THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

AbbVie Inc., *Plaintiff*, v. Payer Matrix, LLC, *Defendant*.	Civil Action No. 1:23-cv-02836 Hon. Jorge L. Alonso Hon. Magistrate Judge Young B. Kim

PLAINTIFF ABBVIE INC.'S NOTICE OF SUPPLEMENTAL EVIDENCE IN SUPPORT OF ITS REQUEST FOR AN EXPEDITED PRELIMINARY INJUNCTION BRIEFING SCHEDULE AND HEARING

I. Introduction

1. In addition to continuing its schemes against AbbVie's patient assistance programs, AbbVie recently discovered that Payer Matrix is now illegally importing non-FDA approved versions of specialty medicines, including AbbVie's medicines, from outside the U.S. and shipping the medicines to U.S. patients. The FDA has made it clear that this practice is illegal and dangerous for the patients who are receiving the non-FDA approved versions of the medicines because the medicines could be contaminated, counterfeit, or improperly labeled, stored, or shipped. Payer Matrix's importation scheme and its related false advertising also create a substantial risk of reputational damage to AbbVie. Accordingly, AbbVie respectfully submits this notice of supplemental evidence in further support of its request for an expedited preliminary injunction briefing and hearing schedule in the event the Court grants AbbVie's Motion for Leave to File a First Amended Complaint ("Motion for Leave"). (*See* Dkts. 205-206.)

II. Procedural History

2. On May 5, 2023, AbbVie filed this lawsuit against Payer Matrix, seeking both monetary damages and injunctive relief. The injunctive relief seeks to preclude Payer Matrix from applying its "alternate funding" program to Skyrizi, Rinvoq, Humira, and any other AbbVie therapies. (Dkt. 1.)

3. On May 31, 2023, AbbVie filed a motion for preliminary injunction against Payer Matrix due to Payer Matrix's continuing fraudulent conduct against AbbVie. (Dkt. 21.) AbbVie also moved for limited, expedited discovery to support its preliminary injunction motion. (Dkt. 39.)

4. On June 24, 2023, Judge Kim granted AbbVie's motion for expedited discovery and set a discovery cutoff date of September 20, 2023. (Dkts. 54, 71.)

5. On October 11, 2023, AbbVie filed its updated brief in support of its motion for preliminary injunction, which incorporated evidence obtained during expedited discovery. (Dkt. 107.) On November 29, 2023, Payer Matrix filed its response. (Dkt. 149.) AbbVie's reply was due on December 20, 2023. (Dkt. 130.) A preliminary injunction hearing was scheduled for January 18, 2024. (*Id.*)

6. On December 4, 2023, this Court requested evidence to ensure there was complete diversity between the parties. (Dkt. 154.) Payer Matrix subsequently revealed for the first time that the administrative trustee for its two member trusts is based in Delaware, where AbbVie is also a citizen. This raised a complex legal question about diversity jurisdiction, resulting in the postponement of the preliminary injunction hearing while the parties engaged in jurisdictional discovery.[1] (*See* Dkt. 162.) The parties completed jurisdictional discovery in late February 2024.

[1] The Court also struck AbbVie's due date for filing its reply brief in support of its preliminary injunction motion. (Dkt. 162.)

7. Although AbbVie concluded the evidence obtained during jurisdictional discovery supported diversity jurisdiction, it proposed amending the complaint to add federal claims under RICO and the Lanham Act based on the evidence Payer Matrix produced during expedited discovery. As a result of AbbVie's expressed intent to file a proposed First Amended Complaint, this Court denied Payer Matrix's pending motion to dismiss the original Complaint and AbbVie's pending motion for preliminary injunction without prejudice to refiling. (Dkt. 172.)

8. On March 4, 2024, AbbVie filed its motion to amend the Complaint and the proposed First Amended Complaint. (Dkt. 178.) Payer Matrix opposed the filing. (Dkt. 196.) The issue was fully briefed on April 15, 2024. (Dkt. 197.)

9. On April 15, 2024, AbbVie also moved to unseal the proposed First Amended Complaint. (Dkt. 200.) Payer Matrix opposed the filing, and the issue was fully briefed on May 6, 2024. (Dkts. 207, 208.)

10. On April 18, 2024, the parties filed their Joint Status Report. AbbVie requested an expedited preliminary briefing and hearing schedule if the Court granted its motion to amend. Payer Matrix proposed waiting to address the preliminary injunction until after the parties briefed Payer Matrix's planned motion to dismiss the First Amended Complaint. (*See* Dkt. 205.)

11. On April 22, 2024, the Court stated that it would consider the parties' proposed case management schedules, including the preliminary injunction briefing schedule, in ruling on AbbVie's Motion for Leave to file a First Amended Complaint. (Dkt. 206.)

12. The evidence described herein, which relates to Payer Matrix's new importation scheme, was obtained recently from issuing public information requests to certain plan sponsors who participate in Payer Matrix's program. This evidence further supports AbbVie's need for an

expedited preliminary injunction briefing and hearing schedule to stop Payer Matrix's misconduct during the course of what is anticipated to be lengthy litigation.[2]

13. Throughout the litigation to date, Payer Matrix has continued to engage in illegal methods of utilizing AbbVie's medicines in its "alternative funding" program. It merely changes its tactics in an attempt to evade detection or when a particular tactic becomes less effective. In doing so, it continues to cause irreparable harm to AbbVie's reputation, drug brands, and customer goodwill.

III. New Evidence of Illegal Importation

14. The recently obtained evidence reveals that Payer Matrix is now marketing a new "alternative funding" option to its plan sponsor clients and specialty drug patients that involves Payer Matrix and its partner "RxFree4me" coordinating the illegal importation of purported AbbVie medicines and other pharmaceutical manufacturers' medicines from outside the United

[2] On July 25, 2024, AbbVie sent a letter to Payer Matrix regarding the importation scheme, requesting that Payer Matrix agree to cease and desist from making false and misleading representations to AbbVie patients about imported medicines. AbbVie also requested that Payer Matrix provide additional information to AbbVie about its importation program, including the names of all pharmacies located outside the U.S. that have shipped medicines to AbbVie patients. On August 9, Payer Matrix provided a responsive letter that confirmed that one of its partners does source medicines internationally but denied that (1) the medicines are illegally imported, (2) regulatory safeguards are being circumvented, and (3) its advertisements are false and misleading. Payer Matrix provided no further explanation for its positions, stating that it "will not respond to each unfounded accusation" and that it "will not 'cease and desist' from engaging in lawful activities." Payer Matrix also declined AbbVie's request to provide additional information about the importation program, stating it will not provide "free discovery" at this stage of the proceedings. Additionally, Payer Matrix took the position that AbbVie is not entitled to obtain publicly available records about Payer Matrix's program due to the discovery stay in this case. Payer Matrix's position contradicts well-established Seventh Circuit legal precedent that draws a distinction between discovery and investigation and makes clear that litigation does not limit parties' access to public records. *See, e.g.*, *Am. Bank v. City of Menasha*, 627 F.3d 261, 265 (7th Cir. 2010) ("The word 'discovery' is not a synonym for investigation. . . . The case law uniformly refuses to define requests for access to federal or state public records under public records laws . . . as discovery demands, even when . . . the request is made for the purpose of obtaining information to aid in a litigation and is worded much like a discovery demand."); *see also Barmore v. City of Rockford*, No. 09 CV 50236, 2014 WL 12791639, at *6 (N.D. Ill. Aug. 20, 2014) (finding that FOIA requests may be issued after the court-ordered discovery cutoff date because there is a distinction between "discovery" and "investigation").

States at reduced prices and falsely and misleadingly representing to the patients and their doctors that the medicines are government-approved versions of AbbVie medicines.[3]

15. Payer Matrix offers this alternate funding option when it is unable to maneuver patients into AbbVie's or any other pharmaceutical manufacturers' patient assistance programs. It is a backup option that Payer Matrix has implemented in light of AbbVie's and other pharmaceutical manufacturers' efforts to stop Payer Matrix's fraud on their patient assistance programs, similar to the drug switching scheme addressed in the Complaint and the proposed First Amended Complaint. (*See* Dkt. 1, ¶¶ 128-131; Dkt. 180, ¶¶ 375-413.)

16. Like its other schemes, Payer Matrix charges its plan sponsor clients a percentage of their "savings" from the illegally imported medicines as a "cost avoidance fee." Additionally, preliminary information indicates that Payer Matrix may earn additional revenue by marking up the price of the illegally obtained medicines.

17. Payer Matrix made its expedited discovery production in early August 2023. This production included emails that indicated Payer Matrix's leadership team and RxFree4me's President were strategizing about other alternate funding options involving AbbVie's drugs in light of the difficulties Payer Matrix began having in 2023 with fraudulently maneuvering ineligible patients into AbbVie's free-drug program. However, the meaning of the emails did not become clear, nor was it confirmed that Payer Matrix was moving forward with any such plans, until now.

18. Payer Matrix's new marketing materials reveal that it is promoting and facilitating the illegal importation of specialty drugs with RxFree4me. For example, on July 9, 2024, one of Payer Matrix's plan sponsor clients received materials advertising Payer Matrix's and

[3] AbbVie does not yet have access to all relevant evidence and information, and therefore, the information set forth herein is preliminary and subject to change as AbbVie learns more through further investigation and, eventually, discovery.

RxFree4me's new "International Drug Sourcing" program. The advertisement stated in part, "Payer Matrix is proud to announce a new vendor partner, RxFree4me. For those clients who are interested in international sourcing, Payer Matrix can help facilitate the coordination of services with RxFree4me as it is part of our advocacy to find the best funding solutions." The advertisement then describes the six-step international sourcing process that Payer Matrix's "Care Coordinators" execute through outreach to patients and their doctors. *See* **Exhibit A** at 23. The advertisement further stated that RxFree4me sources from 23 Canadian pharmacies. ***Id.*** at 24. It is not yet clear whether these purported Canadian pharmacies obtain their medicines from Canada or other countries outside the U.S.[4]

19. Payer Matrix's importation scheme violates multiple provisions of the Federal Food, Drug, and Cosmetic Act ("FDCA"), Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified at 21 U.S.C. § 301 *et seq.*), including sections 301(d) and 505(a) (prohibiting the introduction of unapproved new drugs into interstate commerce in the U.S., including unapproved drugs from foreign sources), and section 301(a) (prohibiting the introduction of misbranded drugs into interstate commerce). *See* **Exhibit B** at 3-4; **Exhibit C** at 2-4 (summarizing the unapproved new drug and misbranded drug provisions of the FDCA); *see also* FDCA, § 801(d)(1) (prohibiting the importation of drugs manufactured outside the U.S. for commercial use unless certain exceptions apply); 42 U.S.C. § 262(a) (stating that no person shall introduce or deliver for introduction into interstate commerce any biological product unless certain conditions are met).

[4] Other plan sponsors have produced marketing materials via public records requests that refer to Payer Matrix's new Enhanced Care Management Program ("ECMP"), which it offers in partnership with a company called Pharma Strategies. One of these plan sponsors identified the ECMP marketing materials as materials for Payer Matrix's drug importation program. Although AbbVie's cease and desist letter to Payer Matrix addressed the importation of medicines from outside the United States, Payer Matrix's response to AbbVie's cease and desist letter stated that Pharma Strategies sources *prescriptions* in the U.S. and uses a U.S.-based pharmacy. Payer Matrix's response did not specifically address whether Pharma Strategies and its partner pharmacy source, or facilitate the sourcing of, *medicines* from outside the U.S.

20. The FDA has warned other businesses engaged in similar conduct that importing non-FDA approved specialty drugs from Canada and other countries is illegal and creates health risks for patients. *See* **Exhibits B-C**. Specifically, the FDA has explained that these illegally imported drugs circumvent regulatory safeguards, which creates risks that the drugs may be contaminated, counterfeit, contain varying amounts of active ingredients, or shipped or stored improperly. *See* **Exhibit C** at 4. This risk is elevated for temperature-sensitive drugs, like Skyrizi and Humira, that must be kept cool during shipping. Even if the imported drugs are shipped with cooling systems, international shipping delays can result in the cooling systems not lasting for the length of the shipping delay.

21. Payer Matrix is well aware of the illegality of importing the specialty drugs and the risks it creates for patients. In fact, in May 2023, prior to its decision to engage in illegal importation, Payer Matrix's Chief Business Officer told AIS Health during an interview that "Payer Matrix will not source any product outside the United States, due to several reasons, including regulatory compliance, risk and the additional burden this places on the member." Angela Maas, *Before AbbVie Lawsuit, Payer Matrix's CBO Defended Company's Business Model*, AIS Health (May 18, 2023), https://www.mmitnetwork.com/aishealth/spotlight-on-market-access/before-abbvie-lawsuit-payer-matrixs-cbo-defended-companys-business-model-2/ [https://perma.cc/2JWR-XJUX].

22. Despite the illegality of the practice, the well-known risks to patients, and the FDA's warnings to similar businesses, Payer Matrix misleads patients and doctors to believe that the medicines are legally obtained and that there are no differences between the FDA-approved AbbVie medicines the patients were receiving before joining Payer Matrix's program and the non-FDA approved medicines they receive after joining Payer Matrix's program. Specifically, Payer

Matrix falsely represents to patients and their doctors that the Canadian pharmacies it uses are "licensed," "authorized," and "government approved." *See* **Exhibit D**, opening paragraph. Payer Matrix also misleadingly represents that it will retain a "licensed physician" on the patients' behalf (***id.*** ¶¶ 4, 10), apparently referring to a Canadian physician who will issue a new Canadian prescription and package the product for the patient. Additionally, Payer Matrix falsely and misleadingly advertises to patients that their medicines will remain the same (***id.*** ¶ 9), even though they will now be receiving non-FDA versions of purported AbbVie medicines. Finally, Payer Matrix intentionally omits the material information that international shipping delays may cause delays in the patients' receipt of medicines, including, for example, U.S. Customs' holding of the medicine packages.

23. Contrary to Payer Matrix's "government approved" representations, the FDA has issued the following warning about illegally imported drugs:

> The substitution of FDA-approved prescription drugs with unapproved drugs poses significant health risks to U.S. consumers. . . . [S]ourcing drugs from uninspected, unregulated, and/or unknown supply chains can result in serious health consequences, especially in vulnerable patient populations, which may receive medications that are adulterated and are not shipped and/or stored properly.

Exhibit C at 2, 4.

24. Accordingly, Payer Matrix's false and misleading representations and marketing of its imported medicines, including marketing them as government-approved versions of AbbVie's medicines, creates a likelihood of reputational damage to AbbVie and further supports AbbVie's claims against Payer Matrix, including its claims under the Lanham Act and the Illinois Uniform Deceptive Trade Practices Act and for tortious interference with business opportunity. *See e.g., Par Sterile Prods., LLC v. Fresenius Kabi USA LLC*, No. 14 C 3349, 2015 WL 1263041, at *4-5,

7 (N.D. Ill. March 17, 2015) (Alonso, J.) (denying motion to dismiss Lanham Act and related state law claims based on alleged false advertising that a drug was FDA-approved).

25. In addition to Payer Matrix's new importation scheme, AbbVie continues to catch efforts by Payer Matrix to maneuver its clients' members into AbbVie's patient assistance program.

26. Payer Matrix has proven time and time again that nothing short of a court order will stop its efforts to improperly profit from AbbVie's medicines and utilize these medicines in its "alternate funding" program through illegal methods.

WHEREFORE, AbbVie respectfully submits this Notice of Supplemental Evidence in further support of its request for an expedited preliminary injunction briefing schedule.

Dated: August 12, 2024

Respectfully submitted,

/s/ *Valarie Hays*

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Counsel for Plaintiff AbbVie Inc.

CERTIFICATE OF SERVICE

I, Valarie Hays, one of the attorneys for Plaintiff AbbVie Inc., hereby certify that on August 12, 2024, I caused the foregoing **PLAINTIFF ABBVIE INC.'S NOTICE OF SUPPLEMENTAL EVIDENCE IN SUPPORT OF ITS REQUEST FOR AN EXPEDITED PRELIMINARY INJUNCTION BRIEFING SCHEDULE AND HEARING** to be filed through the CM/ECF system of the United States District Court for the Northern District of Illinois thereby serving all counsel of record electronically.

By: */s/ Valarie Hays*
Valarie Hays

EXHIBIT A

INTERNATIONAL DRUG SOURCING

Payer Matrix

RxFree4me

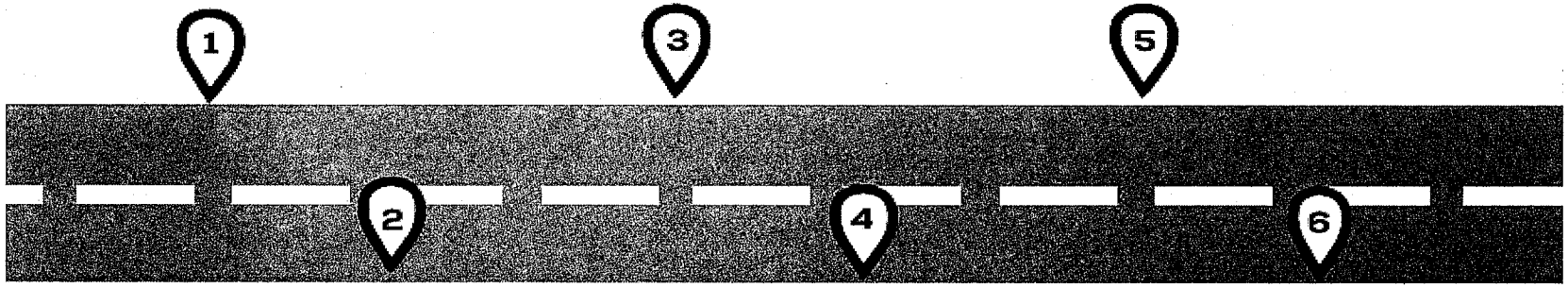
International Sourcing

Payer Matrix is proud to announce a new vendor partner, RxFree4me. For those clients who are interested in international sourcing, Payer Matrix can help facilitate the coordination of services with RxFree4me as it is part of our advocacy to find the best funding solutions. RxFree4me has years of experience reducing prescription drug costs for health plans. The simple implementation process requires no contract, no vendor changes, and no upfront fees and can be completed in as little as 24 hours.

Initial Assessment
The Payer Matrix team assesses member eligibility.

Consent
Member agrees to the program by signing the authorization form.

Scheduling Shipment
Member calls RxFree4me directly to schedule shipment of medication.



Communication
A care coordinator (CC) will communicate eligibility to the member and discuss next steps.

Prescription Transfer
A CC works with the member's provider to seamlessly send the prescription to RxFree4me.

Prescription Delivery
Medication typically arrives within 3-5 business days, after presciption is provided.

INTERNATIONAL DRUG SOURCING

About RxFree4me

- **RxFree4me Mission**
  - *To provide our members and clients access to necessary medication at the lowest possible cost while making the process as simple as possible.*
- **14 Years of Cost Reduction History**
  - *Over 1.2 Million Members served.*
- **Stop Loss Discounts**
  - *Offers discounts for diabetic medications, most brand drugs, and more.*
- **24/7 Member Support**
  - *Benefit from 24/7 customer support with no agreement required between RxFree4me and the client.*
- **Flexible process and 24-hr implementation**
  - *Members receive their same brand medications delivered to their door for a $0 copay.*
- **Sourcing from 23 Canadian pharmacies**

EXHIBIT B

WARNING LETTER

ElectRx and Health Solutions, LLC

MARCS-CMS 614251 — MARCH 02, 2023

Product:

Drugs

Recipient:

ElectRx and Health Solutions, LLC

United States

Issuing Office:

Center for Drug Evaluation and Research | CDER

United States

FROM: The United States Food and Drug Administration

RE: Causing the Introduction of Unapproved and Misbranded Drugs into Interstate Commerce

DATE: March 2, 2023

WARNING LETTER

The United States (U.S.) Food and Drug Administration (FDA) has observed that ElectRx and Health Solutions, LLC ("ElectRx") causes the introduction of unapproved new drugs and misbranded drugs into interstate commerce in violation of sections 301(a), 301(d), and 505(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) [21 U.S.C. §§ 331(a), 331(d), and 355(a)].

There are inherent risks to consumers who purchase unapproved new drugs and misbranded drugs. Unapproved new drugs do not carry the same assurances of safety and effectiveness as those drugs subject to FDA oversight. Drugs that have circumvented regulatory safeguards may be contaminated, counterfeit, contain varying amounts of active ingredients, or contain different ingredients altogether. Accordingly, FDA requests that ElectRx cease causing the introduction of unapproved and misbranded drugs for sale to U.S. consumers. This is critical to shielding the American public from potential harm.

ElectRx contracts with public and private sector employers throughout the U.S. to provide select prescription drugs to employees. ElectRx acts as a broker between foreign pharmacies and the employee-sponsored health insurance plans to provide enrolled employees with prescription drugs. ElectRx accepts the employee's U.S. prescription and facilitates the dispensing of the prescription drug by a foreign pharmacy. The foreign pharmacy then ships the drug directly to the employee in the U.S. Invoices for prescription drugs purchased through ElectRx state, "You may have noticed that the medication which has been shipped to you is different

in name or presentation to that which you may have received in the past. IF YOU HAVE ORDERED A BRANDED DRUG the name may appear different to the one you are used to. The reason for this is that you have been supplied internationally branded product and for various reasons drug companies market their products under different names and packaging in different countries." Additionally, several of ElectRx's formularies include the statement, "Please note that the medications ordered from the ElectRx formulary are sourced internationally, and may be marketed with a different name or a different strength to medications in the USA." These statements demonstrate that ElectRx has designed its business to operate in a manner that substitutes the FDA-approved drugs prescribed by the U.S. healthcare provider with unapproved drugs. This distribution scheme is particularly concerning, as employees are likely inclined to trust that they will receive safe and effective drugs through their employer's "insurance" plan and may not question their legitimacy.

The substitution of FDA-approved prescription drugs with unapproved drugs poses significant health risks to U.S. consumers. For example, ElectRx offers certain drugs on its formularies for which the FDA-approved version is subject to a Risk Evaluation and Mitigation Strategy (REMS)[1] program, has a narrow therapeutic index (NTI)[2], is a controlled substance, and/or is indicated to treat serious conditions such as HIV, cancer, or hepatitis. ElectRx also offers maintenance medications that are indicated for conditions such as high blood pressure, high cholesterol, and acid reflux. Substituting an unapproved drug for the FDA-approved drug prescribed by a patient's healthcare practitioner can negatively affect patient outcomes because the healthcare practitioner may unknowingly make subsequent treatment decisions based on the patient's response to the unapproved drug. This can also cause potentially dangerous drug interactions with the patient's other medications. This is of particular concern for drugs subject to REMS programs and NTI drugs. Moreover, the substitution of FDA-approved prescription drugs with unapproved versions that may have substantially different risk profiles can pose serious health risks to consumers, especially in vulnerable patient populations that suffer from serious conditions.

Prescription medicines that are approved for use in the United States have been reviewed by FDA for safety, effectiveness, and quality and are subject to FDA-regulated manufacturing controls and FDA inspections of manufacturing facilities. Unapproved foreign drugs circumvent these safeguards, which are designed to protect patients. Unapproved drugs do not have the same assurance of safety and efficacy as drugs subject to FDA oversight and may be subpotent, superpotent, or adulterated with unknown active ingredients. Treatment with drugs that may be subpotent, superpotent, or adulterated can lead to drug resistance and/or therapeutic failures, and jeopardize the effectiveness of alternative drug therapies on patient outcomes.

FDA has also established processes to recall unsafe, substandard, and poor-quality drugs within the legitimate U.S. drug supply chain. No such safeguards exist for unapproved drugs illegally distributed in the U.S. from foreign sources such as those provided through ElectRx. In addition, the unapproved versions of FDA-approved drugs offered by ElectRx may have different trade names and/or strengths in their labeling than their FDA-approved counterparts. Such differences can cause patient confusion and lead to medication errors.

Examples of drugs offered on ElectRx's formularies and a general description of their respective indications are depicted in the table below. These include drugs that are for vulnerable patient populations with serious medical conditions. This is not an exhaustive list of the drugs offered on ElectRx formularies.

Advair Diskus (asthma, COPD)	Invirase (HIV)
Afinitor (cancer)	Opsumit (pulmonary arterial hypertension)
Astagraf XL (organ rejection)	Tasigna (cancer)

Descovy (HIV)	Truvada (HIV)
Epivir-HBV (hepatitis)	Vemlidy (hepatitis)
Gilotrif (cancer)	Vimpat (epilepsy)
Inlyta (cancer)	Zortress (organ rejection)

Unapproved New Drugs:

As described above, 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. Because these products are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease and/or affect the structure or function of the body, these products are drugs within the meaning of section 201(g)(1) of the FD&C Act [21 U.S.C. § 321(g)(1)]. These products are also new drugs as defined by section 201(p) of the FD&C Act [21 U.S.C. § 321(p)] because they are not generally recognized as safe and effective for their labeled uses. With certain exceptions that do not apply here, new drugs may not be introduced or delivered for introduction into interstate commerce without prior approval from FDA, as described in section 505(a) of the FD&C Act [21 U.S.C. § 355(a)]. No FDA-approved applications pursuant to section 505 of the FD&C Act [21 U.S.C. § 355] are in effect for these products. Accordingly, their introduction or delivery for introduction into interstate commerce violates sections 301(d) and 505(a) of the FD&C Act [21 U.S.C. §§ 331(d) and 355(a)].

For example, one of the drugs provided via ElectRx is tacrolimus extended-release capsules, manufactured by Astellas and marketed as "Advagraf." While there are FDA-approved versions of tacrolimus extended-release capsules on the market in the U.S., including "Astagraf XL" manufactured by Astellas, there are no approved drug applications pursuant to section 505 of the FD&C Act in effect for the "Advagraf" provided by ElectRx. Extended-release capsules of tacrolimus administered orally are NTI drugs. FDA-approved tacrolimus extended-release capsules are indicated for the prophylaxis of organ rejection in kidney transplant patients in combination with other immunosuppressants in adult and pediatric patients who can swallow capsules intact. FDA-approved tacrolimus extended-release capsules bears a boxed warning, commonly referred to as a "black box warning," which is the strongest warning FDA requires, indicating that the drug carries a significant risk of serious or even life-threatening adverse effects. The boxed warning addresses an increased risk for developing serious infections and malignancies with tacrolimus or other immunosuppressants that may lead to hospitalization or death, and increased mortality in female liver transplant patients.

Misbranded Drugs:

Prescription drugs, as defined in section 503(b)(1) of the FD&C Act [21 U.S.C. § 353(b)(1)] include those that, because of their toxicity or other potentiality for harmful effect, and/or the method of their use, and/or the collateral measures necessary for their use, are not safe for use except under supervision of a practitioner licensed by law to administer them. Prescription drugs, as defined in section 503(b)(1)(A) of the FD&C Act, can be used safely only at the direction, and under the supervision, of a licensed practitioner. Because ElectRx advises consumers that their U.S. prescriptions are being filled with less expensive, foreign drugs, ElectRx concedes that these drugs are prescription drugs.

A drug is misbranded under section 502(f)(1) of the FD&C Act [21 U.S.C. § 352(f)(1)] if the drug fails to bear adequate directions for its intended use(s). "Adequate directions for use" means directions under which a layperson can use a drug safely and for the purposes for which it is intended (21 CFR 201.5). The drugs offered by ElectRx are prescription drugs intended to treat conditions that are not amenable to self-diagnosis and treatment by persons who are not medical practitioners. Therefore, adequate directions for use cannot be written for these drugs, and they must qualify for one of the exemptions to section 502(f)(1) to avoid being misbranded. The exemption to section 502(f)(1) found at 21 CFR § 201.100 does not apply to unapproved new drugs because that exemption requires that such drugs bear "the labeling authorized by the approved new drug application." In addition, because these drugs are not approved in the U.S., they are also not exempt under 21 CFR 201.115(a) from the requirements of section 502(f)(1) of the FD&C Act. Because none of the exemptions to section 502(f)(1) apply, these drugs are misbranded under section 502(f)(1).

By causing these products to be shipped to U.S. consumers, ElectRx is causing the introduction of misbranded drugs into interstate commerce in violation of section 301(a) of the FD&C Act [21 U.S.C. § 331(a)].

FDA is sending this Warning Letter to ElectRx because of the risks posed by its conduct in causing the importation of unapproved new drugs and misbranded drugs to U.S. consumers. FDA's regulation and oversight of the drug approval process protects consumers by requiring rigorous scientific standards for new drug approval, labeling review for accuracy and completeness, and manufacturing procedures and testing performed under closely controlled conditions at FDA-registered and inspected facilities.

This letter is not intended to identify all the ways in which your activities might be in violation of U.S. law. You should promptly cease causing the distribution of unapproved new drugs and misbranded drugs to U.S. consumers and correct any other violations of the FD&C Act.

Please notify this office in writing within 15 working days of receipt of this letter describing the specific steps you have taken or will take to address any violations and to prevent their recurrence. Include an explanation of each step being taken to remedy and prevent the recurrence of any violations, as well as copies of related documentation. Failure to adequately address this matter may result in legal action, including but not limited to, seizure, injunction, and/or temporary restraining order without further notice. If the corrective action(s) cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. This letter notifies you of our concerns and provides you with an opportunity to address them. If you believe that your products are not in violation of the FD&C Act, include your reasoning and any supporting information for our consideration within 15 working days. Please direct your response, and any inquiries concerning this letter, to FDA at CDERDrugSupplyChainIntegrity@fda.hhs.gov.

Sincerely,
/S/
S. Leigh Verbois, Ph.D.
Director, Office of Drug Security, Integrity, and Response
Office of Compliance
Center for Drug Evaluation and Research

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1 A REMS is a drug safety program that the U.S. Food and Drug Administration (FDA) can require for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks. REMS are designed to reinforce medication use behaviors and actions that support the safe use of that

medication.

2 Narrow therapeutic index (NTI) drugs are drugs where small differences in dose or blood concentration may lead to serious therapeutic failures and/or adverse drug reactions that are life-threatening or result in persistent or significant disability or incapacity.

Was this helpful? Yes No

More Warning Letters (/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters)

EXHIBIT C

WARNING LETTER

CanaRx Services Inc

MARCS-CMS 554740 — FEBRUARY 26, 2019

Product:

Drugs

Recipient:

Mr. Gregory Anthony Howard

CanaRx Services Inc

United States

Issuing Office:

Center for Drug Evaluation and Research

United States

TO: Mr. Gregory Anthony Howard

FROM: The United States Food and Drug Administration

RE: Causing the Introduction of Unapproved and Misbranded Drugs into Interstate Commerce

DATE: February 26, 2019

WARNING LETTER

The United States (U.S.) Food and Drug Administration (FDA) recently reviewed your websites listed at the bottom of this letter and determined that you and your affiliates cause the introduction of unapproved new drugs and misbranded drugs into interstate commerce in violation of sections 301(a), 301(d), and 505(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) [21 U.S.C. §§ 331(a), 331(d), and 355(a)]. While this letter refers to CanaRx Services Inc/CRX Intl (hereinafter CanaRx), the violations discussed apply to all entities conducting business by or on behalf of CanaRx. FDA requests that you immediately cease causing the distribution of violative drugs to U.S. consumers.

UNAPPROVED NEW DRUGS

CanaRx operates as a prescription drug provider that engages in activities to cause the introduction of unapproved new drugs from foreign sources into the United States in violation of the FD&C Act. Because these products are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease and/or affect the structure or function of the body, these products are drugs within the meaning of section 201(g)(1) of the FD&C Act [21 U.S.C. § 321(g)(1)]. These products are also new drugs as defined by section 201(p) of the FD&C Act [21 U.S.C. § 321(p)] because they are not generally recognized as safe and effective for their labeled uses. New drugs may not be introduced or delivered for introduction into interstate commerce without prior approval from FDA, as described in section 505(a) of the FD&C Act [21 U.S.C. § 355(a)]. No FDA-approved applications pursuant to section 505 of the FD&C Act [21 U.S.C. § 355] are in effect for these products. Accordingly, their introduction or delivery for introduction into interstate commerce violates sections 301(d) and 505(a) of the FD&C Act [21 U.S.C. §§ 331(d) and 355(a)].

Specifically, CanaRx contracts with public and private sector employers throughout the U.S. to provide select prescription drugs to employees. CanaRx acts as a broker between foreign pharmacies and the employer-sponsored health insurance plan to provide enrolled employees with prescription drugs. CanaRx accepts the employee's U.S. prescription and facilitates its reissue under the direction of a foreign physician. The reissued prescription is subsequently filled by a pharmacy contracted by CanaRx in that foreign physician's jurisdiction. The foreign pharmacy then ships the drug directly to the employee in the U.S. For each shipment, CanaRx uses the same templated invoice, which contains the standard disclaimer, "[d]epending on your country, our medications may appear to be different in size, shape or color." Having this disclaimer in each invoice demonstrates that CanaRx has designed its business to operate in a manner that substitutes the FDA-approved drugs prescribed by the U.S. healthcare provider with unapproved drugs. This distribution scheme is particularly concerning, as employees are likely inclined to trust that they will receive safe and effective drugs through their employer's "insurance" plan and may not question their legitimacy.

The substitution of FDA-approved prescription drugs with unapproved drugs poses significant health risks to U.S. consumers. For example, CanaRx offers certain drugs on its medication lists for which the FDA-approved version is subject to a Risk Evaluation and Mitigation Strategy (REMS) program, has a narrow therapeutic index, and/or is indicated to treat serious conditions such as HIV, cancer, or hepatitis. CanaRx also offers numerous maintenance medications that are indicated for conditions such as high blood pressure, high cholesterol, and acid reflux. Furthermore, the FDA-approved versions of several drugs listed on CanaRx's medication lists have been subject to one or more recalls in the U.S. FDA has established processes to recall unsafe, substandard, and poor quality drugs within the legitimate U.S. drug supply chain. No such safeguards exist for unapproved drugs illegally distributed in the U.S. from foreign sources such as those provided through CanaRx. Therefore, many of the foreign versions of FDA-approved drugs substituted by CanaRx may also have been subject to recalls that were not carried out in the U.S. CanaRx's operation does not appear to provide U.S. consumers with any protection or recourse should they receive or be harmed by drugs that may have been recalled in a foreign country.

In addition, several of the unapproved versions of FDA-approved drugs offered by CanaRx have different trade names and/or dosage amounts in their labeling than their FDA-approved counterparts. Such differences can cause patient confusion and lead to medication errors. Moreover, the substitution of FDA-approved prescription drugs with unapproved versions that may have substantially different risk profiles can pose serious health risks to consumers, especially in vulnerable patient populations that suffer from serious conditions such as HIV, cancer, or hepatitis. Unapproved drugs do not have the same assurance of safety and efficacy as drugs subject to FDA oversight and may be subpotent, superpotent, or adulterated with unknown

active ingredients. Treatment with drugs that may be subpotent, superpotent, or adulterated in such vulnerable patient populations can lead to drug resistance and/or therapeutic failures, and jeopardize the effectiveness of alternative drug therapies on patient outcomes.

Examples of drugs offered on CanaRx's medication lists and a general description of their respective indications are depicted in the table below. These include drugs that are for vulnerable patient populations with serious medical conditions. Such vulnerable patient populations may have received drugs subject to a recall or may have experienced medication errors due to receiving drugs with different dosages or risk profiles, which can lead to side effects that are life-threatening.

Baraclude (hepatitis)	Norvir (HIV)
CellCept (organ rejection)	Reyataz (HIV)
Foradil (asthma, COPD)	Stivarga (cancer)
Gilotrif (cancer)	Tegretol (epilepsy, nerve pain)
Gleevec (cancer)	Tracleer (pulmonary arterial hypertension)
Inlyta (cancer)	Truvada (HIV)
Invirase (HIV)	Zortress (organ rejection)

MISBRANDED DRUGS

Prescription drugs, as defined in section 503(b)(1)(A) of the FD&C Act [21 U.S.C. § 353(b)(1)(A)], can only be used safely at the direction, and under the supervision, of a practitioner licensed by law to administer such drugs. Because CanaRx advises consumers that their U.S. prescriptions are being filled with less expensive, foreign approved drugs, CanaRx intends for these drugs to be used as prescription drugs. This is especially concerning considering that CanaRx offers drugs that have a narrow therapeutic index (NTI) on its medication lists. One such drug currently offered by CanaRx is Tegretol. Substituting an NTI drug without the U.S. prescriber's direction poses significant health risks to patients. In particular, small differences in dose or blood concentration for NTI drugs may lead to serious therapeutic failures or adverse drug reactions that are life-threatening, or result in persistent or significant disability or incapacity.

A drug is misbranded under section 502(f)(1) of the FD&C Act [21 U.S.C. § 352(f)(1)] if the drug fails to bear adequate directions for its intended use(s). "Adequate directions for use" means directions under which a layperson can use a drug safely and for the purposes for which it is intended (21 CFR 201.5). The drugs obtained through CanaRx are intended to treat conditions that are not amenable to self-diagnosis and treatment by persons who are not medical practitioners. Therefore, adequate directions for use cannot be written for these drugs, and they must qualify for one of the exemptions to section 502(f)(1) to avoid being misbranded. The exemption to section 502(f)(1) found at 21 CFR § 201.100 does not apply to unapproved new drugs because that exemption requires that such drugs bear "the labeling authorized by the approved new drug application." Furthermore, unapproved new prescription drugs also do not qualify for the exemption set forth at 21 CFR 201.115, which also requires an approved new drug application (NDA) or active investigational new drug application (IND). Consequently, a prescription drug that is a new drug and has not been approved by FDA, or is not subject to an exemption from the premarketing approval requirements under the FD&C Act, cannot qualify for the exemptions to section 502(f)(1). Because none of the exemptions to section 502(f)(1) apply, these drugs are misbranded under section 502(f)(1).

These drugs are also misbranded under section 502(f)(2) of the FD&C Act [21 U.S.C. § 352(f)(2)] because they fail to bear "adequate warnings against use…where [their] use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application…." This is particularly concerning because certain drugs offered by CanaRx are subject to REMS programs (e.g., Tracleer and CellCept). Specifically, the REMS program for Tracleer restricts distribution to minimize: the risk of fetal exposure and serious birth defects in female patients who are exposed to Tracleer and the risk of liver damage in patients who are exposed to Tracleer. Prescribers must order and review pregnancy tests prior to the initiation of treatment, monthly during treatment, and for one month after stopping treatment. In addition, prescribers must order and review liver function tests prior to the initiation of treatment and monthly during treatment. Furthermore, to comply with the REMS program for Tracleer, this drug must be mailed to patients from pharmacies certified in the REMS program. Pharmacies are also restricted from dispensing more than a 30-day supply and must verify the required testing prior to dispensing. The REMS for CellCept requires healthcare providers to report pregnancies to a registry and has an educational component regarding fetal toxicity. CanaRx is causing important safety measures that are put in place for the FDA-approved versions of these drugs to be bypassed.

By causing these products to be shipped to U.S. consumers, CanaRx is causing the introduction of misbranded drugs into interstate commerce in violation of section 301(a) of the FD&C Act [21 U.S.C. § 331(a)].

* * *

FDA is taking this action against CanaRx because of the risks posed by its conduct in facilitating the importation of unapproved new drugs and misbranded drugs to U.S. consumers. FDA's regulation and oversight of the drug approval process protects consumers by requiring rigorous scientific standards for new drug approval, labeling review for accuracy and completeness, and manufacturing procedures and testing performed under closely controlled conditions at FDA-registered and inspected facilities. Unapproved new drugs and misbranded drugs do not have the same assurance of safety and effectiveness as drugs subject to FDA oversight, and may be contaminated, counterfeit, contain varying amounts of active ingredients, or contain different ingredients altogether.

Substituting an unapproved drug for the FDA-approved drug prescribed by a patient's healthcare practitioner can negatively affect patient outcomes because the health care practitioner may unknowingly make subsequent treatment decisions based on the patient's response to the unapproved drug. This can also cause potentially dangerous drug interactions with the patient's other medications. In addition, sourcing drugs from uninspected, unregulated, and/or unknown supply chains can result in serious health consequences, especially in vulnerable patient populations, which may receive medications that are adulterated and are not shipped and/or stored properly.

This letter is not intended to identify all the ways in which your activities might be in violation of U.S. law. You should promptly cease causing the distribution of unapproved new drugs and misbranded drugs to U.S. consumers and correct all other violations of the FD&C Act. Failure to do so immediately may result in further regulatory action, including seizure or injunction without further notice.

Please notify this office in writing within 10 working days of receipt of this letter of any steps you have taken or will take to correct the violations set forth above and to prevent their recurrence. If the corrective action(s) cannot be completed within 10 working days, state the reason for the delay and the time within which the correction(s) will be completed. Your response, and any other inquiries concerning this letter, should be sent to FDA's Internet Pharmacy Task Force at FDAInternetPharmacyTaskForce-CDER@fda.hhs.gov (mailto:FDAInternetPharmacyTaskForce-CDER@fda.hhs.gov).

Table of Websites Affiliated with CanaRx
Connecting URL
http://abacushealth.biz
http://abacushealth.com
http://abcscripts.com
http://adirondackhealthcanarx.com
http://albanymedsintl.com
http://amherstmeds.com
http://amsterdammeds.com
http://ashleywardrx.com
http://aspireindianacanarx.com
http://auburnmeds.com
http://averillparkmeds.com
http://bayarearooferscrx.com
http://bethlehemmeds.com
http://brandscripts.com
http://burlingtonmeds.com
http://burlingtonscripts.com
http://burlingtonscripts.com/BCBS
http://burlingtonscripts.com/BCE
http://burlingtonscripts.com/HP
http://canarx.com
http://canarxalbco.com
http://capitalotbmeds.com
http://ccmhg.com/mymedicationadvisor
http://cityofgreensburgrx.com
http://cityofschenectadymeds.com
http://columbiacountymeds.com
http://crownpointrx.com
http://crxdirect.com
http://crxintl.com
http://crxmeds.com
http://crxmeds.com/CCC.html
http://crxmeds.com/TC.html
http://csdameds.com
http://dcsmeds.com
http://delameds.com

http://dickinsoncrx.com
http://dphrx.com
http://enterprisemeds.com
http://entrustscripts.com
http://etmwmeds.com
http://everettmeds.com
http://everettmeds.com/BCE
http://everettmeds.com/HP
http://fallrivermeds.com
http://franklinmeds.com
http://greateramsterdammeds.com
http://guilderlandmeds.com
http://hardwoodmeds.com
http://hcgitmeds.com
http://herrsscripts.com
http://hudsonfallsmeds.com
http://iscrx.com
http://jaynescrx.com
http://jcccanarx.com
http://jsfscripts.com
http://knauzrx.com
http://leemasonryrx.com
http://madisonmeds.com
http://mainesensemeds.com
http://mainesensemeds.com/CORE-HRA
http://mainesensemeds.com/HSA
http://mansfieldmeds.com
http://mcsmeds.com
http://mmhcanarx.com
http://mohonasenmeds.com
http://montgomerymeds.com
http://munciemeds.com
http://mygloberx.com/GlobeAR
http://mygloberx.com/GlobeCMG
http://mygloberx.com/GlobeMetallurgical
http://mygloberx.com/GlobeNiagara
http://mygloberx.com/GlobeSelma

http://mygloberx.com/GlobeWVA
http://mymedadvisor.com
http://mymedicationadvisor.com
http://mymodernmeds.com
http://myyocscripts.com
http://newcastlemeds.com
http://niskayunacsdmeds.com
http://otsegomeds.com
http://pagechesterrx.com
http://panostoncrx.com
http://pbvrx.com
http://phbrx.com
http://plattsburghmeds.com
http://pogominemeds.com
http://portlandmeds.com
http://pramcrx.com
http://pramcrx.com/Pram-TC
http://ptdc36meds.com
http://reveremeds.com
http://richmondrx.com
http://romemeds.com
http://saratogacanarx.com
http://sbtmeds.com
http://sbtmeds.com/CC.html
http://scottsburgrx.com
http://selectmailmeds.com
http://shenendehowameds.com
http://slcmeds.com
http://slumeds.com
http://spartanscripts.com
http://ssehpmeds.com
http://stangersurveyingrx.com
http://steubenmeds.com
http://stickleycanarx.com
http://suarezmeds.com
http://theabacusgroup.com
http://tnameds.com

http://townofclarksvillerx.com
http://troymeds.com
http://ualocal467crx.com
http://ulsterscripts.com
http://vineyardsrx.com
http://voorheesvillemeds.com
http://wbameds.com
http://westminstercanterburymeds.com
http://westsuburbanhealth.com/wellness/mymedicationadvisor
http://witrx.com
http://www.canarx.com/AdirondackHealthCanaRx
http://www.canarx.com/AmherstMeds
http://www.canarx.com/AmsterdamMeds
http://www.canarx.com/AuburnMeds
http://www.canarx.com/AverillParkMeds
http://www.canarx.com/Burlington
http://www.canarx.com/CrownPointRx
http://www.canarx.com/CRXMeds
http://www.canarx.com/DELAMeds
http://www.canarx.com/EntrustScripts
http://www.canarx.com/EverettMeds
http://www.canarx.com/GreaterAmsterdamMeds
http://www.canarx.com/GuilderlandMeds
http://www.canarx.com/HaverhillMeds
http://www.canarx.com/HenCoMeds
http://www.canarx.com/HighlandsCountyRx
http://www.canarx.com/LeeMasonryRx
http://www.canarx.com/LewisMeds
http://www.canarx.com/MaineSenseMeds
http://www.canarx.com/MohonasenMeds
http://www.canarx.com/MontgomeryMeds
http://www.canarx.com/MuncieMeds
http://www.canarx.com/NewCastleMeds
http://www.canarx.com/OtsegoMeds
http://www.canarx.com/PLATTSBURGHMeds
http://www.canarx.com/PortlandMeds
http://www.canarx.com/REVEREMeds

http://www.canarx.com/REVEREMeds/BCBS.html
http://www.canarx.com/REVEREMeds/HP.html
http://www.canarx.com/ROMEMeds
http://www.canarx.com/SLCMeds
http://www.cseameds.com
http://www.goodhealthgateway.com
http://www.mainesense.org/?page_id=461
http://www.minuteman-nashoba.org/employees-retirees/mymedicationadvisor
http://www.pnwmeds.com
http://www.rcscsdmeds.com
http://www.scantichealth.org/prescription-plans.html
http://www.schenectadymeds.com
http://www.schenectadymeds.com/MVP_General.htm
http://www.schenectadymeds.com/NonMedicare1.htm
http://www.somervillema.gov/sites/default/files/documents/MMA-OrderingInstructions.pdf
http://www.wayland.k12.ma.us/administration/human_resources/benefits
http://www.webster-ma.gov/index.php?option=com_content&view=article&id=141&Itemid=705
http://www3.newton.k12.ma.us/hr/medflexinfo
http://youngcrx.com

Table of Business Entities Affiliated with CanaRx
(b)(4)
(b)(4)
(b)(4)

Sincerely,

/s/

Thomas Christl
Director
Office of Drug Security, Integrity, and Response
Office of Compliance
Center for Drug Evaluation and Research

Was this helpful? Yes No

More Warning Letters (/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters)

EXHIBIT D

GREAT BEND
PUBLIC SCHOOLS · USD 428

John Popp <john.popp@usd428.net>

Re: Your Forms - Michael @ Payer Matrix

1 message

[redacted] Fri, May 17, 2024 at 12:26 PM

To: Michael Belgiorno <Michael.Belgiorno@payermatrix.com>

[redacted]

Payer Matrix [redacted]

Member Name [redacted]

Payer Matrix, LLC is a patient advocacy company committed to helping ensure that customers are able to obtain medication, products and/or services, (the "Product") from licensed pharmacies and/or government approved dispensaries. Payer Matrix will set up orders on the Customer's behalf with RxFree4me. This Authorization Form shall govern all sales of Product facilitated by Payer Matrix and RxFree4me's authorized pharmacies and/or government approved dispensaries located in Canada, (collectively, the "Pharmacy"). I acknowledge and authorize Payer Matrix as follows:

1. Payer Matrix does not provide telepharmacy, telehealth or other health-related services and does not provide health insurance of any type. We only provide prescription discounts. You are not seeking any medial information from Payer Matrix or RxFree4me.

2. Your insurance/plan sponsor is responsible for all payments to pharmacies from whom you receive payment discounts. Payer Matrix does not make payments to any pharmacy or healthcare provider.

3. You authorize Payer Matrix to contact your Prescriber to send your prescription to RxFree4me or you will send your prescription to RxFree4me directly via FAX or mail. The prescription has not been altered in any way or filled prior to submission.

4. You are aware that Payer Matrix will be transmitting your personal health information by electronic means (e.g. fax or internet) to its employees, agents, affiliates and service providers including the physician retained on your behalf. I provide my authorization to allow any licensed physician retained by RxFree4me on my behalf to obtain my medical history, drug history, contact information and other necessary documentation from my U.S. physician ("My Own Physician"). I further authorize the physician retained by RxFree4me on my behalf and My Own Physician being in contact with one another to discuss my medical condition, as it pertains to the prescribing of my medication. I understand the reason for this authorization is to provide the licensed physician retained my behalf with the full opportunity to conduct an independent analysis of whether my prescription is appropriate, and discuss any potential medical complications that may arise. By using Payer Matrix related to the prescriptions, information related to the prescriptions provided to RxFree4me will be collected from pharmacies that fill your prescription. I further understand that my medical information will not be used for any other purpose, will be kept in strict confidence, and will not be sold to any third parties.

5. This program is voluntary. The authorizations and consents that I am providing herein to Payer Matrix commence on the date I sign this form and will continue until I revoke them. I understand I can revoke the authorizations I have granted at any time by giving written notice to Payer Matrix of my intentions in that regard.

6. I am the age of majority, am fully competent to make my own health care decisions and have obtained any prescription(s) for the Product in a lawful manner. I have been taking the prescribed medication for a minimum period of thirty (30) days immediately prior to the date that I submit my prescription to RxFree4me for filling.

7. It is my responsibility to have My Own Physician conduct regular physical examinations, including any and all suggested testing to ensure that I have no medical problems which would constitute a contraindication to me taking the Product. I certify that I have had a physical examination by My Own Physician within the last twelve (12) months from the date hereof.

8. It would be a violation of the law to falsify any information provided to Payer Matrix and RxFree4me, including, but not limited to, any information on this Authorization. I agree to truthfully, and to the best of my knowledge, answer all of the questions in this Authorization. I further agree and understand that I will be solely responsible for any adverse effects that I may suffer from taking or continuing to take the Product in the event that I have failed to fully furnish my complete and accurate medical history and/or if I fail to notify My Own Physician and RxFree4me of any change in my physical or medical condition.

9. RxFree4me will only verify and provide Product that My Own Physician has already prescribed to me. No new prescription medications will be provided by RxFree4me affiliates. I also understand that no controlled medications, narcotics, tranquilizers, or other medications that RxFree4me and/or its affiliates deem inappropriate, will be provided.

10. I appoint Payer Matrix to act as my agent in order to take all steps that it deems necessary to have an order set up with RxFree4me and have the Product dispensed by the Pharmacy, to the same extent as I could do if I were personally present at the Pharmacy, including: (a) collecting personal health information about me; (b) disclosing that information to and having a licensed physician perform an independent medical review in order to obtain a valid prescription for the Product, if necessary; and (c) packaging the Product and delivering it to me. I hereby waive any requirement of the physician to conduct a physical examination.

11. There will be no additional fees charged to me in the event that an independent medical review is required to obtain a valid prescription for the Product.

12. I initiated contact with and understand that the Pharmacies for RxFree4me are located in Canada.

13. The Product is sold and dispensed by the Pharmacy in accordance with the laws of the jurisdiction in which the Pharmacy is located. Title to the Product passes from the Pharmacy to me when the Product leaves the Pharmacy. The Pharmacy delivers the medication to my agent in the Pharmacy's jurisdiction. Typically this agent is a delivery service, in which case I give the Pharmacy or its agent authority to select the agent on my behalf.

14. The review of my medical information by a physician is in no way intended as a means to diagnose any medical condition and does not substitute the requirement for me to obtain my own professional medical advice from My Own Physician. I agree to a direct all questions to My Own Physician. I will consult My Own Physician before taking any new drug or changing my daily health regimen.

15. Any and all agreements reached or contracts formed and transactions undertaken with or involving the Pharmacy are and shall be deemed to be made in the jurisdiction of the Pharmacy and shall be governed by the laws of the jurisdiction of the Pharmacy applicable to such contracts, agreements and transactions(unless RxFree4me elects otherwise in its sole discretion). The Courts of that jurisdiction shall have sole and exclusive jurisdiction over any dispute that may arise between me and the Pharmacy and I agree to consent to the Courts of that jurisdiction for any and all such dispute or disputes (unless RxFree4me elects otherwise in its sole discretion).

16. Payer Matrix, RxFree4me, and/or the Pharmacy may communicate with me via email or telephone to discuss my order or pending refill order for the Product.

"I have read and understand the forgoing terms and I agree that they shall be binding upon me and my heirs, assigns, successors and personal representatives."
OR
"I am the parent/legal guardian/power of attorney for the customer disclosed herein, am over the age of majority, and have full authority to sign for and provide the above representations to Payer Matrix on the customer's behalf."

[redacted]
Print Name

[redacted]
Signature Date

Email: PayerMatrix.com
Telephone: 877 305-6202
Fax:

[redacted]

On Fri, May 17, 2024 at 12:20 PM Michael Belgiorno <Michael.Belgiorno@payermatrix.com> wrote:

Whoops! It would help if the attachment sent too!

Michael Belgiorno

Reimbursement Care Coordinator

Payer Matrix, LLC

P: (877) 305-6202 Ext. 6208

Payer Matrix urac [redacted]

From: Michael Belgiorno
Sent: Friday, May 17, 2024 1:19 PM
[redacted]
Subject: Your Forms - Michael @ Payer Matrix

Hey [redacted]

Here is that form we spoke about. Let me know if you have any questions!

Best,

Michael Belgiorno

Reimbursement Care Coordinator

Payer Matrix, LLC

P: (877) 305-6202 Ext. 6208

Payer Matrix urac