Merck's Deadly Vioxx Playbook, Redux: A Debunked Smear Campaign Against Its Competing Drug—the FDA-approved, Nobel prize-honored Ivermectin

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Global Research, September 09, 2021
TrialSiteNews 7 September 2021

Theme: Media Disinformation, Science and Medicine

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Latest news reports of a cluster of ivermectin overdoses in Oklahoma were debunked by the hospital. Not one such case. The doctor who fabricated the story hadn't work there in two months.

On February 4, 2021, Merck, which is readying release of its new COVID-19 treatment drug, molnupiravir, issued a press release about that new drug's competition, ivermectin.[1] Merck itself had developed ivermectin, now off-patent, for human use, securing FDA approval in 1987, and distributed most of its 3.7 billion doses safely used worldwide since.[2-4] It was thus curious that Merck's press release about use of ivermectin for COVID expressed "a concerning lack of safety data in the majority of studies."[1]

Recently, many news reports[5-8] picked up on Merck's theme, lambasting the use of a dangerous horse de- wormer by gullible consumers. The most recent were by the *BBC*,[9] *Rolling Stone*,[10] *The Guardian*,[11] *MSN*[12] and others, about Oklahoma hospital facilities being strained with ivermectin overdoses, delaying other emergency care. The hospital system in question debunked the story, noting that it had not one case of ivermectin overdosing and that the doctor who fabricated the story hadn't worked there in two months.[13,14]

These false alarms about ivermectin safety, echoing Merck's, are scientific nonsense. Ivermectin is FDA approved for human use,[4] its discovery honored with the 2015 Nobel Prize for medicine, for "improving the health and wellbeing of millions," with "limited side effects."[15] One of the safest modern drugs, it is well tolerated even at very high doses (details below). By a quirk of molecular biology, ivermectin binds to SARS-CoV-2 spike protein and obstructs the morbidity of the virus.[16-18] It thereby also obstructs Merck's

anticipated billions in revenues from its new COVID entry. As to Merck's past playbook for such obstacles, consider its $410 million disinformation campaign for its deadly drug Vioxx,[19] withdrawn in 2004.

"Dodge Ball Vioxx." In a scathing critique of Merck's duplicitous promotion of Vioxx,[20] Richard Horton, the editor-in-chief of *Lancet*, noted how Merck prepared a sales presentation, entitled "Dodge Ball Vioxx,"[21] with instructions for dodging awkward inquiries from physicians. To the question, "I am concerned about the cardiovascular effects of Vioxx?" the answer that Merck instructed was: "DODGE!"

"Neutralize," "discredit," "destroy." Merck knew early of Vioxx's cardiovascular risks, which resulted in up to 139,000 heart attacks and strokes, 30-40% of them likely fatal.[22,23] Merck not only concealed some such deaths,[22,24]but it systematically attacked those who warned of these fatal risks. It created a spreadsheet that named Vioxx critics and noted plans for each, including "neutralize," "neutralized" or "discredit."[25,26] Merck also listed its staff assigned to each critic—an entire "task force" to one. On October 15, 2001, one Merck executive emailed another: "We may need to seek them out and destroy them where they live."[1,26]

Regulatory Capture.[27] Horton, the *Lancet* editor, noted the role of the FDA in enabling Merck's Vioxx scandal. The FDA saw "the pharmaceutical industry as its customer," not the US public.[20] When an associate FDA director, David Graham, MD, blew the whistle on Vioxx's deadly record, he was subjected to threats, abuse, and lies orchestrated by his FDA superiors.[28] The FDA Commissioner who approved Vioxx resigned and then went on to become senior counsel for Merck's PR firm.[28] Horton summarized, "with Vioxx, Merck and the FDA acted out of ruthless, short-sighted, and irresponsible self-interest."[20]

Good journalists get extremely angry when they've been had. The major media do not generally spew scientific nonsense. It would appear to take a budget on the order of the $410 million for Merck's prior Vioxx promotion[19] to get incisive, respected journalists such as Paul Waldman of the *Washington Post*[29] and Rachel Maddow of MSNBC[30] to be duped into echoing Merck's February PR claim that ivermectin is unsafe. Yet good journalists get extremely angry when they've been had. Any newsroom can fact check that ivermectin is FDA approved for human use, Nobel prize-honored, developed by Merck, now molnupiravir's competitor, and extremely safe. Such brazen overreach can easily backfire into focus on Merck's prior drug misinformation campaign. It takes rare PR brilliance for Merck, with its new drug release pending, to prompt a searing revisit of its past tactics in promoting its deadly drug, Vioxx.

On the science behind ivermectin and COVID-19, including clinical, animal, and molecular studies, see this recently published review.[18] Its lead author is a prominent clinical researcher at Yale. Two coauthors are in the line of the only two Nobel prize-honored treatment breakthroughs for infectious diseases since the one for streptomycin in 1952. Notably, coauthor Thomas Borody in 1990 published the first clinical trial for the cure for *H. pylori* (peptic ulcers).[31] That cure consisted of three repurposed inexpensive drugs: two

antibiotics and bismuth.[18] It was adopted immediately in Australia, in 1990, saving an estimated 18,000 lives.[32] A decade later, after the patents for the billion dollar palliative drugs, Tagamet and Zantac, expired, that cure became the standard of care for peptic ulcers in the rest of the world.[18]

Ivermectin safety. Ivermectin is well tolerated even at ten times the standard dose of 200 µg/kg,[33,34] and at high doses, in particular, for COVID-19 treatment.[35,36] Cancer patients who took ivermectin at five times that standard dose daily for up to 180 consecutive days had no serious adverse effects from it, in experimental protocols with harsh additional drugs.[37] Of 19 patients who took extreme overdoses up to 1,000-fold that standard dose of either ivermectin or the closely related abamectin, all using veterinary forms, only one 72-year-old male who took 440 times the standard dose died.[38]

As noted, ivermectin is FDA approved for human use,[4] and as is the case with all but one of current COVID- 19 treatment drugs, is used off-label for COVID treatment. More generally, 21% of all drug prescriptions in the US are off-label.[39,40]Since many news reports have hopelessly confounded the human and veterinary forms of ivermectin, this clarification is useful. Only human drug forms of ivermectin can be recommended for human use. Products for external animal use generally contain ingredients unfit for human consumption. The injectable liquids typically contain glycerol formal, which tastes nasty but is not toxic; these can be overdosed if not dispensed carefully. Most COVID-19 patients facing life-and-death decisions without access to the human drug have used the 1.87% horse paste in a squeeze tube for oral animal ingestion.

Do no harm. It should be noted that in the US, the standard treatment recommendation for the early stage of COVID is palliative, to take Tylenol.[41] (Note, incidentally, that in the US, acetaminophen (Tylenol) overdoses account for more than 100,000 calls to poison control centers, 56,000 emergency room visits and an estimated 458 deaths from acute liver failure each year.[42]) Therefore, per the Hippocratic oath of do no harm, given the safety of ivermectin and solid indications of clinical efficacy against COVID-19,[18] it is unconscionable to place obstacles to such clinical use. It is clear that the quest for profits has at times subverted public health, for example, with Merck's Vioxx, and with the ten-year delay in the deployment of the cure for peptic ulcers until the patents for two billion-dollar drugs expired. It behooves all parties to study the science and refrain from and rectify misleading, negative reports about ivermectin.

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Below are links to key documents, including internal files from Merck and publications from major scientific journals as relate to the above.

1. Merck press release of April 28, 2000: University of California, San Francisco, Industry Documents Library, qqqw0217. "In response to speculative news reports. Merck & Co., Inc. today confirmed the favorable cardiovascular safety profile of Vioxx."[1]
2. Seife, Oct 1, 2016. *Scientific American*. How the FDA Manipulates the Media. "The U.S. Food and Drug Administration has been arm-twisting journalists into

relinquishing their reportorial independence, our investigation reveals."[43]

3. Moynihan 2009. Court hears how drug giant Merck tried to "neutralize" and "discredit" doctors critical of Vioxx.[26]

4. Horton 2004, Lancet. Vioxx, the implosion of Merck, and aftershocks at the FDA.[20]
5. Merck's sales presentation, "Dodge Ball Vioxx."[21] University of California, San Francisco, Industry Documents Library, nghw0217, 2007.
6. Testimony of David J. Graham, MD, Associate Director for Science and Medicine, FDA, Office of Drug Safety.[22]
7. Curfman et al., 2000. Expression of concern: Bombardier et al., "Comparison of upper gastrointestinal toxicity of rofecoxib and naproxen in patients with rheumatoid arthritis.[24]
8. Gotzsche, 2017, with forewords by Richard Smith, past editor-in-chief, *The British Medical Journal*, and Drummond Rennie, deputy editor, *JAMA. Deadly Medicines and Organized Crime*.[28] Excerpts from Chapter 19.
9. List of doctors, Neutralize/discredit. University of California, San Francisco, Industry Documents Library, pmhw0217, 2007.[25]
10. Email from Douglas Alan Greene to Barry J. Gertz, October 14, 2001. University of California, San Francisco, Industry Documents Library, khpd0217.[44]
11. Topol, 2004, New England Journal of Medicine. Failing the Public Health — Rofecoxib, Merck, and the FDA.[45]
12. Eric Topol loses provost/chief academic officer titles at Cleveland Clinic and Lerner College, *Medscape*, December 11, 2005.[46] "Dr Eric Topol may no longer be the provost of the medical college he helped establish and has lost his title as chief academic officer at the Cleveland Clinic, a result of institutional 'reorganization,' the renowned cardiologist was told one week ago today. Topol was informed that the change was 'effective immediately,' despite the fact that the board of trustees will only today be voting on the restructuring plan. Conspicuously, Topol's ostensible loss of authority . . . came days after a federal jury heard Topol's videotaped deposition in the latest Vioxx lawsuit. In it, Topol accused Merck of 'scientific misconduct' and testified that Merck's former chair, Raymond Gilmartin, had in the past called fellow Harvard MBA alumnus Malachi Mixon, the chair of the clinic's board of trustees, to complain about Topol's vocal anti-Vioxx stance."
13. 2001 Profit Plan for Vioxx. University of California, San Francisco, Industry Documents Library, mxpd0217, September 1, 2000.[19]
14. Grant, *The Scientist*, April 29, 2009. Merck published fake medical journal.[47] It had the appearance of a peer reviewed journal, but was instead a marketing tool.
15. Letter from James Fries, MD, to Raymond Gilmartin, CEO of Merck, January 9, 2001, University of California, San Francisco, Industry Documents Library, ltgw0217.[48] As described in a letter from a Stanford University professor, James Fries, MD, to the CEO of Merck, Merck "employees have systematically attacked

those investigators or speakers who expressed what Merck staff felt were critical opinions." Fries noted individual cases of eight scientists with academic appointments jeopardized, speaking engagements canceled.

16. NPR, November 10, 2007. Timeline: The Rise and Fall of Vioxx.[49]

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Notes

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2. Yagisawa M, Foster PJ, Hanaki H, et al. Global Trends in Clinical Studies of Ivermectin in COVID-19. *The Japanese Journal of Antibiotics.* 2021;74(1).
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13. Lie But Fake News Ran with It Anyway. *MSNBC-TV.* September 5, 2021. https://msnbctv.news/2021/09/05/oklahoma-dr-jason-mcelyea-spreads-fear-porn-that-people-taking- ivermectin-are-flooding-local-hospitals-turns-out-to-be-complete-lie-but-fake-news-ran-with-it-anyway/.
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