#MillionsMissing ME/CFS Protest Demands
http://millionsmissing.meaction.net/protest-demands

On May 25, 2016, at the #MillionsMissing demonstrations, Myalgic Encephalomyelitis (ME) and Chronic Fatigue Syndrome (CFS) patients and families, advocacy organizations and individual activists call for the US Department of Health and Human Services to implement the following list of demands.

Our goal is to give the 1 to 2.5 million[i] disabled American ME/CFS patients 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/CFS research, and millions of medical providers are missing out on proper clinical training to diagnose and help patients manage this devastating illness.

For ME/CFS patients and their families, we demand:

1. **Increased Funding and Program Investments**
   Funding and program investments commensurate with the disease burden

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

3. **Accurate Medical Education**
   Replacement of misinformation with accurate medical education and clinical guidelines

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

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Rationale and Details
for the #MillionsMissing ME/CFS Protest Demands

For ME/CFS patients and their families, we demand:

1. <u>Funding and Program Investments Commensurate with the Disease Burden</u>
The NIH must dedicate funding and program investments for ME/CFS commensurate with the disease burden, and they must do this without continued delay, as patients have already been waiting three decades.

<u>Rationale</u>
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.

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/CFS[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/CFS 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/CFS 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/CFS research strategy.

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

2. Clinical Trials to Secure Medical Treatments for ME/CFS

HHS must fund and incentivize ME/CFS clinical trials to secure medical treatments for ME/CFS. 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/CFS 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/CFS 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/CFS patients.

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

3. <u>Accurate Medical Education and Clinical Guidelines</u>

The Centers for Disease Control and Prevention (CDC) must immediately discard its erroneous and outdated information related to ME/CFS and replace it with accurate medical education and clinical guidelines. The guidelines must be based on the most recent scientific information and the practices of ME/CFS experts, and be preapproved by a panel of recognized disease experts.

<u>Rationale</u>

It is morally reprehensible and medically unethical for the CDC to continue to disseminate erroneous and outdated information that can hurt patients. In spite of the findings of the 2015 Institute of Medicine (IOM) report, the CDC still includes references to psychological theories and treatments, such as GET (graded exercise therapy) and CBT (cognitive behavior therapy), even though the IOM report discredits the idea that this disease is psychological. This perpetuates medical confusion and puts ME/CFS patients at significant risk of harm. To address this situation, the CDC must immediately issue new ME/CFS medical education and clinical guidelines in the following manner:

<u>Details</u>

- The CDC must immediately revise their ME/CFS medical education and clinical guidelines to replace erroneous and outdated information with updated, correct information based on the 2014 IACFS/ME Primer,[vii] and the IOM report, supplemented with the August 2015 recommendations from the CFS Advisory Committee. The IOM report stated that ME/CFS is not a psychological disease, yet much of the influential research on ME/CFS has focused on psychological factors.[viii] A 2015 NIH Pathways to Prevention (P2P) Report called for the retirement of the Oxford case definition[ix] because it is overly broad and includes people with other conditions including mental illness. Yet findings using the Oxford case definition are still being referenced in CDC material, even in new medical education information from the CDC and other medical education providers. This encourages an unethical focus on psychological factors and treatments, such as GET and CBT.

- All medical education content must be approved by recognized ME/CFS 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/CFS

HHS must demonstrate a serious commitment to ME/CFS 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/CFS experts and patients.

Rationale

HHS's lack of leadership and commitment to ME/CFS 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.[x] HHS's short-sighted policies and unilateral actions have destroyed the scientific and medical infrastructure for ME/CFS that could have advanced research and proper care for patients.[xi] 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/CFS must be developed and executed in conjunction with those who intimately know the disease: ME/CFS 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."[xii] 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/CFS 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/CFS, 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/CFS Working Group must continue. Finally, to ensure we make fast progress in the context of the NIH's organizational structure, ME/CFS 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.[xiii]

- CDC Leadership, Oversight and Commitment
  To demonstrate their serious commitment to urgently address ME/CFS, the CDC must restore the ME/CFS budget which was eliminated in their 2017 budget justification submitted to Congress.[xiv] 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/CFS.

Closing Note: These demands could change if there is any new information coming from the NIH, the CDC or HHS before the date of the #MillionsMissing demonstration on May 25, 2016.

Contact
To learn more, please contact
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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/CFS 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] 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

[viii] 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

[ix] 2015 Pathways to Prevention Report - Page 16

https://prevention.nih.gov/docs/programs/mecfs/ODP-P2P-MECFS-FinalReport.pdf

[x] 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.

[xi] 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."

[xii] 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

[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 Recommendation #5

[xiv] 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.