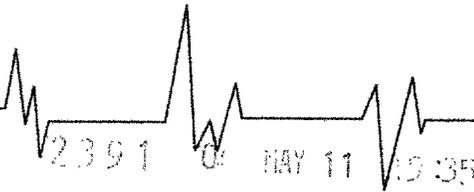


C Connecticut Health Advocacy Forum

C/O American Lung Association of Connecticut
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Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, Room 1061 (HFA-305)
Rockville, MD 20852

Docket ID 2004S-0170

May 3, 2004

To Whom it May Concern:

The Health Care Advocacy Forum is a diverse alliance of health organizations and advocacy groups focused on improving the health and well being of Connecticut's residents. Many of our organizations are dedicated to finding treatments and cures for the serious diseases that afflict our citizens, with the goal of ensuring access to high quality, affordable medications.

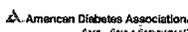
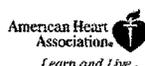
As a collective voice for the patient and consumer communities we represent, we strongly support the outcomes and comparative effectiveness studies required by Section 1013 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. This provision has the potential to both improve quality of care and maximize patient outcomes.

However, given the focus on prescription drugs as the first priority, we are concerned that this research will be used to determine patients' access to medicines solely based on cost and not efficacy. Consequently, we urge that the following comments be used as guidelines to help ensure that government-sponsored health outcomes research (including research on comparative- and cost-effectiveness of medicines) meets patients' needs and supports continued strides in overall medical care:

- Research should be conducted in the context of overall health care quality improvement. It should occur as part of a broad agenda to improve health care quality and patient outcomes across the health care system. Efforts focused on cost-containment for one service or product alone (e.g., medications) often shift costs from one medical service to another without improving patient outcomes.
- Health outcomes research should consider the full range of health care interventions and evaluate total health care costs or savings over the length of a treatment horizon, not just the costs of specific treatments. Long-term savings can be achieved with proper treatment, which in the short term may be costlier. This should be taken into consideration.

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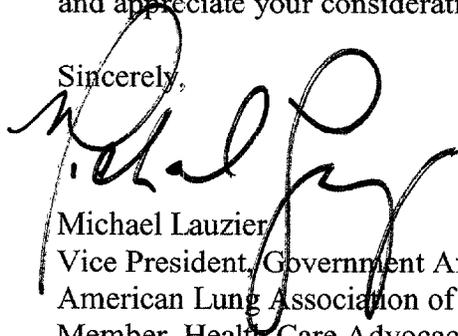


- Patients have unique medical needs that are not reflected in population-level research. Medical judgment and patient choice, within the bounds of appropriate medical practice, must always be the overriding force in decisions about individual care.
- Research also should evaluate the needs of patient sub-populations, who often respond differently to medicines and need a variety of treatment options/combinations for the best outcome. This is particularly true for patients suffering from arthritis and Alzheimer's disease.
- Research findings should support patient access to appropriate health technologies, and not be used as a tool to restrict or delay access to treatment choices. A new, "incremental" advance in medicine can appear similar to others in the same class but in fact provide important, cost-saving benefits such as fewer side effects or improved compliance.
- Government decisions about the focus and design of research programs should be made through open, transparent procedures with the involvement of stakeholders, including patients, providers and medical researchers. Findings should be communicated in an understandable way to stakeholders, including the range of peer-reviewed results on all treatment options.
- Research should evaluate both the direct benefits and the indirect benefits of health care interventions, including quality of life, patient functionality and economic productivity.
- Government is well positioned to help design and support research programs evaluating the benefits and risks of medical innovations, evaluating prospectively the value of different types of medical evidence in different clinical settings, and identifying the best methods to rapidly and broadly disseminate knowledge of medical advances. Standards for evidence should be consistent, transparent, and objective; additionally, standards should be established independently of potentially conflicted parties, including payers.
- This research is designed primarily to inform the clinical decision-making process rather than the reimbursement process. Payers may have a conflict between reducing costs and maximizing quality and patient outcomes. Reimbursement decisions should be driven by quality and outcomes and not by cost.
- Within a therapeutic class there should be a minimum of three medications before prior authorization is allowed in order to maintain doctor-patient choice. A minimum of two medications must be available without restriction.

- Certain types of medicines should never be subjected to prior authorization restrictions due to the complexity of the condition being treated and the higher potential for adverse events from medication switches. Medications that should be exempt from prior authorization include those to treat epilepsy, HIV, cancer, asthma, diabetes, heart disease and mental illness.
- Restrictions on access to care must include a fair and consistent appeals process readily accessible to patients and providers.

Thank you for the opportunity to comment on this important issue. Access to medicines is an important issue for both patients and consumers, and the physicians that treat them. Our organizations are focused on ensuring that patients have access to the most appropriate medical care available to them. We will be closely monitoring this matter and appreciate your consideration.

Sincerely,

A handwritten signature in black ink, appearing to read "Michael Lauzier", written over the typed name and title.

Michael Lauzier
Vice President, Government Affairs
American Lung Association of Connecticut
Member, Health Care Advocacy Forum