

## What does FDA do for us?

Recently, we have gone through massive changes in the administrative institutions in our country. We heard loud voices about waste and fraud. Many offices of federal government activities were closed, staff eliminated or limited by a large percent. And, as usual in cases like this, there are people who applaud the process and those who cry about it. However, when you ask some of them about what those closed or limited budget institutions do for us as the general population, most people cannot really answer. So, today, I want to focus on the Federal Drug Administration that experienced some cuts and limitations in the recent budget project.

FDA has a food division and drug division. The food division focuses on processing information and inspecting what we buy in grocery stores, what is produced in meat processing factories, farms, and sometimes small food production shops. Their rules apply to what is organic, what is clean and non-toxic, what is contaminated. The inspections are random and there are definitely less than enough inspectors who can visit thousands of places where food is being processed and delivered to consumers. In other words, every person who eats and that is 100% of the population is affected by shortages or lack of attention from FDA to make sure that our food is safe. I wonder if you remember the shortages of baby formula several years ago. It occurred because one of the largest facilities producing the formula was closed due to possible contamination of it when the actual facility experienced damage to the physical building and production line. That facility was responsible for 40% of all US-based formula and, unfortunately, there were cases of babies being sick and possibly one of them died. The drug division of FDA is responsible for making sure that all pharmaceutical products go through a process of clinical trials according to the world-wide approved regulations for safety and effectiveness. In other words, if you get sick and you take a prescription medication, you need to be sure that the medication you take will not kill you, will not make you sicker, will not counteract with any other medication you may use, and that you actually will get better. And



again, FDA inspects all levels of clinical process of development of the new and old medicines: from the chemistry lab, where the new drugs are invented, to all phases of clinical trials and their sponsors and managers, to manufacturing process, and finally marketing and distribution. A year ago, we experienced a very interesting case of a new drug working in a very safe and effective way but manufactured with multiple production deviations by a producing vendor in North Carolina. The sponsor pharmaceutical company possibly did not review the operations of that facility. As a result, the approval of the new drug was delayed by FDA until the operations at manufacture were corrected for safety reasons. Again, the FDA experienced massive changes and eliminations in their drug division this year again.

If you look at this very short summary of the role of the government in FDA's actions, does it look like we should be eliminating their personnel? I do not think so. As a clinician, I want to trust my partners in developing new drugs, making sure the old ones are still safe, and that the food I eat is not making me sick. I am sure you feel the same way. There is nothing worth more than our health and life. Well, let us think twice before we agree to criticize our government spending, especially on budgets related to our safety.

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