

Asthma Therapy Coalition

December 6, 2004

Via Hand Delivery

Division of Dockets Management
U.S. Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852
ATTN: Docket No. 2003P-0029

Re: Follow-up to Comments on the Proposed Rule Regarding Use of Ozone-Depleting Substances; Removal of Essential-Use Designation

To Whom It May Concern:

The Asthma Therapy Coalition ("ATC") respectfully submits this statement in follow up to the comments that it submitted on August 16, 2004 in response to the U.S. Food and Drug Administration's ("FDA") Proposed Rule, 69 Fed. Reg. 33602 (June 16, 2004), which would remove chlorofluorocarbon ("CFC")-containing albuterol metered-dose inhalers ("MDIs") from the list of products deemed to be an "essential use" under the Federal Clean Air Act. This rule would effectively ban CFC albuterol MDIs from the U.S. market place.

ATC submits this statement in response to the limited number of other comments submitted to Docket No. 2003P-0029 that are consistent with ATC's position on this critical public health issue. The fact that so few stakeholders voiced concerns about the devastating economic and public health impact of a premature phase-out is likely attributable to the overall lack of funding on the part of those who will be most profoundly impacted by the rule. Further, since the closure of FDA's comment period (*i.e.*, August 16, 2004), the Centers for Medicare and Medicaid Services ("CMS") finalized a rule regarding its Medicare payment policies for calendar year ("CY") 2005, 69 Fed. Reg. 66,235 (Nov. 15, 2004). It is critical that FDA consider the additional impact of CMS's rule on the cost impact of its own rule before finalizing it. ATC submits this statement in an effort to ensure that the Agency has adequate information regarding the economic impact of the rule that will allow it to make a fully reasoned decision.

I. ECONOMIC IMPACT OF TRANSITION

The transition from a U.S. market place where less expensive generic (*i.e.*, multi-source CFC-containing) albuterol MDIs are available to one where only branded (*i.e.*, HFA-containing) albuterol MDIs are available will inevitably have the following effects: (1) an increase in the average amount spent on MDIs by both patients and third party payers; (2) a decrease in the demand for MDIs due to the lack of less expensive alternatives to branded MDIs; (3) a shift of some demand to patient assistance programs like Bridges to Access and free samples from

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GlaxoSmithKline ("GSK"); and (4) an increase in the number of emergency department ("ED") visits and hospital admissions in response to a decrease in the use of albuterol MDIs.

These potentially devastating effects are reflected in ATC's economic analysis of the financial impact of FDA's proposed transition to CFC-free albuterol MDIs. Overall, a transition away from CFC-containing generic albuterol MDIs would impose a cost to the American health care system of at least *\$1.4 billion for every year that multiple generic substitutes are not yet able to re-enter the U.S. market.*

A. Economic Analysis

ATC's economic analysis begins with a projection of the U.S. population by age using a 1.0% annual growth rate, which is consistent with recent demographic trends. Using asthma incidence rates for these age groups, the asthmatic population is separated from the entire population.¹ Each of these groups is segmented further based on health insurance profiles.² **Appendix 1** shows the profile of each patient group used in this segmentation as well as a graphical comparison of insurance type by age group. Each asthma sufferer is assumed to use 2.5 MDIs each year.³

Using pay profiles (**Appendix 2**) for each segment, the total annual cost to both patients and third party payers for albuterol MDIs is calculated for each year until 2015 (*i.e.*, using 2015 as the predicted year that generic HFA-containing MDIs may be able to re-enter the U.S. marketplace). Due to the elastic effect of albuterol consumption that occurs as price increases,⁴ a meaningful analysis here requires an additional medical care component. When asthma sufferers stop taking their medications, their symptoms do not simply disappear. Instead, asthma attacks may lead to patients to seek primary care in EDs and, in some cases, may lead to hospital admissions, both costly adverse effects. See **Appendix 3** for a summary of these effects.

The annual cost is determined for two scenarios: (1) in a market place where both generic and branded albuterol MDIs are available and thus provide an opportunity for price competition;⁵ and (2) in a market where a barrier to entry exists for generic albuterol MDIs.⁶ The difference between these scenarios for any given year represents the increase in total healthcare costs that would be incurred if the transition occurred in that year. These costs reflect the increase in drug payments by patients and payers, effects of price elasticity resulting in a greater number of ED and hospital stays, and cost reductions due to prescription drug assistance programs (*i.e.*, GSK's Bridges to Access and two million free samples).⁷ A time series comparison allows for an accounting of the trends in asthma cases that show an increase in

¹ American Lung Association, *Trends in Asthma Morbidity and Mortality* (Apr. 2004).

² U.S. Census Bureau, *Health Insurance Coverage in the United States: 2002* (Sept. 2003).

³ COPD and other respiratory disorders for which albuterol is prescribed were not considered.

⁴ This refers to 15% elasticity when co-payments double. Goldman, et al, *JAMA* (May 19, 2004).

⁵ This assumes 90% generic penetration.

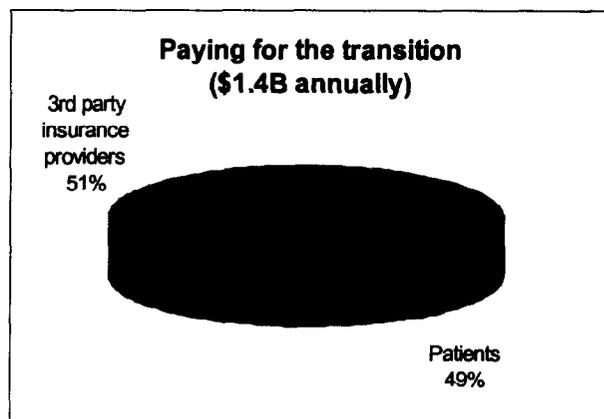
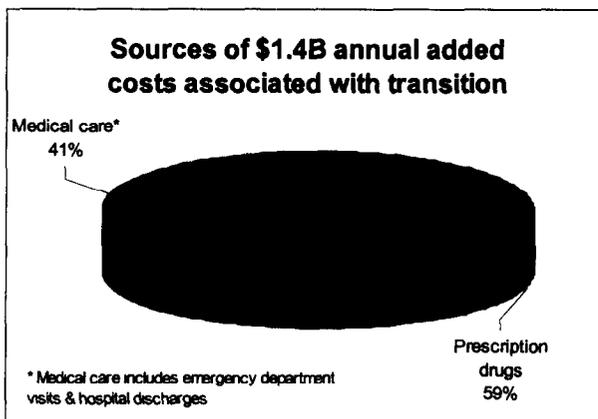
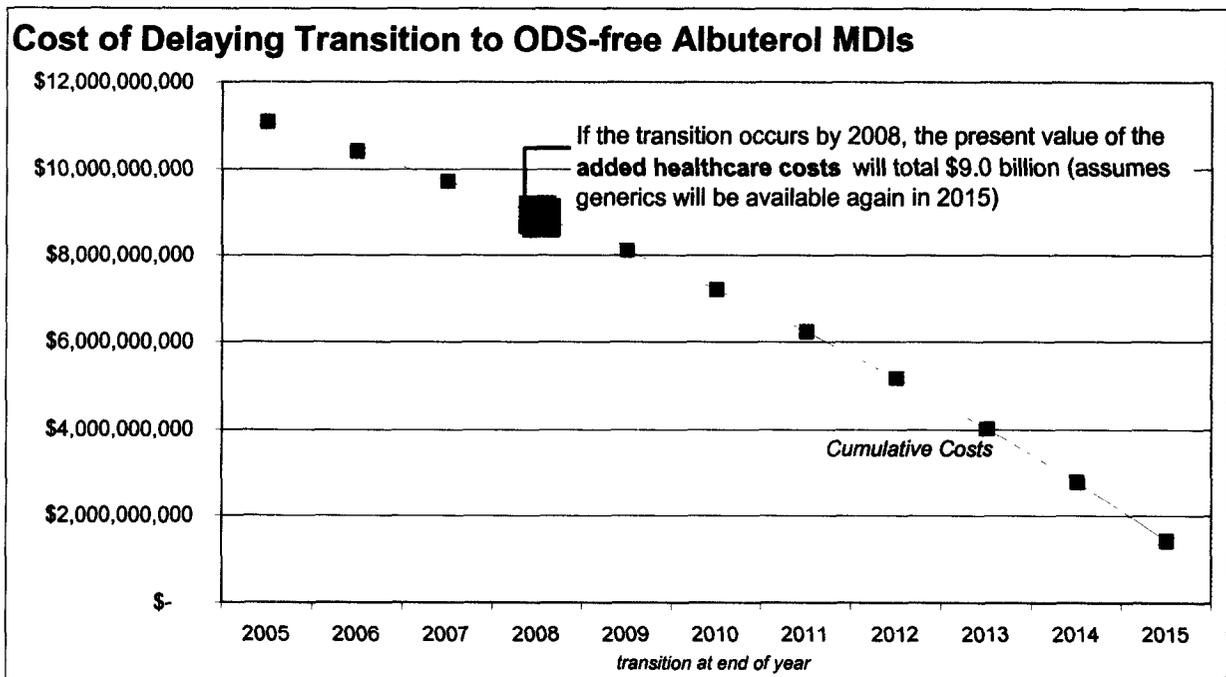
⁶ In this environment, it was assumed that Proventil[®] HFA and Ventolin[®] HFA each have 50% market share and that Ventolin HFA users must consume 4 MDIs per year based on product label instructions. Proventil HFA users continue to use 2.5 MDIs per year.

⁷ GSK previously disclosed that nearly 18,000 asthmatics were receiving Ventolin[™] HFA through Bridges to Access. It was assumed that annual enrollment of Ventolin[™] HFA users increases 25% annually, based on a growing need among low-income patients as healthcare costs increase. Because GSK is not able to ensure that the two million free MDIs will be distributed among those who need it most, we assume that they are distributed proportionately across all insurance groups, *i.e.*, 70% to private insurance holders, 15% to the uninsured, etc.

asthma prevalence where previous analyses had failed to do so.⁸ As shown in the graph below, this approach provides a simple reference for determining the cumulative cost if a transition were to occur during any given year between 2006 and 2015.⁹

A reasonable delay in the phase-out of CFC albuterol MDIs will achieve both greater savings to the U.S. health care system and provide health benefits. The costs represented in the graphs below include those related to prescription drugs for patients and payers, ED and hospital discharges.

As stated above, ATC estimates that *the transition from CFC-containing albuterol MDIs would cost at least \$1.4 billion for each year that no generic substitute product is available.* Even taking the position that IVAX Laboratories, Inc. ("IVAX") new HFA albuterol product will be priced at 30% of the cost of true branded products once it enters the market (discussed below), historical experience suggests that multiple generics are necessary to truly provide affordable access.



⁸ Increases in asthma cases in this study result from using static prevalence rates with an increasing population size.

B. Effect of IVAX's Entry into Market

ATC is aware that FDA recently approved IVAX's HFA albuterol inhaler (NDA No. 021457). However, the product is not yet available in the U.S. market and it is not clear when it will actually enter the market. Regardless of the price point for IVAX's product, based on the "BX" rating for the product in FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"), it will be marketed as a *branded* product that will not be substitutable for prescriptions written for Ventolin[®] HFA or Proventil[®] HFA. Therefore, this approval does not create a true multi-source albuterol MDI market in the sense that multi-sourced generic drugs have the effect of driving prices down. In contrast, with an Orange Book rating of "AB", the product would be substitutable, which would help reduce costs.¹⁰

IVAX will be forced to rely on its sales force and marketing strategy to gain market share. The battle between brands is fought on loyalty, experience, features and benefits, not price. Moreover, ATC estimates that the combined sales force and marketing budget of Schering-Plough and GSK are significantly larger than those of IVAX, making IVAX's ability to penetrate the market difficult.

Further, ATC reminds FDA that Neil Flanzraich, Vice Chairman and President of IVAX, addressed its marketing plans during a shareholder's meeting on June 13, 2003: "We will be one of a very few number of players in a very large and important market. We think we are going to capture the largest part of what will then be a \$2 billion market, and that is not too far away". Clearly, IVAX is viewing this product at a \$40 per inhaler (i.e., 50 million inhalers at \$40 per = \$2 billion) price point rather than as a lower-cost generic-like product that will be accessible to lower-income asthma and COPD sufferers. This means that: (1) for insured asthma patients, the co-pay will be equivalent to that of other branded products on the market; and (2) for uninsured asthma patients, the out-of-pocket costs are likely to remain a barrier to access. Further, GSK has stated that its price will remain frozen for the next few years. One would expect Schering-Plough and IVAX to price at that same level. An IVAX price that is significantly less than that of GSK would leave money on the table because, again, the competition for market share is expected to be about features and benefits, not price.

Moreover, IVAX stated to FDA prior to the close of the comment period that it would provide information to the Agency regarding its own patient assistance programs and plans to distribute free samples. By virtue of offering these programs, ATC can only believe that IVAX's albuterol HFA product will be a branded product offered at a branded price. If IVAX's commitment to affordable medicine did not warrant such programs previously, ATC is concerned that IVAX's albuterol HFA will not be as affordable as they are portraying it to be. Yet, to the best of ATC's knowledge to date, no public information about these programs has been released.

⁹ A discount rate of 7% was used, based upon the rate chosen by FDA in its own calculations.

¹⁰ Under the Social Security Act, a "multiple source drug" is defined as a covered outpatient drug for which there are two or more drug products that: (1) are rated as therapeutically equivalent; (2) are rated as pharmaceutically equivalent and bioequivalent; and (3) are sold or marketed in the State during the period.

II. PATIENT ASSISTANCE PROGRAMS

Inclusion of prescription drug assistance programs, namely GSK's Bridges to Access, into ATC's economic analysis offsets patient costs of the transition by up to \$6 million by 2010 *assuming* the sponsors of these programs grow enrollment annually by 25%.

A. Limitations of Patient Assistance Programs

Despite the availability of assistance programs, ATC is concerned about the reality that the patients who need most to rely on them neither have Internet access nor the opportunity to sit down with their providers and find out how to avail themselves of these programs. This may be attributable to the use of passive approaches to promoting these programs. For example, in its comments to this docket, GSK provided FDA with a list of "steps to make patients, physicians and other health care providers aware of Bridges to Access." This awareness effort relies on patients accessing the program website, Customer Resource Center ("CRC") and/or having discussions with informed healthcare providers. However, patient assistance programs that provide free or discounted sources of prescription medication are valuable only to the extent that the patients they are intended to serve have the opportunity to engage in meaningful dialogue with their physicians about treatment options and the availability of medications. As we explain further, outreach efforts such as GSK's are misdirected.

Inadequate dialogue with patients: A recent study demonstrated that 67% of patients with chronic diseases failed to inform their own practitioners of plans to reduce their medication use due to cost constraints.¹² This study further showed that these patients were rarely prompted by a practitioner on the issue of drug affordability and therefore perceived that the practitioner was unable to offer assistance¹³. The reality of a communication disconnect between patients and their own health care providers raises serious concerns as to the potentially life-saving effectiveness that these programs could have, especially as the healthcare provider is the patient's link to these programs.

Neediest patients lack Internet access: Internet access amongst low-income families lags significantly behind that of more affluent Americans. According to the National Telecommunications and Information Administration, 75% of individuals in the U.S. with a household income less than \$15,000 and 67% of individuals with a household income between \$15,000 and \$24,000 *do not use the Internet*.¹⁴ This is a disconcerting communication disconnect – information about assistance programs is web-based while those who need this information lack access to the web.

¹¹ Piette, John D., *Cost-Related Medication Underuse – Do Patients With Chronic Illnesses Tell their Doctors*. Archives of Internal Medicine, Vol. 164, at 1449-1755 (Sept. 13, 2004).

¹² *Id.*

¹³ *Id.*

¹⁴ U.S. Department of Commerce, Economics and Statistics Administration, National Telecommunications and Information Administration, *A Nation On-Line: How Americans Are Expanding the Use of the Internet* (Feb. 2002).

Toll-free numbers and sales force are misdirected: Although it is technically true that a patient without Internet access could use the CRC toll-free telephone number, the patient would actually have to know about the toll-free number. Perhaps that number is listed on the information cards that GSK's field representatives distribute to clinicians, but only to those located in the sales representatives' territories and to those who specifically request the information. However, GSK has explained that its sales representatives will distribute free samples in territories that "may" (*i.e.*, incidentally) include lower-income areas. Therefore, for the most part, representatives are not sending information to patients directly, but rather shifting the burden to the Internet and physicians to promote it.

It is ATC's understanding that GSK's promotional efforts do not include direct patient outreach to proactively encourage the enrollment of those who most need assistance. ATC concedes that it is not necessarily the obligation of a pharmaceutical company to proactively promote free access programs. However, while GSK is essentially promoting its program to FDA as a means to convince the Agency to finalize the rulemaking in accordance with its business interests, the company is failing to market this program in a way that is appropriately targeted to the populations about which the Agency is most concerned. This is hypocrisy. To claim that patient assistance programs, by mere virtue of their existence and ostensible marketing efforts, will respond meaningfully to the problem of patient access to affordable therapy pays nothing more than lip service to a potential public health crisis.

While GSK has boasted to FDA that it "already has in place effective patient assistance programs," hundreds of thousands of asthma and COPD sufferers are not being reached. ATC refers the Agency to its August 16, 2004 submission to this docket, which further analyzes the penetration of Bridges to Access in uninsured populations.

B. Limitations of Free Samples

Piette's study (discussed above) attributes an increase in medication costs to the distribution by pharmaceutical companies of free product samples.

Free sample programs reflect perverse incentives: The marketing rationale is that these programs encourage patients to switch to more expensive treatment regimens. The consumer loyalty that free samples induce makes a subsequent switch from branded drugs to less expensive generics more difficult.¹⁷ Piette suggests that samples actually exacerbate the problem of cost-related medication underuse and urges providers to remain vigilant when using free samples by balancing patients' short-term benefits against the long-term consequences.¹⁸

Receipt of free samples necessitates doctor visits: A strong association between the number of office visits and the receipt of free samples has been identified. When the number of annual physician visits by a patient increases from 1 to 5, the likelihood of the patient receiving

¹⁵ *Id.*

¹⁶ *Id.*

¹⁷ Taira, Deborah A. *Prescription Drugs: Elderly Enrollee Reports of Financial Access, Receipt of Free Samples, and Discussion of Generic Equivalents Related to Type of Coverage*. The American Journal of Managed Care. Vol. 9(4):305-312 (Apr. 2003) (basing study on the behavior of elderly patients who have health insurance).

¹⁸ US Department of Commerce (Feb. 2002).

free samples of prescription drugs increases from 0.52 to 0.72.¹⁹ Therefore, multiple visits to the doctor are necessary for a patient to maintain a continuous supply of free inhalers.

However, according to the Urban Institute, uninsured children are more likely to lack a regular source of medical care. Among those reporting a regular source of care, children without health insurance are instead more likely to seek care via a hospital ED.²⁰ Further, 1 out of 4 uninsured children with asthma experience unmet medical needs, at quintuple the rate of children who have health insurance.²¹ Clearly, there is a significant gap in the ability of the current U.S. health care system to provide free drug samples to those in need because they do not make regular visits to the doctor.

The supply of free inhalers is inadequate: There are nearly 800,000 asthmatic children under the age of 18 in the U.S. without health insurance.²² Providing every asthmatic child who has unmet needs with an annual supply of albuterol MDIs would require more than 3 million MDIs each year. According to its label, GSK's Ventolin™ HFA must be discarded three months after opening the package so that every patient would require at least 4 inhalers each year, regardless of how many doses are actually used. Therefore, 2 million free MDI samples could, at the very most, provide 500,000 patients with the albuterol they need for a year. ATC reiterates that the samples would be distributed by GSK sales representatives whose territories "may" include low-income areas. This provides little assurance that those who are in dire need of the free samples the most would actually receive them. One can only assume that these samples will be distributed proportionately among asthmatics who have various insurance coverage. Thus, only 15% of the 2 million inhalers will end up in the hands of those who really need them – 75,000 uninsured patients.

The most recent program proposed to assist the CFC transition is a GSK coupon for Ventolin™ HFA. Again, although GSK's efforts to provide assistance are commendable, the effectiveness and intent of such a program is suspect. Of the 3 million \$10 coupons to be distributed, 2 million will be enclosed with GSK's free samples. In light of the skepticism regarding the effectiveness of the free samples and the fact that this new program piggy-backs on that program, it seems unlikely that those who need the coupons the most will actually receive them. Further, even if they do, a \$10 discount may not provide a sufficient subsidy to keep albuterol affordable enough. Ultimately, the coupons provide a promotional tool designed to augment sales and create brand loyalty. An early incentive to attract patients to use Ventolin™ HFA will provide more for GSK's long-term bottom line (*i.e.*, measured in terms of market share and revenue) compared to the short-term benefits that low-income patients will enjoy.

¹⁹ Taira, Deborah A. *Prescription Drugs: Elderly Enrollee Reports of Financial Access, Receipt of Free Samples, and Discussion of Generic Equivalents Related to Type of Coverage*, *The American Journal of Managed Care.*, Vol. 9(4):305-312 (Apr. 2003).

²⁰ The Urban Institute, *Key Findings from the 2002 National Health Interview Survey - Access to Care among Uninsured and Insured Children: Well-Child Checkups, Usual Source of Care and Unmet Needs* (Aug. 2004).

²¹ *Id.*

²² American Lung Association, Epidemiology & Statistics Unit, Research and Scientific Affairs, (Apr. 2004); U.S. Census Bureau, *Health Insurance Coverage in the United States: 2002* (Sept. 2003).

C. The "Teachable Moment" is a Myth

Generic albuterol MDIs do not need to be removed from the market prematurely in order to promote appropriate asthma management. As Dr. Anthony Marinelli of the American Thoracic Society suggested at the Pulmonary-Allergy Drugs Advisory Committee ("PADAC") meeting on June 10, 2004, "I think our goal in the transition process is use the switch as a *teachable moment* to review and hopefully improve the care of patients with asthma. Delisting CFC albuterol will provide clinicians and patients alike an opportunity to review and improve their asthma-care plan."

However, this logic leads to a fallacy. Improving patient treatment plans should be an ongoing effort and a priority of the U.S. Stakeholders Group, regardless of whether the patient can choose between Ventolin™ HFA, Proventil™ HFA or generic albuterol. Comments from the Asthma & Allergy Foundation of America ("AAFA") are disconcerting. Education is a pillar of AAFA (and other members of the U.S. Stakeholders Group) and yet the group is asking FDA to deliver strategies for organizations to collaborate on education.²³ If members of the U.S. Stakeholders Group can allocate resources to push for a transition away from CFC albuterol MDIs, then FDA might expect them to allocate resources towards programs targeted at educating providers and patients. As a consortium, the U.S. Stakeholders Group has been in existence since 1996. In November, 2004, the group finally submitted a few details of a Proposed Outreach and Education Initiative. For a group that has had at least eight years to plan for the transition, ATC is surprised that more was not presented and that it has taken so long for the Stakeholders to present their initiative.

Another flaw in this theory is that by removing generic albuterol MDIs from the U.S. market, FDA effectively removes the *only* affordable prescription rescue asthma inhaler from the U.S. market. Although ATC agrees from a medical perspective that certain asthma patients should become less reliant on albuterol, not all patients can afford to do so. The most popular non-rescue asthma product is GSK's blockbuster product, Advair™ Diskus, which can cost a patient up to \$170²⁴ for a single month's supply. In a CFC-free albuterol world, physicians will prescribe prohibitively expensive branded controller drugs in addition to more expensive albuterol rescue drugs.²⁵ The net effect will be that patients will be able to afford less and thus use less medication than they did prior to the transition. The only "lesson" to patients is how insensitive the health care system is to economic limitations.

III. TAKING INTO ACCOUNT THE MEDICARE DRUG BENEFIT

The new CMS rule, issued November 15, 2004, will shift Medicare beneficiaries away from albuterol nebulizers to albuterol MDIs--the latter will be covered under the new Part D prescription drug benefit, which takes effect in January 2006.²⁶ It is unclear at this point what

²³ AAFA comments submitted to FDA dated August 16, 2004.

²⁴ AG Rx (New York State Attorney General's Office - Prescription Drug Price Website).

²⁵ In 2003, this product was the eight most heavily advertised product at cost to GSK of approximately \$101,000,000. *Euro RSCG Worldwide Wins Advair DTC*, Medical Media and Marketing (Nov. 2004).

²⁶ 59 Fed. Reg. at 66342.

the cost impact will be to the Medicare program. What is clear is that FDA's decision to take generic albuterol alternatives off the market prematurely will inevitably impose an added cost burden on the Medicare program, likely decreasing the program's ability to spend on other life-saving medications. ATC implores FDA to carefully consider the impact of its decision on the Medicare program as it finalizes the rule.

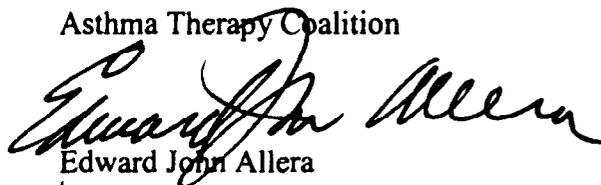
Certainly, the Agency recognizes how critical it is for senior Americans to have access to lower cost drugs. During an August 30, 2004 talk at the National Association of Chain Drug Stores' conference in San Diego, CA, Former Commissioner Mark McClellan noted the integral role generic drugs will play in the Medicare drug benefit, and implored pharmacists to keep consumers apprised about less expensive options. He stated: "I believe it is extremely important for us to make sure seniors know about the availability of generics and the savings they can get from using them. . . . When they are approved and regulated by the FDA, they are just as safe as the more expensive brand-name versions and just as effective as well."²⁷

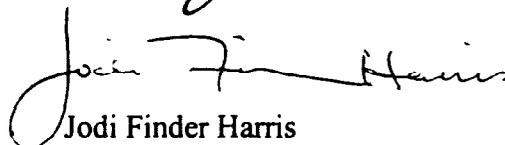
IV. CONFLICTING CONCERNS BETWEEN FDA'S OBLIGATIONS UNDER THE HATCH-WAXMAN AMENDMENTS AND INTERNATIONAL COMITY

ATC certainly understands the Agency's reluctance to abrogate the United States' obligations under the Montreal Protocol. Yet, as explained further in its August 16 comments, a premature phase-out will amount to an affront to the Drug Price Competition and Patent Term Restoration Act of 1984, which has become a cornerstone of the American health care system. Given the dramatic differences in our nation's health care system and the unfaltering need for FDA to act in the best interests of the public health, it is ATC's position that a phase-out plan that is executed in a *reasonable* period of time (*i.e.*, waiting until branded HFA albuterol products come off patent and more affordable generic alternatives are permitted to enter the U.S. market) would still allow the Agency to act in good faith under the Montreal Protocol.

Respectfully submitted,

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²⁷ Medical Marketing and Media (Oct. 2004).

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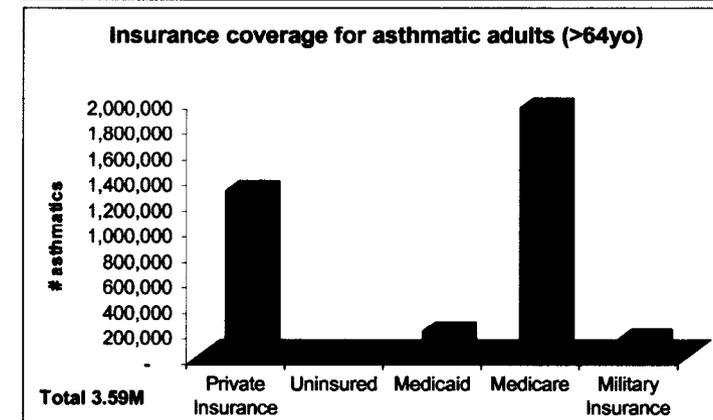
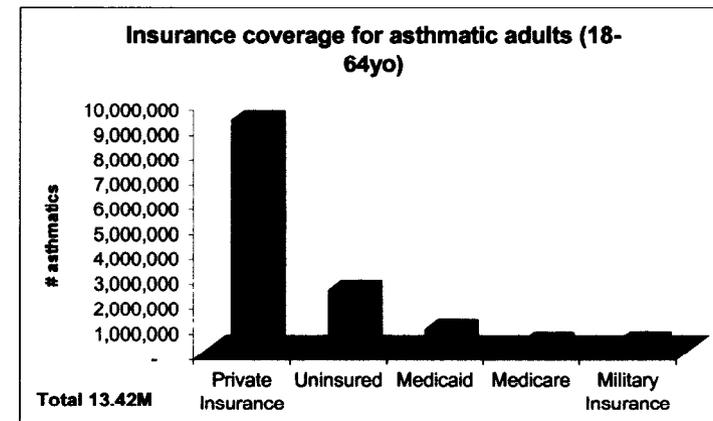
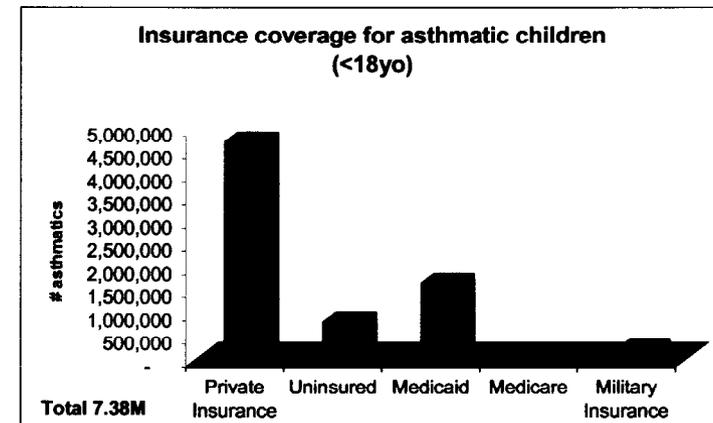
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Appendix 1

Asthma prevalence by insurance and age, 2004¹	
Total Asthma Prevalence	24,392,900
Private insurance - any plan	15,271,115
<i>Employment-based</i>	13,400,922
- Children (<18yo)	4,329,860
- Adults (18-64yo)	8,380,547
- Adults (>65yo)	690,515
<i>Direct purchase</i>	1,870,193
- Children (<18yo)	364,258
- Adults (18-64yo)	901,224
- Adults (>65yo)	604,711
Uninsured - Total	3,286,347
- Children (<18yo)	797,244
- Adults (18-64yo)	2,472,759
- Adults (>65yo)	16,344
Government Insurance - Total	5,835,438
<i>Medicaid</i>	2,725,540
- Children (<18yo)	1,642,598
- Adults (18-64yo)	886,820
- Adults (>65yo)	196,123
<i>Medicare</i>	2,372,523
- Children (<18yo)	48,110
- Adults (18-64yo)	377,489
- Adults (>65yo)	1,946,925
<i>Military health care</i>	737,375
- Children (<18yo)	199,311
- Adults (18-64yo)	403,230
- Adults (>65yo)	134,834

¹ From American Lung Association, *Trends in Asthma Morbidity and Mortality* (Apr. 2004) & U.S. Census Bureau, *Health Insurance Coverage in the United States: 2002* (Sept. 2003).



Appendix 2

Pay Profiles by Insurance Type		CFCs available		CFC-free (HFA only)	
		Generic	Branded	Generic	Branded
<i>Patient Co-pay & 3rd Party Payer Amount</i>					
Private insurance	Retail price ¹	\$ 22.61	\$ 38.62		\$ 38.62
	Mfr rebate (15.1% of mfr price) ¹	N/A	\$ 4.35		\$ 4.35
	Patient pays ¹	\$ 10.00	\$ 22.00		\$ 22.00
	<u>Weighted average cost to patient²</u>		\$ 11.2		\$ 22.00
	3rd party payer pays ¹	\$ 12.61	\$ 12.27		\$ 12.27
	<u>Weighted average cost to 3rd party payer²</u>		\$ 12.58		\$ 12.27
Uninsured	Patient pays ¹	\$ 22.61	\$ 38.62		\$ 38.62
	<u>Weighted average cost to patient²</u>		\$ 24.21		\$ 38.62
Medicaid	Retail price ¹	\$ 22.61	\$ 38.62		\$ 38.62
	Mfr rebate (11 & 30% generic & branded mfr prices) ¹	\$ 0.51	\$ 9.00		\$ 9.00
	Patient pays ³	\$ 0.78	\$ 1.64		\$ 1.64
	<u>Weighted average cost to patient²</u>		\$ 0.86		\$ 1.64
	3rd party payer pays	\$ 21.32	\$ 27.98		\$ 27.98
<u>Weighted average cost to 3rd party payer²</u>		\$ 21.99		\$ 27.98	
Medicare	Patient pays ⁴	\$ 2.00	\$ 5.00		\$ 5.00
	<u>Weighted average cost to patient²</u>		\$ 2.30		\$ 5.00
	3rd party payer pays	\$ 20.10	\$ 24.62		\$ 24.62
<u>Weighted average cost to 3rd party payer²</u>		\$ 20.55		\$ 24.62	
Military Healthcare	Patient pays	\$ 3.00	\$ 9.00		\$ 9.00
	<u>Weighted average cost to patient²</u>		\$ 3.60		\$ 9.00
	3rd party payer pays	\$ 19.10	\$ 20.62		\$ 20.62
<u>Weighted average cost to 3rd party payer²</u>		\$ 19.25		\$ 20.62	

¹ Pricing data from *The Impact on Patients and Payers of Designating Albuterol a Non-Essential Use of an Ozone Depleting Substance*. National Economic Research Associates, September 8, 2003.

² Computation of weighted average cost to patient uses 90% market share for generic albuterol MDIs and 10% share for branded

³ Medicaid patient co-payment is the weighted average co-pay across 38 state Medicaid programs. Data from Kaiser Family Foundation, Kaiser Commission of Medicaid and the Uninsured.

⁴ Medicare patient co-payment is based on the Medicare Prescription Drug, Improvement and Modernization Act of 2003 and assumes seniors will spend > \$3,600 out of pocket. The Federal government will pick up balance of payment.

Appendix 3

Estimate of Effects on Medical Care		TOTAL NET EFFECT PER YEAR BASED ON 2001/2002 DATA \$ 570,321,000		
		ODS case	ODS FREE	Net effect/year
Hospital Discharges				
Volume (in 2001) ¹		454,000	499,400	45,400
Rate (in 2001) per 10,000 people ¹		0.16%	0.18%	
Change in rate from 2x copay increase ²	10%			
Total Direct Cost ¹		\$ 4,407,300,000	\$ 4,848,030,000	\$ 440,730,000
Cost per discharge		\$ 9,708	\$ 9,708	
Private Insurance Co-pay (20%)		\$ 1,942	\$ 1,942	
Uninsured Payment		\$ 9,708	\$ 9,708	
Medicaid Co-pay		\$ 100	\$ 100	
Medicare co-pay		\$ 876	\$ 876	
Military health care co-pay (20%)		\$ 1,942	\$ 1,942	
Emergency Room visits				
Volume (in 2002) ¹		1,898,000	2,220,660	322,660
Rate (in 2001) per capita ¹		0.67%	0.79%	
Change in rate from 2x copay increase ²	17%			
Total Direct Cost ¹		\$ 762,300,000	\$ 891,891,000	\$ 129,591,000
Cost per ER visit		\$ 402	\$ 402	
Private Insurance Co-pay		\$ 100	\$ 100	
Uninsured Payment		\$ 402	\$ 402	
Medicaid Co-pay		\$ -	\$ -	
Medicare co-pay (20% of charges)		\$ 80	\$ 80	
Military health care co-pay		\$ 30	\$ 30	

¹From *Trends in Asthma Morbidity and Mortality*. American Lung Association, April 2004

²From Goldman, et al, *JAMA* May 19, 2004. This represents only an estimate; these percentages represent changes across three therapeutic areas and the authors did not provide an estimate for asthma alone. Elimination of generic albuterol MDIs will force the doubling of patient co-payments.