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 May 29, 2018

DECLARATION OF CORTELYOU KENNEY

I, CORTELYOU KENNEY, declare as follows:

1. I am a Supervising Attorney with the Media Freedom Information and Access Clinic at Yale Law School, and counsel in this action to plaintiff Charles Seife. I am duly licensed to practice law in the State of New York and am admitted to the bar of the Southern District of New York.

2. This declaration is submitted in opposition to these motions for summary judgment filed by defendants Food and Drug Administration (FDA) and the Department of Health and Human Services (HHS) and by intervenor-defendant Sarepta Therapeutics (Sarepta) (collectively, defendants), and in support of plaintiff's cross-motion for summary judgment.

3. This declaration is made upon personal knowledge, and the facts stated herein are true and correct.

4. At issue on this motion is the proper application of FOIA Exemption 4 to information withheld from the CSRs for Sarpeta's Study 201 and Study 202.

5. Seife communicated to opposing counsel both verbally and by email the more limited scope of his objections to the CSR redactions. On January 8, 2017, I submitted to opposing counsel an annotated version of the *Vaughn* Index they had provided, identifying the withheld efficacy and safety information and redacted document names that he contended could not properly be withheld.

6. On February 20, 2018, I further informed opposing counsel that Seife does not seek patient consent forms submitted by patients in the studies that were highlighted in the annotated *Vaughn* Index.

7. In this same email, and over the phone, I also made clear that Seife does not and will not seek any age, weight, height, or other patient demographic information.

8. Finally, this is to place before the Court true and correct copies of the following documents that are being submitted in support of plaintiff's cross-motion for summary judgment:

Clinical Study Reports	
Exhibit A	Plaintiff's Index of Challenged Redactions in the Clinical Study Reports
Exhibit B	Index for Sarepta's Exhibit B
Exhibit C	Plaintiff's Excerpts from Redacted Clinical Study Reports and Documents for Comparison
Excerpts from Public FDA Dispute	
Exhibit D	Ellis Unger, *Office of Drug Evaluation-I: Decisional Memo*, *in* Center for Drug Evaluation and Research Summary Review 84 (2016), http://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/206488Orig1s000SumR.pdf, pp. 2-43.
Exhibit E	Janet Woodcock, *Center Director Decisional Memo*, *in* Center for Drug Evaluation and Research Summary Review 69 (2016),

	http://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/206488Orig1s000SumR.pdf, pp. 2-16.
Exhibit F	Ellis Unger, *Agency Scientific Dispute – Appeal*, *in* Center for Drug Evaluation and Research Summary Review 42 (2016), http://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/206488Orig1s000SumR.pdf, pp. 2-28.
Exhibit G	Luciana Borio, *Scientific Dispute Resolution Appeal Regarding Eteplirsen*, *in* Center for Drug Evaluation and Research Summary Review 15 (2016), http://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/206488Orig1s000SumR.pdf, pp. 2-28.
Exhibit H	Robert Califf, *Scientific Dispute Regarding Accelerated Approval of Sarepta Therapeutics' Eteplirsen (NDA 106488-Commisioner's Decision* (Sept. 16, 2016), *in* Center for Drug Evaluation and Research Summary Review 2 (2016), http://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/206488Orig1s000SumR.pdf, pp. 2-15.
Select Documents from the FOIA Production	
Exhibit I	Email from Dr. John Jenkins, then Director of the Office of New Drugs, to Dr. Robert Califf, then FDA Commissioner, regarding memo, dated September 14, 2016 at 5:35 PM, pp 2-6.
Exhibit J	Emails Related to Dr. Richard Moscicki: • Email chain from Dr. John Jenkins, then Director of the Office of New Drugs, to Dr. Ellis Unger, Director of Office of New Drugs - Office of Drug Evaluation I (ODE I), regarding Briefing Document Issues Final, dated February 09, 2016 6:58 PM, pp. 2-3. • Email from Dr. Ellis Unger, Director of Office of New Drugs - Office of Drug Evaluation I (ODE I), to Dr. Billy Dunn, Director of the Office of Drug Evaluation I - Division of Neurology Products (DNP), and Dr. Robert Temple, Deputy Center Director for Clinical Science, regarding Briefing Document Issues Final, dated February 09, 2016 4:40 PM, p. 4. • Email chain from Jennifer Rodriguez, Acting Associate Commissioner for External Affairs, to Dr. Richard Moscicki, then Deputy Center Director for Science Operations for the Center for Drug Evaluation and Research, regarding Media Question – Sarepta Involvement, dated April 06, 2017 4:43 PM, p. 5. • Email chain from to Dr. Richard Moscicki, then Deputy Center Director for Science Operations for the Center for Drug Evaluation and Research, to Jennifer Rodriguez, Acting Associate Commissioner for External Affairs,

	regarding Media Question – Sarepta/ethics on engagement, dated April 07, 2017 12:15 PM, pp. 6-12. • Email chain from Dr. John Jenkins, then Director of the Office of New Drugs, regarding DMD, dated August 06, 2015 3:45 PM, pp. 15-16. • Email from Dr. Ashutosh Rao, Chief, Laboratory of Applied Biochemistry, regarding Update on dystrophin chat, April 08, 2014 1:04 PM, pp. 18-19. • Email from Diane Berry, Vice President, Global Health and Policy Affairs of Sarepta, to Mary Gross, FDA employee, CC'ing Dr. Richard Moscicki, then Deputy Center Director for Science Operations for the Center for Drug Evaluation and Research, regarding Dystrophin Workshop – Mar 20, dated February 27, 2015 3:05 PM, pp. 18-19. • Email from Shamim Ruff, Senior Vice President and Chief Regulatory Affairs Officer of Sarepta, to Dr. Woodcock, Director of the Center for Drug Evaluation and Research, CC'ing Dr. Richard Moscicki, then Deputy Center Director for Science Operations for the Center for Drug Evaluation and Research, regarding Dystrophin Results, Friday, May 20, 2016 2:12 PM, pp. 20-21. • Email from Dr. Richard Moscicki, then Deputy Center Director for Science Operations for the Center for Drug Evaluation and Research, to Dr. Woodcock, Director of the Center for Drug Evaluation and Research, regarding IHC baseline differences, dated September 16, 2016 2:55 PM, p. 23. • Email from Dr. Richard Moscicki, then Deputy Center Director for Science Operations for the Center for Drug Evaluation and Research, to Dr. Woodcock, Director of the Center for Drug Evaluation and Research, regarding New Memo, dated September 15, 2016 4:14 PM, p. 24. • Email chain from Dr. Billy Dunn, Director of the Office of Drug Evaluation I - Division of Neurology Products (DNP), to Dr. Richard Moscicki, then Deputy Center Director for Science Operations for the Center for Drug Evaluation and Research, regarding DMD, dated February 25, 2017 7:54 AM, p. 25.
Exhibit K	Emails related to the patient representative: • Email chain from Dr. John Jenkins, then Director of the Office of New Drugs, to Jayne E. Peterson Director, Division of Advisory Committee and Consultant Management, and Dr. Ellis Unger, Director of Office of New Drugs - Office of Drug Evaluation I (ODE I), regarding Office Director Signature Needed: CDER Vote Memo for Apr 25 PCNS, dated April 6, 2016 5:42 PM, pp. 2-4. • Email chain from Dr. Robert Califf, then FDA Commissioner, to Elizabeth Dickinson, Senior Deputy Chief Counsel, and Rachel Sherman, Principal Deputy Commissioner, regarding FW: highly confidential, dated September 5, 2016 7:21 AM, pp. 5-6.
Exhibit L	Emails to/from Dr. Farkas:

	• Email chain from Dr. Ronald Farkas, Clinical Team Leader, to Dr. John Jenkins, then Director of the Office of New Drugs, regarding Update on eteplirsen – public presentations, dated February 23, 2014 12:35 PM, pp. 2-15.
Exhibit M	Correspondence related to the *Annals of Neurology* article: • Email chain from Dr. Ellis Unger, Director of Office of New Drugs - Office of Drug Evaluation I (ODE I), to Dr. Clifford B. Saper, Editor-in-Chief, *Annals of Neurology*, regarding Retraction of correction of [sic] paper in Annals of Neurology, dated November 29, 2016, pp. 2-7. • Letter from Dr. Robert Califf, then FDA Commissioner, and Dr. Ellis Unger, Director of Office of New Drugs - Office of Drug Evaluation I (ODE I), to Dr. Clifford B. Saper, Editor-in-Chief, *Annals of Neurology*, undated, pp. 8-11. • Unger EF, Califf RM. Regarding "Eteplirsen for the treatment of Duchenne muscular dystrophy." *Annals of Neurology*. 2017;81(1):162-164, pp. 12-14.
Sarepta's Communications	
Exhibit N	Mendell, JR et al., Eteplirsen for the treatment of Duchenne muscular dystrophy. *Annals of Neurology*. 2013. 74(5): 637-647, pp. 2-41.
Exhibit O	Sarepta Therapeutics, *Sarepta Therapeutics Announces Publication of Eteplirsen Clinical Study Results in Annals of Neurology: Results Show Significant Increase in Dystrophin Production and Stabilization of Walking Ability in Duchenne Muscular Dystrophy Patients*, Aug. 8 (2013), pp. 2-5.
Public Information	
Exhibit P	SEC Statement: • Sarepta Therapeutics Current Report (Form 8-K) (May 3, 2018), http://investorrelations.sarepta.com/static-files/de5e4a97-3c26-41f4-a1d2-3993f308462d, pp. 2-77.
Exhibit Q	Advisory Committee: • Sarepta Therapeutics. *Peripheral and Central Nervous System Drugs, Advisory Committee: Eteplirsen Briefing Document, Available for Public Disclosure Without Redaction.* April 25 2016, https://www.fda.gov/downloads/advisorycommittees/committeesmeetingmaterials/drugs/peripheralandcentralnervoussystemdrugsadvisorycommittee/ucm497064.pdf, pp. 2-77.
Exhibit R	FDA Approval Documents:

	• Xiang Ling, Office of Biometrics, U.S. Food and Drug Administration, *Statistical Review and Evaluation [of Exondys 51]* (2016), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/206488Orig1s000StatR.pdf, pp. 2-35. • *Exondys 51 (eterplirsen) Injection Label*, https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/206488lbl.pdf (last accessed May 29 2018), pp. 36-46. • U.S. Food and Drug Administration, Center for Drug Evaluation and Research Medical Review(s) (2016), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/206488Orig1s000MedR.pdf (last accessed May 29, 2018) *(Excerpts)*, pp. 47-73.
Exhibit S	ClinicalTrials.gov: • Sarepta Therapeutics, [*Study 201] Efficacy Study of AVI-4658 [Exondys 51] to Induce Dystrophin Expression in Selected Duchenne Muscular Dystrophy Patients*, www.ClinicalTrials.gov (Nov. 9, 2015), https://clinicaltrials.gov/ct2/show/study/NCT01396239?term=eteplirsen&rank=6&sect=X70156, pp. 2-32. • Sarepta Therapeutics, *[Study 202] Efficacy, Safety, and Tolerability Rollover Study of Eteplirsen in Subjects With Duchenne Muscular Dystrophy*, www.ClinicalTrials.gov (Nov. 15, 2016), https://clinicaltrials.gov/ct2/show/study/NCT01540409, pp. 33-47 • Sarepta Therapeutics, *[Study 301] Confirmatory Study of Eteplirsen in DMD Patients (PROMOVI)*, www.ClinicalTrials.gov (Oct. 3, 2017), https://clinicaltrials.gov/ct2/show/NCT02255552, pp. 48-60. • Sarepta Therapeutics, *[Study 28] Dose-Ranging Study of AVI-4658 [Exondys 51] to Induce Dystrophin Expression in Selected Duchenne Muscular Dystrophy (DMD) Patients*, www.ClinicalTrials.gov (Oct. 6, 2015), https://clinicaltrials.gov/ct2/show/NCT00844597, pp. 61-79. • Adverse Events from Listed Trials, pp. 80-89.
Exhibit T	European Medicines Agency Clinical Trials Registry: • Study 201, https://www.clinicaltrialsregister.eu/ctr-search/trial/2016-005000-26/3rd (Mar. 16, 2017), pp. 2-6. • Study 202, https://www.clinicaltrialsregister.eu/ctr-search/trial/2016-005001-39/3rd (Mar. 16, 2017), pp. 7-11.
Exhibit U	FDA and EMA Guidance: • U.S. Department of Health &Human Services, Food & Drug Administration, Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research, *Duchenne Muscular Dystrophy and Related Dystrophinopathies: Developing Drugs for Treatment, Guidance for Industry, February 2018* (2018), https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM450229.pdf, pp. 2-17.

	• European Medicines Agency Committee for Medicinal Products for Human Use, *Guideline on the clinical investigation of medicinal products for the treatment of Duchenne and Becker muscular dystrophy* (2015), http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2015/12/WC500199239.pdf, pp. 18-37.
Exhibit V	Clinical Endpoints in Scientific Literature: • 6-Minute Walk Test o Servais L, Grelet M, Seferian A, et al., Movement monitoring at home and during study visits identifies sources of variability in 6MWT performance in Duchenne muscular dystrophy. *Neuromuscular Disorders*. 2016; 26:S152-S153, pp. 2-3. o ATS Statement. *American Journal of Respiratory and Critical Care Medicine*. 2002;166(1):111–117, pp. 4-10. o McDonald CM, Henricson EK, Han JJ, et al. The 6-Minute Walk Test as a New Outcome Measure in Duchenne Muscular Dystrophy. *Muscle & Nerve*. 2010;41(4):500-520, pp. 12-21. • North Star Ambulatory Assessment: o North Star Clinical Network, *The North Star Ambulatory Assessment*, http://www.musculardystrophyuk.org/assets/0000/6388/NorthStar.pdf (last accessed May 21, 2018), pp. 22-24. o Ricotti V, Ridout DA, Pane M, et al. The NorthStar Ambulatory Assessment in Duchenne muscular dystrophy: considerations for the design of clinical trials. *Journal of Neurology, Neurosurgery, and Psychiatry*. 2016;87(2):149-155, pp. 25-32. • Maximum voluntary isometric contraction testing (MVICT) o Meldrum D, Cahalane E, Conroy R, Fitzgerald D, O. H. Maximum voluntary isometric contraction: reference values and clinical application. *Amyotrophic Lateral Sclerosis*. 2007 Feb;8(1):47-55. Erratum in: *Amyotrophic Lateral Sclerosis*. 2008;9(1):63, pp. 33-44. • 9-Hole Peg Test: o *9-Hole Peg Test (9-HPT)*, National Multiple Sclerosis Society, https://www.nationalmssociety.org/For-Professionals/Researchers/Resources-for-Researchers/Clinical-Study-Measures/9-Hole-Peg-Test-(9-HPT) (last accessed May 21, 2018), pp. 45-46. • Pediatric Quality of Life (PEDSQL): o James W. Varni, *The PedsQL Measurement Model for the Pediatric Quality of Life Inventory*, PedsQL, http://www.pedsql.org/about_pedsql.html (last accessed May 29, 2018), pp. 47-48.

	○ Davis SE, Hynan LS, Limbers CA, et al. The PedsQL™ in Pediatric Patients with Duchenne Muscular Dystrophy: Feasibility, Reliability, and Validity of the Pediatric Quality of Life Inventory Neuromuscular Module and Generic Core Scales, *Journal of Clinical Neuromuscular Disease*. 2010;11(3):97-109, pp. 49-61. • Pulmonary Test Functions: ○ Schoser B, Fong E, Geberhiwot T, et al. Maximum inspiratory pressure as a clinically meaningful trial endpoint for neuromuscular diseases: A comprehensive review of the literature. *Orphanet Journal of Rare Diseases*. 2017;12:52, pp. 62-73. • Overview: ○ Bushby K et al. Diagnosis and management of Duchenne muscular dystrophy, part 2: implementation of multidisciplinary care. *The Lancet Neurology*. 2010;9(2):177-189, pp. 74-90. ○ Bushby K, Connor E. Clinical Outcome Measures for Trials in Duchenne Muscular Dystrophy: Report from International Working Group Meetings. *Journal of Clinical Investigations* (London). 2011;1(19):1217-1235, pp. 91-127. ○ Mah JK. An Overview of Recent Therapeutics Advances for Duchenne Muscular Dystrophy. *Methods in Molecular Biology*., 2018;1687:3-17, pp. 128-142.
Exhibit W	Test Methods in the Scientific Literature: • Immunohistochemistry: ○ *Overview of Immunohistochemistry (IHC)*, ThermoFisher Scientific, https://www.thermofisher.com/us/en/home/life-science/protein-biology/protein-biology-learning-center/protein-biology-resource-library/pierce-protein-methods/overview-immunohistochemistry.html (last accessed May 21, 2018), pp. 2-10. ○ Sarepta Therapeutics, *Comment on the Food and Drug Administration (FDA) Notice: Submission of a Proposed Draft Guidance for Industry on Developing Drugs for Treatment of Duchenne Muscular Dystrophy; Establishment of a Public Docket* (2014), https://www.regulations.gov/document?D=FDA-2014-D-1264-0030, pp. 11-21. • Creatine Kinase: ○ Mendell JR, Shilling C, Leslie ND, et al. Evidence-based path to newborn screening for Duchenne muscular dystrophy. *Annals of Neurology*. 2012;71(3):304-313, pp. 22-31. • Western Blots:

	○ Mahmood T, Yang P-C. Western blot: Technique, theory, and trouble shooting. *North American Journal of Medical Sciences*. 2012; 4(9):429-434, pp. 32-37.
Exhibit X	Sarepta's Scientific Publications: • Alfano L, Berry K, Mendell J, Eliopoulos H, Han L, Lowes L. Effects of long-term eteplirsen treatment on upper limb function in patients with Duchenne muscular dystrophy: findings of two phase 2 clinical trials. *Neuromuscular Disorders*. 2017; 27:S216-S216, p. 2. • Anthony K, Feng L, Arechavala-Gomeza V, et al. Exon skipping quantification by quantitative reverse-transcription polymerase chain reaction in Duchenne muscular dystrophy patients treated with the antisense oligomer eteplirsen. *Human Gene Therapy Methods*. 2012; 23(5):336-345, pp. 3-12. • Arechavala-Gomeza V, Graham IR, Popplewell LJ, et al. Comparative analysis of antisense oligonucleotide sequences for targeted skipping of exon 51 during dystrophin pre-mRNA splicing in human muscle. *Human Gene Therapy* 2007;18(9):798-810, pp. 13-25. • Cirak S, Arechavala-Gomeza V, Guglieri M, et al. Exon skipping and dystrophin restoration in patients with Duchenne muscular dystrophy after systemic phosphorodiamidate morpholino oligomer treatment: an open-label, phase 2, dose-escalation study. *The Lancet*. 2011;378(9791):595-605, pp. 26-64. • Cirak S, Feng L, Anthony K, et al. Restoration of the dystrophin-associated glycoprotein complex after exon skipping therapy in Duchenne muscular dystrophy. *Molecular Therapy* 2012;20(2):462-7, pp. 65-70. • Colan S, Cripe L, Eliopoulos H, Lucas K, Moody S, Mendell J. Effects of Long-Term Treatment with Eteplirsen on Cardiac Function: Left Ventricular Ejection Fraction in Eteplirsen-Treated Patients, *Annals of Neurology*. 2017; 82:S325-S325, p. 71. • Cripe L, Colan S, Eliopoulos H, et al. Effects of long-term treatment with eteplirsen on cardiac function. *Neuromuscular Disorders*. 2017;27:S114-S114, p. 72. • Kinali M, Arechavala-Gomeza V, Feng L, et al. Local restoration of dystrophin expression with the morpholino oligomer AVI-4658 in Duchenne muscular dystrophy: a single-blind, placebo-controlled, dose-escalation, proof-of-concept study, *The Lancet Neurology*. 2009; 8(10):918-928., pp. 73-90. • Kinane TB, Mayer OH, Duda PW, Lowes LP, Moody SL, Mendell JR. Long-Term Pulmonary Function in Duchenne Muscular Dystrophy: Comparison of Eteplirsen-Treated Patients to Natural History. *Journal of Neuromuscular Diseases*. 2018; 5:47-58, pp. 92-103. • Kinane TB, Mayer O, Lowes L, et al. Respiratory Function in Eteplirsen-Treated Duchenne Muscular Dystrophy (DMD) Patients Compared to

	Natural History. *American Journal of Respiratory and Critical Care Medicine* 2017;195:A2649, p. 104. • Kinane B, Mayer O, Lowes L, et al. P.219 - Respiratory function in eteplirsen-treated Duchenne muscular dystrophy (DMD) patients compared to natural history. *Neuromuscular Disorders*. 2016;26(Supplement 2):S154, p. 105. • Kole R, Leppert BJ. Targeting mRNA Splicing as a Potential Treatment for Duchenne Muscular Dystrophy. *Discovery Medicine*. 2012;14(74):59-69, pp. 106-14. • Mendell J, Powers J, Duda P, Eliopoulos H. Clinical safety of eteplirsen, a phosphorodiamidate morpholino oligomer (PMO), in Duchenne muscular dystrophy (DMD) patients amenable to skipping exon 51 of the DMD gene. *Neuromuscular Disorders*. 2016; 26:S153-S154, pp. 115-17. • 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, pp. 118-33. • Mendell JR, Sahenk Z, Rodino-Klapac LR. Clinical trials of exon skipping in Duchenne muscular dystrophy. *Expert Opinion on Orphan Drugs* 2017; 5(9):683-690, pp. 134-42. • Muntoni F, Voit T, Servais L, et al. A Phase I/IIa Clinical Trial in Duchenne Muscular Dystrophy Using Systemically Delivered Morpholino Antisense Oligomer to Skip Exon 53 (SKIP-NMD). *Human Gene Therapy. Clinical Development*. 2015; 26(2):92-95, pp. 143-46. • Sazani P, Weller DL, Shrewsbury SB. Safety Pharmacology and Genotoxicity Evaluation of AVI-4658, *International Journal of Toxicology*. 2010; 29(2):143-156, pp. 147-60. • Sazani P, Van Ness KP, Weller DL, Poage D, Nelson K, Shrewsbury SB. Chemical and Mechanistic Toxicology Evaluation of Exon Skipping Phosphorodiamidate Morpholino Oligomers in mdx Mice. *International Journal of Toxicology*. 2011; 30(3):322-333, pp. 161-72. • Sazani P, Van Ness KP, Weller DL, Poage DW, Palyada K, Shrewsbury SB. Repeat-Dose Toxicology Evaluation in Cynomolgus Monkeys of AVI-4658, a Phosphorodiamidate Morpholino Oligomer (PMO) Drug for the Treatment of Duchenne Muscular Dystrophy. *International Journal of Toxicology*. 2011; 30(3):313-321, pp. 173-81. • Sazani P, Magee T, Charleston JS, et al. In Vitro Pharmacokinetic Evaluation of Eteplirsen, SRP-4045, and SRP-4053; Three Phosphorodiamidate Morpholino Oligomers (PMO) for the Treatment of Patients with Duchenne Muscular Dystrophy (DMD). *Neurology*. 2015; 84(14 Supplement):P5.061, pp. 182-85. • Schnell F, Donoghue C, Dworzak J, et al. Development of a validated western blot method for quantification of human dystrophin protein, *Neuromuscular Disorders*. 2016; 26:S160-S160, p. 186. • Schnell FJ, Donoghue C, Dworzak J, et al. Development of a validated Western blot method for quantification of human dystrophin protein used

	in phase 2 and 3 clinical trials of eteplirsen for the treatment of Duchenne muscular dystrophy. *Neuromuscular Disorders*. 2017;27(Supplement 1):S16, pp. 187-88.
Exhibit Y	Conference Presentations: • Aartsma-Rus A, Ferlini A, McNally EM, Spitali P, Sweeney HL. 226th ENMC International Workshop: Towards Validated and Qualified Biomarkers for Therapy Development for Duchenne Muscular Dystrophy 20-22 January 2017, Heemskerk, the Netherlands, *Neuromuscular Disorders*. 2018; 28:77-86, pp. 2-11. • Ferlini A, Flanigan KM, Lochmuller H, Muntoni F, 't Hoen PAC, McNally E. 204th ENMC International Workshop on Biomarkers in Duchenne Muscular Dystrophy 24–26 January 2014, Naarden, The Netherlands. *Neuromuscular Disorders*. 2015; 25(2):184-198, pp. 12-26. • Hoffman EP, Facilitating orphan drug development: Proceedings of the TREAT-NMD International Conference, December 2015, Washington, DC, USA. *Neuromuscular Disorders*. 2017; 27(7):693-701, pp. 27-35. • Muntoni F, Bushby KD, van Ommen GJ. 149th ENMC International Workshop and 1st TREAT_NMD Workshop on: "Planning Phase I/II Clinical Trials using Systematically Delivered Antisense Oligonucleotides in Duchenne Muscular Dystrophies." *Neuromuscular Disorders*. 2008; 18:268-275, pp. 36-43. • Muntoni F. The development of antisense oligonucleotide therapies for Duchenne muscular dystrophy: Report on a TREAT-NMD workshop hosted by the European Medicines Agency (EMA), on September 25th 2009. *Neuromuscular Disorders*. 2010; 20(5):255-362, pp. 44-51.
CSR Transparency	
Exhibit Z	FDA Statements: • *About the FDA: Transparency*, U.S. Food and Drug Administration (Mar. 24, 2018, 3:58 PM), https://www.fda.gov/AboutFDA/Transparency/default.htm, pp. 2-4. • Scott Gottlieb, *Fostering Transparency to Improve Public Health*, U.S Food & Drug Administration (Jan. 16, 2018), https://www.fda.gov/NewsEvents/Speeches/ucm592549.htm, pp. 5-9. • U.S. Food & Drug Administration, *FDA Commissioner Scott Gottlieb, M.D., on new steps FDA is taking to enhance transparency of clinical trial information to support innovation and scientific inquiry related to new drugs* (January 16, 2018), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm592566.htm, pp. 10-12. • Janet Woodcock, *FDA's New Pilot Program Aims for More Transparency about New Drug Approvals* (Mar. 19, 2018),

	https://blogs.fda.gov/fdavoice/index.php/tag/clinical-data-summary-pilot/, pp. 13-14.
Exhibit AA	EMA Datasharing Policy: • European Medicines Agency. *External guidance on the implementation of the European Medicines Agency policy on the publication of clinical data for medicinal products for human use* 11 April 2017, EMA/90915/2016, Version 1.2 *(*2017), http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2017/09/WC500235371.pdf , pp. 2-106. • Michael Mehzer, *EMA Transparency: New Clinical Reports Go Live*, Regulatory Focus, Oct. 20, 2016, https://www.raps.org/news-articles/news-articles/2016/10/ema-transparency-new-clinical-reports-go-live?feed=Regulatory-Focus, pp. 107-10.
Exhibit BB	Academic Articles Regarding Clinical Data: • Sharfstein JM, Miller JD, Davis AL, Ross, JS, McCarthy ME, Smith B, Chaudry A, Alexander GC, Kesselheim AS. Blueprint for Transparency at the U.S. Food and Drug Administration: Recommendations to Advance the Development of Safe and Effective Medical Products. *The Journal of Law, Medicine & Ethics*. 2017;45(2_suppl):7-23. http://journals.sagepub. com/doi/pdf/10.1177/1073110517750615 • Peter Lurie & Allison Zieve, *Sometimes the Silence Can Be Like Thunder: Access to Pharmaceutical Data at the FDA*, 69 *Law and Contemporary Problems* 85 (2006), https://scholarship.law.duke.edu/lcp/vol69/iss3/5/, pp. 52-64. • Rising K, Bacchetti P, & Bero L. Reporting Bias in Drug Trials Submitted to the Food and Drug Administration: Review of Publication and Presentation. *PLOS Medicine*. (2008) 5(11): e217, pp. 64-74. o Correction: Reporting Bias in Drug Trials Submitted to the Food and Drug Administration: Review of Publication and Presentation. *PLoS Med* 6(1): e1000017, p. 75. • Aaron Kesselheim & Michelle Mello, Confidentiality Laws And Secrecy In Medical Research: Improving Public Access To Data On Drug Safety, *Health Affairs* 26(2) (2007), pp. 76-84. • Turner EH, Matthews AM, Linardatos E, Tell RA, Rosenthal R. Selective publication of antidepressant trials and its influence on apparent efficacy. *N Engl J Med*. 2008;358(3):252-260, pp. 86-93. • Hartung D, et al. Reporting Discrepancies between the ClinicalTrials.gov Results Database and Peer Reviewed Publications. *Annals of Internal Medicine*. 2014;160(7), pp. 94-106. • Eunice Yu & Peter Lurie. Transcranial Magnetic Stimulation Not Proven Effective. *Biological Psychiatry*. 2010;67:e13, p. 107. • Keller MB, Ryan ND, Strober M, et al. Efficacy of Paroxetine in the Treatment of Adolescent Major Depression: A Randomized, Controlled Trial. *Journal of the American Academy of Child and Adolescent Psychiatry*. 2001;40(7):762-772, pp. 108-18.

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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 29st day of May 2018, in New Haven, CT.

Cortelyou Kenney, Esq.