

Transparency in Drug Pricing Continues to Challenge the Pharmaceutical Market

(Sources: An article by Wayne Winegarden for Forbes Magazine, an article by Sandra Levy for Drug Store News, and an article by Bloomberg and featured in Supply Chain Brain)

Faced with continued rising drug prices, U.S. lawmakers continue to propose counterproductive reforms that ultimately will make a bad situation worse due to a serious lack of understanding regarding the cause of the problem – a drug pricing system that is complicated by the current third-party payer system, according to Wayne Winegarden, a writer/contributor at Forbes Magazine.

However, Health and Human Services (HHS) secretary, Alex Azar has proposed a solution that, if implemented would make substantial improvements to drug pricing in the pharmaceutical market. By simplifying the drug pricing system, the cost of a drug would be determined by the list price of the drug.

Mr. Winegarden gives an example to demonstrate how the system works. If the list price of a medication is US\$100 and a patient has a US\$0 co-pay but 20% co-insurance, then the patient would pay US\$20 upon receipt of the medication. While it would seem logical that the cost to insurers would be US\$80 for the medication, under the current system this is not the case. Pharmacy benefit managers (PBMs) have negotiated rates with insurers which reduce the list price of the drug. Insurers pay based on the negotiated price, an average savings of 44 percent. So, the US\$100 drug would be US\$56 for the insurer, not the US\$100 price that the patient's cost is based upon.

Since PBM revenues are based upon the spread between patient pricing and insurer pricing, the difference is used to generate their fees and rebates. This also gives PBMs an incentive for list prices to increase as quickly as possible – increased prices equal increased spreads and higher profits.

Secretary Azar's proposed reforms would change the pricing incentives of the industry on a fundamental level. Under the proposed changes, "safe harbor protections" (protection against legal liabilities or penalties on the rebates that manufacturers pay PBMs) would be "expressly excluded" for any rebates paid to the PBMs but will be granted when offered to the patient at the time of purchase. This means that rebates will cease to be paid to the PBMs for Medicare Part D plans, as well as Medicaid-managed care plans, and will instead go directly to the patients. This will greatly improve price transparency, creating a much-needed improvement to the drug pricing system. Additionally, the incentive for list prices to unnecessarily increase will also be eliminated. In total, the HHS proposal would effectively create a more transparent pricing structure, allowing patients to benefit from this transparency.

Executives from the nation's seven largest drug companies testified on Capitol Hill on March 12th. Pharmaceutical Research and Manufacturers' Association president and CEO, Stephen Ubl, emphasized that the industry is ready to undertake reforms.

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- ◆ *Scott Gottlieb* will step down as Commissioner of the U.S. Food and Drug Administration, citing a desire to spend more time with his family. Gottlieb won over his skeptics by elevating certain issues during his two-year tenure, including e-cigarettes, opioids and drug prices. His willingness to call out drug makers for what he dubbed as their "shenanigans" and "kabuki drug pricing" was widely applauded by Republicans and Democrats alike. A successor has not yet been named.

- ◆ **Amazon** has appointed **Nader Kabbani** to take over its new pharmacy initiative. Kabbani, a 14-year veteran of Amazon, will head Amazon's PillPack organization, which Amazon purchased for US\$800 million in June of 2018. While Kabbani has no healthcare background, he is highly experienced in supply chain and logistics, having lead **Amazon Flex**, the company's program that hires individuals to make deliveries on a flexible schedule. Separately, eMarketer reported that Amazon Prime memberships will hit 51.3% of U.S. households in 2019. This represents 63.9 million households, up from 58.7 million in 2018. Growing participation is attributed to an increase in lower-income households.

- ◆ **United Healthcare** (U.S.) is taking steps to extend drug discounts directly to consumers. It is working with **OptumRx** to expand its consumer point-of-sale prescription drug discount

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As Brexit Crisis Deepens and Deadline Looms, Pharma Companies Make Contingency Plans

(Sources: Company press release by World Courier, an article by William Schomberg and Michael Holden for Reuters, and an article by Kevin Grogan for Scrip)

On Tuesday, March 12th, British lawmakers handed Prime Minister Theresa May another humiliating defeat. For the second time, her Brexit plan she had agreed upon with the European Union was rejected, sending the UK into a deeper political crisis. While the March 13th vote rejected a no-deal Brexit, that vote is not binding. The next vote will occur on March 14th to extend the time to come up with deal that is agreeable to all parties.

The ongoing turmoil and divisiveness leaves the world's fifth largest economy faced with several different scenarios: leave the EU without a transition strategy; delay the March 29th exit date that is currently law; hold a snap election; attempt a third time to get her deal passed; or, the country could hold another referendum on the Brexit.

The pharmaceutical industry is faced with across-the-board impacts that could substantially disrupt supply chains and operations, as well as tremendously affect drug approval processes and regulatory requirements. All over Europe, companies are developing strategies to deal with the Brexit fallout

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“During today’s Senate Finance Committee hearing, our member companies demonstrated the industry’s commitment to working with members of Congress on both sides of the aisle on policies to transform our health care system. Significant reforms aimed at changing the marketplace will be disruptive for our industry, but we believe they are necessary to improve patient affordability and lower costs.”

Ubl acknowledged that PhRMA is engaged with the Association for Accessible Medicines (AAM) to develop a modified version of the CREATES Act aimed at increasing competition from generic medicines. Additionally, PhRMA is supportive of the administration’s proposal to reform the rebate system. And while PhRMA is committed to working with the Administration and Congress to address Medicare Part B cost concerns, it is opposed to the proposed International Pricing Index Model.

Susan Collins (R-Maine) stated “There are a lot of people getting very wealthy along this supply chain, while regular Americans are paying “crushingly high” prices for their drugs. The rebates and discounts on drugs from pharmaceutical companies – which are high to begin with – are offered to middle men without being passed along to consumers.”

She further emphasized that an additional area that needs to change is patient ‘gaming’ in which brand-name manufacturers file multiple patents on a drug in order to keep competitors out of the market.

John Kilgour, vice president of acute and alternate care sales for specialty pharmaceutical distribution at Cardinal Health, noted “You have to be very mindful of your pharmacy operations, make sure you are optimizing the inventory you have on hand, and look at technology to see if there are things you can do creatively and innovatively that maybe have not been done before.”

The Senate Special Committee on Aging is also holding a three-part hearing on prescription drug pricing this week, and will hear from individuals adversely affected by the high cost of prescription drugs.

Brexit (cont.)...

and subsequent complications. Manufacturers, wholesalers and related pharmaceutical companies are all in the crosshairs of the challenges presented by Brexit.

World Courier, a subsidiary of AmerisourceBergen (U.S), has spent considerable time and effort in preparing for the potential outcomes of Brexit. Currently, World Courier operates in 27 countries with 51 offices. Their focus now lies in the expansion of their in-house brokerage teams in the U.K. and across the European Union so that they can effectively provide customers with a detailed understanding of local customs and regulatory requirements. The company has also revved up investment in its Dublin facilities so that it can serve its customers who have relocated their operations to Ireland. The same is true for its other European facilities that must now serve other relocated customers in other parts of Europe.

Currently, World Courier is the only major specialty logistics provider in the U.K. that has Authorised Economic Operator Customs Simplification Status (AEOC), a demonstration of their secure role in the international supply chain that follows EU standards. The company also holds GDP certification against three major GDP standards (EU, GDP, USP 1079 and WHO GDP). This ensures their standard of distribution across the world.

Japanese drug maker, Shionogi & Co., Ltd. is also looking ahead to a possible move of its legal base out of the U.K., as have other Japanese manufacturers such as Sony and Panasonic. Japanese pharmaceutical manufacturers have been some of the most vocal when it comes to expressing concern over the Brexit fallout and its implications. The company will potentially move its European base from London to the Netherlands. Unnamed sources told The Financial Times that Shionogi will merge its European operations with its Dutch subsidiary, giving it a financial advantage in bypassing London, with the possibility of lowering its tax liability in Japan. The company has not confirmed the move, but certainly the relocation of its European headquarters to London in 2012 has lost its appeal in light of the Brexit situation.

The government of Japan has also made its dissatisfaction known to the British government, following the UK vote to leave the EU in 2016, by expressing its concerns with the relocation of the European Medicines Agency, now located in Amsterdam. At that time, the Japanese government stated that if the EMA were to transfer to another EU member state, “the appeal of London as an environment for the development of pharmaceuticals would be lost, which could possibly lead to a shift in the flow of R&D funds and personnel to continental Europe. This could force Japanese companies to reconsider their business activities.” This seems to be the case, in large part, behind Shionogi’s move to the Netherlands.

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programs to apply to all new employer-sponsored plans with the goal of making medications more affordable while improving health outcomes. The company will require that any discounts offered to pharmacy benefit managers will be included in the consumer price. The program will only support new employer clients that incorporate point-of-sale discounts to consumers as part of their plan.

- ◆ **Purdue Pharma**, the maker of the widely criticized opioid, *OxyContin*, is exploring the possibility of bankruptcy as a way of dealing with their significant liabilities from approximately 2,000 lawsuits filed pertaining to the opioid crisis. These lawsuits allege that Purdue and others, including *Teva Pharmaceuticals*, directly contributed to the deadly opioid crisis sweeping the U.S. *Teva Pharmaceuticals* is the maker of the opioids *Fentora* and *Actiq*, and a generic version of *OxyContin*. Additionally, *Teva’s* drug distribution subsidiary, *Anda* (and others) has been cited in lawsuits for failing to employ internal controls that could have been used to identify any suspicious activity with order of opioids.

- ◆ **General Electric** will sell its biopharma business unit, **GE Life Sciences**, to **Danaher Corporation** for US\$2.14 billion. **Pharmaceutical Diagnostics**, currently part of GE Life Sciences is not included in the transaction and will remain within the **GE Healthcare** portfolio. GE Healthcare has a global presence of more than 4 million imaging, mobile diagnostic and monitoring units. In 2018, this business, excluding BioPharma, generated approximately US\$17 billion of revenue, and is a leader in imaging, monitoring and diagnostics. It also provides services, accessories, consumables, education, training and consulting.

(Sources: *BioPharmaDive*, *Consumer Affairs*, *Drug Store News*, *Haaretz*, and *Scrip*)