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<u>http://PatientSafetyAmerica.com</u>

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<u>*Question:*</u> According to the CDC, how many Americans have died from a drug overdose in the past 22 years? A) 250,000 B) 500,000 C) 750,000 D) 1,000,000 E) 1,250,000

Prosecuting Corporate Executives for Wrongdoing My morning newspaper revealed the penalty Elizabeth Homes received for defrauding various investors in Therano's supposedly revolutionary technology to measure a host of things in a drop of blood. Although



pregnant and appealing for leniency, she was given 11+ years in prison for her wrongdoing.

A lawyer wrote in *JAMA Internal Medicine* about the circumstances under which corporate executives may be held criminally liable for their illegal activity by the Department of Justice (DOJ).¹ Civil prosecutions are simpler than criminal prosecutions and it seems that unless a company cooperates in releasing documents that could lead to the criminal prosecution of an executive, there is little chance that the DOJ can get a conviction. The situation has evolved some since about 2015 to make prosecution of individuals easier, so Ms. Holmes' conviction may be a product of those changes. Corporate executives behind the opioid epidemic have rarely been jailed for their wrongdoing that led to more than 100,000 deaths in the US. Frankly, I think the difference may have more to do with rich investors being cheated out of their money than ordinary people becoming victims of lethal opioid addiction.

Contact Allergens in Natural Skin Care Products

Contact dermatitis (skin rash) is the fifth most common skin disease. Since 1996, the prevalence of dermatitis from personal care products (PCPs) has increased almost 3-fold. More products are being marketed as *natural* PCPs. The FDA has not defined the meaning of 'natural' allowing companies to use the term to imply that their product may be safer because it is 'natural.' A team of three investigators asked how often *known* skin allergens were found in the ingredients label of natural PCPs.² About 1650 products sold by three major chains were investigated for the presence of skin allergens. They found that 94% had at least one contact allergen. The average number of contact allergens was 4.3. The message for patients is that skin care products that are deemed 'natural' may cause contact dermatitis.

Lobbying Expenditures by the Healthcare Industry

A small team of investigators decided to examine the OpenSecrets database of lobbying at the federal level to determine the types of companies responsible for healthcare lobbying expenditures from 2000 to 2020.³ They divided the expenditures into four types as follows: pharmaceutical and health product manufacturers, providers of healthcare, payers for healthcare, and healthcare policy organizations. They normalized all dollars spent to 2020 dollars. In 2020 the expenditures were \$714 million, up from \$358 million in 2000. Only

¹<u>https://jamanetwork.com/journals/jamainternalmedicine/art</u> <u>icle-abstract/2796502</u>

² <u>https://pubmed.ncbi.nlm.nih.gov/36103164/</u>

³ <u>https://pubmed.ncbi.nlm.nih.gov/36306120/</u>

firms with more than \$12,500 in *spending per quarter* must report into the database.

In 2020 the pharmaceutical and health product manufacturers spent \$308 million, providers spent \$287 million, payers \$81 million, and policy organizations spent \$38 million. The point of all this is to show that a huge amount of money is being spent to persuade lawmakers at the federal level to come down on the side of the industry rather than on the side of those who depend on it to maintain health. It seems to me that entities spending less than \$50,000 per year (\$12,500 per quarter) may do a lot of lobbying without having to report it. Also, lobbying at the state level is not included in the summary.

Electrolytes and Eating Disorders

Electrolytes are essential for normal bodily function, especially the heart. A Canadian team of researchers asked if there is an association between precursor electrolyte abnormalities and subsequently diagnosed eating disorders in adolescents and adults.⁴ Their study involved 697 people older than 13 years living in Ontario and diagnosed with an eating disorder. The goal was to determine if a person with abnormal levels of potassium, sodium, magnesium, phosphate, or acid-base imbalance is more likely than someone without these disorders to present later with an eating disorder (anorexia or bulimia).

Cases with a first diagnosis of an eating disorder were identified and an electrolyte panel sought from 30 days to 3 years prior to the diagnosis. Matched controls that had no diagnosis of an eating disorder and had electrolyte measurements were identified. Of patients diagnosed with an eating disorder, 18% had a precursor electrolyte abnormality, whereas those with no such diagnosis had a 7.5 % chance of a precursor electrolyte abnormality. Hypokalemia (low potassium) was by far the most common electrolyte abnormality. The authors conclude that incidentally found electrolyte abnormalities may indicate the need to consider an eating disorder as the cause. The message for patients is to pay attention to your electrolyte levels and seek a cause if they are abnormal. Eating disorders are much more common in young women than in young men.

Lowering High Blood Pressure

There may never be a last word on lowering high blood pressure (bp); however, I thought it might be useful to capture current thinking as presented by three MDs in a review article in the *JAMA*.⁵ Before I begin that, I want to caution readers to follow instructions that came with your bp monitor. With mine came instructions to sit quietly for 5 minutes in a chair with feet on the floor. Place the pressure cuff on your arm at the same height as your heart. No talking. My experience is that no matter how careful I may be, my measurements are likely to vary by 10 points systolic and 5 points diastolic. Let's dive into the targeted numbers.

The goal is to have a bp of 130/80 or less. For each reduction of 10 points in systolic bp, one's cardiovascular risk drops about 25%. The first line of lowering bp is lifestyle changes and weight loss. Consume less sodium and more potassium, do moderate exercise, and use alcohol in moderation. The author asserts that use of medications should be initiated only when bp is elevated and there is appreciable cardiovascular risk. The author asserts that only 44% of US adults with high bp have it controlled to 140/90. Maybe this holiday season, you should give yourself the gift of a lower bp. Maybe you should delay your plan until it is time to make a new year's resolution.

Deaths Associated with Alcohol Consumption

A team of experts from the US-CDC and Canada sought assess the magnitude of excessive alcohol to consumption on the portion of deaths attributable to that excess.⁶ They defined excess alcohol consumption as lethal conditions known to be due to alcohol alone: acute death from binge drinking, or chronic, daily consumption involving 1-2 drinks in women and 2-4 drinks in men. They looked at CDC data from 2015 to 2019, finding almost 700,000 deaths/year in the age range of 20-64 years. Of those deaths, about 13% were attributable to excessive alcohol use. There was a 2-fold age variation in the percentage of deaths attributable to excessive alcohol use. In the 20-49-year-old group, 1 in 5 deaths were attributable to excessive alcohol use. The authors call for limiting the density of alcohol-marketing stores, increasing taxes on alcohol, and providing treatment for excessive alcohol consumption.

⁴<u>https://jamanetwork.com/journals/jamanetworkopen/fullart</u> <u>icle/2798207</u>

⁵ <u>https://jamanetwork.com/journals/jama/article-abstract/2798165</u>

⁶ https://pubmed.ncbi.nlm.nih.gov/36318209/

Potassium and Magnesium for Acute Atrial Fibrillation (AFib)

As we age, the likelihood of AFib increases and carries a higher risk of stroke compared to when it is not present. A huge team of investigators based in Austria wondered if intravenous administration of potassium and magnesium to patients coming to the ER with nonpermanent AFib would improve their chances of reversal of AFib to normal heart rhythm.⁷ About 2,500 cases of AFib from 2009 to 2020 (55% men, average age 68 years) were given the electrolyte treatment or ordinary care. Those that received the potassium and magnesium had a 19% reversion to normal rhythm, whereas those with ordinary treatment had only a 10% reversion. The use of potassium and magnesium in such conditions may be worth a try. Low blood levels of these electrolytes are associated with an increased chance of AFib.

Money Problems after Traumatic Injury

A team of investigators looked at the debt status of 3165 post-injury patients (2019-2020) with commercial health insurance and matched these to 2223 patients that served as controls.⁸ The study group was working-age adults aged 21-64 years. They found that injured patients had a 23% higher likelihood of debt in collection than uninjured controls, a 70% higher amount in collections than controls, and a 110% higher bankruptcy rate than controls. The authors call for strategies to reduce the outof-pocket charges that come with serious injuries. One solution would be for traumatic injuries to be excluded from deductible payments of patients. Another way would be to set an out-of-pocket cost indexed to the patient's financial status. It seems inhumane to me to add high-medical-bill trauma to the trauma already caused by serious injury.

Vaccination Rate and COVID-19 Mortality

A small team of investigators asked if there was a relationship between the vaccination rate in a population and the rate of COVID-19 mortality as the omicron and delta variants (2021-2022) swept through 21 highly developed countries and across states of the US.⁹ Among the 21 countries, the US had the lowest overall vaccination rate (63%) and the highest mortality rate (112/100,000 population). The highest vaccination rates (except the Republic of Korea) were in Japan and Spain

at 80% and their COVID-19 mortalities were only 10/100,000 and 44/100,000, respectively. In the 10 most-vaccinated US states the COVID-19 mortality was 75/100,000 and in the 10 least-vaccinated states the mortality was 146/100,000. A similar pattern was reflected in all-cause mortality. Although other factors besides vaccination rate affected outcomes, the point is clear that vaccination rates made a difference in what portion of the population died of COVID-19.

A Call to Fix Hospital Rankings

One does not have to drive far in Houston to see a sign claiming some glorious ranking by the US News and World Report (USNWR) for a hospital. Such rankings are widely used by hospitals to attract patients. But are these rankings trustworthy? A couple of MDs explained in JAMA Surgery why they believe the USNWR ranking system needs to change to be more honest about the quality of care delivered.10 The USNWR rankings depend on three factors: 1-staff, equipment, and environment; 2- processes between staff and patients, and 3- outcomes of patient care. Expert opinion determines about 85% of the 'process' parameter. Hospitals have begun campaigning for expert votes. There is a conflict of interest in that physicians are likely to vote for their institution and not for competitors in their area. The vote is too reputation dependent, and unaffiliated physicians outside the region have little first-hand knowledge of process quality when they vote.

The proposed fixes to the process measure include doing away with physician voting and replacing this with a measure of equity and *evidence-based care*. My reaction to the latter is joy, knowing that too much care is *not* evidence based. How that is done may be a challenge. The practice of soliciting physician votes should cease. So, next time you spot a sign bragging about a USNWR high ranking, roll your eyes back.

Interesting Links

https://www.dallasnews.com/news/courts/2022/10/31/jury-awards-21-million-to-man-in-vegetative-state-after-leg-surgery-at-dallashospital/

Doctors to be held accountable for misinformation: https://www.medpagetoday.com/special-

⁷ https://pubmed.ncbi.nlm.nih.gov/36260333/

⁸ https://pubmed.ncbi.nlm.nih.gov/36367739/

⁹ https://pubmed.ncbi.nlm.nih.gov/36399335/

Dallas jury awards \$21 M to man left in vegetative state after leg surgery:

¹⁰ https://jamanetwork.com/journals/jamasurgery/articleabstract/2798639

reports/exclusives/101529?xid=nl_mpt_DHE_2022-11-01&eun=g1330759d0r&utm_source=Sailthru&utm_medium=email& utm_campaign=Daily%20Headlines%20Evening%202022-11-01&utm_term=NL_Daily_DHE_dual-gmail-definition

Medical misinformation (Lydia Green): https://www.kevinmd.com/2022/10/punishing-doctors-forspreading-misinformation.html

Unique Device Identifiers have been added to the FDA's MAUDE database to improve focus on devices that are not working as intended:

https://content.govdelivery.com/accounts/USFDA/bulletins/332541a

Sad malpractice case involving a misdiagnosed 2-year old: https://komonews.com/news/local/trial-in-seattle-childrenshospital-deadly-mold-lawsuit-begins-aspergillus

Leapfrog on hospital safety: https://www.hospitalsafetygrade.org/search?

Five ways hospitals harm patients: <u>https://lowninstitute.org/five-ways-hospitals-harm-patients-that-need-to-stop-now/</u>

The crisis of boarding in emergency rooms:

https://www.acep.org/globalassets/new-pdfs/advocacy/emergencydepartment-boarding-crisis-sign-on-letter-11.07.22.pdf

Connection between Church and Health Care – Real Health Care: https://churchhealth.org/about/

The great American Medical debt machine: <u>https://www.pestemag.com/lost-to-follow-up/the-great-american-medical-debt-machine</u>

Post Roe US women are struggling to get abortions: https://www.commonwealthfund.org/publications/podcast/2022/no v/us-women-struggle-get-abortions-post-roe-world

Health insurance that's not good enough:

https://www.statnews.com/2022/11/04/millions-americans-healthinsurance-isnt-good-enough/

Extending health coverage for the working poor (one way is to expand Medicaid):

https://www.commonwealthfund.org/blog/2022/unfinishedbusiness-extending-health-care-coverage-all-low-income-americans

COVID had more impact on community hospitals:

https://www.cidrap.umn.edu/news-perspective/2022/08/studyshows-outsized-covid-impact-community-hospitals

State prescription affordability boards:

https://www.commonwealthfund.org/blog/2022/can-stateprescription-drug-affordability-boards-address-high-cost-drug-prices

Debt sharks cashing in when patients can't pay their medical bills: <u>https://khn.org/news/article/how-banks-and-private-equity-cash-in-when-patients-cant-pay-their-medical-bills/</u> If you ever think we patient advocates are going to get transparency and accountability from the medical industry, think again: <u>https://www.kxan.com/investigations/a-long-time-before-congress-</u> takes-up-medical-error-transparency

Plane-crash level of deaths (200,000/year) from mistakes in hospital care is told to CMS (Colleagues Helen, Armando, and Lisa are quoted):

https://www.forbes.com/sites/michaelmillenson/2022/11/17/addre ss-plane-crash-level-patient-harm-hhs-tells-hospitals-as-politicalcurrents-swirl/?sh=1135fde55e9c

Hospital billing is a crime against patients: <u>https://prospect.org/health/hospital-billing-crime-against-american-</u> patients/

Some negative press about Leapfrog's hospital ratings: https://www.msn.com/en-us/health/medical/grades-are-in-forhospital-conditions-nationwide-how-did-western-north-carolinafare/ar-AA14m4J2

Medicare and secret surveillance: https://thehealthcareblog.com/blog/2022/10/31/the-secretsurveillance-capitalism-that-suffuses-medicare/

How big Pharma took over patient groups to keep drug prices high: <u>https://breachmedia.ca/how-big-pharma-took-over-patient-groups-to-keep-drug-prices-high/</u>

How medical boards communicate with patients (Patient safety advocates in ACTION):

https://podcast.clearhq.org/e/communicate_sexual_misconduct/

Hospital that retained dangerous orthopedic surgeon can be held accountable for harm he caused:

https://www.news4jax.com/news/local/2022/11/21/i-team-judgegrants-plaintiffs-permission-to-seek-punitive-damages-against-stvincents-in-cases-involving-former-orthopedic-surgeon/

Drug-resistant fungal outbreak in two Las Vegas hospitals: https://www.staradvertiser.com/2022/11/26/breakingnews/nevadas-superbug-cases-climb-at-2-las-vegas-hospitals/



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Find past newsletters: http://patientsafetyamerica.com/e-newsletter/

Answer to question: (D) 932,000 https://www.cdc.gov/opioids/data/index.html