Dr. James L. Mulshine

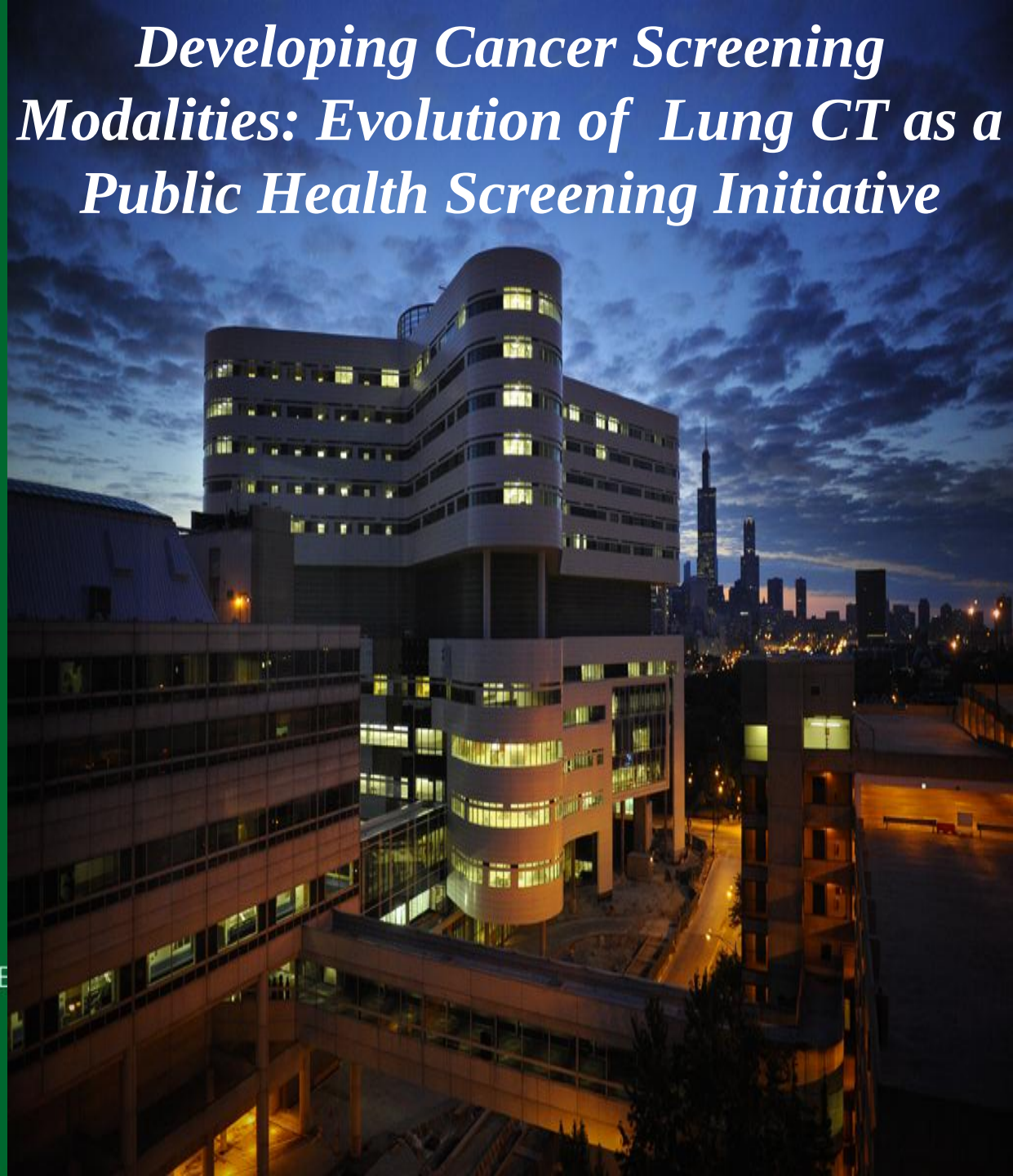
DISCLOSURE OF CONFLICTS OF INTEREST

GLOBAL EDUCATION GROUP (GLOBAL) REQUIRES INSTRUCTORS, PLANNERS, MANAGERS AND OTHER INDIVIDUALS AND THEIR SPOUSE/LIFE PARTNER WHO ARE IN A POSITION TO CONTROL THE CONTENT OF THIS ACTIVITY TO DISCLOSE ANY REAL OR APPARENT CONFLICT OF INTEREST THEY MAY HAVE AS RELATED TO THE CONTENT OF THIS ACTIVITY. ALL IDENTIFIED CONFLICTS OF INTEREST ARE THOROUGHLY VETTED BY GLOBAL FOR FAIR BALANCE, SCIENTIFIC OBJECTIVITY OF STUDIES MENTIONED IN THE MATERIALS OR USED AS THE BASIS FOR CONTENT, AND APPROPRIATENESS OF PATIENT CARE RECOMMENDATIONS.

THE FACULTY REPORTED THE FOLLOWING FINANCIAL RELATIONSHIPS OR RELATIONSHIPS TO PRODUCTS OR DEVICES THEY OR THEIR SPOUSE/LIFE PARTNER HAVE WITH COMMERCIAL INTERESTS RELATED TO THE CONTENT OF THIS CME ACTIVITY:

DR. JAMES MULSHINE HAS INDICATED HE HAD NO RELEVANT FINANCIAL RELATIONSHIPS WITHIN THE PAST 12 MONTHS.

Developing Cancer Screening Modalities: Evolution of Lung CT as a Public Health Screening Initiative



March 22, 2013

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RUSH UNIVERSITY MEDICAL CENTER

IT'S HOW MEDICINE SHOULD BE

Disclosures 3/13

- Board of Trustees: Lung Cancer Alliance & Prevent Cancer Foundation
- Scientific Advisory Board to I-ELCAP, Roy Castle Foundation, Biodesign Institute, Arizona State U and Illinois Institute of Technology, Affiliate Council, U of C Inst of Translational Med.
- Chair, MD Anderson DOD External Review Committee for lung cancer research
- Member and National Steering Committee, Quantitative Imaging Biomarker Alliance, RSNA; ASCO, IASLC Prevention & Tobacco Committees; AATS Guidelines Committee
- Consultant to NHRI, UK, Irish Cancer Society, Dublin; Collaborator European Institute, Milan
- **I have no financial relationships to disclose**
- **I will discuss the following investigational use in my presentation: lung cancer screening**

Sustaining the Tobacco Epidemic

- **The major tobacco companies now spend over $8.4 billion per year—more than $23 million every day—to promote their products, and many of their marketing efforts directly reach kids.**

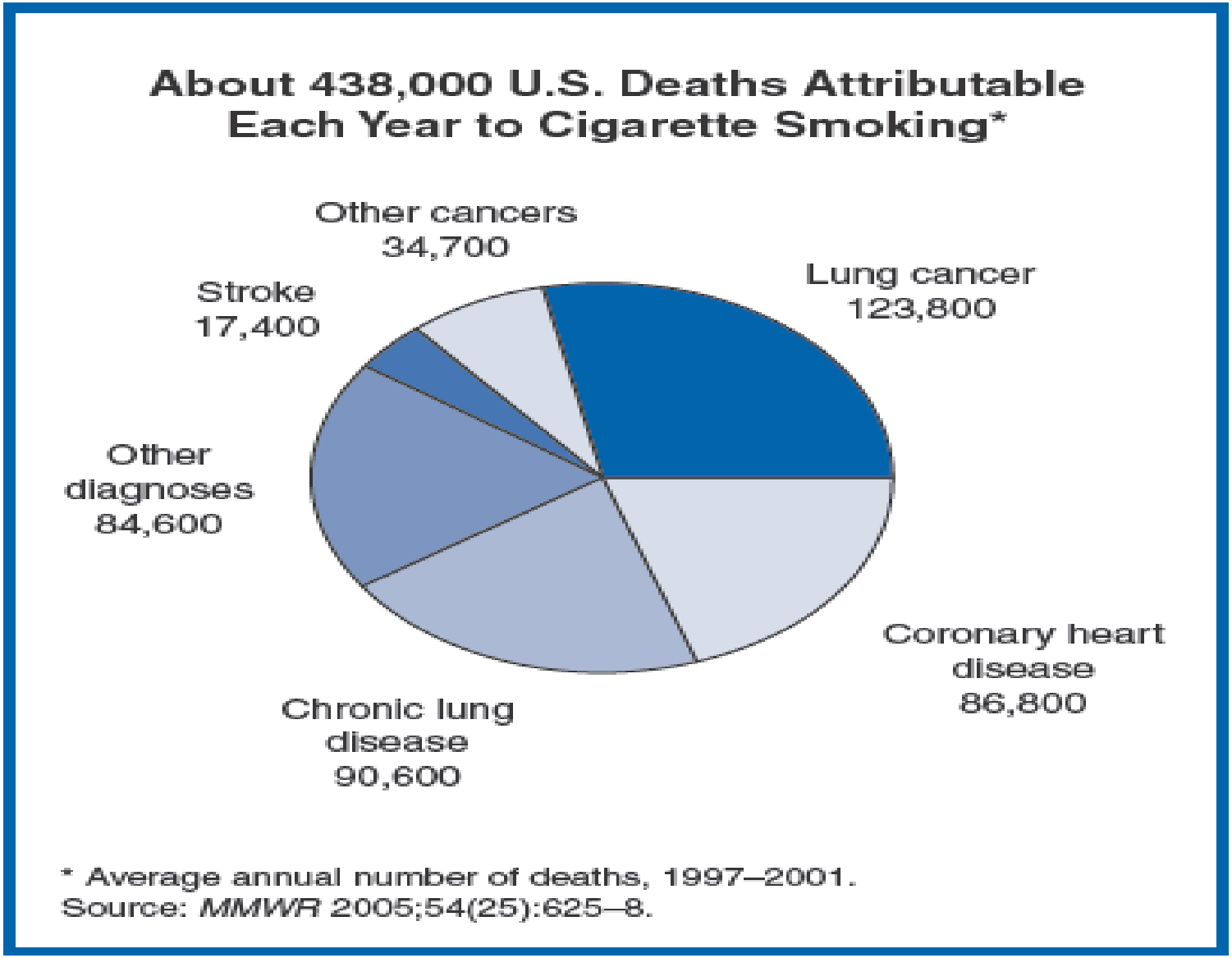
U.S. Federal Trade Commission (FTC), Cigarette Report for 2009 and 2010, 2012

- **The cigarette companies are addicted to underage smoking. Almost 90 percent of all regular smokers begin smoking at or before age 18, and hardly anybody tries their first cigarette outside of childhood**

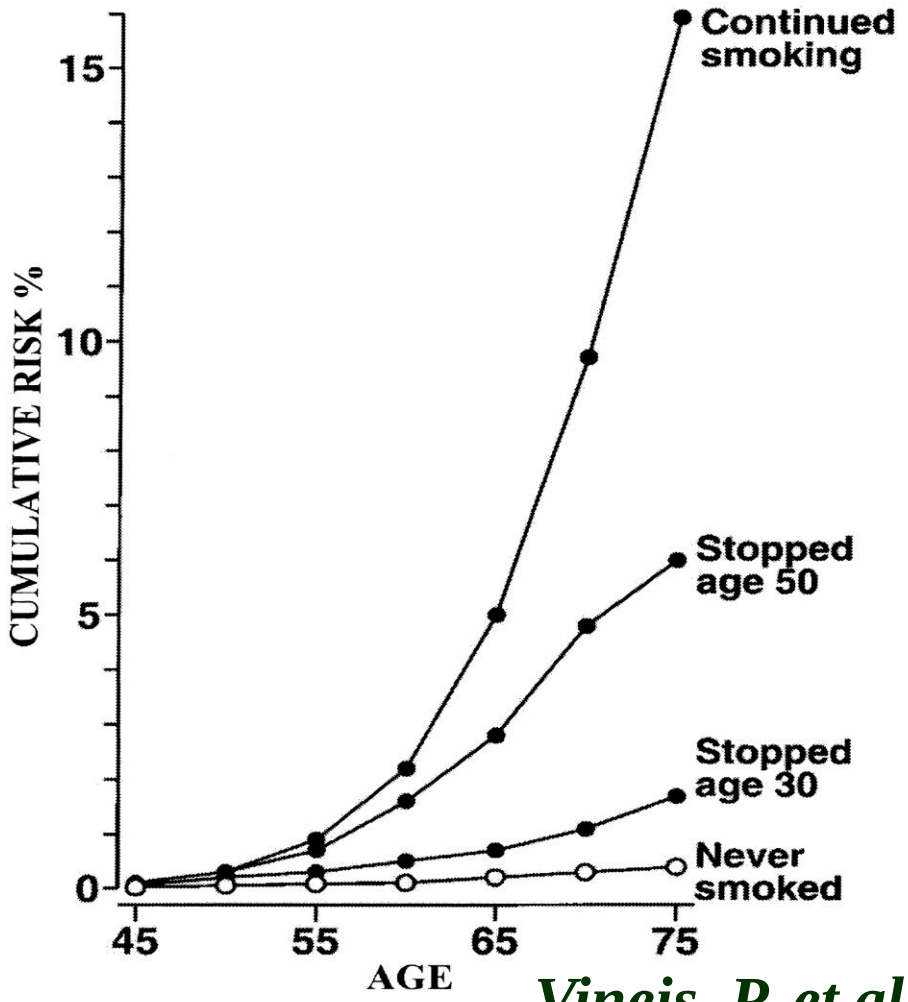
Calculated based on data in Substance Abuse and Mental Health Services Administration (SAMHSA), Results from the 2005 National Survey on Drug Use and Health (NSDUH), 2006

Campaign for Tobacco-Free Kids

Lung Cancer & Tobacco Mortality



Lifelong Risk of Lung CA Post Smoking



Data from Sirs Doll & Peto unequivocally demonstrates that the risk of lung CA after smoking never returns to normal

Vineis, P. et al. JNCI 2004;96:99-106

The National Lung Screening Trial

- **The NLST is a prospective randomized controlled trial started 2002**
- **Randomization: Annual CXR vs. CT**
- **Number of subjects: 53,000**
- **Number of screening sites: 30 sites, including current PLCO sites (10), and ACRIN sites (20)**
- **Duration: 3 screening rounds, with follow-up to 2009—extended to 2011**
- **Trial costs $250M and nearly a decade**

National Lung Screening Trial Research Team, NEJM 365(5):395-409, 2011.

NLST Trial Result

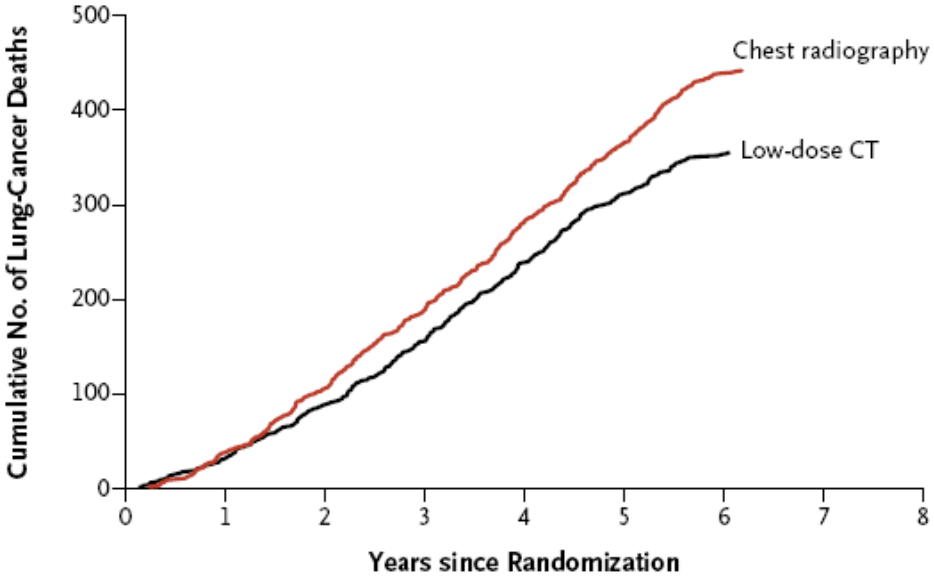


Figure 1. Cumulative Numbers of Lung Cancers and of Deaths from Lung Cancer.

The number of lung cancers (Panel A) includes lung cancers that were diagnosed from the date of randomization through December 31, 2009. The number of deaths from lung cancer (Panel B) includes deaths that occurred from the date of randomization through January 15, 2009.

N Engl J Med 2011;365:395-409.

Recent Mortality-Reduction Estimates

- **NLST reported a 20.3% reduction compared to CXR arm (NCI website)**
- **Long-term follow up from NY-ELCAP suggested a 36%, 64% mortality reduction compared to CPS or CARET outcomes (Henschke et al Cancer, 2011)**
- **CISNET Modeling of NY-ELCAP outcomes suggested 46% mortality (Foy et al Cancer, 2011)**
- **PLCO(M2012) smoking tool- NLST 30% mortality reduction (Tammemagi et al NEJM, 2013)**
- **True magnitude of benefit not established**

Lower Cost, Better Value than Breast, Cervical, Colorectal Cancer Screening

- Used actuarial model to determine cost of screening service delivered using published "best practice" for all components of the screening process
- Lower incremental cost to commercial insurers
  - <$1 PMPM for LC screening. Total health benefit cost >$300 PMPM
- Lower cost per life-year saved
  - ~$18,000 per life-year saved

Pyenson et al. Health Affairs, 2012;31:770-9. PMID: 22492894

Why Cost Benefit Matters

- **USPSTF grades cancer screening services based on strength of evidence for clinical benefit and cost efficiency (http://www.uspreventiveservicestaskforce.org/uspstf/grades.htm).**
- **Only Grade A or B is reimbursed by Medicare (http://www.healthcare.gov/law/features/rights/preventive)**

Improving Efficiency/Cost of LDCT Screening

- **Better define risk strata to define population that maximizes screening yield**
- **Refine diagnostic work up algorithm to find screening-detected cases with minimal morbidity**
- **Improve intervention to remove or ablate detected primary lung cancer with minimal mortality**
- **Establish rational basis for frequency of screening follow up**
- **Validate candidates and targets for adjuvant therapy for more aggressive screen-detected cancers**

Improve Diagnostic Work-up

- **NELSON published diagnostic work up efficiency in NEJM and found a sensitivity of 95%, specificity of 99% using a Siemens Lung Care volume measurement tool***
- **I-ELCAP and NELSON use a nodule growth criteria to separate clinically significant from non-malignant behaving nodules using quantitative imaging (filter for overdiagnosis)^**
- **RSNA (QIBA) is defining imaging protocols and QC/QS criteria to ensure robust measurements**

*van Klaveren RJ et al NEJM, 2009 ^Wagnetz et al AJR, 2012

Moving To Rapid Learning

- Institute of Medicine (IOM) Roundtable suggested that a new clinical paradigm be developed that takes better advantage of data generated in the course of healthcare delivery which would speed and improve the development of evidence for real-world decision making for complex management processes

Conclusion:

- Congruence on refining components of the screening process could accelerate progress with improving screening management outcomes

I-ELCAP
73 Institutions
with
60,869 Participants
and
131,942 CT scans

I-ELCAP

Annals of Internal Medicine
Established in 1927 by the American College of Physicians

From: Definition of a Positive Test Result in Computed Tomography Screening for Lung Cancer: A Cohort Study

Ann Intern Med. 2013;158(4):246-252. doi:10.7326/0003-4819-158-4-201302190-00004

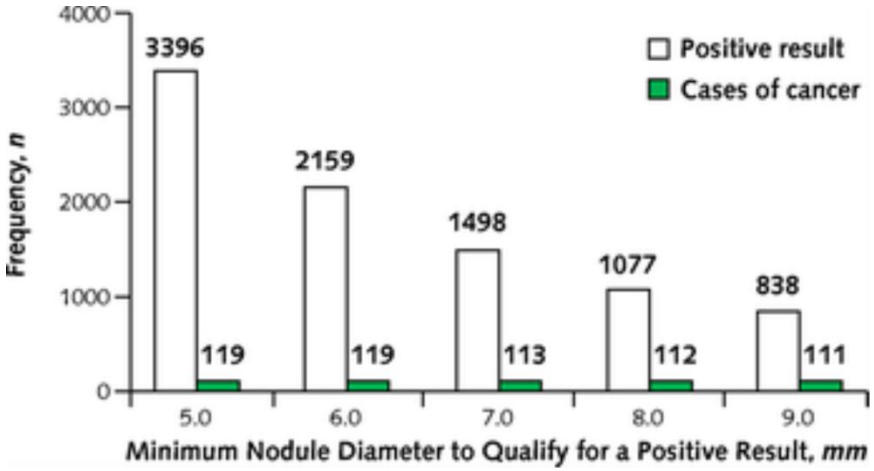


Figure Legend:

Frequency of a positive result and cases of lung cancer diagnosed within 12 mo of baseline enrollment.

Can We Afford "Technology"

Is Technological Change In Medicine Worth It?

When costs and benefits are weighed together, technological advances have proved to be worth far more than their costs.

*by **David M. Cutler and Mark McClellan***

H E A L T H A FFA I R S ~

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