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Healing an Ailing Pharmaceutical System: A Prescription for Reform

The public's health is too important to allow these three current situations to exist;

(1) The FDA's independent authority over the pharmaceutical industry is too important to continue allowing industry to be the major funder of the drug-regulating part of the agency with more than $800 million dollars in user fees in FY 2017, estimated by the FDA to exceed $1 billion by FY 2018. Big Pharma certainly gets its money's worth.

(2) The current Declaration of Helsinki, concerned with medical research involving human subjects, states that "the benefits, risks, burdens and effectiveness of a new intervention must be tested against those of the best proven intervention(s), except in the following circumstances," alluding to diseases without a proven intervention, in which the new intervention could be tested against a placebo or no intervention.

Because of its importance in improving the public's health, this principle must, in the future, be similarly applied to the large proportion of drugs currently being approved *without* having their benefits and harms tested against the "best proven intervention." Since this is not the current standard, the U.S., Canada, and other countries are approving too many "me too" drugs, without any evidence of unique clinical benefit but often causing unique harm to patients after, sometime before, they are approved.

(3) The rapidly increasing lack of access to over-priced medicines, not only in developing countries but in the US, Canada and other economically more advanced nations, results in preventable deaths and serious illness to hundreds of thousands of patients a year. Without utilizing a desperately needed, but existing, rarely used legal intervention, this economically-derived unhealthy hierarchy places profits from patented drugs above preventable human death and disease. In the U.S., when urgently needed patented drugs are unaffordable, any officer of the government, acting on behalf of patients whose medical care is publicly funded, can invoke 28 USC Sec. 1498, legal principal of which dates back to 1910, and thereby exercise the government's authority to use a patented invention without permission from the patent holder. The patent holder is entitled to reasonable compensation. This means that the government could immediately authorize and purchase easy-to-use generic versions of drugs with the patented delivery devices for the life-saving opioid overdose antidote, naloxone. Along with Baltimore City Health Commissioner Dr. Leana Wen, Public Citizen two weeks ago requested the Trump administration to exercise this authority to save thousands more lives in Baltimore alone.

The U.S. law, 28 U.S.C. § 1498, referred to above, states:

"Whenever an invention described in and covered by a patent of the United States is used or manufactured by or for the United States without license of the owner thereof or lawful right to use or manufacture the same, the owner's remedy shall be by action

> against the United States in the United States Court of Federal Claims for the recovery of his *reasonable and entire compensation* for such use and manufacture."

For the rare circumstances in which drug licenses are used by the government under section 1498, only two cases are known to us. In the 1960s and 1970s, the U.S. government Department of Defense (DOD) licensed for manufacture the antibiotic tetracycline and the tranquillizer meprobamate and used these drugs for the military without permission from the patent holders. Similarly, in the fall of 2001, the threat of a compulsory license was used to drive down the price of the patented drug Cipro by almost 50 percent.

Government employment of section 1498 for compulsory use of all patented items in order to substantially lower the cost to the public has resulted, as of 2003, in an estimated 300 cases litigated against the government, only one-third of which were won by the patent-owning plaintiffs. It is thought that in a much larger number of instances of using section 1498, the patent-holder did not sue because the government provided compensation deemed reasonable.

Frequently cited examples of successful use of section 1498 by the government include other DOD cases in which department purchased night-vision goggles and lead-free bullets that violate patents.

It is ironic that the DOD has generally used section 1498 much more than the U.S. Department of Health and Human Services (HHS)(formerly the Department of Health, Education, and Welfare [HEW]) and that there are no HEW/HHS examples of patented drugs being made at a lower cost by a generic manufacturer as a result of invoking this important part of our laws.

In the wake of an unprecedented number of lifesaving drugs that are unaffordable to most individuals or government agencies, it is unconscionable that this long-existing legal authority has not been used for the benefit of lives In this country that will otherwise be lost or severely impaired.