THERAPEUTIC HEALTHSPAN RESEARCH, INNOVATION, AND VALIDATION ENHANCEMENT ACT OF 2025

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SECTION 2. FINDINGS

(A) FINDINGS — Congress finds that:

(1) Chronic diseases are the leading cause of death and disability in the United States, placing a significant burden on individuals, families, and the healthcare system.

(2) Life expectancy in the United States has declined sharply over the past decade and trails significantly behind peer nations, with substantial disparities between income levels and between urban and rural populations.

(3) Early intervention and prevention strategies that target the underlying biological processes of aging and chronic diseases hold promise for improving healthspan, the period of life free of age-related chronic diseases and disabilities.

(4) Current healthcare and pharmaceutical business models prioritize treatment of acute conditions over prevention, lacking strong incentives to invest in preventive therapies and population health improvement.

(5) Equitable access to preventative health products is essential for promoting healthcare equity and reducing disparities in chronic disease burden.

(6) The current regulatory framework for the Food, Drug, and Cosmetic Act (FD&C Act) emphasizes the development and approval of treatments for manifested diseases, one disease at a time, over the development and approval of products aimed at preventing chronic diseases through positive impacts on intermediate health markers.

(7) Enabling access to safe and effective interventions that can extend the period of healthy, independent living would have significant benefits for individuals, society, and the economy.

(8) Developing and evaluating the evidence to support healthspan products and claims is inherently more complex than assessing the safety and effectiveness of drugs for treating specific, established diseases.

(9) Healthspan is a multifaceted, long-term outcome that can be influenced by many factors beyond the drug's direct effects.

(10) Given these complexities, encouraging and incentivizing innovation in this area is crucial for promoting the overall health and well-being of the nation.

SECTION 3. PURPOSE

(A) IN GENERAL — The purpose of this Act is to establish a regulatory framework to support, incentivize, and oversee the development of products regulated by the Food and Drug Administration ("FDA") which are intended to lengthen healthspan, the period of life free from the chronic diseases and conditions responsible for most mortality and disability in the general population.

(B) BACKGROUND—By age 65, most people have begun to experience multiple chronic health conditions, as well as functional and cognitive decline. These conditions adversely

affect the ability to withstand infection or recover from other health threats, as shown by the high mortality rate among older individuals and the chronically ill during the COVID-19 Pandemic. By increasing healthspan, many of the economic and societal burdens of disease and frailty can be reduced, allowing individuals to remain self-sufficient longer, with less pain, suffering, debilitating loss of function, and dependency on acute and chronic medical care. Advances in the study of aging biology strongly support the prospects of identifying and targeting the shared root causes of age-related chronic diseases and some forms of cancer. The quest to convert this science into evidence-based solutions for people of all ages presents a daunting challenge. The enormous time and costs inherent in achieving definitive evidence of effectiveness for such interventions impedes investment in and development of these potential solutions.

(C) NEED FOR NEW FRAMEWORK.

(1) The current regulatory framework for the approval of new drugs and biologics is well-suited for products that treat a disease or condition after onset. Prevention under the current framework is similarly focused on addressing one disease at a time, usually after well-known markers of the disease have been detected. A regulatory framework, complementary to, but in no way altering, the existing framework, is needed for products specifically intended to prevent or reduce the risks of multiple chronic conditions and associated disabilities among the general or pre-disease populations. This need results from the much greater time and costs to develop interventions aimed at preventing multiple chronic diseases compared to those for treating a single disease.

The general approach to preempting multiple disease may include developing new therapeutics, repurposing older products, providing evidence-based claims for dietary supplements, and studying innovative combinations of products to delay the onset of chronic conditions or slow their progression. It may also include the use of wearable devices and passive monitoring systems, and other medical device technologies, to track subclinical indicators of disease. Medical devices, enabled by artificial intelligence, hold the potential to guide behavior and interventions that can help individuals maintain or even improve their health and avert or slow progression toward chronic disease. Artificial intelligence platforms may identify new endpoints, including molecular biomarkers, to support the development of drugs, devices, and nutritional regimens to lengthen healthspan and support a healthier and more resilient population.

(D) SCOPE — Pursuant to the THRIVE Act of 2025, preempting multiple chronic diseases may include:

(1) Development of new therapeutics

(2) Repurposing of older products, or repositioning investigational products for healthspan indications

(3) Making of evidence-based healthspan claims for dietary supplements

(4) Study of innovative combinations of products

(5) Use of wearables and passive monitoring systems

(6) Medical device technologies to track subclinical indicators of disease

(7) Medical devices enhanced by artificial intelligence

(8) Development of new endpoints, including molecular biomarkers

SECTION 4. FRAMEWORK FOR THE DEVELOPMENT OF HEALTHSPAN PRODUCTS

SEC. [505H]. A FRAMEWORK FOR THE DEVELOPMENT OF HEALTHSPAN PRODUCTS.

(A) DEFINITIONS — For purposes of this section—

(1) The term 'increases healthspan' means reduces the risk and/or delays the onset of age-related disabilities and the occurrence of multiple chronic age-related conditions, including but not limited to:

(a) Cardiovascular disease

(b) Type 2 diabetes

(c) Metabolic Dysfunction-Associated Steatohepatitis (MASH)

(d) Some forms of cancer

(e) Parkinson's disease, dementia, and Alzheimer's disease

(f) Frailty, including osteoporosis and age-related loss of muscle mass and function

(g) Ocular conditions such as cataracts and macular degeneration and other sensory conditions such as hearing loss.

(2) The term 'healthspan drug' means a drug, as defined in section 201(g)(1) of the FD&C Act (21 U.S.C. 321(g)(1)), or a biological product, as defined in section 351(i)(1) of the Public Health Service Act (42 U.S.C. 262(i)(1)), that is intended to increase healthspan.

(3) The term 'healthspan food' means a food, as defined in section 201(f) of the FD&C Act (21 U.S.C. 321(f)), that is intended to improve healthspan. Claims about healthspan food can be achieved as a qualified health claim under existing law.

(4) The term 'healthspan dietary supplement' means a dietary supplement, as defined in the Dietary Supplement Health and Education Act of 1994, that is intended to improve healthspan.

(5) The term 'healthspan device' means a device, as defined in section 201(h)(1) of the FD&C Act (21 U.S.C. 321(h)(1)), that is intended to improve healthspan.

(6) The term 'healthspan indication' means a description of the benefit that the product has been shown to provide or is likely to provide. This benefit would typically be described as a reduction in the risks of acquiring two or more age-related chronic diseases and/or disabilities.

(7) The term 'healthspan product' means a healthspan drug, healthspan device, or healthspan food.

(8) The term 'healthspan designation' means approval as a healthspan product under this section.

(9) The term 'human drug application' means an application submitted under section 505(b) of the Act or an application for licensure of a biological drug product under section 351 of the Public Health Service Act.

(10) The term 'general adult population' means United States population eighteen years old and older free of chronic diseases and obesity. Reasonable exclusions, such as pregnant individuals, may be applied.

(11) The term 'defined population' means a specified subset of the general adult population from which evidence supporting a healthspan indication is drawn.

(12) The term 'Tier 1' healthspan product means a healthspan product that has been shown based on robust scientific and early clinical evidence reasonably likely to increase healthspan in a defined population.

(13) The term 'Tier 2' healthspan product means a healthspan product that has been shown, based on intermediate clinical evidence, as likely to increase healthspan in a defined population.

(14) The term 'Tier 3' healthspan product means a healthspan product that has been shown based on substantial evidence of effectiveness to increase healthspan in a defined population.

(15) The term ‘robust scientific evidence’ means evidence from a combination of in vitro, animal model, and human genomic studies, which together, is persuasive to experts that a product is reasonably likely to increase healthspan.

(16) The term ‘early clinical evidence’ means evidence from human pharmacologic studies and clinical trials of 10 weeks’ duration or longer, which alone or together, is persuasive to experts that a product is reasonably likely to increase healthspan.

(17) The term ‘intermediate clinical evidence’ means evidence from one or more clinical trials of 26-weeks’ duration or longer, which alone or together, is persuasive to experts that a product is reasonably likely to increase healthspan.

(18) The term 'substantial evidence' of effectiveness means evidence that may include, but is not limited to:

(a) Adequate and well-controlled investigations

(b) Long-term observational data

(c) Validated surrogate and biomarker data

(d) Real-world evidence meeting criteria established by the Secretary

(B) REGULATION —

(1) To the extent not contrary to this section [505H], healthspan products will be subject to regulation under the Federal Food, Drug, and Cosmetic Act and Public Health Service Act, as applicable.

(2) The Secretary of Health and Human Services may establish, by regulation:

(a) Requirements for the approval, suspension, and withdrawal of healthspan food, drug, and device applications

(b) Relevant postmarketing requirements

(c) Marketing and promotional limitations for all healthspan products

(C) HEALTHSPAN DRUG —

(1) SAFETY STANDARD FOR APPROVAL — For each tier of healthspan marketing approval, a healthspan drug must be found to be safe for use under the conditions prescribed, recommended or suggested in the labeling of the product, supported by safety testing and available data (including history of use of the ingredient(s)) commensurate with the applicable healthspan tier of approval.

(2) EVIDENTIARY STANDARD FOR APPROVAL —

(a) Tier 1. To obtain approval for a Tier 1 healthspan drug, a sponsor must:

i. present sufficient evidence that the drug appears reasonably likely to improve healthspan in a defined population; and

ii. demonstrate that the reasonably likely benefit of increased healthspan, including the magnitude of such benefit, in such defined population, is sufficient to outweigh the safety risks associated with use of the drug.

iii. Sufficient evidence may consist of a combination of data from digital or mechanistic, *in silico/in vitro* models of cellular aging, animal model, clinical, epidemiologic, and real-world studies, some or all, which taken together are reasonably likely to predict a healthspan benefit.

iv. Clinically relevant healthspan endpoints may include endpoints based on biomarkers, surrogates, or measures of physical and cognitive function.

(b) Tier 2. To maintain Tier 1 approval and obtain approval as a Tier 2 healthspan drug, on or before [seven] years on the market, the sponsor must:

i. provide intermediate clinical evidence demonstrating that the drug is likely to increase healthspan in a defined population.

ii. demonstrate the likely benefit on healthspan in such defined population, including the magnitude of such improvement, continues to outweigh risks suggested by the accumulated safety data from the intended patient population.

iii. Interim, reliable clinical evidence may include data from randomized, controlled clinical trials of at least 2 years duration, or alternative study designs showing statistically significant effects on healthspan biomarkers or surrogate endpoints likely to predict

healthspan benefit, or composite endpoints that do not show consistent effects across components.

iv. The indication of a product that fails to gain Tier 2 healthspan approval shall be withdrawn or modified in a way that appropriately states the limitation of available evidence to support the indication. A modified indication would require that the drug continues to be considered safe for use.

(c) Tier 3. To maintain Tier 2 approval and obtain approval as a Tier 3 healthspan drug, on or before [fourteen] years on the market, the sponsor must:

i. demonstrate with substantial evidence of effectiveness, including adequate and well-controlled studies, that the drug increases healthspan in a defined population.

ii. demonstrate the benefit on healthspan in such defined population, including the magnitude of such improvement, continues to outweigh risks suggested by the accumulated safety data from the intended patient population.

(d) A Tier 3 healthspan drug shall be considered to have full, unconditional healthspan approval.

(e) The indication of a product that fails to gain Tier 3 healthspan approval shall be withdrawn or modified in a way that appropriately states the limitation of available evidence to support the indication. A modified indication would require that the drug continues to be considered safe for use.

(3) ENHANCED PHARMACOVIGILANCE AND REGISTRY REQUIREMENT—

(a) For Tier 1 approval, the sponsor may be required to:

i. submit and obtain approval for a registry protocol and/or an active surveillance plan

ii. monitor for adverse events of special interest

iii. submit periodic safety updates that will typically exceed in frequency those required for products approved for disease indications

(b) For Tier 2 approval, the sponsor may be required to:

i. develop and obtain approval of an active surveillance plan

ii. monitor for adverse events of special interest submit periodic safety updates that may exceed those required for products approved for disease indications

(D) HEALTHSPAN DEVICE —

(1) SAFETY STANDARDS FOR APPROVAL —

Healthspan device, and components thereof, shall be subject to sections 201(s) and 409 of the Act.

(2) EVIDENTIARY STANDARDS FOR APPROVAL —

(a) Tier 1. To obtain approval for a Tier 1 healthspan device, a sponsor must:

i. Present sufficient evidence that the device appears reasonably likely to improve healthspan in a defined population; and

ii. Demonstrate that the reasonably likely benefit of increased healthspan, including the magnitude of such benefit, in such defined population, is sufficient to outweigh the safety risks associated with use of the device.

iii. Sufficient evidence may consist of a combination of data from digital or mechanistic, *in silico/in vitro* models of cellular aging, animal model, clinical, epidemiologic, and real-world studies, some or all, which taken together are reasonably likely to predict a healthspan benefit.

iv. Clinically relevant healthspan endpoints may include endpoints based on biomarkers, surrogates, or measures of physical and cognitive function.

v. If a diagnostic test or predictive biomarker, present evidence that supports the product's utility for reliably providing information or feedback that will substantially help to increase healthspan.

(b) Tier 2. To maintain Tier 1 approval and obtain approval as a Tier 2 healthspan device, after [seven] years on the market, the sponsor must:

i. provide intermediate clinical evidence that the device likely improves healthspan in a defined population; and

ii. demonstrate that the improvement in healthspan in such defined population, including the magnitude of such improvement, is reasonable in light of known safety concerns associated with use of the device.

(c) Tier 3. To maintain Tier 2 approval and obtain approval as a Tier 3 healthspan device, after [fourteen] years on the market, the sponsor must:

i. demonstrate by substantial evidence of effectiveness, including adequate and well-controlled studies, that the device materially improves healthspan in the general adult population; and

ii. demonstrate that such improvement, including the magnitude of such improvement, is sufficient considering known safety concerns associated with use of the device in the general adult population.

(3) REGISTRY REQUIREMENT — In addition to the efficacy demonstration requirements, prior to maintaining approval under subsection (2)(B), the sponsor must limit marketing of the healthspan device under a registry protocol to obtain

systematically collected data on the safety and efficacy-related outcomes.

(E) HEALTHSPAN FOOD —

(1) Evidence that a food, as defined in section 201(f) of the Act (21 U.S.C. 321(f)), may increase healthspan can be submitted to the Secretary. Healthspan food claims can be achieved as a qualified health claim under existing law and processes.

(F) HEALTHSPAN DIETARY SUPPLEMENT —

SAFETY STANDARDS FOR APPROVAL—Healthspan supplements must comply with the same safety standards set forth in the Act.

(1) EVIDENTIARY STANDARDS FOR HEALTHSPAN CLAIMS

(a) Tier 1. To make a Tier 1 healthspan claim for a dietary supplement, a manufacturer must:

i. present sufficient evidence that the supplement is reasonably likely to improve healthspan in a defined population; and

ii. demonstrate that the reasonably likely benefit of increased healthspan, including the magnitude of such benefit, in such defined population, is sufficient to outweigh the safety risks associated with use of the supplement.

iii. Sufficient evidence may consist of a combination of data from mechanistic, advanced imaging technology, in vitro models of cellular aging, animal model, clinical, epidemiologic, and real-world studies, some or all, which taken together are reasonably likely to predict a healthspan benefit.

iv. Clinically relevant healthspan endpoints may include endpoints based on biomarkers, surrogates, or measures of physical and cognitive function.

(b) Tier 2. To maintain Tier 1 claim approval and obtain Tier 2 approval, after 7 years, the manufacturer must:

i. Provide evidence from at least two adequate and well-controlled human studies

ii. Demonstrate consistent effects across studies

iii. Show evidence of safety in long-term use

iv. Submit systematic surveillance data

(c) Tier 3. To maintain Tier 2 claim approval and obtain Tier 3 approval, after 14 years, the manufacturer must:

i. Provide evidence from multiple adequate and well-controlled studies

ii. Include diverse population representation

iii. Demonstrate long-term safety and effectiveness

iv. Show evidence of population-level benefits

(2) COEXISTING CLAIMS —

(a) A dietary supplement healthspan claim is available only to the manufacturer or collaborating manufacturers.

(b) Awarding of the healthspan claim does not prevent marketing of similar products with structure-function claims.

(c) Manufacturers of similar products may not make a healthspan claim, refer to the claim, or imply the claim.

(d) Manufacturers of similar products without a healthspan claim may apply for the same or a higher tier claim after the exclusivity of the issued claim has expired.

(3) POST-MARKET REQUIREMENTS —

(a) Manufacturers making healthspan claims must:

i. Maintain records of all complaints and adversities.

ii. Promptly report serious adverse events.

iii. Conduct post-market surveillance as appropriate for the product.

iv. Submit annual reports summarizing safety and effectiveness data.

(4) RELATIONSHIP TO EXISTING AUTHORITY —

(a) Nothing in this section shall be construed to:

i. Modify existing dietary supplement regulations except as specifically provided.

ii. Affect the authority of the Secretary under the Dietary Supplement Health and Education Act.

iii. Create a premarket approval requirement for dietary supplements not making healthspan claims.

(G) TIER TRANSITION PROCEDURES —

(1) APPLICATION FOR ADVANCEMENT---

(a) Sponsors shall submit applications for tier advancement no later than 180 days before the expiration of the current tier period

(b) The Secretary shall review and act upon such applications within 90 days

(2) FAILURE TO ADVANCE —

(a) Products failing to advance to higher tiers shall:

i. Receive a 180-day period to submit additional data

ii. Be permitted to maintain current tier status pending review

iii. Be subject to labeling revisions as directed by Secretary

(H) ADMINISTRATIVE APPEALS —

(1) APPEAL RIGHTS---Sponsors may appeal:

(a) Denial of tier advancement

(b) Withdrawal of tier designation

(c) Labeling requirements

(2) PROCEDURES---

(a) Appeals must be filed within 60 days.

(b) The Secretary shall act within 90 days of the appeal.

(c) Products maintain status pending appeal

SECTION 5. HEALTHSPAN PRODUCT DEVELOPMENT PROGRAM
SEC. [505I].

(A) ESTABLISHMENT — The Secretary shall establish a program to expedite the development of healthspan products and facilitate ongoing communication between the Secretary and sponsors of healthspan products.

(B) HEALTHSPAN PRODUCT DEVELOPMENT MEETINGS —

(1) TYPE H MEETINGS—A sponsor of a healthspan product may request 1 or more meetings with the Secretary to—

(a) discuss the overall development program and goals for the product;

(b) obtain guidance on using novel endpoints and biomarkers;

(c) discuss study designs appropriate for demonstrating healthspan benefits;

(d) review proposed evidence generation plans;

(e) obtain feedback on evidence collection strategies.

(2) MEETING TYPES —

(a) Type H1: Initial Healthspan Development Strategy Meeting

(b) Type H2: End of Phase 2 Meeting specific to healthspan endpoints

(c) Type H3: Pre-NDA/BLA Meeting for healthspan designation

(d) Type H4: Risk evaluation strategy meeting

(e) Type H5: Any other meeting needed to clarify specific product development points, including toxicology, safety, dosing and product quality

(3) MEETING TIMEFRAMES — The Secretary shall meet with sponsors within—

(a) 75 calendar days of receipt of Type H1 or H2 meeting request

(b) 60 calendar days of receipt of Type H3 or H4 meeting request

(c) 45 calendar days of receipt of Type H5 meeting request

(4) Meetings described in this subsection shall be in addition to, and not in place of, any other meetings or meeting types the applicant or sponsor may request under applicable regulations or guidance, provided that meetings not covered under this subsection may be denied as unnecessary if the same or essentially the same issues have been the subject of a Type H meeting or reasonably could have been the subject of a Type H meeting.

(C) HEALTHSPAN DEVELOPMENT OFFICE —

(1) ESTABLISHMENT — The Secretary shall establish an Office of Healthspan Product Development within the Center for Drug Evaluation and Research to—

(a) coordinate review of healthspan products;

(b) provide specialized expertise in aging biology and biomarkers;

(c) develop guidance documents on healthspan product development;

(d) facilitate coordination with external stakeholders;

(e) review dietary supplement healthspan claim applications;

(f) maintain a public database of approved healthspan claims for dietary supplements; and

(g) develop guidance on evidence requirements for dietary supplement healthspan claims.

(2) ADVISORY COMMITTEE —

(a) The Secretary shall establish within the Food and Drug Administration a Healthspan and Prevention Innovation Advisory Committee to:

i. Review applications

ii. Evaluate biomarkers and outcomes

iii. Develop detailed criteria for incentives, the award of prizes as authorized under this Act and such other recommendations to encourage innovation in the field of healthspan interventions and preventive medicine, nutrition, and wellness.

(D) HEALTHSPAN RESEARCH GRANTS. —

(1) IN GENERAL — The Secretary shall award grants to sponsors for:

(a) Conducting Phase 2 clinical trials of healthspan products with primary endpoints at 10 weeks after baseline or longer.

(b) Development and validation of healthspan biomarkers

(c) Real-world evidence collection for healthspan products

(2) PRIORITY — Priority shall be given to:

(a) Studies of approved products being repurposed as healthspan interventions

(b) Novel trial designs incorporating innovative endpoints

(c) Development programs incorporating patient experience data

E. HEALTHSPAN VOUCHER PROGRAM—

(3) AWARD — The Secretary shall award a priority review voucher to sponsors who:

(a) Obtain Tier 3 approval for a healthspan product, or

(b) Successfully repurpose an approved product as a Tier 2 or Tier 3 healthspan product

(4) TRANSFERABILITY — The voucher shall be fully transferable.

(5) REDEMPTION—The voucher entitles the holder to priority review of any single human drug application submitted under section 505(b)(1).

(a) GUIDANCE DOCUMENTS—The Secretary shall issue guidance on:

i. Qualifying healthspan biomarkers

ii. Novel clinical trial designs for healthspan products

iii. Use of real-world evidence for healthspan products

iv. Development considerations for healthspan drugs

v. Development considerations for healthspan devices

vi. Development considerations for healthspan dietary supplements

SECTION 7. CLAIM EXCLUSIVITY AND ENFORCEMENT
SEC. [505K].

(A) HEALTHSPAN CLAIM EXCLUSIVITY —

(1) IN GENERAL — Upon approval of a healthspan product under section [505H], the holder of such approval shall have the exclusive right to make healthspan claims for the approved ingredient(s) or combination of ingredients for the duration of:

(a) 7 years for Tier 1 approved products

(b) Additional 7 years upon achieving Tier 2 approval

(c) Additional 7 years upon achieving Tier 3 approval

(2) SCOPE OF EXCLUSIVITY — During the applicable exclusivity period:

(a) The Secretary shall not approve any additional product making the same or substantially similar healthspan claims for the same ingredient(s) [or combination of ingredients?]

(b) No entity or individual may make healthspan claims for products

containing the same ingredient(s) or combination of ingredients without authorization from the exclusivity holder

(3) DIETARY SUPPLEMENTS —

(a) Exclusivity periods under this section shall apply to evidence-based healthspan claims for dietary supplements

(b) Exclusivity shall be limited to the specific claim language and evidence presentation

(c) Other manufacturers may make the same or similar claims if supported by independent evidence meeting the standards of Section 4(f)

(d) This Act neither modifies the Dietary Supplement Health and Education Act of 1994 (DSHEA) nor limits the marketing of dietary supplements as enabled by that law. The provisions herein create additional options and incentives for supplement manufacturers to seek healthspan claims.

(B) ENFORCEMENT OF EXCLUSIVITY —

(1) IN GENERAL — For products granted healthspan claim exclusivity under this section:

(a) The Secretary shall not grant approval of any additional product for the same healthspan indication during the exclusivity period.

(b) No entity or individual may make, use, prescribe, dispense, offer to sell, or sell any product making the same or substantially similar healthspan claims during the exclusivity period.

(2) VIOLATION OF HEALTHSPAN CLAIM EXCLUSIVITY —

(a) Any entity or individual that makes, uses, prescribes, dispenses, offers to sell, or sells a product with the same or substantially similar healthspan claims during the exclusivity period shall be deemed to have violated the healthspan claim exclusivity and be liable to the holder of such exclusivity.

(b) Whoever actively induces violation of healthspan claim exclusivity shall be liable as a violator

(C) PRIVATE RIGHT OF ACTION —

(1) REMEDY FOR VIOLATION—The holder of healthspan claim exclusivity under this section shall have remedy by civil action for violation of such exclusivity

(2) INJUNCTIVE RELIEF —

(a) The several courts having jurisdiction of cases under this section may grant injunctions in accordance with the principles of equity to prevent the violation of any right secured by healthspan claim exclusivity granted under this section, on such terms as the court deems reasonable

(b) In cases of willful violation of healthspan claim exclusivity, the court may

issue immediate temporary restraining orders and preliminary injunctions upon a showing of substantial likelihood of success on the merits

(3) DAMAGES —

(a) Upon finding for the claimant, the court shall award:

i. Damages adequate to compensate for the violation of exclusivity, but in no event less than a reasonable royalty for the unauthorized use

ii. Interest and costs as fixed by the court

iii. Attorney fees to the prevailing party in exceptional cases

(b) When damages are not found by a jury, the court shall assess them

(c) The court may increase damages up to three times the amount found or assessed in cases of willful violation

(4) STATUTE OF LIMITATIONS —

(a) No recovery shall be had for any violation of healthspan claim exclusivity committed more than six years prior to filing the complaint

(D) RELATIONSHIP TO OTHER EXCLUSIVITY PERIODS —

(1) Healthspan claim exclusivity under this section shall be:

(a) Independent of any other marketing exclusivity or patent term granted under this Act or other Federal law

(b) In addition to any other applicable exclusivity periods

(c) Fully transferable separate from other forms of exclusivity

(E) NOTICE REQUIREMENTS —

(2) The holder of healthspan claim exclusivity shall:

(a) Mark products with notice of exclusivity

(b) Maintain a publicly accessible registry of protected claims

(c) Provide notice to known competitors making unauthorized claims

SECTION 8. RELATION TO STATE LAW

(A) PREEMPTION —

(1) IN GENERAL — No State or political subdivision of a State may establish or continue in effect any requirement that:

(a) Relates to the regulation of healthspan products approved under this Act

(b) Conflicts with requirements under this Act

(c) Limits the availability of approved healthspan products

(2) PRESERVATION OF STATE AUTHORITY — Nothing in this Act shall be construed to preempt:

(a) State product liability laws

(b) State consumer protection laws

(c) State professional licensing requirements

SECTION 9. HEALTHSPAN INNOVATION PRIZES

(A) ESTABLISHMENT — The Secretary shall establish the Healthspan Innovation Prize Program to incentivize development of products that help reduce the risks and/or slow the onset of multiple age-related chronic diseases, disabilities, and some forms of cancer.

(B) PRIZE CATEGORIES. —

(1) BREAKTHROUGH PREVENTION/REJUVENATION PRIZE —

(a) Up to five prizes of $100,000,000 each shall be awarded to sponsors who develop products that:

i. Demonstrate substantial reduction in the risks, onset, and/or severity of two or more major chronic diseases and disabilities in a defined pre-disease population

ii. Are cost-effective compared to standard interventions.

(b) Eligible conditions include:

i. Cardiovascular disease

ii. Type 2 diabetes

iii. Metabolic dysfunction-associated steatohepatitis (MASH)

iv. Alzheimer's disease, other dementias, and neurodegenerative conditions

v. Major age-related cancers

vi. Frailty and other complications of age-related skeletal muscle depletion

vii. Other conditions designated by the Secretary

SECTION 10. PREVENTIVE MEDICINE EXCLUSIVITY ENHANCEMENTS

(A) ENHANCED EXCLUSIVITY. —

(1) PREVENTION IMPACT EXCLUSIVITY. —

(a) The Secretary shall award an additional 3 years of market exclusivity to products that demonstrate:

i. Significant prevention of disease onset in high-risk populations

ii. Reduction in healthcare utilization and costs

iii. Improvement in quality-of-life metrics

(2) POPULATION HEALTH EXCLUSIVITY. —

(a) The Secretary shall award an additional 2 years of market exclusivity to products that achieve:

i. Documented improvement in population health outcomes

ii. Reduction in health disparities

iii. Cost savings to the healthcare system

(B) TRANSFERABLE EXCLUSIVITY VOUCHERS. —

(1) AWARD. — The Secretary shall issue transferable exclusivity vouchers to sponsors who:

(a) Successfully develop preventive therapies

(b) Demonstrate population-level health improvements

(c) Achieve significant cost savings

(2) TERMS. —

(a) Vouchers shall be fully transferable

(b) May be applied to any product in sponsor's portfolio

(c) Must be used within 5 years of issuance