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July 9, 2019

**Division of Dockets Management
Department of Health and Human Services
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852**

Dear Food and Drug Administration,

My name is Raymond R. Carlson, R.Ph. and I submit this petition in good faith and under statutory section CFR 21, Part 10, Subpart B, Sec. 10.30.

A. Action Requested:

That the Food and Drug Administration investigate compliance with Section G, entitled "Drug Use Review" within the Omnibus Reconciliation Act of 1990 (OBRA-90) (H.R. 5835)(101st). This petition requests the FDA to enforce or cause to enforce compliance with OBRA-90 within retail and mail order pharmacies if violations are found to be occurring.

Evidence supporting OBRA-90 violations have been attached for your consideration. Given the loss of life and economic impact of the opiate crisis, antibiotic overuse, and the general misuse of most all categories of prescription drugs, a federal law

B. Statement of Grounds

In 1990 Congress passed OBRA-90: Drug Use Review (copy attached) in order to thwart the abuse and misuse of prescription drugs and to save federal funds. The law was supported by the general pharmacy community. In summary, the law was meant to slow down the prescription dispensing process to ensure public safety and reduced the waste of federal prescription dollars. States were given three years to comply and only if they wanted to continue to receive federal funding. For the purpose of this petition, OBRA-90 has four basics components which states were to promulgate laws/rules:

- 1). The pharmacist must offer the service of prescription counseling.
- 2). The pharmacist must make a reasonable effort to record patient-specific information as well as comments relevant to individual drug therapy.
- 3). The pharmacist must review a patient's drug therapy before the prescription is dispensed (Prospective Drug Review).
- 4) The state program must provide for ongoing periodic examinations of drug claims in order to detect patterns of fraud, abuse, and gross overuse through the establishment of a Drug Use Review Board.

Social media is rot with expressions of frustration felt by pharmacists in retail and mail order setting. Our local pharmacists association with 550 members, the Eastern Ohio Pharmacists Association (EOPA), met on March 19, 2017 in order to debate a resolution which asked for agency assessment of dispensing practices. In recognition of today's high volume environment, the resolution passed overwhelmingly in spite of knowing that its passage might subject individual pharmacists to increased scrutiny from the Ohio State Board of Pharmacy (OSBP).

A letter to the Ohio Board of Pharmacy was drafted but several EOPA officers refused to sign for fear of employer reprisal. Without the ability to forward an association letter, a citizen's petition was circulated asking for the same OSBP dispensing assessment. Both the petition and resolution were delivered to the OSBP in April of 2017.

The EOPA resolution and Citizens petition were discussed briefly at the July 2017 Ohio Board of Pharmacy Meeting. No indication was shown that the issue was of priority and a single sentence in the board minutes reflect the amount of consideration it was given.

The decision to file a Writ of Mandamus against the Ohio Board of Pharmacy

Previous meetings of EOPA which saw over 200 pharmacists attending each centered on the growing opiate crisis. As important a social issue this obvious scourge of both life and property has become, often times we fail to consider others who have been impacted by unlawful adherence to dispensing laws.

While removing the garbage one afternoon at my pharmacy, a friend of mine who was driving by slowed down, rolled down his window and asked if he and his wife could meet with me to talk about the medications she was receiving. His name is Randy Beatty and his wife was Lynn. We never had that conversation since she was found dead on her living room floor two weeks later. Her blood sugar so low as not to be detected by EMS upon arrival. Lynn was active within our community and dearly loved by many. The relationship she had with her spouse started with visiting all 48 continental states on their honeymoon.

After the funeral I received a bag full of her prescription medications. There were 17 with additional OTC meds in the mix. Randy indicated that he brought Lynn to pick up her medications almost exclusively and never once had time been spent talking to her about any potential dangers. The independent pharmacy they used to purchase from was shut out of their employer's contract a few years previous. The mail order facility called several times a week to notify her that refills were on the way but never had the call been in regards to Lynn's drug therapy.

A search of interactions with the various medications found 21. Randy said that the only interaction they had with staff was when they asked if there were any questions. His comment to me: "what the hell did we know to ask?"

The physician had prescribed Prednisone 20mg to be taken three (3) times a day. A total of 270 tablets were dispensed with 3 refills. Lynn had a medical device (insulin pump) and was taking a prescription medication (B-blocker) which would have masked any symptom of hypoglycemia she would have experienced once the prednisone "high" began to give way to its corresponding low. There was 21 drug interactions between the various medications she was taking. These dangers, hidden though they may be, can be added to the opiate crisis when the life of a 49 year old is cut short. The decision to file a Writ of Mandamus against the Ohio Board of Pharmacy was made at that time. The Writ was filed on Jan 11, 2018. (Attached)

The basis for the action rested on a law that requires the Board of Pharmacy to "investigate if it has information that laws are being violated". Enclosed for your consideration is the Writ of Mandamus as well as the board's motion to dismiss and my subsequent response.

The Seventh District Court of Appeals did not grant the public standing which I sought. Therefore, the merits of the case were not considered and the case was dismissed. I have included a copy of the court's opinion on the matter. Included in their comments is a mention that had standing been granted, not enough evidence of law/rule violations were submitted and my efforts would have failed.

In July of 2018 and immediately after the court had made its ruling, I commissioned a study through the University of Akron in order to gauge pharmacist's adherence to OBRA-90. The full study is attached for your consideration. In the two of three OBRA-90 that were able to be examined, the study shows compliance rarely exceeds 20%. This level, if consistent with what is expected throughout the industry, would not be expected to be reasonable compliance with the people's law.

The Drug Use Review Board established under OBRA-90 has minutes posted online and indicate years of brief meetings which contain little or no conversation about a pending opiate problem. Enclosed you will find two such meeting minutes. The misuse, abuse, and gross overuse that OBRA was to have detected was missed.

C. Environmental Impact:

It is estimated that 75% of addiction began with the abuse and misuse of prescription drugs. Irresponsible behavior by pharmacists and pharmacy business models as the dispensers of such drugs have allowed for the irresponsible behavior amongst those who have addictive tendencies. First and foremost we must consider the human behavior of those who are addicted and the amount of resources consumed as a result of their behavior.

The larger the number of addicts, the greater the market for such products, the larger the area deforested to supply that need.

A statement from the DEA:

Now in its ninth year, DEA has collected a total of nearly 11 million pounds (more than 5,400 tons) of expired, unused, and unwanted prescription medications through its Take Back Day events.

This amount represents only a percent of drugs that are either consumed irresponsibly or discarded into public landfills or water systems. Since federal OBRA-90 was meant to reduce irresponsible use of prescription drugs, the amount of unused drug should be such that "take-back" programs would not be needed.

Before the Seventh District Court of Appeals would consider the argument brought in *Carlson vs. The Ohio State Board of Pharmacy*, standing must be granted. The decision to seek "Public Standing" seemed appropriate since the three elements needing to be had appeared obvious with respect to the opiate crisis: 1). Is it an issue the people care about? 2). Is it an issue that impacts most citizens? 3). Is it an issue that would likely result in continued public injury? Understanding that such public standing had not been given in the state

of Ohio in 16 years, legal advice suggested from the onset that standing be sought on federal pollution law.

It is possible to consider the damage being done to both human and environment to be of greater consequence and impact because of direct consumption of labeled drugs compared to those that might have been illegally dumped into a waterway and eventually consumed. The dispensing of prescription drugs without regard to state and federal laws that were meant to prevent abuse and overuse can be considered more dangerous than the occasional illegal dumping that may or may not be eventually consumed. This exposure which is labeled for direct consumption is not only direct, but coordinated and condoned.

D. Economic Impact

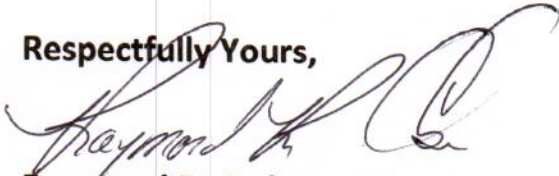
This information is to be submitted only when requested by the commissioner and after review of this petition.

OBRA-90 adherence involves a federal law and perhaps Ohio's reluctance to investigate it has more to do with jurisdiction. A copy of their motion to dismiss is attached and represents this petitioner's only known unfavorable view.

The frustrations felt by this petition to bring this OBRA matter to the attention of both state agency and association alike have moved this effort before the public and the FDA. It is hoped that the public might educate themselves on OBRA-90 enough to recognize that current dispensing practices are not at the "reasonable level" they expected when they enacted OBRA-90. Certainly our nation's opiate crisis should serve as an indicator if one takes the time to consider the law for all it was meant to prevent.

E. Certification

Respectfully Yours,



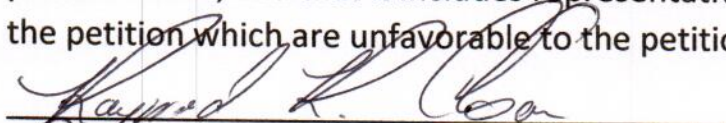
Raymond R. Carlson, RPh

Pharmacist/Owner

RC Compounding Services, LLC

RC Outsourcing, LLC

The Undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petition which are unfavorable to the petition.


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