June 14, 2023

Lina Khan
Chair
Federal Trade Commission
600 Pennsylvania Avenue, NW
Washington, DC 20580
antitrust@ftc.gov

Re: Non-EHB, Alternative Funding Programs, and Unfair Trade Practices

Dear Chairwoman Khan:

Aimed Alliance is a 501(c)(3) not-for-profit health policy organization that seeks to protect and enhance the rights of health care consumers and providers. We are writing to bring to your attention an unfair trade practice that is harming consumers with chronic health conditions. In particular, we are writing to discuss how third party companies are **partnering with health plans to implement non-essential health benefit (non-EHB) and alternative funding schemes. These profit-maximization schemes unfairly force patients who are prescribed specialty medications to enroll in programs that improperly take advantage of financial assistance available to such patients.**

Given the authority of the Federal Trade Commission (FTC) to protect consumers from unfair trade practices, we are requesting a meeting with your office to discuss the FTC's role in protecting consumers from non-EHB and alternative funding schemes.

I. Background

When patients cannot afford their prescriptions medications, eligible patients may rely on financial assistance from non-profit organizations, drug manufacturers, and other sources (referred to collectively as financial assistance) to help meet their health plan's cost-sharing requirements (e.g., copayments). This is especially true of vulnerable patients with serious, rare, complex, or chronic conditions who are prescribed specialty drugs for which there are no generic alternatives. Typically, this financial assistance should be applied to the patient's deductible and annual out-of-pocket limits. However, in recent years, health plans and pharmacy benefit managers (PBMs) have increasingly implemented what are known as "copay accumulator programs."[1] Under copay accumulator programs, the health plan or PBM accepts financial assistance intended for the consumer's benefit; yet, those dollars are not counted toward the consumer's deductible or annual

[1] Spondylitis Association of America, *Copay Accumulators Programs: What They Are And How They Might Impact Your Out-Of-Pocket Costs*, https://spondylitis.org/spondylitis-plus/copay-accumulator-programs-what-they-are-and-how-they-might-impact-your-out-of-pocket-costs/ .

out-of-pocket limit.[2] In other words, copay accumulator programs are used to capitalize on financial assistance for the benefit of the plan and to the detriment of the patient.

Recently, health plans have expanded this practice to further exploit financial assistance by contracting with third-party vendors to manage their specialty medication benefits through non-EHB[3] and alternative funding schemes.[4] Our understanding is that these vendors' fees are based on either a percentage of the cost savings achieved, or the amount of financial assistance secured.[5] PBMs actively market these partnerships to health plans as a solution for lowering plan costs.[6] However, these schemes are unfairly structured to exploit financial assistance and force patients who are prescribed specialty medications to enroll in these schemes. Although these programs are often pitched by PBMs, to our knowledge these third-party companies are independent companies and not legal subsidiaries of any PBM or health plan.

A. Non-EHB Schemes

An essential health benefit (EHB) is an important designation under the Patient Protection and Affordable Care Act (ACA). Under the ACA, health plans must cover ten types of EHBs, one of which is prescription drugs.[7] Federal law requires that all cost-sharing paid by or on behalf of the patient for in-network EHBs must be counted towards meeting the patient's deductible and annual out-of-pocket limit.[8] However, under non-EHB schemes, specialty drugs are inappropriately deemed as non-EHBs—even for individuals with serious, rare, complex, or chronic conditions whose medically necessary treatments truly are essential. As such, these schemes allow the third-party program to capitalize on the maximum amount of financial assistance available without applying the assistance toward the patient's deductible or annual out-of-pocket limits.[9]

[2] SaveonSP, *Employers FAQ*, https://saveonsp.com/employers/; PrudentRx, The PrudentRx Copay Program Frequently Asked Questions, at p. 1, https://membershealthplannj.com/wp-content/uploads/2020/11/Member-FAQ_PrudentRx-Copay-Program.pdf.
[3] Examples include SaveonSP, PrudentRx, and PillarRx.
[4] Examples include PayorMatrix, SharkRx.
[5] MMIT, *Industry Experts Question Alternative Funding Companies that Carve Out Some Specialty Drugs, 'Abuse' Charities*, https://www.mmitnetwork.com/aishealth/spotlight-on-market-access/industry-experts-question-alternative-funding-companies-that-carve-out-some-specialty-drugs-abuse-charities/.
[6] ExpressScripts, SaveonSP, https://www.express-scripts.com/corporate/solutions/lowering-costs#saveonsp; See also, Human Resources County of San Luis Obispo, *Save on Specialty Medications with Express Scripts SaveOnSP*, https://www.slocounty.ca.gov/Departments/Human-Resources/Department-News/Save-on-Specialty-Medications-with-Express-Scripts.aspx; While these outside companies are marketed as unrelated partners to PBMs, these schemes have been pitched to plans by a PBM and not by representatives of the third-party companies See e.g. *IPBC and SaveonSP Training – 20210216*, https://vimeo.com/513414094 (SaveonSP is pitched to health plans by an ExpressScripts representative); see also New Mexico Retiree Health Care Authority, *Annual Meeting of the Board of Directors*, https://www.nmrhca.org/wp-content/uploads/2021/07/2021-7-15-Board- Book.pdf.
[7] See generally, CMS, Information on Essential Health Benefits (EHB) Benchmark Plans, https://www.cms.gov/CCIIO/Resources/Data-Resources/ehb.
[8] 42 U.S.C. § 18022 – Essential health benefits requirements.
[9] *See generally*, CMS, Information on Essential Health Benefits (EHB) Benchmark Plans, https://www.cms.gov/CCIIO/Resources/Data-Resources/ehb.; SaveonSP, https://saveonsp.com/.

When a health plan partners with a non-EHB program, the health plan or non-EHB vendor first notifies consumers about the program's coercive details when the consumer is attempting to fill certain specialty medication prescriptions. Consumers are told that they will receive their specialty medication for $0 or at a low-cost if they enroll in the program.[10] While consumers may be presented with the "choice" to enroll in the specialty medication program, these non-EHB schemes are coercively structured to ensure enrollment. Specifically, these programs tell patients that if they do not wish to enroll in the program then they will be responsible for a coinsurance payment—which can run between 30 to 70 percent—and this payment will not count towards their deductible or annual out-of-pocket limit.[11] As a result, patients are left with no other choice than to enroll in these third-party programs to avoid unmanageable coinsurance payments.

The program's low or $0 copay is created by determining the maximum amount of financial assistance available annually for a specialty medication and then dividing that amount by 12 to determine the amount of monthly assistance available.[12] Once the amount of available monthly assistance is determined, health plans are advised to set the monthly copay to at least the monthly amount of financial assistance available.[13] After this calculation is made, the non-EHB program contacts the consumer to obtain the consumer's personal information for the purpose of applying for a manufacturer copay assistance program. For consumers already enrolled in a manufacturer copay assistance program, the consumer is automatically integrated into the non-EHB program, often without prior notification.[14]

B. Alternative Funding Schemes

Third-party vendors have taken non-EHB schemes one step further by implementing what are known as alternative funding programs. These schemes operate almost identically to non-EHB schemes—health plans and PBMs partner with third-party companies to manage specialty medication benefits while imposing the same coercive enrollment structure and excluding financial assistance from counting towards the patient's deductible and annual out-of-pocket limit.[15] However, alternative funding schemes are distinguishable from non-EHB programs because alternative funding schemes target a broader range of financial assistance. While non-EHB schemes primarily target manufacturer copay assistance programs, alternative funding schemes typically also target assistance from foundations, non-profits, or other charitable sources. Additionally, some even source medications from outside the United States, which is illegal under

---

[10] *IPBC and SaveonSP Training* – 20210216, https://vimeo.com/513414094.
[11] *Id.*; PrudentRx, PrudentRx *Copay Program Frequently Asked Question*, https://www.pcsb.org/cms/lib/FL01903687/Centricity/Domain/200/Member%20FAQ-%20The%20PrudentRx%20Copay%20Program.pdf.
[12] *Id.*
[13] *Id.*
[14] *Id.*
[15] CareFactor, *PaydHealth Program*, (see attached PDF).

federal law except under very limited circumstances.[16]

Typically, financial assistance programs from charities and foundations have income-eligibility requirements that many patients do not qualify for; yet the vendor nevertheless applies for such assistance on the patients' behalf even if the application will ultimately be denied. Under alternative funding schemes, some program materials state "if a member does not qualify for a program then the medication will go back through the [PBM] and be processed under the plan['s] prescription benefit."[17] This back and forth can be confusing for consumers and cause delays between when a consumer is denied financial assistance and when the needed medication is processed back through the plan.[18] For consumers with complex and chronic conditions, delays in accessing medically necessary treatments can result in patients continuing to experience symptoms without relief; further deterioration of their health; and other long-term health consequences.

II. The FTC Has Authority To Regulate Unfair Trade Practices By Third-Party Companies Engaging in Non-EHB and Alternative Funding Programs

The FTC has authority to investigate, gather information on, and prosecute business conduct that affects commerce.[19] Moreover, the FTC only needs a "reason to believe" that a violation of the FTC Act has occurred to issue a complaint setting forth the alleged violation.[20] It is a violation of the FTC Act to engage in an "unfair or deceptive practices in or affecting commerce."[21] The FTC's scope of authority is broad and has limited exceptions to when conduct is outside its jurisdiction.

The FTC has explained that its authority can be limited based on the (1) businesses' status or (2) activity in question.[22] First, the FTC is prohibited from regulating certain entities such as banks, credit unions, and some non-profit organizations.[23] This exemption is *solely* based on the status of these organizations.[24] Alternative funding programs are not an exempt entity based on status.[25] Although some alternative funding programs identify themselves as "patient advocacy"

---

[16] *Id.*; FDA, *ElextRx and Health Solutions, LLC,* https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/electrx-and-health-solutions-llc-614251-03022023.
[17] CareFactor, *PaydHealth Program*, (see attached PDF).
[18] *Id.*
[19] FTC, *A Brief Overview of the Federal Trade Commission's Investigative, Law Enforcement, and Rulemaking Authority,* https://www.ftc.gov/about-ftc/mission/enforcement-authority .
[20] *Id.*
[21] FTC Act Section 5(a).
[22] FTC, *Opinion 03-1,* (Aug. 19, 2003), https://www.ftc.gov/legal-library/browse/advisory-opinions/opinion-03-1-1
[23] *Id.*
[24] *Id.*
[25] 15 U.S.C.§ 45 (a)(2).

companies,[26] a term typically associated with non-profits that support patients and caregivers,[27] these programs are for-profit companies.

Second, certain activities are exempt from the FTC's authority. Specifically, the McCarran-Ferguson Act exempts activities that constitute "the business of insurance" but only to the extent that such activities are regulated by state law.[28] This limitation is narrow and does not prohibit the FTC from exercising its authority over certain practices engaged in by insurance companies, but rather the limited conduct identified as the "business of insurance."[29] Moreover, in 2020 Congress passed the *Competitive Health Insurance Reform Act*, which removes the "business of insurance" exemption from federal anti-trust laws.[30] While the *Competitive Health Insurance Reform Act,* does still permit certain conduct to be exempt from the FTC's jurisdiction, the McCarran-Ferguson Act should not impair the FTC's ability to regulate these companies. Moreover, even if the McCarran-Ferguson Act applied, the conduct of non-EHB and alternative programs does not constitute the "business of insurance."

A. Non-EHB and Alternative Funding Schemes Do Not Constitute the Business of Insurance

In *Union Labor Life Insurance Co. v. Pireno*, the Supreme Court explained that, under the McCarran-Ferguson Act, a three-part factual inquiry is necessary to evaluate whether a particular activity constitutes the business of insurance.[31] Specifically, the alleged conduct must be assessed to determine if the activity (1) has the effect of transferring or spreading a policyholder's risk; (2) is an integral part of the policy relationship between the insurer and the insured; and (3) is a practice limited to entities within the insurance industry.[32] This inquiry requires a factual analysis of the activities in question, and no single element of the inquiry is determinative.[33]

1. Non-EHB and alternative funding schemes do not spread a policyholder's risk

In making its ruling in *Pireno,* the Supreme Court relied on *Group Life & Health Ins. Co. v. Royal Drug Co.*, 440 U. S. 205 (1979). In *Royal*, the petitioner was an insurance company that offered policies entitling insured persons to purchase prescription drugs for $2 each from any

[26] PR Newswire, *Leading Patient Advocate Slams AbbVie's Moves to Deny Vital Drugs to Needy Patients,* (May 23, 2023), https://www.prnewswire.com/news-releases/leading-patient-advocate-slams-abbvies-moves-to-deny-vital-drugs-to-needy-patients-301831464.html .
[27] Beacon for Rare Diseases, *What are patient advocacy groups?,* https://www.rarebeacon.org/rare-diseases/why-patient-groups-matter/
[28] FTC, *Opinion 03-1,* (Aug. 19, 2003), https://www.ftc.gov/legal-library/browse/advisory-opinions/opinion-03-1-1
[29] *Id.*; Union Labor Life Ins. Co. v. Pireno, 458 U.S. 119 (1982).
[30] Public Law No: 116-327, https://www.congress.gov/bill/116th-congress/house-bill/1418/text.
[31] *See* Union Labor Life Insurance Co. v. Pireno, 458 U.S. 119, 129 (1982).
[32] *Id.*
[33] *Id.*

pharmacy participating in a pharmacy agreement with the insurer.[34] Policyholders were also allowed to purchase prescription drugs from a nonparticipating pharmacy, but in the event they did they would have to pay full price for the drugs, and would be reimbursed by the insurer for only a part of that price.[35] Nonparticipating pharmacies filed an antitrust action alleging that the insurer and three participating pharmacies conspired to fix prescription drug prices and encourage policyholders to boycott nonparticipating pharmacies.[36] The trial court granted the insurer and participating pharmacies' motion for summary judgment on the ground that the agreements were exempt from the antitrust laws under the McCarran-Ferguson Act because the agreements were the "business of insurance," regulated by Texas. The Court of Appeals reversed. The Supreme Court ultimately held that the alleged conduct did not constitute the business of insurance.

In holding that the pharmacy agreements did not constitute the business of insurance, the Court reasoned that a core element of insurance is the underwriting or spreading of risk between the insurer and the policyholder.[37] However, the pharmacy agreements did not serve that purpose because they were merely arrangements for the purchase of goods and services by the insurer to enable the insurer to minimize its costs and maximize its profits.[38] The Court intended to make it clear that simply contracting with a health plan to help the health plan *as a business* would not qualify the contracting company to be engaging in the "business of insurance".

Similarly, non-EHB and alternative funding schemes are not mechanisms for underwriting or spreading risk. As explained in a Congressional Research Service Report,

> A function of insurance is to spread risk across a group of people. This is achieved in health insurance when people contribute to a common pool (risk pool) an amount at least equal to the expected cost resulting from use of covered services by the group as a whole. In this way, the actual costs of health services used by a few people are spread over the entire group. This is the reason why insuring larger groups is considered less risky—the more individuals participating in a risk pool, the less likely that the serious medical experiences of one or a few persons will result in catastrophic financial loss for the entire pool.[39]

Insurers understand that individuals prescribed specialty medications often have chronic, rare, or serious conditions, and therefore expect such patients to be more likely to utilize covered services compared to certain other groups in the risk pool (e.g., individuals without such

[34] 440 U.S. 205
[35] 440 U.S. 205.
[36] 440 U. S. 209.
[37] 440 U.S. 214 (citing *SEC v. Variable Annuity Life Ins. Co.,* 359 U.S. 65 (1959) (holding that when a company bears no risk it cannot be considered the business of insurance)).
[38] 440 U. S. 214.
[39] https://crsreports.congress.gov/product/pdf/RL/RL32237

conditions). Insurers spread this known risk across the risk pool when it calculates premiums to be charged to those enrolled in its health plans.

As such, non-EHB and alternative funding schemes are not used to spread risk; rather, their sole purpose is to contain insurers' costs, maximize insurers' profits, and drive the vendors' revenues. These programs utilize financial assistance available to enrollees to subsidize and reduce the financial burden of coverage among enrollees who tend to be higher utilizers of covered items and services. As noted by the Court in *Royal*, " . . . cost-savings arrangements may well be sound business practice, and may well inure ultimately to the benefit of policyholders in the form of lower premiums, but *they are not the business of insurance*."[40] (emphasis added).

Additionally, the vendors in these non-EHB and alternative funding schemes do not share any risk with the health insurers they partner with. These programs "procure high cost" specialty treatments through avenues such as manufacturer copay assistance programs; charitable assistance programs; or international importation.[41] When alternative funding programs source the medication from a third-party, any cost-sharing required is paid by the consumer and the health plan, not the alternative funding program. Moreover, if a medication is unable to be sourced from an alternative funding method, the medication is covered under the plan's regular pharmacy benefit. Thus, regardless of whether the alternative funding program procures the medication, the vendor maintains no risk because the plan not the alternative funding source will always pay the cost.

In sum, non-EHB and alternative funding programs do not serve the core purpose of insurance—spreading risk. Rather, like the pharmacy agreements in *Royal*, their primary purpose is to reduce plan costs and maximize profits by sourcing certain specialty medications from manufacturer copay assistance programs; charitable assistance programs; or through international importation.

2. Non-EHB and alternative funding schemes are not an integral part of the policy relationship between the insurer and the insured

In *Pireno,* Union Labor Life Insurance Co. (ULL) entered an arrangement with New York State Chiropractic Association (NYSCA), a chiropractic trade group, whereby NYSCA's Peer Review Committee would help ULL evaluate whether claims were reasonable and necessary. A chiropractor sued ULL after ULL frequently referred to the Committee for review his treatments of ULL policyholders and his charges for such treatments. The Committee sometimes deemed such treatments unreasonable or charges unreasonable. The chiropractor alleged that ULL had used the Committee's review process as the vehicle for a conspiracy to fix the prices that chiropractors would be permitted to charge for their services. The district court dismissed his claim, concluding that the peer review practices were the business of insurance and thus exempt from antitrust

[40] Union Labor Life Ins. Co. v. Pireno, 458 U.S. 119 (1982).
[41] ShaRX, *Sourcing Hope Through Advocacy,* https://www.sharxplan.com/about-sharx/ .

scrutiny. The court of appeals reversed.

The Supreme Court held that the peer review practices at issue were not the business of insurance. The Court rejected the argument that the peer review process directly involved the interpretation and enforcement of the insurance contract and therefore should satisfy part two of the three-part factual inquiry. Instead, the Court held that ULL's use of the Committee was not an integral part of the policy relationship between insurer and insured.

The Court compared the Committee arrangement to the pharmacy agreements at issue in *Royal.* In that case, the pharmacy agreements were "between [the insurer] and pharmacies engaged in the sale and distribution of goods and services other than insurance." Similarly, ULL's use of the Committee was "a separate arrangement between the insurer and third parties not engaged in the business of insurance." Furthermore, the Court stated:

> As in *Royal Drug*, petitioners have shown, at the most, that the challenged peer review practices result in 'cost savings to [ULL] which may be reflected in lower premiums if the cost savings are passed on to policyholders.' To grant the practices a[n] exemption on such a showing 'would be plainly contrary to the statutory language, which exempts the business of insurance and not the business of insurance companies.'[42]

The third-party vendors contracted by insurers under non-EHB and alternative funding schemes are not insurance companies themselves. As explained above, our understanding is that they are independent companies and not legal subsidiaries of any PBM or health plan. As such, these companies are similar to the Committee in *Pireno,* in that they provide services pursuant to an agreement that is distinct from the contract between the insurer and policyholder; with such services being intended to result in cost savings for the insurer. At the same time, non-EHB and alternative funding schemes are even less intimately tied to the policy relationship between the insurer and insured compared to a review committee that has the final say on coverage of a treatment, se these vendors simply use consumers' information (e.g., prescription type, name, type of insurance coverage, income) to seek out alternative sources of funding for specialty medications, including by applying for third-party financial assistance on consumers' behalf. As such, these activities are purely administrative and can be more accurately described as the business of insurance companies than the business of insurance.

3. Non-EHB and alternative funding schemes are not limited to parties within the insurance industry

Like the pharmacies in *Royal* and the review committee made up on chiropractors in *Pireno,* the vendors that contract with health insurers and PBMs to implement these non-EHB and alternative funding schemes are not insurers themselves. Indeed, certain alternative funding

[42] Union Labor Life Ins. Co. v. Pireno, 458 U.S. 119 (1982)

programs self-identify as a "non-insurance solution . . . to help procure . . . drugs . . . through multiple avenues."[43] Therefore, non-EHB and alternative funding schemes involving these independent third-party service providers are not limited to parties within the insurance industry.

However, even if these vendors can be considered parties within the insurance industry, this factor alone is not dispositive. As explained by the Supreme Court, no singular part of the three-part inquiry is determinative with respect to whether a practice is the business of insurance. Therefore, even if non-EHB and alternative funding schemes are deemed as involving only parties within the insurance industry, the other two factors analyzed above overwhelmingly support the conclusion that these schemes are not the business of insurance.

B. Alternative funding programs are not regulated by state law

There is no applicable state law that would prevent the FTC from acting on alternative funding programs' unfair business practices. While several states have passed insurance laws prohibiting copay accumulators, these laws do not apply to the practices at issue here.[44] State laws that prohibit copay accumulator programs simply require health insurers that collect pharmaceutical manufacturer and other third-party assistance on behalf of a consumer to count such assistance towards the consumer's deductible and annual out-of-pocket limit. These insurance laws do regulate how alternative funding programs market these schemes, contract with insurers and PBMs, or enroll consumers into copay assistance programs or other financial assistance programs.

.

III. Non-EHB and Alternative Funding Schemes Are Unfair Practices under the FTC Act

Under Section 5(a) of the FTC Act, the FTC has authority to prevent corporations from using "unfair or deceptive acts or practices in or affecting commerce."[45] For the FTC to have jurisdiction over the conduct at issue, the business practice must be either deceptive or unfair; it is not required to be both deceptive and unfair.[46] The FTC has authority to regulate unfair practices when the Commission has "reason to believe" a violation has occurred.[47] A practice is unfair where the practice (1) causes or is likely to cause substantial injury to consumers; (2) cannot be reasonably avoided by consumers; and (3) is not outweighed by countervailing benefits to consumers or competition.[48]

Based on our analysis, non-EHB and alternative funding schemes are unfair as defined by

---

[43] ShaRX, *About Us,* https://www.sharxplan.com/about-sharx/.
[44] Aimed Alliance, *Copay Accumulators,* https://aimedalliance.org/copay-accumulators-enacted-laws/ .
[45] FTC, A Brief Overview of the Federal Trade Commission Investigative, Law Enforcement, and Rulemaking Authority, https://www.ftc.gov/about-ftc/mission/enforcement-authority .
[46] *Id.*
[47] *Id.*
[48] FTC, Federal Trade Commission Act: Section 5: Unfair or Deceptive Acts or Practices, at p. 8, https://www.federalreserve.gov/boarddocs/supmanual/cch/ftca.pdf

the FTC Act. Therefore, we urge the FTC to investigate these practices and take appropriate enforcement action to protect consumers.

A. Non-EHB and alternative funding schemes cause or are likely to cause substantial injury to consumers

A substantial injury occurs when a consumer experiences a genuine harm.[49] The FTC applies an objective test to determine if a genuine harm has occurred.[50] Emotional distress is usually insufficient, however, a financial injury will satisfy the genuine harm requirement.[51]

Non-EHB and alternative funding schemes cause consumers to experience financial losses. When a consumer is forced to enroll in the third-party company program under either a non-EHB or alternative funding scheme, any financial assistance the consumer receives will not count towards meeting their deductible or annual out-of-pocket limit.[52] As a result of the assistance not being counted towards the consumer's deductible or annual out-of- pocket limit, the individual is required to pay thousands of additional dollars before they reach their deductible and annual out-of-pocket limit. In other words, because the assistance is accepted for the plan's benefit and not counted towards the consumers deducible or annual out- of-pocket limit, consumers lose the full financial benefit of the financial assistance. As such, these schemes cause consumers to experience genuine financial harm.

B. Consumers cannot reasonably avoid enrolling in these programs

The FTC has found that a practice is not unfair if a consumer can reasonably avoid the injury.[53] However, a practice may be considered unfair if the consumer is coerced into purchasing unwanted products or services.[54]

As explained in Section I above, non-EHB and alternative funding schemes are structured to coerce consumers to enroll in the third-party company's program. These schemes present consumers with two bad options, either of which leads to financial injury over time. If consumers enroll in these programs, they receive their medications at a lower upfront cost; however, their financial assistance will be collected for the benefit of the plan and not count towards their deductible or annual out-of-pocket limit. As a result, they will have to pay significantly more out

[49] *Id.*
[50] FTC, The FTC's Use of Unfairness Authority: Its Rise, Fall, and Resurrection, https://www.ftc.gov/news-events/news/speeches/ftcs-use-unfairness-authority-its-rise-fall-resurrection.
[51] *Id.*
[52] SaveonSP, Employers FAQ, https://saveonsp.com/employers/; PrudentRx, The PrudentRx Copay Program Frequently Asked Questions, at p. 1, https://membershealthplannj.com/wp-content/uploads/2020/11/Member-FAQ_PrudentRx-Copay-Program.pdf; CareFactor, PaydHealth Program, https://www.wchcs.org/Downloads/Paydhealth%20general%20letter%20for%20EMPLOYEES.pdf.
[53] FTC, Federal Trade Commission Act: Section 5: Unfair or Deceptive Acts or Practices, at p. 8, https://www.federalreserve.gov/boarddocs/supmanual/cch/ftca.pdf .
[54] *Id.*

of pocket before these amounts are satisfied. If they do not enroll, then they are required to pay between a 30 to 70 percent coinsurance and, on top of that, the coinsurance *still will not* count towards their deductible or annual out-of-pocket limit.[55] As a result, most consumers are forced to choose the lesser of two evils—enrollment. In short, there is no reasonable way for consumers who are prescribed a specialty medication that is managed by a third-party program to avoid financial injury.

C. Allowing non-EHB and alternative funding schemes to collect financial assistance and not count this assistance towards deductibles and annual out-of- pocket limits does not benefit consumers or competition

Lastly, for a practice to be unfair, its overall net effect on consumers must be negative, and any harm incurred by the consumer cannot be outweighed by an alternative benefit to consumers or competition.[56] Non-EHB and alternative funding schemes do not have an underlying benefit to consumers or competition that would outweigh the net harm experienced by consumers forced to enroll in these programs.

While plans, PBMs, and the partnering companies operating these schemes would likely argue that consumers receive a net benefit because they receive their medications for a low-cost or for $0, this argument ignores the fact that in the larger picture of the plan year, these programs cost patients thousands of additional dollars per year as they work to meet their deductible and annual out-of-pocket limit. For example, the AIDS Institute estimated that when an individual patient is subject to a copay accumulator program, the individual can pay over $7,000 a year in *additional* health care costs.[57] As a result, the short term benefit of paying less at the pharmacy counter for a specialty drug does not outweigh the additional financial pressures that consumers experience as a result of not having assistance counted toward their deductibles and annual out-of-pocket limits. As such, the long-term financial harm outweighs any short-term benefit under these programs, and the overall net impact of these programs is negative for consumers.

Moreover, these programs can also place consumers in a legally precarious position with pharmaceutical companies and federal agencies. For instance, Johnson & Johnson recently filed a lawsuit against SaveOnSP, a company that implements non-EHB programs. In its complaint, Johnson & Johnson alleges that the SaveOnSP program interferes with the contractual relationship

---

[55] SaveonSP, Employers FAQ, https://saveonsp.com/employers/; PrudentRx, The PrudentRx Copay Program Frequently Asked Questions, at p. 1, https://membershealthplannj.com/wp-content/uploads/2020/11/Member-FAQ_PrudentRx-Copay-Program.pdf; CareFactor, PaydHealth Program, https://www.wchcs.org/Downloads/Paydhealth%20general%20letter%20for%20EMPLOYEES.pdf; PaydHealth, Select Drugs and Product Program Questions & Answers, https://mennonitevillage.org/wp-content/uploads/2021/03/Select-Drugs-and-Products-Program_HR-FAQ-2020-03.pdf.
[56] FTC, *The FTC's Use of Unfairness Authority: Its Rise, Fall, and Resurrection* (May 30, 2003), https://www.ftc.gov/news-events/news/speeches/ftcs-use-unfairness-authority-its-rise-fall-resurrection.
[57] AIDS Institute, *Discriminatory Copay Policies Undermine Coverage for People with Chronic Illness,* at p. 9 (2023), https://aidsinstitute.net/documents/TAI-Report-Copay-Accumulator-Adjustment-Programs-2023.pdf.

between Johnson & Johnson and the consumers to whom it provides copay assistance. Specifically, Johnson & Johnson argues that its patient assistance program prohibits consumers from enrolling in any other assistance program, and that SaveOnSP forces consumers to violate this agreement by requiring consumers to enroll in the SaveOnSP program which it considers another assistance program.[58] While Johnson & Johnson has not yet sued any consumer who participates in its copay assistance programs for breach of contract, programs like SaveOnSP's open consumers up to this possibility. Additionally, in its recent lawsuit against Payer Matrix, AbbVie has alleged that Payer Matrix uses consumer information to fraudulently apply to AbbVie's copay assistance and charitable assistance program, despite their financial assistance programs explicitly prohibiting the use alternative funding programs.[59] By using consumers' information to apply to these programs, these alternative funding programs create a risk that charitable assistance programs could bring legal claims against consumers for participating in such schemes. Finally, alternative funding programs that import prescription drugs from outside of the United States could subject consumers to violations of federal law. Federal law prohibits the importation of prescription medications from outside the United States, with limited exceptions.[60] The FDA has stated these programs are not a permissible exception to the general prohibition on importation. As such, alternative funding programs create legal risk for consumers when they import prescription drugs on consumers' behalf.[61]

In summary, we strongly believe that non-EHB and alternative funding schemes satisfy the definition of an unfair practice under the FTC Act. Therefore, Aimed Alliance encourages the FTC to take appropriate enforcement action against these programs.

IV. Conclusion

In conclusion, we would greatly appreciate an opportunity to meet with your office and discuss these unfair trade practices that impair patient access to necessary treatments. Thank you for your time and consideration.

Sincerely,
Ashira Vantrees
Counsel

---

[58] Johnson & Johnson v. SaveOnSP, *Complaint*, https://www.drugchannelsinstitute.com/files/22-cv-02632.pdf.
[59] AbbVie v. Payor Matrix, *Complaint*, https://drugchannelsinstitute.com/files/Abbvie-vs-PayerMatrix-23-cv-02836.pdf.
[60] Aimed Alliance, *Letter to FDA Importation of Prescription Drugs from Outside the United States and Canada,* https://aimedalliance.org/wp-content/uploads/2023/03/Aimed-Alliance-Letter-to-FDA-February-2023.pdf.
[61] Food and Drug Administration, *Warning Letter: Elect Rx and Health Solutions LLC.,* https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/electrx-and-health-solutions-llc-614251-03022023#:~:text=ElectRx%20contracts%20with%20public%20and,enrolled%20employees%20with%20prescription%20drugs.