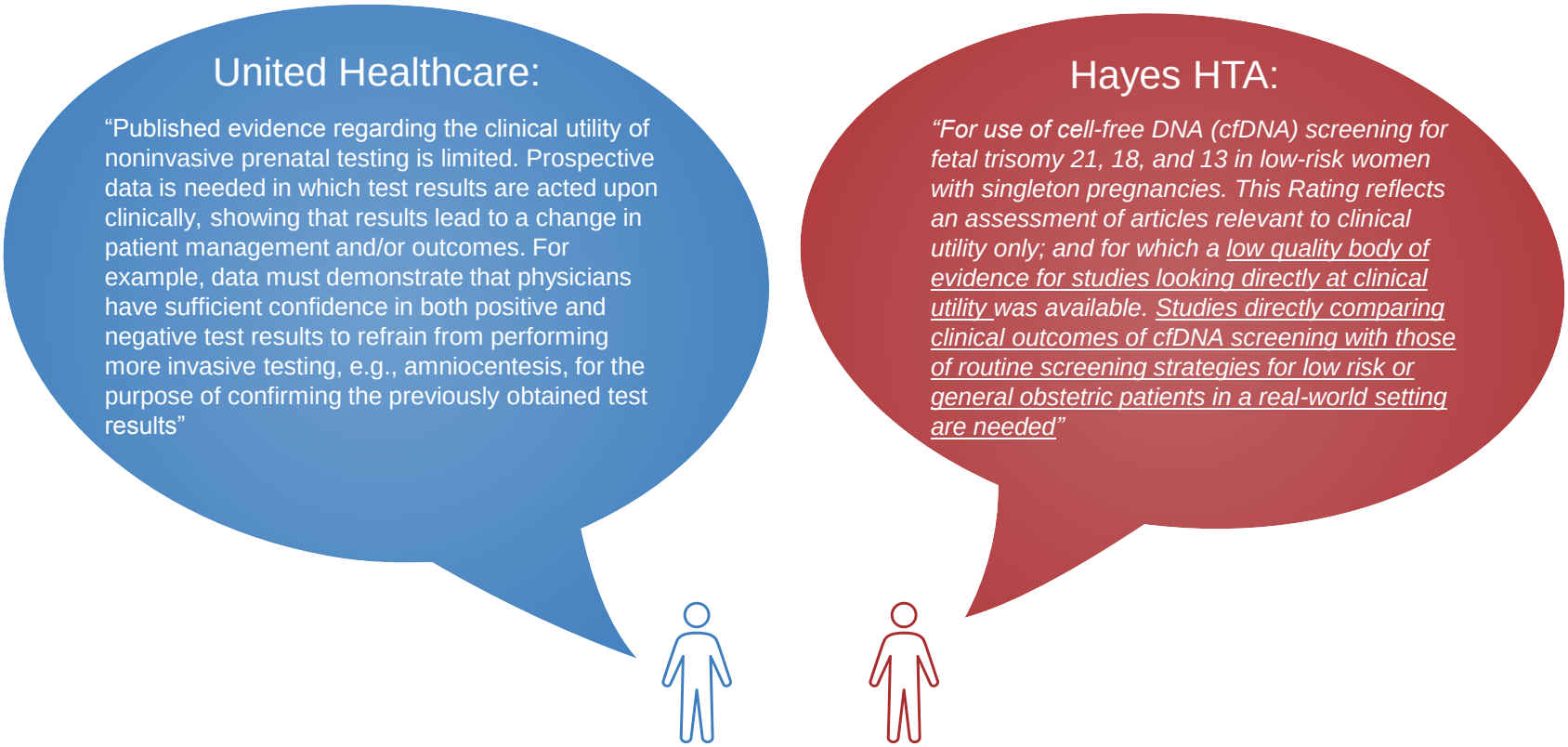
# Illumina/Harvard Pilgrim on NIPT: Addressing the Biggest Commercial Problem in Diagnostics

Ammar Qadan, VP Global Market Access, Illumina, Inc.
Roger Longman, CEO, RealEndpoints

# NIPT US: ~40% Covered Lives for Average Risk (<35y) Patients

*Major holdouts (United, Aetna) and HTA (Hayes) cite lack of real world data on clinical and economic impact*



# “Something For The Pharma To Learn From…..”

## Illumina and Harvard Pilgrim Partner on Value-Based Contract

Announce first ever next-generation sequencing agreement for non-invasive prenatal testing

News Center / Feature Articles

February 1, 2018

Illumina announced today that it has signed a value-based contract with Harvard Pilgrim Health Care, a not-for-profit health services company that provides insurance coverage to approximately 1.2 million people in Massachusetts, Connecticut, New Hampshire and Maine. The goal of the agreement is to accelerate wider patient access and reimbursement of next-generation sequencing (NGS) for non-invasive prenatal testing (NIPT).

Many payers limit NIPT coverage to pregnant women of advanced maternal age (35 years of age or older), while NIPT for women with average-risk pregnancies (under 35 years), remains uncovered by many major insurance companies. However, as part of the contract with Illumina, Harvard Pilgrim will provide open market access of NIPT for average-risk pregnancies, which will allow more pregnant women to take advantage of NIPT technology.

"Harvard Pilgrim is thrilled to have reached this first-of-its-kind agreement with Illumina, which allows us to expand patient access to NIPT," said Michael S. Sherman, Chief Medical Officer of Harvard Pilgrim Health Care. "Through this partnership with Illumina, Harvard Pilgrim is furthering its quality agenda by making this test available to pregnant women of average risk and can do so in a way that limits the extent to which this expansion might increase overall healthcare costs."

Illumina's contract with Harvard Pilgrim will help create real world data needed by payers and employers to demonstrate the clinical and economic value of NIPT for detecting aneuploidy births (babies with genetic anomalies).

Harvard Pilgrim has pioneered value-based healthcare programs in pharmaceuticals, but this agreement will be the first ever NGS-based value-based contract.

"While we have entered into innovative outcomes-based agreements for pharmaceuticals, this is the first agreement we have done for an NGS-based screening test, and we hope that it will provide a model for balancing access and affordability for advances in personalized medicine," added Sherman.

"We are thrilled to partner with Harvard Pilgrim on the first ever value-based contract of its kind involving NGS-based assays," said Ammar Qadan, Vice President, Global Market Access at Illumina. "We expect this study to demonstrate the value of NIPT for average-risk pregnancies and to help accelerate the adoption and reimbursement of NIPT."

The collaboration also includes a two-year, real world study in the Harvard Pilgrim population that will assess the total costs and clinical outcomes of NIPT versus traditional screening practices.

genomeweb

## Illumina, Harvard Pilgrim Strike Average-Risk NIPT Deal

Feb 02, 2018 | staff reporter

NEW YORK (GenomeWeb) – Illumina has struck a deal with Harvard Pilgrim Health Care to provide noninvasive prenatal testing to women with average-risk pregnancies. The nonprofit health services company covers around 1.2 million people in Massachusetts, Connecticut, New Hampshire, and Maine.

Under the terms of the value-based contract, Harvard Pilgrim will cover NIPT for average-risk pregnancies. However, if one-year costs of testing exceed a pre-established baseline, Illumina will reimburse Harvard Pilgrim for the costs.

An Illumina spokesperson said that an independe
administrative claims database to help determine
and costs."

That third party will also collect clinical outcome a
average-risk pregnancies leads to improved outc

Some data points that will be analyzed include wh
tests like amniocentesis as well as whether it has
chromosomal abnormalities who are born at spec
analyze the impact of covering NIPT for average-r

The goal is to "determine the real-world clinical ar
provide the data that is currently lacking for payor

"Through this partnership with Illumina, Harvard P
test available to pregnant women of average risk
this expansion might increase overall healthcare c
Sherman said in a statement.

Ammar Qadan, Illumina's vice president of global
demonstrate the value of NIPT for average-risk pr
reimbursement of NIPT."

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11:30 AM PST | FEB 1, 2018 | BC EXTRA | COMPANY NEWS

## ILLUMINA, HARVARD PILGRIM IN FIRST VALUE-BASED NGS CONTRACT

BY JAIME DE LEON

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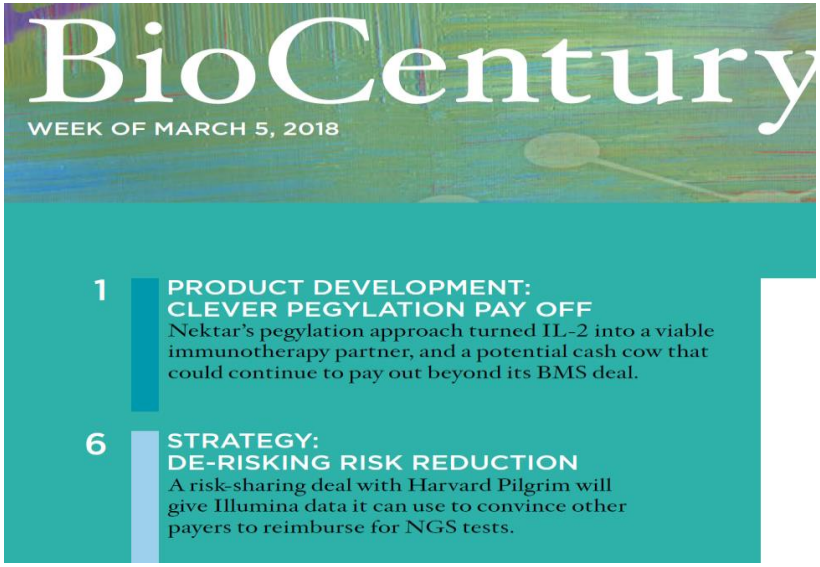
Illumina Inc. (NASDAQ:ILMN) and Harvard Pilgrim Health Care Inc. (Boston, Mass.) signed a value-based contract for reimbursement of non-invasive prenatal testing (NIPT) that uses next-generation sequencing. Illumina said the collaboration is the first ever value-based contract for NGS-based assays.

Harvard Pilgrim said it will provide open market access to NIPT for average-risk pregnancies. The deal also includes a two-year real-world study in the Harvard Pilgrim patient population to evaluate total costs and clinical outcomes of NIPT compared to traditional screening.








illumina®

# The Illumina/Harvard-Pilgrim value-based agreement around NIPT

1

## Risk-Sharing

- Expands NIPT access to all pregnant women vs. high-risk only
- Illumina to pay for screening costs beyond baseline up to a significant maximum

2

## Real-World Evidence Study

- 2 year outcomes study to develop further evidence to support NIPT in average-risk
- RE analysis of medical and pharmacy claims for over 10K pregnancies.
- Outcomes include pregnancy, neonatal and post-natal utilization and costs

**Real Endpoints, working with Skaggs School of Pharmacy, Univ. Colorado, responsible for data aggregation, analytics and financial reconciliation**

# Finding a partner, defining a deal

- **Illumina and RE outlined several potential deal archetypes**
- **RE discussed deal archetypes with several payers**
  - Nationals can afford “wait-and-see” attitude; regionals more open to new approaches
  - Structural simplicity preferred to analytic perfection
- **Harvard Pilgrim**
  - Faced increasingly competitive market
  - Comfortable with risk-sharing programs
  - Interested in deal which allowed adoption of differentiating new technology with low immediate financial risk
  - Willing to collaborate on longer-term RWE study

# Quickly settled on basis for two-part deal…the contract itself another question

- **Basic deal structure agreed to *before* first all-hands meeting at HP**
- **Time from first meeting to term sheet: 6 weeks**
  - Illumina able to move very fast
  - Biggest sticking point: defining appropriate risk-caps for both parties
- **Contract itself was more challenging…**
  - While it had signed >12 pharma risk shares, HP had never done a Dx-focused risk-share
  - Back-and-forth with lawyers was time-consuming

# Value-based contracting in diagnostics: necessary…in the right situations

- Persuasive clinical & economic argument for using the diagnostic – but no strong guideline recommendation or compelling RWE
- Diagnostic must have significant potential expense impact for payer to be willing to take on the work of a deal
- Outcomes metrics must be both meaningful and retrievable (preferably through claims, not lab)
- Payer must bear the separate expense of the diagnostic