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## When Good Information Truly Matters: Public Sector Decision Makers Acquiring and Using Research to Inform Their Decisions

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**WHEN GOOD INFORMATION TRULY MATTERS:  
PUBLIC SECTOR DECISION MAKERS ACQUIRING AND  
USING RESEARCH TO INFORM THEIR DECISIONS**

*Mark Gibson\**

INTRODUCTION

Since our nation's inception, there have been a variety of debates about the proper boundaries between the several branches of U.S. federal and state governments. The argument at the heart of these debates centers on how best to advance the public interest. While each branch operates under a different set of powers, restraints, and processes, if this dedication to the public interest is internalized into the deliberations of judges, legislators, and bureaucrats, then the quality of the information these branch officials use to inform their decisions is crucial to determining how well the public is served.

In the past, officials of the three branches typically depended on others to provide them with the bulk of the information necessary to complete their work. Legislators would receive information from lobbyists, advocates, legislative colleagues, and constituents. Executive branch officials heard from the same sources during policy formation, and because of their role in program administration, heard a great deal from vendors hoping to sell goods and services to the government as part of policy implementation. Judges heard from the parties arguing cases before them and in some cases, "friends of the court." This dependency has traditionally relied on the process of advocacy, where both sides present their arguments to the official and the official as decision maker determines the relative merits of the

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arguments in order to serve the public interest. Unfortunately, in this model there is no guarantee that the information presented to these officials by the respective advocates is of good quality. It is conceivable that both sides, in their push to prevail, will present only the information that is most supportive of their preferred policy or helpful to their case and most damaging to their opponents', without providing a clear view of the quality or thoroughness of the information used. In policy formation and implementation, this problem often manifests itself through advocates emphasizing emotional examples that may not be representative of the broader implications of an issue or through vendors claiming to have a study that shows that their product is superior while conveniently forgetting to mention multiple other studies that do not. Furthermore, judges are accustomed to having the parties before them provide information selected not for its thoroughness or factual strength but for its ability to support their case.

This paper explores a trend among public officials to become more active in gathering the information they use to inform their decisions. It is a trend in which executive branch officials seek and increasingly commission independent research to balance the marketing information supplied by vendors of goods and services, be they road contractors or cardiologists. This is a trend that finds legislators funding nonpartisan research and participating in networking and training to enhance their ability to access and interpret relevant high quality information; a trend in which members of the judicial branch appoint their own experts to provide information on highly technical subjects, and attend training on how to better assimilate scientific information into their decision making; a trend that is greatly enhancing the ability of officials throughout all branches of government to make informed policy decisions.

This paper is based on the author's personal experience as senior staff in legislative leadership, a governor's office, and as deputy director of the Center for Evidenced-based Policy, an academic center dedicated to linking high quality research to the practice of policy making. Part I introduces a research process known as a "systematic review" that is widely seen as the gold

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standard of clinical research. Part II explores the Drug Effectiveness Review Project (DERP) as an example of using systematic reviews to support public policy decisions. DERP is a collaboration of fifteen states and two other organizations that commissions and uses systematic reviews of global research to inform drug purchasing decisions in their Medicaid, corrections, workers' compensation, general healthcare, and employee benefits programs. Finally, the paper sets out examples of the criticisms being leveled at DERP and responses to those criticisms in order to give public officials a sense of the tone and substance of the debate that DERP has engendered.

#### I. SYSTEMATIC REVIEWS AS A DECISION MAKING TOOL FOR PUBLIC OFFICIALS

By their nature, public policy makers and the courts deal with very serious questions. It is understandable that those who work in these fields would covet information that would make their decisions unerringly correct. While the science available for supporting decisions in health policy has improved substantially, these improvements do not signal the approach of a time when definitive information is available to settle every question. The improvements have not created a "silver bullet" for each vexing issue but rather a useful tool that in some cases provides clear direction or aids in simply ruling out unhelpful courses. It behooves anyone involved in health policy issues to understand how to access and evaluate the specific information available for any given question.

One of the greatest advances in making research more useful to policy makers is the growing production and use of systematic reviews (SR) and, when appropriate, the meta-analysis of clinical evidence in healthcare. A well prepared SR allows one to have far greater confidence that the level of global knowledge on a given set of questions is accurately represented.<sup>1</sup> This is because the SR

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<sup>1</sup> DRUG EFFECTIVENESS REVIEW PROJECT Home Page, at <http://www.ohsu.edu/drugeffectiveness/methods/index.htm> [hereinafter DERP].

conscientiously searches for all available relevant evidence, rigorously analyzes its quality, and then synthesizes the best evidence in a manner that communicates the sum of that knowledge.

Of course, any public official worthy of the title hopes for research that provides “road to Damascus” clarity on the issue of the moment. While this is possible, it is more likely that the assistance provided even by a SR will be more nuanced. Often, officials must settle for the “best available” evidence at the time, which may include gaps and inconsistencies. Even less directly helpful can be the knowledge that there is no good evidence available to address a given issue. However, even this modest knowledge can be useful. Considering that in public policy, a failure to make a decision constitutes a decision to maintain the status quo, understanding the best available evidence can help a public sector decision maker judge the relative risk of selecting between the status quo and a possible initiative. For policy makers, judges, and jurors, understanding that there is no good evidence can provide a key counter to the claims of advocates expressing certainty in the merit of their position, product, or client.

## II. DRUG EFFECTIVENESS REVIEW PROJECT: POLICY MAKERS DIRECTLY ACQUIRING AND USING RESEARCH

On average, healthcare and education are the two largest expenditures in state budgets. Among the states, Medicaid expenditures now exceed expenditures on primary and secondary education.<sup>2</sup> One of the fastest growing segments of Medicaid spending is for prescription drugs. States are working diligently to ensure that they receive value for the dollars they spend. One strategy includes promulgating preferred drug lists, a process in which the state creates incentives for patients to use drugs that are similar in effectiveness but lower in cost. The key to successfully using a preferred drug list is making sure that the preferred drug is

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<sup>2</sup> NATIONAL GOVERNOR’S ASSOCIATION AND NATIONAL ASSOCIATION OF STATE BUDGET OFFICERS, *THE FISCAL SURVEY OF THE STATES: JULY 2005 4*, (June 2005) available at <http://www.nasbo.org/Publications/fiscalsurvey/fsspring2005.pdf>.

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of equal or greater effectiveness than other drugs used to treat a given condition. To ensure that they have the best possible information on which to base their selection of preferred drugs, fifteen states (and two other organizations) have formed an international collaboration called the Drug Effectiveness Review Project (DERP).

DERP provides systematic evidence-based reviews of the comparative efficacy/effectiveness and safety of drugs in twenty-six of the most commonly prescribed drug classes. The project is funded by multiple public and private entities, including fifteen states, the California Healthcare Foundation, and the Canadian Coordinating Office for Health Technology Assessment. In governing the project, these participating entities determine and prioritize the classes to be reviewed and the content of the research questions. When a systematic review is completed, each member organization makes its own decision on whether and how the results will inform the policies for which it is responsible.

The project is administered by the Center for Evidence-based Policy (CEP) at Oregon Health & Science University (OHSU).<sup>3</sup> The CEP supports the project's governance, contracting, and communications processes.

The reports are produced by a consortium of Evidence-based Practice Centers (EPCs), which are research organizations that are competitively selected by the federal Agency for Healthcare Research and Quality (AHRQ).<sup>4</sup> The research process is coordinated by the Oregon EPC at OHSU. The Oregon EPC is independent and separate from the CEP at OHSU.<sup>5</sup>

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<sup>3</sup> OREGON HEALTH AND SCIENCE UNIVERSITY, <http://www.ohsu.edu/policycenter> (last visited Dec. 2005). Details regarding DERP, including current drug class reports, are available to the public at the project website <http://www.ohsu.edu/drugeffectiveness>.

<sup>4</sup> EVIDENCE-BASED PRACTICE CENTERS, <http://www.ahrq.gov/clinic/epc> (last visited Dec. 2005). Other than commissioning research with these Centers, DERP has no relationship with AHRQ.

<sup>5</sup> DERP, *supra* note 1.

*A. DERP Process*

The entire DERP process is fully transparent and patterned after the systematic review process followed by AHRQ. Public input is solicited and considered multiple times for each report. All sources of information are fully disclosed, and investigators are prohibited from having any economic interests in the subjects they study.

The DERP process begins with the creation of a set of research questions. These key questions are formed through an iterative process in which interested parties exchange feedback in public meetings held in participating states and researchers and policy makers consult with one another directly in order to create a first draft. This draft is then posted on the project web site and comments are solicited from the industry and the public at large. Once public comment has been received and considered, the policy makers representing the organizations participating in the project agree on the final form of the key questions. Because the questions define the scope and focus of the report, the drugs in the class, populations of interest, diseases affected by the drugs, outcomes of interest, and the most appropriate types of studies to be included in the report, creating these questions can take several months.

When the key questions are finalized, they are sent to each pharmaceutical manufacturer in the United States and Canada along with a request for any research evidence the manufacturer is willing to share that is relevant to the questions. Informational dossiers submitted by the drug companies in response to this request are forwarded to the researchers for their consideration as they compile the report. Five to ten percent of the citations in a typical evidence report come as a result of these submissions.<sup>6</sup> Dossiers submitted by the companies are available to the public upon request.

As dossiers are gathered, the researchers begin their own search for clinical evidence. They routinely search the major clinical data bases such as EMBASE, MedLINE, and the Cochrane

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<sup>6</sup> Estimate provided by John Santa, MD, MPH, Medical Director for DERP.

Registries of Clinical Trials and Systematic Reviews.<sup>7</sup> In addition, the bibliographies of studies considered relevant are also searched for citations not found through the electronic databases.

Studies identified as potentially useful are then read in detail to determine if they are relevant to the key questions. If they are found to be relevant, the design and execution of the study is carefully evaluated and those studies with flawed methodology are then removed from consideration. Evaluating the quality of the relevant research is a critical step because much of the research available to compare similar drugs is of poor quality. Even randomized controlled trials, regarded as the gold standard of clinical research, can be poorly designed, executed, or reported in ways that leave consumers and decision makers with a misleading view of reality. Common shortcomings in the research and the reporting of such research are succinctly catalogued by David Sackett and Andrew Oxman and include but are not limited to:

- run in periods where only patients previously determined to tolerate the drug are included in the trial thereby underestimating the adverse events associated with the drug in the trial;
- high dose/low dose comparisons where the drug of the company sponsoring the study is administered at a high dose while a competitor's drug is administered at a low dose thus increasing the chance that the high dose drug will show a greater response;
- multiple study analyses (meta-analyses) that include only studies that show a favorable result and eliminating studies that show indeterminate or unfavorable findings;
- when the overall research is indeterminate, the performance of subgroup analyses until favorable results can be found then report only the favorable results and ignore the rest.<sup>8</sup>

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<sup>7</sup> G. Gartlehner et al., *Drug Class Review on Second Generation Antidepressants* 9, 9-10 (2006), at <http://www.ohsu.edu/drugeffectiveness/reports/documents/Antidepressants%20Final%20Report%20Update%202.pdf>.

<sup>8</sup> David L. Sackett & Andrew D. Oxman, *HARLOT plc: An Amalgamation of the World's Two Oldest Professions*, 327 BRITISH MEDICAL JOURNAL 1442,



After carefully analyzing studies that are potentially useful, studies found to be of good quality are then synthesized into a draft report which is both posted for public comment on the project's web site and sent out to peer reviewers who have experience in both evaluating evidence and with the subject area addressed by the drug class under review. Once received, the public and peer review comments are considered in detail. Legitimate concerns raised by either the public or the peer reviewers that fit the scope of the report are addressed in the final draft, which is posted on the project website in the public domain.<sup>9</sup>

DERP does not consider the cost of the drugs in its reports nor does it recommend a preferred drug in a class. The manner in which a report is used (or not used) is entirely up to the participating organization and the policies in their jurisdictions. These uses range from creating prescriber education materials based on the reports, to evaluating the clinical advice given by a pharmacy benefits manager, to being the primary source of clinical information for a preferred drug list pharmacy and therapeutics committee. States that use the reports to inform their pharmacy and therapeutics committees have open public meetings for decision making, and provide opportunities for public testimony on the policies under consideration.<sup>10</sup>

Completed reports are eventually updated as new drugs, new evidence, and new issues are identified and assessed in the context of previous evidence. For example, the Statin drug class report has been updated four times since the original report was completed in 2002. The report for atypical antipsychotic medication is currently being updated in order to assess the importance of observational trials and a recent large comparative trial.

The experience of public decision makers in the DERP project is illustrative of some of the advantages, disadvantages, and challenges such an approach brings. One of the greatest advantages of using systematic reviews in this way is that

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1442-1445 (2003), available at [http://www.urmc.rochester.edu/smd/student/defib/pdf/BMJ\\_Harlot.pdf](http://www.urmc.rochester.edu/smd/student/defib/pdf/BMJ_Harlot.pdf).

<sup>9</sup> DERP, *supra* note 1.

<sup>10</sup> Information on the decision making bodies of each state participating in DERP are available on the Project website. *Id.*

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decision makers have better information at their disposal on the comparative effectiveness and safety of the medications they are buying than other purchasers or even their suppliers. This allows them to have confidence that the drugs they select are high quality and that the savings they achieve by preferring one drug over another do not compromise the quality of the healthcare delivered to their patients.

The process of creating a systematic review can pose many challenges. First, it can take a significant amount of time to complete. While most states would prefer to receive the information on drug classes in the space of just a few months in order to make decisions more quickly, on average, these comparative drug class studies take between eight and ten months to complete. Overall, the DERP project has taken approximately three years to complete twenty-five original reviews. Moreover, systematic reviews must also be updated on a regular basis. Depending on the amount of research underway in a given class, this may need to be done annually and in some cases even more frequently.

In addition to being time consuming, systematic reviews can also be expensive. For instance, the first classes reviewed by DERP averaged \$110,000 per report. Also, in their completed form, SRs are highly technical documents, making translation for use in the policy process laborious as well. However, these challenges can be overcome through planning, patience, expense sharing among interested parties, and careful summation of the studies that allow officials and the public to accurately understand the essence of the research.

Unfortunately, as one might expect, those threatened by the use of this research have attempted to discredit the research or limit its use. These efforts have run a continuum from blatant misrepresentation to reasonable questions of methodology that will require ongoing deliberation within the research and policy communities. The DERP experience can give public officials a sense of the tone and substance of the debate they will experience even when they are using what is demonstrably the best available information to inform their work.

*B. Criticism of DERP Reports*

The use of DERP reports raises several important concerns. However, when judging DERP's approach, or any other attempt to use systematic reviews to inform public decisions, it is important to compare it to the other information development and dissemination strategies currently used in government and industry. Recognizing this context is important because new initiatives are often judged in comparison to a hypothetical ideal rather than against the current approaches they seek to change. This allows defenders of the status quo to argue against constructive change without explicitly defending the status quo. Thus, critics will profess support for evidence based medicine while they belittle DERP because its reports do not take into account the infinite variability of individuals. Of course, no study using existing technology could ever provide that level of detail, so the fact that DERP is a marked improvement over what is currently available to help policy makers, consumers, and providers decide which drugs are better overall is denigrated because it does not provide perfect information for every patient.<sup>11</sup> The common criticisms of DERP and their implications for other public sector decision makers using similar research to inform their decisions are addressed in detail below.

*1. DERP Conflicts with the Principles of Evidence-Based Medicine*

The criticism that DERP conflicts with the principles of evidence-based medicine almost always relies on selective reference to Dr. David Sackett, an international authority on evidence-based medicine. Critics cite Dr. Sackett's article from 1996 as support for their claim that all forms of information, including observational studies and patient preference, should be used in DERP's assessment of the efficacy or effectiveness of the drugs it studies.<sup>12</sup> These criticisms ignore that in that same article,

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<sup>11</sup> MENTAL HEALTH ASSOCIATION IN CALIFORNIA, *Background*, [http://www.mhac.org/advocacy/alliance\\_background.cfm](http://www.mhac.org/advocacy/alliance_background.cfm).

<sup>12</sup> David L. Sackett et al., *Evidence Based Medicine: What It Is and What It Isn't*, 312 BRITISH MEDICAL JOURNAL 71, 71-72 (1996).

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Sackett went on to say:

It is when asking questions about therapy that we should try to avoid the non-experimental approaches, since these routinely lead to false-positive conclusions about efficacy. Because the randomized trial, and especially the systematic review of several randomized trials, is so much more likely to inform us and so much less likely to mislead us, it has become the gold standard for judging whether a treatment does more good than harm.<sup>13</sup>

The systematic review of all available randomized controlled trials (RCTs) called for by Sackett is exactly what DERP provides. This is in sharp contrast to the kind of information generally used as the basis for establishing comparative efficacy in the industry. There is no evidence that pharmaceutical companies conduct systematic comparative reviews of the drug classes. Many purchasers rely on cost effectiveness analyses that begin with a bare minimum of evidence and a consultant's opinion rather than a synthesis of the entire relevant evidence. Additionally, most purchasers, insurers, and pharmacy benefits managers consider the information they rely on for their decisions to be proprietary and therefore secret, even if they profess to be "evidence-based." Thus, there is no way to judge the quality or objectivity of the information used. It appears that DERP's standard of evidence is of higher quality than that of its primary critics.

More fundamentally, the question should not be whether DERP or any information effort is consistent with anyone's assertion of what is or is not evidence-based medicine. Rather, the truly important question is whether decisions to wisely purchase or prescribe drugs are helped or hindered by properly executed systematic reviews comparing drugs within classes. Clearly, the appropriate use of these reviews can be of enormous help to decision makers. This is especially true when the alternative is to depend on a model of research and information dissemination that has at its core the selective use of information to maximize market share. Similarly, the practice of evidence-based medicine could be helped substantially if the healthcare industry as a whole shared

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<sup>13</sup> *Id.*

DERP's commitment to systematically reviewing all high quality evidence, and to public participation and full disclosure of all research results.

### *2. DERP is Not Sufficiently Transparent and Inclusive*

The critical elements of the DERP process—key questions, research considered, industry dossiers, public comments, draft reports, final reports, local decision making processes—are transparent and inclusive: they are either posted on the DERP website or available on request.<sup>14</sup> The current participants in DERP all have public processes in which the DERP reports are available or presented in public.

Again, the DERP process compares favorably to that used generally by healthcare purchasers, providers, and manufacturers. In fact, the overall information available to practitioners and consumers could be improved substantially if similar standards of transparency and inclusiveness were adopted by drug and device manufacturers, pharmacy benefits managers, insurers, and the creators of practice guidelines.

### *3. DERP Defines Evidence Too Narrowly*

This criticism seeks to discredit DERP because of its emphasis on randomized controlled trials (RCTs) in determining comparative efficacy/effectiveness.<sup>15</sup> However, making the breadth of the evidence the primary indicator of its quality is a mistake. A more useful approach is to determine whether the evidence in question is appropriate for the use to which it is put.

DERP relies primarily on RCTs to determine the efficacy/effectiveness of medications under review because, as Sackett stated, they are much less likely to mislead us than other forms of research that are less rigorous in their efforts to eliminate

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<sup>14</sup> DERP Methods, <http://www.ohsu.edu/drugeffectiveness/methods/index.htm>.

<sup>15</sup> ISPOR HEALTH SCIENCE POLICY COUNCIL, WHERE DOES OUTCOMES RESEARCH FIT INTO EVIDENCE-BASED HEALTHCARE DECISION-MAKING?, available at [http://www.ispor.org/councils/Decision\\_making.asp](http://www.ispor.org/councils/Decision_making.asp).

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bias and confounding factors from their work. To minimize the potential for bias, RCTs require random assignment of study participants to either the group receiving the experimental intervention (active) or the group not receiving the experimental intervention (control). Those who evaluate the effects of the intervention must be blind to whether the subject was in the active or control arm of the study. Well-prepared RCTs are almost always conducted in highly controlled settings with carefully selected participants who have similar characteristics in order to make sure the methodology is carefully carried out, and to attempt to make certain that changes observed are actually due to the treatment and not to chance, subconscious decisions made by researchers, or an underlying characteristic of the subject. The highly controlled nature of these trials is very effective at removing bias from the study, but legitimate questions remain about how readily they can be generalized to a community care setting in much more complicated patients.

To address some of these concerns, researchers are developing large scale community based trials that still have randomization and blinding in their procedures, but reflect more closely the results one could expect in the real world. DERP recognizes that well-prepared large scale practical controlled trials comparing the effectiveness of these drugs in community practice settings can be better than RCTs done in a research setting, and we use them whenever they are available.<sup>16</sup> Unfortunately, such effectiveness studies are rare and the fact that our inclusive search strategy finds so few of them highlights a flaw in the priority setting among the major funders of comparative drug research.

In addition, while DERP gives preference to well done RCTs when assessing efficacy/effectiveness, it also routinely considers observational studies when evaluating adverse events because these studies often include larger populations and are of longer duration than RCTs. This addresses the problem posed by the fact that RCTs are often too short and the sample size too small to find

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<sup>16</sup> Sean R. Tunis et al., *Practical Clinical Trials: Increasing the Value of Clinical Research for Decision Making in Clinical and Health Policy*, 290 JAMA 1624, 1624-32 (2003).

adverse events associated with longer term and broader use. This is especially important given the number of medications now designed to be taken for the remainder of a patient's life.

These issues of breadth versus quality of evidence will continue to be a focus of intense discussion because at present there is no consensus among clinicians, researchers, or decision-makers about the validity of observational studies for assessing the comparative effectiveness of different drugs. The most common comparative observational studies—retrospective designs such as the case-control study, and prospective designs such as cohort studies—were designed to test hypotheses about causal agents in the epidemiology of disease. Their suitability for drawing valid conclusions about comparative efficacy or effectiveness in clinical practice has not yet been established.

To advance this discussion, DERP is testing whether observational studies are useful in determining efficacy or effectiveness by investing resources to evaluate the quality of evidence generated by observational studies of atypical anti-psychotic medications, ADHD medications, targeted immune modulators, and inhaled corticosteroids. This effort, along with initiatives underway by AHRQ related to the Medicare Modernization Act,<sup>17</sup> should shed additional light on whether they are useful and if so, what methods are essential to that utility.

Even given this ongoing debate, the DERP approach appears to compare favorably to the common practice of using narrow placebo controlled efficacy trials as the basis for direct-to-consumer and physician-focused advertising campaigns. It is also clearly superior to the practice of manipulating evidence related to a product by suppressing research that does not support the desired point of view or by only releasing partial results from major studies.<sup>18</sup> The willingness of the DERP project to use its limited resources in a good faith effort to analyze the appropriate use of

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<sup>17</sup> Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003). See also <http://www.effectivehealthcare.ahrq.gov/aboutUs/aboutUs.cfm#MMA>.

<sup>18</sup> P. Juni et al, *Are Selective COX 2 Inhibitors Superior to Traditional Non Steroidal Anti-inflammatory Drugs*, 324 BRITISH MEDICAL JOURNAL 1287, 1287-1288 (2002).

observational studies and to disclose those results publicly speaks to the project's commitment to the public interest.

*4. DERP Findings Do Not Sufficiently Address Variations Among Subpopulations<sup>19</sup>*

In every DERP review, one of the key questions always focuses on what the evidence shows about any differential impact of a medication on a given subpopulation, and whether that population is defined by gender, race, age or ethnicity. DERP reports only reach conclusions regarding subpopulations that are supported by the evidence. Unfortunately DERP's research has found that there is a real shortage of good quality studies of subpopulations. This lack of information is largely the result of the decisions made by the funders of primary research, rather than DERP.

Nonetheless, this raises the question of whether DERP participants should limit the use of evidence from RCTs if studies do not focus specifically on a given subpopulation and should instead consider less rigorously designed studies, if available, on that subpopulation. Those who advocate for this position would seem to argue for adopting a lower standard of evidence for such groups by ignoring high quality information developed in other groups until more rigorous studies of the precise group in question can be completed. Additional study and discussion should be undertaken within the research and policy communities to determine if the public interest is better served if the treatment for subpopulations is based on lower quality studies that include them rather than high quality studies that look at a general population. Few dispute, however, that the major funders of research (including the pharmaceutical industry) should design and fund more high quality studies that directly consider the effects of treatments on subpopulations.

*5. DERP Confuses the Absence of Evidence for Evidence of No*

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<sup>19</sup> AGENCY FOR HEALTHCARE RESEARCH AND QUALITY Info Page, [http://www.mhac.org/advocacy/alliance\\_background.cfm](http://www.mhac.org/advocacy/alliance_background.cfm).



*Difference Among Drugs*

A careful reading of all of the DERP reports will show that DERP never claims that the lack of evidence of a difference should be interpreted as evidence that there is no difference. DERP reports specify what evidence exists and what evidence is lacking, and it is up to the purchasers who use the reports to decide if they are willing to pay more for medications that have no evidence of superiority.

Concerns have been expressed that some DERP participants make value decisions in the absence of evidence. The systematic review of long acting narcotics used for the relief of chronic pain, for example, shows that there are no fair or good quality randomized controlled trials comparing these drugs to each other. While there is no good quality evidence comparing the effectiveness of these drugs, there are substantial price differences among them. So, the policy question raised by this lack of evidence coupled with a significant difference in price focuses on what constitutes good stewardship of taxpayer dollars and whether public payers for health services should insist on some credible clinical evidence before paying a significantly higher price for a comparable medication.

*6. DERP is Focused Solely On Cost and Should Be Rejected  
Because it May Be Misused and Do Harm to Vulnerable Persons*

A classic example of this criticism is an article in *The Medical Herald*.<sup>20</sup> In its April 2005 edition, the newspaper headlined the story “States Misuse Evidence-Based Medicine.” As reported, several physicians and the chairman of the board at Pfizer Pharmaceuticals roundly condemned using medical evidence in policy formulation as a danger to vulnerable populations, especially racial minorities. The article supports the use of evidence in a clinical setting by a single practitioner in consultation with a patient but alleges, for example, that “minorities will be

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<sup>20</sup> Tom Toolen, *States Misuse Evidence-Based Medicine*, THE MEDICAL HERALD, Apr. 2005 at 1.

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hardest hit by faulty analysis by untrained government bureaucrats, with many being denied life-saving drugs because they cost too much.”<sup>21</sup>

While the article is full of numerous suggestions that using evidence in Medicaid policy decisions, especially decisions to control costs, will result in denial of beneficial services to vulnerable populations, there is not one example cited that documents this. Curiously, the authors focus their worries on programs that are using high quality evidence, rather than those programs that ignore evidence and use draconian measures such as limiting the number of prescriptions Medicaid recipients receive regardless of their condition or the effectiveness of additional prescriptions to treat them.

The article, written without quoting one Medicaid official or representative of DERP, seems to take the position that working to control the cost of Medicaid is optional. It conveniently ignores the enormous cost increases recently seen in Medicaid, the consensus that they are unsustainable, and the role that drug expenditures play in those increases. The article conveniently sidesteps the question of whether it is better to use or ignore good quality evidence when taking unavoidable steps required to control costs in Medicaid. The parties quoted in the article seem to argue that it is permissible to deny persons access to life saving medications by pricing them at a level that is unaffordable to millions of Americans while it is unconscionable for state governments to try to use evidence to make sure that their policies are clinically sound.

## CONCLUSION

Public sector decision makers in all branches of government need consistently good information to inform the important decisions they make. Legislators and executive branch officials need such information in policy formation and implementation, and the judiciary needs it to determine if the law is being followed. Research that is directly applicable to public sector healthcare decisions is improving and increasing in prevalence. This trend is

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<sup>21</sup> *Id.* at 25.

supported by a more aggressive acquisition of good quality research by public sector decision makers. The barriers to increasing this acquisition even further can be reduced by a wider recognition of its utility that increases demand for it, by jurisdictions sharing the costs of directly commissioning research relevant to policy, and by focusing the research on questions that have immediate relevance to the public interest. The public interest is well served when good quality research is used to inform public sector decisions, and by a vigorous debate about what defines good quality research and decision making processes for these purposes.