EXHIBIT C

UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT AGENCY

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In the Matter of

SIMFAROSE PHARMACY

Docket No.: 23-37
SIMFAROSE SUPPLEMENTAL PREHEARING STATEMENT

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SimfaRose Pharmacy hereby respectfully submits its prehearing statement as follows.

This supplemental prehearing statement is prepared based on the information currently available to SimfaRose. SimfaRose reserves and preserves the right to amend, supplement, modify and change this supplemental prehearing statement during the course of ongoing discovery and investigation and in response to the clarification of the opinion testimony of its proposed expert that the Government agreed to provide at the prehearing conference.

ISSUES

On December 17, 2021, an army of DEA agents and local law enforcement led by DI Melissa Szwanke, a former Florida attorney, stormed the pharmacy under the guise of an *ex parte* Administrative Inspection Warrant (AIW), immediately disconnected the surveillance camera system, falsely imprisoned the pharmacist in a closed room, refused to provide him medical assistance or let him speak to counsel, and illegally seized a monumental amount of pharmacy and personal property in flagrant violation of the limited authority conferred under Controlled Substances Act (CSA) and the issuing Magistrate's clear directives. This is how the DEA obtained the "evidence" it relies on in seeking to revoke SimfaRose's registration more than two (2) years later. Whether the tribunal will prohibit the DEA from offering evidence it illegally seized in violation of the CSA under the exclusionary rule to effectively defer future misconduct.

Whether the DEA's purported expert's opinion is admissible, reliable, has any probative or evidentiary value, or will assist the tribunal in deciding this case. The DEA's case is built entirely on their proposed expert, Thomas Hamilton's, opinions, which are essentially that he merely did not see anything in the documents he reviewed that red flags were addressed and resolved. Hamilton, however, was at best best spoon fed extremely limited evidence by the DEA that it pre-screened for him (e.g., what DEA's IT Specialist unilaterally deemed the "patient profile" in SimfaRose's QS/1 pharmacy software system and "medical expense reports" he downloaded from the illegally seized server) instead of letting him review everything they seized.

Whether pre-hearing discovery, including but not limited to prompt identification of the patients, the specific prescriptions at issue, identification and production of the documents that the DEA reviewed, the documents DEA provided Hamilton for review, and production of the documents upon which Hamilton's opinions are based (e.g., the prescriptions, "patient profiles," patient charts," "RX profiles," and "medical expense reports" DEA "recovered" from the original electronic data in the server it seized on December 17, 2021), will be permitted to afford SimfaRose due process and effectively prepare for a hearing and defend the claims against it.

REQUESTED RELIEF

SimfaRose hereby requests that the Tribunal recommend that the Pharmacy's DEA C.O.R. No. FS0588004 be returned to the Pharmacy because the Pharmacy's continued registration is not inconsistent with the public interest under 21 U.S.C. §§ 823(g)(1) and 824(a)(4) and the OSC be withdrawn.

STIPULATIONS

The Government's proposed stipulations in the Paragraphs designated as 1-14 of its prehearing statement are accepted. SimfaRose cannot at this time respond to the remaining proposed stipulations in the Government's prehearing statement or propose any meaningful stipulations of its own because the Government refuses to disclose the identity of these patients or confirm whether the list of potential patients it provided the Government's counsel is correct. SimfaRose reserves and preserves the right to seek leave to amend, supplement or modify its prehearing statement accordingly upon confirmation from the Government and discovery of the patients at issue.

PROPOSED WITNESSES

1. Dr. Charles Bonanno, Pharm.D., MBA, BCGP, 10016 Pines Blvd. Pembroke Pines, FL 33024
2. Dr. Robert M. Parrado, R.Ph., 7922 Flowerfield Drive, Tampa FL 33615
3. Dr. Tracey J. Schossow, B.S. Pharm, Pharm D. 18520 N.W. 11th Court, Pembroke Pines, Fl 33029
4. Dr. Michelle Krichbaum, BA, PharmD, BCPP, 8950 N Kendall Dr, Miami, FL 33176
5. Dr. Goar Alvarez, Pharm.D., C.Ph., 3200 S University Drive, Ft. Lauderdale, FL 33328
6. All witnesses listed in the Government's prehearing statement, the exhibits references therein and any and all documents provided by the Government in this proceeding.
7. The patients at issue in the OSC that the Government and their Prescribers.

SUMMARY OF TESTIMONY

Dr. Charles Bonanno

Dr. Charles Bonanno is the pharmacy manager at Simfarose Pharmacy. He has been the pharmacist in charge (PIC) since the latter part of 2019. Prior to him, Scott Mazza was the pharmacist in charge. Dr. Bonanno will testify to his history in the Pharmacy industry. He will testify to his background in pharmacy, why he became a pharmacist, and why he feels strongly about caring for patients on an individual basis and emphasizing that every individual patient needs to be treated with independent care, dignity, and respect. Dr. Bonanno will testify to the Oath of a Pharmacist and its significance and how it guides and informs the standard of care. The mission of Simfarose Pharmacy is "to put people first in everything we do."

Dr. Bonanno will testify to his over thirty eight (38) years of experience, working in various Pharmacies including independent and retail, working for the government, owning multiple locations, operating Specialty Pharmacies, and operating businesses.

Dr. Bonanno will testify to the standard of care he, as the PIC, expects the Pharmacy and all Pharmacists there to exercise. He will testify to the usual standard of practice that he has experienced over his neary 40 year experience, along with changes in the industry, scrutiny from government and insurance entities, and medical progressions and advancements that alter the way Pharmacies operate and interact with their patients and respective physicians.

Dr. Bonanno will testify that he has complied and cooperated with requests from the government including the DEA and SimfaRose's compliance with the CSA.

Dr. Bonanno will testify how he operates the Pharmacy and the business model he has created, which is unique. Dr. Bonanno will testify to the Pharmacy's unique status as providing an exceedingly high quality of care and exceedingly more services than most community

Pharmacies, especially in the Southeast Florida area. Dr. Bonanno will testify to the accreditations he has earned over the years as well as the Pharmacy has achieved.

Dr. Bonanno will testify to his clinical knowledge in the field of Pharmacy and pharmacology. He will testify to his Board Certification of Geriatrics. He will testify to the use of medications, the interactions of different medications, and the benefits and risks of using certain medications to provide patients with the highest possible quality of life.

Regarding abuse and diversion, Dr. Bonanno will testify that he does not fill prescriptions that he believes are illegitimate, nor would he in any circumstance. Dr. Bonanno will testify that he screens patients personally and physically from the time they set foot inside the door, assessing them in a variety of ways including communication and motor skills. Dr. Bonanno will testify that he screens patients to determine if the patient is filling other prescriptions at other pharmacies, and if so, advising that the patient also fills those prescriptions at the Pharmacy. Dr. Bonanno will testify that he declines to service incoming patients if he does not feel comfortable servicing them or he feels that a prospective patient is engaging in any abuse or diversion of controlled substances.

Dr. Bonanno will testify to the changes in the pharmaceutical industry and the theory of "red flags" that help identify and eliminate abuse and diversion of drugs. He will testify that over time, he is aware that abusers and diverters have changed their tactics and "red flags" have changed. Dr. Bonanno will testify to his experience identifying potential concerns with prescriptions and how he has resolved them over the years to rebut the Government's alleged expert's testimony and opinions.

Dr. Bonanno will testify to the various policies and procedures that he has established at the Pharmacy. He will testify to retaining Dr. Brushwood, a pharmacy expert and attorney, to

design and implement the VIGIL Process at the Pharmacy. Dr. Bonanno will testify that he uses the VIGIL Process in addition to other procedures and systems in place to ensure quality care for patients. He will testify that patients sign a Medication Use Agreement (Proposed Exhibit 14) and that research has shown the Medication Use Agreement reduces the risk of abuse and diversion.

Dr. Bonanno will testify to the updated policies the Pharmacy has followed over the course of time. Dr. Bonanno will testify that part of patient care, along with identifying red flags, is by accessing the patient's E-FORCSE profile. He will testify that E-FORCSE is Florida's PDMP program and that E-FORCSE program has built in "red flag" indicators, along with various other features to indicate: doctor shopping, pharmacy shopping, early fills, prescription history, opiate naivety, prescribers and physicians, NARXCARE SCORES, Overdose Risk Scores, State Indicators, MME calculations, and more. Dr. Bonanno will testify that it is routine practice for the Pharmacy to request the E-FORCSE history of each patient whose prescription they are filling.

In addition to interacting with patients personally and speaking with physicians, he will testify to using various software platforms to help ensure he is providing proper care. He will testify to his use with the reject codes regarding the DUR process within QS1. He will testify to the DUR work-flow program installed as a feature within QS1 that serves as a safety-check. He will testify to the "clinical check" feature installed on QS1 where he can run reports on patients to view any potential concerns or red flags associated with prescriptions.

Dr. Bonanno will testify that in addition to E-FORCSE, the Pharmacy also uses features within QS1 to identify and resolve possible concerns or red flags with prescriptions. Dr. Bonanno will testify that QS1 has a built-in system to perform a clinical review of the patient's

prescriptions, alerting the pharmacist of possible concerns, if any, at which point the pharmacist makes a sound professional judgment whether the alert needs further resolution or not. The "Work-Flow" process measures drug-drug interactions, duplicate therapy, drug-to-food interactions, and other clinical checks. He will testify to his regular use of the "Work-Flow" and how he is alerted, and views the alerts while filling prescriptions. He will testify that the "clinical-check" feature on QS1 also provides alerts with certain severity levels to assess a patient's particular prescriptions, providing the pharmacist with additional information to make a sound professional judgment.

He will testify to features within E-FORCSE that alert the Pharmacy of indicators of potential misuse/abuse. He will also testify to the effects of scrutiny from insurance providers, including Medicaid and Medicare, and how that relates to legitimate prescriptions and legitimate medical purposes.

Dr. Bonanno will also testify that CMS and Part D plan sponsors have opioid policies which include but are not limited to enhanced DUR and soft or hard stops. Dr. Bonanno will testify to the additional steps that he must take and additional documentation he must provide to fill such prescriptions, which must be approved in order to receive payment. Dr. Bonanno will further testify that in order to receive payment for insurance patients, the prescriptions must be authorized/approved by the insurance company.

Dr. Bonanno will testify to the communications he has had with prescribers, discussing, among other things, alternative medications, the risks and benefits, and other plans put in place. Dr. Bonanno will testify to the communications he has had with patients, discussing, among other things, alternative medications, the risks and benefits, and other plans put in place. Dr. Bonanno will testify to the effect that electronic prescriptions have had on the verification of

legitimate prescriptions, eliminating or at least reducing the possibility of forged prescriptions and abuse/diversion.

Dr. Bonanno will testify that he exercises sound professional judgment to make decisions while operating the pharmacy and as the PIC. He will testify that he does not only use one method of taking patient notes, prescription notes, or dictating communications with prescribers. He will testify that sometimes he writes notes on the front/back of prescriptions, sometimes he uses the QS1 pharmacy management software's notes section, sometimes he writes a note in the patient's physical file, or other measures to record/document communications, patient interactions and the like. He will testify that many of his patients have been long-time patients at his pharmacy and he builds relationships with them (and all other patients of the pharmacy), thus learning more about them than other pharmacies. He will testify that, according to Florida Administrative Code Rule 64B16-27.800 Requirement for Patient Records, "a patient record shall be maintained for a period of not less than four (4) years from the date of the last entry in the profile record." Therefore, Dr. Bonanno will testify that the documentation of resolutions performed prior to the last 4 years could have been made, were made, and are no longer required to be kept. Dr. Bonanno will testify that, in regards to documentation of resolutions of red flags, some documentation (unknown to Dr. Bonanno) might be in the possession of the government when the government seized documents within and outside the scope of the AIW (Gvt. Proposed Ex. No. 5). Dr. Bonanno will testify to his efforts in recovering other means of documentation of red flags that would help address the issues stated in the OSC for presentation in this case.

He will testify to the various methods and features that he uses to ensure he is filling legitimate prescriptions for a legitimate medical purpose.

Dr. Bonanno will testify to his efforts to reduce patients' prescription quantities and dosages, along with his effort to provide his patients with a high quality of life, reducing pain. Dr. Bonanno will testify to the patient records, including the medical expense reports, indicating that the patient, in conjunction with the pharmacist and physician is often tapered down, constituting a conscious effort to reduce a patient's dependency on certain drugs, resolve red flags, and provide the patient with a high quality of life. He will also testify that he has declined to service potential patients or discharged patients if he did not believe the patients' prescriptions were legitimate. He will testify that he takes his oath seriously and does not fill any and all prescriptions that are presented to him at the Pharmacy.

Dr. Bonanno will testify that the use of two opiates to treat pain is an appropriate approach for certain individuals, in certain circumstances. Dr. Bonanno will testify that certain patients are recommended to be given immediate-release opiates initially per the guidance of the CDC. Dr. Bonanno will testify that the CDC does not require patients to be transitioned to an extended-release drug without careful consideration of the risks it poses to the patient. Dr. Bonanno will testify that there are few alternatives of extended-release opioids. Dr. Bonanno will testify that extended-release opioids are also abused and diverted and are not safer than immediate-release opioids.

Dr. Bonanno will testify to the effect that various lawsuits, settlements, and news coverage have had on the stigma regarding extended-release opiates. Dr. Bonano will testify to the effect that, in particular, the "Purdue settlement" affected the oxycontin market and led to insurance companies not covering it and patients not wanting to be prescribed it. Dr. Bonanno will testify to the lack of alternatives of extended-release medications, including the lack of coverage from insurance companies. Dr. Bonanno will testify that 8/10 patients were prescribed

an extended-release drug at some time and the medication was inappropriate to treat the patients' needs.

Dr. Bonanno will testify to the MME conversion figures and its effect on assessing patient risk. Dr. Bonanno will testify to the MME providing a guide and gauge to help a pharmacist determine proper drug therapy and pain management, however, the MME conversion does not take the particular patient into account. He will testify that he is alerted each time he views a patient's E-FORCSE that, "Per CDC guidance, the MME conversion factors prescribed or provided as part of the medication-assisted treatment for opioid use disorder should not be used to benchmark against dosage thresholds meant for opioids prescribed for pain." He will testify that the CDC recommends certain MMEs, but the CDC has made clear they are not requirements and subject to treating the individual at hand, especially given the fact that the MME number provided does not take into account any personal data or info.

Dr. Bonanno will testify to the alleged concerns associated with claimed drug cocktails. He will testify to the use of certain combinations of medications and the reasons why certain drugs do not possess inherent risks that are often associated with drug cocktails. He will testify to the effects of certain drugs on their respective pathways.

Dr. Bonanno will testify to his methodology of pricing at the pharmacy and factors that affect the price of prescription drugs. He will testify that his pricing model is different from retail pharmacies because he is an independent specialty pharmacy, with different access to purchasing and pricing power. He will testify further that he is different from other independent pharmacies because he operates multiple business units under the same roof, thus pricing of certain medications is affected to account for many variables. He will talk about his pricing structure and his relationship with manufacturers/wholesalers, and distributors. He will talk about the costs

associated with purchasing and filling controlled prescriptions in addition to non-controlled prescriptions. He will testify that what he charges is not the true amount received because of insurance patients and companies.

Dr. Bonanno will testify about factors affecting the price of prescription drugs and that the prices for the prescription drugs that the Government's expert claims are "high" were set, in part to prevent and deter potential abuse and diversion and so that the pharmacy did not become sought out only to receive opioids with a line of patients out of the door. He will testify that he knows of other pharmacies that charged lower prices than Respondent, who have since been stripped of their license because they were labeled "pill-mills."

He will testify to his conversations with Former DEA Administrator Susan Langston regarding pricing, which she did not find problematic, nor did she find the pricing to be an indicia of potential diversion or abuse.

He will also discuss working with patients of all backgrounds and financial means to ensure that patients receive the proper care and do not put them at risk.

Dr. Bonanno will testify that the DEA, to his knowledge, has not recommended nor required that a pharmacy may not fill a prescription from a patient living a certain number of miles away from the pharmacy. He will testify that he has limited his reach to the tri-county area regarding controlled substance patients in an effort to be situated well-above the standard. He will testify that he has questioned patients from far distances (such as out of state or across the state) seeking controlled substances, in which case he has also declined to fill prescriptions.

Dr. Bonanno will testify to the pharmacy's relationship with the patients (especially the pharmacist/patient relationship), the patient's underlying conditions and their prescribed prescriptions, the services the Pharmacy provides to the patients, assessing the benefits and risks

involved with dispensing controlled substances to individual patients, and the overall health and well-being of the patients seeking to aid in the patient's high quality of life. He will testify to each patient's individualized pain, their treatment plan, and unique situations.

Dr. Bonanno will testify that the Pharmacy identified, addressed, and resolved the alleged red flags at issue prior to dispensing the prescriptions and that in dispensing these prescriptions the Pharmacy complied with all applicable state and federal laws, including the pharmacy's corresponding responsibility, and standards of professional pharmaceutical care. He will also testify that each and every prescription at issue in this is valid and was issued by a practitioner in the usual course of their professional practice and for legitimate medical purposes.

Regarding patient AW, Dr. Bonanno will testify that she began filling her prescriptions in 2008 and that the late AW was opioid tolerant. Dr. Bonanno will testify to her various non-acute pain conditions including degenerative disk disease. He will testify to her suffering from multiple myeloma, a very painful form of bone cancer that caused her excruciating pain, and to her medical treatment. He will testify that patient AW's pain was exacerbated from lytic lesions, which destroys and leaves holes in the bone. He will testify that AW had insurance but also paid in part cash for some of her prescriptions because they were not covered by her insurance.

Regarding patient CS, Dr. Bonanno will testify that she suffers from degenerative disc disease, specifically at L4-L5 and L5-S1 (See, Resp't Ex. 65 at 12). In addition to her back pain, CS suffers pain from a .45 caliber hollow point gunshot wound to her ankle, which resulted in mal angulation of the tibia and foot facing another direction, resulting in misalignment of her ankle (See, Resp't Ex. 65 at 12-14). He will testify that she is overweight, has trouble walking, and is disabled (See, Resp't Ex. 65 at 14). He will testify that CS did not have insurance during the time stated in the OSC.

Regarding patient DE, Dr. Bonanno will testify that he has been filling prescriptions for DE since 2008 and that DE is not opioid naive. He will testify that DE suffers from back pain and also grossly overweight. He will testify that DE paid cash during the time he lost his Caremark insurance and before he had FBCBS insurance and that Dr. Bonanno worked with DE to provide an affordable alternative plan when he lost his insurance.

Regarding patient DaB, Dr. Bonanno will testify that he suffers chronic pain from a variety of severe and painful conditions, including cancer. He will testify that DaB was exposed to uranium while serving in the Gulf War and handling tank shells containing this substance. He will testify that DaB is at risk for an atraumatic fracture and has a Z-score of -3.4 which classifies him as osteoporotic (See, Resp't Ex. 67 at 11). He will testify that DaB has no teeth and with that, DaB is severely depressed (See, Resp't Ex. 67 at 21). He will testify that DaB is extremely frail and mal-nurished. Dr. Bonanno will also testify that DaB has a condition - cryoglobulinemia - where his blood thickens and causes severe pain (See, Resp't Ex. 67 at 15). Dr. Bonanno will testify to working with DaB to taper down his medicines (see Resp't Ex. 67 at 22-23).

Regarding patient DeB, Dr. Bonanno will testify that he started filling DeB's prescriptions in 2009. He will testify that DeB suffers from chronic pain mostly in his spine. He will testify that patient DeB was shot in the back and neck in which bullet fragments are still presently in his body (see Resp't Ex. 68 at 41). He will testify that DeB also suffered from degenerative disc disease. He will testify that DeB continued to work and wanted to be functionable. He will testify that DeB did not have insurance during the time stated in the OSC.

Regarding patient HS, Dr. Bonanno will testify that he started filling HS's prescriptions in 2011. He will testify that HS was injured at work and suffered from disc bulges and

degeneration of his spine. He will testify that HS did not have insurance during the time stated in the OSC.

Regarding patient JR, Dr. Bonanno will testify that he started filling JR's prescriptions in 2009. He will testify that JR suffers from moderate and severe stenosis along with other conditions involving back pain. He will testify that JR was involved in a motor vehicle accident that intensified patient's pain. He will testify that JR did not have insurance during the time stated in the OSC.

Regarding patient KF, Dr. Bonanno will testify that he started filling KF's prescriptions in 2010. He will testify that patient FK suffers from many serious illnesses, including bi-polar disorder in addition to her chronic pain symptoms. He will testify that her insurance approved prior authorization of fentanyl patch (see Resp't Ex. 71 at 24-25) and Oxyocodone (see Resp't Ex. 71 at 37). He will testify that patient is enrolled in Medicare Part D plan. He will testify that KF lived close to the Pharmacy's prior location.

Regarding patient MS, Dr. Bonanno will testify that he started filling MS's prescriptions in 2010. He will testify that the notes recorded in the QS1 system demonstrate that the pharmacy identified, addressed, and resolved the alleged red flags attributed to MS' prescriptions prior to dispensing them. These include the May 12, 2021 notes (see Resp't Ex. 72 at 9 & Gov't Ex. 43). He will testify that patient MS suffers from chronic back and knee pain, further intensified by a motor vehicle accident in 2010. He will testify that MS did not have insurance during the time stated in the OSC.

Regarding patient RS - Dr. Bonanno will testify that he started filling RS's prescriptions in 2016. He will testify to RS's chronic back pain resulting from degenerative discs, bulging discs, and disk herniations. He will testify that RS did not have insurance during the time stated

in the OSC regarding cash payments. He will testify that RS was involved in a motor vehicle accident in 2014 which intensified and furthered his pain.

Dr. Robert M. Parrado, R.Ph.

Mr. Parrado is a Florida pharmacist and expert in pharmacy practice in the State of Florida and the standard of care that has been qualified as such by courts and this tribunal in proceedings such this and retained by the DEA as an expert pharmacy witness. He will testify regarding his background, training, skill, education, specialized knowledge, and extensive experience, including his service as president and chairman of the Florida Pharmacy Association. He was a member of the Florida Board of Pharmacy when it adopted Rule 64B16-27.831 governing the standards of practice for validating prescriptions for controlled substances and refusing to fill a prescription and participated in the formulation of the rule.

He will testify about the requirements of and the purpose and intent behind this Rule and other state and federal and statutes, rules, and regulations regarding the obligations of a pharmacist with respect to controlled substances, patient safety and wellbeing, and the standard of care for the practice of pharmacy in the State of Florida. He will testify that it was never the intent of Rule 64B16-27.831 to require a pharmacist to include a note on a prescription or in the pharmacy's records concerning his validation. He will discuss Rule 64B16-27.800 on Requirement for Patient Records and testify that the rule was examined and reviewed by the Florida Board of Pharmacy when it adopted Rule 64B16-27.831 and that the consensus of the Board of Pharmacy was that Rule 64B16-27.800 was not intended to require that the patient records include notes on the validation of a controlled substance prescription. He will discuss Rule 64B16-27.810 on review of patient records of drug use, including over utilization and testify that the rule was examined and reviewed by the Florida Board of Pharmacy when it

adopted Rule 64B16-27.831and that the consensus of the Board of Pharmacy was that Rule 64B16-27.810 was not intended to require that the patient records include notes on the validation of a controlled substance prescription. He will testify that nothing in the language or intent of Rule 64B16-27.800, Rule 64B16-27.813 and Rule 64B16-27.831 requires that a pharmacist document on a prescription or in the pharmacy's records that a prescription was validated and that while he was a member of the Florida Board of Pharmacy the Board never imposed discipline on any pharmacist in Florida for such an alleged violation of any such practice of failing to document resolution of a red flag for filling a prescription.

He will testify about the response to the DEA's construction and enforcement of Florida law in proceedings such as this, including review of Rule 64B16-27.800 and consideration of amendments to Rule 64B16-27.800 by the Florida Board of Pharmacy.

He will testify that Rule 64B16-27.810 is limited to therapeutic appropriateness of a particular prescription under a clinical prospective drug utilization review (DUR) and not a red flag analysis. He will also testify that Rule 64B16-27.831 sets forth the standard of care governing the controlled substance prescriptions dispensed in this case and that the Pharmacy complied with this Rule and all other applicable federal and state statutes, rules and regulations in dispensing the prescriptions at issue in this case.

He will discuss the trial testimony Joseph Ranaszzisi, on October 13, 2021 in the case of In Re National Prescription Opiate Litigation that nowhere in the regulations of the DEA or its Pharmacist's Manual is there a requirement that a pharmacist must document a resolution of red flags for opioid prescriptions and that there has been no "Dear Registrant Letter" sent by the DEA to a pharmacist instructing that he or she must document resolution of red flags. He will discuss the letter of Thomas W. Prevoznik, Deputy Assistant Administrator, Diversion Control

Division of the DEA, to Kevin N, Nicholson dated November 4, 2019 that federal law and DEA regulations do not impose a specific quantitative minimum or maximum limit on the amount of medication that may be prescribed in a single prescription or the duration of treatment intended with the prescribed control substance and that "it is up to each practitioner to treat a patient according to his or her professional medical judgment."

He will discuss the CDC Clinical Practice Guideline for Prescribing Opioids, including that the guidelines are voluntary, do not require mandatory compliance and are intended to be flexible to support, not supplant, clinical judgment and individualized patient centered decision making. He will also discuss the 2022 Guidelines section which says: "Payers and health systems should not use this clinical practice guideline to set rigid standards related to dose or duration of opioid therapy." He will discuss the significance of the prescriptions for the particular patients at issue in this case for the particular drugs at issue in this case and the documentation demonstrating that the prescription was verified. He will give an expert opinion that once a prescription for a particular drug for a particular patient has been verified it does not have to be re-verified each month an identical drug is prescribed for the identical patient. He will also discuss the primary importance in validating prescriptions for controlled substances and opioids for a pharmacist to know well both the prescriber and the patient and how that rule was properly applied for the prescriptions at issue in the present case.

He will testify about his review of the records maintained by SimfaRose, his site inspection of the pharmacy, and interviews of its employees and Dr. Bonanno, and the pharmacy's compliance with the CSA and Florida law. He will testify about the measures taken by the pharmacy to ensure that the prescriptions at issue in this case were validated and issued for legitimate medical purposes. He will testify that the opinions of the DEA's proposed expert in

this proceeding are not supported by the evidence in this case, including records maintained by the pharmacy he reviewed, CDC guidelines, and state and federal law, and that the prescriptions at issue in this case were legitimate and validated by the pharmacist prior to dispensing, were prescribed for legitimate medical purposes in the ordinary course of professional practice, and that any so-called red flags presented by the prescriptions at issue in this case were identified and appropriately addressed and resolved before they were dispensed and they were not knowingly filled in violation of federal or state law or the standards of professional practice of pharmacy in the State of Florida.

Tracey J. Schossow, B.S. Pharm., Pharm. D.

Tracey J. Schossow is a licensed Florida pharmacist and an expert pharmacy witness for the DEA since 2014. She will testify about her extensive qualifications, experience, education and background. She has been qualified by this tribunal as an expert on the standard of care for the practice of pharmacy in the state of Florida and testified on behalf of the DEA in numerous revocation proceedings such as this and in state courts on behalf of the state of Florida.

She will testify concerning the opinions offered by Mr. Hamilton as to the standard of care offered in this case and based on her personal and professional knowledge, training, education, and experience as a pharmacist and expert witness for the DEA. She will testify about the manner and extent to which the opinions and testimony offered by Mr. Hamilton in this case deviate from and are inconsistent with the standards of care and policies, practices, and expectations of pharmacists at Publix pharmacies managed by Mr. Hamilton.

Michelle Kirchbaum, B.A., Pharm.D., BCPP

Dr. Krichbaum is a Florida pharmacist, Board certified in psychiatric pharmacotherapy including substance use disorders, and an expert in pain management and palliative care. She

will testify to the safety and efficacy of opioids when used in chronic pain management. She will also testify to the co-prescribing of other analgesics and behavioral health medications with opioids as part of multi-modal pain management. She will discuss short acting versus long acting opioids regarding safety, efficacy, and current clinical guidelines and recommendations. She will also discuss the low misuse rates of prescription analgesics in the United States. Dr. Krichbaum has published primary and tertiary literature in the field of pain management and regularly gives Continuing Education (CE) and Continuing Medical Education (CME) on a state and national level regarding various Pain and palliative care topics. Additionally, she has served as faculty at Nova Southeastern University and Broward Health Medical Center where she taught pain management and substance use disorders for pharmacy students, pharmacy residents, allopathic medical students, and allopathic and osteopathic medical residents.

Dr. Kirchbaum will testify regarding her background, training, skill, education, specialized knowledge, and experience in the practice of pharmacy and the treatment of pain and other medical conditions and to the standard of care for treating pain. She will testify as to her review of the evidence in this case and that the prescriptions at issue were properly dispensed. Dr. Kirchbaum will also testify that she is critical of Mr. Hamilton's opinions. She will testify that a 2018 study published in the Journal of the American Medical Association found, among other things, that 96% of patients with long term immediate release opioid analgesic therapy continue to receive immediate release formulations without transitioning to an extended release, that the overall patient population that added an extended release opioid was 3.9%-4.3% and only 0.7% switched to an extended release opioid. See, Hwang CS, Kang EM, Ding Y, et al. Patterns of Immediate-Release and Extended-Release Opioid Analgesic Use in the Management of Chronic Pain, 2003-2014. *JAMA Netw Open.* 2018;1(2):e180216.

doi:10.1001/jamanetworkopen.2018.0216. She will testify that immediate release opioid formulations may be, and are, continued long term because of their more flexible dosing schedules, availabilities in low-dose combinations with nonopioid analgesics, lower costs, and more favorable insurance reimbursement policies. Additionally, past regulatory actions and interventions have primarily emphasized the risks associated with ER/LA formulations, particularly for long-term use in patients with chronic pain, which may have preferentially raised awareness about the risks associated with ER/LA formulations.

Dr. Kirchbaum will testify concerning the CDC Guidelines, including the 2022 Guidelines which provide, among many other things, that clinicians should use additional caution with ER/LA opioids and consider a longer dosing interval when prescribing to patients with renal or hepatic dysfunction because decreased clearance of medications among these patients can lead to accumulation of drugs to toxic levels and persistence in the body for longer durations. She will also testify that a fair-quality study demonstrated a higher risk for overdose among patients treated with ER/LA opioids than among those treated with immediate-release opioids, especially within the first 2 weeks of therapy, with relative risk decreasing with longer duration of exposure (7,192). Clinical evidence reviews did not find evidence that continuous, time-scheduled use of ER/LA opioids is more effective or safer than intermittent use of immediate-release opioids or that time-scheduled use of ER/ LA opioids reduces risk for opioid use disorder.

Dr. Kirchbaum will also testify that SAMHSA's 2019 National Survey on Drug Use and Health found that among people aged 12 or older, the percentage who were past year misusers of prescription pain relievers declined from 4.7 percent (or 12.5 million people) in 2015 to 3.5 percent (or 9.7 million people) in 2019.

Dr. Kirchbaum will testify that extended release/long acting opioids are not safer than immediate release opioids and that extended release/long acting opioid formulations are significantly and independently associated with the likelihood of overdose. See, Zedler, B. K., Saunders, W. B., Joyce, A. R., Vick, C. C., & Murrelle, E. L. (2018) Validation of a screening risk index for serious prescription opioid-induced respiratory depression or overdose in a US commercial health plan claims database. *Pain Medicine*, *19*(1), 68-78.

Dr. Kirchbaum will testify that "cocktail" prescribing is common and legitimate and justified in this case and will refute the opinions of the Government's proposed expert. She will testify that there are different types of pain and explain how they are treated. Dr. Kirchbaum will also testify that ER/LA formulations can be more expensive, have limited availability at times, and testify to the extent to which they are covered by insurance.

Dr. Goar Alvarez, Pharm.D., C.Ph.

Dr. Alvarez is a Florida pharmacist and Florida pharmacy expert. Dr. Alvarez is a professor and Assistant Dean at the Nova Southeastern University College of Pharmacy (the Government's proposed expert's *alma mater*), Director of the Nova Southeastern University Clinic Pharmacy, and the Director of Pharmacy at South Florida State Hospital. He received his bachelor's degree in pharmacy from Florida A&M University and his Doctor of Pharmacy from Nova Southeastern University. Dr. Alvarez is past Speaker of the FPA House of Delegates and past President of the Florida Pharmacy Association. He is also the 2002 recipient of the James H. Beal "Pharmacist of the Year" award. In 2012 Dr. Alvarez received the Interamerican Pharmacists Association's prestigious "Roman Corrons Inspiration and Motivation" Award. A year later, in 2013 he received the "RQ Richards Award" for outstanding achievement in the field of pharmacy public relations in the State of Florida. In 2017 he received the APhA/NASPA

"Bowl of Hygeia" Award which recognizes pharmacists who possess outstanding records of civic leadership. Dr. Alvarez was appointed to the Florida Board of Pharmacy by Governor Rick Scott in 2014.

Dr. Alvarez will testify that the opinions of the Government's proposed expert regarding red flags, the standard of care, and a pharmacists corresponding responsibility are not supported by and inconsistent with the actual standard of care for dispensing controlled substances and a pharmacist's corresponding responsibility under federal law and Florida state law as taught by him and others in academic settings and practice settings, particularly retail pharmacy practice. He will testify what red flags are and that all red flags are resolvable. Dr. Alvarez will testify that the Pharmacy complied with applicable law and the standard of care in dispensing the prescriptions at issue in this case.

PROPOSED DOCUMENTARY EVIDENCE

Exhibit 1. Oath of a Pharmacist (1 page)
Exhibit 2. 21 USC 823(g) (1 page)
Exhibit 3. 21 USC 824(d) (1 page)
Exhibit 4. 21 CFR 1306.04 (1 page)
Exhibit 5. 21 CFR 1306.06 (1 page)
Exhibit 6. 21 USC 829 (2 pages)
Exhibit 7. 64B16-27.810 (1 page)
Exhibit 8. 64B16-27.800 (1 page)
Exhibit 9. 64B16-27.831 2023 Final (1 page)
Exhibit 10. 64B16-27.300 (1 page)
Exhibit 11. Simfarose ACHC Certificate of Accreditation (2 pages)
Exhibit 12. Charles Bonanno Geriatrics Certification (1 page)
Exhibit 13. Simfarose VIGIL Policy (2 pages)
Exhibit 14. Simfarose Medical Use Agreement (5 pages)
Exhibit 15. Simfarose Questionnaire (2 pages)
Exhibit 16. Simfarose Pharmacy Policy (6 pages)
Exhibit 17. Florida Pharmacy Association C.E. Validation of Prescriptions for Controlled Substance (18 pages)
Exhibit 18. Dr. Charles Bonanno Certificate of Completion of Continued Education (1 page)
Exhibit 19. CMS 2019 Medicare Part D Opioid Policies/ Information for Pharmacies (2 pages)

Exhibit 20. Express Communications Opioid Safety Edits (3 pages)
Exhibit 21. EFORCSE History Request Log (6 pages)
Exhibit 22. 2016 CDC Guidelines for Chronic Pain (52 pages)
Exhibit 23. 2022 CDC Guidelines for Chronic Pain (100 pages)
Exhibit 24. U.S. Dept. of Health/ Opioids in Medicare Part D (16 pages)
Exhibit 25. Declaration of Charles Bonanno re. the Dec. 17, 2021 AIW execution (8 pages)
Exhibit 26. Declaration of Andrea L. Wolfson re. the Dec. 17, 2021 AIW execution (5pages)
Exhibit 27. Declaration of John Tartaglia re. the Dec. 17, 2021 AIW execution (25 pages)
Exhibit 28. Sur-Reply Charles Bonanno (8 pages).pdf
Exhibit 29. Sur Reply Sarina Bonanno (2 pages)
Exhibit 30. Sur Reply Gladyz Suarez (2 pages)
Exhibit 31. Def's reply in motion for leave to file video (3 pages)
Exhibit 32. Declaration DI Szwanke declaring Charles Bonanno was not forbidden consulting with counsel (2 pages)
Exhibit 33. Video showing DEA denying Charles Bonanno access to counsel during AIW execution (flash drive)
Exhibit 34. Video Recording showing DEA further denying counsel to Charles Bonanno and stating it was a "crime scene" (flash drive)
Exhibit 35. C.S Prescriptions and Corresponding Documents (422 pages)
Exhibit 36. Da.B. Prescriptions and Corresponding Documents (158 pages)
Exhibit 37. D.E Prescriptions and Corresponding Documents (430 pages)
Exhibit 38. De.B. Prescriptions and Corresponding Documents (109 pages).pdf
Exhibit 39. H.S. Prescriptions and Corresponding Documents (308 pages)
Exhibit 40. J.R Prescriptions and Corresponding Documents (99 pages)
Exhibit 41. M.S Prescriptions and Corresponding Documents (79 pages)
Exhibit 42. K.F Prescriptions and Corresponding Documents (334 pages)
Exhibit 43. A.W Prescriptions and Corresponding Documents (766 pages)
Exhibit 44. A.W. E-FORCSE (14 pages)
Exhibit 45. C.S. E-FORCSE (9 pages)
Exhibit 46. D.E. E-FORCSE (9 pages)
Exhibit 47. Da.B. E-FORCSE (6 pages)
Exhibit 48. De.B. E-FORCSE (8 pages)
Exhibit 49. H.S. E-FORCSE (6 pages)
Exhibit 50. J.R. E-FORCSE (4 pages)
Exhibit 51. K.F. E-FORCSE (28 pages)
Exhibit 52. M.S. E-FORCSE (9 pages)
Exhibit 53. R.S. E-FORCSE (7 pages)
Exhibit 54. A.W. Medical Expense Report (137 pages)
Exhibit 55. C.S. Medical Expense Report (35 pages)
Exhibit 56. D.E. Medical Expense Reports (57 pages)
Exhibit 57. Da.B. Medical Expense Report (19 pages)
Exhibit 58. De.B. Medical Expense Report (32 pages)
Exhibit 59. H.S. Medical Expense Report (54 pages)
Exhibit 60. J.R. Medical Expense Report (50 pages)

Exhibit 61. K.F. Medical Expense Report (158 pages)
Exhibit 62. M.S. Medical Expense Report (46 pages)
Exhibit 63. R.S. Medical Expense Report (26 pages)
Exhibit 64. A.W. Patient Files (101 pages)
Exhibit 65. C.S. Patient Files (54 pages)
Exhibit 66. D.E. Patient Files (30 pages)
Exhibit 67. Da.B. Patient Files (169 pages)
Exhibit 68. De.B. Patient Files (50 pages)
Exhibit 69. H.S. Patient Files (58 pages)
Exhibit 70. J.R. Patient Files (52 pages)
Exhibit 71. K.F. Patient Files (75 pages)
Exhibit 72. M.S. Patient Files (37 pages)
Exhibit 73. R.S. Patient Files (36 pages
Exhibit 74. K.F. MTM Report (25 pages)
Exhibit 75. AW Workflow Safety Check DUR Report (9 pages)
Exhibit 76. Dr. Trobman letter regarding patient care for C.S. (1 page)
Exhibit 77. Dr. Trobman letter regarding patient care for De.B. (1 page)
Exhibit 78. Dr Mendez letter regarding patient care for D.E. (1 page)
Exhibit 79. Dr. Herbert Slavin Affidavit for patient AW (2 pages)
Exhibit 80. AW Files Previously Provided to Government (4,191 pages)
Exhibit 81. Curriculum Vitae for Dr. Robert M. Parrado (18 pages)
Exhibit 82. Curriculum Vitae for Dr. Tracey Schossow (6 pages)
Exhibit 83. Excerpt from trial testimony of Dr. Francisco Vilasuso (21 pages)
Exhibit 84. R.S. Prescriptions (256 pages)
Exhibit 85. 21 CFR Part 1306 .11-15(up to date as of 6-22-2023) (5 pages)
Exhibit 86. 21 CFR Part 1306.01-09 (up to date as of 6-22-2023)(5 pages)
Exhibit 87. DEA Pharmacist Manual (124 pages)
Exhibit 88. NCPDP Reject 88 (4 pages)
Exhibit 89. CS Workflow Safety Check DUR Report (3 pages)
Exhibit 90. DE Workflow Safety Check DUR Report (3 pages)
Exhibit 91. DaB Workflow Safety Check DUR Report (4 pages)
Exhibit 92. DeB Workflow Safety Check DUR Report (2 pages)
Exhibit 93. HS Workflow Safety Check DUR Report (2 pages)
Exhibit 94. JR Workflow Safety Check DUR Report (2 pages).pdf
Exhibit 95. KF Workflow Safety Check DUR Report (4 pages)
Exhibit 96. MS Workflow Safety Check DUR Report (2 pages)
Exhibit 97. RS Workflow Safety Check DUR Report (2 pages)
Exhibit 98. Curriculum Vitae of Matthew Hermenau (9 pages)
Exhibit 99. Article about Susan Langston In Tears about DEA's Action - Feds, Pharmacies Grapple With Pain Pill Dilemma | Health News Florida (7 pages)
Exhibit 100. Video of DEA Meeting 2015 (flash drive)
Exhibit 101. Audio of June 14 2023 Florida Board Rules Meeting (flash drive)
Exhibit 102. Curriculum Vitae of Michelle Krichbaum (14 pages)
Exhibit 103. 64B16-27.831 History of Changes (22 pages)
Exhibit 104. 64K-1.007 Indicators of Controlled Substance Abuse (1 page)
Exhibit 105. Dr. Bonanno Notes about Ordering (3 pages)

Exhibit 106. 2014 Video - Texas State Board of Pharmacy and Anti-Diversion Industry Working Group (ADIWG) video regarding DEA red flags (flash drive)
Exhibit 107. Memorandum dated January 25, 2018 from U.S. the Associate Attorney General Memorandum to the Heads of Civil Litigating Components U.S. Attorneys Re: Limited Use of Agency Guidance Documents in Affirmative Civil Enforcement Cases (2 pages)
Exhibit 108. Medicare Part D Prescription Opioid Policies (30 pages)
Exhibit 109. NABP Stakeholders' Challenges and Red Flag Warning Signs Related to Prescribing and Dispensing Controlled Substances (2015) (17 pages)
Exhibit 110. Medicare Part D Opioid Policies: Information for Pharmacists (2 pages)
Exhibit 111. NABP Report of the Task Force on Prescription Drug Abuse (2016) (8 pages)
Exhibit 112. Letter from Deputy Administrator Rannazzisi to Carmen Cantizone, NABP, dated August 24, 2011 (2 pages)
Exhibit 113. FDA Safety Announcement Harm from Sudden Discontinuation of Opioid Pain Medicines and Required Label Changes to Guide Prescribers on Gradual, Individualized Tapering (April 29, 2019) (4 pages)
Exhibit 114. CMS Medicare Learning Network Fact Sheet, Medicare Prescription Drug (Part D) Opioid Policies (6 pages)
Exhibit 115. HHS Guidance Co-Prescribing Naloxone (2 pages)
Exhibit 116. FDA Drug Safety Communication (April 13, 2023) (18 pages)
Exhibit 117. FDA ER/LA Opioid Analgesic Class Labeling Changes and Postmarketing Requirements (September 10, 2013) (18 pages)
Exhibit 118. DEA Deputy Assistant Thomas Prevoznik letter to National Association of Chain Drug Stores (2 pages)
Exhibit 119. American Medical Association letter to Walmart's Chief Medical and Analytics Officer (2 pages)
Exhibit 120. Article - A Misguided Department of Justice Lawsuit Forces Pharmacists Between Patients and Their Doctors (10 pages)
Exhibit 121. Opioid Settlement Attorney General Moody Secures Relief for Opioid Crisis | My Florida Legal (4 pages)
Exhibit 122. Florida Board of Pharmacy Controlled Substances Standards Subcommittee Minutes of September 21, 2015 Public Meeting (5 pages)
Exhibit 123. Clinical Checking in QS1 (141 pages)
Exhibit 124. Goar Alvarez Profile (1 page)
Exhibit 125. Simfarose Discharge List (2 pages)
Exhibit 126. State of Florida Settlement Agreement with CVS (153 pages)
Exhibit 127. State of Florida Settlement Agreement with Walgreens (146 pages)

OTHER MATTERS

1. Respondent objects to the Government's proposed evidence obtained during the AIW (Gvt. Proposed Ex. No. 5). Respondent argues the evidence offered by the Government was

obtained illegally during the Government's improper execution of the AIW. The Government went beyond the scope of the AIW by seizing items not listed in the AIW, in addition to violating individual constitutional rights. The Pharmacy respectfully requests this Tribunal to consider excluding the tainted evidence proposed in the Government's case.

2. Respondent requests a final determination of the Internal Investigation launched regarding the execution of the AIW performed by Melissa Szwanke.
3. Respondent does not have in its possession original evidence of prescriptions and corresponding documentation/comments on those prescriptions due to the Government's seizure of such items, and the Government's continued possession of such evidence. Respondent is offering the next best evidence that it has in its possession - any recovered evidence and any evidence not in the Government's possession.
4. The Government has not, at any time, asked the Pharmacy to present to them any documents, justifications, or reasons how it resolved certain red-flags
5. Respondent seeks to take the deposition of the DEA's expert witness. The Government has not indicated that the expert has viewed documents in the Pharmacy's ordinary course of business to help resolve red-flags; has not spoken with any of the prescribers to determine what the prescriptions were for or whether the prescriptions were for legitimate reasons; has not reviewed the medical history or any records particular to the patients; and has not examined any of the patients. The expert witness is not a licensed medical doctor, nor is he a specialty doctor in any of the specialties of the prescribers who in fact wrote the prescriptions. The expert witness is not a licensed doctor and lacks the education, training, and expertise of a medical doctor. The expert is offering an opinion of a doctor - that the prescriptions at issue written by board certified physicians "were not

written for a legitimate medical purpose." Therefore, a pretrial deposition will allows for a determination of facts as to whether there is a proper predicate for the expert to proffer expert opinion, whether he has the requisite expertise to give an expert opinion, and whether his expert opinions should be allowed into evidence, which will, for the sake of an efficient hearing, save a substantial time at the hearing in this case.

POSITION REGARDING HEARING SITUS

Respondent respectfully requests the hearing of the case to be conducted in Southeast Florida. Holding a hearing in Arlington, Virginia would not allow the Pharmacy to present its witnesses. Holding a hearing would deny the Pharmacy a fair opportunity to present evidence necessary for a full and true disclosure of all of the facts of the case. Holding a hearing in Arlington, Virginia would impose an onerous financial burden on a small independent community pharmacy.

BEST ESTIMATE AS TO TIME REQUIRED FOR PRESENTATION OF CASE

SimfaRose anticipates it will require 5-7 days exclusive of cross-examination to present its case-in-chief.

Dated: July 24, 2023

Respectfully submitted,

By: *s/ John A. Tartaglia, III*
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Attorneys for Respondent
SimfaRose Pharmacy

To: Paula M. Trahos
David M. Locher

CERTIFICATE OF SERVICE

This is to certify that the undersigned, on July 24, 2023, hereby served a copy of the foregoing Supplemental Prehearing Statement upon the following recipients: (1) Paula M. Trahos, Esq., counsel for the Government, via email to paula.m.trahos@dea.gov, and to the DEA Government Mailbox at dea.registration.litigation@dea.gov; and (2) David M. Locher, counsel for the Government, via email at david.m.locher@dea.gov.

By: *s/ John A. Tartaglia, III*