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# Norvir: Gouging Medicare on AIDS Drugs

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Under Medicare Part D, people with Medicare and American taxpayers are paying five times the price that Medicaid pays for the HIV/AIDS drug Norvir, a product of Abbott Laboratories. A year's treatment with the drug costs at least $6,326 under Medicare Part D, compared to around $1,230 under Medicaid. An estimated 100,000 number of people with Medicare have HIV/AIDS.[1]

If there is one drug that illustrates why Medicare should negotiate directly with manufacturers for lower prices for Medicare Part D drug coverage, it is Norvir. The role the federal government played in the development of this life-sustaining drug and the manipulation of its price by the patent holder, Abbott Laboratories, demonstrates the urgent need for the full power of the federal government to be used to restrain the power and greed of the pharmaceutical industry.

Norvir (Ritanovir) is a protease inhibitor used in treatments that stem the progression of HIV. It was developed by Abbott Laboratories with the help of $3.5 million in grants from the National Institutes of Health.[2] The drug was approved by the Food and Drug Administration in 1996 after Abbott conducted three relatively small clinical trials lasting less than a year each.[3] Although initially marketed as a standalone protease inhibitor, it is now generally used in conjunction with other protease inhibitors to boost their effectiveness against HIV.

Abbott quickly recouped its investment in Norvir; the drug's use as part of multi-drug regimens generated over $1 billion in revenue for the company.[4] Yet in 2003, the company increased the price for Norvir by 400 percent, raising the per pill cost from $1.71 per 100 mg pill to $8.57 per pill.[5] The price hike was designed to steer customers away from treatments that used Norvir in conjunction with drugs made by Abbott's competitors and toward Kaletra, a new drug Abbott had developed that combines Norvir and other protease inhibitors into one pill.

Abbott denies the price hike for Norvir was designed to make drug regimens including both Norvir and competitors' drugs less competitive, but internal company documents show the price increase was in fact designed to achieve this goal.[6] Before deciding on the price increase, Abbott executives weighed another option: taking Norvir pills off the market and selling only a liquid formulation that would discourage use because it tasted like "vomit."[7] To explain the sudden absence of Norvir pills, Abbott would claim that it needed the pills for humanitarian efforts in Africa, according to internal company documents.[8]

Abbott executives settled on a 400 percent price increase, despite concern that the company would be perceived as a "big, bad, greedy pharmaceutical company."[9] To deflect criticism, the company announced that it would exempt Medicaid and state AIDS Drug Assistance Programs from the price increase.[10] These exemptions, however, were not voluntary. Federal law requires that pharmaceutical companies pay rebates to Medicaid and ADAP that will hold any price increases to the rate of inflation. It would have been illegal for Abbott to try to increase the cost to Medicaid or ADAP programs by 400 percent.

Private insurers, however, bore the full brunt of the price hike for Norvir. And once Medicare Part D started in 2006, the private insurance companies offering Part D prescription drug plans also pay the price increase, contrary to Abbott's claim in the *Wall Street Journal* that Medicare had also been exempted.[11]

Because Medicare is not subject to the price limits that apply to Medicaid and because Medicare is prohibited by law from negotiating directly with drug manufacturers, American taxpayers and people with Medicare pay over five times the price for Norvir that states pay through their Medicaid programs.

- On January 10, 2007, the lowest price for a monthly supply of 60 100 mg Norvir pills, a typical drug regimen, available from a Part D plan in New York City is $527.22 (Humana PDP Standard). That is over five times the $102.60 that Abbott says it will continue to charge Medicaid for the same regimen.

- On January 1, 2006, over 6 million people, including many with HIV/AIDS, were switched from Medicaid drug coverage to Medicare drug coverage, with most of their cost sharing, including the "doughnut hole," covered through the Extra Help program. For an individual receiving drug coverage from Medicaid in 2005, taxpayers paid only $102.60 for a typical Norvir drug regimen. Now taxpayers are paying over five times that amount for the same number of pills.

- The price difference puts a person on a standard HIV treatment in the "doughnut hole," earlier in the year, and adds $400 a month to their out-of-pocket spending during this gap in Part D coverage, when consumers pay the full cost of their medicines.[12]

- The earlier onset of the doughnut hole also raises the costs to Medicare, which pays the private Part D plans for 80 percent of their drug costs during catastrophic coverage (after $3,850 in out-of-pocket spending by the Part D enrollee). Medicare pays for more months of catastrophic coverage and pays more for each pill.

Because Medicare is prohibited under current law from negotiating a lower price from Abbott, it is powerless to prevent this price gouging of both taxpayers and people with Medicare. Legislation (HR 4) now before Congress requiring the Secretary of Health and Human Services to negotiate lower drug prices would correct this artificial imbalance of power.

Norvir is an essential component of treatment regimens that keep many people with HIV/AIDS alive. For this reason, the Centers for Medicare and Medicaid Services rightly requires that all Part D plans cover the drug,[13] effectively eliminating what little leverage the Part D plans have in their negotiations with the manufacturers. If HR 4 becomes law, the federal government likewise could not credibly use the threat not to cover Norvir in any negotiations with Abbott. The drug is too important to the treatment of HIV/AIDS, and, regardless, the bill prohibits the HHS Secretary from establishing a formulary, or list of covered drugs.[14]

But the federal government has other leverage it could use. Specifically, the federal government has the right under the Bayh-Dole Act to override the patent on pharmaceuticals developed with government support when the patent holder fails to make the product publicly available on "reasonable terms," or uses its patent monopoly to disrupt competition in the market place or to endanger public health.[15] Even the threat of such action is likely to force drug manufacturers to the negotiating table. When the U.S. faced a series of Anthrax attacks in 2001, HHS Secretary Tommy Thompson threatened to override the patent on the antibiotic CIPRO, forcing the manufacturer to cut its price by over 75 percent.[16] The federal government should not

remain passive when taxpayers, older adults and people with disabilities are victimized by pharmaceutical companies seeking only to maximize their profits. It should use all the leverage it can bring to bear to negotiate affordable drug prices for taxpayers and people with Medicare.

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[1] "The Role of Part D for People with HIV/AIDS: Coverage and Cost of Antiretrovirals Under Medicare Drug Plans," Kaiser Family Foundation, July 2006. (http://www.kff.org/hivaids/upload/7548.pdf)
[2] "Norvir Patent Under Fire at NIH Meeting," *Windy City Times*, June 2, 2004. (http://www.windycitymediagroup.com/gay/lesbian/news/ARTICLE.php?AID=5142)
[3] "Petition to Use Authority Under Bayh-Dole Act to Promote Access to Ritonavir, Supported by National Institute of Allergy and Infectious Diseases Contract No. AI27220," Essential Inventions, Inc., January 29, 2004. (http://www.essentialinventions.org/legal/norvir/norvir-29jan04petition.pdf)
[4] Ibid.
[5] "Inside Abbott's Tactics To Protect AIDS Drug," *Wall Street Journal*, January 3, 2007. (http://www.post-gazette.com/pg/07003/750966-28.stm)
[6] Ibid.
[7] Ibid.
[8] Ibid.
[9] Ibid.
[10] Comments at NIH Public Meeting Regarding Norvir and Bayh-Dole March-in Provisions, Abbott Laboratories, May 25, 2004. (http://www.essentialinventions.org/drug/nih05252004/leiden.pdf)
[11] Ibid.
[12] Under a common drug regimen that combines 60 100 mg pills of Norvir with Reyataz ($761.48 for 60 150 mg pills) an individual would enter the doughnut hole in March (assuming they are not taking any other drugs). If the price for Norvir were kept at Medicaid rates, with no change to the price for the companion drug Reyataz, the gap in coverage would be delayed until May.
[13] Medicare Modernization Act 2007 Final Guidelines – Formularies, CMS, 2007. (http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/CY07FormularyGuidance.pdf)
[14] 110th Congress, Session 1. H.R.4, Medicare Prescription Drug Price Negotiation Act of 2007.
[15] Ibid.
[16] "Durbin Says Medicare Must Have Authority To Negotiate Drug Prices," Press release from Office of Senator Richard J. Durbin, December 14, 2006. (http://durbin.senate.gov/record.cfm?id=267001&&)