



## Background

### Declaration of David Waisel, M.D.

#### Statement Regarding Dennis McGuire

Ohio's lethal injection protocol requires 10 mg of midazolam, at a 5 mg/mL concentration, and 40 mg of hydromorphone, at a 10 mg/mL concentration, to be injected intravenously at the same time. The protocol requires additional injections if a sufficient time for death to occur has passed but the prisoner has not died.

Intramuscular injection of the same drugs is also contemplated in some circumstances by the execution protocol.

Midazolam is a benzodiazepine. It is administered to induce sedation, anxiolysis and amnesia. The sedation effect causes the recipient to be sleepy. In sufficient doses, the anxiolytic effect will decrease the experience of fear and anxiety. In sufficient doses, the amnestic effect means the person will not remember what happened to him or her while the drug was acting on him or her. In sufficient doses, midazolam can also have a ventilatory (respiratory) depressant effect, which means it slows down the recipient's breathing rate and may cause the recipient to eventually stop breathing.

Unlike the barbiturate sodium thiopental, however, midazolam is not generally considered a general anesthetic, and it is not generally administered to induce suppression of the relevant clinical responses to noxious stimuli.

Sedation does not supply suppression of the relevant clinical responses to noxious stimuli; one can be sedated but still consciously experiencing one's surroundings, including painful and horrific stimuli such as air hunger, even if the sedated person appears to the lay person as being unaware of the surroundings.

Air hunger is being unable to satisfy the physiologic and psychologic urge to breathe. Patients describe it as similar to the sensation of suffocation. Simple examples are the feelings you get when the air is knocked out of you, or when you try to hold your breath for as long as possible. While these can be scary, and the sensation of breathing is met with palpable relief, at all times you know that you will be able to breathe again. This knowledge ameliorates the feelings about the

air hunger.

More severe sensations of air hunger are described in patients who do not know if they will be able to breathe again. This brings about feelings such as one patient described: "I have never been so panicked, scared and horrified in my life. I was suffocating. I would have done anything even to take a small breath. I was scratching, clawing and flailing about. When the medication finally worked [to allow her to breathe], I never felt so relieved. I will love you

guys forever.”

In general, the sensation of air hunger becomes intense with a relatively small rise of carbon dioxide (CO<sub>2</sub>). We normally breathe out CO<sub>2</sub>, the waste from our body. Not being able to do so creates panic.

Anxiolysis can be overcome by painful stimuli, such as air hunger, especially at the 10 mg dose of midazolam in Ohio’s execution protocol.

The amnestic effect of midazolam is irrelevant in the execution context; just because a person does not remember suffering upon waking up does not mean the person did not experience the agony and suffering as it happened.

Hydromorphone is an opioid. It is administered to relieve pain, and also causes ventilatory (respiratory) depression. But opioids, including hydromorphone, are not general anesthetic agents, they are generally not administered to induce anesthesia, and they generally do not produce unconsciousness or amnesia, let alone a state of anesthesia. One of the most respected textbooks in anesthesia states: “High doses of opioids usually eliminate spontaneous respirations without necessarily producing unconsciousness.”

According to the World Health Organization’s accepted definitions, a Body Mass Index (BMI) of 18.5-25 is normal; 25-30 is overweight; 30-35 is obese, class 1; 35-40 is obese, class 2 (also known as severe obesity); 40-50 is obese, class 3 (also known as morbid obesity); and more than 50 is superobesity.

Brain imaging data suggest that increases in CO<sub>2</sub> and associated feelings of air hunger cause widespread increases in brain activity, including brain regions associated with stress and anxiety (amygdala, prefrontal cortex) and pain (periaqueductal gray).

Dennis McGuire is 5’10” tall, weighs approximately 253 lbs (115 kg), and has a thick (approximately 19-inch) neck. His body mass index is 36.3, which is considered severe obesity.

Ohio’s execution protocol calls for 10 mg of midazolam. That is 0.087 mg/kg for a 115 kg man like McGuire.

The midazolam package insert indicates that the dose of midazolam needed for the induction of anesthesia using only midazolam is 0.3- 0.35 mg/kg. For a 115 kg man like McGuire, that is roughly 35- 40 mg.

The midazolam package insert also notes that in resistant cases, up to 0.6 mg/kg (or 70 mg for a 115 kg man like McGuire) is needed to induce anesthesia.

In patients in whom there is an additional medication given (such as hydromorphone), the range of recommended doses of midazolam is 0.15-0.35 mg/kg, roughly 17.5-40 mg as applied to McGuire, with the recommended dose being 0.25 mg/kg, or roughly 29 mg for McGuire.

Thus, the dose of midazolam called for in Ohio's protocol, at 0.087 mg/kg for a 115 kg man like McGuire, is roughly 1/3 the recommended dose.

In other words, McGuire will be receiving much less than the low end of the recommended dose range, and he will be receiving substantially less than the recommended dose itself. Even if he subsequently receives another injection of 10 mg midazolam and 40 mg hydromorphone, the written execution protocol is unclear when that will occur, and most likely will not occur before 5 minutes.

A state of general anesthesia (as has apparently been the goal for previous lethal injection actions in Ohio) is required to ensure that McGuire will not feel the agony of air hunger. Laymen often equate what looks like a person sleeping, as occurs during sedation, to be equivalent to an anesthetized person. But it is not. Painful stimuli cannot be reliably blocked by sedation. Sedation still leaves a substantial likelihood of experiencing air hunger.

In the 1980s, high dose opioids were used to ensure hemodynamic stability for cardiac surgery. Fentanyl was used at a dose of 75-100 µg per kilo. For a 115 kg man like McGuire, 75 µg per kilo is equal to 8.625 mg of fentanyl. With that dose of fentanyl, however, patients still reported intraoperative awareness, even in combination with benzodiazepines (which is the class of drug in which midazolam falls). In a 115 kg man like McGuire, the equivalent dose of hydromorphone as compared to fentanyl would be, conservatively figured, at least 130 mg. That is three times the amount of hydromorphone called for in Ohio's protocol (40 mg).

Intravenous hydromorphone takes 15 minutes to reach peak effects. Although there may be a ventilatory depressant effect before that point, it is variable as to what point that occurs.

The implication of the inadequate dose of midazolam and the hydromorphone (which does not produce unconsciousness) is that there is, at the very least, a substantial risk an inmate such as McGuire will be aware of and experience air hunger as the ventilatory depressant effects of hydromorphone and midazolam take effect.

It is important to recognize that McGuire is at even greater substantial risk to experience air hunger because of his body habitus. Although the substantial risk would be present, the likelihood of thin persons experiencing airflow obstruction that would lead to air hunger is lower than persons with a certain body habitus who are more likely to have airflow obstruction and experience air hunger.

Consider the obstruction that occurs with heavy snorers as they sleep (formally called Obstructive Sleep Apnea ("OSA")). As they sleep, the soft tissue collapses around the pathway between the trachea and the mouth. At some point, the soft tissue blocks the ability for the person to breathe. They then wake up from sleeping, sit up and clear their airway and breathe. The sensation before they clear their airway has been described as feeling like they are

suffocating and starving for air.

McGuire is at considerable risk for this obstruction. To be sure, diagnosing risk for obstruction while sleeping requires taking a history, performing a physical examination and formal testing. Nonetheless, since testing is expensive and difficult to get, clinicians use well-defined surrogate data to determine the risk of obstruction. Perhaps the most common is the STOP-BANG analysis, which uses 8 categories to determine risk of obstruction: male gender, age > 50, BMI >35, neck size > 40 cm (15.7 inches), hypertension, daytime sleepiness, snoring, observed apnea. McGuire has the first 5 of these categories; having 5/8 categories gives him a 77% likelihood of having formal Obstructive Sleep Apnea. We do not have information about 2 of the categories, snoring or observed apnea, but we do know that McGuire reports that while sleeping, he at times feels like he is choking and losing his breath, and has to sit up to relieve that feeling. This is very typical for patients with obstruction to breathing while sleeping, like OSA.

It is substantially likely that the slow onset of the ventilatory depressant effect will result in McGuire having repeated episodes of obstruction, and as the execution proceeds, it will be more difficult for him to clear the obstruction, in part due to the inability to sit up. So McGuire, lying flat, a position which exacerbates obstructive breathing, will experience a period of unsuccessfully trying to remove the airflow obstruction, which is the same agonizing and horrifying feeling as suffocation.

If McGuire were to have OSA, he may have greater sensitivity to the ventilatory depressant effects of opioids. Thus, the ventilatory depressant effect may be accelerated in McGuire. This does not resolve the problem. First, not all people with OSA are sensitive to opioids. Second, he will still have obstructive symptoms and experience air hunger, albeit earlier in the execution. Third, although his experience may be shorter, it is extremely unlikely that it will shorten it a relevant length. He will still experience the agony and horror of feeling like he is suffocating, and it will start earlier in the execution. In light of the insufficient dose of midazolam, it is substantially likely that McGuire will be aware of this agony and horror.

Inmate McGuire is at substantial, palpable, objectively intolerable risk of experiencing the agony and horrifying sensation of unrelenting air hunger during the midazolam/ hydromorphone execution under Ohio's execution protocol.

It is substantially likely that McGuire will remain awake and actively conscious for up to 5 minutes, during which he will increasingly experience air hunger as the drugs suppress his ability to breathe.

In summary, due to the inadequacy of anesthesia from the midazolam, the length of time it takes for the ventilatory depressant effect of the drugs, and McGuire's habitus, he is at substantial, objectively intolerable risk for experiencing the agony and horrifying sensation of being unable to breathe for

a relevant time, as he slowly suffocates to death.

All of the opinions above are predicated on a successful intravenous administration of the midazolam and hydromorphone. The substantial risks of serious harm described above will be exponentially magnified if the administration of the medications is not completely successful, or if the intramuscular injection provisions of Ohio's protocol are used, because that will increase the time during which McGuire is aware of his surroundings and of what he is experiencing.