



Testimony in support of SB2106, SD2, HD1
House Committee on Consumer Protection

Hearing scheduled Monday, March 19 @ 2pm in room 325

March 19, 2012

To: House Committee Consumer Protection
Rep. Herkes, Chair, Rep. Yamane, Vice Chair and Committee Members

By: Valerie Chang, JD, Executive Director
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Re: Supporting SB2106, SD2, HD1

Dear Chair Herkes, Vice Chair Yamane and Members of the Committee:

My name is Valerie Chang. I am Executive Director of the Hawaii COPD Coalition. Our organization provides services and support to Hawaii's people affected by Chronic Obstructive Pulmonary Disease (COPD), more commonly known as emphysema, chronic bronchitis and similar conditions. We strongly support SB2106, SD2, HD1, as it is crucial for the many people who have huge medical bills that they cannot otherwise pay with appropriate insurance coverage.

COPD has risen to the third leading cause of death in the US and is also the second leading cause of disability in the US; many COPD patients have multiple chronic health conditions and out of pocket expenses for these medications can be HUGE. The Burden of COPD in Hawaii 2010 report by the Hawaii Department of health estimates that over 30,800 Hawaii adults have been diagnosed with COPD; likely an equal or greater number remain undiagnosed. The report also estimates over \$55 million each year in Hawaii hospitalizations due to COPD. It is estimated that 24 million people in the United States suffer from COPD, with at least half of them not yet diagnosed.

In 2011 alone, our organization conducted over 1300 lung function tests at 40 different clinics, including 6 on the Big Island, 3 on Molokai, 3 on Maui and 2 on Kauai, and many in other medically underserved communities. In those clinics, a significant number of patients had low lung function and one-third of those had never smoked or been exposed to lung irritants; many had no idea that their lung function was lower than normal. The Hawaii COPD Coalition has been conducting free lung testing at many locations throughout Hawaii since 2008. Our organization has also held annual COPD Education Days from 2007, with 160 to 300+ attendees attending each year, as well as exhibitors, healthcare students and professionals.

I strongly SUPPORT SB2106, SD2, HD1, "Relating to Health" In its November 13, 2008 CDC report, an article about COPD was released in its Morbidity and Mortality Weekly Report (MMWR) with key findings: CDC estimates that additional health care costs total \$6000 each year for every COPD patient in the US. More than 126,000 Americans die of COPD each year, one every four minutes! Some COPD patients with a genetic form of emphysema require weekly intravenous infusions of Alpha-1 Antitrypsin, to maintain their lungs and livers, as there is no cure for this genetic form of emphysema. Mean annual costs for these infusions can exceed \$40,000. <http://chestjournal.chestpubs.org/content/119/3/745.full>. Patients cannot absorb these costs. There are other conditions that have similar issues and costs.

Thank you again for the opportunity to testify in support of SB2106, SD2, HD1.

Chest

chestjournal.chestpubs.org

LATE TESTIMONY

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The Direct Medical Costs of α_1 -Antitrypsin Deficiency*C. Daniel Mullins, PhD, Xingyue Huang, MS, Sanjay Merchant, MS, MBA, James K. Stoller, MD, FCCP and for the Alpha One Foundation Research Network Registry Investigators[†]

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Abstract

Background: For individuals with emphysema because of severe α_1 -antitrypsin deficiency, specific therapy called IV augmentation therapy has been available since 1989. Such therapy consists of IV infusion of pooled human plasma α_1 -antiprotease.

Methods: To assess the direct medical costs of having α_1 -antitrypsin deficiency, the current study surveyed members of the Alpha One Foundation Registry for individuals with α_1 -Antitrypsin Deficiency regarding their annual expenditures for treatment of this disease. Data regarding demographic features, α_1 -antitrypsin status, and health-resource utilization were collected from a self-administered questionnaire. Respondents were asked to provide total health-care expenditures, but costs by specific items of care (eg, drugs, physician visits, etc) were not available.

Results: Mean annual cost estimates were higher for Pi*ZZ-phenotype individuals (\$30,948, n = 292) than for non-Pi*ZZ-phenotype individuals (\$20,673, n = 53; p = 0.049). Among Pi*ZZ-phenotype individuals, self-reported costs of health-care services were further analyzed for those 288 individuals whose α_1 -antiprotease use status was reported. For the 185 current α_1 -antiprotease users, the mean annual cost was \$40,123 (median, \$36,000).

Conclusions: Annual health-care expenditures by individuals with α_1 -antitrypsin deficiency are very high, whether or not they are currently receiving augmentation therapy. Augmentation therapy adds substantial costs, especially for heavier individuals who are receiving weekly infusions.

 α_1 -antitrypsin deficiency cost registry

α_1 -Antitrypsin deficiency is an autosomal codominant condition that predisposes to early-onset emphysema, chronic liver disease (ie, hepatitis, cirrhosis, hepatoma), panniculitis, and vasculitis.^{1,2,3} Although population-based studies show a frequency of approximately 1 in 3,500 live births in the United States and predict a prevalence of 100,000 severely deficient Americans,^{4,5,6,7,8} < 10% of affected individuals have been detected to date.⁴ Putative reasons for this underdetection include underrecognition of α_1 -antitrypsin deficiency by health-care providers⁹ and freedom from clinical consequences despite severe deficiency in some individuals.

For individuals with emphysema because of severe α_1 -antitrypsin deficiency, specific therapy called IV augmentation therapy has been available since 1989. Such therapy consists of IV infusion of pooled human plasma α_1 -antiprotease. To date, only a single preparation of pooled human plasma α_1 -antiprotease has received US Food and Drug Administration approval (Prolastin; Bayer; West Haven, CT), although other preparations as well as other treatment strategies are currently under study. Limitations of the current treatment include the substantial expense of the drug and the associated infusions, as well as current inability to produce enough pooled human α_1 -antiprotease to treat all appropriate candidates.

Because α_1 -antitrypsin-deficient individuals may experience several chronic debilitating illnesses and may receive life-long, costly therapy, the clinical and economic burden of illness can be high. In a modeled cost-benefit analysis of IV augmentation therapy, Hay and Robin¹⁰ estimated that at 70% efficacy, the cost per life-year saved with augmentation therapy was \$28,000 to \$72,000 (1990 US dollars), and that at 30% efficacy, the cost ranged from \$50,000 to \$128,000 per life-year saved based on an assumed yearly treatment cost of \$30,000. A more recent study by Alkins and O'Malley¹¹ showed a lower incremental cost-effectiveness ratio of \$13,971 for severe α_1 -antitrypsin-deficient individuals. The estimate by Alkins and O'Malley¹¹ is more current, uses a discount rate of 7%, and focuses on survival data from the National Institutes of Health Registry. Although estimates by both Hay and Robin¹⁰ and Alkins and O'Malley¹¹ are useful in estimating the cost-effectiveness relationship of augmentation therapy, they may fall short in estimating the economic burden of α_1 -antitrypsin deficiency because they are based on models, they fail to consider patient-reported information, and they do not capture information regarding the full spectrum of associated conditions related to α_1 -antitrypsin deficiency.

To assess the direct medical costs of having α_1 -antitrypsin deficiency, the current study surveyed members of the Alpha One Foundation Registry for Individuals with α_1 -Antitrypsin Deficiency to assess the annual expenditures by affected individuals for treating this disease.

Materials and Methods

The cost of treating α_1 -antitrypsin deficiency includes the cost of treating attributable illnesses and the cost of augmentation therapy. The cost of α_1 -antiprotease treatment includes the cost of the drug and the cost of the infusion. Furthermore, because the dose of α_1 -antiprotease is weight based, treatment costs were calculated for three patient types: females (50 kg), average-weight males (75 kg), and heavier males (100 kg). Drug cost and administration estimates were based on 1999 Medicare reimbursement rates for the relevant current procedural terminology (CPT) codes and estimated costs for Prolastin, assuming a standard reimbursement rate of 95% of the average wholesale price. The CPT code used for these calculations was 90780, representing the first hour of α_1 -antiprotease infusion (listed at \$36.73 for 1999). Calculations for the monthly cost of infusion were based on the same CPT code (90780) for the first hour of infusion, and also code 90781, which represents each additional hour of infusion therapy (listed at \$18.48 in 1999).