

111TH CONGRESS  
1ST SESSION

# H. R. 3502

To amend the Public Health Service Act to establish an Office of Mitochondrial Medicine at the National Institutes of Health, and for other purposes.

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## IN THE HOUSE OF REPRESENTATIVES

JULY 31, 2009

Mr. McDERMOTT (for himself, Mr. CONNOLLY of Virginia, Ms. WASSERMAN SCHULTZ, Mr. JOHNSON of Georgia, Mr. TIM MURPHY of Pennsylvania, Mr. ELLSWORTH, Ms. ESHOO, Mr. KIRK, Mr. ADLER of New Jersey, Mr. MCGOVERN, Mr. BOSWELL, Mr. THORNBERRY, Mr. VAN HOLLEN, and Mr. THOMPSON of California) introduced the following bill; which was referred to the Committee on Energy and Commerce

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## A BILL

To amend the Public Health Service Act to establish an Office of Mitochondrial Medicine at the National Institutes of Health, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*  
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Mitochondrial Medi-  
5 cine Research and Treatment Enhancement Act”.

6 **SEC. 2. FINDINGS AND PURPOSE.**

7 (a) FINDINGS.—Congress finds the following:

1           (1) Mitochondrial disease results when there is  
2           a defect that reduces the ability of the mitochondria  
3           in a cell to produce energy. As the mitochondria fail  
4           to produce enough energy, the cell will cease to func-  
5           tion properly and will eventually die. Organ systems  
6           will begin to fail, and the life of the individual is  
7           compromised or ended.

8           (2) There are more than 40 specifically identi-  
9           fied mitochondrial diseases, but the vast majority  
10          have not yet been identified.

11          (3) Mitochondrial diseases are a relatively newly  
12          diagnosed group of diseases, first recognized in the  
13          late 1960s. Diagnosis is extremely difficult for a  
14          number of reasons.

15          (4) Mitochondrial diseases can present them-  
16          selves at any age, with associated mortality rates  
17          that vary depending upon the particular disease. The  
18          most severe diseases result in progressive loss of  
19          neurological and liver function, and death within  
20          several years.

21          (5) According to the National Institute of Envi-  
22          ronmental Health Sciences, half of those affected by  
23          mitochondrial disease are children, who show symp-  
24          toms before age five and approximately 80 percent  
25          of whom will not survive beyond the age of 20.

1           (6) Mitochondrial dysfunction is also associated  
2           with numerous other related disorders, including  
3           many common neurological diseases (such as Parkin-  
4           son's, Alzheimer's, ALS, and autism), and other dis-  
5           eases associated with aging, diabetes, cancer, and  
6           obesity.

7           (7) Mitochondrial disease is most commonly the  
8           result of genetic mutation, either in the nuclear  
9           DNA or in the mitochondrial DNA. Some  
10          mitochondrial diseases also are attributable to envi-  
11          ronmental factors, including prescription medica-  
12          tions, that interfere with mitochondrial function.

13          (8) Researchers estimate that one in 4,000 chil-  
14          dren will develop a mitochondrial disease related to  
15          an inherited mutation by the age of 10 years, and  
16          that 1,000–2,000 children are born each year in the  
17          United States who will develop mitochondrial disease  
18          in their lifetimes. However, studies of umbilical cord  
19          blood samples show that one in 200 children are  
20          born with both normal and mutant mitochondrial  
21          DNA, and the number of children with these  
22          mutations who actually develop a disease is un-  
23          known.

1           (9) There are no cures for any of the specifi-  
2           cally identified mitochondrial diseases, nor is there a  
3           specific treatment for any of these diseases.

4           (10) Improving our basic understanding of  
5           mitochondrial function and dysfunction has potential  
6           application to numerous areas of biomedical re-  
7           search. The National Institutes of Health has taken  
8           an increased interest in mitochondrial disease and  
9           dysfunction and has sponsored a number of activities  
10          in recent years aimed at advancing mitochondrial  
11          medicine, including incorporating research into func-  
12          tional variation in mitochondria in the Trans-  
13          formative Research Grants Initiative.

14          (b) PURPOSE.—It is the purpose of this Act to pro-  
15          mote an enhanced research effort aimed at improved un-  
16          derstanding of mitochondrial disease and dysfunction and  
17          the development of treatments for mitochondrial disease.

18      **SEC. 3. ENHANCEMENT OF RESEARCH AND TREATMENT**  
19                      **ACTIVITIES RELATED TO MITOCHONDRIAL**  
20                      **MEDICINE.**

21          (a) MITOCHONDRIAL MEDICINE RESEARCH EN-  
22          HANCEMENT.—Part A of title IV of the Public Health  
23          Service Act (42 U.S.C. 281 et seq.) is amended—

24                  (1) by redesignating section 404H as section  
25          404I; and

1           (2) inserting after section 404G the following  
2       new section:

3   **“SEC. 404H. OFFICE OF MITOCHONDRIAL MEDICINE.**

4       “(a) ESTABLISHMENT.—There is established within  
5 the Office of the Director of NIH an office to be known  
6 as the Office of Mitochondrial Medicine (in this section  
7 referred to as the ‘Office’), which shall be headed by a  
8 Director (in this section referred to as the ‘Director’), ap-  
9 pointed by the Director of NIH.

10      “(b)   MITOCHONDRIAL    MEDICINE    RESEARCH  
11 PLAN.—

12           “(1) IN GENERAL.—The Director shall develop,  
13       make publicly available, and implement a written  
14       plan to facilitate research into mitochondrial medi-  
15       cine.

16           “(2) CONTENTS.—The plan required under  
17       paragraph (1) shall include the following objectives:

18               “(A) Improving coordination of research  
19       related to mitochondrial medicine among the  
20       national research institutes and between the  
21       National Institutes of Health and outside re-  
22       searchers.

23               “(B) Providing training to research sci-  
24       entists and health professionals engaged in re-  
25       search related to mitochondrial medicine.

1           “(C) Providing training to health care pro-  
2           viders regarding the diagnosis of mitochondrial  
3           disease and dysfunction.

4           “(D) Establishing scientific review groups  
5           with expertise in mitochondrial medicine to  
6           oversee relevant research projects in the Na-  
7           tional Institutes of Health.

8           “(3) CONSULTATION.—In developing the plan  
9           under paragraph (1), the Director shall consult  
10          with—

11           “(A) the Director of the National Cancer  
12          Institute;

13           “(B) the Director of the National Institute  
14          of Child Health and Human Development;

15           “(C) the Director of the National Institute  
16          of Environmental Health Sciences;

17           “(D) the Director of the National Heart,  
18          Lung, and Blood Institute;

19           “(E) the Director of the National Institute  
20          of Neurological Disorders and Stroke;

21           “(F) the Director of the National Institute  
22          of Diabetes and Digestive and Kidney Diseases;

23           “(G) the Director of the National Eye In-  
24          stitute; and

1           “(H) the heads of such other institutes  
2           and offices as the Director considers appro-  
3           priate.

4           “(4) UPDATES.—The Director shall update the  
5           plan required under paragraph (1) on a biennial  
6           basis.

7           “(c) RESEARCH GRANTS.—In addition to any grants  
8           otherwise awarded by the National Institutes of Health  
9           for research in mitochondrial medicine, the Director shall  
10          annually award—

11           “(1) at least five grants for integrated, multi-  
12          project research programs related to mitochondrial  
13          medicine; and

14           “(2) at least five grants for planning activities  
15          associated with integrated, multi-project research  
16          programs related to mitochondrial medicine.

17          “(d) CENTERS OF EXCELLENCE.—

18           “(1) IN GENERAL.—The Director may award  
19          grants to institutions or consortiums of institutions  
20          to establish Mitochondrial Medicine Centers of Ex-  
21          cellence to promote interdisciplinary research and  
22          training related to mitochondrial medicine.

23           “(2) USE OF FUNDS AWARDED.—A grant  
24          awarded under paragraph (1) shall be used to—

1           “(A) conduct basic and clinical research re-  
2           lated to mitochondrial medicine;

3           “(B) facilitate training programs for re-  
4           search scientists and health professionals seek-  
5           ing to engage in research related to  
6           mitochondrial medicine;

7           “(C) develop and disseminate programs  
8           and materials to provide continuing education  
9           to health care professionals regarding the rec-  
10          ognition, diagnosis, and treatment of  
11          mitochondrial disease and dysfunction; and

12          “(D) provide living stipends for research  
13          scientists and health professionals enrolled in  
14          mitochondrial research training programs.

15          “(e) NATIONAL REGISTRY; BIOREPOSITORY.—

16               “(1) NATIONAL REGISTRY.—The Director shall  
17               establish a national registry for the maintenance and  
18               sharing for research purposes of medical information  
19               collected from patients with mitochondrial disease or  
20               dysfunction.

21               “(2) BIOREPOSITORY.—The Director shall es-  
22               tablish a national biorepository for the maintenance  
23               and sharing for research purposes of tissues and  
24               DNA collected from patients with mitochondrial dis-  
25               ease or dysfunction.



1       “(f) DEFINITION.—In this section, the term  
2 ‘mitochondrial medicine’ means medical treatment related  
3 to mitochondrial disease or dysfunction.”.

4       (b) DEVELOPMENT OF MITOCHONDRIAL MEDICINE  
5 RESEARCH PLAN.—The Director of the Office of  
6 Mitochondrial Medicine shall develop and make publicly  
7 available the mitochondrial medicine research plan re-  
8 quired under section 404H(b)(1) of the Public Health  
9 Service Act, as added by subsection (a) of this section,  
10 not later than 180 days after the date of the enactment  
11 of this Act.

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