

## Citizen Petition

06/082024

The undersigned submits this petition under Title 21 of the Code of Federal Regulations, Part 10.30 (Citizen Petitions) of the Federal Food, Drug, and Cosmetic Act to request the Commissioner of Food and Drugs to issue a new regulation.

### **A. Action Requested**

I request that the Food and Drug Administration classify aging as a disease. This classification will have significant implications for research, development, and approval of interventions aimed at keeping Americans healthy, and reducing the burden of chronic disease and comorbidities on our healthcare systems.

### **B. Statement of Grounds**

#### **1. Definition and Impact of Aging:**

- Aging is characterized by the gradual decline of physiological functions and an increased risk of chronic diseases and mortality. This process involves multiple biological pathways and affects all organ systems.
- The impact of aging on public health is profound, contributing to the majority of morbidity and mortality in the United States and globally. Diseases commonly associated with aging include cardiovascular diseases, cancers, diabetes, Alzheimer's disease, and osteoarthritis. Comorbidities further exacerbate healthspan problems, putting Americans out of work and damaging our economy.

#### **2. Scientific Evidence:**

- Extensive research has identified numerous biomarkers and molecular pathways involved in the aging process, including genomic instability, telomere attrition, epigenetic alterations, loss of proteostasis, deregulated nutrient sensing, mitochondrial

dysfunction, cellular senescence, stem cell exhaustion, gut dysbiosis, and altered intercellular communication. See the 2023 Hallmarks of Aging paper.

- Interventions targeting these pathways have shown promise in extending lifespan and healthspan in various model organisms. Examples include caloric restriction, senolytics, NAD<sup>+</sup> precursors, rapamycin, epigenetic reprogramming with transcription factors such as OSK, and metformin.

### **3. Economic and Social Considerations:**

- The economic burden of aging-related diseases is substantial, with healthcare costs escalating due to the increasing prevalence of chronic conditions among the elderly population, particularly comorbidities.
- Classifying aging as a disease would promote investment in research and development of therapies aimed at preventing or reversing the aging process, potentially reducing healthcare costs and improving quality of life for the aging population, allowing them more healthy productive working tax-contributing years.
- Because it is requested that we include information *unfavorable* to the petition, it should be noted that significantly longer lifespans would heavily strain our already overburdened Social Security system.

### **4. Regulatory Precedents:**

- The FDA has recognized conditions with complex, multifactorial etiologies, such as obesity, as diseases. Aging similarly represents a multifactorial process that leads to significant health detriments.
- Other regulatory bodies and scientific organizations, such as the World Health Organization, have acknowledged the significance of addressing aging and related conditions as part of their health strategies.

## **C. Environmental Impact**

The undersigned claims a categorical exclusion under 21 CFR 25.30 and 25.31. To the best of the petitioner's knowledge, no extraordinary circumstances exist that would require an environmental assessment.

#### **D. Economic Impact**

Pursuant to 21 CFR 10.30(b), information on economic impact will be submitted upon request by the Commissioner.

#### **E. Certification**

The undersigned certifies that, to the best of their knowledge and belief, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Sincerely,

DocuSigned by:  
*Zach Richardson*  
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Zach Richardson

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