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Drugmakers Aim to Strike Down Medicare Drug Price Negotiations while Some Drugs May be Sidelined as a Result of the Inflation Reduction Act

(Sources: Two articles by Jessica Merrill for Scrip Intelligence, and an article by Spencer Kimball for CNBC)

The lawsuits are mounting against the U.S. government's implementation of the new Medicare drug pricing negotiation program. The first lawsuit was filed by Merck & Co. and Bristol Myers Squibb, followed by a surprising second suit filed by the U.S. Chamber of Commerce (the "Chamber").

"I think we expected a lawsuit from the pharmaceutical industry, which is the most directly impacted by the law, but it was interesting to see a lawsuit from the Chamber of Commerce, which broadly represents a huge swath of the industry," Morrison Foerster partner and former FDA chief counsel Stacy Cline Amin said in an interview. "Seeing the Chamber lawsuit really reflects what a deeply significant issue these price negotiations could be for the economy as a whole," she said.

Sources at the Chamber said that the lawsuit was filed because government price controls harm patients and stifle American innovation. "The new provisions in the U.S. Inflation Reduction Act (IRA) violate fundamental protections for free enterprise enshrined in our Constitution, which would have far-reaching implications in the future," the Chamber said in a statement.

There is significant potential for other lawsuits to follow, but navigating these lawsuits through the court system will take time. The best opportunity for the industry to slow down the implementation of the Medicare program, which is progressing under a fast timetable established by the IRA, would be a preliminary injunction. Any measures short of an injunction would require substantive changes to the program by a court decision in one of the cases, followed by a likely appeal and potentially a review by the U.S. Supreme Court, according to legal experts.

Additional lawsuits arguing different grounds could also increase the chance for the industry to get a successful preliminary injunction before the program is significantly set in motion. Should this happen, it would be an important first step to slow down the process, given that the first 10 drugs to face Medicare price negotiations by the Centers for Medicare & Medicaid Services (CMS) are expected to be announced in September of this year. However, the actual negotiated prices will not go into effect until 2026.

The focus of both lawsuits is on the lack of "negotiation" in the Medicare process because drug manufacturers will be hit with excessive tax penalties if they choose not to accept the prices offered by CMS.

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In Brief...

- **Pfizer** has issued a warning of a nationwide *penicillin* shortage, particularly its prefilled syringes of *Bicillin*, which comes in a long-acting form or in a combination of two different *penicillin* types. Pfizer attributes the short supply to a "complex combination" of factors, including significant demand increases and a rise in syphilis infection rates. The company has prioritized its manufacturing capacity of long-acting *Bicillin* to meet the spike in demand. As it stands, all doses of the company's combination *penicillin* syringes are expected to run out in the third quarter of this year.
- **McKesson Canada** unveiled a 233,000-s.f. pharmaceutical distribution facility in Surrey, British Columbia. The center delivers medications, vaccines, specialty pharmaceuticals, and over-the-counter products to more than 1,300 hospitals, clinics, and pharmacies across British Columbia, with a specialty pharmacy being one of its key features, along with state-of-the-art technology and cold chain storage.
- U.S. regulators have discovered another manufacturing plant with significant issues run by **Intas Pharmaceuticals** Ltd., a generic drugmaker whose quality issues have caused one of the worst shortages of cancer medications in decades. One of its facilities was shut down after the **U.S. Food and Drug Administration (FDA)** found shredded documents about drug quality, indicating serious lapses at the plant, and raising doubts about the safety and efficacy of its drugs. While the FDA did not comment specifically on the Intas inspection, a spokesperson said the agency continues to monitor the quality of drugs coming into the U.S. At least one supplier from China has been tapped to relieve the cancer drug shortage but China is facing drug shortages within its own borders.
- The **Heathcare Distribution Alliance** presented its *Distribution Industry Awards for Noble Achievements (DIANA Awards)* at the *2023 HDA Business Leadership Conference* in Colorado Springs, Colorado. Nine pharmaceutical and consumer product manufacturers were honored with the awards. *Mike Kaufmann*, former CEO of Cardinal Health, was

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Drugmakers(cont.)...

Merck's lawsuit argues the program violates the Takings Clause of the U.S. Constitution's Fifth Amendment and First Amendment prohibition against forced speech, while the Chamber's lawsuit includes various arguments (including the violation of the separation of powers articles in the Constitution, due process under the Fifth Amendment and excessive fines clause under the Eighth Amendment) in addition to the First Amendment argument. Merck has already said it was prepared to take the flight all the way to the Supreme Court, if necessary.

Meanwhile, Eli Lilly & Co. CEO David Ricks highlighted how Medicare drug price negotiations are already impacting R&D investment during a J.P. Morgan investor call. As a result of the IRA, Lilly has deprioritized three drugs, however he did not elaborate on which three drugs they would be or how advanced in development they were.

One of the industry's biggest arguments against the legislation has been that it would dissuade investment in small molecule drugs, which are only granted nine years on the market before potentially facing drug price negotiations (biologics are granted 13 years.)

There are also unintended negative consequences as a result of the IRA, Ricks pointed out, and gave real world examples. The expansion of Lilly's SGLT2 inhibitor *Jardiance (empagliflozin)*, first approved for diabetes in 2014, its subsequent approval for a new indication for heart failure in 2022 probably would not have happened under the IRA.

"We did a whole Phase III program on that in the middle of the lifecycle; probably that ends up being more valuable than the original indication, but no one would have pursued that," he said. "What we would have done is gone back, found a new SGLT2 inhibitor that we haven't registered yet and have started all anew, and in the meantime, people would have been dying of congestive heart failure."

He also noted that in other cases drugs may simply not have been made available to Medicare patients, referencing drugs that are most widely used in younger patient populations, like the new oral migraine drugs.

Another potential long-term issue is the downstream effect on the availability of generic drugs if fewer small molecules are developed. Small molecule drugs are frequently more quickly adopted which substantially lowers healthcare costs, as opposed to biosimilar version of biologics.

"Because we will have fewer small molecolues and the ones that do make it will be approved for fewer uses, we will have far less generic surplus value in the health care system forever," he said.

Many of the issues raised by Ricks have been industry talking points against the Medicare negotiation program since the IRA was signed into law, and as the program is implemented, some of the consequences of the legislations will become much clearer.

The industry, whether through pending or future lawsuits, or changes to their R&D, will continue to push for changes to some elements of the IRA program, not the least of which is to curtail the steep penalty tax that will be levied on companies who do not comply with the Medicare-negotiated price.

In Brief (cont.)

also awarded the *2023 Nexus Award for Lifetime Achievement*.

- The *Patients Before Middlemen Act* has been introduced in the **U.S. Congress** by the **Senate Finance Committee**. If enacted into law, it would prevent pharmacy benefit managers (PBMs) that contract with *Medicare Part D* plans from tying service fees to the price of a drug, rebates, discounts or other fees. PBMs would also not be allowed to stipulate compensation based on drug price as a condition of entering into a contract. In addition, the bill would establish an enforcement mechanism that would require PBMs to repay the **Department of Health and Human Services** any amount that exceeds the designated fees.
- *Mark Cuban's* **Cost Plus Drug Company** is partnering with **Coherus** to offer *Yusimry (adalimumab-aqvh)*, a *Humira* biosimilar manufactured by **AbbVie**. Cost Plus plans to offer *Yusimry* for $569.27 plus dispensing and shipping fees starting in July of 2023. *Yusimry* will also be included in *Team Cuban Card* prescription benefit program through participating pharmacies. The Team Cuban Card allows patients to fill prescriptions at a local independent pharmacy at the same low prices they expect from Cost Drugs Plus.
- The **World Health Organization (WHO)** has granted an emergency use listing (EUL) to **SK Biosciences'** COVID-19 vaccine, *SKYCovione*. *SKYCovione* is a self-assembled nanoparticle vaccine and the 12th COVID-19 vaccine to receive an EUL from the WHO.
- **Biogen** has taken steps to "refresh" its board of directors. The company announced that *Susan Langer* has been named a new member of the board while current board members *Alex Denner, Ph.D.*, *William Jones*, and *Richard Mulligan, Ph.D.* will all step down. This will leave two unfulfilled board seats. Langer previously headed corporate strategy at Biogen, where she led more than a dozen transactions and other company-wide initiatives.
- **Novartis'** generics and biosimilars unit, **Sandoz** (soon to be a stand-alone company) has projected sales of pipeline products to add US$3 billion to its top line over the next five years, largely in part to its emphasis on biosimilars. The company plans to invest in high-value biosimilars and currently holds 24 candidates in its pipeline. Sandoz projects the market for biosimilars and generics to double over the next nine years due to an aging population and blockbuster products, such as *Humira* and *Keytruda*, losing exclusivity.
- **Geo-Young Corp.**, South Korea's leading drug distributor has been granted permission to acquire a 25% stake in **Baekje Pharmaceutical**, the country's second lead drug distributor. With the acquisition stake, it is expected that Geo-Young will emerge as a giant in the pharmaceutical distribution industry. Founded in 2002 by Chairman Cho Sun-hae, Geo-Young has secured 80% of domestic Korean pharmacies as customers by ramping up scale and diversifying its pharmaceutical distribution business.

(Sources: Bloomberg, Company Press Releases, Drug Store News, FiercePharma, Korean Biomedical Review, PharmaPhorum and PR Newswire)