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Drug makers in Asia push hard into biomedicine

WASHINGTON

Advances with generics set stage for trade fight involving care for poor

BY GARDINER HARRIS

Chinese and Indian drug makers have taken over much of the global trade in medicines and now manufacture more than 80 percent of the active ingredients in drugs sold worldwide. But they had never been able to copy the complex and expensive biotech medicines increasingly used to treat cancer, diabetes and other diseases in wealthy nations — until now.

These generic-drug companies say they are on the verge of offering cheaper copies of huge sellers like Herceptin for breast cancer, Avastin for colon cancer, Rituxan for non-Hodgkin's lymphoma and Enbrel for rheumatoid arthritis. Their entry into the market in the next year — made possible by hundreds of millions of dollars invested in biotechnology plants — could not only transform the care of patients in much of the world but also ignite a counterattack by major pharmaceutical companies and diplomats from wealthier countries.

Already, the United States has been trying to stop an effort by poorer nations to strike a new international bargain that would allow them to get around patent rights and import cheaper Indian and Chinese knockoff drugs for cancer and other diseases, as they did to fight AIDS. The debate turns on whether diseases like cancer can be characterized as epidemics.

The debate has intensified in recent weeks, as world leaders prepared to gather at the United Nations on Monday and Tuesday to confront surging deaths from noncommunicable diseases. It is only the second global health issue the U.N. General Assembly has deemed urgent enough to call a meeting to discuss.

Ten years ago, the United Nations tackled the exploding AIDS crisis. Now it will consider an international agenda for cancer, heart disease, diabetes and other chronic diseases that cause about two-thirds of all deaths, according to the World Health Organization. A working draft of the agreement, provided to The New York Times, whose global edition is the International Herald Tribune, bows to wealthy nations' insistence that no explicit reference to "epidemic" be applied to noncommunicable diseases.

Wealthy nations and the pharmaceutical industry agreed 10 years ago to give up patent rights and the profits that come with them in the face of an AIDS pandemic that threatened to depopulate much of Africa, but they see deaths from cancer, diabetes and other noncommunicable diseases as less dire and, in some cases, as the inevitable consequence of better and longer living.

Participants in the negotiations, which include nongovernmental organizations, described the Obama administration's position on the issue and provided e-mail from European diplomats that laid out the U.S. stance.

Officials at the U.S. State Department
DRUGS, PAGE 3

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Advances in generic drugs set stage for trade battle

DRUGS, FROM PAGE 1

and the Office of the U.S. Trade Representative declined to answer directly whether the administration believed that diseases like cancer and diabetes could be called epidemics. On Friday, Mark Toner, a State Department spokesman, said: "Regardless of what you call it, this is clearly such a pressing challenge globally that world leaders are gathering in New York next week to discuss ways to confront this threat."

The U.S. government has a long history of pushing for strong patent protections in international trade and other agreements to protect important domestic industries like pharmaceuticals and ensure continued incentives for further inventions.

The new biotech copycats are likely to stir sharp debate among advocates for the poor. Already, some contend that the billions spent to treat AIDS crowded out cheap and simple solutions to other afflictions of poverty, like childhood diarrhea. The new biotech copycats will be less expensive than the originals, but they will never be cheap. It is unlikely that many African nations will be able to afford such a costly medicine for breast cancer when far cheaper ones for colon and testicular cancer are going wanting.

Dr. Yusuf K. Hamied, chairman of the Indian drug giant Cipla, electrified the global health community a decade ago when he said he could produce cocktails of AIDS medicines for \$1 a day — a small fraction of the price charged by branded pharmaceutical companies. That price has since fallen to 20 cents a day, and more than six million people in the developing world now receive treatment, up from little more than 2,000 in 2001.

Dr. Hamied said by telephone last week that he and a Chinese partner, Bio-Mab, had together invested \$165 million to build plants in India and China to produce at least a dozen biotech medicines. Other Indian companies have also built such plants. Since these medicines are made with genetically engineered bacteria, they must be tested extensively in patients before sale. Dr. Hamied promised to sell the drugs at one-third of their usual prices, which usually run to tens of thousands of dollars for a course of treatment, once the tests are complete.

"And once we recover our costs, our prices will fall further," he said.

Dr. Peter Piot, a former director of the U.N. AIDS agency, said the parallels between the current dilemma over cancer drugs and the one 10 years ago over AIDS medicines were striking.

"Without a major reduction in the prices of the essential oncology drugs, there's no way we can really improve survival from cancer," said Dr. Piot, currently the director of the London School of Hygiene and Tropical Medicine.

But he also said he was more cautious about the promise of generics this time because biotech medicines are not easy to copy. "I believe these medicines will make a huge difference, but I would like to see the evidence that the quality is good before giving it to my patients or taking it myself," he said.

Having suffered global opprobrium 10 years ago when they were seen as blocking efforts to save the lives of millions of poor AIDS patients, executives for branded drug makers are being far more cautious this time about insisting that high prices are necessary. Sara Radcliffe, a spokeswoman for the Biotechnology Industry Organization, said companies supported copycat versions of biotech medicines as long as "countries do not abuse the flexibilities in international law with respect to compulsory licensing in true public health emergencies."

Patents generally give inventors rights to 20 years of exclusive sales, but international law allows countries to issue compulsory licenses of patents to competitors under a variety of circumstances, including to protect public health. There are generally limits to exporting such licensed products, making it difficult for poor countries with little ability to make drugs — particularly biotech drugs — to take advantage of the system. Epidemics loosen those export restrictions.

In retrospect, the battle 10 years ago over AIDS medicines was a skirmish compared with the one likely to erupt over cancer, diabetes and heart disease. The AIDS drug market was never a major moneymaker for global drug giants, while cancer and diabetes drugs are central to the companies' survival.

Roche earns \$19 billion a year, or half its annual drug sales, selling Rituxan, Avastin and Herceptin. And sales of Herceptin have been rising faster in the developing world than in wealthier nations, making the developing world a crucial market.

Mexico alone spends about \$120 million on Herceptin, a figure that represents nearly one-half of 1 percent of all government spending on health care, said Dr. Alejandro Mohar, director general of the National Cancer Institute of Mexico. In 2007, Mexico guaranteed access to Herceptin for all women with breast cancer through a public insurance program.

Hermillia Villegas, a 47-year-old mother of two in Jalisco, Mexico, whose husband is a janitor, recently learned she had a virulent form of breast cancer that responds well to treatment with Herceptin. Her doctor initially told her that each of 17 treatments with Herceptin would cost her more than \$3,000.

"I don't have that kind of money," she said. The new health insurance program, she said, had saved her life.