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The prescription drug marketplace is unique. It operates unlike any other market, in terms of both supply and demand. One expects some diminution of competition in a market in which strong market exclusivity provisions apply in order to stimulate innovation. Competition is even more fragile than it should be, however, because it has been undermined by inherent market dysfunction on the demand side, occasional collusion and, perhaps most important, by systematically-applied anti-competitive governmental policy. These factors have combined to result in rapid, uncontrollable drug cost inflation.

- As an integrated, non-profit integrated health care delivery system that purchases more than $2.5 billion in prescription drugs annually for its 8.2 million members, Kaiser Permanente is acknowledged to be among the most effective private purchasers of prescription drugs. While we manage an overwhelming percentage of our drug benefits internally, we do have pharmacy network arrangements that are operated with the assistance of a pharmacy benefit management company (PBM).

<u>The Prescription Drug Marketplace</u>

- From the standpoint of the purchaser, there are four stages of the prescription drug supply marketplace. These are roughly defined by the intellectual property and market exclusivity status of each drug class. I call them:

  - The pure monopoly stage
  - The competing monopoly/oligopoly stage
  - The early commodity stage
  - The mature commodity stage

  - In the monopoly stage, there is a true breakthrough drug with no reasonable therapeutic alternatives. The new drug is such a clear advantage over existing drugs for a condition that it quickly becomes the standard of care to the relative exclusion of existing drugs. Under these circumstances, there is little opportunity for a purchaser to stimulate competition among manufacturers. Manufacturers are roughly free to set launch prices, they rarely discount those prices, and purchasers are price takers.

  - In the competing monopoly/oligopoly stage, the possibility for competition arises. This stage represents the lion's share of the market at any given time. Here, there are multiple similar drugs on the market, all still under market exclusivity protection. Depending on

how similar the drugs are – that is, how substitutable they are for each other -- organized purchasers have the ability to either switch patients in a medically appropriate manner among the drugs (if the drugs are highly substitutable) or at least start new patients on a preferred drug (if the drugs are similarly effective, but switching would be disruptive to therapy). In either case, there is a competitive opportunity that can be taken advantage of. This is the area where formularies can be applied for the greatest effect on overall costs.

- In the third stage, generics appear on the market, and well-organized purchasers can use the same tools as in the second stage to drive use of the less expensive generics. (Kaiser Permanente has taken advantage of the availability of generic lovastatin, for example, to provide the same quality of care to more patients at a much lower cost than still-branded statin alternatives.)

- By the fourth stage, most or all drugs in a class are generically available. Absent raw material supply problems, excessive consolidation among manufacturers or outright collusion, or a combination of these factors, these markets operate as commodity markets and little management is necessary to assure competitively low priced drugs. We applaud the Commission for intervening when necessary to preserve competition in these markets.

- On the demand side:

  - There has been a massive migration from out-of-pocket cash payment to third party point-of-sale coverage of prescription drugs. Twelve years ago, 65 percent of prescription sales involved a consumer reaching into her purse or his wallet to pay for the drug. Today, ¾ of all prescriptions are paid for at least in part by some form of insurance.

  - From the seller's standpoint, there are multiple, often conflicting consumer/purchaser stakeholders. Pharmacists, employer-payers/insurers, physicians and patients all have potentially confluent interests, but historically they have not succeeded in stimulating significant price competition among manufacturers. As a result, competition for most of the prescription drug marketplace has been fragile, at best.

  - Only integrated delivery systems, like Kaiser Permanente, that have internalized the physician, pharmacist and payer role, historically effectively created competition among manufacturers. Most payer/purchasers did not effectively organize their potential market power to be able to drive utilization of drugs, and therefore stimulate price competition. This changed with the advent and rapid growth of PBMs.

<u>The Important Role of PBMs in the Marketplace</u>

- PBMs developed the infrastructure to stimulate competition in the less integrated world. We believe that there is a significant risk that overregulation of PBMs, particularly in terms of indiscreet disclosure of negotiated discount and rebate arrangements, has the

potential to undermine the ability of PBMs to be able to continue to negotiate prices effectively with manufacturers.

- Rebates are simply the conduit by which lower prices can be realized in the context of the network insurance drug coverage arrangements. Rebates can have the potential to create divisive interests between PBMs and their customers, particularly when the customers have disclaimed an interest in the rebates in favor of smaller administrative fees. Many employers and health plans took this approach during the 1990s. Kaiser Permanente, for one, always assured that it paid its full share of administrative costs in exchange for access to rebates to assure that the PBM's interest was in good service, rather than in maximizing rebates when a different interest in utilization management might dictate a different approach. This potential for conflict was well-known to the health care industry, including the benefits consultants who advised many large employers in the 1990s. We do not know why more PBM customers did not make the same election that Kaiser Permanente did.

- It is important and sensible that in their contractual relationships, PBMs and their employer/payer customers share adequate information to assure that the PBMs is acting in the customer's best interest. However, in what is fundamentally an oligopoly prescription drug market, it is equally important to maximize market competition among drug manufacturers. We believe that price competition can best be achieved when negotiated prices and rebates are kept confidential. Widespread public disclosure of prices is unnecessary to assure that the ultimate payer receives most of the benefit of drug rebate arrangements. Auditors operating under strict confidentiality agreements can assure that rebates are shared properly while maintaining confidentiality of prices. More expansive disclosure would ultimately result in fewer discounts and rebates, exacerbating the existing drug cost crisis.

- We are most concerned about reports of PBMs interchanging clinically equivalent, more expensive drugs for less expensive drugs, when enough of the rebate is not shared with the customer to result in a lower net price. Otherwise, it is difficult to comprehend the benefit of this to the ultimate customer. There may be instances when a switch to a more expensive drug (or to a drug with a longer period of market exclusivity than a drug soon to be generically available) is mutually beneficial to the customer and the PBM. This, however, is a subtle business judgment that requires open information. In my mind a rebate agreement that encourages the use of Nexium instead of Prilosec, or Clarinex instead of Claritin, should have a good economic rationale for the ultimate payer, including consideration of longer-term implications. These situations are highly individualized, however, and aggressive government intervention could have a highly anti-competitive impact.

- PBMs should be more open with their customers with the reasoning behind therapeutic interchanges, and we believe that this is happening. We believe that the reported abuses were fundamentally anomalous, and are being rectified in the marketplace through contractual arrangements between PBMs and their customers.

The Impact of Formularies

The Commission staff specifically requested that I address the operation of formularies in the marketplace. Kaiser Permanente's formulary process differs significantly from that of other health plans and most PBMs, but there are important common points that can be made.

- Formularies are the central component to the infrastructure on the demand side of the market to facilitate drug price competition, whether the formulary has been developed by an integrated delivery system like Kaiser Permanente or by a PBM serving a less-integrated, network-based or indemnity population.

    - Formularies are most effective when established by the physicians who will use the formulary, and particularly when a group of physicians will be using one formulary. It is the multiplicity of formularies with which most physicians must contend when treating patients enrolled in different PBMs and health plans that has generated most of the dissatisfaction among providers with formularies. These physicians have little, if anything, to do with the establishment of the formulary. For these reasons, most physicians view formularies as interfering with their work, rather than supporting their work, and most PBMs experience significantly less formulary-compliant prescribing than group and staff model HMOs. The extent to which a PBM can effectively apply its formulary is the determining factor in how well it can negotiate lower drug costs.

    - Despite some shortcomings, the formulary is at the core of the effort to create price competition among drug manufacturers, and they need to, left to work without significant governmental interference. Most proposals at the state level to regulate formularies would have the effect of making it harder to get manufacturers to compete on price.

- A frequent criticism of formularies is that they place economic considerations ahead of clinical considerations. I believe this criticism is ill-founded. In order to effectively implement a formulary, formulary managers (clinical review staff and the pharmacy & therapeutics committees that make formulary decisions) need to know the relative (and if possible comparative) safety and effectiveness of different drugs. Without this information, it is impossible to be able to assess whether a PBM or plan will be able to move market share to one or more drugs in a class. Without a reasonable estimate of this, price negotiation is unlikely to be effective. For this practical reason, clinical matters take precedence in time and importance over economics. I believe that employer and health plan customers of PBMs demand that PBMs meet appropriate levels of performance in the area. Most critics have an agenda – to limit price competition in the market as a whole.

- As a purely economic matter, an additional complication is raised by the manufacturers' strategy to replace drugs for which patent and market exclusivity is nearing an end with follow-on molecules that have longer market exclusivity. In these instances, changing the formulary to the new drug to achieve an immediate short-term lower price may have a longer-term inflationary effect. PBMs should be, and I believe are, on the lookout for this problem, and I encourage them to communicate openly with their customers about these risks and opportunities to assure that the customers' interests are primary in their consideration.

Other Significant Factors Affecting Competition in the Prescription Drug Marketplace

Finally, while much attention has been focused here and in the media on private actors in the marketplace, and allegations that drug costs are higher than they should be due to PBM rebate arrangements, it is important to put this discussion in the context of the role of anti-competitive governmental policies that have the effect of placing floor price controls on the market, driving up prices for all private payers of drugs.

- The best known and most severe of these policies is the formula used to establish Medicaid rebate levels under federal law. Under the Medicaid rebate program, manufacturers must provide rebates to Medicaid in the amount of the greater of 15.1% of the reported average manufacturer price or the difference between that average manufacturer price and the statutorily-defined "best price" offered in the private market. Because Medicaid represents upwards of 17 percent of the total prescription drug market, manufacturers are generally reticent to offer discounts of much greater than the 15 percent minimum rebate.

    - Authors of the pending Medicare drug benefit legislation in Congress, aware of the negative impact of this formula, propose to exempt from the "best price" calculation drug prices negotiated for purposes of serving the Medicare population. This is a rational reaction, but one needs to ask why the rule shouldn't be eliminated altogether when policymakers know that it sets a price floor on prescription drugs.

    - Medicaid and the private market would both be better off if the link between their price levels was severed and Medicaid was provided a flat rebate, and greater flexibility to negotiate lower prices with manufacturers. The price-floor effect of the "best price" formula means that Medicaid realizes rebates of approximately 19 percent. Severing this link would significantly enhance competition in the private marketplace, allowing PBMs and health plans to achieve lower costs in what could be highly competitive markets. Medicaid could benefit from a modestly larger flat rebate and greater flexibility in managing drug benefits. The idea that "it's unfair for taxpayers to pay more than the 'best price'" is attractive on its face, but it is ultimately self-defeating, and its effect is to cost consumers billions of dollars in additional drug costs every year without a corresponding justification.

- Requiring unnecessarily widespread disclosure of discount and rebate arrangements would also have a chilling effect on price negotiations, because manufacturers offering different prices to different purchasers are likely to be publicly criticized by those who oppose discounting in advancing their own anti-consumer business purposes. This would have an anti-competitive effect, causing all purchasers to pay higher prices, including those who have the ability of move market share among putative competitors. There are alternatives that would allow adequate transparency while preserving purchasers' (and consumers') interests in unbridled competition.

Thank you for holding these important hearings, and thank you for consideration of the views presented here.