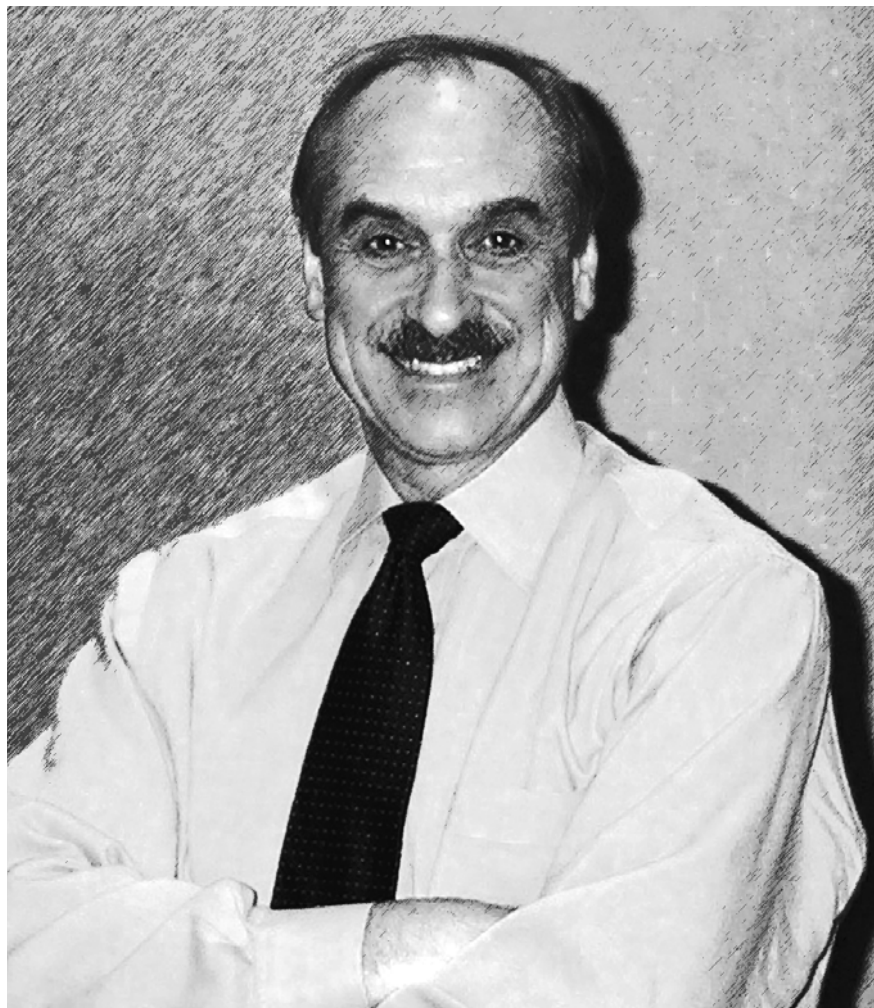


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Pharmaceutical Executive

Q&A WITH BRYAN R. LUCE



Shaping the Future of Medicare

Pharma will focus on approving safer, more effective drugs that have real-life applications.

The Medicare coverage Advisory Committee, a group of experts with the agenda of making the national coverage process more open, predictable and understandable, will begin the two-year process of guiding the nation's Medicare policy this summer. Bryan R. Luce, PhD, founder of The Medtap Institute at the Bethesda, Maryland-based United BioSource Corporation, will serve on this influential committee, bringing his expertise in evidence-based drug evaluation services to the table.

So far, Luce has noticed "a more formalized approach of bringing real evidence from trials to bear on the coverage process," he says. "The government is looking at real evidence from clinical trials, and in particular, for evidence that the products work in a real-world scenario."

Honored to play such an integral role in shaping the future of Medicare, Luce says he expects to see huge shifts in the healthcare landscape, and many improvements for the millions of elderly and disabled Americans whom Medicare insures.

Pharm Exec: What kinds of changes can we expect to see from drug companies as a result of the MMA?

The landscape has shifted. The drug companies are now looking at evidence to ensure that the products have real-life applications, instead of just being effective and safe in clinical trial settings. Increasingly, they are being asked to provide better information about their drugs' safety and effectiveness, in terms of how they will be used in the real world.

Right now, the clinical trials of drugs and most medical devices—or at least the invasive ones that require FDA approval—do not have real-life applications. Scientists who conduct clinical trials are very focused on research settings and they have a very careful protocol.

And patients, typically, are not typical patients; they don't have multiple diseases. Traditionally, they have been middle-aged white males, not people of lower socio-economic conditions, or the elderly.

If the studies included the aforementioned populations, would the research be more accurate?

Even if the research was conducted in those populations, the clinical trial settings and the formalization of the research (with these careful protocols and very careful inclusion criteria) are still very different from real-world patients and real-world doctors.

How will the MMA reconcile this?

What is different is that Medicare and managed care are asking for better evidence that these products are actually safe once they're in the real world. They want to ensure that they're actually effective compared with other products and other kinds of services that the patient could have. »

What is a more efficient way of evaluating drugs?

One technique is [the use of] patient diaries. When necessary, they are used in trials for what we call patient-reported outcomes. The idea is that only patients can tell you about their quality of life—how they are feeling and whether they sleep at night, whether they have pain, and so forth. I mean, we can't really give tests for pain, or say, sleeplessness. Diaries also can be used in post-marketing clinical trials.

What role does post-marketing play in this?

Drug companies always have done continued research. But it hasn't been too formalized and the research designs have not really been good. They've been focused mostly on marketing just to increase product uptake. But from a scientific standpoint, it has been a very soft science in essence.

What has changed, and what contin-

ues to change, is that Medicare and the other major payors, like Medicaid and managed care, are really expecting more continued formal research into the real-world application.

What are the challenges pharma companies will face with new post-marketing studies?

Obviously, one of the big obstacles is changing the mindset of both the pharmaceutical industry itself and the medical establishment. Neither party, including physicians, managed care professionals, and prescription drug plans (PDPs), has a good history and track record of performing clinical trials that provide better evidence about the true effectiveness and safety of the product in the real world.

We are going to see shifts in the traditional ways in which the industry sells

patients' claims in sufficient time to make use of that information. Because right now there appears to be a two-year lag between the time the data is collected and the time it's available to look at. This obviously is too long.

Where do pharmacoeconomics and evidence-based medicine intersect?

Well, they definitely do intersect. The cost of healthcare has become so great that it's important to review the evidence to determine whether the drug is a good value for the money. And so pharmacoeconomics plays an integral role in the decision-making process about what makes sense for Medicare, what makes sense for managed care, and what makes sense for Medicaid, in terms of which drugs should be available for patients. Having said that, very few organizations, including Medicare,

The cost of healthcare has become so great that it's important to review the evidence to determine whether the drug is a good value for the money. Yet, pharmacoeconomics is rarely included in the decision process.

drugs. I think it will require a cultural shift within the industry. I think there's a real need for clinical medicine—whether it's in managed care or in these PDPs or wherever—to participate in this research. Because if they're demanding this kind of real-world effectiveness and safety evidence, they've got to be willing to participate in collecting it—and that costs money.

What has been Medicare's role in collecting patient data?

Medicare has a fabulous data set that can track how patients are doing. But it's going to have to include this new drug benefit into the data set. The whole process needs to move more quickly so that we have the data from

formally include pharmacoeconomics in their decision processes.

Why is that the case?

It's mostly political in nature. Congress has been very skeptical about not providing healthcare technologies and drugs to Medicare beneficiaries solely because of the cost. And so Congress has not really been supportive of Medicare in using pharmacoeconomics as a formal criterion. Having said that, it's very clear that the products and procedures that are very, very expensive go through a more stringent review. And we know that Medicare is more likely to put conditions around the use of very expensive products. So those that are very expensive are likely to be indicated



Bryan Luce is the founder and senior research leader for The Medtap Institute at United BioSource Corporation (UBC), and director of science policy at UBC. Previously, he was chairman, president, and CEO of Medtap. The author of more than 80 scientific publications and three textbooks, Luce also has worked as a consultant for many government agencies and pharmaceutical and device firms. He currently serves on the Medicare Coverage Advisory Committee, and on the Advisory Board of Harvard University's Center for Risk Analysis.

for very special populations, or only used in certain major hospitals that specialize in that area.

Will the coverage decisions made be permanent or will they evolve?

We honestly don't know. But we do know that Mark McClellan has instituted a new coverage policy, "Coverage with Evidence Development."

McClellan basically said that for certain kinds of important products and services where the evidence for the drug's effectiveness is not sufficient, it will require a formal post-marketing survey that's either going to be a practical clinical trial—which is a real-world effectiveness trial—or it's going to be some kind of registry. The registry would help to continue to develop evidence so that coverage decisions will be explicit and that only patients that participate in these trials or in this registry will be covered.

So, the government will only pay for patients who agree to be in these trials. I believe they are still working out who's paying for this because I don't believe Centers for Medicare and Medicaid Services is prepared to pay for this

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research. This would assume that the manufacturer pays for a great deal of this research effort and that Medicare pays for the health-care itself.

Will this type of shared responsibility be the norm in the future?

Yes. This could be the norm in the next three to five years. Medicare is stepping forward and saying that it will only cover the important and expensive products under these set conditions. And then the assumption is that it is going to review that evidence down the road and make a final decision. ☉

Did You Know?

 Coverage With Evidence Development (CED) is a new approach

that CMS is considering implementing to foster a better, more thorough understanding of a drug's risks and benefits over time. This kind of coverage would be applied to situations when there are substantial safety concerns or potential side effects associated with a particular product.

For example, the CED would apply to cases when concerns for a product's safety have not been adequately outlined or when the available clinical studies do not describe risks and benefits in detail. It also can be beneficial when there are questions about the comparative effectiveness of new products compared with existing products.

To address these concerns, CMS has offered to conduct simple and inexpensive clinical studies. Some of these methods include: the creation of databases that monitor patient safety and provide feedback to physicians; longitudinal or cohort studies in which patients are followed over time to provide long-term evaluation of drug safety; prospective comparative studies known as "practical clinical trials," which require a formal comparison group and can be used to evaluate real-world outcomes, such as quality of life or cost effectiveness; and randomized clinical trials.

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