## What Is the Maximum Permissible Dose of Morphine—or Fentanyl?

A Question of Physician Compliance and Quality of Care

BRADFORD D. WINTERS, Ph.D., M.D., Johns Hopkins University School of Medicine

DAVID N. HOFFMAN, J.D., Columbia University, Bioethics Masters Program

+ The indictment of an Ohio physician on 25 homicide charges highlights the responsibility of compliance officers to monitor excess doses of pain medications that can produce life limiting levels of respiratory depression.

+ Hospital medication dispersal control systems set limits on the amount of medication that can be withdrawn to be administered to a patient, but they also necessarily allow for overrides to respond to clinical circumstance and physician decision-making.

+ This session will present the clinical and pharmacologic knowledge compliance officers need to establish the proper level of hospital auditing needed to insure that patients are getting all the pain medication they need, and nothing more.

1

"There are no bad words. Bad thoughts. Bad intentions, and wooooords."

— George Carlin

tags: comedy, george-carlin, humor, philosophy

2

Murder?

## William Husel Charged With 25 Counts Of Murder

By STEVE BROWN & PAIGE PFLEGER • JUN 5, 2019

PAIGE PFLEGER / WOSU

Franklin County prosecutors on Wednesday announced 25 murder charges have been filed against Dr. William Husel, the former Mount Carmel intentisve care physician accused of ordering "excessive" doses of painkillers for patients who died shortly after receiving them.

3

Pain is a Vital Sign?

Yes, since 1999.

HEALTH AGENCIES UPDATE

### Veterans' Pain a Vital Sign

The US Department of Veterans Affairs (VA) is instructing physicians and nurses who treat veterans to regard pain as a "fifth vital sign" to be routinely assessed along with blood pressure, pulse, temperature, and respiration.

Numerous studies indicate that pain is often unrecognized or inadequately treated. The agency found that recent VA initiatives to improve end-of-life care for veterans revealed that pain management was not well addressed in dying patients.

The new directive, aimed at addressing pain in a more systematic and thorough manner, is part of an effort to reduce pain and suffering experienced by many of the 3.4 million veterans cared for by the VA. Physicians and nurses will ask patients to rate their pain on a scale of 1 to 10 and discuss ways to manage it.

The VA plans to have the program in place at the 1100 sites where it delivers health care within the next 2 or 3 years. The agency will also spend up to $5 million on pain management research.



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HEALTH AGENCIES UPDATE

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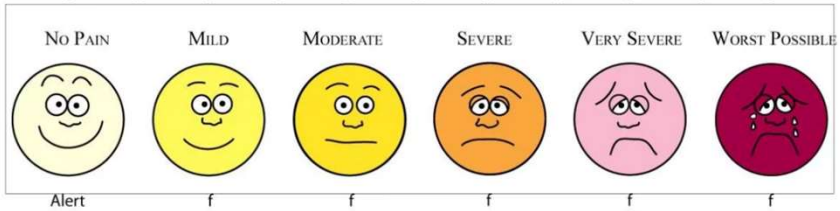
5

# Universal Pain Assessment Tool

This pain assessment tool is intended to help patient care providers access pain according to individual patient needs. Explain and use 0-10 Scale for patient self-assessment. Use the faces or behavorial observations to interpret experssed pain when patient cannot communicate his/her pain intensity.

0 1 2 3 4 5 6 7 8 9 10




Alert
Smiling

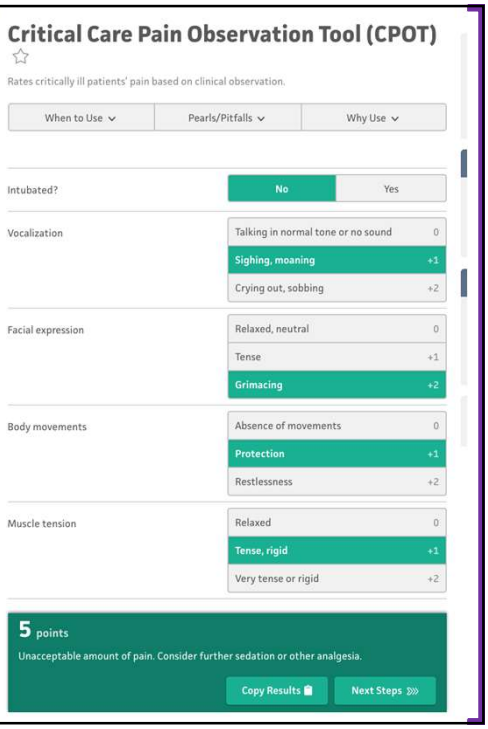
NO
PAIN

NADA DE
DOLOR

6

# Can we do better than smiley faces?

https://www.mdcalc.com/critical-care-pain-observation-tool-cpot#evidence




7

# What is the right dose?

- It depends on many factors
  - Current opioid use (how much?, how long?)
  - Tolerance
    - Adult patients receiving, for one week or longer:
      - at least 60 mg oral morphine or morphine equivalent per day
  - Metabolic factors (variable impact depending on which opioid)
    - Kidney disease
    - Liver disease
    - Other meds
    - Other factors
  - This engenders the concept of Effective Dose (ED) vs. Lethal Dose (LD)
  - **And especially…. What is your Goal?????**
    - **Pain management in the living**
    - **Pain management in the dying**

8

# Lethal Dose

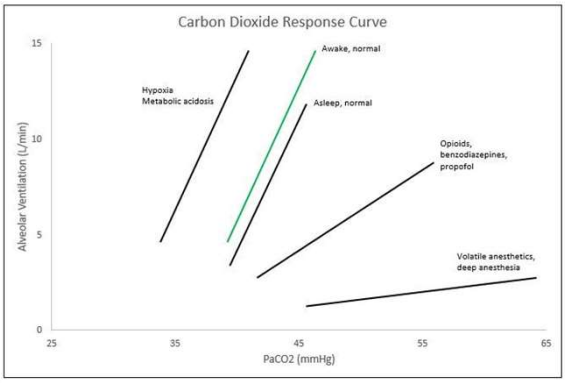
- Lethal dose of fentanyl in “normal” people is about 2 milligrams (20 mg Morphine)


2mg fentanyl

9

# The problem with opioids

- Opioids can kill by depressing respiration
  - Rate slows
  - Breaths get shallow
  - Carbon dioxide response curve shift
  - CO2 builds up causing acidosis and eventually hypoxia




10

## But, with these…

- The respiratory depressant effect of opioids is not really an issue.
- At least until the time comes to get the patient weaned from a mechanical ventilator

11

## Ventilated Patients

- Respiratory depression is not that much of an issue until you try to wean them from the ventilator
- But determining pain level can be challenging
- Pain scales
  - Smiley face scales not so useful hence the Critical Care Scale
- Sedation scales

12

## Non-ventilated patients

- Still use pain and sedation scales but it is trickier since they may arrest if too much is given
- Risk is also impacted by environment (ICU vs. floor) since provider to patient ratio varies widely as does monitoring
- Careful titration to a validated pain score tool
- Individualized, multi-modal guided by a pain specialist (usually an anesthesiologist)
- Rescue therapy (naloxone and airway equipment) immediately available
- End-of-life Care
  - Often include both opioids and benzodiazepines (valium-like drugs)
    - Benzos help with anxiety since opioids are not really anti-anxiety meds
  - Medically there should be no limit so long as decisionmaker understands that higher doses can hasten death through respiratory depression.

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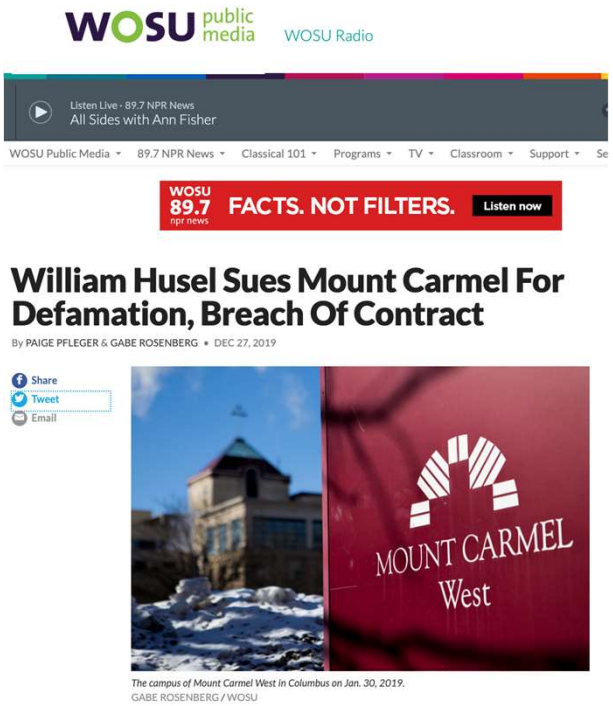
## Right Dose (Effective Dose) vs.Lethal dose?

- Any dose of opioids can be lethal depending on the circumstances
- Upper limits varies from patient to patient
- ***There is no one size fits all answer…….***

14

Is the law a help or a hindrance?

15




16

**INVESTIGATION** TIMELINE

BECAUSE OF YOU MOUNT CARMEL

Mount Carmel is continuing to do everything we can to understand what happened regarding the deaths of patients under the care of Dr. William Husel.

**What we know about the investigation as of February 22, 2019.**

*Based on what we've learned about this report, we should've begun a more expedited process to investigate and consider immediate removal of Dr. Husel from patient care at that time.*

*Three patients died between October 25, 2018 and November 21, 2018.*

**OCT 25 2018** Mount Carmel received a formal report related to Dr. Husel's care.

**NOV 19** Mount Carmel received another formal report related to Dr. Husel's care.
Mount Carmel broadened its internal investigation.

**NOV 21** While investigating the Nov. 19 report, Mount Carmel received another report related to Dr. Husel's care.
Mount Carmel removed Dr. Husel from providing patient care.

**DEC 5** Mount Carmel's findings as of this date showed that Dr. Husel ordered excessive and potentially fatal doses for at least 24 patients.

**DEC 5** Mount Carmel terminated Dr. Husel's employment.
Mount Carmel notified the State Medical Board of Ohio.
At our request, leaders from Mount Carmel met with Prosecutor Ron O'Brien to report our findings.

**DEC 7** Mount Carmel notified the Ohio Boards of Pharmacy & Nursing.

**DEC 11** Mount Carmel leaders began training staff on changes in procedures and on existing and updated policies.

*1st Contact with families began*

**DEC 27** Mount Carmel contacted families of the patients affected by Dr. Husel's actions to notify and apologize to them.

**DEC 28** Based on what Mount Carmel learned, the investigation was expanded.
Mount Carmel identified three (3) more patients for a total of at least 27.

*2nd Contact with families began*

**JAN 14 2019** Mount Carmel again reached out to families to share additional details and let them know information would be made public.

*Public announcement and apology*

**JAN 14** A patient's family filed a lawsuit.
Mount Carmel's CEO released a detailed public statement, including an apology that asked the community for forgiveness.

**JAN 16** Mount Carmel identified a 28th patient.
Mount Carmel continued to expand its investigation to other intensive care patients treated by Dr. Husel.

**JAN 24** Mount Carmel identified six (6) patients who received excessive doses of pain medication that went beyond providing comfort but were likely not the cause of their deaths.
Mount Carmel contacted the additional families of the patients affected by Dr. Husel's actions.
Mount Carmel announced that there are now at least 34 patients affected by Dr. Husel's actions.

*Mount Carmel has been investigating whether any of the affected patients received excessive doses of pain medication when there was still an opportunity for treatment to improve their immediate condition.*

**FEB 22** Mount Carmel identified a 35th patient.
Mount Carmel identified five (5) cases in which this possibility is a concern.
Mount Carmel contacted the families involved.

***November to present***
*Mount Carmel and Trinity Health leaders are gathering facts, collecting data from patient medical records, and continuing to fully cooperate with all authorities.*

***December 5, 2018 to January 14, 2019***
*Mount Carmel respected the prosecutor's request to minimize public release of any information to avoid negatively impacting the ongoing investigation.*

*Mount Carmel originally scheduled this announcement for January 16, 2019.*

A Member of Trinity Health

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# What Happened on February 1, 2019?

Husel from providing services to Medicaid patients.

**Jan. 25, 2019:** Two more lawsuits were filed against Husel and Mount Carmel, bringing the total number of suits to six.

- Ohio Department of Medicaid suspends Husel's provider agreement following allegations of excessive dosing. The department referred its findings to the Ohio Attorney General's Medicaid Fraud Control Unit.
- The Ohio Medical Board suspends Husel's osteopathic medicine and surgery license.

**Jan. 28, 2019:** The family of Jeremia Hodge files the seventh lawsuit against Mount Carmel and William Husel.

- The family of Norma Welch files the eighth lawsuit against Mount Carmel and William Husel.

**Jan. 29, 2019:** Mount Carmel says 23 employees have been placed on administrative leave, including members of its management team.

**Jan. 31, 2019:** Ninth lawsuit filed against Mount Carmel and Husel, on behalf of Rebecca Walls.

**Feb. 1, 2019:** Mount Carmel announces it was placed in "immediate jeopardy" by the Centers for Medicare and Medicaid, amid an investigation by the Ohio Department for Health.

**Feb. 4, 2019:** Mount Carmel submits "plan of correction" to Centers for Medicare and Medicaid.

**Feb. 5, 2019:** Three more lawsuits are filed on behalf of the families of Timothy Fitzpatrick, Larry Brigner and James Nickolas Timmons. That brings the total number of wrongful death suits to 12.

- Mount Carmel's chief pharmacy officer Janet Whittey leaves the hospital.

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# What happened on February 1st for CMS to place the hospital in "immediate jeopardy"?

Nothing actually !!!*

*SEE Appendix Q

19

# So what did happen?

CMS determined that Patients at Mount Carmel West Were In

## "immediate jeopardy"

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# Federal Regulation:
# 42 CFR 488.301

Title 42 Part 488 → Subpart E → §488.301

Title 42 → Chapter IV → Subchapter G → Part 488 → Subpart E → §488.301
Electronic Code of Federal Regulations e-CFR

21

# Federal Regulation Definitions:

**§488.301 Definitions.**

As used in this subpart—

***

***Abuse*** is the willful infliction of injury, unreasonable confinement, intimidation, or punishment with resulting physical harm, pain or mental anguish. Abuse also includes the **deprivation by an individual, including a caretaker,** of goods or services that are necessary to attain or maintain physical, mental, and psychosocial well-being. Instances of abuse of all residents, irrespective of any mental or physical condition, cause physical harm, pain or mental anguish. It includes verbal abuse, sexual abuse, physical abuse, and mental abuse including abuse facilitated or enabled through the use of technology. ***Willful,*** as used in this definition of abuse, means the individual must have acted deliberately, not that the **individual must have intended to inflict injury** or harm.

***

***Immediate jeopardy*** means a situation in which the provider's **noncompliance** with one or more requirements of participation has caused, or **is likely to cause**, serious injury, **harm**, impairment, or death to a resident.

***

***Neglect*** is the failure of the facility, its employees or service providers to provide goods and services to a resident **that are necessary to avoid physical harm, pain, mental anguish, or emotional distress**

22

## State Operations Manual

Appendix Q - Guidelines for Determining Immediate Jeopardy
(Rev. 102, Issued: 02-14-14)

| Triggers | |
|---|---|
| **Issue** | **Triggers** |
| D Failure to protect from undue adverse medication consequences and/or failure to provide medications as prescribed. | 1. Administration of medication to an individual with a known history of allergic reaction to that medication;<br>2. Lack of monitoring and identification of potential serious drug interaction, side effects, and adverse reactions;<br>3. Administration of contraindicated medications;<br>4. Pattern of repeated medication errors without intervention;<br>5. Lack of diabetic monitoring resulting or likely to result in serious hypoglycemic or hyperglycemic reaction; or<br>6. Lack of timely and appropriate monitoring required for drug titration. |
| E Failure to provide adequate nutrition and hydration to support and maintain health. | 1. Food supply inadequate to meet the nutritional needs of the individual;<br>2. Failure to provide adequate nutrition and hydration resulting in malnutrition; e.g., severe weight loss, abnormal laboratory values;<br>3. Withholding nutrition and hydration without advance directive; or<br>4. Lack of potable water supply. |
| F Failure to protect from widespread nosocomial infections; e.g., failure to practice standard precautions, failure | 1. Pervasive improper handling of body fluids or substances from an individual with an infectious disease;<br>2. High number of infections or contagious diseases without appropriate reporting, intervention and care;<br>3. Pattern of ineffective infection control precautions; or<br>4. High number of nosocomial infections caused by cross contamination from staff and/or equipment/supplies. |

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## Appendix Q:

| | |
|---|---|
| D Failure to protect from undue adverse medication consequences and/or failure to provide medications as prescribed. | 1. Administration of medication to an individual with a known history of allergic reaction to that medication;<br>2. Lack of monitoring and identification of potential serious drug interaction, side effects, and adverse reactions;<br>3. Administration of contraindicated medications;<br>4. Pattern of repeated medication errors without intervention;<br>5. Lack of diabetic monitoring resulting or likely to result in serious hypoglycemic or hyperglycemic reaction; or<br>6. Lack of timely and appropriate monitoring required for drug titration. |

24

# SOM:

- EXAMPLE CASE #2: Confused, debilitated 75-year-old female admitted as an inpatient to the hospital has orders to discontinue all nutrition and hydration support.



25

# SOM

- EXAMPLE CASE #2 (Continued): (Refer to B “Investigation”) During the investigation, the surveyor finds that the chart does not include a copy of the patient’s advance directive. The progress note does not contain any documentation of the patient ever stating a wish to have nutrition and hydration withdrawn at the end of life. The patient has a diagnosis of advance dementia with a documented history of refusal to eat in a long-term care facility.
- The patient had been admitted because of continued weight loss and dehydration related to the refusal to eat or drink. The patient has a daughter who actively participates in her mother’s care, is identified as the legal representative, and is identified in the social service notes as the closest living family member. The primary care physician documented a discussion with the daughter concerning the patient’s poor prognosis for meaningful recovery. While death is not imminent as a result of the dementia, death is the expected result at some unknown time in the future.



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# SOM

- EXAMPLE CASE #2 (Continued): (Refer to B "Investigation")

- The chart does not include any documentation that the daughter expressed a wish to have nutrition and hydration support withdrawn. The social worker was unable to confirm that the daughter had expressed a wish to have all support withdrawn. The social worker is uncertain why the nutrition and hydration were discontinued. When contacted, the daughter is unaware that support has been withdrawn and is very upset.
- The surveyor copies the order sheet, the progress notes and the social service notes. The surveyor clearly documents the interviews with the social worker and the daughter. There is a discrepancy between the written order for withdrawal of support and the daughter's and the social worker's knowledge of the situation. The surveyor decides to present the information to the team prior to contacting the physician.



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# "Immediate Jeopardy"

# Why does this matter?

28

Which brings us to the Double Effect

What, you may ask, is the double effect?

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521 U.S. 793, 138 L.Ed.2d 834

793 **Dennis C. VACCO, Attorney General of New York, et al., Petitioners,**

**v.**

**Timothy E. QUILL et al.**

**No. 95–1858.**

Argued Jan. 8, 1997.

Decided June 26, 1997.

30

## 117 SUPREME COURT REPORTER at 2298

Furthermore, a physician who withdraws, or honors a patient's refusal to begin, life sustaining medical treatment purposefully intends, or may so intend, only to respect his patient's wishes and ''to cease doing useless and futile or degrading things to the patient when [the patient] no longer stands to benefit from them. The same is true when a doctor provides aggressive palliative care; in some cases, painkilling drugs may hasten a patient's death, but the physician's purpose and intent is, or may be, only to ease his patient's.

31

## Continued…

The American Medical Association emphasizes the ''fundamental difference between refusing life-sustaining treatment and demanding a life ending treatment.'' Of course, as respondents' lawsuit demonstrates, there are differences of opinion within the medical profession on this question. A doctor who assists a suicide, however, ''must, necessarily and indubitably, intend primarily that the patient be made dead.'' Id., at 367. Similarly, a patient who commits suicide with a doctor's aid necessarily has the specific intent to end his or her own life, while a patient who refuses or discontinues treatment might not. (citations omitted).

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## Footnote number 11:

11. Respondents also argue that the State irrationally distinguishes between physician-assisted suicide and ‘‘terminal sedation,’’ a process respondents characterize as ‘‘induc[ing] barbiturate coma and then starv[ing] the person to death.’’ Brief for Respondents 48–50; see 80 F.3d, at 729. Petitioners insist, however, that ‘‘ ‘[a]lthough proponents of physician-assisted suicide and euthanasia contend that terminal sedation is covert physician-assisted suicide or euthanasia, the concept of sedating pharmacotherapy is based on informed consent and the principle of double effect.’ ’’ Reply Brief for Petitioners 12 (quoting P. Rousseau, Terminal Sedation in the Care of Dying Patients, 156 Archives Internal Med. 1785, 1785–1786 (1996)).

33

## Footnote number 11 (cont.):

Just as a State may prohibit assisting suicide while permitting patients to refuse unwanted lifesaving treatment, it may permit palliative care related to that refusal, which may have the foreseen but unintended ‘‘double effect’’ of hastening the patient’s death. See New York Task Force, When Death is Sought, supra n. 6, at 163 (‘‘It is widely recognized that the provision of pain medication is ethically and professionally acceptable even when the treatment may hasten the patient’s death, if the medication is intended to alleviate pain and severe discomfort, not to cause death’’).

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What is wrong with this argument?

35

FDA?

What does the FOOD, DRUG AND COSMETICS ACT

HAVE TO DO WITH THIS?

36

# The Doctors role

EDITORIAL

**The Opioid Crisis in the United States: Chronic Pain Physicians Are the Answer, Not the Cause**

Raeford E. Brown Jr, MD, FAAP,*† and Paul A. Sloan, MD*

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**The Opioid Crisis in the United States: Chronic Pain Physicians Are the Answer, Not the Cause**

Raeford E. Brown Jr, MD, FAAP,*† and Paul A. Sloan, MD*

Opioids for the treatment of acute pain and the pain of malignancy have been strongly encouraged for more than 25 years.[1] In the past 2 decades, the treatment of chronic noncancer pain using long-term opioid therapy has become more common. However, recent studies have revealed the astonishing rapidity with which the therapeutic use of prescription opioids can become challenging.[2] In light of this public health problem, chronic pain physicians have often been maligned as the root cause of addiction and death because of good faith efforts to treat selected patients suffering long-standing pain with opioids. But, anesthesiologists practicing chronic pain medicine do not prescribe the most opioids, and the multidimensional management most often practiced by these clinicians appears to be a paradigm for responsible opioid treatment of patients with all types of pain. Chronic pain physicians must take the lead as educators of the entire field of medicine on the appropriate and comprehensive management of acute and chronic pain.

common pathway for patients originally prescribed legal opioids continues to be a recurrent theme in a small, but not insignificant, population.[5]

State and federal governments track groups of clinicians most involved in the prescribing of opioids. As one would expect, there is remarkable variation in prescribing practices between specialties and the individuals within each specialty.[6] From these data, one can begin to comprehend some of the reasons for the excess of opioids prescribed. For a substantial number of physicians in the United States, the treatment of pain and the prescribing of opioids represent a major portion of their practice. Opioid prescribing as a method to quickly bring pain under control is fast and easy. Government and insurers also reimburse prescription writing. Responding to a patient's concerns with a prescription, even in the face of clinical signals suggestive of a high abuse potential, is a default behavior driven by economics and time considerations. Most important, perhaps, the time required to write a prescription is minimal.


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With that as context:

Let’s return to OHIO

39

The Columbus Dispatch

bscribe&g2i_campaign

## Mount Carmel says doctor gave 27 near-death patients potentially fatal doses of pain medication

By JoAnne Viviano
The Columbus Dispatch
Posted Jan 14, 2019 at 5:57 PM
Updated Jan 22, 2019 at 2:27 PM

Mount Carmel Health System says one of its intensive-care doctors gave “significantly excessive and potentially fatal” doses of pain medication to at least 27 near-death patients between 2015 and 2018.

Dr. William Husel, who had worked for the system since 2013, has been fired, and details of an internal investigation by Mount Carmel have been turned over to authorities, the health system’s top executive said in a statement Monday.

>>Complete coverage: Find out more on this on-going investigation at Mount Carmel

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The Columbus Dispatch

## Feds warn Mount Carmel could lose Medicare funding over patient-death scandal

By Bethany Bruner
The Columbus Dispatch

By Rita Price
The Columbus Dispatch
Posted Feb 1, 2019 at 8:09 PM
Updated Feb 1, 2019 at 9:54 PM

The federal Centers for Medicare and Medicaid Services have notified Mount Carmel Health that two of its hospitals involved in the patient-death scandal could be terminated from the Medicare program due to pharmaceutical-services deficiencies "so serious they constitute an immediate threat to patient health and safety."

41

## Hospital tightens drug access, rules after excessive dosages

By KANTELE FRANKO Associated Press, February 12, 2019

COLUMBUS, Ohio (AP) — The Ohio hospital system that found a doctor ordered possibly fatal doses of powerful painkillers for dozens of patients has tightened policies and drug access to address problems in pharmaceutical services that jeopardized Medicare participation for two hospitals, according to corrective plans submitted to the U.S. Centers for Medicare and Medicaid Services.

The changes outlined for Mount Carmel West hospital in Columbus and Mount Carmel St. Ann's in suburban Westerville included further limiting when and how such medication can be accessed from an automated dispensing system using emergency orders outside of the usual protocols.

42

The Columbus Dispatch

## Mount Carmel investigation finds five patients may have survived with proper care

The 500-microgram level is borderline lethal and there is no medical reason to order such a large dose, the sources said. Some patients received 1,000 micrograms and one received as much as 2,000 micrograms, according to wrongful-death lawsuits filed in Franklin County Common Pleas Court and details in Ohio Department of Health inspection reports.

The Columbus Dispatch
Posted Feb 22, 2019 at 11:16 AM

43

The Columbus Dispatch

At least five patients who died after receiving excessive doses of painkillers under a former Mount Carmel doctor's care might have lived if given proper treatment, health system officials confirmed for The Dispatch on Friday.

The five patients are among the nearly three dozen intensive-care patients who died after receiving the doses ordered by Dr. William Husel, system officials said. Reviews of medical histories, patient records and the care they received show that the five might have survived, according to Dr. Dan Roth, executive vice president and chief clinical officer for the Livonia, Michigan-based Trinity Health, Mount Carmel's parent.

The Columbus Dispatch
Posted Feb 22, 2019 at 11:16 AM

44

Begging the question:

How much FENTANYL is too much?

45

The Columbus Dispatch

## Husel charged with 25 counts of murder in Mount Carmel deaths

Posted Jun 5, 2019 at 7:47 AM
Updated Jun 6, 2019 at 1:50 AM

Dr. William Husel walked into the lobby of Columbus police headquarters in a tailored dark suit Wednesday and shook the hand of a cold-case homicide detective who had spent the past six months investigating him.

Surrounded by uniformed police officers, Husel walked to the back of the elevator and lowered his head as the doors closed.

At the Franklin County Jail, he was handcuffed, asked to take off his shoes and socks and patted down in the booking room. Two hours later, the 43-year-old wore the earth tones of a jail inmate as a Franklin County Common Pleas Court

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MOUNT CARMEL

**Media Statement on behalf of Ed Lamb**

We're continuing to do everything we can to understand what happened regarding the deaths of patients under the care of Dr. William Husel and to make changes to ensure it never happens again. We remain committed to providing accurate information to our community and colleagues as we learn more through our investigation. As part of that commitment, we have the following information to share:

- We continue reviewing the records of all patients who were treated by Dr. Husel and died in the hospital. At this point, we have identified one additional patient who received an excessive and potentially fatal dose of medication ordered by Dr. Husel. As we have done with each of the affected families, we have contacted the loved ones of this patient. This brings the number of patients involved to at least 35, including at least 29 who received a potentially fatal dose of medication ordered by Dr. Husel.

  As previously shared, we also have been investigating whether any of the affected patients received excessive doses of pain medication when there was still an opportunity for treatment to improve their immediate condition. We are aware of five cases in which this possibility is a concern, and we are reaching out to the loved ones of these patients to share this information.

These events are heartbreaking, unacceptable and inconsistent with the values and care processes of Mount Carmel. As we work to understand how this happened, we continue to implement meaningful changes to ensure they never happen again. So far, we have:

- Added a new protocol to set maximum appropriate doses for pain medication in our electronic medical record system;
- Implemented a new escalation policy for deviations in our pain medication protocols;
- Restricted the ability to bypass pharmacy review of medication orders;
- Increased clinician education on standards and practices regarding end-of-life care;
- Implemented numerous other initiatives to ensure patient medication safety;
- Initiated a review of our culture of safety initiative to identify what needs to change; and
- Engaged independent experts who are assisting us with this process.

Our internal investigation is ongoing, and we continue to share information and cooperate fully with authorities, including law enforcement.

Providing safe, compassionate, people-centered care remains our highest priority – just as it remains the highest priority for more than 11,000 Mount Carmel colleagues who dedicate their lives every day to the people we serve. We continue to learn from this, and we will improve.

###

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Mount Carmel West Statement by CEO Lamb:

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48

Mount Carmel West Statement by CEO Lamb:

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49

# Where do we go from here?

# And what's a Compliance Officer to do?

50

# Creating a Healthy Board/Medical Staff Relationship:

## Current Trends and Practices


Center for Healthcare Governance
One North Franklin, Suite 2800
Chicago, Illinois 60606
Phone: (888)540-6111
www.americangovernance.com

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MedGenMed
Medscape General Medicine

MedGenMed. 2004; 6(1): 57.
Published online 2004 Mar 23.

PMCID: PMC1140733
PMID: 15208568

**The War Is On: Why Your Medical Staff Needs to Incorporate and Obtain Its Own Independent Counsel**

Charles Bond, Esq.

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Charles Bond Esq. (cont.):

The hospital industry, led by its lawyers (notably Horty Springer & Mattern of Pittsburgh, Pennsylvania, who represent hundreds of hospitals nationwide), is out to decimate the independence of medical staffs and take away physicians' rights. Their objective is clear: they want to place unfettered power and economic control over doctors in the hands of hospital administrators.

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Just because you are paranoid does not mean -

that the whole world in not

OUT TO GET YOU.

54

**We are now far into the *fifth* year, since a policy was initiated, with the *avowed* object, and *confident* promise, of putting an end to slavery agitation.**
**Under the operation of that policy, that agitation has not only, *not ceased*, but has *constantly augmented.***
**In *my* opinion, it *will* not cease, until a *crisis* shall have been reached, and passed.**
**"A house divided against itself cannot stand."**
**I believe this government cannot endure, permanently half *slave* and half *free*.**
**I do not expect the Union to be *dissolved* -- I do not expect the house to *fall* -- but I *do* expect it will cease to be divided.**
**It will become *all* one thing or *all* the other.**

*Abraham Lincoln*,
**House Divided Speech**
**Springfield, Illinois**
**June 16, 1858**

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# What's a Compliance Officer to do?

Learn to Say No. . . By Saying Yes.

And learn to love your Doctors*

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# learn to love your Doctors*

Even if they don't like to be told what to do.

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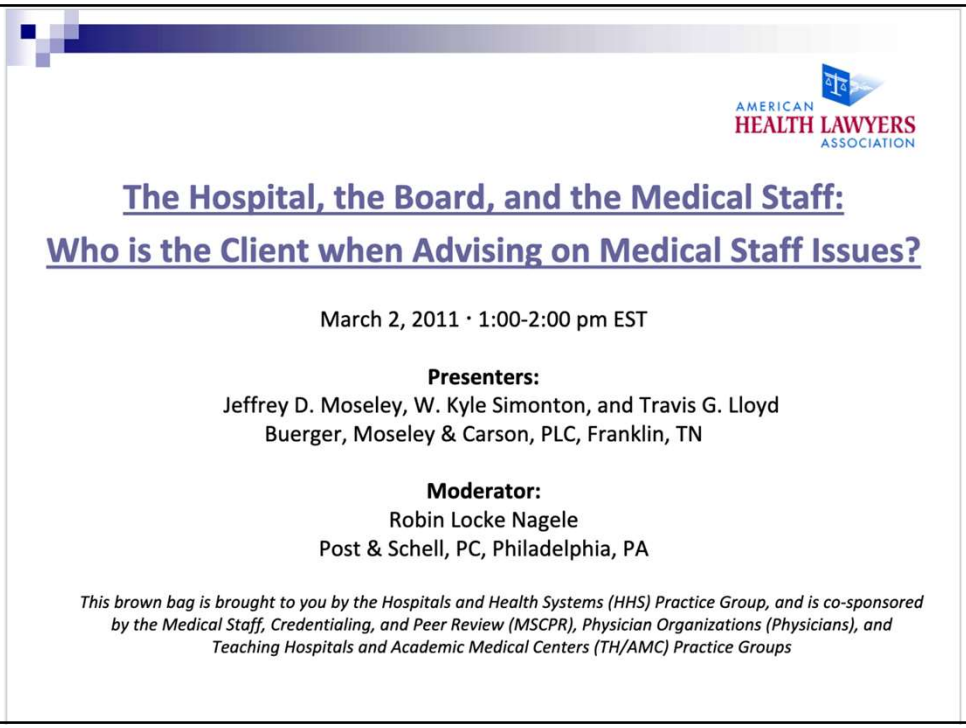


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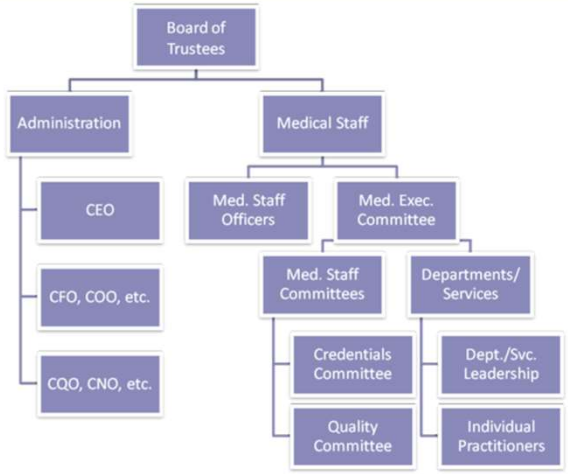
## Organizational Model

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## Medical Staff as Separate Entity

- When conflicts between the hospital and medical staff emerge, question might arise as to whether the medical staff should be treated as an unrepresented party (in accordance with the directives of Rule 4.3) rather than a constituent of the hospital
  - Recall, though, that even if the medical staff is merely considered a constituent of the hospital, the lawyer must, per Rule 1.13(f), explain who the client is when he/she knows or reasonably should know that the interests of the organization and constituent are adverse
  - In fact, Rule 1.13, Comment 10 provides that in such cases the lawyer should advise the constituent that he/she cannot represent the constituent and that the constituent may wish to obtain independent representation

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## Medical Staff as Separate Entity

- How might Joint Commission standards bear on this issue?
  - Some standards offer indirect support for status as separate entity
    - MS.01.01.01 (as revised) (see Introduction and EP 10)
    - LD.01.02.01, EP 1 ("unique responsibilities and accountabilities")
    - LD.02.04.01 (conflict management process for leadership groups)
    - MS.01.01.03 (no unilateral amendment of medical staff bylaws)
  - But others support the idea that it is subordinate to the board and perhaps part of a single entity
    - LD.01.05.01 (medical staff accountable to board)
    - LD.01.03.01 (board ultimately accountable)
    - See also Medicare Conditions of Participation (governing body accountable for hospital – 42 CFR § 482.12), state licensing regulations, and analogous provisions of the medical staff bylaws

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What we confront in the opioid epidemic is a classic ethical dilemma,

A conflict between two or more ethical principles.

What are they?

Minimize pain. . . While preventing addiction.

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And what about drug diversion?

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PAIN!

What if a pain management patient has no Oxy in their drug screen?

Does the Dx matter?

Prognosis: chronic vs. EOL

What if they test positive for heroin?

…and Oxy?

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## PAIN!

What if a pain management patient has no Oxy in their drug screen?

WHAT, you are not testing your pain management patients?

You should be.

Well, no, not you, your hospital.

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## What should we do with addicted patients?

## To discharge, or not to discharge?

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What should we do with addicted patients at the end of life?

67

## Think about Terri Schiavo

Should she have gotten Palliative sedation at the end of her life?

68

What about Palliative Surgery as an alternative?

Treat the pain at it's source.

What is a good outcome for Palliative surgery?

What is Palliative surgery?

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So. . .What's a Compliance Officer To Do?

Start with the basics . . .

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Put these near the Pyxis machine:*

*Get a better Photo


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Learn to love your PYXIS


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# Learn to love your PYXIS

Ask it for favors. . . and information

73

# Tell your IT department. . .

You want an exception report for your birthday.

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# Think about tracking:

Five most frequent prescribers (orderers) of opioids (by frequency and volume).

Five highest doses of opioids each month.

Frequency of Pyxis system overrides for opioids above the institutions baseline.

Correlation of tox screens to opioid orders/scripts

Discharge from care vs. referral of non-compliant pain management patients

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# Every patient should get:

1) Care not scorn
2) Treatment not judgment.
3) Referral, not discharge from care

4) all the pain medication they need, and nothing more.

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Make sure everyone in your hospital knows:

There is no maximum dose of Fentanyl or Morphine

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Questions, Comments:



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