The Whole Plant Act

Amendment Package: H.R. 10150, the Advancing Botanical Drug Development Act of 2026

Targeted amendments to H.R. 10150 as introduced on August 27, 2026 by Ms. Boebert and Mr. Van Orden and referred to the Committee on Energy and Commerce. Read against the introduced text as printed, end to end. Section references in the left-hand position are to H.R. 10150 and to the Federal Food, Drug, and Cosmetic Act it amends. Independent policy analysis, drafted to be lifted into amendment form by Legislative Counsel.

This is a short package against a short bill, and it is deliberately not accompanied by a comparison. A comparison in this series sets two frameworks for regulating cannabis against each other on shared axes. H.R. 10150 never mentions cannabis, carries a short title, ten findings, and one operative section that adds a single clause to the drug code. There is no axis to compare on, and forcing one would misdescribe the bill.

Section 1. Short title

This package may be cited as the Whole Plant Amendments to the Advancing Botanical Drug Development Act of 2026.

Section 2. What the bill gets right, and what it actually does

The incentive is sound and the Whole Plant Act does not oppose it. Botanical drug development is genuinely harder and more expensive than single-molecule development, for the reasons the bill's findings give at paragraph (5): natural variability in plant-derived raw material, sourcing controls, batch consistency, constituent characterization, and standardization. A pathway that has produced only a handful of approvals since 2004 is not working, and an exclusivity period is a conventional answer to that problem.

The findings are also worth preserving for their own sake. Paragraphs (2), (3), (8) and (10) state that many chronic and age-related diseases involve multiple biological pathways, that most approved therapies target a single pathway, and that botanical drugs containing multiple naturally occurring constituents can act on several pathways at once, safely and to the public benefit. That is a congressional finding in support of whole-plant and multi-constituent preparations, and it should survive this package intact.

What the bill does operatively is narrow. Section 3 adds clause (vi) to section 505(c)(3)(E) of the Federal Food, Drug, and Cosmetic Act, giving a botanical drug approved under section 505(b)(1) a 12-year period during which no application under section 505(b)(2) or section 505(j) that references or relies upon that drug may become effective. It blocks follow-on applications that lean on the approved drug's record. It does not, by its terms, block an independent full application supported by its own data, it creates no patent right, and it does not reach a person selling a cannabis item under State law, who files no application at all.

It is also prospective by its own terms. Clause (vi)(I) reaches a botanical drug approved "pursuant to an application submitted after the date of enactment of this clause," so a drug already approved, and a drug whose application is already pending, get nothing from it. That matters for the cannabis case specifically: a whole-plant product already in the approval pipeline would not carry this exclusivity. The exposure this package addresses is therefore about the next application rather than the current one, which is the better time to fix it.

The exposure is therefore indirect, and the amendments below address it at the two points where it is real.

Section 3. The exclusivity does not attach against what was already public

Amend new section 505(c)(3)(E)(vi) by adding at the end:

Exclusivity under this clause does not operate against an application, a product, or a person by reason of the use of a botanical substance, a preparation, a constituent, or a method of characterization that was publicly known before the approval on which the exclusivity rests. Publication in a public-domain reference standard, a publicly available registry of characterized botanical preparations, a pharmacopoeial monograph, or the published scientific literature establishes that the matter was publicly known.

Why this matters more for a botanical drug than for a synthetic one: a botanical drug is a multi-constituent preparation of a plant, and the plants in question have in many cases been prepared and used in substantially the same way for a very long time. A 12-year exclusivity resting on an approval of such a preparation should not be capable of operating against the preparation's own prior art. This is the same principle the Whole Plant Act applies at Federal Section 6, where a public-domain reference standard and registry are prior art and no approval can enclose what the record already holds.

The Food and Drug Administration has already said what a botanical drug is, and it says it in the framework's own terms. Its Botanical Drug Development guidance provides at section VI.G that for a single-source botanical "the entire botanical mixture generally is considered to be the active ingredient," and at section IV that botanical drugs "are generally heterogeneous mixtures" whose "active constituents are not identified." Section III.B supports therapeutic consistency through a totality-of-the-evidence approach rather than assay of a single moiety. So the article approved under clause (vi) is the mixture, which is the article the plant has been supplying all along, and Federal Section 6(4) characterizes a whole-plant preparation as the entire botanical mixture, including its cannabinoids, its associated compounds and the interaction among them, for exactly that reason.

The bill's own findings make the point sharper than this package could on its own. Paragraph (9) states that advances in computational biology, artificial intelligence, and systems pharmacology have created new opportunities to identify and develop innovative botanical drug combinations capable of addressing complex diseases through multi-pathway mechanisms. That is an accurate description of where the field is going, and it is also a description of how a publicly known plant's combinations get claimed: a screen run over constituents that have been in the literature for decades produces a combination that is new as a filing and old as a fact. A 12-year exclusivity behind such a filing is an exclusivity over the plant's own chemistry unless the record says otherwise first. Nothing in this package opposes the screening. It asks that the public-domain record exist alongside it, so that what the literature already holds cannot be enclosed by being rediscovered.

Section 4. Approval does not preclude the constituent from food or supplement use

Amend section 3 of the bill by adding a new subsection:

Neither the approval of a botanical drug, nor the institution and public disclosure of substantial clinical investigations of a botanical drug, nor exclusivity under section 505(c)(3)(E)(vi), precludes the marketing of a naturally occurring constituent of the same botanical source as a food, a dietary ingredient, or a dietary supplement, where that constituent occurs naturally in the source and was marketed or present in the food supply before the approval or the institution of investigations. The exclusions at section 201(ff)(3)(B) and the prohibition at section 301(ll) of this Act do not apply to such a constituent.

This is the amendment that does the work. The mechanism that forecloses State-compliant operators is not the exclusivity in this bill; it is the drug-preclusion rule that already exists in the Federal Food, Drug, and Cosmetic Act, under which an article approved as a drug, or taken into public clinical investigation, can no longer be marketed in food or as a dietary supplement. H.R. 10150 does not create that rule. What it does is put a 12-year prize on taking the step that triggers it, which makes the trigger far more likely to be pulled and makes it rational for a sponsor to pull it deliberately.

A note on citations: section 201(ff)(3)(B) is the dietary-supplement exclusion and section 301(ll) is the food-side prohibition, both cited as sections of the Federal Food, Drug, and Cosmetic Act; the same provisions are codified at sections 321(ff)(3)(B) and 331(ll) of title 21, United States Code, which is how the Federal Whole Plant Act cites them. The precise interaction of the two, and whether a further conforming reference is needed, should be confirmed by counsel before introduction.

Section 5. State-authorized programs are not reached

Amend section 3 of the bill by adding a new subsection:

Nothing in this Act, and no exclusivity under section 505(c)(3)(E)(vi), affects, limits, or provides a basis for an action against the cultivation, manufacture, distribution, sale, possession, or use of a botanical substance under a program authorized by State or Tribal law, or against a person licensed, registered, or otherwise authorized under such a program acting within it.

This is a savings clause rather than a change of substance, and it exists because the reading matters more than the text. Clause (vi) operates on applications, so it does not reach a State-licensed operator on its face. A savings clause removes the argument before someone makes it, and costs the bill nothing.

Section 6. Define the subject

Amend new section 505(c)(3)(E)(vi)(II). As introduced, it defines a botanical drug as "a botanical drug subject to subsection (a), as determined by the Secretary by regulation," which leaves the entire scope of a 12-year statutory exclusivity to a definition the bill does not supply and a regulation that does not yet exist.

The definition should at minimum state that a botanical drug is a drug product derived from one or more plants, algae, or macroscopic fungi, consisting of a multi-constituent preparation rather than a single purified molecule, and that a purified or synthesized single constituent is not a botanical drug for purposes of this clause.

The second half is the operative part. Without it, a sponsor who isolates and purifies one cannabinoid could claim a botanical drug's exclusivity for what is, in substance, a single-molecule product, which is the opposite of what the bill's own findings say it is paying for.

Section 7. Publicly funded data and reference materials

Add to section 505 of the Federal Food, Drug, and Cosmetic Act: "Nonclinical and clinical data from a study of a botanical drug, its botanical raw material, or a constituent of either, conducted or supported in whole or in part with Federal funds under a funding agreement entered into after the date of enactment, shall be published, with participant-level data released only in de-identified form, through a repository with controlled access where the risk of re-identification requires. Chemistry, manufacturing, and controls data from such a study shall be filed in a Type II Drug Master File and kept confidential, and the holder shall issue a letter of authorization to reference the file to any applicant on request, without royalty and at a published fee not exceeding the cost of maintaining the file, on the same terms for every applicant. Any person may rely on those data in an application under this section as if holding a right of reference to them, and each such funding agreement shall grant that right. This subsection does not reach data generated without Federal funds, does not require public disclosure of a trade secret or confidential commercial information, and does not alter a period of exclusivity, including exclusivity for a new chemical entity, for a new clinical investigation, or for an orphan drug, or the title of a contractor to a subject invention under chapter 18 of title 35, United States Code. Nothing in this subsection requires or permits the publication of traditional, ceremonial, or community-held knowledge, or of culturally sensitive information about a community, its practices, or its genetic resources, without that community's authority, as determined under its own governance and given with free, prior, and informed consent, and de-identification does not satisfy this sentence." A 12-year exclusivity should not rest on studies the public paid for and no one else may use, and nothing here takes from a sponsor anything it paid for or was promised. Federal Sec. 6(13).

Direct the Secretary to hold and make available physical reference materials for botanical raw materials characterized in a public-domain reference standard: reference lots with assigned values, a stated uncertainty, and a stated stability life for whole-plant preparations, and certified reference materials for single constituents where an accredited producer exists. They are available to any person at not more than cost and without restriction on their use, with a retained sample of each lot for retesting and a public equivalent within 12 months where a needed material is available only from a single private source or from none, so that therapeutic consistency can be shown without a private reference lot. Commercial suppliers remain free to sell reference materials. Federal Sec. 6(12).

Section 8. Congruence

Where this package and the standalone Federal Whole Plant Act would differ, the standalone Act governs. The disapplication in Section 4 of this package is narrower than the disapplication at Federal Section 6, which reaches naturally occurring cannabinoids generally; this package's provision is written to the botanical category H.R. 10150 addresses so that it can be adopted on that bill's own terms.

Sections 3 through 7 of this package are independent of each other and can be adopted singly. Section 4 is the one that matters most. Section 5 is the one most likely to be accepted without argument.