NEWS IN BRIEF

NOTED

• Leaders of the U.S. Congress expect to pass a continuing resolution in September to fund the federal government at current levels through March, avoiding a possible government shutdown before the fall election. The agreement does not affect the automatic budget cuts ("sequestration") scheduled to arrive in January if suitable measures are not taken to reduce the federal deficit. The cuts would be expected to take a $2.4-billion bite out of the NIH budget.

• For $3 billion in cash, GlaxoSmithKline will buy Human Genome Sciences (HGS) of Rockville, MD. Among its cancer projects, HGS is running a randomized phase II trial of mapatumumab with sorafenib (Nexavar; Onyx Pharmaceuticals and Bayer Healthcare Pharmaceuticals) in advanced hepatocellular cancer.

• The American Society of Clinical Oncology (ASCO) is creating a breast cancer-specific prototype for CancerLinQ, the society’s initiative for a rapid learning system in cancer care. CancerLinQ is designed to assemble and analyze millions of unconnected medical records in a central knowledge base. Among its benefits, CancerLinQ will let investigators explore clinical data in unprecedented ways and generate research hypotheses, according to ASCO.

• Dendreon of Seattle, maker of the prostate cancer immunotherapy treatment Provenge (sipuleucel-T), has cut 600 jobs and will close 1 of its 3 manufacturing sites, as it seeks to reduce its annual costs by about $150 million.

• The NIH is expanding access to the NIH Clinical Center in Bethesda, MD, to extramural researchers. The nation’s largest hospital devoted entirely to clinical research, the center until now exclusively served the agency’s intramural research program. A new grant program, Opportunities for Collaborative Research at the NIH Clinical Center, will support partnerships with outside researchers.

• Global spending on oncology drugs will reach at least $93 billion in 2016, making this the largest category among total drug spending, which will near $1.2 trillion that year, predicts a report from the IMS Institute for Healthcare Informatics of Parsippany, NJ.

Compounds (with data from the Developmental Therapeutics Program), including 102 U.S. Food and Drug Administration–approved drugs.

The NCI team is completing additional database analyses, and will soon add comparative genomic hybridization and whole-exome sequencing databases and tools.

Industry Gains Incentives for Drugs for Children

The U.S. Food and Drug Administration (FDA) reauthorization bill signed into law by President Obama in July adds provisions intended to bolster drug development for rare childhood diseases such as cancers.

Known as the FDA Safety and Innovation Act, the bill establishes a more stable business environment for drug developers by permanently authorizing the Best Pharmaceuticals for Children Act and the Pediatric Research Equity Act.

Unfortunately, those 2 acts have given little economic incentive to develop drugs that are specific for rare pediatric diseases, contributing to a long-standing gap for childhood therapeutics, including those for cancer. “The gap is growing as our knowledge of molecular mechanisms increases, and we are learning that diseases require specific pediatric therapies, which one can’t simply move directly from the adult to the pediatric realm,” comments Peter Adamson, MD, chair of the Children’s Oncology Group and chief of clinical pharmacology and therapeutics at the Children’s Hospital of Philadelphia.

The FDA bill tackles this lack of incentives head-on in an unusual way: Manufacturers who get a drug for a rare pediatric disease approved and on the market earn a voucher requiring the FDA to review a second drug within 6 months of submission of an application for its approval. Proponents say the vouchers will be significant assets for companies and will act as major incentives to create pediatric drugs.

However, the act does not incorporate proposals to extend the existing legal requirements by mandating consideration of appropriate pediatric testing of molecularly targeted oncology drugs approved for adult use that may be effective against other types of cancer in children.

BY THE NUMBERS

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