Oppose 2024 Senate Bill 0332

Eszter Szabo
Bethesda, MD 20817
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Dear Chair and Members of the Committee,
https://www.gene.com/download/pdf/tamiflu_patientinfo.pdf

This bill is supported by the Love for Lochlin Foundation in Maryland according to Delegate Kerr who is the sponsor of it in the House. Lochlin was a 5-year-old boy who sadly died from sepsis linked to the flu in 2020, when he was treated with Tamiflu after an urgent care visit. The Foundation is promoting, among other things, vaccination against flu as a solution to flu related sepsis death via free mobile clinics in Frederick County, MD. https://www.loveforlochlin.com/

This bill is condemnable as who would want to see even one more child die at such young age. However, one needs to look a bit further than just assume that the solution to the issue here is either vaccination against the flu or legislative solution with respect to sepsis.

Lochlin was prescribed Tamiflu 2 days after he started his flu symptoms. Tamiflu's side effects according to this study from Japan https://pubmed.ncbi.nlm.nih.gov/22156085/ includes death. "**Conclusions:** These data suggest Tamiflu use could induce sudden deterioration leading to death especially within 12 hours of prescription. These findings are consistent with sudden deaths observed in a series of animal toxicity studies, several reported case series and the results of prospective cohort studies. From "the precautionary principle" the potential harm of Tamiflu should be taken into account and further detailed studies should be conducted."

More on this topic can be found here https://circleofmamas.com/health-news/recent-flu-death-uncovers-more-tamiflu-risks/

"Instead, how about asking these questions?

- What percent of the pediatric influenza deaths every year were administered Tamiflu?
- What percent of these deaths were vaccinated?

The antiviral medication (oseltamivir) was found to cause severe side effects such as hallucinations, severe vomiting and diarrhea, and even death, in it's own clinical trials and post marketing surveillance.

Many people who die of the flu, either were vaccinated, or given Tamiflu:
🙏 Kinsley Sandvik, 8 years old from Maryland, dies on Valentine's Day of 2020 of blood poisoning after being given Tamiflu.
https://www.fox5dc.com/news/8-year-old-maryland-girl-loses-life-from-flu-complications
🙏 Kaylee Roberts, 16 years old, dies from flu after being given Tamiflu.
https://www.cnn.com/…/flu-ohio-teen-kaylee-rober…/index.html

🙏 Luca Calanni, 11 years old dies from the flu. Got a flu shot 2 months prior, and dies after Tamiflu.
https://buffalonews.com/…/death-of-11-year-old-from-flu-ha…/
🙏 Liliana "Lily" Clark, 13 years old dies 2 weeks after she was diagnosed with the flu. Dies after Tamiflu.
https://nypost.com/…/idaho-teen-dies-two-weeks-after-she-w…/
🙏 Jade DeLucia, 4 years old, received a flushot in March 2019 but still came down with the flu in December.
https://www.dailymail.co.uk/…/Four-year-old-girl-not-vaccin…
🙏 Canadian Joanne Ens, 24 years old, dies from flu after taking Tamiflu.
https://winnipeg.ctvnews.ca/manitoba-woman-24-dead-days-aft…

STUDIES
"The mechanisms of sudden-onset type adverse reactions to oseltamivir."
2017 https://www.ncbi.nlm.nih.gov/pubmed/27364959
"Oseltamivir is contraindicated for people aged 10-19 in principle in Japan, due to concern about abnormal behaviours. Sudden death is another concern. This review examines growing evidence of their association and discusses underlying mechanisms of these sudden-onset type reactions to oseltamivir."
"Oseltamivir and early deterioration leading to death: a proportional mortality study for 2009A/H1N1influenza." 2011 https://www.ncbi.nlm.nih.gov/pubmed/22156085
"Of 119 deaths after Tamiflu was prescribed, 38 deteriorated within 12 hours (28 within 6 hours), while of 15 deaths after Relenza, none deteriorated within 12 hours. Pooled OR for early deterioration and overall death were 5.88 (95% CI: 1.30 to 26.6, p = 0.014) and 1.91 (p = 0.031) respectively. Baseline characteristics including risk factors did not contribute to early deterioration after Tamiflu use."
Is oseltamivir (Tamiflu) safe? Re-examining the Tamiflu 'ado' from Japan.
2010. https://www.ncbi.nlm.nih.gov/pubmed/20121561
The author also alarms the potential risk of sudden death related to oseltamivir and foresees how the problem may be solved in the future.
"Fatal neuropsychiatric adverse reactions to oseltamivir: Case series and overview of causal relationships". 2008. https://npojip.org/english/published-paperJRS431.pdf
"This paper reports eight cases in total: five of these died and three survived. Two died as a result of accidents resulting from abnormal behaviour. Three others died suddenly during sleep (two infants and one adult). One of the infants and the adult were found at autopsy to have severe lung oedema. A 14-year-old boy experienced agitation, cyanosis, loss of consciousness and seizures but recovered completely, while a 10-month-old girl showed retarded development and mental retardation after initially appearing to recover from the acute event involving loss of consciousness and seizure. A 15-year-old boy had a delayed onset of complications but developed prolonged neuropsychiatric adverse reactions after taking an almost complete course of Tamiflu; in this case the symptoms lasted for two weeks."

The MD bill itself asks for hospitals and urgent care centers to create diagnosing and treatment protocols for sepsis both in children and adults. The current widely practiced sepsis protocol is using antibiotics, however many infections are antibiotic resistant. It seems there is an interest to use vaccination as a possible way to avoid various infections that may lead to sepsis. However, sepsis mainly develops in individuals with weak immune system or as a result of infections during or following hospital care. This is stated here by the World Health Organization https://www.who.int/news-room/fact-sheets/detail/sepsis

Key facts from this page linked directly above dated July 2023, which is based heavily on a study "funded by The Bill & Melinda Gates Foundation, the National Institutes of Health, the University of Pittsburgh, the British Columbia Children's Hospital Foundation, the Wellcome Trust, and the Fleming Fund" are:

- "A recent scientific publication estimated that in 2017 there were 48.9 million cases and 11 million sepsis-related deaths worldwide, which accounted for almost 20% of all global deaths (1).
- In 2017, almost half of all global sepsis cases occurred among children, with an estimated 20 million cases and 2.9 million global deaths in children under 5 years of age (1).
- Regional disparities in sepsis incidence and mortality exist; approximately 85% of sepsis cases and sepsis-related deaths worldwide occurred in low- and middle-income countries (1).
- Health care-associated infections are one of the most frequent types of adverse event to occur during care delivery and affect hundreds of millions of patients worldwide every year."

Further "To combat this important global health threat, WHO responded with a WHO Secretariat Report and, in May 2017, the Seventieth World Health Assembly adopted Resolution WHA70.7 on *Improving the prevention, diagnosis and clinical management of sepsis*. The key pillars of Resolution WHA 70.7 are to:

1. develop WHO guidance on sepsis prevention and management;
2. draw attention to public health impacts of sepsis and estimate the global burden of sepsis;
3. support Member States to define and implement standards and establish guidelines, infrastructure, laboratory capacity, strategies, and tools for identifying, reducing incidence of, and morbidity and mortality due to sepsis; and
4. collaborate with UN organizations, partners, international organizations, and stakeholders to enhance sepsis treatment and infection prevention and control including vaccinations."

The UN Sustainable Development Goals states: "The prevention and/or appropriate diagnosis and management of sepsis is also linked to adequate vaccine coverage, quality universal health coverage, capacity to comply with the International Health Regulations, preparedness, and water and sanitation services. The challenge, however, remains how to achieve universal prevention, diagnosis and management of sepsis."

Currently there is no gold standard screening protocol to identify sepsis or protocol to treat sepsis, nor is there a meaningful reporting for sepsis events as this scientific study states it here: https://pubmed.ncbi.nlm.nih.gov/31954465/

The following quote is about this issue based on NY state's law about sepsis treatment: https://www.pulmccm.org/p/regulations-sepsis-treatment

"Does Regulating Sepsis Care Improve Outcomes?
New York regulators and its governor tout their state's 16% relative reduction in mortality from sepsis (30% to 25%) from 2014 to 2016, combined with a 20% increase in case identification (11,000 to 13,000/year). That math suggests an unchanged absolute number of about 3,300 deaths from sepsis each year at the observed hospitals. Generally speaking, the most efficient way to improve observed survival from a disease is to identify more cases, which tend to be milder in severity, or false positives.

Any such secular trends are not discernible in the aggregated data in the paper, but 45% of the 49,000 patients (2014-2016) were described as having septic shock. However, in a 2015 New York state health department report, 49% of the patients had septic shock. Were the presenting patients less ill as time went on?

Sepsis mortality has been declining nationwide, in states without such regulations. But the study purporting to show this also admits that depending on which competing epidemiologic case definition is used, observed sepsis incidence in the U.S. during a given time period can arbitrarily be tripled, or reduced by 70%. With the uncertainty in case definition, it's hard to have confidence in national numbers.

There's no way to know, but it seems likely that rapid sepsis identification and delivery of antibiotics at high-performing institutions under the New York regulations saved lives. Whether mandating the other elements of the bundles is helpful or necessary is less clear.

Risks Of Regulation of Sepsis Care
The New York legislation represents a new level of governmental control of medical practice, legislating care for a condition affecting more than one million Americans each year.

Editorialists worried that:
Clinical practice guidelines often make recommendations involving proprietary medical devices and pharmaceuticals. Device and pharmaceutical companies could lobby state governments to include these products in future regulations. If these lobbying efforts are not transparent, conflicts of interest may lead to abuse of the regulatory process."

The story behind the CMS sepsis core measure suggests these concerns are valid:

The National Quality Forum (NQF) is the only guideline-issuing entity in the U.S. whose performance measures result in changes to Medicare and Medicaid rules and thus are backed by state power. The NQF's review process is designed to include industry representation.

According to a slides presented by a physician at the National Institutes of Health, in 2013 the National Quality Forum endorsed an earlier version of its sepsis performance measure, proposed by the original advocates of EGDT for sepsis. The NQF's endorsed measure included a requirement for measuring central venous pressure and central venous oxygenation. This decision came despite objections from multiple professional societies, and disregarded the pending results from the Process, Arise, and Promise trials. (In 2014 and 2015, these three trials together definitively refuted any benefit of standardized measurement of CVP or ScvO2 in sepsis.)

It so happened that in 2013, the co-chair of the NQF steering committee reviewing the sepsis core measure was the vice-president of AdvaMed, a trade association for medical device manufacturers. Also on the board of directors of AdvaMed since 2008: the CEO of Edwards Lifesciences, the manufacturer of a proprietary central venous catheter to measure CVP and ScvO2. Edwards Lifesciences funded the original EGDT trial and subsequently provided hundreds of thousands of dollars in funding and speaker's fees to that study's author and institution.

After publication of the Process trial less than a year later, the National Quality Forum revised its performance measure, changing use of CVP and ScvO2 from required to optional.

The New York regulations were created without suggestions of undue industry influence, but it's worth noting they are grounded in similar history, evidence, and politics as the CMS core measure.

At least three states (Pennsylvania, Washington, and Illinois) are considering similar legislation mandating the use of sepsis bundles, based on New York's model."

The current bill in Maryland doesn't yet mandate one protocol for sepsis but if this would be the case in the future, one wants to oppose this bill. Doctors need to be able to practice medicine based on individual patient needs and not mandated protocols that are influenced by pharmaceutical companies and researchers paid by Big Pharma. I support encouraging the medical community to find working diagnoses for sepsis in children and adults, even though as the above information shows even that is very difficult, but I am against a mandated and codified law which will limit patients' choice for possible treatment at the hospital or urgent care level.

Here is one treatment that might not make a cut for such a protocol even though it successfully worked. IV vitamin C treatment can be used to treat sepsis.
https://www.npr.org/sections/health-shots/2017/03/23/521096488/doctor-turns-up-possible-treatment-for-deadly-sepsis

Please vote against this bill.

Sincerely,