The percentages of PsARC responders included ACR 70 response rates, and the Psoriasis Rheumatology's ACR 20, ACR 50, and 90 and the Physician's Global Assessment of Psoriasis. All of these uses are illegal. HGH is the only Food and Drug Administration (FDA) approved product that can only be prescribed for the approved indications. In children, the approved indications are to treat growth hormone deficiency, chronic kidney disease, Turner syndrome, small for gestational age infants who do not catch up to normal range, Prader-Willi syndrome, idiopathic short stature, SHOX gene haploinsufficiency, and Noonan syndrome. In adults, HGH is legal for AIDS-related wasting syndrome, short-bowel syndrome, and growth hormone deficiency. Distribution of HGH, or possession with intent to distribute, for any off-label use is a felony, punishable with up to 5 years in prison and fines. Without question, those attempting to market or distribute HGH claiming it will aid healing, slow or reverse the aging process, or be scanning consumers and breaking the law,” warned Rep. Tom Davis (R-Va.), the oversight committee’s ranking Republican member. And yet, some estimate that illegal HGH sales far outweigh the sanctioned market. Dr. Thomas Perls told the House committee in February that anti-aging sales amount to $2 billion a year. “I personally have found Web sites of 279 antiaging clinics that advertise HGH treatment, and 26 pharmacies that distribute the drug to these clinics or sometimes directly to users,” said Dr. Perls of Boston University. “I have certainly discovered only a fraction of what exists out there,” he added. In a JAMA article in 2005, Dr. Perls said that legal sales of HGH in 2004 amounted to about $622 million annually. For a little more than 200,000 initial and refill prescriptions, according to data from IMS Health, a market research company (JAMA 2005;294:2086-90). Dr. Alan Rogol, a professor of clinical pediatrics at the University of Virginia, Charlottesville, also expressed dismay at the House hearing at what appears to be the growing misuse of HGH. Off-label use comes with increased risk of side effects such as acromegaly, and increased resistance or diabetes, said Dr. Rogol. He also said that in many cases, HGH purchasers were getting something other than HGH. The prices being advertised are too low, and “many of these preparations are taken orally and cannot be the protein hormone HGH, for it is not active by this route,” said Dr. Rogol, who testified on behalf of the Endocrine Society. Another potential danger is that of the illicit sales are of human tissue-derived pituitary growth hormone, which has been removed from the market because it has the potential to contain the pathogen that causes Creutzfeld-Jakob disease. And yet, some of this type of hormone is still available in Eastern Europe and through the Internet. It is my opinion for an adult there are no legitimate off-label uses,” Dr. Rogol emphasized in an interview. But both Dr. Rogol and Dr. Hellman acknowledged that there were nonphysician or physician prescribers. It’s in the public interest to keep a registry or to create some other way to keep track of HGH use, Dr. Hellman said. Physicians legitimately using HGH “should have no problem having their work scrutinized,” he said.

Unapproved IV Colchicine Drugs Face FDA’s Teeth

Companies marketing unapproved drugs that contain injectable colchicine to treat gout have 30 days to stop manufacturing and 180 days to stop shipping the drug, which has caused 23 reported deaths, according to the U.S. Food and Drug Administration. All injectable colchicine drugs on the market 180 days after the FDA’s announcement on Feb. 6 must have the agency's approval. Refusal could result in regulatory action, including seizure, injunction, or other legal action, according to the FDA statement. The enforcement measure marks the seventh action taken by the agency against companies marketing and selling unapproved drugs since issuing a Compliance Policy Guide. Colchicine tablets will remain on the market for now. Injectable colchicine has been approved for treatment of gout in the U.S. since the 1970s. It is rarely administered because its use results in harm in the absence of gout.

For more information on the FDA’s action, please go to http://www.fda.gov/cder/drug/unapproved_drugs/colchicine_qa.htm.