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G2 INTELLIGENCE Upcoming Events

Conference:

Lab Institute 2017
October 25-27. Hyatt Regency Washington on Capitol Hill, Washington, DC
www.labinstitute.com

No Final LDT Framework in 2016: FDA Seeks Further Input from Stakeholders, New Administration

The U.S. Food and Drug Administration (FDA) has provided laboratories with some much needed good news—the agency will not finalize its laboratory-developed test (LDT) guidance document before the end of the year. In fact, the FDA confirmed Nov. 18 that it will instead work with the new administration on appropriate reforms to ensure LDTs are safe and effective.

According to a statement from the FDA, which G2 received in response to a request for confirmation of the status of the guidance document:

> "The FDA believes that patients and health care providers need accurate, reliable, and clinically valid tests to make good health care decisions—inaccurate or false test results can harm individual patients. We have been working to develop a new oversight policy for laboratory developed tests, one that balances patient protection with continued access and innovation, and realize just how important it is that we continue to work with stakeholders, our new Administration, and Congress to get our approach right. We plan to outline our view of an appropriate risk-based approach in the near future. It is our hope that such an approach will help guide continued discussions."

Agency representatives had previously indicated an intent to release before the end of 2016 a final version of the draft guidance document released in October 2014. That guidance set forth a framework for FDA oversight of LDTs.

Continued on page 2

What Trump Administration Could Mean for ACA and Labs

Now that the election has concluded, labs and others in the health care industry have a new concern—what will the fallout be? President-elect Trump promised throughout the campaign to repeal the Affordable Care Act (ACA). Many have expressed concern about what will happen if he makes good on that promise.

In a Nov. 14, 2016 press conference, however, President Obama cautioned that "the federal government and our democracy is not a speedboat, it's an ocean liner" and it takes a lot of hard work and time to make major changes.

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■ No Final LDT Framework in 2016, *from page 1*

> *"We appreciate the FDA's acknowledgment that stakeholder input and the ongoing bipartisan work carried out in the House and Senate is the appropriate process to advance comprehensive statutory reform of the LDT regulatory framework."*
>
> — Alan Mertz, President, ACLA

Industry reaction mostly positive

The American Clinical Laboratory Association commended the agency's decision to work with lawmakers on LDT reforms, after having vigorously opposed the draft framework—even hiring high profile legal counsel and issuing a white paper in early 2015 detailing legal arguments against the FDA's authority to impose the framework. ACLA's legal team, former Solicitor General Paul D. Clement, now a partner with Bancroft PLLC, and Laurence H. Tribe, Professor of Constitutional Law at Harvard University, prepared a White Paper asserting that FDA regulation of LDTs is not supported in the language of the Food, Drug & Cosmetic Act (FDCA), the proposed regulation interferes with the practice of medicine, and FDA guidance flouts administrative law requirements for rulemaking.

"We appreciate the FDA's acknowledgment that stakeholder input and the ongoing bipartisan work carried out in the House and Senate is the appropriate process to advance comprehensive statutory reform of the LDT regulatory framework," said ACLA President Alan Mertz in a statement. "Today's announcement by the FDA has paved the way for a transparent discussion on meaningful reform that would protect diagnostic innovation and patient access."

Other laboratory industry stakeholders expressed similar happiness at the delay, as did congressional leaders who had been promoting alternatives to the FDA's framework, including Energy & Commerce Committee Chairman Fred Upton who stated it "was the right call" and imposing regulations "via non-binding guidance documents is not the best approach." He indicated the committee is working on bipartisan solutions and "forging significant consensus among a number of patient groups, labs, and manufacturers around a 21st century approach uniquely designed with all diagnostic tests in mind from the outset."

But not everyone is ecstatic about the delay. Andrew Fish, executive director of AdvaMed Diagnostics, a trade association serving the medical device industry issued a statement indicating that "AdvaMedDx is disappointed that FDA final guidance on LDT oversight is not forthcoming at this time." Echoing Upton's comments, Fish mentioned the need for a broader look at diagnostics oversight as a whole saying AdvaMedDx was "encouraged by congressional interest" in LDT oversight "in the context of broader diagnostics reform legislation." The statement emphasizes the organization's commitment to working with all stakeholders to achieve legislation addressing "risk-based oversight of all diagnostics, including LDTs" and stated it was "imperative that this legislation recognizes FDA's critical oversight role and serves public health and innovation, and we hope FDA will share its current thinking on LDT oversight to help inform the legislative discussion."

Delayed but not forgotten

As can be seen from AdvaMedDx's reaction to the delay, continued conversation is welcomed but concern regarding LDTs isn't going away.

Health care attorney Danielle Sloane, of Bass Berry & Sims in Nashville, commented that "Laboratories are collectively breathing a sigh of relief at the FDA's

announcement in conjunction with the knowledge that congressional action is also less likely to come to fruition under the new administration. However, the issues that drew the FDA's concern remain, so I expect to see continued FDA vigilance in the market, particularly with respect to direct-to-consumer marketing of laboratory tests and situations in which the ordering practitioner is affiliated with the performing laboratories."

> *"[T]he FDA's announcement focuses on balancing patient protections and innovation which is really where the sticking point has been in the whole debate."*
>
> — Jen Madsen, MPH, Arnold & Porter

Highlighting the same concerns Mertz mentions in ACLA's statement, Jen Madsen, MPH, a health policy advisor at Arnold & Porter in Washington, DC, points out that "the FDA's announcement focuses on balancing patient protections and innovation which is really where the sticking point has been in the whole debate." She predicts that if Congress does not pass compromise legislation in the upcoming user fee negotiations in 2017, it could be a significant period of time before a revised regulatory approach emerges, given that it will take some time for the new administration to get people sworn in, including a new HHS Secretary.

"One barrier to congressional action is the lack of consensus in the community" about the right path to regulate LDTs, so the situation "will remain ambiguous for at least a while." Noting various stakeholders favor modernization of CLIA in addition to or in place of heightened FDA involvement in LDT oversight, Madsen adds "the device industry has also been arguing that statutory change is needed" because the FDA's medical device regulatory framework doesn't apply perfectly to diagnostics, she says, "so there are arguments that a different review process is needed for all diagnostics, not just lab tests."

This latest status update regarding FDA efforts is not a vast change from the agency's prior statements other than to step away from its indication it would finalize the framework this year. The expressed intent to work with stakeholders and Congress in addition to the new administration is in keeping with steps outlined in December 2015 by Jeffrey Shuren, director of the FDA's Center for Devices and Radiological Health, at a hearing before the U.S. House of Representatives Energy and Commerce Committee. Shuren indicated then that the agency planned the following steps before finalizing the guidance:

- Coordinate with CMS on laboratory oversight and FDA plans to develop draft guidance regarding quality system requirements for LDTs, "to provide clarity for laboratories on how they can leverage compliance with CLIA requirements to satisfy those applicable FDA guidelines";
- Work with CMS and accrediting bodies and CLIA-exempt state laboratory programs, "to identify any potential overlaps between CMS and FDA activities" and look for ways to increase efficiency; and
- "Ongoing meetings with stakeholders, including laboratories, patients, traditional IVD manufacturers, and medical practitioners."

Takeaway: Labs get at least a temporary reprieve from increased oversight of laboratory-developed tests as the FDA waits for the new administration and further congressional and stakeholder input.

What Trump Administration Could Mean for ACA and Labs, *Continued from bottom of p.1*

He also advised that the new administration must consider how various issues will play themselves out before committing to specific courses of action. He specifically mentioned doing away with Obamacare has been the "holy grail" for Republicans and advised that the new administration must take a look at the program and see what works before taking action. And already, it seems that President-elect Trump is doing just that, as he has indicated some measures initiated under the ACA will remain.

Immediate change faces significant hurdles

To demonstrate the ocean liner analogy that President Obama described, here are some challenges that will slow down any major changes:

- **Filibuster.** Our existing legislative processes do present a challenge to repealing ACA entirely. "One would assume once you have Republican control of both the House and Senate you should have an easier time enacting legislation," said Bill Hoagland, senior vice president of the Bipartisan Policy Center. But he explains that while the Republicans have control of both the House and the Senate, there are fewer than 60 Republicans in the Senate which is the "critical number to overcome a filibuster." "There is a firewall or a check and balance against policy," he explains. Thus, any action taken through a regular process will require some bipartisanship, he explains, particularly in the Senate.
- **Unpopularity.** Not only does President-elect Trump enter the office with a low popularity rating —as evidenced by demonstrations in which many constituents angrily declare he is "not [their] president" —but the members of Congress are also plagued by popularity woes, with a November Gallup poll showing only 11% of Americans approve of Congress. The silver lining is that this unpopularity could be an incentive for both sides to work together, suggests Hoagland.
- **State insurance role.** One of the proposed changes to health care insurance is to allow insurers to sell across state lines. Hoagland points out, however, that state policies could be a stumbling block—state insurance commissioners set rates and policies. Additionally, there is concern that such sales could create a race to the bottom, he adds.
- **Packed agenda.** "Congress has a lot on their plate," notes Hoagland. As he discussed in his keynote presentation at G2's recent Lab Institute in Washington, D.C. the federal debt limit comes up in March—requiring Congressional attention—and Congress also will need to address Supreme Court, Cabinet and other appointments. That packed agenda could delay or slow down any legislative action with regard to health care.

Hoagland does anticipate there will ultimately be a more active legislative agenda in the new administration with efforts in both the house and senate to make major changes to the ACA and tax reform. "It won't be as quick and as fast as Mr. Trump thinks it will happen and that will hopefully afford an opportunity for a more bipartisan approach."

Complete repeal already scaled back

Although significant details of any plan remain to be revealed, President-elect Trump has already stepped back from total repeal by indicating in an interview with 60 Minutes and in other statements that he intends to keep the ACA provisions

concerning pre-existing conditions and children remaining on parent's health insurance until age 26.

It is also noteworthy that in a Nov. 21 video update about the policy plans for the first 100 days, President-elect Trump mentioned several initiatives his administration will tackle in the first 100 days with executive actions that will be implemented "day one." The only reference to health care at all came when he stated his agenda is based on a core principle of "putting America first" and making sure the "next generation of production and innovation" happen in America, whether it be "producing steel, building cars or curing disease"—and this statement was made in the context of creating jobs and wealth for American workers.

Budget reconciliation option for change

There is one alternate route to make changes more swiftly or easily for the new administration and that is the budget reconciliation act process—which only requires a simple majority, Hoagland says. He cautions that if that reconciliation path is used to repeal the ACA without any democratic support it could cut a rough path forward for any policies approved in that process and highlighted the risk that lab copays could make a reappearance

Alan Mertz similarly cautioned the attendees at G2's recent Lab Institute to watch what might be included in any budget reconciliation legislation that could impact labs.

Value focus unlikely to change

Another question on the forefront of laboratories and other providers is any potential impact on reimbursement reforms such as PAMA and MACRA and the shift to value-based health care delivery and payment models. "Republican and Democratic policy analysts [agree] that fee-for-service reimbursement system is part of the problem of cost escalation," responds Hoagland. He doesn't foresee a change in that focus on shifting from fee-for-service to value-based reimbursement. "It's hard to argue against paying for value."

Takeaway: Though change to ACA and health care systems may be coming, it may not come quickly or be as wholesale as promised or anticipated. G2

Texas Federal Court Puts a Hold on Overtime Pay Change

Employers were set to face a new Fair Labor Standards Act (FLSA) rule that was to go into effect on Dec. 1, 2016 and would double the minimum salary threshold for the overtime exemption—rendering more than 4 million employees eligible for overtime. But on Nov. 22, a Texas federal court granted a reprieve, issuing a preliminary injunction preventing the change from taking effect until the court has a chance to decide the issues raised in litigation challenging the change to the overtime exemption. More than 20 states and numerous business groups sued to stop the change, claiming the requirement unconstitutionally regulates the states, forcing them to adopt a wage policy.

For further discussion and analysis of the court's decision and what it means for employers, see "Insight: The New Overtime Rules are Put on Hold. What Does That Mean for You?" written by guest blogger, Mike O'Brien, an employment attorney and litigator. *Insight* is a new feature available on the G2 Intelligence website and the *Lab & Pathology Insider* weekly email newsletter. G2

2017 Clinical Laboratory Fee Schedule Brings a Bit of Good News for Molecular Testing

The Centers for Medicare and Medicaid Services (CMS) issued the final 2017 Clinical Laboratory Fee Schedule (CLFS) on Nov. 21, providing an early holiday present for a small group of labs that provide new specialty molecular tests and dodged deep cuts proposed in the preliminary schedule.

Here is a look at some key changes you need to know about going into 2017:

Seven Molecular Assays Stave Off Big Cuts

16 CPT codes for molecular tests that CMS added to the CLFS this year were the subject of debate as CMS proposed interim gapfill prices for these esoteric and pricey assays, at a discount from their regionalized prices. Led by providers of the assays, the industry asked CMS to reconsider the interim rates. "The proposed gapfill rates are inconsistent with rates established by commercial payers and the Protecting Access to Medicare Act of 2014," contended The Coalition for 21st Century Medicine.

CMS apparently took heed, dropping the rate cuts and either restoring or increasing the regional prices for seven of the 16 tests listed. Companies benefiting from the change of course included:

- **CareDx**, which instead of a 77 percent cut got a 47 percent increase on its AlloMap test to identify heart transplant recipients at low risk of rejection (CPT 81595);
- **Biodesix**, which got a 57 percent hike on its Veristrat lung cancer aggressiveness test (81538);
- **Genomic Health**, which got a 51 percent hike on its Oncotype DX colon cancer recurrence test (81525);
- **BioTheranostics**, which got a 23 percent hike on its metastatic tumor origins diagnostic test (81540);
- **Invitae**, which avoided a 33 percent cut on its hereditary breast cancer panel (81432);
- **CardioDx**, which instead of a 28 percent cut got a modest 1.4 percent increase on its coronary artery disease risk test Corus CAD (81493); and
- **Veracyte**, which instead of a 22 percent cut got a 12 percent increase on its thyroid nodule assessment assay Affirma (81545).

2017 Medicare Rate for New Molecular Diagnostic Tests

(Tests for which discounts were proposed but not adopted are shown in **boldface**)

CPT Code	Test	Final National Limitation Rate	Proposed National Limitation Rate	2017 Price
81412	9-Gene Ashkenazi Jewish Screen	$597.91	$597.91	$597.91
81432	**Hereditary Breast Cancer Panel, 14 Genes**	**$925.00**	**$622.53**	**$925.00**
81433	Hereditary Breast Cancer, Duplications/Deletions Panel	$159.48	$159.48	$159.48
81434	Hereditary Retinal Disorder Screen	$597.91	$597.91	$597.91
81437	Hereditary Neuroendocrine Tumor	$597.91	$597.91	$597.91
81438	Hereditary Neuroendocrine Tumor, Duplications/Deletions	$597.31	$597.31	$152.21
81442	Noonan Gene Screen	$597.91	$597.91	$597.91

2017 Medicare Rate for New Molecular Diagnostic Tests, *Cont'd*

(Tests for which discounts were proposed but not adopted are shown in **boldface**)

CPT Code	Test	Final National Limitation Rate	Proposed National Limitation Rate	2017 Price
81490	Vectra Screen	$586.50	$586.50	$597.91
81493	**Corus CAD**	**$1,035.10**	**$741.01**	**$1,050**
81525	**Oncotype DX**	**$2,062.10**	**$848.86**	**$3,104**
81538	**Veristrat**	**$1,341.87**	**$283**	**$2,112**
81540	**bioTheranostics**	**$2,355.46**	**$1,522.17**	**$2,900**
81545	**Affirma**	**$2,864.45**	**$2,240.16**	**$3,200**
81595	**AlloMap**	**$1,920.98**	**$732.00**	**$2,821**
0009M	VisibiliT	$132.86	$132.86	$598
0010M	4K Score	$260	$260	$260

CMS also increased pricing for fetal aneuploidy trisomy risk testing (CPT 0009M) from $132.86 to $598.

New Pricing Formula for Differential Drug Testing G Codes

The other significant development in the final CLFS affects pricing of the four definitive drug tests capable of identifying individual drugs and distinguishing between structural isomers, for which CMS issued HCPCS G codes in 2016—G0480, G0481, G0482 and G0483. To pay for these tests, CMS used a crosswalking formula under which: i. the first two tests performed were paid at the full price of the crosswalk CPT code 82542; and ii. the remaining tests within that code were paid at 25 percent of the crosswalk price.

Industry asked CMS to modify the formula for 2017 claiming that it understates the true costs of performing accurate tests. They expressed concerns that physician office labs without quality control and multiple calibrations were generating a high volume of G0483 claims in the first part of 2016. CMS made two proposals to address their concerns:

- **Proposal 1:** Change the crosswalk formula to allow four tests to be priced at the full crosswalk price; and
- **Proposal 2:** Create a new G code to recognize labs that perform a less sophisticated version of differential drug tests.

In the end, CMS opted for Proposal 1. Allowing the four tests to be priced at the full crosswalk price should adequately recognize the resources required to perform these procedures, CMS explains.

New Formula for Crosswalking Price of G Code Differential Drug Tests

CPT Code	2017 Crosswalk Formula*
G0480	4 x 82542 + 3 x .25 x 82542
G0481	4 x 82542 + 10 x .25 x 82542
G0482	4 x 82542 + 17 x .25 x 82542
G0483	4 x 82542 + 25 x .25 x 82542

* Note: 82542 = full crosswalk price for CPT code 82542

Editor's Note: For information about revamped G Codes for Definitive Drug Testing as well as changes in the crosswalking of 14 existing CPT Codes, see www.g2intelligence.com/crosswalked-codes-in-2017-clinical-laboratory-fee-schedule-3.

Takeaway: Here are the three key things to know about the newly finalized CLFS:

1. *Proposed deep cuts in molecular diagnostic tests were not implemented—in several cases, CMS actually granted significant price increases.*
2. *The pricing formula for the four differential drug test G codes has been changed to allow for billing at the full crosswalk price of CPT 82542.*
3. *CMS crosswalked 14 G and CPT codes into existing CPT codes to eliminate duplication.*

4 Things about the OPPS Final Rule That Labs Need to Know

On Nov. 14, the Centers for Medicare and Medicaid Services (CMS) published in the Federal Register the Medicare Hospital Outpatient Prospective Payment System (OPPS) final rule for 2017. In case you do not have the time to read the hundreds of pages in the final rule, here is a summary of the four things lab and pathology managers need to know about it.

At a Glance: 2017 Payment Rates

OPPS rates for 2017 are going up by 1.65% based on the following factors:

- Market basket update of +2.7%;
- Productivity adjustment of -0.3%;
- Update for ACA payment cuts of -0.75%.

Overall, CMS estimates that OPPS payments will increase by 1.7% during the year.

1. Elimination of "-L1" Modifier for Unrelated Tests

Current Rules: Designated lab tests from the Clinical Laboratory Fee Schedule (CLFS) are among the ancillary and support services covered by the OPPS bundled rate paid to hospitals for services provided in the hospital outpatient department (HOPD). *Exception:* Lab tests appearing on the same claim as other hospital outpatient services are paid separately at the CLFS rate if they are "unrelated," i.e., ordered by a different practitioner for a different diagnosis. Hospitals use the "-L1" modifier to seek separate payment for "unrelated" tests.

Example: A physician does an in-office biopsy and sends the sample to the hospital lab for testing. Later that day, the same patient shows up at the ER with a lacerated elbow and receives blood testing. The hospital would add the blood test to the ED claim and use the "-L1" modifier to indicate that it was unrelated to the biopsy test.

New Rules: The final rule eliminates the "-L1" modifier. In addition to being confusing and hard to use, CMS determined that the modifier was no longer necessary. "We believe that, in most cases, 'unrelated' laboratory tests are not significantly different than most other packaged laboratory tests provided in the HOPD," the final rule explains.

Impact: From now on, all lab tests listed on a claim with other hospital outpatient services will be bundled into the OPPS payment, even if ordered by a different provider for a different diagnosis.

2. Expansion of Molecular Pathology Test Exception to ADLTs

Current Rules: Another exception to bundled payments is molecular pathology tests. *Reasoning:* These are relatively new tests with use patterns that differ from conventional lab tests. And because they are less tied to the primary service provided in the HOPD, they should be paid separately from the OPPS bundle.

New Rules: The final rule expands the OPPS packaging exemption to all advanced diagnostic lab tests (ADLT) regardless of whether they are molecular pathology lab tests. The same rationale for excluding molecular pathology lab tests from bundled payments applies to all tests that meet ADLT criteria, according to CMS.

Impact: To qualify for the exemption, the test must qualify as an ADLT under section 1834A(d)(5)(A) of the ACA.

2 Other Situations when Lab Tests Are Separately Payable

As before, HOPD lab tests will be payable separately, i.e., not covered by the OPPS bundled payment, if:

1. The tests are the only services provided to a beneficiary on a claim; or
2. The tests are preventive.

3. Packaging Based on Claim Rather than Date of Service

Current Rules: Whether payment for an outpatient service is made as part of the OPPS bundle or separately is designated at the code level by assigning a status indicator to CPT and HCPCS codes. So-called "conditional packaging" indicators are used for lab tests that can be paid either way depending on the circumstances. Some of these indicators, e.g., "Q1" + "S," "T" or "V," are used to package services with other services provided on the same date of service; other indicators, e.g., "Q2," package services on the same claim regardless of date of service.

New Rules: The final rule changes the rules for "Q1" and "Q2" to ensure consistency in package indicator use. "We do not believe that some conditional packaging status indicators should package based on date of service," CMS explains, "while other conditional packaging status indicators package based on services reported on the same claim."

Impact: From now on, all packaging will occur at the claim level and not be based on the date of service. The change will principally affect packaging of lab tests covered by the OPPS provided during a hospital stay lasting longer than one day.

4. Off-Campus Hospital Outpatient Department Rules: Impact on Labs

The part of the OPPS that has gotten the most attention are the provisions affecting services provided in off-campus hospital outpatient departments that recently began billing under the OPPS. From now on these services will be paid not under the OPPS but the physician fee schedule at rates of roughly 50 percent of the OPPS rates.

The good news: The de facto 50 percent rate cut does not apply to services currently paid under the OPPS based on other Medicare fee schedules. And since OPPS lab rates are based on the CLFS, the new rules will not affect labs.

The bad news: However, the new physician fee schedule based rates for off-campus provider-based departments—that are about 50 percent of the OPPS rate for

the service—will cover pathology services provided by entities that meet the criteria for being an off-campus hospital outpatient department that started billing under OPPS on or after Nov. 2, 2015.

Takeaway: 4 Things to Do. If you receive payment from Medicare for hospital outpatient lab services under the OPPS, you'll need to make the following adjustments in 2017:

1. *Stop using the "L-1" modifier to claim separate payment for lab tests provided by a different provider for a different diagnosis;*
2. *Seek separate payment for tests that qualify as ADLTs;*
3. *Use the new "Q1" and "Q2" status indicators to package lab tests provided during a hospital stay lasting longer than one day;*
4. *Bill for outpatient pathology services at the new physician fee schedule rather than OPPS rate if: i. you qualify as an off-campus hospital outpatient department; and ii. you began OPPS billing on or after Nov. 2, 2015.* G2

2017 OIG Work Plan Holds Few Surprises for Labs

There are few surprises in the Health and Human Services Office of Inspector General's 2017 Work Plan. The OIG's annual Work Plan provides a summary of new and continuing reviews that the agency is undertaking to protect the integrity of, and find opportunities to improve the efficiency of, U.S. Health and Human Services programs. The OIG revises the work plan midway through the year as well.

Here are some highlights of the issues the OIG addresses that laboratories and pathologists will be concerned about:

- Although listed as a new item, the OIG's mandatory review of implementation of the Protecting Access to Medicare Act of 2014 (PAMA) is actually a returning item. The OIG issued its latest report on this topic just a few months ago in September. Once again, the OIG will provide an update on the status of the Centers for Medicare & Medicaid Services (CMS) efforts to implement PAMA as well as its annual analysis of the top 25 laboratory tests based on Medicare payment.
- The OIG continues to review histocompatibility laboratories and whether payments for these labs' services complied with Medicare.
- A long time feature of the OIG's Work Plans, independent clinical laboratory billing requirements continues to make the list of OIG concerns. The agency will carry on its review of Medicare payments to independent clinical laboratories—specifically, looking for labs that "routinely submit improper claims."
- In addition to its focus on PAMA, the OIG also includes a new item reviewing CMS implementation of the Quality Payment Program under the Medicare Access and CHIP Reauthorization Act (MACRA). The OIG indicates it will address "timelines and key milestones CMS has established" for implementation as well as "key challenges and potential vulnerabilities CMS is facing during implementation."

Takeaway: Labs continue to receive attention in the OIG's annual Work Plan but only in continuing projects. G2

Studies Address Impact of DTC Genetic Testing on Risk Perception and Prescribed Therapies

Consumers buying direct-to-consumer personal genome tests (DTC-PGT) want to believe good news, according to an article published in the September issue of *Nature Biotechnology*. While participants' perception of their personal risk changed after receiving results showing decreased and increased risk, there was an "optimism bias"—with a greater change in perception resulting from good news. Additionally, the researchers found that following receipt of PGT results, consumers primarily seek medical attention in response to large, surprising results.

"The significance and modest magnitude of observed risk updating suggests that neither excessive overreaction nor complete disregard for the test results was prevalent in our sample"

— Joshua Krieger, Massachusetts Institute of Technology

Despite high-profile regulatory scrutiny of DTC-PGT (see box), there is not much evidence showing how use of these services impacts consumers' medical decision making.

The researchers modeled risk perception as a combination of baseline beliefs and learning in response to genetic news. Health care utilization was assessed as a function of changes in these risk perceptions. Eight conditions were evaluated (Alzheimer's disease, Parkinson's disease, breast cancer, lung cancer, colon cancer, prostate cancer, type II diabetes, and coronary heart disease).

The study included 617 real-world consumers who individually sought out and purchased PGT services from 23andMe before the U.S. Food and Drug Administration (FDA) banned DTC health reports. The participants were enrolled in the Impact of Personal Genomics (PGen) study, a longitudinal study of real DTC genomics customers. Risk perceptions were assessed through surveys at baseline and again six months post results.

The researchers found that participants had a slight "optimistic bias" in perception of baseline risk. This perception varied by condition, but the average level of optimism across the conditions was 42 percent, reflecting below-average risk perception versus an average 19 percent perception of above-average risk.

On average, following receipt of test results, participants updated their risk perceptions. However, the magnitude of this updating was asymmetric, meaning that results showing "good news"—a decreased risk of a condition—led to a significantly bigger drop in risk perception compared to the relative increase in risk perception following the receipt of "bad news" or results showing an increased risk of disease. This pattern in results existed regardless of the participants' initial reason for purchasing the test.

"The significance and modest magnitude of observed risk updating suggests that neither excessive overreaction nor complete disregard for the test results was prevalent in our sample," writes lead author Joshua Krieger, from the Massachusetts Institute of Technology. "A pattern of general and moderately increased concern across several conditions did not appear to spark decisions to use medical services, whereas a single higher-amplitude risk perception change increased the odds of engaging in follow-up medical action."

The authors caution that the six-month results regarding follow-up medical action may be conservative, given the likelihood some patients will wait until a routine check-up to raise the PGT test results with health care providers.

A separate study, also involving the PGen Study Group, found that pharmacogenomic results indicating an atypical drug response are common among patients requesting DTC-PGT. Receipt of these results is associated with prescription medication changes, although less than one percent of DTC consumers report unsupervised changes to their prescription medications six months following testing.

The concern, of course, is that receipt of DTC-PGT results will prompt consumers to "self-manage their treatments," including changing doses or abandoning treatment altogether, without consulting a physician or pharmacist.

This study relied on data from 961 new DTC-PGT customers (23andMe and Pathway Genomics) who were enrolled in 2012 and surveyed prior to the return of results, as well as six months after receipt of results. "Atypical response" was defined as pharmacogenomic results indicating an increase or decrease in risk of an adverse drug event or likelihood of therapeutic benefit, the authors report.

The researchers found that 91.2 percent of consumers received at least one pharmacogenomic result indicating atypical drug metabolism—a number consistent with previous estimates. In response to the PGT results, fewer than six percent of participants changed a prescription medication within six months of testing and less than one percent reported making changes without consulting a health care provider.

Takeaway: Studies address potential impact of DTC-PGT results on changes in risk perception and on health care utilization among real-world consumers.

FDA Enforcement Efforts Regarding DTC Genetic Testing

The FDA's concerns about direct-to-consumer provision of genomic analysis received mainstream attention in 2013 with its efforts to stop 23andMe from marketing its Personal Genome Service directly to consumers. The FDA has continued to focus on direct-to-consumer marketing of genomic testing with several letters issued to companies since last year:

- **Pathway Genomics**—(Sept. 21, 2015) The FDA said a non-invasive blood test (which could be shipped directly to patients) screening for up to 10 difference cancer types was a high risk test requiring FDA approval.
- **DNA4Life**—(Sept. 21, 2015) The FDA said DNA4Life was improperly marketing its Pharmacogenetic Report directly to consumers when the test constituted a medical device requiring FDA clearance. The test predicted patient response to 120 commonly prescribed medications.
- **Interleukin Genetics**—(Nov. 4, 2015) The FDA said the companies' DTC genetic tests for determining risks for diabetes, heart attack and obesity appeared to be unapproved medical devices.
- **Sure Genomics**—(Feb. 16, 2016) The FDA said the company's SureDNA test was a medical device requiring FDA review—the test was a kit allowing consumers to mail saliva samples for genetic testing to determine disease risk and drug reaction risk.

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