

Assessing different perspectives on the value of a pharmaceutical innovation

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Abstract

Numerous pharmaceutical products are launched each year for the treatment of various medical conditions. The prescriber is in a difficult position to determine which the optimal product is for a specific patient, when he has available immediate release as well as sustained action capsules and tablets, chewable tablets and liquid dosage forms. Some have activity within 15 minutes while others take longer. Some are more costly but have never been implicated with gastric distress; some are very widely prescribed and others are not well known. Some are promoted as enhancing compliance and others for schedule simplicity.

In order to make sense of the array of diverse product attributes and to determine the value associated with different dosage form features, separate panels of practicing physicians, practicing pharmacists and patients were asked to ascribe value to a list of 10 drug product features that were mentioned in drug product advertisements in medical journals, by indicating what percentage price increase that feature might merit over a basic product without that feature. In addition, the respondents were asked to rank order the mentioned product features.

In all three panels, efficacy and safety were accorded the highest status. Pharmacists and patients appeared to be most welcoming of some of the listed features. This pilot study demonstrates that there appears to be a recognized value assigned to some product features and it may differ by audience.

Introduction

Pharmaceutical products can often ameliorate disease symptoms, control and stabilize chronic conditions, reduce risk factors and even cure some conditions. Some new drugs frequently reach a market where existing drugs treat the same conditions, often providing some improvement over the older therapy – e.g., perhaps doing so more rapidly, or more safely or with fewer adverse events or treatment failures. Since new drugs reaching the market are often not tested “head-to-head”, against current therapies, but rather are evaluated against placebos in Phase III registration trials, it is difficult for a pharmacist or prescriber to assess the relative value of two therapeutic options for the same condition.

Today, if a physician wants to know which the best product in a category is, or which drug demonstrates the greatest efficiency, there are only a limited number of resources to turn to. The Physician’s Desk Reference (PDR) or MIMS describe individual

drugs but the prospective prescriber will have to study multiple monographs, if they even exist, since they are paid for by their manufacturers and not all drugs are included. No one has the time to undertake that effort.

Services such as the Medical Letter makes comparisons of therapeutic areas from time to time, but often these are not frequent enough to be definitive and they are rather brief. Other reference works, such as Facts and Comparisons list the most significant features of the drugs comprising a category but do not offer recommendations.

And on top of this uncertainty, one can never tell what features or characteristics are important to an individual prescriber. The determination of value has been little studied in the serious professional and scientific literature. In 1993, Coyle and Drummond published a paper: “Does Expenditure on Pharmaceuticals Give Good Value for Money: Current Evidence and Policy Implications,” in *Health Policy*¹ that asked some of these questions. A few years later in 1996, Grund published

an article, "The Societal Value of Pharmaceuticals: Balancing Industrial and Healthcare Policy," in *PharmacoEconomics*, but the focus was societal². More recently, there have been further efforts to discern value, such as the article by Berndt, "Pharmaceuticals in U.S. HealthCare: Determinants of Quantity and Price," in the *Journal of Economic Perspectives*³.

Moreover, the pharmacist or physician faces a second hurdle in that the newer, sometimes improved product may often have a higher price than the older product. In essence, the prescriber is caught in the dilemma of having to determine the new drug's value. Value can be difficult to define, and is often quite subjective. This question is faced by consumers of all manner of goods and services on an everyday basis. Is the self cleaning oven worth the \$100 greater price versus a manually cleaned oven? Is the video camera with six hours capacity worth the higher price, compared with a four hour capacity camera?

The assessment of value sometimes becomes so complex that consumers and potential buyers give up the quest of independently determining value and turn to professional resources. In consumer goods, that might be a report in "Consumer Reports" or in another journal for lay persons. In health care, for example, a prescriber can review journal reports about new health technologies, or wait for assessments from organizations such as the Emergency Care Research Institute (ECRI), the National Institute for Health and Clinical Excellence (NICE) or other health technology assessment organizations, or from respected neutral publications such as "The Medical Letter" or "Facts and Comparisons".

Unfortunately though, such product evaluation bodies rarely conduct or have head-to-head comparisons. They often must resort to comparing results from different placebo controlled trials. In addition, the goal of selecting the product(s) of greatest value is made quite difficult by the wide array of diverse product features such as differing efficacy claims, tolerability profiles, formulations, dosage forms and indications.

There are continuing calls for a more efficient and improved, and less costly health care system in the United States and in most countries around the globe. Pharmaceuticals account for more than 10 percent of total healthcare expenditures in many developed countries, and a higher percentage in lesser developed countries. Pharmaceuticals are only evaluated for safety and efficacy in clinical trials, but increasingly they must demonstrate economic value when compared to other treatments or no treatment at all. Data on costs and treatment outcomes (e.g., morbidity, mortality, quality of life) are collected either prospectively or retrospectively, and economic analysis such as cost-effectiveness or cost-benefit can be conducted to ascertain relative value. Pharmacoeconomic studies along with clinical trial data can often provide a better measurement of treatment value than clinical trials alone, but unfortunately, the outcomes data used in pharmaco-economic analysis is not available until after a product has been on the market for an extended period of time, such as a year or longer, when there are a sufficient number of users.

To understand the true value of pharmaceuticals it may be prudent to go beyond the commonly used outcomes of morbidity, mortality and quality of life. Indeed other attributes such as ease of compliance, fewer side effects, doctor familiarity with the product, patient understanding of the disease treatment, can also influence how a drug is perceived, valued, used by patients and ultimately even the outcomes. For the last twenty years, pharmacoeconomic studies have demonstrated that certain medications can reduce emergency room visits and hospital admissions even though they may be expensive on a first look¹; the use of statin therapy to treat people with high cholesterol, for example, reduces hospital admissions and cardiac surgeries²; also the use of anti-retroviral drugs reduces mortality and morbidity for HIV/AIDS patients^{3,4}. In summary, drugs can be a viable economic alternative to patients being hospitalized with catastrophic illnesses³.

Some medicines, when taken as prescribed, can reduce costs in health care and increase productivity. People with depression often report related ailments such as back pain, headaches, lack of focus, and even heart disease. While depression treatment may not directly act upon these other disorders, often it is associated with more successful treatment, improved worker productivity and decreased hospitalizations³.

New drugs in a therapeutic class may have fewer side effects, and improved safety records and effectiveness which encourage compliance with the prescribed regimens⁵. Improved compliance can ultimately lead to better patient outcomes⁶. So, we are left with a quandary for health care professionals in their evaluation of competing drug products.

Objective

The objective of this study was to more fully characterize the determinants of pharmaceutical product value and to develop a simplified value assessment methodology to aid in formulary decision making.

Since today, even without comparative risk/benefit and other quantitative data, some products within a therapeutic category become very popular with healthcare providers and others languish on pharmacy shelves and in warehouses with minimal sales activity. There must be some features or variables about these drug products that drive this differentiation.

This study was conducted in an effort to ascertain the perceived value of selected drug product features.

Methods

Several pharmacy students were recruited in 2007 to review pharmaceutical product advertisements in twelve leading American medical journals from issues published in 2005 and 2006. From these twelve journals, which comprised general medical and several medical specialties, drug advertisements were individually analyzed and the principal message determined

Assessing different perspectives on the value of a pharmaceutical innovation

and recorded. Messages included claims such as, for example, “more potent than existing products”, or “new levels of safety”.

The messages from those advertisements (N=200) were condensed into 10 categories, by the investigators, which are shown in Table 1. There were, of course, many more messages in the 200 advertisements that were reviewed, but duplicates were eliminated as were messages that appeared as only to inform readers of the availability of a product, without featuring any advantages or reasons why that specific product should be prescribed. The investigators reduced the number of message categories by a continuous chain of refinement to eliminate duplicate categories by referring, where necessary to the original advertisement to gauge the thematic and athematic message components.

Table 1. Key product features from medical journal drug advertisements*

Combination Product; Relieving Pill Burden
Ease of Use
Facilitates Compliance
Full Range of Strengths Available
Highly Effective/Superior
No Addiction Risk
Once daily Dosing
Rapid Relief/Effect
Safety
Schedule Simplicity
*listed alphabetically

The list of product features seen in Table 1 was shown to three groups of respondents who were asked to rank them from one to ten according to importance and to provide an estimate of what they would consider a reasonable and fair percentage price increase over a basic product lacking that specific feature. Each of the ten characteristics was considered independently.

This pilot study was administered to a convenience sample of practicing pharmacists (n=12), practicing physicians (n=12) and patients (n=12) at a large medical center in a major urban area in the Northeast USA. Each respondent was asked to provide their personal opinion, and not as a representative of any group or organization.

One final word about the methodology is probably in order. In the United States, pharmaceutical product advertisements are not pre-screened or approved by the F.D.A. or any governmental agency, as is the case in numerous countries. Manufacturers push as far as they believe they can go without subsequent FDA rebuke and in some cases, advertisements do not provide a fair balance of risks and benefits, and benefits may be exaggerated or bloated a little, but not enough to warrant governmental intervention.

For example a firm could promote its antacid as “the woman’s antacid” even if clinical results do not demonstrate any special advantage for women using that product versus any other antacid on the market.

Results

The findings differed as evaluated by the three cohorts. In terms of willingness to pay an increased price for innovative features, patients and pharmacists were the most welcoming of improved features (price increase ranged from 5-30% and 10-50%, respectively, and for all product features), and physicians the least (price increase ranged from 0-10%, and only for two product features). Across all three study groups the greatest price increases were consistently for efficacy and safety.

Table 2. Evaluation of higher price worthiness for additional feature by Physicians (M.D.s), Pharmacists, and Patients. (Mean scores)

Feature	M.D.s (%)	Pharmacists (%)	Patients (%)
Rapid Relief	0	10	20
Ease of Use	0	15	5
Facilitate Compliance	0	10	10
Schedule Simplicity	0	15	10
Highly Effective/Superior	10	15	20
Once Daily dosing	0	15	10
Safety	10	50	30
Combination Product	0	15	20
No Addiction Risk	0	20	30
Full Range of Strengths	0	10	10

When asked specifically to rank order the ten product features (Table 3), improved efficacy or safety were the number one choice for all three study groups. However, after efficacy and safety, there were subtle yet noteworthy differences in ranking for other product features. For example, where compliance was noted as relatively unimportant to patients and pharmacists, it was considered much more important by physicians. And, where rapid symptom relief was less important to physicians, it was clearly more meaningful to pharmacists and patients.

Table 3. Ranking of importance of drug product features by Physicians, Pharmacists, and Patients
(1=highest, 10=lowest)

Feature	M.D.s	Pharmacists	Patients
Rapid Relief	7	2	4
Ease of Use	6	3	3
Facilitates Compliance	2	10	8
Schedule Simplicity	5	5	7
High Effective/ Superior	3	4	1
Once Daily Dosing	4	6	2
Safety	1	1	6
Combination	8	7	5
No addiction	10	9	9
Full Range of Strengths	9	8	10

Discussion & Conclusion

The results obtained from this pilot study cannot be generalized because of a very small sample size, as well as the use of a convenience sample of respondents. Nevertheless, our study provides proof of concept that there are measurable differences in perceived value of pharmaceuticals based on product characteristics and upon whom one asks, and that in order to fully assess value it is necessary to include a broad perspective comprising providers and patients. Although we did not include payers or payer advisors in our study, clearly this group should be included as well in future research.

In addition, our method and findings can be useful in drug development decision making, where pharmaceutical manufacturers can perhaps guide research and development efforts along the lines of characteristics most highly valued by patients, providers and payers. This preliminary study suggests that a more robust follow-up investigation using an increased sampling frame with greater geographic dispersion, along with randomization of respondents, could be highly informative. A more complete treatment of this subject would include the assessments of feature value by consumers/patients, the very persons who must endure the effects of these medications. In addition, it could be useful to add a willingness to pay evaluation in an effort to appreciate real monetary numbers instead of theoretical percentage increases supplied by the respondents to this study. Also, more detail could be provided on the product features – especially regarding relative efficacy,

safety and tolerability. Perhaps greater price increases would be acceptable with greater improvements in efficacy and/or lower risks of side-effects. One commonly heard dilemma from personnel at health authorities and managed care organizations is: How does one differentiate products where there may be very little difference among products in a class and between the original molecules? Here, we might find that while the clinical effectiveness is quite similar, that different metabolic pathway may lead to fewer interactions, or one may cause less gastritis, or be more greatly tolerated and therefore be taken close to the prescribed regimen, and may lead to superior outcomes. And this may be expected to influence patient preference for certain products because of their unique features.

Traditionally, product pricing decisions by pharmaceutical companies consider the avoided cost of care without drug treatment such as surgery or hospitalization, and a further consideration of other therapies; competing drugs or medical procedures, but they normally do not consider patient opinion. Yet, if patients report to their physician that one drug was responsible for unpleasant diarrhea, that physician will most likely veer toward the use of a different product in the future.

Finally, studies like this hold the possibility of demonstrating to health plans, Ministry of Health or Social Security personnel that while they might not place a high value on certain product characteristics or features, that the persons who must endure the disease and the use of the product – the patient, may feel differently about the importance or worth of some aspects of the product. As members of, and contributors to, health plans and/or national health care systems, patient perspectives and preferences are critical to consider.

The authors urge investigators to explore this area further using randomly selected and larger sample sizes (to allow for statistical tests and modeling), diverse populations of patients, providers and payers, and more comprehensive and detailed value assessment techniques.

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References:

1. Coyle D. Drummond M. Does expenditure on pharmaceuticals give good value for money?: current evidence and policy implications, *Health Policy*, 26, 1, 55-75, November 1993.
2. Grund J. The Societal Value of Pharmaceuticals: Balancing Industrial and Healthcare Policy, *PharmacoEconomics*, vol 10, Nr. 1, Pages 14-22, July 1996.
3. Berndt ER. Pharmaceuticals in U.S. Health Care: Determinants of Quantity and Price, *Journal of Economic Perspectives*, vol 16, Nr. 4, Fall 2002, pages 45-66.
4. Brophy JM, Joseph L, Rooleau JL. Beta Blockers Improve Survival and Decrease Hospitalization in Patients with Heart Failure, *Annals of Internal Medicine*, 134, Nr. 7, 594, 3 April 2001.

Assessing different perspectives on the value of a pharmaceutical innovation

5. John IP, Kantipudi S, Khasnis, A, Cholia, A, Dickinson M. Statin Therapy Is Associated with Improved Survival in Ischemic and Non-Ischemic Heart Failure, Congestive Heart Failure, Vol 10, Nr. 6, Pages 313-315, November/December 2004.
6. PhRMA, Value of Medicines: Facts and Figures 2006 <http://www.phrma.org/files/attachments/Value%20of%20Medicine%202006.pdf> (Accessed 13/2/2010)
7. Gadelha AJ, Accacio N, Costa RLB, Galhardo MC et al. Morbidity and Survival in Advanced AIDS in Rio de Janeiro, Brazil, Revista do Instituto de Medicina Tropical e Sao Paulo, Jul/Aug, 2002.
8. Wertheimer AI, O'Brien T, Levy R. The Value of Incremental Pharmaceutical Innovation for Older Americans, National Pharmaceutical Council, Reston, VA, 2001.
9. Fincham JE. Patient Compliance with Medication: Issues and Opportunities, Haworth, Binghamton, NY, 88, 2007.
10. Lichtenberg FR. Are the Benefits of Newer Drugs Worth Their Cost? Evidence From the 1996 MEPS, Health Affairs, Vol 20, nr. 5, pages 241-251, Sept/October 2001.