Practices (ISMP), “Information about
nized pioneer in the area of medication
minimize the potential adverse events
approval by the U.S. Food and Drug
living with dementia despite its recent
prescribing aducanumab to older adults
are uniting behind a simple message:
medical organizations, and many experts
and Long-Term Care Medicine, other
a tremendous amount of attention and
treat Alzheimer's disease is garnering a
Med Dir Assoc
adverse events, especially patient deaths,
victions likely have an adverse effect
on reporting and process improvement”
of loss of a license, a job, and possible
criminal conviction is a missed opportu-
nonpunitive
The question remains: is criminal pros-
Treating Unintentional Error
The first thing to know is that existing
dementia drugs, the ones that have been
have limited effective-
best at. These medications include the
dochetal inhibitor — done-
(Aricept), rivastigmine (Exelon),
galantamine (Razadyne) — and an
NMDA (N-methyl-D-aspartate)
receptor antagonist, memantine (Namenda).
Each works by boosting or regulating the levels of
cellular messengers (acetylcho-
line for cholinesterase inhibitors or gluta-
mate for memantine) that are involved in
learning, memory, and judgment (Mayo
Clinic Staff. “Dementia: Diagnosis and
Treatment,” Mayo Clinic, updated July 2021,
https://mayo.in/3Fc7hpJ).
"The way to think about [cholin-
esterase inhibitors] is they slow down the
decline from dementia by about three
months compared to people who don’t
take them,” said Lea C. Watson, MD,
MPH, a geriatric psychiatrist in Denver and
co-chair of the Society’s Behavioral
& Mental Health Advisory Council, in an interview with Caring. “They don’t
make things better.” Well-meaning out-
put clinicians in the community may
prescribe the drugs thinking they can
keep patients on them indefinitely, she
said, but “they’re not benign.” Their
significant side effects include
insomnia, diarrhea, weight loss, and
arythmias. All of these dementia
drugs are candidates for depre-
scribing in the nursing home setting,
where dementia patients are perhaps
catching their last fight. "When people
live in a nursing home, it’s usually a
sign that dementia has progressed and
the medications would not be helpful,”
Dr. Watson said.
FDA Approves Aducanumab
and Faces Immediate Outrage
Aducanumab (Aduhelm), which is made
by the pharmaceutical company Biogen,
entered the picture in June 2021 when
the FDA granted the drug accelerated
approval as a treatment for Alzheimer’s
disease (FDA News Release, June 7,
this decision, the FDA’s Periperal
and Central Nervous System Drugs
Advisory Committee had overwhelm-
ingly voted against recommending
approval (Nadag, Nov. 6, 2020, https://
bit.ly/3LH6g0W).
The FDA’s decision on the approval of
aducanumab has been widely criticized.
Continued from last page
medication) were typically a result of
flawed systems. If a system is flawed to the point where
it permits medication errors, is it fair or
to just punish a single health care
practitioner? Why not fix the system
and incorporate fail-safe measures and
redundancies learned from human fac-
tors engineering?
The medical community could
learn from the Federal Aviation
Administration’s Aviation Safety
Reporting System (ASRS), which is a
confidential and voluntary reporting
system of adverse occurrences and
near misses. Not having actionable
data because a practitioner chose not
to disclose a medication error due to a fear
of loss of a license, a job, and possible
criminal conviction is a missed opportu-
nity to correct a system in need of repair.
Adverse Effects
High-profile criminal charges and con-
victions likely have an adverse effect
on practitioners and health care facili-
ties making voluntary disclosures when
adverse events, especially patient deaths,
occur.
According to an internationally recog-
nized pioneer in the area of medication
safety, Michael Cohen, RN, MS, ScD
(hon), president emeritus and founder
of the Institute for Safe Medication
Practices (ISMP), “Information about
the cause and nature of medication errors
is important. Yet even when no patient
harm occurs after a medication error,
health care practitioners won’t want to
risk disciplinary action for their involve-
ment, and may just choose to hide an
incident under the rug.” Consequently,
valuable information is forever lost that
could prevent future adverse events.
Dr. Cohen’s sentiments are echoed
by the American Nurses Association
(ANA) in a statement responding to
Vaught’s criminal conviction: “ANA
believes that the criminalization of med-
ical errors could have a chilling effect on
reporting and process improvement”
(Nursing World, Mar. 23, 2022, https://
One of the witnesses at Vaught’s trial,
Ramona Smith, an investigator with the
Tennessee Bureau of Investigation, testi-
fied that “Vanderbilt Medical Center
carried a heavy burden of responsibility in
this matter.” Yet interestingly no charges
were brought against Vanderbilt even
though it failed to report the fatal medica-
tion error to the Tennessee Department
of Health and the Centers for Medicare
& Medicaid Services. Additionally,
a physician at Vanderbilt listed the cause
of death as “natural.” (Vanderbilt settled
with the former patient’s family for an
undisclosed amount.)
Past Prosecutions
Unfortunately, Ms. Vaught’s case is
not the first time that medication errors have
been treated as criminal homicides and
will likely not be the last. Several years
ago an overly aggressive district attorney
in Denver, CO, charged three nurses
with criminally negligent homicide after
a fatal dose of penicillin was adminis-
tered to a newborn who immediately
went into cardiac arrest and died.
On behalf of ISMP, which is consid-
ered one of the leading organizations
regarding medication safety, Dr. Cohen
provided expert testimony for one of
the nurses, who pled not guilty. Dr.
Cohen analyzed all the relevant medical
information and found that there were
myriad errors in a broken system that
allowed for the lethal dose of penicillin:
the obstetrician who ordered the drug
was covering for another obstetrician;
the covering obstetrician did not need
to prescribe penicillin for the pregnant
mom (who had had a sexually trans-
mitted infection more than 10 years
prior); the pharmacy made a 10-fold
error in dispensing; and a drug refer-
ence book contained inaccurate infor-
mation regarding whether the medication
could be given intravenously instead of
intramuscularly.
These were only some of the system’s
errors that ISMP identified. Dr. Cohen
noted that “by reconstructing how the
system failures contributed to the tragic
outcome, the jury was able to under-
stand how the flawed system allowed
the nurse to make such an error.” The
nurse in this case was found not guilty,
but criminal conviction is clearly not a
path any practitioner wants to travel down.
Treating Unintentional Error
The question remains: is criminal pros-
cution the correct approach to an
unintentional error? If we have learned
anything about medication errors, it is
that they are system problems.
This prompts the question: is it fair
to criminally scapegoat a single health
care practitioner? There are important
societal goals, such as making the medici-
cation delivery system safer. Perhaps,
using the legal system to punish those
involved with medication errors is not
the most enlightened approach to
enhance safety.
In this instance, the legal profes-
sion can learn from the Hippocratic
Oath: Primum non nocere (First, do no harm).
Mr. Horowitz is Of Counsel at Arnall
Golden Gregory LLP. His practice in-
volves regulatory compliance concern-
ing skilled nursing facilities, hospices,
and home health agencies. He previ-
ously served as Assistant Regional
Counsel at the U.S. Department of
Health and Human Services and rep-
resented the Centers for Medicare &
Medicaid Services. Disclosure: The au-
tor previously served as the Director of
Clinical and Legal Affairs for ISMP.
and microhemorrhages, “and requires regular brain scans to monitor for these problems.” (See also: “A Year in Review” on page 10 of this issue of Caring).

In September 2021, the Society’s position statement on aducanumab said, “We believe that the lack of evidence of benefit, along with the significant potential for dangerous side effects (>30% of study participants had brain swelling or bleeding), high medication delivery cost (initial pricing for the drug alone is projected at $56,000.00/y, and it requires intravenous infusion), and potential for providing false hope is likely to have extraordinarily negative consequences for the 6 million people and their caregivers living with dementia in this country.”

The statement adds that “AMDA also acknowledges that our PALTc workforce bears a disproportionate burden because of the high concentration of people living with dementia in long-term care. We must answer to families and caregivers who are desperate to try ‘anything that might help’; however, it is our responsibility to resist the urge to prescribe a potentially dangerous and ineffective medication that is untested in our population, even if it has FDA approval” (1777).

Dr. Watson, the lead author of the statement, said that based on the process and the evidence, the drug should never have been approved. It’s especially important for medical professionals to understand that it hasn’t been tested on anyone in a nursing home, she said.

Focus on Emotions First
Before Educating Loved Ones

Long-term care professionals may hear from family members who are curious about whether aducanumab may be appropriate for their loved ones. In an interview, Paige Hector, LMSW, a professional social worker, recommended working to understand the emotions of family members before turning to education mode.

“Perhaps they’re looking for reassurance or simply to feel heard,” she said. “Consider how you can respond appropriately in a way that eases their pain.” For example, you could “acknowledge how much they love their mother, how desperately they’d like this disease to go away, and how this is super hard.”

If a family member asks about aducanumab, it can be helpful to note that it’s only approved for people who are in the mild stages of Alzheimer’s disease, said Lauren Hunt, PhD, RN, FNP, a geriatric nursing care specialist and assistant professor at the University of California at San Francisco. “It is not indicated for people with moderate to severe dementia, which accounts for most people in the nursing home setting,” she said.

You may also wish to note the drug’s serious side effects, such as brain bleeds, and point out that “many behavioral symptoms and problems for people with moderate to severe dementia in the nursing home can be managed with nonpharmacological interventions,” Dr. Hunt said.

Indeed, nonpharmaceutical strategies such as individualized person-centered care, private rooms, and household models of care such as the Green House model have been shown to improve the quality of life for people living with dementia and their caregivers, Dr. Watson said. (Readers can visit www.nursinghometoolkit.com for more on nonpharmacological strategies.)

What’s next on the medical front in dementia and Alzheimer’s disease? According to the Mayo Clinic, drugs that target beta amyloid (like aducanumab) and tau tangles are in clinical trials, and researchers are exploring whether anti-inflammation treatments are helpful (“Alzheimer’s Treatments: What’s on the Horizon?” Mayo Clinic, June 30, 2021, https://mayoclinic.org/3LHgqZ6). Other approaches are being studied, too.

In the big picture, however, “there are things that can make the process of having dementia better, but there are no imminent cures for people already living with dementia,” Dr. Watson said. “We need to change the focus from cure to care.”