

Director Collins's Response to Congress Isn't Good Enough

In a formal House of Representatives letter of support, **55 bipartisan members of Congress** called upon National Institutes of Health (NIH) Director Francis Collins to take action on myalgic encephalomyelitis (ME), commonly known as chronic fatigue syndrome (CFS).

As the letter explains, "ME/CFS is a complex, debilitating, and chronic disease afflicting **1 to 2.5 million Americans**. It costs individuals, the U.S. health care system, and our economy an estimated **\$17-\$24 billion** annually. Yet, as the Institute of Medicine noted in its report, 'Beyond Myalgic Encephalomyelitis/Chronic Fatigue Syndrome: Redefining an Illness,' there has been '**remarkably little research funding**' to date to discover its cause or possible treatments."

The letter specifically encourages 1) the strengthening of NIH efforts in ME/CFS biomedical research, 2) a reinvigorated trans-NIH ME/CFS working group housed within the National Institute of Neurological Disorders and Stroke (NINDS), and 3) additional intramural and extramural research programs. The letter, which follows a similar call to action led by Congresswoman Lofgren in 2014, emphasizes these actions must be taken in a **timely manner** while reporting to congress about additional ME/CFS planning and research activities.

Breaking Down Director Collins's Response

"The complexity of ME/CFS and the need for an inter-disciplinary approach to better understand and develop treatments for this disease necessitate a trans-NIH approach...the Trans-NIH ME/CFS Working Group...is a team effort among 23 Institutes, Centers and Offices."

Fact Check: The Trans-NIH ME/CFS Working Group was established in 1999. In 17 years, the working group produced just **one RFA**, issued only **one batch** of administrative supplements, and hosted a mere **four events**.

SMCI's Response: A multi-disciplinary approach is best for ME/CFS, but there must be clear responsibility and accountability for **action, progress, and funding** within the NIH.

"[T]he NIH has already funded seven supplements to existing awards focused on understanding the causes and mechanisms of ME/CFS."

Fact Check: These awards were **one-time supplements** only available to existing NIH grant recipients and do not include continued or sustained funding for long-term investment.

SMCI's Response: We applaud the NIH's supplemental funding as a first step, but the total NIH financial commitment to ME/CFS continues to be **insufficient to make progress** against this disease.

"The NIH is preparing two Requests for Applications (RFAs) which will support ME/CFS collaborative research centers and a Data Management Coordinating Center. These RFAs will be released once they are finalized."

Fact Check: On October 29, 2015, Director Collins announced that the NIH would reinvigorate ME/CFS research. Since Director Collins's announcement, the NIH has issued 362 RFAs totaling just under \$2.9 billion. **The last RFA for ME/CFS was issued in 2005.**

SMCI's Response: The NIH recently announced additional details regarding two Funding Opportunity Announcements (FOAs) scheduled to be published in Dec. 2016. While a first step, these actions **lack the critical urgency this extremely debilitating disease merits** and fall short of the significant investment needed to secure a biomarker for, understand the pathology of, research the epidemiology of, and create regional centers of excellence for this disease.

October 28, 2016 // * Source: Francis Collins, letter to The Honorable Anna Eshoo, September 29, 2016.

Here's What's Missing:

- A plan to ramp up funding
- A Request for Applications (RFA) for biomarkers or key biological questions
- Recognition of, or a plan to address, barriers to clinical trials
- A plan to progress clinical trials on drugs currently being used off label by ME/CFS patients

Here Are Our Immediate Needs:

- Specific dollar amounts and a sustained commitment for RFAs and other research programs
- The status of the planning effort to create a coordinated NIH research strategy
- Specific activities planned for FY 2017 and 2018
- Specific timelines for the working group RFI responses, the public release of intramural study protocol, and continued reporting to congress and the ME/CFS community

Here's How to Learn More:

- Contact Emily Taylor, SMCI advocacy and engagement manager, by email at ETaylor@SolveCFS.org or by phone at (704) 364-0016, ext. 209



Solve ME/CFS Initiative

Leveraging patient-centered research to cure ME/CFS

www.SolveCFS.org