www.alacritaconsulting.com

European Medtech:

The Grass Is Not Greener

June 2013

Alacrita LLC
One Broadway, 14th Floor
Kendall Square, Cambridge, MA 02142

Alacrita LLP
London BioScience Innovation Centre
2 Royal College Street, London NW1 0NH

alacrita

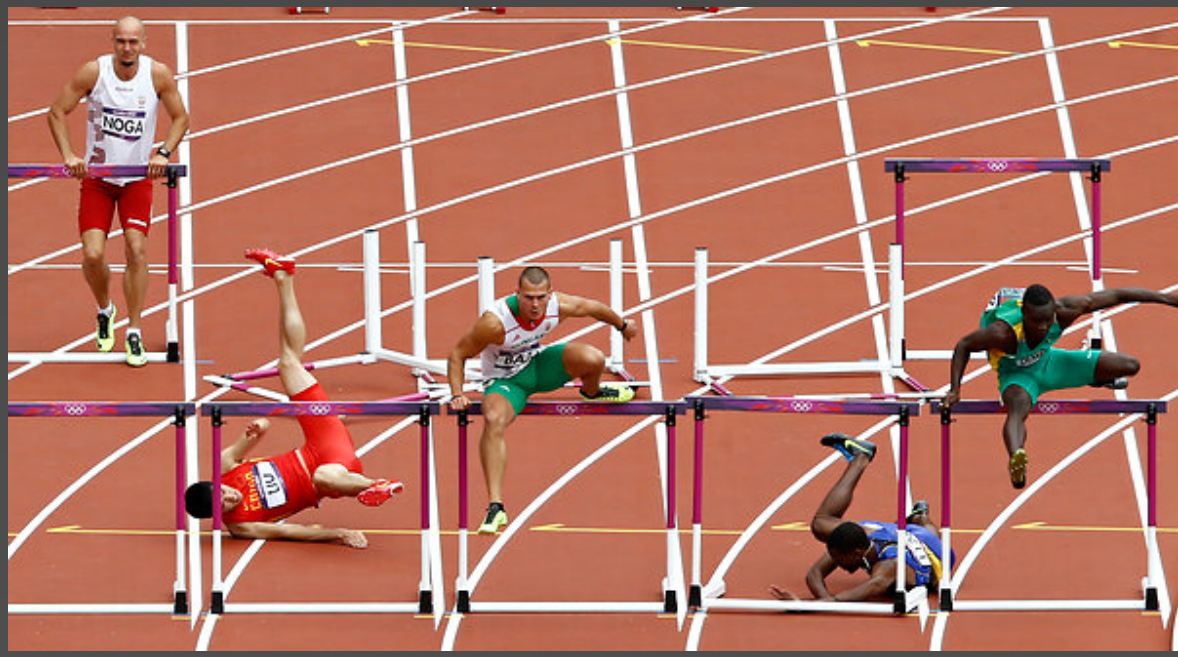
US medtech woes

"AdvaMed, Device Companies Claim FDA's 510(k) Pre-Review Guidance Lacks Objectivity"
October 2012

"Medical Device Manufacturers to Lay Off Thousands"
November 2012

"Medical device tax: has it changed the medtech investment cycle?"
May 2013

"Sluggish FDA device approvals frustrate cardiologists"
May 2013



alacrita

The myths of "greener grass" in Europe

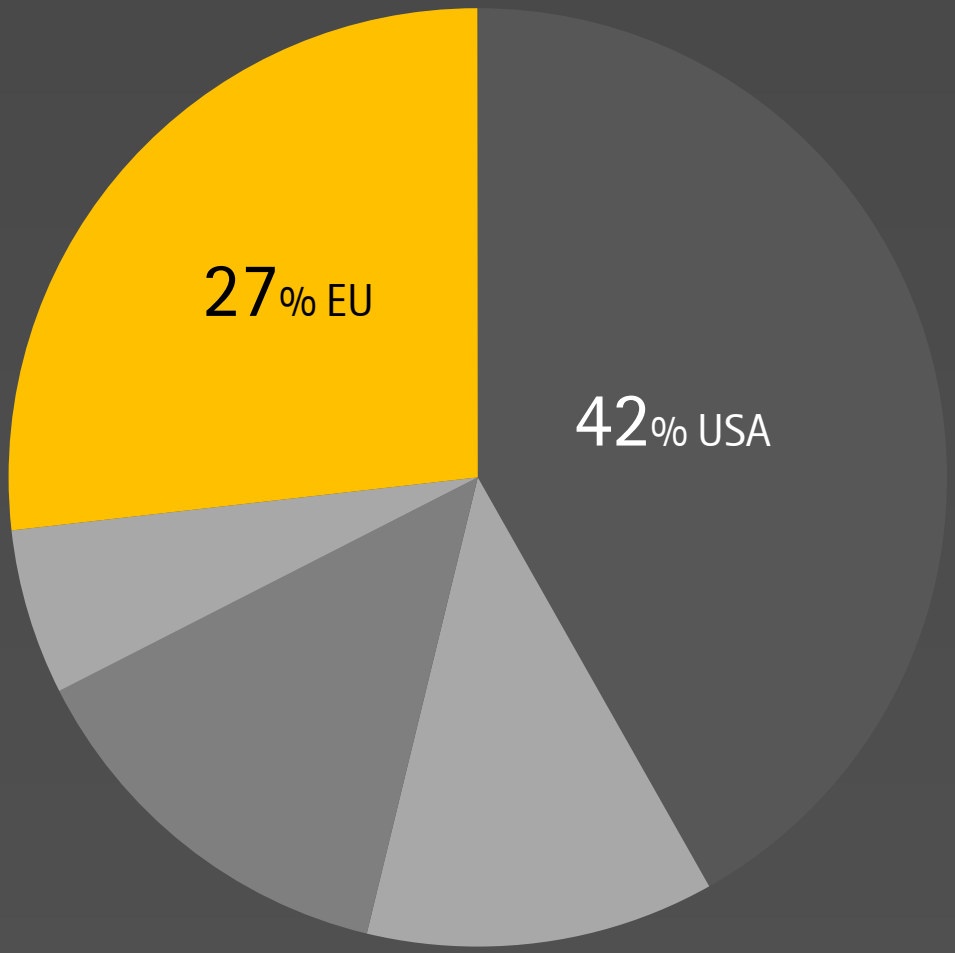
Myth: Europe is the second largest medtech market globally

Myth: CE Mark is less risky and much faster to achieve than a 510(k) and proves product viability

Myth: CE Mark provides access to 27 countries allowing rapid commercialisation across Europe

alacrita

Europe may be the second largest medtech *region…*



2011 medtech sales
Source: EUCOMED, Espicom, Frost & Sullivan, Alacrita analysis

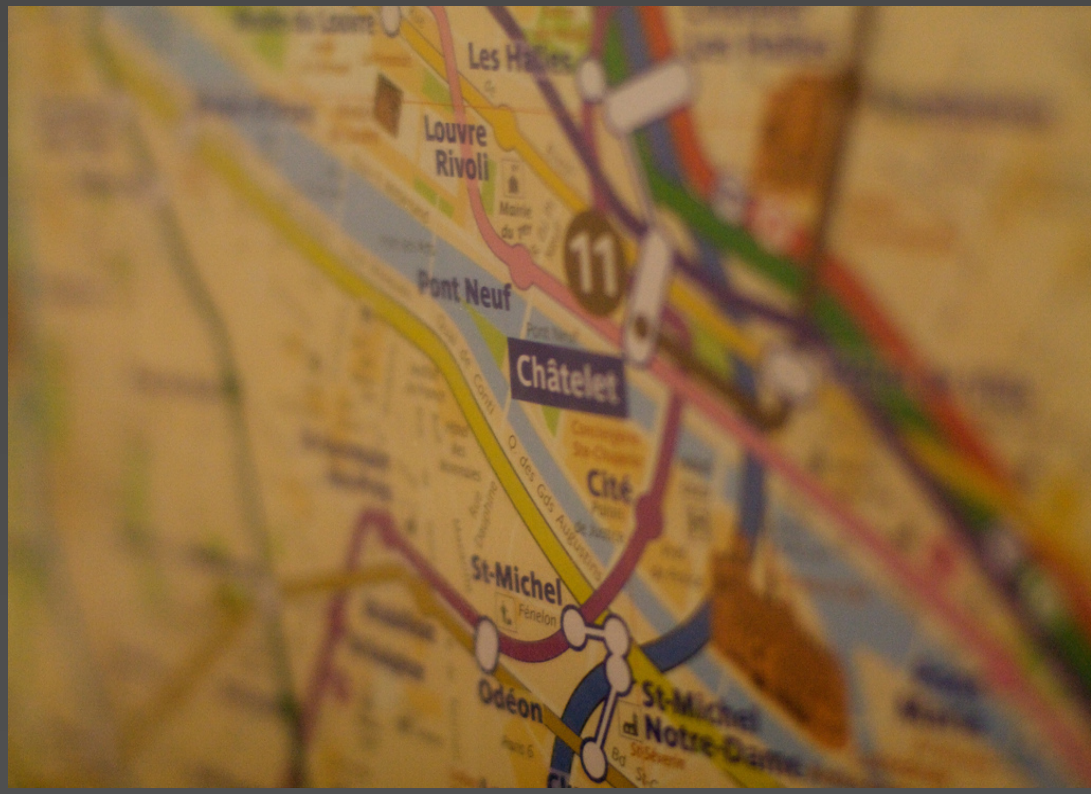
alacrita

...but Europe is very hard to navigate

Not a "single market"
27 national markets subdivided into many distinct regions

Reimbursement systems
Shifted from best possible care to best value, acceptable care

Bureaucracy
A word created in Europe



alacrita

The CE mark hurdle is set to rise

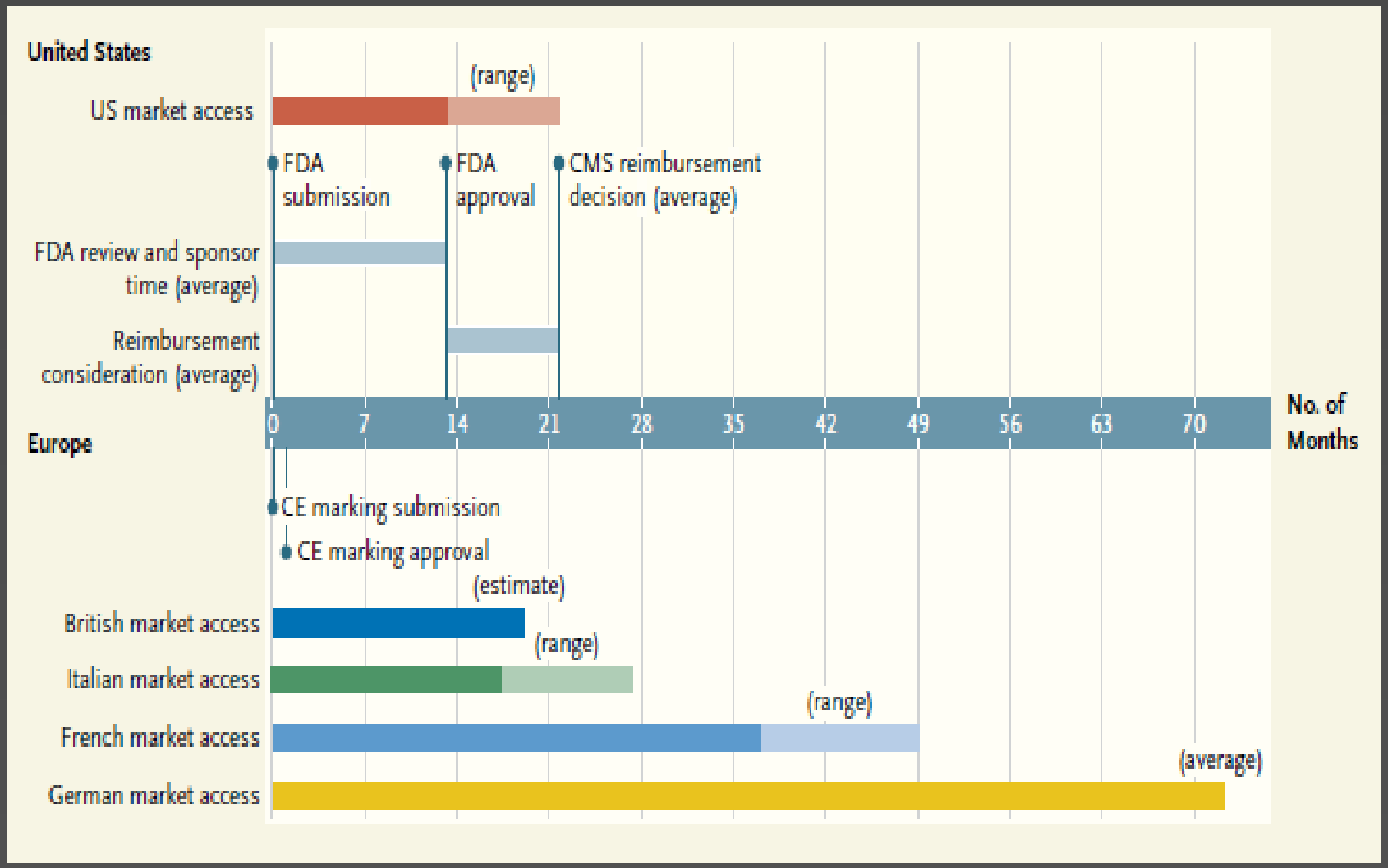
EU Regulation on IVDs will:

- Re-rate risk categories
- Require more clinical evidence requirements
- Tighten up assessment procedures

For medical devices:

- EC has proposed a new level of scrutiny
- Members of the EP proposing new system of pre-market approval
- Changes likely from 2017 onwards

Time-to-market vs. time-to-CE mark

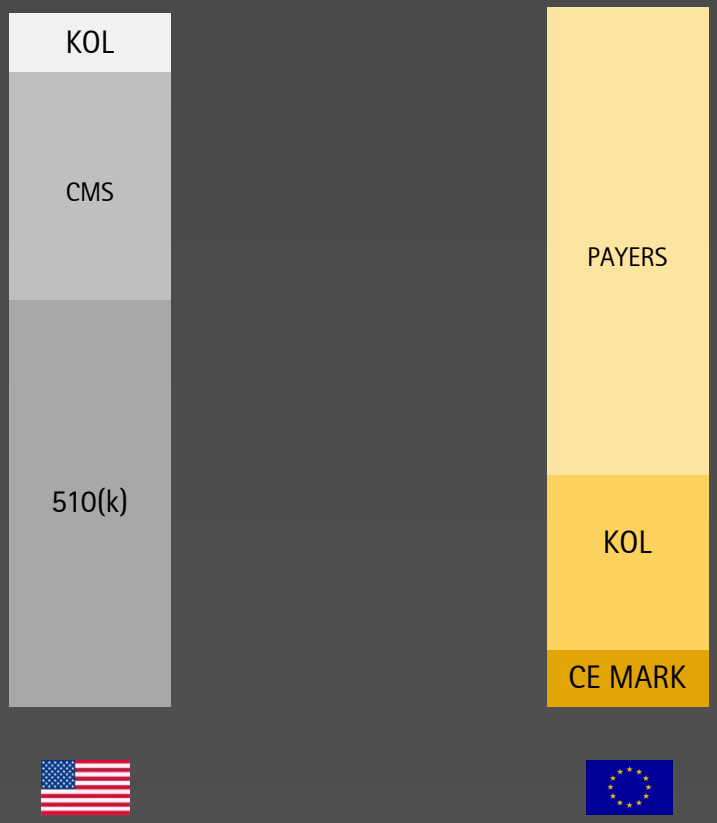


N Engl J Med 2012; 367:485-488

alacrita

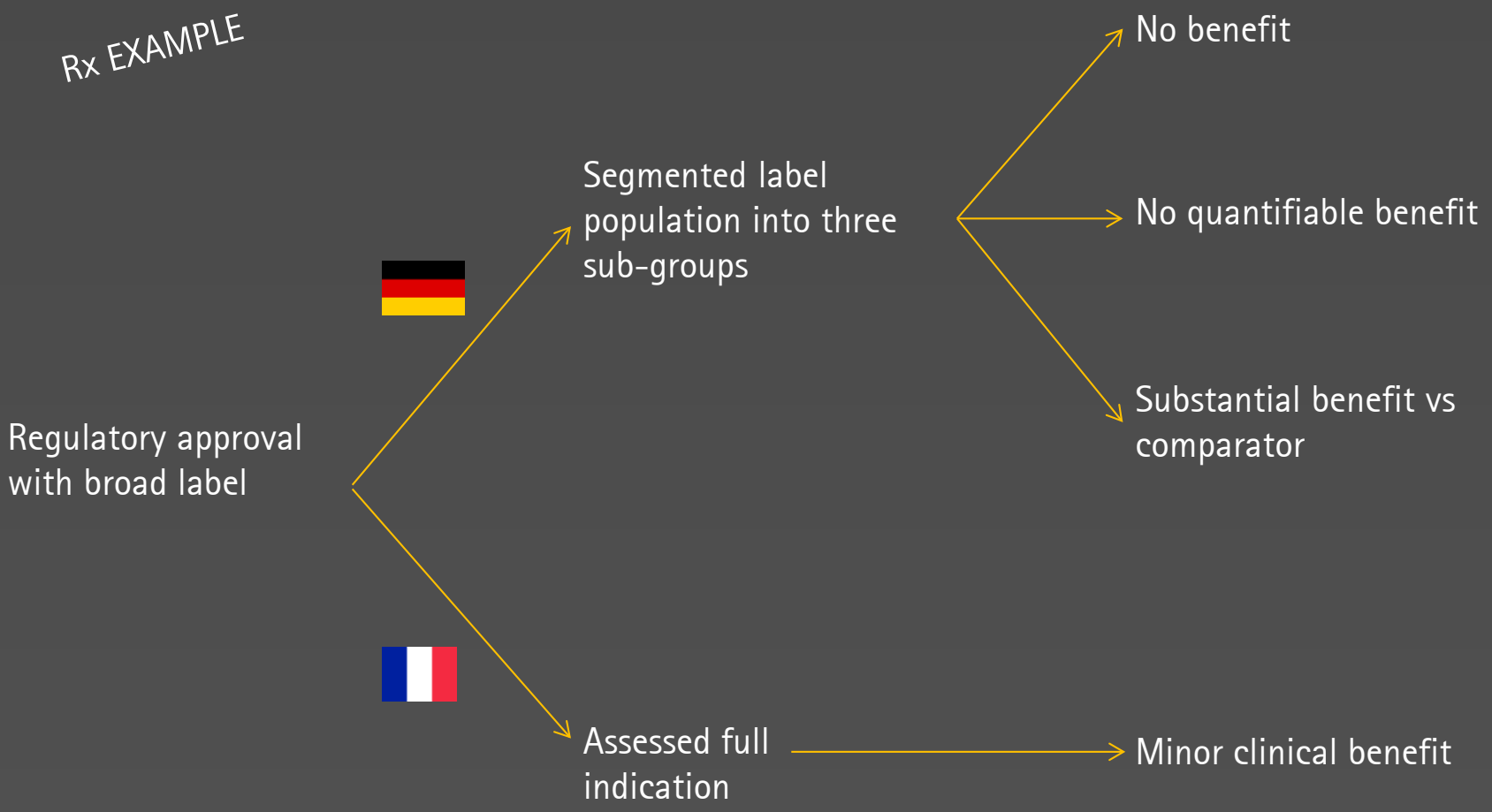
Different risk profiles, same hurdle height

ILLUSTRATIVE



alacrita

EU payers can take differing views



alacrita

Payers often restrict both access and price

DRAFT GUIDELINE

NICE National Institute for Health and Care Excellence

Oncotype DX is recommended in people with oestrogen receptor positive (ER+), lymph node negative (LN–) and human epidermal growth factor receptor 2 negative (HER2–) early breast cancer to guide chemotherapy decisions if:

- the person is assessed as being at intermediate risk, and
- where the decision to prescribe chemotherapy remains unclear, so that information on the biological features of the cancer provided by Oncotype DX is likely to help in predicting the course of the disease, and
- the manufacturer provides it to NHS organisations at the price offered through the confidential arrangement agreed with NICE.

oncotype DX® Breast Cancer Assay

What payers really want

Does it provide value?

How well does it work?

- Safety
- Clinical performance
  - Setting
  - Patient subgroups
  - Comparator(s)

Can it save money?

- Price
- Health system costs
- (Societal costs/benefits)

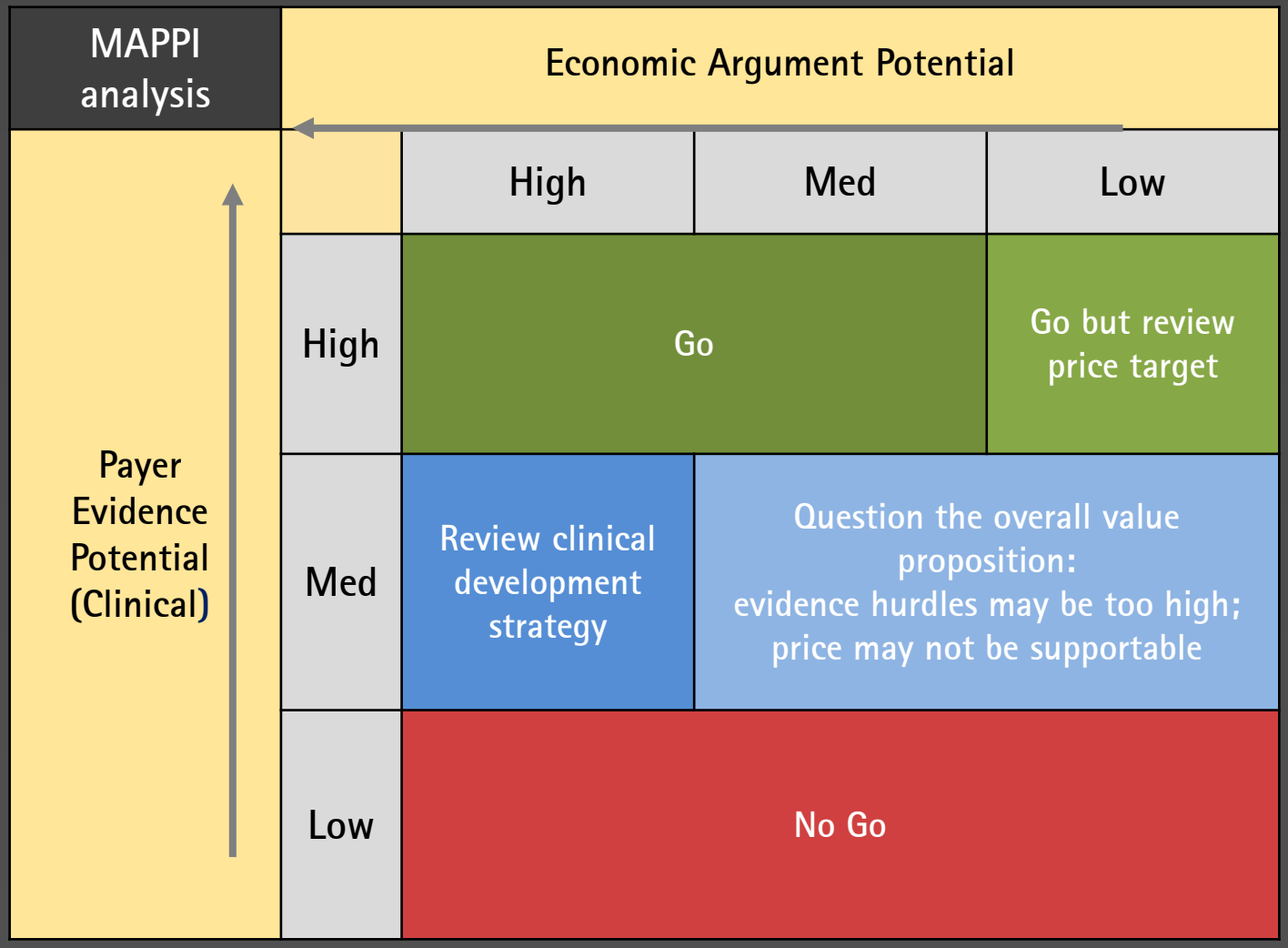
Payer relevance extends to early development

- Post launch: value dossier, pricing negotiations, HEOR trials, Service Impact Models, etc

---

- During development:
  - Payer value elements (clinical and economic) in product profile
  - Clinical trial design to address payer needs
  - Additional payer evidence programme

Design 'strategic market access' into the project



Source: Therapeutic Challenges Analysis, adapted from: http://www.therachallenges.com/mappi.html

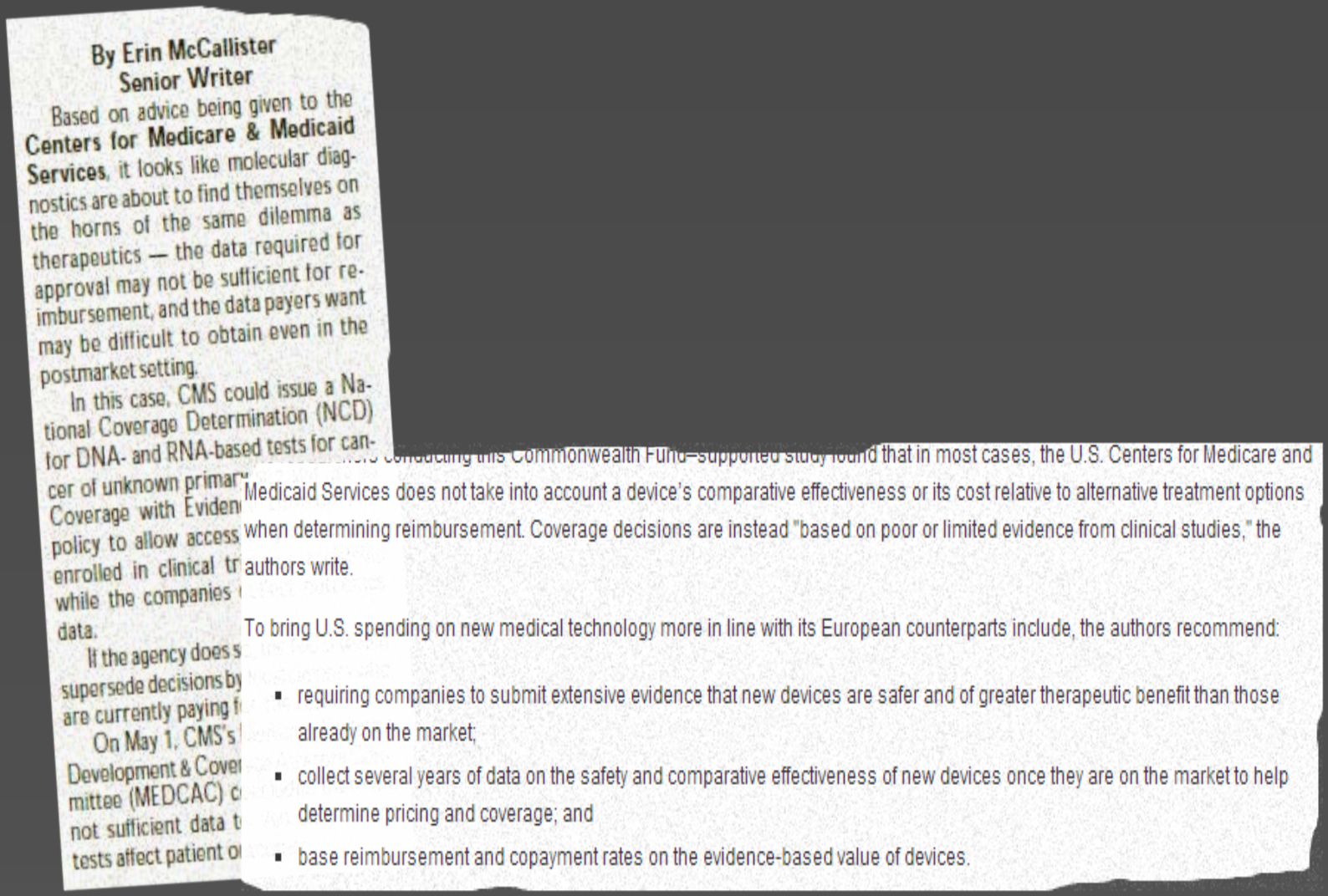
alacrita

Seek input from 'real payers'

Illustrative Payer Research Panel

Germany	▪ Head of product supply and reimbursement of a Statutory Health Insurance covering 4m ▪ Negotiates NUBs (Neue Untersuchungs- und Behandlungsmethoden) with hospitals
	▪ Member of INEK (Institute for the Hospital Remuneration System) ▪ Involved in the definition DRG codes and associated reimbursement rates ▪ Reviews applications for NUBs at national level
France	▪ Member of the CNEDiMTS at HAS (Haute Authorité Santé) ▪ Reviews and votes on new products/indications (SA & ASA, reimbursement recommendations)
	▪ President of the COMEDIMS (New Drug Committee) at APHP (Paris Public Hospital Group) ▪ Vice President of the AMM Commission at AFSSAPS
Italy	▪ Member of regional Commissioni Regionali Dispositivi Medici: evaluates novel Medical Devices and issues recommendations on their use
	▪ Member of Lombardi HTA agency
UK	▪ Member of NICE appraisal committee ▪ Head of the Liverpool Health Economics Unit
	▪ Formulary Advisor for Surrey & Sussex NHS Trust; leads regional Joint D&T Committee ▪ Member of the External Reference Group on Cost Impact Modeling for NICE

This will soon be a part of the US scene…



By Erin McCallister
Senior Writer

Based on advice being given to the **Centers for Medicare & Medicaid Services**, it looks like molecular diagnostics are about to find themselves on the horns of the same dilemma as therapeutics — the data required for approval may not be sufficient for reimbursement, and the data payers want may be difficult to obtain even in the postmarket setting.

In this case, CMS could issue a National Coverage Determination (NCD) for DNA- and RNA-based tests for cancer of unknown primary

Coverage with Eviden

policy to allow access

enrolled in clinical tr

while the companies

data.

If the agency does s

supersede decisions by

are currently paying f

On May 1, CMS's

Development & Cover

mittee (MEDCAC) c

not sufficient data t

tests affect patient o

conducting this Commonwealth Fund–supported study found that in most cases, the U.S. Centers for Medicare and Medicaid Services does not take into account a device's comparative effectiveness or its cost relative to alternative treatment options when determining reimbursement. Coverage decisions are instead "based on poor or limited evidence from clinical studies," the authors write.

To bring U.S. spending on new medical technology more in line with its European counterparts include, the authors recommend:

- requiring companies to submit extensive evidence that new devices are safer and of greater therapeutic benefit than those already on the market;
- collect several years of data on the safety and comparative effectiveness of new devices once they are on the market to help determine pricing and coverage; and
- base reimbursement and copayment rates on the evidence-based value of devices.

alacrita

Europe is no panacea, but remains important

Europe is worth considering…

…and although it's not as easy as you think…

…it may provide valuable market access lessons

alacrita

www.alacritaconsulting.com

Anthony Walker, PhD

awalker@alacritaconsulting.com

Alacrita LLC
One Broadway, 14th Floor
Kendall Square, Cambridge, MA 02142

Alacrita LLP
London BioScience Innovation Centre
2 Royal College Street, London NW1 0NH

alacrita