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Debt Deal Leaves Labs, Pathologists Vulnerable to Payment Cuts

Key threats are Medicare spending cuts that could be made by a joint House-Senate committee and approved by Congress or triggered automatically if no deficit-reduction bill is enacted.

The debt ceiling deal reached Aug. 2 by Congress and the White House exposes clinical laboratories and pathologists to potential Medicare cuts under several scenarios.

The legislation, the Budget Control Act (S. 365), raises the debt ceiling through 2012, includes no tax increases, and requires trillions in federal spending cuts in two stages. Medicare is off the table in the first, but not in the second.

The initial stage calls for $900 billion in discretionary spending cuts over 10 years, which could affect agencies within the U.S. Department of Health and Human Services, including the National Institutes of Health and the Centers for Disease Control and Prevention.

In the next round, a bipartisan committee takes center stage. Composed of 12 members, six Democrats and six Republicans, from the House and the Senate, its task is to come up with an additional $1.2 trillion to $1.5 trillion in savings over 10 years, beginning in 2013 *(related story, p. 3)*.

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Myriad Wins in Challenge to Gene Patents

A divided federal appeals court has upheld an appeal by Myriad Genetics that challenged a lower court's ruling that its patents on the BRCA1 and BRCA2 genes were invalid because they are products of nature.

In a 2-1 decision, the U.S. Court of Appeals for the Federal Circuit ruled that Myriad's patents are valid because they involve DNA isolates that are "markedly different" in molecular composition than the DNA that exists in chromosomes in the body.

Not surprisingly, the biotech firm, based in Salt Lake City, hailed the decision for siding with its view that the isolates are "new chemical matter with important clinical utilities which can exist only as a product of human ingenuity," said company president and CEO Peter Meldrum.

The decision also benefits the biotechnology, agricultural, and pharmaceuticals industries that rely on strong patent protection to develop products to better people's lives, he said. But the broad coalition of providers, researchers, and patients that filed suit against Myriad says the patents stifle research and curtail women's access to a lifesaving test. For more, see the *Focus*, p. 4-5.

INSIDE *NIR*

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Labs, Pathologists Vulnerable, *from p. 1*
The committee has a tight timetable. Its recommendations are due by Nov. 23, and Congress must take a straight up-or-down vote on them, with no amendments or filibuster, by Dec. 23. The president retains veto power, however.

Fending Off Lab Coinsurance and Worse

Clinical lab groups are mobilizing to see that the committee does not recommend coinsurance for Medicare lab services (exempt from beneficiary cost sharing since 1984 in the switch to the Part B fee schedule), any further cut in fee schedule reimbursement, or both. The threat of coinsurance popped up in the debt ceiling negotiations as an option to establish, as a matter of principle, a uniform 20 percent coinsurance for all Medicare services.

The American Clinical Laboratory Association (ACLA), in its grassroots outreach materials to get members to lobby their senators and representatives during the August congressional break, notes that cost sharing for lab services means more out-of-pocket expense for beneficiaries and higher administrative costs for labs, which must bill for and collect the coinsurance, even though the average amount owed is less that the time and expense to collect it.

It also runs counter to the government's emphasis on prevention and wellness. This year, beneficiary cost sharing was eliminated for most Medicare-covered screening services.

Lab services inform an estimated 70 percent of medical decisionmaking but comprise only 1.6 percent of Medicare spending, ACLA points out. And labs have sustained multiple fee schedule cuts over the past two decades, resulting in a reduction of about 40 percent in real (inflation-adjusted) terms. More cuts are ahead under the health care reform law. It mandated an annual cut of 1.75 percent for five years (starting this year), a cumulative 9 percent cut that is the largest among all Part B providers.

Also under the law, labs will take an additional permanent cut through a productivity adjustment to the consumer price index (though this could never make the fee schedule update fall below zero). The adjustment will amount to an added 11 percent cut over 10 years.

The hardest-hit labs, ACLA says, will be independent labs serving rural or nursing home populations. In some cases, Medicare beneficiaries are 80 percent or more of the patient base. Further cuts would be devastating to their business and would likely force them to curtail services or close their doors.

Overhauling Physician Payment Policy

Pathology and other medical groups are working to have the committee include in its recommendations a repeal of the sustainable growth rate (SGR) system used to update the Medicare physician fee schedule. The deal did not include SGR repeal or any fix to the looming SGR cut of nearly 30 percent in Medicare physician reimbursement as of Jan. 1, 2012.

It remains to be seen whether an SGR fix will be part of the committee's deliberations or taken up separately. The current thinking in Washington, according to well-placed sources, is that the former course is likely. The American Medical Association is

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pushing to have the committee repeal the SGR, block the 2012 cut, provide stable fee increases over five years, and introduce alternative payment and delivery models that achieve quality care, lower costs, and program savings.

Finding the money to pay for fundamental physician payment reform over 10 years (estimated price tag: $300 billion) or even another short-term physician fee fix could tempt lawmakers to offset the cost of either remedy by cuts elsewhere in the Medicare budget, including lab spending.

If All Else Fails

If the House-Senate joint committee fails to achieve a majority on a compromise package to achieve savings of at least $1.2 trillion over 10 years or if Congress or the president do not go along the panel's recommendations, this would trigger automatic cuts of that amount split between defense and nondefense spending beginning in 2013.

Medicare provider payments would be cut, limited to 2 percent of total program spending. This sequestration, however, would not involve any cut in Medicare benefits or added cost sharing or any cuts in Medicaid, Social Security, or veterans' benefits.

While labs are designated as "suppliers" under Medicare, not providers, industry sources told *NIR* they are operating under the assumption that labs could be ensnared in the provider payment reductions. Said one Washington source, "I think there is no practical difference for these purposes between providers and suppliers and labs would be vulnerable to payment reductions in the sequestration process."

Who's Who on Deficit Reduction 'Super Committee'

The debt ceiling deal reached Aug. 2 by Congress and the White House required formation of a bipartisan 12-member House-Senate "super committee" to recommend at least $1.2 trillion in savings over the next 10 years. The panel has roughly three months to craft a package that Congress must vote up or down, with no amendments or filibuster, before Christmas.

House Speaker John Boehner (R-Ohio) has named the following GOP members to the panel: Ways and Means Chairman Dave Camp (Mich.), Energy and Commerce Chairman Fred Upton (Mich.), and Republican Conference Chairman Jeb Hensarling (Texas). Hensarling will be the "super committee" co-chair.

Senate Majority Leader Harry Reid (D-Nev.) has appointed the following Democrats to the panel: Patty Murray (Wash.) as the committee's co-chair, Finance Committee Chairman Max Baucus (Mont.), and John Kerry (Mass.). On the Republican side, Minority Leader Mitch McConnell (Ky.) has selected Jon Kyl of Arizona, Pat Toomey of Pennsylvania, and Rob Portman of Ohio.

At press time, House Minority Leader Nancy Pelosi (D-Calif.) had yet to name her picks for Democratic members of the panel.

G2 Intelligence notes there is a great deal of skepticism about whether the joint committee can achieve a majority compromise package and avoid a stalemate. McConnell has said his picks will oppose any revenue increase, while Pelosi has said Medicare cuts would not be acceptable without a revenue increase.

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focus on: Genetic Testing

Court Upholds Myriad's Gene Patents: Boon or Bane?

Yes, Virginia, companies can patent and control your genes. They cannot, however, patent methods to compare the gene sequences.

That, in a nutshell, is the long-awaited judgment of a federal appeals court that has upheld patents granted to Myriad Genetics and the University of Utah Research Foundation for the BRCA1 and BRCA2 genes associated with hereditary breast and ovarian cancer.

In a 2-1 decision released July 29, the U.S. Court of Appeals for the Federal Circuit (Washington, D.C.) ruled that the patented DNA isolates are "markedly different" in molecular composition from DNA that exists inside chromosomes in the body. As a result, they are not simply a product of nature, which would render them ineligible for a patent.

The decision is a clear win for Myriad, which had appealed a lower court ruling that essentially invalidated patents for its highly profitable BRACAnalysis® test, finding that the genes were a product of nature. Under patent law, products of nature, abstract ideas, and physical phenomena are patent-ineligible.

It also comes as a relief to biotechnology companies, many of which weighed in to support Myriad, because the case challenged the whole idea of gene patenting. Currently, about 20 percent of human genes are patented, including genes associated with Alzheimer's disease, muscular dystrophy, colon cancer, asthma, and many other illnesses.

To the broad-based coalition of plaintiffs that filed suit against Myriad, the appellate court ruling only serves to restrict scientific research and patients' access to medical care.

The landmark lawsuit was filed in May 2009 by the American Civil Liberties Union (ACLU) and the Public Patent Foundation on behalf of breast cancer and women's health groups, individual women, geneticists, and scientific association representing approximately 150,000 researchers, pathologists, and laboratory professionals (*Association for Molecular Pathology, et al. v. U.S. Patent and Trademark Office, et al.*). The College of American Pathologists and the American Society for Clinical Pathology were among the co-plaintiffs. In March 2010, senior judge Robert W. Sweet of the U.S. District Court for the Southern District of New York ruled in the plaintiffs' favor.

In Sweet's opinion, Myriad's patents on BRCA1 and BRCA2 were ruled invalid, because the isolated DNA was not really different from the DNA in the body and provides the same information. Writing for the majority in the appellate decision, judge Alan D. Lourie rejected this reasoning, saying that since DNA is a chemical, the chemical structure is what matters and that "informational content is irrelevant to that fact." In dissenting, judge William C. Bryson said that extracting a gene "is akin to snapping a leaf from a tree. Like a gene, a leaf has a natural starting and

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stopping point. It buds in the spring from the same place that it breaks off and falls during autumn. Yet prematurely plucking the leaf would not turn it into a human-made invention."

The ACLU called the latest ruling a blow to the idea that patent law cannot impede the free flow of ideas in scientific research. "Human DNA is not a manufactured invention, but a natural entity like air or water," said Chris Hansen, a staff attorney with the ACLU Speech, Privacy, and Technology Project. "To claim ownership of genetic information is to unnecessarily block the free exchange of ideas."

The appeals court also rejected arguments by the Obama administration which, in its friend-of-the-court brief, contended that isolated DNA should not be patented and that many of the gene patents issued by the U.S. Patent Office are invalid.

As the patent holder, Myriad has the exclusive right to perform diagnostic testing on the BRCA genes, to license the testing to other users, and to threaten litigation for patent infringement against any unlicensed use of the genes.

Myriad has held these patents since the late 1990s. But it was not the only entity to implement clinical BRCA testing services. Starting in 1996, the University of Pennsylvania's Genetic Diagnostic Laboratory (GDL), co-directed by plaintiffs Haig H. Kazazian Jr., M.D., and Arupa Ganguly, Ph.D., provided BRCA1/2 diagnostic services to women. By 1999, however, accusations by Myriad that GDL's BRCA testing services infringed its patents forced the lab to stop providing such services.

Critics say the patents give Myriad a monopoly on the BRCA genes, making it impossible for women to access alternate tests or get a comprehensive second opinion about their results. It also allows Myriad to charge a high price for its BRACAnalysis® test.

Appellate Ruling on Method Claims

Myriad did not prevail, however, on its patent claims on the process of analyzing whether a patient's genes had mutations that raised the risk of cancer. The court said the process was not patentable because it involved only "patent-ineligible abstract mental steps."

While the court held that five of the company's six method claims at issue did not satisfy the patent-eligibility requirements, Myriad noted that, "with respect to the BRCA1 and BRCA2 genes, it has 237 method claims for the BRACAnalysis test which were not affected by this ruling and remain in full force and effect providing Myriad with equally strong method of use patent protection."

Myriad did persuade the appellate court to reverse the lower court's ruling that its method claim to screening potential cancer therapeutics via changes in cell growth rates is directed to a patent-ineligible scientific principle. The appeals court said this involves "transformative" steps and thus can be patented.

What's Next?

The original plaintiffs in the case have some options if they want to move forward, said Hansen: seek a rehearing before the same three-judge panel, petition for a rehearing en banc (before all members of the Court of Appeals for the Federal Circuit), or ask the U.S. Supreme Court to hear the case. At press time, it was unclear what direction the plaintiffs will choose.

Although the case could be appealed to the Supreme Court, industry analysts believe Myriad will retain its patent-protected position for its BRACAnalysis test for some time.

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Snapshot of National Health Care Spending

Annual health care spending in the United States is expected to increase at a higher rate (5.8 percent) over the next 10 years than the estimated annual growth in the economy (4.7 percent) over that same period, according to a July 28 report released by the Centers for Medicare and Medicaid Services (CMS).

The rise in health care spending is attributed mainly to expanded Medicare coverage and other changes mandated by the health care reform law (the Patient Protection and Affordable Care Act, PPACA). However, the projected 5.8 percent annual growth is only 0.1 percentage point higher than it would be without the reform law. That law is expected to expand access to health care for an estimated 30 million people by 2020.

This year, national health care spending is projected to be $2.7 trillion, but by 2020 it will hit $4.6 trillion, fueled largely by growth in the aging population and expanded coverage of Americans under the health care reform law, according to the annual report by CMS economists and actuaries. The report is published online in the health policy journal Health Affairs *and will also appear in the journal's August issue.*

The portion of the gross domestic product (GDP) devoted to health care spending, currently about 17.6 percent, is expected to reach 19.8 percent by 2020, accounting for nearly one-fifth of the economy.

In releasing the report, CMS officials noted some important caveats. The spending projections "remain subject to substantial uncertainty given the variable nature of future economic trends and a lack of historical experience" with PPACA. They also do not mirror any changes due to a deficit-reduction deal reached by Congress and the White House.

Highlights of the Big Picture

- ❏ In 2010, reflecting the recent recession, all health care spending is expected to grow only 3.9 percent, a historically low rate, down 0.1 percentage point from a previous low of 4 percent in 2009.
- ❏ In 2014, due to PPACA's expansion of public and private health care coverage, health care spending is expected to grow by 8.3 percent, compared with 5.5 percent in 2013. Beginning in 2014, new eligibility guidelines for Medicaid and the start of state-based health insurance exchanges will enable millions of the currently uninsured to obtain health insurance.
- ❏ In 2014, spending on prescription drugs and physician and clinical services will grow faster than spending on hospital services because the newly insured Americans will be younger and healthier on average than those currently insured.
- ❏ By 2020, prescription drug spending will account for 11 percent of national health spending, a jump of one percentage point over the spending rate in 2013 (10 percent).
- ❏ In 2014, spending on physician and clinical services will grow by 8.9 percent, an increase of 3.1 percentage points and $17.8 billion over what the spending would have been in the absence of the health care reform law. By 2020, physician and clinical services spending is projected to account for 19 percent of national health spending, unchanged from 2013.
- ❏ By 2020, the share of health spending by all levels of government will increase to 49 percent (or a total of $2.3 trillion), compared with 44 percent in 2009. The federal government will pick up two-thirds of that share.

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- ❏ Medicare spending will grow by only 1.7 percent in 2013, compared with a 5.9 percent rate in 2011. However, the report cautions, this assumes scheduled physician payment reductions under the current update formula, and Congress has repeatedly blocked such scheduled reductions.

- ❏ Medicare expenditures are expected to increase about 6.4 percent a year during 2015-2020, as Medicare enrollment grows at an average rate of 2.9 percent due to the influx of eligible baby boomers. The full impact of increased enrollment will be offset by provisions in PPACA that call for reduced fee-for-service payments to Medicare providers.

- ❏ Medicaid spending growth is expected to increase substantially—to about 20.3 percent per year—beginning in 2014 because of the expanded eligibility provisions in PPACA. By 2020, Medicaid is projected to account for nearly 20 percent of national health spending, up from 15 percent in 2009.

FDA Speaks Out on In Vitro Companion Diagnostics

In much-anticipated draft guidance to industry, the Food and Drug Administration (FDA) is proposing that in vitro diagnostic (IVD) devices and the corresponding therapeutic product be approved or cleared contemporaneously, wherever possible, for the use indicated in the product's labeling.

Comments on the draft guidance will be accepted until Sept. 12, 2011. The guidance is available online at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm262292.htm.

The guidance, announced July 12, clarifies FDA's definition of a companion diagnostic, urges manufacturers to engage early with the agency so that its expectations are included in development plans, and highlights the FDA's intention to conduct simultaneous reviews of a drug or biologic therapy and its corresponding companion diagnostic.

There are instances where the FDA may approve a targeted medicine in the absence of a cleared or approved companion diagnostic. In cases where the therapy is intended to treat a serious or life-threatening disease or condition for which there is no available satisfactory treatment and when the potential benefits outweigh the risks of not having a cleared or approved companion diagnostic, the therapy could be approved first while the companion diagnostic may be approved or cleared later through the appropriate device submission process.

The FDA defines an IVD companion diagnostic device as an in vitro diagnostic device that provides information essential for the safe and effective use of a corresponding therapeutic product. The use is stipulated in the labeling instructions of both the diagnostic device and the corresponding therapeutic product, as well as in the labeling of any generic equivalents of the therapeutic product.

FDA does not include in this definition clinical laboratory tests intended to provide information to the physician regarding use of a therapeutic product but that information is not a determining factor in the safe and effective use of the product.

The guidance also notes that studies of companion diagnostics generally will be significant-risk devices requiring an investigational device exemption (IDE). FDA says that, in its experience to date, companion diagnostics generally will be Class III devices requiring premarket approval, but there could be instances where a 510(k) would be sufficient.

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Medicare Enrollment Alert: Time to Revalidate Your Status

The easiest and quickest way to revalidate enrollment information, advises CMS, is by using the Internet-based PECOS (Provider Enrollment, Chain, and Ownership System), at https://pecos.CMS.hhs.gov.

Providers and suppliers that enrolled in Medicare prior to March 25, 2011, must revalidate their enrollment under new risk-screening criteria required by the health care reform law. Providers and suppliers enrolled on or after March 25 have already been subject to this screening and need not revalidate at this time, said the Centers for Medicare and Medicaid Services (CMS).

Newly enrolling and revalidating providers and suppliers are placed in one of three categories: limited, moderate (including independent clinical labs), or high, each representing the level of risk to Medicare posed by the particular category of provider or supplier. This determines the degree of screening used by the Medicare Administrative Contractor (MAC) to process enrollment applications.

Between now and March 2013, MACs will be sending notices to individual providers and suppliers. Upon receipt, you have 60 days from the date of the letter to submit complete enrollment forms. Failure to do so may result in the deactivation of your Medicare billing privileges.

Reminder: August is a one-issue month for *NIR*.

Upcoming Events From G2

***Webinar** (2 p.m. – 3:30 p.m. Eastern)*

Aug. 17
Back to the Future: How the Proposed Lab Copay—and Other Medicare Changes—Could Impact Your Lab's Bottom Line

Conferences

Sept. 23
Molecular Diagnostics—Fall 2011
W San Francisco
San Francisco

Oct. 19
Lab Leaders Summit 2011
Come for the summit and stay for Lab Institute
Ritz-Carlton Pentagon City
Arlington, Va.

Oct. 19-21
Lab Institute 2011
Crystal Gateway Marriott
Arlington, Va.

Dec. 12-14
LabCompete: Laboratory Sales & Marketing
Sheraton Wild Horse Pass Resort
Chandler, Ariz.

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