

UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF CALIFORNIA

In re DYNAVAX SECURITIES  
LITIGATION

Case No. 4:16-cv-06690-YGR

**ORDER GRANTING MOTION TO DISMISS  
WITH LEAVE TO AMEND**

Dkt. No. 51

This Document Relates To:  
  
ALL ACTIONS.

Lead Plaintiff Kwok Pang, individually and on behalf of all other persons similarly situated, brings this consolidated class action against Defendants Dynavax Technologies Corporation, Eddie Gray, Michael S. Ostrach, and Robert Janssen for violation of federal securities laws. Plaintiff alleges violation of Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. § 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder (17 C.F.R. § 240.10b-5) based upon knowingly or recklessly disseminating false and misleading statements about the Dynavax’s development and efforts to gain FDA approval of HEPLISAV-B, an investigational adult hepatitis B vaccine. The consolidated amended complaint on behalf of the putative class was filed March 17, 2017. (Dkt. No. 47.)

Defendants have filed a Motion to Dismiss pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure on the grounds that plaintiff has not pleaded the elements of the 10(b) claim with sufficient particularity as required by the Private Securities Litigation Reform Act (PSLRA), 15 U.S.C. § 78u-4(b), and that the claim for control person liability under section 20(a) fails for the same reason.

United States District Court  
Northern District of California

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1 Having carefully considered the papers submitted, the operative pleading in this action, the  
2 matters judicially noticeable,<sup>1</sup> and the parties' oral arguments, and for the reasons set forth below,  
3 the Court **GRANTS** the Motion to Dismiss **WITH LEAVE TO AMEND**. Plaintiff allegations regarding  
4 false and misleading statements all turn on the assertion that adverse cardiac events occurring in the  
5 company's latest clinical trial should have been disclosed along with other "Adverse Events of  
6 Special Interest" or "AESIs" that were disclosed to investors. However, plaintiff now concedes  
7 that the adverse cardiac events did not fall into the AESI category for the study. Consequently,  
8 plaintiff's repeated incorporation of this same mistaken allegation undermines the viability of the  
9 entire complaint.

10 **I. SUMMARY OF FACTS**

11 Defendant Dynavax is a clinical-stage biopharmaceutical company with multiple product  
12 candidates in development for the prevention of infectious disease, the treatment of autoimmune  
13 and inflammatory diseases, and the treatment of cancer. (Consolidated Amended Complaint, Dkt.  
14 No. 47 ["CAC"] at ¶ 2.) Defendant Eddie Gray is the CEO and a director of the company;  
15 defendant Michael S. Ostrach is a Senior Vice President, Chief Financial Officer, and Chief  
16 Business Officer; and defendant Robert Janssen is a Vice President of Clinical Development and  
17 Chief Medical Officer. (*Id.* ¶ 3.) Dynavax's HEPLISAV-B vaccine was, during the relevant time  
18 period, Dynavax's "lead vaccine product candidate," and its only product candidate in a Phase III  
19 clinical trial development stage of the FDA approval process. (*Id.* ¶ 26.) In a 2015 SEC filing,  
20 Dynavax represented that it did "not have any products that generate revenue" and advised  
21 investors that "[i]f we are unable to generate significant revenues or achieve profitability, we may  
22 be required to reduce or discontinue our current and planned operations, enter into a transaction that  
23 constitutes a change in control of the company or raise additional capital on less than favorable  
24 terms." (*Id.* ¶ 26.)

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26 <sup>1</sup> Defendants' Request for Judicial Notice (Dkt. No. 51-1, "RJN"), unopposed by plaintiff, is  
27 **GRANTED**. The Court takes judicial notice of the press releases, call transcripts, Securities  
28 Exchange Commission filings, and Food and Drug Administration (FDA) documents referenced in  
the complaint. The Court does not, however, consider the statements in the Declaration of Jeff  
Lombard beyond those identifying and authenticating the documents. Plaintiff's objection to the  
use of a declaration to extend the arguments and avoid page limitations is well taken.

1 Dynavax submitted to the FDA its initial Biologics License Application (“BLA”) for  
2 HEPLISAV-B in April 2012. In February 2013, in response to the initial BLA, the FDA issued a  
3 Complete Response Letter (“CRL”) notifying Dynavax that the BLA could not be approved as  
4 presented because there was insufficient data to support the safety of HEPLISAV-B, and that a  
5 larger safety database was needed to assess the possibility of rare autoimmune side effects. (*Id.* ¶  
6 5.)

7 In late 2013 or early 2014, following negotiations with the FDA, Dynavax finalized the  
8 design of its Phase III clinical trial known as “HBV-23.” (*Id.* ¶ 6.)<sup>2</sup> In October 2015, Dynavax  
9 completed HBV-23, and compiled the data regarding safety and efficacy based on the larger patient  
10 database in that clinical trial. The results of HBV-23 revealed what defendants would later refer to  
11 as “a numerical imbalance in a small number of cardiac events” not observed in the prior clinical  
12 trials for HEPLISAV-B. (*Id.* ¶ 35.) Defendant Janssen was the senior executive charged with  
13 evaluating the clinical trial data from HBV-23 and overall strategy for communicating FDA  
14 approval prospects. According to a former Dynavax employee, the cardiac events data from HBV-  
15 23 posed a challenge for the company, leading it to retain an outside consultant to review the  
16 clinical trial data, in addition to performing its own review and analysis. (*Id.* ¶ 37.)

17 On January 7, 2016, Dynavax issued a press release and an SEC Form 8-K announcing that  
18 it had preliminary “top-line results” from HBV-23, and had plans to resubmit a revised BLA for  
19 approval of HEPLISAV-B at the end of the first quarter of 2016. (*Id.* ¶¶ 39, 40.) It stated, in part:

20 The coprimary endpoint of HBV23 was to evaluate the overall safety of  
21 HEPLISAV-B with respect to clinically significant adverse events . . . . All  
22 adverse events considered to represent potential autoimmune disorders (Adverse  
23 Events of Special Interest, or AESIs) were reviewed by an independent panel of  
24 experts from the Mayo Clinic. . . . Of the 33 AESIs in the study, 21 were  
25 adjudicated to be autoimmune events by the independent panel, with 11 reported  
26 in participants who received HEPLISAV-B and 10 in participants who received  
27 Engerix-B.

28 <sup>2</sup> In an October 2013 investor call, Dynavax represented that it had finalized a study design to meet the objective of “providing confidence to the [FDA] regarding HEPLISAV’s safety profile. . . . and evaluate the overall safety of HEPLISAV[-B] with respect to clinically significant adverse events.” (RJN Exh. 2 at 4.)

1 (*Id.* ¶ 40.)<sup>3</sup> Defendant Janssen was quoted in the press release as saying:

2           These topline results are consistent with our expectations. With regard to the  
3           principal safety focus, Adverse Events of Special Interest, the results reflect a  
4           distribution consistent with randomization. To see such statistically significant  
5           differences in immunogenicity so consistently and across all groups and patient  
6           subsets, confirms the potential of HEPLISAV-B for people in need of protection.

7 (*Id.* ¶ 42.) There was no discussion in the press release regarding cardiac events.<sup>4</sup> Dynavax  
8 indicated in other announcements that complete results of HBV-23 would be available in February  
9 2016. (*Id.* ¶ 44.)

10           On March 8, 2016, Dynavax filed a Form 10-K with the SEC stating that “[t]he primary  
11           objectives of HBV-23 were: (1) to evaluate the overall safety of HEPLISAV-B with respect to  
12           clinically significant adverse events; and (2) to demonstrate the noninferiority of the peak  
13           seroprotection rate induced by HEPLISAV-B compared to Engerix-B in subjects with type 2  
14           diabetes mellitus . . . . Based on preliminary top-line results from HBV-23 released in January  
15           2016, both co-primary endpoints were met.” (*Id.* ¶ 48.) That same date, Dynavax issued another

16           <sup>3</sup> The January 7 Press Release, as provided in full in the RJN, further stated that:  
17           Both co-primary endpoints [of the HBV-23 clinical trial] were met. The rates of  
18           clinically significant adverse events were consistent with randomization and  
19           similar to rates in prior trials and HEPLISAV-B provided a statistically significant  
20           higher rate of seroprotection than [the comparison/competitor vaccine] EngerixB  
21           in diabetic participants and in all participants as a group.  
22           (RJN Exh. 5 at 1.)

23           <sup>4</sup> In their RJN, defendants provided a transcript of the January 7, 2016 investor call. (RJN  
24           Exh. 6.) In that call, defendant Gray stated that he was “very pleased to report today that this study  
25           met all of our expectations . . . . HEPLISAV-B and HBV-23 met our expectations with respect to  
26           safety and immunogenicity. We are on track to submit our BLA at the end of this quarter.” (RJN  
27           Exh. 6 at 3.) Defendant Janssen stated: “regarding safety, in HBV-23, the overall safety profile of  
28           HEPLISAV-B was similar to that of Engerix-B. Adverse events were generally balanced between  
          the vaccine groups and AESIs as predetermined by FDA were also balanced. Additionally, as with  
          every study, especially of this size, we’ve noted some numerical imbalances, none of which are  
          statistically significant.” (*Id.* at 5.) Contrary to defendants’ statement that “no one on the  
          conference call asked any questions regarding numerical imbalances” (Motion at 7:3), analysts did  
          pose follow-up questions regarding what defendants meant by imbalances, to which Gray  
          responded that “the key message here is that all of the numbers appear to be balanced. The only  
          obvious imbalance in numbers appears to be Bell’s palsy, and that’s balanced out across the total  
          database.” (RJN Exh. 6 at 7-8.)

1 press release and Form 8-K stating that the “third pivotal study had met both co-primary  
2 endpoints,” that it planned to resubmit HEPLISAV-B to the FDA for approval by the end of the  
3 month, and that “[b]ased on our expectation of a six-month review, if our application is approved  
4 we expect to launch this product in the fourth quarter of this year.” (*Id.* ¶ 46.)

5 On March 30, 2016, Dynavax issued a press release and filed a Form 8-K stating that the  
6 FDA had accepted for review its new BLA based upon the results of HBV-23. (*Id.* ¶ 50.) On April  
7 27, 2016, Dynavax issued a press release and filed a Form 8-K announcing that the FDA has issued  
8 a notification that the Prescription Drug User Fee Act (PDUFA) action date for HEPLISAV-B was  
9 extended by three months to December 15, 2016. (*Id.* ¶ 53.) In that press release, Dynavax stated  
10 that:

11 HEPLISAV-B has a safety profile similar to that of existing vaccines. The  
12 investigational vaccine’s safety profile is based on clinical trials that generated  
13 safety data from more than 10,000 HEPLISAV-B compared with more than 4000  
14 ENGERIX-B participants.

14 (*Id.* ¶ 54.)

15 On June 11, 2016, Dynavax issued a press release and Form 8-K announcing that it had  
16 presented new efficacy data on HEPLISAV-B at the 76th Annual Scientific Sessions of the  
17 American Diabetes Association in April 2016, and that:

18 In the total trial population, the rates of adverse events, serious adverse events and  
19 deaths were similar between the HEPLISAV-B and Engerix-B groups. All  
20 adverse events considered to represent potential immune-mediated disorders were  
21 reviewed by an independent, blinded Safety Evaluation and Adjudication  
22 Committee, which classified these events as not related to vaccination.

22 (*Id.* ¶ 57.)

23 On August 5, 2016, Dynavax issued two press releases and a Form 8-K announcing its  
24 financial results for the second quarter, as well as the FDA’s scheduling of a November 16, 2016  
25 Vaccines and Related Biological Products Advisory Committee (VRBPAC) meeting as the next  
26 step in its review of HEPLISAV-B. (*Id.* ¶ 61.) One of the press releases also stated that, in the  
27 HBV-23 trial, HEPLISAV-B “demonstrated a similar safety profile to the existing vaccine.” (*Id.* ¶  
28 62.)

1 On September 2, 2016, the FDA issued a notice cancelling the VRBPAC meeting. (*Id.* ¶  
2 65.) On this news, the stock price per share of Dynavax declined from \$15.94 on September 1,  
3 2016, to close at \$10.91 on September 2, 2016. (*Id.* ¶ 77.) On September 4 and 6, respectively,  
4 Dynavax issued a press release and filed a Form 8-K announcing that the VRBPAC meeting had  
5 been cancelled by the FDA, and stating that remaining questions would be addressed via  
6 information requests from the FDA over the coming weeks. (*Id.* ¶ 65.)<sup>5</sup>

7 On October 3, 2016, Dynavax filed a Form 8-K stating that it had received “anticipated  
8 requests for information from the [FDA] review team in connection with the pending [BLA] for  
9 HEPLISAV-B . . . . [and t]he review team’s questions are in line with the company’s expectations.”  
10 (*Id.* ¶ 67.) It continued, stating that Dynavax was “working with the FDA to resolve remaining  
11 questions regarding the BLA in order to enable the FDA to complete its review by the scheduled  
12 Prescription Drug User Fee Act (‘PDUFA’) action date of December 15, 2016, which remains  
13 unchanged.” (*Id.*)

14 On October 26, 2016, Dynavax issued a press release and Form 8-K announcing “sub-group  
15 results” from the HBV-23 clinical trial, which stated:

16 In the total Phase 3 trial population, the rates of adverse events, serious adverse  
17 events and deaths were similar between the HEPLISAV-B and Engerix-B groups.  
18 The most common local adverse event was injection site pain and the most  
19 common systemic adverse events were fatigue, headache and malaise. All  
20 adverse events considered to represent potential immune-mediated disorders were  
21 reviewed by an independent, blinded Safety Evaluation and Adjudication  
22 Committee (SEAC). The SEAC classified all potential immune-mediated  
23 disorders as unrelated to vaccination.

24 (*Id.* ¶ 70.)

25 On November 7, 2016, Dynavax issued a press release and a Form 8-K announcing  
26 financial results for the third quarter and stating that:

27 In late August, the U.S. Food and Drug Administration (FDA) cancelled its  
28 previously scheduled Vaccines and Related Biological Products Advisory  
Committee (VRBPAC) meeting to review the Biologics License Application

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<sup>5</sup> The September 4 Press Release stated that, despite the cancellation of the VRBPAC meeting and the further questions from the FDA, the PDUFA date of December 15, 2016 “remains unchanged.” (RJN Exh 14.)

1 (BLA) for HEPLISAV-B™ [Hepatitis B Vaccine, Recombinant (Adjuvanted)].  
2 The FDA indicated that remaining questions on the BLA will be addressed  
3 between Dynavax and the FDA review team. The Company has since provided  
4 responses to information requests by the FDA related to remaining questions . . . .  
5 In the total Phase 3 trial population, the rates of adverse events, serious adverse  
6 events and deaths were similar between the HEPLISAV-B and Engerix-B  
7 groups. . . . Preparations for launch of HEPLISAV-B are continuing . . . .

8 (*Id.* ¶ 75.)

9 On November 14, 2016, the FDA issued a second complete response letter (CRL) to  
10 Dynavax, this time regarding the March 2015 BLA submission. Dynavax’s press release regarding  
11 the second CRL indicated that the FDA sought:

12 information regarding several topics, including clarification regarding specific  
13 adverse events of special interest (AESIs), a numerical imbalance in a small  
14 number of cardiac events in a single study (HBV-23), new analyses of the  
15 integrated safety data base across different time periods, and post-marketing  
16 commitments. In the CRL, the FDA acknowledged that it has not yet completed  
17 its review of *responses received from Dynavax in early October*, including those  
18 pertaining to AESIs and *the numerical imbalance in cardiac events*. The  
19 responses included an extensive analysis that included independent expert  
20 consultation supporting our view that the imbalance was driven by an  
21 unexpectedly low number of events in the comparator arm. It would appear the  
22 Agency could not fully assess the responses in the current review period. In the  
23 CRL, there is no request for additional clinical trials and there are no apparent  
24 concerns with rare serious autoimmune events.

25 (*Id.* ¶ 78, emphasis supplied.) The press release that day quoted defendant Gray as stating, “[t]he  
26 CRL is consistent with our opinion that HEPLISAV-B is approvable and we are seeking to meet  
27 with the FDA as soon as possible.” (*Id.* ¶ 79.) On an earnings conference call that same day, when  
28 queried by an analyst about details of the cardiac events, Gray stated “we are not going to go into  
any more detail than we have given . . . . We have [an] imbalance in a single term which the  
agency referred to as cardiac events and so we have utilized their language in our communication  
of it.” (*Id.* ¶ 82.) When pressed on “not having more transparency” in the call, Gray responded by  
stating that it “would not be normal practice to talk about numeric imbalances unless it reaches  
some degree of statistical significance or [if] perhaps you feel there is a good reason to believe that  
there might be a relationship. This situation meets neither of those criteria. And I think I will ask

1 Rob [Janssen], as our Chief Medical Officer, who has [lived] with this data for the last year to give  
2 you his assurance of our confidence in this position.” (*Id.* ¶ 84.) Janssen added,

3           So I led the team that did all the analyses and wrote the BLA and responses to the  
4 information requests and actually did many of the analyses myself, wrote the  
5 response to the information requests. We did seek external consultation from  
6 very highly regarded external experts. And all of this expanded work I think just  
7 continued to convince me that there is no relationship between the cardiac events  
8 and the vaccine.”

9 (*Id.* ¶ 85.)

10           The next business day, the price of Dynavax common stock dropped 64% -- from \$11.60  
11 per share on Friday, November 11, 2016, to close at \$4.10 per share on Monday, November 14,  
12 2016. Thereafter, in March 2017, Dynavax announced a restructuring of the company, suspension  
13 of manufacturing, commercial, and other preparations related to HEPLISAV-B, and reduced its  
14 workforce by 40%. (*Id.* ¶ 90.)

## 15 **II. APPLICABLE STANDARD**

16           A motion to dismiss under Rule 12(b)(6) tests the legal sufficiency of the claims alleged in  
17 the complaint. *Ileto v. Glock, Inc.*, 349 F.3d 1191, 1199-1200 (9th Cir. 2003). “Dismissal can be  
18 based on the lack of a cognizable legal theory or the absence of sufficient facts alleged under a  
19 cognizable legal theory.” *Balistreri v. Pacifica Police Dep’t*, 901 F.2d 696, 699 (9th Cir. 1990).  
20 All allegations of material fact are taken as true and construed in the light most favorable to the  
21 plaintiff. *Johnson v. Lucent Techs., Inc.*, 653 F.3d 1000, 1010 (9th Cir. 2011). To survive a motion  
22 to dismiss, “a complaint must contain sufficient factual matter, accepted as true, to ‘state a claim to  
23 relief that is plausible on its face.’” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl.*  
24 *Corp. v. Twombly*, 550 U.S. 544, 557 (2007)).

25           Section 10(b) of the Securities Exchange Act of 1934 makes it unlawful for any person to:

26           use or employ, in connection with the purchase or sale of any security registered  
27 on a national securities exchange . . . any manipulative or deceptive device or  
28 contrivance in contravention of such rules and regulations as the Commission  
may prescribe as necessary or appropriate in the public interest or for the  
protection of investors.

1 15 U.S.C. § 78j(b). One of those rules promulgated under the Act is Securities and Exchange  
2 Commission Rule 10b–5, which makes it unlawful to, among other things, “make any untrue  
3 statement of a material fact or to omit to state a material fact necessary in order to make the  
4 statements made, in the light of the circumstances under which they were made, not misleading.”  
5 17 C.F.R. § 240.10b–5(b).

6 To state a claim under Section 10b, a plaintiff must “show that the defendant made a  
7 statement that was ‘misleading as to a material fact.’” *Matrixx Initiatives, Inc. v. Siracusano*, 563  
8 U.S. 27, 38 (2011) (quoting *Basic Inc. v. Levinson*, 485 U.S. 224, 238 (1988) (emphasis in  
9 original)). Thus, a plaintiff must allege: “(1) a material misrepresentation or omission by the  
10 defendant; (2) scienter; (3) a connection between the misrepresentation or omission and the  
11 purchase or sale of a security; (4) reliance upon the misrepresentation or omission; (5) economic  
12 loss; and (6) loss causation.” *Id.* at 37-38 (quoting *Stoneridge Investment Partners, LLC v.*  
13 *Scientific–Atlanta, Inc.*, 552 U.S. 148, 157 (2008)). Under the PSLRA, “the complaint shall specify  
14 each statement alleged to have been misleading, the reason or reasons why the statement is  
15 misleading, and, if an allegation regarding the statement or omission is made on information and  
16 belief, the complaint shall state with particularity all facts on which that belief is formed.” 15  
17 U.S.C. § 78u-4(b). The PSLRA also requires particularity in pleading the required state of mind:  
18 “in any private action arising under this chapter in which the plaintiff may recover money damages  
19 only on proof that the defendant acted with a particular state of mind, the complaint shall, with  
20 respect to each act or omission alleged to violate this chapter, state with particularity facts giving  
21 rise to a strong inference that the defendant acted with the required state of mind.” 15 U.S.C. § 78u-  
22 4(b)(2). Thus the PSLRA requires a plaintiff alleging securities fraud to “plead with particularity  
23 both falsity and scienter.” *Zucco Partners, LLC v. Digimarc Corp.*, 552 F.3d 981, 990 (9th Cir.  
24 2009) (internal quotation omitted); *see also Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S.  
25 308, 313 (2007); 15 U.S.C. § 78u-4(b)(1)- (2).

### 26 **III. DISCUSSION**

27 Defendants argue that the section 10(b) claim must be dismissed because, among other  
28 things, plaintiff has failed to allege a materially false statement sufficient to state a claim under

1 Section 10(b). The heightened pleading requirements of the PSLRA require that a plaintiff specify  
2 each misleading statement, why the statement is misleading, and the facts giving rise to inferences  
3 or statements made on information and belief. 15 U.S.C. § 78u-4; *see also Tellabs*, 551 U.S. at  
4 321; *In re Rigel Pharm., Inc. Sec. Litig.*, 697 F.3d 869, 877 (9th Cir. 2012) (quoting 15 U.S.C. §  
5 78u-4(b)(1)).

6 Section 10(b) and Rule 10b-5(b) “do not create an affirmative duty to disclose any and all  
7 material information,” but instead a duty to include all facts necessary to render a statement  
8 accurate and not misleading, once it elects to disclose that material information. *Matrixx*, 562 U.S.  
9 at 44-45, 47 (“Even with respect to information that a reasonable investor might consider material,  
10 companies can control what they have to disclose under these provisions by controlling what they  
11 say to the market.”); 17 C.F.R. § 240.10b-5(b). A fact is only material if “a reasonable investor  
12 would have viewed the undisclosed information as having *significantly* altered the total mix of  
13 information made available.” *Matrixx*, 563 U.S. at 44. “Silence, absent a duty to disclose, is not  
14 misleading” as there is no “affirmative duty to disclose any and all material information.” *Id.* at 45.  
15 Rather, material information only needs to be disclosed if its omission would “affirmatively create  
16 an impression of a state of affairs that differs in a material way from the one that actually exists.”  
17 *Brody v. Transitional Hosps. Corp.*, 280 F.3d 997, 1006 (9th Cir. 2002).

18 Here, the allegations of the CAC are that defendants made materially false and misleading  
19 statements by offering information about certain positive aspects of the HEPLISAV-B safety  
20 profile, including the rates of occurrence of certain AESIs during the HBV-23 clinical trial, but  
21 failed “to disclose the occurrence of *other AESIs* of which they were aware or that they recklessly  
22 disregarded, including ‘a numerical imbalance in a small number of cardiac events.’” (CAC ¶ 41,  
23 emphasis supplied.) Plaintiff alleges:

24 Given that HBV-23 was designed in a purported effort to address the FDA’s  
25 safety concerns about HEPLISAV-B, that investors were concerned specifically  
26 about the HEPLISAV-B’s safety profile, that Defendants observed cardiac events  
27 in HBV-23 but not in either of the Company’s prior Phase III studies for  
28 HEPLISAV-B, that *AESIs* were an area of known concern to the FDA, and that  
the FDA considered cardiac events to be among the more serious of safety  
concerns, Defendants’ statements about the results of HBV-23 deprived investors

1 of information critical to assessing HEPLISAV-B's prospects and timeline for  
2 obtaining FDA approval.

3 (*Id.*, emphasis supplied.) Similarly, in paragraph 43 of the complaint, plaintiff alleges:

4 The foregoing statements in the January 7 Press Release were false and  
5 misleading. Defendants' discussion of the "topline results" from HBV-23 in the  
6 January 7 Press Release mentioned certain aspects of the safety profile of  
7 HEPLISAV-B and the occurrence of certain AESIs, but *failed to disclose the*  
8 *occurrence of other cardiac AESIs, including "a numerical imbalance in a small*  
9 *number of cardiac events."* The occurrence of such cardiac events in HBV-  
10 23. . . . constituted red flags which, given the FDA's known concern *regarding*  
11 *adverse events of special interest* and that cardiac events were considered to be  
12 among the more serious of safety concerns for the FDA, signaled that such issues  
13 certainly would not be resolved during the 2016 fiscal year. Defendants'  
14 statement that the "topline results" were "consistent with [their] expectations" was  
15 false when made, and Defendants' omission of any mention of the *occurrence of*  
16 *cardiac AESIs* rendered misleading their discussion of adverse events of special  
17 interest that occurred in HBV-23.

18 (*Id.* ¶ 43, emphasis supplied.) Thus, the focus of plaintiff's allegations is on "cardiac AESIs" and  
19 whether the cardiac events observed in the HBV-23 clinical trial should have been disclosed along  
20 with reporting the occurrence of other "AESIs" in order for the statements to avoid being  
21 misleading. For each of the statements identified as the basis for their claim, plaintiffs refer back to  
22 paragraphs 41 and 43 for the reasons why those statements are false or misleading. (*See id.* ¶¶ 47,  
23 49, 66, 68, 71, 76.)

24 Defendants argue that this reliance on failure to disclose "cardiac AESIs" is the fatal flaw of  
25 the complaint. The clinical trial specifically analyzed "[a] pre-specified list of autoimmune and  
26 inflammatory disorders" referred to as Adverse Events of Special Interests, or "AESIs," and cardiac  
27 events or diseases were not among the AESIs included in the definitions for the study. (*See* RJN  
28 Exh. 25 at 19, 80.) The alleged press releases and filings identified in the complaint referred to the  
AESIs as defined for the purposes of the study. As plaintiff acknowledges, the FDA uses the term  
AESIs to refer to events of scientific and medical concern "specific to the sponsor's product or  
program." (CAC ¶ 7 n.3.) In the HBV-23 clinical trial, Dynavax worked with FDA to identify a list  
of autoimmune and inflammatory disorders that constituted the AESIs for the study. (RJN Exh. 25  
at 19.)

United States District Court  
Northern District of California

1 At the hearing on the motion, plaintiff acknowledged the “fatal flaw” argued by defendants,  
2 conceding that the complaint as drafted misconstrued the term AESIs. Plaintiff now contends that  
3 failure to disclose the cardiac events—in the context of defendants’ other statements about the  
4 safety of the HEPLISAV-B vaccine, the clinical trial results, and FDA approval timeline—made  
5 the statements false and misleading, even if cardiac events are not AESIs.

6 The Court has reviewed the CAC carefully. Plaintiff’s reliance on paragraphs 41 and 43 to  
7 explain why each identified statement is false or misleading, and the acknowledged error regarding  
8 cardiac events being AESIs, renders the allegations inactionable. Whatever merit plaintiff’s  
9 arguments in opposition may have, they are not the allegations made in the complaint.

10 **IV. CONCLUSION**

11 Accordingly, the Motion to Dismiss is **GRANTED WITH LEAVE TO AMEND**. In amending,  
12 plaintiff is directed to specify each statement upon which the claim is based, whether such  
13 statement is alleged to be an affirmative misrepresentation or an omission, and why each statement  
14 was materially false or misleading.<sup>6</sup>

15 Plaintiff shall file an amended complaint no later than **October 3, 2017**. Defendants shall  
16 file their response within 21 days of the filing of the amended complaint.

17 This terminates Docket No. 51.

18 **IT IS SO ORDERED.**

19 Date: September 12, 2017

  
YVONNE GONZALEZ ROGERS  
UNITED STATES DISTRICT COURT JUDGE

22 <sup>6</sup> Because the Court finds that plaintiff has failed to allege actionable statements or  
23 omissions under section 10(b), the Court need not address whether plaintiff adequately alleged  
24 scienter, inapplicability of the PSLRA’s safe harbor provisions, or section 20(a). Nevertheless, the  
25 Court notes that plaintiff must allege facts to support an inference of scienter that is “cogent and  
26 compelling, thus strong in light of other explanations,” evaluating the circumstances holistically.  
27 *South Ferry LP, No. 2 v. Killinger*, 542 F.3d 776, 784 (9th Cir. 2008) (noting abrogation of holding  
28 in *In re Vantive Securities Litigation*, 283 F.3d 1079 (9th Cir. 2002)).

On a separate note, defendants are cautioned that they should disclose fully to the Court the  
history of a case cited for its precedential value. To do otherwise is potentially sanctionable  
conduct. (*See* Motion at 12, 16 and Reply at 7 [citing *In re Vantive Corp. Sec.*, 110 F.Supp. 2d  
1209, 1216 (N.D.Cal. 2000) and noting that it was affirmed, but not indicating that the Ninth  
Circuit decision was subsequently abrogated by the Supreme Court in *Tellabs*]).