



ALTERNATIVE FUNDING INITIATIVES

Responding to Challenges to Patient
Assistance Programs

Eve Brunts
Alison Fethke
Margaux Hall

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Today's Presenters



EVE M. BRUNTS

Health Care
Boston

eve.brunts@ropesgray.com



MARGAUX J. HALL

Health Care
Washington, D.C.

margaux.hall@ropesgray.com



ALISON FETHKE

Health Care
Chicago

alison.fethke@ropesgray.com

Notice

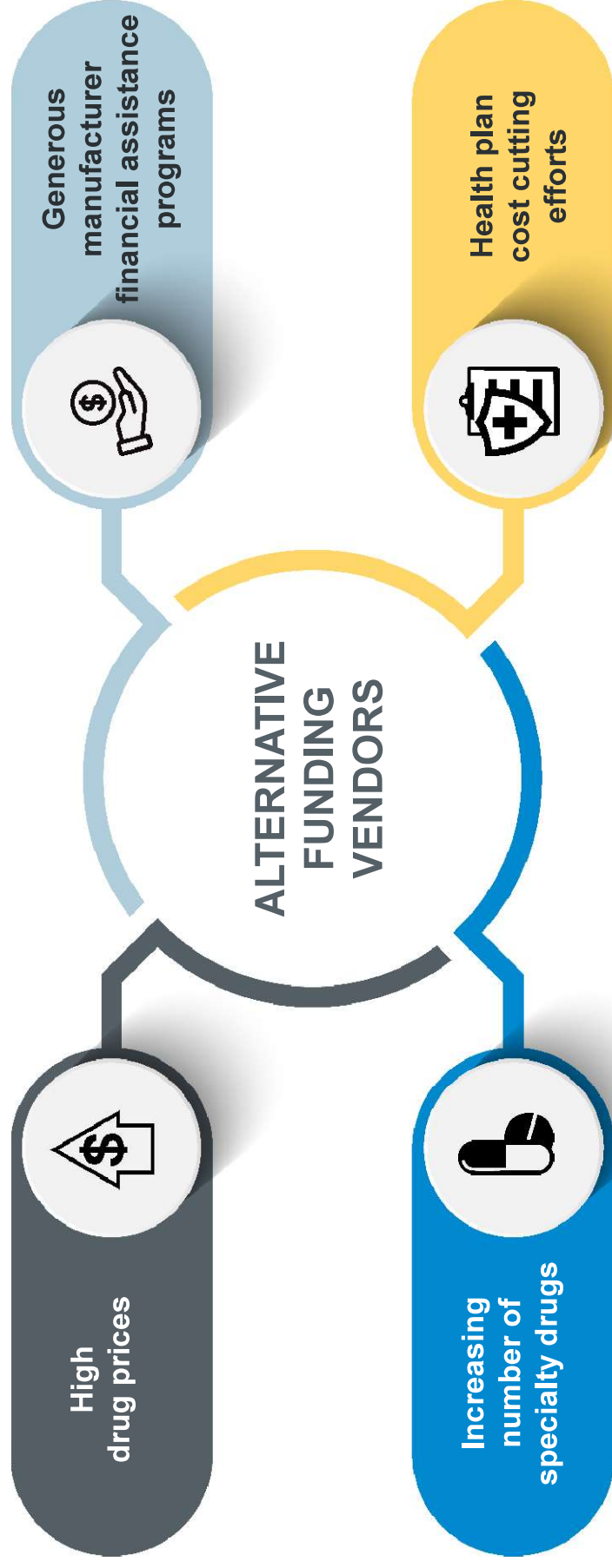
Information communicated in this presentation was assembled based on information reported online (e.g., on alternative funding vendor websites, health plan brochures), in news reports, in government communications and in court filings (including allegations made in such filings). Activities of alternative funding vendors may vary and, as noted in this presentation, activities of alternative funding vendors are not always transparent.

This presentation and our comments today do not constitute legal advice.

AGENDA

- Introduction
- Alternative Funding Initiatives
- Government and Industry Responses
- Potential Future Developments and Challenges

Introduction



Introduction: What Are Alternative Funding Initiatives?

Concept	Commercial health plans reduce costs by: (1) leveraging patient assistance programs offered by pharmaceutical companies and charitable foundations or (2) accessing lower cost drugs from abroad
Approaches	- Copay accumulator and maximizer programs - Accessing free drug programs - Filling prescriptions through foreign pharmacies
Implementation	- Commercial health plans assisted by growing number of alternative funding vendors - Operations of alternative funding vendors and messaging on activities are not always transparent

Introduction: Differing Perspectives on Alternative Funding Initiatives

Pharmaceutical Manufacturer

- Diversion of scarce resources from patients in need
- Misuse of patient assistance programs, contravening terms and conditions
- Potential disruption in therapy for patients
- Distress to patients from uncertainty of coverage/costs
- Interests of patient organizations generally align with those of pharmaceutical manufacturers
- Potential increase in health system costs (through avoided rebates and administrative fees)

Health Plan/Alternative

- Saving employers and patients money
- Enhancing access to specialty medication while keeping costs low
- *Not all health plans share this uniform perspective*

Introduction: Alternative Funding Vendor *Examples*

Vendor	Sample Service Offering
	Drug importation (https://electrx.com)
	Free drug programs (https://impaxrx.com)
	Free drug programs (https://www.paydhealth.com)
	Free drug programs (https://payermatrix.com)
	Copay programs (https://www.prudentrx.com)
	Copay programs (https://www.saveonsp.com)
	Free drug programs (https://scriptsourcing.com)
	Free drug programs (https://sharxplan.com)

Introduction: Vendor Service Descriptions



script**sourcing**

For you, this means healthier, happier employees as well as significant savings not only in your healthcare spend but also in worker attendance and productivity. In addition, with ScriptSourcing as part of a robust healthcare plan, you'll attract new talent and retain your valuable employees.



A platform of transparency and trust

Trust is key to everything we do at Payer Matrix so that we can provide the best care to our members.



SHARx is not a discount program. We are a company with hundreds of combined years in the health care space with the expertise to bring hope and healing through pharmaceutical access. The families you serve need the care, compassion, and knowledge we provide.



Experts in the healthcare and pharmaceutical industries founded SaveOnSP with one goal in mind: to administer plan benefits designed to provide cost savings for both plan sponsors and their participants.

The SaveOnSP team works with plan sponsors to implement cost-reducing strategies on some of the most commonly used specialty medications. SaveOnSP keeps plan participants front-of-mind and ensures a seamless experience during the plan's benefit change.



Check the ElectRx Partial Drug List to see if your medication is one of the hundreds of prescription drugs available. If you don't see your prescription, don't worry! Give us a call because this list is only a partial list and our list is constantly changing, so your medication may be covered. Don't miss your chance to save money.

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Copay Accumulators

- Manufacturer copay assistance does **not** count toward the patient's deductible and out-of-pocket maximum
- Manufacturer copay assistance funds patient's cost-sharing ***until*** manufacturer's annual copay assistance limits are reached
 - Patient must pay deductible and copays once manufacturer copay assistance annual limit is reached
 - Those payments count toward their annual health plan deductible and out-of-pocket maximum
- Vendors reportedly receive a share of the savings on drug costs

Copay Maximizers

- The pharmacy benefit plan resets the patient's cost sharing amount to be equal to the total annual value of the copay funds
- The maximum value of the manufacturer's coupon/card is applied evenly throughout the benefit year
- *Example:* A patient goes to fill a prescription and uses manufacturer copay assistance to help cover his cost share of the medication
 - The pharmacy benefit plan resets the patient's cost sharing amount to be equal to the total annual value of the copay funds.
 - If a copay program pays a maximum of \$1,200 per year in benefits for a specific drug, the patient's cost sharing for that drug would be set at \$100 per month
- The manufacturer copay assistance payments *may* not count toward the patient's deductible and out-of-pocket maximums

“Non-Essential” Health Benefits

- Health plans (working with alternative funding vendors), in operating copay accumulators and maximizers, may characterize the relevant drugs as non-“essential health” benefits” so that the Affordable Care Act (ACA) annual cost-share limits do not apply to the drugs and they can maximize funding from manufacturer copay assistance programs
 - Re-classify certain drugs as non-essential health benefits then raise the copays for the drugs
- Under the ACA, many health plans (other than self-insured plans) must offer “essential health benefits,” which include prescription drugs
 - Health plans must cover at least the greater of: (1) one drug in every United States Pharmacopeia (USP) therapeutic category and class; or (2) the same number of drugs in each USP category and class as the state’s essential health benefit-benchmark plan
- Insured plans offered through a health exchange/marketplace have maximum annual out-of-pocket spending limits on cost sharing for “essential health services”
 - 2024 Limits: \$9,450 for an individual and \$18,900 for a family

Leveraging Free Drug Programs

- Health plans leverage the availability of free drug programs (PAPs) from drug manufacturers or charitable foundations
- Health plans (working with alternative funding vendors) limit or deny coverage for certain drugs and direct members to free drug programs
 - Vendor communications to member may not be clear
 - Vendors may assist member with completion of the PAP application
 - Coverage may be re-instated if member is not eligible for free drugs
 - Potential for gaps in patient access to drugs
- Vendors reportedly receive a share of the savings on drug costs
- Open question regarding whether such programs save money for health plans

Leveraging Free Drug Programs

Exemplar Patient Message:

To Whom It May Concern:

We received your request for preauthorization of [Drug]. At this time, we are upholding our prior denial based on medical necessity.

We have provided [Doctor X] with the denial and the information related to a Patient Assistance Program (“PAP”) which is available for this medication and should be the next step in this process.

If the response from the PAP is unfavorable, then this should be referred to the [Plan] along with all medical records to be reviewed for medical necessity and reconsideration for payment under the medical plan.

Accessing Drugs from Abroad

- Vendor contracts with health plans to provide prescription drugs to members.
- Vendor accepts the U.S. prescription and facilitates the dispensing of the prescription drug by a foreign pharmacy
 - Described as “personal importation” facilitated by a foreign pharmacist, who processes, packages, and ships the medication directly to the employee in the U.S.
- Communications may put member on notice that medication has a different name or strength because member has been shipped internationally branded product

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Copay Accumulators and Maximizers

- Federal copay accumulator rule permits the health plans offered through the health exchange / marketplace as well as self-insured plans to implement copay accumulators

Use of Direct Support Offered by Drug Manufacturers 45 C.F.R. § 156.130(h)

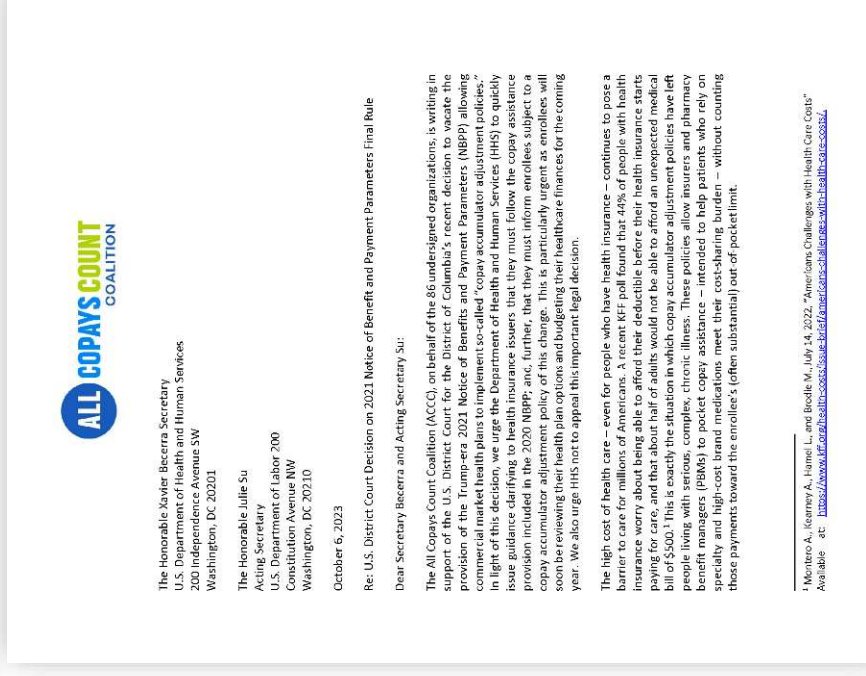
2019	2020
Notwithstanding any other provision of this section, and to the extent consistent with state law, amounts paid toward cost sharing using any form of direct support offered by drug manufacturers to enrollees to reduce or eliminate immediate out-of-pocket costs for specific prescription brand drugs that have an available and medically appropriate generic equivalent are not required to be counted toward the annual limitation on cost sharing	Notwithstanding any other provision of this section, and to the extent consistent with State law, amounts paid toward reducing the cost sharing incurred by an enrollee using any form of direct support offered by drug manufacturers for specific prescription drugs may be, but are not required to be, counted toward the annual limitation on cost sharing. . . .

Copay Accumulators and Maximizers

- Federal copay accumulator rule recently vacated by the D.C. District Court in summary judgment (September 29, 2023)
- ***HIV and Hepatitis Policy Institute, et al. v. HHS et al.***
 - Individuals and patient advocacy groups challenged the copay accumulator rule on three grounds:
 - Rule was contrary to the statutory text, which defines “cost-sharing” broadly and without regard to the source of the cost-sharing amount
 - Rule conflicts with other HHS “cost sharing” interpretations as any expenditure required “by or on behalf of” an enrollee
 - Rule was arbitrary and capricious
 - Court ruled that HHS acted arbitrarily and capriciously in declining to define “cost sharing” and permitting insurers to engage in conduct that would rest on contradictory interpretations of the same statutory and regulatory provisions
 - Court remanded the issue to HHS for further rulemaking to interpret the statutory and regulatory definitions of “cost sharing” with 2019 rule applicable in interim

Copay Accumulators and Maximizers

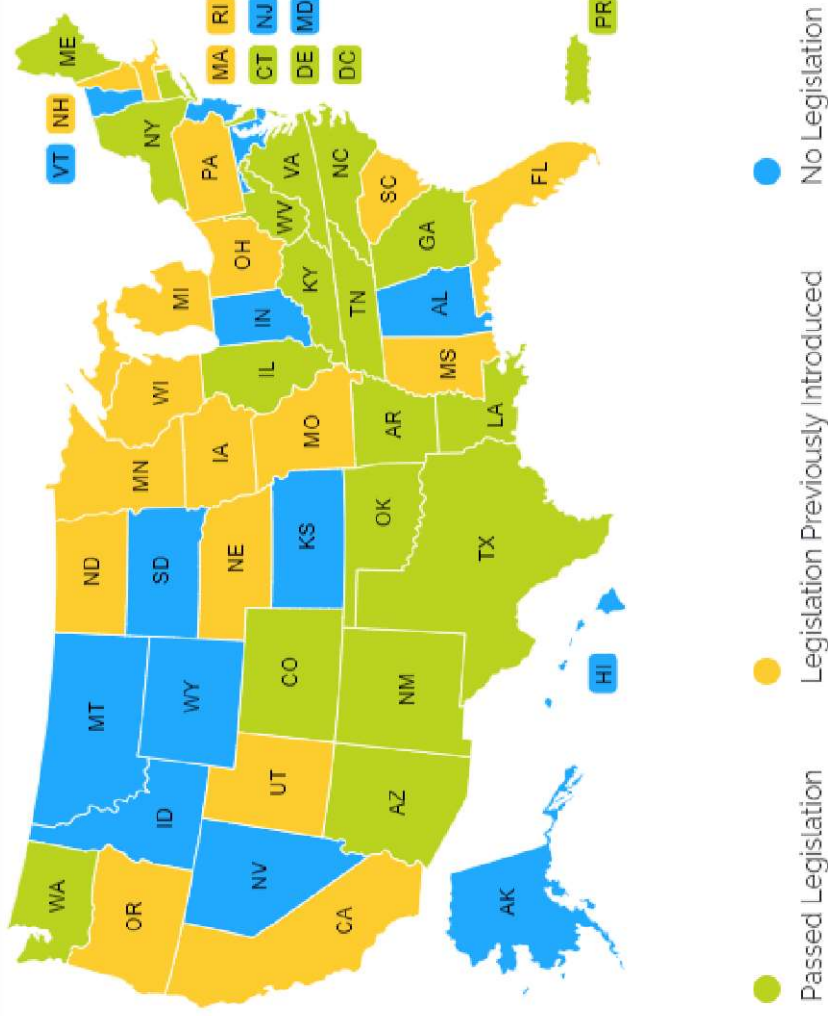
- Early support from patient organizations for *HIV and Hepatitis Policy Institute* decision
- Example: All Copays Count Coalition
 - Call for HHS and Department of Labor to clarify impact of court decision
 - Have health plans notify members of impact
 - Take need for copay assistance into account when reconsidering regulations
 - Signed by 86 patient organizations



State Legislation

- Backdrop of now-vacated federal copay accumulator rule:
 - “Notwithstanding any other provision of this section, and **to the extent consistent with *State law***, amounts paid toward reducing the cost sharing incurred by an enrollee using any form of direct support offered by drug manufacturers for specific prescription drugs may be, but are not required to be, counted toward the annual limitation on cost sharing...”
- States have enacted legislation requiring that health plans count copay support towards a member’s deductible and out-of-pocket limits
 - 20 states and Puerto Rico
- Scope of copay accumulator bans vary. Different approaches on when manufacturer assistance must be counted:
 - Always
 - For brand drugs only if no generic
 - For brand drugs if no generic or generic but brand access only after prior authorization/step edit/exceptions process

State Legislation



Source: All Copays Count Coalition (<https://allcopayscount.org/state-legislation-against-copay-accumulators/> - Accessed October 20, 2023)

Alternative Funding Vendor Litigation

- *Johnson & Johnson Health Care Systems v. SaveOnSP (2022)*
 - Affiliate of pharmaceutical manufacturer brought suit against alternative funding vendor alleging that vendor:
 - Circumvented statutory cost-share limits
 - Inflated patients' copay costs to extract more funds from the patient assistance program and reduce health plan costs
 - Coerced patients to enroll in vendor program
 - Levered its "illicit" program to "surreptitiously extract inflated amounts of patient assistance"
 - Causes of action: State tortious interference and deceptive trade practices
- Suit survived a motion to dismiss in January 2023

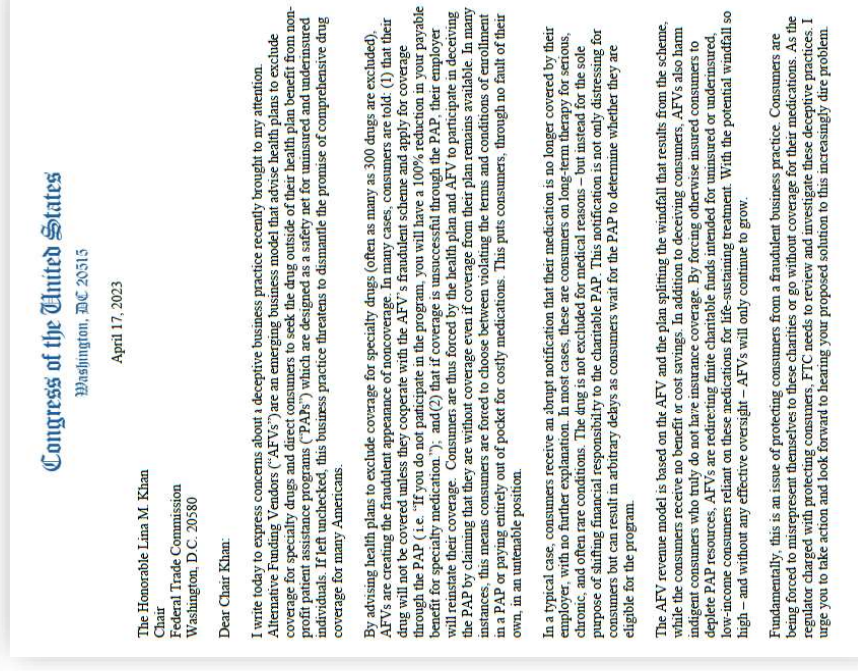
Alternative Funding Vendor Litigation

- ***AbbVie v. PayerMatrix* (2023)**
 - Pharmaceutical manufacturer brought suit against alternative funding vendor on grounds that vendor enrolls insured patients into a free drug program intended only for the uninsured and underinsured
 - “Sham exclusion of coverage” for specialty drugs
 - Coercive and deceptive tactics to get members to participate
 - Concealing involvement once eligibility terms changed to exclude individuals applying through alternative funding programs
 - Alleged deceptive business/trade practices and tortious interference with business opportunity

Leveraging Free Drug Programs

Letter to Federal Trade Commission (April 2023)

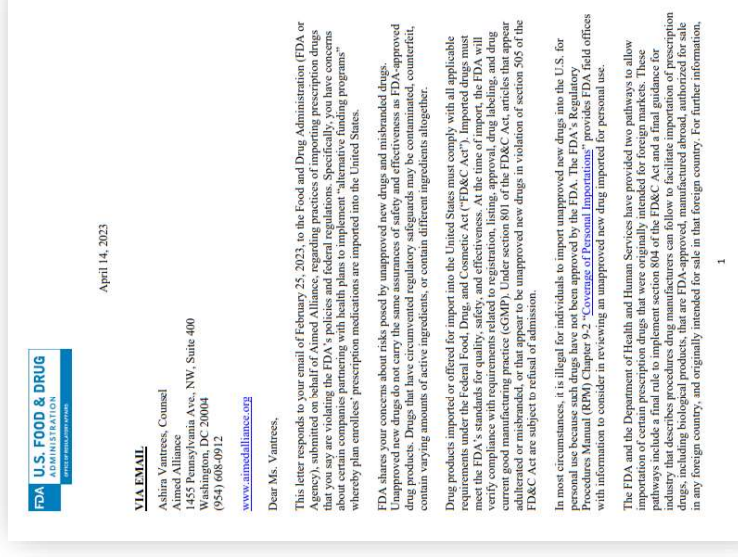
- Members of Congress call attention to “emerging business model that advise health plans to exclude coverage for specialty drugs and direct consumers to seek the drug outside of their health plan benefit from nonprofit patient assistance programs”
- FTC urged to investigate the “deceptive practices” of alternative funding vendors and defining the issue as “protecting consumers from a fraudulent business practice”



Accessing Drugs from Abroad

FDA's Response Letter to Aired Alliance (April 2023)

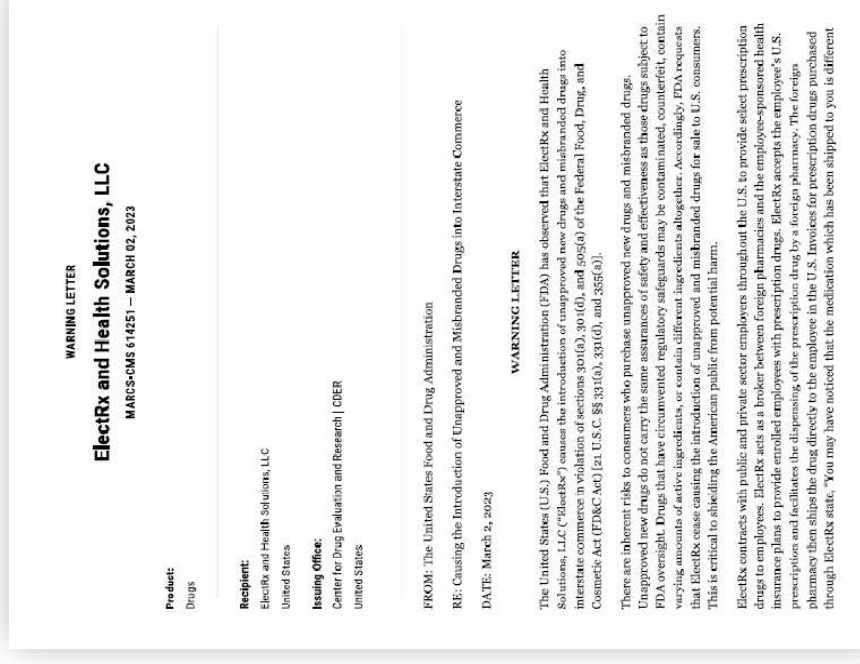
- Organization raised “concerns about certain companies partnering with health plans to implement ‘alternative funding programs’ whereby plan enrollees’ prescription medications are imported into the United States”
- FDA acknowledges the concerns and restates regulatory framework without specific application to alternative funding programs



Accessing Drugs from Abroad

FDA Warning Letter to ElectRx (March 2023)

- ElectRx “causes the introduction of unapproved new drugs from foreign sources into interstate commerce in the United States in violation of the FD&C Act by substituting the FDA-approved drugs prescribed by a patient’s physician with unapproved drugs sourced from foreign pharmacies”
- ElectRX acts as “broker between foreign pharmacies and the employee-sponsored health insurance plans to provide enrolled employees with prescription drugs”
- The “distribution scheme is particularly concerning” because employees likely “trust that they will receive safe and effective drugs through their employer’s ‘insurance’ plan and may not question their legitimacy”
- ElectRx response to FDA states that activities fall within the personal importation exemptions and also comply with international pharmacy standards



Potential Manufacturer Responses

- Free Drug Programs (PAPs)
 - Revised eligibility terms
 - Patients eligible only if truly uninsured, **not** “underinsured” (*i.e.*, no coverage for the prescribed drug)
 - Patient ineligible if alternative funding vendor involvement
 - Enhanced review/monitoring of applications
- Copay Programs
 - Revised eligibility terms
 - Patient ineligible if full benefit does not go to patient
- Litigation
- Policy Advocacy
 - Efforts to enhance transparency for patients

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Potential Future Developments and Challenges

Use of alternative funding initiatives as leverage in rebate negotiations?

Increased use of alternative funding initiatives given other drug pricing changes (e.g., under Inflation Reduction Act) and growing number of specialty drugs?

Utilization of enhanced information on copay accumulators from transparency requirements?

Patient advocacy to enhance transparency?

Further examination of whether programs generate cost savings?

Novel Legal Theories in Litigation ?

