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February 18, 2005

Divisions of Dockets Management
U.S. Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 2003P-0029
Use of Ozone-Depleting Substances; Removal of Essential-Use Designations

Dear Sir or Madam:

In the *Federal Register* Notice dated June 16, 2004, for the above captioned matter, the U.S. Food and Drug Administration ("FDA") requested comments on the proposal to remove the essential-use designation for albuterol MDIs. We previously submitted two reports to the docket in this matter. In these reports, we developed a model to examine the effects on patients and third-party payers (public and private) in the first year after removing the essential-use designation for albuterol CFC MDIs. Subsequently, there have been several developments in the marketplace for albuterol.

Enclosed is a supplemental report entitled, "Factors that Improve Patient Access after Removing the Essential-Use Designation for Albuterol CFC MDIs." We prepared this supplement to incorporate the effects of seven recent developments regarding albuterol explicitly into our model.

National Economic Research Associates, Inc. ("NERA"), an international firm of economists, was retained by GlaxoSmithKline to analyze the economic issues raised by the FDA in connection with designating albuterol non-essential. Our research represents our independent views on the current and projected market environments for selling albuterol. For over 40 years, NERA economists have contributed to understanding the economic issues in business, legal, regulatory, and public policy forums.

Sincerely,

Richard P. Rozek

RPR:pmb
Enclosure

FACTORS THAT IMPROVE PATIENT ACCESS AFTER REMOVING THE ESSENTIAL-USE DESIGNATION FOR ALBUTEROL CFC MDIs

by
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Supplemental Comments submitted to the
U.S. Food and Drug Administration
[Docket No. 2003P-0029]

February 18, 2005

n/e/r/a
Consulting Economists

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Factors that Improve Patient Access after Removing the Essential-Use Designation for Albuterol CFC MDIs

by

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and
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I. PATIENTS ADEQUATELY SERVED

This report provides additional information relevant to the U.S. Food and Drug Administration's ("FDA") proposed rule "to amend its regulation on the use of ozone-depleting substances ("ODSs") in self-pressurized containers to remove the essential-use designations for albuterol used in oral pressurized metered-dose inhalers ("MDIs")."[1] We prepared these comments to supplement the two reports we previously submitted to the docket in this matter.[2] As part of our earlier work, we developed a model to examine the effects on patients and third-party payers (public and private) in the first year after removing the essential-use designation for albuterol CFC MDIs. In this supplemental report, we incorporate seven recent developments regarding albuterol into our model.

These recent developments, which we describe in detail below, substantially reduce our estimated cost impact for both patients and third-party payers. For example, our estimate of the

[*] The authors are Senior Vice President and Senior Analyst, respectively, at National Economic Research Associates, Inc. ("NERA"). GlaxoSmithKline ("GSK") provided financial support for the economic research described in this report.

[1] Department of Health and Human Services, FDA, 21 CFR Part 2, Docket No. 2003P-0029, RIN 0910-AF18, "Use of Ozone-Depleting Substances; Removal of Essential-Use Designations," *Federal Register*, Vol. 69, No. 115, June 16, 2004 ("NPR"), p. 33602. In this report, we refer to removing the essential-use designation for albuterol chlorofluorocarbons ("CFC") MDIs as the policy change.

[2] "The Impact on Patients and Payers of Designating Albuterol a Non-Essential Use of an Ozone Depleting Substance," National Economic Research Associates, Inc., September 8, 2003 ("NERA Report 1"); and "Economic Issues Raised in the FDA's Proposed Rule on Removing the Essential-Use Designation for Albuterol MDIs," National Economic Research Associates, Inc., August 13, 2004 ("NERA Report 2").

cost impact per MDI on patients without prescription drug insurance (i.e., cash payers) who obtain albuterol MDIs through retail channels such as pharmacies decreased 86 percent from our original estimate.[3] Further, manufacturers have committed to provide *six million* albuterol hydrofluoroalkane ("HFA") MDIs samples/vouchers to physicians[4] and 500,000 albuterol HFA MDIs to clinics that target low-income patients after the policy change. The availability of these albuterol MDIs offsets the potential reduction in demand among uninsured patients that is estimated in the NPR.[5] Most importantly, our conclusion remains that patients will be adequately served after the policy change.

II. COMPARISONS OF ORIGINAL AND CURRENT RESULTS

As described in our previous reports, our original estimate of the cost impact reflected conservative assumptions regarding the marketplace for selling albuterol MDIs after the policy change including:

- no additional samples,
- no manufacturer rebates to government programs such as Medicaid above the legally mandated minimum,
- two albuterol HFA MDI products available to patients,
- no discounts to other payers above current levels for albuterol HFA MDIs,
- no additional price competition for the albuterol HFA MDI products, and

[3] The calculation is [(($1.21-$8.61)/ $8.61)*100] = -86 percent.

[4] Samples are available at no cost to patients, and physicians tend to distribute samples to indigent patients. Agency for Healthcare Research and Quality, "Medical Practices Can Benefit from Specific Policies for Interacting with Pharmaceutical Representatives," *Research Activities*, No. 244, December 2000, http://www.ahrq.gov/research/dec00/1200RA9.htm#head2. Centers for Medicare & Medicaid Services, "Health Care Industry Market Update, Pharmaceuticals," January 10, 2003, p. 29, http://www.cms.hhs.gov/reports/hcimu/hcimu_01102003.pdf. Agency for Healthcare Research and Quality, "Health Care Costs and Financing, Community Health Centers Need More Resources to Provide Proper Care to High-Risk Asthma Patients," *Research Activities*, No. 231, November 1999, http://www.ahrq.gov/research/nov99/1199ra9.htm.

[5] The NPR contains estimates that demand may be reduced by 360,000 to 1,080,000 albuterol MDIs among the uninsured due to price increases after the policy change. NPR, p. 33615.

- higher average co-payments charged to patients with private insurance for brand products than for generic products.

Under these assumptions, we estimated that the average increase in total costs per MDI in the first year after the policy change to be $9.87 per MDI where

- patients pay an average increase of $7.33 per MDI, and
- third-party payers pay an average increase of $2.54 per MDI.[6]

Several recent developments will reduce the cost impact to patient and third-party payers such as commitments by manufacturers to provide samples and discount coupons for albuterol HFA MDI products after the policy change,[7] increased competition from a third brand albuterol HFA MDI product,[8] and expanded manufacturer patient assistance programs. To assess the effects of these developments, we incorporated explicitly the following seven factors into our model:

- two million samples of Ventolin® HFA MDIs per year from GSK;[9]
- three million $10 *Ventolin® HFA Savings Checks* (discount coupons) to patients per year from GSK;[10]
- two million samples of Proventil® HFA MDIs per year from Schering;[11]

[6] NERA Report 1, pp. 17-18.

[7] We understand that some of these commitments are contingent on albuterol being designated non-essential effective December 31, 2005 or shortly thereafter.

[8] IVAX received approval to sell its brand albuterol HFA MDI product on October 29, 2004. FDA, Center for Drug Evaluation and Research, *Electronic Orange Book*, and "A Powerful Proprietary Pipeline," IVAX 2002 Annual Report, p. 12.

[9] Currently, no samples of albuterol MDIs (CFC or HFA) are available. Generic companies generally do not provide product samples. Pioneer companies generally discontinue promotion activities (e.g., samples) when generic products enter the market. However, brand manufacturers have committed to begin providing samples prior to the policy change to facilitate patient transition to brand albuterol HFA MDIs. For example, Schering-Plough Corporation ("Schering") will provide 500,000 samples of Proventil® HFA MDIs in the six months prior to the policy change. "Re: Docket No.: 2003P-0029, Use of Ozone-Depleting Substance; Removal of Essential-Use Designations," Schering, January 28, 2005 ("Schering Comments"), p. 3. We do not model the benefits of samples provided prior to the policy change.

[10] "Re: Docket No. 03P-0029, Notice of Proposed Rule: Use of Ozone-Depleting Substances; Removal of Essential-Use Designations," GSK, August 25, 2004 ("GSK Comments"), pp. 6-7.

[11] Schering Comments, p. 3.

- 500,000 Proventil® HFA MDIs to community health centers (i.e., clinics) from Schering ;[12]
- two million vouchers/samples of brand albuterol HFA MDIs per year from IVAX;[13]
- albuterol HFA MDI products to low-income patients through patient assistance programs from GSK, Schering, and IVAX; and
- a list price for IVAX's brand albuterol HFA MDI product at 20 percent below Schering's list price for Proventil® HFA MDI.[14]

Incorporating all seven factors into our model, we estimated the average increase in total costs per MDI in the first year after the policy change to be $4.32 per MDI where

- patients pay an average increase of $4.17 per MDI, and
- third-party payers pay an average increase of $0.15 per MDI.

These seven recent developments alone potentially reduce the average total cost increase per MDI in the first year after the policy change by 56 percent from our original estimate.[15] If we considered other market factors such as additional competition,[16] buyer power,[17] insurance

[12] Schering will provide these Proventil® HFA MDIs to targeted clinics that serve uninsured patients within six months of the policy change. Schering Comments, pp. 2-3.

[13] "Re: Docket No. 2003-0029, Use of Ozone-Depleting Substances; Removal of Essential-Use Designation," IVAX Research, Inc., January 12, 2005 ("IVAX Comments"), pp. 6-7.

[14] IVAX Comments, p. 5.

[15] The calculation is [(($4.32-$9.87)/ $9.87)*100] = -56 percent.

[16] Specifically, competition for market share between existing sellers of albuterol HFA MDI products as well as entrants with new versions of albuterol in non-ODS delivery systems. For example, IVAX developed a second non-CFC albuterol product in its patented breath activated inhaler and received an approvable letter from the FDA in July 2004. "IVAX Receives FDA Approvable Letter for Albuterol HFA in Breath-Activated Inhaler," July 7, 2004, http://www.ivax.com. Sepracor also developed a competing product, Xopenex HFA® (levalbuterol HFA MDI), and submitted a New Drug Application to the FDA in May 2004. "Sepracor Submits New Drug Application for XOPENEX HFA® Metered-Dose Inhaler to FDA," May 13, 2004, http://www.prnewswire.com/cgi-bin/stories.pl?ACCT=105&STORY=/www/story/05-13-2004/0002173499.

[17] For example, private insurers, the federal government, group purchasing organizations, and pharmacy benefit managers are able to influence (e.g., through formularies) the products used by large numbers of patients. As a result, they have the ability to exert buying or monopsony power to receive additional discounts when negotiating prices with manufacturers. Similarly, new corporate programs are being developed to provide health care coverage to formerly uninsured, part-time workers. These programs enable the covered patients to obtain pharmaceutical products at lower prices. Freudenheim, "60 Companies Plan to Sponsor Health Coverage for Uninsured," http://www.nytimes.com/, January 27, 2005.

coverage of outpatient prescription pharmaceuticals for Medicare enrollees,[18] patient assistance programs funded by public sources,[19] and patient discount cards (government and private[20]), our estimate of the cost impact per MDI in the first year after the policy change would decrease further. Beyond the first year, these factors as well as those we analyzed explicitly operate to further diminish the cost impact on patients and payers over time.[21] In the remainder of this report, we provide a detailed explanation of our model and how we incorporated the seven factors enumerated above.

III. MODEL

A. Overview

We undertook a comprehensive study of the flow of albuterol MDIs and associated annual revenues and costs through the entire U.S. healthcare system under two scenarios:

- the marketplace as it currently exists with brand and generic versions of albuterol CFC MDIs and two brand versions of albuterol HFA MDIs ("Current Marketplace"); and
- the projected marketplace after removing the essential-use designation for albuterol CFC MDIs where three brand versions of albuterol HFA MDIs will be available ("Projected Marketplace").

The participants in the marketplace for selling pharmaceutical products such as albuterol include manufacturers; wholesalers or distributors; retailers, non-federal hospitals, government

[18] A provision in the Medicare Prescription Drug, Improvement and Modernization Act of 2003 provides people eligible for Medicare with an entitlement to coverage for outpatient prescription pharmaceuticals beginning in 2006.

[19] For example, see "State Pharmaceutical Assistance Programs (includes seniors, disabled, uninsured and others)," National Conference of State Legislatures, updated July 15, 2003, http://www.ncsl.org/programs/health/drugaid.htm.

[20] For example, several pharmaceutical manufacturers including Abbott Laboratories, AstraZeneca, Aventis, Bristol-Myers Squibb Company, GSK, Johnson & Johnson, and Novartis sponsor the *Together Rx* prescription savings program.

[21] In contrast, the NPR takes a static view that nothing will change in terms of the competitive environment until generic competition emerges in 2010 or 2015. However, numerous market developments have already occurred such as IVAX's entry into the marketplace with a third albuterol HFA MDI product and manufacturers' commitments to provide samples.

agencies, health maintenance organizations ("HMOs"), clinics, federal facilities; third-party payers (public and private); and patients. In conducting our analysis, we analyzed the impact of the policy change for each participant. It is necessary to distinguish the types of channels through which albuterol is distributed as the participants, mark-ups, rebates, and other factors differ across channels. We relied on detailed, product-specific data from the IMS Retail Perspective®/Provider Perspective®[22] on the use of albuterol MDIs to measure revenues and associated costs to the relevant participants for each scenario. As described in our original report, we consolidated the 13 channels through which this IMS audit tracks sales of albuterol MDIs into four groups based on the magnitude of the average dollars per MDI that IMS reports that the members of the group paid during 2001 and 2002 and whether the channels contained public or private institutions as follows: Group 1 represents retail channels;[23] Group 2 represents clinics, HMOs, and universities; Group 3 represents non-federal hospitals; and Group 4 represents federal facilities and prisons.[24] We analyzed each of the four groups separately.[25] Since different types of patients obtain prescriptions through retail channels, we further divided Group 1 into three subgroups: Cash, Medicaid, and Insurance (Private). We

[22] IMS recently renamed this database the National Sales Perspectives®: Retail & Non-Retail. Other data sources we relied on include Verispan, National Association of Chain Drug Stores, American Lung Association, and the U.S. Census Bureau.

[23] Specifically, Group 1 represents the IMS channels: chain drug stores, independent drug stores, mail order pharmacies, food stores, long-term care facilities, home healthcare, and miscellaneous-other.

[24] NERA Report 1, p. 13.

[25] In contrast, the NPR relies on the IMS National Prescription Audit *Plus*® ("NPA Plus") audit which measures sales through selected retail channels only. Further, the data relied on by the NPR excludes some retail channels such as the Internet, mail order, and long-term care pharmacies. NPR, p. 33610, and Department of Health and Human Services, FDA, Center for Drug Evaluation and Research, Pulmonary-Allergy Drugs Advisory Committee Meeting Transcript, June 10, 2004, p. 70. Data from this audit is used in the NPR to estimate the price differential between brand and generic albuterol MDIs to calculate the lower bound of the potential reduction in demand of albuterol MDIs by uninsured patients and to calculate the cost impact (referred to in the NPR as "consumer expenditures" and "Increased Expenditures on albuterol") after the policy change. NPR, pp. 33610-3. To the extent uninsured patients obtain albuterol MDIs through non-retail channels (e.g., clinics) at lower prices, this estimated price increase overstates the NPR's estimated potential reduction in demand by uninsured patients. In addition, measuring the differential in brand and generic "price" through retail channels only and multiplying this differential by all generic sales through both retail and non-retail channels (e.g., clinics, universities, HMOs, non-federal hospitals, federal facilities, and prisons) may overstate the cost impact as these buyers are more apt to negotiate lower prices. In footnote 53, we discuss how this "price" actually represents retailer revenues from both patients and third-party payers rather than prices borne solely by patients. In footnote 41, we discuss the data the NPR relies on to estimate the upper bound of the potential reduction in demand of albuterol MDIs by uninsured patients and how this data is not representative of prices incurred by uninsured patients.

measured the cost impact of the policy change as the difference between the values derived from the current and projected marketplace scenarios.

B. Description of Analysis Incorporating Seven Factors[26]

1. Current Marketplace (before Policy Change)

a. Revenues for Manufacturers, Wholesalers, and Retailers

The IMS data we relied on reports sales from wholesalers to purchasers (retailers in the case of Group 1 channels). Therefore, we estimated annual wholesalers' revenues from sales of brand[27] and generic albuterol MDIs (SA-1, line P) based on:

- annual brand and generic albuterol MDI sales (SA-1, lines J-K), and
- retailers' acquisition costs (or wholesaler prices) for brand and generic albuterol MDIs (SA-1, lines L-M).

First, we calculated the share of albuterol MDIs sales through all Group 1 channels as a percent of total albuterol MDIs sales through all four groups from 2001 to 2002 of 83.9 percent (SA-1, lines A-C). Second, we multiplied this percentage by our estimate of annual demand for albuterol MDIs (50,000,000)[28] to determine that 41,950,000 albuterol MDIs will be sold through Group 1 channels collectively (SA-1, lines D-E). Third, we allocated the total albuterol MDIs sold through Group 1 into three subgroups, Cash Payers (13.3 percent), Medicaid Payers (14.9 percent), and Insurance Payers (71.8 percent) (SA-1, lines F-G).[29] Finally, we estimated how many of the albuterol MDIs sold through each subgroup would be brand and generic products based on the share of brand and generic albuterol MDIs sold through Group 1 channels from 2001 to 2002 (SA-1, lines H-K).

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[26] We describe our analysis for Group 1 (retail channels) in detail. Approximately 84 percent of the albuterol MDIs were sold through Group 1 channels in 2001 to 2002. For convenience, we note the appropriate exhibit and line in the supplemental appendix ("SA") attached to this report. Our analyses for Groups 2, 3, and 4 follow a similar pattern. We note differences in our analyses of these other groups.

[27] In the Current Marketplace, we use the term "brand" to represent both brand CFC and HFA albuterol MDI products.

[28] We based this estimate on our review of IMS data of total annual sales of albuterol MDIs from 1992 to 2002. Subsequently, we reviewed sales data for 2003 and 2004. They are consistent with this estimate.

[29] These percentages were based on data reported by Verispan.

Once we determined the annual unit sales of brand and generic albuterol MDIs through each subgroup, we calculated the associated retailers' acquisition costs (or wholesaler prices) for brand and generic albuterol MDI products. To estimate the weighted average price of each brand albuterol MDI, we summed the total revenue for all brand albuterol MDI products (Ventolin® CFC, Ventolin® HFA, Proventil® CFC, and Proventil® HFA) sold through Group 1 channels in 2001 and 2002 and divided by the sum of the total units (SA-1, line L). We performed a comparable calculation for generic albuterol MDI products (SA-1, line M). We multiplied the unit sales of annual brand and generic albuterol MDI by the weighted average brand and generic prices, respectively, to determine the annual wholesalers' revenues for brand and generic albuterol MDIs (SA-1, lines N-P).

From the annual wholesalers' revenues, we determined annual manufacturers' revenues, net of rebates (SA-1, line AA). Manufacturers' gross revenues equal 96 percent of wholesalers' revenues (SA-1, lines Q-S).[30] We then subtracted manufacturer rebates paid directly to Medicaid and Insurance Payers.[31] We assumed manufacturers' rebates to Medicaid Payers for brand and generic albuterol MDIs before the policy change are 30.0 percent and 11.0 percent of manufacturers' prices,[32] respectively (SA-1, lines T-X, column 2).[33] We assumed manufacturers' rebates to Insurance Payers for brand albuterol MDIs equal 15.1 percent of manufacturers' prices based on our understanding of a minimum manufacturer rebate for a brand product (SA-1, lines T-X, column 3). Subtracting the annual manufacturers' rebates

[30] The National Association of Chain Drugs Stores reported that for the average retail prescription cost, the manufacturer and wholesaler received 75.6 percent and 3.3 percent of the cost, respectively. IMS data reported sales at the wholesaler level. Thus, the total IMS wholesaler revenue represents 78.9 percent (75.6 percent+3.3 percent) of the total cost. The revenue due the manufacturer is 96 percent of the total amount reported by IMS (75.6 percent/78.9 percent). "Industry Statistics, Industry Facts-at-a-Glance, Pharmaceutical Pricing," National Association of Chain Drug Stores, http://www.nacds.org/wmspage.cfm?parm1=507.

[31] Currently, Cash Payers receive no rebates from manufacturers.

[32] As described above, manufacturers' prices are equal to 96 percent of wholesalers' prices.

[33] The Omnibus Budget Reconciliation Act of 1990 ("OBRA 90") provides that manufacturers of brand and generic pharmaceuticals pay a minimum rebate of 15.1 percent and 11.0 percent, respectively, on the wholesale price on products dispensed to outpatients covered by Medicaid. Medicaid receives larger rebates if manufacturers offer lower prices to other purchasers in the U.S. "Prescription Drugs, Expanding Access to Federal Prices Could Cause Other Changes," U.S. General Accounting Office, GAO/HEHS-00-118, August 2000. Also see William von Oehsen, "Pharmaceutical Discounts under Federal Law: State Program Opportunities," speech at the National Conference of State Legislatures Fifth Health Policy Conference, November 16, 2001.

from the annual manufacturers' gross revenues yielded the annual manufacturers' revenues from sales of brand and generic products, net of rebates (SA-1, lines Y-AA).

For Group 1, we estimated the annual retailers' revenues (SA-2, lines I-K).[34] We calculated the brand and generic retail price per MDI to each subgroup (SA-2, lines E-F) by applying a retail mark-up (SA-2, lines C-D) to the weighted average retail acquisition cost (previously calculated, SA-2, lines A-B) for brand and generic albuterol MDIs separately.

- Retailers' mark-ups on brand albuterol MDIs for Cash Payers, Medicaid Payers, and Insurance Payers average 28.8 percent, 28.8 percent, and 14.4 percent, respectively (SA-2, line C).[35]
- Retailers' mark-ups on generic albuterol MDIs for Cash Payers, Medicaid Payers, and Insurance Payers average 363.3 percent, 234.5 percent, and 234.5 percent, respectively (SA-2, line D).[36]

For each subgroup, we multiplied the estimated annual brand and generic unit sales of albuterol MDIs (previously calculated, SA-2, lines G-H) by the retail price for brand and generic albuterol MDIs, respectively, to determine the annual retailers' revenues for brand and generic albuterol MDIs (SA-2, lines I-K).

b. Costs Borne by Patients and Third-Party Payers

Once we determined the flow of revenues to manufacturers, wholesalers, and retailers, we calculated how the associated costs would be distributed across patients and third-party

[34] For Groups 2, 3, and 4, retailers' revenues are not applicable as clinics, universities, HMOs; non-federal hospitals; and federal facilities and prisons, respectively, obtain pharmaceutical products from wholesalers and provide them directly to patients for specified payments (or lack thereof).

[35] We derived the weighted average price for brand albuterol MDIs to chain stores, food stores, and independent stores of $29.99 for the period May 2002 to February 2003 from IMS data, and the average retail price of $38.62 for the period May 2002 to April 2003 for the same channels from Verispan data. The retailer mark-up is equal to the average retail price of $38.62 less the average retail acquisition cost of $29.99, divided by the average retail acquisition cost or 28.8 percent. We assumed Insurance Payers negotiated a 50 percent discount on the retailer mark-up.

[36] We derived the weighted average price for generic albuterol MDIs to chain stores, food stores, and independent stores of $4.88 for the period May 2002 to February 2003 from IMS data, and the average retail price of $22.61 for the period May 2002 to April 2003 for the same channels from Verispan data. The retailer mark-up is equal to the average retail price of $22.61 less the average retail acquisition cost of $4.88, divided by the average retail acquisition cost or 363.3 percent. The retailer mark-up to Medicaid of 234.5 percent is based on a Federal Maximum Allowable Cost or MAC, which includes a dispensing fee of $19. We assumed Insurance Payers negotiate a discount similar to Medicaid. Individual states or insurers may implement lower prices than MAC.

payers. For Group 1, the annual total costs borne by patients and third-party payers equal the retailers' revenues less applicable manufacturer rebates (SA-2, lines K-M), where:

- § patients bear the full costs for cash purchases;
- § the government bears all costs for patients with Medicaid coverage; and
- § patients with insurance coverage pay differential co-payments for brand and generic pharmaceutical products of $22 and $10 per unit, respectively, and the Insurance Payers bear the remaining costs[37] (SA-2, lines N-O).[38]

2. Projected Marketplace (after Policy Change)

We analyzed the projected marketplace for albuterol

- § assuming three brand albuterol HFA MDI products will be available and[39]
- § incorporating the seven manufacturer commitments listed in Section I.[40]

Using our model, we estimated the manufacturers', wholesalers', and retailers' revenues and associated costs to patients and third-party payers after removing the essential-use designation for albuterol CFC MDIs.

[37] We used data for the average co-payment in 2003 from "Strategic Health Plans Update 2002," *Health Strategies Group*.

[38] For Groups 2, 3, and 4, annual costs borne by patients and third-party payers are equal to the wholesalers' revenues. Patients purchasing albuterol at clinics, universities, or through HMOs pay identical co-payments of $5 for brand and generic pharmaceutical products, and the associated organization bears the remaining costs; non-federal hospitals bear all costs for patients obtaining albuterol through this channel; and the federal government bears all costs for patients obtaining albuterol through federal facilities and prisons (SA-5, lines R-S).

[39] In our original report, we assumed only two brand albuterol HFA MDI products would be available (Ventolin® HFA and Proventil® HFA). Subsequently, IVAX has received FDA approval for its brand albuterol HFA MDI product.

[40] The NPR acknowledges manufacturer commitments that existed prior to June 16, 2004 but does not measure the benefits to patients. For example, with respect to its estimated potential reduction in demand of albuterol MDIs by uninsured patients, the NPR cites GSK's commitment to provide 2 million samples per year but states, "[w]e are unable to include the commitment to distribute free MDIs into our quantitative analysis because of uncertainty about the recipients." NPR, p. 33610.

a. Revenues for Manufacturers, Wholesalers, and Retailers

Similar to the Current Marketplace analysis, we calculated the annual wholesalers' revenues (SA-3, line J). The two components of this calculation are:

- annual brand albuterol HFA MDI sales (SA-3, line H) and
- retailers' acquisition cost (or wholesaler price) for brand HFA MDI products (SA-3, line I).

The share of albuterol MDIs sales through Group 1 channels remained 83.9 percent of total albuterol MDI sales (SA-3, lines A-C). However, we adjusted the estimated annual demand of albuterol MDIs from 50,000,000[41] to 49,000,000 to reflect 1,000,000 brand albuterol HFA MDIs that will be provided directly to low-income patients through manufacturer patient

[41] With regard to the effect (or lack thereof) of the policy change on demand, we based our analysis of the demand on actual data for albuterol MDIs. The NPR relied on a general survey article that summarized studies encompassing a variety of pharmaceutical products including cough and cold medications and over-the-counter products to determine the elasticity of demand that is one component of its estimated potential reduction in demand. The NPR did not use data for albuterol in estimating these elasticities used to reach the conclusion that sales would fall after the policy change. In addition, the NPR relied on two distinct sources to estimate the price increases to uninsured patients after the policy change to calculate the upper and lower bound estimates of the potential reduction in demand. As previously discussed in footnote 25, the NPR relies on data from the NPA Plus to calculate the lower bound estimate. These data are also the foundation for the NPR's estimate of the overall cost impact of the policy change to the healthcare system. To calculate the upper bound estimate, the NPR relies on prices for brand and generic albuterol MDI products from a single Internet website, http://www.drugstore.com, on a particular date. NPR, p. 33614. We understand that pharmacy sales through this website represent less than one percent of total U.S. pharmacy sales. GSK, p. 12. These Internet prices are not representative of the prices incurred by uninsured patients. In a previous submission to the docket, we addressed problems with the information relied on in the NPR to estimate measures of elasticity and price increases. NERA Report 2, pp. 9-11 and 21-24. We based our estimate of 50,000,000 MDIs per year after the policy change on our review of IMS data of total annual sales of albuterol MDIs from 1992 to 2002, a period that includes the introduction of generic CFC MDI products, and the product characteristic that albuterol MDIs are rescue medications for patients with asthma or chronic obstructive pulmonary disease. Subsequently, we reviewed sales data for 2003 and 2004. They are consistent with this estimate.

assistance programs (SA-3, line D).[42] By adjusting overall demand, we assumed low-income patients may purchase pharmaceutical products through each channel (e.g., Group 1 – Cash Payer or Insurance Payer, or clinics/HMOs/universities.) We multiplied the percentage of albuterol MDIs sales through Group 1 channels by the adjusted annual demand of 49,000,000 MDIs to calculate that 41,111,000 brand albuterol HFA MDIs will be sold through Group 1 channels, collectively (SA-3, line E). Since GSK, Schering, and IVAX have each committed to provide 2,000,000 albuterol HFA MDIs annually after the policy change, we further adjusted estimated unit sales through Group 1 by 6,000,000 MDIs (SA-3, line F).[43] We multiplied the estimated annual sales through Group 1 collectively by the same percentage allocation as above to determine the annual unit sales through each subgroup (SA-3, line G-H). It was not necessary to separate these sales into brand and generic products since all products sold after the policy change will be brand products.

[42] Generic companies generally do not sponsor patient assistance programs. In 2002, sales of brand albuterol HFA MDIs represented less than six percent of total sales of albuterol MDIs. During this time, manufacturers provided tens of thousands of brand albuterol MDIs through patient assistance programs. After the policy change, brand products will account for all albuterol MDIs used by patients. Therefore, the number of MDIs provided through patient assistance programs will likely increase substantially. We assumed that one million brand albuterol HFA MDIs will be provided through patient assistance programs at no cost to patients after the policy change. Currently, GSK and Schering both provide albuterol MDI products to low-income patients through their respective patient assistance programs. GSK has provided information on an education and outreach program it will initiate when albuterol is designated non-essential. GSK Comments, pp. 8-9. Similarly, Schering has provided information on "an aggressive HFA awareness and access communication plan [it will initiate] aimed specifically at patients in areas of high asthma prevalence utilizing English and Spanish materials" to provide information on its patient assistance programs after the policy change. Schering reported that in the past year, the company "provided more Proventil brand of products…than any other Schering drug." Schering Comments, pp. 3-4. In addition, the U.S. Stakeholders Group on MDI Transition has provided information on an education and outreach program it will initiate to improve awareness among patients and caregivers regarding patient assistance programs and the availability of samples. "Re: Docket No. 2003P-0029, Use of Ozone-Depleting Substances; Removal of Essential-Use Designations," U.S. Stakeholders Group on MDI Transition, November 2004, pp. 1-5. IVAX implemented a patient assistance program on February 1, 2005 to provide its brand albuterol HFA MDI product to low-income patients. IVAX comments, pp. 5-6. Besides the patient assistance programs sponsored by manufacturers, certain public agencies also have such programs. There is more information available about both public and private programs as a result of recent efforts such as HelpingPatients.org, https://www.helpingpatients.org/Intro.php.

[43] Manufacturers generally provide these samples to physician offices, who distribute the pharmaceutical products to patients. Patients who visit physician offices typically obtain pharmaceutical products through retail channels. Thus, we applied all samples through Group 1 channels. Similarly, we adjusted the estimated annual unit sales through Group 2 channels to reflect 500,000 Proventil® HFA MDIs Schering has committed to provide to community health centers (i.e., clinics) after the policy change. Schering Comments, pp. 2-3. Note that while these free products benefit clinics, we assumed patients continue to pay a co-payment of $5 for all pharmaceutical products obtained at clinics. We assumed patient costs are not reduced.

Once we determined the annual brand albuterol HFA MDI sales through each subgroup, we calculated the retailers' acquisition costs (or wholesaler prices) for brand albuterol HFA MDI products. We assumed that after the policy change, all products will be sold at the current brand albuterol HFA MDI price, adjusted for IVAX's price discount. First, we calculated the weighted average price of an existing brand albuterol HFA MDI product sold through Group 1 channels to be $27.88 per MDI.[44] Second, we calculated the price IVAX will charge for its brand albuterol HFA MDI product to be twenty percent less than the current average price of $27.88 per MDI or $22.30 per MDI.[45] Third, we assumed IVAX will obtain 21 percent of sales of brand albuterol HFA MDIs as the third market entrant.[46] Weighting the prices accordingly, we calculated the average price for a brand albuterol HFA MDI product after the policy change to be $26.71 per MDI[47] (SA-3, line I).[48] We multiplied the annual unit sales of brand albuterol HFA MDI products by the average brand price to determine the annual wholesalers' revenues (SA-3, line J).

From the wholesalers' revenues, we determined annual manufacturers' revenues, net of rebates and patient discount coupons (SA-3, line K-O). Like above, manufacturers' gross revenues are equal to 96 percent of wholesalers' revenues (SA-3, line K). However, we assumed conservatively that manufacturers' rebates to Medicaid for brand products *decreased* to the minimum 15.1 percent as mandated by OBRA 90, and Insurance Payers continued to receive rebates of 15.1 percent (SA-3, lines L-M).

In addition to providing traditional rebates to third-party payers, GSK has committed to providing a new manufacturer discount directly to patients in the form of three million, $10 discount coupons annually after the policy change. These coupons will be available to all patients throughout the U.S. to use immediately upon purchase of the product at the pharmacy.

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[44] The sum of total revenue for Ventolin® HFA and Proventil® HFA sold through Group 1 channels in 2001 and 2002 divided by the sum of the total MDIs is equal to $27.88.

[45] The calculation is [($27.88)x(80 percent)] = $22.30. Schering's price for Proventil® HFA is approximately the same as the weighted average price for Proventil® HFA and Ventolin® HFA.

[46] Daniel Haines, Rajan Chandran, and Arvind Parkhe, "Winning by Being the First to Marketing…or Second?," *The Journal of Consumer Marketing*, Vol. 6, No. 1, Winter 1989, p. 64.

[47] The calculation is [($27.88)x(79 percent)+($22.30)x(21 percent)] = $26.71.

[48] By comparison, the average price of a prescription for a brand pharmaceutical product in 2003 was $83.66. "Industry Statistics, Industry Facts-at-a-Glance, Pharmaceutical Pricing," National Association of Chain Drug Stores, data extracted August 10, 2004.

They directly benefit patients who purchase albuterol MDIs through Group 1 (retail) channels (cash or insured).[49] We assumed one million coupons will be redeemed.[50] Thus, the total value of the coupons redeemed is $10,000,000. We assumed these coupons are redeemed proportionally through channels which albuterol is sold to patients who incur at least $10 in costs per MDI; that is, 15.63 percent and 84.37 percent will be redeemed by Cash Payers and Insurance Payers, respectively.[51] Thus, the benefit to cash patients and insurance patients is equal to $1,563,000 and $8,437,000, respectively (SA-3, line N). We subtracted the annual manufacturers' rebates and patient discount coupons from the annual manufacturers' gross revenues to calculate the annual manufacturers' revenues from sales of brand albuterol HFA MDI products, net of rebates and patient discount coupons (SA-3, line O).

For Group 1 channels, we also estimated the annual retailers' revenues (SA-4 line E). We calculated the retail prices for brand albuterol HFA MDIs to each subgroup (SA-4, line C) by applying the same estimated retailers' mark-ups for brand products (SA-4, line B) to the retailers' acquisition cost (or wholesaler price) described previously (SA-4, line A). For each subgroup, we multiplied the annual brand albuterol HFA MDI sales (SA-4, line D) by the retail price to determine the annual retailers' revenues for brand albuterol HFA MDIs (SA-4, line E).

b. Costs Borne by Patients and Third-Party Payers

Once we determined the flow of revenues to manufacturers, wholesalers, and retailers, we calculated how the associated costs would be distributed across patients and third-party payers. Analogous to the Current Marketplace analysis for Group 1 channels, the annual total costs borne by patients and third-party payers equal the retailers' revenues less applicable manufacturer rebates (SA-4, lines F-G) where:

[49] A patient's cost will have to be $10 or more per prescription before the coupon will apply to the transaction. For example, a patient with a co-payment of only $5 per prescription will not be eligible to use a coupon. The broad based distribution of the coupons will benefit all patients including the low-income patients with insurance. Since Medicaid patients do not incur costs for prescription pharmaceutical products, they will not be eligible to redeem these patient discount coupons.

[50] Based on our understanding of the pharmaceutical industry, we assumed one third of the coupons will be redeemed. Coupon redemption rates for point-of-sale coupons are in the range of 20 to 50 percent. See, for example, "Coupons and Rebates," *Business Owner's Toolkit*, http://www.toolkit.cch.com/text/P03_7016.asp.

[51] The calculations are Cash Payers: [13.3 percent/(13.3 percent+71.8 percent)] = 15.63 percent and Insurance Payers: [71.8 percent/(13.3 percent+71.8 percent)] = 84.37 percent. See SA-3, line G.

- patients bear the full costs for cash purchases, *less patient discount coupons*;
- the government bears all costs for patients with Medicaid coverage; and
- patients with insurance coverage pay a brand co-payment of $22[52] *less patient discount coupons*, and the Insurance Payers bears the remaining costs due retailers (SA-4, lines H-K).

IV. COST IMPACT DUE TO POLICY CHANGE[53]

For each of the four groups, we determined the cost impact due to the policy change in the first year incorporating the seven recent developments described above. We calculated the average change in costs per albuterol MDI borne by patients and third-party payers. Our results for patients are as follows:

[52] We assumed that after the policy change, all patients with insurance coverage will pay a brand co-payment of $22.

[53] In contrast to the model we constructed, the information presented in the NPR is not comprehensive enough to measure the cost impact of the policy change to different participants in the marketplace for albuterol. Instead, the NPR performs a calculation to estimate the cost impact equal to the "current *retail price* difference of approximately $23 between branded and generic CFC MDIs," derived from the NPA Plus audit, multiplied by an estimated number of generic albuterol MDI products that would have been sold if the policy change was not implemented (emphasis added). NPR, p. 33610 and Tables 2-3. There are two problems with the estimated price differential the NPR used in this calculation. First, the NPR relies on data from a single quarter, which may not capture the extent to which pharmaceutical prices fluctuate within a year. Asthma is a disease that has seasonal tendencies. See http://asthma.about.com/cs/seasonalasthma. Second, and more importantly, we understand that the NPA Plus data measure *total revenues* received by a pharmacy from patients and third-party payers. For example, they include both patient co-payments and insurer payments. As described above, these IMS data measures sales through selected retail channels only. Using the change in retailers' revenues of $23 as a proxy for the increase in cost to patients overstates the cost impact to patients to the extent third-party payers pay a portion of the costs or patient costs are lower through non-retail channels. The estimate in the NPR does not measure the cost impact to patients or third-party payers, but rather the change in revenues to retailers. In contrast to the $23 differential in the analysis presented in the NPR, we found the difference in retail price between brand and generic albuterol MDIs at the retail pharmacy level to be $8.22, $11.68, and $15.54 depending on whether the patient was in the Retail-Cash, Retail-Private Insurance, or Retail-Medicaid subgroup, respectively (SA-2, line E minus line F). As previously described, the NPR relies on this same $23 price differential in its lower bound estimate of the potential reduction in demand by uninsured patients and a distinct price differential obtained from the Internet site http://www.drugstore.com in its upper bound estimate. Neither source provides data representative of prices paid by uninsured patients through retail or non-retail channels. The NPR's estimate of the number of generic albuterol MDI products that would have been sold if the policy change was not implemented is based on an assumption that nothing will change in terms of the competitive environment until generic competition emerges for albuterol HFA MDIs in 2010 or 2015. However, numerous market developments have already occurred such as IVAX's entry into the marketplace with a third albuterol HFA MDI product and manufacturers' commitments to provide samples. Lastly, while the NPR acknowledges manufacturers' commitments (e.g., GSK's commitment to provide 2 million samples), these factors are not incorporated into its estimated potential reduction in demand or cost impact. As a result, the estimates of reduced demand and cost impact in the NPR are overstated.

- Cash-paying patients will pay an average increase of $1.21 per MDI.
- Patients with Medicaid coverage or patients who acquire their MDIs at non-federal hospitals or federal facilities/prisons will incur no increase in costs.
- Patients with private insurance coverage will pay a higher price due to a differential co-payment for brand and generic products of $22 and $10, respectively. On average, they will pay an increase of $6.71 per MDI.[54]
- The cost per MDI for patients who acquire their MDIs at clinics/HMOs/universities (Group 2) will be reduced by $0.10. These patients will benefit since they pay identical co-payments for brand and generic pharmaceutical products and there will be an increased availability of free and discounted MDIs[55] after the policy change.
- Overall, patients will incur an average cost increase of $4.17 per MDI.

Our results for third-party payers are as follows:

- The cost per MDI for the private Insurance Payers in Group 1 will be reduced by $4.58. Insurance Payers will benefit since patients covered by their plans will pay higher average co-payments for brand pharmaceuticals, and some insurance payers will negotiate rebates from the competing manufacturers of albuterol in HFA MDIs, which they do not receive from the current generic manufacturers.
- The costs to other Payers will increase, on average, by $6.15 to $14.19 per MDI.
- Overall, third-party payers will incur an average cost increase of $0.15 per MDI.

The total cost impact on patients and payers in the first year due to the policy change is, on average, $4.32 ($4.17 + $0.15) per MDI. See Exhibit S-1.

[54] The average difference in co-payments for brand and generic pharmaceutical products is $12. Since some patients are already using the brand albuterol, they are already paying the higher co-payment amount. The total cost increase we calculated reflects that these patients will experience no increase in their co-payment for brand albuterol MDIs. It reflects that some of these patients will receive free MDIs (e.g., samples) as well as discounted MDIs (e.g., GSK patient discount coupon).

[55] For example, free and discounted pharmaceutical products will be available through patient assistance programs and patient discount coupons.

Comparing our original analysis with our current analysis incorporating seven recent developments, the cost impact to patients and third-party payers in the first year after the policy change falls from $9.87 per MDI to $4.32 per MDI. See Exhibit S-2. We initially estimated the overall increase in costs to the healthcare system in the first year after the policy change at $494 million.[56] With the seven recent developments, our current estimate of the overall increase in costs is $216 million, a decrease of 56 percent from our original estimate. Additional competition, buyer power, coverage of prescription pharmaceuticals for Medicaid enrollees, public patient assistance programs, and patient discount cards will likely further decrease the impact in the first year. The six million samples manufacturers' have committed to provide through physicians ensure that a patient unable to purchase albuterol MDIs will have access to the product at zero price after the policy change. Our supplemental analysis reinforces adopting a near-term effective date (e.g., December 31, 2005) for removing the essential-use designation for albuterol CFC MDIs as all patients will continue to be adequately served by the albuterol HFA MDIs after the policy change.

[56] NERA Report 1, Exhibit 5.

CHANGE IN ANNUAL COSTS AND COSTS PER MDI TO PATIENTS AND THIRD-PARTY PAYERS

ASSUMES FDA DESIGNATES ALBUTEROL NON-ESSENTIAL AND INCORPORATES SEVEN RECENT DEVELOPMENTS

GROUPS 1 - 4

	Total Costs Current: Before the FDA Policy Change (Dollars) (1)	Total Costs Estimated: After the FDA Policy Change (Dollars) (2)	Change in Annual Costs (Dollars) (2)-(1) (3)	Estimated Annual Unit Sales (Units) (4)	Change in Costs per MDI (Dollars) (3)/(4) (5)
Patients					
Cash	$ 152,306,103	$ 159,076,847	$ 6,770,744	5,579,350	$ 1.21
Medicaid	0	0	0	6,250,550	0.00
Private Insurance	344,212,504	546,176,356	201,963,852	30,120,100	6.71
Clinics/Universities/HMOs	10,750,000	10,535,000	(215,000)	2,150,000	(0.10)
Non-Federal Hospitals	0	0	0	3,000,000	0.00
Federal Facilities/Prisons	0	0	0	2,900,000	0.00
Total:	$ 507,268,607	$ 715,788,203	$ 208,519,596	50,000,000	$ 4.17
Third-Party Payers					
Cash	$ -	$ -	$ -	5,579,350	$ -
Medicaid	121,271,005	159,709,042	38,438,037	6,250,550	6.15
Private Insurance	255,998,819	118,186,049	(137,812,770)	30,120,100	(4.58)
Clinics/Universities/HMOs	2,635,900	26,634,910	23,999,010	2,150,000	11.16
Non-Federal Hospitals	21,914,400	63,886,200	41,971,800	3,000,000	13.99
Federal Facilities/Prisons	9,611,006	50,758,120	41,147,114	2,900,000	14.19
Total:	$ 411,431,130	$ 419,174,321	$ 7,743,191	50,000,000	$ 0.15
		Total:	$ 216,262,787	Total:	$ 4.32

- not applicable
( ) negative

Note: Analysis includes seven recent developments in the marketplace for albuterol: GSK samples, GSK patient discount coupons, Schering samples, Schering MDIs for clinics, IVAX vouchers/samples, manufacturer patient assistance programs, and IVAX price discount.

Source: NERA Appendix Exhibits, SA-1 to SA-6.

COMPARISON OF CHANGE IN COSTS PER MDI TO PATIENTS AND THIRD-PARTY PAYERS[1] IN ORIGINAL ANALYSIS[2] AND SUPPLEMENTAL ANALYSIS[3]

ASSUMES FDA DESIGNATES ALBUTEROL NON-ESSENTIAL

GROUPS 1 - 4

Type of Payer	Change in Costs Per MDI: Original Analysis[2] (Dollars) (1)	Change in Costs Per MDI: Supplemental Analysis[3] (Dollars) (2)	Difference in Cost Impact per MDI (Dollars) (2)-(1) (3)
Patients			
Cash	$ 8.61	$ 1.21	$ (7.40)
Medicaid	0.00	0.00	0.00
Private Insurance	10.57	6.71	(3.86)
Clinics/Universities/HMOs	0.00	(0.10)	(0.10)
Non-Federal Hospitals	0.00	0.00	0.00
Federal Facilities/Prisons	0.00	0.00	0.00
All Patients	7.33	4.17	(3.16)
Third-Party Payers			
Cash	$ -	$ -	$ -
Medicaid	12.47	6.15	(6.32)
Private Insurance	(2.65)	(4.58)	(1.93)
Clinics/Universities/HMOs	17.91	11.16	(6.75)
Non-Federal Hospitals	15.38	13.99	(1.39)
Federal Facilities/Prisons	15.33	14.19	(1.14)
All Third-Party Payers	2.54	0.15	(2.39)
Total (All Patients and All Third-Party Payers):	$ 9.87	$ 4.32	$ (5.55)

- not applicable
( ) negative

[1] Represents cost impact in the first year after albuterol is designated non-essential.

[2] See, “The Impact on Patients and Payers of Designating Albuterol a Non-Essential Use of an Ozone Depleting Substance,” National Economic Research Associates, Inc., September 8, 2003, Exhibit 5.

[3] Supplemental Analysis incorporates seven recent developments in the marketplace for albuterol: GSK samples, GSK patient discount coupons, Schering samples, Schering MDIs for clinics, IVAX vouchers/samples, manufacturer patient assistance programs, and IVAX price discount.

Source: "The Impact on Patients and Payers of Designating Albuterol a Non-Essential Use of an Ozone Depleting Substance," National Economic Research Associates, Inc., September 8, 2003, Exhibit 5; and NERA table, "Change in Annual Costs and Costs per MDI to Patients and Third-Party Payers, Assumes FDA Designates Albuterol Non-Essential and Incorporates Seven Recent Developments, Groups 1-4," Exhibit S-1.

ESTIMATED ANNUAL WHOLESALERS' AND MANUFACTURERS' REVENUES FOR SALES OF BRAND AND GENERIC ALBUTEROL MDIs TO CASH, MEDICAID, AND INSURANCE PAYERS THROUGH GROUP 1 CHANNELS[1]

		Cash Payers (1)	Medicaid Payers (2)	Insurance Payers (3)
A.	Group 1, Total Unit Sales, 2001 - 2002	78,616,000	78,616,000	78,616,000
B.	Groups 1-4, Total Unit Sales, 2001 - 2002	93,720,000	93,720,000	93,720,000
C.	Group 1, Share of Total Unit Sales, 2001 - 2002 (A/B)	83.9 %	83.9 %	83.9 %
D.	Estimated Annual Unit Demand[2]	50,000,000	50,000,000	50,000,000
E.	Group 1, Estimated Annual Unit Sales (CxD)	41,950,000	41,950,000	41,950,000
F.	Share of Group 1 Sales[3]	13.3 %	14.9 %	71.8 %
G.	Estimated Annual Unit Sales (ExF)	5,579,350	6,250,550	30,120,100
H.	Group 1, Share of Unit Sales for Brand Albuterol MDIs, 2001-2002	11.9 %	11.9 %	11.9 %
I.	Group 1, Share of Unit Sales for Generic Albuterol MDIs, 2001-2002	88.1 %	88.1 %	88.1 %
J.	Estimated Annual Brand Unit Sales (GxH)	663,943	743,815	3,584,292
K.	Estimated Annual Generic Unit Sales (GxI)	4,915,407	5,506,735	26,535,808
L.	Group 1, Weighted Average Retailers' Acquisition Costs for Brand Albuterol MDIs, 2001-2002[4]	$ 26.82	$ 26.82	$ 26.82
M.	Group 1, Weighted Average Retailers' Acquisition Costs for Generic Albuterol MDIs, 2001-2002	$ 5.68	$ 5.68	$ 5.68

ESTIMATED ANNUAL WHOLESALERS' AND MANUFACTURERS' REVENUES FOR SALES OF BRAND AND GENERIC ALBUTEROL MDIs TO CASH, MEDICAID, AND INSURANCE PAYERS THROUGH GROUP 1 CHANNELS[1]

		Cash Payers (1)	Medicaid Payers (2)	Insurance Payers (3)
N.	Estimated Annual Wholesalers' Revenues for Brand Albuterol MDIs (JxL)	$ 17,806,951	$ 19,949,118	$ 96,130,711
O.	Estimated Annual Wholesalers' Revenues for Generic Albuterol MDIs (KxM)	$ 27,919,512	$ 31,278,255	$ 150,723,389
P.	Estimated Annual **Wholesalers' Revenues** for Brand and Generic Albuterol MDIs (N+O)	$ 45,726,463	$ 51,227,373	$ 246,854,100
Q.	Estimated Annual Manufacturers' Gross Revenues for Brand Albuterol MDIs (Nx96%)[5]	$ 17,094,673	$ 19,151,153	$ 92,285,483
R.	Estimated Annual Manufacturers' Gross Revenues for Generic Albuterol MDIs (Ox96%)[5]	$ 26,802,732	$ 30,027,125	$ 144,694,453
S.	Estimated Annual **Manufacturers' Gross Revenues** for Brand and Generic Albuterol MDIs (Q+R)	$ 43,897,405	$ 49,178,278	$ 236,979,936
T.	Percentage Manufacturers' Rebates for Brand Albuterol MDIs[6]	- %	30.0 %	15.1 %
U.	Percentage Manufacturers' Rebates for Generic Albuterol MDIs[7]	- %	11.0 %	- %
V.	Annual Manufacturers' Rebates for Brand Albuterol MDIs (QxT)	$ -	$ 5,745,346	$ 13,935,108
W.	Annual Manufacturers' Rebates for Generic Albuterol MDIs (RxU)	$ -	$ 3,302,984	$ -
X.	Annual Manufacturers' Rebates for Brand and Generic Albuterol MDIs (V+W)	$ -	$ 9,048,330	$ 13,935,108

ESTIMATED ANNUAL WHOLESALERS' AND MANUFACTURERS' REVENUES FOR SALES OF BRAND AND GENERIC ALBUTEROL MDIs TO CASH, MEDICAID, AND INSURANCE PAYERS THROUGH GROUP 1 CHANNELS[1]

		Cash Payers (1)	Medicaid Payers (2)	Insurance Payers (3)
Y.	Estimated Annual Manufacturers' Revenues for Brand Albuterol MDIs, Net of Rebates (Q-V)	$ 17,094,673	$ 13,405,807	$ 78,350,375
Z.	Estimated Annual Manufacturers' Revenues for Generic Albuterol MDIs, Net of Rebates (R-W)	$ 26,802,732	$ 26,724,141	$ 144,694,453
AA.	Estimated Annual **Manufacturers' Revenues** for Brand and Generic Albuterol MDIs, **Net of Rebates** (Y+Z)	$ 43,897,405	$ 40,129,948	$ 223,044,828

- not applicable

[1] Group 1 channels include chain stores, independent stores, mail order, food stores, long-term care, home healthcare, and miscellaneous - other.

[2] Based on IMS data analysis of total annual unit sales from 1992 to 2002.

[3] Based on the combined share of total prescription unit sales in 2001 and 2002 of albuterol MDIs to Cash, Medicaid, and Third-Party Payers as reported by Verispan, SPA.

[4] Equal to the sum of the total revenue for brand albuterol MDI products (Ventolin CFC, Ventolin HFA, Proventil CFC, and Proventil HFA) in 2001 and 2002 divided by the sum of the total units sold for brand albuterol MDIs products in 2001 and 2002.

[5] The National Association of Chain Drugs Stores reported that for the average retail prescription cost in 2002, the manufacturer and wholesaler received 75.6% and 3.3% of the cost, respectively. IMS data reported sales at the wholesaler level. Thus, the total IMS wholesaler revenue represents 78.9% (75.6%+3.3%) of the total cost. The revenue due the manufacturer is 96% of the total amount reported by IMS (75.6%/78.9%).

[6] Assumes Cash Payers receive no manufacturer rebates. Rebates to Insurance and Medicaid Payers are based on typical manufacturer rebates for branded product. OBRA 90 provides that manufacturers of branded pharmaceuticals pay a minimum rebate of 15.1% on the wholesale price on branded products dispensed to outpatients covered by Medicaid. Medicaid receives larger rebates if manufacturers offer lower prices to any other purchasers in the U.S.

[7] OBRA 90 provides that manufacturers of generic pharmaceuticals pay a minimum rebate of 11.0% on the wholesale price on generic products dispensed to outpatients covered by Medicaid.

Source: IMS data; Verispan, SPA data; "Industry Statistics, Industry Facts-at-a-Glance, Pharmaceutical Pricing," National Association of Chain Drug Stores, http://www.nacds.org/wmspage.cfm?parm1=507; "Prescription Drugs, Expanding Access to Federal Prices Could Cause Other Changes," U.S. General Accounting Office, GAO/HEHS-00-118, August 2000; and William von Oehsen, "Pharmaceutical Discounts under Federal Law: State Program Opportunities," speech at the National Conference of State Legislatures Fifth Health Policy Conference, November 16, 2001.

ESTIMATED ANNUAL RETAILERS' REVENUES AND COSTS TO PATIENTS AND THIRD-PARTY PAYERS FOR SALES OF BRAND AND GENERIC ALBUTEROL MDIs TO CASH, MEDICAID, AND INSURANCE PAYERS THROUGH GROUP 1 CHANNELS[1]

		Cash Payers (1)	Medicaid Payers (2)	Insurance Payers (3)
A.	Group 1, Weighted Average Retailers' Acquisition Costs for Brand Albuterol MDIs, 2001-2002[2]	$ 26.82	$ 26.82	$ 26.82
B.	Group 1, Weighted Average Retailers' Acquisition Costs for Generic Albuterol MDIs, 2001-2002	$ 5.68	$ 5.68	$ 5.68
C.	Estimated Retailers' Mark-ups on Brand Albuterol MDIs[3]	28.8 %	28.8 %	14.4 %
D.	Estimated Retailers' Mark-ups on Generic Albuterol MDIs[4]	363.3 %	234.5 %	234.5 %
E.	Retail Prices for Brand Albuterol MDIs [A+(AxC)]	$ 34.54	$ 34.54	$ 30.68
F.	Retail Prices for Generic Albuterol MDIs [B+(BxD)]	$ 26.32	$ 19.00	$ 19.00
G.	Estimated Annual Brand Unit Sales	663,943	743,815	3,584,292
H.	Estimated Annual Generic Unit Sales	4,915,407	5,506,735	26,535,808
I.	Estimated Annual Retailers' Revenues for Brand Albuterol MDIs (ExG)	$ 22,932,591	$ 25,691,370	$ 109,966,079
J.	Estimated Annual Retailers' Revenues for Generic Albuterol MDIs (FxH)	$ 129,373,512	$ 104,627,965	$ 504,180,352
K.	Estimated Annual **Retailers' Revenues** for Brand and Generic Albuterol MDIs (I+J)	$ 152,306,103	$ 130,319,335	$ 614,146,431
L.	Annual Manufacturers' Rebates for Brand and Generic Albuterol MDIs	$ -	$ 9,048,330	$ 13,935,108

ESTIMATED ANNUAL RETAILERS' REVENUES AND COSTS TO PATIENTS AND THIRD-PARTY PAYERS FOR SALES OF BRAND AND GENERIC ALBUTEROL MDIs TO CASH, MEDICAID, AND INSURANCE PAYERS THROUGH GROUP 1 CHANNELS[1]

	Cash Payers (1)	Medicaid Payers (2)	Insurance Payers (3)
M. Annual Total Costs borne by Patients and Third-Party Payers (K-L)	$ 152,306,103	$ 121,271,005	$ 600,211,323
N. **Annual Costs to Patients**[5]	$ 152,306,103	$ -	$ 344,212,504
O. **Annual Costs to Third-Party Payers** (M-N)	$ -	$ 121,271,005	$ 255,998,819

- not applicable

[1] Group 1 channels include chain stores, independent stores, mail order, food stores, long-term care, home healthcare, and miscellaneous - other.

[2] Equal to the sum of the total revenue for brand albuterol MDI products (Ventolin CFC, Ventolin HFA, Proventil CFC, and Proventil HFA) in 2001 and 2002 divided by the sum of the total units sold for brand albuterol MDIs products in 2001 and 2002.

[3] Based on the weighted average price for brand albuterol MDIs to chain stores, food stores, and independent stores of $29.99 for the period May 2002 to February 2003, derived from IMS data, and the average retail price of $38.62 for the period May 2002 to April 2003 for the same channels, Verispan, SPA data. The retailer mark-up is equal to the average retail price of $38.62 less the average retail acquisition cost of $29.99, divided by the average retail acquisition cost or 28.8%. We assumed Insurance Payers negotiated a 50% discount on the retailer mark-up.

[4] Based on the weighted average price for generic albuterol MDIs to chain stores, food stores, and independent stores of $4.88 for the period May 2002 to February 2003, derived from IMS data, and the average retail price of $22.61 for the period May 2002 to April 2003 for the same channels, Verispan data. The retailer mark-up is equal to the average retail price of $22.61 less the average retail acquisition cost of $4.88, divided by the average retail acquisition cost or 363.3%. The retailer mark-up to Medicaid of 234.5% is based on a Federal Maximum Allowable Cost or MAC, which includes a dispensing fee of $19. We assumed Insurance Payers negotiated a discount similar to Medicaid.

[5] Assumes patients that are Cash Payers receive no assistance. We understand patients with Medicaid coverage receive pharmaceutical products at no cost. Assumes patients with Insurance Coverage pay a copayment of $22 and $10 for brand and generic albuterol MDIs, respectively, based on the estimated average co-payment in 2003 reported in "Strategic Health Plans Update 2002" by *Health Strategies Group* .

Source: IMS data; Verispan, SPA data; "Strategic Health Plans Update 2002," *Health Strategies Group* ; "Prescription Drugs, Expanding Access to Federal Prices Could Cause Other Changes," U.S. General Accounting Office, GAO/HEHS-00-118, August 2000; William von Oehsen, "Pharmaceutical Discounts under Federal Law: State Program Opportunities," speech at the National Conference of State Legislatures Fifth Health Policy Conference, November 16, 2001; NERA table, "Estimated Annual Wholesalers' and Manufacturers' Revenues for Sales of Brand and Generic Albuterol MDIs Payers through to Cash, Medicaid, and Insurance Group 1 Channels"; and information provided by GSK.

ESTIMATED ANNUAL WHOLESALERS' AND MANUFACTURERS' REVENUES FOR SALES OF BRAND HFA ALBUTEROL MDIs TO CASH, MEDICAID, AND INSURANCE PAYERS THROUGH GROUP 1 CHANNELS[1]

ASSUMES FDA DESIGNATES ALBUTEROL NON-ESSENTIAL AND INCORPORATES SEVEN RECENT DEVELOPMENTS

		Cash Payers (1)	Medicaid Payers (2)	Insurance Payers (3)
A.	Group 1, Total Unit Sales, 2001 - 2002	78,616,000	78,616,000	78,616,000
B.	Groups 1-4, Total Unit Sales, 2001 - 2002	93,720,000	93,720,000	93,720,000
C.	Group 1, Share of Total Unit Sales, 2001 - 2002 (A/B)	83.9 %	83.9 %	83.9 %
D.	Estimated Annual Unit Demand (adjusted for specified free units)[2]	49,000,000	49,000,000	49,000,000
E.	Group 1, Estimated Annual Unit Sales (CxD)	41,111,000	41,111,000	41,111,000
F.	Group 1, Estimated Annual Unit Sales less Samples (E-6,000,000)[3]	35,111,000	35,111,000	35,111,000
G.	Share of Group 1 Sales[4]	13.3 %	14.9 %	71.8 %
H.	Estimated Annual Unit Sales (FxG)	4,669,763	5,231,539	25,209,698
I.	Group 1, Weighted Average Retailers' Acquisition Costs for Brand HFA Albuterol MDIs, 2001-2002, Adjusted for IVAX discount[5]	$ 26.71	$ 26.71	$ 26.71
J.	Estimated Annual **Wholesalers' Revenues** for Brand HFA Albuterol MDIs (HxI)	$ 124,729,370	$ 139,734,407	$ 673,351,034
K.	Estimated Annual **Manufacturers' Gross Revenues** for Brand HFA Albuterol MDIs (Jx96%)[6]	$ 119,740,195	$ 134,145,031	$ 646,416,993
L.	Percentage Manufacturers' Rebates for Brand HFA Albuterol MDIs[7]	- %	15.1 %	15.1 %
M.	Annual Manufacturers' Rebates for Brand HFA Albuterol MDIs (KxL)	$ -	$ 20,255,900	$ 97,608,966
N.	Annual Manufacturers' Patient Discount Coupons[8]	$ 1,563,000	$ -	$ 8,437,000
O.	Estimated Annual **Manufacturers' Revenues** for Brand HFA Albuterol MDIs, **Net of Rebates and Patient Discount Coupons** (K-M-N)	$ 118,177,195	$ 113,889,131	$ 540,371,027

ESTIMATED ANNUAL WHOLESALERS' AND MANUFACTURERS' REVENUES FOR SALES OF BRAND HFA ALBUTEROL MDIs TO CASH, MEDICAID, AND INSURANCE PAYERS THROUGH GROUP 1 CHANNELS[1]

ASSUMES FDA DESIGNATES ALBUTEROL NON-ESSENTIAL AND INCORPORATES SEVEN RECENT DEVELOPMENTS

- not applicable

Note: Shading denotes recent developments in the marketplace for albuterol incorporated into analysis.

[1] Group 1 channels include chain stores, independent stores, mail order, food stores, long-term care, home healthcare, and miscellaneous - other.
[2] Equal to 50,000,000 albuterol MDIs, based on IMS data analysis of total annual unit sales from 1992 to 2002, less 1,000,000 albuterol MDIs provided through GSK, Schering, and IVAX patient assistance programs.
[3] GSK, Schering, and IVAX will each provide 2 million samples of Ventolin HFA, Proventil HFA, and Volare HFA, respectively.
[4] Based on the combined share of total prescription unit sales in 2001 and 2002 of albuterol MDIs to Cash, Medicaid, and Third-Party Payers as reported by Verispan, SPA.
[5] Based on economic literature, assumes IVAX obtains 21% of sales of brand albuterol HFA MDIs. Based on IVAX submission to docket on January 12, 2005, assumes IVAX price equal to $22.30 per HFA MDI (20% discount of weighted average price for brand albuterol HFA MDI products in 2001 to 2002 of $27.88 per MDI). Thus, the average price per HFA MDI is equal to $26.71 (21%x$22.30+79%x$27.88).
[6] The National Association of Chain Drugs Stores reported that for the average retail prescription cost in 2002, the manufacturer and wholesaler received 75.6% and 3.3% of the cost, respectively. IMS data reported sales at the wholesaler level. Thus, the total IMS wholesaler revenue represents 78.9% (75.6%+3.3%) of the total cost. The revenue due the manufacturer is 96% of the total amount reported by IMS (75.6%/78.9%).
[7] Assumes Cash Payers receive no manufacturer rebates. Rebates to Insurance and Medicaid Payers are based on typical manufacturer rebates for branded products. OBRA 90 provides that manufacturers of branded pharmaceuticals pay a minimum rebate of 15.1% on the wholesale price on branded products dispensed to outpatients covered by Medicaid. Medicaid receives larger rebates if manufacturers offer lower prices to any other purchasers in the U.S.
[8] Assumes 1,000,000 GSK patient discount coupons redeemed by Cash and Insurance Payer patients. Share of Brand HFA MDI sales through Cash and Insurance Payers equal to 15.63% (13.3%/(13.3%+71.8%)) and 84.37% (71.8%/(13.3%+71.8%)), respectively. Value of patient discount coupon equal to $10. Thus, Cash Payer patients redeem $1,563,000 (15.63%x1,000,000 MDIsx$10) and Insurance Payer patients redeem $8,437,000 (84.37%x1,000,000 MDIsx$10).

Source: IMS data; Verispan, SPA data; "Industry Statistics, Industry Facts-at-a-Glance, Pharmaceutical Pricing," National Association of Chain Drug Stores, http://www.nacds.org/wmspage.cfm?parm1=507; "Prescription Drugs, Expanding Access to Federal Prices Could Cause Other Changes," U.S. General Accounting Office, GAO/HEHS-00-118, August 2000; William von Oehsen, "Pharmaceutical Discounts under Federal Law: State Program Opportunities," speech at the National Conference of State Legislatures Fifth Health Policy Conference, November 16, 2001; "Re: Docket No. 03P-0029, Notice of Proposed Rule: Use of Ozone-Depleting Substances; Removal of Essential-Use Designations," GSK, August 25, 2004, pp. 5-8; "Re: Docket No. 2003-0029, Use of Ozone-Depleting Substances; Removal of Essential-Use Designation," IVAX Research, Inc., January 12, 2005, pp. 5-7; Daniel Haines, Rajan Chandran, and Arvind Parkhe, "Winning by Being the First to Marketing…or Second?," *The Journal of Consumer Marketing* , Vol. 6, No. 1, Winter 1989, p. 64; and "Re: Docket No.: 2003P-0029, Use of Ozone-Depleting Substance; Removal of Essential-Use Designations," Schering Corporation, January 28, 2005, p. 3.

ESTIMATED ANNUAL RETAILERS' REVENUES AND COSTS TO PATIENTS AND THIRD-PARTY PAYERS FOR SALES OF BRAND HFA ALBUTEROL MDIs TO CASH, MEDICAID, AND INSURANCE PAYERS THROUGH GROUP 1 CHANNELS[1]

ASSUMES FDA DESIGNATES ALBUTEROL NON-ESSENTIAL AND INCORPORATES SEVEN RECENT DEVELOPMENTS

		Cash Payers (1)	Medicaid Payers (2)	Insurance Payers (3)
A.	Group 1, Weighted Average Retailers' Acquisition Costs for Brand HFA Albuterol MDIs, 2001-2002, Adjusted for IVAX discount	$ 26.71	$ 26.71	$ 26.71
B.	Estimated Retailers' Mark-ups on Brand HFA Albuterol MDIs[2]	28.8 %	28.8 %	14.4 %
C.	Retail Prices for Brand HFA Albuterol MDIs [A+(AxB)]	$ 34.40	$ 34.40	$ 30.56
D.	Estimated Annual Unit Sales	4,669,763	5,231,539	25,209,698
E.	Estimated Annual **Retailers' Revenues** for Brand HFA Albuterol MDIs (CxD)	$ 160,639,847	$ 179,964,942	$ 770,408,371
F.	Annual Manufacturers' Rebates for Brand HFA Albuterol MDIs	$ -	$ 20,255,900	$ 97,608,966
G.	Annual Total Costs borne by Patients and Third-Party Payers (E-F)	$ 160,639,847	$ 159,709,042	$ 672,799,405
H.	Annual Costs to Patients[3]	$ 160,639,847	$ -	$ 554,613,356
I.	Annual Manufacturers' Patient Discount Coupons	$ 1,563,000	$ -	$ 8,437,000
J.	**Annual Costs to Patients, Net of Patient Discount Coupons** (H-I)	$ 159,076,847	$ -	$ 546,176,356
K.	**Annual Costs to Third-Party Payers** (G-H)	$ -	$ 159,709,042	$ 118,186,049

- not applicable

Note: Shading denotes recent developments in the marketplace for albuterol incorporated into analysis.

ESTIMATED ANNUAL RETAILERS' REVENUES AND COSTS TO PATIENTS AND THIRD-PARTY PAYERS FOR SALES OF BRAND HFA ALBUTEROL MDIs TO CASH, MEDICAID, AND INSURANCE PAYERS THROUGH GROUP 1 CHANNELS[1]

ASSUMES FDA DESIGNATES ALBUTEROL NON-ESSENTIAL AND INCORPORATES SEVEN RECENT DEVELOPMENTS

[1] Group 1 channels include chain stores, independent stores, mail order, food stores, long-term care, home healthcare, and miscellaneous - other.

[2] Based on the weighted average price for brand albuterol MDIs to chain stores, food stores, and independent stores of $29.99 for the period May 2002 to February 2003, derived from IMS data, and the average retail price of $38.62 for the period May 2002 to April 2003 for the same channels, Verispan, SPA data. The retailer mark-up is equal to the average retail price of $38.62 less the average retail acquisition cost of $29.99, divided by the average retail acquisition cost or 28.8%. We assumed Insurance Payers negotiated a 50% discount on the retailer mark-up.

[3] Assumes patients that are Cash Payers receive no assistance. We understand patients with Medicaid coverage receive pharmaceutical products at no cost. Assumes patients with Insurance Coverage pay a co-payment of $22 for brand HFA albuterol MDIs, based on the estimated average co-payment in 2003 reported in “Strategic Health Plans Update 2002” by *Health Strategies Group* .

Source: IMS data; Verispan, SPA data; “Strategic Health Plans Update 2002,” *Health Strategies Group* ; and NERA table, "Estimated Annual Wholesalers' and Manufacturers' Revenues for Sales of Brand HFA Albuterol MDIs to Cash, Medicaid, and Insurance Payers through Group 1 Channels, Assumes FDA Designates Albuterol Non-Essential and Incorporates Seven Recent Developments."

ESTIMATED ANNUAL WHOLESALERS' AND MANUFACTURERS' REVENUES AND COSTS TO PATIENTS AND THIRD-PARTY PAYERS FOR SALES OF BRAND AND GENERIC ALBUTEROL MDIs THROUGH GROUPS 2, 3, AND 4[1]

		Group 2 (1)	Group 3 (2)	Group 4 (3)
A.	Total Unit Sales, 2001 - 2002	4,046,000	5,633,000	5,425,000
B.	Groups 1-4, Total Unit Sales, 2001 - 2002	93,720,000	93,720,000	93,720,000
C.	Share of Total Unit Sales, 2001 - 2002 (A/B)	4.3 %	6.0 %	5.8 %
D.	Estimated Annual Unit Demand[2]	50,000,000	50,000,000	50,000,000
E.	Estimated Annual Unit Sales (CxD)	2,150,000	3,000,000	2,900,000
F.	Share of Unit Sales for Brand Albuterol MDIs, 2001-2002	26.0 %	48.0 %	20.1 %
G.	Share of Unit Sales for Generic Albuterol MDIs, 2001-2002	74.0 %	52.0 %	79.9 %
H.	Estimated Annual Brand Unit Sales (ExF)	559,000	1,440,000	582,900
I.	Estimated Annual Generic Unit Sales (ExG)	1,591,000	1,560,000	2,317,100
J.	Weighted Average Acquisition Costs for Brand Albuterol MDIs, 2001-2002[3]	$ 14.44	$ 10.04	$ 8.22
K.	Weighted Average Acquisition Costs for Generic Albuterol MDIs, 2001-2002	$ 3.34	$ 4.78	$ 2.08
L.	Estimated Annual Wholesalers' Revenues for Brand Albuterol MDIs (HxJ)	$ 8,071,960	$ 14,457,600	$ 4,791,438
M.	Estimated Annual Wholesalers' Revenues for Generic Albuterol MDIs (IxK)	$ 5,313,940	$ 7,456,800	$ 4,819,568
N.	Estimated Annual **Wholesalers' Revenues** for Brand and Generic Albuterol MDIs (L+M)	$ 13,385,900	$ 21,914,400	$ 9,611,006

ESTIMATED ANNUAL WHOLESALERS' AND MANUFACTURERS' REVENUES AND COSTS TO PATIENTS AND THIRD-PARTY PAYERS FOR SALES OF BRAND AND GENERIC ALBUTEROL MDIs THROUGH GROUPS 2, 3, AND 4[1]

		Group 2 (1)	Group 3 (2)	Group 4 (3)
O.	Estimated Annual Manufacturers' Revenues for Brand Albuterol MDIs (Lx96%)[4]	$ 7,749,082	$ 13,879,296	$ 4,599,780
P.	Estimated Annual Manufacturers' Revenues for Generic Albuterol MDIs (Mx96%)[4]	$ 5,101,382	$ 7,158,528	$ 4,626,785
Q.	Estimated Annual **Manufacturers' Revenues** for Brand and Generic Albuterol MDIs (O+P)	$ 12,850,464	$ 21,037,824	$ 9,226,565
R.	**Annual Costs to Patients**[5]	$ 10,750,000	$ -	$ -
S.	**Annual Costs to Third-Party Payers** (N-R)	$ 2,635,900	$ 21,914,400	$ 9,611,006

- not applicable

[1] Group 2 channels include clinics, HMOs, and universities; Group 3 channels include non-federal hospitals; and Group 4 channels include federal facilities and prisons.

[2] Based on IMS data analysis of total annual unit sales from 1992 to 2002.

[3] Equal to the sum of the total revenue for brand albuterol MDI products (Ventolin CFC, Ventolin HFA, Proventil CFC, and Proventil HFA) in 2001 and 2002 divided by the sum of the total units sold for brand albuterol MDIs products in 2001 and 2002 for each Group.

[4] The National Association of Chain Drugs Stores reported that for the average retail prescription cost in 2002, the manufacturer and wholesaler received 75.6% and 3.3% of the cost, respectively. IMS data reported sales at the wholesaler level. Thus, the total IMS wholesaler revenue represents 78.9% (75.6%+3.3%) of the total cost. The revenue due the manufacturer is 96% of the total amount reported by IMS (75.6%/78.9%).

[5] Assumes patients through Group 2 channels pay a co-payment of $5 for brand and generic albuterol MDIs. Assumes patients who obtain products through Group 3 and 4 channels receive albuterol MDIs at no cost.

Source: IMS data; "Industry Statistics, Industry Facts-at-a-Glance, Pharmaceutical Pricing," National Association of Chain Drug Stores, http://www.nacds.org/wmspage.cfm?parm1=507; and information provided by GSK.

ESTIMATED ANNUAL WHOLESALERS' AND MANUFACTURERS' REVENUES AND COSTS TO PATIENTS AND THIRD-PARTY PAYERS FOR SALES OF BRAND HFA ALBUTEROL MDIs THROUGH GROUPS 2, 3, AND 4[1]

ASSUMES FDA DESIGNATES ALBUTEROL NON-ESSENTIAL AND INCORPORATES SEVEN RECENT DEVELOPMENTS

		Group 2 (1)	Group 3 (2)	Group 4 (3)
A.	Total Unit Sales, 2001 - 2002	4,046,000	5,633,000	5,425,000
B.	Groups 1-4, Total Unit Sales, 2001 - 2002	93,720,000	93,720,000	93,720,000
C.	Share of Total Unit Sales, 2001 - 2002 (A/B)	4.3 %	6.0 %	5.8 %
D.	Estimated Annual Unit Demand (adjusted for specified free units)[2]	49,000,000	49,000,000	49,000,000
E.	Estimated Annual Unit Sales (CxD)	2,107,000	2,940,000	2,842,000
F.	Free Units to Clinics[3]	500,000	-	-
G.	Estimated Annual Unit Sales less Free Units to Clinics (E-F)	1,607,000	2,940,000	2,842,000
H.	Weighted Average Acquisition Costs for Brand HFA Albuterol MDIs, 2001-2002, Adjusted for IVAX discount[4]	$ 23.13	$ 21.73	$ 17.86
I.	Estimated Annual **Wholesalers' Revenues** for Brand HFA Albuterol MDIs (GxH)	$ 37,169,910	$ 63,886,200	$ 50,758,120
J.	Estimated Annual **Manufacturers' Revenues** for Brand HFA Albuterol MDIs (Ix96%)[5]	$ 35,683,114	$ 61,330,752	$ 48,727,795
K.	**Annual Costs to Patients**[6]	$ 10,535,000	$ -	$ -
L.	**Annual Costs to Third-Party Payers** (I-K)	$ 26,634,910	$ 63,886,200	$ 50,758,120

- not applicable

Note: Shading denotes recent developments in the marketplace for albuterol incorporated into analysis.

ESTIMATED ANNUAL WHOLESALERS' AND MANUFACTURERS' REVENUES AND COSTS TO PATIENTS AND THIRD-PARTY PAYERS FOR SALES OF BRAND HFA ALBUTEROL MDIs THROUGH GROUPS 2, 3, AND 4[1]

ASSUMES FDA DESIGNATES ALBUTEROL NON-ESSENTIAL AND INCORPORATES SEVEN RECENT DEVELOPMENTS

[1] Group 2 channels include clinics, HMOs, and universities; Group 3 channels include non-federal hospitals; and Group 4 channels include federal facilities and prisons.

[2] Equal to 50,000,000 albuterol MDIs, based on IMS data analysis of total annual unit sales from 1992 to 2002, less 1,000,000 brand albuterol HFA MDIs provided through GSK, Schering, and IVAX patient assistance programs.

[3] Represents 500,000 Proventil HFA MDIs provided by Schering to Community Health Centers (clinics).

[4] Based on economic literature, assumes IVAX obtains 21% of sales of brand albuterol HFA MDIs. Based on IVAX submission to docket on January 12, 2005, assumes IVAX price to Group 2, Group 3, and Group 4 equal to $19.31, $18.14,and $14.91, respectively per HFA MDI (20% discount of weighted average price for brand albuterol HFA MDI products in 2001 to 2002 to Group 2, Group 3, and Group 4 of $24.14, $22.68, and $18.64, respectively, per MDI). Thus, the average price per HFA MDI to Group 2, Group 3, and Group 4 is equal to $23.13 (21%x$19.31+79%x$24.14), $21.73 (21%x$18.14+79%x$22.68), and $17.86 (21%x$14.91+79%x$18.64), respectively.

[5] The National Association of Chain Drugs Stores reports that for the average retail prescription cost in 2002, the manufacturer and wholesaler received 75.6% and 3.3% of the cost, respectively. IMS data reports sales at the wholesaler level. Thus, the total IMS wholesaler revenue represents 78.9% (75.6%+3.3%) of the total cost. The revenue due the manufacturer is 96% of the total amount reported by IMS (75.6%/78.9%).

[6] Assumes patients who obtain pharmaceutical products through Group 2 channels pay a co-payment of $5 for brand albuterol HFA MDIs, including the 500,000 free units provided to clinics. Therefore, annual costs to patients equals $10,535,000 (2,107,000x$5).
Assumes patients who obtain products through Group 3 and 4 channels continue to receive albuterol MDIs at no cost.

Source: IMS data; "Industry Statistics, Industry Facts-at-a-Glance, Pharmaceutical Pricing," National Association of Chain Drug Stores, http://www.nacds.org/wmspage.cfm?parm1=507; information provided by GSK; “Re: Docket No. 03P-0029, Notice of Proposed Rule: Use of Ozone-Depleting Substances; Removal of Essential-Use Designations,” GSK, August 25, 2004, pp. 5-8; “Re: Docket No. 2003-0029, Use of Ozone-Depleting Substances; Removal of Essential-Use Designation,” IVAX Research, Inc., January 12, 2005, pp. 5-7; Daniel Haines, Rajan Chandran, and Arvind Parkhe, “Winning by Being the First to Marketing…or Second?,” *The Journal of Consumer Marketing* , Vol. 6, No. 1, Winter 1989, p. 64; and “Re: Docket No.: 2003P-0029, Use of Ozone-Depleting Substance; Removal of Essential-Use Designations,” Schering Corporation, January 28, 2005, p. 2-3.