Gastroenterology News

Anil K. Rustgi, Section Editor

New AGA President Outlines Goals

The new President of the AGA is Dr. Daniel K. Podolsky, Mallinckrodt Professor of Medicine at Harvard Medical School and Chief of Gastroenterology at Massachusetts General Hospital. Dr. Podolsky says he plans to pursue 4 major goals during his presidential tenure.

"The first is to build on recent successes in expanding the programs available to practicing gastroenterologists, particularly initiatives in support of practice begun by the AGA's Clinical Practice Session and the Committee on Practice Management and Economics."

Podolsky, the immediate past GASTROENTEROLOGY Editor-in-Chief, notes that his second goal involves further development of the AGA's long-term research agenda. "A prime priority is moving forward an initiative begun by AGA to obtain a Congressional mandate for a national commission on digestive disease research needs." This would include developing a long-term national strategy for funding this research.

Daniel K. Podolsky, M.D.

Podolsky says he also intends to focus on "laying the groundwork for expanded AGA direct support for research through the development of a research endowment under the auspices of the group's foundation. Third, his plan is to develop substantive partnerships and collaborations with other GI societies in Latin America, Europe, and Asia."

Podolsky says his fourth goal is to continue the process begun earlier at AGA to create a new strategic plan, "and with that to look at changes in governance and decision-making which would allow it to be more effective in meeting the breadth of its agenda. In particular, we intend to consider the specific needs of the core constituencies which collectively make up our diverse organization, while not losing sight of our overall commitment to advancing the field of gastroenterology."

Novel Coronavirus Associated With SARS Outbreak

Two independent "early release" original articles in the online edition of *The New England Journal of Medicine* (April 10), "provide strong evidence" that a novel coronavirus is involved in the etiology of the severe acute respiratory syndrome (SARS).

The articles were based on studies led, respectively, by scientists from the U. S. Centers for Disease Control (CDC) and Prevention and the Bernard–Nocht Institute for Tropical Medicine, Hamburg, Germany. In a search for unknown viruses, both groups analyzed clinical specimens from patients with SARS using cell culture and molecular techniques (Figure 2).

"We received clinical specimens from patients in 6 countries and tested them, using virus isolation techniques, electron-microscopical and histologic studies, and molecular and serologic assays, in an attempt to identify a wide range of potential pathogens," the CDC report states. A variety of specimens (blood, serum, material from oropharyngeal swabs or washings, material from nasopharyngeal swabs, tissues of major organs collected at autopsy) was cultured. In terms of results, laboratory testing did not consistently identify any classic respiratory or bacterial respiratory pathogen, "However, a novel coronavirus was isolated from patients who met the case definition of SARS."

The Hamburg study involved specimens from patients in Hanoi, Vietnam, with suspected or probable SARS, also according to WHO case definition. Specimens also were sampled from healthy "contact" persons. Stool samples from patients in Germany served as controls. "Genetic characterization indicated that the virus is only distantly related to known coronaviruses (identical in 50% to 60% of the nucleotide sequence)," the authors state. "Virus was detected in a variety of clinical specimens from patients with SARS but not in controls.

"High concentrations of viral RNA of up to 100 million molecules per milliliter were found in sputum. Viral RNA was also detected at extremely low concentrations in plasma during the acute phase and in feces during the late convalescent phase. Infected patients showed seroconversion on the Vero cells (African green monkey kidney cells) in which the virus was isolated."

Meanwhile, on April 12, scientists at the British Columbia Cancer Agency in Vancouver, Canada, an-

nounced they had sequenced the genome of the new coronavirus suspected of causing SARS. Two days later, on April 14, the CDC announced it, too, had sequenced the genome for the coronavirus. According to the federal agency, while the findings are nearly identical, the significant difference is that the CDC-determined sequence has 15 additional nucleotides, which provides the important beginning of the sequence, CDC scientists said.

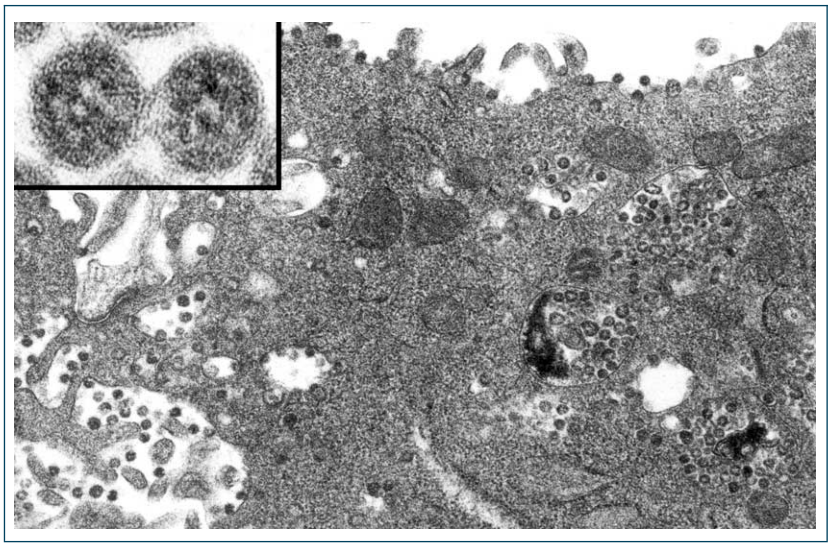

Figure 2. This thin section electron micrograph of infected Vero E6 cell, shows particles of coronavirus, suspected as the cause of severe acute respiratory syndrome (SARS). Other viruses are still under investigation as potential causes.

"The sequence data confirm that the SARS coronavirus is a previously unrecognized coronavirus. The availability of the sequence data will have an immediate impact on efforts todevelop new and rapid diagnostic tests, antiviral agents, and vaccines. This sequence information will also facilitate studies to explore the pathogenesis of this new coronavirus," the agency stated.

The CDC credits collaborators at National Microbiology Laboratory, Canada, University of California at San Francisco, Erasmus University, Rotterdam, and Bernhard–Nocht Institute, Hamburg for information that facilitated this sequencing effort.

The World Health Organization reported further evidence on April 15th that the new coronavirus causes SARS. In a Netherlands laboratory, primates experimentally infected intranasally with the virus developed an illness resembling SARS. WHO officials say the agency is "99% sure" that SARS is caused by a new coronavirus.

For the CDC's "interim" case definition of SARS, go to: http://www.cdc.gov/ncidod/sars/casedefinition.htm

Approval of Enteryx for GERD Recommended by FDA Panel

The Gastroenterology and Urology Devices Advisory Panel of the Food and Drug Administration has recommended that the agency approve endoscopic injection of Enteryx for the treatment of GERD. The material, EVOH and tantalum, is injected into the lower esophageal sphincter (LES), where it precipitates as a spongy material on contact with fluid, forming a physical barrier to reflux. The device works through modification of compliance of the LES due to the volume and mechanical properties of the Enteryx material and fibrous encapsulation of the material. It prevents sphincter shortening during gastric distention.

"It's an interesting and promising new technology. But it still needs to be studied," says Dr. Stuart Spechler, Chief of Gastroenterology at the Dallas VA Medical Center and Professor of Medicine at the University of Texas Southwestern Medical Center at Dallas. "We need good long-term studies, controlled clinical trials demonstrating safety and efficacy, before we can decide where this is going to fit into our armamentarium in the treatment of reflux disease."

Along with their recommendation, the advisory panel proposed several conditions for approval of Enteryx:

1. The patient information brochure should make it clear that patients who are not responsive to PPI are not candidates for treatment.
2. The labeling should state that the effects of re-treatment are unknown.
3. The labeling should note that the device is a permanent implant.
4. The patient information brochures and the product labeling should reword the sentence containing the word "lifelong" to state that the device is a "minimally invasive alternative to drug use or antireflux surgery."

"My bottom line is for clinicians is that we really need a lot more information before we should start using this on our patients," Spechler says.