Meeting Recommendations. August 18-19, 2015. Last accessed September 12, 2015. http://www.hhs.gov/advcomcfs/recommendations/2015-08-18-19-recommendations.pdf Recommendation #5

[xv] Centers for Disease Control and Prevention. Justifications of Estimates for Appropriations Committees. Fiscal Year 2017. http://www.cdc.gov/budget/documents/fy2017/fy-2017-cdc-congressional-justification.pdf Page 15.