



Richard M Fleming^{1*}, Matthew R Fleming¹ and Tapan K Chaudhuri²

¹FHHI-OmnificImaging-Camelot, El Segundo, CA, USA

²Eastern Virginia Medical School, Norfolk, VA, USA

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*Corresponding author: Richard M Fleming, PhD, MD, JD, FHHI-OmnificImaging-Camelot, El Segundo, Los Angeles, CA, USA,
E-mail: DrRichardMFleming@gmail.com

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Short Communication

Holding big Pharma Accountable

How can the FDA actually do its job, if the information reported to the FDA does not correctly report how these drugs work, including the pharmacodynamics and pharmacokinetics of these medications to the FDA? Isn't the FDA dependent upon Big Pharma to update the FDA and Physicians, Hospitals, Insurance Companies including CMS and patients, regarding all facts and information known about a drug? It is unconscionable to state, "Definitive human studies to demonstrate possible redistribution have not been reported." when there has been several diagnostic studies [1-38] published showing the redistribution of these drugs.

As a result, physicians have been incorrectly told that many of these drugs, in contrast to older drugs, require two doses to look for heart disease, instead of one. The misinformation has resulted in each patient over the last three decades receiving a second injection of radioactive isotope. Using a conservative estimate [39], there are approximately 10 million such studies performed each year in the United States alone. Using 10 mCi as an estimate for these second-injected doses, this means there has been an *additional* 3 billion millicuries or an extra 3 million curies being given to patients-radiation which hospital and clinic personnel have also been exposed to. 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 the patients and insurance companies, meaning the additional costs to the patients and insurance, including CMS, is more on the order of \$24-36 billion. Diagnostically, by failing to use only one dose of these drugs and image earlier when the redistribution can actually be seen and measured [1-38], there is a failure to find up to 40% of ischemic heart disease (redistribution "wash-in") and there is a conservative [36,39] death rate of 100 thousand Americans each year equaling a potential 3 million deaths due to missing this redistribution by failing to look for ischemic heart disease at the right time.

If the manufactures of opioids, insulin, uBiomes stool-specimen testing, and the fixing of drug prices in the marketplace are sufficient to result in action being taken by

Recently Big Pharma has been in the news for increased costs associated with insulin and the opioid epidemic and the consequential costs associated with human suffering and loss of life. While these investigations and the holding of Big Pharma accountable have taken many years (in fact many *decades*), it did not occur until there was sufficient public outrage and a considerable economic impact on an already strained medical and insurance system.

Over the last several weeks the FBI has raided offices at uBiome where questionable billing practices for testing have been brought to light. On social media the general public has been reassured by uBiome that insurance will cover the costs of these tests. Also during the last few weeks, the U.S. Federal Government has disclosed new investigations of pharmaceutical companies who have been involved in potential "price fixing" of generic drugs, dramatically controlling the costs of medications, which so many people depend upon.

While these investigations may seem like we are making progress, what about the less obvious and potentially more fatal misrepresentations being made by Big Pharma?

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."

the federal government, surely the failure to update the FDA on this clinically significant information is long past due.

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