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Analysis of Change Paper

Recommendation on Qnexa

This is an exciting time for the pharmaceutical industry in terms of its impact on weight loss in America. It has been thirteen years since the last approved weight loss drug and since that time, no other pharmaceutical company has come as close to Vivus has in the last couple weeks. On February 22, the FDA Federal Advisory Panel strongly recommended the approval of Qnexa, Vivus’ obesity drug (Pollack). The drug is said to be a combination of two existing drugs, phentermine, the surviving part of the fen-phen combination, and the epilepsy and migraine drug, topiramate. In clinical trials, the use of Qnexa led to an average weight loss of about ten percent of the individual’s total body weight after one year. Although in some cases, some of the weight was gained back in the second year, this looks like a glimpse of hope for the American citizens struggling to fight against their increasing waistbands and all the negative health consequences associated with it. Not only was the effect of this drug weight loss, it also seemed to have positive effects on blood pressure and blood sugar, some blood lipids, and consequently, the quality of life.

In the past, the FDA took extra precautions against approving diet pills hastily, one reason being because of the bad reputations a lot of them held throughout the past several decades for safety issues. For example the recall on many weight loss pharmaceutical alternatives, such as fenfluramine in combination with dexfenfluramine (Drugs), which caused serious heart and lung problems only served to displace trust in the public’s eyes of the FDA’s capabilities to protect them. However, with a sixty-six percent of obesity in America and another third that is overweight, a drug that targets obesity might not be shunted to the side so casually. In fact, this drug, if approved, is easily forecasted to be used by millions of people.

To put matters into perspective, after the announcement of the advisory panel to the FDA, Vivus’ stock nearly doubled. This could mean big news for the industry as well as the American citizens! This overpowering recommendation of the approval for the drug (20 to 2) was based on the notion that the potential benefits of the drug outweighed the seeming risks of taking it, which includes the typical side effects of most recalled or unapproved drugs: heart problems and birth defects.

Ultimately the decision is up to the FDA, also known as the U.S. Food and Drug Administration. They are the agency responsible for ensuring that all new drugs are safe and effective (Meyer). They decide whether the studies submitted by the drug companies are valid and have satisfactorily demonstrated that the drug in question is safe and effective under the set guidelines and conditions of use. After all that data has been analyzed, it is up to their judgment on the population as a whole that the benefits of the drug will outweigh the risks (Jenkins). It is only when, “the benefits of a drug are thought to outweigh the risks, and the labeling instructions allow for safe and effective use, [does the] FDA consider a drug safe for approval and marketing…” (Meyers).

As of now, the date for the final decision from the FDA is set for April 17th. Although it was not the FDA that made the recommendation, prospects look good for their approval. The advisory committee is said to have a powerful sway in the FDA’s decision in the past. Advisory committees to the FDA consist of a panel of outside experts on the applications to market new drugs and the FDA policies who intercede on the behalf of the FDA by giving their independent opinions and recommendations on the drug in question. They assess the safety, effectiveness, and application of the human drug (Advisory). “In 2010, the same advisory committee, with a somewhat different membership, recommended 10 to 6 against approval, and the F.D.A. then rejected the drug.” (Pollack). The FDA generally follows an advisory committee’s recommendation, although it is not bound to do so.

As the people await the FDA’s final decision, the company’s main priority is to minimize the potential risks: heart problems and birth defects. They are taking measurements and discussing ways with the FDA to increase the awareness and coming up with ways to ensure pregnant women do not take the medication.

In my opinion, I think the approval of this drug will alleviate a lot of the problems we have here in America. There is a pressing urgency to come up with any solution or even a quasi-solution to this massive epidemic. Although, I traditionally do not advocate the use of pharmaceuticals or believe them to be a “cure-all,” I feel I must find a compromise when I think of all the additional challenges and suffering that is brought upon by being overweight. The pains me because I know the detrimental effects are not only on the quality of millions of people’s lives but their loved ones as well, not to mention the economic hardships it is causing. And things only seem to be getting worse.

If the FDA does assess the quality of the drug on the parameters of safety and efficiency and in the end, deem it to be safe for consumption, I will be in line with their decision. I do not believe it should be used as the only form of therapy; however, I hope it will be used as a first step toward a healthier, more wholesome lifestyle. At the end of the day, it is up to the doctor and patient to assess the potential risks and how to reduce them. In the end, I hope the individual takes up the responsibility to make informed decisions about the drug, as well as their own life.

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