

Statement of

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Chairman Whitfield, Ranking Member Stupak, and Subcommittee Members, thank you for the opportunity to discuss ways in which GlaxoSmithKline (GSK) is working with the Health Resources and Services Administration (HRSA) Office of Pharmacy Affairs (OPA) to improve the 340B Drug Discount Program so that the patients served by this program have access to the medicines they need.

My name is David Brown. I am the Director of Government Contracts and Pricing Programs for GSK with the responsibility for operational support of the GSK Federal and state contracted business. This includes calculating and reporting government mandated prices, including Ceiling Prices under the 340B Drug Discount Program.

GSK is a world wide pharmaceutical company with combined sales of over \$37 billion, an annual R&D investment of \$5 billion and 100,000 employees world-wide with over 24,000 employees in the United States. GSK has leading products in four major therapeutic areas - anti-infectives, central nervous system (CNS), respiratory and gastrointestinal/metabolic. In addition, we are a leader in the important area of vaccines and have a growing portfolio of oncology products.

As stated in our mission statement, GSK is committed to "improve the quality of human life by enabling people to do more, feel better and live longer," and we value any opportunity to provide input into a process that improves the access and delivery of important medicines to patients.

GSK works to improve patient access to medicines through a wide variety of programs. Through the GSK Global Community Partnerships program, we provide money, medicines, time and equipment to help improve health and education in underserved communities. We support public health initiatives and local community projects around the world and donate medicines to support disaster relief efforts and impoverished communities. This includes funding major health initiatives in developing countries to tackle lymphatic filariasis (LF), HIV/AIDS, malaria, and diarrhea-related disease. In the United States, GSK is also committed to helping patients with limited means gain access to the breakthrough medicines we discover. This is accomplished through multiple programs including the “Bridges to Access” and “Commitment to Access” programs, as well as through our participation in all of the major government programs designed to improve access to medicines for those most in need, such as the 340B Drug Discount Program.

Under section 340B of the Public Health Service Act, manufacturers agree to charge 340B Covered Entities no more than the “Ceiling Price” for covered drugs, which is a discounted price that is calculated under a federal formula, by taking the Average Manufacturers Price (AMP) for the drug and reducing that price by the Medicaid rebate percentage. 340B Covered Entities include public hospitals, community health centers, AIDS Drug Assistance Programs and other entities that serve indigent and medically needy Americans.

340B Covered Entities typically purchase covered drugs at a contract price through their wholesaler. The contract purchase price usually includes both the drug cost (which, if the entity qualifies, should be no more than the manufacturer's 340B Ceiling Price) and a wholesaler distribution fee.<sup>1</sup> We understand that the contract purchase price is typically agreed upon solely between the 340B Covered Entity and the wholesaler. The wholesaler generally starts with the quarterly 340B drug Ceiling Price, which is confidentially communicated to it by each manufacturer, and then may add a wholesaler distribution fee. The 340B Covered Entities, however, have historically not always had the same systematic access to the quarterly 340B drug Ceiling Prices that the wholesalers have had. This can make it difficult for 340B Covered Entities to determine what they are paying for the drugs versus what they may be paying in wholesaler distribution fees. Without this information, the Covered Entities can not effectively negotiate with the wholesaler over the wholesaler's distribution fee. GSK has been working with OPA and the 340B Prime Vendor on cost effective ways to address this issue.

Beginning in 2003, improving 340B Covered Entity access to manufacturer 340B drug Ceiling Prices was raised as a major issue at the 340B Coalition conferences held each year. In 2004 and 2005, the Health and Human Services Office of Inspector General issued several reports that identified 340B program issues and made recommendations for program improvements, including a recommendation that Covered Entities be given easier access to 340B Ceiling Price information. In order to help address these issues, GlaxoSmithKline began meeting with the OPA in an effort to

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<sup>1</sup> As noted by the Office of Inspector General in its recent October 2005 Report (OEI-05-02-00072), according to HRSA "it is acceptable for wholesalers to charge covered entities 340B Ceiling Prices plus a distribution fee, which varies based on standard business practice."

provide our expertise in an atmosphere of frank dialogue and cooperation. Following these very productive discussions, GSK decided to voluntarily post its 340B drug Ceiling Prices on a secure website accessible to participating 340B Covered Entities, starting on October 1, 2005.

Other than GSK, through the secure Prime Vendor Program website that I will discuss in more detail below, I am not aware of any government agency, pharmaceutical manufacturer or contracting agent who routinely offers easy access to all quarterly Ceiling Prices to 340B Covered Entities.

GlaxoSmithKline has supported access to its manufacturer 340B Ceiling Prices for eligible 340B Covered Entities since the beginning of the program in 1993. Historically, this was done through company responses to individual requests for quarterly Ceiling Price information from eligible entities or their GSK Account Managers, and as such reached only those entities that requested the information. To facilitate broader access to this information, we decided to be the first pharmaceutical manufacturer to share its Ceiling Prices with eligible 340B Covered Entities by helping to develop an innovative website provided through the 340B Prime Vendor Program / HealthCare Purchasing Partners International, LLC (340B PVP). We believe this will enable all interested Covered Entities that participate in the 340B Prime Vendor Program to have secure and easy access to up-to-date drug Ceiling Price information with no added costs to the entities.

Specifically, GSK entered into a one year voluntary agreement with the 340B PVP to provide systematic access to 340B Ceiling Prices to Covered Entities enrolled in the 340B PVP. The key elements of making this pricing available include the following:

- 340B PVP will receive quarterly 340B Ceiling Prices by 11 digits National Drug Code (NDC) from GSK.
- 340B PVP will post quarterly 340B Ceiling Prices on their secure website on the first of each calendar quarter and maintain two consecutive quarters of data at one time.
- Eligible Covered Entities will be granted access to the 340B PVP secure website through a password protected user interface
- All entities are required to sign / agree to the confidentiality clause contained in the 340B PVP standard enrollment agreement prior to receiving access to the secure website.

In deciding to move forward with an external website, GSK worked with OPA to ensure that the confidential and sensitive pricing information that would be posted on the website for 340B Covered Entities would not become available to competitors or to those not eligible to participate in the program. The pharmaceutical market is a highly competitive commercial market populated with other companies competing in many therapeutic classes. Since GSK is the only pharmaceutical company providing website access to 340B Ceiling Prices at this time, we needed to do so in a way that would reduce the risk of competitive disadvantages in the marketplace.

By previously providing GSK 340B Ceiling Prices to eligible 340B Covered Entities on a confidential basis upon request, GSK had already decided that it was willing to take some commercial risk that those prices would be improperly disclosed to our competitors, but we concluded that the benefits to the 340B entities requesting such information outweighed these risks to GSK. We believe that the new external, website provided by the 340B Prime Vendor has provided a mechanism that will best ensure against sensitive Ceiling Price information being released to competitors or non-Covered Entities while enabling the Covered Entities to gain access to pricing information in an efficient, easy manner. Ultimately, we decided that leading the way on this issue was the right thing to do. Improved access to manufacturer Ceiling Price information will help inform the Covered Entities about the components of the ultimate purchase price of pharmaceutical products and as such will increase their capabilities to provide care to the underserved patient populations they represent.

In addition, in order to work cooperatively with the OPA in an effort to ensure that GSK's 340B Ceiling Prices are being calculated accurately, GSK has also agreed to send a copy of its quarterly 340B Ceiling Prices, as well as relevant product package size information, to OPA. That way, OPA may compare them to the 340B Ceiling Prices calculated using data maintained by CMS. For the GSK 340B Ceiling Prices effective 4Q2005, the OPA Affairs used GSK's data to review the reported GSK 340B Ceiling Price calculations and to compare them to internal CMS calculations. We are pleased to report that OPA recently informed us that they found a match for more than 99% of

GSK's Ceiling Prices. GSK works hard to calculate Ceiling Prices accurately, and we were pleased to have achieved a 99%-plus accuracy rate.

GSK remains committed to working with the OPA to meet the needs of the 340B eligible entities and enable the successful administration of the 340B Drug Discount Program. We believe that by taking a leadership role in identifying and proactively resolving issues such as providing improved access to manufacturer 340B Ceiling Price information to eligible entities, GSK can help make the program more effective and efficient and ultimately improve patient access to needed drug therapy.

Again, thank you for the opportunity to testify today. I look forward to answering any questions you might have.