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# GLAD, SAD, BAD, and MAD Policies and Programs: A Call to Evaluate Efficiency in Pharmaceutical Systems

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## ABSTRACT

The pharmaceutical landscape is a complex mix of innovation, regulation, and market forces. As healthcare systems face rising costs and increasing demand for effective treatments, it is essential to evaluate the efficiency of policies and programs that determine access to and affordability of medications. This editorial introduces a framework of GLAD, SAD, BAD, and MAD policies and programs to categorize the efficiency and economic viability of pharmaceutical interventions. By critically assessing these categories, we aim to highlight the need for a systematic review of current practices and encourage a shift toward more sustainable healthcare solutions.

Keywords: GLAD, SAD, BAD, MAD, Evaluate Efficiency, Pharmaceutical Systems

### GLAD Policies or Programs: Promoting Cost-Effective Medications

GLAD policies represent the ideal scenario in pharmaceutical systems, where cost-effective medications are prioritized and promoted. These policies aim to ensure that patients have access to treatments that provide optimal therapeutic benefits without imposing excessive financial burdens on healthcare systems or individuals.

For instance, the implementation of value-based pricing models can exemplify GLAD policies. In the United Kingdom, the National Institute for Health and Care Excellence (NICE) evaluates new medications based on their cost-effectiveness relative to existing treatments. This approach has led to the rejection of several high-cost drugs that do not demonstrate sufficient value for money (1). The Expert Committee on Pharmacoeconomics in Iran is also performing a similar role, albeit with limited authority.

Another example is the use of generic medications, which can significantly reduce costs while maintaining therapeutic efficacy. The U.S. Food and Drug Administration (FDA) has reported that the introduction of generics saves consumers billions annually (2). The policy of prescribing generic drugs in Iran has also saved millions of dollars annually on pharmaceutical costs. However, policies supporting domestic production have challenged the competitiveness of domestic generic products.

These initiatives demonstrate GLAD policies that emphasize patient access to affordable and effective treatments.

### SAD Policies or Programs: Accepting effective, but not Cost-Effective Medications

SAD policies acknowledge the presence of effective medications but fail to address their cost-effectiveness. These programs may lead to disappointment among patients and healthcare providers due to the high prices associated with these treatments, which often fail to deliver corresponding benefits.

A notable example is Nusinersen (Spinraza®) for Spinal Muscular Atrophy (SMA). It was initially priced at $805,000 for the first year in the USA, then $380,000 annually, and it is intended to be a lifelong treatment. The ICER recommends a fair price of $72,800–$130,000 per year, which is 10 times lower (3). Similarly, Myozyme for enzyme replacement therapy in late-onset Pompe disease is not cost-effective at all, as it exceeds the cost-effectiveness threshold by many times in Iran. However, it clearly helps improve patients' quality of life and longevity (4).

Such SAD policies highlight the need for a more balanced approach that considers both clinical efficacy and economic efficiency.

### BAD Policies or Programs: Implementing High Costs and Ineffective Medications

BAD policies are characterized by the implementation of high-cost medications that lack demonstrated effectiveness. These programs represent a significant waste of resources, as they burden healthcare systems with expenses that do not translate into tangible health outcomes.

One example is the use of Aducanumab (Aduhelm) for Alzheimer's disease. The problem was that FDA approval was based on the reduction of amyloid plaques (a surrogate biomarker) rather than actual clinical improvement. Independent studies found no significant improvement in cognitive function (5, 6). Similarly, the use of Ocrelizumab (Ocrevus®) for primary progressive Multiple Sclerosis (MS) (7). Although initially touted as a significant breakthrough in MS treatment, long-term data showed that its impact on patients' disability was negligible (8, 9).

Such BAD policies not only strain healthcare budgets but also undermine trust in pharmaceutical interventions.

### MAD Policies or Programs: Using High-Cost, Ineffective, and Harmful Medications

MAD policies represent the worst-case scenario in pharmaceutical systems. Some expensive medications, although they prolong a patient's life, may increase their suffering and pain due to severe complications or a reduced quality of life. This concept is also known in medical ethics as medical futility or burdensome treatment (10). These programs highlight a failure in regulatory oversight and a lack of ethical responsibility.

A clear example is the opioid crisis in the USA, where potent opioid medications were widely

prescribed despite increasing evidence of their addictive potential and limited effectiveness in managing chronic pain (11, 12).

Another example is that cancer patients who received chemotherapy in the last month of life had a lower quality of life and a more difficult death (13-16). Cancer treatments, while crucial for survival, can sometimes lead to a reduced quality of life for patients due to various side effects and long-term consequences. These can include physical symptoms like pain, fatigue, nausea, and cognitive changes, as well as emotional distress, anxiety, and depression. Extending life at any expense is not always in the patient's best interest. Sometimes, the best approach is to decrease suffering rather than prolong life.

The promotion of such medications under MAD policies has caused widespread suffering, pain, and higher mortality rates.

## Call to Action

Classifying pharmaceutical policies into GLAD, SAD, BAD, and MAD categories serves as a wake-up call for stakeholders in healthcare, including policymakers, practitioners, and patients, to evaluate the effectiveness and efficiency of current practices.

To move towards a more sustainable and efficient pharmaceutical system, we must prioritize:

1. Value-Based Care: Implementing pricing models that align medication costs with their therapeutic value.
2. Rigorous Evaluation: Enhancing regulatory frameworks to guarantee that only effective medications receive market approval and cost-effective medications receive insurance coverage.
3. Patient-Centered Approaches: Involving patients in conversations about treatment choices, emphasizing both effectiveness and cost.
4. Transparency: Promote openness regarding drug outcomes, pricing, and coverage policies to enable healthcare providers and patients to make well-informed decisions.

By adopting these strategies, we can create a healthcare environment that prioritizes patient well-being while maintaining fiscal responsibility. It is time to critically assess our pharmaceutical policies and programs using the GLAD, SAD, BAD, and MAD frameworks to foster a healthier future for everyone.

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