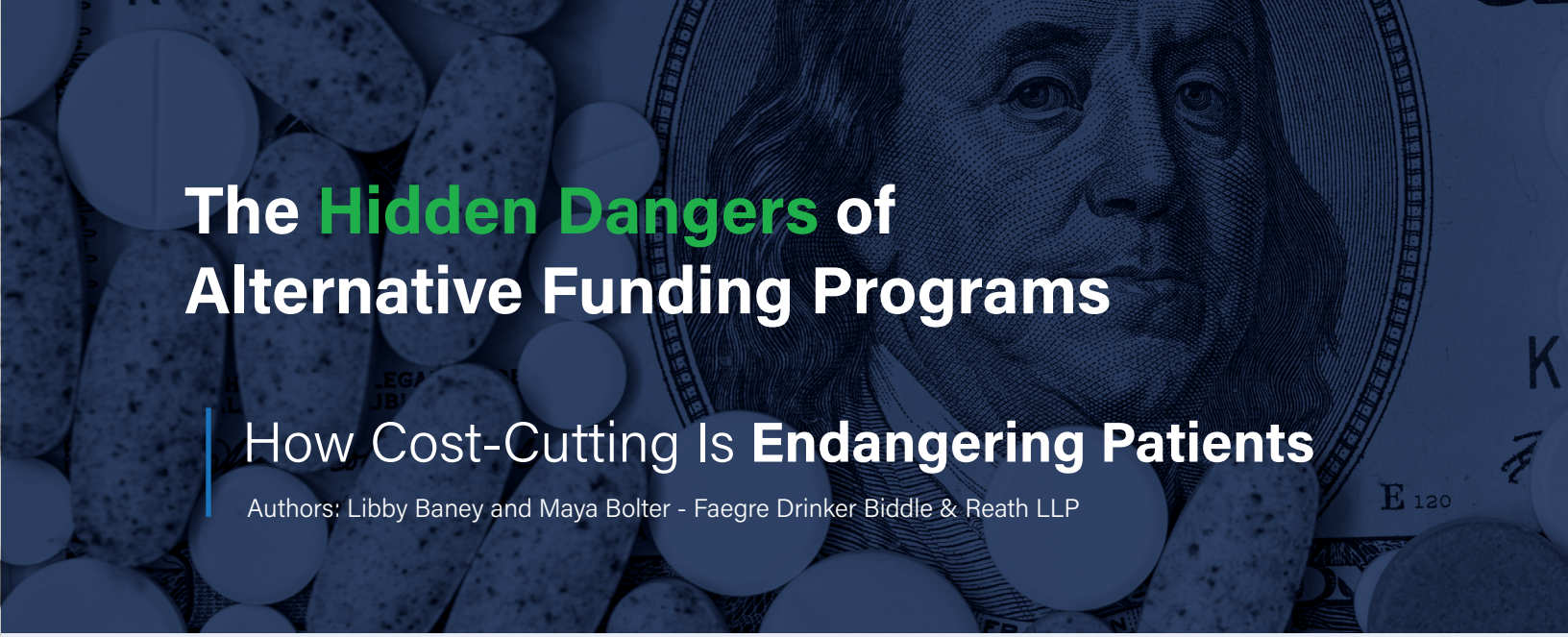

The Hidden Dangers of Alternative Funding Programs

How Cost-Cutting Is **Endangering Patients**

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The Escalating Risks to Patient Safety

Increasingly, commercially insured patients in the United States are being coerced by their insurance providers to obtain prescription medications illegally from international sources, rather than from properly regulated domestic pharmacies. These international sources sell drugs that are not approved by the U.S. Food and Drug Administration (FDA) and operate outside the safe U.S. supply chain. This practice puts patients at risk of receiving counterfeit or substandard medicine obtained from unknown foreign sources and stored or shipped in unknown conditions. Further, patients may not even be aware that they are at risk.

How the Scheme Works

Employers regularly depend on benefits consultants and vendors to advise on the complexities of employee insurance plans, especially those that are self-funded. However, some vendors exploit this trust by implementing cost-cutting strategies that cross the line into illegality, such as programs that facilitate the provision of prescription drugs from foreign pharmacies to commercially insured U.S. patients. In these cases, an employer health plan will work with a third-party vendor to promote alternative funding programs ("AFPs") as a way to cut employer costs under their health plan. Through international sourcing, AFP payers provide minimal coverage for drugs under the employer plan's formulary. Patients are told that the drug is not covered or that insurance will pay for only a small part of the drug's cost when the patient tries to obtain the drug from a domestic U.S. pharmacy. The patient is then referred to a vendor who will provide the prescription drug at a significantly reduced cost by referring the patient's prescription to be filled outside the United States. Some patients do not even know before the drug arrives that they are receiving a prescription product from a foreign country.

The foreign entities that are paid by commercial insurance plans to ship drugs to U.S. patients are not subject to U.S. law and may be violating their own country's laws by exporting prescription medicine to the United States. This practice puts patients at risk of receiving potentially dangerous counterfeits or substandard medicine coming in unregulated from overseas. In 2023, about two-thirds of American workers were covered by self-funded insurance plans, which may employ such tactics and thus jeopardize patient safety.[1]

1 Employees covered by self-funded health insurance U.S. 1999-2023 | Statista

A Case Study in Unlawful Drug Importation

A recent Maryland court case exposed the hazards associated with illegally imported pharmaceuticals. In 2021, a patient was prescribed Biktarvy® (an FDA-approved medicine to treat HIV), and for years he took the drug as prescribed. However, upon a change in insurance coverage in 2024, the patient's new pharmacy benefit manager (PBM) pushed him to enroll in an AFP to receive coverage for his medication. This AFP required him to obtain his Biktarvy® from a new mail-order source. But when the patient received Biktarvy® in the mail from this new source in February 2024, it was a Turkish product in Turkish language, rather than the FDA-approved medicine he'd been taking for years. This patient is among an estimated 12% of Americans enrolled in an AFP, underscoring the extent of this issue.[2]

In response, Gilead Sciences, Inc., the manufacturer of Biktarvy®, initiated a lawsuit against entities involved in the illegal importation of Gilead-branded medicine, including not only the Turkish pharmacy but also the U.S. companies that caused their customer – a U.S. patient – to fill his prescription for Biktarvy® from the Turkish pharmacy: an AFP, a PBM, and a health insurance administrator. Gilead brought claims under the Lanham Act, the federal trademark statute, alleging that these entities' importation of foreign products infringed on Gilead's U.S. trademarks. In December 2024, the court granted a temporary restraining order against the AFP scheme. In its ruling, the court emphasized the patient safety risks from medicine sourced from foreign pharmacies in contrast to FDA-approved medicine sourced from state licensed pharmacies.

Unseen Risks for Patients

> *"... if it's about living or dying this month, I think most patients would find that pretty darn material, that they don't have a patient information document that they can read."*
> - ***The Honorable Julie Rubin, 24-cv-3566-JRR***

Patients are unaware of the risks associated with foreign medications provided through AFPs. For the Biktarvy® patient discussed above, his one prescription was processed through a multi-step, convoluted network of intermediaries:

1. The patient's health insurance was managed by his employer-sponsored health plan's third-party administrator, Meritain Health, Inc. incorporated in NY.

2. The PBM, ProAct, Inc. incorporated in NY referred the patient to RxValet, an AFP incorporated in GA, with whom the patient's health plan contracted.

3. Rx Valet then directed the patient to have his healthcare provider submit his prescription to a domestic mail-order pharmacy, Advanced Pharmacy incorporated in SC.

4. Rather than filling the prescription, Advanced Pharmacy referred the prescription to Affordable Rx Meds, a Florida-based prescription referral service.

5. Affordable Rx Meds then arranged for medication to be shipped to the patient from a Turkish pharmacy, which ships prescriptions to the patient via an international courier (e.g. DHL and FedEx). The medication, which was labeled in Turkish and manufactured in a Turkish facility that is not approved by the FDA for U.S. patients.

6. The patient's insurance then pays for the international medication as part of the patient's insurance benefit.

Foreign medication arriving at a U.S. patient's front door from halfway across the world lacks the critical oversight of the FDA and the federal and state laws and regulations that protect consumers from

2 A primer on copay accumulators, copay maximizers, and alternative funding programs | Journal of Managed Care & Specialty Pharmacy

counterfeits and substandard medicine. As the Maryland court noted, this opaque and unregulated supply chain heightens patient risk:

> *"There's no black box FDA warnings on Turkish Biktarvy...There's no 800 number, patient hotline...There's no FDA-approved language. There's no means by which to contact the FDA if you have a problem or concerns about your medication...There's a lack of chain of custody documentation which impairs Gilead's abilities to issue targeted recalls."*
>
> - ***The Honorable Julie Rubin, 24-cv-3566-JRR***

Risk. Risk. Risk.

International sourcing programs run by AFPs are increasingly adopted by municipalities, small businesses, and school systems,[3] yet the medications obtained through these channels pose critical safety risks due to the absence of FDA and state regulator oversight. Risks include:

Lack of Proper Storage and Handling: The FDA and state pharmacy laws mandate strict temperature and handling regulations to maintain medication efficacy. AFPs use commercial couriers that fail to guarantee these conditions, increasing the risk of compromised drugs.

Risk of Counterfeit Medications: Operating out of the closed U.S. supply chain, including the Drug Supply Chain Security Act (DSCSA), these complex schemes increase risk of patients receiving counterfeit medicine. Notably, the U.S. Trade Representative's 2024 Notorious Markets Report focused on the risks of foreign drug supply chains and counterfeit medicine.[4]

Insufficient Transparency: Foreign medications frequently lack essential labeling, patient instructions, and recall mechanisms, leaving patients vulnerable to severe health risks.[5][6]

The Need for Action

> *"My concern is we're talking about a very important issue, providing patient access to low-priced, proper medication, and that is important, but I'm not willing to make that the primary issue where the flip side is at what cost. And I don't mean dollars and cents, the cost of patient safety is not an appropriate trade-off."*
> - ***The Honorable Julie Rubin, 24-cv-3566-JRR***

While the FDA and Department of Justice possess the authority to prosecute AFPs for distributing misbranded drugs, enforcement has thus far been limited to issuing warning letters to companies such as CanaRx and ElectRx and Health Solutions, LLC.[7][8] Despite receiving citizen petitions urging FDA to act, as of February 2025 the FDA has yet to pursue direct enforcement actions.[9] Due to FDA inaction thus far, it's been up to manufacturers, employers, providers, and state regulators to act.

> *"There are patients relying on their drugs to be FDA approved and all the bells and whistles that go along with that."*
>
> - ***The Honorable Julie Rubin, 24-cv-3566-JRR***

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3 See, e.g., Town of Wilbraham, Massachusetts Full-Time Employee Benefits; Mamaroneck Schools Health Care Benefits; SHARx Services Agreement with Town of Prosper, TX.
4 2024 Review of Notorious Markets of Counterfeiting and Piracy (final).pdf
5 U.S.C. Title 21 - FOOD AND DRUGS (FDCA Sections 505(a), 301(a), (d))
6 IF11056.pdf (SECURED)
7 ElectRx and Health Solutions, LLC - 614251 - 03/02/2023 | FDA
8 CanaRx Services Inc - 554740 - 02/26/2019 | FDA
9 Aimed-Alliance-Citizen-Petition-3.1.24.pdf

What Can State & Federal Policymakers Do?

State and federal policymakers can take proactive measures to curb AFP schemes and ensure compliance with safety standards and with the law:

- Include AFP transparency measures in PBM reforms.
- Prohibit programs that manipulate benefit designs to the detriment of patients.
- Seek to ban AFPs in commercial insurance markets.
- Encourage the FDA to enforce existing laws against illegal prescription drug importation.