

PUBLIC HEALTH SERVICE

Meeting of the  
Interagency Coordinating Committee on  
Human Growth Hormone and Creutzfeldt-Jakob Disease

November 30, 2017, 2:30 PM

National Institutes of Health  
Building 31, Room 9A22  
Bethesda, Maryland

Committee Members Attending

Dr. Patricia Bright, FDA (by phone)  
Dr. Judith Fradkin, NIDDK  
Dr. Ellen Leschek, NIDDK  
Dr. James Mills, NICHD (by phone)  
Dr. Avindra Nath, NINDS  
Dr. Griffin Rodgers, NIDDK, Chairman  
Dr. Lawrence Schonberger, CDC (by phone)

Also Attending

Dr. Joe Abrams, CDC (by phone)  
Dr. Greg Germino, NIDDK  
Mary Harris, NIDDK (by phone)  
Dr. Ryan Maddox, CDC (by phone)  
Amy Reiter, NIDDK  
Dr. B. Tibor Roberts, NIDDK  
Dr. Robert Tilghman, NIDDK  
Diane Tuncer, NIDDK

Westat Contract

Dr. Leschek reported that Westat is in the fifth year of the current 5-year contract. The contract is up for competitive renewal.

National Hormone and Pituitary Program (NHPP) Cohort Update

Dr. Leschek noted that there have been no new clinically or pathologically confirmed cases since the last meeting, nor have there been any new clinically suspicious cases. The total number of confirmed cohort CJD cases therefore remains at 32, with 17 neuropathologically confirmed and 15 clinically confirmed. There was one case discussed at the 2016 meeting that had raised low-level suspicion for CJD, but after obtaining more medical records it was determined that the patient did not have CJD. Thus, there are no cases currently under investigation. There is still one confirmed U.S. CJD case-patient not in the NHPP cohort who had received commercially produced pituitary hGH.

Dr. Leschek reminded the committee that the source for death records is now the National Death Index (NDI) Plus database, which provides more detailed information than the standard NDI database. Dr. Leschek has been investigating 95 additional possible cohort cases for which the causes of death were now available; most of these cases have been adjudicated as unlikely to be CJD. Several cases have yet to be adjudicated because Dr. Leschek is awaiting their death certificates. Dr. Leschek also raised the possibility that there could be a death listed in NDI Plus that may match a name in the cohort, but it would be impossible to know conclusively because of a paucity of information about the cohort member in question. The Committee decided that a

new category—*i.e.*, “unknown vital status”—be created for these cases, at least until any new information about the cohort member clarifies the situation.

Dr. Leschek also reported that Dr. Arun Venkatesan has accepted the open position of the committee’s neurological review group (NRG).

Dr. Nath called attention to cases of ALS occurring at a relatively young age in people who received NHPP growth hormone, including one that had not been [discussed at the 2012 meeting](#), bringing the total to four. Drs. Nath, Leschek, and Schonberger are reviewing the records from all four and seeking to determine whether any additional information is available. In addition, Dr. Schonberger will contact the CJD surveillance groups in the U.K. and France to inquire about the number of ALS cases in their cohorts. A few studies over the past 50 years have attempted to examine the possibility of ALS transmission from one individual to another (directly or via bodily tissues or medical instruments), but the available data have been sparse and inconclusive.

#### Updates on Fact Sheet and Public Inquiries

Ms. Tuncer stated that the comprehensive and summary fact sheets were updated to reflect the new foreign cases mentioned at the 2016 meeting. Scientific papers discussed at the 2016 meeting were added to the resource list. For reference, the [comprehensive fact sheet is here](#), the [summary version is here](#), and the [resource list is here](#).

Ms. Harris reported that there were 13 inquiries regarding hGH and CJD over the past year (compared to five the year before). Six were from confirmed cohort members. None of the calls were suggestive of potential new cases of CJD.

#### Recent Progress in CJD Research

Dr. Schonberger noted three recent papers of interest:

1. Orrú CD, Yuan J, Appleby BS, *et al.* [Prion seeding activity and infectivity in skin samples from patients with sporadic Creutzfeldt-Jakob disease](#). *Sci Transl Med.* 2017; 9: eaam7785.
2. Ritchie DL, Adlard P, Peden AH, *et al.* [Amyloid- \$\beta\$  accumulation in the CNS in human growth hormone recipients in the UK](#). *Acta Neuropathol.* 2017; 134: 2609-2616.
3. Ritchie DL, Barria MA, Peden AH, *et al.* [UK Iatrogenic Creutzfeldt-Jakob disease: investigating human prion transmission across genotypic barriers using human tissue-based and molecular approaches](#). *Acta Neuropathol.* 2017; 133: 579-595.

#### Report on CJD in Foreign and Commercial GH Recipients

Dr. Schonberger reported one new foreign (non-U.S.) hGH/CJD case in France in 2017 (bringing the French total to 121 for hGH-related cases). This brings the total to 210 foreign cases.

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Director, NIDDK