

Statement of
The Honorable Patrick Leahy

United States Senator
Vermont
October 6, 2004

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"BioShield II: Responding to An Ever-Changing Threat"
Joint Hearing of the Senate Judiciary Committee
And the Senate Health, Education, Labor and Pensions Committee
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Mr. Chairman, the focus of today's joint hearing with the Health, Education, Labor and Pensions Committee is an important one. In our increasingly uncertain world, the American people deserve assurance that government and industry are doing all that they can to protect their health and well-being. But this morning, the answer to that question is far from clear.

As we meet today to discuss how to prepare our nation for the dire possibility of a catastrophic bioterrorist attack, the likes of which I hope we will never see, we learn that we are not prepared to meet the biological threat that comes every year -- influenza.

I had hoped that the Bush Administration would have learned their lesson from last year's experience with flu vaccine shortages. Instead, we see health officials across the country, including in my home state of Vermont, asking healthy people to forgo their flu shot. I think the American people deserve an answer from the Bush Administration as to why it had not planned and prepared better. If they can not be prepared for the seasonal flu - an annual occurrence -- what does that portend about their ability to prepare for biological terrorist attacks?

One of the primary problems with the flu vaccine that is highlighted by the Administration's inability to ensure sufficient supply appears to be the concentration of producers. This market concentration is something that the government can control. The brand pharmaceutical industry is too concentrated and they fiercely lobby to extend their patents to prevent generic pharmaceuticals from giving consumers more affordable medicine.

Our constituents and members of Congress need to ask why this country is so dependent on just two suppliers of this important vaccine. With all the pharmaceutical suppliers in this country, why is our government relying on a foreign supplier which has just been put out of business by the British government.

I would hope the big brand pharmaceutical companies would demonstrate their capability to respond to this crisis by answering the call of this flu vaccine problem rather than pushing for patent extensions and windfall profits. We must address the potential crisis and make agreements

to license and produce the vaccine the world needs now. We must not find ourselves in this position again.

I understand personally the pressing need to develop treatments for deadly biological, radiological and chemical agents that could potentially be used as instruments of terror - I was the target of an anthrax-laced letter in 2001. Although the strain of anthrax sent through the mail to me, Senator Daschle, and others could effectively be treated with existing antibiotics, effective countermeasures currently exist for very few of the most dangerous potential biological, radiological and chemical threats.

I am pleased that Congress took action this year to enact the Project BioShield Act of 2004. I commend Senator Kennedy for his leadership in that effort. Under that bill, Congress approved streamlined procedures for bioterrorism-related federal procurement, research funding, and hiring needs. We guaranteed that the federal government would purchase new countermeasures through an advance appropriation of \$5.593 billion over the next 10 years and we established the authority for emergency use of as yet unapproved countermeasures. These are all common-sense incentives to provide for the development and delivery of new countermeasures to the American people.

Today we are examining the question whether further action on the part of Congress is needed to fulfill the original goals of Project BioShield, with a particular focus on legislation introduced last year by Chairman Hatch and Senator Lieberman. The Biological, Chemical, and Radiological Weapons Countermeasures Research Act of 2003 (S.666) proposes a vast list of intellectual property, antitrust, liability and tax giveaways to provide the pharmaceutical and biotechnology industries with further incentive for the development of new countermeasures.

I have serious concerns about the wide-ranging consequences of this bill. It strikes me as giving everything but the kitchen sink away to the brand pharmaceutical industry. Its sweeping scope threatens to dismantle the careful balance of intellectual property rights struck with the Hatch-Waxman Act, and to roll back the gains made in recent years to lift the barriers preventing affordable generic drugs from reaching the market under the Schumer-McCain Greater Access to Affordable Pharmaceuticals Act.

The definition of "countermeasure" under S. 666 is so broad as to likely affect the patent life and terms of market exclusivity on virtually all current and new pharmaceutical products, not just those identified by the Secretary of Health and Human Services to be essential for the protection of the American public. Such a broad extension of patent life and market exclusivity will amount to billions of dollars in lost savings to the purchasers of prescription drugs in this country - most notably would be the Medicare and Medicaid programs. Similarly, this open-ended definition seems to expand the provisions of the bill providing the pharmaceutical industry with immunity from liability.

Despite its many gifts to brand pharmaceuticals, this legislation does not assure the American public that an actual product will be delivered to the federal government for stockpiling and eventual use in a case of emergency. Should it become clear that further incentives beyond the Project BioShield Act of 2004 are truly needed to provide for the safety of the American people against bioterror threats, I am hopeful that we can address the matter with circumscription,

striking a careful balance between encouraging development of much-needed new countermeasures and encouraging development of a pharmaceutical market that is fair to the American consumer. I look forward to hearing the testimony of our witnesses.