



AMERICAN SOCIETY OF HEALTH-SYSTEM PHARMACISTS

Pharmacists in health systems helping people make the best use of medications

August 14, 1998

Laurie Beth Burke, RPh, MPH  
Senior Regulatory Research Officer  
Food and Drug Administration  
HFD - 40, Rm. 17B04  
5600 Fishers Lane  
Rockville, MD 20857

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.98  
AUG 17 16:45

Dear Laurie:

Enclosed are the results from the survey on the use of pharmacoeconomic information in formulary decision making in managed care organizations conducted by the ASHP Center on Managed Care Pharmacy. This information can be entered into the public docket on health care economics information (Docket 98d-0468).

Please note the enclosed results are based on a sample size of 102 respondents. The data we discussed on July 27, 1998 were based on 87 responses and should be discarded.

We plan to conduct a similar survey late in 1998. I will keep you informed as our plans progress. Please contact me with any questions or concerns.

Sincerely,

*Colleen O'Malley*

Colleen H. O'Malley, M.S.  
Director, Center on Managed Care Pharmacy

Q:\COMPESUR.FDA(cj)  
Enclosures

cc: William A. Zellmer  
Charles E. Myers  
Gary C. Stein

98D-0468

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**AMERICAN SOCIETY OF HEALTH-SYSTEM PHARMACISTS***Pharmacists in health systems helping people make the best use of medications***ASHP Pharmacoeconomics Survey  
August 1998**Methodology

The ASHP Center on Managed Care Pharmacy conducted a survey on the use of pharmacoeconomic information in formulary decision making in managed care organizations. The two page, thirteen-item questionnaire was faxed and mailed to 371 ASHP members on July 16, 1998. (275 surveys were faxed and 96 surveys were mailed.) ASHP received 102 completed surveys. The survey response rate is 27%. Respondents work in health maintenance organizations or pharmacy benefit manager companies and spend at least 5% of their work in formulary management.

The responses to all questions were on a six point Likert scale, with 1 meaning "strongly disagree" and 6 meaning "strongly agree". We have collapsed the responses into two figures for each question—the percent that agreed and the percent that disagreed.

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**Please fax to Colleen O'Malley at ASHP - 301-657-1615 by Wednesday, July 22, 1998**

1. Do you spend at least 5% of your work time in formulary management for a managed care organization (MCO)?  
**Yes** \_\_\_ **No** \_\_\_  
 If **No**, please forward this survey to the correct person in your MCO.

2. Pharmaceutical manufacturers routinely use pharmacoeconomic information in marketing to my MCO.

	Strongly Disagree					Strongly Agree	
	1	2	3	4	5	6	N/A

3. The pharmacoeconomic information distributed by pharmaceutical manufacturers generally meets high standards for reliability.

	Strongly Disagree					Strongly Agree	
	1	2	3	4	5	6	N/A

4. My MCO would like to receive from manufacturers scientifically rigorous pharmacoeconomic studies on their products.

	Strongly Disagree					Strongly Agree	
	1	2	3	4	5	6	N/A

5. My MCO is in a position to put pressure on manufacturers to conduct scientifically rigorous pharmacoeconomic studies on their products.

	Strongly Disagree					Strongly Agree	
	1	2	3	4	5	6	N/A

6. Pharmacoeconomic information distributed by manufacturers is considered in making formulary decisions for my MCO.

	Strongly Disagree					Strongly Agree	
	1	2	3	4	5	6	N/A

7. I am well equipped to critically analyze the pharmacoeconomic information distributed by manufacturers.

	Strongly Disagree					Strongly Agree	
	1	2	3	4	5	6	N/A

8. The physician members of the P&T Committee in my MCO are well equipped to interpret pharmacoeconomic information when making formulary decisions.

	Strongly Disagree					Strongly Agree	
	1	2	3	4	5	6	N/A

9. One or more pharmacists in my MCO are well trained to review and analyze pharmacoeconomic literature.

Strongly  
Disagree

1

2

3

4

5

Strongly  
Agree

6

N/A

10. One or more pharmacists in my MCO are well trained to conduct pharmacoeconomic analysis.

Strongly  
Disagree

1

2

3

4

5

Strongly  
Agree

6

N/A

11. Pharmacoeconomic analyses conducted by my MCO are routinely used in making formulary decisions.

Strongly  
Disagree

1

2

3

4

5

Strongly  
Agree

6

N/A

12. The FDA should apply the FTC's "competent and reliable" evidence standard in assessing pharmacoeconomic information distributed by manufacturers.

Strongly  
Disagree

1

2

3

4

5

Strongly  
Agree

6

N/A

13. The FDA should apply the same degree of rigor in assessing a manufacturer's pharmacoeconomic information as it does in assessing clinical claims.

Strongly  
Disagree

1

2

3

4

5

Strongly  
Agree

6

N/A

Q:\CS\NPESURVEY.

# Pharmacoeconomics Survey

Question	1 %	2 %	3 %	4 %	5 %	6 %	Total %
2	4	13	25	24	22	13	100
3	8	37	22	26	8	1	100
4	0	1	5	11	26	57	100
5	7	13	9	24	35	12	100
6	9	21	26	22	17	6	100
7	3	8	13	30	33	13	100
8	10	21	32	16	19	3	100
9	7	10	13	14	27	29	100
10	18	10	22	10	22	19	100
11	15	24	13	14	17	19	100
12	0	1	3	15	40	40	100
13	2	2	6	6	26	58	100

*****1998*****	
% Disagree (Net 1,2,3)	% Agree (Net 4,5,6)
42	58
67	33
6	94
29	71
55	45
24	76
62	38
30	70
50	50
51	49
4	96
10	90

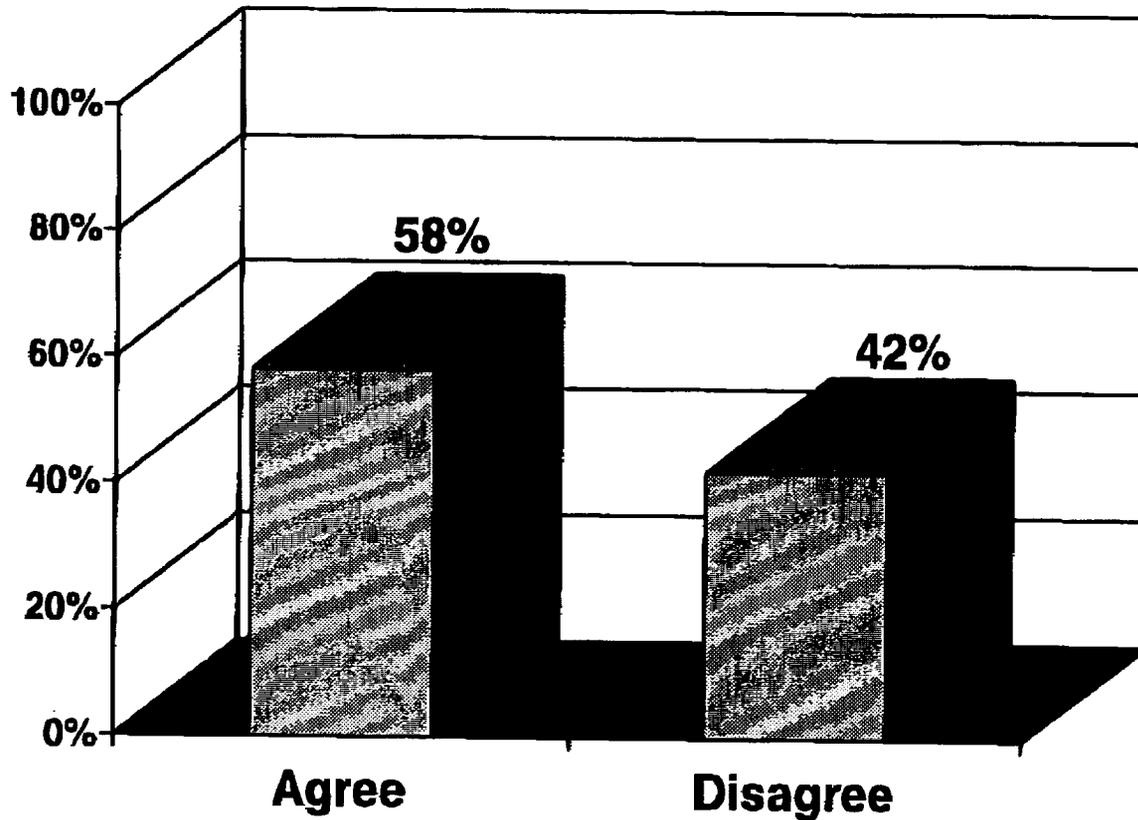
*****1995*****	
% Disagree (Net 1,2,3)	% Agree (Net 4,5,6)
N/A	N/A
82	18
N/A	N/A
49	51
N/A	N/A
39	61
N/A	N/A
11	89

July, 1998: Sample size = 102.

301 594 6759 P.06/18  
 FDA/CDER/DDMAC  
 AUG-17-1998 16:19

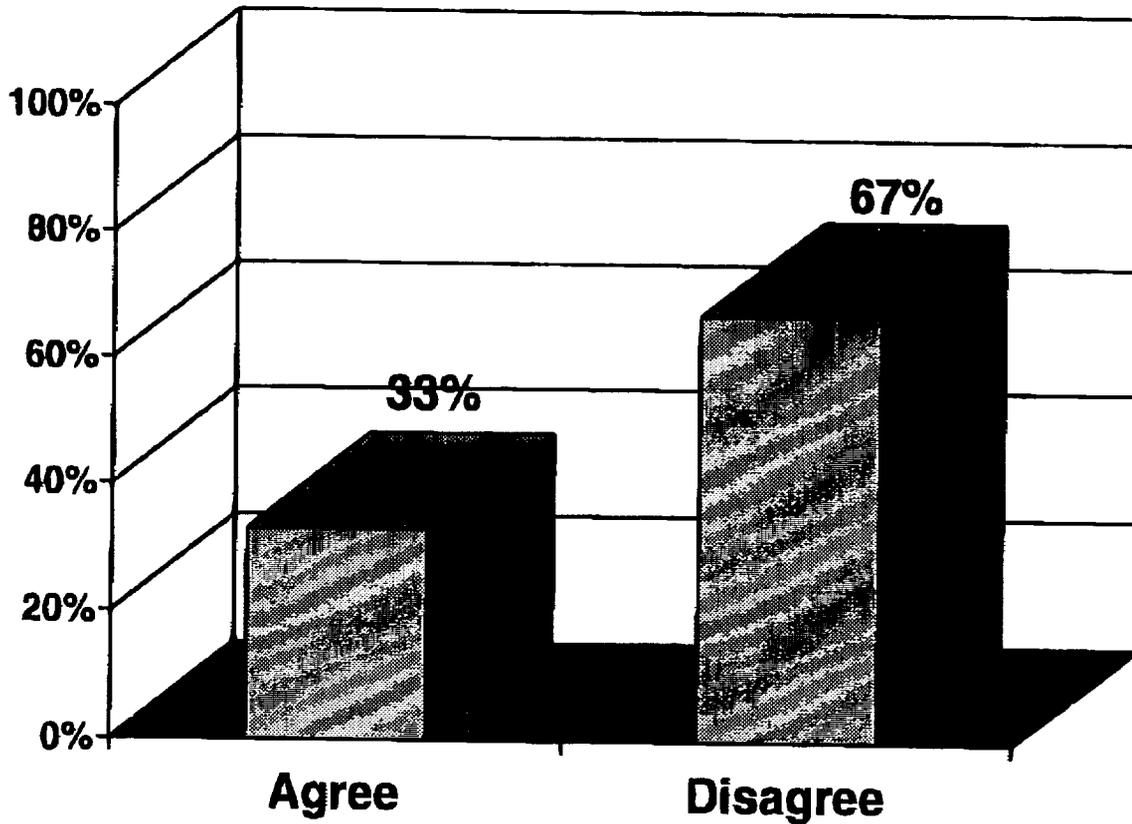


***Pharmaceutical manufacturers routinely use pharmacoeconomic information in marketing to my MCO. (sample size 102)***



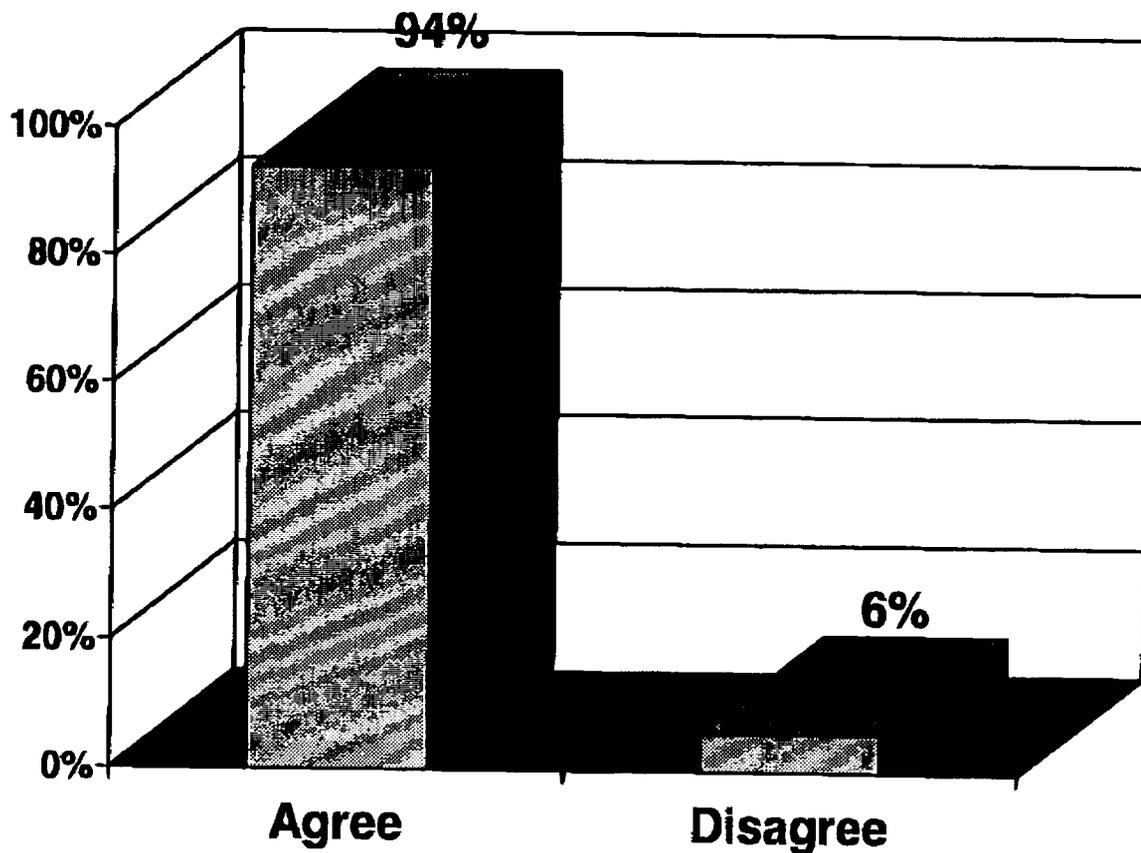


***The pharmacoeconomic information distributed by pharmaceutical manufacturers generally meets high standards for reliability. (sample size 102)***



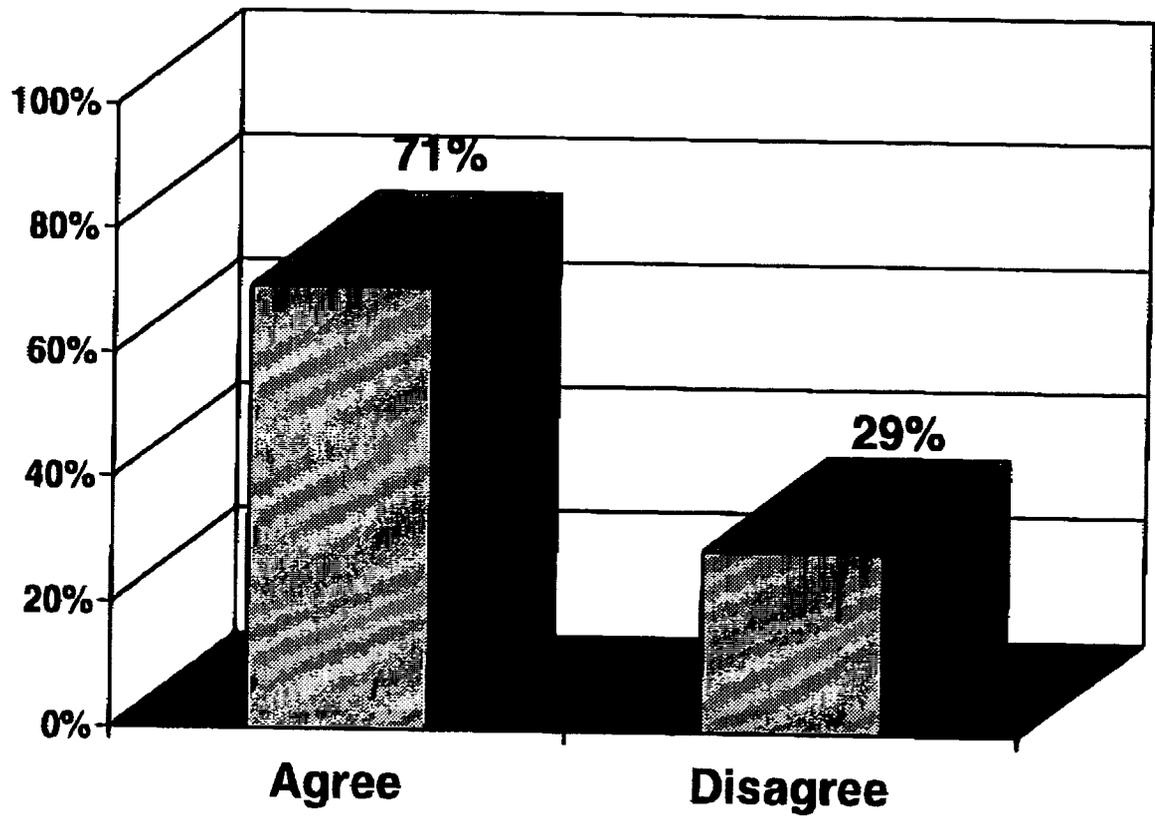


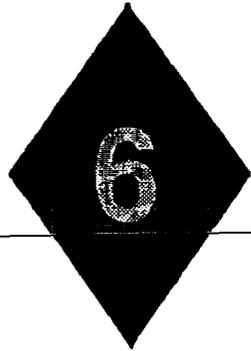
***My MCO would like to receive from manufacturers scientifically rigorous pharmacoeconomic studies on their products. (sample size 102)***



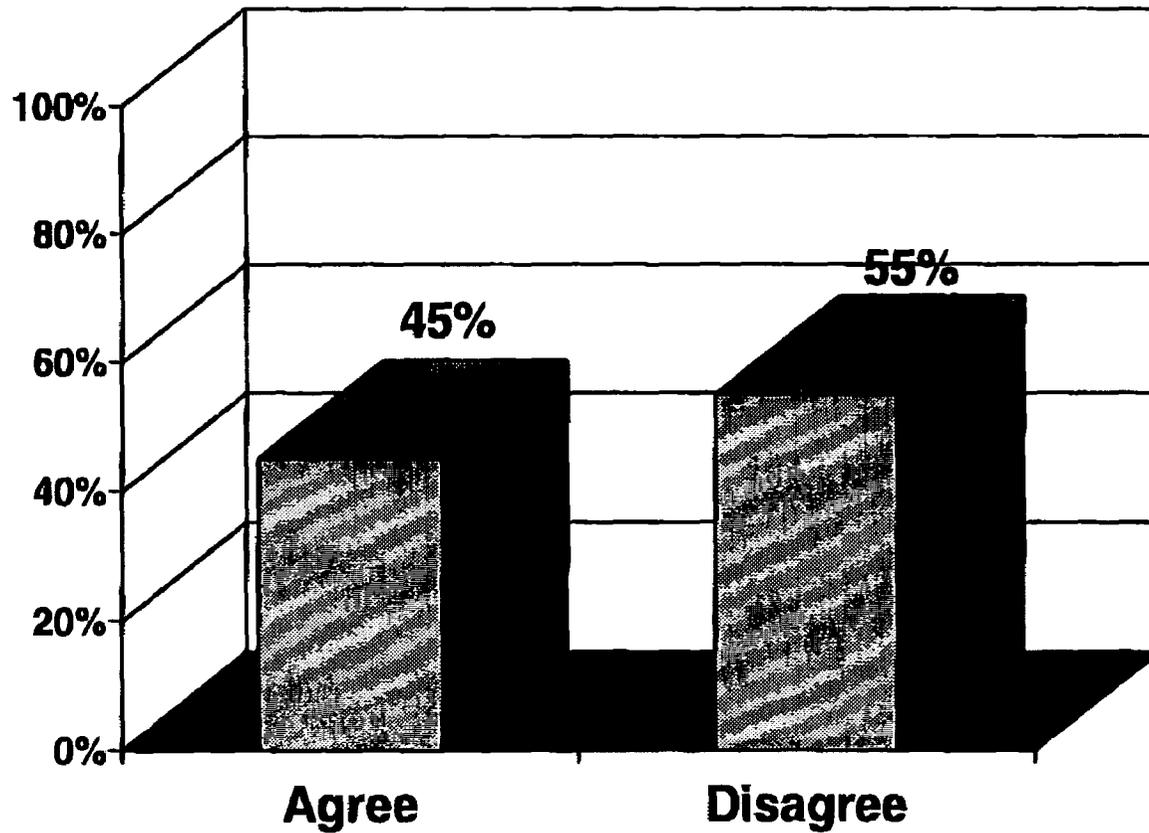


***My MCO is in a position to put pressure on manufacturers to conduct scientifically rigorous pharmacoeconomic studies on their products. (sample size 102)***



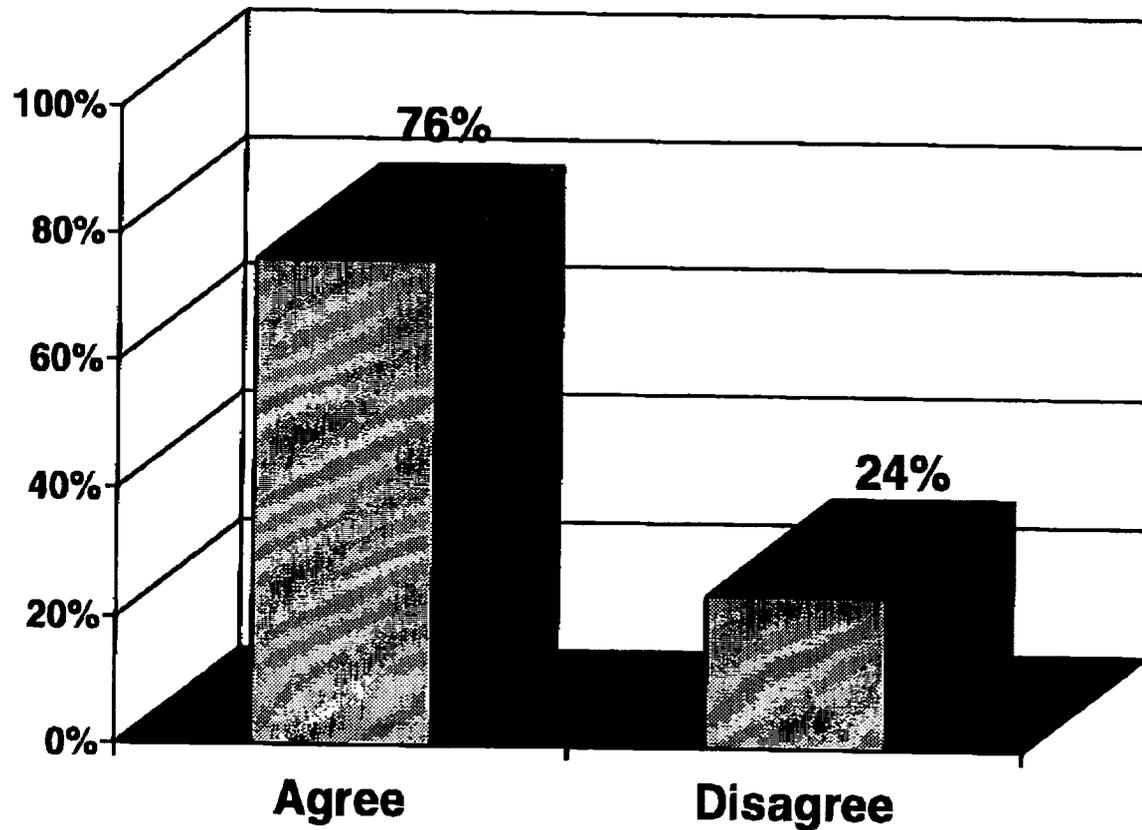


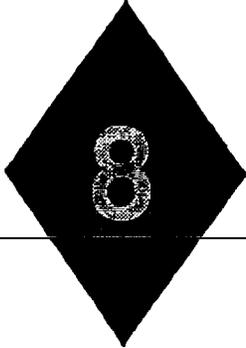
***Pharmacoeconomic information distributed by manufacturers is considered in making formulary decisions for my MCO. (sample size 102)***



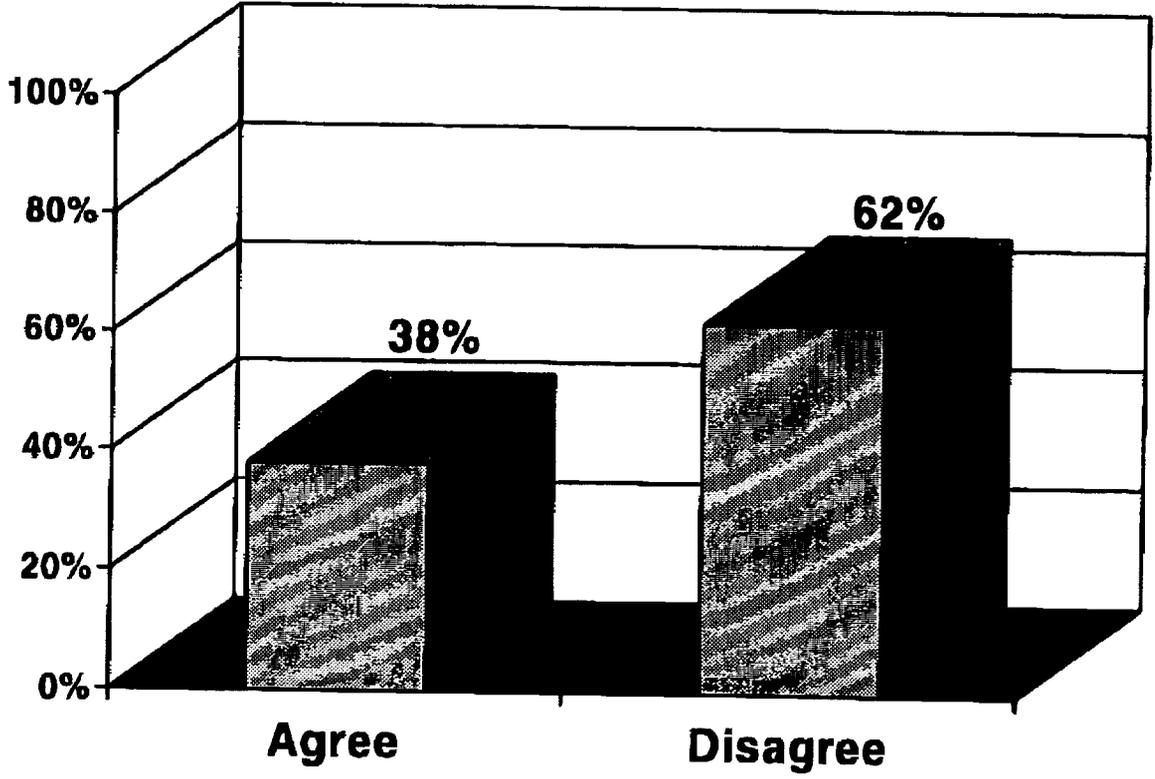


***I am well equipped to critically analyze  
the pharmacoeconomic information  
distributed by manufacturers.  
(sample size 102)***



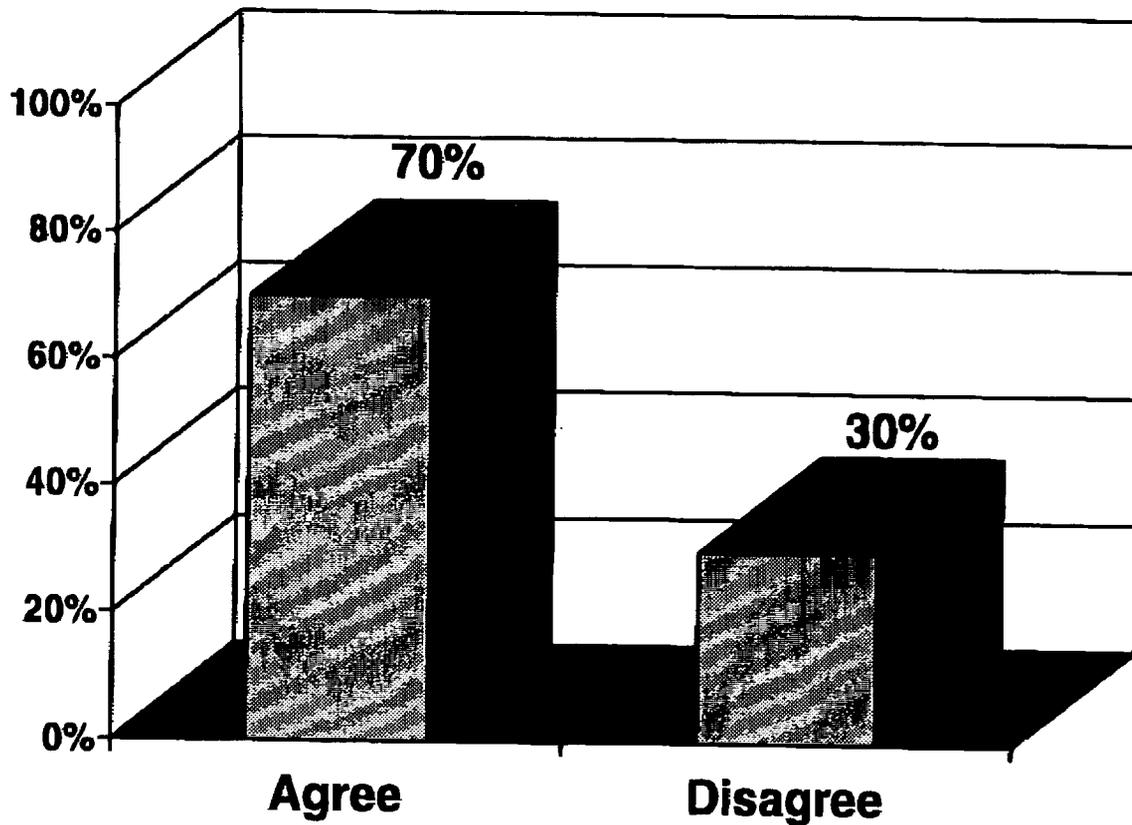


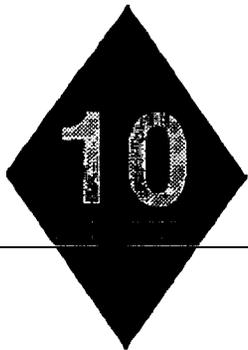
***The physician members of the P& T Committee in my MCO are well equipped to interpret pharmacoeconomic information when making formulary decisions. (sample size 102)***



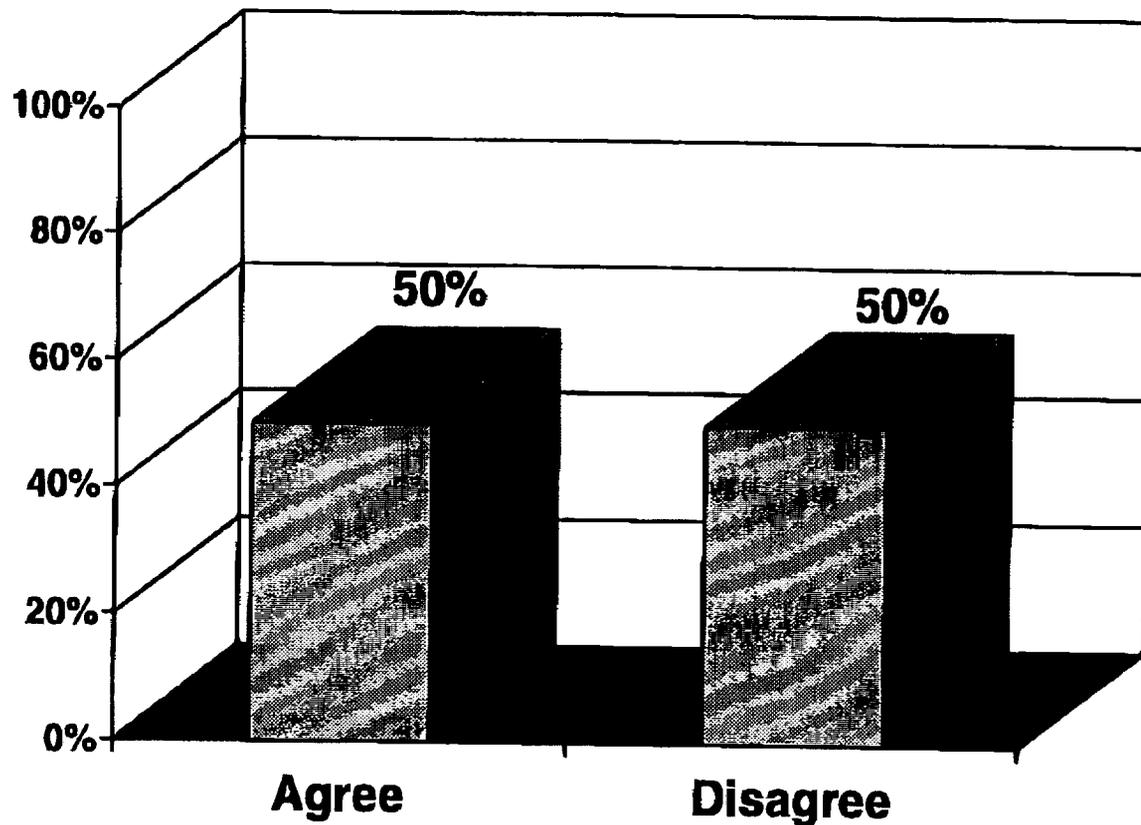


***One or more pharmacists in my MCO are well trained to review and analyze pharmaco-economic literature.***  
***(sample size 102)***



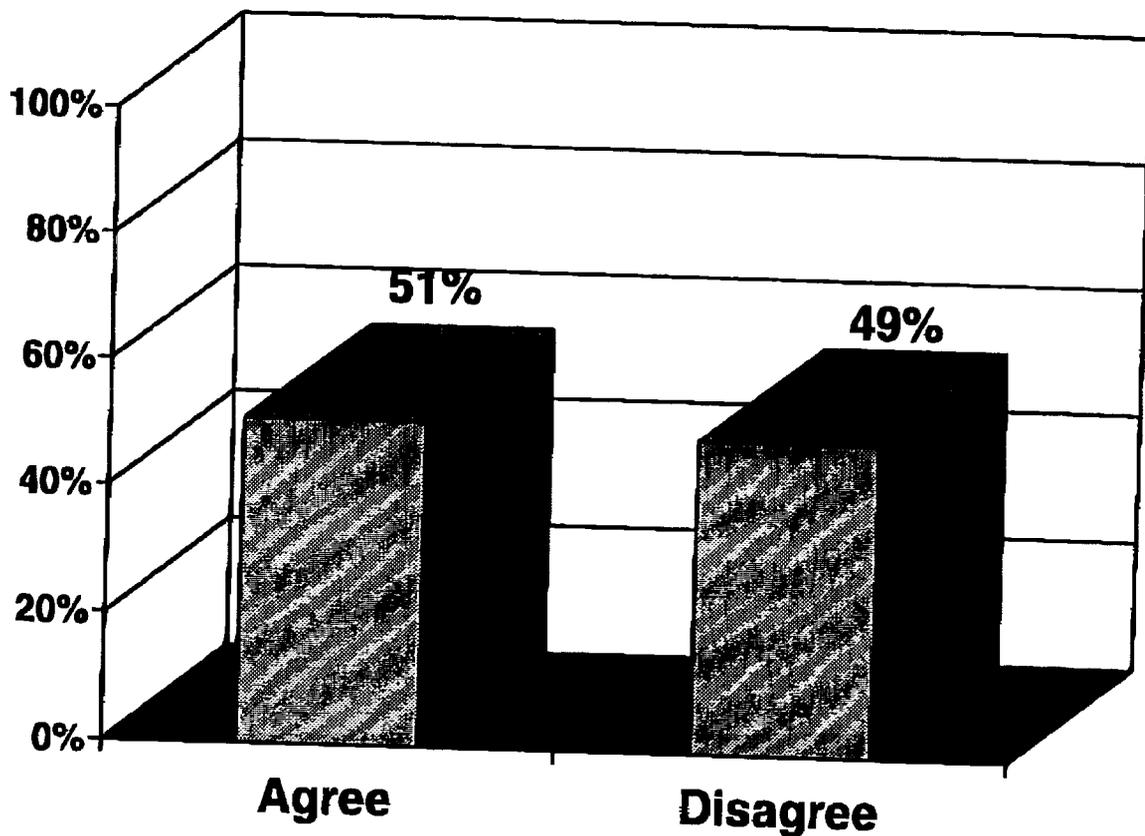


***One or more pharmacists in my MCO are well trained to conduct pharmacoeconomic analysis.***  
***(sample size 102)***



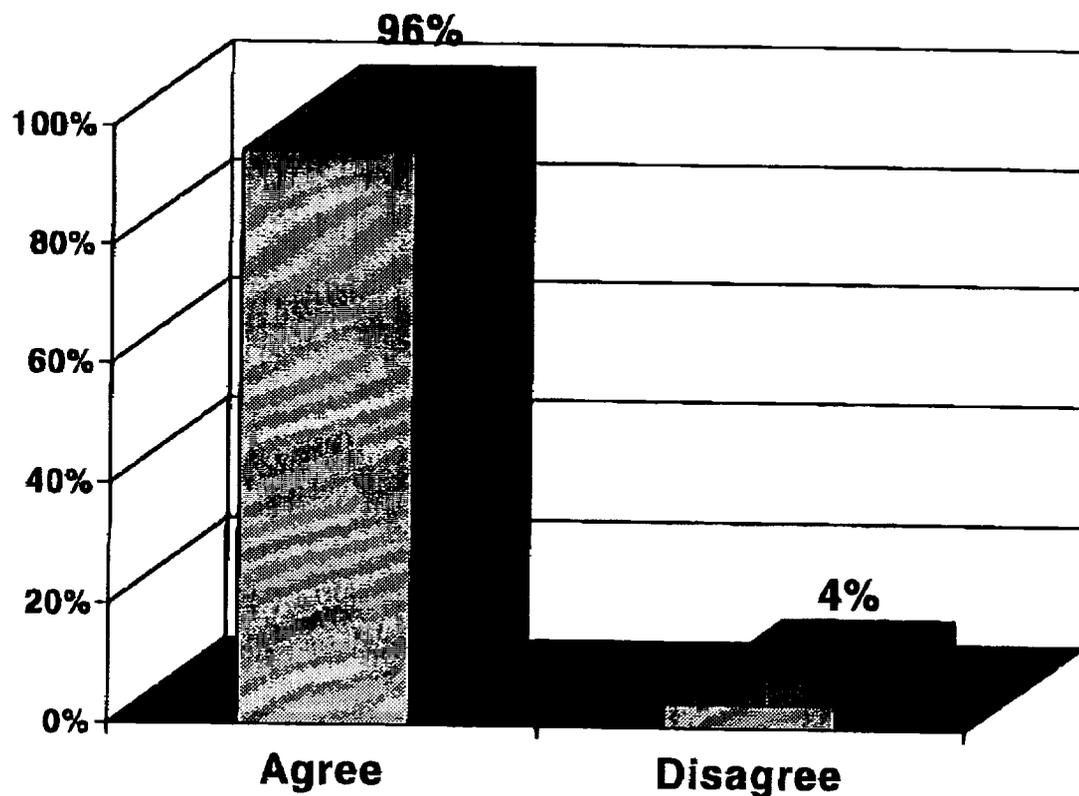


***Pharmacoeconomic analyses conducted by my MCO are routinely used in making formulary decisions. (sample size 102)***



12

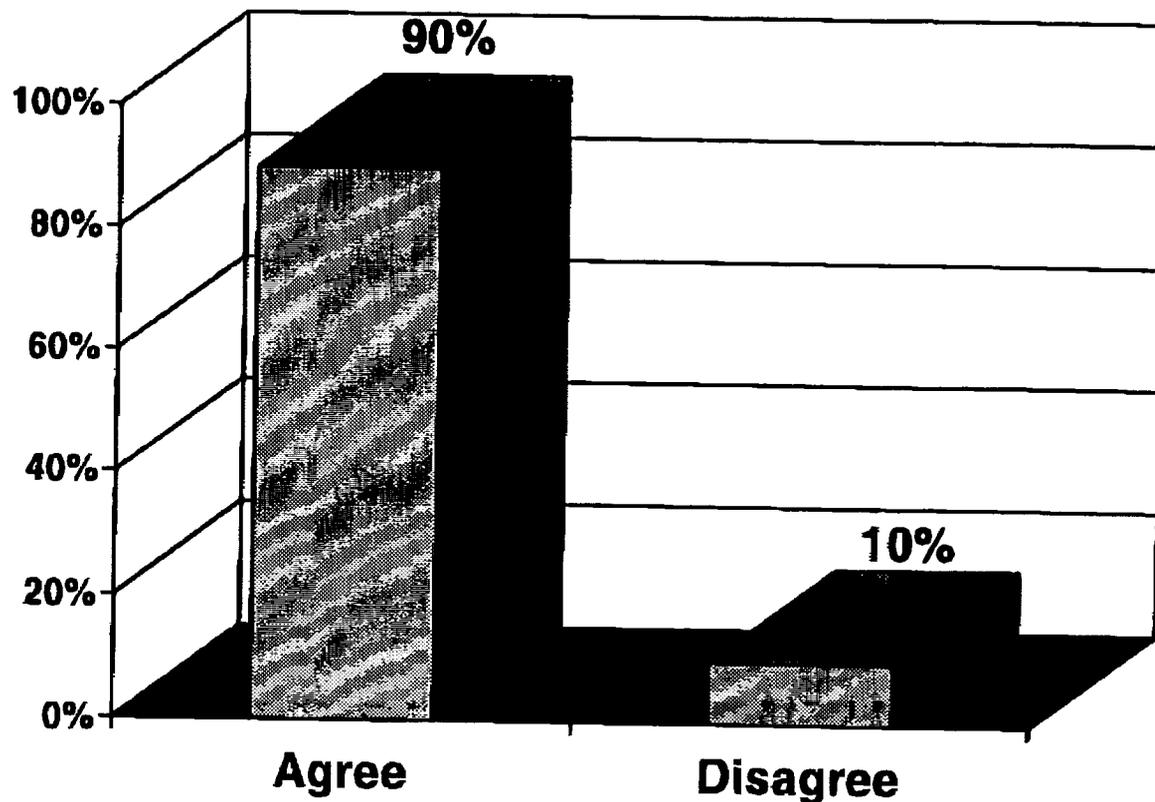
***The FDA should apply the FTC's  
"competent and reliable" evidence  
standard in assessing  
pharmacoeconomic information  
distributed by manufacturers.  
(sample size 102)***



**13**

***The FDA should apply the same degree of rigor in assessing a manufacturer's pharmacoeconomic information as it does in assessing clinical claims.***

***(sample size 102)***



# facsimile

Date Aug 17, 1998

Number of pages including cover sheet

TO:

Jennie Butler

Phone

Fax Phone

7-6870

FROM:

Laurie Beth Burke, R.Ph., M.P.H.  
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and Labeling Staff  
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CC:

REMARKS:

Urgent

For your review

Reply ASAP

Please Comment

For docket # 98D-0668

Thank You.