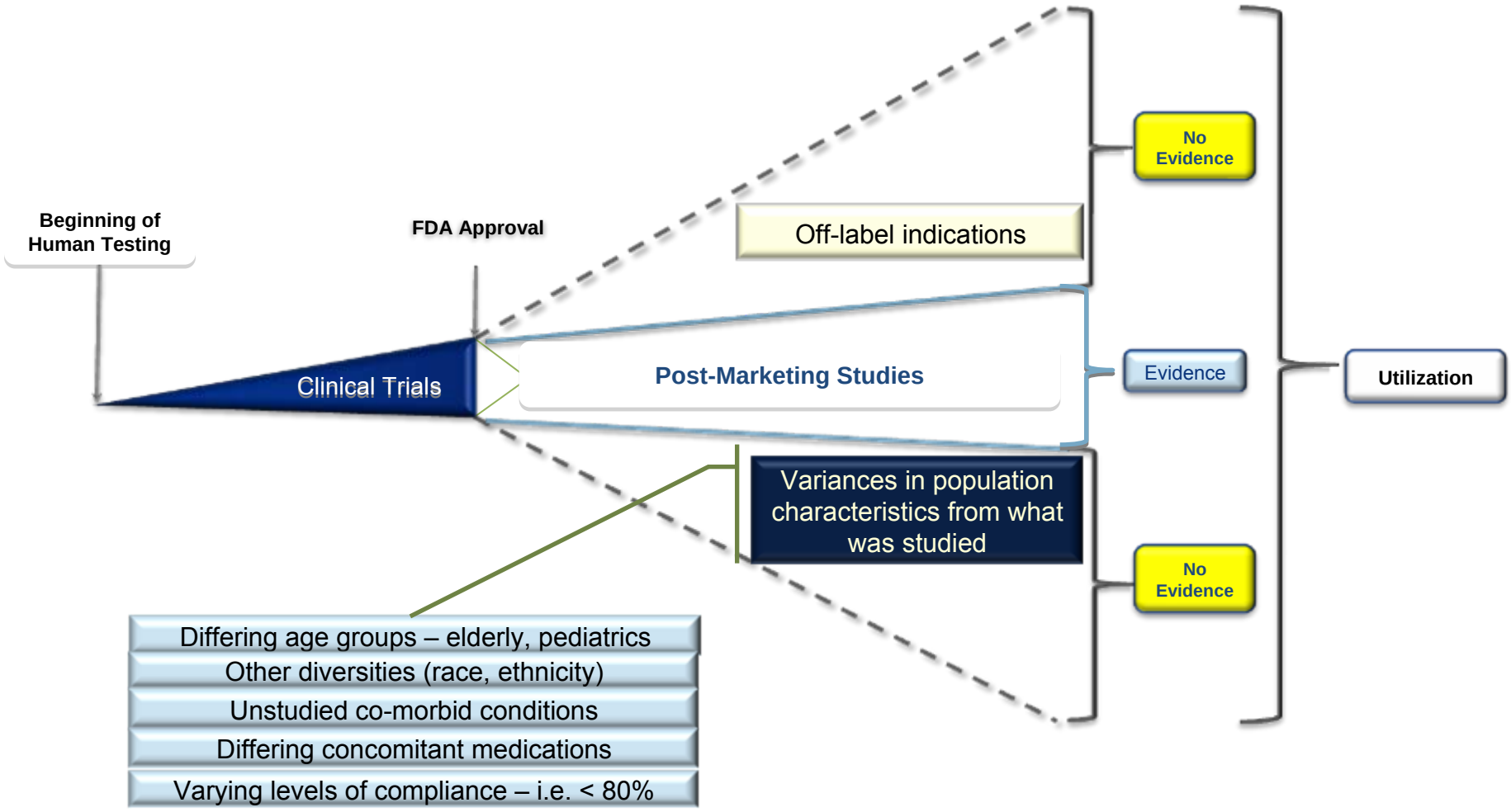
Communicating Findings from Active Medical Product Surveillance

Brian Sweet, BS, Pharm., MBA
Chief Pharmacy Officer
Nov. 17, 2010

WELLPOINT
Health. Care. Value.

The Importance of Real World Evidence



WELLPOINT
Health. Care. Value.

The Safety Evidence Gap

Real-World Effectiveness

	Efficacy (Clinical Trial Data)	Effectiveness (Real-World Data)
Objective	Is it safe under ideal circumstances	Is it safe under usual circumstances
Setting / Design	Controlled clinical trial	Real-world clinical practice
Purpose	Regulatory approval (FDA)	Safety in populations
Intervention or treatment	Fixed regimen	Flexible regimen
Comparator	Placebo/active comparator	Active comparator/usual care
Subjects	Homogenous/highly selective (stringent inclusion/exclusion criteria)	Heterogeneous / any subjects
Outcomes	Clinical efficacy & safety endpoints	Clinical, humanistic, economic & safety endpoints

Goal of Outcomes-Based Formulary

The goals of our Outcomes-based Formulary are to provide our members with drugs and therapies that will help:

- **Improve** clinical health outcomes
- **Improve** quality of life
- **Improve** productivity at work, school, and leisure activities
- **Reduce** total cost of care (pharmacy and medical)

A more expensive medication can be less expensive if it is safer and if the member's health is improved, resulting in use of less healthcare resources

- **Improved** health outcomes
- **Reduced** emergency room visits
- **Reduced** hospitalizations

WELLPOINT
Health. Care. Value.

Process of Outcomes-Based Formulary

Promote Evidence-Based Medicine (Critical Review of the Clinical Trial Data)

- We critically review the clinical trial data to determine if the study is of sufficient quality to be used for decision-making. Poor quality studies may have misleading results, and therefore are not used for decision-making.

Evaluation of the Clinical Value of a Drug

- High quality evidence is used to determine if a drug is favorable, comparable, or unfavorable to another drug. We provide drugs that will help result in better outcomes for our members.

Determine Real-World Outcomes and Total Cost of Care

- We conduct analyses using integrated pharmacy, medical, and lab data from one of the largest claims databases in the world. We are able to determine which drugs are most likely to result in favorable outcomes in a “real-world” setting.

Advance Health Care Quality and Improve Outcomes

- We combine high-quality clinical trial data and real-world outcomes data to provide our members with drugs that will result in optimal outcomes (i.e. clinical, quality of life, productivity, and total cost of care).

WELLPOINT
Health. Care. Value.

Evaluating Safety Evidence

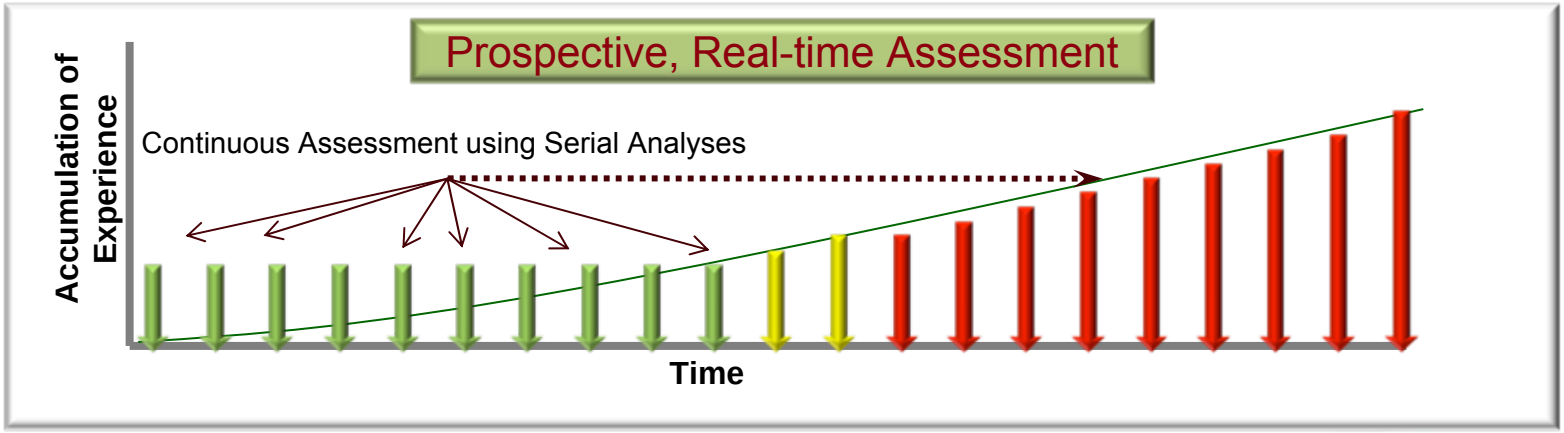
Our evidence quality criteria for evaluating safety data varies from quality criteria used in clinical efficacy due to differing evaluation designs. We often struggle with limited availability of safety data.

- Data sources:
  - Observational data
  - Case reports
  - FDA medical reviews
  - Other sources that provide insight

WellPoint Healthcare Safety Sentinel System

WellPoint's investment in an active surveillance system

- Size and depth of our data
- Research experience and capabilities of HealthCore subsidiary
- Transparency and commitment to share developmental learnings
- Commitment to working collaboratively with FDA in the Sentinel Initiative

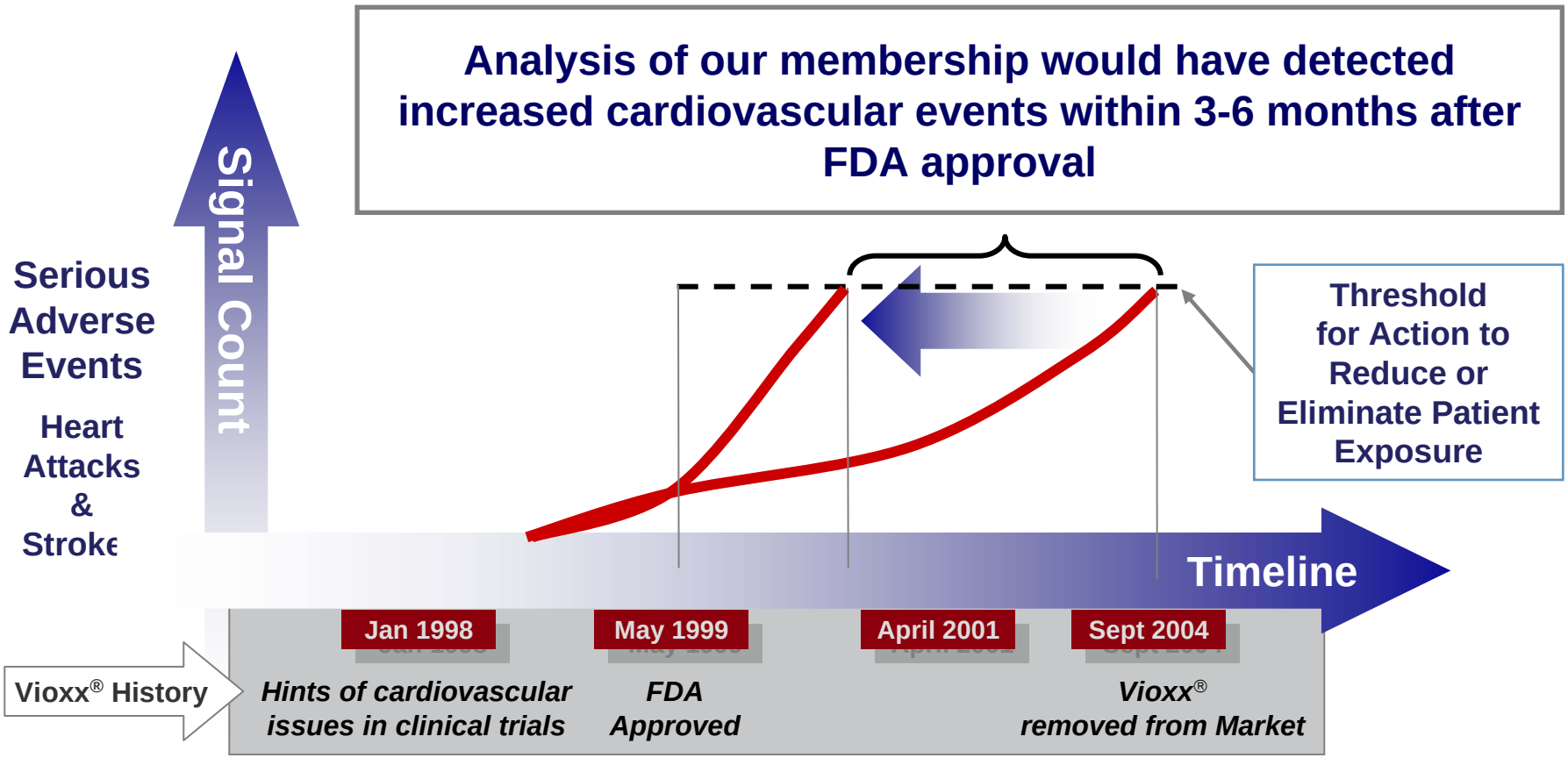


How We Handled Vioxx

- Placed PAs on all Cox-2 inhibitors.
- Removed Vioxx from the formulary two years before Merck pulled from the market.

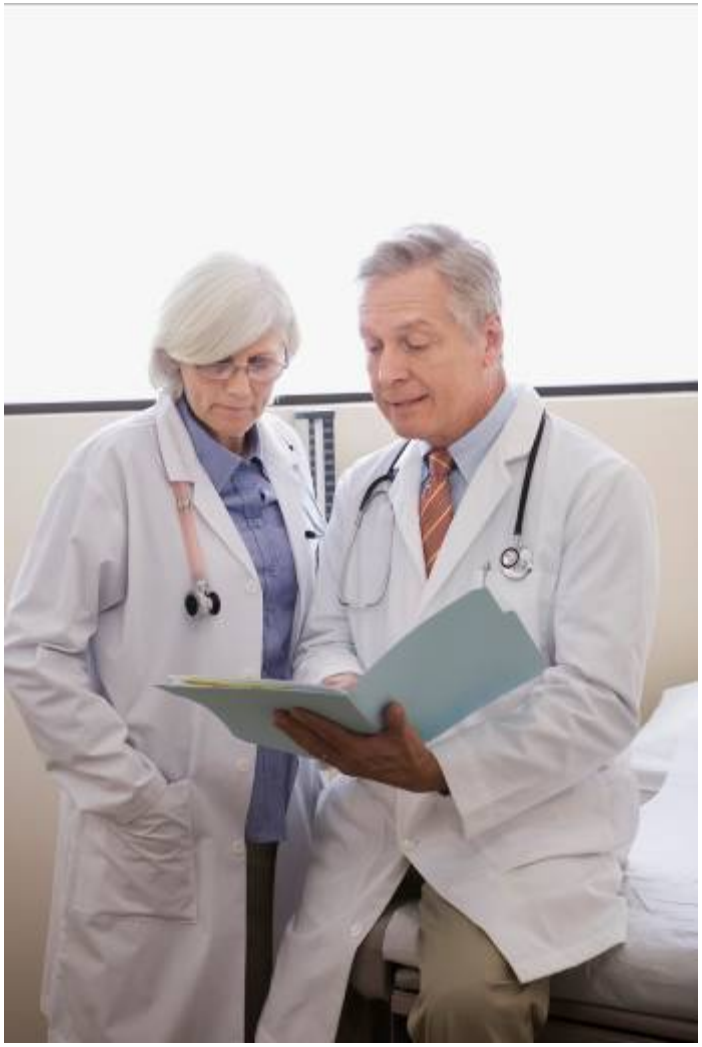
WellPoint Healthcare Safety Sentinel System: Vioxx Case Study

33 million members' claims, pharmacy, and laboratory data enables population safety and public health research



How Would We Handle a Vioxx in the Future?

- With an earlier signal, efforts to better understand the significance and population variability can be undertaken.
- Then, a more rigorous epidemiologic safety study would be performed to confirm the signal.
- This could allow for more precise controls and an education campaign targeted at the specific population at risk occurring sooner.



WELLPOINT
Health. Care. Value.

Sharing Safety Information

- Communicate signals of potential issues to regulators and sponsors immediately.
- Communicate validated findings to sponsors, data partners, and payers as soon as feasible.
- Communicating with the public is critical—the question mark is the timing.
- Be transparent and clear about valid findings with all stakeholders (Good example: CDC's www.flu.gov for H1N1 information in 2009/2010)
- Explain safety issues in context with previous findings from other sources including clinical trials.
- Avoid warnings to the public with a lack of specific information, as they could potentially create greater issues.

WELLPOINT
Health. Care. Value.

Appropriate Context for Findings

Most medical findings are based on weighing the benefits versus the risks.

- Treatment decisions are based on the patient-physician interaction.
- One size does not fit all.
- One-to-one interaction between physician and patient is the most effective form of communication.
- Safety data can inform that part of the dialogue.