Federal judge blocks rule lowering drug prices for poor hospitals

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In a little noticed ruling late last month, United States District Judge Rudolph Contreras of Washington, D.C., a recent Obama appointee, threw out a federal regulation requiring giant pharmaceutical companies to discount drugs developed for treatment of rare diseases when those drugs are sold to hospitals that treat primarily low-income patients and are used in the treatment of common ailments.

The effect of the ruling is to squeeze the working class even more on health care costs—reducing the availability of potentially life-prolonging medications—while giving the already gargantuan industry profits another boost.

In 1992, the US government enacted what has become known as "340(B) coverage," which requires drug manufacturers to provide certain medicines at discounts to hospitals treating a large percentage of low-income patients.

The recently enacted Patient Protection and Affordable Care Act, commonly known as Obamacare, significantly expands the hospitals included in 340(B) coverage, while exempting "orphan drugs," which are defined by a 1983 Act of Congress as drugs developed to treat rare conditions—those affecting fewer than 200,000 people in the United States.

The expression "orphan drug" derives from the assertion that were it not for special governmental incentives, private drug companies would ignore medications for rare conditions altogether because their development and sale are not sufficiently profitable absent special treatment.

To implement the expanded 340(B) coverage, the Health and Human Services Department issued a new regulation requiring medications that are classified as orphan drugs to be sold at a 340(B) discount when they are prescribed to treat common disorders.

Prozac (fluoxetine), for example, was developed to treat autism, which makes it an "orphan drug." The medication is also widely prescribed to treat depression, a common disorder. Under the regulation, only Prozac sold for the treatment of autism was exempted from the 340(B) discount.

On May 23, Judge Contreras granted an injunction in favor of the Pharmaceutical Research and Manufacturers of America (PhRMA), a pro-industry group, forbidding discounts to orphan drugs, even when they are sold for treating common conditions, ruling that the Department of Health and Human Services lacked authority to make the regulation.

Thus, low-income hospitals must pay full price for all Prozac sold, even though most is being used for the treatment of a common condition.

According to the friend of the court *amicus curiae* brief filed by Safety Net Hospitals for Pharmaceutical Access, a non-profit corporation representing about 1,000 hospitals that participate in the 340(B) program, pharmaceutical manufacturers manipulate the orphan drug classification to make extra profits.

"One study published in 2010 found that 43 brand name drugs with orphan designations each reached global annual sales of greater than $1 billion," and are "known as 'blockbuster' drugs," according to the amicus brief. "Many of these drugs have an orphan indication," but like Prozac, "are more commonly used for non-orphan indications."

If the regulation is not upheld, the amicus wrote, "Hospital drug costs will increase, leading to reduced services and increased drug costs for patients, and patients will find it more difficult to access certain types of care."

This dispute over "orphan drugs" and "340(B)" discounts underscores the irrationality of leaving health

care in private hands, where decisions are based on raising industry profits and CEO pay rather than meeting the health needs of the population.