

3. Where Dey states herein that it will produce documents, it will produce such documents pursuant to the Wisconsin Rules of Civil Procedure and pursuant to the Temporary Qualified Protective Order, entered on May 11, 2005, in the action entitled State of Wisconsin v. Abbott Laboratories, et al., in the Circuit Court of Dane County, Wisconsin (the "Protective Order"), to the extent such documents exist and can reasonably be obtained.

4. The responses made herein are based on Dey's investigation to date of those sources within its control where it reasonably believes responsive information may exist, including a reasonable number of outside sales representatives. Dey reserves the right to amend or supplement these responses in accordance with applicable rules and court orders.

5. Dey objects to the Document Requests to the extent they seek information concerning documents or things not within Dey's possession, custody, or control.

6. Dey objects to the Document Requests to the extent they impose on Dey an obligation to search or produce electronic mail ("email") or other electronically stored data in any format on the grounds that such Document Requests are overly broad, unduly burdensome, harassing, and not reasonably limited in scope. Dey will confer with Plaintiff to determine a mutually agreeable protocol for Dey and Plaintiff to respond to Document Requests concerning information contained in electronic mail and electronic data.

7. Dey objects to the Document Requests to the extent they seek deposition testimony and witness statements that are subject to protective orders in other jurisdictions.

8. Dey objects to the Document Requests to the extent they seek information constituting confidential or proprietary information, including, without limitation, customer identities, customer pricing, customer purchasing habits, trade secrets, and information of a commercially sensitive nature or that is protected from disclosure by statute. Dey will provide such information pursuant to the Protective Order.

9. Dey objects to the Document Requests as overly broad, unduly burdensome, and not reasonably calculated to lead to discovery of admissible evidence to the extent they seek documents or information concerning pharmaceutical products not at issue in this litigation. Dey will provide documents and information relating only to pharmaceutical products identified in the Amended Complaint, namely generic forms of acetylcysteine, albuterol sulfate, cromolyn sodium, and metaproterenol sulfate.

10. Dey objects to the Document Requests as overly broad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence to the extent they seek documents or information concerning any discontinued product dated after the date of such product's discontinuation.

11. Dey objects to the Document Requests to the extent they seek information concerning branded drugs.

12. Dey objects to the Document Requests as overly broad, unduly burdensome, and not reasonably calculated to lead to discovery of admissible evidence to the extent they purport to seek information covering a period of more than 13 years – i.e., from January 1, 1993 to the present.

13. Dey objects to the Document Requests as overly broad, unduly burdensome, and not reasonably calculated to lead to admissible evidence to the extent they purport to seek information or documents dated prior to the periods of statutory limitation applicable to the claims in the Amended Complaint. Dey further objects to the Document Requests to the extent they seek information or documents created after the filing of the Complaint on June 3, 2004.

14. Dey objects to the Document Requests to the extent they purport to impose on Dey obligations that exceed those imposed by the Wisconsin Rules of Civil Procedure.

15. Dey objects to the Document Requests to the extent they seek information protected by the attorney-client privilege, the medical records privilege, the work product doctrine, the consulting expert privilege, third-party confidentiality agreements or protective orders, or any other applicable privilege, rule, or doctrine.

16. Dey objects to the Document Requests to the extent they are unduly burdensome, overbroad, oppressive, or seek information irrelevant to this action or not reasonably calculated to lead to the discovery of admissible evidence.

17. Dey objects to the Document Requests to the extent they are duplicative or redundant.

18. Dey objects to the Document Requests to the extent they seek information that is duplicative of other materials that Dey will produce in response to Plaintiff's document demands.

19. Dey objects to the Document Requests to the extent they are vague, ambiguous, or do not identify with sufficient particularity the information sought.

20. Dey objects to the Document Requests to the extent they seek information relating to health insurance programs not relevant to the allegations in the Amended Complaint on the grounds that such information is neither relevant to the issues in this action nor reasonably calculated to lead to the discovery of admissible evidence.

21. Dey objects to the Document Requests to the extent they seek information relating to Dey's activities that are outside the scope of the allegations in the Amended Complaint.

22. Dey objects to any implications and to any explicit or implicit characterization of facts, events, circumstances, or issues contained in the Document Requests. Any response by Dey is not intended to indicate and does not indicate that Dey agrees with any such implication

or any such explicit or implicit characterization of facts, events, circumstances, or issues contained in the Document Requests, or that such implication or characterization is relevant to this action.

23. Dey hereby incorporates by reference as if fully set forth herein any objection or reservation of rights made by any co-defendant in this action to the extent such objection or reservation of rights is not inconsistent with Dey's position in this litigation.

OBJECTIONS TO DEFINITIONS AND INSTRUCTIONS

24. Dey objects to Plaintiff's definition of "You", "Your" and "Your Company" on the grounds that it is overly broad and unduly burdensome. Dey further objects to this definition to the extent it includes entities and persons that are not parties to this action.

25. Dey objects to Plaintiff's definition of "Document" and "Documents" on the grounds that it is vague, ambiguous, and overbroad. Dey further objects to this definition to the extent it includes documents that are protected by the attorney-client privilege, the work product doctrine, or any other applicable doctrine or privilege. Dey further objects to this definition to the extent it seeks to impose obligations on Dey that are greater than, or inconsistent with, Dey's obligations under the Wisconsin Rules of Civil Procedure. Dey further objects to this definition to the extent it purports to include within its scope documents or information containing or consisting of proprietary information, trade secrets, or information of a competitively sensitive nature.

26. Dey objects to the definition of any word or phrase defined in the "DEFINITIONS" section but not thereafter used in any of the Document Requests on the grounds that such definition is irrelevant and prolix.

27. Dey objects to the instructional paragraphs preceding the individual Document Requests (the "Instructions") on the grounds that the Instructions are vague, ambiguous, and overly broad. Dey further objects to the Instructions as unduly burdensome to the extent they

seek to impose on Dey obligations inconsistent with, or greater than, Dey's obligations under the Wisconsin Rules of Civil Procedure.

SPECIFIC RESPONSES AND OBJECTIONS TO THE DOCUMENT REQUESTS

The General Objections and Reservations of Rights and the Objections to Definitions and Instructions stated above apply to and are incorporated into each and every individual response to the individual Document Requests set forth below, whether or not expressly incorporated by reference in any individual response. Dey also responds and objects specifically to the individual Document Requests as follows:

DOCUMENT REQUESTS

REQUEST NO. 7

All documents listed in Appendix A attached hereto in unredacted form. Each of these documents is identified in the Third Amended Master Consolidated Class Action Complaint Amended to Comply With the Court's Class Certification Order on the page listed in Appendix A and with the bates number identified in Appendix A. (Those without bates numbers are otherwise identified, e.g., paragraph 290).

DEY'S RESPONSE AND OBJECTIONS

Dey objects to this document request as overly broad, unduly burdensome, and not reasonably calculated to lead to discovery of admissible evidence to the extent it seeks documents or information concerning pharmaceutical products not at issue in this litigation. Dey also objects to this document request to the extent it seeks proprietary information, trade secrets, or information of a competitively sensitive nature. Dey further objects to this document request to the extent it seeks information protected from disclosure by the attorney-client privilege, the work product doctrine, third-party confidentiality agreements, or any other applicable doctrine or privilege. Dey also objects to this request to the extent it purports to impose on Dey obligations that exceed those imposed by the Wisconsin Rules of Civil Procedure. Dey further objects to this request to the extent it seeks information that is duplicative of other materials Dey will produce in response to Plaintiff's discovery requests.

Subject to and without waiving the foregoing general and specific objections, Dey states that it has produced or will produce the documents in its possession that are responsive to this Request (specifically, those documents bearing the Bates-stamps DL-CA-001201; DL-CA-00080; DL-TX-0014029; DL-TX-0014439; OEI-03-01-00410; DL-TX-0011179; DL-TX-0004775; and DL-TX-0024844).

REQUEST NO. 8

Documents discussing or concerning the policy and practice of each defendant concerning the disclosures providers and pharmacy benefit managers may make of the drug price information they receive from the defendant or drug wholesalers from 1993 to the present.

DEY'S RESPONSE AND OBJECTIONS

Dey objects to this document request as overly broad and unduly burdensome because it, inter alia, is not limited to the State of Wisconsin and seeks documents or information concerning pharmaceutical products not at issue in this litigation. Dey further objects to this document request as vague and ambiguous because, inter alia, it contains numerous terms that are themselves vague, ambiguous, or undefined, including “policy,” “practice,” “disclosures,” “providers,” “pharmacy benefit managers”, and “drug price information”. Dey objects to this Request to the extent it seeks documents that are in the possession of third parties. Dey also objects to this document request to the extent it seeks proprietary information, trade secrets, or information of a competitively sensitive nature. Dey further objects to this document request to the extent it seeks information protected from disclosure by the attorney-client privilege, the work product doctrine, third-party confidentiality agreements or protective orders, or any other applicable doctrine or privilege. Dey also objects to this document request to the extent it seeks information concerning documents or things not within Dey’s possession, custody, or control. Dey further objects to this document request to the extent it seeks information concerning branded drugs.

Subject to and without waiving the foregoing general and specific objections, Dey states that it has produced customer contract files that may contain documents that are responsive to this Request.

REQUEST NO. 9

Exemplar agreements between each defendant and providers and pharmacy benefit managers applying defendants’ policies and practices relating to the disclosures such entities may make of the drug price information they receive from defendant or wholesalers.

DEY'S RESPONSE AND OBJECTIONS

Dey objects to this document request as overly broad and unduly burdensome because it, inter alia, is not limited to the State of Wisconsin and seeks documents or information concerning pharmaceutical products not at issue in this litigation. Dey further objects to this document request as vague and ambiguous because, inter alia, it contains numerous terms that are themselves vague, ambiguous, or undefined, including “disclosures,” “practices and policies,” “exemplar agreements”, “providers”, “pharmacy benefit managers”, and “drug price information”. Dey also objects to this document request to the extent it seeks proprietary information, trade secrets, or information of a competitively sensitive nature. Dey further objects to this document request to the extent it seeks information protected from disclosure by the attorney-client privilege, the work product doctrine, third-party confidentiality agreements or protective orders, or any other applicable doctrine or privilege. Dey also objects to this document request to the extent it seeks information concerning documents or things not within Dey's possession, custody, or control. Dey further objects to this document request to the extent it seeks information concerning branded drugs.

Subject to and without waiving the foregoing general and specific objections, Dey states that it has produced customer contract files that may contain documents that are responsive to this Request.

REQUEST NO. 10

Any sworn statement or deposition of any current or former employee or agent relating to any claim or investigation about or connected with: a) whether the defendant's published Average Wholesale Price (AWP) was or is inaccurate, or b) whether the defendant's published Wholesale Acquisition Cost (WAC) was or is inaccurate, or c) whether the defendant misrepresented its Average Wholesale Price or Wholesale Acquisition Cost to any publication, person, entity, or official, or d) whether the defendant violated a federal “best price” law or regulation, or e) whether the defendant's agents furnished free samples to providers for improper reasons.

DEY'S RESPONSE AND OBJECTIONS

Dey objects to this document request as overly broad and unduly burdensome because it, inter alia, is not limited to the State of Wisconsin and seeks documents or information concerning pharmaceutical products not at issue in this litigation. Dey further objects to this document request as vague and ambiguous because, inter alia, it contains numerous terms that are themselves vague, ambiguous, or undefined, including “Average Wholesale Price”, “Wholesale Acquisition Cost”, “federal ‘best price’ law or regulation”, “free samples”, and “improper reasons.” Dey also objects to this request to the extent it seeks deposition testimony and witness statements that are subject to protective orders in other jurisdictions. Dey further objects to this document request to the extent it seeks information protected from disclosure by the attorney-client privilege, the work product doctrine, third-party confidentiality agreements or protective orders, or any other applicable doctrine or privilege. Dey also objects to this document request to the extent it seeks information concerning documents or things not within Dey’s possession, custody, or control. Dey further objects to this document request to the extent it seeks information concerning branded drugs. Dey also objects to this document request to the extent it purports to impose on Dey obligations that exceed those imposed by the Wisconsin Rules of Civil Procedure.

Subject to and without waiving the foregoing general and specific objections, Dey states that it will produce depositions of current and former Dey employees or agents that were deposed in actions related to AWP, subject to any protective orders which may bar production of such depositions.

Dated: January 9, 2006

Respectfully submitted,

By: 
John Markson (State Bar No. 1018620)
John Moore (State Bar No. 1010235)

Bell, Gierhart & Moore, S.C.
44 East Mifflin Street
P.O. Box 1807
Madison, WI 53701

Counsel for Defendant
Dey, Inc.

Of Counsel:

Paul F. Doyle
Christopher C. Palermo
Antonia F. Giuliana
KELLEY DRYE & WARREN LLP
101 Park Avenue
New York, New York 10178
(212) 808-7800



DEY LABORATORIES
2751 Napa Valley Corporate Drive
Napa, CA 94558
TEL (707) 224-3200 FAX (707) 224-8918

January 13, 1996

Ms. Beth Raider
First Data Bank
1111 Bayhill Drive
San Bruno, CA 94066

New Product Announcement: DEY Ipratropium Bromide Inhalation Solution

DEY Laboratories is pleased to introduce **IPRATROPIUM BROMIDE INHALATION SOLUTION**, a generic alternative to Atrovent® Inhalation Solution. DEY Ipratropium Inhalation Solution is AN rated (see attached FDA ANDA approval #74-755). It is manufactured in our Napa facility and is backed by our commitment to quality, competitive pricing, and customer satisfaction.

Effective immediately, please update your database to reflect the introduction of this new DEY product as follows:

NDC/Order Number	Description	Vial Size	Strength	Units per Ctn	Ctns per Case	AWP	WAC
49502-685-03	Ipratropium Bromide Inhalation Solution 0.02%	2.5mL	0.5mg/2.5mL	25	12	\$44.10	\$25.50
49502-685-60	Ipratropium Bromide Inhalation Solution 0.02%	2.5mL	0.5mg/2.5mL	60	12	\$105.60	\$60.90

We began shipping the product on January 10, 1997. Attached are package labeling and full prescribing information for your records.

Please fill out the attached form when you have finished loading the product into your database and fax it back to me at the number shown on the form. Should you require further information, please feel free to contact me at (800) 755-5560 extension 745.

Sincerely yours,

Todd Galles
Senior Product Manager

DL - CA 00120

CONFIDENTIAL

Atrovent is a registered trademark of Boehringer Ingelheim, Inc.
Please see attached full prescribing information.

REDBOOK

Product Listing Verification
 Medical Economics
 Five Paragon Drive Montvale NJ
 07645-1742
 (201) 358-2228 Fax (201) 722-2666

9/11/98 - checked AWP+WAC
 pricing (backup
 attached):
 dgardien

DEY LABORATORIES
 2751 NAPA VALLEY CORP. DRIVE
 NAPA CA 94558

CONFIDENTIAL

DL - CA 00080

Please Respond By: 09/11/1998
 Contact Name: ~~EVE GARDNER~~ Todd Galles
 Phone Number: 800-755-5560

NDC/HRI/UPC CATALOG NUMBER NDA/ANDA STATUS	PRODUCT NAME, ADDITIONAL DESCRIPTION, FORM ROUTE OF ADMINISTRATION, STRENGTH, SIZE, QTY GENERIC DESCRIPTION	OBC	PT	DEA	UD	AWP	DIRP	WAC	SRP	EFFECTIVE DATE	
04135-3980-10 49502-203-01	ACE AEROSOL CLOUD ENHANCER ACC 1 EA DEVICE			03	RX	18.00	✓	15.00	✓	08/01/98	
49502-0181-04 ANDA	ACETYL CYSTEINE SOL IH 10% 4.00 ml 12 EA ACETYL CYSTEINE	AN		02	RX	67.80	✓	0.00	25.80	✓	01/01/91
49502-0181-10 ANDA	ACETYL CYSTEINE SOL IH 10% 10.00 ml 3 EA ACETYL CYSTEINE	AN		02	RX	40.26	✓	0.00	15.27	✓	01/01/91
49502-0181-30 ANDA	ACETYL CYSTEINE SOL IH 10% 30.00 ml 3 EA ACETYL CYSTEINE	AN		02	RX	110.48	✓	0.00	41.97	✓	01/01/91
49502-0182-00 ANDA	ACETYL CYSTEINE SOL IH 20% 100.00 ml 1 EA ACETYL CYSTEINE	AN		02	RX	92.21	✓	0.00	75.90	✓	01/01/91

Instructions: please make corrections directly on this printout

OK as is OK with changes

Signature _____ Date _____

2/10/96
Revised 3/1/96

Bid Price Worksheet

Dey Laboratories

Group Name: *Cefi-fax*

Contract No.: *CFX-0541*

Strength	Size	Brand Name	#PKg	Prod. #	Estimated Usage	Current Price	Recommended Price	Pricing Comm. Revision
Acetoxystyrene Sulfates								
10%	4 mL	MUCOSIL	12	18104				
10%	10 mL	MUCOSIL	3	18110				
10%	30 mL	MUCOSIL	3	18130				
20%	4 mL	MUCOSIL	12	18204				
20%	10 mL	MUCOSIL	3	18210				
20%	30 mL	MUCOSIL	3	18220				
20%	100 mL	MUCOSIL	1	18200				
Albuterol Inhalation Aerosol								
90 mcg/inhal	17 g	(mg by Ozone)	1	30317	Price/Pkg	\$9.50	\$8.75	5.40%
Albuterol Sulfate Inhalation Soln.								
0.083%	3 mL	DEY-LUTE	21	69703	Price/Pkg	\$12.00	\$9.50	9.10%
0.083%	3 mL	DEY-LUTE	30	69703	Price/Pkg	\$14.40	\$11.30	10.80%
0.083%	3 mL	DEY-LUTE	60	69760	Price/Pkg	\$28.80	\$22.80	21.60%
0.1%	20 mL	(mg by Ozone)	1	19620	Price/Pkg			
Albuterol Syrup								
2 mg/3 mL	1 pt.	(mg by WCV)	1	79216	Price/Pkg			
Cromolyn Sodium Inhalation USP								
20 mg/2 mL	2 mL		60	68902	Price/Pkg	\$29.00	\$25.00	
20 mg/2 mL	2 mL		120	68912	Price/Pkg	\$57.00	\$50.40	50.40%
Mometasone Sulfate Inhalation Soln. USP								
0.4%	2.5 mL	DEY-LUTE	25	67803				
0.6%	2.5 mL	DEY-LUTE	25	67803				
Sodium Chloride Solution								
0.45%	3 mL	(mg by ALP)	100	82003	Price/Pkg			
0.45%	5 mL	(mg by ALP)	100	82005				
0.9%	3 mL	(mg by ALP)	100	83003				
0.9%	5 mL	(mg by ALP)	100	83005				
0.9%	15 mL	(mg by ALP)	24	83015				
0.9%	3 mL	DEY-VIAL	250	03003				
0.9%	5 mL	DEY-VIAL	250	03005				
0.9%	10 mL	DEY-VIAL	125	03010				
0.9%	20 mL	DEY-VIAL	100	03020				
3%	15 mL	DEY-PAK	50	64015				
10%	15 mL	DEY-PAK	50	64115				
Water Purified								
	5 mL	(mg by ALP)	100	81005	Price/Pkg			
Other Products								

Information Section:
 Monthly Quarterly Price change to meet competition
 Administrative Fee: % Signed:
 Pricing Justification: (use this section to detail competitive information, soft/dual sources, compliance, non-existing business, or any other pertinent information.)

THIS ACCOUNT NEEDS AWP-40% OR BETTER TO SEE PROFIT, DUE TO THE EMPLOYER GROUPS THEY SERVICE.

HAVE NOT MADE THE SWITCH TO OUR PRODUCT LINE DUE TO THE SPREAD, ESPECIALLY ON THE CROMOLYN, UNIT DOSE, AND MDI.

IF WE WANT THE BUSINESS THEY ASK FOR THE FOLLOWING PRICE REVISIONS

UTILIZATION FOR Q-2-96
 UNIT DOSE: 1325 CARTONS
 MDI: 3,705 UNITS
 CROMOLYN: 930 CTNS / 60'S

ARCOLA OFFERS:
 25.00 / 60'S

WARRICK AT:
 10.00 W/ 10% REBATE ON UNIT DOSE
 5.75 W/ 5% REBATE ON MDI

APPROVED

Pricing Committee Approval:
 Approved Approved w/revision Denied
C. S. Miller 10/10/96
 Pricing Committee Representative Date

DL-IX-0014029

Forming B

DL - TX - 0014439

Group Name:

Prod #	Brand Name	#/Pkg.	Strength	Size	Usage	Estimated Price	Current Price	Recommended Price	Information Section:
18104	Acetylsalicylic Acid Solution	12	10%	4 mL	MUCOSIL	12.75	12.90	12.75	<input type="checkbox"/> Price change to meet competition <input type="checkbox"/> Monthly <input type="checkbox"/> Quarterly
18110	MUCOSIL	3	10%	10 mL	MUCOSIL	9.30	9.50	9.30	
18130	MUCOSIL	3	10%	30 mL	MUCOSIL	19.50	20.00	19.50	
18204	MUCOSIL	12	20%	4 mL	MUCOSIL	13.98	14.98	13.98	
18210	MUCOSIL	3	20%	10 mL	MUCOSIL	10.20	10.50	10.20	
18230	MUCOSIL	3	20%	30 mL	MUCOSIL	21.30	22.50	21.30	
18200	MUCOSIL	1	20%	100 mL	MUCOSIL	33.00	33.00	33.00	
30317	Abuterol Inhalation Aerosol	1	90 mcg/inhal	17 g	(mg by Glaxo)	8.90	8.90	8.90	Pricing justification: (use this section to detail competitive info/offers, sole/dual source, compliance, new/existing business, or any other pertinent information.) USAGE WAS UNAVAILABLE TO VENDORS DUE TO SOME PROBLEMS AT WHOLESALE BUT WE WERE ASSURED THAT DURING THE COURSE OF THE CONTRACT THEY WOULD BE MADE AVAILABLE BY THERAPEUTIC CLASS.
69703	Abuterol Sulfate Inhalation Soln.	25	0.083%	3 mL	DEY-LUTE	8.75	8.90	8.75	Abuterol pricing based on where I feel Vantick will come in B price is adapted from Purchase Connection Alternate
69733	DEY-LUTE	30	0.083%	3 mL	DEY-LUTE	23.40	23.40	23.40	
69760	DEY-LUTE	60	0.5%	20 mL	(mg by Glaxo)	19.80	21.30	19.80	
19820	Abuterol Syrup	1	0.5%	20 mL	(mg by Glaxo)	4.75	5.00	4.75	
79516	Cromolyn Sodium Inhalation, USP	1	2 mg/5 mL	1 pt.	(mg by NOVIA)	4.50	4.80	4.50	
68902	Metaproterenol Sulfate Inhalation Soln., USP	60	20 mg/2 mL	2 mL		30.00	26.50	27.20	cromolyn pricing is at AWP -40% and 35% respectively-bear in mind we are competing with the branded spread and the generic perception of everything should be AWP - 50
68912	DEY-LUTE	120	20 mg/2 mL	2 mL		58.80	51.00	54.80	
97803	DEY-LUTE	25	0.4%	2.5 mL	DEY-LUTE	7.50	7.50	7.50	
67603	DEY-LUTE	25	0.6%	2.5 mL	DEY-LUTE	7.50	7.50	7.50	
82003	Sodium Chloride Solution	100	0.45%	3 mL	(mg by ALP)	8.50	8.50	8.50	
82005	(mg by ALP)	100	0.45%	5 mL	(mg by ALP)	8.50	8.50	8.50	
83003	DEY-VIAL	250	0.9%	3 mL	DEY-VIAL	30.00	30.00	30.00	
83005	DEY-VIAL	250	0.9%	5 mL	DEY-VIAL	30.00	30.00	30.00	
83010	DEY-VIAL	125	0.9%	10 mL	DEY-VIAL	31.00	31.00	31.00	
83020	DEY-VIAL	100	0.9%	20 mL	DEY-VIAL	35.00	35.00	35.00	
84015	DEY-PAK	50	3%	15 mL	DEY-PAK	27.50	27.50	27.50	
81005	Water, Purified	100	10%	5 mL	(mg by ALP)	8.50	8.50	8.50	

APPROVED
 11/3/96

Pricing Committee Approval: Approved Denied
 Approved with revision Denied
 Pricing Committee Representative: [Signature]
 Date: 11/3/96

THIS BID IS FOR CIGNA'S MAIL ORDER AND HMO(STAFF) FACILITIES
 PRICES SHOULD BE FOR ALL CIGNA FACILITIES AND TEL-DRUG
 ON LINE ITEM AWARD ONLY ONE VENDOR WILL BE SELECTED FOR EACH LINE ITEM

Contract No.:

DEY LABORATORIES
 2571 Napa Valley Corporate Drive
 Napa, CA 94558
 1-800-755-5560

12/20/95

*Letter to:
 Claudio Suenne,
 cc. Leticia Adams
 West Coast Mgt - Generic Drug
 cc: Pam Harris
 R.F. Novak*

McKESON DRUG COMPANY
Source Program Proposal

McK Econo	Generic Name	Strength	Size	No. /Ctn.	Product #	Brand Name	AWP	WAC	Suggested Sell Price	Source Net Price	% Discount from WAC
3286028	Acetylcysteine Solution	10%	4 mL	12	18104	Mucomyst	67.80	25.80	18.00	15.48	-40.0%
3284007	Acetylcysteine Solution	10%	10 mL	3	18110	Mucomyst	40.26	15.27	13.50	10.69	-30.0%
3225265	Acetylcysteine Solution	10%	30 mL	3	18130	Mucomyst	110.48	41.97	33.50	27.28	-35.0%
3286044	Acetylcysteine Solution	20%	4 mL	12	18204	Mucomyst	81.36	31.08	21.50	18.65	-40.0%
2474112	Acetylcysteine Solution	20%	10 mL	3	18210	Mucomyst	48.66	18.57	16.20	12.99	-30.0%
3286143	Acetylcysteine Solution	20%	30 mL	3	18230	Mucomyst	133.43	50.64	39.90	32.92	-35.0%
3225323	Acetylcysteine Solution	20%	100 mL	1	18200	Mucomyst	92.21	75.90	59.90	45.54	-40.0%
1615160	Albuterol Sulfate Inhalation Soln.	0.083%	3 mL	25	69703	Proventil	30.25	14.50	12.00	10.25	-29.3%
1160233	Albuterol Sulfate Inhalation Soln.	0.083%	3 mL	30	69739	or	36.30	17.40	14.40	12.30	-29.3%
2442119	Albuterol Sulfate Inhalation Soln.	0.083%	3 mL	80	69760	Ventolin	72.60	34.50	28.80	24.60	-28.7%
1162569	Cromolyn Sodium Inhalation, USP	20 mg/2 mL	2 mL	60	68902	Intal	42.00	34.20	29.00	25.65	-25.0%
1161603	Cromolyn Sodium Inhalation, USP	20 mg/2 mL	2 mL	120	68912	Intal	84.00	66.00	58.00	51.30	-22.3%
3427604	Metaproterenol Sulfate Inhalation Soln.	0.4%	2.5 mL	25	67803	Alupent	30.75	11.00	10.00	8.64	-21.5%
3614757	Metaproterenol Sulfate Inhalation Soln.	0.6%	2.5 mL	25	67803	Alupent	30.75	11.00	10.00	8.64	-21.5%
1106871	Sodium Chloride Solution	0.9%	3 mL	100	83003	---	24.20	13.00	10.94	8.75	-32.7%
1107653	Sodium Chloride Solution	0.9%	5 mL	100	83005	---	24.20	13.00	10.94	8.75	-30.0%

7 Ord. # A16 MDI
 325896A

? 14.00 12.50

*21 start date
 Alu to nugs
 DL - FX p.0011179
 Marris waiting for terms prop.*



DEY LABORATORIES
 2751 Napa Valley Corporate Driv
 Napa, CA 9455
 TEL.(707) 224-3200 FAX (707) 224-891

PROFITABILITY ENHANCEMENT FOR YOU

Dey Laboratories is pleased to present a year-long special program for Dey's Cromolyn Sodium Inhalation Solution USP, 20 mg/2 mL, and our new Ipratropium Bromide Inhalation Solution 0.02%, 2.5 mL (availability pending FDA approval and official launch date).

For every dollar of Dey Cromolyn Sodium unit-dose purchased, Dey will provide free goods of either:

- Cromolyn Sodium Inhalation Solution USP, 20 mg/2 mL, at 1.0 times the rebate amount
- OR-
- Ipratropium Bromide Inhalation Solution 0.02%, 2.5 mL, when it launches, at a value of 1.5 times the rebate amount for Cromolyn

This program will be based on demonstrated Cromolyn Sodium Unit-Dose Solution Market Share according to the following schedule:

50% - 60% Market Share	2% Rebate
61% - 70% Market Share	4% Rebate
71% - 80% Market Share	6% Rebate
81% - 90% Market Share	8% Rebate
91% + Market Share	10% Rebate

Rebate is calculated as a percentage of total quarterly dollar purchases of Dey's Cromolyn Sodium Inhalation Solution USP, 20 mg/2 mL.

Program Requirements

- You must be able to document market share and sign this agreement.

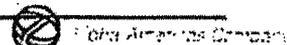
Program Agreement

- This offer is valid for acceptance through September 30, 1996.
- Agreement Period: One Year Start: October 1, 1996 Expiration: September 30, 1997
- Rebate Choice: Free goods will be provided for product indicated; select one only. Free goods product selection may not be changed during the term of agreement.
 - Cromolyn Sodium Inhalation Solution USP, 20 mg/2 mL (1.0 x Rebate Dollars) (credit memo)
 - Ipratropium Bromide Inhalation Solution 0.02%, 2.5 mL (1.5 x Rebate Dollars)
- All previous contract terms and conditions shall remain the same and are not altered by this agreement.
- This rebate agreement supersedes all previous rebate agreements for Cromolyn Sodium Inhalation Solution USP, 20 mg/2 mL between Dey and Customer. All previous rebate agreements for Cromolyn Sodium Inhalation Solution USP, 20 mg/2 mL, will be considered null and void as of effective date of this agreement.
- Acceptance of this offer constitutes an affirmative representation by Customer that products purchased under this offer are solely for Customer's "own use" as defined in the Abbott Laboratories, et al. vs. Portland Retail Druggists Association, et al. case (425 U.S. 1, 96 S.Ct. 1305(1976)). Customer agrees that product will not be sold to any third party, except to patients serviced through Customer's normal pharmacy business.
- Customer agrees to report equivalent values to Medicaid or any other Federal or State government or private insurance payor.
- Information contained in this offer is confidential and is not to be shared with any parties other than Dey.
- Product availability for Ipratropium Bromide Inhalation Solution 0.02%, 2.5 mL, is subject to final FDA approval and official launch date.
- Free goods earned in this program are non-returnable.
- Customer must provide baseline market share documentation at implementation of program.
- Customer must attach a sample of documentation used to calculate market share. Dey reserves the right to approve use of documentation and corroborate through independent sources.
- Customer Market Share documentation to be submitted to Dey within thirty (30) days after close of quarter.
- Dey shall provide the rebate quarterly, in the form of free goods, within thirty (30) days after receipt of Customer's quarterly market share documentation.

ACCEPTED:

Company Name: American Drug Stores
 Signature: [Signature]
 Printed Name: Anthony R. Michelich
 Title: Pharmaceutical Buyer
 Date: 10/3/96

Dey Laboratories, L.P.,
 By Dey Laboratories, Inc., its general partner
 Signature: [Signature]
 Printed Name: R. F. Mozak
 Title: VP, Sales & Marketing
 Date: 12/18/96



PAGE NO.

PREPARED BY
DATE

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

To: Police Committee
From: Jim Bucaric

I met with IAC to discuss our
contract offer IAC - DIST.

Tom Kennedy (IAC) said he wanted
to keep net pricing hidden ^{from 3rd party} by
raising the purchase price on our offer
by 25%. IAC then requires a
25% rebate back to IAC.

I have summarized the pricing. If
this offer is accepted, the highest
price will go into McKesson as a
chargeback contract. Dey will then
rebate IAC 25% on contract
purchases on a quarterly basis.

Any questions - pls. call.

Jim B.

DL - TX - 0024844

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**EXCESSIVE MEDICARE
REIMBURSEMENT FOR ALBUTEROL**



JANET REHNQUIST
Inspector General

MARCH 2002
OEI-03-01-00410

OFFICE OF INSPECTOR GENERAL

<http://www.oig.hhs.gov/>

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended, is to protect the integrity of the Department of Health and Human Services (HHS) programs, as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections conducted by the following operating components:

Office of Audit Services

The OIG's Office of Audit Services (OAS) provides all auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work done by others. Audits examine the performance of HHS programs and/or its grantees and contractors in carrying out their respective responsibilities and are intended to provide independent assessments of HHS programs and operations in order to reduce waste, abuse, and mismanagement and to promote economy and efficiency throughout the Department.

Office of Evaluation and Inspections

The OIG's Office of Evaluation and Inspections (OEI) conducts short-term management and program evaluations (called inspections) that focus on issues of concern to the Department, the Congress, and the public. The findings and recommendations contained in the inspections reports generate rapid, accurate, and up-to-date information on the efficiency, vulnerability, and effectiveness of departmental programs.

Office of Investigations

The OIG's Office of Investigations (OI) conducts criminal, civil, and administrative investigations of allegations of wrongdoing in HHS programs or to HHS beneficiaries and of unjust enrichment by providers. The investigative efforts of OI lead to criminal convictions, administrative sanctions, or civil monetary penalties. The OI also oversees State Medicaid fraud control units which investigate and prosecute fraud and patient abuse in the Medicaid program.

Office of Counsel to the Inspector General

The Office of Counsel to the Inspector General (OCIG) provides general legal services to OIG, rendering advice and opinions on HHS programs and operations and providing all legal support in OIG's internal operations. The OCIG imposes program exclusions and civil monetary penalties on health care providers and litigates those actions within the Department. The OCIG also represents OIG in the global settlement of cases arising under the Civil False Claims Act, develops and monitors corporate integrity agreements, develops model compliance plans, renders advisory opinions on OIG sanctions to the health care community, and issues fraud alerts and other industry guidance.

EXECUTIVE SUMMARY

PURPOSE

This report compares the amount Medicare reimburses for albuterol to the prices available to the Department of Veterans Affairs (VA) and to acquisition costs for suppliers.

BACKGROUND

Medicare does not pay for over-the-counter or most outpatient prescription drugs. However, Medicare Part B will cover drugs that are necessary for the effective use of durable medical equipment. One such product, albuterol, is an inhalation drug commonly used with a nebulizer to treat patients suffering from asthma or emphysema. Medicare paid \$296 million for albuterol in 2000. In general, Medicare reimburses a covered drug at 95 percent of the drug's average wholesale price. Medicare payments include both the 80 percent that Medicare reimburses and the 20 percent coinsurance payment for which beneficiaries are responsible.

Albuterol is usually provided to Medicare beneficiaries by suppliers, who then submit claims for reimbursement to Medicare. Suppliers can purchase drug products through group purchasing organizations, wholesalers, and directly from manufacturers. Unlike Medicare, the VA provides veterans with drugs purchased directly from manufacturers or wholesalers. There are several purchase options available to the VA, including the Federal Supply Schedule, blanket purchase agreements, and VA national contracts.

We compared Medicare's current reimbursement amount for albuterol to amounts paid by the VA and to acquisition costs for suppliers and wholesalers. We obtained reimbursement amounts for albuterol from Medicare and acquisition costs from the VA. To obtain supplier and wholesaler acquisition costs, we collected prices from wholesale catalogs, supplier invoices, and *Drug Topics Red Book*.

FINDINGS

Medicare and its beneficiaries would save \$264 million a year if albuterol were reimbursed at the median price paid by the VA

The Medicare reimbursement amount for albuterol is more than nine times greater than the VA price. The VA purchases generic albuterol through the Federal Supply Schedule for a median price of only \$0.05 per milligram (mg), while Medicare reimburses at \$0.47 per mg. We estimate that Medicare and its beneficiaries would save \$264 million a year if reimbursement for albuterol were set at the median amount available to the VA. Medicare beneficiaries would receive \$53 million of this savings through reduced coinsurance payments. Based on the Federal Supply Schedule, the VA's median acquisition cost for albuterol has fallen by more than 50 percent over the last three years, from \$0.11 per mg in 1998 to \$0.05 per mg in 2001. During the same time period, Medicare's reimbursement amount has remained constant at \$0.47 per mg.

Medicare and its beneficiaries would save between \$226 million and \$245 million a year if albuterol were reimbursed at prices available to suppliers

Medicare's reimbursement amount for albuterol was nearly six times higher than the median catalog price. Like the VA, catalog prices for albuterol have fallen over the last several years, from \$0.23 per mg in 1996 to its current median price of \$0.08 per mg. We found that Medicare would save \$245 million a year by basing albuterol reimbursement on the current median catalog price. In addition, we found that the median supplier invoice price was \$0.09 per mg, and the median wholesale acquisition cost reported by manufacturers was \$0.11 per mg. If Medicare based albuterol reimbursement on these prices, the program and its beneficiaries would save between \$226 million and \$239 million a year.

Less than one percent of albuterol suppliers were responsible for providing the majority of the product to Medicare beneficiaries in 2000

Medicare reimbursed 6,522 suppliers for albuterol claims in 2000. However, just 34 of these suppliers received more than \$1 million each in Medicare reimbursement for albuterol in 2000, with five having between \$11 million and \$35 million in paid claims. These 34 suppliers, who all provided home-delivery/mail-order services to beneficiaries, received 63 percent of the Medicare payments for albuterol in 2000. Therefore, the majority of the albuterol supplied to Medicare beneficiaries was provided by suppliers that purchase a large quantity of the

product. We believe that suppliers that purchase albuterol in such large quantities may receive volume discounts from manufacturers and wholesalers.

RECOMMENDATION

Medicare should reduce excessive reimbursement amounts for albuterol

Despite numerous attempts by the Centers for Medicare & Medicaid Services (CMS) to lower reimbursement amounts for prescription drugs, the findings of this report illustrate that Medicare still pays too much for albuterol. We have consistently found that the published average wholesale prices currently used by Medicare to establish reimbursement amounts bear little or no resemblance to actual wholesale prices that are available to suppliers and large government purchasers.

We understand that unlike most drugs covered by Medicare, albuterol is usually provided by suppliers rather than administered by physicians. These suppliers obviously need to make a profit from the products they provide, yet the spread between what Medicare reimburses for albuterol and the price at which suppliers are able to purchase the drug is significant. Reimbursement levels for albuterol not only impact the Medicare program, but also affect Medicare beneficiaries who pay increased coinsurance amounts.

We offer the following options for reducing excessive reimbursement amounts for covered drugs:

- ▶ Authorizing a commission to set payment rates.
- ▶ Calculating national estimated acquisition costs based upon the average manufacturer prices reported to the Medicaid program.
- ▶ Collecting more accurate average wholesale prices from drug pricing catalogs or other sources.
- ▶ Increasing the discount off the published average wholesale prices.
- ▶ Basing payment on physician/supplier acquisition costs.

- ▶ Establishing manufacturers' rebates similar to those used in the Medicaid program.
- ▶ Creating a fee schedule for covered drugs based on the Federal Supply Schedule.
- ▶ Using CMS' inherent reasonableness authority.
- ▶ Using competitive bidding.

Agency Comments

The CMS agreed that the amounts being reimbursed for drugs in the Medicare program are excessive, and that it is clear that the payment system for outpatient drugs needs revision. The agency noted that it must find a way to ensure that the program pays appropriately for all Medicare benefits, including covered drugs and the services required to furnish those drugs. The CMS went on to state that they are looking forward to working with the Congress and the OIG to revise the Medicare payment system for prescription drugs.

TABLE OF CONTENTS

	PAGE
EXECUTIVE SUMMARY	I
INTRODUCTION	1
FINDINGS	
Department of Veterans Affairs Costs	6
Supplier Acquisition Costs	7
Suppliers Reimbursed by Medicare	8
RECOMMENDATION	9
APPENDICES	
A. Selected OIG Reports on Drug Reimbursement	11
B. Calculation of Potential Savings for Albuterol	12
C. Centers for Medicare & Medicaid Services Comments	13

INTRODUCTION

PURPOSE

This report compares the amount Medicare reimburses for albuterol to the prices available to the Department of Veterans Affairs (VA) and to acquisition costs for suppliers.

BACKGROUND

Medicare Coverage of Albuterol

Medicare does not pay for over-the-counter or most outpatient prescription drugs. However, Medicare Part B will cover drugs that are necessary for the effective use of durable medical equipment. One such product, albuterol, is an inhalation drug commonly used with a nebulizer to treat patients suffering from asthma or emphysema. Albuterol is usually provided to beneficiaries by suppliers, who then submit claims for reimbursement to Medicare. Medicare paid \$296 million for the unit dose form of albuterol in 2000. This total represents over 43 percent of the \$683 million Medicare paid for all inhalation drugs that year. Medicare payments include both the 80 percent that Medicare reimburses and the 20 percent coinsurance payment for which beneficiaries are responsible.

Medicare Drug Reimbursement

The Centers for Medicare & Medicaid Services (CMS), which administers the Medicare program, contracts with four durable medical equipment regional carriers to process all claims for durable medical equipment and associated supplies, including inhalation drugs. Each carrier is responsible for determining the reimbursement amount for inhalation drugs in their respective region based on Medicare's reimbursement methodology.

Medicare's current reimbursement methodology for prescription drugs is defined by Section 4556 of the Balanced Budget Act of 1997. The carriers base their reimbursement amount for a covered drug on its average wholesale price as published in *Drug Topics Red Book* or similar pricing publications used by the pharmaceutical industry. If a drug is available only as a single brand-name product, reimbursement is calculated by taking 95 percent of the drug's average wholesale price. For drugs like albuterol that have both brand and generic sources

available, reimbursement is based on 95 percent of the median average wholesale price for generic sources. However, if a brand-name product's average wholesale price is lower than the median generic price, Medicare reimburses 95 percent of the lowest brand price.

Recent Attempts to Lower Medicare Drug Reimbursement

Section 4316 of the Balanced Budget Act of 1997 allows the Department of Health and Human Services to diverge from Medicare's statutorily defined payment method if the method results in payment amounts which are not inherently reasonable. In late 1998, CMS regional carriers attempted to use this authority to lower what it considered excessive reimbursement for several items. One of these items was albuterol, which was targeted for an 11 percent fee reduction. However, the lower reimbursement amounts were never implemented as Congress suspended the use of inherent reasonableness through a provision of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999. This provision required (1) the General Accounting Office (GAO) to complete a study on the potential effects of using inherent reasonableness measures, and (2) the Department of Health and Human Services to publish new inherent reasonableness regulations based on the findings of the GAO report. The GAO report, issued in July 2000, found that inherent reasonableness reductions for some items were justified; however, the GAO questioned the methodology the carriers used in their collection of pricing data for albuterol. The Department has not issued any new inherent reasonableness regulations since the publication of the GAO report.

The CMS has also included albuterol and several other inhalation drugs in a competitive bidding project in the San Antonio, Texas area that uses market forces to set accurate prices for durable medical equipment and related supplies. In November 2000, CMS announced the selection of suppliers who had submitted competitive bids for the included items. New prices for these items went into effect on February 1, 2001. The new reimbursement amount for albuterol set by the competitive bidding process is approximately 32 percent below the usual Medicare price. The CMS hopes to use the results from these demonstrations more generally in the Medicare program.

On May 31, 2000, CMS announced plans for Medicare to utilize newly available average wholesale prices for approximately 50 drugs, including albuterol. The new prices were developed for Medicaid through investigations conducted by the Department of Justice and the National Association of Medicaid Fraud Control Units. The revised pricing data was obtained from wholesale pricing catalogs and then provided to First DataBank, publisher of a pricing compendium used by the pharmaceutical industry. First DataBank agreed to use the new data when reporting average wholesale prices to the States. However, the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, enacted by Congress in December 2000, placed a moratorium on any decreases in Medicare drug reimbursement amounts. The Act required GAO to complete a comprehensive study addressing both the appropriateness of drug reimbursement amounts and the adequacy of current payments for related practice expenses. The Department of Health and Human Services must then revise CMS' drug reimbursement methodology based on GAO's recommendations.

The GAO issued the first of two reports addressing drug pricing issues on September 21, 2001. This report found that physicians and suppliers can obtain covered drugs for substantially less than the Medicare reimbursement amount. The GAO concluded that Medicare should revise its drug payment methodology to more closely reflect available market prices. The second report, released October 31, 2001, found that payments made to oncologists relative to their practice expenses are close to the average for all specialties, and that the payments are 8 percent higher under the physician fee schedule than under the previous method that reimbursed based on the charges physicians billed for services. However, the GAO also found that recent modifications to the physician fee schedule substantially lowered payments for certain services, including chemotherapy administration. The GAO recommended changes to improve Medicare's physician payment system.

Department of Veterans Affairs Drug Reimbursement

Unlike Medicare, the Department of Veterans Affairs (VA) purchases drugs for its healthcare system directly from manufacturers or wholesalers. There are several options available to the VA when purchasing drugs, with the most common being the Federal Supply Schedule. The Federal Supply Schedule provides agencies like the VA with a simple process for purchasing commonly used products in any quantity while still obtaining the discounts associated with volume buying. Using competitive procedures, contracts are awarded to companies to provide supplies over a given period of time at the Federal Supply Schedule price. However, the VA is sometimes able to negotiate prices lower than Federal Supply Schedule amounts through other avenues such as blanket purchase agreements and VA national contracts.

Cost of Drugs for Suppliers

Suppliers can purchase drug products through group purchasing organizations, wholesalers, and directly from manufacturers. Group purchasing organizations provide their members with lower cost products by negotiating prices for specific drugs from manufacturers. The member can then purchase drugs at the negotiated price either directly from the manufacturer or from a wholesaler who accepts the group purchasing organization's price. Wholesalers purchase large volumes of drugs from manufacturers and sell them directly to suppliers.

Related Work by the Office of Inspector General

The Office of Inspector General (OIG) has studied a number of issues relating to Medicare drug reimbursement. Brief summaries of selected studies are presented in Appendix A.

METHODOLOGY

Medicare Reimbursement

Medicare classifies drugs using codes in the Healthcare Common Procedure Coding System. These codes, commonly referred to as procedure codes, define the type of drug and, in most cases, a dosage amount. There are currently two procedure codes for albuterol, one for a unit dose solution and another for a concentrated solution. Because nearly all of the billing for albuterol is for the unit dose form of the drug, we only reviewed the reimbursement amounts for the unit dose code. The term “unit dose” refers to a 3 milliliter (ml) solution of 0.083 percent albuterol. The procedure code for the unit dose form of albuterol is J7619. This code is defined as, “albuterol, all formulations including separated isomers, inhalation solution administered through durable medical equipment, unit dose form, per 1 milligram (mg).” We obtained current fee schedule reimbursement amounts for procedure code J7619 from the four durable medical equipment regional carriers. The reimbursement amount for albuterol was the same for each of the four carriers.

We accessed CMS’ National Claims History File to determine Medicare’s total payments for albuterol and other inhalation drugs in 2000. We also used this file to analyze albuterol supplier data for the year 2000.

Matching Procedure Codes to National Drug Codes

The VA and suppliers use national drug codes rather than procedure codes to identify drug products. Because of these coding differences, we used the April 2001 CD-ROM edition of *Drug Topics Red Book* to identify the specific national drug codes that match the procedure code definition for albuterol. Each drug manufactured or distributed in the United States has a unique national drug code. National drug codes identify the manufacturer of the drug, the product dosage form, and the package size. Because Medicare uses only generic versions of albuterol to determine its reimbursement amount, we only selected generic albuterol national drug codes. We found 19 national drug codes for generic albuterol that matched the procedure code definition of J7619.

The procedure code for the unit dose form of albuterol is reimbursed per mg. However, VA prices and wholesale prices were all based on 3 ml vials of 0.083 percent albuterol solution. Consequently, we needed to convert ml prices of albuterol into mg prices. A 3 ml vial of 0.083 percent albuterol solution contains 2.5 mg of albuterol. Therefore, 1 ml of solution contains 0.833 mg of albuterol (2.5 divided by 3). For each national drug code, we multiplied

the number of milliliters of albuterol solution by 0.833 to determine the milligram amount, e.g., 75 ml of solution multiplied by 0.833 equals 62.5 mg. We then divided the drug price by the number of milligrams to determine a per mg price.

Department of Veterans Affairs Prices

To determine the VA's current costs for albuterol, we obtained a file from the VA website containing their 2001 contracted prices. The VA pricing file contained Federal Supply Schedule prices for 11 of the 19 matching albuterol national drug codes. To determine a single VA price, we calculated the median price per mg for these 11 codes.

We also compared the 2001 VA prices to VA prices in the years 1998 through 2000. We determined the percentage change each year in VA prices, and multiplied this number by the amount Medicare paid in a given year. These figures represent the amount Medicare total payments would have increased or decreased if the Medicare reimbursement amount changed at the same rate as the VA price. In order to estimate this figure for 2001, we assumed that 2001 Medicare payments for albuterol would equal 2000 payments.

Prices Available to Suppliers and Wholesalers

To determine actual wholesale prices for albuterol, we reviewed year 2001 print and online catalogs from four drug wholesalers and two group purchasing organizations. The six pricing sources we used provide drug products to suppliers and physician practices. We then computed a single catalog price for albuterol by calculating the median price per mg of the corresponding national drug codes.

In addition to catalog prices, we also used actual albuterol invoices to determine supplier acquisition costs. The invoices were collected by the OIG during a review of inhalation drug utilization. The invoices were obtained during site visits to suppliers throughout the country, and were for albuterol purchased between June 1998 and August 2000. To determine a single invoice price, we calculated the median price per mg for the 91 invoice prices collected from suppliers.

We also obtained manufacturer-reported wholesale acquisition costs from the April 2001 CD-ROM edition of *Drug Topics Red Book*. The *Drug Topics Red Book* defines wholesale acquisition cost as manufacturer-quoted list prices to wholesale distributors; these prices are not reflective of bids, rebates, volume purchase agreements, or other types of exclusive contracts. Eleven of the 19 albuterol national drug codes had wholesale acquisition costs

reported in 2001. From these costs, we calculated a median per mg wholesale acquisition cost for albuterol.

Calculating Potential Medicare Savings

To calculate potential Medicare savings, we compared Medicare's reimbursement amount for 1 mg of albuterol to VA prices, wholesale acquisition costs, catalog prices, and invoice prices. We determined the percentage difference in prices by subtracting the median source price from the Medicare price, and then dividing this number by the Medicare price. These percentages indicate how much Medicare would save if reimbursement for albuterol were based on prices provided by other sources. We then multiplied these percentages by the total amount Medicare paid for albuterol in 2000 to calculate dollar savings. A table showing the data used to calculate potential savings is presented in Appendix B.

This inspection was conducted in accordance with the *Quality Standards for Inspections* issued by the President's Council on Integrity and Efficiency.

FINDINGS

Medicare and its beneficiaries would save \$264 million a year if albuterol were reimbursed at the price paid by the VA

The Medicare reimbursement amount for albuterol is over nine times greater than the median VA price

The median Federal Supply Schedule price available to the VA for generic albuterol is only \$0.05 per mg, compared to \$0.47 per mg for Medicare. We estimate that Medicare and its beneficiaries would save \$264 million a year if reimbursement for albuterol were set at the median amount paid by the VA under the Federal Supply Schedule. The savings represent 89 percent of the \$296 million Medicare paid for albuterol in 2000.

Medicare beneficiaries would receive \$53 million of the \$264 million in savings through reduced coinsurance payments. A Medicare beneficiary using a typical monthly amount of albuterol (250 mg) would pay \$23.50 in Medicare coinsurance. That coinsurance amount is nearly double what the VA would pay outright (\$12.50) to purchase one month's supply of the drug. Table 1 below compares the Medicare reimbursement amount to median prices available through other sources. It also provides Medicare savings and beneficiary coinsurance based on various reimbursement levels.

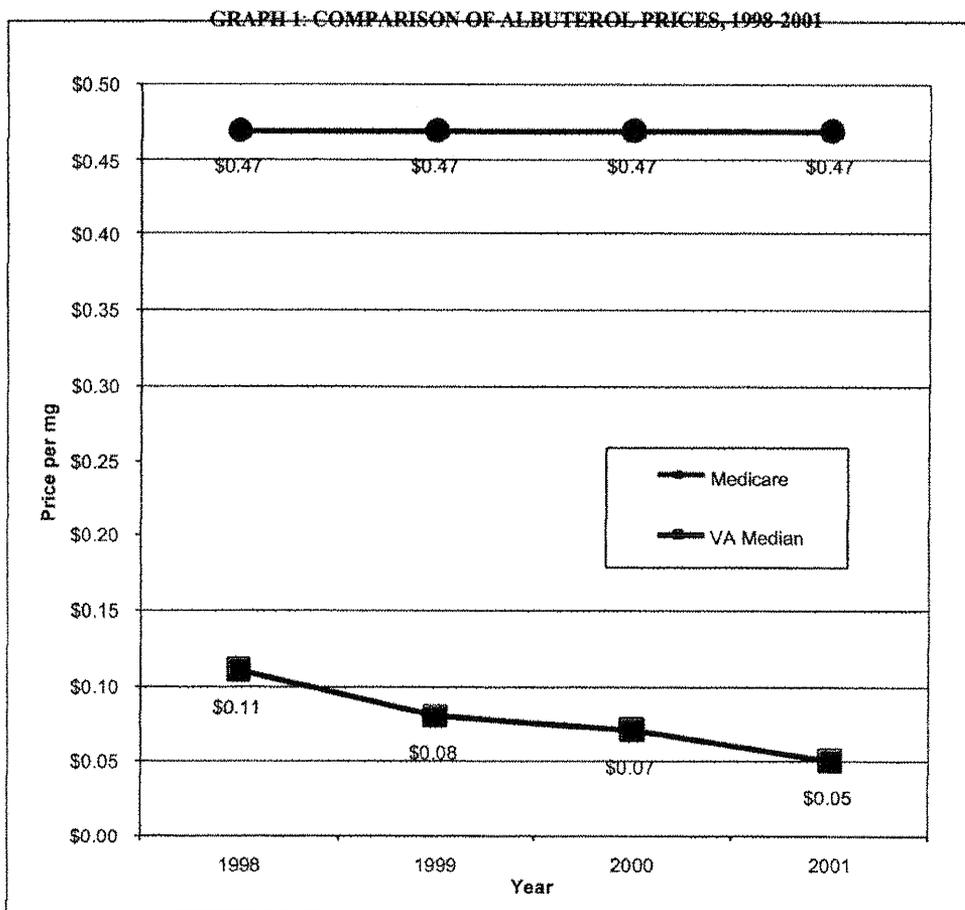
TABLE 1: COMPARISON OF ALBUTEROL PRICES

	Medicare Reimbursement	VA Price	Medicare Coinsurance	Medicare Savings
Medicare	\$0.47	\$117.50	\$23.50	N/A
Department of Veterans Affairs	\$0.05	\$12.50	\$2.50	\$264,222,803
Wholesale Catalogs	\$0.08	\$20.00	\$4.00	\$245,349,746
Supplier Invoices	\$0.09	\$22.50	\$4.50	\$239,058,727
Wholesale Acquisition Cost	\$0.11	\$27.50	\$5.50	\$226,476,689

Sources: 2001 Medicare Carrier and Department of Veterans Affairs Websites, 2001 Wholesale Catalogs, 1998-2000 Supplier Invoices Collected by OIG, 2001 *Drug Topics Red Book*

Between 1998 and 2001, the median VA cost for albuterol decreased by over 50 percent, while the Medicare reimbursement amount remained the same

The VA price for albuterol has fallen by more than 50 percent over the last three years, from \$0.11 per mg in 1998 to \$0.05 per mg in 2001. During the same time period, Medicare's reimbursement amount (based on reported average wholesale prices) has remained constant at \$0.47 per mg. If the Medicare reimbursement amount for albuterol decreased at a rate equal to the VA's purchase price, Medicare and its beneficiaries would have saved \$68 million in 1999 and \$108 million in 2000. The program could save another \$161 million in 2001. The graph below illustrates the changes in VA and Medicare pricing over the last 3 years.



Sources: Medicare Carrier and Department of Veterans Affairs Websites

Excessive Medicare Reimbursement for Albuterol

OEI-03-01-00410

Medicare and its beneficiaries would save between \$226 million and \$245 million a year if albuterol were reimbursed at prices available to wholesalers and suppliers

Medicare payments for albuterol would be reduced by 83 percent if reimbursement amounts were based on prices listed in wholesale catalogs

Medicare and its beneficiaries would save \$245 million a year if the reimbursement amount for albuterol equaled the median price available to suppliers through wholesalers and group purchasing organizations. This represents 83 percent of the \$296 million Medicare and its beneficiaries reimbursed for the drug in 2000. Catalog prices for generic albuterol ranged from a low of \$0.07 per mg to a high of \$0.15 per mg. The Medicare reimbursement amount (\$0.47 per mg) was nearly six times more than the median catalog price (\$.08 per mg).

Like VA prices, catalog prices for albuterol have gone down over the last several years. In earlier reports, we found that the average catalog price for albuterol was \$0.23 per mg in 1996, and \$0.13 per mg in 2000. The current catalog price of \$0.08 per mg of albuterol is 65 percent less than the catalog price of the drug five years earlier.

Medicare payments for albuterol would be reduced by 81 percent if reimbursement amounts were based on supplier invoice prices

Invoices reviewed by the OIG listed prices ranging from \$0.08 to \$0.14 per mg for albuterol purchased by suppliers between 1998 and 2000. The median price for albuterol purchased by these suppliers was \$0.09 per mg, 81 percent less than the Medicare reimbursement amount. Medicare and its beneficiaries would save \$239 million a year if albuterol were reimbursed at the median invoice price.

Medicare payments for albuterol would be reduced by 77 percent if reimbursement amounts were based on manufacturer-reported wholesale acquisition costs

Published wholesale acquisition costs for albuterol ranged from \$0.09 to \$0.18 per mg in April 2001. The median wholesale acquisition cost was \$0.11 per mg. Individual drug manufacturers reported these wholesale acquisition costs to *Drug Topics Red Book*. The *Drug Topics Red Book* defines wholesale acquisition cost as manufacturer-quoted list prices

to wholesale distributors, not reflective of bids, rebates, volume purchase agreements, or other types of exclusive contracts.

If Medicare based its reimbursement for albuterol on manufacturer-reported wholesale acquisition costs rather than average wholesale prices, the program and its beneficiaries would save \$226 million a year.

Less than one percent of albuterol suppliers were responsible for providing the majority of the product to Medicare beneficiaries in 2000

Medicare reimbursed 6,522 suppliers for albuterol claims in 2000. However, just 34 of these suppliers received more than \$1 million each in Medicare reimbursement for albuterol in 2000, with five having between \$11 million and \$35 million in paid claims. These 34 suppliers, who all provided home-delivery/mail-order services to beneficiaries, received 63 percent of the Medicare payments for albuterol in 2000. Therefore, the majority of the albuterol supplied to Medicare beneficiaries was provided by suppliers that purchase a large quantity of the product. We believe that suppliers that purchase albuterol in such large quantities may receive volume discounts from manufacturers and wholesalers.

RECOMMENDATION

Medicare should reduce excessive reimbursement amounts for albuterol

Despite numerous attempts by the Centers for Medicare & Medicaid Services (CMS) to lower reimbursement amounts for prescription drugs, the findings of this report illustrate that Medicare still pays too much for albuterol. We have consistently found that the published average wholesale prices currently used by Medicare to establish reimbursement amounts bear little or no resemblance to actual wholesale prices that are available to suppliers and large government purchasers.

We understand that unlike most drugs covered by Medicare, albuterol is usually provided by suppliers rather than administered by physicians. These suppliers obviously need to make a profit from the products they provide, yet the spread between what Medicare reimburses for albuterol and the price at which suppliers are able to purchase the drug is significant. Reimbursement levels for albuterol not only impact the Medicare program, but also affect Medicare beneficiaries who pay increased coinsurance amounts.

We offer the following options for reducing excessive reimbursement amounts for covered drugs:

- ▶ Authorizing a commission to set payment rates.
- ▶ Calculating national estimated acquisition costs based upon the average manufacturer prices reported to the Medicaid program.
- ▶ Collecting more accurate average wholesale prices from drug pricing catalogs or other sources.
- ▶ Increasing the discount off the published average wholesale prices.
- ▶ Basing payment on physician/supplier acquisition costs.
- ▶ Establishing manufacturers' rebates similar to those used in the Medicaid program.
- ▶ Creating a fee schedule for covered drugs based on the Federal Supply Schedule.

- ▶ Using CMS' inherent reasonableness authority.
- ▶ Using competitive bidding.

Agency Comments

The CMS agreed that the amounts being reimbursed for drugs in the Medicare program are excessive, and that it is clear that the payment system for outpatient drugs needs revision. The agency noted that it must find a way to ensure that the program pays appropriately for all Medicare benefits, including covered drugs and the services required to furnish those drugs. The CMS went on to state that they are looking forward to working with the Congress and the OIG to revise the Medicare payment system for prescription drugs. The full text of CMS' comments is presented in Appendix C.

Selected OIG Reports on Drug Reimbursement

Medicare Reimbursement of Prescription Drugs (OEI-03-00-00310), January 2001. We found that Medicare and its beneficiaries would save \$1.6 billion a year if 24 drugs were reimbursed at amounts available to the VA. We also found that Medicare would save \$761 million a year by paying the actual wholesale price for 24 drugs.

Medicare Reimbursement of Albuterol (OEI-03-00-00311), June 2000. We found that Medicare and its beneficiaries would save \$120 million or \$209 million a year if albuterol was reimbursed at amounts available through Medicaid and the VA, respectively. Medicare and its beneficiaries would save \$47 million or \$115 million a year if Medicare reimbursed albuterol at prices available at chain and Internet pharmacies.

Comparing Drug Reimbursement: Medicare and the Department of Veterans Affairs (OEI-03-97-00293), November 1998. We found that Medicare and its beneficiaries would save \$1 billion in 1998 if the allowed amounts for 34 drugs were equal to prices obtained by the VA. Furthermore, Medicare allowed between 15 and 1600 percent more than the VA for the 34 drugs reviewed.

Are Medicare Allowances for Albuterol Sulfate Reasonable? (OEI-03-97-00292), August 1998. We found that Medicare would allow between 56 to 550 percent more than the VA would pay for generic versions of albuterol sulfate in 1998, and 20 percent more than the average Medicaid payment for albuterol sulfate in 1997. We also found that Medicare allowed 333 percent more than available acquisition costs for the drug in 1998. Customers of mail-order pharmacies would pay up to 30 percent less than Medicare for albuterol sulfate in 1998.

Excessive Medicare Payments for Prescription Drugs (OEI-03-97-00290), December 1997. We found that Medicare allowances for 22 drugs exceeded actual wholesale prices by \$447 million in 1996. For more than one-third of the 22 drugs reviewed, Medicare allowed amounts were more than double the actual wholesale prices available to physicians and suppliers. Furthermore, we found that there was no consistency among Medicare carriers in establishing and updating drug reimbursement amounts.

A Comparison of Albuterol Sulfate Prices (OEI-03-94-00392), June 1996. We found that many of the pharmacies surveyed charged customers less than the Medicare allowed amount for generic albuterol sulfate. The five buying groups surveyed had negotiated prices between 56 and 70 percent lower than Medicare's reimbursement amount for the drug.

APPENDIX A

Suppliers' Acquisition Costs for Albuterol Sulfate (OEI-03-94-00393), June 1996. We found that Medicare's allowances for albuterol sulfate substantially exceeded suppliers' acquisition costs for the drug. The Medicare program could have saved \$94 million of the \$182 million allowed for albuterol during the 14-month review period if Medicare reimbursement amounts had been based on average supplier invoice costs.

**APPENDIX
B**

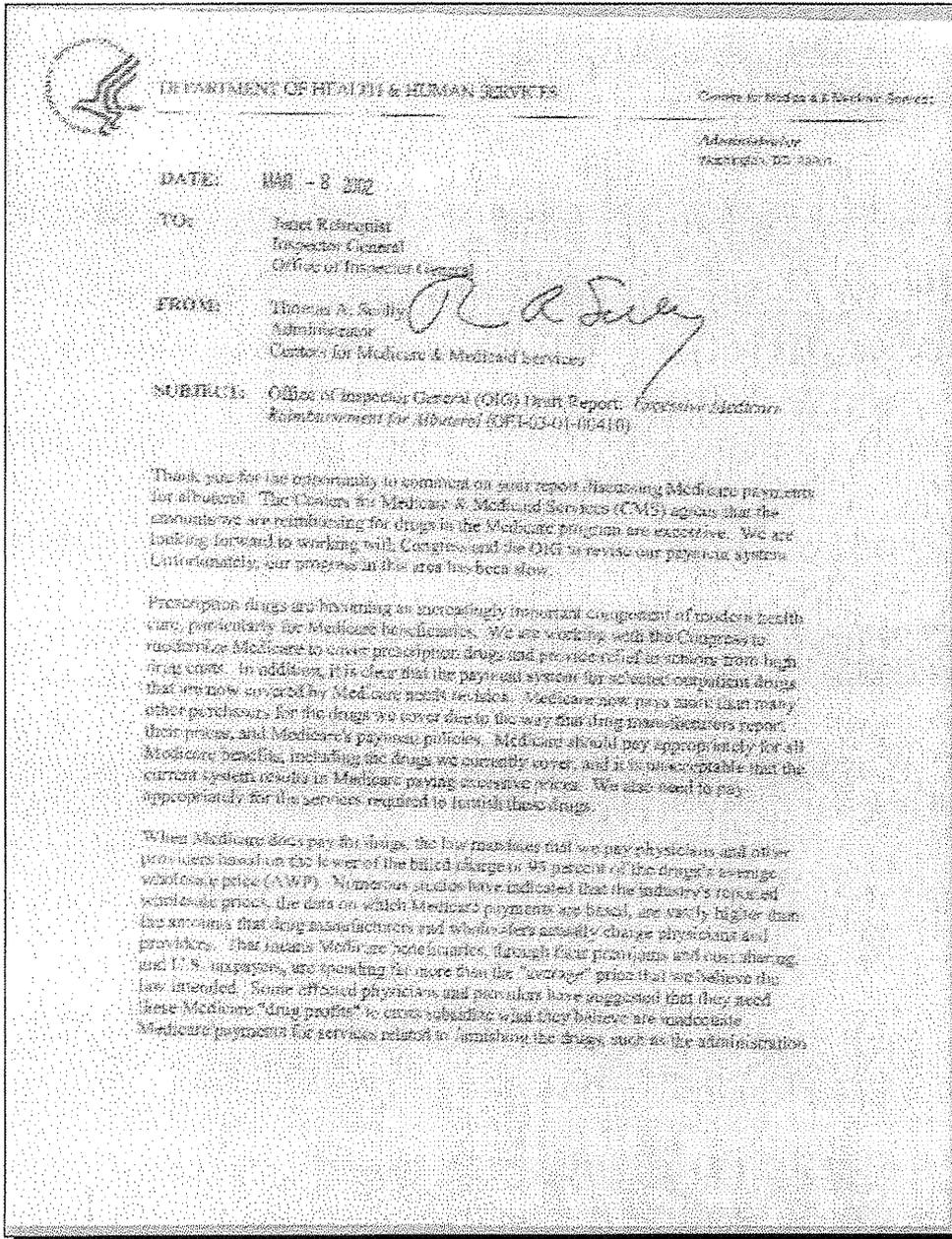
Calculation of Potential Savings for Albuterol

- (1) To determine percentage differences in albuterol prices, we subtracted the source price from the Medicare price. We then divided this number by the Medicare price.
- (2) To calculate potential savings, we multiplied Medicare's 2000 total payments (\$295,677,899) for albuterol by the percentage difference in price.

	Source Price	Medicare Price	Medicare Price	Percentage Difference	Potential Savings
Department of Veterans Affairs	\$0.05 to \$0.10	\$0.05	\$0.47	89.4%	\$264,222,803
Wholesale Catalogs	\$0.07 to \$0.15	\$0.08	\$0.47	83.0%	\$245,349,746
Supplier Invoices	\$0.08 to \$0.14	\$0.09	\$0.47	80.9%	\$239,058,727
Wholesale Acquisition Cost	\$0.09 to \$0.18	\$0.11	\$0.47	76.6%	\$226,476,689

*Percentage rounded to the nearest tenth

Centers for Medicare & Medicaid Services Comments



Page 2 - Janet Rabinowitz

of chemotherapy for cancer. We need to pay appropriately for both the drugs and the services related to furnishing the drugs.

Clearly, Medicare drug pricing is a complex issue. Over the years, numerous legislative efforts have failed to develop an effective alternative to AWP and ensure that Medicare and its beneficiaries do not pay more than they should for the limited number of prescription drugs that Medicare covers. We are committed to working with Congress on a bipartisan basis to ensure that Medicare pays accurately for all of its benefits.

Congress, CMS, and your office have long recognized the shortcomings of AWP as a way for Medicare to combat its drugs. Your office has published numerous reports showing that true market prices for the top drugs billed in the Medicare program by physicians, independent dialysis facilities, and durable medical equipment suppliers were significantly less than the AWP reported in the *Red Book* and like publications. As competitive discounts have become widespread, the AWP mechanism has resulted in increasing payment distortions. However, Medicare has continued to pay for these drugs based on the reported AWP amount. By offering physicians and providers deep discounts, your reports conclude that the drug manufacturers are able to use profit margins to manipulate physicians and providers to use their products for Medicare beneficiaries. It is simply unacceptable for Medicare to continue paying for drugs in a way that results in excessive prices.

In the past, Congress and the Agency has attempted to remedy disparities between Medicare payments based on AWP and the amount actually paid competitively by physicians and providers. However, these efforts have not been successful.

In December 2000, Congress enacted the Medicare, Medicaid, and State Children's Health Insurance Program Benefits Improvement and Protection Act, which established a moratorium on decreases in the rates of Medicare drug payments, while the General Accounting Office (GAO) conducted a study of Medicare drug pricing and related payment issues. We look forward to reviewing the GAO's findings and working with Congress to revise Medicare's drug payment policy. We must ensure that beneficiaries and Medicare pay appropriately for both the drugs that we cover and the services related to furnishing the drugs.

Medicare beneficiaries rely on prescription drugs, and the coverage they pay for covered drugs is tied directly to the prices that Medicare pays. We must find a competitive way to ensure that Medicare beneficiaries and taxpayers are no longer paying excessive prices for drugs that are far above the competitive discounts that are widely available today. We need to pay appropriately for all Medicare benefits, including the prescription drugs we cover and the services required to furnish those drugs.