

AMCP *Format* Dossier Requests: Manufacturer Response and Formulary Implications for One Large Health Plan

JOSHUA J. SPOONER, PharmD, MS; PRANAV K. GANDHI, BPharm, MS; and SUSAN BROWN CONNELLY, PharmD, MBA

ABSTRACT

BACKGROUND: The Academy of Managed Care Pharmacy (AMCP) *Format for Formulary Submissions*, a template for health plans to use in developing formulary submission guidelines, has been widely adopted since its initial release in 2000. Many health plans request a dossier (a standardized set of clinical and economic evidence prepared by pharmaceutical manufacturers) to provide information for consideration during the formulary decision-making process. While dossier quality has reportedly improved over time, there is no recent research examining the response rate to dossier requests and the quality of dossiers received.

OBJECTIVE: To perform an evaluation of pharmaceutical manufacturers' response to a request for a product dossier prepared using the AMCP *Format*, and to determine if dossier receipt was associated with a favorable formulary placement.

METHODS: The pharmacy and therapeutics (P&T) committee of a mid-Atlantic health plan with approximately 3 million members reviewed 43 drug products from February 2004 through December 2005. A university-based clinical evaluation subcontractor requested dossiers in the AMCP *Format* by telephone and e-mail from the manufacturers' drug information center about 8 weeks before the committee meeting. A retrospective evaluation of the materials received from the manufacturers was performed. A logistic regression model was developed to determine if dossier receipt increased the likelihood of second-tier copayment formulary placement for new product reviews.

RESULTS: Dossiers were requested for 43 products. We received dossiers for 25 products (58%), other drug information (e.g., journal reprints, product labeling) for 10 products (23%), a formulary kit for 4 products (9%), and no response for the remaining 4 products (9%). Of the 25 dossiers, 21 (84%) generally followed the AMCP *Format*. Unlocked interactive budget impact models were included in 5 dossiers (20%), and modeling reports (without an unlocked interactive model) were included in 12 dossiers (48%). Dossiers were more likely to be received when the time between U.S. Food and Drug Administration (FDA) approval and dossier request was ≥ 4 months (65% vs. 27% when < 4 months; $P < 0.05$) and when requested from a large manufacturer (top 25 in sales) compared with smaller manufacturers (75% vs. 43%; $P < 0.05$). Dossier receipt did not improve a product's likelihood for preferred formulary placement; none of the new products for which dossiers were received were assigned to the second copayment tier compared with 33% of the new products with no supporting dossier. The logistic regression model failed to find any correlation between dossier receipt and preferred formulary placement.

CONCLUSIONS: Manufacturers met the request for a dossier nearly three fifths of the time. The dossiers were of high quality and generally followed the AMCP *Format*; the models included in dossiers varied widely in their design and utility. The product manufacturer's size and the time between FDA approval and dossier request influenced the likelihood of dossier receipt. Receipt of a dossier did not appear to influence the likelihood of a product attaining preferred formulary status.

KEYWORDS: Dossier, Formulary submission guideline, Manufacturer, Formulary, Response rate

J Manag Care Pharm. 2007;13(1):37-43

Note: A commentary on the subject of this article appears on pages 66-67 of this issue.

The pharmacy and therapeutics (P&T) committees of health plans have traditionally requested drug information from pharmaceutical manufacturers to assist them in the formulary review process. Until the turn of the century, manufacturers often responded to this request by providing information regarding potential price rebates and sending formulary kits containing marketing materials and clinical trial reprints.¹ Concerns pertaining to the comprehensiveness and veracity of information provided by manufacturers led to the development of formulary submission guidelines, which served to formalize, standardize, and expand the information required for formulary review.² In 2000, the Academy of Managed Care Pharmacy (AMCP) developed its *Format for Formulary Submissions*, a template for health plans to use to develop their own formulary submission guidelines.³ The *Format* has since been modified several times, most recently in April 2005.⁴ While the use of formulary submission guidelines was slow to evolve,⁵ they have come into widespread use, with more than 50 health plans, pharmacy benefit managers, hospitals, state Medicaid programs, or other public agencies (covering more than 100 million people) adopting the AMCP *Format* or a *Format*-like process.⁶

The centerpiece of the formulary submission process is the dossier, a standardized set of clinical and economic evidence prepared by pharmaceutical manufacturers and presented to health plans in response to unsolicited requests, for the plans' consideration during the formulary decision-making process. Many health plans questioned the quality of the first sets of dossiers they received, citing what they perceived to be poorly constructed dossiers containing incomplete or unreliable data.^{7,8} While the quality and completeness of dossiers have reportedly improved over time,^{9,10} recent research examining the response rate

Authors

JOSHUA J. SPOONER, PharmD, MS, is director, clinical and outcomes services, and SUSAN BROWN CONNELLY, PharmD, MBA, is senior director, clinical services and continuing education, Advanced Concepts Institute, University of the Sciences in Philadelphia; PRANAV K. GANDHI, BPharm, MS, is a first-year PhD student, University of Florida, Gainesville.

AUTHOR CORRESPONDENCE: Joshua J. Spooner, PharmD, MS, Director, Clinical and Outcomes Services, Advanced Concepts Institute, University of the Sciences in Philadelphia, 600 South 43rd St., Philadelphia, PA 19104-4495. Tel: (215) 596-7471; Fax: (215) 596-8598; E-mail: j.spoone@usip.edu

Copyright© 2007, Academy of Managed Care Pharmacy. All rights reserved.

TABLE 1 Characteristics of the Products for Which AMCP Format Dossiers Were Requested

	New Product Reviews n = 31	Class Reviews n = 12	Total n = 43 (%)
Therapeutic area			
Cardiovascular agents	4	5	9 (21)
Central nervous system agents	6	3	9 (21)
Endocrine/metabolic agents	7	0	7 (16)
Anti-infective agents	6	0	6 (14)
Gastrointestinal agents	1	4	5 (12)
Renal/genitourinary agents	5	0	5 (12)
Respiratory agent	1	0	1 (2)
Antineoplastic agent	1	0	1 (2)
Time between FDA approval and dossier request—mean [SD]	5.2 [2.9] months	9.0 [4.4] years	–
Manufacturer size (in pharmaceutical sales)*			
1-10	8	8	16 (37)
11-25	6	2	8 (19)
26-50	4	1	5 (12)
≥51	13	1	14 (33)
FDA chemical type and review classification†			
New molecular entity, standard review (1s)	12	8	20 (47)
New molecular entity, priority review (1p)	4	1	5 (12)
New ester, salt, or other covalent derivative, standard review (2s)	1	1	2 (5)
New formulation, standard review (3s)	7	2	9 (21)
New combination, standard review (4s)	4	0	4 (9)
New combination, priority review (4p)	2	0	2 (5)
New indication, standard review (6s)	1	0	1 (2)

* Manufacturer size (in descending order) by total pharmaceutical sales in the calendar year preceding the dossier request.

† Alphanumeric code indicates the U.S. Food and Drug Administration (FDA) designation for chemical type (number) and review classification (letter).

AMCP = Academy of Managed Care Pharmacy.

to dossier requests and the contents of dossiers received is lacking. The purpose of this study was to perform an evaluation of pharmaceutical manufacturers' responses to a request for a product dossier prepared using the *AMCP Format for Formulary Submissions*.

Methods

The university-based unit of the authors (Advanced Concepts Institute [ACI] of the University of the Sciences in Philadelphia) was contracted by a health plan to develop and present detailed product reviews (written and oral presentations) to their P&T committee in 2004 and 2005. This multistate health plan is located in the mid-Atlantic region of the United States, provides medical and pharmacy benefit coverage for approximately 3 million members, and offers a pharmacy benefit with a 3-tier copayment design. The health plan's P&T committee meets semimonthly to conduct both new product reviews and class reviews.

To support the development of the detailed product reviews, ACI requested *AMCP Format* dossiers by telephone or e-mail from the product manufacturers' drug information center about 8 weeks before the committee meeting. If notified that a dossier was not available, ACI requested other drug information materials to support monograph development. If no materials were received within 4 weeks of the committee meeting, a follow-up request for a dossier or other drug information was made. The P&T committee did not delay a product review if materials were not received from the manufacturer; in such instances, a detailed product review was prepared using information obtained by ACI through other sources.

A retrospective analysis of the manufacturers' responses to the dossier request was performed. All materials received during the 6-week period starting on the initial dossier request date and ending 2 weeks before the P&T committee meeting (the submission date of review materials to the health plan) were catalogued. The materials were classified into 1 of 3 categories: (1) dossier (materials titled or identified as such; or materials not titled or identified as a dossier that clearly followed the *AMCP Format* or another submission format); (2) formulary kit (materials titled or identified as such); or (3) other drug information (including product labeling, reprints of key publications, meeting abstracts and posters, and economic analyses).

Each dossier was examined by 1 of 2 clinical pharmacists to determine if it included the information requested for each subject heading in version 2.0 of the *AMCP Format* (the current version of the *AMCP Format* for the majority of the study period): Product Description, Place of Product in Therapy, Summaries of Key Clinical and Economic Studies, Spreadsheet of All Clinical Studies, Product Value and Overall Cost, Reprints of All Key Trials, Summaries of Outcomes Studies and Economic Evaluation Supporting Data, A Review of Clinical and Disease Management Intervention Strategies, Formulary Submission

Checklist, and Model. If included in the dossier, the pharmacoeconomic or disease impact-model was classified as a working model (a spreadsheet or other model allowing for baseline variable manipulation and calculation review) or a model report (the results of a model were presented, but a working model was not included). Lastly, the reviewer's subjective determination on whether the dossier followed the AMCP *Format* was recorded; dossiers exhibiting general accordance with the *Format's* prescribed layout and content without any evidence of omission of requested information were considered to have followed the AMCP *Format*.

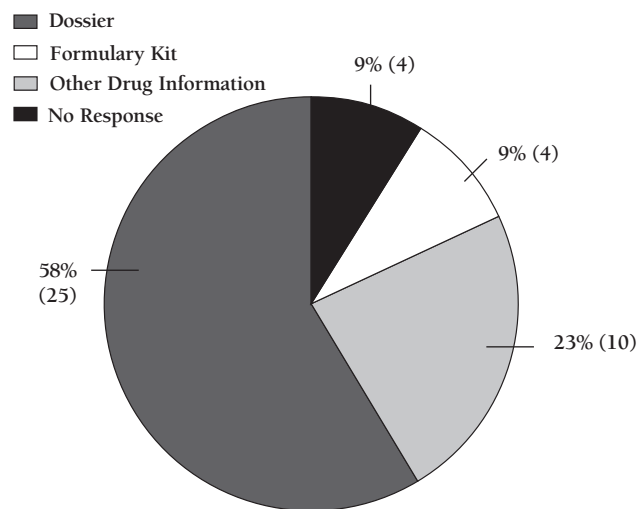
For comparison purposes, dossier requests were classified as new product reviews (requested to aid a committee review of a recently approved single product) or a class review (requested to aid a committee review of all the products within the class). For each dossier request, the request lag time (equal to the time difference between the U.S. Food and Drug Administration [FDA] approval date of each agent and the date of the dossier request) was calculated, and the size of the product manufacturer (based on the preceding year's sales data)^{11,12} was determined. The FDA chemical type and review classification of all products were also noted.

Tests of significance were performed on continuous and categorical data (*t* test and chi-square, respectively) to determine if any statistically significant differences existed between groups (new product reviews vs. class reviews, and groupings for manufacturer size, dossier request lag time, and FDA chemical type/review classification). Following the P&T committee review, the committee's decision on the product's formulary placement was noted. All new products received a full formulary review. For new product reviews, a logistic regression model was developed to determine if dossier receipt was associated with a favorable (second-tier copayment) formulary placement. In addition to dossier receipt, variables accounted for in the regression model included (at the time of formulary review) manufacturer size, number of competing in-class agents, number of competing in-class agents on formulary, presence of in-class generic formulary agents, and cost comparison (average wholesale price) to competing in-class formulary agents.

Results

The P&T committee selected 43 drug products for review at 10 committee meetings occurring during the evaluation period (a mean number of 4.3 [± 3.8] per committee meeting; range: 2-13). The characteristics of these products are reviewed in Table 1. A majority of the products (72%) were new product reviews. Eight therapeutic areas were covered by dossier requests; products in the cardiovascular and central nervous system therapeutic areas were most commonly requested. The mean length of time between FDA product approval and the dossier request was 5.2 \pm 2.9 months for products covered by new product reviews and 9.0 \pm 4.4 years for products cov-

FIGURE 1 Manufacturer Response to an AMCP Format Dossier Request (N=43)



AMCP=Academy of Managed Care Pharmacy.

ered by class reviews. Thirty-seven percent of all dossier requests went to the 10 largest pharmaceutical manufacturers (by U.S. sales figures), and more than half of all requests went to the top 25 manufacturers. Fifty-eight percent of the products were classified by the FDA as new molecular entities, followed by new formulation (21%) and new combination (14%); a majority of the products (84%) underwent a standard FDA review.

The manufacturer response to an AMCP *Format* dossier request is presented in Figure 1. Of the 43 products for which dossiers were requested, dossiers were received for 25 (58%). Formulary kits were sent in response to a dossier request for 4 products (9%), other drug information was sent for 10 products (23%), and no response was obtained from the manufacturers of the remaining 4 products (9%).

Dossiers were more likely to be received when the lag time between FDA approval and dossier request was ≥ 4 months (65% [13/20] when ≥ 4 months vs. 27% when < 4 months; $P < 0.05$) (Table 2). The receipt of dossiers tended to be higher when requested for products covered by class reviews (75%) than those for new product reviews (52%), although this difference did not achieve statistical significance. The size of the manufacturer of the requested product played a role in dossier receipt; receipt of dossiers was more likely when requested from a larger manufacturer than from a smaller one (75% for top 25 manufacturers vs. 43% for all others; $P < 0.05$). Dossier receipt was also more likely for new molecular entities compared with new formulations (76% vs. 22%; $P < 0.01$).

TABLE 2 Dossiers Received, Stratified by Review Type, Manufacturer Size, FDA Chemical Type/Review Classification, and Time between FDA Approval and Dossier Request

	Requested	Received (%)
Class reviews	12	9 (75)
New product reviews	31	16 (52)
By manufacturer size (sales rank in preceding year)		
1-25	24	18 (75)*
≥26	19	7 (43)
By FDA chemical type		
New molecular entity	25	19 (76)
New ester, salt, or other covalent derivative	2	1 (50)
New formulation	9	2 (22)†
New combination	6	3 (50)
New indication	1	0 (0)
By FDA review classification		
Standard review	36	22 (61)
Priority review	7	3 (43)
New product reviews: stratified by length of time between FDA approval and dossier request		
<4.0 months	11	3 (27)‡
4.0-7.9 months	13	10 (77)
≥8.0 months	7	3 (43)

* $P < 0.05$ for comparison of manufacturer size by sales in previous year, 1-25 vs. 26, chi-square test.

† $P < 0.01$ for comparison of new molecular entity vs. new formulation, chi-square test.

‡ $P < 0.05$ for comparison of ≤4.0 months vs. 4.0-7.9 months and ≥4.0 months, chi-square test.

FDA=U.S. Food and Drug Administration.

The size of the dossiers received ranged from 39 to 210 pages of content, excluding clinical trial reprints. The majority of the dossiers that were received (84%) were judged by the authors to have generally followed the AMCP Format. Three of the 4 dossiers that were judged to have not followed the AMCP Format excluded numerous studies (with positive and negative results) from the dossier, while the fourth failed to provide succinct study summaries for the key clinical studies. None of the dossiers followed any other recognized dossier format such as the Regence BlueShield or Ontario guidelines. Dossier sections that were included or addressed in less than 70% of submissions were (1) a pharmacoeconomic or disease manage-

ment impact model (included in 68% [48% + 20%] of dossiers), (2) reprints of all key trials (68%), (3) summaries of outcomes studies and economic evaluation supporting data (64%), (4) a review of clinical and disease management intervention strategies (40%), and (5) the formulary submission checklist (0%) (Table 3). There were no statistically significant differences between new product reviews and class reviews with regard to likelihood of inclusion in any one section of a dossier. Additional information (information not requested in the AMCP Format) was included in 36% of the dossiers; executive summaries, and a section titled “answers to frequently asked questions” accounted for most of the additional content.

Pharmacoeconomic or disease-impact models were included in 17 of the 25 dossiers received. Of these, only 5 (20% of all dossiers, 29% of all dossiers with models) included unlocked interactive economic or budget-impact models in which the user could alter key variables and enter health plan-specific data. All 5 of these models were budget-impact models. The remaining 12 models (48% of all dossiers, 71% of all dossiers with models) provided only reports describing the economic analyses performed in varying length and detail.

Overall, products evaluated as part of a new product review were assigned preferred formulary placement (second copayment tier) 16.1% (5/31) of the time. Receipt of a product dossier to support the development of the detailed product review did not improve a product’s likelihood for preferred formulary placement; none of the 16 new product reviews for which dossiers were received were assigned to the second copayment tier of the formulary, compared with 5 of the 15 new product reviews (33%) for which dossiers were not received. The logistic regression model failed to find any correlation, positive or negative, between dossier receipt and preferred formulary placement for new product reviews.

Discussion

In October 2006, the AMCP executive director announced that the Academy would begin the process of evaluating the utility of dossiers in the formulary decision process.¹³ While a few studies have evaluated the quality of responses received in response to a dossier request,^{10,14} to our knowledge there have been no publications describing the response rate to dossier requests and no evaluations about how dossiers might affect the formulary decision-making process. While we do not know the methodology or extent to which this forthcoming research will address those questions, our analysis represents the first attempt at answering some of these important questions.

In this analysis, manufacturers supplied a dossier in response to a request for an AMCP Format dossier 58% of the time. This percentage is lower than anticipated, especially given the large-scale adoption of the AMCP Format by health care management organizations.^{6,15} While some manufacturers stated that they believed dossier production inflicted a great expense

TABLE 3 Characteristics of Submitted Dossiers According to AMCP Format Version 2.0 Criteria

	AMCP Format Version 2.0 Section Number	New Product Reviews	Class Reviews	Total
		n = 16, %	n = 9, %	n = 25, %
Product description	1.1	100	100	100
Place of product in therapy	1.2	100	100	100
Summaries of key clinical and economic studies	2.1	100	89	96
Spreadsheet of all clinical studies	2.2	88	78	84
Product value and overall cost	4	81	78	80
Reprints of all key trials	5.1	81	44	68
Summaries of outcomes studies and economic evaluation supporting data	2.4	56	78	64
A review of clinical and disease management intervention strategies	2.3	44	33	40
Formulary submission checklist	5.3	0	0	0
Model	3, 5.2			
A model report (but no working model)		56	33	48
A working model (spreadsheet or other model for data input)		19	22	20
No model		25	45	32

on their organization,^{16,17} no recent complaints have been noted. As evidence suggests that adoption of a systematic formulary review process may lead to an increase in pharmaceutical spending in health programs,¹⁸ manufacturers should strive to develop dossiers for those organizations that have adopted such evidence-based formulary reviews.

Factors that influenced the likelihood of dossier receipt included the length of time between FDA approval and the dossier request, and product manufacturer size. A period of at least 4 months between FDA approval of a product and request of a dossier increased the likelihood of dossier receipt by 140% for new product reviews. The AMCP *Format* recommends that manufacturers should have dossiers completed by the time of the product launch to avoid any delays in responding to unsolicited dossier requests;⁴ our findings indicate that many manufacturers may not be meeting this recommendation. The higher likelihood of dossier receipt for products covered by class reviews (75%) over new product reviews (52%) may be a result of the difference in lag time between the 2 types of reviews. Large manufacturers (top 25 in sales) were able to meet requests for dossiers more frequently (75%) than were small manufacturers (43%); this difference remained once the dossier requests with a lag time <4 months were eliminated (8/10 [80%] for large manufacturers vs. 5/10 for small manufacturers [50%]). Large manufacturers are likely to have more internal resources or financial resources available for developing dossiers, which may contribute to the different rates of dossier receipt.

While the likelihood of dossier receipt appeared to be

greater for requests made in 2005 (64%) compared with 2004 (52%), this is skewed by the fact that 2005 had all 12 product requests pertaining to class reviews. With a focus only on new product reviews, the likelihood of dossier receipt fell to 50% for 2005, indicating a flat rate of dossier receipt over the 2-year evaluation period.

“Other drug information” and formulary kits were received in response to 33% of requests. While formulary kits have essentially been replaced by dossiers as the information package of choice for health care decision makers, manufacturers continue to produce and distribute them. Several manufacturers offered to provide them in addition to the dossier if we so desired. However, we did not receive any formulary kits that were labeled as dossiers, an experience described by others.¹⁹ Despite repeated attempts, no response of any kind was received in response to 9% of the requests. We found this result surprising; at the very least a minimal response (such as study reprints) should have been received. Notably, all 4 of the “no responses” came from smaller manufacturers.

The majority of the dossiers that were received generally followed the AMCP *Format*. Three of the 4 dossiers that did not follow the AMCP *Format* failed to include summaries of all the trials that included the product. While we judged some dossiers to have followed the AMCP *Format* even if they had failed to include 1 or 2 studies in the spreadsheet of all clinical/outcomes/economic studies, these 3 dossiers were missing a large number of trials from their spreadsheets, and 2 of the 3 dossiers appeared to include only those trials that provided

the most favorable data for the product under consideration. While we have observed that it is common practice for manufacturers to choose the most favorable trials when selecting the trials that receive the detailed study summaries in the dossier, it is unacceptable (and against *Format* guidelines) to exclude any trials from the spreadsheet, regardless of the trial's results. Models were included in 68% of the dossiers we received, somewhat higher than the 45% observed in a larger study of 115 dossiers.¹⁴ While the smaller sample size of our study may account for some of this difference, the different time frames of these studies (2004-2005 for our study compared with 2002-2005 for the comparator study) was not a factor because the percentage of dossiers containing models in the comparator study was actually lower in 2004-2005 (37%) compared with 2002-2003 (51%).¹⁴

Products evaluated as a new product review received preferred formulary placement 16.1% of the time. By itself, receipt of a dossier did not influence the formulary decision. Our finding that none of the products with dossiers received preferred formulary status was far less than the 54% reported by Fullerton and Atherly for another health plan,⁹ although the requirements for formulary acceptance and level of formulary placement were not clearly delineated in their report. Our results are also inconsistent with the recent case report from Watkins et al.²⁰ Nevertheless, in the current study, products for which dossiers were received fared worse than those products for which dossiers were not received, as 33% of those products without dossiers were assigned preferred formulary status. While we would not suggest that submission of a dossier actually lessens a product's chances for preferred formulary placement, it is clear that preparation of a dossier provides no guarantee that a product will be looked on favorably by a P&T committee. A logistic regression model accounting for several other factors that influence formulary decision making failed to find any correlation between dossier receipt and preferred formulary product placement.

Limitations

While the logistic regression model employed in the current study accounted for many factors that could potentially influence formulary placement (e.g., number of competing in-class agents, number of competing in-class agents on formulary, presence of in-class generic formulary agents, and cost comparison (average wholesale price) to competing in-class formulary agents), 2 of the most significant variables that influence formulary decision making, the safety and efficacy of the product, were not included in the model. To do so would have required development of comparative measures for safety and efficacy that would have to be validated and would certainly generate considerable controversy. Nonetheless, we believe that this model represents a useful first step in analyzing the influence of dossiers in the formulary decision-making process.

In addition to the limitations in the logistic regression model, several other limitations in our analysis merit mention. First, a change in the *AMCP Format* criteria occurred with the release of *Format* version 2.1 in April 2005.⁴ While *Format* version 2.1 requested some additional information to be supplied in dossiers, all the information requested in *Format* version 2.0 was carried over into the new version (albeit streamlined in places). As such, a quantitative evaluation using the *Format* version 2.0 criteria for dossiers received throughout the entire evaluation period is acceptable because it did not result in any differences in evaluating the dossiers received throughout the analysis period.

Second, one manufacturer of a single product under review claimed to have a product dossier but refused to send it to us, stating it would only send a dossier to the health plan directly. Since we were prohibited from revealing the identity of the health plan we were working with, we had to accept the manufacturer's offer to send "other drug information" (product labeling and study reprints) in place of the dossier. While the possibility exists that other manufacturers did not send dossiers because (1) we were not a health plan and (2) we did not identify the health plan we were working with, no other manufacturer explicitly stated that these factors would prevent us from receiving a dossier.

Third, we utilized the FDA approval date as one benchmark for assessing the likelihood of dossier receipt. The product launch date may be a better index for dossier availability than the FDA approval date since not all FDA-approved products have been launched by their manufacturer. Three of the products under evaluation in this study had received FDA approval but had not been launched by their manufacturer prior to the date of the initial dossier request. However, this did not affect our findings, as removal of these 3 products from the analysis did not alter the statistical significance of any of the results.

Conclusions

In summary, manufacturers provided a dossier in response to a specific request for an *AMCP Format* dossier nearly 60% of the time. These dossiers generally followed the *AMCP Format* and addressed most of the information requested in the *Format*. While the models included in dossiers varied widely, most were not unlocked interactive economic or budget-impact models that allowed the user to alter key variables and enter health plan-specific data, thereby limiting the model's utility. Factors such as the size of the manufacturer of the product and the length of time between the product's FDA approval date and the dossier request can predict the likelihood of receiving a dossier. While we did not find that the receipt of a dossier improved a product's likelihood for preferred formulary placement, manufacturers should continue to provide dossiers in response to unsolicited requests for product information. Additional research in this field can help further determine the influence that dossiers play in the formulary decision-making process.

What is already known about this subject

- The majority of U.S. health plans or their pharmacy benefit managers request product dossiers from manufacturers according to the AMCP *Format*.
- The information contained in dossiers can influence drug formulary decisions and product placement in copayment tiers.

What this study adds

- The university-based clinical evaluation subcontractor for a large health plan of approximately 3 million members received product dossiers for 58% of requests made in 2004 and 2005.
- The size of the product manufacturer (based on sales data) and the length of time between FDA approval of the product and the request for a dossier are directly related to the likelihood of receiving a product dossier.
- Receipt of a dossier was not influential in the formulary placement of the product for this large health plan.

10. Neumann PJ. Quality of dossiers submitted under the AMCP *Format*. Presented at: Academy of Managed Care Pharmacy 17th Annual Meeting and Showcase; April 22, 2005; Denver, CO.
11. Annual company reports. *Med Ad News*. 2004;23(9).
12. Annual company reports. *Med Ad News*. 2005;24(9).
13. Cahill J. Welcoming address. Presented at: Academy of Managed Care Pharmacy 2006 Educational Conference; October 6, 2006; Chicago, IL.
14. Colmenero F, Brauer C, Sullivan SD, Watkins JB, Neumann PJ. An audit of 106 economic analyses contained in AMCP dossier submissions 2002-2005. Podium presentation at: International Society for Pharmacoeconomics and Outcomes Research Eleventh International Meeting; May 20-24, 2006; Philadelphia, PA.
15. Russo M, Balekdijan D. Managed care mandate: show us the value. *Pharm Exec*. September 2003;80-88.
16. Stergachis A. *Format for Formulary Submissions*: challenges, opportunities, and expectations for industry. Presented at: Academy of Managed Care Pharmacy 2001 Educational Conference; October 19, 2001; Dallas, TX.
17. Otrompke J. A new format for making more cost-effective drug coverage decisions takes off. *Manag Healthc Exec*. February 1, 2002.
18. Mitchell A. Antipodean assessment of activities, actions, and achievements. *Int J Technol Assess Health Care*. 2002;18:203-12.
19. Avey S. News from the Foundation for Managed Care Pharmacy. June 2003. Available at: <http://www.fmcpnet.org/fmcp.cfm?c=news&t=detail&id=78>. Accessed October 26, 2006.
20. Watkins JB, Minshall ME, Sullivan SD. Application of economic analyses in U.S. managed care formulary decisions: a private payer's experience. *J Manag Care Pharm*. 2006;12(9):726-35. Available at: <http://www.amcp.org/data/jmcp/726-735.pdf>. Accessed January 8, 2007.

DISCLOSURES

No outside funding supported this research. The preliminary results of this analysis were presented, in part, as a poster at the AMCP Annual Meeting, April 20-23, 2005, in Denver, CO. The authors disclose no potential bias or conflict of interest relating to this article.

Author Joshua J. Spooner served as principal author of the study. Study concept and design were contributed primarily by Spooner, with input from author Susan Brown Connelly. Data collection was the work of Spooner; data interpretation was primarily the work of Spooner, with input from Connelly and author Pranav K. Gandhi. Writing of the manuscript was the work of Spooner; its revision was the work of all authors.

REFERENCES

1. Fullerton DS, Atherly DS. Formularies, therapeutics, and outcomes: new opportunities. *Med Care*. 2004;42(4 suppl.):III39-44.
2. Langley PC. Formulary submission guidelines for Blue Cross and Blue Shield of Colorado and Nevada: structure, application, and manufacturer responsibilities. *Pharmacoeconomics*. 1999;16:211-24.
3. Foundation for Managed Care Pharmacy. *The AMCP Format for Formulary Submissions*. Version 1.0. A Format for the Submission of Clinical and Economic Evaluation Data in Support of Formulary Consideration by Managed Health Care Systems in the United States. Alexandria, VA: Academy of Managed Care Pharmacy; 2000.
4. Foundation for Managed Care Pharmacy. *The AMCP Format for Formulary Submissions*. Version 2.1. A Format for Submission of Clinical and Economic Data in Support of Formulary Consideration by Health Care Systems in the United States. Alexandria, VA: Academy of Managed Care Pharmacy; 2005.
5. Cross M. Formulary submission process catches on . . . slowly. *Manag Care*. 2002;11:32-36.
6. Neumann PJ. Evidence-based and value-based formulary guidelines. *Health Aff*. 2004;23:122-34.
7. Hrachovec J, Watkins J. Challenges and expectations for MCOs: update and future directions. Presented at: Academy of Managed Care Pharmacy 2001 Educational Conference; October 19, 2001; Dallas, TX.
8. Atherly DE, Sullivan SD, Fullerton DS, et al. Incorporating clinical outcomes and economic consequences into drug formulary decisions: evaluation of 30 months of experience. Presented at: International Society for Pharmacoeconomics and Outcomes Research Sixth International Meeting; May 21, 2001; Arlington, VA.
9. Fullerton DS, Atherly DE. Formulary development at Regence BlueShield—a formula for success. *Value Health*. 2002;5:297-300.