The Roles of IABs & WHO in Resolving Issues in the Development and Regulation of Biologicals

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During the past 50 years, a number of issues have emerged in the development and regulation of biological products. The ultimate responsibility for addressing those issues rests with the regulatory agencies of individual countries. However, the desirability for a more coherent international approach became obvious early on. Two organizations – the World Health Organization (WHO), and the International Association for Biologicals (IABs) – have taken the lead in attempting to establish international consensus on issues as they have emerged. As biological products have grown beyond vaccines for infectious diseases to include many new therapeutic products such as monoclonal antibodies and growth factors, the need for an international approach has become even more clear and the value of WHO and IABs has similarly become more important.

As an example, the issue of which cells are acceptable as substrates for the production of biological products has recurred in one form or another ever since the development of cell cultures in the 1950s, and continues even up to the present.

The major cell substrate events that occurred over the past 50 years are reviewed briefly, including the outcomes of the 7 most significant meetings. Cell DNA has been discussed for 30 years with incomplete resolution of some aspects of the issue. The currently available information on the potential oncogenicity of cellular DNA derived from continuous cell lines for which there is no evidence of either viral integration or extrachromosomal viral elements is reviewed. Issues associated with the continuing regulatory uncertainty about

cell DNA are discussed, and a perspective is provided on the DNA issue. Finally, a summary of the outcome of a recent IABs conference on current cell substrate issues is presented.