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Personalized Medicine: Perspectives on the New Science of Genetic Testing and Molecular Diagnostics

Health Industry Forum
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Lewis G. Sandy MD
Senior Vice President, Clinical Advancement
UnitedHealth Group

The Context: Scientific

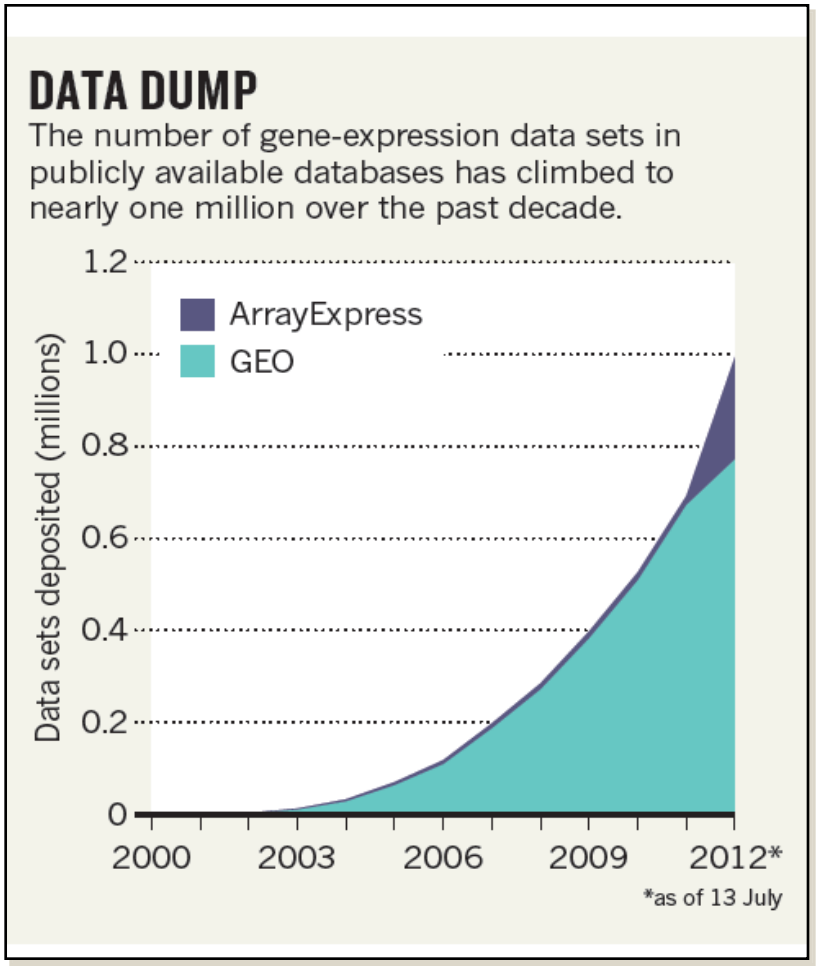
Accelerating ease and lower cost of human genome sequencing, SNP genotyping and DNA analysis via microarrays

Explosive growth in correlation analysis in molecular medicine

Increased appreciation of: HTE (heterogeneity of treatment effects) in traditional RCTs and throughout EBM; gene/environment interactions;

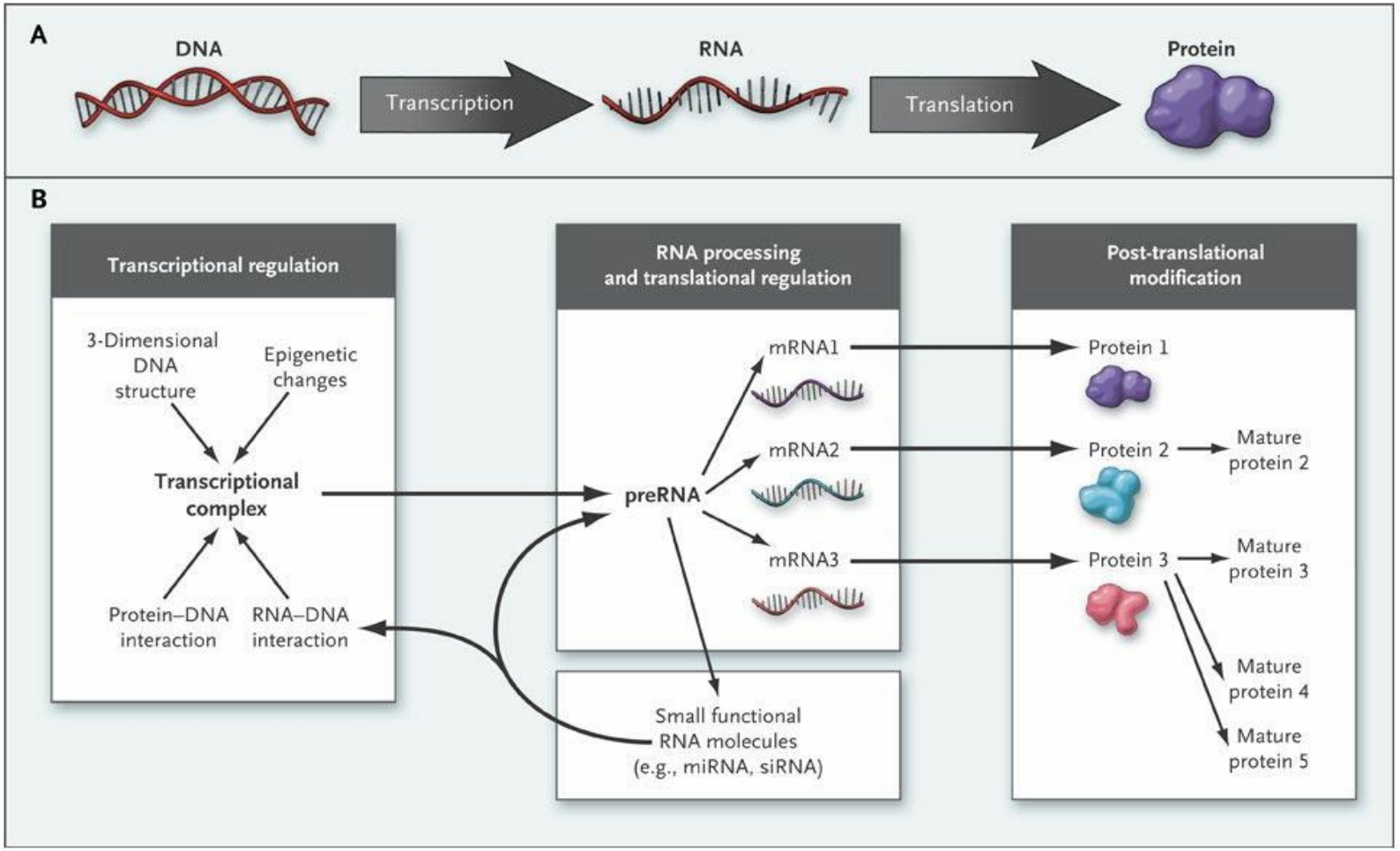
Other disciples connecting to molecular medicine: Bioinformatics, Computational Biology, POC Diagnostics, Wireless Medicine

Clinical Applications are emerging, notably in Oncology, Transplant, Pharmacogenomics



Source: NATURE | VOL 487 | 19 JULY 2012

The Increasing Complexity of the Central Dogma of Molecular Biology



Source: Feero WG et al. N Engl J Med 2010;362:2001-2011

Personalized Medicine: Trends and Prospects
UnitedHealth CHRM Working Paper:

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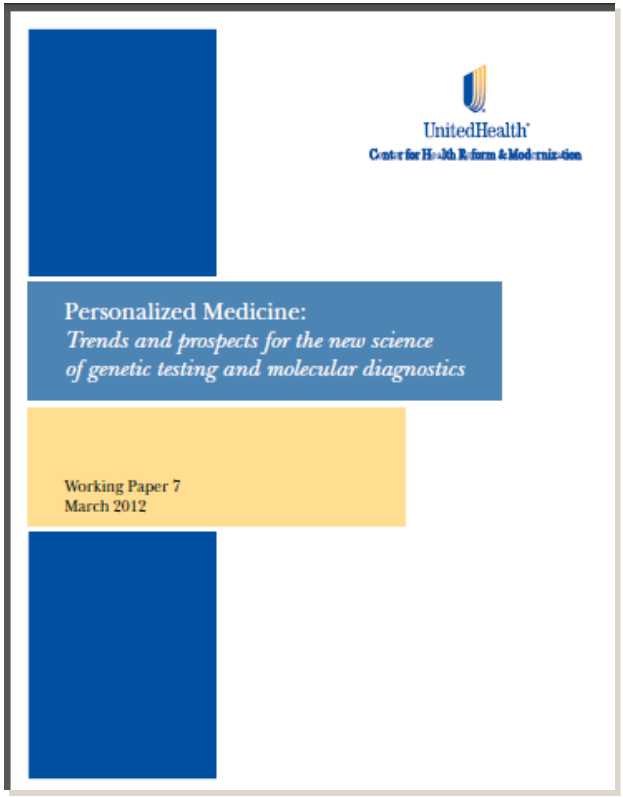
Current Environment

- Estimates suggest that there are between 1,000 to 1,300 genetic tests currently available
- Currently genetic testing is thought to be available for about 2,500 conditions, both rare and common[1]
- Genetic tests have the potential to benefit more than 60 percent of the population[2]
  - » According to one estimate, clinical laboratory tests influence about 70 percent of health care decisions[3]



Key question: where are we in the eyes of consumers, physicians and other stakeholders, including payers?

Sources:
1) National Institutes of Health, "Welcome to GeneTests," March 2012.; Genetic Alliance, "Promotion of Genetic Testing Services Directly to Consumers."; U.S. Department of Energy, "Human Genome Project Information – Gene Testing," September 17, 2010.
2) Department of Health and Human Services Secretary's Advisory Committee on Genetics, Health, and Society, "U.S. System of Oversight pf Genetic Testing: A Response to the Charge of the Secretary of Health and Human Services," April 2008: 1-192.
3) AdvaMed, "Harnessing Advanced Diagnostics Technology for Early Diagnosis and Prevention."

New national survey on consumers' perceptions of genetic testing

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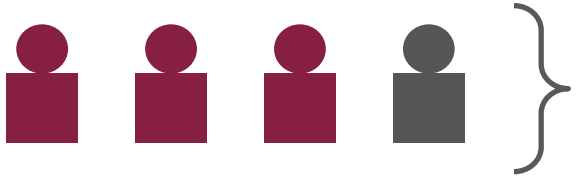
Finding: Consumers are cautiously optimistic about the promise these tests hold for the future of medicine

Consumers are optimistic



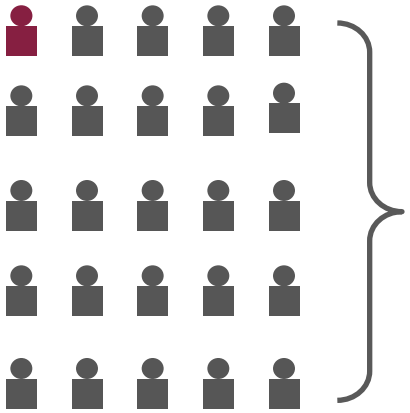
Three-quarters of American consumers believe that genetic testing:

1) helps doctors diagnose preventable conditions
2) offer more personalized treatment options

Consumers believe use of tests will increase in the next five years, but do not expect to get tests themselves

74 percent of American consumers believe that use of genetic testing in the U.S. will increase

80 percent of American consumers believe that the number of different kinds of genetic testing available will increase



Only 4 percent of respondents expect to get a test in the next five years

Sources:
1) UnitedHealth Center for Health Reform & Modernization/Harris Interactive survey of consumers, January 2012.

New national survey on physicians' perceptions of genetic testing

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Finding: Physicians are also cautiously optimistic about the promise these tests hold for the future of medicine

Physicians believe tests could be helpful

Three-quarters of physicians say there are patients who have not yet had a genetic test but who would benefit from having one

However, physicians are concerned about cost to patients and to the health care system

Approximately 60 percent of physicians are concerned about the cost of genetic tests to their patients

56 percent of physicians believe genetic testing will increase health care costs in the future

Physicians cite numerous barriers to incorporating genetic testing into their practice

- Cost of Tests / Reimbursement
- Lack of familiarity with tests
- Questions about the validity of tests
- Lack of evidence of test effectiveness / utility
- Less or not relevant to practice
- Questions about patient ability to understand results

Sources:
1) UnitedHealth Center for Health Reform & Modernization/Harris Interactive survey of physicians, January 2012

Spending projections

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Finding: UnitedHealthcare data and claims suggest the cost of genetic testing for members was about $500 million in 2010

Category of Molecular Diagnostic and Genetic Test				
	Infectious Disease	Cancer	Inherited Conditions, Other	All Categories
Spending Percentage				
Employer and Individual	38%	17%	45%	100%
Medicare Advantage	8%	26%	66%	100%
Managed Medicaid	63%	5%	32%	100%
All Members	39%	16%	45%	100%

- Between 2008 and 2010, average annual spending increased 14 percent
- Per person spending on genetic testing for UnitedHealthcare's Medicare and Medicaid members was higher than for UnitedHealthcare's employer-sponsored and individually insured population by 16 percent and 24 percent, respectively

Sources:
1) UnitedHealth Center for Health Reform & Modernization, 2012
Sums may not add to totals because of rounding.

Estimated number of test procedures per 1,000 UnitedHealthcare members, 2010

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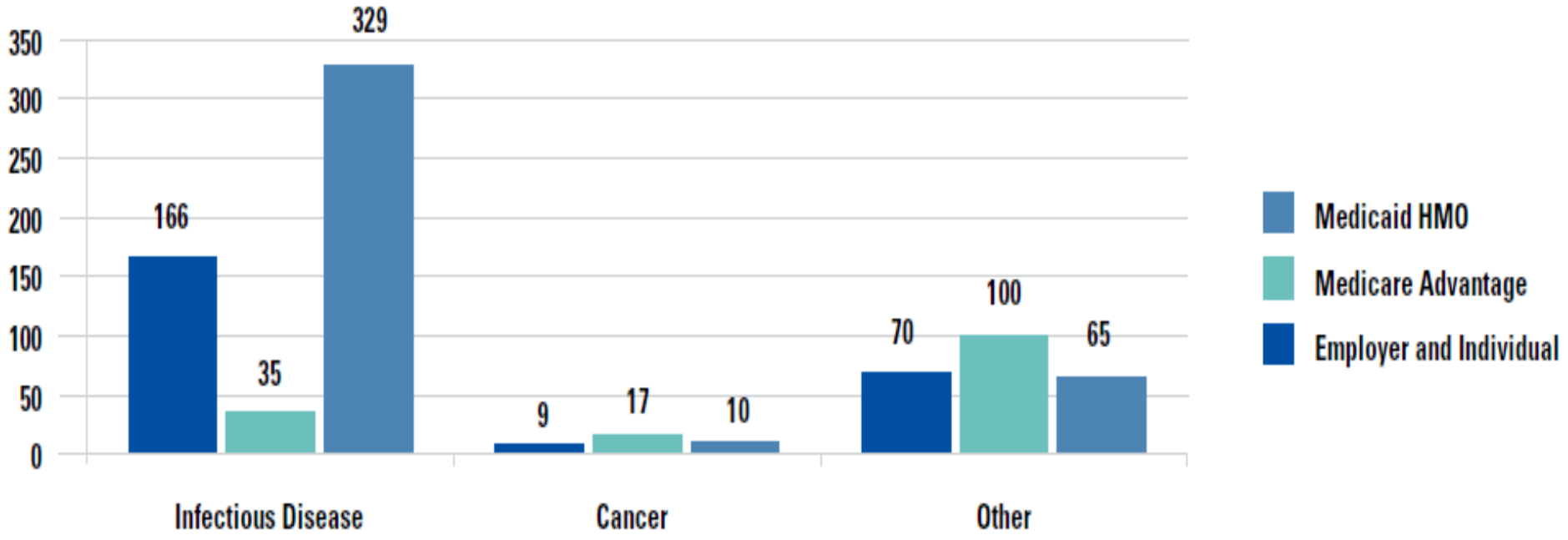

Sources:
1) UnitedHealth Center for Health Reform & Modernization, 2012

Estimated U.S. spending by payer on molecular diagnostics and genetic testing, 2010

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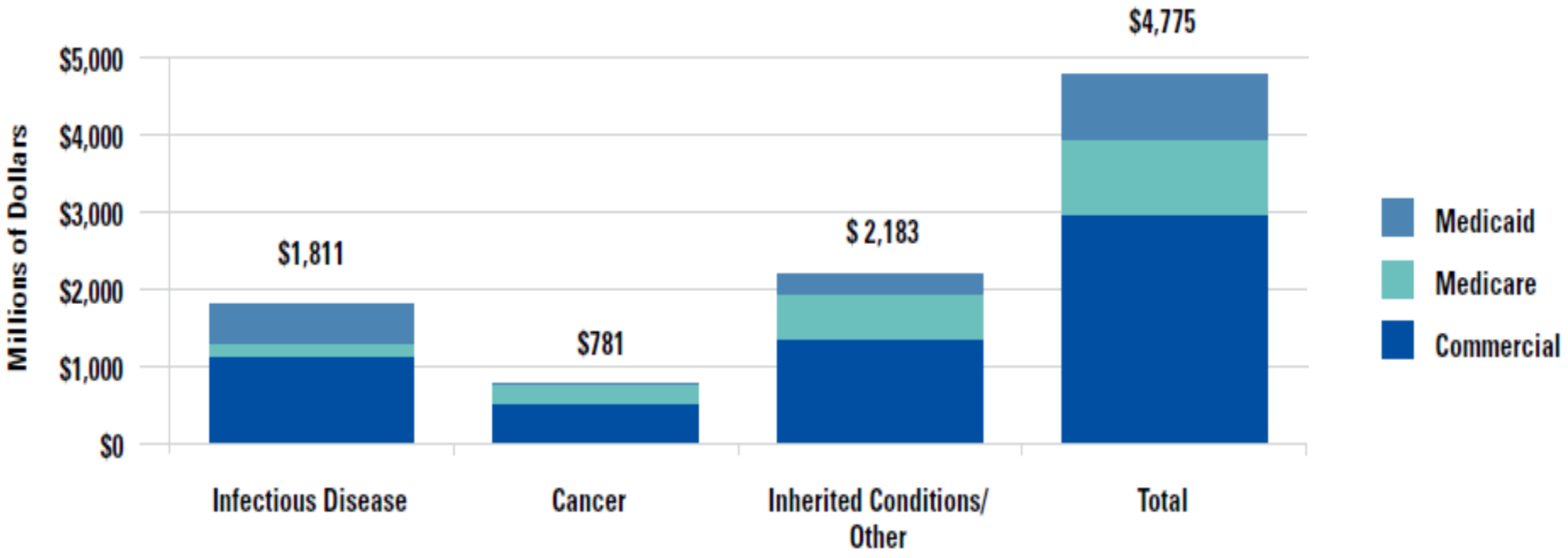

Sources:
1) UnitedHealth Center for Health Reform & Modernization, 2012

Issues in Establishing the Value Proposition of Personalized Medicine

- Current State: often “promising but unproven”; or proven but with narrow clinical utility.
- Often unclear:
  - Analytic validity
  - Definitions of appropriate patients
  - Impact on clinical care process or outcome
  - Role in care compared to current practice
- Difficult to study with traditional methods
- Sometimes more fervor than science
  - Confusing association with causality
  - Genetic determinism vs. complex system thinking
- Even proven tests often used inappropriately (BRCA)

Evidence in a PM World—New Data, Methods, Insights

- Increased use of modeling/simulation approaches
- The opportunity created by “Big Data”—sophisticated analysis of observational data
- Need for new (and large) data sets: phenotypes, functional status, patient-reported outcomes
- Sorry, but we still need to do prospective trials…
- Closing the gap between typical care and optimal care

Practical recommendations

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	Recommendations	Consumers	Physicians
1	Protecting, supporting, and informing patients through data confidentiality, non-discrimination, and decision-support	✓	
2	Benefiting patients by developing the clinical evidence base to determine which tests work	✓	✓
3	Stimulating future progress by encouraging the development of tests that are proven to work	✓	✓
4	Monitoring care through more transparent coding and reporting	✓	✓
5	Protecting patients by ensuring that lab tests are performed safely and accurately	✓	
6	Making it easier for health professionals to stay up-to-date as genetic science evolves		✓

Thank you!

All UnitedHealth Center for Health Reform Working Papers are available here:

www.unitedhealthgroup.com/reform/

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