people during World War I; a desperate economic situation; and a totalitarian system that had started another terrible war—all made the smooth, stepwise progression from eugenic theory to compulsory sterilization and, finally, to the killing of mentally ill patients possible. As were Hitler and the other political leaders, most of the doctors and scientists involved in the crimes of the Nazi period were convinced that society had to be cleaned from "bad" genes and even from the affected individuals. In the interest of a "stronger" and "healthier" race, they regarded the unbelievable cruelties against helpless patients as acceptable or even necessary. They would undoubtedly have welcomed the technical possibilities of present-day genetics. Otherwise, most of them were rather "normal" people, or even good scientists. This is alarming, even for a democratic society.

PETER PROPPING
Institut für Humangenetik der Universität Bonn

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Minimum Qualifications for Directors: DNA-based Genetic-testing Laboratories

To the Editor:

In the Spring of 1989, the DNA Testing Subcommittee of the Quality Assurance Committee of CORN (Council of Regional Networks for Genetic Services) was formed. Representatives of the 10 U.S. regions, as defined by the Genetic Disease Branch of Maternal and Child Health, were appointed by their local DNA-testing committees. To date, this subcommittee has accomplished the following: (1) a nationwide listing of truly clinical DNA-testing laboratories (Survey of Clinical DNA Diagnostic Laboratories 1990, 1991); (2) oversight of two nationwide interlaboratory comparison programs, one in 1989 (20 laboratories) and one currently in progress (70 laboratories); and (3) development of minimum laboratory-director qualifications for genetic-testing labs. A description of the latter is the topic of this correspondence.

The subcommittee began its task by surveying all laboratory directors identified in its nationwide survey, to determine their training and experience. On the basis of these data, the committee composed a draft document. This was sent out for comments in April 1991, to these same individuals. The period for written comments ended in October 1991. The final recommendations (as voted on and approved by the subcommittee) are presented in the Appendix.

It must be stressed that the DNA-testing subcommittee felt that there was an urgent need for definition of minimum qualifications for directors in laboratories offering genetic testing. They have chosen to leave the areas of nongenetic applications of the DNA-based technology to other groups, e.g., The Working Group on DNA Analysis Methods (TWGDAM), which has established criteria for forensic-DNA-laboratory directors (Guidelines for a Quality Assurance Program for DNA Analysis 1991). It is the sincere hope of the DNA testing subcommittee that persons in a position

to hire for such laboratories will keep these guidelines in mind, such that over time there will be a more uniform acceptance of DNA-based genetic testing as a valid part of laboratory medicine.

PATRICIA MURPHY (subcommittee chair),* JEAN AMOS,† NANCY CARPENTER,‡ RAY FENWICK,‖ M. E. HODES,§ THADDEUS KELLY,# KARLA MATTESON,** WILLIAM SELTZER,†† J. EDWARD SPENCE,‡‡ STEPHEN THIBODEAU,‖‖ VICKIE VENNE,§§ VINCENT WILSON,## AND JONATHAN ZONANA*** (members of the DNA Testing Subcommittee, Quality Assurance Committee, Council of Regional Networks for Genetic Services)

**New York State Department of Health, Wadsworth Center, Albany; †Center for Human Genetics, Boston University School of Medicine, Boston; ‡Chapman Institute of Medical Genetics, Children's Medical Center, Tulsa; ‖Institute for Molecular Genetics, Baylor College of Medicine, Houston; §Department of Medical and Molecular Genetics and Department of Medicine and Pathology, Indiana University School of Medicine, Indianapolis; #Division of Medical Genetics, University of Virginia, Charlottesville; **University of Tennessee Developmental and Genetic Center, Knoxville; ††Department of Pediatrics, University of Colorado School of Medicine, Denver; ‡‡Clinical Genetics Center, Department of Pediatrics, Carolinas Medical Center, Charlotte; ‖‖Department of Laboratory Medicine and Pathology, Mayo Clinic, Rochester, MN; §§Nichols Institute, San Juan Capistrano, CA; ##Molecular Genetics/Oncology Laboratory, The Children's Hospital, and Department of Pathology, University of Colorado School of Medicine, Denver; and ***Department of Medical Genetics, Oregon Health Sciences Clinic, Portland*

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Appendix

Minimum Laboratory-Director Qualifications: DNA-testing Laboratory

I. Definitions
   A. Type of laboratory: DNA-based analyses undertaken to determine the genetic status (carrier or disease) of a person at risk for an inherited disease.
   B. Type of director: clinical laboratory director is the individual responsible for the overall operation of the laboratory, including but not limited to the duties outlined in section II.

II. Duties of laboratory director:
   A. Technical
      1. Supervises all work performed, as indicated by signature on all laboratory reports;
      2. Provides, directly or indirectly, advice to referring physicians, regarding appropriateness, significance/interpretation of laboratory tests, and results;
      3. Assures that appropriate methods and information are used to produce and interpret data;
      4. Selects reference labs;
      5. Assures that laboratory participates in an interlaboratory comparison program (i.e., performance evaluation);
      6. Defines, implements, and monitors quality-control/quality-improvement policies for the laboratory.

   B. Administrative
      1. Insures employment of qualified personnel, sets performance standards, and provides ongoing educational training of staff;
      2. Sets goals and allocates resources (people, space, and working capital);
      3. Promotes a safe laboratory environment and facilitates staff safety training;
      4. Insures that the laboratory functions effectively with applicable accrediting and regulatory agencies and is in compliance with appli-

cable federal, state, and local laws and regulations.

III. Qualifications of laboratory director: an appropriate doctoral degree (M.D., Ph.D., etc.) with ABMG eligibility or certification in clinical molecular genetics and 4 years of postdoctoral experience, of which 2 years must be in the field of clinical molecular genetics testing.