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AARP® **R**X WATCHDOG **R**X REPORT

A CONSUMER NEWSLETTER ON PRESCRIPTION DRUG COSTS

AARP Adds Quality Rx Research to Its Website

Starting today, AARP is offering a new feature on its website, www.aarp.org. By clicking on **Health and Wellness, Effectiveness and Safety of Drugs/ResearchRX**, anyone with a computer has access to comparative information about the effectiveness and safety of medicines within nine prescription drug classes. A class is a group of drugs that are similar in effect and are used to treat the same illness, for example statins for lowering cholesterol or nonsteroidal anti-inflammatory drugs for treating arthritis. There will soon be results for 25 drug classes. AARP's conclusions found on the site are based on an independent review and assessment of the available medical evidence undertaken by the Drug Effectiveness Review Project of Oregon Health and Science University's Center for Evidence-based Policy.

Evidence-Based Research

What the Rx Industry Might Not Want You to Know

When you need a medication you want the best there is. You want the drug that's most effective with the fewest side effects. But how do you and your doctor determine if there is a difference among the many drugs available to treat your condition, and if there is a difference how do you determine which is best for you?

The Food and Drug Administration offers the American consumer no help with answering this question. Before a new drug can be marketed, the FDA requires only that the therapy be proven more effective than a placebo. There is no requirement for head-to-head studies showing how that drug compares to other medicines designed to treat the same condition.

So where can you find comparative information? A good way to start is to rely on a process called evidence-based research, now available at www.aarp.org. In this process, medical research that studies the use of drugs to treat a specific condition is collected, systematically reviewed and analyzed. In the analysis the effectiveness and side effects of a drug are compared with similar drugs.

If one drug stands out from the rest, you and your doctor

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Strong Opposition From the Pharmaceutical Industry

In 2001 in Oregon, Medicaid drug spending was projected to increase by 60 percent over two years. Gov. John Kitzhaber's administration responded by seeking legislative authorization to establish a preferred drug list. To maintain the health benefits of the proper use of medicines, the administration wanted its list to be based first on a comparison of the effectiveness and safety of medications and then on their price.

In spite of AARP's support, the drug industry fiercely opposed the measure and succeeded in keeping the proposed legislation bottled up in committee until the evening the legislature was scheduled to adjourn. A compromise bill passed only after Gov. Kitzhaber promised to veto the entire Human Services budget.

The industry remains determined to discourage state Medicaid and other public programs from using evidence-based research from the Drug Effectiveness Review Project, now a collaboration of 14 states and two private organizations, to

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Evidence-based Research

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can begin your treatment with that drug. It is still very important for you to track the benefits and side effects you are experiencing because we don't all react to medicines in the same way and a change may need to be made.

Often research does not show that one drug is better. But that's good to know as well. If no drug is shown to be more effective or have fewer side effects, then it makes common sense to choose the drug that's least expensive. For too many people, not being able to afford a drug is the biggest barrier to experiencing the effectiveness of that drug.

Since the regulations that govern the approval of new drugs and their use do not require comparing one drug with another, evidence-based research needs to be funded separately. This funding is now coming from federal and state sources and needs to be continued at an increased level. And, in addition to funding for the research, adequate funds must be allocated to disseminate the results to patients and healthcare providers. ○

Strong Opposition

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create preferred drug lists. The industry tactics seek to create fear that needed medications will be denied and that the research process itself is flawed. For example:

- The industry says that the process is only about cutting costs. The fact is that the reports produced by the DERP do not mention cost. They focus only on effectiveness, safety and subpopulations.
- The industry says that using DERP research will make states liable in court for damages resulting from patients not getting the drugs they need. The fact is that having better clinical information to substantiate clinical decisions makes it less likely that a state will be sued, particularly since the DERP research does not replace the role of the patient's doctor. The doctor still has to prescribe the drug after independent consultations with his or her patient.
- The industry says that the DERP limits the evidence it uses in its reviews, which implies that the reviews are incomplete or biased. The reality is that the DERP limits the evidence it uses only by not considering poorly designed or executed studies. Including only good quality evidence substantially improves the quality of the reviews. ○

Systematic Reviews: The Gold Standard

Systematic reviews are the gold standard for evaluating large amounts of clinical information. They avoid the pitfall of relying only on recent studies and instead take a cumulative look at what the science on a subject shows.

They are designed to answer these three questions:

- What is the relative **effectiveness** of drugs within this class for treating these conditions?
- What is the relative **safety** of drugs within this class when used to treat these conditions?
- What does the evidence show about a **differential effect of these drugs on sub-populations based**

on gender, race, age or ethnicity?

These reviews systematically work through five steps:

- Carefully determining the questions the research will answer. This includes a statement of what interventions will be studied, for what conditions, and for what outcomes.
- Carefully searching all available evidence related to the questions. This usually entails a thorough search of all of the major medical databases such as EMBASE, MedLINE, and the Cochrane Registries. In addition, the bibliographies of studies found to be relevant are searched for citations that might not have shown up in the databases. Efforts are made to find

unpublished information that may be useful. And drug manufacturers are asked to provide any evidence that they think might apply to the questions.

- Evaluating studies that are relevant to the key questions to ensure they are well designed and well executed. Those studies that are of good quality are then used in the analysis of the evidence.
- Synthesizing, or analytically combining, these studies into a thorough report.
- Conducting peer reviews and allowing for a public comment period that lets all interested parties provide feedback on the evidence, the methods and the conclusions.

Vioxx: A Rush to Judgment

What the Evidence Showed About Vioxx . . . and How Television Commercials May Have Persuaded Us Otherwise

In determining the relative value of different drugs of the same class, it's important to know what the FDA does and does not do. The FDA tells us whether a drug is better than a sugar pill for treating specific conditions and whether a drug is safe when used as suggested. The FDA does not tell American consumers how one drug compares to another in effectiveness or safety. Nor is the FDA responsible for giving patients or doctors any sense of the value of a specific prescription drug. That task falls to the companies themselves, to physicians, to other licensed practitioners and to patients.

Finally, the FDA works to make sure that the drug industry sticks to the facts in its advertising.

Pharmaceutical companies are not likely to promote anything negative about their drugs. While the FDA is able to make certain that they do not say or write anything beyond what they have proven, the “image” any drug company is able to project to doctors and patients is another matter. Take Vioxx for example.

Early Suggestions of Risk

Merck developed Vioxx in the '80s and '90s to counter inflammation and pain from arthritis. While the drug was effective compared to a sugar pill, Vioxx was never shown to be more effective than ibuprofen — an inexpensive, over the counter, arthritis medicine. So when it comes to the pain and swelling of arthritis, Vioxx never was shown to be more effective than ibuprofen.

By 2001, the major advantage of Vioxx appeared to be fewer side effects — especially stomach upset and irritation. That is important since ibuprofen and other arthritis medicines can cause significant stomach irritation. However, the same study that showed Vioxx safer for stomachs also suggested that it caused heart problems that could lead to death in a small number of patients. The FDA decided that the makers of Vioxx could market the drug but should warn doctors about potential heart problems.

The warning to doctors came with mountains of other

information as part of a very long, complicated document. The commercials ran continually on television.

What image did the commercials project? One series focused on an appealing youthful figure skater burdened by the pain of osteoarthritis. The voice over says “one little pill, Vioxx, can provide powerful 24-hour pain relief” as our skater glides effortlessly in the background. The image was all about effectiveness — “one little pill.”

Evidence Research Caught the Problem

Not everyone bought the commercial's image. Physicians, pharmacists and consumers in Oregon and Washington had the advantage of access to an evidence-based report comparing the effectiveness and side effects of all arthritis medicines like Vioxx. Decision makers presented with this evidence could see that risking a heart problem for a drug no more effective than ibuprofen — even if it caused less stomach irritation — didn't make sense. They recommended that Vioxx not be included on preferred drug lists.

Subsequent research has of course confirmed the 2001 concerns. Vioxx is no longer available. This is unfortunate in many respects since it does cause less stomach irritation and likely would be useful in younger patients with stomach problems and no heart disease. The problem for the drug industry is that using the drug that way is not consistent with developing the consumer mind set needed to sell large quantities. We have spent billions of dollars on a therapy that was never more effective than less expensive drugs, turned out to be dangerous for some and now isn't available to those who could actually benefit from it.

AARP is working hard to disseminate to the public the kind of quality evidence that kept Vioxx off of some states' preferred drug lists. This research will be invaluable in assisting consumers to determine whether a medicine brings value to them. With such evidence in hand, we can talk with our doctors in a more informed way. Prescription drugs are important purchases. We need to spend the resources we have for the most value. We need to make that value decision based on the evidence not on advertising. ○

Why AARP Supports Evidence-Based Research

Better Information Leads to Better Decision Making

One challenge facing today's users of prescription drugs is to understand the proliferation of medicines designed to treat a single illness. To date, consumers, their doctors and other health care professionals have had almost no single source of comparative information about the effectiveness and safety of the different drugs from which they might choose to treat a specific condition.

Through its collaboration with the Drug Effectiveness Review Project (DERP), a collaboration of 13 state governments and two private organizations, AARP is making available on the Internet better information about the comparative effectiveness of prescription drugs. Anyone with access to a computer can now go to AARP.org and see the results of systematic reviews

of past and current research showing how well and how safely various drugs perform in treating a condition. This is objective, independent information compiled by researchers with no ties to the pharmaceutical industry. It can help patients make better health care decisions as well as stretch their health care dollars.

Some interest groups oppose the use of evidence-based research to establish preferred drug lists for state programs such as Medicaid. AARP believes their concerns can be addressed through a variety of consumer protection measures.

AARP sees this research as a vital component in its affordable health care campaign, an effort to secure access to high-quality health care for all Americans. ○

Glossary

Drug class: A group of medicines similar in effect that are used to treat the same illness, for example statins for lowering cholesterol or nonsteroidal anti-inflammatory drugs for treating arthritis.

Effectiveness: How well an intervention works to improve health outcomes when it is implemented under conditions of actual application.

Evidence-based method: A strategy for explicitly linking clinical practice recommendations to the underlying scientific evidence that demonstrates effectiveness.

Peer review: Review of health care provided by a medical staff with training equal to the staff which provided the treatment.

Preferred drug list (PDL): A list of drugs, classified by therapeutic category or disease class, that are considered preferred therapy for a given managed population. Also known as a formulary.

Systematic review: A critical assessment and evaluation of research (not simply a summary) that attempts to address a focused clinical question using methods designed to reduce the likelihood of bias. An organized method of locating, assembling and evaluating a body of literature on a particular topic using a set of specific predefined criteria. A systematic review may be purely narrative or may include a quantitative pooling of data, referred to as a meta-analysis.