THRIVE Act Overview

The **Therapeutic Healthspan Research, Innovation, and Validation Enhancement (THRIVE) Act of 2025** presents a means for advancing beyond our current sick-care model by adding a focus on **increasing healthspan**—the period of life free from age-related chronic diseases and disabilities. The intent is not to supplant continued advances in treating diseases, but to build on this progress to prevent multiple chronic diseases.

The Opportunity

Among the most important predicates of the THRIVE Act:

- Abundant scientific discoveries strongly support the expectation that the aging process can be slowed and that the onset and severity of age-related diseases can be reduced.
- Multiple analyses strongly support that increasing healthspan will produce enormous economic benefits that far exceed the required total private and public investment costs required to achieve them.
- The rapidly increasing median age in the US, without corresponding increase in healthspan, is already resulting in unsustainable loss of productivity and healthcare costs.

The Major Challenges

The primary challenges addressed by the THRIVE Act are—

- The enormous time and costs inherent in generating the necessary evidence to approve "prevention" products under the current regulatory system.
- The lack of incentives for investing in the development of preventive products.

Principles underlying the Solutions

1. **Regulatory Framework for Healthspan Products**
    - The THRIVE Act provides an optional framework for developing and gaining approval of FDA-regulated products intended to increase healthspan. The Act is complementary to the established frameworks for regulating drugs/biologics, devices, and dietary supplements. It does not in any way change or affect these long-established frameworks.
    - In contrast to the current framework, the THRIVE Act—
        1. Provides a tiered approval system (Tier 1, Tier 2, Tier 3) based on the increasing level of evidence supporting the effectiveness and safety of healthspan products.

2. Includes drugs/biologics, devices, and dietary supplements, because as different as these products are, they all have a role in increasing healthspan.

3. Establishes that the levels of evidence across these product categories involves consistent scientific rigor and evidence-based decision making, calibrated to the types of claims that can be approved under each tier.

2. **Tiered Approval System**

The tiered system takes on the current *very steep, high mountain* of evidence needed under the existing system for approving products aimed at increasing healthspan. Instead, the Act provides for a series of *smaller mountains* of increasing height, which make development of healthspan claims much more approachable.

- **Tier 1**: Requires robust scientific and early clinical evidence that the product is reasonably likely to increase healthspan. Approval lasts for 7 years.
- **Tier 2**: Requires intermediate clinical evidence demonstrating the product is likely to increase healthspan. Approval extends for an additional 7 years.
- **Tier 3**: Requires substantial evidence of effectiveness from long-term studies, demonstrating significant healthspan benefits. Approval extends for an additional 7 years.

It is useful to compare the THRIVE tiers with FDA's current pathways:

- Very roughly, the evidence standard in Tier 3 can be understood to be equivalent to that of a full FDA approval.
- The Tier 2 evidence standard is like those for accelerated approval of cancer treatments and other acute, serious conditions, which allows for FDA approval based on surrogate endpoints that have not been clinically validated but which are reasonably likely to predict a clinical outcome. Under current law, a product intended for prevention of chronic diseases would not meet the narrow and specific threshold for accelerated approval.[1]
- Tier 1 draws from levels of evidence that have been recognized in other contexts, such as authorization of health claims for foods, literature-based drug approvals, and general recognition of safety or effectiveness determinations. It requires a lower level of clinical evidence than Tier 2, but the evidence still must be persuasive to experts. Typically, most Tier 1 candidates will be already-

[1] Interestingly, FDA's Center for Veterinary Medicine has such a provision for conditions that are not immediately life-threatening. See 1243.2100 Eligibility for Conditional Approval Under the Expanded Conditional Approval (XCA) Criteria

approved drugs and some dietary supplements for which safety is well established, and the estimated benefit-risk relationship is acceptable in relation to the types of claims that would be permitted under Tier 1.

The THRIVE Act defines many of the terms needed by FDA to implement the tiered levels of evidence needed to authorize the marketing of healthspan products, but much more work will be required to address all the important details. FDA guidances would be written to lay out how it would interpret and implement this law.

Other Provisions of the THRIVE Act

The THRIVE Act includes provisions that are intended to enhance the ecosystem for developing healthspan products. These should not be thought of as "giveaways." They are incentives designed to shift the balance of effort and investment towards developing and approving products specifically designed and studied for use in preventing major chronic diseases.

3. **Healthspan Product Development Program**
    - Expedites the development of healthspan products through structured meetings (Type H1 to H5) between sponsors and FDA.
    - Establishes an Office of Healthspan Product Development within the FDA to coordinate reviews and provide expertise.
4. **Healthspan Claim Exclusivity and Enforcement**
    - Grants exclusivity periods for healthspan claims (7 years for each tier) to incentivize innovation.
    - Makes the labeling-based exclusivity valuable by establishing a private right of action for sponsors to protect their rights and prevent unauthorized use of their claims.
5. **Healthspan Innovation Prizes**
    - Establishes substantial prizes to incentivize the development of products that reduce the risks and/or slow the onset of multiple age-related chronic diseases.
6. **Preventive Medicine Exclusivity Enhancements**
    - Awards additional market exclusivity and, in some cases, priority review vouchers, for products that demonstrate significant prevention of disease onset and improvement in population health outcomes.

7. **Post-Market Surveillance and Reporting**
    - Requires enhanced pharmacovigilance and registry protocols to monitor the safety and effectiveness of healthspan products continuously.

Conclusion

The THRIVE Act is a visionary solution to the enormous healthcare challenges in the United States and through the world. The Act aims to catalyze sustained action for harnessing the science that will allow us to maintain a healthy and resilient population and materially reduce the incidence of chronic diseases and disabilities. The Act is inspired and supported by the explosive growth of aging biology research, technology, and machine learning, and recognizes the evolving sources of new forms of scientific evidence on which regulatory decisions may be based

The wide variety of regulated products can only be part of a comprehensive system that includes education and encouragement of healthy habits from kindergarten to senior care facilities. By addressing the limitations of the current regulatory and business models, THRIVE aims to foster innovation, improve public health, and reduce healthcare disparities. The overarching vision of the THRIVE ACT is a healthier, more resilient American public and a more sustainable system of wellness and healthcare.