

Chronologic order of events:

[REDACTED] was a 42-year-old female with a past medical history significant for herniated lumbar discs, RSD, migraines, seizures, and bipolar disorder. At the time of her presentation to the clinic on 9/25/2013 she was already seeing a neurologist (Dr. [REDACTED] of [REDACTED], OH) and a psychologist, Ms. [REDACTED] at [REDACTED] in [REDACTED], OH. At her initial visit it was noted that her mood issues had been stable and well controlled on Abilify 10mg daily, Cymbalta 60mg daily, and Xanax 1mg qid, for some time. This was a regimen she remained on, with good results as noted repeatedly throughout the record, for the next five years.

Her pain regimen consisted of gabapentin 800mg bid and oxycodone 15mg qid for a total MME of 90.0. It is reasonable to assume the Cymbalta, which has effect on neuropathic pain, was also contributing to her pain control. Her prior pain specialist, a Dr. [REDACTED] of [REDACTED], OH, had retired. A new pain management referral was ordered at that initial visit.

In October of 2013 her pain was noted to be poorly controlled and her gabapentin dose was increased to a total of 2400mg daily. A few days later she saw her neurologist who noted she had had a seizure that exacerbated her back pain (Exhibit 9b p 98) and she was now ambulating with a cane. He recommended she not increase her gabapentin any higher, and ordered new imaging. At the next clinic visit she was reporting the increased gabapentin was not helping her pain and she was in fact having more falls (these usually precipitated by sudden increases in her pain, noted on Exhibit 9b p 94), and her dose was reduced back to its prior level. She was then started on a Lidoderm patch that proved to be of some benefit. Over the next few visits her gabapentin was reduced further and she began to transition to Lyrica. In March 2015 she was seen again by Neurology who offered her a muscle relaxer which she turned down in favor of PT, and he increased her Lyrica.

She began PT on 3/6/14 (Exhibit 9b p 74) which was aggravating her pain and at the next clinic visit on 3/17/14 her oxycodone was increased to 30mg q6h for an MME of 180.0 so she could stay in PT. She was then referred to [REDACTED] Rehabilitation Hospital for more intensive PT and was being seen there twice weekly (Exhibit 9b p 71) with good results. She then developed a skin pyoderma (Exhibit 9b p 68) that was apparently linked to the lyrica (Exhibit 9b p 57) and this med was stopped in favor of gabapentin.

In January 2015 she was reporting that she had started engaging in light home remodeling along with her spouse (Exhibit 9b p 49) but this was aggravating her pain and her oxycodone was increased to 30mg q4h for an MME of 270.0. Her Lidoderm and gabapentin were continued, and she was counseled to stop smoking. She had also been referred to an alternate neurologist at her request and was due to see Dr. [REDACTED] of [REDACTED], OH (notes on Exhibit 9b p 250, note the date is marked 1/7/14 but should

be 1/7/15) but she eventually continued to follow up with Dr. [REDACTED] until he relocated. Meloxicam was also added not long after. PT ended by 6/2/15 (Exhibit 9b p 40) after about ten weeks total time due to stalled progression, but she continued to do her exercises at home (Exhibit 9b p 36). She also had developed some shoulder pain and was seen by Orthopedics, Dr. [REDACTED] of [REDACTED], OH, who gave her a steroid injection. Over the next few months she was restarted on Lyrica as now it was apparent her prior skin issues were not connected, which she was able to tolerate, and was started on a nicoderm patch. She was able to stop smoking by summer of 2018. She had to stop the Lidoderm in the spring of 2017 as her insurance would not cover the DAW's and the generic patches failed to adhere; her Lyrica was increased as a result and she was started on baclofen in addition to her other meds. In November 2015 she had a UDS done which was within normal limits (Exhibit 9b p 34), and at one point she reported she had been using a TENS unit with some relief (Exhibit 9a p 23). Her issues were then very stable for the next year and a half.

Nearly four years after her first visit she had her only episode of a loss of her meds; this was reported at the 7/8/17 visit when she had had an argument with her son who discarded her meds in the toilet (Exhibit 9a p 38). A discussion occurred at that visit about the need to keep her meds secure. A UDS was collected the following month (8/25/17, exhibit 9a p 93) which was positive for gabapentin, oxycodone, and Lyrica but negative for benzodiazepines. At her next visit these results were discussed and she maintained she was taking her Xanax daily. A repeat UDS was ordered but was missed at the next two visits, but one was eventually collected during a hospitalization in July 2018 which was positive for both opiates and benzodiazepines, as expected.

She was admitted to [REDACTED] Medical Center on 7/2/18 for three days after being found unresponsive at home. According to the hospital records (Exhibit 9a p 54-85) she had been alert and conversing when her spouse had left for work in the morning at 5AM but when he returned home at mid-afternoon she was asleep and 'snoring loudly' (Exhibit 9 pg 79). It was only some time later when he tried to arouse her and couldn't that he called EMS. They noted her VS were stable and she was breathing spontaneously but was not responding to sternal rub. A 4mg dose of intranasal Narcan was given without effect (Exhibit 9a p 69) and she was taken to [REDACTED] Regional where she was intubated due to not protecting her airway, and exhibiting decerebrate posturing. She was given another 2mg IV Narcan there, also without effect, and admitted to ICU for rhabdomyolysis and hypokalemia with a K+ of 2.5. During her stay the UDS was done as noted above. There was speculation by one physician that she may have overdosed on benzodiazepines (Exhibit 9a p 55) but even that provider noted on the same page that they were able to establish no clear cause for her syncopal event, which was also stated by the ICU physician (Exhibit 9a p 59). It is noteworthy that her benzodiazepine level in the UDS was not quantified. On Exhibit 9a p 57 her spouse reported there was a suicide note and empty bottles around her, but this was refuted per his report on p 64, where he reported that she had no prior history of suicidality, had no prior suicidal gestures, and there was no evidence when she was picked up of loose pills or empty bottles. She was also seen by Psychiatry who noted no issues and cleared her for discharge (Exhibit 9a p 59).

She was seen in clinic a few days after the admission at which time she reported she had not been feeling well prior to the episode, mostly with vomiting and diarrhea. Her records were reviewed and her meds were continued as there was no clear indication this was an overdose event. At a later visit she was referred once again to PT, and her last visit with the clinic was on 11/2/18.

Rebuttal to the State's expert witness:

In rebuttal to the State's assertion that multiple sections of the ORC and Ohio Administrative Code were violated, it is relevant to point out that the expert report ignores or misrepresents these facts:

The expert report claims 'OARRS reports appear to have been checked several times, although it does not appear that they were not checked as often as every 90 days'. In fact her OARRS report was documented as being checked only once in the record, on 10/15/18 (Exhibit 9a p 12) and in any case the State's recommendations of regular OARRS reviews did not go into effect until nearly two months *after* the clinic's last visit with her on 11/2/18.

The state's expert claims her care at the clinic continued until 3/11/2020, which is plainly contrary to facts.

The expert report states 'urine drug screens were noted to have been performed on at least two occasions. Both were noted to have not shown alprazolam present'. There are in fact three UDSs documented in the chart, on 11/17/15 (Exhibit 9b p 29), 8/25/17 (Exhibit 9a p 93) and 7/2/18 (Exhibit 9a p 64). Only the UDS on 8/25/17 showed no benzodiazepines; this was discussed with the patient at her next visit and the presence of benzodiazepines was confirmed on the next UDS.

The expert report mentions the hospitalization and, while it notes no clear cause was identified, remarks that polypharmacy was a possible cause, and criticizes the lack of a prescription for Narcan was offered at her subsequent visits. It should be noted that during the episode she had received multiple doses of Narcan (Exhibit 9a pp 69 & 79) without effect. Also, the requirement of prescribing Narcan for patients on both opiates and benzos did not go into effect until OAC Rule 4731-33-03 on 4/30/19, almost a year later. Prior to this, according to OAC Rule 4731-11-14 of 12/23/18, prescribing of Narcan was recommended but not required.

It is also important to note that her decerebrate posturing could have been caused by a seizure¹. That the patient had bona fide seizures was well known; these are mentioned in her neurology notes and the clinic documented an anecdote of one witnessed by her father with hypersalivation and post-ictal confusion (Exhibit 9b p 40).

It is also possible that the posturing was due to hypoxia, as she was hypersolomnent and not protecting her airway as noted in the ER notes. Per her own report she had not been feeling well, and it's possible she took OTC meds that interacted negatively with her prescription regimen. It is noted in Exhibit 9a p 16 that she would try Benadryl for her recurring skin issues, and at her last clinic visit on 11/2/18 she

admitted to taking a very high dose of Benadryl (150mg) after 5 days of insomnia which had affected her recall of her visit a few weeks prior (Exhibit 9a p 7).

The rhabdomyolysis indicates she had been in bed most of the day (from her spouse's departure at about 5AM until after he returned home at 4:30PM) and while this is usually accompanied by hyperkalemia, a paradoxical hypokalemia as a result of a secondary, hormone-modulated response is a known possibility². She also noted she had been having a couple weeks' worth of GI complaints including diarrhea, and may have developed the hypokalemia as a result of these symptoms, which may have induced an arrhythmia.

The expert report criticizes the continuing of her meds after the hospitalization, but as noted above, the admitting team was not able to determine any clear cause of the apparent syncopal event (certainly not enough to clearly call it an overdose), and sudden cessation of opiates in particular can lead to a greatly increased risk of subsequent overdose³. It stands to reason such drastic measures should not be done based solely on speculation when the consequences can be so dire.

The expert report also claims 'the patient was referred to a Pain Management specialist several times but failed to keep those appointments'. In fact she was only referred to pain management at her initial visit on 9/25/13 and, as she was generally adequately controlled for the entire five years while in the clinic's care, and was being managed in conjunction with Neurology and Psychiatry, with a combination of therapies which, besides opiates, included NSAIDs, topicals, neuropathic agents, steroid injections and PT, was able to help her spouse with his home remodeling work, and historically preferred to try alternative measures prior to increasing her opiates, it was not felt adding another physician to her team was a priority.

In short, in addition to inadequately addressing the clearly documented, extensive efforts to manage ■■■'s pain, the state's expert witness report contains many inaccuracies and outright fallacies that call its very credibility into question.

Thank you for the opportunity to review this case. Please let me know if you have any questions or concerns.

Respectfully submitted,

A handwritten signature in black ink, appearing to be 'SJA', with a stylized, overlapping loop structure.

Steven J. Arnold, MD

References

1. Dhameliya, N. (2021, December 31). *Decerebrate Posture : Cause, symptoms, Treatment, Exercise* .: Samarpanphysioclinic.com. <https://samarpanphysioclinic.com/decerebrate-posture-cause-symptoms-treatment-exercise>
2. Zhang, W., Li, C., Huang, H., & Li, W. (2013, April 17). *Rhabdomyolysis presenting with severe hypokalemia in hypertensive patients: A case series*. Bmcresnotes.Biomedcentral.com. <https://bmcresnotes.biomedcentral.com/articles/10.1186/1756-0500-6-155>
3. Kennedy, M. C., Crabtree, A., Nolan, S., Mok, W. Y., Cui, Z., Chong, M., Slaunwhite, A., & Ti, L. (2022, December 1). *Discontinuation and tapering of prescribed opioids and risk of overdose among people on long-term opioid therapy for pain with and without opioid use disorder in British Columbia, Canada: A retrospective cohort study*. Journals.Plos.org. <https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1004123>