

Testimony of
Mr. Carlos Angulo

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Testimony of Carlos Angulo, Partner, Zuckerman Spaeder LLP,
On Behalf of the Coalition for a Competitive Pharmaceutical Market
Before a Joint Hearing of the Senate Health, Education, Labor and Pension Committee
And the Senate Judiciary Committee
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Good morning Chairman Hatch and Ranking Member Leahy, Chairman Gregg and Ranking Member Kennedy, and distinguished Members of the Committees. My name is Carlos Angulo and I am here to testify on behalf of CCPM, the Coalition for a Competitive Pharmaceutical Market, on S. 666, the Biological, Chemical, and Radiological Weapons Act. I want first to express my appreciation to the Committees for the opportunity to express the Coalition's views on this important bill.

CCPM is an organization of employers, insurers, generic drug manufacturers and others committed to improving consumer access to affordable pharmaceuticals and promoting a vigorous, competitive prescription drug market. CCPM supports public policies that facilitate timely access to affordable pharmaceuticals. The Coalition, of course, also is committed to assisting federal, state, and local governments and the American people in their efforts to develop quick, effective, and accessible responses to bioterrorism.

The Coalition's membership is broad and diverse, and includes numerous prominent purchasers of pharmaceuticals, such as General Motors Corporation, Caterpillar, Inc., Eastman Kodak Company, and Delphi Corporation. On behalf of the Coalition, I would like to share with the Committees today our experience regarding prescription drug cost increases and to underscore our belief that in its current form, S. 666 would dramatically delay generic drugs from coming to market and cause a crippling increase in prescription costs for America's employers, health plans, and consumers.

Impact of Unsustainable Prescription Drug Costs

By way of background, large and small businesses, consumers, unions, governors, the federal government and health plans throughout the nation are aggressively attempting to manage soaring prescription drug costs. These expenditures are growing at annual rates of up to 20 percent and are unsustainable. Current pharmaceutical cost trends are increasing premiums, raising co-payments, pressuring reductions in benefits, and undermining the ability of businesses to compete. CCPM members seeking to continue to provide prescription drug coverage to employees and subscribers face a tremendous challenge in light of these skyrocketing pharmaceutical costs. Coalition for a Competitive Pharmaceutical Market ? 202-626-4796 ? competitiveRx.com

For example, General Motors--the largest private provider of health care coverage in the nation, insuring over 1.1 million workers, retirees, and their families--spent over \$1.3 billion last year on prescription drugs. Despite GM's use of state of the art management techniques that assure the most appropriate and cost-effective use of prescription drugs, its pharmaceutical bill continues to grow at a rate of 12 percent to 16 percent a year--more than quadrupling the general inflation rate.

Similarly, Eastman Kodak Company, which insures 150,000 covered lives, spends 31 percent of its health care dollars on prescription drugs. Kodak spent roughly \$99 million on drugs in 2003 and costs are growing each year.

The experience of insurers is no different. The 41 Blue Cross and Blue Shield Plans that collectively provide health care coverage for 91 million Americans, represented in CCPM by the Blue Cross and Blue Shield Association (BCBSA), are continuing to experience increases in prescription drug costs. The BCBS Federal Employee Program, for example, had drug increases over the last year of 9.67 percent. BCBSA expects these costs to continue to grow, exacerbating the difficulty of providing a meaningful level of coverage for prescription drugs while keeping premiums as affordable as possible. Such drug cost increases are driven by multiple factors, including higher utilization, direct-to-consumer advertisements, drug price increases, and, especially, delayed generic competition.

If S. 666 passes in its current form, these costs will escalate dramatically and America will have a health care bill it cannot afford to pay.

The Coalition Supports Policies to Strengthen the Nation's Defense Against Bioterrorism CCPM strongly supports legislation aimed at improving our ability to respond to terrorist uses of chemical or biological weapons. There can be no denying that the events of September 11 forever changed the way in which we live and work. Today, we recognize that in order to protect our employees, our families, and our friends, we must be prepared for every type of situation.

For this reason, we wholly support the goals of the Project BioShield Act of 2004, or "BioShield I," which went into effect just this summer. We also recognize that the effort to prepare our nation against terrorist threats should include incentives to stimulate the development and production of drugs and other counter measures, and therefore, we support certain provisions of S. 666, such as the provisions for tax credits, fast-track Food and Drug Administration (FDA) review of applications for countermeasures, protection against product liability suits, and the creation of a Terror Weapon Countermeasures Purchase Fund.

CCPM Believes that S. 666 Will Dramatically and Unnecessarily Increase Health Costs It is also clear, however, that the goal of encouraging a response to bioterrorism must be balanced against the overall costs to American consumers and an already overburdened health care system. Unfortunately, as currently drafted, S. 666 has many unnecessary provisions that will increase costs without significantly benefiting the anti-terrorism effort. Specifically, there are four provisions in the legislation that would seriously hinder employers' ability to provide affordable health care to their employees; dramatically increase prescription drug costs nationwide, without

significant benefit to the anti-terrorism goals of the bill; and in fact, deny public access to affordable versions of the countermeasure products that the bill seeks to make available to the American public First, S. 666's "wild card" exclusivity provision, found in Section 5(d)(1) of the bill, would give brand pharmaceutical companies a broad mandate to extend a patent for two years on virtually any drug they choose, even if it is completely unrelated to terrorism. This extension of brand company monopolies would force consumers and employers to pay billions of dollars in prescription drug costs beyond what they would pay if generic drugs were permitted to enter the market as provided under current law, without significantly advancing any anti-terrorism goals.

Today, drugs that have sales in excess of \$2 billion per year are not uncommon. Yet when the patents and other exclusivities on those drugs expire and generic competition begins, the price typically drops between 75% and 90% within a matter of months. Thus, the cost of this provision for a single drug could be in the billions of dollars.

Second, Section 5(f) of S. 666 expands by up to seven years the non-patent statutory exclusivity periods for countermeasures. This change dramatically alters the careful policy balance struck by Congress under the 1984 Hatch-Waxman Act and last year's amendments to that legislation, which sought to provide incentives for innovation while at the same time ensuring swift public access to affordable drug products. S. 666 alters this delicate balance by extending broadly--in certain cases, by over 100%--brand company monopolies at the expense of consumer access to generic drugs.

Third, Section 5(c) of S. 666 would provide patent extensions for the full period taken to complete regulatory review for countermeasures. In certain cases, this provision could go so far as to reinstate patents on drugs that have been off patent, forcing generic alternatives off the market. By denying consumers timely access to more affordable medications--or forcing them off the market altogether--this bill only exacerbates the problems of unsustainable health care costs and the growing number of uninsured Americans.

Fourth, Section 5(f) of S. 666 penalizes the generic industry for merely following the law in submitting generic applications with required patent certifications by providing that a generic company that submits such an application for a generic version of a countermeasure must wait an additional five years for FDA approval beyond what is required under current law. This provision in effect penalizes generic companies for merely attempting to enter the market--contradicting the very intent of the Hatch-Waxman Act.

In short, each of these four provisions of S. 666, standing alone, could cost America's employers, insurers, and consumers billions of dollars, without substantially assisting in the antiterrorism cause. As innovators, patent-holders and competitors in the world market, CCPM members respect the integrity and value of intellectual property protection. However, we oppose practices that detract from true innovation and new product development and merely serve to preserve old innovations and to expand existing monopolies.

Congress has at one time or another expressly declined to enact into law each of the four provisions discussed above, either during the deliberations leading up to enactment of BioShield I or during passage of other pharmaceutical bills.

Lawmakers rightly determined that each of these provisions seriously distorted the balance between encouraging innovation and keeping health care costs in line. If any one of these provisions were to pass as part of S. 666, it would impose enormous costs on the health care industry. Taken together, the costs imposed by these provisions are unsustainable.

Instead of moving forward with S. 666 as currently drafted, we would encourage the Committees to consider limiting any extension of BioShield I to include provisions such as product liability protections, "fast track" review of countermeasures by the FDA, and incentives in the form of tax credits and public funding. Each of these provisions advances the antiterrorism goals of the earlier legislation without unduly burdening the health care system.

Conclusion

Every day, the choice of generic products creates substantial savings for consumers; as much as 70 percent to 80 percent when compared to the brand product, resulting in savings of more than \$10 billion dollars a year in savings for consumers, employers, insurers, and taxpayers, as well as state and federal governments. Generic drugs play an indispensable role in the search for answers about how to decrease health care costs, while increasing access to important medicines and assuring health care coverage availability. However, S. 666 as currently drafted would dramatically limit Americans' access to affordable drug choices and lead to increased premiums, higher co-payments, fewer health benefits, and reduced access to quality care--particularly for the uninsured and poorly insured.

In these uncertain times, encouraging the development of drugs as countermeasures is a laudable goal. We are looking forward to working with Senate leaders to further enhance BioShield I, while avoiding the adverse effects of S. 666 to healthcare providers, employees, retirees, workers, patients, and the uninsured.

Thank you for allowing me to testify today. I welcome any questions from the Committees.