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Short Communication

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Should Big Pharma be Held Legally Liable for Misrepresentations made to the FDA?

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Recently Big Pharma has been increasingly in the news for escalating the costs of prescription insulin. On August 27, 2019, a U.S. Court in Oklahoma held Johnson and Johnson at least partially liable for the opioid epidemic, fining them $572 Million. Johnson and Johnson announced it will appeal that decision.

During these last several months, the FBI has raided the business offices of uBiome and last week, previously published papers supporting the thesis of uBiome were questioned with the expectation of retraction. During the last few months, the U.S. Federal Government has also disclosed investigations of pharmaceutical companies, thought to have been involved in potentially "price fixing" generic drugs, thereby dramatically increasing the costs of medications, which so many people rely upon.

While these investigations and the holding of Big Pharma legally accountable have taken many decades, it has only occurred after there was sufficient public outrage and a considerable economic cost to an already strained medical and insurance system.

These investigations may seem like we are making progress, but what about the less obvious and potentially more fatal misrepresentations being made by Big Pharma to the FDA about their drugs?

The FDA mission statement is "The Food and Drug Administration is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation".

How can we expect the FDA to complete its legal mandate to the people, as established by Congress, if Big Pharma is allowed to misrepresent their drugs to the FDA? Aren't the FDA, and the American people, in fact, dependent upon Big Pharma to honestly and transparently submit all the facts and information known about their drugs and to update the FDA whenever those facts and knowledge change? Shouldn't Big Pharma be held legally accountable for any misrepresentations they make to the FDA? And shouldn't that legal liability be even greater when they intentionally and knowingly misrepresent those facts?

So, it is for the companies, which make and sell the radioactive drugs sestamibi and tetrofosmin. At this time we will focus primarily on the company responsible for sestamibi, as this is the company where sufficient information has now been presented to the FDA-OCI for action.

Sestamibi is used for the diagnosis of heart disease and breast cancer along with other medical problems. Here we are looking specifically at the manufacture and sale of sestamibi for the diagnosis of heart disease and the resulting treatment making decisions.

The first author became involved with sestamibi as a Cardiology Fellow in 1990. He wrote the first SPECT paper on the competing drug teboroxime [1] and was involved in the original clinical investigations of these two drugs, referred to as imaging isotopes. The competition between the two drugs was intense and while teboroxime was marketed as rapidly acting, sestamibi was able to obtain control of the market, by telling physicians and nuclear medicine department personnel, that they didn't need to worry about the

timing of patient imaging. This clearly was an advantage and resulted in sestamibi taking over the market, resulting in a huge financial benefit for the company.

Physicians and nuclear imaging departments were told, as was the FDA, that while sestamibi was immediately taken up by the heart within minutes, everyone needed to wait 15 to 60-minutes before obtaining images, and that once these 15 to 60-minutes had passed, the image results would not change for the next 3-4 hours. Doctors and nuclear departments were told that sestamibi did not redistribute and because of this, it would take two doses of sestamibi for diagnostic heart studies to be performed. This was and is in fact, not the truth, and the pharmaceutical company, which makes and sells sestamibi knew this and has continued to perpetuate this misrepresentation to the FDA, despite published proof to the contrary [2-4].

These published papers [2-4] clearly demonstrate that sestamibi not only redistributes (is taken up and released by cardiac cells), depending upon the amount of coronary artery disease (blood flow) someone has, but that to find this heart disease, requires that imaging begins within the first few minutes, rather than waiting 15-60 minutes as the company has said. It also means that only one dose of sestamibi is needed to correctly diagnose heart disease – not two.

The misrepresentation by the companies, which have made and sold sestamibi has resulted in each patient over the last thirty years, receiving a second injection of radioactive drug. Using a conservative estimate [5] provided by others, there are approximately 10 million such cardiac studies performed each year in the United States alone.

Using 10 mCi as an estimate for the second-injected dose of sestamibi, this means there has been an additional 3 billion millicuries or an extra 3 million curies, which have been given to patients during this time. Extra radiation that was given during an era of isotope shortages throughout the world. Radiation which hospital and clinic personnel have also been exposed to, which was not medically needed. Placed in perspective, the Fukushima Daiichi 2011 event released 10 million curies.

These same conservative estimates would place the sale of these 300 million additional second injections around $12 billion to physicians and hospitals. This price is typically doubled or tripled when passed onto patients and insurance companies including CMS, meaning the additional cost to everyone, which the companies profited from, is more on the order of $24-36 billion.

Diagnostically by failing to image patients at five-minutes post-stress and instead waiting for 15 to 60-minutes to pass before obtaining the first heart image, there is a failure to find up to 40% of ischemic heart disease (redistribution "wash-in"), with a conservative [5] death rate of 100 thousand Americans each year, equaling a potential 3 million deaths due to misdiagnosis resulting from a failure to look for heart disease at the right time. A misdiagnosis directly resulting from the information provided by the companies to doctors, nuclear medicine departments and the FDA.

All of this information has now been made publicly available through peer-reviewed medical journals. The drug companies, which make and sell sestamibi, have attended medical conferences where this information has been presented for almost two decades. Despite multiple published papers, the current manufacturer has continued to deny Sestamibi Redistribution—a denial which has resulted in (1) a significant increase in sales and profits by this drug company; (2) increased radiation exposure of patients and clinical imaging and ancillary personnel who work with and around these patients; and (3) a failure to detect critical heart disease by the insistence of a timing sequence too late to discover many critically ill patients but convenient for the sales of Sestamibi.

If the manufactures of opioids, insulin, uBiome's stool-specimen testing, and the fixing of drug prices in the marketplace are sufficient to result in action being taken by the Courts and federal government, isn't the intentional and knowing misrepresentation of the redistribution of sestamibi to the FDA - resulting in tens of billions of dollars of profits, with millions of extra "curies" of radiation exposure of patients and hospital personnel and the misdiagnosis of millions of people with critical heart disease - sufficient to warrant an investigation by Congress and the FDA? And more importantly, shouldn't this investigation result in these companies being held criminal accountability in Federal Courts if found guilty of such intentional and knowing misrepresentation(s)?

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