Questions for the Opposition

1. What specific federal statute or FDA regulation does House Bill 26-1056 violate?
2. Does 21 U.S.C. 384, also known as Section 804, prohibit importation under defined conditions, or does it establish a statutory framework for it?
3. Can you identify the specific FDA safety or quality requirement that would not be met under the compliant personal use importation pathways contemplated in this bill?
4. Are you asserting that the FDA's longstanding personal use importation enforcement policy is unlawful or improperly applied?
5. Colorado enacted SB19-005 to pursue Canadian importation under the same federal statutory framework. How do you reconcile that action with your claim that importation is unlawful in Colorado?
6. Under ERISA, plan sponsors retain fiduciary liability for plan oversight. On what legal basis should fiduciaries be denied access to plan data necessary to fulfill those obligations?
7. Beyond general assertions, what documented enforcement action or regulatory finding demonstrates that compliant personal use importation is unlawful or unsafe?

Questions for Supporters

1. Please identify the federal statutory provisions that govern prescription drug importation and explain how this bill operates within them.
2. Can you explain how FDA's personal use importation policy defines safety, quality, and compliance parameters?
3. Does House Bill 26-1056 create a new importation authority, or does it clarify participation in frameworks that already exist under federal law?
4. Does this bill alter or weaken any FDA safety, inspection, or compliance standards?
5. How does ERISA define a plan sponsor's fiduciary duty with respect to plan assets and access to plan data?
6. Is international pharmaceutical manufacturing already a component of the U.S. drug supply chain, and are those

facilities subject to FDA safety and quality oversight?

7. If a vendor violates federal law by smuggling medications, does this bill authorize or protect that conduct?

Overview of HB26-1056: Common Opposition Claims and Factual Clarifications

This document addresses seven common objections raised against HB26-1056. It begins with a brief overview clarifying what the bill does and does not do, followed by sections that state each claim as it is most often presented to legislators, provide a concise factual response, and cite controlling statutory or case authority. The purpose is to clarify the scope and intent of the bill and to ground discussion in existing law rather than rhetoric or speculation.

What HB26-1056 Does	What HB26-1056 Does Not Do
Prohibits PBMs and consultants from false statements about existing federal and CO law to self-funded employers.	Does not create or expand any prescription drug importation authority.
Requires PBMs and consultants to provide basic financial data to employers, upon written request.	Does not regulate employer-sponsored or self-funded health plans.
Allows employers to meet existing ERISA fiduciary duties by accessing their own pharmacy cost data (what they paid).	Does not require participation in any pharmacy stewardship or sourcing program.
Reduces employer exposure to fiduciary lawsuits tied to pharmacy cost opacity.	Does not create a new insurance product or mandate coverage.
Clarifies employer rights that already exist under federal law and CO law.	Does not remove or replace PBMs, carriers, or provider networks.
Regulates PBM and consultant conduct, not employer benefit design.	Does not authorize Alternative Funding Programs or eliminate drug coverage.
Aligns with Colorado's existing policy under SB19-005 and the federal framework in 21 U.S.C. § 384.	Does not weaken FDA safety, GMP quality standards, or chain-of-custody rules.

1. False statement: "HB26-1056 creates a new importation pathway."

Response: HB26-1056 does not create, expand, or authorize any new importation pathway. It expressly limits optimized sourcing and pharmacy stewardship programs to what is already authorized under federal law and FDA regulation, and it states that the bill does not create insurance, mandatory coverage, or employer participation requirements. The bill's purpose is to prevent PBMs and health care consultants from misrepresenting existing law and to ensure employers can access drug-level cost data needed to meet ERISA duties.

This approach is not new for Colorado. Colorado already enacted SB19-005, signed by Governor Polis, which relied on the same federal importation structure under 21 U.S.C. § 384

and required compliance with federal safety and quality standards. HB26-1056 aligns with that existing framework, and supports its intent. It clarifies rights, enforces truth, and compels transparency. It does not create a new lane.

Specific quotes:

- "Pharmacy stewardship programs and prescription drug optimized sourcing programs are authorized by state law when implemented in compliance with federal law." (HB26-1056, § 10-16-171(6)(b))
- "This section does not restrict or limit the right of a self-insured employer to purchase prescription drugs through a lawful prescription drug optimized sourcing program… including personal-use importation programs permitted under federal law." (HB26-1056, § 10-16-171(5))
- "Nothing in this section shall be construed to create a new insurance product or mandatory coverage." (HB26-1056, § 10-16-171(6)(c))
- "The Canadian prescription drug importation program is created…" (Colorado Senate Bill 19-005, enacted 2019)
- "For approval of the program under 21 U.S.C. sec. 384." (Colorado Senate Bill 19-005, enacted 2019)
- "Consistent with the federal act." (Colorado Senate Bill 19-005, enacted 2019)

2. False statement: "HB26-1056 regulates self-funded plans."

Response: HB26-1056 regulates PBMs and health care consultants operating in Colorado. It does not regulate employer plan design, benefits, or participation. It establishes standards for truthfulness and requires disclosure of prescription drug cost information upon written request, enabling employers to carry out existing fiduciary duties. Enforcement is directed at vendors, not employers.

Specific quotes:

- "This section does not require an employer to adopt or participate in a prescription drug optimized sourcing program." (HB26-1056, § 10-16-171(7)(a))
- "The commissioner shall enforce this section with respect to a pharmacy benefit manager or health-care consultant." (HB26-1056, § 10-16-171(8))
- "Nothing in this section shall be construed to create a new insurance product or mandatory coverage." (HB26-1056, §

10-16-171(6)(c))

3. False statement: "The bill creates patient data privacy risk."

Response: The data disclosure requirement contains zero patient-specific data and zero protected health information. It is limited to financial fields and basic drug identifiers needed to understand what the plan paid. Claims that HB26-1056 creates HIPAA risk are unrelated to the bill text. If you have been informed of this concern, at best whomever is saying this has not read or understood the bill, or at worst their intention is to deceive and manipulate.

Specific quotes:

- "Detailed cost information… including: (i) total drug cost per claim; (ii) total member-paid portion per claim; (iii) total plan-paid portion per claim; and (iv) national drug code, quantity, strength, and days of supply." (HB26-1056, § 10-16-171(4)(a))

4. False statement: "Importation exposes patients to counterfeit/unsafe drugs."

Response: Drug safety is governed by current good manufacturing practice (GMP) and documented chain of custody, not geography. Federal law already defines when a drug is unsafe, and those standards apply regardless of where the drug is manufactured. Claims to the contrary improperly conflate illegal internet sellers with regulated Tier-1 supply chains operating under licensing, prescription verification, and documented handling controls. In fact, such a claim undermines the safety of the existing U.S. pharmaceutical industry safety and quality standards, as 80+% of ingredients for U.S. medications are already imported from international sources.

Specific quotes:

- "A drug… shall be deemed to be adulterated… if the methods used… do not conform to current good manufacturing practice… as to safety… identity and strength… quality and purity." (21 U.S.C. § 351(a)(2)(B))
- "Approximately 80% of the active pharmaceutical ingredients used in U.S. drugs are manufactured overseas." (U.S. Government Accountability Office, 2020)
- "If it appears… that such article is adulterated, misbranded, or in violation of section 355… then such article shall be refused admission." (21 U.S.C. § 381(a))
- "FDA may allow entry of a prescription drug imported for personal use when the drug is not for commercial

distribution and the quantity imported is limited to an amount consistent with personal use." (FDA Regulatory Procedures Manual, ch. 9-2)

5. False statement: "Prescription drug importation is illegal under federal law."

Response: Federal law regulates importation and grants FDA authority to refuse noncompliant products, known as "adulterated" medications. Congress enacted a statutory importation framework, and FDA has long applied a personal-use importation policy which has been used by millions of Americans and tens of thousands of employers for nearly 3 decades.

Specific quotes:

- "The Secretary… shall promulgate regulations permitting pharmacists and wholesalers to import prescription drugs…" (21 U.S.C. § 384(a))
- "FDA may allow entry of a prescription drug imported for personal use…" (FDA Regulatory Procedures Manual, ch. 9-2)
- "If it appears… that such article is adulterated, misbranded, or in violation of section 355… then such article shall be refused admission." (21 U.S.C. § 381(a))

6. False statement: "HB26-1056 authorizes or relies on Alternative Funding Programs (AFPs)."

Response: AFPs are not referenced or authorized in HB26-1056. PBM lobbyists have defined AFPs as "vendors who then market their services to self-funded health plans to encourage the plan not to cover certain medications." HB26-1056 does not mandate or encourage plans not to cover medications. The voluntary programs described in the bill preserve coverage, and prescriptions not fulfilled through a pharmacy stewardship program continue to process through the existing PBM and network.

Specific quotes:

- "Prescriptions not fulfilled through the pharmacy stewardship program continue to process under the health benefit plan's existing pharmacy benefit manager, carrier, and network." (HB26-1056, § 10-16-171(2)(c)(i))
- "A pharmacy stewardship program is not: (a) insurance; (b) a health plan; (c) a pharmacy benefit manager; or (d) a third-party administrator." (HB26-1056, § 10-16-171(2)(c)(iii))

- "This section does not require an employer to adopt or participate in a prescription drug optimized sourcing program." (HB26-1056, § 10-16-171(7)(a))

7. False statement: "Employers do not have a fiduciary need or right to access Rx cost data."

Response: This statement is not only false, it puts CO employers at risk. ERISA fiduciaries are legally required to act in the interest of plan participants and control plan expenses, which requires access to accurate pharmacy cost data. Courts have confirmed that fiduciaries face liability when they fail to monitor prescription drug costs or evaluate available alternatives.

Specific quotes:

- "A fiduciary shall discharge [their] duties… solely in the interest of the participants and beneficiaries… defraying reasonable expenses of administering the plan." (ERISA § 404(a)(1), 29 U.S.C. § 1104(a)(1))
- "Failed to adequately monitor the plan's prescription drug expenses" and "failed to investigate and consider lower-cost alternatives." (*Lewandowski v. Johnson & Johnson*, complaint)
- "Prudent fiduciaries would have taken readily available steps to reduce the plan's prescription drug costs." (*Stern v. JPMorgan Chase*, complaint)
- "Defendants cannot avoid their fiduciary obligations by blindly relying on third-party service providers." (*Stern v. JPMorgan Chase*, complaint)