Legacy Healthcare Welcomes U.S. Congressional Legislation Proposing 12-Year Market Exclusivity for US FDA Newly Approved Botanical Drugs

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The "ADVANCING BOTANICAL DRUG DEVELOPMENT ACT OF 2026," introduced on Aug 27, 2026, would provide 12-year post-approval market exclusivity to encourage investment in FDA-regulated botanical drugs innovation

EPALINGES, Switzerland, Sept. 3, 2026 /PRNewswire/ -- Legacy Healthcare welcomes the introduction in U.S. Congress of the "ADVANCING BOTANICAL DRUG DEVELOPMENT ACT OF 2026" by Rep. Lauren Boebert (Sponsor) and Rep. Derrick Van Orden (Co-sponsor). To encourage investment in this important and overlooked drug category,

the proposed bill intends to provide FDA-regulated botanical drugs with a 12-years market exclusivity period post-approval.

Rep. Boebert made the following statements on botanical drugs' importance to patients, public health and the bill.

- *"Because they contain many natural compounds, they can work on multiple targets at once, which may help with complex chronic and age-related conditions such as Alzheimer's, Parkinson's (…)"*
- *"The bill seeks to expand treatment options for complex chronic and age-related diseases while maintaining existing FDA safety and efficacy requirements."*
- *"The legislation would address barriers to late-stage development of botanical medicines by providing a defined period of regulatory exclusivity for qualifying products (…) thereby creating the certainty needed to support rigorous development of so promising multi-constituent therapies can reach patients."*

"Botanical drugs can indeed act on multiple biological targets at once, offering potential to unlock treatments for many unmet medical needs""A clear and appropriate period of post-approval market exclusivity will strengthen the ability to attract investment in this emerging drug category – much favored by patients."

Legacy Healthcare's lead candidate – Cinainu – is the first botanical drug for an autoimmune disease authorized to enter Phase 3 by the U.S. Food and Drug Administration and Japanese health authorities (PMDA). In a Phase 2/3 study in alopecia areata (AA), Cinainu demonstrated efficacy, long-term effect and no autoimmune related side-effects, a first. The company is now raising financing to conduct the FDA and PMDA-authorized Phase 3 program. If approved, Cinainu will be the first treatment for children, adolescents and adults with both severe and moderate AA. Cinainu is supported by intellectual-property protection extending through 2043.

The proposed bill is available here. Rep. Boebert's press release is available here.

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