The Cause of The Opioid Epidemic

The opioid epidemic arose in the United States due to the confluence of multiple factors. Some of these factors represent a failure of the medical service and the medical regulatory systems in the United States. Another major factor was the intense lobbying efforts of pharmaceutical companies and their dishonesty about the addictive effects of their opioid drugs. It is important to recognize that this was not due to science research conclusively indicating that these drugs were not addictive and safe to use for reducing pain. The science articles that were cited to support claims that opioids should be used more often for pain management were not definitive peer-reviewed studies. One article was a letter to the editor of the New England Journal of Medicine in 1980 that claimed that only 4 hospitalized patients of 11,882 who were prescribed opioids became addicted but no evidence was provided to support that claim. This article was not peer-reviewed and does not represent a definitive scientific research report. A study reported in 1986 that was widely cited to support the claim that opioids were not addictive when prescribed to relieve pain, only involved 38 people. A single study with such a small scope is definitely not what scientists consider to be sufficient evidence to justify a high level of confidence in the conclusions. Yet many in the medical service community cited this study and the NEJM Letter to the Editor and advocated for increased use of opioids for pain reduction as a humane and appropriate treatment methodology. This is an example of the failure of medical practice to base their methodology on sound scientific research.

This was exacerbated by the intense lobbying by pharmaceutical companies of the federal government, medical organizations, and physicians to increase use of opioids for widespread pain management for a large number of different health problems. Some of that lobbying involved the use of false or exaggerated data presented by the pharmaceutical companies. The U.S. Food and Drug Administration should have more thoroughly evaluated the safety of these pharmaceutical agents and at least advised about the lack of sufficient scientific evidence to justify such widespread use and claims of safety if not limiting their use. But the FDA was likely influenced by the pharmaceutical industry as well as concerned members of the medical community who advocated that use of opioids to reduce pain was a humane practice.

This case is a good example of the importance of basing decisions about the safety and efficacy of medical therapies, agents, and devices on sound scientific evidence that is published in reputable science journals after thorough peer review by qualified and respected experts in the relevant field. There should be multiple studies that have been conducted by independent research groups who can be verified to have no significant conflicts of interest. The studies should have been conducted on a sufficient number of subjects over a sufficient period of time to generate statistically valid results that indicate a marked benefit versus risk of adverse effects at the 95% confidence level with a high level of statistical power. The widespread use of opioids in the 1990s and 2000s was not based on such scientific evidence and instead was due to other factors as described in an

article in one of the most highly respected science journals, **Nature**, (Sept 11, 2019), Sarah DeWeerdt, https://www.nature.com/articles/d41586-019-02686-2 .

In contrast there is an abundance of such scientific research evidence regarding the effectiveness and safety of the vaccines used in the United States to provide protection from COVID-19. Thus, the opioid epidemic is not sound evidence that scientific research is an unreliable guide regarding the most effective and safest medical practices.