

OPERATIONAL CHALLENGES

... FOR INITIATING A LIFE
CYCLE APPROACH TO DRUG
REVIEW



OPERATIONAL CHALLENGES

... FOR INITIATING A LIFE CYCLE
APPROACH TO our understanding of
~~DRUGS REVIEW~~



OPERATIONAL CHALLENGES

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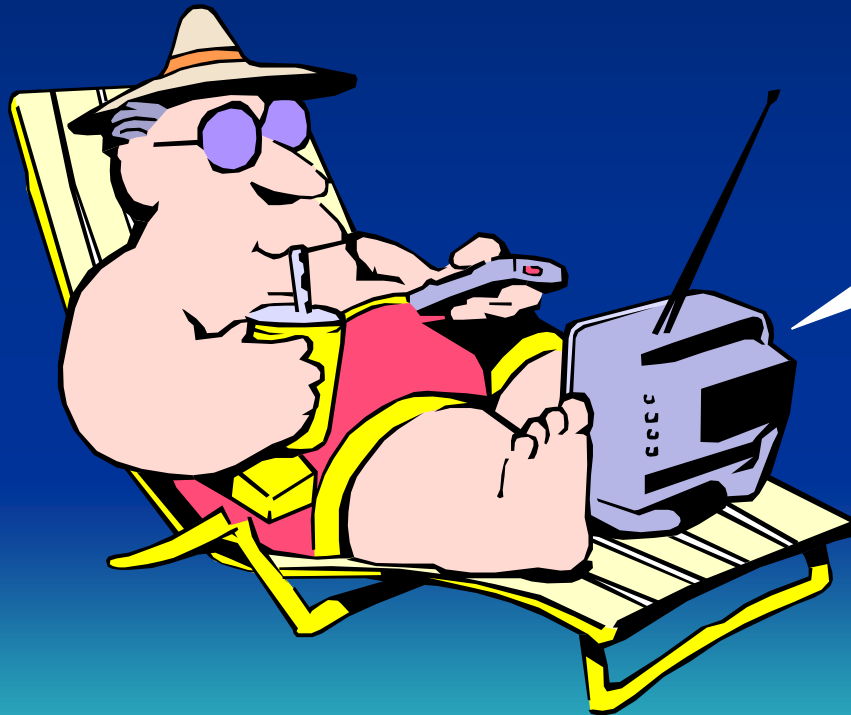
Chair, National Steering Committee, Centers
for Education and Research on Therapeutics

IOM Drug Roundtable, March 12, 2007



But first...

**a word from
our sponsors!**

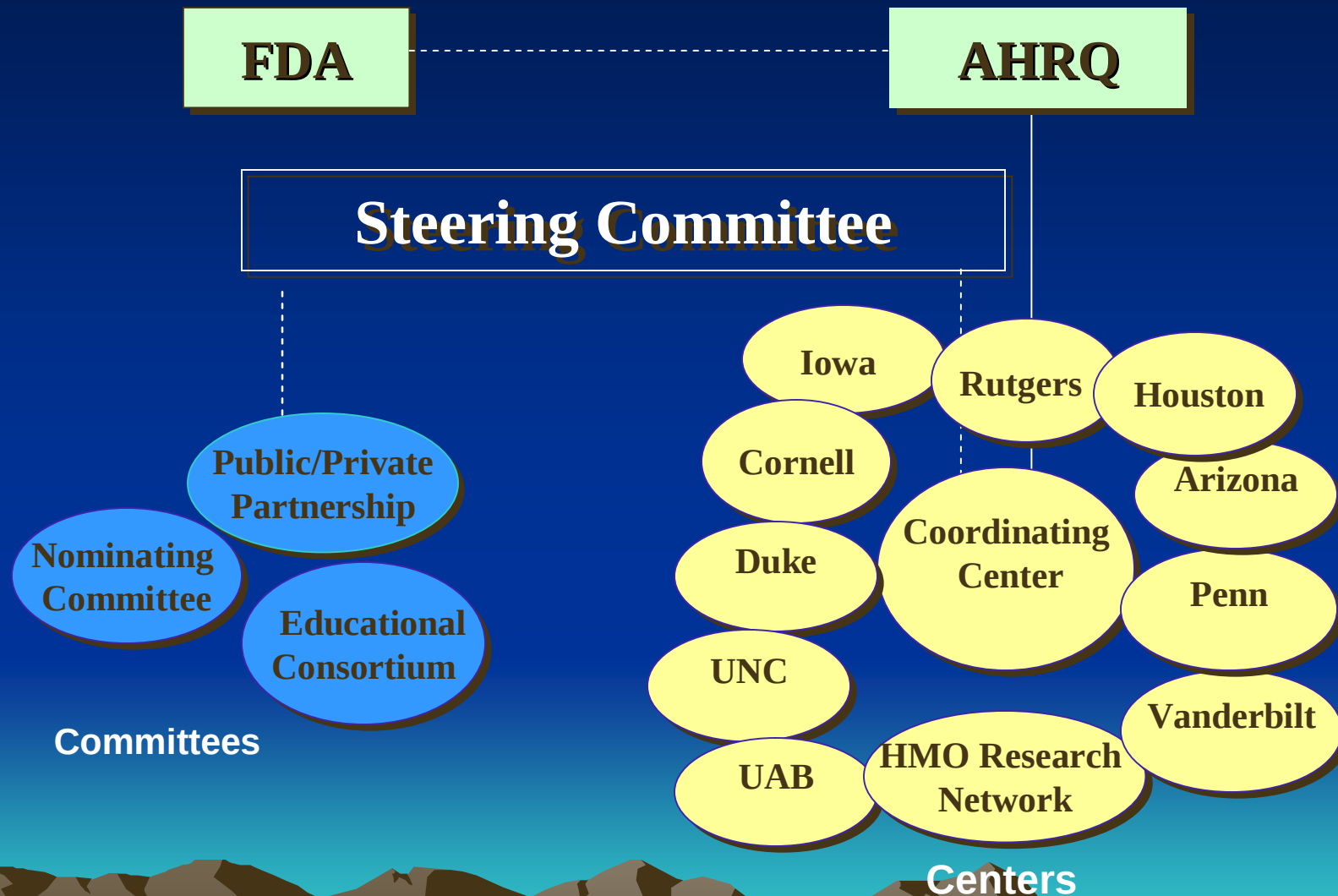


THE CERTS



- FDAMA mandated
- AHRQ funded
- Nationally coordinated/steered
- Eleven Centers
- Public Private Partnership based
- RISK centered

CERTs Structure



OPERATIONAL CHALLENGES

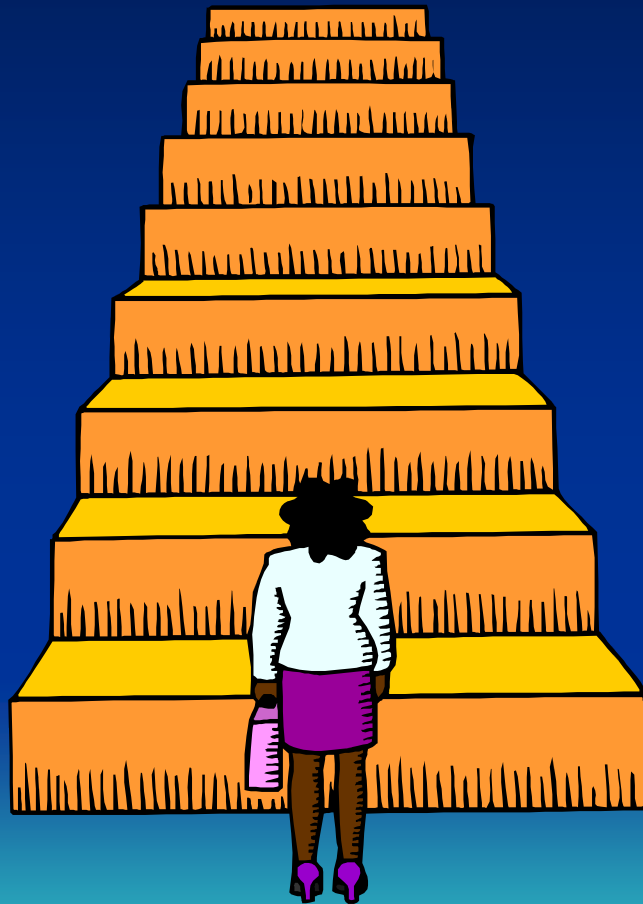
METHODS
PEOPLE
EVIDENCE
ORGANIZATIONS



OPERATIONAL CHALLENGES ...METHODS



Remember, Product Safety Builds Over Time!



Phase 4 Studies



Phase 3 Studies



Phase 2 Studies



Phase 1 Studies

OPERATIONAL CHALLENGES ...METHODS

Power calculations for safety

Power calculations for uncertainty

Calculus for benefit to risk ratio and balance (much less “continuous”, 4.5)

Benchmarks for “acceptable” risk and uncertainty

Integration of post-marketing evidence with pre-marketing basis



OPERATIONAL CHALLENGES ...METHODS

Effectiveness beyond efficacy
(much less five years, 5.4)

And

How to manage risk (much less
Evaluate Risk-Maps, 4.4)



OPERATIONAL CHALLENGES ...PEOPLE



OPERATIONAL CHALLENGES ...PEOPLE

Workforce current and needed

Best location for staff (and which
staff ... rec 3.4)

Staffing mix

Competencies

Training and education

Certification and m.o.c.

Academic infrastructure



OPERATIONAL CHALLENGES ...EVIDENCE



OPERATIONAL CHALLENGES ...EVIDENCE

Limitations of pre-clinical predictive value, limits of generalizability from pre-approval RCTs, limits of spontaneous reports

Needs and best sources for population-based data, harnessing the powers of the automated medical record and other LAMPs (much less how to talk about it, 4.13)



OPERATIONAL CHALLENGES ...ORGANIZATIONS



OPERATIONAL CHALLENGES

...ORGANIZATIONS

Role clarification ... which work best
done in industry, agency, practice,
academia

Role clarification ... best locus of work
in each organization (much less
alignment across ..)

Culture of Safety

Cross organizational collaboration,
public private partnerships



OPERATIONAL CHALLENGES ...ORGANIZATIONS

Oh, yes ... and who should PAY
for what and how?

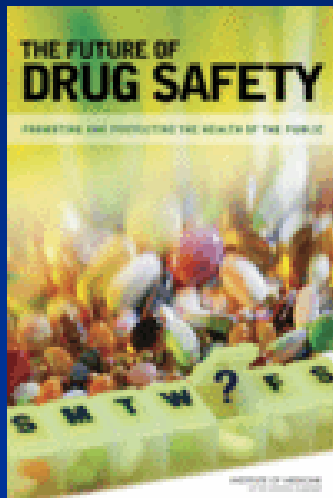


OPERATIONAL CHALLENGES ...and now a little 'extra'!



IOM Report on Drug Safety

Late Breaking
News!



The Future of Drug Safety:
Promoting and Protecting the
Health of the Public

www.iom.edu

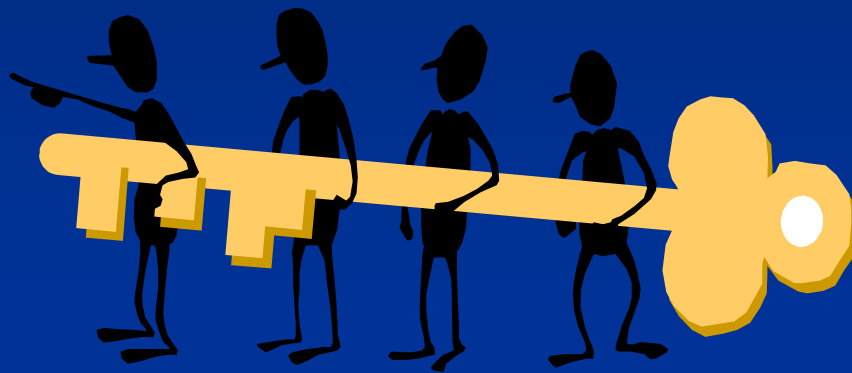
OPERATIONAL CHALLENGES ...and now a little 'extra'!

VISION: IT'S NOT JUST ABOUT
A LIFETIME OF DRUG SAFETY
... IT'S DRUG SAFETY FOR THE
PUBLIC'S HEALTH: SAFE
DRUGS SAFELY AND WELL
USED



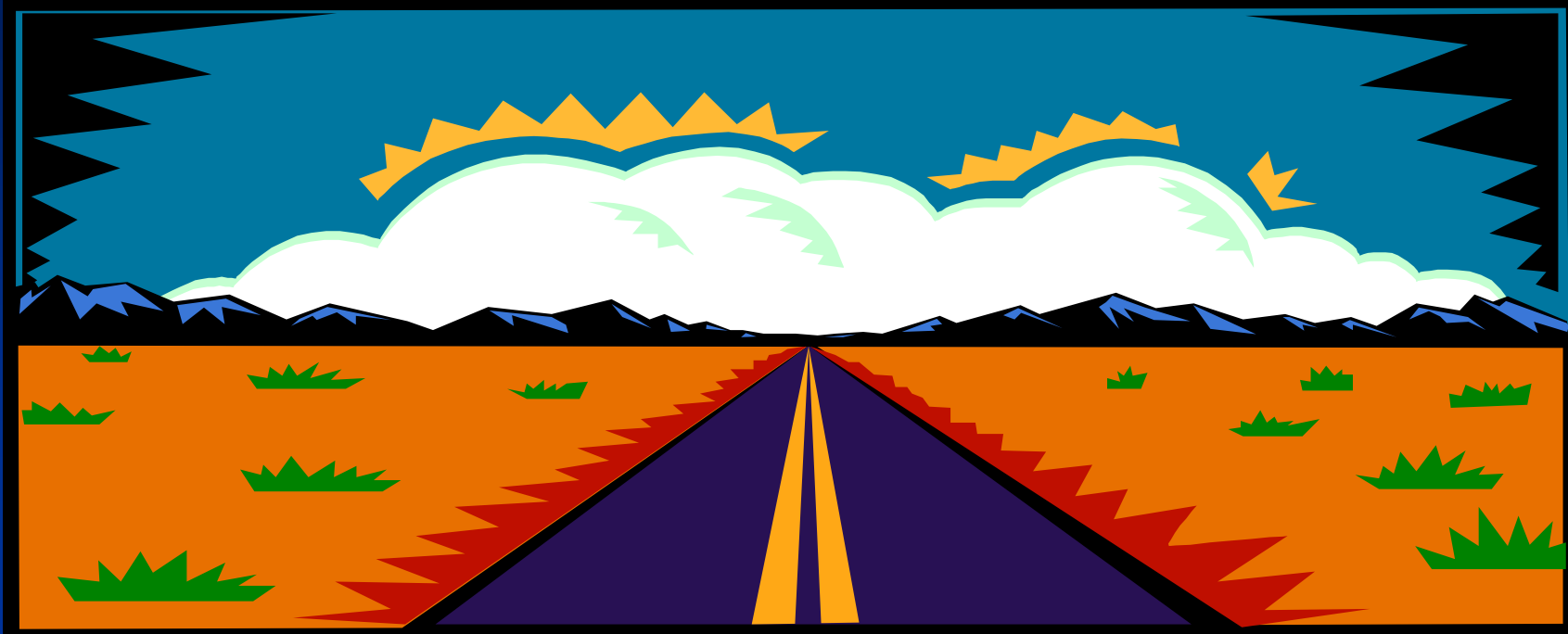
LIFETIME DRUG SAFETY

The Way Forward: a Public Health System's KEY PARTNERS



- Industry
- Government
- Practice
- Public
- Academia including...
the CERTs

THE PUBLIC HEALTH, THE
FDA, AND YOU... US!!



SO, LET'S G.O.W.I! FDA
HAS ASKED FOR OUR
OWNERSHIP!!!