United States Senate
COMMITTEE ON FINANCE
WASHINGTON, DC 20510–6200

January 31, 2007

Via Electronic Transmission

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Acting Administrator Norwalk:

The United States Senate Committee on Finance (Committee) has exclusive jurisdiction over the Medicare and Medicaid programs. Accordingly, the Committee has a responsibility to the more than 80 million Americans who receive health care coverage under Medicare and Medicaid to oversee the proper administration of these programs, including reviewing pricing practices that could impact the cost to taxpayers of purchasing prescription drugs. In recent years, the cost to Medicaid of purchasing prescription drugs has grown faster than any other single area of the program. As a result of the combination of increasing costs and tight fiscal constraints, some States have been forced to reduce prescription drug benefits. Considering that prescription drugs are such an integral part of quality health care, such reductions in benefits may be detrimental to the health of Medicaid beneficiaries.

During the 109th Congress, the Committee studied issues relating to the Medicare and Medicaid programs' coverage of prescription drug benefits, including the use of the nominal price exception (NPE/nominal pricing) under the Medicaid Drug Rebate Program.[1] We write to share our findings to assist you in the rulemaking process in which you are currently engaged.

In particular, the Committee was concerned about the consequences of nominal pricing when used as a marketing tool, including, but not limited to, driving up best price and lowering the amount of rebates manufacturers pay States for Medicaid drugs. Based on the Committee's review of nominal pricing, our Committee Staff crafted legislative provisions regarding the NPE in the Deficit Reduction Act of 2005 (DRA), which the President signed into law on February 8, 2006. Section 6001(d) of the DRA requires manufacturers to report information on sales at nominal prices to the Secretary of Health and Human Services (HHS). It also specifies the purchasers for which sales at nominal prices may be excluded from the calculation of best price. It limits the merely nominal exclusion to sales at nominal prices to the following: a covered entity described in section

[1] Congress amended the Social Security Act by adding section 1927, which created the Medicaid Drug Rebate Program for outpatient pharmaceuticals, when it passed the Omnibus Budget Reconciliation Act of 1990 (OBRA 1990).

340B(a)(4) of the Public Health Service Act (PHSA), an intermediate care facility for the mentally retarded (ICF/MR), a State-owned or operated nursing facility, and any other facility or entity that the Secretary determines is a safety net provider to which sales of drugs at a nominal price would be appropriate, based on certain factors such as type of facility or entity, services provided by the facility or entity, and patient population.

On December 16, 2006, the Centers for Medicare and Medicaid Services (CMS) issued a proposed rule seeking to implement the provisions of the DRA pertaining to prescription drugs under the Medicaid program. The proposed rule addressed the changes to the nominal price exception contained in section 6001(d) of the DRA, but failed to give the Secretary the full authority Congress intended. The proposed rule includes three of the four categories of purchasers for which manufacturers will continue to be able to exclude sales made at nominal prices from their best price calculations. CMS's elimination of the fourth category concerns us. The proposed rule also addresses a broad range of issues relating to the determination of average manufacturer price (AMP), determination of best price, treatment of authorized generics, and new manufacturer reporting requirements, among others. In particular, we noted that CMS raised concerns regarding the continued use of the NPE as a marketing tool:

> CMS has concerns that despite the fact that the DRA limits the nominal price exclusion to specific entities, the nominal price exclusion will continue to be used as a marketing tool. Historically, patients frequently remain on the same drug regimen following discharge from a hospital. Physicians may be hesitant to switch a patient to a different brand and risk destabilizing the patient once discharged from the hospital. We believe that using nominal price for marketing is not within the spirit and letter of the law. We are considering crafting further guidance to address this issue. CMS invites comments from the public to assist us in ensuring that all aspects of this issue are fully considered.

Based on the Committee's review of how the pharmaceutical industry has used the NPE under the Medicaid Drug Rebate Program, we share CMS's concern that nominal pricing may continue to be used as a marketing tool. The purpose of this letter is to report to CMS the Committee's findings with respect to its review of nominal pricing.

In 2004, we sent letters to 19 pharmaceutical manufacturers requesting information and data to assess how frequently the NPE was used, in what contexts, and for what purposes. In addition, we sought to determine: (1) whether, and to what extent, the NPE is used to promote access to prescription drugs as intended by Congress; and (2) whether refinements should be made to the existing statutory language to ensure that the NPE is not used for purposes other than those intended. Our Committee Staff focused on the top twenty pharmaceutical manufacturers, based on U.S. sales in 2003.[2] Our Committee Staff also focused on data related to eight leading therapeutic drug classes by U.S. sales

[2] http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599_42720942_44304255,00.html One of the top-twenty manufacturers was excluded because it did not manufacture a brand name drug.

in 2003.[3] The eight drug classes reviewed were: statins, proton pump inhibitors, anti-depressants, anti-psychotics, erythropoietins, seizure disorder drugs, calcium channel blockers, and anti-arthritics/non-steroidal anti-inflammatory drugs (NSAIDs).[4]

In 2005, we sent a second letter to the same 19 pharmaceutical manufacturers based on concerns that some manufacturers appeared to be applying the NPE more broadly than Congress originally intended. The second letter requested information to understand further how some manufacturers used the NPE and why some others were not using it. Some manufacturers were asked about their use of the NPE for periods of only one quarter. A number of manufacturers were asked why they did not utilize nominal pricing, whether the manufacturers' customer bases included charitable organizations, and whether other discounts or special pricing were offered to those customers. Finally, we sent a third letter to one manufacturer, after our Committee Staff determined that one manufacturer had used the NPE outside the timeframe of the Committee's inquiry. This third letter focused specifically on that manufacturer's past policies and practices with respect to the NPE. All manufacturers voluntarily complied with the Committee's requests for documents and information.

Our Committee Staff reviewed the manufacturers' responses, including information regarding written policies and procedures related to the NPE and sales information on specific drugs. After reviewing the first and second round of responses, our Committee Staff identified several specific practices and held meetings with the six manufacturers that engaged in one or more of those practices to learn more about them. The Committee Staff also contacted one manufacturer that did not engage in nominal pricing to learn more about why it had not used the NPE. During those conversations, our Committee Staff also solicited opinions from the manufacturers' representatives as to whether the NPE should be subject to legislative or administrative changes.

In addition to information gathered directly from the pharmaceutical manufacturers, our Committee Staff considered other relevant sources of information, including: reviewing various reports prepared by the Government Accountability Office (GAO) and the Office of Inspector General (OIG) at HHS related to prescription drug coverage under Medicaid; analyzing HHS regulations regarding the Medicaid Drug Rebate Program; and reviewing publicly available complaints and settlement agreements from lawsuits where the use of the nominal price exception was part of alleged misconduct by a number of pharmaceutical manufacturers. Our Committee Staff also held meetings with CMS, the Department of Veterans Affairs (VA), the HHS OIG, and the GAO to discuss the Medicaid Drug Rebate Program generally and the NPE specifically.

[3] http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599_42720942_44304299,00.html

[4] Some manufacturers did not produce a drug in any of the eight classes, therefore specific drug information and data were not obtained from those manufacturers.

Our Committee Staff determined that the NPE was used primarily as a competitive or marketing tool among the pharmaceutical manufacturers surveyed and was not used primarily for charitable purposes as intended by Congress. Our Committee staff made eight observations based on the information submitted to and obtained by the Committee:

1. Most manufacturers surveyed used the NPE inconsistent with Congressional intent

2. Most manufacturers' policies did not reflect use of the NPE for charitable purposes

3. Most manufacturers used the NPE for products in the best-selling classes of drugs

4. Hospitals appeared to be the primary recipients of nominal pricing

5. Most manufacturers did not differentiate between for-profit and not-for-profit entities when offering nominal pricing

6. A charitable purpose was rarely a factor considered by manufacturers in deciding to offer nominal pricing

7. Manufacturers' nominal pricing agreements frequently included market share requirements

8. Manufacturers' overall use of the NPE appears to have declined from 2003 forward

The Committee's findings and observations are discussed below in more detail, preceded by a brief background regarding the rationale for and Congressional intent behind the NPE and its use for charitable purposes.

Nominal Pricing Background

Congress included the NPE in the Medicaid reforms of OBRA 1990 to ensure that efforts to more closely align Medicaid's drug pricing with pricing for private purchasers did not threaten the steep discounts on pharmaceutical products offered to certain purchasers. Recognizing that charitable and other organizations that provide health care to populations with limited access to health care often receive special discount prices for pharmaceutical products, Congress wanted to encourage manufacturers to continue offering deep discounts to such purchasers. Specifically, by excluding nominal prices from a manufacturer's best price calculation, Congress, under the original law, intended to allow pharmaceutical manufacturers to continue offering discounts to charitable organizations without dramatically increasing the rebate due to states. If nominal prices were not excluded from a manufacturer's best price calculation, a manufacturer that offered discounts to charitable organizations greater than those offered to regular customers would have to remit to the State Medicaid program a rebate for the difference

between AMP and the deeply discounted price. Concerned that manufacturers might stop offering such discounts as a result, Congress saw the nominal pricing exception as a way to maintain the practice of deep discounts to charitable organizations while still attempting to more closely align Medicaid's drug pricing with pricing for private purchasers.

Legislative history provides some insight into the intended purpose of the NPE as originally crafted. In 1990, before Congress passed OBRA 1990, the then-Chairman of the Senate Special Committee on Aging prepared and submitted for publication in the Congressional Record a statement entitled "Analysis of Drug Manufacturer Medicaid Drug Discount Proposals and Necessary Elements of Medicaid Drug Price Negotiation Plan," which stated that under the Rebate Program, the "merely nominal" prices that were excluded from best price calculations were those "such as the sale of birth control pills for a penny a pack to Planned Parenthood." A report by the Senate Special Committee on Aging, entitled "Developments in Aging: 1990," echoed this explanation for the exception, stating that "Congress did not want to threaten" the dramatic discounts offered to "charitable organizations and clinics" by requiring manufacturers to calculate and remit rebates based on prices not calculated with the market or any profit motive in mind.[5] During Congressional deliberations on OBRA 1990, the Senate Committee on Finance refined this explanation of "nominal price" slightly by defining the prices offered to Planned Parenthood, for example, as "token" prices.

Our Committee Staff held discussions with CMS officials regarding the regulatory history of the NPE. CMS officials told our Committee Staff that the definition of nominal as less than ten percent of AMP was the product of negotiations involving pharmaceutical manufacturers, pharmacists and the States. Specifically, CMS officials stated that the charitable intent behind including the NPE in the original law was mentioned during those negotiations.

The Department of Veterans' Affairs (VA), a major purchaser of drugs, has defined nominal prices more narrowly than CMS and described the conditions under which it believes nominal pricing may be used. In 1996, the VA Office of General Counsel sent a letter to pharmaceutical manufacturers that included the following discussion of nominal pricing:

> The "nominal" pricing exclusion in the Veterans Health Care Act of 1992, Section 603 (38 U.S.C. 8126) was not intended to protect incentive use schemes by eliminating from non-FAMP calculations all below-cost sales of a covered drug that result from customers' purchases of sizable quantities of packages at a standard commercial price. VA views "nominal" pricing as being pricing, usually below cost, designed to benefit the public by financially aiding disadvantaged, not-for-profit covered drug dispensaries or researchers using a drug for an experimental or non-standard purpose.

In addition, in 2000, the VA proposed amending its Master Agreement with pharmaceutical manufacturers to define "nominal price" as "[a]ny price less than 10% of the non-FAMP in the previous quarter from a sale (usually below cost) designed to

[5] S. Rep. No. 102-28(I) (Mar. 22, 1991).

benefit the public by financially aiding disadvantaged, not-for-profit covered drug dispensaries or researchers using a drug for an experimental or non-standard purpose.[6] VA officials advised our Committee Staff that the proposed change to the Master Agreement was never adopted due to opposition from the pharmaceutical industry, however, the VA's interpretation of nominal pricing as stated in the 1996 letter has not changed.

Nonetheless, several manufacturers surveyed by the Committee asserted that the NPE in no way limits sales at nominal prices to not-for-profit or charitable organizations. Several manufacturers, including those who did not use the NPE, stated to the Committee that sales at nominal prices are defined mathematically and are not limited to certain charitable organizations. For example:

> Company G: ". . . the Act does not restrict nominal pricing solely to not-for-profit entities . . . . "
>
> Company J: "It is the company's understanding that, as currently defined by Congress, the Medicaid Rebate Agreement and CMS, a nominal price is determined mathematically as any price less than ten percent of the AMP in the same quarter for which the AMP is computed."
>
> Company K: "[Company K] interpret[s] the phrase "nominal price," for purposes of the Medicaid program, to denote a quantitative test in accordance with Section I.(s) of the Medicaid rebate template issued by [CMS]."

It appears to us that manufacturers were on notice that the primary intent of the NPE was to benefit charitable organizations. We note that some manufacturers have been legally counseled against broadly interpreting the NPE. For instance, one major law firm in Washington advised its clients in a "Health Care Reimbursement Client Alert: Medicaid Rebate Program," with the following precautionary statement:

> The exclusion of nominal prices from BP [best price] calculations was primarily intended to avoid a chilling effect on manufacturers' in-kind contributions to charitable programs. CMS has adopted a bright-line rule that a nominal price is any price lower than 10% of AMP for the quarter. . . . Clients should also be careful if relying on nominal price in ordinary commercial situations where the absence of a purchase requirement might be questioned, because the exclusion of nominal prices is likely to be interpreted narrowly by CMS and it could be an area of potential inquiry on audit.

It appears to us that language in the explanatory material submitted by the Committee during consideration of OBRA 1990 and the subsequent Senate Committee on Aging report support the rationale and Congress's intent to limit the use of the NPE to charitable purposes. Congress most certainly did not intend for manufacturers to use the NPE as a marketing tool. Recognizing that nominal price is not defined by statute and that the definition adopted by CMS did not limit its applicability to charitable organizations, Congress enacted the DRA provisions requiring manufacturers to report

[6] The Committee does not have the original draft amended Master Agreement, but obtained this definition from the American Bar Association's response to the proposed amendments.

information on sales at nominal price to the Secretary and specifying the entities to which the nominal price exception applies.

Nominal Pricing Observations

1. Most Manufacturers Surveyed Used the NPE Inconsistent with Congressional Intent

Based on the information provided to the Committee by the manufacturers surveyed, it appears the pharmaceutical industry's practice with respect to the NPE can be grouped into three general categories: 1) manufacturers that appeared not to use the NPE; 2) manufacturers that appeared to use the NPE consistent with Congressional intent; and 3) manufacturers that appeared to use the NPE inconsistent with Congressional intent. Four manufacturers fell into category 1, three fell into category 2, and the majority of the manufacturers—12 out of 19—fell into category 3.

Manufacturers J, L, O and R, reported that they did not use the NPE. Manufacturer R, however, stated that it ". . . may consider use of the NPE under circumstances where it is commercially useful to do so and where it can be offered for all sales of a particular product to the relevant customer or customers for a period of at least one full calendar year." All 19 manufacturers reported having charitable organizations in their customer base and no manufacturers reported refraining from nominal pricing because it was ambiguous. Manufacturers L and R indicated that although they did not use the NPE, they provided their products for free through patient assistance programs and other organizations.

Manufacturers C, G, and M provided information to the Committee that appeared to demonstrate use of the NPE consistent with Congressional intent. Manufacturers C and G sold drugs at nominal prices exclusively to not-for-profit organizations and did not place any conditions on sales at nominal prices. These manufacturers did not make nominal prices available to any not-for-profit organizations and only a very limited number of drugs were made available at nominal prices. In addition, Manufacturer C only offered nominal pricing for a limited period and did not offer any of its drugs for sale at a nominal price at the time of the Committee's inquiry. Manufacturer M had a general policy not to offer its drugs for sale at nominal prices, but continued to offer a drug it acquired to a single not-for-profit organization pursuant to a pre-existing agreement.

Twelve manufacturers—A, B, D, E, F, H, I, K, N, Q, P, and S— provided information to the Committee that appeared to demonstrate use of the NPE inconsistent with Congressional intent. Information regarding use of the NPE inconsistent with Congressional intent is discussed more fully below.

2. Most Manufacturers' Policies Did Not Reflect Use of the NPE for Charitable Purposes

Not one of the 19 manufacturers surveyed had written policies or procedures that addressed use of the NPE; however, several manufacturers provided policies, operations

procedures, best price assumptions, or similar documents that explicitly defined nominal price and/or addressed the inclusion of nominally priced drugs in calculating best price. Most manufacturers provided a description of their nominal pricing policy, but this was typically limited to a description of how pricing practices/proposals/contracts are evaluated or a statement that the company does not routinely make sales involving the NPE. Most manufacturers' policies did not reflect an intent to use the NPE for charitable purposes. The policy descriptions provided by the manufacturers surveyed included the following statements:

> "[Manufacturer Q] does not routinely make sales at nominal price, therefore we are not able to describe in detail the factors and circumstances which [Manufacturer Q] takes into account in determining whether sales of covered outpatient drugs should be made at prices that are considered to qualify for the nominal price exception. Instead, [Manufacturer Q] would review each transaction on a case-by case basis to ensure that the transaction met all legal requirements and that the transaction had a rational business purpose…"
>
> "Contract Prices that are less than 10% of a quarter's Average Manufacturer Price ("AMP") are excluded from Best Price." [Manufacturer P]
>
> "Some products in [Manufacturer P's] product line have generic alternatives, and [Manufacturer P] sometimes elects to lower prices to establish price parity with generic products. From time to time, this price matching may have resulted in a price that could be calculated as nominal according to the definition set forth in the statutes. [Manufacturer P] has generally applied the NPE to these prices."
>
> "Specific pricing at ten percent of AMP or less is not offered as a condition of sale; however, when various discounts or other price concessions for a particular customer are aggregated, it may be that some portion of the total price reduction may be conditioned on the promise to purchase one or more additional drug products. We note that such offers are contemplated by and protected by elements of federal law, to the extent that certain conditions are met. " [Manufacturer F]

In addition, only two manufacturers—G and I—specifically described the types of entities eligible for the NPE and only Manufacturer I specifically indicated that its policy was to use the NPE for charitable purposes.

3. Most Manufacturers Used the NPE for Products in the Best-Selling Classes of Drugs

The Committee obtained information regarding 84 drugs that were offered at nominal prices by the manufacturers surveyed. Eighteen of these products were among the eight best-selling classes of drugs. Ten of the 15 manufacturers that offered nominal pricing offered at least one of these drugs at the NPE. Three manufacturers only offered nominal pricing for their products in the eight best-selling classes of drugs. Of at least 30 drugs still offered at nominal prices as of March 2005, four were in the eight-best selling classes.

Two of the three manufacturers that used the NPE consistent with Congressional intent offered nominal pricing on drugs from the eight best-selling drug classes. Manufacturer C offered nominal pricing on only one drug and, of the three drugs offered by Manufacturer G at nominal prices, two were in the eight best-selling classes.

4. Hospitals Appeared to be the Primary Recipients of Nominal Pricing

Hospitals appeared to be the primary recipients of nominal prices offered by those manufacturers that used the NPE consistent with Congressional intent. For those manufacturers that provided nominal prices only to not-for-profit entities, the NPE was only available to select not-for-profit entities. Manufacturer C offered nominal pricing to disproportionate share hospitals (DSH) that were participating covered entities in the 340B program, acute care teaching hospitals, and Federal government facilities purchasing from the Federal Supply Schedule. Manufacturer G offered nominal pricing "only with respect to certain of its products and only for certain not-for-profit hospitals."

Hospitals were also the primary recipient of nominal pricing offered by those manufacturers whose use of nominal pricing appeared inconsistent with Congressional intent. Of the 12 manufacturers that offered nominal pricing to both for-profit and not-for-profit customers, six manufacturers indicated that hospitals were their only, or main, recipients of nominal prices. Another three manufacturers indicated that HMOs were offered nominal pricing. Some manufacturers identified the types of hospitals that received nominal pricing, which included acute care hospitals, DSH hospitals, teaching hospitals, and public hospital systems. Other recipients of nominal pricing identified by the manufacturers surveyed included Public Health Service covered entities, entities that serve the uninsured and organizations that offer family planning services.

By making the NPE available almost exclusively to hospitals, it appears manufacturers may have encouraged use of their drugs to the exclusion of competing products. They may also have created a spillover effect whereby patients who received their drugs while in the hospital continued to use them after discharge. Based on the information provided by manufacturers, the Committee cannot conclude that the primary intent of those manufacturers offering nominal pricing to hospitals was to compete against other manufacturers' products or create a spillover effect. However, other information obtained by the Committee suggests that the use of nominal pricing in hospitals may increase demand for a product outside the hospital setting.

For instance, comments submitted to the VA in response to its efforts to narrow the definition of nominal price acknowledge that market penetration was the primary goal of providing nominal pricing to hospitals. The American Bar Association and at least one law firm representing a manufacturer, wrote to the VA concerning the nominal price definition in VA's 2000 draft Amended Master Agreement, and stated: "Nominal prices have historically been granted to entities that do not fit within the VA's narrow definition. For example, a manufacturer may grant nominal prices to hospitals in order to penetrate an established market . . ."

5. Most Manufacturers Did Not Differentiate Between For-Profit and Not-for-Profit Entities

Although many of the hospitals and other organizations that were offered nominal prices may have been not-for-profit companies, not one of the manufacturers surveyed indicated that this was the reason for offering nominal pricing. The Committee asked the 12 companies that appeared to use nominal pricing beyond Congressional intent to identify differences in the way they treated for-profit and not-for-profit customers with respect to determining eligibility for nominal pricing. One manufacturer did not address the question, and the remaining 11 manufacturers indicated that there was no difference in how for-profit and not-for-profit organizations were treated. The following are sample responses from a few of these manufacturers:

> "Purchasers are not limited to non-profit entities." (Manufacturer P)
>
> "In offering nominal pricing, [Manufacturer A] does not distinguish between for-profit and not-for-profit entities, consistent with the Medicaid rebate statute and the Medicaid rebate agreement."
>
> "[Manufacturer B] has not made distinctions between for-profit and not-for-profit hospitals when determining eligibility for nominal prices."

6. A Charitable Purpose Was Rarely a Factor When Offering Nominal Pricing

The Committee asked manufacturers to describe the factors and circumstances taken into account when determining whether sales of covered outpatient drugs should be made at nominal prices. Only one of the 15 manufacturers that reported using the NPE indicated that the existence of a charitable purpose was a factor considered when offering nominal pricing, while most manufacturers that reportedly used the NPE indicated that competitive market factors were taken into account when offering nominal pricing. Four manufacturers did not indicate to the Committee the factors and circumstances they took into account when offering nominal prices. One manufacturer reported that it used nominal pricing on a case-by-case basis when all legal requirements were met and a rational business purpose existed. Seven manufacturers listed a variety of factors, including: the business or competitive environment for a product; the degree of formulary control exercised by eligible customers; potential to increase patient access to the product; health outcomes information; and patient population, affordability and public policy considerations.

The following statements were made by manufacturers that indicated factors other than a charitable purpose, such as competitive marketing, when determining whether sales of covered outpatient drugs should be made at prices that are considered to fall within the NPE:

> "[Manufacturer I] may offer Nominal Pricing on Multiple Source Drugs (i) to meet generic pricing on that same drug or (ii) to government entities and to not-for-profit institutions for charitable purposes."
>
> ". . . .[Manufacturer P] sometimes elects to lower prices to establish price parity with generic alternatives to its products. From time to time, this pricing parity may have resulted in a price that could be calculated as nominal according to the

definition set forth in the Medicaid Rebate Agreement, and in such instances, [Manufacturer P] has applied the NPE to these prices."

"[Manufacturer E was presented with credible evidence of] a price offer from a generic manufacturer that was nominal relative to the Company's pricing structure for [drug]. The Company exercised its right of first refusal and entered into a contract to sell [drug] to [customer] at the low price, hoping to maintain brand loyalty through [customer's] significant presence in the market."

"Again, the determinative criteria were the competitive product pricing and the degree of formulary control involved." (Manufacturer S)

"[Manufacturer K] consider[s] the market for the product (e.g., sites of demand, training medical practitioners, ability to influence prescriber or patient behavior, or formulary position), the nature of the customer, and the competitive environment (existence of generic or lower cost competition)."

"When determining whether and to whom sales of covered outpatient drugs should be made at nominal prices, as that term is defined in the rebate statute and rebate agreement, [Manufacturer A] takes into account the relevant customer(s) and the relevant economic and market conditions for sale of that particular product. For example, [Manufacturer A] will consider the overall pricing strategy for the product, the performance and pricing of competitive products, other discounts offered on the product, the type of customer, the potential to increase patient access to the product, and the effect of any discounts (nominal or otherwise) on net sales."

"The existence of alternative products has generally been a factor in [Manufacturer N's] contracts with nominal pricing in that [Manufacturer N] typically entered into those contracts at or near the time of patent expiration for certain products in order to try to retain sales in the face of competition from generic alternatives. While far less common, [Manufacturer N] has also from time to time entered into nominal pricing arrangements for certain products not facing generic competition in situations involving alternative products, such as situations involving nominal pricing from a competitive branded product."

[Manufacturer H] takes a number of factors into consideration in developing pricing and contracting strategies, including any decisions about whether nominal pricing would be included in our strategies. Those factors include, among others, the business environment for a specific product, the number of competing products, health outcomes information, patient population, competitor pricing, affordability, and public policy considerations.

7. Nominal Pricing Agreements Frequently Included Market Share Requirements

A majority of the 15 manufacturers that reported using nominal pricing placed conditions or limits on the offer of nominal pricing. The Committee asked manufacturers what types of contractual arrangements govern their company's drug sales that fall under the NPE and specifically mentioned market share requirements and single quarter nominal pricing. Three manufacturers—F, G, and Q—did not provide information on the contractual terms associated with nominal pricing. Another three manufacturers—C, E, and M—indicated that there are no conditions attached to their offers of nominal pricing,

and one manufacturer—B—stated that, except for nominal price contracts with DSH hospitals, contracts for sales at nominal prices generally included a market share requirement. The remaining eight manufacturers—A, D, H, I, K, N, P, and S—all indicated that contracts for sales at nominal prices involved one or more of the following requirements or arrangements: market share requirements, volume requirements, nominal prices offered only for a single quarter of the year, formulary placement requirements, and unrestricted access requirements. Examples of manufacturer's statements about these terms follow:

> "Contracts offering Nominal Pricing may include a market share percentage provision." (Manufacturer I)
>
> "Generally, [Manufacturer A] pricing to institutional customers, including hospitals, conditions discounts on various factors such as agreements to make products available to patients on a less restrictive basis than would otherwise be the case and market share performance criteria."
>
> 'Market share requirements may or may not be the basis for some of a series of discounts or other price concessions that may result in NPE pricing." (Manufacturer F)
>
> "A market share percentage is included in [Manufacturer B's] contracts with hospitals as a requirement for eligibility for nominal pricing."
>
> "Certain historical contracts that included nominally priced products required formulary access for the nominally priced product, and/or for some or all of the other products in the contract." (Manufacturer N)
>
> "Certain historical contracts that included nominally priced products may have required, in addition to formulary access or availability, the customer to make a greater commitment to using the nominally priced and/or certain other products in the contract by granting them 'preferred' or 'exclusive' positioning." (Manufacturer N)

All of these conditions or terms appear designed to increase the use of the product being offered at a nominal price. The Committee believes that the inclusion of such terms in nominal pricing contracts signals that the primary intent of the nominal price offer was to increase market share, and was therefore inconsistent with Congressional intent.

Use of the NPE May Be Declining

As of March 2005, most of the manufacturers that reported using the NPE indicated that they had reduced their use, stopped using it, or planned to stop using it once existing NPE contracts expired. While most of the practices uncovered would not be permitted under the DRA, only two manufacturers did not indicate an intention to eliminate or limit use of the NPE. Five manufacturers no longer used the NPE at all, and eight manufacturers had reduced or limited their use of the NPE. One manufacturer explained that it was reducing use of the NPE because it originally used nominal pricing only in an effort to meet price competition from a competitor that was offering its

products at nominal price. Two manufacturers explained their decision to stop using nominal pricing as follows:

> "[Manufacturer N] discontinued its nominal pricing practices after concluding that the technical and administrative complexity and cost needed to sustain the nominal pricing programs outweighed the limited commercial benefits of preserving such programs."

> "[Manufacturer S] evaluated the commercial results of each of its nominal price contracts and determined that these discounts were not commercially justified."

As with some manufacturers' rationale for offering nominal pricing, the rationale offered for discontinuing nominal pricing also appear related to pricing or business strategies.

We respectfully submit these findings and observations to assist CMS as it considers crafting further guidance to address the use of the nominal price exception as a marketing tool. In addition, we respectfully request that CMS keep the Committee fully informed regarding the development of additional guidance and/or regulations pertaining to the NPE. Finally, please let us know whether or not further statutory changes may be necessary to address our shared concern regarding the NPE.

We look forward to hearing from you regarding the contents of this letter by February 15, 2007. In particular, we are interested in your addressing the reason why, in the proposed rule, the Secretary was not given the full authority Congress intended. Any questions or concerns should be directed to our Committee Staff, David Schwartz and Emilia DiSanto, at (202) 224-4515. *All correspondence should be sent via facsimile to (202) 228-2316 (majority) and (202) 228-2131 (minority), and original by U.S. mail*. All formal correspondence should be sent via electronic transmission in PDF format to thomas_novelli@finance-rep.senate.gov or via facsimile to (202) 228-2131 and original by U.S. mail.

Sincerely,

Max Baucus
Chairman

Charles E. Grassley
Ranking Member