**UNITED STATES DEPARTMENT OF JUSTICE**

**Drug Enforcement Administration**

|  |  |
| --- | --- |
| In the Matter of  **Pronto Pharmacy, LLC** | **Docket No. 19-42** |

**AMICUS BRIEF**

**CONCERNING THE STANDARD OF PRACTICE IN PHARMACY, LAW AND DECISION OF THE ADMINSISTRATIVE LAW JUDGE**

THE CALYX GROUP

Jack Folson, Jr

[calyxgroup@yahoo.com](mailto:calyxgroup@yahoo.com)

28228 Warren Road

Westland, Michigan 48185

(908) 327-7322

(269) 659-0814 Facsimile

Expert in Pharmacy Practice: Hospital, Retail Chain, Retail Independent, Sterile Compounding, Non-Sterile Compounding, Former Director of Pharmacy.

I have been retained by the respondent to review this case.

The decision in this case will have far-reaching deleterious effects on the professions of Medicine, Nursing and other Mid-Level Practitioners and Pharmacists

June 4, 2020

After reading the TRIAL TRANSCRIPT and ALJ DECISION many glaring errors became apparent. This document is intended to enlighten the court as to the true nature of the STANDARD of CARE as it pertains to the practice of PHARMACY. The practice of Pharmacy has many traditional and emerging roles and a one size fits all standard cannot apply. The proof of this is that certain facets are known as retail establishments, institutional establishments, healthcare organizations and others. Within these broad categories there are subdivisions.

What is clear here is that Pronto Pharmacy is acting as a specialty pharmacy which specializes in pain management as well as non-sterile compounding. Since Dr. Sullivan seems not to have any experience in pain management nor non-sterile compounding it is understandable that he does not grasp of the fine nuances in these fields. Since I have experience in the fields listed above the following is submitted to enlighten the court.

**RED FLAGS OF DIVERSION**

**BACKGROUND**

As far as can be determined as a practicing Pharmacist who is not an attorney the Red Flags of Diversion gained the most traction in the Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 and 5195 case. However, in that case the Pharmacies in question were regular chain drug stores but Pronto Pharmacy is a specialty Pharmacy which specializes in pain management and compounding. Therefore, they are in different classes. It’s like the difference between a general practitioner and a surgeon.

True, they are both doctors, but their level of training is not the same and the selection of patients is not the same. A general practitioner might be able to stitch you up after a fall but removing your gall bladder would clearly be beyond his scope of practice. With that in mind consider that Dr. Clement has advanced training in therapeutics, pain management, Dentistry, Forensics, and more than 45 years, experience and the typical CVS Pharmacist has less than 5 years, experience.

The business model for CVS focuses on high speed production and Pronto Pharmacy is focused on disease state management. And, just like people might travel long distances to seek out a surgeon that has a high level of training and a history of positive outcomes the same would be true of Pronto Pharmacy. You would be hard pressed to find a CVS Pharmacist that could have the time to investigate chronic pain treatment modalities and how they impact severely compromised patients.

However, Dr. Clement has numerous sources of information that the typical Pharmacist would not be aware of. As a clinical Pharmacist, I have seen some of his vast library of information and was suitably impressed. So, things that might be a “red flag” to the inexperienced Pharmacist are little more than footnote for us. Many of our patients have been on service for many years so the red flags may have been resolved years or even decades ago. Therefore, the documentation of the same might not be captured by an investigator that does not interview the patient, the Physician, or the Pharmacist. Often, the pertinent information is archived.

In the Holliday CVS case one issue was the dispensing of narcotic prescriptions from prescribers with expired or revoked DEA registrations. This did not happen at Pronto Pharmacy.

**HIGH DOSE OPIOIDS**

At trial, the expert witness for the DEA, Mr. Sullivan contended that the Oxycodone and Hydrocodone were the highest available dosage form. However, this is misleading in the world of pain management. Many states require that the prescriptions for C-2 narcotics contain a maximal daily dose, and in the Holliday CVS case the maximum daily dose for Oxycodone was 6 tablets of 30mg which is 180 mg per day. I have seen this dose in several states, and it is considered the top of the Oxycodone range for severe pain.

However, at Pronto Pharmacy the maximum daily dose of Oxycodone was a mere 90 mg. In fact, the equivalent dose in Morphine Milligram Equivalents in hospitalized patients can top 210 mg per day in acute cases. In certain cancer patients, the dose could be even higher. So, in the overall scheme of things the current standard of care for these types of patients is to keep them at 90 mg per day or less if in chronic pain. It is understandable that a professor of diversion would not know about the clinical ramifications of the specialist level of pain management. However, he correctly stated that the practice of Pharmacy is moving more towards disease state management, which correctly describes Pronto Pharmacy and its practice.

A similar example would be for Vancomycin which is an antibiotic with a narrow therapeutic index. Typically, the dose in hospital is 500 mg twice a day for 3 days. However, in Lyme Disease, the dose is titrated by peak and trough levels and can be as high as 2000 mg intravenously every 12 hours. With careful titration and attention to the appropriate blood levels and presenting symptoms a clinical pharmacist who is in charge of the therapy can ensure safe and effective outcomes for these patients that require this medication for about 6 weeks at home.

So, no. These are not excessively high doses in the patient population that is being treated. Remember, these patients have been stabilized on these medications for years and continue to get the same doses from other Pharmacies currently. To single Pronto Pharmacy out of all the drug stores in America and by way of immediate suspension order without a hearing could be seen as **Unconstitutional**. His right to make a living (life, liberty and pursuit of happiness) was taken away many months before the hearing began.

Just like in the CVS case in which Professor Doering testified that he could not foresee anything that would change his opinion we see that Professor Sullivan who is also a teacher, but not a practitioner in the specialty of pain management, also could not foresee anything that could enlighten him either. However, in neither case were the patients considered. But to close the avenues for patient care without considering the patients would be improper. Presently, because of the criminalization of pain management suffering has increased and has led, to an increase in Heroin use. Due to the dangers associated with heroin use this, more than anything else in this case is an immediate threat to public safety. To put it plainly the actions by the DEA are causing the thing that they are trying to avoid.

According to the Office of the Inspector General’s report on the DEA as prescription opioids has remained relatively flat the increase of heroin use has been skyrocketing. Death by fentanyl, which was once a rarity, is becoming a big player in the death of Americans due to opioids. If Pronto Pharmacy were actually in the business of diversion, I would applaud the DEA’s effort to rid the profession of bad actors. However, in this case it seems that there are too many irregularities to come to that conclusion. Not only is there no evidence to the level of “more likely than not” but the level of “preponderance of evidence” has not been met either.

**MULTIPLE PRESCRIBERS**

Although the case glossed over this red flag, a patient going to multiple prescribers to obtain high dose opioid medications is a well-established red flag of diversion. The basis of this is that the patient, prescriber, pharmacy relationship is not present. Although the presence of this is not proof of diversion, it has been highly touted as suspicious. However, there are many reasons that this could be explained or cleared. On the PDMP dataset if a patient goes to a clinic and sees several prescribers in that clinic it will show up as multiple prescribers, but, on closer examination the fact that the prescribers are at the same address could be determined. If the prescriber has multiple offices and the patient is seen at different offices or the information is entered into the computer incorrectly the PDMP data could appear to be that of drug seeking behavior or merely that of convenience for the patient or the prescriber.

What is glaring in this case is that every patient noted in the allegation only got medications from one specific prescriber for that individual patient. So, this firmly establishes for each patient the prescriber, patient, pharmacy relationship and should be the firm foundation that this case should be based upon. This is important for several reasons because when relationships are formed it causes variations in behavior that do not happen without a relationship.

If a pharmacy acts only as a source of medication for a particular patient, then they are more likely to obtain whatever they need wherever they find convenient. Often, such a patient will seek out the lowest cost. On other occasions that type of patient will be concerned specifically with service. However, when there is a relationship such as with a specialist, that patient will reasonably travel higher distances, and avoid other specialists in the field. Pronto Pharmacy is a compounding pharmacy which is a specialty. Pronto Pharmacy is a pain management pharmacy which is a specialty. A reasonable and prudent medical observer of the actions of the patients, prescribers and pharmacists involved would see this relationship as normal everyday specialty practice.

**DISTANCE**

The red flag of distance serves as a discussion point in Pharmacy. If a patient, travels so far that they pass several Pharmacies to get to a specific Pharmacy many issues may be in play. One is cost. Since many patients have insurance and many Pharmacies take most insurances the cost to the patient is most likely the same. However, more than 8.5 % of Americans are without insurance now and 13.5 % were at the time of the Affordable Care Act according to the census bureau (<https://khn.org/news/number-of-americans-without-insurance-rises-in-2018/> ). Coupled with that are the increasing number of American Nationals that are not counted and the illegal immigrants who for the most part do not have insurance would make this red flag an unreliable indicator of actual diversion. In fact, in light of the current trend of insurance companies, bolstered by the Pharmacy Benefit Managers (PBM’s) this is likely to become increasingly irrelevant if it is not already.

The business practices of these near monopolies are akin to those of Standard Oil before it was broken up by the Sherman Antitrust Act ( <https://en.wikipedia.org/wiki/Standard_Oil> ). The PBM’s attack smaller retail Pharmacies with substandard reimbursement while paying their larger Pharmacy chain operations a premium for the same medications on the same day (<https://communityoncology.org/march-30-what-cvs-is-doing-to-mom-and-pop-pharmacies-in-the-us-will-make-your-blood-boil/> ) . This effectively leads to small retail Pharmacies being forced to charge larger copayments and the chains being able to charge lower copayments. Kickbacks and Rebates between wholesalers, insurers and PBM’s which are hidden in convoluted pricing schemes all the while under the secrecy of “Trade Secrets” threaten to undermine the patient’s overall Freedom of Choice (42 CFR sec 431.51).

According to the Pharmacy trade publication which is one authority in standard of care in Pharmacy practice:

<https://www.pharmacytimes.com/contributor/jeffrey-fudin/2017/10/opioid-red-flags-for-consideration->

“Of late, some community pharmacy chains have changed policies that have been developed around the pretext of patient safety.Such policies include limited-day supply of opioids for acute pain. However, this may present a bitter inconvenience for patients who **legitimately require** opioids for a major acute injury and also maximizes the profitability associated with multiple copays and dispensing fees for drugs that cost pennies. To our knowledge, there is no evidence to support that limited supplies for legitimate patients improves safety or mitigate risk. In fact, there is sufficient data to support that placing such barriers, at least for patients requiring long-term opioids, may actually contribute to the heroin epidemic.”

It would be reasonable for a patient to travel outside of their local area when faced with such discrimination by the Chain Pharmacies such as CVS, Walgreens, Rite-Aid and others if they have chronic pain. With their combined market share it would be, almost impossible for such a patient to be, treated properly at all times.

Because Pronto Pharmacy is a specialty Pharmacy that specializes in pain management and compounding it is reasonable for their clientele to travel distances that normal Pharmacy patients without intractable pain and are low income or without insurance would travel. As Director of Pharmacy in Home Infusion companies I have personally needed to send delivery prescriptions for pain management medications as much as 4 hour drives away. This has been a common practice in the specialty of pain management for over 25 years. There is one company that I worked for that sent hemophilia patients various clotting factors nationwide. To single out pain management as criminal while ignoring the vast number of therapies is improper intrusion of government into a patient’s constitutionally guaranteed right of life, liberty, and the pursuit of happiness.

The State of Florida is a big player in the practice of **Mail Order Pharmacy** and as such provides medications (controlled and non-controlled) to patients in other states. This in and of itself should **invalidate the red flag of distance** since this practice is condoned and supported by the Florida State Legislature and the Florida Board of Pharmacy. To discriminate against Florida Pharmacies treating Florida patients is grotesque.

In terms of documentation, I have personally seen patient interviews that were conducted between Dr. Clement and his patients that were in intractable pain. As an expert in the field of diversion as well as pain management, it is clear that without clear cut guidelines from the DEA, FDA, JCAHO or ISMP the steps were reasonable and prudent. Other similarly practicing Pharmacists would concur with my conclusions.

The DEA removed **all of the documentation** from Pronto Pharmacy as well as the backups but did not return them to Dr. Clement intact. In fact, because of the **negligence of the DEA** some of the data was never retrievable, thus making it impossible for Dr. Clement to present the necessary notations on the prescription images, patient notes, patient profiles, and physician notes therein. Then accused him of not having the proper documentation. In some circles this would be considered tampering with evidence. This is a very suspicious activity on the part of the DEA.

**EARLY FILLS**

Narcotic prescriptions are not refillable and thus cannot be refilled early. There has never been a C-2 narcotic refilled at Pronto Pharmacy. That said, let’s look at early fills. **Intractable pain** is a very complex syndrome complete with changing dynamic clinical states. These changes in morbidity can mean that a patient may be stabilized on a particular regimen and suddenly fall out of pain control and as such need higher doses of pain medications. The opposite is true also. A patient may find that after reaching steady state blood levels they would find that they could tolerate the pain for longer times between medication.

Drug interactions play an important role in these changes. Therefore, for a patient to require an early fill of their medication is not uncommon, nor is a gap in treatment for several months. The goal of therapy is the reduction of pain to tolerable levels. If a patient runs out of the medication anxiety can often lead to an increased sensation of pain. This is why patients, especially ones that have to travel far for their medications often come in 2 – 7 days early from time to time. In fact, the insurance companies have set up override codes for this very fact. Every Pharmacy system in America has the ability to track override codes.

However, since the DEA destroyed the data in the Pronto Pharmacy computer these codes, which are no more than 6 characters spread out over 3 different fields cannot be presented. The malfeasance of the DEA could be considered contributary negligence in this case. Other places that such documentation could be found are on the front or back of the original prescriptions. Not to mention the electronic patient profiles, all of which were available to the DEA but not presented at trial.

**DRUG COCKTAILS**

In this case the DEA continually referred to combinations of medications as Drug Cocktails, which has no basis in clinical pharmacy nor medicine. It might be a street term but since we as Pharmacists do not operate in the street the use of that terminology is more akin to propaganda than actual medical practice. Many patients with chronic pain have comorbidities and as such require medications to treat other issues. To cherry pick out two or three conditions and to assign criminality to them without benefit of knowing what the patient’s condition is rises to the height of absurdity and should be discounted.

There is a plethora of double-blind, prospective and retrospective studies that conclude that the combination of several combinations of oxycodone, hydrocodone, gabapentin, cyclobenzaprine, ibuprofen, ketoprofen, alprazolam, temazepam, oxazepam, baclofen and others have increased efficacy in terms of pain management and the management of comorbidities commonly associated with inflammation, pain and paralysis. There are competing step care **protocols** as well as **empirical therapy** in use in hospitals, home infusion and community Pharmacy and therefore to criminalize the ones being used in these cases without benefit of the patient interview or prescriber input would raise serious doubts about this red flag. The current information that the DEA uses to evaluate the use of opioids in the treatment of chronic pain is geared towards primary care practitioners and not specialists.

CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016 <https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fmmwr%2Fvolumes%2F65%2Frr%2Frr6501e1er.htm>

Even still because of the fear of retribution by the DEA most prescribers went too conservative in their approach. Indeed, the CDC as well as the FDA agree that these standards may be too constricting in a majority of pain patients.

Feds issue new warning to doctors: Don't skimp too much on opioid pain pills

<https://www.usatoday.com/story/news/health/2019/04/24/opioid-pain-pills-crackdown-doctors-prescriptions-cdc-fda/3562373002/>

This has left too many patients not getting the pain relief that they deserve. In fact, pain relief is a fundamental human right according to the International Treaty on Human Rights that the United States is a signatory to.

Pain management: a fundamental human right.

<https://www.ncbi.nlm.nih.gov/pubmed/17578977>

One of the most exciting developments in pain management is **opioid rotation**. In this technique short acting opioids are rotated or alternated in patients that have developed tolerance. Analgesic tolerance is defined pharmacologically as a reduced potency of the analgesic effects of opioids after repeated administration or the need for higher doses to maintain the same effect. Tolerance is such a factor that State Legislatures nationwide and Congress are grappling with the clinical ramifications of their directives for example: The Intractable Pain Treatment act of Texas indicates that there is overwhelming evidence that all types of pain, either of malignant or nonmalignant origin, are undertreated and reluctance to use narcotics for selected patients with nonmalignant painful medical conditions stems from the **mistaken belief** that they will become narcotic "addicts." Data from the medical literature do not support such a contention. Since Dr. Sullivan is not practicing in the field of pain management or hospital or long-term care it is not unexpected that these new treatment modalities are not on his radar.

Opioid rotation for cancer pain – Americn Cancer Society Journal <https://acsjournals.onlinelibrary.wiley.com/doi/full/10.1002/(SICI)1097-0142(19991101)86:9%3C1856::AID-CNCR30%3E3.0.CO;2-G>

Other Examples:

* 2009 Clinical Guidelines from the American Pain Society and the American Academy of Pain Medicine on the use of chronic opioid therapy in chronic noncancer pain: what are the key messages for clinical practice?<https://www.ncbi.nlm.nih.gov/pubmed/19776687>
* Negative mood mediates the effect of poor sleep on pain among chronic pain patients.<https://www.researchgate.net/publication/43148187_Negative_Mood_Mediates_the_Effect_of_Poor_Sleep_on_Pain_Among_Chronic_Pain_Patients>
* The intractable pain treatment act of Texas <https://europepmc.org/abstract/med/1348377>
* Opioid Cumulative Daily Morphine Milligram Equivalents (MME) Limit – MME Decrease – Alabama Medicaid. <https://medicaid.alabama.gov/alert_detail.aspx?ID=13378>

**CASH PAYMENTS**

As was stated before **suspicion of diversion is not actual diversion**. However, as a diversion expert I am aware that there are people who attempt to fraudulently obtain narcotics from Pharmacies and one thing that tips a Pharmacist off is that the patient attempts to purchase the medication by using cash. This is particularly concerning when it is known that the patient has insurance available. But there are many reasons that this so called “red flag” may be investigated and cleared. By checking the PDMP data it is possible to see that a patient has, in the past, obtained the medication in question by using insurance. If this is found to be true it is possible that the patient is trying to divert, especially in the face of other red flags such as distance, early fill, unreasonable therapy and the like. However, in this case the historical PDMP data was not produced by the DEA at trial, so it is impossible to say for sure that this condition of ignoring past payment methods existed for any of the patients in question.

This is crucial information. There are so many legitimate reasons that a patient would pay cash that were not addressed at trial. The patient in question could not have insurance at all. The patient could have a lapse in coverage. The patient might have insurance that is provided by their employer and they might not want the employer to know that they have chronic pain. Examples of that might be truck drivers or medical personnel or heavy equipment operators.

The local pharmacies might not accept their insurance. Pronto Pharmacy could not have a contract with the patient’s insurance. This item was proven at trial. If there is no PBM contract there is no insurance contract. It is common knowledge that Pronto Pharmacy’s business model includes the principle of not accepting insurance company contracts.

It is also proven at trial that there is no law, Federal, State, or Local that requires contracting with a PBM for a Pharmacy. In fact, I used to be the Supervising Pharmacist of a place called Cash Rx Plus Pharmacy in New York City, who did not take insurances either. Many Pharmacies take a few insurances and not others. With the shrinking margins that are forced upon community pharmacies nationwide many are cherry-picking which insurance companies to contract with. Some are avoiding them altogether. This is an increasing trend in the marketplace.

The USD or United States Dollar, which is the fiat currency of the THE UNITED STATES OF AMERICA has a statement on every denomination. It says, “THIS NOTE IS LEGAL TENDER FOR ALL DEBTS PUBLIC AND PRIVATE.” According to 31 U.S. Code § 5103 United States coins and currency (including Federal reserve notes and circulating notes of Federal reserve banks and national banks) are legal tender for all debts, public charges, taxes, and dues. Foreign gold or silver coins are not legal tender for debts. The prevailing sentiment on this is that all United States money as identified above are a valid and legal offer of payment for debts when tendered to a creditor. There is, however, no Federal statute mandating that a private business, a person or an organization must accept currency or coins as for payment for goods and/or services. Private businesses are free to develop their own policies on whether or not to accept cash unless there is a State law which says otherwise. For example, a bus line may prohibit payment of fares in pennies or dollar bills. In addition, movie theaters, convenience stores and gas stations may refuse to accept large denomination currency (usually notes above $20) as a matter of policy.

Currently, there is no law in this country that contravenes 31 U.S. Code § 5103. Therefore, if a patient offers to pay in cash it might seem suspicious but does not necessarily rise to the level of actual diversion. This is important because any patient has the right to expect that the Pharmacy will act within the law in this matter and in light of their freedom of choice and fundamental human right suspicion may be present but does not require that the patients, themselves to be subject to this requirement.

If a Pharmacist does not reasonably believe that the medication is going to be diverted there is no reason not to accept cash. Currently, the PDMP system at present cannot distinguish between cash, credit, debit or healthcare payment cards. All, of these things come up on the system as cash. With the growing cost of medications, the payment of copayments as well as full prices by credit or debit cards is increasing. Healthcare payment cards often are the form that employers use to decrease their overall healthcare costs by limiting the benefit to their employees. The employer matches contributions to the funds made through payroll deductions with specific limitations and these are in fact insurance in a broad sense. It removes the bureaucracy of insurance companies, PBM’s and switches from the overall cost of healthcare.

**COMPOUNDING VS MANUFACTURING**

The Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Act, was legislatively negotiated to strike “a balance between two potentially competing policy interests—inducing pioneering development of pharmaceutical formulations and methods and facilitating efficient transition to a market with low-cost, generic copies of those pioneering inventions at the close of a patent term.” The Hatch-Waxman Act was, at least according to two economists, the first change in patent terms since 1861. So, one of the pillars of the generic drug push by Congress was to ensure that patients had low cost alternatives to brand name drugs.

Compounding has been a primary facet of the practice of Pharmacy since the beginning of the profession. Prior to that it was only done legally by physicians or their assistants. In the United States, compounding pharmacies are licensed and regulated by their respective states like all other pharmacies. National standards have been created by Pharmacy Compounding Accreditation Board (PCAB). However, accreditation is not mandatory and inspections for compliance occur only every three years for particular facets of compounding.  As mentioned, some confusion has arisen when the traditionally patient-specific nature of compounding gets blurred by the making the multi-product "batches" such as in anticipation of similar orders. Notably, the Food and Drug Administration (FDA) has always had authority to regulate "manufacturing" – which is when drug products are not made or modified as to be *tailored in some way to the individual patient* – regardless of whether this is done at a factory or at a pharmacy. And conversely, truly legitimate/traditional compounding does not cease to be so merely by having a high *frequency* or occurrence – indeed, progressing towards *more* prevalent drug product customization is an appealing aspect of personalized medicine. <https://en.wikipedia.org/wiki/Compounding>

Since I have experience in Manufacturing (Schering-Key) as well as sterile compounding (Director of Pharmacy of several Home Infusion Pharmacies) along with non-sterile compounding (more than 30 years in Retail Pharmacy) very few Pharmacists nationwide have my level of experience and as such I could be thought of as an authority on the subjects. It was apparent that the Administrative Law Judge (Mr. Dowd), the Diversion Expert (Mr. Alpert), the Prosecutor (Mr. Beerbower), as well as the Expert Witness (Mr. Sullivan) are not likely to understand the level of care and clinical issues in this case better than myself. Additionally, since I have extra training in reading and understanding the law, although I am not an Attorney, I could be considered a Lawyer (a person learned in the law) as defined in Black’s Law Dictionary 3rd Edition. However, I do not delude myself into thinking that my knowledge of the law is all encompassing or greater than that of a Lawful Man acting in the course of the profession of Pharmacy. But I do maintain that my interpretation of all these sometimes apparently conflicting laws and regulations are understandable to myself.

**DEFINITION OF MANUFACTURING**:

21 U.S. Code § 802

(15) The term “manufacture” means the production, preparation, propagation, compounding, or processing of a drug or other substance, either directly or indirectly or by extraction from substances of natural origin, or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of such substance or labeling or relabeling of its container; except that such term does not include the preparation, compounding, packaging, or labeling of a drug or other substance in conformity with applicable State or local law by a practitioner as an incident to his administration or dispensing of such drug or substance in the course of his professional practice. **The term “manufacturer” means a person who manufactures a drug or other substance**.

**DEFINITION OF COMPOUNDING:**

Section 503A of the Federal Food, Drug, and Cosmetic Act SEC. 503A.

PHARMACY COMPOUNDING.

(a) In General.--**Sections 501(a)(2)(B), 502(f)(1), and 505 shall not apply** to a drug product if the drug product is compounded for an identified individual patient based on the unsolicited receipt of a valid prescription order or a notation, approved by the prescribing practitioner, on the prescription order that a compounded product is necessary for the identified patient, if the drug product meets the requirements of this section, and if the compounding--

(1) is by--

(A) a licensed pharmacist in a State licensed pharmacy or a Federal facility, or

(B) a licensed physician, on the prescription order for such individual patient made by a licensed physician or other licensed practitioner authorized by State law to prescribe drugs; or

(2) (A) is by a licensed pharmacist or licensed physician in limited quantities before the receipt of a valid prescription order for such individual patient; and

(B) is based on a history of the licensed pharmacist or licensed physician receiving valid prescription orders for the compounding of the drug product, which orders have been generated solely within an established relationship between--

(i) the licensed pharmacist or licensed physician; and

(ii) (I) such individual patient for whom the prescription order will be provided; or

(II) the physician or other licensed practitioner who will write such prescription order.

At trial, Mr. Sullivan indicated his opinion that compounding should be narrowly drawn. This flies in the face of 200 years of Pharmacy Practice standards. In fact, what he defines as when it is proper to compound is based upon his opinion and that of the manufacturers. However, Pharmacists nationwide would not agree. If a patient is unable to afford their medication their clinical outcomes are less than optimal. Price can be a major factor in compliance, so when Pronto Pharmacy minimizes the impact of price, they are acting within the spirit of the law that created generics in the first place. Because the batches are small it could be inferred that the danger is also decreased. Manufacturers’ errors lead to nationwide recalls (Cimetidine), but small batch compounding can only affect a few people, and therefore safer for the public. When I started in the profession all Pharmacies were required to have compounding supplies as a condition of registration in every state in the union. However, as the manufacturers gained more of a stranglehold on the government with their bribes and corruption, compounding in Pharmacy began to diminish. We found that as insurance penetration into the profession increased the reimbursement for compounding decreased. But Congress and the State Boards of Pharmacy have not totally abandoned the profession and compounding still has its place as a pillar of Pharmacy. Without compounding there will be no intravenous admixtures, specialized solutions to complex problems or innovation.

In this case all the things that are required for compounding instead of manufacturing are present. Each prescription for a compound is for a specific patient. There is a Physician – Pharmacist relationship. There is a Patient – Pharmacist relationship. In the anticipatory compounding reasonable, limited quantities are being compounded and the necessary prescriptions do actually show up in reasonable time frames. All over the country anticipatory compounding is done and a typical limit is about **3 weeks** but may actually loom as high as **3 months** in some cases. This is the standard of care in compounding Pharmacy. For Mr. Sullivan not to realize this is further proof of his lack of experience and thus, he is not an expert in this realm. Diversion Expert Alpert admitted at trial that he has absolutely no understanding of compounding. The DEA did not produce even one piece of evidence that shows mastery of the subject of compounding.

**ANTICIPITORY COMPOUNDING OF CONTROLLED SUBSTANCES**

The DEA contended that Pronto Pharmacy illegally manufactured controlled substances. However, without mastery of the laws concerning compounding their contention fails on its face. Let’s look at the pertinent statutes:

**21 U.S. Code § 841.Prohibited acts**

**(a)Unlawful acts** Except as authorized by this subchapter, it shall be unlawful for any person knowingly or intentionally—

**(1)**to [manufacture](https://www.law.cornell.edu/definitions/uscode.php?width=840&height=800&iframe=true&def_id=21-USC-479169343-1668295555&term_occur=999&term_src=),[distribute,](https://www.law.cornell.edu/definitions/uscode.php?width=840&height=800&iframe=true&def_id=21-USC-1480972831-1668295559&term_occur=999&term_src=title:21:chapter:13:subchapter:I:part:D:section:841) or[dispense,](https://www.law.cornell.edu/definitions/uscode.php?width=840&height=800&iframe=true&def_id=21-USC-284885341-1668295560&term_occur=999&term_src=title:21:chapter:13:subchapter:I:part:D:section:841) or possess with intent to manufacture, distribute, or dispense a controlled substance

Taken by itself I could see their point. However, there are exceptions in play.

This information is available on the DEA website, Findlaw, website and elsewhere. Since the wording in this part is particularly voluminous and Pronto Pharmacy was in possession of a valid DEA license at the time that was without blemish and not expired this is the only pertinent part that might be under question.

**21 USC § 1301.13 Application for registration; time for application; expiration date; registration for independent** **activities; application forms, fees, contents and signature; coincident activities**

(iii) **Dispensing or** Instructing (includes… Retail Pharmacy…) A Pharmacist may manufacture aqueous or oleaginous solution or solid dosage form containing a narcotic controlled substance in a proportion not exceeding 20 percent of the complete solution, compound or mixture,

**Business Activity –** (iv) Dispensing or instructing (includes Practitioner, Hospital/Clinic, **Retail Pharmacy**, Central Fill Pharmacy, Teaching institution)

**Controlled substances Schedules ll-V**

**DEA Application Forms** New – 224 Renewal – 224a

**Application Fee** $731

**REGISTRATION PERIOD** 3 years

**Coincident Activities allowed** May conduct research and instructional activities with those substances for which registration was granted, except that a mid-level practitioner may conduct such research only to the extent expressly authorized under state statute. ***A Pharmacist may manufacture an aqueous or oleaginous solution or solid dosage form consisting a narcotic controlled substance in Schedule ll – V in a proportion not exceeding 20% of the complete solution, compound or mixture***. A Retail Pharmacy may perform central fill activities

As can be seen the when the DEA contended that Pronto Pharmacy needed to be registered as a manufacturer the law says otherwise. Compounding of controlled substances takes place in every state of the union and has since the beginning. If the prohibition is against a certain substance the law could be changed such as it was in the case of heroin, laudanum, opium and so many others. If it were meant to restrict C-2 medications the law could have been changed long before now. The reporting of the C-2 medications in question to PDMP was proper according to the silence on the part of the DEA who brought this case. The question of exceeding the 20% maximum was not a point of contention in the case and therefore is not in question here.

To remove anticipatory compounding from Pharmacy Practice would have many far-reaching negative consequences for patient care and an exponential increase in unnecessary waste. After all, to pierce anticipatory compounding would too broadly define the issue. It would include antibiotics, antipsychotics, neuroleptics, vitamins, tablets, capsules, pills, troches, solutions, emulsions, creams, lotions, macerations, decoctions, ointments, suppositories and all the other dosage forms that exist. It is highly unlikely that the Legislature would have as its intent such an egregious threat to public safety or such burdensome costs to be placed on the American people. The FDA regulates compounding and manufacturing. The DEA is in charge of administration and enforcement of the Controlled Substances Act. The State Boards of Pharmacy regulate compounding. Therefore, a practicing pharmacist would need to be abreast of sometimes overlapping jurisdictions and subsequently possible contradictory information.

**Conclusion**

These are but a few indicators that the search for truth was not existent in this procedure. Everything presented here is common knowledge and available to the DEA and was available before the proceedings. It seems that prosecutorial myopathy was in play here. But, because the DEA has an agenda which is based upon incomplete information and a desire to combat the so called “Opioid Epidemic” and has had their feet held to the fire by the Office of the Inspector General’s Report on the DEA <https://oig.justice.gov/reports/2019/e1905.pdf> their focus on diversion could be seen as overzealous. Unfortunately, individual practitioners have been made the scapegoat of this misguided witch hunt. The biggest issue is that suspicion of diversion is not necessarily actual diversion.

Before starting this case, the DEA could have interviewed the prescribers and found out about the individual patient’s needs. However, they did not. Had they done so, and wrongdoing was found they could have censured the prescriber and notified the Pharmacists in the state to avoid the narcotic prescriptions of that prescriber. If no wrongdoing had been found the DEA could have concentrated its resources in other areas.

Before starting this case, the DEA could have looked at the PDMP data and surmised that these patients were stabilized on pain management therapies. Even if they didn’t fully understand the effects of enzyme induction, drug interactions, tolerance, or comorbidity protocols there is ample information to figure these things out in the public space. However, they did not focus their gaze on possible treatment of patients but rather on suspicion and innuendo.

A reasonable and prudent individual might conclude that discovering the truth was not the goal in this investigation.

RESPECTFULLY SUBMITTED

Jack Folson, Jr – Clinical Pharmacist

Owner – THE CALYX GROUP

28228 Warren Road

Westland, Michigan 48185

908-327-7322

Expert in Pharmacy Practice

**CERTIFICATE OF SERVICE**

I HEREBY CERTIFY that on June 9, 2020, a true and correct copy of the foregoing was electronically filed via ECF and/or served via e-mail upon the following:

|  |  |  |
| --- | --- | --- |
| **John E. Beerbower, Esq.**  Diversion & Regulatory Litigation Section  Drug Enforcement Administration  Office of Chief Counsel  8701 Morrissette Drive  Springfield, VA 22152  John.E.Beerbower@usdoj.gov  DEA.Registration.Litigation@usdoj.gov |  | **Dale R. Sisco // Dominic A. Isgro**  SISCO- LAW  1110 N. Florida Avenue  Tampa, FL  33602  (813) 224-0555  (813) 221-9736 FAX  dsisco@sisco-law.com  Florida Bar No. 559679 disgro@sisco-law.com  Florida Bar No. 113318  *Attorneys for the Respondent* |
| **Hearing Clerk**  Office of Administrative Law Judges  Drug Enforcement Administration  8701 Morrissette Drive  Springfield, VA 22152  ECF-DEA@usdoj.gov |  |  |