

DeGette QFRs for Drug Supply Chain Hearing

Lori Reilly, Pharmaceutical Research & Manufacturers of America (PhRMA)

- 1. Will PhRMA commit to working with your member companies to share information with my office about your contracts with other drug supply chain players, including sharing specific examples of contract terms?**

PhRMA does not have any source of information about specific types of deals or negotiations, and cannot comment on individual company pricing decisions or offer insight into this question.

- 2. Please explain the factors pharmaceutical companies consider when setting the Wholesale Acquisition Cost (WAC) price. To the extent possible, please explain in the context of insulin and/or retail pharmaceutical products that have competing branded products in a therapeutic class.**

Manufacturer may base WAC pricing decisions on a range of factors including affordability, access, and reinvestment needs for R&D to develop tomorrow's innovative medicines. Rebates are used in private negotiations by manufacturers to gain access to payer formularies and determine level of formulary tier placement. Manufacturers pay rebates as a percentage of the current list price (WAC price) at the time the pharmacy dispenses the medicine to the patient. The manufacturer sets the "list" price of a medicine, but is actually paid the "net" price, which is the amount after rebates and any other discounts and fees have been removed.

In recent years, net prices have been growing much more slowly than list prices. Focusing on list prices alone results in a perception that drug prices are growing at unsustainable rates, when the prices manufacturers actually receive are in fact growing at low single digit rates. According to IMS Institute for Healthcare Informatics, brand net prices grew at just 3.5% in 2016, after taking into account discounts and rebates.

- 3. Do pharmaceutical companies ever feel pressure to raise list prices in order to be more competitive with PBMs and health plans in terms of formulary placement? To the extent possible, please explain in the context of insulin and/or retail pharmaceutical products that have competing branded products in a therapeutic class.**

Manufacturer may approach rebate negotiations in a number of ways, and pricing decisions are based on a range of factors including affordability, access, and reinvestment needs for R&D to develop tomorrow's innovative medicines. PhRMA does not have any source of information about specific types of deals or negotiations, and cannot comment on individual company pricing decisions or offer insight into this question.

- 4. How do pharmaceutical companies develop life cycle management strategies for their products? To the extent possible, please explain in the context of insulin and/or retail pharmaceutical products that have competing branded products in a therapeutic class.**

As a trade association, PhRMA does not have access to proprietary company data regarding their life cycle management strategies. Generally, researchers follow the trajectory of the science in developing new treatment options, whether it is for a new medicines or additional research to expand treatments to additional patient populations, other diseases and conditions, or to provide new formulations, dosage forms, or drug combinations/regimens that meet the unmet medical needs of patients. In turn, these innovations may result in improved health outcomes and a reduction in unnecessary hospitalizations for patients. Further, these innovations increase brand-to-brand competition, spur continued innovation, and provide payers with increased leverage in negotiating rebates and other discounts.

For example, continued innovation in insulins has resulted in robust brand-to-brand competition on both price and clinical effects and expanded treatment options for patients to help better manage their disease and avoid costly complications. Advances in insulin therapy include new delivery systems and longer-acting formulations which provide greater flexibility in dosing and easing treatment complexity. Given that fewer than half of Americans treated for diabetes have the disease successfully controlled, advances helping to facilitate patient adherence are remarkably valuable to patients.¹ Importantly, the broad range of long-, short-, and rapid-acting insulins available to patients has also enabled payers to leverage competition to negotiate substantial discounts and rebates on these medicines.¹

5. Do pharmaceutical companies ever stop offering or restrict access to previous versions of a product once a new/updated version comes out? Has this ever happened in the context of insulin?

As a trade association, we are not privy to proprietary information about individual companies' business practices and therefore are not in a position to comment. However, the pharmaceutical market is extremely large with thousands of products on the market. Products may come on and off the market for many reasons reflecting the evolving nature of science and innovation, the changing needs of patients impacting demand, advances made in therapy, as well as removal due to safety issues that cannot be corrected.

6. How do pharmaceutical companies change their marketing strategies for older versions of their products when new versions are approved for marketing?

As a trade association, PhRMA is not privy to proprietary information about individual companies' marketing strategies and therefore are not in a position to comment.

Chip Davis, Association for Accessible Medicines (AAM)

1. Please describe how incremental innovations and so-called “product hopping” and “evergreening” affect the ability of generic companies to enter the market and build

¹ Barrett P, Langreth R. The Crazy Math Behind Drug Prices: Intermediaries that Negotiate to Lower Prices May Cause Them To Increase Too. *Bloomberg Businessweek*, June 29, 2017. <https://www.bloomberg.com/news/articles/2017-06-29/the-crazy-math-behind-drug-prices>; Langreth R, Keller M, Cannon C. Decoding Big Pharma's Secret Drug Pricing Practices. *Bloomberg*. June 29, 2016. <https://www.bloomberg.com/graphics/2016-drug-prices>.

more competition in certain therapeutic classes. To the extent possible, please explain in the context of insulin.

Incremental changes to branded products are often used for the purposes of extending branded monopolies rather than improving patient outcomes. Branded manufacturers use such changes to shift large patient populations from one branded drug to an incrementally different new one prior to the patent expiry of the legacy product in order to insulate themselves from generic competition. This practice is commonly referred to as “product hopping” or “evergreening.” Additionally, branded manufacturers have begun filing large numbers of late-stage patents after the product has already been on the market for a number of years to delay market entry of less-expensive competitor biosimilar medicines. Even though these patents may be of questionable validity, they can create enormous costs for biosimilar manufacturers for who are forced to litigate each patent at significant cost. While AAM does not typically comment on specific products or product classes, or engage in validity analysis of any specific patents, the insulin market

2. Do Risk Evaluation and Mitigation Strategies (REMS) or limited distribution create barriers to entry for biosimilar insulin products?

AAM is not aware of specific instances in which REMS or limited distribution are barriers to entry for biosimilar insulin products. However, as FDA leaders have noted, there are significant incentives for brand manufacturers to create such barriers. This is why we encourage Congress to enact the CREATES Act and the FAST Generics Act.

Nonetheless, the development and market entry of biosimilar insulin products could face significant challenges unless Congress enacts legislation to place biosimilar medicines on a competitive playing field within Medicare Part D. Because biosimilars are precluded from offering the same 50 percent discount as brands in the Coverage Gap Discount Program, they face significant barriers to gaining formulary coverage and patient uptake. We encourage Congress to quickly include biosimilars in the Coverage Gap Discount Program, which is projected to save money for patients and the Medicare program.

3. Given the FDA’s recent focus on competition, what more do you think the agency can do to facilitate competition for medicines like insulin?

We have heard anecdotally from our members that the insulin market presents unique challenges for generic manufacturers. There are market and regulatory barriers that manufacturers must consider. One notable issue is how FDA will handle the “Deemed to Be a License” guidance required by the Biologics Price Competition and Innovation Act (BPCIA), under which FDA will shift some New Drug Applications currently marketed under the Food Drug and Cosmetics Act to Biologic Licenses under the Public Health Service Act. The agency must ensure that insulin products are handled on a case-by-case basis that allows for substitution of appropriate products when necessary. Additionally, FDA needs to ensure that it reliably and quickly communicates with sponsors of follow-on products to ensure that applications move quickly through the agency.

Elizabeth Gallenagh, Healthcare Distribution Alliance

- 1. Please explain that type of service model (e.g., direct store delivery, self-warehousing, dock-to-dock, drop shipments) your member companies most commonly use for insulin products.**

Pharmaceutical distributors offer a wide array of delivery methods for specialty products, including insulin. Orders are shipped via the most appropriate transportation method depending on order size and service level agreements including small parcel shipments, courier delivery, and less than truckload for large hospital systems or large pharmacies. Manufacturers may mandate that distributors use certain packing types for some products requiring specialty handling.

- 2. Is the amount your member companies typically pay pharmaceutical manufacturers to acquire drugs typically tied in some way to the drug's WAC price? To the extent possible, please explain in the context of insulin and/or retail pharmaceutical products that have competing branded products in a therapeutic class.**

Pharmaceutical wholesale distributors will generally purchase brand pharmaceuticals at WAC or WAC with a slight percentage decrease adjustment based on negotiations between the individual wholesale distributor and the manufacturer. WAC represents the manufacturer's list price, and does not include rebates, prompt pay, or other adjustments in price resulting from proprietary negotiations between the manufacturer and wholesaler. Each WAC is specific to the drug, strength, dosage form, package size, and manufacturer. Company negotiations, volume purchases, discounts, availability from multiple manufacturers and other contract terms and agreements may result in larger price adjustments off WAC particularly related to generic pharmaceuticals. Even after company negotiations the fundamental outcome remains static.

The provisions in our organization's antitrust policy preclude HDA from being privy to, or providing a venue for any discussion about prices and/or the components of prices among members. As members may not discuss pricing, pricing formulas, policies or the terms of their purchase and sales contracts in any HDA sponsored venue, the organization is unable to provide any comments or answer questions about specific drug products, including insulin, their prices or negotiations that take place between member companies and their suppliers and/or customers.

- 3. Do pharmaceutical companies ever provide your member companies with discounts, additional payments, or other financial incentives to acquire data about the distribution of their products?**

In exchange for the variety of distribution and logistics services that primary distributors provide to manufacturers, they charge manufacturers what are referred to as "bona fide service fees" for the provision of these services. Some examples of these core services include inventory handling and inventory management, providing manufacturers with data about where (and in which settings) their products are utilized; verifying downstream customer eligibility to purchase products at pricing established under various programs or contracts between such customers and given manufacturers; and processing relevant chargebacks to manufacturers.

These fees, which are not passed on to the customer, represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement. This model reduces demand volatility — aligning order patterns more closely to actual patient demand and, eliminating artificial demand spikes, allowing for a supply chain that operates more smoothly and predictably.

4. Please explain how drug wholesalers and distributors work with PBMs to ensure access to insulin products.

Pharmaceutical wholesale distributors do not contract with PBMs for rebates related to formulary placement of branded prescription drugs, whether insulin or otherwise. Rather, such relationships exist between pharmaceutical manufacturers and their agents with PBMs and the health plans to which such PBMs provide services. PBM-owned mail order and specialty pharmacies may contract with pharmaceutical wholesale distributors for prescription drug distribution services.

5. Do your member companies' contractual relationships with PBMs ever extend beyond mail order pharmacy operations? If yes, please provide details on the other types of business arrangements PBMs sometimes have with wholesalers and distributors.

To our knowledge, no. As noted above, pharmaceutical wholesale distributors do not contract with PBMs for rebates related to formulary placement of branded prescription drugs. PBM-owned mail order and specialty pharmacies may contract with pharmaceutical wholesale distributors for prescription drug distribution services.

David Mitchell, Patients for Affordable Drugs

1. We understand that your organization collects stories from all over the country about how high drug prices are affecting patients. How often do you hear from patients experiencing a heavy burden due to the cost of their insulin?

A very large percentage of the stories we receive come from insulin users—we estimate around 15 percent. This issue touches Americans of every state, race, religion, job status, and political party. Taking insulin is not a choice – it is a matter of life and death for thousands of Americans across the country.

2. Are there any common themes in patient stories about insulin that Congress should be aware of?

Patients often express frustration. Like me, they do not understand how the price of insulin has risen so dramatically for a drug invented in the 1920s under a patent sold for \$3. Patients often mention struggling to afford not only insulin, but all of the other supplies needed. They fear losing insurance and being unable to purchase this drug that is essential for them to live.

- 3. Have you heard from many patients about their experiences with patient assistance programs (PAPs) run by pharmaceutical companies? Please identify any common themes that you think Congress should be aware of and explain in the context of insulin to the extent that it's possible.**

Common comments include:

“I don't qualify for assistance”

“Assistance program funding comes and goes and is unreliable”

“I live in fear that assistance programs will not be there”

Patients should not have to rely on these programs which are not charity but rather are marketing programs of the drug companies. It is estimated that drug companies make as much as \$21 million for every one million invested in so-called assistance programs. Insulin should be affordable without patient reliance on company-controlled funding.

- 4. Options to appeal health plan determinations are often available to patients who are not able to access the specific type of insulin they need. Have you heard from patients who have made appeals to health plans in an effort to get a specific drug? Please describe their experiences and any common themes that you think Congress should be aware of.**

Patient appeals can be made. But they too often take too long to be resolved, and insurance plan “rules” often trump patient and physician judgment. It is simple: When a patient and his or her physician report that a given product is not performing for the patient for any reason—outcomes or side-effects—the patient must be able to receive the alternative product.

Mark Merritt, Pharmaceutical Care Management Association (PCMA)

- 1. Please describe whether and how pharmaceutical companies use intellectual property protections as part of your negotiations on rebates. Please explain in the context of insulin and/or retail pharmaceutical products that have competing branded products in a therapeutic class.**

In general, drug manufacturers use intellectual property (IP) protections such as patents and market exclusivities to create a temporary monopoly on selling a particular drug or biologic. These IP protections were designed to encourage more research. However, the system has come to be abused by manufacturers. In the case of insulin, drug manufacturers have continually adjusted formulations, creating insulin analogs that are easier to use and less likely to trigger dangerous low blood sugar episodes. These new formulations also serve to provide drug manufacturers with new IP protections and preserve the manufacturers' monopolies. This practice of making slight product changes to preserve monopoly protections is called evergreening, and it keeps brand prescription drugs under patent protection so other drugmakers cannot copy formulas and offer lower-cost versions.

- 2. Please describe how patient assistance programs and discount cards offered by pharmaceutical companies affect PBMs' ability to negotiate rebates. To the extent**

possible, please explain in the context of insulin and/or retail pharmaceutical products that have competing branded products in a therapeutic class.

The notion of drug manufacturer patient assistance programs can be misleading when used for patients with health insurance. Such practices, including coupon and “free” drug programs, entice insured patients to use higher-cost medications when more cost-effective, clinically appropriate alternatives exist. They undermine formulary cost-sharing strategies designed to give patients incentives to use the most cost-effective, clinically appropriate medications. For insured patients whose cost-sharing is paid by manufacturers, those plans—and ultimately, consumers—end up paying manufacturers the full cost of a drug. This formulary subversion is considered to violate anti-kickback statutes and is barred in federal programs, such as Medicare and Medicaid. Ultimately, these types of programs undermine the expert pharmacy benefit management services that sponsors hire PBMs to perform on their behalf, and result in increased health care costs for all Americans. These schemes are carried out by drug manufacturers across most drug classes, including insulin.

- 3. Are rebates collected by PBMs from pharmaceutical companies and passed onto PBM clients sometimes based on a percentage of list price (WAC) or some modified version of list price (e.g., WAC- or Average Wholesale Price-based formulas)? If yes, is it possible that this rebate structure could put pressure on pharmaceutical companies to raise list prices?**

PCMA is not privy to contract negotiations of its members’ business, but our understanding is that some contracts are negotiated based on percentage discounts from an industry standard. PBMs manage drug benefits to get sponsors and patients the lowest net cost, recommending benefit and cost-sharing designs that encourage the use of the most cost-effective, clinically appropriate drugs. The pharmaceutical industry introduced rebates as a method for providing price concessions; PBMs would welcome a different way to get to lowest net cost. PBMs respond to requests for proposals (RFPs) from potential clients, which lay out the payer’s terms and conditions. Each plan determines what percentage of rebates it wants the PBM to pass through to it, and how much (if any) it wants the PBM to retain as payment for services. We understand that PBMs offer sponsors inflation protection against manufacturer price increases that also mitigates against PBMs having an incentive for manufacturers to raise their prices. Each drug manufacturer independently decides the price of its drug. The launch price of new drugs and price increases of existing drugs bear no correlation to the rebates and discounts manufacturers negotiate with PBMs. There are high-priced drugs with low rebates and lower-priced drugs with high rebates. It all depends on how much direct competition a given drug faces in the market. This data argues against the notion that PBM contracts with manufacturers pressure them to increase prices.

- 4. Are administrative fees collected by PBMs from pharmaceutical companies sometimes based on a percentage of list price (WAC) or some modified version of list price (e.g., WAC- or AWP-based formulas)? If yes, is it possible that this fee structure could put pressure on pharmaceutical companies to raise list prices?**

Again, PCMA is not privy to the details of our companies' negotiations with drug manufacturers or other entities and has not even a general understanding of the basis for administrative fees.

5. When a pharmaceutical company chooses to raise a product's list price above an agreed upon threshold under a price protection clause, can that result in the pharmaceutical company paying an additional rebate?

The question seems to describe what is called a price protection agreement. Some sponsors request this in order to set a ceiling price for drugs. Typically, when drug prices rise, a rebate is issued for anything that exceeds an agreed-upon price threshold.

In practice, as evidence shows, neither price protection agreements, nor any other kind of price concession negotiated by PBMs drives the list price of drugs. Drug manufacturers set their prices and PBMs can negotiate price concessions to the extent manufacturers' products are substitutable for one another in the marketplace.

Matt Eyles, America's Health Insurance Plans (AHIP)

1. When designing pharmacy benefits and formularies for health plans, how do your member companies balance clinical evidence about various treatment options with contractual guarantees to pharmaceutical companies about formulary placement?

Health plans' pharmacy benefit designs and formularies leverage science by relying on existing evidence on safety and effectiveness. This evidence-based approach to coverage policy and medical management involves a systematic review of the safety and effectiveness of medical interventions, including drugs, devices, services, and procedures. In conducting these reviews, health plans' pharmacy and therapeutics committees rely on a variety of evidence-based resources, typically following a hierarchy of evidence that gives the most weight to randomized clinical trials. The types of evidence that health plans rely on include, but are not limited to:

- Randomized Clinical Trials (RCTs)
- Specialty society guidelines/best practices
- Current scientific and clinical peer reviewed medical literature
- CMS coverage decisions and quality metrics
- AHRQ guidelines
- USPSTF recommendations
- Well-designed observational studies
- Expert consensus

Health plan pharmacy policies and formularies are also dictated to some extent by federal and state mandates, as well as employer/client requests. Additionally, health plans periodically review their coverage policies and update them based on new information/evidence, such as FDA safety notices, new drug approvals, new scientific/clinical research findings, and updated professional society guidelines.

2. To what extent do your member companies track how rebate dollars passed on by PBMs and pharmaceutical companies are used by health insurance plans?

Rebate amounts typically are calculated and paid by a manufacturer to a health plan (or PBM) on an aggregate basis, long after an individual prescription is filled by a consumer. Because rebates are extended based on actual aggregate utilization of a specific population, they are paid several months after the drug has been prescribed and dispensed and all the data can be reconciled. In designing their plan benefits and developing premium rates in advance of the upcoming coverage year, health plans calculate an estimate of the aggregate rebates they expect to receive.

Since drug costs comprise a significant portion of a health plan's total costs, plans may use these estimated discounts to reduce the premiums they charge for the overall benefit, improve benefit packages, and/or lower out-of-pocket costs. Alternatively, plans may incorporate advance estimates into lower point-of-sale pricing for individual drugs that generate the rebates. By reducing the net price and cost of drugs, all consumers benefit. This represents a broad and direct benefit for millions of customers, whether they get their coverage through Medicare, on their own, or through their employer.

In discussing rebates, it's important to understand the role they play within the broader system for setting the cost of drugs that consumers pay at the pharmacy. For some branded drugs and biologics without therapeutic alternatives, manufacturers' willingness to negotiate on price is small or nonexistent. For generic prescriptions, accounting for 89 percent of dispensed medications, rebates or discounts are not generally offered. Further, rebates are not commonly found for physician-administered drugs, which account for 30 percent of prescription drug spending.

3. Are rebate dollars retrieved from pharmaceutical companies or passed on by PBMs considered under the Medical Loss Ratio (MLR)? If yes, please explain how rebate dollars factor into MLR calculations.

Health insurance providers must provide consumer rebates if they do not meet a set threshold for the percentage of revenue spent on medical claims (generally, 80 or 85 percent depending on the market). Prescription drug rebates are included in the medical loss ratio (MLR) calculation. The costs for prescription drugs are treated as other health claims, while prescription drug rebates are treated as revenue. Both claims and revenue are reconciled and reported in the second quarter of the year for the previous plan year for a set of products, and insurance providers file MLR reports with HHS at this time. Any rebates owed are distributed in the third quarter and are based on the average MLR ratio over the prior three years.