Policy/Regulatory Implications

Nneka C. Onwudiwe PharmD PhD MBA

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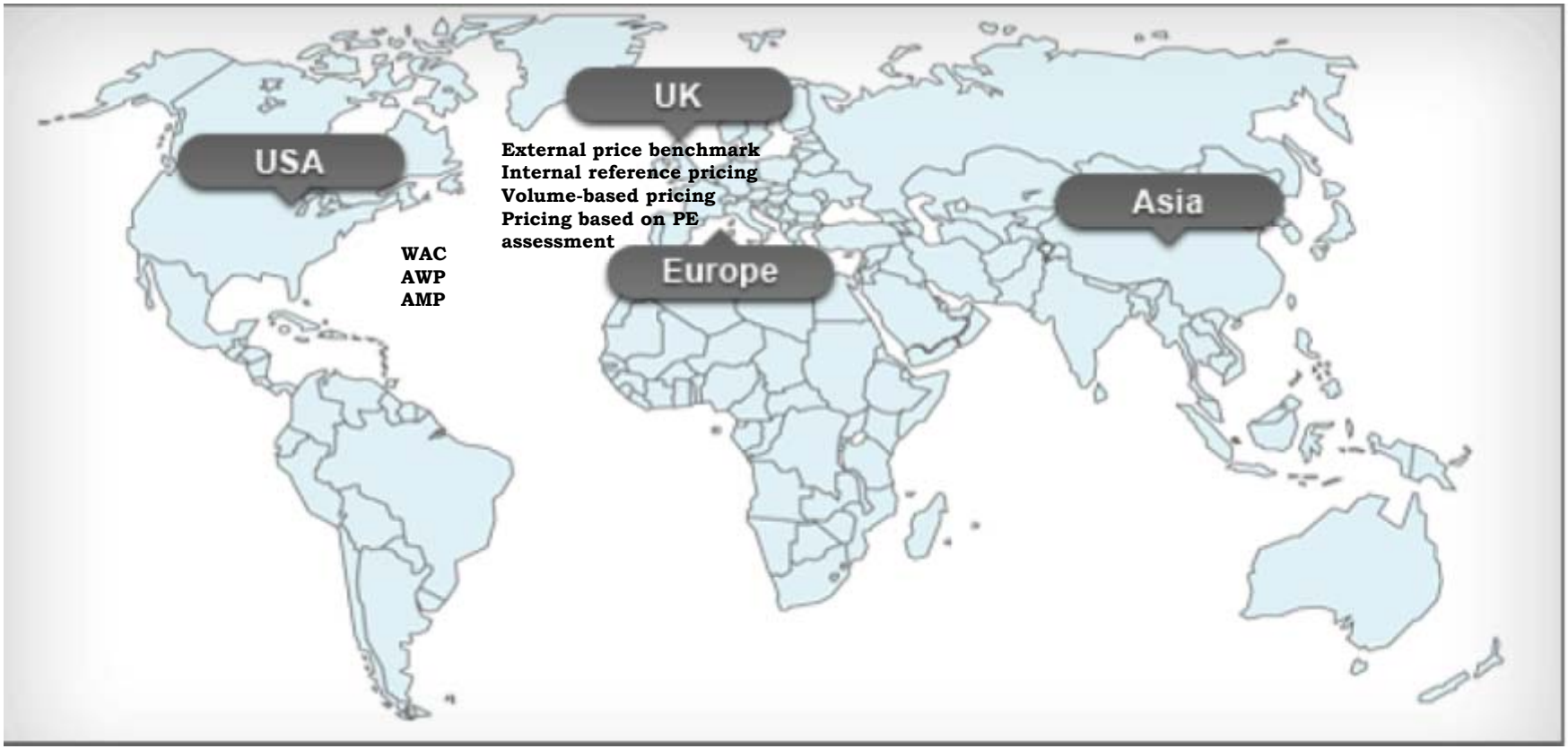
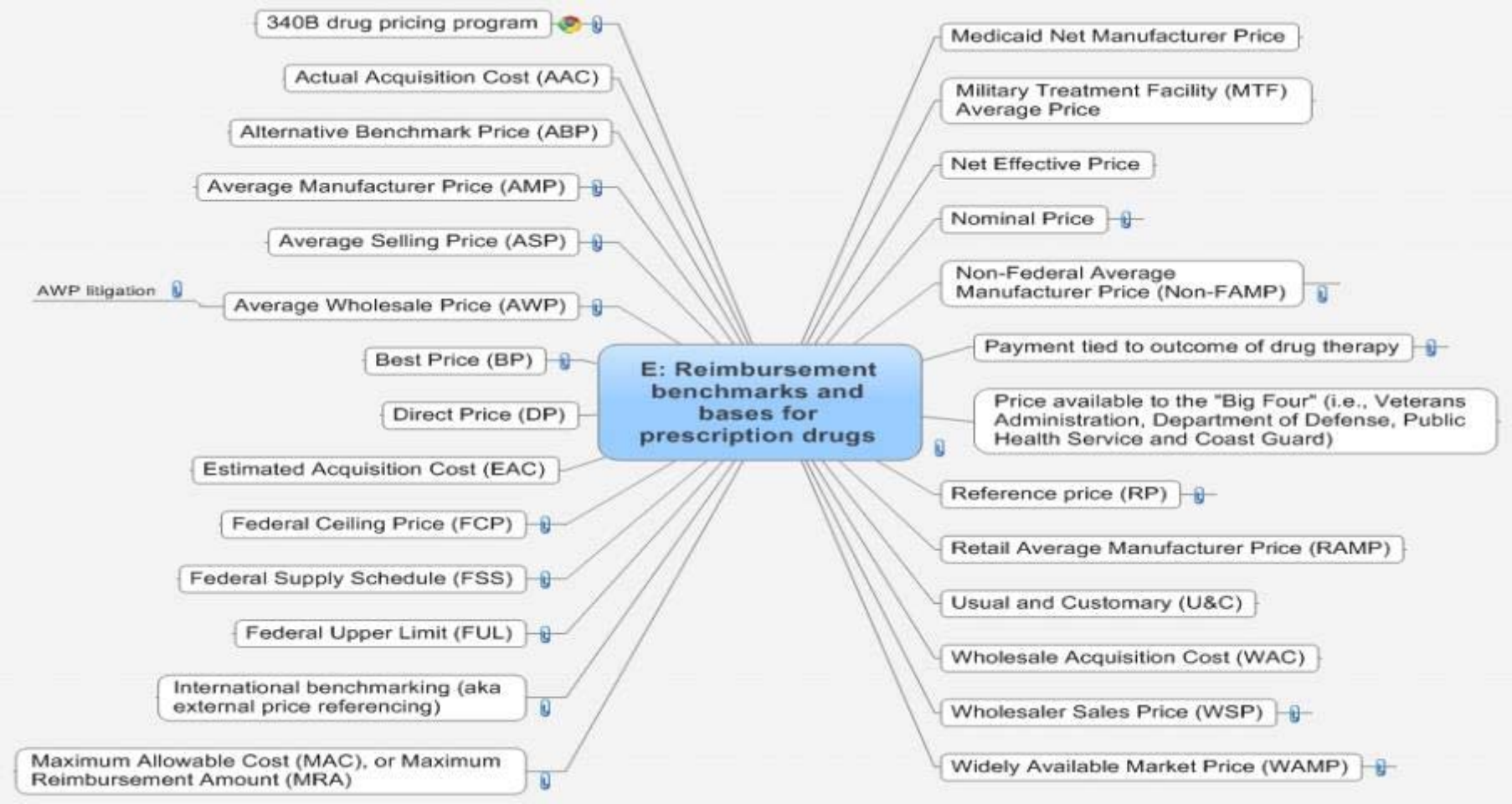
Pricing Strategies Worldwide



Pricing Strategies in the US Drug Supply Chain



Source: Reimbursement benchmarks and bases for prescription drugs. http://www.amcp.org/MapE/

List or Transaction Price?

Source: http://drugbenefitsolutions.com/prescription-costs/

Benchmark Criteria

TABLE 3 Best Benchmark Criteria and Alternative Price Benchmarks

Best Benchmark Criteria	Alternative Price Benchmarks
1. Accessible – readily available	AAC – actual acquisition cost
2. Timely	AMP – average manufacturer price
3. Administratively simple and efficient	ASP – average sales price
4. Comprehensive	AWP – average wholesale price[a]
5. Durable (not an interim solution)	EAC – estimated acquisition cost
6. Stable (won't produce more litigation)	FUL – federal upper limit
	MAC – maximum allowable cost
7. Easily understood	MLP – manufacturer list price[b]
8. Transparent and unambiguous	WAC – wholesale acquisition cost[c]
9. Auditable	
10. Trustworthy	
11. Not anticompetitive	
12. Acknowledges complexity of drug distribution system	

[a]AWP may also be referred to as suggested wholesale price (SWP) when supplied by the manufacturer.

[b]MLP might replace AWP as a multiple of WAC and would be reported by the manufacturer rather than calculated by the publisher of drug price data.

[c]WAC may also be referred to as direct price (DP) or list price (LP).

Curtiss, Frederic R. What is the price benchmark to replace average wholesale price (AWP)? *Journal of Managed Care Pharmacy* 16.7 (2010): 492-501.

	Accessible	Timely	Administratively simple	Comprehensive	Easily understood	Transparent	Trustworthy
AAC	✓						
AMP							✓
ASP	✓					✓	✓
AWP	✓	✓	✓				
EAC							
FUL	✓					✓	
MAC	✓						
MLP							
WAC	✓	✓	✓			✓	
NADAC	✓	✓					✓

AAC – actual acquisition cost
AMP – average manufacturer price
ASP – average sales price
NADAC-national average drug acquisition cost
AWP – average wholesale price
EAC – estimated acquisition cost
FUL – federal upper limit
MAC – maximum allowable cost
MLP – manufacturer list price
WAC – wholesale acquisition cost


COSTS
CT
BENEFITS
BLVD

Issues for Stakeholders

- "…cost prices should be jurisdiction specific because of differences in relative or absolute price levels among jurisdictions"…
- but there can be different pricing strategies and benchmarks within the same jurisdiction

Key issues for drug pricing data

- ✓ Data availability and methodology
- ✓ Transparency in reporting
- ✓ Limits comparability and generalizability of results
- ✓ Differences in cost-effectiveness estimates
- ✓ Interpretation of the value of therapies
- ✓ Economic evidence to inform decision-making in a particular population or treatment setting
- ✓ Inefficient use of scarce health care resources

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VALUE IN HEALTH

Transferability of Economic Evaluations Across Jurisdictions: ISPOR Good Research Practices Task Force Report

Michael Drummond, DPhil,[1] Marco Barbieri, PhD,[2] John Cook, PhD,[3] Henry A. Glick, PhD,[4] Joanna Lis, PhD, Msc,[5] Farzana Malik, PhD, MPhil, BA,[6] Shelby D. Reed, PhD, RPh,[7] Frans Rutten, PhD, MSc,[8] Mark Sculpher, PhD,[9] Johan Severens, PhD[10]

[1]Centre for Health Economics, University of York, York, UK; [2]3 Innovus, Uxbridge, Middlesex, UK; [3]Merck & Co. Inc., North Wales, PA, USA; [4]University of Pennsylvania, Philadelphia, PA, USA; [5]Sanofi-Aventis Group Poland, Warsaw, Poland; [6]Merck Serono International SA, Geneva, Switzerland; [7]Duke Clinical Research Institute, Durham, NC, USA; [8]Erasmus University Medical Centre, Rotterdam, The Netherlands; [9]Centre for Health Economics, University of York, York, UK; [10]Maastricht University and University Hospital Maastricht, Maastricht, The Netherlands

ABSTRACT

A growing number of jurisdictions now request economic data in support of their decision-making procedures for the pricing and/or reimbursement of health technologies. Because more jurisdictions request economic data, the burden on study sponsors and researchers increases. There are many reasons why the cost-effectiveness of health technologies might vary from place to place. Therefore, this report of an ISPOR Good Practices Task Force reviews what national guidelines for economic evaluation say about transferability, discusses which elements of data could potentially vary from place to place, and recommends good research practices for dealing with aspects of transferability, including strategies based on the analysis of individual patient data and based on decision-analytic modeling.

Keywords: cost-effectiveness analysis, decision-analytic models, economic clinical trials, resource allocation.

Background to the Task Force

In December 2004, the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) Health Science Policy Council recommended that the issue "Transferability of Economic Data: When Does a Difference Make a Difference?" be considered by the Board of Directors. The Council's recommendations concerning transferability of economic data were as follows: define key variable economic data and define guidelines for acceptance data from outside a country, taking into consideration existing national guidelines. After further development of the issue by the Health Science Policy Council, the Board approved the creation of a Task Force on Good Research Practices on Transferability of Economic Data in Health Technology Assessment in May 2005 and advised that the Task Force be under the leadership of the Health Science Policy Council. Task Force leadership and reviewer groups were finalized by December 2005.

Task Force members were experienced in health economics and technology assessment and were drawn from both industry and academia. In addition, several members had experience in working with reimbursement agencies in their respective countries. The members came from Italy, The Netherlands, Poland, Switzerland, the United Kingdom, and the United States.

Beginning in May 2006, the Task Force conducted monthly and bimonthly teleconferences to develop core assumptions and an outline before preparing a draft report. A face-to-face meeting was held in January 2005 to develop consensus for the draft final report. The draft final report was posted on ISPOR's Web site in April 2008, and the task force's reviewer group and ISPOR general membership were invited to submit their comments for a 1-month review period. In total, 50 individuals or groups responded. All comments received were posted on the ISPOR Web site and presented for discussion at the Task Force Forum at ISPOR's 13th Annual International Meeting in May 2008. Comments and feedback from the forum were considered and, when appropriate, incorporated and acknowledged in the final report.

Address correspondence to: Michael Drummond, Centre for Health Economics, Alcuin A Block, University of York, Heslington, York, YO10 5DD, UK. E-mail: md1@york.ac.uk

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Introduction

A growing number of jurisdictions now request economic data in support of their decision-making procedures for the pricing and/or reimbursement of health technologies. In most cases, the requests for data are supported by national guidelines on the conduct of economic evaluation [1,2]. Because more jurisdictions request economic data, the burden on study sponsors and researchers increases, especially as the various national guidelines may insist on the presentation of local data or the use of specific methods.

There are many reasons why the cost-effectiveness of health technologies might vary from place to place, including the incidence and severity of the disease in question, the availability of health care resources, clinical practice patterns, and relative prices [3]. The extent of variation in estimates has been shown in a review of economic evaluations of medicines undertaken in Western Europe [4]. It was found that, in 17 out of 27 cases, the variation in the estimates of the incremental cost-effectiveness ratios could be considered to be substantial (a twofold difference likely to change the decision to reimburse the drug). Therefore, it is reasonable for national guidelines to request that analyses be relevant to the local context.

Nevertheless, the requirement that economic evaluations should use local data or that particular methods should be used means that analyses increasingly need to be customized for each setting. Therefore, the objectives of the Task Force were: 1) to review what national guidelines for economic evaluation say about transferability; 2) to discuss which elements of data could potentially vary from setting to setting; and 3) to recommend

Policy Implications for Stakeholders

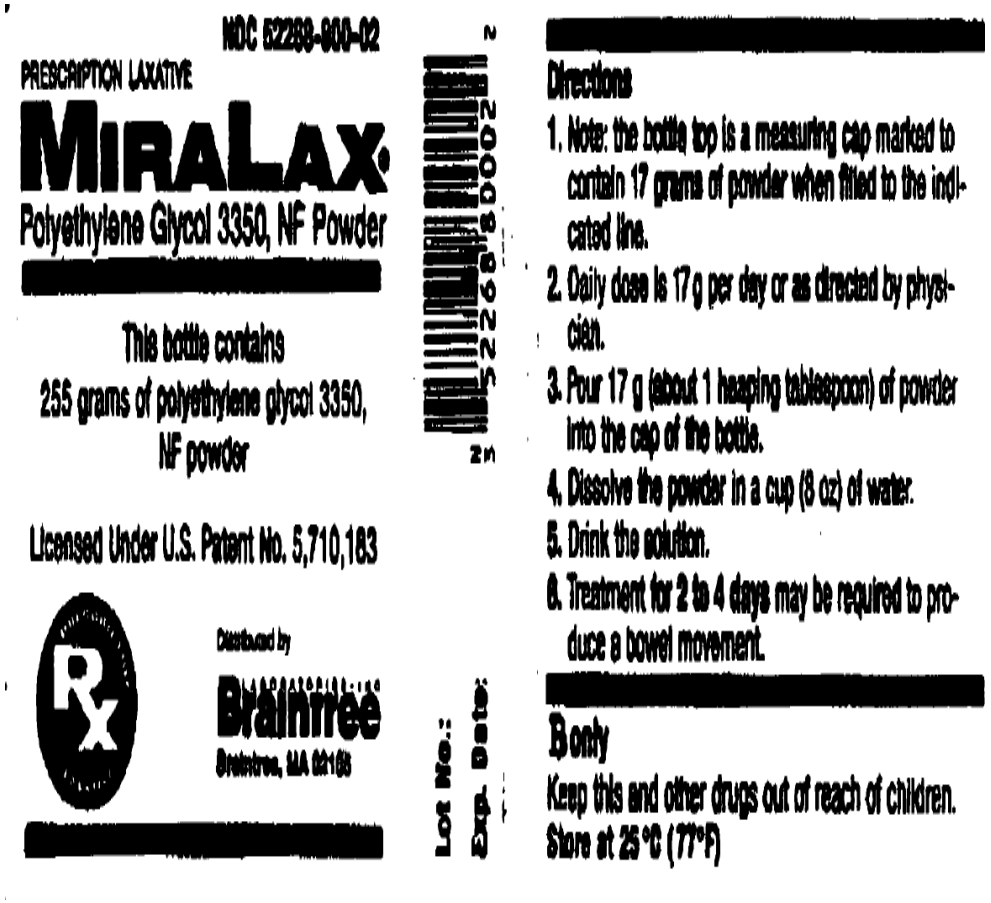
- Comparative claims in promotion and advertising
  - *Drug sponsors are permitted to include truthful, non-misleading information about the price of their products*
    - Price comparisons should include contextual information such as the two drugs are not comparable in terms of safety and efficacy, as well as information on the source and date of pricing information
    - Further substantiation needed for claims about "cost savings" or "lower treatment cost"
  - *Brand vs generic products, which have been found to be interchangeable*
- Price differences within therapeutic classes
- Increases in pharmaceutical expenditure
- Changes to manufacturers launch strategies
- Access to medications
- Reduction in gross margins to pharmacies
- Pharmaceutical pricing and reimbursement policies
  - Overpayment of ingredient costs for drugs by state Medicaid agencies
  - Increasing cost sharing by patients
- Information sharing and price transparency
  - rebates and discounts which may differ by type of purchaser

Example: Comparative Promotional Claims

- Example: Notice of Violation issued for

  Miralax (polyethylene glycol 3350 NF powder)

  – Mar 29, 2001



Braintree LABORATORIES, INC

November 8, 2000

Dear Director of Nursing,

Unable to solve your patient's constipation problems?

If so, we would like to introduce you to a new prescription laxative therapy, **MiraLax**™ (Polyethylene Glycol 3350, NF Powder) which combines all the benefits of softening, bulking, lubricating and osmotic actions into one laxative.

❑ **Savings for VNA patients**	**MiraLax**	**OTC**[1]
▪ Cost per day:	$0.80	$1.00
▪ Cost per week:	$5.60	$7.00
▪ Cost per year (26 weeks of usage)	$145.60	$182.00
▪ Percentage covered by Medicaid/Private Insurance:	100%	0%
▪ BOTTOM LINE:	$0.00	$182.00

❑ Convenient

MiraLax is taken only once a day and is tasteless and odorless. Fiber products may need to be taken 2-3 times per day and have a gritty texture. MiraLax is highly effective, increasing the volume and frequency of bowel movements. It is gentle acting and well-tolerated.

❑ Complaints

Nursing staff may hear fewer complaints with MiraLax. As opposed to harsh stimulants which typically increase the likelihood of soiling linens, MiraLax is gentle and predictable resulting in regular bowel movements within 2-4 days.

MiraLax is indicated for the treatment of occasional constipation, and should be used for 2 weeks or less or as directed by a physician. Patients with symptoms suggestive of bowel obstruction or underlying metabolic conditions should be thoroughly evaluated before initiating MiraLax therapy. Unpleasant side effects are unlikely, although nausea, bloating, cramps, flatulence, or diarrhea could occur. Please see full prescribing information on the back of the advertisement included in this packet.

Please review MiraLax with your Medical Director and patient's Primary Physician. If you would like to know more about MiraLax, please complete the attached form and fax to 781-843-7932 or call 1-888-MiraLax. For samples of MiraLax please have a physician sign and complete the enclosed sample request card. Thank you for your support.

Sincerely,

Lynne Gagne
Product Manager

[1] Red Book, October 2000

545GENID18750

60 Columbian Street West, P.O. Box 850929, Braintree, MA 02185-0929 • www.braintreelabs.com • (781) 843-2202 • FAX (781) 843-7932 • 1-800-874-6756

Clinical Studies

CLINICAL TRIALS

In one study, patients with less than 3 bowel movements per week were randomized to MiraLax, 17 grams, or placebo for 14 days. An increase in bowel movement frequency was observed for both treatment groups during the first week of treatment. MiraLax was statistically superior to placebo during the second week of treatment.

In another study, patients with 3 bowel movements or less per week and/or less than 300 grams of stool per week were randomized to 2 dose levels of MiraLax or placebo for 10 days each. Success was defined by an increase in both bowel movement frequency and daily stool weight. For both parameters, superiority of the 17 gram dose of MiraLax over placebo was demonstrated.

Misleading Comparisons

Preference Claims - A patient preference claim that appears in the MiraLax Sell Sheet depicts blurred but discernable images of containers of Metamucil and Citrucel next to a sharply focused picture of MiraLax. The headline reads, "*Which Laxative Would Your Patients Prefer?*" followed by a chart that selectively presents and compares presumed preference features of MiraLax vs. Fiber (e.g. Metamucil and Citrucel). This comparative preference claim is misleading because it suggests that patients prefer MiraLax to Metamucil and Citrucel without data to provide adequate substantiation for this claim.

Cost Savings Claims – A chart appears in the Dear Director of Nursing Letter that compares the (daily, weekly, and annual) costs of therapy with MiraLax to the therapy costs associated with all other OTC laxatives. The chart is misleading because it implies that all costs associated with laxative therapy have been evaluated, not simply the acquisition price of the drug. The chart also implies that efficacy and/or outcomes of the different therapies are the same without supporting evidence. The chart also does not disclose that retail or wholesale prices listed do not necessarily correlate with the price actually paid for the drugs by a pharmacy or consumer.

Standardization Towards a Single National Pricing Benchmark?