Doctor LaRusso suggests that "significant attention by all concerned parties—from medical school through internal medicine, through fellowship, accrediting, and credentialing agencies—need to be directed towards a new curriculum that takes these concerns into account, as well as recognizes the changing skill sets of the individuals that enter the subspecialty." He envisions this could include shortening, or contracting, the overall training period, from medical school through subspecialty, from 10 years to 8.

As he prepares to serve as president of the AGA Institute, Dr LaRusso reflects that "gastroenterology is at a point when challenges and opportunities are converging, and, if we can act innovatively, we can make major transformative changes in the discoveries that we make, the manner by which we educate, and ultimately the care we provide patients and society. The AGA Institute is at the forefront of leading the field into the future, and I'm proud to serve as president."

FDA Licenses First Biologic Product to Prevent Hepatitis B Reinfection in Liver Transplant Patients

The US Food and Drug Administration (FDA) on April 6 announced the approval of HepaGam B for the prevention of hepatitis B reinfection in liver transplant recipients. HepaGam B is the first immune globulin product approved for this purpose.

The drug is now approved for use to prevent hepatitis B recurrence after liver transplantation in hepatitis B surface antigen (HBsAg)-positive liver transplant patients. HepaGam B is a purified hepatitis B surface antibody (ant-HBs) that is specific for the hepatitis B virus. Patients who undergo hepatitis B-related liver transplantation require long-term post-transplant prophylaxis with hepatitis B immune globulin.

Clinical trial data showed the biologic was highly effective at preventing hepatitis B recurrence and the dosing regimen used consistently yielded anti-HBs levels that exceeded target therapeutic levels. In a trial of HBV-infected persons undergoing liver transplantation, the study found a reduction in virus recurrence rate from 86% to about 13%. Adverse reactions were similar to other immune globulin products for other indications and included headache and hypertension.

HepaGam B is manufactured by Cangene Corp. (Winnipeg, Canada). It was approved last year by the FDA for treatment after acute exposure to blood containing HBsAg, perinatal exposure of infants born to HBsAg-positive mothers, sexual exposure to HBsAg-positive persons, and household exposure to persons with acute hepatitis B virus infection. It was approved earlier this year by Health Canada for prevention of hepatitis B recurrence after liver transplantation in adult patients.

"This approval provides a new treatment option for the reduction of hepatitis B recurrence in liver transplant patients with a prior history of this serious disease," said Jesse Goodman, MD, MPH, director of FDA's Center for Biologics Evaluation and Research. "It is the first immune globulin product—one of several classes of proteins derived from human plasma—approved for this use."

In terms of patient safety, as with other products made from human plasma, Hepagam B may carry a risk of transmitting infectious agents such as viruses and, theoretically, the Creutzfeldt-Jakob disease agent. Individuals known to have severe, potentially life-threatening reactions to human globulin should not receive HepaGam B or any other immune globulin (human). Individuals who are deficient in immunoglobulin (Ig)A may have the potential for developing IgA antibodies and have severe, potentially life-threatening allergic reactions.

The FDA also warns that the maltose contained in HepaGam B can interfere with some types of blood glucose monitoring systems. Only testing systems that are glucose specific should be used in patients receiving HepaGam B. This interference can result in falsely elevated glucose readings that can lead to untreated hypoglycemia or inappropriate insulin administration, resulting in life-threatening hypoglycemia.

HCV Findings Presented at EASL: Long-Term Follow-Up and the Criteria of a Cure

Sustained virologic response (SVR) rates of up to 60 have been reported with peginterferon alfa plus ribavirin in Genotype 1 HCV mono-infected patients. Although the benefits of viral eradication have been well established, the overall durability of an SVR is less well known.

A study led by Dr Mark G. Swain, Professor of Medicine, Gastrointestinal Research Group, at the University of Calgary, Canada, sought to quantify the long-term durability of an SVR achieved with peginterferon alfa-2a, administered as monotherapy, or as combination therapy with ribavirin.