

Senate Special Committee on Aging
Hearing on Generic Drugs
September 21, 2006

Testimony of
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Consumers Union, independent non-profit publisher of Consumer Reports

Mr. Chairman, Members of the Committee:

Thank you for the invitation to testify today. Consumers Union is the independent non-profit publisher of Consumer Reports, and does extensive work on health insurance and costs, quality, and prescription drug issues.¹

For the past three years, Consumers Union/Consumer Reports has been developing its CRBestBuyDrugs.org program, a public information project and free service to everyone. I've attached several sample BestBuyDrug reports. We currently have provided information for 15 different classes of medicine, and will expand that to 20 in the near future. As you can see, it is useful information for all age groups, but especially for seniors who take more prescriptions.

The goals of our project are to:

- improve the quality of care by ensuring people get the safest, effective drugs with the least side effects;
- improve access by helping consumers choose drugs that are most affordable (taking into account effectiveness, side effects, safety, and price); and
- help consumers and taxpayers by reducing the long-range cost burdens of health insurance, Medicare, and Medicaid.

Briefly, we take the objective, unbiased, scientific, publicly-transparent work of the Oregon Health and Science University's Drug Effectiveness Review Project (DERP) and translate their technical reports into plain English. (Mr. Chairman, July 20, 2005 you had an excellent hearing with one of the leaders of that Oregon project that is still the best

¹ Consumers Union is a nonprofit membership organization chartered in 1936 under the laws of the State of New York to provide consumers with information, education and counsel about goods, services, health, and personal finance. Consumers Union's income is solely derived from the sale of Consumer Reports and ConsumerReports.org, its other publications and from noncommercial contributions, grants and fees. In addition to reports on Consumers Union's own product testing, Consumer Reports and ConsumerReports.org, with approximately 6.5 million combined paid circulation, regularly carry articles on health, product safety, marketplace economics and legislative, judicial and regulatory actions that affect consumer welfare. Consumers Union's publications carry no advertising and receive no commercial support.

explanation of the DERP process that I know of.) We then match their findings of safety and effectiveness with recent average prices for the various drugs and come up with recommended Best Buy Drugs. Outside experts (doctors and pharmacists) peer review each of our reports. We update the reports as new science becomes available and prices change.

The Best Buy recommendations are the drugs in a class that would probably be the safest² and most effective at the lowest cost generally for most consumers. But we stress in all our publications that you should consult with your doctor on a case by case basis. This is not cookbook medicine. It is guidance on a conversation-starting place for consumers, doctors, and pharmacists, based on the best science and evidence currently available. While our Best Buy recommendations work for most people, we clearly recognize that different people may on occasion need different drugs that are not Best Buys—and this is particularly true in the mental health sector where many of the drugs do not work consistently well or without serious side effects. That is why Consumers Union has fought for decades to ensure that all HMOs, insurance plans, and Medicare and Medicaid should have effective exceptions and appeals processes. Effective, easy-to-use exceptions policies are a policy priority for Consumers Union.

Sometimes the recommended Best Buy is a brand name drug (like Lipitor as you can see on our Statin enclosure where Lipitor is more successful in achieving effective large reductions in cholesterol). Sometimes the Best Buy drug is a much cheaper generic or over-the-counter (as you can see in our comparison of Nexium versus the OTC Prilosec in the Proton Pump Inhibitor pamphlet, where the overwhelming number of people could save about \$150 by switching to the OTC). In certain cases, e.g., drugs to treat overactive bladder, we passed over the most effective and lowest cost drug due to concerns about side effects. Usually Best Buy Drugs are the lowest cost drugs, but not always.

But obviously, in cases where safety and effectiveness issues are very similar, the Best Buy drug is usually a generic. CMS Administrator McClellan has frequently cited some studies we've done on how, if a senior in consultation with their doctor and pharmacist switched from brand drugs to generics, they could save so much they would not fall into the Part D doughnut. I've attached a press release describing one of our studies in this area. (I note again, the savings can apply to all age brackets, not just seniors.) In this example of 5 drugs that a real senior might easily be taking, they can save \$2300 to \$5300 by switching to generics that are just as safe and effective as the brand drugs.

The doughnut hole is tremendously controversial and we would like to see it eliminated. But until legislation is enacted, using the free tools of the Best Buy Drug program can help many seniors and people with disabilities safely and effectively avoid the gap in coverage.

² It is interesting to note that among the 15 States that use DERP as an aid to the development of their Medicaid preferred drug lists (PDLs), almost all of them avoided the costly mistake of including Vioxx on their PDLs, thus saving thousands of lives and millions of dollars in medical expenses.

Congress needs to do more to make safe generics available

While consumers can do a lot to save money on prescription drugs, most seniors still are not Internet users and are not comfortable with the latest shopping tools. Our nation's level of health literacy is abysmal, and it is hard to get the generic 'word' to people. Even many physicians are suspicious of generics or cannot be bothered with them—a problem that hopefully e-prescribing can help erase. Therefore, we hope Congress can do more to help consumers and doctors have increased understanding and access to generics.

This autumn

We urge you to take a number of steps this fall to promote generics.

First, we hope you will urge CMS to make Part D plans' generic dispense rate (data that is **already** being reported to CMS each quarter) **public** so that enrollees—and groups like Consumer Reports that could rate plans--can see which plans have been best at generally helping people find the better deals while also saving dollars for Medicare.

Second, when the Congress deals with Medicare Part B physician payment problems and/or begins to legislate Pay for Performance (P4P), please include as one performance goal the generic dispense rate. While this is not commonly considered a quality issue, we believe making drugs affordable so people actually can buy them and take them **is** a quality issue. Once e-prescribing is in place, this will be easy to encourage and monitor electronically, and we urge that the groundwork for this consumer service be laid as soon as possible. In general, we hope some prescribing information and best practices will be part of P4P. As just one example, in early January, the FDA issued a press release to consumers, saying that when you see your doctor for a head cold, don't accept a prescription for an antibiotic, because it doesn't work! Why should it be the patient's job, when they are seeing someone they trust and feeling utterly miserable, to resist a doctor's offer of a shot? A good P4P system would not pay for anti-biotics that accompany visits coded for the common head cold.

Also, while we have no reports of problems, it might be a useful oversight function to ask how well the MMA provision 1860D-10(k) is working. This is the provision that requires a PDP to make sure its pharmacy network tells a patient when there is a lower cost generic available under the plan.

In the 110th Congress

We strongly hope that Congress will do more to promote generics, either in the FDA budget or as part of the Prescription Drug User Fee Act #IV (PDUFA) or in the key Chairman Enzi-Senator Kennedy reform bill (S. 3807). Because PDUFA expires September 30, 2007, it is almost certain that there will be major FDA legislation in the 110th. This will be a golden opportunity to:

--institutionalize a system that prevents backlogs in generic approvals from developing;

--ensure that the FDA starts to deal with the backlog of biogeneric approvals (as the Europeans are already doing) and that they continue to resist industry efforts to make biogenerics more difficult to substitute because of name changes; Attached is our previous letter to the Committee on this subject.

--close loopholes in the law that continue to allow brand companies to delay and subvert generic competition. For example, there is the legislation by Senators Stabenow and Lott and Ranking Member Kohl (S.2300) that we hope will be adopted. Among other things, this bill would stop petition-delaying abuses, make sure pediatric exclusivity is only granted for drugs that might actually ever be used by a child, and allow the FDA to override dilatory tactics. Almost daily there are news reports about legalistic abuse of the generic approval process. It seems like some companies are still putting more creative energy into their legal departments to delay generics than they are their drug research departments, and this whole area needs to be tightened up.

--systemize the review of drugs that could be safely moved from prescription status (and the accompanying cost of a doctor's visit) to cheaper, over-the-counter status. For example, if Claritin is okay OTC, why not Allegra (if there are no safety concerns)?

If you revisit the Medicaid program, either as part of the budget process or in reviewing the work of the Leavitt Commission, we hope you can do more to encourage all States to consult with the Oregon Health and Science University's Drug Effectiveness Review Project in the development of their Preferred Drug Lists (PDLs). Currently, 15 States consult the DERP work in establishing their PDLs. All should. It makes no sense for individual states to try to replicate the tremendous work of DERP. We believe that by using the evidence from the DERP work, more States will have better PDLs, ensuring that Medicaid beneficiaries get the best, safest value for the dollar.

In the long run

Someone has said that the 'the whole Medicare prescription drug debate is silly; the real debate should be why the cost of drugs is so high.'

In the long run, we believe that the high cost of drugs could be moderated by better funding and aggressive use of the MMA's Section 1013. This section provides for AHRQ research on outcomes of health care items and services—and would let us pay for those things that work the best. For example, there are many classes of drugs to treat heart disease and high blood pressure, and we spend a lot of time debating the merits of drugs within each class. But which class is best in which circumstances? Today, we look at all drugs and devices like people look at the children of Lake Wobegon—and say they

are all above average. But of course, in reality some are not above average, and we need to identify what works best, when, and for whom. Another way to help this process is to encourage FDA and CMS's cooperation and coordination in CMS's Coverage with Evidence Development (CED) initiatives.

The brand and bio industries resist generics because they end the period of monopoly patent profits. The industries say that promoting generics makes it harder to finance research on breakthrough drugs that will cure mankind's most dreaded diseases. But are there better ways to encourage breakthrough research? We hope you will consider a hearing on innovative ideas that do not rely on patent monopolies/high consumer prices to provide the dollars for truly breakthrough research. While Consumers Union has no position on the following ideas, they are the kind of proposals that could be explored and developed in Congressional hearings. For example,

--some have proposed a prize or rewards system to encourage breakthrough (not me-too) research on key sectors, such as the prevention or cure of Alzheimer's disease. Clearly, it would be worth tens of billions of dollars upfront to Medicare/Medicaid and the public to find a cure for Alzheimer's disease that was also affordable.

--why not use Medicare's buying power to control costs while promoting innovation? One could set up a system where future growth of Part D would be budgeted to grow with population growth, GDP, etc. But if costs exceeded the budgeted amount (perhaps due to relentless direct-to-consumer advertising) companies with products covered by Medicare would owe a rebate to Medicare of the budget overrun amount, but on old product only. If a company had a product certified by the FDA as a new molecular entity or life-saving breakthrough, they would be exempt from the rebate for a number of years. Drug companies would quickly know that the way to grow would be to concentrate on breakthrough products (not just me-toos).

Thank you for your time and your continuing excellent work on these key consumer issues.



Nonprofit Publisher
of Consumer Reports

July 19, 2006

The Honorable Gordon Smith
Chairman, Committee on Aging
United States Senate
Washington, DC 20510

Dear Chairman Smith:

As the Senate Committee on Aging studies the issue of generic drugs, Consumers Union, the independent, non-profit publisher of *Consumer Reports*, hopes you will consider the topic of generic biologics, otherwise known as biogenerics or follow-on protein products. In particular, we urge you to guide the FDA to promptly establish a pathway for the approval of safe biogenerics.

As the last twenty-five years have shown, biologics are amazing drugs. These medicines, which are molecules derived from living organisms and not just chemicals, provide treatments for conditions ranging from growth abnormalities to cancer. They are revolutionary and their contribution to medicine will only continue to increase.

Nevertheless, the financial burden that biologics pose to the American consumer and the federal government through its Medicare Part D prescription drug benefit and the Medicaid program cannot be underestimated. Biologics routinely cost upwards of \$10,000 for a year's treatment.³ Less common treatments, such as Avastin, a colon cancer therapy, cost as much as \$49,000 for a ten month course.⁴ These financial costs may be moderated, though, through biogenerics. With an estimated \$10 billion worth of these drugs coming off patent by 2011, there is a great opportunity to use generics to reduce the cost of biologics for the consumer and the government.⁵

Much of the delay on biogenerics is attributed to safety concerns. Given their highly specific allergic profiles, biologics pose a greater danger for adverse reactions in patients than do standard chemical drugs. These concerns can be addressed if biogenerics are subject to extensive non-clinical and limited clinical trials. Indeed, such an approach has been adopted in Europe, where, just this year, the European Medicines' agency (EMA) released comprehensive guidelines for the approval and regulation of biogenerics. The European approach has been simple. First, they released a general, overarching guideline that specifies the kinds of non-clinical and clinical trials that all protein products would

³ Statement of Senator Orrin Hatch on June 23, 2004. Hearing entitled, "The Law of Biologic Medicine."

⁴ "The Growth of Generic Drugs." 31 Jan. 2006. *Red Herring*. 5 July 2006. <<http://www.redherring.com/>>

⁵ "FDA Looks at Biogeneric Issue, but Action Unlikely in Near Term." 10 Nov. 2004. *Specialty Pharmacy News*. 10 July 2006. <<http://www.aishealth.com/DrugCosts/specialty/SPNFDABiogeneric.html>>

need to undergo to demonstrate efficacy and safety.⁶ Second, they have been progressively releasing additional product-specific amendments that give detailed criteria for testing and approval. For example, in February of this year, the agency adopted an annex guideline on human growth hormone⁷ and a month later, one on epoetin.⁸ The agency plans to release additional guidelines about other classes of drugs.

In contrast, no abbreviated biogenerics' approval pathway has been put in place in the United States. While the FDA has conceded that the simple biologics regulated under the Federal Food, Drug, and Cosmetic act (FDCA), such as growth hormone and epoetin, can be approved, it has offered no guidance about how generic versions of such drugs should be manufactured and tested. Additionally, the agency has argued that it has no legal authority to create a similar pathway for the majority of biologic drugs, which are regulated under the Public Health Service (PHS) Act. As the FDA will not act on the topic of biogenerics without Congressional guidance, it is imperative that Congress provide direction on this issue.⁹

Consumers Union is deeply committed to protecting the consumers' health, well-being, and finances. The European Medicines' Agency's example offers compelling evidence that safe, cost-saving biogenerics can be made. We hope that you and the Committee on Aging will take timely action and prompt the FDA to establish a timeline for releasing guidelines for the approval and regulation of biogenerics.

Thank you for your consideration of this point.

Sincerely,

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Anuradha Phadke
Staff Assistant

⁶ [EMEA/CHMP/42832/05](#) Guideline on Similar Biological Medicinal Products Containing Biotechnology-Derived Proteins As Active Substances: Non-clinical and Clinical Issues. (CHMP adopted February 2006).

⁷ [EMEA/CHMP/94528/05](#) Annex Guideline on Similar Biological Medicinal Products containing Biotechnology-Derived Proteins as Active Substance: Non-Clinical and Clinical Issues - Guidance on Similar Medicinal Products containing Somatropin (CHMP adopted February 2006).

⁸ [EMEA/CHMP/94526/05](#) Annex Guideline on Similar Biological Medicinal Products containing Biotechnology-Derived Proteins as Active Substance: Non-Clinical and Clinical Issues - Guidance on Similar Medicinal Products containing Recombinant Erythropoietins (CHMP adopted March 2006).

⁹ "Omnitrope (somatropin [rDNA origin]): Questions and Answers." 30 May 2006. *US Food and Drug Administration*. 6 July 2006. <<http://www.fda.gov/cder/drug/infopage/somatropin/qa.htm>>