REVIEW ARTICLE

Pharmacoeconomics 1998; 14 Suppl. 1: 15-24
1170-7690/98/0001-0015/$05.00/0

The Role of Cost-Effectiveness Analysis in Managed-Care Decisions

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Abstract

This article considers the role of cost-effectiveness studies in the formulary and disease-state management decisions of managed-care entities. In a recently published symposium volume [Soc Sci Med 1997; 45 (4): 505-647], US managed-care entities were found to be among the leaders in applying cost-effectiveness studies to healthcare decisions. At the same time, a number of barriers were identified that hinder their wider usage in the managed-care sector. These factors are analysed in this paper along with the prospects for future changes. The potential roles for government policy in this area are also discussed in the final section of the article.

One of the major premises underlying the growth of managed care is that it would lead to increased cost effectiveness in healthcare decisions and outcomes. Many conceptual analyses have been performed on the incentives for cost-effectiveness behaviour by different managed-care organisational structures. However, very little is known about the actual decision-making procedures used by managed-care organisations (MCOs) to achieve cost effectiveness in their resource allocations.

A recent symposium focused on the use of cost-effectiveness studies by the public and private healthcare decision makers.[1] The papers in this symposium concentrated on the role of cost-effectiveness evaluation in the reimbursement and utilisation of pharmaceuticals, since new medicines have been the subject of vastly more studies than other types of medical interventions. Indeed, there have been literally hundreds of cost-effectiveness studies performed for different drug treatments in recent years.

Separate analyses were undertaken on the use of cost-effectiveness studies in the United States by health maintenance organisations (HMOs), pharmacy benefit management firms (PBMs) and hospitals operating in markets with differing levels of managed-care competition. In addition, analyses were undertaken on the uses of cost-effectiveness studies by public decision makers responsible for drug pricing and reimbursement decisions in 6 other countries (Australia, France, Germany, The Netherlands, Sweden and the United Kingdom).

The studies in our symposium found that cost-effectiveness studies are an important input among many factors currently utilised in healthcare decisions. However, it was difficult to find many case examples where cost-effectiveness analyses were the decisive factor in drug adoption, pricing or reimbursement decisions. This was true in the US managed sector as well as for public sector decisions in the 6 other countries surveyed.

There is an emerging consensus among private and public decision makers that the influence of cost-effectiveness studies will grow significantly in importance in the future. This is based on a number of developments currently occurring in the healthcare system.

In the remainder of this paper, use of cost-effectiveness evaluations within the US managed-care sector is considered in greater detail. The factors hindering greater usage of cost-effectiveness evaluations are analysed along with the opportunities for its future growth. The possible role of government regulation is also discussed in the final section.

1. Incentives of MCOs to Use Cost-Effectiveness Studies

The concept of the HMO dates back to the early post-World War II period. As managed care has evolved, HMOs may employ physicians and own hospitals (i.e. staff and group plans) or they may obtain services from physicians and hospitals on a contractual basis (i.e. network HMOs and independent practice associations or IPAs). One important characteristic that HMOs have in common is that they are reimbursed prospectively for the delivery of contracted healthcare benefits. As a consequence, HMOs bear significant financial risks for cost overruns. Hence, they should be less willing than the fee-for-service sector to adopt expensive new technologies without documentation of substantial benefit.

A relatively new type of MCO is the PBM. PBMs specialise in managing the outpatient prescription benefits of managed-care plans for HMOs and employers (see Shulman, this issue[2]). This is done usually on a 'carved out' basis, where drug benefits are managed separately from other covered healthcare services. While some PBMs have a long history as claims processors or mail order houses, it is only more recently that PBMs have implemented formularies and other programmes specifically designed to influence the drug therapy choices of physicians, pharmacists and patients. By creating financial incentives to use formulary-listed drugs, PBMs can achieve significant savings in the drug budget. These savings are derived in part from the price discounts obtained from drug manufacturers to gain access to the formulary.

The fact that PBMs generally manage the drug budget separately from other covered medical services makes their responsiveness to cost-effectiveness studies somewhat problematical. In particular, the trade-offs between drug expenditures on the one hand and medical costs (physician visits, emergency room treatment, hospitalisations, etc.) on the other are an integral part of the cost-effectiveness studies of many new drug therapies. By contrast, the mission and financial incentives of PBMs have been more narrowly focused on the costs and quality of drug therapies.

While there is a potentially significant incentives problem in this organisational structure, it is still true that PBMs are ultimately the agents of HMOs and employees. Their clients are presumably concerned about the broader impacts of drugs on their healthcare plans. Hence, it is incumbent on PBMs to recognise and respond to these impacts as reflected in cost-effectiveness studies and other outcome analyses. One manifestation of this is the development by PBMs of disease-state management programmes centred on the optimal use of drug therapy for high-cost chronic diseases such as diabetes and asthma.

Some of the same issues pervade the use of cost-effectiveness studies to guide decisions about inpatient drug utilisation in hospitals. Hospitals have a long history of using restrictive drug formularies as a means of economising on pharmacy budget costs. Hospital pharmacies still tend to be managed as separate cost centres. However, hospitals are increasingly paid on a prospective basis to treat particular diseases or conditions. It remains an interesting question for research whether hospitals operating in more mature managed-care markets behave in a different manner from those experiencing fewer cost containment pressures.

2. The Use of Cost-Effectiveness Studies by PBMs

At a recent symposium, the use of cost-effectiveness studies by PBMs was examined.[3] PBMs currently manage the drug benefits for approximately 150 million covered lives. In terms of their

Table I. Effects of formulary closure for a moderate-sized health maintenance organisation (values in US dollars)

Drug class	Initial average ingredient cost per prescription	Formulary average ingredient cost per prescription	Savings per prescription	Yearly savings
ACE inhibitors	28.55	23.52	5.03	40 452
H_2 blockers	73.00	67.00	6.00	40 501
HMG-CoA reductase inhibitors	64.65	45.83	18.82	82 173
Antibiotics	9.67	7.46	2.21	52 960
Calcium antagonists	39.86	37.71	2.15	15 472
Total savings				231 558

Source: Norrie Thomas, presentation to Center for Pharmaceutical Outcomes Research Conference, University of North Carolina, April 1995.

ACE = angiotensin converting enzyme; **HMG-CoA** = hydroxy-methylglutaryl coenzyme A.

influence on drug prescription and utilisation decisions, PBMs therefore potentially have a dominant influence in the managed-care sector. Hence, this is a useful place to begin an analysis of the decision-making practices of managed-care entities with respect to prescription drug policies.

Our analysis of this sector focused on 5 leading PBMs (Medco, PCS, Diversified, ValueHealth and Pharmacy Gold). These PBMs account for 80% of beneficiaries covered in formulary plans. We were particularly interested in how cost-effectiveness analysis affects the decision to list new drugs on to their formularies. Usually each new drug is evaluated within a short time period after it is approved for marketing by the Food and Drug Administration (FDA).

2.1 The Drug Formulary Process

PBMs typically use a 2-stage or bifurcated decision process in the formulary listing process. In the first stage, the Pharmacy and Therapeutics (P&T) committee, composed primarily of physicians and clinical pharmacists, evaluates a new drug's tolerability and efficacy and its interchangeability with existing drug therapies. On the basis of this review, the P&T committee can decide as follows: that the new drug must be listed on the formulary (because it offers significant therapeutic gains over established therapies); that it cannot be listed on the formulary (because of inferior therapeutic properties); or that it may be listed on the formulary (since it is determined to be broadly interchangeable with existing drug therapies).

If the P&T committee determines that a new drug is in fact a close substitute for existing drugs (for example, because it is a new ACE inhibitor with similar therapeutic properties to established ACE inhibitors), then cost becomes the key consideration for its inclusion on the formulary. In this case, business executives within the PBM firms typically become involved in the decision-making process and pricing discussions are undertaken with the drug manufacturer. Typically, the price negotiated relative to its close substitutes will determine whether a new drug in a crowded therapeutic class like the ACE inhibitors is ultimately included on the formulary.

2.2 Cost-Effectiveness Analyses in Formulary Decisions

Overall, the formulary selection process of PBMs for closely substitutable products has been driven by price discounting considerations. Cost-effectiveness studies have played a limited role in the selection of drugs placed on the formularies. The formularies of PBMs surveyed for this study have historically been relatively inclusive. However, there also is a strong dynamic toward more restrictive formularies, along with the development of corresponding financial incentives for formulary compliance. This trend reflects the fact that manufacturers are willing to negotiate larger discounts for the increased market shares obtainable from more restrictive formularies.

Table I provides an example of the savings to a medium-sized HMO from closing their formulary.

The savings are concentrated in the large market drug classes that have several closely substitutable therapeutic products. The annual savings vary across drug classes, up to a high of 30% for the statins [hydroxy-methylglutaryl coenzyme A (HMG-CoA) reductase inhibitors] class of cholesterol-reducing agents. In terms of savings for the overall drug budget, our survey of leading PBMs found that the use of various types of drug formularies (including different compliance measures) typically yielded savings of between 5 and 15%.[3]

Cost-effectiveness studies can have a significant effect on formulary decisions when a new drug offers a unique therapeutic advantage. Such drug therapies are also typically more expensive than established therapies. Hence, formulary decision makers are confronted with the issue of whether the expected additional benefits of the drug therapy are worth the higher expected costs. While we found that drug therapies with unique or important therapeutic benefits are almost always listed on the formulary, they may be subject to utilisation restrictions and prior authorisation by the PBMs. Many of the new biotech drugs have been subject to prior authorisation because of their unique therapeutic profiles and very high costs. Cost-effectiveness studies can be a useful input in the decision on whether a new drug should be subject to such restrictions.

PBMs also develop treatment guidelines for drugs listed on their formularies. These are then disseminated to physicians in the formulary book and in newsletters. Misoprostol, a drug taken for prophylaxis by individuals at risk of ulcers from NSAIDs, provides a case example. PBMs have developed guidelines stipulating what kind of patients should receive this drug (e.g. the elderly, those with prior history of gastric ulcers, and those with concomitant debilitating illnesses). These guidelines are consistent with the findings of cost-effectiveness studies on misoprostol as well as accepted medical practice on this drug.[4] In this situation, cost-effectiveness studies provided useful information in the development of these treatment guidelines.

2.3 Barriers to the Use of Cost-Effectiveness Analyses

PBMs have pointed to several barriers that hindered the wider use of cost-effectiveness evaluations in formulary decisions. These barriers relate to the relevance, timeliness and objectivity of these studies. On the issue of relevance, PBMs indicated that cost-effectiveness studies are often performed on patient populations very different from their covered enrollees. In addition, the studies frequently compare the new drug to a placebo or older-line therapy rather than the drug treatment of choice. Furthermore, treatment protocols that differ from typical medical practice procedure may be used, in terms of special measures used to ensure compliance and other interventions.[5,6]

With respect to timeliness, PBMs have indicated that information on a new drug's cost effectiveness is often not available when formulary adoption decisions are being made. Finally, PBMs expressed considerable scepticism about the objectivity of many cost-effectiveness studies given that they are often funded by the developer of the drug.

While many of these concerns appear valid, there are necessarily trade-offs among them. Consider the issue of relevance versus timeliness. Cost-effectiveness studies, which utilise the efficacy data from randomised clinical trials, can be available early in the drug's marketing life and provide a useful starting point to assess a drug's cost effectiveness. However, clinical studies of efficacy must conform to FDA regulations with respect to the choice of the comparator, patient populations, treatment protocols, clinical endpoints, etc.[5,6] Hence, the initial cost-effectiveness studies on a drug typically augment the clinical trial data with modelling analyses and information from other sources, (i.e. observational databases and epidemiological studies). Over time, cost-effectiveness analyses can be refined as new information becomes available from the market under more normal conditions of medical care.

There are also trade-offs between objectivity and timeliness. In particular, to address concerns about objectivity, many firm-supported cost-effectiveness studies use investigators from the university

community and then subject the findings to peer review. While peer review may allay concerns about the objectivity of these studies, the reviewing process can be very slow, aggravating concerns about having the information in a timely fashion.

To the extent that PBMs have significant concerns about the relevance, timeliness and objectivity of externally derived studies, they can expend resources to adapt and refine these studies to their own situation. For example, suppose a cost-effectiveness analysis indicates that a new drug is expected to increase total drug expenditures, but there is also reason to expect some offsetting savings from reduced outlays on emergency room visits or hospitalisations. The PBM could assess whether this is borne out by the medical claims data of its own enrollees.

This is, of course, not as easy as it sounds. PBMs often have very comprehensive data bases on drug claims, but not comparable information on other medical claims (physician services, hospitalisations, diagnostics, etc.). Hence, they often need to enlist the cooperation of the associated managed-care plan to obtain these data. Furthermore, they need to make considerable investments in integrating and analysing the data. This is in fact happening, but such efforts are in their initial stages at present.

2.4 Disease-State Management Programmes

From an economic standpoint, the drug selection policies of PBMs have achieved significant cost savings in the drug budgets of employers and MCOs. This is the principal factor underlying their rapid growth in recent years. However, managing drug choices separately from other healthcare decisions is subject to important limitations. By its very nature, this approach cannot capture the broader cost efficiencies associated with an integrated approach to disease and disability problems.

These system-side savings and benefit opportunities are potentially much larger than the cost reductions in the pharmacy budget realisable from a carved-out management approach to drug benefits. For this reason, some observers believe that the management of drugs and other healthcare components in separate 'boxes' is a transitional feature of the US medical system. They envision that prescription drugs will be 'carved back' in as patient care becomes more integrative in character in the future.

PBMs are among the many entities (HMOs, hospitals, drug manufacturers, etc.) now giving increased attention to the concept of disease-state management. This concept involves the development of optimal treatment protocols across all medical modalities on a disease-specific basis. Since the measurement of outcomes is a necessary attribute of this approach, the use of cost-effectiveness analyses is expected to grow in conjunction with the spread of these programmes.

Our survey of the disease-state management programmes of the leading PBMs indicated that an incremental approach is being pursued. PBMs are focusing their activities on several high-cost chronic conditions such as asthma and diabetes.[3] In particular, they have targeted their programmes to identifying high-risk patients who have been prescribed inappropriate drug therapies and those experiencing drug compliance problems. They then provide educational information and take other measures designed to prevent these patients from getting 'out of control' and ending up in the emergency room/hospital, with its attendant high costs.

To the extent that a PBM is successful in improving drug prescriptions and increasing the drug compliance of patients with diabetes or asthma, this may mean an increase in the managed-care plan's total drug expenditures. However, as noted, PBMs often have incentive contracts in which their revenues are tied to the drug budget savings. Hence, successful outcomes in their disease-state management programmes can mean lower revenues to the PBM. It therefore becomes critical that they document the overall savings and increases in patient welfare of these programmes through outcome assessment to avoid being penalised as a result of successful outcomes.

Over time, it remains an open question whether PBMs can develop the appropriate organisational structure and incentives to be key players in the disease-management area. Their current strength is their extensive databases on prescription claims and their knowledge of optimal drug treatment regimens. However, PBMs are limited by their relative lack of information on other forms of medical outcomes and claims. As discussed, they are currently making significant investments to acquire and integrate this information into their databases through a variety of cooperative ventures and programmes with their managed-care clients.

3. The Use of Cost-Effectiveness Studies by HMOs

3.1 Utility of Cost-Effectiveness Studies to HMOs

Lyles et al. have analysed the use of cost-effectiveness studies by HMOs.[7] They used a representative sample of 51 large and medium-sized HMOs. As noted previously, many HMOs rely on PBMs to assess the cost effectiveness of new drugs. Lyles et al.[7] found that 54% of the IPA/network plans relied on PBM assessments (among other sources) but only 24% of the staff/group plans used these sources.

All types of plans relied extensively on peer-reviewed journals, but staff/group models were much more likely to rely on assessments of other HMOs than IPA/network plans (74 *vs* 37%). In addition, Lyles et al.[7] found that staff/group plans were more likely to have the internal capability to do their own assessments. The more proactive involvement with cost-effectiveness study evaluation by staff/group plans is consistent with the fact that they are more likely to take an integrative approach to healthcare.

Lyles et al.[7] also examined the utility of various cost-effectiveness analysis sources along a number of dimensions – i.e. quality, validity, timeliness, comprehensiveness and availability. They found that timeliness and comprehensiveness were the most important components affecting the overall utility of information. With regard to the importance of specific sources for decision making, they found that PBM studies (for those using them) and cost-effectiveness studies of other HMOs received the highest rankings. Peer-reviewed studies received high scores compared with non–peer-reviewed publications. Government reports received the very lowest ratings, primarily because of their lack of timeliness and availability.

HMOs expressed some of the same reservations about cost-effectiveness studies as PBMs regarding the relevance, objectivity and timeliness of existing studies emanating from industry sources. However, HMOs, especially larger integrated plans, are devoting significant resources to internal evaluations and are also performing collaborative studies with pharmaceutical firms. Staff HMOs are also at the forefront of integrated disease-management plans. Some examples of these developments are presented in the next 2 sections.

3.2 The Cholesterol Reduction Intervention Study

Some of the larger staff model HMOs have been at the forefront of performing novel in-house cost-effectiveness studies. One particularly noteworthy study in this regard is the Cholesterol Reduction Intervention Study (CRIS), a joint study supported by Southern California Kaiser Permanente and Merck. This study by Oster et al. examined the cost effectiveness of a stepped-care treatment protocol[1] versus the use of a newer, more expensive drug, lovastatin, as first-line therapy.[8]

Stepped-care regimens have been advocated as a way of lowering costs without compromising medical outcomes. CRIS represents the first real

1 Under the stepped-care regimen, the generic drug nicotinic acid (niacin) was chosen as the first-line therapy. Patients who did not achieve their targeted goals with nicotinic acid within a given interval were then sequentially moved to other drug therapies. The last step in this treatment chain was lovastatin, a member of the HMG-CoA reductase inhibitor class of cholesterol-reducing agents. Drugs in this class are generally better tolerated than older therapies like nicotinic acid, but they are also more expensive.

test of that proposition under conditions of normal medical practice. Specifically, patients were randomly assigned to the 2 treatment groups, but otherwise the trial design sought to replicate normal clinical practice procedures at Kaiser Permanente. In particular, provider and patient compliance with the study interventions were not enforced, and the patients paid for their medications in accordance with their customary insurance coverage.

Oster et al.[8] found that at the end of the 1-year study period, costs of the stepped therapy regimen were indeed lower, but at the same time fewer patients had achieved their cholesterol reduction goals. This cost-effectiveness study with its naturalistic study design addressed some of the main concerns that MCOs have with studies based on clinical trial data. The findings of CRIS influenced Kaiser to put lovastatin on its formulary, rather than position it as a second-line drug treatment option.

The cost effectiveness of stepped-care protocols also remains an important research issue in several other therapeutic areas in which newer and more expensive therapeutic agents have been introduced with better patient tolerability than older-line therapies (e.g. hypertension and depression). Further studies of this kind are currently under way.

3.3 Disease Management Programmes

All but one of the 51 HMO plans surveyed by Lyles et al. reported having implemented or planning to implement a disease management programme.[7] These programmes incorporate multimodality treatment strategies, written protocols and the measurement of disease-specific outcomes. A high percentage of the HMOs surveyed predicted greater future use of assessments for decisions regarding prescription drugs.

Some HMOs have taken a leadership position in developing integrated disease-state management programmes. Particularly noteworthy in this regard is the alliance between John Deere Healthcare and the Mayo Clinic.[9] John Deere provided the Mayo Clinic with its extensive integrated medical records database on its employees for use in the development of medical treatment guidelines. During the past 4 years, the Mayo Clinic has developed treatment guidelines for 12 diseases and conditions that account for 60 to 70% of Deere's health costs. The programme is now being tested and refined in the company's employee-only staff model clinics. The company eventually plans to introduce its integrated disease management programme to its 300 000-member commercial HMO. Other HMOs developing disease-state management programmes include Group Health of Puget Sound, Minnesota Health Partners and Kaiser Permanente.

4. The Use of Cost-Effectiveness Studies by Hospital Pharmacies

Sloan et al. conducted a survey of the use of cost-effectiveness studies by 103 hospital pharmacies.[10] Hospitals as a group tend to employ very restrictive drug formularies. There were several indications of this in the Sloan study. First, almost 80% of the hospitals permitted therapeutic interchange, with certain drug categories being commonly targeted (e.g. anti-infectives and anti-ulcer drugs). Furthermore, approximately three-fifths of the hospitals spent less than 5% of their budgets on nonformulary drugs. The hospitals used a variety of management policies to ensure compliance with formularies including monitoring prescribers for excessive use of nonformulary drugs.

While hospitals employ aggressive drug formularies in many therapeutic areas, cost-effectiveness studies were found to play a minor role in their decision making. Only 37% responded that information on cost effectiveness was often presented to the hospital P&T committee when a new drug was under consideration for addition to the formulary. One of the key hypotheses tested by Sloan et al.[10] was that the hospital pharmacies under the highest cost pressures from managed care would be more likely to adopt process innovations such as cost-effectiveness evaluations in order to obtain less costly and more cost-effective provision of healthcare. Somewhat surprisingly, they found that the use of cost-effectiveness studies was not significantly

related to the extent of managed-care penetration in a particular hospital's market.

Many of the reasons given for the limited use of cost-effectiveness studies in hospital formulary decisions are the same as those for other managed-care entities: i.e. the relevance of studies to their patient populations, lack of timeliness, objectivity concerns, etc. However, compared with PBMs and HMOs, many hospitals also have less in-house capacity to evaluate the quality of cost-effectiveness studies. In responding to managed-care pressures, hospitals have given the highest priority to reducing their length of stays and admission rates. To date, they have exhibited less interest in process innovations that affect *per diem* costs. Hence, cost-effectiveness studies of pharmaceuticals have not been a high priority item on their radar screens.

As managed care evolves, this may change, and hospital pharmacies may become more receptive to process innovations such as cost-effectiveness evaluations that can help them achieve lower overall *per diem* costs. This will require organisational changes and the addition of more individuals trained in cost-effectiveness analyses.

5. Public Policy Interventions

What public interventions, if any, are appropriate in the case of cost-effectiveness evaluations? One can enumerate 3 possible roles for the public sector in the context of the decentralised US healthcare system. First, the government could be an enlightened consumer of cost-effectiveness studies with respect to public sector healthcare decisions (i.e. in the Medicare and Medicaid programmes). Second, the government could be a primary source of objective information about cost-effectiveness studies either by sponsoring its own studies or reviewing the quality of information from other sources. Third, the government could regulate cost-effectiveness studies along the lines of the current reviews of tolerability and efficacy of pharmaceuticals.

With respect to the first point, cost-effectiveness analyses have been used by US public sector agencies on a very limited basis. Medicare has used technology assessments for some of its coverage decisions. However, this has not typically included outpatient pharmaceuticals, which are currently covered by Medicare only on a very selective basis. One notable exception is the use of cost-effectiveness analysis to decide whether Medicare should cover vaccination for pneumococcal pneumonia.[11] State Medicaid programmes appear to use cost-effectiveness evaluations very rarely for pharmaceuticals and other medical modalities.[12,13]

Turning to the second point, the Agency for Health Care Policy Research (AHCPR) is the federal agency that is broadly charged with undertaking cost-effectiveness evaluations of pharmaceuticals and other healthcare interventions. Since information is a public good, there is a clear rationale for public support of cost-effectiveness research. However, the usefulness of government studies to MCOs has been somewhat mixed to date. While these reports received relatively high scores from HMOs on validity and comprehensiveness, they received very low scores in terms of timeliness and availability.[7] The long delays associated with the government evaluation process contributed to its relatively low overall ranking among the external sources of information utilised by managed-care entities.

In the case of the third point, the role of the government as a regulator of cost-effectiveness information has received particular policy attention for pharmaceuticals recently. The FDA has authority over pharmaceutical labelling and the claims made in advertising and promotional materials. In March 1995, the FDA presented draft guidelines for pharmacoeconomic claims that followed closely its regulations on tolerability and efficacy claims.[14] In particular, these guidelines stated that all pharmacoeconomic claims must be substantiated by 'two adequate and well controlled studies.' The FDA draft regulations also discouraged the use of mathematical and computer modelling, indicating they would be permitted only when it is impractical to gather data using adequate and well controlled studies.

The benefits of implementing regulations along the lines of the 1995 FDA proposal must be weighed against the costs of such interventions. One can foresee a number of potential problems. First, given the heterogeneity of users, imposing a methodological straitjacket is likely to yield results that are not pertinent to the needs of many users. Second, such stringent regulation is likely to limit innovation in the conduct of such studies and result in higher overall costs of doing these studies.[15] Furthermore, if timeliness of research findings is currently a problem for users, imposing such regulations on studies would almost inevitably lead to further delays. Many users of cost-effectiveness studies think a need exists for more objective analyses. However, there is scepticism that expanded FDA regulation would fulfil this need.[16]

5.1 The Development of New FDA Regulations on Pharmacoeconomic Claims

The FDA proposed regulations were highly prescriptive in nature, even compared with other single-payer countries where the government is the dominant purchaser of pharmaceuticals. For example, the recently issued UK guidelines for pharmacoeconomic studies accepts medical evidence from a diverse set of sources, provided the evidence can be justified by objective analyses.[17] This is essentially the position of the staff of the US Federal Trade Commission (FTC), which submitted critical comments on the FDA draft regulations. The FTC submission advocated a more flexible approach to pharmacoeconomic claims, indicating that FDA should require 'competent and reliable evidence' to support any claim that is made without *a priori* specification to the type of evidence required.[18]

A new standard was recently adopted by Congress in the FDA Modernization Act of 1997 (FDAMA). This act directs FDA to rely on the standard of competent and reliable evidence in deciding what pharmacoeconomic information can be presented to MCOs by drug companies. The FDA is now working on new draft guidelines for the promotion of pharmacoeconomic claims and it has encouraged interested parties to submit comments on how the agency should implement this new standard.[19,20]

As an alternative to increased FDA regulation, some researchers have suggested more market-oriented approaches to the review of the quality and objectivity of cost-effectiveness studies.[21,22] This could take a number of forms. One model in this regard is provided by the independent auditing of financial data by publicly certified accountants and the rating of bonds by organisations such as Moody's and Standard and Poor. Under this kind of approach, the government could play a role in certifying the organisations doing the reviews of cost-effectiveness claims, but not evaluate the actual claims themselves. These third-party organisations could also be funded through different mechanisms. The options include funding on a 'no-strings' basis from a consortium of producers and users of cost-effectiveness studies as well as public or quasi-public subsidies for this activity.

6. Conclusions

The use of cost-effectiveness analysis in managed care is still in its early stages. It is viewed as useful input in evaluating new drugs and other medical treatments. However, its actual influence on decision making has been quite limited to date. Some of the reasons for this relate to the perceived quality and availability of the studies themselves. Another major reason relates to the current organisational characteristics of most MCOs and the corresponding incentives to use these techniques. In particular, MCOs in their initial development phase have focused on reducing unit costs through the negotiation of price discounts, rebates and capitation fees on a component-by-component basis (i.e. for drug services, physicians' services, diagnostics, hospitalisation, etc.).

It is significant that many observers expect that the next stage of development in the US healthcare system will involve managing care on an integrative system-wide basis. Correspondingly, greater attention will be given to the measurement of outcomes including measures of quality and effectiveness of care as well as cost. In this emerging environment,

cost-effectiveness studies are likely to play an expanding role in the area of managed care. There will be increased opportunities to integrate formularies, drug assessments and disease-state management.

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