From: Antonio Burrell

October 25, 2012

FTC-2012-0068
Robert L. Jones, Deputy Assistant Director,
Premerger Notification Office, Bureau of Competition
Room 302, Federal Trade Commission,
Washington, DC 20580

RE: Comments on Premerger Notification; Reporting and Waiting Period Requirements; HSR IP Rulemaking, Project No. P989316

Dear Mr. Jones,

My name is Antonio Burrell and I am a resident of the Commonwealth of Pennsylvania. I am writing to express my support for the Federal Trade Commission's proposed rule to amend the premerger notification requirements as applied to pharmaceutical companies. As a former insurance agent who sold life and health insurance, I am aware of the difficulty that Americans face in getting access to affordable prescription drugs. During my time as an insurance agent, I primarily sold Medicare Part D prescription drug coverage and life insurance. This experience exposed me to the country's burgeoning senior population and the issues they face with regards to prescription drugs.

It is with these issues in mind that I support the proposed amendment to include the All Commercially Significant Rights Test ("Significant Rights Test") to the premerger notification rules. Ensuring that there is robust competition in the pharmaceutical market is not only a pocketbook issue for many Americans, but a health issue as well. However, while I support the proposed rule I also believe that measures should be taken to ensure that the FTC does not overly pursue the prevention of licensing and acquisitions in the pharmaceutical market. Overzealousness by the FTC can have the opposite effect of expanding competition and consumer choice. Thus, in this comment I will discuss not only the reasons that that proposed amendments should be promulgated, but also some factors the FTC should consider before and after promulgation of the proposed amendment.

My comment will address three issues:

- The implications of the proposed amendment on American consumers;
- The implications the proposed Amendment will have on Medicare Part D; and

- Factors the FTC should take in consideration before and after promulgating the proposed amendment.

I. The Proposed Amendment's Implications On Americans

One of the most talked about issues in the public today is the United States healthcare system. However, when the healthcare system is discussed, it is generally with regards to the public's access to healthcare providers such as doctors and hospitals. What is discussed less often is American's access to quality and affordable prescription drugs. Presumably this is because there is a general consensus that by providing society with better access to healthcare providers there will be less of a societal need for prescription drugs. Many prescription drugs are usually prescribed after a person develops a chronic illness that could have been prevented with better access to medical care. And while this reasoning may be true, the fact remains that many Americans do and will still need affordable prescription drugs for the foreseeable future.

A Center For Disease Control study showed that from years 2005 to 2008 approximately 47% of Americans used some form of prescription drug.[1] Statistics also show that as individuals grow older they are more likely to use prescription drugs.[2] That same study showed that 65% of individuals age 65 and older used some form of prescription drug.[3] This rate of use comes at a substantial cost to Americans. In 2005, the cost of prescription drugs reached $750 per capita.[4] These statistics regarding the utilization and cost of prescription drugs evidence why having affordable and accessible prescription drugs are important economic issues for many Americans. However, this issue does not only affect the pocketbooks of many American families. The costs of these drugs have larger implications on the well being of our nation, people's health is at stake.

There is no doubt that many of the factors that go into the high cost of prescriptions drugs is out of consumer's and the government's control. Many biotechnology, pharmacology, and pharmaceutical companies report billions of dollars in

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[1] Center for Disease Control, Report, Health, United States, 2011: With Special Feature on Socioeconomic Status and Health Pg. 321 (2011), *available at* http://www.cdc.gov/nchs/data/hus/hus11.pdf#099.

[2] Id.

[3] Id.

[4] Steve Morgan and Jae Kennedy, The Commonwealth Fund, Prescription Drug Accessibility and Affordability in the United States and Abroad, Pg. 3 (2010) *available at* http://www.commonwealthfund.org/~/media/Files/Publications/Issue%20Brief/2010/Jun/1408_Morgan_Prescription_drug_accessibility_US_intl_ib.pdf

costs for drug discovery and development.[5] Whether or not these numbers are accurate is up to debate. However, it is fair to assume that, warranted or not, the pharmaceutical industry is using these discovery and developmental cost to justify the astronomical prices that Americans and insurance companies are paying for prescription drugs every year. For this reason, it is very important that the FTC, to the extent that it can, makes sure that the pharmaceutical industry is keeping a check on itself by way of robust competition amongst pharmaceutical companies. By ensuring that pharmaceutical entities are competing with each other with regards to developing, obtaining licensing, and marketing prescription drugs, consumers will benefit from the resulting increased choice and competitive pricing. The Significant Rights Test is a step in that direction and is in the spirit of the Hart-Scott-Rodino Antitrust Improvements Act.

II. Implications The Proposed Amendments Will Have On Medicare Part D

This proposed amendment may have real positive implications for individuals enrolled in Medicare Part D, Medicare's prescription drug program. As a result, this proposed amendment may positively affect many of America's seniors and people with disabilities. While every person on "traditional Medicare" is not enrolled in Medicare Part D, most decide to enroll. Medicare enrollees generally have more health issues than the rest of the population, and as a result, they usually use prescription drugs at a higher rate than the rest of the population. However, while the rate at which Medicare enrollees use prescription drugs affects market consumption and therefore prices, enrollee utilization is not the primary reason the proposed rule will have implications on the prescription drug program. The reason the proposed amendment will likely have an affect on Medicare Part D has less to do with Medicare Part D enrollees and more to do with the way in which Medicare Part D is structured.

When Medicare Part D was authorized in 2003, with the passage of the Medicare Modernization Act, the law prohibited the federal government from negotiating prices for drugs with pharmaceutical companies. This provision in the Medicare Modernization Act took a markedly different approach from Veterans Affairs drug benefit program that does negotiate with pharmaceutical companies. Thus, since 2006, when the prescription drug program was rolled out, the government engages in no negotiations with pharmaceutical companies for the pricing of drugs even though these drugs cost the government billions of dollars.

The government, in prohibiting itself from negotiating prescription drug costs with pharmaceutical companies is remarkable because now pharmaceutical companies have no incentive to keep drugs costs low with respect to Medicare Part D enrollees. The Medicare prescription drug plan in essence guarantees pharmaceutical companies Medicare clientele. Further, this clientele is expected to increase as the baby boomers

[5] Matthew Herper, *The Truly Staggering Costs of Inventing New Drugs*, Forbes Magazine (2012) *available at* http://www.forbes.com/sites/matthewherper/2012/02/10/the-truly-staggering-cost-of-inventing-new-drugs/

continue to age into retirement. However, there are a few boons for American's seniors and the federal government's pocketbook.

First, President Obama has pushed for repeal of the Medicare Modernization Act's prohibition against government negotiation of prescription drug prices. However, this was before passage of Affordable Care Act, he has not discussed it since. President Obama would have to make it part of his agenda once more and then we would likely have to wait until if he reelected to see movement on this issue. Second, even though the government does not negotiate with pharmaceutical companies, the private insurance companies that provide the Medicare prescription drug programs do. While these negotiations keep cost down to some extent, most experts believe that the benefits by way of savings to enrollees and the government are not nearly as substantial as they would be if the government negotiated itself. Lastly, enrollees and the government are somewhat protected by the natural competition in the pharmaceutical market. By ensuring that there is robust competition in the pharmaceutical market, the proposed rule may help Medicare Part D that is otherwise at the mercy of the pharmaceutical industry with regards to pricing for prescription drugs. This would likely save the federal government money and also have the affect of lowing premium, co-pay, and coinsurance costs for Medicare Part D enrollees.

III. The "All Commercial Significant Rights Test" Its Effect On Potentially Reportable

The proposed Significant Rights Test I believe is a small but positive step in the right direction to reigning in the substantial economic costs that average Americans face in the private market. The Significant Rights Test will also help keep down costs that seniors and the federal government face with regards to the Medicare Part D program. However, with that said, I believe the FTC should take a closer look at what implications this proposed amendment will have on not only larger pharmaceutical companies but also smaller pharmacology and biotechnology companies that will also be affected.

It appears that the essence of the All Significance Rights test is to change the premerger notification rules so that licensing transactions in the pharmaceutical industry may now be classified as potentially reportable to FTC's Premerger Notification Office (PNO). I believe the FTC's approach is justified because it appears that many pharmaceutical and biotechnology companies have attempted and succeeded in avoiding reporting transactions to the PNO by opting for licensing deals instead of asset purchases. These companies avoided the PNO even though the licensing transactions are just as likely to reduce competition in the pharmaceutical market. Thus, removing this impediment to being designated potentially reportable is the correct course. However, designating licensing contracts as potentially reportable will not only effect multi-billion dollar pharmaceutical companies, but will also affect the much smaller (and sometimes start-up) biotechnology and pharmacology companies that exist solely for the reason of entering into one of these lucrative deals. Thus, it is important that we consider what affects this change will have on all parties that will be affected.

Broadening the scope of what transactions are "potentially reportable" to the PNO will add transactional and administrative costs to pharmaceutical licensing deals that have never before existed. As a result, companies will have to expend additional money and effort analyzing potential transactions to determine if the transaction moves from "potentially reportable" to actually reportable by engaging in a valuation of the acquisition and determining the size of the parties involved. These additional transaction costs could have the affect of chilling business deals between biotechnology and pharmaceutical companies. How much of a chilling effect there will be is unclear, but there are two scenarios that come to mind:

1. A pharmaceutical company will be reticent to enter into a licensing transaction with a biotechnology company because the pharmaceutical company believes the deal will be challenged by the government; or

2. A biotechnology company will be reticent to enter into a licensing transaction with a pharmaceutical company because it fears that the FTC will allege that the deal with the pharmaceutical company burdens competition and thus should be prevented.

The abovementioned scenarios are not out of the realm of possibility, and may actually occur quite often. Increasing administrative costs and thus lowering economic incentives to enter into pharmaceutical licensing deals may have the strongest impact on: i) smaller more financially unstable biotechnology companies, and ii) pharmaceutical consumers who will probably face decreased choice and increased cost as a result of stronger FTC scrutiny. Further, there are also prospective licensing transactions between biotech and pharmaceutical companies that initially do not meet valuation and size of the person criteria because the actual drugs are still in the developmental process. However, these deals could evolve to a size at which they would have to be reported to the PNO. The current draft of the proposed amendment does not address this phenomenon, and it should be considered.

However, even considering some of these concerns, there does not appear to be any need to change the language of the proposed amendment. Nevertheless, the FTC should consider the abovementioned scenarios as well as the issues surrounding prospective licensing transactions. I suggest that the FTC issue guidelines to assist companies going forward. By providing guidelines, there will be less uncertainty in the pharmaceutical industry, and as a result, less of a chilling effect on pharmaceutical licensing contracts. Further, the FTC should also consider how aggressively it will use this new authority at the outset will set the tone going forward. If the FTC is not overly aggressive in seeking to prevent licensing transactions, parties will be less reticent about entering into these deals. Nevertheless, the FTC must strike a balance and use its new authority when it is warranted.

This proposed amendment, elucidated with proper guidelines, and enforced judiciously, will serve as a proper check on competition without unduly saddling the pharmaceutical industry.

IV. Conclusion

Americans spend exorbitant sums amounts of money on prescription drugs. These costs place a strain on American families. Moreover, the costs of prescription drugs are more than a pocketbook issue, but a health issue as well. The issues of costs and health become of even greater concern in the context of Medicare Part D. With regards to Medicare Part D, the government is prohibited from negotiating with pharmaceutical companies to keep costs down and Medicare enrollees are generally less healthy and use more prescription drugs than the rest of Americans. Under these circumstances, it is even more important to ensure that there is an adequate amount of competition in the pharmaceutical market so as to ensure robust choice and competitive pricing. The proposed Significant Rights Test is a step towards reaching that goal. However, proper guidance and judicious enforcement by the FTC will be key to ensure competition without unduly burdening the pharmaceutical industry.

Sincerely,

Antonio Burrell