An open letter to the General Public

Currently medication is readily available and the standard of care for many ailments. There is so much trust put into our doctors and health care system. Many believe that if something is prescribed by a doctor and filled in a pharmacy; that it can be nothing but helpful. Most wouldn't even blink twice at the thought of our medication being contaminated. The biggest issue anyone ever thinks about is the price. However, maybe that should be put on the back burner if we realized what lengths some companies would go to, to save a buck.

The article "Americans Need Generic Drugs. But Can They Trust Them?" – NYT, 05-11-2019, shed light on this situation. In an attempt to mass produce generic drugs for Americans and to line the pockets of companies, the FDA has allowed companies to outsource their manufacturing of American drugs to other countries; namely, China and India. Now, in America, we have the FDA to help regulate our manufacturing processes. In these other countries, these standards are supposed to be kept. One former FDA investigator found that 9 out of 10 manufacturing sites abroad were not only allowing contaminated drugs to be sent to America but covering their tracks about it too. Supposedly to minimize diplomatic tensions, the FDA was allowing them sometimes months, to cover their tracks by giving them scheduled inspections and inspectors taking underhanded gifts of hotel upgrades and outings from said foreign manufacturers. Once these revelations were revealed, it seemed that the FDA struggled to address these safety concerns. There was a pilot program put in place to crack down on these companies, allowing for unscheduled mandatory action against those companies so they couldn't falsify test results that would lead to Americans getting substandard drugs. However, not long after, the FDA abandoned that program with not much of an explanation and downgraded from a mandatory action, to a voluntary action against those companies.

I would hope that any drug I would ingest, that is sold in America and backed by the FDA would constantly hold it self to the highest standards. Its insane to me that our own regulatory system seems to be lax when it comes to cheaper manufacturing in other countries. Why would we not keep that caliber of bio-equivalence that American drug manufactures are supposed to have? According

to author Katherine Eban's book 'Bottle of Lies', "the laws regarding generic drugs incentivized speed over quality." With speed, came higher profits and that's where these companies dropped the ball on caring about the quality of the generic drug being manufactured. It seemed, many knew what was going on and apparently would strategize on how to pass the inspections without changing their practices. The ethical compass on some of those people involved must be very skewed. In another article, it explains how an Indian whistle blower found out his company "often used lower-quality ingredients to save money, manipulated quality control data, or just made up numbers out of thin air" which obviously endangered American patients taking these drugs. After researching into this issue, it showed it took years for something to be done to verify that these overseas generic drug makers were not par with the brand name manufacturers and many patients were suffering from that. An NPR article on this issue explains how in Africa, they were shipped the lowest quality generic drugs where often there was NO trace of the active ingredient. Forget Americans getting substandard medications, how do we allow HUMANS in general to not receive the care they need when they think they are addressing an issue.

Someone needs to answer for this crisis. Although one company was indeed fined millions of dollars and was indicted, there is still many companies involved in this health care fraud. There shouldn't just be unannounced inspections IF someone reports an issue with a drug company. There should be a standard of practice that is followed routinely no matter what. There are transplant patients that are forced to take generic drugs that then start rejecting that transplant until they are regulated back on to the brand name drugs. This is a multifaceted problem. From brand name companies making medicine too expensive; to generic drug companies being greedy and cutting corners; to the FDA being overwhelmed and, in some instances, may be just not caring if politics and money are involved. It's a sad case and I hope that I will not become the brunt of this issue one day. You can lobby and write and yell but sadly I think these practices will still be apparent. I am glad I am educated on this issue now and I hope that more patients are, so they can make the choice to choose generic or to at least investigate alternatives that there may be. At this point I would assume educating the masses on this issue is the first step in getting something done. Maybe when realizing that these medications could be substandard, the public will use their buying power and NOT use

this drug or maybe put pressure on the doctors and companies that push them, and another option hopefully can then be made available. So, educate your selves people! Do the research! Use your strongest power; the power of the dollar. When other pockets are no longer being lined, that is when many of their eyes will open.

Sincerely,

Vanessa Marino, a concerned aspiring dental hygienist

References

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