

PREPARED STATEMENT OF T. MARK JONES, PRESIDENT OF VEN-A-CARE OF
THE FLORIDA KEYS, BEFORE THE COMMITTEE ON ENERGY AND
COMMERCE OF THE UNITED STATES HOUSE OF REPRESENTATIVES,
DECEMBER 7, 2004

Mr. Chairman and Members of the Committee, good morning. I am T. Mark Jones, President of Ven-A-Care of the Florida Keys. I wish to thank you for the opportunity to appear before you today to discuss a matter of vital importance to government health care benefit programs such as Medicaid: The diversion of hundreds of millions of taxpayer dollars because some pharmaceutical manufacturers report falsely inflated prices, knowing that government programs use those reports in setting reimbursement amounts. Ven-A-Care's past president, Zachary Bentley, appeared before this Committee on September 21, 2001 and testified about the impact of the same deceptive practices on the Medicare Program. Due in large part to the hard work of this Committee, protections against such drug manufacturer misconduct were included in the Medicare Modernization Act. I would draw the Committee's attention to the extensive evidence presented during the September 2001 hearing that exposes how drug manufacturers' deceptive reports of prices has damaged the Medicare Program and its elderly and disabled beneficiaries. Today's hearing focuses on excessive reimbursement for pharmaceutical products by the States' Medicaid Programs, where the same kinds of deceptive price reports, by some drug manufacturers, are causing wide scale financial harm to our country's joint state and federal healthcare program for our poor.

As the information from this Committee's prior investigations revealed, Medicare reimburses pharmacies directly for a limited number of drugs, such as the inhalant drug Ipratopium Bromide when administered with a nebulizer. However, a very large portion of Medicare Part B drug expenditures directly reimburse physicians who administer the

drug and may receive a direct financial benefit from their decision to use a particular drug. State Medicaid Programs, on the other hand, reimburse all providers for a much larger number of drugs than does Medicare Part B, and the vast majority of Medicaid drug expenditures are paid to pharmacies that dispense the drug to the Medicaid beneficiary. Accordingly, the manufacturers' marketing of the financial inducements, made possible by their false price reports, is usually directed at pharmacies when Medicaid reimbursement is at issue. As the cost of the War On Terror climbs and our national deficit grows, Congress faces increasing pressure to reduce federal contributions to State Medicaid Programs. Congressional and Executive Branch scrutiny of deceptive price reporting practices by drug manufacturers will do much to insure that the scarce dollars remaining are no longer diverted from their intended purpose of caring for our poor. Federal and State Medicaid funds must not be used as financial incentives that support individual drug companies' marketing efforts.

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A brief discussion of Ven-A-Care's history will help put my remarks in the proper context. Ven-A-Care is a very small specialty pharmacy that was created in the late 1980s to provide infusion, inhalation and injectible pharmaceuticals to seriously ill patients, outside of the hospital setting, in the Florida Keys. We immediately experienced a high demand for our services due to the large numbers of patients suffering from HIV related illnesses in Key West. Our early success attracted the attention of National Medical Care, then the health care subsidiary of WR Grace Corporation, that organized the referring physicians in the community into a single venture and attempted to recruit Ven-A-Care's principals with promises of making us multi-millionaires within a few short years. Our

examination of the NMC business plan revealed what appeared to be an unlawful arrangement where excessive reimbursement for pharmaceuticals would be used to generate exorbitant profits. Our concerns about the propriety of the venture were elevated by then recent experiences. In one instance, we received from Medicare a payment for a cancer therapy in an amount many times our cost as a very small pharmacy. Assuming that a mistake had been made, we voluntarily returned the money to Medicare. In another instance, we became concerned that the Florida Medicaid Program was paying excessive amounts for certain infusion therapies and we informed the program supervisors. The organizers of the NMC venture made it very clear to us that “success” would result from using funds generated by inflated pharmaceutical reimbursements to financially induce the participating physicians to increase their prescriptions, of expensive pharmaceutical therapies, many fold beyond that which had previously resulted from their best medical judgment. We did not believe that we could properly participate and we declined. As a result, the participating physicians re-directed their referrals to the new venture in which they had an economic interest and Ven-A-Care soon lost virtually its entire market. After reporting our concerns to the appropriate federal authorities and assisting them in their investigations of NMC’s business practices, Ven-A-Care brought its first action under the Federal False Claims Act which ultimately led to the United States recovering nearly \$500,000,000 and WR Grace divesting itself of its healthcare businesses.

Our experience with the NMC venture was soon followed by other opportunities to share in other business arrangements where excessive government reimbursement for pharmaceuticals was used to fund kick-back arrangements and increase utilization of expensive drug therapies. Again we reported these situations to the government, gathered

evidence through our own investigations and took other actions to assist the United States Department of Justice, the HHS OIG and later the States' Attorneys General in their efforts to identify and address the causes of the inflated reimbursement that was fueling the kinds of kick-back arrangements to which Ven-A-Care had been exposed.

As an industry insider, Ven-A-Care has had access to information that the federal and state governments needed to understand the root cause of the inflated Medicaid drug reimbursements. The following summarizes what we discovered:

- a.) The United States government's policy has been that Medicaid reimbursement for drugs should be based upon the cost of the drug to the pharmacy, or other health care provider, who purchases the drug in the free marketplace and must not be based upon government price controls or government negotiating power. This is significantly different from the situation where the government agency buys the drug directly, such as for the public health service, and gets the benefit of the much lower Federal Supply Schedule Prices.
- b.) Medicaid programs pay pharmacies a dispensing fee over and above the amount reimbursed for the cost of the drug itself. The drug manufacturers' deceptive price reports cause the Medicaid Programs to pay excessive reimbursement for the drugs' cost to the pharmacy or other provider. All state Medicaid Programs as required to limit their reimbursement for the cost of the drug itself to an amount no greater than that based upon the program's estimate of the acquisition cost (EAC) which in turn is to be based upon prices "generally and currently available" in the marketplace.

- c.) Therefore, “reimbursement” in the context of the Medicaid pharmacy benefit, is the amount that a state Medicaid Program pays the pharmacy, or other provider, for the cost of the drug that it dispenses or otherwise provides to a Medicaid beneficiary.
- d.) State Medicaid programs look to prices reported directly to them by the manufacturer, as in the case of the Texas Program, or indirectly through prices the manufacturer causes to be reported by the three recognized drug price compendia; Red Book, First Data Bank and Medi-Span.
- e.) The manufacturers report prices, and cause prices to be reported by the compendia, in three basic formats: Average Wholesale Price (AWP) - a representation of the price of the drug from the wholesaler to the pharmacy or other provider. Wholesaler Acquisition Cost (Cost) – a representation of the cost of the drug to the wholesaler from the manufacturer. Direct Price (DP) - a representation of the price the manufacturer charges the pharmacy when it buys the drug directly from the manufacturer.
- f.) The term “spread” denotes the difference between one price or cost and another. In the context that we are addressing today, it means the difference between the cost of the drug to the pharmacy or other provider and the amount Medicaid reimburses for the cost of the drug. The greater the spread, the greater the profit.
- g.) When the manufacturer of a drug reports, or causes the reporting of, an AWP, WAC or DP that is materially and deceptively greater than the actual prices in the marketplace, it causes the Medicaid Programs to calculate an estimated

acquisition cost that is higher than the cost at which the drug is generally and currently available in the marketplace and thus reimburse at an inflated amount that causes the spread on the drug to be inflated.

h.) The manufacturers who have chosen to provide deceptive price reports have actively, albeit surreptitiously, taken steps to counteract government efforts to better estimate drug acquisition costs of prudent purchasers in the marketplace.

--Medicaid reimbursement at a discount off of AWP (eg AWP- 15%) is counteracted by companies who report AWP's resulting in spreads of hundreds and even thousands of a percent.

--Medicaid reimbursement based upon WAC plus a percent, such as that paid by Florida and Massachusetts, is counteracted by companies that report, or cause the reporting of, false inflated WACs.

--Medicaid reimbursement based upon DP, such as that paid for some drugs by California, is counteracted by companies that report, or cause the reporting of, false inflated DPs.

--Efforts by states that require direct reporting of prices, such as Texas are counteracted by companies that report false prices directly to the state program.

--Efforts by CMS to set caps based on the Federal Upper Limit (FUL), are similarly counteracted because FULs are based upon 150% of the lowest publicly available price for a generic and FULs are inflated when the underlying reported prices are false.

i.) The participating manufacturers then engage in conduct known as “marketing the spread” by means such as the following.

-- Some manufacturers will have direct discussions with large customers after which they will take action to increase reimbursement by further inflating their reported prices in order to persuade the large customers to buy their drugs.

-- Some manufacturers will train their sales personnel to pitch the higher reimbursement spreads on their drugs, as compared to their competitors’, directly to the pharmacies.

-- The reimbursement spread on manufacturers’ drugs is routinely marketed through software programs and data provided by wholesalers and group purchasing organizations that show the pharmacy the comparative spreads on different manufacturers’ drugs so that the pharmacy can choose the drug with the greatest spread.

Over the last several years, Ven-A-Care has been vigilant in reporting industry insider information to the United States Department of Justice, the HHS OIG and the States’ Attorneys General that has enabled them to identify and begin to address pharmaceutical pricing fraud by drug manufacturers. I am only at liberty to discuss a small portion of those efforts in this open proceeding; however, they are instructive:

- 1.) The United States ex rel. Ven-A-Care v. Bayer: Settled in 2001, the “Bayer 1” case resulted in the recovery of \$14,000,000 by the Medicaid program and set the stage for similar actions throughout the United States, as well as more focused Congressional interest such as this Committee’s September 21, 2001 hearing. The concept of reimbursement based upon Average Selling Price (“ASP”) was included in the Bayer settlement agreement and later incorporated into the Medicare Modernization Act.
- 2.) Texas ex rel Ven-Care v. Dey Laboratories and Schering-Plough/Warrick: Ven-A-Care brought the first case under the Texas False Claims Act against drug manufacturers for reporting falsely inflated pricing information in order to cause the Texas Medicaid Program to pay inflated reimbursement which

was in turn used as a marketing tool to induce pharmacies and other health care providers to select the manufacturers' drug over their competitors. Then Texas Attorney General, now United States Senator, John Cornyn, joined with Ven-A-Care and became the first State Attorney General to pursue action against pharmaceutical manufacturers for such deceptive price reports that cause Medicaid to overpay for drugs. To date, Dey Laboratories has paid \$18,500,000 and Schering Plough has paid \$27,000,000 to compensate the Texas Medicaid Program.

- 3.) Texas ex rel. Ven-Care v. Roxane and Boehringer Ingelheim: In this case the Texas Attorney General has joined with Ven-A-Care to pursue recoveries of excessive Medicaid reimbursements allegedly caused by deceptive pharmaceutical manufacturer price reports. This case is currently in active litigation.
- 4.) Texas ex rel. Ven-Care v. Abbott Laboratories, Baxter, B. Braun McGaw: In this case the Texas Attorney General has joined with Ven-A-Care to pursue recoveries of excessive Medicaid reimbursements allegedly caused by deceptive pharmaceutical manufacturer price reports. This case is currently in active litigation.
- 5.) California ex rel. Ven-A-Care v. Abbott Laboratories: In this case the California Attorney General has joined with Ven-A-Care to pursue recoveries of excessive Medicaid reimbursements allegedly caused by deceptive pharmaceutical manufacturer price reports. This case is currently in active litigation.
- 6.) Florida ex rel. Ven-A-Care v. Dey, Schering-Plough and Roxane Laboratories: In this case the Florida Attorney General has joined with Ven-A-Care to pursue recoveries of excessive Medicaid reimbursements allegedly caused by deceptive pharmaceutical manufacturer price reports. This case is currently in active litigation.

In addition to the above, the following states have brought similar actions against drug manufacturers for deceptively reporting drug prices resulting in their Medicaid Programs paying excessive reimbursement: New York, Massachusetts, Connecticut, Minnesota, Kentucky, Wisconsin, Arkansas, Ohio, Montana, and Nevada.

Since the settlement of the Bayer 1 case in 2001, approximately \$2,400,000,000 has been recovered from drug manufacturers in cases, brought under the federal and

various states' False Claims Acts, seeking recovery of excessive reimbursements paid by the Medicare and Medicaid Programs or recoveries of amounts underpaid to the Medicaid Rebate Program. (See, "The Role of the False Claims Act in Reducing Medicare and Medicaid Fraud by Drug Manufacturers: An Update", prepared for Taxpayers Against Fraud Education Fund by Andy Schneider, Principal Medicaid Policy, LLC, November 2004.) Perhaps more importantly, the industry insider information provided by Ven-A-Care has assisted the HHS OIG to better understand how drug manufacturers' deceptive price reports cause immense damage to the Medicare and Medicaid Programs. The HHS OIG addressed this in the OIG Compliance Program Guidelines for Pharmaceutical Manufacturers, 68 Federal Register No. 89, pages 23731-23743 (May 5, 2003). The OIG has made it clear that it considers such conduct to be fraudulent and to violate the False Claims Act and the anti-kickback laws. I have attached a full copy of the OIG's Guidelines. However, the following excerpts are directly relevant to today's proceedings:

"Integrity of Data Used To Establish or Determine Government Reimbursement. Many federal and state health care programs establish or ultimately determine reimbursement rates for pharmaceuticals, either prospectively or retrospectively, using price and sales data directly or indirectly furnished by pharmaceutical manufacturers. The government sets reimbursement with the expectation that the data provided are complete and accurate. The knowing submission of false, fraudulent, or misleading information is actionable. A pharmaceutical manufacturer may be liable under the False Claims Act if government reimbursement (including, but not limited to, reimbursement by Medicare and Medicaid) for the manufacturer's product depends, in whole or in part, on information generated or reported by the manufacturer, directly or indirectly, and the manufacturer has knowingly (as defined in the False Claims Act) failed to generate or report such information completely and accurately. Manufacturers may also be liable for civil money penalties under various laws, rules and regulations. Moreover, in some circumstances, inaccurate or incomplete reporting may be probative of liability under the federal anti- kickback statute."

“Average Wholesale Price. The “spread” is the difference between the amount a customer pays for a product and the amount the customer receives upon resale of the product to the patient or other payer. In many situations under the federal programs, pharmaceutical manufacturers control not only the amount at which they sell a product to their customers, but also the amount those customers who purchase the product for their own accounts and thereafter bill the federal health care programs will be reimbursed. To the extent that a manufacturer controls the “spread,” it controls its customer’s profit.”

“Average Wholesale Price (AWP) is the benchmark often used to set reimbursement for prescription drugs under the Medicare Part B program. For covered drugs and biologicals, Medicare Part B generally reimburses at “95 percent of average wholesale price.” 42 U.S.C. 1395u (o). Similarly many state Medicaid programs and other payers base reimbursement for drugs and biologicals on AWP. Generally, AWP or pricing information used by commercial price reporting services to determine AWP is reported by pharmaceutical manufacturers.”

“If a pharmaceutical manufacturer purposefully manipulates the AWP to increase its customers’ profits by increasing the amount the federal health care programs reimburse its customers, the anti-kickback statute is implicated. Unlike bona fide discounts, which transfer remuneration from a seller to a buyer, manipulation of the AWP transfers remuneration to a seller’s immediate customer from a subsequent purchaser (the federal or state government). Under the anti-kickback statute, offering remuneration to a purchaser or referral source is improper if one purpose is to induce the purchase or referral of program business. In other words, it is illegal for a manufacturer knowingly to establish or inappropriately maintain a particular AWP if one purpose is to manipulate the “spread” to induce customers to purchase its product.”

“In the light of this risk, we recommend that manufacturers review their AWP reporting practices and methodology to confirm that marketing considerations do not influence the process. Furthermore, manufacturers should review their marketing practices. The conjunction of manipulation of the AWP to induce customers to purchase a product with active marketing of the spread is strong evidence of the unlawful intent necessary to trigger the anti-kickback statute. Active marketing of the spread includes, for example, sales representatives promoting the spread as a reason to purchase the product or guaranteeing a certain profit or spread in exchange for the purchase of a product.”

Notwithstanding such explicit warnings from the OIG, the drug manufacturer’s executives, who report inflated drug prices, often contend that their deceptive conduct should be blamed on the government reimbursement programs themselves. They argue

that their reported prices are no more than “list” prices and need not be good faith representations of what their drugs actually sell for in the marketplace. Executives and other representatives from these companies have actually gone so far as to represent that it is “the industry standard” for them to make up any price they choose and report it for use by government reimbursement programs no matter how many hundreds or, in many cases, thousands of a percent that their represented prices exceed the true prices that they know are generally and currently available in the marketplace. Such assertions have been rejected by the courts. For example, in a recent case, In re Lupron Mktg. & Sales Practices Litig., 295 F. Supp. 2d 148 (D. Mass. 2003), brought to recover such price fraud damages for Medicare beneficiaries whose 20 per cent co-payment had been inflated, United States District Court Judge Stearns spoke directly to such preposterous assertions by the drug company defendants:

“But this is not a case of nondisclosure. Defendants did not stand mute. As alleged in the Amended Complaint, defendants trumpeted a lie by publishing the inflated AWP, knowing (and intending) them to be used as instruments of fraud.” Id at 647.

“Defendants repeatedly assert that they had no duty to disclose what was publicly known to everyone, that is, that the Lupron® AWP was a “sticker price” and never intended to reflect the drug’s true average wholesale price. In support of this argument, defendants cite a number of government reports acknowledging that the published AWP for prescription drugs often exceed their acquisition cost. The argument is ultimately unpersuasive. **There is a difference between a sticker price and a sucker price.** If one were confronting a modest markup of the actual AWP for Lupron® (which 300% is not), intended to make sales of the drug for the treatment of Medicare patients commercially viable (given the 95% of AWP reimbursement rate), it is unlikely that there would have been a government investigation of TAP’s marketing practices. Similarly, if the same inflated AWP had not been used to set reimbursement rates for private purchasers and insurers, the Amended Complaint would not have been filed. The Blues, in their response to defendants’ argument, have it exactly right: “[I]f everything [about Lupron®] was known to everybody, why did [d]efendants emphasize secrecy?” Blues Memorandum, at 7. Finally, the recognition on the part of

government regulators of inefficiencies in the administration of Medicare does not, as defendants contend, amount to condonation of fraudulent conduct. (Emphasis added) Id at 648.

“...As defendants portray the Congressional purpose in setting the reimbursement rate at 95% of AWP, Congress meant to turn a blind eye to the inflated AWP as a means of enticing physicians to treat Medicare patients. In other words, Congress deliberately invited the very fraud of which defendants are accused. As defendants describe it, “a determination that AWP must be set at the actual cost to providers would result in lower Medicare payment levels to physicians, prompting many of those physicians to stop treating Medicare patients because it is not cost-effective for them to do so.” Defendants’ Memorandum, at 32. The suggestion that Congress would deliberately condone a bribery scheme using public funds to enrich drug manufacturers and physicians is, to say the least, unusual.”
Id at 648.

The above excerpts from Judge Stearn’s decision illustrate the following corrupted logic underlying certain drug companies’ rationalization that they have no duty to tell the truth about prices: government reimbursement systems that trust price representations by drug companies are easy to cheat; therefore many companies cheat; therefore cheating is the industry standard; therefore cheating isn’t really cheating. After Judge Stearns rejected the proposition that such a complete lack of integrity is somehow excused, if it occurs within the pharmaceutical industry, the drug companies in question agreed to pay \$150,000,000 in damages.

Like the Defendants in the Lupron case, the manufacturers, who choose to have their drugs covered by Medicaid, know that state Medicaid Programs are relying on their price reports to estimate the drug’s cost for reimbursement purposes. For a significant portion of the dollars expended by the states’ Medicaid Programs, reimbursement is based upon reported prices that fairly and reasonably reflect the price at which the drug is generally and currently available in the marketplace. It is only where the manufacturers

choose to falsely report their prices that Medicaid pays an inflated amount. This inflated “spread” is what enables the manufacturers participating in this scheme to use the taxpayers’ money to arrange financial inducements which are then used to persuade customers to purchase their drug instead of a competitor’s. Moreover, in many cases, the government dollars that are diverted in this manner encourage excessive utilization of the drug therapy and otherwise have a corruptive influence on the healthcare delivery system.

Testimony and documents secured from employees of pharmaceutical companies merely corroborate that the drug manufacturers participating in this deceptive practice are fully aware that they are misleading the States’ Medicaid Programs. We understand that the Committee has also been provided with some of this evidence. We hope that it will be carefully considered, because it reveals scenarios such as:

- 1.) A drug company executive suggesting further inflation of price reports, but presented with subordinates’ concerns about the increased government scrutiny of price reporting practices in 2000, articulated his conscious decision to risk government sanctions in order to maximize sales for as long as he could get away with it.
- 2.) A drug company executive presented with a competitor, who had caused a greater spread on WAC based reimbursement in Florida and other states reported admittedly false inflated WAC prices to the compendia in an effort to gain greater market share.
- 3.) The four most senior executives of a drug company crafted a written marketing plan directly based upon creating and marketing financial incentives to their customers arising from the company’s manipulation

of Medicare and Medicaid reimbursement through false price representations.

- 4.) Drug company executives choose to inflate the reported AWP for many of their drugs by several hundred percentage points in order to create greater financial incentives for their customers and thus avoid price reductions that would otherwise occur due to natural market forces.
- 5.) Competing drug companies each inflate their price reports for generic versions of the same drug and thus cause the FULs set by CMS to be themselves inflated because they are based upon 150% of the lowest publicly available price.
- 6.) After a branded drug comes off patent, competing drug companies each continually decrease their true price due to competition while continually increasing the spread through their inflated reported price reports, while utilization of the drug increases exponentially.
- 7.) Drug company executives testify that they never change the AWP for a drug once it is established. The evidence shows that they routinely increase AWP to gain or retain market share.
- 8.) Some, but not all, manufacturers fail to report declining AWP even though they know the market price of the drug, to all customers, is falling precipitously in the competitive marketplace and that their deceptive price reports will deprive the Medicaid Program of the benefits of declining prices.

It is my hope that my testimony, as well as the information gathered through this Committee's investigation, will illuminate certain factors which I believe are critical to an understanding the Medicaid reimbursement problem. They are:

- a.) Drug manufacturers choose to have their drugs covered by Medicaid. They are not required to so.
- b.) Drug manufacturers know that Medicaid Programs must estimate the acquisition costs of drugs in setting reimbursement. Millions upon millions of claims are paid by Medicaid programs each year and scarce dollars cannot, and should not, be taken away from benefits in order to investigate and determine the individual cost of each prescription.
- c.) Drug manufacturers know that the State Medicaid Programs rely on the prices the manufacture reports directly or through the price reporting compendia.
- d.) As with any system of government reimbursement, pharmaceutical reimbursement is based upon trust, in this case trust that drug companies will report their prices in good faith.
- e.) The root of the problem of excessive Medicaid reimbursement for pharmaceuticals lies with those drug manufacturers who choose to deceive rather than tell the truth about their prices.
- f.) Dissembling excuses, such as protestations that a company will lose market share if it reports prices truthfully, should not be accepted from pharmaceutical manufacturers. Other industries, such as banking, communications, electrical power, and defense manufacturers have all been faced with similar integrity issues.

- g.) Congress addressed the evil of drug manufacturers' false price representations in the Medicare Modernization Act by requiring manufacturers to report the Average Selling Price for their drugs. These prices are in turn published by CMS. Unfortunately, similar tools have not been provided to the Medicaid Program as evidenced by a comparison of Medicaid FULs with Medicare ASPs for certain drugs, such as Ipratropium Bromide which are reimbursed by both programs. The drug's Medicaid FUL, which is still based on inflated price reports by manufacturers, is several times greater than the ASPs now reported to Medicare.
- h.) Any legislation directed at improving the Medicaid reimbursement system, should not inadvertently create a potential defense through which manufacturers may argue that Congress has somehow absolved them from their past defalcations. Judge Stearns' decision quoted above illustrates that the manufacturers who have participated in this scheme seek to misconstrue the intent of Congress as somehow approving their deceptive conduct.
- i.) Insuring now that drug manufacturers, that have reported inflated prices in the past, face the full consequences of their actions under the law, will provide the best assurance that drug manufacturers will not misrepresent ASP or other price information vital to reimbursement decisions in the future.

In closing, I would ask that this Committee consider the insidious damage that such deceptive practices have on our free market system. The contention by drug manufacturers, that deception is somehow justified when it becomes widespread in their industry, reveals a serious and fundamental integrity flaw that, if left unaddressed,

threatens the taxpayer, the consumer and the industry itself. The noble effort to generate profits must never be permitted to subjugate the higher duty to tell the truth.

Mr. Chairman and Members, thank you for the chance to appear before your Committee. I am happy to answer any questions that you may have.