FOR IMMEDIATE RELEASE:

The American College of Embryology (ACE) opposes regulation of human embryos as diagnostic specimens.

Houston, Texas – September 7, 2010 – ACE opposes ruling DH-08-001 pending in California, which aims to regulate human embryos as diagnostic specimens.

ACE asserts that within diagnostic laboratories that deal with human specimens, there are clear pre-analytical, analytical and post-analytical phases. At the end of the process the specimen is discarded as biological waste or stored, but in either case, the specimen is rendered non-viable. Diagnostic laboratory quality is measured in accuracy, sensitivity and specificity etc, according to the federal standards set by CLIA 88.

On the other hand, human embryos do not become specimens at any stage of the process in the embryology laboratory. On the contrary, embryos are created with the intent to be transferred into the uterus to achieve pregnancy and all efforts are made to keep them viable. Embryology laboratory quality is measured in the percentage of embryos becoming live-born children.

Therefore, the similarity between a diagnostic testing laboratory and an embryology laboratory is only in the word "laboratory", which makes the matter confusing. ACE asserts that the term "Embryology Facility" is much more appropriate.

Consistent with the above, the proposal currently under consideration fails to identify a single embryology laboratory-specific diagnostic test.

Therefore, ACE believes that standards developed for diagnostic specimen testing are not applicable to the practice of embryology.

ACE takes the stance that embryology should not be regulated as either a diagnostic laboratory procedure or a medical practice.

Instead, the unique position of an embryology laboratory has to be recognized and a distinctive set of regulations must be developed specifically for this inimitable field.

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