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July 2026

Prescription Drug Importation: Myths and Facts

Prescription drug importation is often portrayed as unsafe and unlawful, but those claims are often overstated or misunderstood. In reality, Americans already rely on personal importation to access affordable medications, and established regulatory systems abroad provide robust safeguards for quality and patient protection. These practices should be protected—not undermined by policymakers and regulators. A policy framework that enables lawful parallel importation from high-income countries beyond Canada will lead to substantially lower drug prices while maintaining strong patient protections in the long term.

MYTH:

Drug importation cannot substantially help Americans afford prescription drugs

FACT:

By importing prescription drugs for personal use (called "personal importation"), individual Americans often pay 80% less.[1] Personal importation is already a vital source of safe and affordable prescription drugs for millions of consumers.[2] A survey by the Kaiser Family Foundation in 2016 estimated that 8% of Americans or one of their family members had bought prescription drugs from outside the U.S., representing about 19 million people.[3] One peer-reviewed study published in the Journal of the American Medical Association (JAMA) in 2020 concluded that 2.3 million people in the U.S. with prescriptions buy medications internationally because of cost each year.[4] In 2024, the late founder of Patients for Affordable Drugs, David Mitchell, called personal importation a "safety valve" for patients when brand-name drugs are not covered by insurance.[5] Another study in JAMA recommends that Americans buy medications from trusted international online pharmacies when they do not have affordable domestic options.[6] Finally, allowing wholesale drug importation beyond Canada to the European Union would lead to substantially lower drug prices at U.S. pharmacies.[7]

MYTH:

Drug importation is inherently dangerous due to the threat of counterfeit, unapproved, or misbranded drugs

FACT:

Drug importation is generally safe if the imported products have been appropriately evaluated for safety and efficacy, are lawfully manufactured in accordance with good manufacturing practices, and are dispensed by licensed pharmacies operating under established regulatory systems.[8] Most pharmaceuticals that American consumers buy at U.S. pharmacies are not made in the U.S.; they are made overseas and imported.[9] Many brand-name drugs sold abroad are the same products sold in the United States, made by the same manufacturers in the same facilities, and priced differently across countries, such as Australia, Canada, the European Union, New Zealand, and the United Kingdom.[10] Furthermore, the systems in place for drug importation in Europe—called parallel importation—demonstrate a highly developed drug safety regulatory framework that, in many respects, imposes more stringent safeguards than the U.S. system, including at the point of dispensing, in batch-level quality control, and through manufacturing site–specific authorization and transparency requirements.[11]

Legitimate concerns about the quality of and over-dependence on generic drugs from China must be addressed, but those concerns are distinct from the safety of importing brand-name drugs from peer countries.[12] Additionally, the threat of counterfeit drugs is serious, but should not be conflated with safe wholesale drug importation, or personal drug importation from credentialed foreign pharmacies.[13] Furthermore, labeling a personally imported drug as "misbranded" or "unapproved" under the U.S. Food, Drug, and Cosmetic Act (FDCA) does not mean it is unsafe or poses a risk to patients.[14] A drug may be deemed "misbranded" simply because an otherwise FDA-approved product is labeled for sale in a foreign market, and "unapproved" when it is a foreign version of an FDA-approved drug that is lawfully manufactured and marketed abroad.[15]

MYTH:
Drug importation will undermine America's "closed system" and "gold standard" for regulating drugs

FACT:
Legislative reforms that would allow wholesale drug importation from high-income countries or expand opportunities to personally import prescription drugs, dispensed and mailed from licensed pharmacies, do not undermine the U.S. system of regulating drugs. Opponents of drug importation, including the pharmaceutical industry, argue that the United States maintains a "gold standard" in drug safety through a tightly regulated "closed" distribution system, and that importation of lower-cost drugs would undermine those protections and increase the risk of counterfeit or substandard medicines.[16] The U.S. system remains highly advanced, but it is no longer uniquely the "gold standard" in drug safety; in key areas of supply-chain integrity—including importer-side accountability, batch release, and anti-counterfeit controls—the European Union imposes stricter safeguards, while the notion of a wholly "closed" U.S. system is belied by the global reality of pharmaceutical manufacturing and distribution.[17]

MYTH:
Prescription drug importation is categorically illegal

FACT:
Prescription drug importation is <u>not</u> categorically illegal: drug importation is regulated, and personal importation, even where technically prohibited, is supported under federal law.[18] Not only does federal law allow the importation of prescription drugs, but because most drugs sold in U.S. pharmacies are foreign-made, importation is the main artery of our drug supply chain.[19]

So why is there a debate about legalizing or not legalizing drug importation? Because federal law only allows drug manufacturers to reimport their own drugs, meaning drugs made in the U.S. and then exported can only be imported by the manufacturer.[20] Additionally, federal law prohibits the importation of FDA-approved drugs manufactured outside the U.S. for "commercial use," except by drug manufacturers or under their authorization.[21] In practice, manufacturers exercise near-complete control over commercial-scale drug importation.[22] Because independent arbitrage is restricted, manufacturers can maintain geographic price discrimination across markets, sustaining higher prices in the United States.[23] Congress has introduced legislation to authorize additional, regulated distribution channels for importing FDA-approved drugs at lower cost beyond Canada, to the European Union, Switzerland and the United Kingdom.[24]

Additionally, federal law does not prohibit all personal drug importation. According to the FDA, personal importation is illegal under "most" circumstances, because drugs sold outside the U.S. are "often" not approved by the FDA.[25] But what about FDA-approved drugs? The law says that FDA-approved drugs made outside the U.S. can only be imported for "commercial use" by the drug manufacturers or under their authorization.[26] Those statutory restrictions do not extend to "personal use" imports. The FDA also has a personal importation policy under which the agency will use its enforcement discretion to permit an individual to import an unapproved new drug.[27] More importantly, federal law states that the FDA should exercise enforcement discretion to permit personal importation that does not pose an "unreasonable risk" to consumers.[28]

MYTH:

Stopping and destroying illegal opioid imports, such as fentanyl, are the main targets of the FDA's enforcement activities at international mail facilities, not regular prescription drugs

FACT:

Each year, millions of Americans receive lower-cost international prescription drug orders through international mail facilities.[29] According to data obtained under the Freedom of Information Act and investigative reporting, out of 53,000 drug products detained at international mail facilities (and mostly destroyed) by the FDA in 2022, zero were fentanyl, and 33 (0.06%) were opioid drugs.[30] Instead, many drugs that the FDA destroys at international mail facilities are for asthma, cancer, diabetes, and HIV.[31] FDA has since reported refusing admission to more than 72,000 drug products in FY 2025—a roughly 36 percent increase over 2022—suggesting that even more prescription drug shipments intended for patients are being denied entry into the United States.[32]

MYTH:

Section 804 allows only for the importation of lower-cost drugs from Canada, but not from other countries

FACT:

Section 804 of the FDCA allows for the *wholesale* importation of lower-cost drugs from Canada only, but it also (1) empowers the FDA to permit personal importation from any country *using enforcement discretion*, and (2) *expressly permits* personal importation of lower-cost drugs from any country so long as the Secretary of Health and Human Services (the "Secretary") issues a waiver to the individual importer.[33] Specifically, under Section 804(b) and the associated federal rule, states can sponsor programs allowing for wholesale drug importation from Canada. Separately, Section 804(j)(1) authorizes the Secretary to permit personal importation using enforcement discretion, and Section 804(j)(2) gives the Secretary broad authority to issue waivers to import a prescription drug from any country.[34]

MYTH:

Organizations and businesses that facilitate personal drug importation are an inherent risk to patient safety

FACT:

When they conduct due diligence to verify licensed pharmacies, third-party health benefits companies, alternative funding programs, pharmacy storefronts, and international online pharmacies can help Americans obtain safe and lower-cost prescription drugs through personal importation.[35] Exaggerated or unsupported claims about "potential" risks can distort patient decision-making and harm patients.[36] For decades, Americans have gone online to purchase prescription drugs from Canada and other countries where they can afford them.[37] In other instances, Americans have opted to use an international pharmacy benefit from their self-insured plan.[38] Others have walked into "pharmacy storefronts" to get help filling their prescriptions internationally at much lower prices.[39] These drug savings initiatives should be judged by the value of their assistance to patients.[40]

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[1] Andrew W. Mulcahy et al., RAND Corp., *International Prescription Drug Price Comparisons: Estimates Using 2022 Data* (2024), https://www.rand.org/content/dam/rand/pubs/research_reports/RRA700/RRA788-3/RAND_RRA788-3.pdf, at v (finding U.S. prices for brand-name originator drugs were 422% of prices in comparison countries); Washington Post, *Many seniors get cheaper medicine from Canada. That might become harder*, (Oct. 18, 2025), https://www.washingtonpost.com/business/2025/10/18/deminimis-prescription-drugs-tariffs/; PharmacyChecker.com, *Compare Drug Prices From Accredited Online Pharmacies*, https://www.pharmacychecker.com/drug-price-comparisons/ (last accessed Mar. 20, 2026).

[2] David Lim and Lauren Gardner, *Individuals to drive drug imports for now*, Politico-Prescription Pulse (Jan. 9, 2024), https://www.politico.com/newsletters/prescription-pulse/2024/01/09/individuals-to-drive-drug-imports-for-now-00134439; Hong et al., *Socioeconomic and Demographic Characteristics of US Adults Who Purchase Prescription Drugs From Other Countries*, JAMA Network Open 3(6):e208968 (2020) at 1, https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2767592#google_vignette; H.S. Lalani et al., *Strategies to Help Patients Navigate High Prescription Drug Costs*, JAMA 332(20):1741–1749 (2024), https://doi.org/10.1001/jama.2024.17275 (noting international online pharmacies as a last resort for patients lacking affordable domestic options).

[3] Rachel Bluth, KFF Health News, *Faced with Unaffordable Drug Prices, Tens of Millions Buy Medicines Outside U.S.*(Dec. 16, 2016), https://khn.org/news/faced-with-unaffordable-drug-prices-tens-of-millions-buy-medicine-outside-u-s/.

[4] Hong et al., *Socioeconomic and Demographic Characteristics*, JAMA Network Open (2020).

[5] POLITICO Prescription Pulse, *Individuals to drive drug imports for now* (2024).

[6] Lalani et al., *Strategies to Help Patients Navigate High Prescription Drug Costs*, JAMA (2024).

[7] Stephen Salant, *Arbitrage Deterrence: A Theory of International Drug Pricing*, Health Management, Policy and Innovation, Vol. 8, Issue 2 (2023), https://hmpi.org/2023/09/12/arbitrage-deterrence-a-theory-of-international-drug-pricing/.

[8] FDA, *Importation of Certain FDA-Approved Human Prescription Drugs Under Section 801(d)(1)(B); Guidance for Industry*, 85 Fed. Reg. 61,955, 61,956 (Oct. 1, 2020), https://www.fda.gov/media/142474/download (describing statutory and regulatory frameworks governing drug importation); European Medicines Agency, *Parallel Distribution*, https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/parallel-distribution (explaining regulated cross-border distribution of medicines in the EU); see also Directive 2001/83/EC; Directive 2011/62/EU (Falsified Medicines Directive) (requiring licensing, GMP/GDP compliance, and anti-counterfeiting safeguards); FDA, *Importation of Prescription Drugs*, 85 Fed. Reg. 62,094 (Oct. 1, 2020), at 62,095 (certifying that importing lower-cost drugs from Canada will pose no additional risk to the public health); Roger Bate, *Personal Medicine Importation: What Are the Risks, and How Can They Be Mitigated?* (AEI 2019), at 9–10 (finding no quality difference between medicines obtained from credentialed foreign pharmacies and U.S. pharmacies and concluding such purchases can be made safely).

[9] Mary Van Beusekom, CIDRAP (Univ. of Minn.), *Report Details Where Top 100 Brand-Name Rx Drugs Are Made* (Jan. 26, 2022), https://www.cidrap.umn.edu/news-perspective/2022/01/report-details-where-top-100-brand-name-rx-drugs-are-made; U.S. Pharmacopeia, *Global Manufacturing Capacity for Active Pharmaceutical Ingredients Remains Concentrated* (Jan. 8, 2026), https://qualitymatters.usp.org/global-manufacturing-capacity-active-pharmaceutical-ingredients-remains-concentrated; U.S. Senate Special Committee on Aging, *Protecting Seniors' Access to Essential Medications: Securing the Foreign Generic Pharmaceutical Supply Chain* (2026), https://www.aging.senate.gov/imo/media/doc/senate_aging_american_drugs_report.pdf (asserting that "[i]n 2024, the U.S. manufactured 37% of its consumed pharmaceuticals… compared to just over 20 years ago in 2002 when that figure was 83%.").

[10] FDA, *Importation of Certain FDA-Approved Human Prescription Drugs* (2020), at 61,956 (demonstrating that FDA-approved drugs are sold in foreign markets); CIDRAP (Center for Infectious Disease Research and Policy), "Report details where top 100 brand-name prescription drugs are made," University of Minnesota (2022), https://www.cidrap.umn.edu/report-details-where-top-100-brand-name-rx-drugs-are-made (showing that a large majority of top-selling brand name drugs sold in the U.S. are imported from high-income countries, with a plurality coming from Europe); RAND Corporation, "Prescription Drug Prices in the United

States Are 2.5 Times Those in Other Countries" (2021), https://www.rand.org/pubs/research_reports/RR2956.html (showing that the same brand name drugs are priced about 75% lower on average in other high-income countries).

[11] European Medicines Agency, Parallel Distribution (explaining the regulatory framework governing cross-border distribution of medicines in the EU, which permits such distribution without requiring manufacturer authorization, subject to regulatory oversight), https://www.ema.europa.eu; see also Directive 2001/83/EC; Directive 2011/62/EU (Falsified Medicines Directive) (requiring licensing, GMP/GDP compliance, and anti-counterfeiting safeguards for medicines distributed within the EU); Marta E. Wosińska, Brookings Institution, *Rethinking Manufacturing Quality Oversight for Prescription Drugs* (Oct. 8, 2025), https://www.brookings.edu/articles/rethinking-manufacturing-quality-oversight-for-prescription-drugs/ (explaining that the EU's system imposes stricter safeguards on imported drugs—including mandatory batch testing and certification by a qualified person with personal legal responsibility—thereby providing stronger oversight and accountability than the U.S. model, particularly for imports from countries without comparable regulatory regimes such as China and India); Gabriel Levitt, *Enough Excuses on Drug Importation: A New Transnational Paradigm for FDA Regulation and Lower U.S. Drug Prices*, 49 Brook. J. Int'l L. 286 (2024), https://brooklynworks.brooklaw.edu/bjil/vol49/iss1/8/ (arguing that the European Union has surpassed the FDA's "gold standard" and emerged as a "platinum standard" in drug safety regulation).

[12] U.S. Senate Special Committee on Aging, *Protecting Seniors' Access to Essential Medications: Securing the Foreign Generic Pharmaceutical Supply Chain* (2026), https://www.aging.senate.gov/imo/media/doc/senate_aging_american_drugs_report.pdf.

[13] Kevin Outterson & Ryan Smith, *Counterfeit Drugs: The Good, the Bad and the Ugly*, 16 Alb. L.J. Sci. & Tech. 529, 536–37 (2006); American Enterprise Institute — Roger Bate et al., *"Personal Medicine Importation: What Are the Risks, and How Can They Be Mitigated?"* (2019); https://www.aei.org/research-products/report/personal-medicine-importation-what-are-the-risks-and-how-can-they-be-mitigated/ (noting that counterfeit drug risks are commonly invoked in opposition to drug importation legislation and personal drug importation).

[14] 21 U.S.C. § 355(a); 21 U.S.C. § 321(p); see also FDA, *Understanding Unapproved Use of Approved Drugs ("Off-Label")*(explaining that FDA approval is limited to specific uses, formulations, and labeling, and that drugs may be used outside those parameters without being deemed unsafe); Gabriel Levitt, *Enough Excuses on Drug Importation: A New Transnational Paradigm for FDA Regulation and Lower U.S. Drug Prices*, 49 Brook. J. Int'l L. 286, 300–02 (2024) (explaining that drugs may be deemed "unapproved" based on regulatory or labeling differences rather than underlying safety or efficacy).

[15] *Id.*

[16] Pharmaceutical Research and Manufacturers of America (PhRMA), *The Flood of Counterfeit Drugs*, https://phrma.org/blog/the-flood-of-counterfeit-drugs (last accessed March 23, 2026); PhRMA, *The Realities of Drug Importation from Canada*; https://phrma.org/resources/infographic-the-realities-of-drug-importation-from-canada (last accessed March 23, 2026); FDA (August 2025), *Personal Importation* (cautioning that the "FDA cannot ensure the safety and effectiveness of medicine purchased…from foreign sources), https://www.fda.gov/industry/import-basics/personal-importation#whatis; Levitt, *Enough Excuses* (2024) at 287 (analyzing and critiquing these claims).

[17] U.S. Food & Drug Administration, *Safeguarding Pharmaceutical Supply Chains in a Global Economy* (Oct. 30, 2019) (describing the global nature of pharmaceutical manufacturing for the U.S. market); U.S. Senate Special Committee on Aging, *American Drugs, American Safety? Securing the Nation's Drug Supply Chain* (2025) (detailing U.S. reliance on foreign manufacturing and associated vulnerabilities); Marta E. Wosińska, Brookings Institution, *Rethinking Manufacturing Quality Oversight for Prescription Drugs* (Oct. 8, 2025) (explaining that the EU system imposes importer-side accountability, including qualified person certification and batch testing requirements); European Commission, *Falsified Medicines Directive (Directive 2011/62/EU)* (establishing serialization and end-of-supply-chain verification safeguards); FDA, *Drug Supply Chain Security Act (DSCSA)*; FDA, *Counterfeit Ozempic Found in U.S. Drug Supply Chain* (2025); Levitt, *Enough Excuses* (2024).

[18] 21 U.S.C. §§ 335a(b)(5), 355(a), 381(a), (d), (g), 384(b), (j)(1); FDA, *Human Drug Imports* (explaining that importation is regulated and that FDA may exercise enforcement discretion to permit personal importation under certain circumstances), https://www.fda.gov/drugs/guidance-compliance-regulatory-information/human-drug-imports

[19] U.S. Senate Special Committee on Aging, *American Drugs, American Safety? Securing the Nation's Drug Supply Chain*(2025), https://www.aging.senate.gov/imo/media/doc/senate_aging_american_drugs_report.pdf (finding that a substantial share of drugs consumed in the United States rely on foreign manufacturing); Gabriel Levitt, *Not Made in the USA* (PharmacyChecker), https://www.pharmacychecker.com/not-made-in-the-usa/ (documenting the foreign manufacturing origins of many prescription drugs sold in U.S. pharmacies); U.S. Pharmacopeia, *Global Manufacturing Capacity for Active Pharmaceutical Ingredients Remains Concentrated* (Jan. 8, 2026), https://qualitymatters.usp.org/global-manufacturing-capacity-active-pharmaceutical-ingredients-remains-concentrated (finding that API manufacturing is heavily concentrated overseas).

[20] 21 U.S.C. § 381(d)(1)(A).

[21] 21 U.S.C. § 381(d)(1)(B).

[22] 21 U.S.C. § 381(d)(1)(A), (B) (restricting importation of prescription drugs and requiring manufacturer authorization for commercial importation of foreign-manufactured drugs); Stephen Salant, *Arbitrage Deterrence: A Theory of International Drug Pricing*, Health Management, Policy and Innovation, Vol. 8, Issue 2 (2023), https://hmpi.org/2023/09/12/arbitrage-deterrence-a-theory-of-international-drug-pricing/; Stephen Salant, Foreword to *Not Made in the USA* (PharmacyChecker 2024), https://www.pharmacychecker.com/research/not-made-in-the-usa/.

[23] *Id.*

[24] H.R. 3162 - Affordable and Safe Prescription Drug Importation Act of 2025 (amending Section 804 of the FDCA to allow wholesale importation beyond Canada, to the European Union, Switzerland, and the United Kingdom, and create new provisions to govern personal importation from those countries.).
[25] FDA, Personal Importation, https://www.fda.gov/industry/import-basics/personal-importation (last accessed Mar. 23, 2026).
[26] 21 U.S.C. § 381(d)(1)(B).
[27] FDA, *Personal Importation*.
[28] 21 U.S.C. § 384(j)(1).
[29] Phil Galewitz, *Asthma, Cancer, Erectile Drugs Sent From Abroad Make Up Most Confiscations, Despite Opioid Claims*, CNN (Mar. 7, 2023), https://www.cnn.com/2023/03/07/health/fda-drug-shipments-khn-partner/index.html.
[30] *Id.* (reporting on FDA data obtained through FOIA).
[31] *Id.*; H.R. 3162, § 2(a)(6) (2025) (recognizing that Americans who import prescription drugs for personal use may have those drugs seized upon importation).
[32] U.S. Food and Drug Administration, Fiscal Year 2027 Congressional Justification, Food and Drug Administration, Department of Health and Human Services, at 85 (2026), https://www.fda.gov/media/191778/download.
[33] 21 U.S.C. § 384.
[34] *Id*; see 21 U.S.C. § 384(j)(2); Levitt, *Making Drugs Affordable Through Personal Importation*, The Regulatory Review (June 24, 2025); see also Freed, Meredith, Juliette Cubanski, & Tricia Neuman, *FAQs on Prescription Drug Importation*, Kaiser Family Foundation (KFF) (Mar. 11, 2024), https://www.kff.org/health-costs/faqs-on-prescription-drug-importation/.
[35] Lalani et al., *Strategies to Help Patients Navigate High Prescription Drug Costs*, JAMA (2024); Roger Bate, *"Personal Medicine Importation: What Are the Risks, and How Can They Be Mitigated?"* (2019); https://www.aei.org/research-products/report/personal-medicine-importation-what-are-the-risks-and-how-can-they-be-mitigated/; Gabriel Levitt, *Is the FDA Misleading Congress About the Safety of Drug Importation?*, The Nation (Apr. 1, 2019), https://www.thenation.com/article/archive/canarx-prescriptions-drug-importation-fda/ (arguing that FDA statements have overstated the safety risks of personal drug importation and that certain importation programs operating through licensed pharmacies are not a threat to patient safety while providing lower-cost access to medicines).
[36] Stephen Salant, *Arbitrage Deterrence: A Theory of International Drug Pricing*, Health Management, Policy and Innovation, Vol. 8, Issue 2 (2023), https://hmpi.org/2023/09/12/arbitrage-deterrence-a-theory-of-international-drug-pricing/ (explaining that drug manufacturers spend millions warning that imported drugs are unsafe and that such warnings deter importation and protect higher U.S. prices); Gabriel Levitt, *Scare Tactics Over Foreign Drugs*, N.Y. Times (Mar. 25, 2014), https://www.nytimes.com/2014/03/25/opinion/scare-tactics-over-foreign-drugs.html (arguing that safety warnings about foreign drugs are often exaggerated and mischaracterize risks to discourage importation); Roger Bate et al., American Enterprise Institute, *Personal Medicine Importation: What Are the Risks, and How Can They Be Mitigated?* (2019) (noting that risks associated with certain personal importation channels are often overstated when applied to licensed pharmacies in high-income countries); *Drug Makers Use Fear to Deter Imports*, Wall St. J. (Sept. 2003) (reporting that pharmaceutical companies used the "specter of bogus medicine" to influence public and policymaker opinion against drug importation).
[37] Bluth, *Faced with Unaffordable Drug Prices* (2016); Hong et al., *Socioeconomic and Demographic Characteristics* (2020); Lalani et al., *Strategies to Help Patients Navigate High Prescription Drug Costs* (2024); Bate et al., *Personal Medicine Importation* (2019).
[38] Phil Galewitz, *Some Employers Turn to Overseas Pharmacies to Cut Drug Costs*, KFF Health News (reporting that self-insured employers have partnered with international pharmacy programs to provide lower-cost medications to employees); see also Gabriel Levitt, *Is the FDA Misleading Congress About the Safety of Drug Importation?*, The Nation (2019) (describing employer-sponsored programs that facilitate access to prescription drugs from licensed foreign pharmacies).
[39] Phil Galewitz, *Florida Stores Help Consumers Buy Imported Drugs Despite Federal Ban*, KFF Health News (June 6, 2016), https://kffhealthnews.org/news/florida-stores-help-consumers-buy-imported-drugs-despite-federal-ban/ (reporting that storefront businesses in Florida helped customers order lower-cost prescription drugs from pharmacies in Canada and other countries); Phil Galewitz, *In Florida, Drug Importation From Canada Finds New Champions, Old Snags*, KFF Health News (Feb. 25, 2019), https://kffhealthnews.org/news/in-florida-drug-re-importation-from-canada-finds-new-champions-old-snags/ (reporting that such storefront businesses had operated since 2003, served thousands of customers, and continued with little pushback from regulators).
[40] Roger Bate et al., American Enterprise Institute, *Personal Medicine Importation: What Are the Risks, and How Can They Be Mitigated?* (2019) (noting that properly sourced medicines from licensed pharmacies in high-income countries can mitigate safety risks associated with personal importation); Elisabeth Rosenthal, *An American Sickness* (2017) (describing how high U.S. drug prices drive patients to seek more affordable medicines abroad); Lalani et al., *Strategies to Help Patients Navigate High Prescription Drug Costs*, JAMA (2024) (noting that international online pharmacies may serve as a last resort for patients lacking affordable domestic options); POLITICO Prescription Pulse, *Individuals to Drive Drug Imports for Now* (2024) (quoting patient advocates describing personal importation as a "safety valve" for patients facing unaffordable drug prices).