

# Pharmaceutical Executive

A panel of medical directors from managed care organizations discuss how they make formulary decisions  
by William J. Febbo

## Managed Care

CONFIDENTIAL

**W**ith Medicare Part D looming in the industry's immediate future, formulary placement is high on product managers' list of priorities. A brand's formulary status with current health plans may well affect its placement with new Medicare prescription drug plans. So the central question for pharma is "How do managed care organizations make formulary decisions?"

A panel of eight MCO medical directors recently convened to answer that question and evaluate the influence of consumers, physicians, pull-through programs, and outcomes studies. MedPanel, Inc., an online market intelligence company, asked eight US medical directors to comment on the influences that affect whether a drug is included on a typical formulary and what criteria are used to evaluate a new drug entry.

The panel was convened online over a two-week period, and participant identities were concealed from each other to foster more candid responses and maximize the interaction. (See "Panelist Profile," page 38.) This article highlights the study group's findings—which may come as a bit of a surprise to some product managers.

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### Consumers Lack Clout

The panelists unanimously asserted that consumers have little impact on decisions relating to a single drug. This lack of influence is, in large part, a result of the difference between what direct-to-consumer (DTC) advertising focuses on and what drives pharmacy and therapeutics (P&T) committee decisions. "Efficacy, safety, and cost drive the formulary decision process," one panelist said. "Consumer demand is likely based on DTC or another source that does not consider the critical decision points of the P&T committee."

Although DTC advertising may be what influences consumers most, health plans tend to dismiss the information provided in consumer advertising and focus on science.

Consumers also lack a unified means of asserting pressure, panelists emphasized. That's why some medical directors view employer groups, rather than individuals, as the real consumers. Although most participants expected little change in consumers' influence over formulary decisions, there were a few interesting exceptions. One medical director said, "Organizations such as AARP may be able to affect the consumer voice in the future," because they are an organized and powerful group with a public agenda. Taking on formulary decision mak-

ing seems like a natural next step for AARP. As other groups form—or wake up to the formulary issue—consumers will find their influence growing. Another participant asserted that escalating costs will lead to increased consumer involvement over drug availability. Still another stated that although individuals have almost no impact, "High demand may push an earlier termination of a drug's placement than would have otherwise occurred."

"There will be more activity from the consumer, related to influencing the drugs/treatments available," said one participant.

Through DTC, manufacturers are encouraging consumers to take the selection of medicines into their own hands. That empowerment is leading consumers to examine more closely the claims pharmaceutical companies make about their products and how those drugs are being managed by insurance companies. As consumers increasingly coalesce into groups, their voices will be a more powerful force than they currently are in their splintered state. Taken as a whole, the data suggest that a concerted, unified effort on the part of consumers might well influence formulary decisions in the future.

### Physicians as Thought Leaders

Though the panel's opinions concerning

physician influence ranged from “some” to “significant,” the entire group saw huge value in input from opinion leaders and specialists. As areas where that input is most valued, they cited

- » cost management
- » utilization control
- » assistance with getting a drug included on a physician practice’s therapeutic roster
- » filling in gaps between published studies and clinical practice.

Regarding placement on a physicians’ drug roster, in most cases, panelists agreed that the drug’s performance should speak for itself.

Most MCOs represented in the study reach out to external physicians when evaluating new drugs and technologies. Ultimately, the panel found, the specialist’s word is most highly prized by the P&T committee and is relied on by committee members lacking knowledge in specialized disease areas. Overall, the data suggest that both thought leaders and specialists have considerable input on MCO drug evaluations.

The medical directors also described a few different methods of soliciting external input, ranging from inviting physicians to participate in P&T committee discussions or calling on an advisory group to mass e-mail groups of physicians to invite feedback. Not surprisingly, the study population ranked themselves as having “strong influence” over drug formulary decisions. In contrast, even though half of the panelists said they use a pharmacy benefit manager, they indicated that PBMs have little influence on the drug evaluation process.

### Federal Regulations

Panelists were divided on whether the Office of Inspector General (OIG) Final Guidance for pharma manufacturers had any impact on the way they conduct business with companies. Half the participants said it had no impact at all or made little change in their approach. For those that did modify their approach in response to OIG, responses included:

- » “more structured accounting regarding educational and research grants”

- » “less contact”
- » “more at arms length”
- » “limited if any detailing discussions outside of the formulary review process.”

One panelist was surprised by other participants statements about OIG’s lack of impact, responding, “Wow. This has had considerable influence on our business decisions. There is high-level review of all programs with pharmaceutical manufacturers and each partnership or program must be presented and evaluated for the impact and intent for benefit to the managed care company and manufacturer. The scrutiny is considerably increased.”

### No Pull-Throughs

One interesting finding that surfaced during the discussion is that almost none of the panelists are currently implementing product pull-through programs. Some of the reasons given included poor return on investment and concerns with regulatory constraints such as OIG and the Health Insurance Portability and Accountability Act (HIPAA). One panelist mentioned that his company was



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## What manufacturers do you rank as the top five in terms of flexibility, knowledge, and services?

Company	Times chosen
Pfizer	5
AstraZeneca	5
Merck	4
Novartis	4
GSK	4
Aventis	3
Lilly	3
Amgen	2
BMS	2
Allergan	1
J&J	1
Wyeth	1
Sankyo	1
Abbott	1
Genentech	1

SOURCE: MedPanel

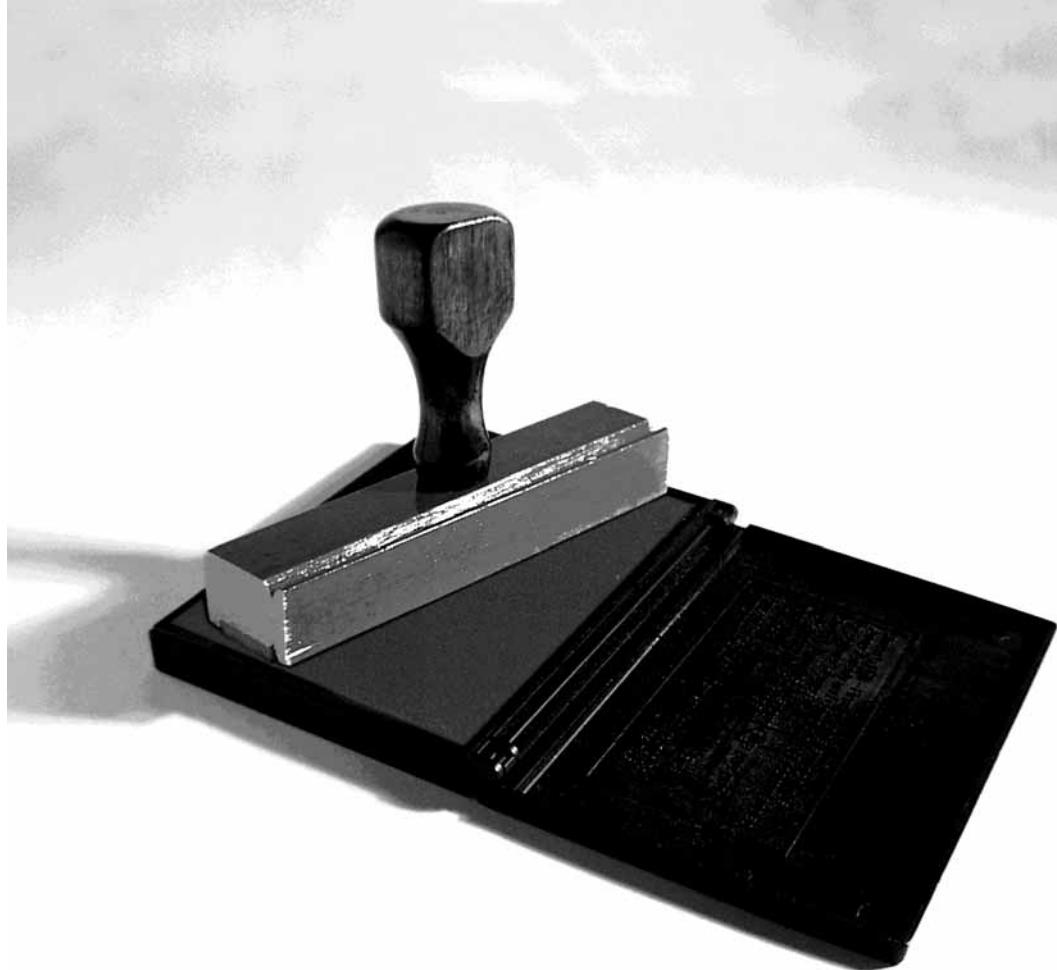
focused on “management of specialty products” instead. Another felt that “push programming to members is considered a better value.”

Other panelists said they would consider programs that “interlace well with our disease management programs” or programs in which the product is “on our preferred tier that the target physician lists and co-promotes.” A preferred scenario, according to one participant is: “Rather than select pull-through partnership programs, the company’s leadership and legal advice will likely support a financial advantage for all. The member can then be influenced by lower out-of-pocket costs, and the employer and managed care company has lower net costs.”

The ultimate product choice involves the patient’s financial decision along with the provider’s responsibility to select best treatment.” Commenting on programs that MCOs are least likely to support, one panelist offered, “Direct promotional mailings to physicians, because they do not bring value.”

### Independent Outcomes

The discussion also revealed that most medical directors are not partnering with manufacturers to conduct outcome studies. A few panelists’ companies have policies against the practice, and several others conduct their own internal outcome studies, “independent of pharma.”



A panelist in this group felt the company “can do better with use of our own internal resources.” Another participant indicated that “evaluating medications in a DUR/DUE [Drug Utilization Review/ Drug Usage Evaluation] fashion” was the MCO’s alternative to conducting internal outcomes studies. And, a third panelist cited “relations with a medical group subsidiary” as the reason for not pursuing these types of partnerships.

Some participants expressed interest in outcome studies but one found the concept “likely very complex in terms of reducing independent variables.” Another interested medical director said, “The subject is of high interest to the company. The expectation is to offer value to the manufacturer for understanding when and what circumstances dictate preferred outcomes for a specific product. The managed

care company further supports manufacturers that commit to measuring outcomes.”

### Decisions, Decisions

When panelists ranked their top criteria for evaluating new drugs for formulary inclusion, cost and efficacy were tied as priority considerations, with safety next on the list. However, when discussing their perspectives on economics, participants agreed that clinical factors outweigh financial considerations unless the P&T committee is comparing entries in a drug class. When products are clinically comparable, financial factors are weighted heavily. Pharmacoeconomics, ease of use, and low side effects tied for the third spot as important criteria.

Although about half of managed care organizations separate medical and pharmacy costs in their bookkeep-

BY THE NUMBERS

3.75

Average importance of outcomes data on formulary management decisions [Ratings Scale: 1=not important, 3=moderately important, 5=very important]

MCOs planning or using mandatory step edits via generic failure prior to branded Rx option

12%

37

Percent of MCOs planning a significant increase in third tier co-pays

## What are your top five criteria for determining if a product will be available on the formulary?

Medical directors value cost and effectiveness as the top formulary criteria.

Criteria	Times chosen
Cost	7
Efficacy/Effectiveness	7
Safety	5
Pharmacoeconomics	2
Ease of use	2
Low side effects	2
Adherence	1
Broad range of indications	1
QD dosing	1
Alternatives unavailable	1
Niche for certain patient type	1
Rebate structure	1
Unique therapeutic class	1
Contract opportunity	1
Current use/Demand	1
Class equivalency vs. superiority	1

SOURCE: MedPanel

ing, linking the two to get the complete picture is common in evaluating new products. Medical costs include all the direct expenditures involved in hospital care, physician diagnoses, diagnostic imaging, and nursing care, while pharmacy costs are limited to the direct costs of drugs. So assessing the integrated costs is the only way to get a picture of true expenditures. Some panelists also use an integrated model to trace costs for certain high-risk populations and to defend pharmacy costs with medical offset figures.

When making decisions that affect

formulary management, more than half of the panelists use the budget-impact models provided by manufacturers. These are economic models that pharma companies develop to help MCOs understand what effect the cost of a new drug will have on their overall profit picture.

### Effects on Pharma Marketing

The data collected and analyzed from the medical director discussion provide insight into the formulary decision trends that product managers and pharma marketers need to prepare for.

**Consumer Influence.** In the future, MCO decision making may be affected more by consumers, but it may also require pharma companies to work together to advocate the benefits of a class of drugs rather than going it alone. By increasing consumer awareness of the benefits of a drug class and encouraging advocacy for drug choice, manufacturers have an opportunity to attract enough consumer interest to create a new channel for asserting influence over MCOs.

**Physician Influence.** It is as important to share cost-of-care information with physicians as it is to give them pure medical data concerning a drug. MCOs are very interested in how physicians choose and use a product in comparison with others in the same class. Those choices reflect the real-world clinical and economic balancing act that takes place in a medical practice. Reading through a P&T committee transcript reveals the power of the individual physician. For an inside look at a P&T committee experience, product managers can read transcripts with-

in the "Formulary Information" menu at [www.expressscripts.com](http://www.expressscripts.com).

**Integrated Data.** Pharma companies can increase their influence over MCO formulary and price decisions by providing them



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with integrated clinical and pharmacy data. Panelists indicated a preference for a cost-of-care approach that incorporates both medical and pharmacy costs, but they also said they

sometimes lack sufficient information to gain perspective on those integrated costs. One panelist noted that it is particularly difficult when a national PBM is responsible for the pharmacy benefit.

**Employer groups.** Because they pay the bills, these groups are currently more influential than consumers in determining formulary inclusion and are an important constituency. Employers and employer groups, by their nature, are organized and have come to exert considerable influence over pricing and formularies.

Just as physician groups have more leverage with MCOs than independent physicians, so employer groups have achieved the same kind of pricing power and other leverage in dealing with managed care organizations. Product managers can increase their communications and educational outreach to these groups, thereby making them feel more included in the pricing process. ④

**Panelist Profile** The participants represented 5.5 million covered lives nationwide. Six of the eight MCOs represented have an "open preferred" formulary structure, one is "closed," and another is a "multi-tier open with preferreds." Half of the MCOs contract with a pharmacy benefit manager, and one MCO formulary is managed by a PBM. All reported a tiered co-pay structure, with average co-pays of \$9, \$21, and \$39, respectively, for the first, second, and third tiers.