

Three Minute Read™

Insights from the Healing American Healthcare Coalition™

December 2022-2



From the Editor: Following Covid and flu updates, the final three article summaries focus on the failures of medical device manufacturers to self-regulate and China's "zero Covid" policy along with an offer to learn the lessons that China has ignored. To read each full article, just click on its headline.



[FDA pauses authorization for last remaining Covid-19 monoclonal antibody treatment](#), by Joseph Choi, The Hill, 11/30/22

TMR Topline – The FDA announced that the Eli Lilly Covid-19 monoclonal antibody treatment bebtelovimab is no longer authorized for emergency use given the probability that it is not likely to be effective against omicron subvariants BQ.1 and BQ.1.1 that account for the majority of new infections. The FDA advised that providers choose "appropriate" treatments including the authorized antivirals Paxlovid, Veklury and Lagevrio. It also recommended the use of convalescent plasma for patients who have compromised immune systems.



[Next Covid-19 Strain May be More Dangerous, Lab Study Shows](#), by Antony Squazzin, Bloomberg, 11/26/22

TMR Topline – A South African [study](#) led by Alex Sigal at the Africa Health Research Institute indicates that a new variant could cause worse illness than the current predominant omicron strain. In Covid-19 samples from an immunosuppressed individual the virus evolved to become more pathogenic over a six-month period.

Patients such as those infected with HIV take a long time to shake off the disease, letting the virus mutate and become better at evading antibodies. Christian Drosten, Germany's most prominent virologist, expressed concern that China's failed zero Covid strategy could spawn a new variant if infections take hold and there is a huge surge in cases.

TMR's Take: In plain English, when it takes a long time for a patient to recover from a Covid-19 infection, that patient has provided a Petri dish within which the virus can mutate.



[Long Covid may cost US economy \\$3.7 trillion](#), by Laura Dyrda, Becker's Hospital Review, 12/1/22

TMR Topline – According to [CNBC](#) the CDC [estimates](#) that long Covid-19 affects 7.7-23 million Americans. Harvard University economist David Cutler found long Covid could cost the U.S. economy \$3.7 trillion since the lingering symptoms make it challenging for people with long Covid to work regularly and obtain life insurance. HHS recommendations for attacking long Covid include more public awareness, funding for long Covid clinics, supporting more long Covid specialists and education for primary care providers to diagnose and treat long Covid. HHS also supports a better reimbursement structure for treating long Covid along with better data tracking and more research and rapid innovation for breakthroughs.



[Authorities are urging indoor masking in major cities as the 'triple-demic' rages](#) by Juliana Kim, NPR, 12/11/22

TMR Topline – The recent surge in cases of Covid, the flu and RSV has been sickening millions of Americans, overwhelming ERs and even causing [a cold medicine shortage](#). CDC Director Dr. Rochelle Walensky noted that the simultaneous combination of viruses has been

straining healthcare systems across the country. [Over 9%](#) of US counties are considered to have a high risk of Covid-19 infection. Washington, Oregon and Los Angeles are urging residents to wear masks indoors, as is New York City's Health Commissioner Dr. Ashwin Vasani.



[‘A constant information lag’: The troubled recall of Philips CPAP machines underscores flaws in device over-](#)

[sight](#), by Brittany Trang, STAT, 12/1/22

TMR Topline – More than ten years after first reports of the soundproofing foam in users' CPAP and BPAP machines breaking down, Philips finally issued a recall. The devices are widely used to help people with sleep apnea keep breathing throughout the night but also are used by people with neuromuscular and degenerative diseases, including children. By 2015, Philips had gotten enough customer complaints to know several of its CPAP and BPAP ventilators had problems with the foam used to soundproof the machines, but the FDA found no evidence that Philips acted on this information. Philips recalled 20 different models in June 2021 but was unable to contact people directly as most are sold through third-party vendors. Many patients either hadn't heard about the recall or were unsure of what to do about it. The FDA found that 28 of 182 suppliers it contacted were not aware of the recall. Lacking the workforce to monitor post-approval performance of medical devices, the FDA must trust companies to keep tabs on emerging issues. The statistics before and after the recall make clear that Philips policing of its own products didn't cut it.



[Exclusive: Musk's Neuralink faces federal probe, employee backlash over animal tests](#), by Rachel Levy, Reuters, 12/5/22

TMR Topline – Neuralink, a medical device company owned by Elon Musk, is under federal investigation by the US Department of Agriculture for violations of the Animal Welfare Act, which governs how researchers treat and test some animals. While the FDA reviews applications for approval of Neuralink's medical device and associated trials, its treatment of animals during research is regulated by the USDA. Neuralink is developing a brain implant it hopes will help paralyzed people walk again and cure other neurological ailments. Since 2018, the

company has killed about 1,500 animals following experiments. Current and former employees say the number of animal deaths is higher than it needs to be due to Musk's demands to speed up research. Rather than follow a more traditional testing approach, Neuralink launches tests in quick succession before fixing issues in earlier tests or drawing complete conclusions. The result: more animals overall are tested and killed, in part because the approach leads to repeated tests.

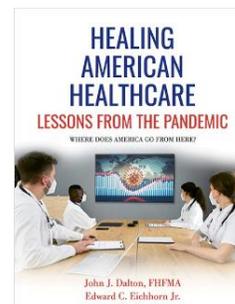
TMR's Take: Both articles are disturbing reading. Letting the fox guard the henhouse rarely is good for the hens.



[How China's Zero-Covid Policy Failed To Prevent Record Infections And Triggered Rare Protests](#), by Silvada Ray, Forbes, 11/28/22

TMR Topline – China has reported

more than 40,000 new Covid-19 cases for the first time since the start of the pandemic, raising questions about the effectiveness of the country's stringent zero-Covid approach which has triggered unprecedented mass protests against the policy across multiple Chinese cities. The uptake of vaccines and boosters among vulnerable groups like the elderly [still remains very low](#). Only 65.7% of people over the age of 80 have been fully vaccinated; 40% of them have received booster shots. [Appearing](#) on CBS News Face the Nation, Dr. Fauci said China's problems stem from the country "not having an effective vaccine" and its refusal to approve more effective foreign-made vaccines. Protesters in cities like Shanghai and Beijing directed their anger at the country's leader Xi Jinping and his administration, which backed the zero-Covid approach. Harsh lockdowns have failed to quash the local spread of the virus, but have caused economic challenges, food shortages and prevented people from accessing non-Covid related health care.



TMR's Take: Looking for the perfect gift for the healthcare policy wonk on your list? Want to learn the lessons that China ignored? Order "Lessons from the Pandemic," the Healing American Healthcare Coalition's new book, available in both soft-cover and eBook versions. Click [here](#) to buy it

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