UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

CHARLES SEIFE, Plaintiff, *v.* FOOD AND DRUG ADMINISTRATION and DEPARTMENT OF HEALTH AND HUMAN SERVICES, Defendants, and SAREPTA THERAPEUTICS, Intervenor-Defendant.	Case No. 1:17-cv-3960 August 30, 2018

REPLY DECLARATION OF CHARLES SEIFE

I, CHARLES SEIFE, declare under penalty of perjury as follows:

1. I submit this supplemental declaration on personal knowledge in further support of my pending cross-motion for summary judgment.

Defendants Concede Substantial Error in Redacting the Representative Pages Submitted for This Court's Review

2. My FOIA request at issue sought the Clinical Study Reports and Appendices for defendant Sarepta's Study 201/202, which total more than 30,000 pages. After my cross-motion for summary judgment was filed, on July 30, 2018, defendant FDA provided me with alternate versions of twenty-seven pages of the representative material submitted for this Court's review, stating that information was indeed improperly withheld from these pages. Those twenty-seven pages were filed with the Court in connection with the pending cross-motions for summary judgment, either by Sarepta as part

of its Exhibit B, Ittig Decl., Ex. B, ECF. No. 73-2, or by me (in Kenney Decl., Ex. C, ECF No. 90-3).

3. Sarepta's Exhibit B includes forty-nine pages chosen by Sarepta as representative examples of the types of withheld information. *See* Ittig Decl. ¶ 4; Sarepta Corrected Mot. for SJ at 15, ECF No. 78. My summary judgment motion challenged the redactions on thirty-one of the pages included in Exhibit B.

4. Kenney Exhibit C separately presents thirty-two sample pages containing redactions I am challenging. Three of these pages are alternative versions of the same page, and one page is duplicated, so Exhibit C contains twenty-nine unique pages containing challenged redactions. Ten of these pages are also included in Sarepta's Exhibit B so that Kenney Exhibit C contains nineteen unique pages with challenged redactions that were not part of Sarepta's representative sample.

5. Stated differently, between Sarepta Exhibit B and Kenney Exhibit C, I challenged the redactions made on fifty representative pages from the FDA production. Through the submission of twenty-seven pages with revised redactions in response to my summary judgment motion, defendants acknowledge that more than half—fully 54%—of the fifty non-duplicated representative sample pages whose redactions I challenged on this motion contained inappropriate redactions. Six of the fifty pages with challenged redactions are now totally unredacted.

6. According to the Sarepta, Sherwood Decl. ¶ 59, ECF No. 104, the same techniques were used to identify and redact confidential commercial information from the entire 30,000 pages in the Clinical Study Reports and Appendices. As established in plaintiff's color-coded index, Kenney Decl., Ex. A, ECF No. 90-1, thousands of pages have been redacted in full or in part. It seems inconceivable that the only inappropriate redactions are contained on the representative twenty-seven pages corrected by defendants on July 30, 2018.

Defendants' Opposition to My Cross-Motion Misportrays Facts

7. Some of the redacted figures that I seek are so-called "spaghetti plots" depicting test results over time in a graphical form. In a spaghetti plot, several patients' results on a specific test are represented on a single timeline. My motion demonstrated that spaghetti plots were improperly withheld because the information they disclose is publicly available or easily discernable. Seife Decl. ¶¶ 61, 66-70.

8. In response, Sherwood's declaration justifies the redaction of spaghetti plots containing results of the 6-minute walk test and pulmonary function tests on the grounds that they depict "different data" from the publicly available spaghetti plots. Sherwood Decl. ¶¶ 7, 14, 17, 55. However, all of the data in the CSRs for Study 201/202 was obtained from the same twelve trial participants by tests administered at specified time points. Although the withheld spaghetti plots may look different or might present the same data in slightly different ways from the publicly available spaghetti plots, they cannot be based on different underlying data.[1] Disclosing the withheld charts would reveal no new test results.

9. Defendants are also incorrect in suggesting that Sarepta's schedule, or timing, of the functional assessment tests is not public.[2] Sherwood Decl. ¶¶ 8, 23 (discussing FDACDER_SAR_00060 -

[1] The first three time points that Sarepta conducted functional assessments were baseline, week 12, and week 24. At these points Sarepta collected data from participants on two consecutive dates, resulting in two values for those time points. Sarepta reported this information to the FDA using the best test results where two values were available for the same time point. *See* Christopher D. Breder, *Clinical Review* (May 9, 2016), *in* Center for Drug Evaluation and Research Medical Review(s) 227, 261 (2016), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/206488Orig1s000MedR.pdf (last accessed Aug. 25, 2018). Although the FDA reviewer used a slightly different method, averaging the two results if two were available for baseline, week 12, and week 24, this would not affect the publicly available results calculated by the FDA after week 24. Regardless of which spaghetti plot contained which permutation or combination of which of these two values, the fact that Sarepta and FDA already went public with these values indicates that the data is not confidential commercial information.

[2] The functional assessments include: the 6-Minute Walk Test (6MWT); Timed 4-Step Test; Maximum Voluntary Isometric Contraction Test (MVICT); North Star Ambulatory Assessment (NSAA) total score, and NSAA components including the Timed 10-Meter Run and Rise Time; the 9-Hole Peg Test; the Pulmonary

FDACDER_SAR_00061); 39 (discussing FDACDER_SAR_00021644); Estepan Decl. ¶ 23. The schedule was not only released by Sarepta in slides presented at the April 26, 2018 FDA Advisory Committee meeting but was also published by Sarepta in a scientific article and released by the FDA.[3]

10. Nor are defendants correct in contending that individual study results by time point are confidential. Sherwood Decl. ¶¶ 6-7, 14, 15, 48 (discussing 6-Minute Walk Test (6MWT)), 6, 8, 15, 16, 26 (discussing North Star Ambulatory Assessment (NSAA) total score and NSAA components including the Timed 10-Meter Run and Rise Time), 27, 51(discussing the Maximum Voluntary Isometric Contraction Test (MVICT) and Hand-Held Dynamometry)). Values for individual patient test results for each measured time point can readily be discerned from the publicly-released plots.

11. Using the patient-level plots released by the FDA, coupled with the public test results, it is possible to create plots depicting individual patient-level results for most of the functional assessment measures. The FDA plots disclose individual results by age of the participant, and because the age of each participant at the beginning and end of the study is known, as are the timing of the assessment tests plots from baseline to week 216, accurate plots of patient level results can be constructed from the public data. This is demonstrated by a stock analyst and his team who were able to create plots

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Function Testing (PFT), including forced vital capacity (FVC), percent predicted FVC (%FVC), forced expiratory volume in 1 second (FEV1), percent predicted FEV1 (%FEV1), FEV1/FVC ratio, maximal inspiratory pressure (MIP), and maximal expiratory pressure (MEP). Ittig Decl., Ex. B, 2-3 (FDACDER_SAR_00028 – FDACDER_SAR_00029).

[3] *See* Mendell JR, Goemans N, Lowes LP, et al. Longitudinal effect of eteplirsen versus historical control on ambulation in Duchenne muscular dystrophy. *Annals of Neurology*. 2016; 79(2):257-271, 259 ("Functional clinical assessments including the 6-Minute Walk Test and pulmonary function tests were performed at each week shown on the time axis.") (Kenney Decl., Ex. X, 119); Sarepta Therapeutics, *Sarepta Presentations for the April 25, 2016 Meeting of the Peripheral and Central Nervous System Drugs Advisory Committee* [Slides], April 25, 2016, 114, https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeeting Materials/Drugs/PeripheralandCentralNervousSystemDrugsAdvisoryCommittee/UCM500822.pdf (last accessed Aug. 23, 2018); Xian Ling, *Statistical Review and Evaluation: Clinical Studies* (May 3, 2016), *in* Center for Drug Evaluation and Research Statistical Review(s) (2016), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/206488Orig1s000StatR.pdf (Kenney Decl., Ex. R, 13-14).

of individual NSAA results (annual) by age, and individual Rise Time results (annual) by age, based only on the annual data publicly available as of April 2016.[4]

12. More specifically, at the time of drug approval, the FDA released individual patient-level plots that include results based on each measured time point for: the 6-Minute Walk Test (6MWT); North Star Ambulatory Assessment (NSAA) total score; NSAA components Timed 10-Meter Run and Rise Time; and Grip Strength for both the right and left hand from the Maximum Voluntary Isometric Contraction Test (MVICT) and Hand-Held Dynamometry.[5]

13. It is possible to obtain the individual patient test results for each time point by "digitizing" these figures. (Digitizing consists of importing a figure or plot into a computer program that translates the results depicted graphically into numeric form, allowing the user to obtain coordinates (x,y) for each set of values.) An example of individual patient test results for patient twelve in the FDA-released data is provided in Exhibit C, a true and correct copy of which is annexed hereto. A free online plot digitizer[6] was used to digitize an FDA plot for Patient 12. The digitized patient test results on each test by patient age were then placed in a statistical dataset. Plots of individual variables by patient age were created using IBM SPSS 25 statistical software, depicted in Exhibit D, a true and correct copy of which is annexed hereto. Since the schedule of test administration was known, plots

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[4] @BosCaptn, Sarepta 4-Year Data Analysis Of Eteplirsen To Treat DMD (2016), https://seekingalpha.com/article/3957059-sarepta-4-year-data-analysis-eteplirsen-treat-dmd (last accessed Aug. 29, 2018).

[5] *See* Eric Bastings, *Division Director Summary Review for Regulatory Action* (July 25, 2016) *in* Center for Drug Evaluation and Research Medical Review(s) 43-48, 72-76 (2016), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/206488Orig1s000MedR.pdf (last accessed Aug. 25, 2018); *see also* Christopher D. Breder, *Clinical Review* (May 9, 2016), *in* Center for Drug Evaluation and Research Medical Review(s) 336-348 (2016), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/206488Orig1s000 MedR.pdf (last accessed Aug. 25, 2018).

[6] WebPlotDigitizer, (Copyright 2010-2017 Ankit Rohatgi), https://apps.automeris.io/wpd/ (last accessed August 16, 2018).

of individual variables by week of trial were also created, through week 216, depicted in Exhibit E, a true and correct copy of which is annexed hereto.

14. Contrary to defendants' contentions, with access to free software and the publicly available materials released by the FDA and Sarepta, it is relatively simple to obtain individual patient results for all of the measured time points through week 216 for the functional assessment tests cited as confidential in the Sherwood declaration.

15. Defendants' other claims that the redacted information remains substantially confidential is similarly misdirected. Their opposition contains a number of errors that either misstate the extent of public information or misperceive the points made in my moving papers demonstrating defendants' failure to establish that disclosing information redacted from the CSRs would actually cause substantial competitive harm. Annexed hereto (as true and correct copies) as Exhibits A and B are tables identifying for the Court the specific claims of confidentiality made by defendants and showing where they are refuted by documentary evidence submitted in support of my cross-motion.

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Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct.

Executed this 30th day of August 2018, in New York, NY.

Charles Seife