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From the Editor-in-Chief

The licensure of biologics is really taking off as we all hoped it would in the '90s. There are a number of key factors including the advanced ability to produce adeno-associated virus (AAV) with baculovirus expression technology (BET), as well as the ability of BET to produce antigens that can successfully be used as vaccines. Then of course, there is the first licensed human gene therapy from uniQure, which is based on AAV-1 that was derived from BET.

Along with the development of numerous AAV gene therapies, we are seeing promising stories with the use of lentiviruses—both *ex vivo* and *in vivo*. These developments have stimulated interest in a lentivirus reference material that can be used to help validate internal reference materials and assays. Such a material would help FDA make potency comparisons among the many products they are asked to review.

In addition, adenovirus is making a comeback with products such as a licensed vaccine for hoof and mouth disease, as well as a number of promising human vaccines.

Concerning cellular therapies, this technology area is really taking off with the most recent successes of the chimeric antigen receptor T-cell therapy developed at the University of Pennsylvania. This is the first personalized cellular therapy of its type.

And when we were asking, "How many antibodies can the market handle for rheumatic diseases?" new antibodies have been appearing on a regular basis for treating cancer. Plus, there are the antibodies that are carrying drugs, and diagnostic agents, to specific tissues in the body. New linkers are making these conjugated products realistic when our attempts in the '90s were so disappointing.

Finally, on a more personal note, a family member has been diagnosed with chronic lymphocytic leukemia and is receiving a humanized antibody (obinutuzumab) in combination with a chemotherapeutic drug. This antibody targets CD20 and kills B-cells while stimulating natural killer cells. Clinical data show that this antibody/drug combination can double the life expectancy of a patient, or at least delay the worsening of the disease.

And since I've only scratched the surface with this letter, there are so many successful and promising biologics that the industry should be entering a period of exponential growth.



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