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OVERSIGHT AND ADMINISTRATION OF THE 340B DRUG DISCOUNT PROGRAM: IMPROVING EFFICIENCY AND TRANSPARENCY

HEARING

BEFORE THE

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

OF THE

COMMITTEE ON ENERGY AND COMMERCE
HOUSE OF REPRESENTATIVES

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CONTENTS

Page

Testimony of:

Wright, Stuart, Deputy Inspector General for Evaluation and Inspections, Office of Inspector General, U.S. Department of Health and Human Services 9

Williams, Denis, Deputy Administrator, Health Resources and Services Administration, U.S. Department of Health and Human Services 16

Von Oehsen, III, William H., Powers, Pyles, Sutter &Verville PC, General Counsel, Public Hospital Pharmacy Coalition 39

Brown, David B., Director, Government Contracts and Pricing Programs, GlaxoSmithKline 53

Hatwig, Christopher A., Senior Director, 340B Prime Vendor Program, HealthCare Purchasing Partners International 58

OVERSIGHT AND ADMINISTRATION OF THE 340B DRUG DISCOUNT PROGRAM: IMPROVING EFFICIENCY AND TRANSPARENCY

THURSDAY, DECEMBER 15, 2005

HOUSE OF REPRESENTATIVES,
COMMITTEE ON ENERGY AND COMMERCE,
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS,
Washington, DC.

The subcommittee met, pursuant to notice, at 2:14 p.m., in Room 2322, Rayburn House Office Building, Hon. Ed Whitfield [chairman] presiding.

Members present: Representatives Whitfield, Blackburn, Stupak, DeGette, and Inslee.

Staff Present: Andrew Snowdon, Counsel; John Halliwell, Policy Coordinator; Jonathan Pettibon, Legislative Clerk; Terry Lane, Deputy Communications Director; Edith Holleman, Minority Counsel; and Chris Knauer, Minority Investigator.

MR. WHITFIELD. First of all, I want to apologize. There are a lot of things going on beyond our control. For those who have come to testify, we genuinely apologize to you, because I know many of you have schedules and planes to catch and so forth. But, unfortunately, we have a markup in the Energy Committee going on now, and we have votes on the floor. We just had a conference on an immigration issue, and we simply could not get around this delay.

So having apologized to you, as soon as Mr. Stupak arrives, we will go on and get this hearing started and we look forward to the testimony from all of you.

Mr. Stupak, I have already made an announcement to apologize for our delay. Today's hearing subject matter is Oversight and Administration of the 340B Drug Discount Program: Improving Efficiency and Transparency, and we have two panels of witnesses today. On the first panel we have Mr. Stuart Wright, who is the Deputy Inspector General for Evaluation and Inspections, Office of Inspector General, U.S. Department of Health and Human Services; and accompanying him is Mrs. Maxwell. We appreciate her being here very much.

In addition, we have Mr. Dennis Williams, who is the Deputy Administrator for the Health Resources and Services Administration at the U.S. Department of Health and Human Services. And I will introduce the second panel when we call them up.

The purpose of today's hearing is to examine the oversight and administration of the 340B drug pricing program. Under this program, institutions that serve some of the Nation's neediest and most vulnerable patients, including public hospitals and community health centers, receive outpatient drugs at a discount. It is estimated that the roughly 12,000 340B entities save between $1.5 and $2 billion annually as a result of the program, savings that are often passed along to taxpayers.

This subcommittee takes its oversight responsibilities very seriously, and if the program is not running smoothly then we need to find out why. Over the past several years this subcommittee has devoted a substantial amount of time to examining drug pricing in various government programs. In December of last year, for example, the subcommittee held a widely publicized hearing which exposed in vivid detail just how much the Medicaid program is overpaying for prescription drugs because most states continue to rely upon average wholesale price as the basis for reimbursement. The theme of that hearing and, indeed, the common theme of all the subcommittee's drug pricing work, has been transparency.

The 340B program certainly fits that mold. It is nonsensical to me that the entities entitled to the 340B discount, the 340B institutions and the prime vendor, do not have access to the ceiling prices. Imagine going to a grocery store which advertises a special discount price, only to find that when you go to the register to check out, no one can tell you what that discount is.

I want to commend the Office of Inspector General for the outstanding work that it has done and continues to do on this issue. In its most recent report on the 340B program, the OIG identified serious deficiencies in the operations of the program and made a variety of recommendations for improvement. I look forward to discussing some of these recommendations with the witnesses today to see what we can do to make the 340B program more efficient and transparent. I want to be clear, however, that this is not necessarily a knock on HRSA. There may well be structural, statutory, or resource problems that need to be identified and addressed.

The OIG's work has also shown that this lack of price transparency can result in 340B entities overpaying by millions of dollars. When Medicaid patients are the recipients, such overcharges, whether accidental or intentional, are passed on to the taxpayers.

It is my understanding that the Office of Inspector General is currently doing additional work that will attempt to quantify 340B overcharges and delve into the reasons behind them. I look forward to holding another hearing when this report is released next spring.

I want to thank all of today's witnesses for providing their experience and expertise to this subcommittee. In particular, I would like to welcome Mr. Brown and recognize GlaxoSmithKline for taking the bold step of voluntarily, I might add, posting its ceiling price calculations so that 340B entities have the ability to make sure that the prices that they are paying are the appropriate prices. If this hearing is able to increase transparency by encouraging other drug manufacturers to do the same, then I think it will have been a success.

[The prepared statement of Hon. Ed Whitfield follows:]

PREPARED STATEMENT OF THE HON. ED WHITFIELD, CHAIRMAN, SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

The purpose of today's hearing is to examine the oversight and administration of the 340B Drug Pricing Program. Under this Program, institutions that serve some of the nation's neediest and most vulnerable patients, including public hospitals and community health centers, receive outpatient drugs at a discount. It is estimated that the roughly 12,000

340B entities save between $1.5 and $2 billion annually as a result of the Program -- savings that are often passed along to taxpayers. This Subcommittee takes its oversight responsibilities very seriously, and if the Program is not running smoothly, then we need to find out why.

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The theme of that hearing -- and indeed the common theme of all the Subcommittee's drug pricing work -- has been ***transparency***. The 340B Program certainly fits that mold. It is nonsensical to me that the entities entitled to the 340B discount -- the 340B institutions and the prime vendor -- do not have access to the ceiling prices. Imagine going into a grocery store which advertises a special discount price on a gallon of milk -- only to find that when you get to the register no one will tell you what that discount is?

I want to commend the Office of Inspector General for the outstanding work that it has done, and continues to do, on this issue. In its most recent report on the 340B Program, the OIG identified serious deficiencies in the operations of the Program and made a variety of recommendations for improvement. I look forward to discussing some of those recommendations with the witnesses today to see what we can do to make the 340B Program more efficient and transparent. I want to be clear, however, that this is not necessarily a knock on HRSA. There may well be structural, statutory, or resource problems that need to be identified and addressed.

The OIG's work has also shown that this lack of price transparency can result in 340B entities overpaying by millions of dollars. When Medicaid patients are the recipients of these drugs, such overcharges -- whether accidental or intentional -- are

passed on to the taxpayers. It is my understanding that OIG is currently doing additional work that will attempt to quantify 340B overcharges and delve into the reasons behind them. I look forward to holding another hearing when this report is released next Spring.

I want to thank all of today's witnesses for providing their experiences and expertise to the Subcommittee. In particular, I would like to welcome Mr. Brown and recognize Glaxo-Smith-Kline for taking the bold step of voluntarily posting its ceiling price calculations so that 340B entities have the ability to make sure that they are paying appropriate prices. If this hearing is able to increase transparency by encouraging other drug manufacturers to do the same, then I think that it will have been a success.

MR. WHITFIELD. At this time I'd like to recognize the Ranking Minority Member, Mr. Stupak of Michigan.

MR. STUPAK. Thank you, Mr. Chairman, and apologize to our witnesses. We're probably going to have to run downstairs for another vote. We're in full committee even as we speak. So I want to give it sort of an abbreviated.

This is our second hearing of this week. It was clear at the Internet pharmacy hearing earlier this week that members on both sides of the aisle believe this committee must follow up and demand actions and actors to find the best solutions to combat illegal sales of controlled substances on the Internet.

Mr. Chairman, I ask for your assurances our staff will continue to work together and address the outstanding issues and concerns identified at the hearing in the next couple weeks, when we get back from the break, because there are a lot of things we've got to do that.

Last but not least, while the 340B is a useful topic, Hurricane Katrina severely damaged the health care system in New Orleans on the gulf coast. Many of those facilities were 340B facilities. I think that's sort of a disgrace, Mr. Chairman, that they have lost -- especially Charity Hospital lost their health care.

We have repeatedly asked for hearings on Katrina-related health care, energy and communications issues and want to take the opportunity to ask that we do a field hearing in New Orleans so the subcommittee can see firsthand and hear firsthand about this gaping hole in our national health care system.

A 340B program is of no value if the providers aren't functioning. With that, Mr. Chairman, I'm going to submit the rest of my statement to the record because I do want to hear from our witnesses and get this hearing moving and hopefully we can have that hearing down in New Orleans maybe over the break. Thank you.

[The prepared statement of Hon. Bart Stupak follows:]

PREPARED STATEMENT OF THE HON. BART STUPAK, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MICHIGAN

Thank you, Mr. Chairman. I believe that most of us are supporters of an effective 340b program. It helps the hospitals, community health centers and clinics that serve the poorest of the poor under very difficult financial circumstances, and we support every effort to make this program more efficient and effective. After all, we have 45 million Americans who are completely without insurance, and many of them are served by 340b entities much less expensively than if they went to hospital emergency rooms. And, as previous work by the Inspector General has revealed, 340b entities are losing tens of millions of dollars every year because of improper calculations of ceiling prices.

As the Inspector General will testify, the Health Resources and Services Administration (HRSA) lacks legislative, regulatory, and contractual authority to enforce an effective and efficient 340b program. Mr. Chairman, legislative authority is our job, and I hope that this is just not another oversight hearing after which we in Congress identify a problem, but do nothing about it. The rest of these authorities require commitments from the top levels of Department of Health and Human Services and the drug companies, and neither of those 800-pound gorillas are in the room.

The Centers for Medicare and Medicaid Services controls all of the data that HRSA needs to calculate the ceiling price for 340b drugs. As the Inspector General has determined, there needs to be close cooperation between these two agencies in the Department of Health and Human Services, and that is not occurring. We on the minority side asked for CMS as a witness, but the Department took the position that it would provide only a single witness at our hearings. So we can't hold CMS's or the Department's feet to the fire and get firm commitments that we can monitor. In our experience, a statement from an agency that it "concurs" with the recommendations in an inspector general's report is generally a commitment to inaction.

Second, the drug companies calculate their own ceiling price, and that is the one that the 340b providers actually pay or use for negotiating lower prices. These providers have no idea if the "official" HRSA price is the same as the price they are working with. If there are overcharges, they are often not recovered by these entities that serve this very vulnerable population. The pharmaceutical companies apparently are very opposed to sharing their ceiling price calculations with the 340b prime vendor, but we can't have a full discussion of this issue because the objecting drug companies, or their association, are not here.

Finally, Mr. Chairman, while 340b is a useful topic, Hurricane Katrina severely damaged the health care system of New Orleans and the Gulf Coast. Many of these facilities were 340b facilities. This, Mr. Chairman, is a national disgrace. We have repeatedly asked for hearings on Katrina-related health care, energy and communications issues, and I want to take this opportunity to ask for a field hearing in New Orleans so the Subcommittee can see and hear first-hand about this gaping whole in our national health care system. A 340b program is of no value if the hospital or health care aren't functioning.

[Additional statements submitted for the record follow:]

PREPARED STATEMENT OF HON. JOE BARTON, CHAIRMAN, COMMITTEE ON ENERGY AND COMMERCE

Thank you, Mr. Chairman, for holding today's hearing. It seems like any time we use "prescription drugs" and "government program" in the same sentence, common sense goes out the window. The 340B Drug Discount Program appears to be no exception.

Under this Program, we tell certain institutions that they are entitled to a discount price for prescription drugs, except they can't know what that price is, and the agency in charge of running the Program has virtually no authority to ensure that they are getting these discounts. Brilliant!

A little over a year ago this Subcommittee held a hearing on Medicaid prescription drug reimbursement. During that hearing I posed the following question: why shouldn't we "go to some system that really is based on actual sales prices with auditing and backup so that we have a transparency in the system so that anybody that has an interest can really find out what's going on?" That premise has shaped this Committee's recent Medicaid reforms, and I hope that it can also be applied to the 340B Program.

I look forward to hearing from the witnesses today about what steps might be taken to improve the 340B Program. Drug manufacturers, wholesalers, CMS, HRSA (her-sa), OIG, the prime vendor, and the 340B entities themselves all have a role to play. If legislation is needed to make this Program more efficient and transparent, Congress may have a role to play as well.

Thank you again, Mr. Chairman, and I yield back the balance of my time.

MR. WHITFIELD. Thank you, Mr. Stupak. We look forward to working with you on the controlled substances issue, as you said, and looking to this additional hearing as well. All of you are aware that this committee is holding an investigative hearing and, when doing so, it has been the practice of our subcommittee of taking testimony under oath. Do any of you have any objection to testifying under oath today?

The Chair would advise you that under the rules of the House and rules of the committee, you are entitled to be advised by counsel. Do you desire to be advised by counsel today? In that case, if you would please stand and raise your right hand.

[Witnesses sworn.]

TESTIMONY OF STUART WRIGHT, DEPUTY INSPECTOR GENERAL FOR EVALUATION AND INSPECTIONS, OFFICE OF INSPECTOR GENERAL, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, ACCOMPANIED BY: ANN MAXWELL, ACTING REGIONAL INSPECTOR GENERAL, CHICAGO OFFICE; AND DENNIS WILLIAMS, DEPUTY ADMINISTRATOR, HEALTH RESOURCES AND SERVICES ADMINISTRATION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

MR. WHITFIELD. Thank you very much and you are now sworn in, and I might add that because of the erratic schedule today, there may be some other members coming in, and I will probably give some of them an opportunity to make opening statements, or all of them, and certainly they have an opportunity to put their opening statement into the record.

And with that, Mr. White, I will recognize you for your opening statement.

MR. WHITE. Thank you. Good afternoon. I'm Stuart Wright, Deputy Inspector General for Evaluation and Inspections for the Office of Inspector General. I am pleased to have Ann Maxwell, Acting Regional Inspector General from our Chicago, office with me today.

I appreciate the opportunity to appear before you to present OIG work related to the 340B program which is managed by HRSA. The 340B program provides for sales of drugs at or below established ceiling prices to certain entities that provide health care to some of the country's most disadvantaged citizens who are typically underinsured or uninsured. Over the past few years we have issued a number of reports looking at various aspects of the 340B program. Our most recent work entitled "Deficiencies in the Oversight of 340B Drug Pricing Program" assessed whether systems exist to ensure that entities participating in the program are able to purchase drugs at or below the statutorily established ceiling price.

Our work has led us to conclude that the 340B program may not be functioning as intended, which was to ensure that appropriate discounts on drugs are available to entities. Specifically our work has found a number of deficiencies in program oversight as well as broader programmatic issues that impact HRSA's ability to administer the program. I have a chart that outlines all parties involved in the 340B program. As the chart illustrates, both the government and the manufacturers calculate 340B ceiling prices. They use the same statutorily defined formula based on the drug pricing data that manufacturers report to CMS for the Medicaid Drug Rebate Program.

The government's calculations are intended for use in programs oversight, while the manufacturers calculations are prices used in the sale of drugs to 340B entities. Theoretically, HRSA and manufacturers calculate the same 340B ceiling prices because they use the same drug pricing elements for the calculation. However, this may not be the case due to differing interpretation of the drug pricing data used in the formula, administrative error, and/or intentional misrepresentation.

Because of the potential for discrepancies which may lead to overcharges, it is important for HRSA to provide oversight. However, we found problems with program oversight related to the following four areas which are discussed in detail in my written statement: the government's calculation of the 340B ceiling price, monitoring program participation, overseeing manufacturers' calculation of the 340B price, and ensuring 340B entities pay at or below the ceiling price.

In terms of the government's record of 340B ceiling prices, we found problems with the accuracy and reliability of the data. For over a decade the government's 340B ceiling prices were calculated using incomplete data to represent package size. In addition, we found that HRSA did not

have 340B ceiling prices for nearly 30 percent of eligible drugs due to missing data.

In terms of monitoring 340B program participants, a June 2004 OIG report found the HRSA's database inappropriately listed 38 percent of sampled entities as participating in the program, when in fact they did not. We also found that HRSA does not verify that manufacturers are correctly calculating 340B ceiling prices. Specifically, HRSA does not compare the government's 340B ceiling prices to the manufacturers' ceiling prices to ensure that the results are the same.

Finally, we found that there is no systematic oversight process in place to ensure that 340B entities receive the ceiling prices to which they are legally entitled. HRSA does not monitor the purchase prices paid by 340B entities to ensure they are at or below the government's 340B ceiling prices.

Beyond these oversight issues, I would like to mention two programmatic issues that limit HRSA's ability to administer the program: confidentiality of the drug pricing data and the lack of adequate enforcement mechanisms.

First, confidentiality provisions in the Medicaid drug rebate statute protect the drug pricing elements used to calculate 340B ceiling price. This impacts HRSA's ability to use the 340B ceiling price data to ensure entities receive the appropriate ceiling praise. HRSA does not currently reveal 340B ceiling prices to participating entities.

Second, with regard to enforcement, we believe HRSA lacks the necessary authority to enforce the manufacturers and wholesalers to comply with the Public Health Service Act. Current law provides noncompliance with 340B provisions can result in termination from participation in Medicaid and the 340B program. However, this remedy is so extreme that it limits the likelihood that it will be used.

To strengthen 340B program oversight, we have recommended that HRSA first ensure that it is correctly calculating the 340B ceiling price with complete and accurate data. Second, develop a strategic plan for correcting the inaccuracies in the 340B participant data base. Third, develop oversight mechanisms to verify that 340B ceiling prices are being correctly calculated by manufacturers. Fourth, develop monitoring mechanisms that allow for a comparison of the government's 340B prices and the prices paid by 340B entities.

We also believe that issues associated with the confidentiality of the data need to be addressed. We believe that permitting some disclosure of information about 340B ceiling prices is essential to improving the operation of the program.

Finally, we have recommended that HRSA seek authority to establish intermediate penalties for program violations.

In conclusion, we are committed to continuing our work related to the 340B program and hope that our work helps ensure this vital program operates as intended. Thank you.

[The prepared statement of Stuart Wright follows:]

PREPARED STATEMENT OF STUART WRIGHT, DEPUTY INSPECTOR GENERAL FOR EVALUATION AND INSPECTIONS, OFFICE OF INSPECTOR GENERAL, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Good afternoon, Mr. Chairman and members of the subcommittee. I am Stuart Wright, Deputy Inspector General for Evaluation and Inspections for the Office of Inspector General (OIG), U.S. Department of Health and Human Services (HHS). I am pleased to have Ann Maxwell, Acting Regional Inspector General from our Chicago office, with me today. I appreciate the opportunity to appear before you to present information regarding the 340B Drug Pricing Program (340B program), which establishes ceiling prices on prescription drugs that are purchased by certain health care entities.

Over the past few years, OIG has issued a number of audit and evaluation reports looking at various aspects of the 340B program. Our most recently published work, "Deficiencies in the Oversight of the 340B Drug Pricing Program," assessed the effectiveness of existing systems and processes that are intended to ensure that entities participating in the program are able to purchase products at or below a statutorily established ceiling price. Currently, we are engaged in another evaluation of the program to determine whether entities participating in the 340B program have actually received the ceiling prices to which they are entitled, and if not, the potential reasons for price discrepancies. Our work has led us to conclude that the 340B program may not be functioning as intended to ensure that appropriate discounts on drugs are available to eligible entities. We have found a number of deficiencies in oversight of the program and have concerns related to broader programmatic issues that negatively impact the program.

My testimony begins with a brief overview of the program, followed by a summary of OIG findings and recommendations that are aimed at improving the 340B program.

Background On The 340B Drug Pricing Program

In 1992, Congress enacted section 340B of the Public Health Service Act (PHS Act), 42 U.S.C. 256b, to establish the 340B Drug Pricing Program. This program, which is managed by the Health Resources and Services Administration (HRSA), provides for sales of drugs at or below established ceiling prices to certain "covered entities" (340B entities) that provide health care to some of the country's most disadvantaged citizens who are typically uninsured or underinsured. 340B entities include such health care entities as public hospitals, AIDS Drug Assistance programs, and community health centers. Based on the most recent HRSA estimates, 340B entities spent $4 billion on covered outpatient drugs in calendar year 2005.

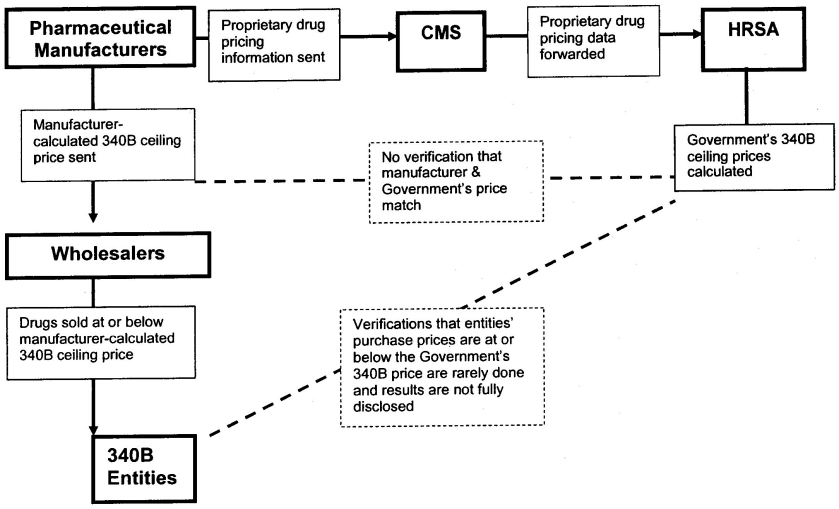
Pursuant to the PHS Act, manufacturers sign a Pharmaceutical Pricing Agreement (Agreement) stipulating that they will charge 340B entities at or below a specified maximum price, known as the 340B ceiling price, for covered outpatient drug purchases. Ceiling prices are guaranteed whether the 340B entity purchases drugs directly from manufacturers or through a wholesaler.

The Government and pharmaceutical manufacturers separately calculate 340B ceiling prices each quarter. The Government's calculations are intended for use in program oversight, while the manufacturers' calculations are the prices used in sales to 340B entities. Both the Government and the manufacturers calculate 340B ceiling prices using the same statutorily-defined formula and the drug pricing data that manufacturers report

to the Centers for Medicare & Medicaid Services (CMS) for the purposes of the Medicaid drug rebate program.

Due to statutory provisions and policies protecting the manufacturers' pricing data, neither the Government's nor the manufacturers' ceiling prices are disclosed to the covered entities. Instead, 340B entities pay the prices they are billed by the manufacturer or wholesaler with no way to verify that they are being charged at or below the 340B ceiling prices to which they are entitled. The chart below illustrates the current flow of 340B ceiling price calculations in the purchase of drugs and oversight of the program. The dotted lines represent where program oversight should be strengthened, as I will discuss further.

Calculation of the 340B Ceiling Price and Purchase Flow



340B Program Oversight Issues

Calculating the 340B Ceiling Price

For many years CMS calculated the 340B ceiling prices used by the program. More recently, HRSA assumed that responsibility. HRSA needs the 340B ceiling prices for research, analysis, audit, and dispute resolution purposes. However, OIG has found systemic problems with the accuracy and reliability of the Government's historical record of 340B ceiling prices. For example, for over a decade, the Government's 340B ceiling prices were calculated using incomplete data to represent package size. HRSA has not established any standards or technical guidance on using the statutorily-defined formula to calculate 340B ceiling prices.

Problems with reliability and accuracy also stem from missing data. When any of the drug pricing elements needed to calculate a ceiling price are missing, an accurate 340B ceiling price cannot be calculated, and HRSA cannot create an accurate record of ceiling prices for program oversight purposes. Missing ceiling prices are most often the result of manufacturers not reporting to CMS, or not reporting in a timely manner, the drug pricing data necessary for the calculation. While HRSA is eventually provided the missing data when they are submitted by the manufacturer to CMS at a later date, HRSA does not have a policy in place to update the ceiling prices when supplemental data are received.

Thus, any missing data elements or 340B ceiling prices simply remain missing. OIG found that HRSA did not have 340B ceiling prices for nearly 30 percent of eligible drugs due to missing data. Another 8 percent of 340B ceiling prices were calculated incorrectly due to missing data.

Monitoring of 340B Program Participation

Based on our review, we concluded that 340B entities' participation in the program is not adequately monitored. HRSA is required to maintain a complete listing of all its participating 340B entities. This permits pharmaceutical manufacturers to verify entities' eligibility for the discount and ensure that their drugs are only shipped to legitimate sites. However, in a June 2004 report, "Deficiencies in the 340B Drug Discount Program's Database," we found that HRSA's participant database inappropriately listed 38 percent of sampled entities as participating in the program when, in fact, they did not. Additionally, we found that the database had incorrect address information for 43 percent of sampled entities. The inaccuracies in the participant database limits HRSA's ability to ensure that only legitimate entities are receiving the 340 ceiling prices.

Ensuring That 340B Entities Pay 340B Ceiling Prices or Below

OIG also found that there is no systematic oversight process in place to ensure that 340B entities receive the ceiling prices to which they are legally entitled. HRSA does not monitor the purchase prices paid by 340B entities to ensure that they are at or below the Government's 340B ceiling prices. Conducting this type of oversight is essential to ensure that Federal grant dollars are spent appropriately.

Rather than establishing a systematic means of monitoring prices, HRSA generally checks the appropriateness of 340B entities' prices only when requested by the entity to do so. An entity may submit a written request to HRSA to conduct a review for a maximum of 10 products. If HRSA agrees to undertake the review, the results will only confirm or refute that the entity has been overcharged. HRSA does not convey the extent of any overcharges due to confidentiality concerns.

Overseeing the Drug Industry's 340B Ceiling Price Calculations

OIG found that HRSA does not verify that manufacturers are correctly calculating 340B ceiling prices. It is especially important for HRSA to monitor manufacturers' ceiling price calculations because the 340B entities are not permitted access to ceiling prices themselves, and therefore cannot perform their own checks. Specifically, HRSA does not compare the Government's 340B ceiling prices to the manufacturers' ceiling prices to ensure that the results are the same. Theoretically, HRSA and manufacturers should calculate the same 340B ceiling prices because they use the same drug pricing elements for the calculation. However, this may not be the case due to differing interpretations of the drug pricing data used in the formula, administrative or other error, and/or intentional misrepresentation.

The lack of written, formal procedures explaining how the Government calculates its 340B ceiling prices increases the possibility of differences in interpretation that could cause manufacturers' ceiling prices to differ. It is also possible for a manufacturer to correctly interpret the calculation but to make an administrative error in applying or transmitting the calculation. Alternatively, manufacturers can benefit from any overpayments that result from their intentional inflation of the 340B ceiling prices or the inappropriate manipulation, to their advantage, of any of the drug pricing data used in the calculation. OIG's current work will attempt to ascertain the extent to which each of these factors may be contributing to 340B entities paying more than the stipulated ceiling prices. A previous OIG report, "Pharmaceutical Manufacturers Overcharged 340B-Covered Entities" (A-06-01-00060), found that five drug manufacturers inappropriately

excluded certain sales from one of the drug pricing elements in the calculation, resulting in overcharges to 340B entities of $6.1 million in 1999.

Broader Programmatic Issues

Confidentiality Provisions

Confidentiality provisions in the Medicaid drug rebate provisions of the Omnibus Budget Reconciliation Act of 1990 (OBRA '90), regarding manufacturers' pricing information, impact HRSA's ability to ensure that 340B entities receive the appropriate ceiling price. The Medicaid drug rebate statute protects the pricing and other data that manufacturers submit to CMS for the Medicaid drug rebate program, in particular Average Manufacturer Price (AMP) and Best Price, as confidential. The law states that the pricing information disclosed by manufacturers "…shall not be disclosed by the Secretary…in a form which discloses the identity of a specific manufacturer, ...[or] prices charged for drugs by such manufacturers," except as the Secretary determines to be necessary to carry out the provisions of the statute or in other limited situations.[1] This provision has been interpreted to mean that HRSA is precluded from revealing exact overcharges to 340B entities, so as not to reveal the 340B ceiling prices to the entities.

Confidentiality provisions related to disclosure of 340B ceiling prices also limit the ability of the Prime Vendor to negotiate for prices below stipulated 340B ceiling prices. The PHS Act mandates the creation of a Prime Vendor Program. The Prime Vendor may attempt to negotiate subceiling prices on behalf of 340B entities. However, the Prime Vendor cannot effectively negotiate subceiling prices if it is not allowed access to the 340B ceiling prices. Such access has been limited by the manner in which the confidentiality provisions have been interpreted.

340B Program Enforcement Authorities

We believe that HRSA lacks the necessary legislative, regulatory, and contractual authority to enforce manufacturer and wholesaler compliance with the PHS Act and the Agreement. The PHS Act does not provide HRSA with the authority to impose civil monetary penalties for noncompliance with the 340B program requirements. Instead, the PHS Act and the companion provisions of the Social Security Act require that manufacturers must comply with the terms of the 340B program and the Medicaid drug rebate statute. Noncompliance could result in termination from participation in the Medicaid and 340B programs. This remedy is so extreme that it limits the likelihood that it will be used. To date, it has never been used. Terminating a manufacturer's participation is an exceptionally severe sanction, given the effect that terminating a manufacturer would have on access to medications for the millions of Medicaid and 340B beneficiaries.

Further, it is CMS and not HRSA that initially receives the data from manufacturers, and manufacturers are not required to report the information directly to HRSA. HRSA does not have statutory authority to compel manufacturers to report complete drug pricing data in a timely matter to CMS. Under the Medicaid drug rebate program statute (pursuant to which manufacturers send data to CMS), the Secretary of HHS has the authority to impose a civil monetary penalty for late submission of drug pricing data. We are unaware of any use of this provision in recent years. Instead, manufacturers are generally notified by CMS of the late data and are afforded the opportunity to supply the previously missing data with a subsequent data submission. While subsequent data submissions do not pose a significant problem for the retrospective Medicaid drug rebate program, which CMS oversees, late submissions of the drug pricing data prevent HRSA's timely and accurate calculations of the Government's 340B ceiling prices. Also, because

[1] 42 USC §1396r8(b)(3)(D)

manufacturers are not required to share the 340B ceiling prices that they calculate with the Government, there are no data available for comparison.

OIG also found limitations with the obligations outlined in the Agreement. The Agreement gives the Secretary of HHS the ability to require manufacturers to reimburse entities for discounts withheld. However, even when HRSA attempts to take action against violators based on the Agreement, HRSA's lack of legal authority makes the Agreement challenging to enforce. For example, in response to the 2003 OIG finding that five manufacturers had overcharged 340B entities by $6.1 million, HRSA issued letters to each of the five drug companies requesting that they develop action plans that include refunding covered entities for overcharges. According to HRSA, the companies have responded to the letters, but refunds have yet to be recovered.

OIG found that the only compliance mechanism that HRSA currently has with regard to refunds is an informal dispute resolution process that has never been utilized. Because the 340B program dispute resolution process is voluntary, manufacturers and 340B entities are not required to participate. If the manufacturer does not cooperate with the dispute resolution process, HRSA can neither compel their participation nor sanction their lack of participation.

OIG Recommendations

OIG's recommendations to improve the 340B Program focus on the steps HRSA can take to strengthen its oversight and management of program operations and on the two broader programmatic issues I just described.

340B Program Oversight

To strengthen HRSA's ability to oversee the program, OIG recommends that HRSA: (1) publish detailed standards for the Government's calculation of 340B ceiling prices, (2) work with CMS to ensure timely receipt of manufacturers' pricing data, and (3) develop a strategic plan for managing the 340B program database. HRSA concurred with these recommendations and has made some progress in implementing them, including launching a new database to track entity participation.

In addition, OIG recommends that HRSA develop oversight mechanisms to verify that 340B ceiling prices are being correctly calculated by manufacturers. We suggest that HRSA selectively audit manufacturers and wholesalers. HRSA has stated its intention to review 340B prices that manufacturers voluntarily supply to them. However, OIG does not believe that this approach provides a sufficiently systematic review of compliance necessary to provide adequate oversight to the program.

OIG also recommends that HRSA develop monitoring mechanisms that allow for a comparison of the Government's 340B prices and the prices paid by 340B entities. There are several ways HRSA could achieve this. For example, HRSA could spot-check covered entity invoices against the Government's record of 340B ceiling prices. Alternatively, HRSA could develop a system for covered entities to access certain secured pricing data to help them determine whether the prices they pay exceed the 340B ceiling prices.

Broader Programmatic Issues

OIG believes that permitting some disclosure of information about 340B ceiling prices is essential to improving the operation of the program. HRSA's options for using 340B ceiling prices to monitor the program are limited due to the confidentiality of the drug pricing data elements used to calculate the 340B ceiling prices. The Social Security Act expressly permits the Secretary to disclose information if disclosure is determined to be "necessary to carry out" the programs, including the 340B program. However, HRSA has been following a CMS interpretation of the confidentiality provision that prohibits

HRSA from using the 340B ceiling prices to monitor the program. OIG sees a need for clarification of the confidentiality provision.

OIG also recommends that HRSA seek authority to establish penalties for program violations. We disagree with HRSA's assessment that it has sufficient authorities to enforce the requirements of the 340B program statute. The Secretary of HHS could terminate a manufacturer's participation in the Medicaid drug rebate and 340B programs, but HRSA has no effective penalties to use for violations of the PHS Act or the Pharmaceutical Pricing Agreement. We believe that legislation authorizing the imposition of penalties and fines would provide HRSA with more effective tools to enforce the 340B program requirements.

Conclusion

We appreciate the Committee's interest in this important subject. Further, we are encouraged by HRSA's response to our recommendations. We believe that HRSA has been responsive in terms of its improvements in the accurate calculation of the 340B ceiling prices and its 340B participant database. However, we encourage HRSA to fully address OIG's recommendations related to strengthening the administration and oversight of the 340B program. In addition, OIG continues to believe that confidentiality issues and a lack of enforcement authority impact HRSA's ability to ensure that the program is functioning properly and that 340B entities are paying at or below the 340B ceiling prices.

OIG is committed to continuing its review of this program and addressing the concerns of congressional oversight committees. As previously mentioned, OIG is currently engaged in a review to determine whether 340B entities pay at or below the statutorily-defined 340B ceiling price, and, if not, the potential reasons for price discrepancies. We anticipate a final report on this topic in Spring 2006. This concludes my testimony. I would be happy to answer your questions.

MR. WHITFIELD. Mr. Wright, thank you very much. At this time, I recognize Mr. Williams for his opening statement.

MR. WILLIAMS. Mr. Chairman, members of the subcommittee, my name is Dennis Williams. I am the Deputy Administrator of the Health Resource and Services Administration, and I'm pleased to appear before you today to discuss the oversight and administration of the 340B drug pricing program in light of the recent reports by the Office of Inspector General.

The 340B program was created by section 602 of the Veterans Health Care Act of 1992. The purpose of the program is to limit the costs of covered outpatient drugs to federally funded grantees and other safety-net health care providers referred to as covered entities. By expanding access to affordable drugs, the 340B program plays an important role in eliminating health disparities and improving the health of the uninsured and underinsured.

HRSA is responsible for ensuring that drug companies and covered entities carry out their responsibilities under the law. Drug companies participating in the Medicaid program are required to enter into pharmacy pricing agreement with HRSA and to provide outpatient drugs

to covered entities at or below a maximum or ceiling price established by the law. In turn, covered entities are prohibited from reselling or transferring a drug obtained with a 340B discount to a person who is not a patient of the entity. They also agree not to request a 340B discount for a drug which is subject to a Medicaid rebate.

HRSA administers the 340B program based on Medicaid drug data received from the Centers for Medicaid and Medicare Services. Currently there are over 12,000 covered entities and approximately 650 drug manufacturers participating in the program. Covered entities have realized significant savings on pharmaceuticals estimated at 20 to 50 percent below list price or average wholesale price. This translates into roughly $1.5 billion to $2 billion savings annually. We estimate an annual purchasing volume of $4 billion, which represents about 1.7 percent of the $230-billion-a-year pharmaceutical market.

Recent reports by the Office of Inspector General have focused on pharmaceutical manufacturers' compliance with their obligation to sell outpatient drugs at or below 340B prices. In a March 2003 audit, the OIG found that five pharmaceutical manufacturers overcharged 340B covered entities $6.1 million for sales during the 1-year period ending September 30, 1999. In September 2004, HRSA sent letters to these companies requesting corrective action plans for payment of the OIG stated overcharges. We are currently working with the drug companies and CMS to resolve the issues raised by the OIG.

At the request of the Department of Justice, which is investigating one of the companies, we have temporarily suspended our inquiry of this company.

In October 2005, the OIG issued a final report concerning the oversight of the 340B program. In this report the OIG made five recommendations:

First, HRSA and CMS should continue to work together to ensure accurate and timely pricing data.

Second, HRSA should establish detailed standards for the calculation of ceiling prices.

Third, HRSA should institute oversight mechanisms to validate 340B price calculations and the prices charged to participating entities.

Fourth, HRSA should seek authority to establish penalties for statutory violations.

And fifth, HRSA should provide participating entities with secure access to certain pricing data.

We have taken several steps to address the findings of the OIG. In September 2005, HRSA signed an interagency agreement with CMS to receive the average manufacturer's price and the Medicaid unit rebate data needed to calculate the 340B ceiling prices. Since that time we have

assumed the responsibility for calculating ceiling prices from CMS. In addition, we have arranged to purchase packet-size data from First Data Bank to accurately compute the 340B prices, and we have increased outreach and technical assistance to encourage enrollment in the 340B program.

In order to validate 340B prices calculated by pharmaceutical companies, we plan to compare quarterly manufacturer pricing data available through the Prime Lender Program with 340B pricing data; contact manufacturers to resolve discrepancies; and, request the IG audit difficult cases and/or refer to the Department of Justice.

HRSA has targeted some of its administrative resources to monitoring allegations of drug diversion by covered entities, and we have referred some cases to the Department of Justice through the OIG. These cases have helped us to examine the need to revise program guidelines to more clearly define the patient-provider relationship under the 340B program. In addition, we are drafting guidelines on the use of multiple contract pharmacies as a way to expand access to discounted drugs, especially in rural areas.

The 340B program is essential to ensuring access to quality health care for the Nation's most vulnerable patient populations. Thank you for the opportunity to report on the oversight and administration of the program. We look forward to working with you to guarantee the 340B drug price program continues to be a valuable Federal resource.

MR. WHITFIELD. Mr. Williams, thank you for your testimony.

[The prepared statement of Dennis P. Williams follows:]

PREPARED STATEMENT OF DENNIS WILLIAMS, DEPUTY ADMINISTRATOR, HEALTH RESOURCES AND SERVICES ADMINISTRATION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Mr. Chairman and Members of the Subcommittee:

My name is Dennis Williams. I am the Deputy Administrator of the Health Resources and Services Administration (HRSA). I am pleased to appear before you today to discuss the oversight and administration of the 340B Drug Pricing Program (340B Program) in light of the recent reports by the Office of the Inspector General.

History of the Program

The 340B Program was created by Section 602 of the Veterans Health Care Act of 1992 (P.L. 102-585), which was enacted on November 4, 1992. As established, the 340B Program limits the cost of covered outpatient drugs to certain safety-net providers, referred to as covered entities. These covered entities include: Federally Qualified Health Centers (FQHCs), Hemophilia Treatment Centers, Ryan White Programs, Sexually Transmitted Disease/Tuberculosis Programs (STD/TB), Title X Family Planning (FP) Clinics, Urban/638 Tribal Programs, Federally Qualified Health Center Look-Alikes and certain Disproportionate Share Hospitals (DSHs).

The 340B drug discount prices, commonly referred to as ceiling prices, are based on Average Manufacturers Price and Medicaid Drug Rebates. Pharmaceutical companies

that participate in the Medicaid program must sign a Pharmaceutical Pricing Agreement that obligates them to participate in the 340B program. Under the 340B program, the selling price may be lower than the ceiling price, but never greater.

HRSA Oversight and Administration

HRSA administers the 340B program based on Medicaid drug data received from the Centers for Medicaid and Medicare Services (CMS) pursuant to an Intra-Agency Agreement. Through our Office of Pharmacy Affairs (OPA), we: enroll eligible entities in the 340B program; maintain a web accessible database that houses eligible covered entity data, program guidelines and other useful information; calculate the 340B discount price; execute Pharmaceutical Pricing Agreements with drug manufacturers; provide information and technical assistance to covered entities via the Pharmacy Services Support Center (PSSC); administer the Prime Vendor Program; and provide program oversight.

The PSSC, operated under a contract with the American Pharmacists Association, provides expert technical assistance to covered entities that want to access the 340B program and to improve their pharmacy programs.

The new Prime Vendor Program, which operates under a competitively awarded agreement with Health Purchasing Partners International, became effective in September 2004, and has three primary functions to increase value for participating covered entities: 1) negotiate drug prices below the statutorily required 340B ceiling price; 2) enter into favorable distribution agreements with multiple drug wholesalers; and 3) provide discounts on other value-added pharmacy products and services. As of November 2005, approximately 2,000 covered entities participate in the Prime Vendor Program and represent over $1.7 billion in combined purchases.

Currently, there are a total of over 12,000 participating 340B covered entities. As of October 2005, approximately 650 drug manufacturers have signed Pharmaceutical Pricing Agreements.

The most important benefit of participation in the 340B Drug Pricing Program is the significant savings on pharmaceuticals estimated at 20% to 50% below list price or average wholesale price. We estimate annual 340B purchasing volume of $4 billion, which represents about 1.7% of the $230 billion a year pharmaceutical market. We estimate that participating entities can save $1.5 billion to $2 billion annually.

In June 2001, the Alternative Methods Demonstrations Projects were initiated to increase access to affordable drugs for uninsured and underinsured patients of covered entities, particularly in rural areas. These projects involve one or a combination of the following three activities: 1) a network of covered entities; 2) multiple contracted pharmacy services sites; or 3) a contracted pharmacy to supplement in-house pharmacy services. As of October, there were 11 approved projects.

2003 OIG Report

In a March 2003 audit, the Office of Inspector General (OIG) found that 5 pharmaceutical manufacturers overcharged 340B covered entities $6.1 million for sales during the 1-year period ending September 30, 1999.

In September 2004, HRSA sent letters to these companies requesting corrective action plans for repayment of the OIG stated overcharges. To date, we have not received refunds from the companies. We are currently working with CMS to resolve the issues raised by the OIG.

2004 OIG Report

In June 2004, the OIG assessed the accuracy of information contained in 340B Drug Discount Program's database. The OIG recommended that HRSA develop a strategic plan for managing 340B program data. In order to implement the recommended

improvements, HRSA contracted with a firm to assist in the completion of these enhancements. We have also entered into a separate contract for the development of the new Web database using the new systems requirements as a guide.

2005 OIG Report

In October 2005, the OIG issued a final report concerning HRSA's oversight of the 340B Program. In this report, the OIG recommended actions to: ensure accurate and timely pricing data; set detailed standards for calculation; create procedures to validate price calculations and prices charged; establish penalties for violations; and, provide access to certain pricing data to help approximate 340B ceiling prices.

HRSA and CMS recently signed an Intra-Agency Agreement (the Agreement). In accordance with the Agreement, we now receive the AMP and the Medicaid Unit Rebate data from CMS to calculate the 340B ceiling prices. In addition, we have increased outreach and technical assistance to covered entities. Currently, we are seeking voluntary data submissions for the Prime Vendor secure Web site; monitoring compliance with 340B legal and regulatory requirements; and working with the OIG and DOJ in instances of drug diversion. These cases of drug diversion have led us to examine the need to revise program guidelines to more clearly define the patient-provider relationship under the 340B Program. Lastly, we plan to compare pharmaceutical company ceiling price data with market place selling price data on a quarterly basis and follow-up with the respective drug company or wholesaler to resolve discrepancies. Unresolved discrepancies may be referred to the OIG and DOJ for assistance.

With over twelve thousand participating covered entities, the 340B Drug Pricing Program plays an important role in improving the health of the uninsured and underinsured. The 340B Program ensures that federally funded grantees and other safety net health care providers purchase prescription medication at significantly reduced prices. In so doing, this program expands access to affordable pharmaceutical drugs, improves health outcomes and eliminates health disparities among the nations most vulnerable.

Thank you for the opportunity to report on the oversight and administration of the 340B Drug Pricing Program. We look forward to working with the Committee to ensure that the 340B Drug Pricing Program continues to be a valuable Federal resource.

MR. WHITFIELD. We are getting ready to have a final vote in the full committee downstairs. So we're going to recess for 15 minutes and when we come back, hopefully we're going to ask these questions, go to the second panel, and there won't be any more interruptions. So we'll recess for 15 minutes, we'll be right back.

[Recess.]

MR. WHITFIELD. The hearing is reconvened and once again I apologize to you all. But, Mr. Wright, I would like to ask you a few questions to start off with here. Does HRSA currently verify that manufacturers are correctly calculating the ceiling prices for their drugs?

MR. WRIGHT. I do not believe that they currently do that, sir.

MR. WHITFIELD. Now, if HRSA and the drug manufacturers are independently calculating these ceiling prices based on the same data, shouldn't their calculations be exactly the same?

MR. WRIGHT. Yes. Theoretically, as I indicated in my opening statement, they should be the same. However, there are some nuances in terms of how the calculations are done. There may, in addition, be sort

of inadvertent administrative error or there could be intentional misrepresentation. Any of those three things would cause there to be a discrepancy. And as a I stated in my statement, as a result of that, it's imperative for HRSA to conduct aggressive oversight to ensure that there are in fact no discrepancies.

MR. WHITFIELD. And so it would not be unusual that there be different prices because of the three or four reasons that you've elaborated on there.

MR. WRIGHT. Correct. And the ongoing work that you referenced in your opening statement is actually looking at invoice prices paid by 340B entities and comparing that to the government's ceiling price. To the extent that there are discrepancies, we will identify them in this ongoing work, and we will calculate any overcharges that are resulting to 340B entities.

MR. WHITFIELD. I'm assuming HRSA would not check to make sure that the covered entities are actually receiving the discount they are entitled to, because of what you already said, they don't really have the mechanism to do that.

MR. WRIGHT. Yes. I believe that they currently do not do oversight of the manufacturer's generated number. There is some spot-checking of the 340B entities' invoices, but that is not systematic and not widespread.

MR. WHITFIELD. And from your report, your investigation, I'm assuming that it's not unusual that there are overcharges; would that be accurate or not?

MR. WRIGHT. Certainly from the audit report that was issued in 1999, there were $6.1 million in overcharges just from five manufacturers and 11 drugs for a period of 1 year. The ongoing work that we have will quantify the overcharges and project total overcharges to all drugs covered under the 340B program. But as of yet I can't quantify that for you.

MR. WHITFIELD. Now we have a witness with GlaxoSmithKline that will be on the second panel, and I said in my opening statement, the fact that Glaxo is now posting its ceiling price on the prime vendor's web site, is that sufficient to increase transparency in the 340B program?

MR. WRIGHT. It is certainly a step in the right direction. We are in favor of anything that increases transparency between the government-calculated 340B ceiling price and those prices paid by the 340B entities. And this is certainly a step in the right direction. It does not cover all drugs and all entities.

MR. WHITFIELD. Now, if HRSA becomes aware of an overcharge, what are the current options in terms of dispute resolution and/or enforcement that's available to HRSA?

MR. WRIGHT. To our understanding, the only enforcement mechanism that is available to HRSA if there is noncompliance with the 340B program requirements is to terminate the manufacturer from both Medicaid and the 340B program. And as I indicated in my statement, that is such a drastic penalty that it is likely not to be used.

MR. WHITFIELD. And are you aware of any incidences where that has been the case?

MR. WRIGHT. I believe it has never been utilized.

MR. WHITFIELD. It's my understanding -- and I'll get to Mr. Williams in just a minute -- or has my time expired -- that HRSA does not believe there are any legislative changes needed at this time. From your experience looking into this issue, do you feel like there are some specific legislative or regulatory or contractual changes that need to be made to improve this program?

MR. WRIGHT. Yes. We have stated very clearly that we think additional intermediate sanctions should be authorized and that HRSA should seek legislative authority to impose civil monetary penalties for situations of noncompliance. I certainly will let Dennis speak, but I believe that HRSA has taken the position that a number of the other things that they're currently undergoing in terms of addressing the previous OIG recommendations should occur first before they make a full assessment about whether or not additional penalties are necessary.

But clearly we've said that there should be additional penalties because the current penalty of kicking manufacturers out of Medicaid and the 340B program is so draconian that it's not likely to be utilized.

MR. WHITFIELD. Mr. Williams, of course you have seen the OIG report, I'm assuming, and was HRSA aware of these problems prior to this report coming out? I'm assuming that you were.

MR. WILLIAMS. Yes, we were aware of them. But I think the IG has done a very good job in systematically looking at a number of these issues and laying them out in one place. So I think they have done a good job and focused us on a number of tasks that I think can help us improve the administration of the program.

MR. WHITFIELD. Now, do you all feel like you need additional legislation or do you feel like HRSA can do it from a regulatory standpoint or what?

MR. WILLIAMS. Our primary job is to administer the program within the legislative context that we currently have, and we are working hard to try to do that. I think the OIG has pointed out some areas where additional authorities under certain circumstances may be useful, but I don't think that we have exhausted all of the possibilities to try to carry out our responsibilities within the existing authority. There are some limitations in that.

MR. WHITFIELD. So officially HRSA is not asking for any legislative changes at this point.

MR. WILLIAMS. Not at this time we're not.

MR. WHITFIELD. Now, on page 21 in the OIG's recommendations, he says that HRSA should establish detailed standards for the calculation of ceiling prices. And in the wake of the OIG report, I was curious, have you all taken any steps to develop some specific procedures for calculating these ceiling prices?

MR. WILLIAMS. No, but we think it's a good idea. We just took over -- CMS up until about September was responsible for actually calculating the 340B ceiling prices, which they then passed on to us. We have agreed with CMS beginning in October that we will now do that calculation, again, with information provided to us by CMS and drug companies. But now that we do have the responsibility, I think the idea of laying out the procedures is a good idea and we'll work on that.

MR. WHITFIELD. Do you all have the ability or the authority to compel manufacturers to provide their ceiling prices?

MR. WILLIAMS. We don't directly. As part of their agreements to participate in the 340B program and the Medicaid drug rebate program, they have an obligation to provide that information.

MR. WHITFIELD. How many of them provide the ceiling prices to HRSA?

MR. WILLIAMS. Up until now they have been providing the information to CMS, and through CMS the calculations have come to us.

MR. WHITFIELD. What about the underlying data to calculate the ceiling price; do they provide that to you?

MR. WILLIAMS. No. They will be. Again, they provide -- up until September they have been providing that information to CMS, the average wholesale price and the other information CMS needed. We'll be getting that information.

MR. WHITFIELD. What about the actual calculation itself?

MR. WILLIAMS. We got the calculation from CMS, up through September. We're going to do that now ourselves, in conjunction with them, but we'll actually do the calculation ourselves.

MR. WHITFIELD. I see my time has expired, so at this point I'll recognize Mr. Stupak.

MR. STUPAK. Mr. Wright, the 2001 OIG report found that 50 percent of the drugs provided by 340B entities were priced at levels exceeding the government's applicable ceiling prices. Do you have any reason to think that is not true today?

MR. WRIGHT. Are you speaking of the June 2004 OIG report?

MR. STUPAK. 2001. Back then they said 50 percent of drugs, or more, were exceeding government levels. Any reason to think that's not true today?

MR. WRIGHT. As I indicated, we're currently doing a review which consists of a random sample of invoices that 340B entities have paid. We'll be able to quantify exactly the extent of the overcharges in terms of the percent and the amount. That isn't information that I have today, and we do hope to report to you in the spring.

MR. STUPAK. Let me ask you this one. In October 2004, HRSA, the Administrator and Chairman Barton promised a comprehensive plan to strengthen the effectiveness of the 340B drug pricing program, and that was based again on an OIG report of 2004. HRSA also concurred with those recommendations. Did you see any evidence of that plan during your work in 2005?

MR. WRIGHT. I think we have had fairly good communication with HRSA regarding the 340B work that we have done. We think, as I indicated in my testimony, that they have been fairly responsive to the OIG recommendations. There are a number of areas where we think they can take additional steps, but in general I think we have been pleased with the actions that HRSA has taken to date based on what we've found.

MR. STUPAK. Is there a plan that came over from 2004 to now?

MR. WRIGHT. I have not seen a specific plan and certainly welcome Mr. Williams to address that. I have seen detailed responses from HRSA in terms of the OIG recommendations that have been made to date, including various correspondence with Members of Congress delineating what they're planning on doing specific to each recommendation.

MR. STUPAK. Let me ask you then, Mr. Williams, has a plan been developed as they said they were going to do in 2004?

MR. WILLIAMS. We have taken a number of steps to try to improve our administration of the program. We're working on the development of a database which will -- one of the things the inspector general pointed out to us is our list of covered entities, addresses, contact information was not up to date.

MR. STUPAK. I'm asking about a comprehensive plan. Was a plan put forth in writing?

MR. WILLIAMS. Not a plan. We have a series of steps which we are working on.

MR. STUPAK. I'm glad you're talking to each other, and I'm glad things are going better, but the point I was asking about is a comprehensive plan as you said you were going to do in October of 2004. I just need to know if there's a plan.

MR. WILLIAMS. Well, if you mean -- as a result of the work of the Inspector General and others, we have identified a number of weaknesses in the program which we are working on.

MR. STUPAK. Are those weaknesses in writing anywhere?

MR. WILLIAMS. They are on our work plan.

MR. STUPAK. Could you submit that work plan in to us? I'm not making this up. Says "comprehensive plan" in quotes, so we want to see that plan.

MR. WILLIAMS. We'd be glad to tell you the steps we're undertaking to improve the program.

[The information follows:]

RESPONSE FOR THE RECORD BY DENNIS WILLIAMS, DEPUTY ADMINISTRATOR, HEALTH RESOURCES AND SERVICES ADMINISTRATION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

What steps are we undertaking to improve the program?

We signed an Interagency Agreement with CMS for fiscal year 2006. We assumed the responsibility of computing 340B ceiling prices beginning October 1, 2005. The Interagency Agreement continues to restrict our use of the data and does not allow for pricing transparency.

On December 30, 2005 we mailed the letter requesting voluntary submission of manufacturer 340B ceiling price data and requested drug company permission to share their pricing data on a password-protected secure web site maintained by the 340B Prime Vendor. We have gotten a positive response from many manufacturers, and have to date received pricing submissions to the Office of Pharmacy Affairs (OPA) from 134 manufacturers. These manufacturers comprise roughly 20 percent of all manufacturers participating in the 340B program. Only one of these companies has voluntarily agreed to permit their data to be shared with the Prime Vendor.

We have compared computed 340B prices with those submitted in Excel format by manufacturers, and have identified pricing discrepancies that allowed us to further review the data submitted and price algorithm assumptions. Informal contact with the OIG has confirmed that there remain pricing discrepancies attributable largely to different package size conventions used by the pharmaceutical industry and CMS.

We hope to have a more formal interaction with OIG by the end of March to discuss findings and problem-solve. In the interim, OPA and its contractor are reviewing data anomalies to discover root causes for pricing errors. These anomalies include mismatches in CMS and First Data package size data, apparent changes in package size for a given National Drug Code (NDC) and incomplete data.

We may seek OMB approval to request that drug companies submit their pricing data in a standard format. Standardization of price submissions will give HRSA the ability to review data submitted in a cost-effective manner while ensuring the quality of the data. We have created a draft Excel template for drug companies' voluntary submission of 340B prices from our experience thus far with manufacturer price submissions. HRSA will explore with HHS and OMB if additional approvals are required to stipulate an Excel format.

MR. STUPAK. Okay. Let me ask you this: Can you explain to me -- the Chairman was asking you about the pricing. There is really two pricing plans, isn't there, one by the government, one for the ceiling price; one by the government they calculate, and then the manufacturers calculate one?

MR. WILLIAMS. Yes.

MR. STUPAK. Is that both plans provided to you so you can check calculations, things like that?

MR. WILLIAMS. Now, we have the drug companies provide information to CMS, who calculates the 340B ceiling prices. The drug companies calculate their own, and they use that as the basis for doing business in the marketplace with covered entities.

MR. STUPAK. Have you ever seen the manufacturers' drug pricing plan?

MR. WILLIAMS. We have seen GlaxoSmithKline. They have voluntarily agreed to give us their 340B ceiling price calculations, and they've provided to us and --

MR. STUPAK. Anyone else besides GlaxoSmithKline?

MR. WILLIAMS. No. We are hopeful that they, having stepped forward -- they're a major company, and stepping forward, voluntarily making information available into the marketplace, and we hope that that will lead others to do the same. Limitations in the law don't allow us to go at this more directly, but if the drug companies voluntarily provide information --

MR. STUPAK. Do you think it would be helpful if the drug companies provided their ceiling price plans?

MR. WILLIAMS. If they provide it voluntarily, and depending on what limitations they put on its use.

MR. STUPAK. Even if they didn't voluntarily, let's say if they had to provide it to you, wouldn't that be helpful? I'm a little disturbed when they say at the beginning, here we spent $61 million for 11 drugs from 5 different manufacturers, a random sample they did. I'm sorry; $6.1 million for 11 drugs from 5 manufacturers.

I mean, if you have got two ceiling prices, you know what yours is because you calculate it, but you don't know what the drug companies' are. How do you know if you're getting the right deal?

MR. WILLIAMS. The law provides certain limitations on the use of the information that we get from drug companies. They can provide us pricing data related to their drug data, and the law puts limitations on what we can do with that limitation and how we can use it.

MR. STUPAK. Are you saying the law puts a limitation on you from getting a ceiling price from the drug companies?

MR. WILLIAMS. From using that ceiling price.

MR. STUPAK. I'm talking about getting it for comparison purposes. If you're trying to figure out if you're getting overpaid or underpaid, I would think you need a yardstick to measure it by. I would think that yardstick would be, since there is two ceiling price plans --

MR. WILLIAMS. Not necessarily. They are calculated in two different ways, but the drug companies calculate using the same formula that we do for a ceiling price. As the OIG has pointed out, we don't know the degree of discrepancy.

MR. STUPAK. Absolutely you wouldn't know it. So wouldn't you want to see it?

MR. WILLIAMS. Sure.

MR. STUPAK. Have you ever asked?

MR. WILLIAMS. I am limited on what I can do with that information.

MR. STUPAK. There's nothing in the law that says you can't ask for it, right, or to make the comparison?

MR. WILLIAMS. No.

MR. STUPAK. The concern I have, and, again, in answer to a question to the Chairman, you said you had not exhausted all your possibilities, and therefore you didn't think you needed any legislative changes. This law has been around since 1993, and we're on our 12th year. I would think we would have exhausted our administrative remedies. After 12 years I think you would try something to get control over this, because the problem is a lack of information being shared between all the parties, correct?

MR. WILLIAMS. I think transparency is an issue in this program. There are covered entities in the marketplace purchasing drugs at certain prices, and the law requires drug companies do make those drugs available to covered entities at certain prices, and not everybody has full information.

MR. STUPAK. The Inspector General says in the report you need more legislative, regulatory, and contractual authority to enforce manufacturer and wholesale compliance with the 340B program. Do you agree?

MR. WILLIAMS. I think our job is to work as best we can within the limitations of the law, and we're trying to do that. I think we've made some progress. Drug companies in the case of --

MR. STUPAK. My question is do you agree with the inspector general when they say you need more legislative, regulatory, and contractual authority to enforce manufacturer and wholesale compliance with 340B program; do you, yes or no?

MR. WILLIAMS. I think we're making progress with the authorities we have, and we're going to continue to try to do that.

MR. STUPAK. It's been 12 years' worth of progress. When will you get to the final analysis here?

MR. WRIGHT. In recent months I think we've made a lot of progress, and there are a lot of opportunities here to improve the situation. I think we look forward to the IG study this spring. I think no one really knows the overall degree to which ceiling prices are not actually being provided to people. I think that information would be very helpful to all of us.

MR. STUPAK. I'll yield back, Mr. Chairman.

MR. WHITFIELD. Mr. Inslee, you're recognized for 10 minutes.

MR. INSLEE. Thank you. I'm probably the least --

MR. WHITFIELD. Mr. Inslee, excuse me, I didn't see Ms. Blackburn. So, Ms. Blackburn, you're recognized for 10 minutes.

MS. BLACKBURN. Thank you, sir, and I will not take all of my time because I know we're going to have a vote very soon, and the others would like the opportunity to question. And I do have several questions for you all, and I want to thank you all for staying while we were between votes.

I want to follow right along, Mr. Williams, with what Mr. Stupak was talking with you about, and please understand I can hear the frustration in your voice, and I don't know if you're frustrated with us or with the situation or with the bureaucracy, which can be very difficult to deal with. And many of us -- I have hospitals that participate in this program, and what we find ourselves looking at is probably we have a lot of bad data that is out here and no confirmation that the hospitals are getting the prices at the levels at which they're supposed to get under this program. So there is a lot of frustration and call to question.

Now, you have mentioned the identified weaknesses that you all -- and that you all have a work plan. Mr. Stupak has asked that you submit that. What I would like to see from you is a time line, because one of the things that frustrates me is the fact that repeatedly we have hearings with different agencies who are always going to get around to it, and they're always go to do something, and in the meantime we have taxpayers that continue to foot the bill for systems that do not work and do not yield the quality of service that they should be yielding. The 340B program is one of those that should be doing a good work, but nobody can really confirm if it is or if it is not, so, therefore, yes, it is going to be questioned. And we are getting our vote.

Going to transparency, Mr. Wright, if I can come to you, please. In your testimony you mentioned that in your review that the 340B entities' participation in the program is not adequately monitored, including 38 percent of the database listed as participating the program when they did not and incorrect address information for 43 percent of the entities.

Now, I tell you, I'm coming to this because when I previously served on government Reform with government efficiency and financial management. One thing that was quite frustrating is the fact that whether it is monetary resources or human capital, there seems to be either a lack of will or a lack of knowledge in how to manage those resources. So, you know, that caught my attention when you said that. A third to a half of your program you feel like you don't have a good handle on.

So based on that, can a drug manufacturer participating in this program be assured that the hospitals they are offering the 340B prices are actually participating in the program? And then what investigations or oversight is being formed to ensure that only eligible entities are receiving those prices?

MR. WRIGHT. It is essential that only eligible entities receive those discounts.

MS. BLACKBURN. How can you assure that?

MR. WRIGHT. The 38 percent of the entities that we sampled told us that they were not participating in the program even though they were listed in the database that contained the full listing of all 340B participants. So since they stated that they weren't participating in the program, one would expect that they had not billed any drugs using 340B prices. But, nevertheless, it is still somewhat disconcerting --

MS. BLACKBURN. If I may interrupt you for the sake of time. You have no confirmation on that. That is just your assumption.

MR. WRIGHT. They said they were not participating.

MS. BLACKBURN. I want to move on with you on that because I'm going to submit the rest of my questions, but I want to know what you're doing as far as penalties. When you talk about the $6.1 million in overcharges, I want to know if you're recouping that money, and what percentage of that you're recouping, and if you're recouping it with penalties. And you're going to get these questions submitted to you for your answers.

I also have some questions on the flow chart dealing with ensuring that manufacturer ceiling price and the government ceiling price are going to match.

With that, Mr. Chairman, I'm going to yield back so that the others have the opportunity before we're called to vote. I thank you.

MR. WHITFIELD. Thank you, Ms. Blackburn.

Mr. Inslee, you're recognized.

MR. INSLEE. Thank you.

I was just reading some staff memorandum, and it says: Drug manufacturers are not required to provide their ceiling price calculations to HRSA, so HRSA does not have ability to compare its ceiling price

calculations to those of the manufacturers in order to identify discrepancies. Is that accurate?

MR. WILLIAMS. Yes, although as we pointed out, one company has come forward and offered to voluntarily provide that information. They also are making that information available to the prime vendor and through the prime vendor in a secure Website.

MR. INSLEE. If you were to conclude that's a problem, that we want HRSA a to have that information so it can act accordingly, is it fair to say that we ought to adopt a statutory requirement that that happen, that HRSA be provided that?

MR. WILLIAMS. Well, that's for this committee and the Congress to decide. I think there are opportunities for us to work with the drug companies and covered entities to create a situation where everybody has the information they need to carry out their obligations under the law.

MR. INSLEE. I guess what I'm trying to get at is if we don't statutorily require that, it's probably not going to happen, is that a fair statement, because for reasons outside of your control, you're not going to accomplish that; is that a fair statement or not?

MR. WILLIAMS. We have not concluded that, no.

MR. INSLEE. Well, so let me ask you this: If we don't compel them to provide it to you and give you the right to obtain it, what can you tell us as to whether or not you'll get that information?

MR. WILLIAMS. I can tell you that we are working with drug companies to try to create a situation where transparency can be improved. At this stage we have made some very good progress there. We have a long way to go, but a good step forward, and we're hoping that the fact that GlaxoSmithKline has stepped forward, this is a very competitive industry, and that people will notice what they do, and we would hope that others would come forward also.

MR. INSLEE. Can you give us any percentages like 50 percent in next 12 months or any assessment at all?

MR. WILLIAMS. No, I can't give you that assurance.

MR. INSLEE. So what incentive do people have for providing you this information right now?

MR. WILLIAMS. I think it is -- I can't speak for the drug companies. GlaxoSmithKline will come forward in the second panel. I think that's a good question for them, what was the incentive of them to give us that information. They felt it was in their interest. We did not, as you point out, force them to give us that information; they came forward voluntarily, and I think that's a good question for them to answer for you, and I think it's probably instructive for other drug companies as well.

MR. INSLEE. Thank you.

MR. WHITFIELD. To follow up 1 minute, could the pharmaceutical pricing agreement be changed to require drug manufacturers to provide the ceiling price calculation?

MR. WILLIAMS. I think the pricing agreement does not carry necessarily the statutory weight that the law does. The agreement lays out some mutual responsibilities, but it's still within the overall framework of the statute that we both operate within.

MR. WHITFIELD. Okay. I'm very sorry to say that we have four more votes on the House floor. And how many minutes are left in this vote? We have about 7 minutes left. So I hate to say we're going to recess this again, and we'll be back just as soon as we can. I hope you're becoming familiar with the cafeteria downstairs and the machines where you can buy Cokes and things to eat. We'll be in recess, and we'll be back just as soon as we can.

[Recess.]

MR. WHITFIELD. We are waiting for Ms. DeGette of Colorado. She had some questions specifically of the first panel, but while we were waiting for her, there was an additional question that I want to ask you.

Mr. Williams, relating to the OIG who had recommended that you selectively audit manufacturers, wholesalers, and covered entities, and I was going to ask, do you intend to follow those recommendations? Then I also was told that there had been some legislation introduced relating to the two audits. Would you briefly comment on that?

MR. WILLIAMS. Well, with respect to the first part we really don't have authority under the law to audit directly. There is legislation, I think, pending, that would give us that authority, but we do not have that authority today.

MR. WHITFIELD. Do you know the status of that legislation?

MR. WILLIAMS. No, I don't.

MR. WHITFIELD. At this time, I recognize Ms. DeGette for her period of questions.

MS. DEGETTE. Thank you so much, Mr. Chairman. I want to thank the panel for staying. I appreciate your patience.

I have a couple of questions. Mr. Wright, the first one is for you. Your report indicates that HRSA has been unable to correctly determine the ceiling price set by drug manufacturers. How was the OIG able to verify that HRSA's methodology was incorrect?

MR. WRIGHT. The report that we issued this past October addressed primarily oversight issues in terms of HRSA's oversight of the program. The report that we had done last June actually quantified the overpayments that 340B entities were incurring as a result of the discrepancies in the data.

As you are aware, we withdrew that report and we are currently redoing it. In the spring, when we report back to this committee the results of that work, we should be able to quantify exactly the extent to which 340B entities are being overcharged. But the October report, which I discussed in the testimony, really only dealt with oversight issues.

MS. DEGETTE. So the upcoming report next spring will talk more about the methodology?

MR. WRIGHT. Will actually quantify the extent to which overcharges are occurring.

MS. DEGETTE. You think you will be able to verify the methodology in that report next spring then?

MR. WRIGHT. Yes, that report will verify the extent to which overcharges are occurring, and then will actually look behind when overcharges occur and try to determine why in fact those overcharges happened.

MS. DEGETTE. Do you think that we need any statutory changes for HRSA to be able to utilize the methodology in the future?

MR. WRIGHT. We have talked about statutory changes in terms of additional intermediate sanctions that HRSA could use to enforce noncompliance.

MS. DEGETTE. Okay.

MR. WRIGHT. The other areas we have talked about just increased HRSA oversight.

MS. DEGETTE. You wouldn't need statutory changes for that?

MR. WRIGHT. No, not for those.

MS. DEGETTE. Mr. Williams, I have some questions for you. The first one I want to ask you is sort of the fundamental question that's been hinted at in many of the other panel member's questions. That is if you have a voluntary reporting system and you have only one company that has voluntarily reported, then how can you administer this system?

MR. WILLIAMS. Well, we have a range of responsibilities under the system, which we, I think, carry out reasonably well with respect to verification.

MS. DEGETTE. Right.

MR. WILLIAMS. A voluntary -- under the structure of the law, we can get information -- we cannot disclose the manufacturer's data or pricing data of the manufacturers. That puts a limitation on what we can use with the data that we have. With a company coming forward, and voluntarily giving us that pricing data and voluntarily allowing us to use that data to verify whether the calculation is correct, they have also voluntarily -- they are also making that information voluntarily available to covered entities who purchase the drug.

MS. DEGETTE. Right.

MR. WILLIAMS. All that brings for that company a transparency in the system that benefits covered entities who purchase and benefits us in our oversight role.

MS. DEGETTE. Right, that's one company.

MR. WILLIAMS. One very large company, yes.

MS. DEGETTE. So that sort of begs the question of what about verification for all the other companies that have not chosen to participate on the system?

MR. WILLIAMS. Well, we rely on a range of tools. If covered entities are uncertain about or have questions about whether they are getting the right price, they can ask us, and we can take that request and try to verify the situation.

MS. DEGETTE. How often does that happen?

MR. WILLIAMS. We get a number of requests.

MS. DEGETTE. Are you able to verify that information?

MR. WILLIAMS. We can take that information -- since we calculate, or CMS has been calculating the 340B ceiling price, we can tell that company or that covered entity whether the price that they are being charged is consistent with a ceiling price that we have calculated. We can't tell them precisely what the price is, but we can tell them whether it is over or under that price.

MS. DEGETTE. Okay. So if CMS has a price, and then someone else, so there are many covered entities, you could just tell them if it's the same as CMS. But there's no independent verification there?

MR. WILLIAMS. A covered entity doesn't have that information, no. The law doesn't allow us to give that to them.

MS. DEGETTE. Have you tried to get the other entities to voluntarily report by trying to persuade them that the same kind of transparency that Glaxo has would benefit them commercially as well? Have you tried to encourage this voluntary --

MR. WILLIAMS. We have lots of conversations with manufacturers as well as covered entities. These have been matters that we have discussed when companies come forward, and hopefully that will help others to see benefits from it.

MS. DEGETTE. Okay. Let me ask another question. Your agency's inability to properly determine the drug manufacturer ceiling price has been highlighted by many, and today as well, as one of the most significant problems with the oversight of the 340B program. Can you explain to me the process that you inherited from the CMS?

MR. WILLIAMS. Well, the process, without going into a lot of detail, involves manufacturers providing information about average wholesale

price. There are also questions about package sizes and other technical information needed to help calculate the price.

As the OIG has pointed out, not all of that information in the past has been accurate and then provided in the form in which we have needed it. We are working on that. We have now arranged with another company, First DataBank, to get the right package size data that we need to calculate a price that is meaningful to a covered entity. So we are making progress in the areas where I think the IG has pointed out some deficiencies in the process.

MS. DEGETTE. What is your timeframe for making those changes?

MR. WILLIAMS. That change is already made.

MS. DEGETTE. Are there any other changes that you intend to make?

MR. WILLIAMS. There are some historical data that we need to go back and correct in time. But in terms of the pricing data, we are getting much better information than we had before.

MS. DEGETTE. What is your timeframe for that? Is that a change you are planning to make?

MR. WILLIAMS. That is already made. We are using that data now in the calculation of it.

MS. DEGETTE. So you are not planning to make any additional changes. Is that what your testimony is?

MR. WILLIAMS. No. As we find deficiencies, we will make changes.

MS. DEGETTE. But at this point, you have identified no additional deficiencies, is that what you are saying? I don't want to put words in your mouth, but I am having a hard time -- I am frankly having a hard time understanding your testimony, because you said that your agency is working to implement some of the recommendations of the OIG, but I don't know specifically what those are, what your timeframe for making them is.

MR. WILLIAMS. We have just taken over in September responsibilities for actually recalculating the 340B price from CMS. Up to this time this has been the total responsibility of CMS.

MS. DEGETTE. I understand.

MR. WILLIAMS. We have taken the results of their calculations and used it. To the extent there were deficiencies in the data they used or in the process they used, that is something they were responsible for at that time.

Now that we have taken over that responsibility, we will address some of the deficiencies that come to our attention. One of the big ones was getting the right package size data for the covered entities.

MS. DEGETTE. Right.

MR. WILLIAMS. And that we have resolved.

MS. DEGETTE. But you didn't tell me which of the other ones you intend to address.

MR. WILLIAMS. We will address all of them as they come to our attention.

MS. DEGETTE. All right. Thank you for clarifying that.

Now, according to the recent -- the OIG report, even if your agency was able to accurately determine the drug manufacturers' ceiling prices, you wouldn't have the authority to enforce compliance or impose penalties, and so the OIG recommends that your agency seek legislation to give you that authority, including the ability to impose penalties.

But in your response you said that HRSA does not want to establish penalties for violation. So my question is, how are you going to enforce compliance by drug manufacturers if there is no punishment for violations?

MR. WILLIAMS. Well, this is a -- we have one big penalty, which is to get them to leave the Medicaid program or the 340B program. That's a very large penalty, which, as the IG correctly points out, the penalty is worse really than the problem we are trying to resolve.

MS. DEGETTE. That is probably why you never actually enforced that penalty; correct?

MR. WILLIAMS. I think we have always -- and CMS, together, we have always tried to, where we identified problems, to work with those to resolve those problems. That's the approach we have always taken.

MS. DEGETTE. Yes, I realize that.

Thank you very much, Mr. Chairman, I yield back.

MR. WHITFIELD. I just want to clarify one other aspect of this, Mr. Williams. I asked you earlier, relating to Exhibit 1 of the OIG report on page 21, about the recommendation that you establish a standard for the calculation of the ceiling price. You have indicated, I believe, that, yes, you are working on that.

Now, they also recommended or pointed out the lack of standardization for package sizes, especially drugs sold in powder form, liquid form, whatever, that presents a major problem to accurate ceiling price calculations. Would you just briefly explain that problem and what you are doing to correct that issue?

MR. WILLIAMS. That we have already resolved. We have a contract with a company called First DataBank. They provide us -- for the drugs that are part of the program. They provide us that information, and we are now putting that information to the calculation for the ceiling price. So that issue has been resolved.

MR. WHITFIELD. When was that contract entered into?

MR. WILLIAMS. In the past 6 months.

MR. WHITFIELD. Six months, okay.

MR. WILLIAMS. I don't know precisely. I can give you the exact date.

[The information follows:]

RESPONSE FOR THE RECORD BY DENNIS WILLIAMS, DEPUTY ADMINISTRATOR, HEALTH RESOURCES AND SERVICES ADMINISTRATION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

When did we sign the first contract with First Data?

OPA's contractor is the entity that holds the contract with First Data Bank. The contractor first signed with First Data Bank on October 1, 2005.

MR. WHITFIELD. Mr. Stupak.

MR. STUPAK. Thank you, Mr. Chairman. Mr. Wright, does the law state that the Secretary can disclose pricing information if necessary to carry out the provisions of the law, or the statute, I should say?

MR. WRIGHT. Yes, that was included in my written statement. If the Secretary, in fact, determines that that's necessary.

MR. STUPAK. So there would be no changes we would have to make in order to get that information?

MR. WRIGHT. If the Secretary were, in fact, to make that interpretation, correct.

MR. STUPAK. So it is not a legislative issue, it's a discretionary issue.

MR. WRIGHT. Certainly.

MR. STUPAK. The law gives that discretion.

MR. WRIGHT. Yes, depending on how one reads the statute and I believe in fact different people have read it differently. The fact of the matter is HRSA is currently precluded either by a statutory interpretation or by a matter of policy from disclosing that information.

MR. STUPAK. Okay.

MR. WRIGHT. So that would have to change.

MR. STUPAK. True. Mr. Williams, Ms. DeGette asked you a little bit about dispute resolutions or how you do enforcement. Let me ask you this question, the Inspector General said the only way HRSA can get a refund is through an informal, voluntary -- informal, voluntary, dispute resolution process, which it has never used. Why hasn't that ever been used?

MR. WILLIAMS. Well, I wouldn't say that's the only way. We tried to resolve differences that are brought to our attention on calculations between a covered entity and a manufacturer. We try to resolve those issues. The $6.1 million discrepancies that the IG found, we have written the companies and asked them to respond to us about how they plan to resolve those issues.

MR. STUPAK. Right. They haven't responded?

MR. WILLIAMS. Well, we have been in touch with them. One company we have not -- we have been asked not to pursue, because the Department of Justice is in discussions with them. The others have responded. CMS has to complete some additional work before we can resolve the issue. But we are in discussion with them. They have responded. It has not been totally resolved, I would agree with you.

MR. STUPAK. If I remember correctly, didn't the letters ask for them to develop a corrective action plan?

MR. WILLIAMS. Yes.

MR. STUPAK. I believe GlaxoSmithKline did for Flonase, and that's the only one; correct?

MR. WILLIAMS. They have responded, I believe, yes.

MR. STUPAK. Yes, Glaxo did on Flonase, so Aventis, Bristol-Myers, Squibb, TAP Pharmaceuticals, they haven't responded with a corrective plan?

MR. WILLIAMS. Well, we are still in discussion with them and CMS to try to resolve the issue, with all but one company where we have not continued discussions because of the Department of Justice investigation.

MR. STUPAK. But if the letter asked to develop a corrective plan and then you enter into discussion, how long are these discussions going to go on?

MR. WILLIAMS. We are hopeful that CMS will be able to resolve the discrepancy at issue.

MR. STUPAK. When were those letters sent? Weren't they sent in 2003?

MR. WILLIAMS. 2004, I believe.

MR. STUPAK. Alright. That was 2004, we are pushing 2006, okay. Mr. Chairman, since only Glaxo is here as a witness on the next panel, I would like to request that you and I sign a joint letter to these other companies and ask them why they have not developed these plans. Hopefully that is something we can agree to do on that. I am concerned about it.

Alright. Mr. Williams, one more question, if I may. We talked a lot about these two plans here, these ceiling plans, prices, I should say. There is one calculated by you and one by the drug companies.

In the past, HRSA hasn't really pushed this issue or really asked the drug companies to come up with their plan, because they said they didn't have the resources to do that. Do you have the resources now to make the comparisons? If you get this information, do you have the resources to make the comparisons, manufacturers and your prices?

MR. WILLIAMS. We have a small, very dedicated and talented staff, and within the resources available to us there are some things that we can do that we do not have unlimited resources.

MR. STUPAK. Well, how many comparisons have you made that -- I know you have a small group there. That's why I want to see if you need more resources.

MR. WILLIAMS. Well, it depends on the nature of the extent of the interactions. We have staff that are able to handle individual issues that come to our attention. We have the staff, and we cannot do unlimited enforcement that way.

MR. STUPAK. How many have you done in the last 12 months?

MR. WILLIAMS. I don't know, but I can supply that to you for the record.

MR. STUPAK. One?

MR. WILLIAMS. I don't know. I will supply that for the record. I don't know off the top of my head.

MR. STUPAK. Alright. Thank you, Mr. Chairman. Thank you, witnesses.

[The information follows:]

RESPONSE FOR THE RECORD BY DENNIS WILLIAMS, DEPUTY ADMINISTRATOR, HEALTH RESOURCES AND SERVICES ADMINISTRATION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

How many comparisons on drug prices have we made in the past 12 months?

Since October 1, 2005 we have conducted price comparisons between manufacturer-submitted 340B prices and the government's calculated 340B prices for roughly twenty manufacturers. This effort represents roughly 2,400 unique NDCs. We have also conducted 3 quarterly comparisons between 340B selling prices submitted by the three national drug wholesalers.

We have compared a market basket of ADAP drug prices with 340B prices on 3 separate occasions. Because of the restrictions on disclosure of 340B pricing information, we were limited to disclosing only that the ADAP drug market basket did or did not exceed the aggregate cost represented by 340B prices. We have also reviewed prices for two Disproportionate Share Hospitals and responded with market basket assessments. We have addressed other covered entity price concerns through our Prime Vendor.

MR. WHITFIELD. Thank you. Obviously there does need to be more transparency in this program. I want to thank the first panel.

At this time I would like to call up the second panel. Mr. William von Oehsen, who is with Powers, Pyles, Sutter & Verville.

Mr. David Brown, who is Director of the Government Contracts and Pricing Programs for GlaxoSmithKline.

Mr. Christopher Hatwig, who is the Senior Director of the 340B Prime Vendor Program at HealthCare Purchasing Partners International. So we welcome you all. I am sure you were convinced that we would never get to you today, but here we are.

As you heard the questions to the first panel, you are aware that this committee is holding an investigatory hearing. When doing so it is the practice to take testimony under oath. Do any of the three of you have any objection to testifying under oath?

MR. VON OEHSEN. No.

MR. BROWN. No.

MR. HATWIG. No.

MR. WHITFIELD. Of course, under the rules of the House and the rules of the committee you are entitled to legal counsel. Do any of you want counsel today.

MR. VON OEHSEN. No.

MR. BROWN. No.

MR. HATWIG. No.

STATEMENTS OF WILLIAM H. VON OEHSEN, III, POWERS, PYLES, SUTTER & VERVILLE PC; DAVID B. BROWN, DIRECTOR, GOVERNMENT CONTRACTS AND PRICING PROGRAMS, GLAXOSMITHKLINE; AND CHRISTOPHER A. HATWIG, M.S., R.PH., FASHP, SENIOR DIRECTOR, 340B PRIME VENDOR PROGRAM, HEALTHCARE PURCHASING PARTNERS INTERNATIONAL

[Witnesses sworn.]

MR. WHITFIELD. You are now under oath. Mr. Von Oehsen, you are recognized for your opening statement.

MR. VON OEHSEN. Thank you, Mr. Chairman. I am Bill von Oehsen, Public Counsel for the Public Hospital Pharmacy Coalition. Thank you for allowing me to share the views of PHPC and its member hospitals participating in the 340B drug discount program. As participants in 340B, PHPC members have a deep interest in effective oversight of the 340B program and express our appreciation to your subcommittee for holding this hearing.

We also want to commend the Office of the Inspector General in issuing its recent report outlining ways to improve administration of the program.

PHPC supports all of the OIG's recommendations and would like to offer additional recommendations and comments. But before turning to those recommendations, I would like to say a few words about our organization and the value of the program to safety net institutions and their patients.

PHPC is a coalition of approximately 330 disproportionate share hospitals which represent a majority of the hospitals participating in 340B. Its membership encompasses a wide range of institutions, both

urban and rural hospitals, public and private, nonprofit hospitals, hospitals with bed sizes over 500, under 50 and in between, religious hospitals, academic medical centers and community hospitals.

But notwithstanding this diversity, PHPC members share a common mission of serving low income and uninsured patients, including significant numbers of the working poor. Indeed, it is because of this mission to serve the poor that PHPC's members all qualify for and participate in the 340B program. Access to discounts and outpatient drugs under the 340B program is vital to the ability of PHPC member hospitals to provide comprehensive pharmacy services to low-income patients and other vulnerable populations. For example, in a conversation last week with one of our long-standing members, the University of Kentucky Hospital, we were told that access to 340B discounts is, quote, the only reason, end quote, why the hospital can keep its outpatient pharmacy and chemotherapy clinic open.

Shands Hospital, University of Florida, has a large population of transplant patients who can live only with extensive pharmaceutical support. 340B pricing helps Shands defray the cost of providing their postoperative medications, which enables them to resume productive lives. Every 340B provider has a story like one of these attesting to the value of the 340B program.

Returning to the OIG report, we believe of all the OIG's recommendations, the three most critical ones are, number one, establishing a well-defined system to assure that covered entities receive the discounts to which they are entitled. Let me be clear, that means the prices calculated by the government, the prices calculated by manufacturers, and the prices actually paid by covered entities all have to be the same.

Number two, giving HRSA the authority to impose meaningful sanctions on manufacturers for overcharging covered entities or other violations.

And, number three, giving covered entities access to information so that they can determine whether they are receiving the correct prices.

PHPC asks Congress and the administration to fix these problems. It is critical that 340B providers receive the full discount on outpatient drugs to which they are entitled under Federal law, and it is critical that the government agencies responsible for administering the program have the resources, authorities, and requisite systems in place to assure that this occurs.

Importantly, in order to improve administration of the 340B program in the above areas, there must be better coordination between HRSA and CMS. The need for coordination between these two agencies is not just limited to the area of sharing and calculating pricing.

Consequently, we recommend that HRSA and CMS establish a permanent working group to address and monitor all the necessary interactions of HRSA and CMS in implementing the 340B program.

There are other areas of 340B program administration which need attention as well which were not addressed in the OIG report. These include, one, stronger enforcement of the 340B pricing agreements between manufacturers and the government.

Number two, Federal assistance in giving facilities access to 340B discounts on drugs that are in short supply, especially IVIG.

Number three, the development of a clear and enforceable procedure for refunding 340B facilities in cases of overcharges.

Number four, the establishment of an effective administrative process to resolve disputes between 340B entities and manufacturers.

In conclusion, we would like to thank the subcommittee for holding this hearing and to commend the OIG for its fine work in assessing some of the problems and complexities of the program and in formulating recommendations for improvement. We agree with the OIG's recommendations and have suggested other areas of reform that if collectively implemented would vastly improve the effectiveness of the 340B program, expanding access to affordable drugs or safety net providers and their patience.

I appreciate the opportunity to testify and look forward to addressing any questions that the subcommittee members may have for me.

MR. WHITFIELD. Thank you, Mr. von Oehsen.

[The prepared statement of William H. Von Oehsen, III follows:]

PREPARED STATEMENT OF WILLIAM H. VON OEHSEN, III, POSERS, PYLES, SUTTER & VERVILLE PC, GENERAL COUNSEL, PUBLIC HOSPITAL PHARMACY COALITION

SUMMARY OF TESTIMONY

The Public Hospital Pharmacy Coalition (PHPC)—an organization that represents approximately 330 disproportionate share hospitals (DSH) participating in the 340B drug discount program—is fundamentally in agreement with the recommendations of the Department of Health and Human Services (HHS) Office of Inspector General (OIG) in its recent report entitled "Deficiencies in the Oversight of the 340B Drug Pricing Program." However, PHPC believes that there are a number of more specific and, in some instances, supplementary measures that should be implemented as soon as practicable to achieve truly responsible and effective administration of the program.

PHPC applauds the OIG for identifying the three most critical elements of necessary reform to the 340B program as it is currently administered by the Health Resources and Services Administration (HRSA). These three elements are: (1) establishment of a precisely defined methodology for determination of correct 340B ceiling prices, combined with a process for routinely making direct comparisons between the 340B ceiling prices calculated by HRSA and the ceiling prices calculated and charged by manufacturers for the same products; (2) authority for HRSA to impose meaningful sanctions on manufacturers in the form of fines and monetary penalties for charging covered entities above the 340B ceiling price or other violations of the 340B

pharmaceutical pricing agreement (PPA); and (3) increased access by 340B entities to information enabling them to determine whether the prices they are being charged under the program are within the applicable statutory ceilings.

There are also several other problems in 340B program administration that are not covered in the OIG's most recent report and which are of continuing concern to the 340B community notwithstanding the hard work by responsible federal officials to administer this important program. These include: (1) undue delay in the execution or limitation on the scope of 340B PPAs (2) the lack of a specific HRSA policy detailing the procedure by which manufacturers should issue refunds to covered entities whenever it is discovered or finally determined that they have sold 340B drugs at above-ceiling prices; (3) the difficulty that many 340B covered entities face in attempting to purchase drugs that are reportedly in short supply at the appropriate ceiling price; and (4) the absence of an effective administrative process for obtaining a binding and judicially reviewable resolution of claims by covered entities that manufacturers have charged prices for drugs that exceed the appropriate 340B ceiling price.

Good afternoon Mr. Chairman. I am Bill von Oehsen, General Counsel and founder of the Public Hospital Pharmacy Coalition (PHPC). Thank you for inviting me to share the views of PHPC and its member hospitals participating in the 340B drug discount program. As participants in the 340B program, PHPC's members have a deep interest in effective oversight of the 340B program and express our appreciation to your Subcommittee for holding this hearing. We also want to commend the Department of Health and Human Services (HHS) Office of the Inspector General (OIG) in issuing its recent report outlining ways to improve administration of the program. PHPC supports all of the OIG's recommendations and, as explained in more detail below, would like to offer additional recommendations and comments. Before turning to those recommendations, however, I would like to say a few words about PHPC and the value of the 340B program to safety net institutions and their patients.

Background on PHPC

PHPC is a coalition of disproportionate share hospitals (DSH) established in 1993 by the National Association of Public Hospitals and Health Systems (NAPH) to represent NAPH members and other DSH hospitals with respect to the 340B drug discount program and other initiatives affecting the availability and cost of pharmaceutical care provided by our member hospitals. PHPC has had a longstanding and very constructive relationship with the office within the Health Resources and Services Administration (HRSA) charged with administering the 340B program, called the Office of Pharmacy Affairs (OPA), and with OPA's staff and director, whose cooperation, commitment to the program, and hard work is greatly appreciated by the 340B community. One of the fruits of OPA's efforts is the prime vendor program which has generated deeper discounts and other value-added services for prime vendor participants, including many PHPC member hospitals.

PHPC's membership stands at approximately 330 hospitals and encompasses a wide range of institutions including both urban and rural hospitals; public and private non-profit hospitals; hospitals with bed sizes over 500, under 50 and in between; Catholic and other faith-based hospitals; academic medical centers; tertiary care hospitals with level one trauma centers, burn units and other specialized services; and community hospitals focused on more traditional acute care services. Notwithstanding such diversity, PHPC's members share a common mission of serving low income and uninsured patients, including significant numbers of the working poor. Indeed, it is because of their mission to serve the poor that PHPC's members all qualify for and participate in the 340B program. Hospital participation in the 340B program is limited to hospitals that receive Medicare DSH payment adjustments of 11.75 percent or higher, a standard that can only

be satisfied if a high percent of the hospital's inpatient care is furnished, on a per day basis, to Medicaid recipients, low income Medicare beneficiaries, and/or other indigent individuals. 340B eligibility is also limited to hospitals that are owned or operated by state or local governments or have a contract with state or local governments to provide a significant level of indigent care (i.e. non-Medicare, non-Medicaid).

The subset of PHPC's membership which overlaps with NAPH's membership – approximately 100 hospitals – provides about 24 percent of all uncompensated hospital care in the U.S. even though it represents only two percent of all U.S. hospitals. Other relevant characteristics from NAPH include the following. Over 55 percent of gross charges are related to patients on Medicaid or are uninsured. Twenty-one percent of all costs in NAPH-member hospitals are uncompensated compared to 5.5 percent of costs nationally. We suspect that PHPC's non-NAPH members have levels of uncompensated costs more comparable to NAPH members than to the national figures.

Value of the 340B Program

Access to discounts on outpatient drugs under the 340B program is vital to the ability of PHPC member hospitals to provide comprehensive pharmacy services to low income patients and other vulnerable populations. The role of pharmaceuticals in meeting the health care needs of individuals, especially those suffering from one or more chronic conditions, has grown significantly over the past two decades. It is therefore no exaggeration to say that access to affordable medications can make the difference between clinically appropriate and inappropriate care, and in some cases, life or death. I often hear from member hospitals that, but for the savings available on drugs bought through the 340B program, the hospitals could not afford to keep their outpatient pharmacies open or would have to limit pharmacy services by adopting strict formularies, higher co-pays or other utilization control measures.

For example, in a conversation last week with one of PHPC's longstanding members, the University of Kentucky Hospital, we were told that access to discounts under the 340B program is the "only reason" why the hospital can keep its outpatient pharmacy and chemotherapy clinic open. Shands Hospital at the University of Florida has a large population of transplant patients who can live only with extensive pharmaceutical support. Many of these patients lack employer-based health insurance and there are gaps in coverage even for those patients that have some form of insurance. 340B pricing helps defray the cost of their post-operative medications, which enables them to resume productive lives. A couple of 340B hospitals in Milwaukee, Wisconsin – St. Joseph Regional Hospital and St. Michael's Hospital – recently reported that they use the savings from the program to maintain a pharmacy assistance program for needy residents in the Milwaukee area and that one of the hospitals invested its 340B savings on Procrit to start a special anemia management clinic for renal disease patients. Every 340B provider – referred to as a "covered entity" in the statute – has a story like one of these attesting to the value of the 340B program.

Even with the savings available under the program, some hospitals still cannot meet the demand for low cost drugs by local residents who lack prescription drug coverage. Indeed, unless a 340B pharmacy has enough paying business to offset its losses in serving the uninsured, access to discounts under the 340B program is not enough to make ends meet. This is the primary reason why many eligible 340B covered entities, especially community health centers, do not even offer pharmacy services, let alone participate in the 340B program.

It is therefore critical that DSH hospitals and other covered entities participating in the 340B program receive the full discount on outpatient drugs to which they are entitled under federal law; and it is critical that the government agencies responsible for administering the program have the resources, authorities, and requisite systems in place to assure that this occurs. Unfortunately, as the OIG report illustrates all too well, 340B

providers can never be sure that they are receiving accurate pricing. Until such problems are resolved, the integrity of the 340B program remains compromised. PHPC asks Congress, HHS and HRSA to fix these problems; and in making this request I believe I am speaking for all 340B providers and the national organizations that represent them. Please note though, in making this request, we do not mean to imply that covered entities do not also have responsibilities for maintaining the integrity of the program. Covered entities have their own obligations under the law. In particular, 340B providers are prohibited from using the discounted drugs for anyone other than their own patients and are required to adjust their Medicaid purchasing and billing practices in order to protect manufacturers from giving 340B discounts and Medicaid rebates on the same drugs. PHPC takes these obligations very seriously and has been active in educating both members and non-members on how to comply with all aspects of the 340B program.

Comments on OIG Report

PHPC is fundamentally in agreement with the recommendations of the OIG in its recent report entitled "Deficiencies in the Oversight of the 340B Drug Pricing Program." PHPC believes, however, that there are a number of more specific and, in some instances, supplementary measures that should be implemented as soon as practicable to achieve truly responsible and effective administration of the program. In my testimony here today, I would like both to address the importance of the OIG recommendations and to urge implementation of some of these other measures which, in our view, extend and supplement the findings and recommendations of the OIG.

PHPC applauds the OIG for identifying the three most critical elements of necessary reform to the 340B program as it is currently administered by HRSA. These three elements are: (1) establishment of a precisely defined methodology for determination of correct 340B ceiling prices, combined with a process for routinely making direct comparisons between the 340B ceiling prices calculated by HRSA and the ceiling prices calculated and charged by manufacturers for the same products; (2) authority for HRSA to impose meaningful sanctions on manufacturers in the form of fines and monetary penalties for charging covered entities in violation of the applicable 340B ceiling price or other violations of the 340B pharmaceutical pricing agreement (PPA); and (3) increased access by covered entities to information enabling them to determine whether the prices they are being charged for drugs under the program are within the applicable statutory ceilings. Importantly, in order to improve administration of the 340B program in these three areas, there must be better coordination between HRSA and the Centers for Medicare & Medicaid Services (CMS), especially the office within CMS responsible for administering the Medicaid rebate program.

Improved Coordination between HRSA and CMS

Both my testimony and the OIG's reported findings should serve to underscore the importance of improving communication between HRSA and CMS. There is a close statutory link between the 340B and Medicaid rebate programs. Although HRSA is responsible for administering the 340B program, it must rely on CMS to compile and provide the data necessary to calculate and verify correct 340B ceiling prices. Fraud or even routine computation errors identified in the Medicaid rebate context can signal errors and overcharges in 340B pricing. There are other areas in which effective administration of the 340B program requires teamwork between HRSA and CMS. For example, the eligibility of a hospital to participate in the 340B program hinges upon its DSH payment adjustment percentage, which is calculated by CMS based on data maintained by CMS. Plus, the obligations of drug manufacturers to execute pharmaceutical pricing agreements (PPAs) with the Secretary of HHS and to participate in the 340B program are contingent on execution of Medicaid rebate agreements that are managed by CMS.

The OIG has identified a number of problems associated with computation and verification of 340B ceiling prices that are attributable to failures in communication or coordination between HRSA and CMS. These problems include CMS's omission of requisite data elements for 340B ceiling price computations and the agency's failure to adequately reconcile package size data necessary to calculate the ceiling prices. Accordingly, OIG has recommended that HRSA and CMS "work together to ensure accurate and timely pricing data for the Government's official record of 340B ceiling prices."

PHPC fully supports this recommendation, but also wants to point out that the need for coordination between HRSA and CMS is not limited to the area of sharing and calculating pricing data. Consequently, we feel that institution of a permanent working group to address and monitor all of the necessary interactions of HRSA and CMS in implementing the 340B program would substantially improve program administration and oversight. In addition to promoting coordination on matters of pricing data flow and computation, a HRSA/CMS working group would be uniquely positioned: (1) to clarify procedures for determining whether a hospital's disproportionate share adjustment meets the 11.75 statutory threshold, (2) to develop mechanisms for protecting manufacturers from giving 340B discounts and Medicaid rebates on the same drug, and (3) to coordinate manufacturer refunds under the 340B and Medicaid rebate programs based on retroactive adjustments to a manufacturer's average manufacturer price (AMP) and best price.

For these and other reasons, formal establishment of a permanent HRSA/CMS working group would be an especially positive step towards the goal of those components "working together" as the OIG has recommended.

Pricing Computation and Verification

Turning now to the need for more concrete administrative reforms, perhaps the most glaring deficiency in 340B program administration identified by OIG is the fact that – in a program designed to impose price-limits on qualifying pharmaceutical sales – the responsible government agency has no system in place for establishing whether the limits have been properly applied or how exactly the price limits are to be calculated. It seems evident that, in order to verify manufacturer compliance with price ceiling requirements, HRSA (1) must determine exactly how, and on the basis of what data, 340B ceiling prices are to be computed, (2) must compute an accurate ceiling price for each covered drug available for purchase under 340B, and (3) must compare its ceiling price determinations with the prices computed and actually charged by drug manufacturers to verify that applicable price ceilings are not being exceeded. As the recent OIG report points out, the present lack of a precise, established methodology for calculating 340B ceiling prices has led to inconsistencies in whether and how certain data elements are utilized in determining applicable 340B price ceilings, and has made it difficult or impossible to determine whether manufacturers have applied "correct" 340B pricing to their products. A specific, detailed methodology is needed but is lacking, for example, to standardize the time periods and package sizes used to calculate 340B ceiling prices. Clearly the first steps HRSA must make towards better fulfilling its responsibilities to oversee the 340B program are to establish a precise methodology by which 340B prices are to be calculated, and to calculate accurate prices for covered drugs using that methodology.

Accurate determinations of ceiling prices by itself will be of little utility, of course, if nothing is done to verify that the ceiling prices calculated independently by drug manufacturers are the same as those HRSA has determined to be accurate and applicable. As the new OIG report emphasizes, the absence of such comparisons is one of the systemic deficiencies in HRSA's administration of the program that makes effective oversight of 340B pricing impossible. Especially since covered entities lack access to ceiling price information, and thus have no basis on which to independently challenge the

accuracy of 340B prices charged by manufacturers, there is no effective way to identify and control overcharging in the 340B program unless HRSA takes affirmative steps to verify that the ceiling prices it calculates are the same prices actually applied to purchases under the program.

Comparisons between the government-calculated 340B ceiling prices and manufacturers' ceiling price figures should therefore be made on a routine basis, and should trigger further specific procedures for inquiry and corrective action where discrepancies are found. OIG has suggested that this could be accomplished by requesting manufacturers to submit some or all 340B prices to HRSA each quarter. PHPC believes that HRSA should not merely request, but should require manufacturers to submit all of the 340B ceiling prices that they have calculated to HRSA each quarter for verification of pricing accuracy. In addition, as the OIG has recommended, HRSA should not only verify consistency between its calculations of 340B ceiling prices and those calculated by manufacturers, but also perform sufficient spot-checking of entity invoices to confirm that actual charges are indeed at or below the properly calculated ceiling prices.

Need for Meaningful Sanctions

The improved monitoring of 340B pricing that is achievable by the above reforms will not lead to more accurate pricing, however, without more effective incentives for manufacturers to comply with pricing requirements and directives from HRSA to remedy pricing violations that may be discovered. As matters now stand, a manufacturer whose product has been determined by HRSA to have been sold to covered entities at an above-ceiling 340B price can refuse to remedy that situation with apparent impunity. For example, several manufacturers whose 340B products had been sold to covered entities at above-ceiling prices, according to the OIG's findings in a report issued in 2003, have taken no action to refund the overcharges, despite explicit letters from HRSA directing them to do so, and have suffered no apparent repercussions as a consequence of their refusal to comply with HRSA's directive.

Although, in theory, this situation enables the Secretary of HHS, under the terms of the 340B pharmaceutical pricing agreement, to terminate Medicaid and Medicare coverage of the non-complying manufacturers' products, it is plain that manufacturers do not take this threat seriously, and are content to simply deny that overcharging occurred and refuse to take any remedial action. In the face of this defiance and delay, HRSA has been unable to effectively obtain the refunds that are owed to 340B providers. As manufacturers are well aware, the chances of HHS deciding to deny coverage of a necessary drug for Medicaid recipients because a manufacturer has violated a pricing requirement in the much smaller and less visible 340B program, are virtually non-existent. PHPC believes the only realistic means to remedy this situation would be legislation conferring statutory authority on HHS, through HRSA, to impose meaningful sanctions, such as fines and monetary penalties, on manufacturers that are found to be in violation of their 340B pricing obligations.

As the OIG has suggested, the requisite legislative amendments to the 340B statute could be modeled after the civil penalty authorities in section 1927(b)(3)(C)(i) of the Social Security Act (Act) which governs sanctions applicable to the Medicaid rebate program. In the alternative, we think a minor revision to section 1128A(a)(2) of the Act could expand the authority of HHS, through the OIG, to impose civil monetary penalties in circumstances where a manufacturer has requested payment from a covered entity in violation of an applicable PPA. In fact, we believe simple insertion of the words "or with the Secretary" in the text of section 1128A(a)(2)(B) would accomplish this purpose.

Pricing Transparency

The third major component of an effective strategy for curing current deficiencies in 340B pricing enforcement would be greater transparency in pricing information for the covered entities that actually purchase drugs under the 340B program. Probably the single greatest frustration expressed to PHPC by its members is the fact that they have no basis on which to assess whether they are being overcharged or not for 340B covered products. PHPC receives frequent reports from its members about specific 340B prices that seem inconsistent, excessive, or questionable when viewed in comparison with the prices negotiated by group purchasing organizations (GPOs) or other purchasers in the private market. Yet while these situations give rise to widespread suspicions of overcharging for 340B drugs, there is ordinarily no concrete action that can be taken by a covered entity to seek relief from suspected overcharges because it has inadequate access to relevant pricing information to challenge the manufacturer's alleged 340B price, or even to compile a sufficient factual record to effectively invoke the informal dispute resolution process created by HRSA in federal guidelines.

In light of the resource limitations that have plagued 340B program administration, as well as the historical deficiencies in oversight and enforcement of 340B pricing obligations, it makes undeniable sense to supplement HRSA's compliance-monitoring efforts by empowering covered entities to play a role in verifying that they are paying statutorily appropriate prices for 340B drugs.

Indeed, we believe that more stringent constraints have been placed on covered entities' access to 340B price information than federal law actually requires. Although certain components of the 340B ceiling price calculation utilize confidential data, disclosure of a drug's 340B ceiling price is not tantamount to disclosure of the drug's AMP, best price or any other specific information that the Secretary of HHS is prohibited from disclosing under Section 1927(b)(3)(D) of the Social Security Act. Because calculation of 340B ceiling prices varies depending on how AMP and best price compare and whether an inflationary cap on price increases is triggered, it is impossible to deduce a drug's AMP or best price just from knowing what the ceiling price is.

In addition, the Social Security Act expressly permits the Secretary to disclose any information to the extent such disclosure is determined "necessary to carry out" Section 1927 of the Act, which pertains to Medicaid rebates as well as, in part, to the limitations on prices of drugs purchased by 340B covered entities and the requirement of 340B participation by manufacturers of Medicaid-covered drugs. Accordingly, we believe the relevant confidentiality provisions of the law may permissibly be construed to allow such disclosures of pricing information to 340B covered entities as the Secretary may determine are necessary to effectively administer the 340B program, and that some disclosure of ceiling price information is in fact necessary to such administration. Language in the standard 340B PPA is consistent with this construction of the law, as is legislative history of the 340B statute.

Even if current law is construed to prevent the Secretary's public disclosure of 340B ceiling prices, however, sound administration of the 340B program demands that some compromise be reached under which covered entities can realistically assess whether they are being or have been overcharged, and bring those situations to the attention of the relevant manufacturers and enforcement agencies. The OIG has recommended that covered entities be afforded secure access to certain pricing data to enable them to detect differences between the prices that they pay and the prices to which they are legally entitled – perhaps through a web-based system by which entities can submit prices and gain a response indicating whether ceiling prices have been exceeded.

PHPC agrees that effective 340B administration demands greater access to price-relevant information by covered entities, and believes that a right to such access should ideally be established by legislative amendment. Nonetheless, we also believe that a more flexible and useful system for affording 340B pricing information to covered

entities than currently exists could be implemented by agency regulations or policy issuances, consistent with legal constraints and manufacturers' legitimate security concerns. It is possible, and unquestionably legally permissible, for manufacturers to voluntarily make 340B pricing data available to covered entities, and we strongly urge manufacturers to consider doing so. Absent such voluntary action on a broad scale in the manufacturer community, however, legislative or administrative action must be taken to create some mechanism for reasonable covered entity access to 340B pricing information directly pertinent to the entity's own determination of whether its rights are being violated, such as, for example, authorization for one designated officer of each covered entity (bound by an appropriately structured confidentiality and data use agreement) to have access to 340B ceiling prices strictly for purposes of reporting to HRSA any discrepancy between those prices and the actual purchase prices paid by the entity for drugs. I should note that GlaxoSmithKline has recently committed to sharing its 340B ceiling price data with the 340B prime vendor program, and that we applaud that action. This is just a first step, however, towards the pricing data accessibility that will be necessary to ensure pricing integrity.

Pharmaceutical Pricing Agreements

There are several other deficiencies in 340B program administration of which PHPC is aware, but which are not within the scope of the OIG's most recent investigation and published report. For example, we understand that there are a number of manufacturers that have avoided or delayed entering into 340B PPAs notwithstanding the continued coverage of their products by Medicaid.

It appears that this situation stems from the fact that there is no defined or regularized process for assuring that manufacturers entering into Medicaid rebate agreements also immediately enter into 340B pharmaceutical pricing agreements as the statute requires. Due to the absence of any such defined process, it seems the obligations of all manufacturers that participate in Medicaid to enter into 340B PPAs have not been uniformly enforced. Some manufacturers have restricted the scope of their 340B obligations by having subsidiaries enter into the PPAs on behalf of only certain manufacturer "business units" (instead of the entire corporate entity manufacturing Medicaid-covered pharmaceutical products), or by executing PPAs through mid-level corporate representatives whose authorities to bind the corporations extend only to isolated business units. We have also heard, in some instances, of manufacturers of Medicaid-covered drugs taking months or years before they sign any 340B agreement at all.

To address these problems, a routine administrative process must be instituted that, at a minimum, assures that a corresponding 340B program PPA is executed contemporaneously with any Medicaid rebate agreement executed between a manufacturer and the Secretary, or within a short, specifically defined time period thereafter. HHS should also clearly designate the agency personnel responsible for obtaining timely and properly executed PPAs and provide for adequate HRSA review of PPAs to verify that they apply to a scope of pharmaceutical products corresponding to the scope of Medicaid coverage of the relevant manufacturer's entire product line.

In addition, although PHPC is cognizant of questions that have been raised as to the present enforceability of the standard pharmaceutical pricing agreement between the Secretary and manufacturers, we believe that certain revisions of that document would facilitate more effective program administration and compliance enforcement. At present, the PPA represents the only direct source of legal obligation on the part of a manufacturer to comply with 340B pricing limitations or other requirements. Yet the manufacturer responsibilities expressly referenced in that agreement are quite limited, and extend little beyond agreeing to charge 340B entities at or below the applicable ceiling prices.

We believe a number of amendments to the PPA could and should be made to address systemic problems of administration and weaknesses in program enforcement that have been noted in the recent OIG report and discussed in my testimony before the Subcommittee. In particular, PHPC believes that the standard 340B PPA should be revised in some or all of the following ways:

- The PPA should require manufacturers to submit the 340B ceiling prices calculated for their drugs to HRSA for purposes of comparison with HRSA's calculations based on CMS data.
- It should require manufacturers to disclose the 340B ceiling prices they calculate for their drugs to designated officers of covered entities, under appropriate confidentiality and data use agreements and security mechanisms, to be established by the Secretary through regulations or policy issuances.
- It should expressly require manufacturers to make all of their covered drug products available to covered entities for purchase at 340B prices.
- It should require manufacturers to calculate and refund 340B overpayments to covered entities, under a procedure to be outlined by the Secretary in published regulations or policy guidance, whenever it is finally determined by the manufacturer or HRSA that 340B overcharges have occurred.
- It should obligate manufacturers to participate in and abide by decisions rendered pursuant to an administrative process established for resolution of pricing disputes.
- It should require a manufacturer to calculate and apply 340B pricing retroactively to any purchases of covered drugs made by covered entities during any significant lag-time that may elapse between execution of the manufacturer's Medicaid rebate agreement and its 340B PPA, and to make appropriate retroactive refunds consistent with such calculations.
- It should require manufacturers to pay covered entities interest on refunds for past overcharges.

In other words, until legislation is passed or regulations are promulgated to implement the OIG's recommendations, amendment and expansion of the standard 340B PPAs may offer an alternative means to some immediate amelioration of programmatic deficiencies.

Refund Procedures

We also believe that a specific policy needs to be developed by HRSA requiring manufacturers to issue refunds to covered entities whenever it is discovered or finally determined that they sold 340B drugs at above-ceiling prices, and that such a policy should provide detailed procedures on how to calculate and issue the refunds. There are a number of different scenarios under which the existence of a 340B overcharge may be established. In some instances, particularly if HRSA oversight of the 340B program is enhanced pursuant to recommendations discussed at this hearing, HRSA may determine that an overcharge has occurred or – as was the case with certain drug sales scrutinized in the OIG's March 2003 report and investigation – the OIG may find that covered entities have been overcharged. In other instances, a manufacturer itself may become aware that it has miscalculated AMP or best price for a drug, and that consequently both Medicaid rebates and 340B ceiling prices have been inaccurately computed. In the latter scenario, there is a defined set of procedures established by CMS to facilitate retroactive adjustments of rebate payments to the Medicaid program, but no parallel process for repayment of 340B overcharges.

Thus we believe that HRSA needs to develop and define a refund process to be implemented contemporaneously with CMS rebate adjustment procedures, where manufacturers retroactively correct AMP or best price calculations. Furthermore, in any

and all other circumstances in which manufacturer overcharges for 340B drugs are found to have occurred, there should be a clearly defined process, established by HRSA, that manufacturers are obligated to follow to afford appropriate refunds of 340B overcharges to affected covered entities.

Drugs in Short Supply

Another frequent topic of complaints that PHPC has heard from its members concerns drugs that are reportedly in short supply and are therefore not being made available to covered entities at 340B prices. According to our members, there have been a number of instances in which covered entities were told by manufacturers that particular products – especially intravenous immune globulin (IVIG) and other blood-derived products – are unavailable for purchase under the 340B program because all available supplies of the products have already been committed to other purchasers under commercial contracts. Often in these situations, the products at issue were readily available for purchase on the commercial market or through group purchasing organizations at prices above 340B ceiling prices, even though they were ostensibly in such short supply that they could not be sold under the 340B program.

This problem is especially serious for disproportionate share hospitals in the 340B program since they are prohibited under the 340B statute from purchasing covered outpatient drugs through their GPOs. Unable to buy product at a 340B price because of a shortage problem, the hospitals are faced with the impossible dilemma of having to either violate federal law by purchasing the drugs at GPO prices, buy the drugs at higher, retail prices that the institution cannot well afford, or deny their patients access to the drugs altogether.

Although HRSA has issued a letter stating its position that manufacturers may not discriminate against 340B entities in allocating drugs that are in short supply, PHPC believes that additional protections are needed to adequately address this problem. HRSA should audit or otherwise review the allocation methods used by manufacturers to ensure that they are not discriminatory and that they do not have a discriminatory effect. Moreover, because large purchasers such as GPOs and managed care organizations have an advantage over smaller purchasers by virtue of being able to contract for most or all of the remaining drugs available, the 340B prime vendor should be directed to take an active role in purchasing drugs in short supply at the request of covered entities. Perhaps most importantly, we believe HRSA should issue a specific policy that not only addresses covered entities' access to 340B pricing for covered outpatient drugs in short supply, but also reinforces the point that Congress' clearly expressed intent in the 340B statute is for covered entities to be able to actually purchase covered drugs at 340B prices, not just to enjoy theoretical discounts on products that are not made available under the program at all.

Effective Dispute Resolution

PHPC also believes that an important step towards enhancing the accountability of manufacturers for pricing violations and empowering covered entities to assist HRSA in monitoring and enforcing pricing compliance, would be institution of an administrative process to resolve disputes between covered entities and manufacturers relating to 340B prices and purchases that culminates in a final and judicially reviewable agency decision. The capacity of covered entities to effectively pursue relief from above-ceiling charges by manufacturers for their drugs is presently unclear. The dispute resolution process defined by HRSA guidelines is not binding on manufacturers. Certain putative class action lawsuits now pending in federal and state courts may test whether common law, third-party beneficiary rights under a contract, or anti-fraud provisions permit covered entities to initiate and pursue court actions for recovery of past overcharges, but disposition of those cases and questions is unlikely in the near future.

PHPC has previously advocated legislative amendments clearly conferring on covered entities a specific, statutory, private right of action against manufacturers for recovery of 340B overcharges, but believes covered entities' rights and interests in being able to independently pursue relief from 340B overcharges might also be protected by the development of suitable administrative procedures. Specifically, the administrative process we envision would be one through which covered entity and manufacturer contentions and evidence of a 340B price dispute would be reviewed and adjudicated by a federal agency decisionmaker, who issues a final agency decision respecting the controversy. Formal, duly promulgated regulations would be the preferable means of defining and establishing such procedures, so that the agency's decision pursuant to the process would have legally binding effect on the parties in the absence of further review by a court. PHPC believes and hopes that the availability of such an administrative process, as well as implementation of the other programmatic reforms I have described, would greatly reduce the likelihood of covered entities deciding that they need to initiate litigation in the courts to enforce their rights to proper 340B pricing.

Conclusion

In conclusion, PHPC would like to commend the OIG for its fine work in assessing some of the problems and complexities of the 340B program as currently administered, and formulating recommendations for change and improvement. My testimony here today by no means comprehensively addresses all of the areas in which there is a need for federal attention and action. However, in the view of PHPC, each of the measures I have suggested is vital to the improvement of the 340B program and to the successful attainment of its statutory goals in both the short and long-term. PHPC would like to thank the Subcommittee for holding this important hearing. I appreciate the opportunity to testify before you today on these critical matters and look forward to addressing any questions that Subcommittee members may have for me.

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Public Hospital Pharmacy Coalition
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William von Oehsen, a principal in the law firm Powers, Pyles, Sutter and Verville P.C. (PPSV), has extensive experience in general health law, legislation and policy, especially in the areas of pharmaceutical pricing, materials management, and third party reimbursement, and food and drug law.

With respect to Mr. von Oehsen's pharmaceutical pricing practice, PPSV offers a wide range of services involving federal and state regulation of drug prices and reimbursement. The U.S. pharmaceutical market is unique in that pricing is regulated, either directly or indirectly, under a complex array of federal and state laws designed to make prescription drugs more affordable to government programs and providers, as well as to seniors and other vulnerable populations. As prescription drug prices continue to climb at double digit inflation rates, the demand for expertise in these laws has also grown. It is not surprising, therefore, that drug pricing has become one of Mr. von Oehsen's most active practice areas.

Mr. von Oehsen serves as general counsel to the Public Hospital Pharmacy Coalition (PHPC) which was launched more than ten years ago to help high-Medicaid public and non-profit hospitals take advantage of a federal law – section 340B of the Public Health Service Act – that requires pharmaceutical manufacturers to give drug discounts on covered outpatient drugs as a condition of the Medicaid program covering and paying for

those drugs. As membership for PHPC has grown, expertise on 340B matters and related drug pricing laws has deepened such that Mr. von Oehsen has become a national leader in this area. He was instrumental in forming the 340B Coalition, a coalition of approximately sixteen national organizations whose members collectively comprise all the entities that are eligible to participate in the 340B program. The 340B Coalition hosts an annual conference for safety net providers, industry, wholesalers and policymakers, that, as a result of its popularity and broad attendance, now serves a major forum in which national drug pricing policy issues are addressed. PPSV is responsible for organizing this annual event and delivering regular presentations on recent developments – regulatory, legislative and judicial.

The 340B program is one of four federal drug discount programs and, because one cannot truly understand federal regulation of drug pricing without an understanding of how these programs interrelate, Mr. von Oehsen has expertise in each of these federal areas. They include the Medicaid drug rebate program, the federal supply schedule and the federal ceiling price. States have also been active in helping individuals, especially seniors and low-income patients, access affordable drugs, and many of these efforts build upon the federal programs. Accordingly, Mr. von Oehsen's drug pricing client base includes a growing number of states that are seeking to lower drug costs for state-funded populations, such as Medicaid recipients, Medicaid expansion populations, prisoners, mental health and other long term care patients, and state employees. Mr. von Oehsen regularly testifies before state legislatures and executive branch officials. Another area of collaboration with states relates to numerous ongoing investigations into potential violations by industry of federal and state drug discount laws and efforts to recover overpayments form industry.

As a result of Mr. von Oehsen's expertise in the drug pricing and FDA areas, he has found himself serving a growing number of pharmacies, both freestanding and institutional, in various legal and regulatory matters. His pharmacy-related projects have involved analysis of federal laws such as Robinson-Patman and the Non-Profit Institutions Act, DEA registration, the Prescription Drug Market Act, Medicare/Medicaid coverage and reimbursement of pharmaceutical care and federal fraud and abuse laws such as Stark and anti-kickback. At the state level, he has state licensure laws. PPSV also assists pharmacy clients with their transactional and litigation needs.

In the food and drug area, Mr. von Oehsen guides companies through the FDA's premarket clearance process; assists companies with product development strategies; provides labeling, advertising, manufacturing and import/export advice; and handles other issues that arise during the progression from initial clinical testing through commercial distribution. He also works on the development and distribution of medical devices, biologics, food, food additives, dietary supplements, animal feeds, and cosmetics. He has also defended clients against FDA enforcement actions. Mr. von Oehsen has lectured and published articles on food and drug related issues.

In addition to his drug pricing and FDA practices, Mr. von Oehsen has considerable experience in advising clients on materials management, managed care, and general health law issues. He works with Medicare/Medicaid and other third-party payment programs, hospitals, HMOs, PPOs, physician groups, and other health care providers. He counsels clients on such issues as managed care, fraud and abuse, third-party reimbursement, mergers and acquisitions, state licensure of health professionals and providers, and confidentiality of records. He also has significant advocacy experience on health legislative issues, including in the areas of drug pricing, managed care, AIDS, long-term care, and Medicare/Medicaid. Mr. von Oehsen is co-author of a book concerning Medicare/Medicaid managed care and state health reform.

Mr. von Oehsen is a member of the District of Columbia Bar. He received his law degree from Georgetown University Law Center in 1988 and a masters from Harvard University in 1984. He earned his undergraduate degree from Princeton University in

1981. Mr. von Oehsen participates in a number of professional organizations including the Food and Drug Law Institute (where he was an Annual Scholar), the American Health Lawyers Association and the American Association of Health Plans. He was also a founding director of the Family AIDS Housing Foundation, now called Building Futures: Family AIDS Housing.

Concentrating in Health Legislation and Policy, Pharmaceutical Pricing, and Food and Drug law, Principal, Powers, Pyles, Sutter & Verville, P.C., Washington, D.C.

EDUCATION

- J.D., Georgetown University Law Center, 1988
- M.T.S., Harvard University, 1984
- A.B., Princeton University, 1981

BAR ADMITTANCE

- Admitted to the District of Columbia Bar, 1990
- Admitted to the Pennsylvania Bar, 1988

MEMBERSHIPS

- Food and Drug Law Institute
- American Health Lawyers Association
- American Association of Health Plans
- Founding Director, Family AIDS Housing Foundation, Inc.
- Annual Scholar, Food and Drug Law Institute, 1978-88

MR. WHITFIELD. Mr. Brown, you are recognized for your opening statement.

MR. BROWN. Thank you, Chairman Whitfield, Ranking Member Stupak and other subcommittee members. Thank you for the opportunity to discuss ways in which GlaxoSmithKline is working with Health Resources and Services Administration Office of Pharmacy Affairs to improve the 340B Drug Discount Program so that the patients served by this drug 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 calculating and reporting government mandated prices, including ceiling prices under the 340B drug discount programs. 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 on our Federal formula by taking the average manufacturers price for the drug and reducing that price by the Medicaid rebate percentage.

Covered entities particularly 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 a manufactured ceiling price, and a wholesaler distribution fee. We understand that the contract purchase price is typically agreed upon solely between the covered entity and the wholesaler. The covered entities, however, have not historically always had the same systemic

access to the quarterly ceiling prices that the wholesalers have had. Without this information, the covered entities cannot effectively negotiate with the wholesaler over the wholesaler's distribution fee.

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 the program improvement, including a recommendation that covered entities be given easier access to ceiling price information.

In order to help address this issue, GlaxoSmithKline began meeting with OPA in an effort to provide our expertise in an atmosphere of frank dialogue and cooperation. Following these very productive discussions, GSK decided to voluntarily post its ceiling prices on a secure website accessible to participating covered entities, starting on October 1, 2005. GlaxoSmithKline has supported access to its manufactured ceiling prices for eligible covered entities since the beginning of the program in 1993.

Historically, this was done through the company responses to individual requests for quarterly ceiling price information from eligible entities or their GSK account managers, and, as such, showing only those entities that request such information.

To facilitate broader access to this information, we decided to be the first pharmaceutical manufacturer to share its ceiling prices with eligible covering entities by helping them to develop an innovative website provided through the 340B Prime Vendor Program, HealthCare Purchasing Partners International LLC. We believe this will enable all interested covered entities that participate in a 340B Prime Vendor Program to have secure and easy access to up-to-date drug ceiling price information with no added cost to the entities.

Specifically, GSK entered into a voluntary agreement with the Prime Vendor Program to provide systemic access to 340B ceiling prices to covered entities enrolled in the Prime Vendor Program. Under this agreement, the GSK ceiling prices are sent to the prime vendor quarterly and posted on their secure website on the first of each calendar quarter. The website will contain two consecutive quarters of data at one time.

Eligible covered entities will be granted access to the 340B secure website through a password protected user interface after signing the confidentiality clause contained in the standard enrollment agreement with the prime vendor. In deciding to move forward with this website, GSK worked with OPA to ensure that the confidential and sensitive pricing information that would be posted on the website for covered entities would not become available to competitors or to those not eligible to participate in the program.

Since GSK is the only pharmaceutical company providing website access to ceiling prices at this time, we needed to do so in a way that

would reduce the risk of competitive disadvantages in the marketplace. Ultimately, we decided that leading the way on this issue was the right thing to do. Improved access to manufactured 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 ceiling prices are being calculated accurately, GSK also agreed to send a copy of its quarterly ceiling prices, as well as relevant product package size information to OPA. That way OPA may compare them to the ceiling prices using data calculated by CMS.

For GSK ceiling prices effective October 1, 2005, OPA recently informed us that they found a match of greater than 99 percent accuracy to internal CMS calculations for the same period. GSK remains committed to working with OPA to meet the needs of the 340B eligible entities and to enable successful administration of the 340B Drug Discount Program.

We believe that by taking a leadership role and identifying and proactively resolving these issues, such as providing improved access to manufacturer 340B price information to eligible entities, GSK can help make the program more effective and efficient and ultimately improve patient access to needed drug therapy.

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

[The prepared statement of David B. Brown follows:]

PREPARED STATEMENT OF DAVID BROWN, DIRECTOR, GOVERNMENT CONTRACTS AND PRICING PROGRAMS, GLAXOSMITHKLINE

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 gastro-intestinal/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 under-served 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.[2] 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 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

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[1] 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."

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.

MR. WHITFIELD. Thank you, Mr. Brown.

Dr. Hatwig, you are recognized for your opening statement.

MR. HATWIG. Thank you. Good afternoon, Chairman Whitfield, Mr. Stupak and members of the subcommittee. My name is Chris Hatwig. I appreciate the opportunity to testify. I am a registered pharmacist and currently serve as Senior Director of the 340B Prime Vendor Program. I am employed by HealthCare Purchasing Partners International, HPPI, which is based in Irving, Texas. HPPI was awarded HRSA's prime vendor contract effective September 10, 2004. As Senior Director of the Prime Vendor Program, I am pleased to appear before you today.

Prior to joining HPPI, I was Director of Ambulatory Pharmacy and Value Analysis Programs at Parkland Health & Hospital Center, a major disproportionate share hospital in Dallas, Texas, where I practiced for 13 years.

The Veterans Health Care Act of 1992 requires HRSA's Office of Pharmacy Affairs to establish a prime vendor for the 340B Drug Discount Program. The mission of the prime vendor is to approve access to affordable medications. Its primary goals include contracting for pharmaceuticals below the 340B ceiling prices, providing covered entities with access to efficient drug distribution solutions, providing contracts for other products and services to meet the unique needs of the covered entities.

The Prime Vendor Program is designed to use the private industry and the free market to increase competition and lower drug prices for all participating covered entities by securing voluntary discounts from the pharmaceutical manufacturers. Since participation in the Prime Vendor Program is voluntary for the eligible covered entities and the manufacturers, the prime vendor must recruit the participants and the manufacturers to the program based on the value that the program provides. HPPI has structured the program to enable covered entities to participate in this program at no cost.

During our first year of directly managing the Prime Vendor Program, we have tripled the number of participating entities to over 2,000. This includes 690 hospital sites and 580 community health centers, which is approximately -- which accounts for approximately $2.2 billion in pharmaceutical purchases annually.

We have successfully leveraged the entity's business to secure sub-ceiling discounts from 18 pharmaceutical manufacturers.

In summary, the Prime Vendor Program provides the following benefits to the participating covered entities:

There is no cost to participate.

It enables covered entities to maintain their existing distributor, while accessing the program.

It offers a contract portfolio of sub-ceiling discounts on branded and generic pharmaceuticals.

It offers discounts on other outpatient pharmacy-related products and services.

It leverages the collective purchasing power of all program participants to secure discounts for the smallest covered entities, which might not otherwise be able to obtain such discounts.

It provides participants a secure website to access the contract's pricing on products and services so all parties know what they should be paying.

A criticism of the 340B Drug Discount Program has been the lack of pricing transparency. For example, participants do not have access to the 340B selling prices to validate the accuracy of the pricing. HRSA's Office of Pharmacy Affairs and GlaxoSmithKline were aware of HPPI's development of a secure site for contract pricing. They approached us to consider a pilot to make Glaxo's reported selling prices available upon a voluntary basis within our website, and we have worked closely with GSK staff to activate the value-added service as of October 1, 2005.

I have also been asked by the subcommittee to share my thoughts on how the 340B program may be improved. Improving the accuracy and the transparency of the 340B ceiling prices is critical to improving the effectiveness and the value of the program. I have three primary recommendations that would serve this purpose.

First, the OPA should consider working directly with the pharmaceutical manufacturers to verify the accuracy of the 340B ceiling prices prior to those prices being made available at the start of each quarter.

Secondly, the OPA should consider establishing a secure mechanism for sharing the 340B ceiling prices with its prime vendor and covered entities.

Third, the OPA should be granted sufficient resources to audit manufacturers, wholesalers and covered entities to ensure accountability with the requirements of the 340B program.

Mr. Chairman, I appreciate the opportunity to appear before the subcommittee to discuss the 340B program and ways to improve its effectiveness. This program is critically important to the safety net providers in their mission to providing access to affordable medications to our most vulnerable patient populations. I look forward to answering any questions this subcommittee may have.

[The prepared statement of Christopher A. Hatwig follows:]

PREPARED STATEMENT OF CHRISTOPHER A. HATWIG, SENIOR DIRECTOR, 340B PRIME VENDOR PROGRAM, HEALTHCARE PURCHASING PARTNERS INTERNATIONAL

Personal Background

Good Afternoon. My name is Chris Hatwig. I am a registered pharmacist and currently serve as Senior Director of the 340B Prime Vendor Program (PVP). I have been employed by HealthCare Purchasing Partners International (HPPI), an LLC based in Irving, Texas. HPPI competed in HRSA's public bid of the 340B Program's Prime Vendor and was awarded the contract effective September 10, 2004. Prior to that, HPPI operated for a year as a subcontractor to AmeriSourceBergen, a pharmacy wholesaler, which served as HRSA's first Prime Vendor for the 340B Drug Discount Program. In the capacity as Senior Director of the 340B Prime Vendor managed by HPPI, I am pleased to appear before you today. By way of background before taking the position at HPPI, I held the position of Director of Ambulatory Pharmacy and Value Analysis Programs at Parkland Health & Hospital System. Parkland is a major disproportionate share hospital located in Dallas, Texas where I practiced for thirteen years. I was responsible for management of Parkland's ambulatory pharmacy and purchasing programs. Parkland is one of the larger and more progressive safety-net healthcare systems in the U.S. It operates a network of community based clinics in medically underserved areas and processes approximately 10,000 outpatient prescriptions per day at an expense in excess of $65 million annually.

Prime Vendor Program

In 1992 Congress enacted the Veterans Health Care Act. Section 340B of that Act required pharmaceutical companies whose drugs are covered by the Medicaid program to provide mandatory discounts on outpatient covered drugs purchased by certain government-supported facilities called covered entities. Today, there are over 12,000 covered entities participating in the 340B Drug Discount Program, which include disproportionate share hospitals, federally qualified health centers, family planning clinics and other government grantees.

The Veterans Health Care Act also requires HRSA's Office of Pharmacy Affairs (OPA) to establish a Prime Vendor for the 340B Drug Discount Program. A primary mission of the 340B Prime Vendor is to improve access to affordable medications for covered entities and their patients. Its primary goals include:

- Contracting for pharmaceuticals below the 340B ceiling prices
- Providing covered entities with access to efficient drug distribution solutions to ensure access to affordable medications
- Providing contracts for other products and services to meet the unique needs of participating covered entities

The Prime Vendor program is designed to use the private industry and the free market to increase competition and lower drug prices for all participating covered entities by securing voluntary discounts from pharmaceutical manufacturers.

Since participation in the PVP is voluntary for the eligible covered entities and manufacturers, the Prime Vendor must recruit participants and manufacturers to the program based on the value it provides. HPPI has structured the program to enable a covered entity to participate in the program using its existing pharmacy wholesaler with no additional costs to the entity. There are eleven wholesalers participating in the current program, greatly improving access to the program and its discounts. During HPPI's first year of managing the Prime Vendor program, it has more than tripled the number of participating covered entities. The program currently represents over 2000 covered entities (including 690 hospitals and 580 community health centers) purchasing $2.2 billion in pharmaceuticals annually. HPPI has successfully leveraged the entities' business to secure sub-ceiling discounts on branded and generic products from 18 pharmaceutical manufacturers. The program's contract portfolio also includes discounts for important products such as vaccines, diabetic meters, and test strips which are not required to be discounted through the 340B program but are critical products for the participating covered entities' preventive health programs. As more covered entities join the program, the value of the program's contract portfolio will continue to grow.

In summary, the 340B Prime Vendor Program provides the following benefits to participating covered entities:

- No cost to participation
- In most cases, enables covered entities to maintain their existing distributor while accessing the program
- Offers a contract portfolio of sub-ceiling discounts on branded and generic pharmaceuticals
- Offers discounts on other outpatient pharmacy related products and services
- Leverages the collective purchasing power of the program's participants to secure discounts for even the smaller covered entities (It is important to note that there are approximately $3.5 billion in 340B related pharmaceutical sales in the U.S. representing only one to two percent of all US pharmacy sales)
- Provides participants a secure website to access the program's contracted pricing on products and services.

Voluntary Transparency of 340B Selling Prices

Many of the Prime Vendor participating hospitals and clinics have expressed a desire to have access to the 340B ceiling prices to validate the accuracy of pricing listed in the pharmacy wholesalers systems. At HPPI, we had already developed a secure website requiring logons and passwords to share our confidential sub-ceiling pricing with participants. We were initially approached by HRSA's Office of Pharmacy Affairs and GlaxoSmithKline (GSK) about conducting a pilot to make GSK's reported selling prices available on a voluntary basis in a secured portion our website. A separate section of the website was proposed to avoid any confusion with the Prime Vendor's separate contract portfolio. We were able to work with GSK staff to finalize an agreement, complete programming enhancements, and activate the value added service on October 1st 2005. The website currently lists GSK's 4th quarter pricing. As of December 5th, we have had 792 hits on the secure site and the GSK price file was downloaded a total of 75 times or nearly 10% of the time a participant accessed the site.

I believe the additional service will encourage more manufacturers to work with the Prime Vendor Program and will eventually lead to manufacturers offering additional sub-ceiling pricing on their products to further benefit the program's participants. The service

offering is available at no cost to any pharmaceutical manufacturer offering sub-ceiling discounts on their products to the program's participants. The new section of the website provides a more efficient method for pharmaceutical manufacturers to directly share their selling prices with eligible covered entities over previous methods. Having access to the selling prices will enable the covered entities to verify they are receiving the accurate pricing through their pharmacy wholesalers and enable them to pursue appropriate resolution of any pricing discrepancies.

Recently I have received inquiries from other pharmaceutical manufacturers about the pilot program and have shared copies of our data sharing agreement for those companies to review.

Suggestions for Improving the 340B Drug Pricing Program

Improving the accuracy and transparency of the 340B ceiling prices is critical to improving the effectiveness and value of the program. The following recommendations would serve this purpose:

1. HRSA should work directly with pharmaceutical manufacturers to verify the accuracy of 340B ceiling prices prior to the prices being made available to pharmacy wholesalers at the start of each quarter.
2. HRSA should identify a secure mechanism for sharing the selling prices with its Prime Vendor to validate its own contracts are indeed sub-ceiling. HRSA should also establish a secure method of providing access to 340B selling prices to pharmacy wholesalers and the eligible covered entities through its contracted prime vendor or other means.
3. HRSA should be granted sufficient resources to audit manufacturers, wholesalers, and covered entities to ensure accountability with the requirements of the 340B program.

I appreciate the opportunity to appear before the subcommittee to discuss the 340B Drug Discount Program and ways to improve its effectiveness. This program is critically important to the safety-net providers in their mission of providing access to affordable medications for the low-income and uninsured populations in the U.S.

MR. WHITFIELD. Thank you, Dr. Hatwig.

Mr. von Oehsen, you are the General Counsel for the Public Hospital Pharmacy Coalition. Just how serious is this overcharge situation? Is this serious, or is this just an isolated incident that happens periodically?

MR. VON OEHSEN. Well, the reality is we don't know how serious it is. There is ample evidence to be very concerned. Back in 2000 we actually submitted some sample prices to the Office of Pharmacy Affairs, because these were prices where there was significant variation between our members. So we submitted a range of prices and said something just doesn't look right here. Can you tell us whether any of these are overcharges?

Well, we got a letter back in 2001, January of 2001, that indicated that in fact a very significant amount of those prices were overcharges. But probably even more disturbing was that for a significant number of those prices, they couldn't tell us whether an overcharge had occurred or not because they didn't have the proper data.

MR. WHITFIELD. So they didn't know either?

MR. VON OEHSEN. They didn't know either.

MR. WHITFIELD. Well, I noticed that on page 17, Exhibit 1 of that report, they say specifically there that you submitted six of your hospital sales data to HRSA for price verification and HRSA subsequently found that 37 out of 50 drug prices exceeded the ceiling prices.

MR. VON OEHSEN. Exactly.

MR. WHITFIELD. Now, from your knowledge, have the hospitals ever recovered those charges?

MR. VON OEHSEN. No. We talked it over with Office of Pharmacy Affairs. I think essentially they just felt like there wasn't anything they could do. I mean, the only recourse they had, was to try to convince the Secretary to try to terminate these drug companies from the Medicaid many practice. Well 340B is a much smaller program than the Medicaid program. There is no way they will do that.

MR. WHITFIELD. That is not a realistic solution?

MR. VON OEHSEN. It really is not.

MR. WHITFIELD. Did HRSA initiate a dispute resolution on those cases that you are aware of?

MR. VON OEHSEN. No.

MR. WHITFIELD. If you were over at HRSA yourself, and you were responsible for HRSA, would you be more aggressive? Do you think there needs to be additional legislation? What is your opinion?

MR. VON OEHSEN. Well, first of all, if you look at the pharmaceutical pricing agreement, there's language in there that manufacturers are required to -- let me just read it to you. Manufacturers are responsible for affording the Secretary or his designee reasonable access to records of the manufacturer relevant to the manufacturer's compliance with the terms of the agreement, which is basically to give the 340B prices.

We think it is right in the pharmaceutical pricing agreement that they should give these prices to HRSA. So that's number one. I would get the prices from the manufacturers. I would compare how they have calculated the prices with how the government has calculated the prices, and that is step 1.

Then step 2 is to make sure that the actual price is being invoiced to the covered entities, comply, you know, is also the same as the 340B ceiling price or lower. Can be lower than the ceiling price, but it can't be higher.

MR. WHITFIELD. You feel the language is adequate now and that HRSA is simply not enforcing it?

MR. VON OEHSEN. I think the government has the authority to require manufacturers to submit their 340B prices to the government. I think that a lot of the manufacturers actually do submit their 340B prices to the government. What Glaxo has done, which is so important, is for

the first time they have disclosed the prices to the covered entities -- or at least the covered entities in the Prime Vendor Program.

MR. WHITFIELD. HRSA keeps saying well, confidentiality prevents us from sharing these prices with the covered entities or the vendors, right?

MR. VON OEHSEN. That's what they say. We strongly disagree with that, though. We think the statute allows them to disclose to the extent necessary for the proper administration of the 340B program. We think this is fundamental to the proper administration of the 340B program. Why can't they disclose it? It would solve all of these problems.

MR. WHITFIELD. So, Mr. Brown, ever since I have been involved in politics, I have always heard that drug manufacturers are very protective of pricing and want to maintain the confidentiality. So why all of a sudden did Glaxo just decide to provide this information?

MR. BROWN. Mr. Chairman, we do believe that the pricing information is confidential, but we also believe that the entity should have the right to the prices that they are due, access to the information to see the prices that they are due, and we felt that by going through the website that we were able to maintain the confidentiality and be able to supply that information.

MR. WHITFIELD. You do not see any reason why other manufacturers would not be willing to do the same, I am assuming?

MR. BROWN. Mr. Chairman, I cannot speak for other manufacturers, but I can speak for GSK. We again believe that its entities should have access to the pricing that they are due, information.

MR. WHITFIELD. Mr. Hatwig, from the Prime Vendor Program, you mentioned single ceiling price list. Would you all support a system whereby manufacturers would submit ceiling prices to HRSA? You would support that, I am assuming?

MR. BROWN. Again, Mr. Chairman.

MR. WHITFIELD. You are speaking only for yourself.

MR. BROWN. Yes, we are speaking only for ourselves. Actually, we do feel that the current legislation and the current mechanisms in the law are sufficient to resolve the issues set in the OIG, and we do support --

MR. WHITFIELD. I do commend you for doing it. I think it is the right thing to do. I think it does help on transparency.

Mr. von Oehsen, you pointed out in your testimony there is often a shortage of drugs at 340B prices, even though these drugs can be purchased elsewhere at higher prices. How significant is this problem?

MR. VON OEHSEN. It is a very significant problem, with respect to IVIG, which is a very expensive drug, and it's a drug which a lot of the patients of these hospitals need.

The problem that they are encountering is that if they go to the manufacturer and ask for the drug at the 340B price it's not available. However, if they were to purchase the drug through their group purchasing organization at a higher price, the drug is available. We frankly don't understand how a drug can be available at a higher price and not at a lower price.

MR. WHITFIELD. So when you raised this issue, what explanations or justifications are you given?

MR. VON OEHSEN. Well, we are hearing that there is a drug shortage problem, and that manufacturers have prior commitments on how they allocate the drugs to other purchasers, and they allocated all of their drugs that are in short supply to commercial purchasers, which leaves nothing left over for 340B.

MR. WHITFIELD. Mr. Brown, what do you say about that, this drug shortage issue?

MR. BROWN. Mr. Chairman, it is not really an issue I am familiar with. So I cannot really comment. It is not a practice at GSK.

MR. WHITFIELD. So you can't comment on that then? You are just not aware of it?

MR. BROWN. I am not aware of that issue.

MR. WHITFIELD. Okay.

Mr. Hatwig, does the prime vendor currently have access to ceiling price calculations?

MR. HATWIG. No, sir.

MR. WHITFIELD. I am assuming it would be quite helpful if you did have that information.

MR. HATWIG. Well, my preference would be just to have access to the ceiling prices and not to actually have all the data, to actually have to calculate them yet again ourselves.

MR. WHITFIELD. Since you are the head of this program, and you deal with it on a day-to-day basis, what do you consider the biggest operational problems that you confront?

MR. HATWIG. Well, with our program, the prime vendor many practice, my biggest challenge in running this program is everything is voluntary. We have to go out and recruit the covered entities to participate in a program that does nothing but save them money. We have to recruit the members in. We also have to -- it is also voluntary for pharmaceutical manufacturers to offer additional discounts through the program.

That is our biggest challenge day to day is building the value of this program. When we won this contract in September of 2004, we really started with nothing. We didn't have participants. We didn't have

suppliers. We had to slowly build this program up to where we thought it would actually make it and it could survive.

We are at a point now where we have a critical mass of customers that pharmaceutical manufacturers are paying attention to it now.

MR. WHITFIELD. What percent of the covered entities would you say are participants with you?

MR. HATWIG. As far as percentage, if you look at the numbers out there, I hear 12,000 eligible covered entities, we are a little over 2,000. But if you were to look at actual purchase, actual 340B-related purchases, I would say we are probably closer to -- we are representing 60 percent of the volume in the country. The word spreads much slower to the smaller entities, because the people at those entities are not at national meetings and things like this. They don't have those resources.

MR. WHITFIELD. I see my time has expired.

Mr. Stupak, you are recognized.

MR. STUPAK. Thank you, Mr. Chairman.

Mr. Hatwig, if you don't have access to any of the ceiling prices then how are you negotiating sub-ceiling prices?

MR. HATWIG. That's a very good question, Mr. Stupak. We are in negotiations with the manufacturers. We demand to know what the 340B ceiling prices are, and in those negotiations, you know, do I know for sure? No, I do not. But I trust that they are sharing their ceiling prices with us, because in many cases we are negotiating a discount off of the actual ceiling price. Because I want to be sure that our contract pricing is staying there, it would be nice to be able to have that price available to us from the OPA.

MR. STUPAK. Sure. Is there any reason not to make it available to the members themselves then?

MR. HATWIG. No, in my opinion, especially when you have got a system like we do. We can share that information with our customers on a secured website with log-ons and passwords. It's certainly a problem, if you, I think, were to throw that information out into the public domain. But as long as there's a secured way of delivering the pricing to the entities that need to know, it's an excellent move for the program.

MR. STUPAK. If you had it and your 2,000 members had access to it, that certainly would help out. But wouldn't it also help be sort of an enhancement mechanism to make sure the program is being run properly?

MR. HATWIG. Yes.

MR. STUPAK. Mr. von Oehsen, I have some questions for you. I know I did. In your testimony, you state that the integrity of the 340B program will remain compromised until the program has the resources, authorities, and the requisite systems in place to assure that this happens.

Mr. Williams, I think, if my memory of his testimony is correct, seems to think that everything is under control. Have you observed any additional resource authorities or systems going into this program, the 340B program?

MR. VON OEHSEN. Do I recommend that there be?

MR. STUPAK. No, no. Do you recognize, do you recognize anything that has been changed or additional resources to make it better in the last 18 months or so?

MR. VON OEHSEN. Oh, yes, I think a couple of years ago Office of Pharmacy Affairs lost some personnel, but they have regained a number of them over the past year. They have also -- there was a reorganization of HRSA, and they moved it from just a branch level up to an office level. So that gave them more direct access, I guess, to the HRSA Administrator.

MR. STUPAK. Could you explain to me the problems with the calculation of the DSH payments to the hospitals and its impact on the 340B program?

MR. VON OEHSEN. Well, this is vitally important to the hospitals, because they can only qualify for the program if their disproportionate share budget is over 11.5 percent, which means they are serving a lot of Medicaid and low-income patients.

The calculation of the DSH adjustment is a fairly complicated one, and I think through litigation and other means it has been determined that there have been some inaccuracies in the calculation of the DSH adjustment.

Unfortunately, it is CMS that really administers the Disproportionate Share Program, and yet it is the eligibility criteria for HRSA. This is one of the areas where we think we need much better communication and cooperation between HRSA and CMS.

What happens is if a hospital says no, our DSH adjustment is really above 11.5, we are really qualified to join this program, HRSA will say, well, we don't administer that program. You need to talk to CMS. Well, CMS will say 340B is not our program, you need to talk to HRSA, and there is really no place to go.

MR. STUPAK. Well, we had hoped that CMS would be here because those are some of the questions I had, but unfortunately we don't have them here today. Maybe our next hearing we can get them, Mr. Chairman. We would like to ask them some of those questions.

MR. STUPAK. Let me ask Mr. Brown, if I can, under the 340B pharmaceutical pricing agreement are you providing those same drugs to the 340B entities in the Medicaid agreement?

MR. BROWN. Congressman, the covered drugs that are covered under Medicaid are offered on the 340B BBA.

MR. STUPAK. There was a little bit of discussion about shortages, and can you shed any light on that for us?

MR. BROWN. Shortage. No, sir, I can't.

MR. STUPAK. Chronic shortages?

MR. BROWN. No, sir, I can't.

MR. STUPAK. Who in your company could, do you know?

MR. BROWN. I can take your request back and provide it to the appropriate people and get that answer back to you, yes, sir.

[The information follows:]

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February 7, 2006

Chairman Ed Whitfield
Subcommittee on Oversight
and Investigations
Energy and Commerce Committee
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515

Congressman Bart Stupak
Subcommittee on Oversight
and Investigations
Energy and Commerce Committee
U.S. House of Representatives
2322 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Whitfield and Ranking Member Stupak:

Thank you for the opportunity to provide additional information to supplement my testimony of December 15, 2005, before the Committee on Energy and Commerce, Subcommittee on Oversight and Investigations of the United States House of Representatives. Specifically, Congressman Stupak, you asked for information regarding the suppressed level of pharmaceutical products made available to 340B covered entities while these drugs were in sufficient supply elsewhere at higher prices.

The reference to shortages was first highlighted in the written statement of Mr. Bill Von Oehsen. In his statement, Mr. Von Oehsen writes:

"According to our members, there have been a number of instances in which covered entities were told by manufacturers that particular products – especially intravenous immune globulin (IVIG) and other blood-derived products – are unavailable for purchase under the 340B program because all available supplies of the products have already been committed to other purchasers under commercial contracts. "

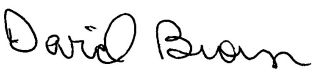
GlaxoSmithKline (GSK) does not manufacturer IVIG or other blood-derived products referenced by Mr. Von Oehsen. After conducting an evaluation of GSK's customary practices in order to address the Committee's information request, I am also not aware of any comparable product shortage issues as outlined by Mr. Von Oehsen involving a product marketed by GSK.

GSK primarily sells and distributes its drug products through wholesalers with very little direct sales to 340B entities. When faced with a Covered Product in short supply, it is not the practice of GSK to restrict purchases of the Covered Products in short supply to commercial purchasers and make them unavailable for purchase under the 340B program. 340B entities, like any commercial purchaser, order from and are supplied through their customary wholesaler with no direction from GSK. During periods of product shortages, the focus of GSK is on ensuring, to the extent feasible, that the patient has uninterrupted access to needed GSK drug therapies. If

necessary, GSK will drop ship product whenever requested to get the product to the patients that need it the most.

Again, thank you for the opportunity to provide additional information. GSK remains committed to working with the Committee on Energy and Commerce and the Office of Pharmacy Affairs to meet the needs of the 340B eligible entities and enable the successful administration of the 340B Drug Discount Program. We continue to 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. Please do not hesitate to contact Janie Kinney, Vice President of Federal Government Relations and Public Policy, at (202) 715-1012 if you have additional questions.

Sincerely,



David Brown
Director, Government Contracts & Pricing Programs

MR. STUPAK. I think I mentioned in the last panel that we are talking about those letters, and I think Glaxo received one of those letters from HRSA -- I think Mr. Williams said it might have been in 2004 -- about overcharges to the 340B program. As we know, the OIG did not review every single drug and Glaxo settled, I think I said, with Flonase, right?

MR. BROWN. Correct.

MR. STUPAK. What about the -- have there been some other overcharges with Glaxo or something with Glaxo, and has that been resolved?

MR. BROWN. Congressman, first we do not believe we have overcharged the 340B entities. GSK and the government did disagree on the interpretation of the law for calculating best price. The matter was investigated by the Department of Justice, to include a review of all the products and relevant transactions, and GSK fully cooperated with that investigation. At the end of the day, we decided it was appropriate to settle this matter. Part of our settlement did include payments to the 340B entities.

MR. STUPAK. On Paxil, you mean?

MR. BROWN. On the drugs that were covered under the settlement.

MR. STUPAK. Good, and Paxil was one of them, I take it.

MR. BROWN. For one quarter, yes, sir.

MR. STUPAK. For one quarter.

MR. BROWN. To the best of my knowledge, Department of Justice has closed the investigation, and we believe this matter is resolved.

MR. STUPAK. You know, you testified earlier that you are providing ceiling prices on a secure website, right?

MR. BROWN. Yes, sir.

MR. STUPAK. For some of the 340B entities that are covered there. Are any other drug companies doing that that you know of?

MR. BROWN. Not to my knowledge at this time.

MR. STUPAK. Since you are doing it, do you see any downside in providing this information? I guess I am a little bit wondering why you are doing it and they are not. Is that part of the settlement or anything?

MR. BROWN. Congressman, no, it was not. I think it is a voluntary thing that we are doing. Again, the one downside is always the confidentiality that the price could be given to entities that are eligible for it or to our competitors, but we do feel that the benefit to the 340B entities outweighs that.

MR. STUPAK. You haven't found that to happen, the information has been secured with the website; have any troubles with that?

MR. BROWN. Congressman, to the best of my knowledge it has been secured, yes.

MR. STUPAK. I know it's only been up for a short time, a couple of months or so, but have there been any problems with that? I am just trying to get as much as I can on the record, because I want the other companies to do the same thing.

MR. BROWN. Sure. As I understand, there have been some problems but it has gotten almost no activity. But Mr. Hatwig could answer that better.

MR. STUPAK. Any problems that you are aware of, Doc?

MR. HATWIG. No, no problems that we have. We have -- since approximately October 1st to December 5th, we had 790 hits on the site. We had members -- that's viewing the pricing, and we had 10 percent of the customers actually download the pricing. So there's interest in the pricing for sure.

MR. STUPAK. I would think if we did this, and I think we should be able to come up with some kind of simple computer program just to be able to do the comparisons, if we have the two prices, the HRSA price, the manufacturer's price, part of enforcement, make it clean, we wouldn't have to have all these hearings and all of these other things, right? Solved that problem, let's go home?

MR. WHITFIELD. I think there are some people out there who would like to go home.

Ms. DeGette.

MS. DEGETTE. Thank you, Mr. Chairman.

Mr. von Oehsen, I just wanted to clarify something you had said in response to Mr. Whitfield's question. You said that you believed that the

agency has the authority to require disclosure, correct? You need to answer verbally.

MR. VON OEHSEN. Yes, disclosure of their 340B ceiling prices, that priority.

MS. DEGETTE. So my follow-up question to that is, do you think then that the company should be required to make disclosure or should it be voluntary as it is now?

MR. VON OEHSEN. I think it should be mandatory. I just don't see how the government is going to be able to verify that the prices are correct unless they are checking their calculations against the manufacturer's calculation.

MS. DEGETTE. Right. And if you only have one manufacturer that is qualifying, that doesn't give you the full information, does it?

MR. VON OEHSEN. Well, it is my understanding that there are a number of drug companies that are actually submitting their 340B price lists, and certainly not all drug companies, but a fair number of them are. I think what GlaxoSmithKline has done is unique in that they are disclosing the prices to the covered entities directly, at least the ones in the Prime Vendor Program.

MS. DEGETTE. Why do you think that is an important addition?

MR. VON OEHSEN. Well, because there are really two challenges here: one, just to make sure that the manufacturers are pricing the drugs correctly, actually paying, and being charged the right price, and there are errors that can occur in that process as well. I mean, I think it would be onerous to ask the government to be, you know, auditing every single input.

MS. DEGETTE. Micromanaging?

MR. VON OEHSEN. Right. So it would be better to give the covered entity the 340B price so that it can do its own comparisons.

MS. DEGETTE. Do you want to add to that response?

MR. HATWIG. I just support that same opinion that I think it is impossible to expect HRSA to monitor and police this with the covered entities, but if at least we give the covered entities the ceiling prices that are participating in the program they can police it themselves.

MS. DEGETTE. And you think that can be done without revealing confidential or proprietary information?

MR. HATWIG. Yes. Through a secured site, I think it can be done.

MS. DEGETTE. Would you agree with that, Mr. Brown?

MR. BROWN. We do agree that you can give the covered entities the ceiling price information voluntarily, as we have done, to a secure site and maintain the confidentiality.

MS. DEGETTE. Great.

Now, Mr. von Oehsen, I wanted to ask you about the OIG report. It is clear that participating entities in the 340B program at best have, and you testified to this, have had incomplete information about purchasing drugs through the program, and at worst are paying inflated prices.

Now, your coalition represents the DSH hospitals throughout the country. So my question is, how much money do you think that the DSH hospitals have overpaid since the program's inception because of the lack of information? Do you have any idea?

MR. VON OEHSEN. We don't. We really don't.

MS. DEGETTE. Do you have the sense that there have been overpayments?

MR. VON OEHSEN. Oh, absolutely.

MS. DEGETTE. Why? Why do you have that sense?

MR. VON OEHSEN. Well, again, referring to this submission that FASHP made to the Office of Pharmacy Affairs, varies. Back in 2000 for six hospitals there were over 100 drug prices where there was significant variation of prices. Something just didn't look right. So we asked the government to let us know whether any of these were overcharges.

Now, back then, HRSA had to rely on the CMS calculations. So they looked at the CMS calculations and they came back and a very large number of those prices were apparently overcharges. So that by itself gave us, you know, real concern that overcharging might be a rampant problem. Then again, manufacturers may be doing a good job, and you know, maybe it was more of a problem earlier in the program than it is now. We just don't know. But it is important that we have a system in place to make sure that it doesn't happen, and if it does happen, that there is some recourse for covered entities to get refunds.

MS. DEGETTE. Well, that is my next question. Currently, what recourse does a covered entity have if it thinks it is being overcharged?

MR. VON OEHSEN. I can't tell you how many e-mails we have sent to Pharmacy Affairs saying, you know, we have a member that was charged this price, it looks like their GPO or someone in the private market is getting a better price. Under 340B these covered entities are entitled to a best price in the market.

Now, there are some exceptions to that, but it doesn't look right, so we send the e-mails to the Office of Pharmacy Affairs asking them to let us know whether an overcharge has occurred, and we don't hear back. There is not much we can do.

MS. DEGETTE. So let me stop you. Have your members received any kind of money back or any kind of responses at all?

MR. VON OEHSEN. We have, and there has been an awful lot of education that has had to go on. There have been some settlements

where there have been some best price violations which have -- which has entitled the Medicaid program to certain refunds. For a long time the negotiators of those settlements didn't realize that this had a direct impact on 340B, so it was not included. We have educated the Department of Justice and the OIG, and we do feel that henceforward, we are going to be included in all of those settlements.

There have been some, GlaxoSmithKline was one of them, and there was -- in fact, there have been some refunds as a result of those settlements with the Department of Justice. Some manufacturers have discovered errors and have voluntarily issued refunds, but some manufacturers really are reluctant to, you know, to issue refunds, and the problem is that there is no refund process in place.

MS. DEGETTE. Right, okay. I got you.

Mr. Brown, I just have one follow-up question for you. This website that you were talking about earlier, I just want to know, for Glaxo has the development and maintenance of the website caused a significant financial or resource burden on your company?

MR. BROWN. Congresswoman, no, it has not.

MS. DEGETTE. Mr. Chairman, I want to thank you for having this hearing. I think it is pretty clear after listening to both of these panels that this is a valuable program, but it is one that is so loose as to have little enforcement, little -- is no quantification as to what is going on. I think everybody would agree it really needs to be tightened up, so I hope we can do more work on this, and I yield back.

MR. WHITFIELD. Thank you, Ms. DeGette. I certainly agree with you, and I think all of the witnesses agree, with maybe very few exceptions. We feel like we have spent the whole afternoon with most of you, and we have enjoyed getting to know you.

One follow-up question I would like to make to Mr. Hatwig. I have been told that during your interview with committee staff you mentioned wanting to see a single unified ceiling price list that would be given to wholesalers; is that correct?

MR. HATWIG. Yes. What I had mentioned was a lot of the discrepancies and all that can happen with the system, there are so many players in delivering pricing to the marketplace. We were just hypothetically thinking about it and talking about the audits and things that could be going on. What if the Office of Pharmacy Affairs worked directly with the manufacturers to create a master price file? One single master price file, and you could even argue technically at that point if it was validated, worked together on and validated before the beginning of the quarter, then the covered entities might not have to see the pricing. You wouldn't have to go through different steps of exposing that pricing, but there would be one single master price file that is created, and then it

could be pushed to all distributors through like the Prime Vendor Program and the relationships with HRSA there. So then, at that point, you are cutting out all of the variations, the fail points in the system that pharmacy wholesalers may make with these price files, because the pharmacy wholesalers are working with every single manufacturer in the marketplace loading their own pricing. There are humans involved.

So if you could go, I guess, go up the food chain, if you will, and address the problems and create a master file there and then push that same price file to everyone, the integrity of the program would be greatly improved.

MR. WHITFIELD. Right.

Mr. von Oehsen, one other question to just follow up on Ms. DeGette. We were talking about these overcharges and little enforceability as far as getting refunds. I am assuming as a representative of your group you have had conversations with your manufacturers about overcharges. What do they basically say to you, generally speaking?

MR. VON OEHSEN. Well, it is a real mixed bag. Some manufacturers are quite willing to cooperate and in fact voluntarily issue refunds. Others say that they will, but then don't follow through, and others just refuse to talk to us or simply claim that they don't owe refunds.

MR. WHITFIELD. And there is not anything you can do, really.

MR. VON OEHSEN. You know, absent some big lawsuit which we would prefer not to do, frankly.

MR. WHITFIELD. Right. Well, I want to thank you all very much. I think it is quite obvious, as Ms. DeGette said, that there are some areas that we need to pursue on this. I am sure we will be back in touch with many of you. I want to thank you for your time and hopefully the next time you come to testify it won't be all afternoon.

So thanks again. The record will remain open for those members who would like to submit additional data or information or opening statements.

With that, this hearing is concluded.

[Whereupon, at 5:25 p.m., the subcommittee was adjourned.]

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