Senate Committee on Finance Questions for the Record

Drug Pricing in America: A Prescription for Change, Part II

February 26, 2019

Questions for:
Olivier Brandicourt, M.D.
Chief Executive Officer
Sanofi

Senator Grassley:
For all witnesses:

The Department of Health and Human Services' proposed rule, "Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees", envisions that drug manufacturers will offer upfront discounts rather than the back-end rebates that are now commonly provided. Some observers argue that a 1996 court case called into question whether manufacturers could offer upfront discounts, resulting in today's rebate-based system. I've heard differing opinions as to whether the issues related to the initial court case are still relevant. If the HHS proposed rule is finalized, can you assure the Committee that your company will offer upfront discounts? If not, why?

As the question notes, one of the practical implications of the Proposed Rule is to incentivize a shift from back-end rebate payments to upfront discounts that are passed through at the point-of-service to the patient (at least in part). We understand that some in the health care industry have raised concerns that the nation's antitrust laws, specifically the Robinson-Patman Act, and long-running antitrust litigation involving drug manufacturers, wholesalers, and pharmacies could prevent or reduce discounting under a pricing structure without rebates. But, the Robinson-Patman Act focuses on price discrimination -- involving any dimension of price -- and it does not distinguish between upfront discounts and rebates. In addition, the referenced litigation, *In re Brand Name Prescription Drugs Antitrust Litigation*, did not result in any change in the ability of a prescription drug manufacturer to offer an upfront discount. Consequently, because Sanofi's view is that the antitrust laws apply equally to upfront discounts and back-end rebates, we do not believe that they present any impediment to offering upfront discounts to patients at the point of sale. Sanofi is committed to working with other stakeholders to lower patient out-of-pocket costs, and the company will carefully review any final rule issued by HHS regarding the Anti-Kickback Statute and its safe harbor regulations -- with the goal of providing point-of-sale discounts to patients in a compliant manner to help lower patient out-of-pocket costs.

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Please describe how you expect your company to respond to the HHS proposed rule to eliminate safe harbor protection for back-end rebates in Medicare Part D that is referenced above if it is finalized. Assuming you are confident that antitrust laws do not prevent your company from offering upfront discounts, specifically, do you envision that your company lowers the list price of a drug to the current after-rebate net price, offer discounts equal to the current rebate amount, or a combination of both?

Sanofi is committed to working with other stakeholders to lower patient out-of-pocket costs, and the company will carefully review any final rule issued by HHS regarding the Anti-Kickback Statute and its safe harbor regulations -- with the goal of providing point-of-sale discounts to patients in a compliant manner to help lower patient out-of-pocket costs.

With respect to list price, if (1) the proposed changes to the anti-kickback statute safe harbors were codified, and (2) Congress implemented similar changes to the commercial insurance market, Sanofi would lower the list prices of its prescription medications for products in competitive categories for which there is currently a material difference between list price and net price on the assumption that patient access and affordability would be improved. Sanofi also supports policy changes that would de-link other payments in the pharmaceutical supply chain from list price.

We support extending the intent behind the anti-kickback statute safe harbor proposed rule to the commercial market so that incentives are aligned across the marketplace. Together, we believe these changes would facilitate Sanofi's ability to lower our list prices. However, we recommend a step-wise approach, implementing changes to the commercial market after the safe harbor rule is implemented on January 1, 2020. Such an approach would provide an opportunity for stakeholders and the government to identify unintended consequences, and address them, prior to extending these policies to the commercial market.

We want to ensure that the new system achieves its goal of improving affordability for patients. For instance, CMS should monitor and evaluate how the new system affects formulary access, utilization management, and patient cost-sharing, particularly with respect to medicines with a lower list price. We also have concerns that changes to the rebate system may lead to new fees, which simply require manufacturers to pay previous rebate values in new ways, rather than creating savings for patients.

Without a better understanding of how these policy changes ultimately would affect the competitive marketplace, patient access, and affordability, we are unable to quantify the amount of upfront discounts or any potential list price reduction.

To what extent are the back-end rebates your company currently offers contingent on the amount of market share realized for your drugs as a result of Part D plan formulary placement and other techniques?

Sanofi negotiates rebates with PBMs and Part D plans to secure better formulary position for our products, which in turn provides the best possible access and cost sharing for the majority of

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Medicare Part D beneficiaries. When evaluating what level of rebates to offer, Sanofi considers the potential business impact of such arrangements.

Please provide a breakdown of percentage of sales that go to each payer (including Medicare, Medicaid, private pay, other) and a similar percentage by volume of the total number of each drug compared to total volume. Please provide this data for the most recent year available.

Primary Care Products

Percentage of Sales by Payer Channel[1]

	Channel						
Product	**Commercial**	**Medicare**	**Medicaid**	**Tricare**	**340B**	**FSS Others[2]**	**Institutional[3]**
Lantus	25%	36%	10%	0%	5%	19%	4%
Toujeo	47%	39%	7%	0%	4%	2%	0%
Soliqua 100/33	77%	15%	3%	0%	3%	1%	0%
Apidra	16%	1%	66%	0%	8%	7%	2%
Admelog	0%	0%	91%	0%	9%	0%	0%
Multaq	24%	57%	2%	0%	3%	12%	2%
Praluent	22%	32%	1%	0%	2%	5%	38%

Percentage by Volume by Payer Channel

	Channel						
Product	**Commercial**	**Medicare**	**Medicaid**	**Tricare**	**340B**	**FSS Others**	**Institutional**
Lantus	25%	36%	10%	0%	5%	19%	4%
Toujeo	47%	39%	7%	0%	4%	2%	0%
Soliqua 100/33	77%	15%	3%	0%	3%	1%	0%
Apidra	16%	1%	67%	0%	7%	7%	2%
Admelog	0%	0%	91%	0%	9%	0%	0%
Multaq	24%	57%	2%	0%	3%	12%	2%
Praluent	22%	32%	1%	0%	2%	5%	38%

[1] Based on gross sales.
[2] This category includes the VA, DOD, and other purchases through Sanofi US's Federal Supply Schedule (FSS).
[3] This category includes Hospital/GPO, Long Term Care, Outpatient, and Staff Model.

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Specialty Care Products

Percentage of Sales by Payer Channel[4]

	Channel				
Product	**Commercial/ Managed Care**	**Medicare**	**Medicaid/VA / DOD/Tricare**	**PHS/ 340B**	**Non-Contracted Sales**
Cerdelga	0%	12%	6%	4%	78%
Cerezyme	0%	15%	15%	22%	48%
Aldurazyme	0%	6%	29%	23%	42%
Fabrazyme	0%	13%	10%	26%	51%
Myozyme	0%	18%	15%	31%	36%
Thyrogen	0%	4%	5%	25%	66%
Caprelsa	0%	6%	10%	0%	84%
Aubagio	47%	33%	11%	2%	7%
Lemtrada	0%	35%	10%	41%	14%
Kevzara	69%	15%	4%	3%	9%
Dupixent	75%	9%	6%	3%	7%
Eloctate	0%	5%	33%	37%	25%
Alprolix	0%	5%	27%	39%	29%
Jevtana	0%	70%	1%	30%	0%
Zaltrap	0%	0%	0%	0%	100%
Elitek	0%	15%	1%	7%	77%
Mozobil	0%	25%	6%	45%	24%
Thymoglobulin	0%	0%	0%	4%	96%

Do your companies hire consultants or lobbyists to promote products at state Medicaid Pharmacy & Therapeutics Committees? To whom do you disclose advocacy activities surrounding state Medicaid programs, if at all?

Sanofi does not hire external consultants or lobbyists to advocate for coverage of our products at state Medicaid Pharmacy & Therapeutics Committees. Sanofi employees do attend state Medicaid Pharmacy & Therapeutics Committees meetings. Relevant advocacy activities to support Medicaid access and coverage of our medicines, if any, are disclosed to states in accordance with individual state laws.

1. **Please describe how the costs of patient assistance programs are accounted for within your company's financial statements. Please also describe the types of**

[4] The data used to derive this information is contracted sales data. Because many of these products are purchased through non-contracted sales, Sanofi has a limited view regarding through which channels these products are purchased. Percentage by volume by channel results in similar percentages to percentage by sales so a separate chart is not provided.

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market information, such as prescribing and use patterns, that your company collects from different types of patient assistance programs and patient hub services.

Within Sanofi's financial statements, Sanofi includes the administrative costs of the company's co-pay assistance programs, other point-of-sale programs, and free drug patient assistance program (Sanofi Patient Connection) in the "Selling and general expenses" line item. For co-pay assistance and other point-of-sale programs, Sanofi records the pharmacy reimbursement amount paid by the company as a reduction in sales. Sanofi records free product provided through Sanofi Patient Connection within "Cost of Sales." Sanofi Care North America, the 501(c)(3) operating foundation that donates free product to Sanofi Patient Connect, records the free goods as a "Contribution" when received from Sanofi and as a "Donation" when donated to Sanofi Patient Connection.

With regard to market information associated with its patient assistance programs and hub services, Sanofi generally collects data that aids in the efficient administration and operation of these programs. For example, the vendors operating Sanofi Patient Connection and the hubs collect information provided by patients on enrollment forms, including patient and provider demographic information, patient insurance information, patient diagnosis, and prescription information necessary to evaluate patient program eligibility and/or administer the program. (Sanofi does not itself receive patient protected health information except in very limited circumstances, such as when a patient reaches out to Sanofi directly when they do not agree with their patient assistance eligibility determination or when Sanofi monitors vendor calls for compliance with company policies and procedures.) With respect to Sanofi Patient Connection, Sanofi does not use this information for purposes other than administering the patient assistance program. With respect to hub services, in addition to using this information to administer hub programs, Sanofi may use this data to develop market and business insights.

With respect to Sanofi's point-of-sale patient assistance programs, Sanofi also receives anonymized program utilization data, including information about patient out-of-pocket costs, the average amounts that Sanofi reimburses pharmacies through the program, abandonment rates, dispensing pharmacies, and the prescribers writing the prescriptions associated with program utilization. This information is used to administer the program. Sanofi may also use this data to develop market and business insights.

2. **Please provide a list of all contributions since January 1, 2014, that your company has made to any tax exempt organizations working on issues related to drugs within your product lines, including but not limited to patient groups, disease awareness groups, medical or professional societies, universities or hospitals, industry associations or leagues. For each contribution, please provide the name of the organization that received the donation, the date the donation was made, the amount of the donation, and a description of the purpose of the contribution (i.e., was the contribution for the general fund, a specific purpose to a specific program, or continuing medical education). Please also note whether the contribution was unrestricted or restricted; if it was restricted, please explain all restrictions. Finally,**

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