# Will Dynavax's New Hepatitis B Vaccine Ever Come to Market?

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The U.S. Food and Drug Administration (FDA) has once again rejected Dynavax Technologies Corp's new hepatitis B virus (HBV) vaccine due to concerns over certain adverse events that occurred during clinical trials for the preventive shot. This is the second time in three years that federal regulators have rejected the vaccine, which health care analysts say casts doubt on whether the drug will ever make it to market on its own, Reuters reports.

The FDA originally rejected the potential new vaccine, Heplisav-B, in February 2013, after several rare serious health events occurred in clinical trials. Dynavax went back to the drawing board immediately and this past January published a promising late-stage study that paved the way for the company to resubmit its application.

However, in September, after reviewing the application, the FDA decided to cancel an advisory committee meeting meant to discuss the vaccine and once again requested more information before making a decision. Then this month, federal authorities sent a complete response letter to the California-based biotech, saying the vaccine had been rejected.

According to Dynavax reps, the FDA's letter did not ask for any additional clinical trials on the vaccine or raise any more concerns about the rare serious events reported in earlier clinical trials. However, the letter did state that more questions must be answered about the safety of the shot before it is considered for approval.

As a result of the rejection, Dynavax shares plunged as much as 72 percent, hitting their lowest price in eight years. Dynavax reps said they will meet with the FDA as soon as possible to discuss their concerns over the shot and that the company expects to resubmit its application for the new hepatitis B vaccine to federal authorities within six months.

Dynavax reps also said they are searching for a potential pharmaceutical or financial partner to help fund the extra time and resources needed to bring the vaccine to market. In the meantime, the company is working on early-stage trials for a new cancer immunotherapy drug, as well as a new treatment for asthma.

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