EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

July 18, 2002
(Senate)

STATEMENT OF ADMINISTRATION POLICY

(THIS STATEMENT HAS BEEN COORDINATED BY OMB WITH THE CONCERNED AGENCIES.)

S. 812 - Greater Access to Affordable Pharmaceuticals Act
(Sen. Schumer (D) NY and 11 cosponsors)

The Administration strongly supports reducing drug costs for seniors and other persons with disabilities quickly. For this reason, the Administration urges rapid action by the Senate Finance Committee and the Senate to pass bipartisan legislation to provide overdue prescription drug coverage and other essential improvements in Medicare benefits.

The Administration is disappointed, however, that the Senate has chosen to use S. 812 as a vehicle for bypassing the usual Senate process for deliberation on an issue as momentous as affordable drug coverage for seniors. The Administration supports steps to encourage fair competition and appropriate use of generic drugs and recognizes that some adjustments to current law would improve the fair entry of generic substitutes into the market and prevent future abuses of the patent laws, which can and do occur today. However, the Administration opposes S. 812 in its current form because it will not provide lower drug prices. S. 812 would unnecessarily encourage litigation around the initial approval of new drugs and would complicate the process of filing and protecting patents on new drugs. The resulting higher costs and delays in making new drugs available will reduce access to new breakthrough drugs. Moreover, this new cause of action is not necessary to address patent process abuses. Clearly, the bill would benefit from consideration by the Senate=s experts on Hatch-Waxman law on the Judiciary Committee, the proper committee of jurisdiction for this bill.

Prescription Drug and Medicare Related Amendments

Legislation to provide prescription drug coverage, lower drug costs, and improve the Medicare program deserves immediate markup in the Finance Committee followed by referral to the full Senate for action. S. 2, the Twenty-First Century Medicare Act, is an example of a Medicare drug benefit proposal that would provide far more substantial relief for seniors than generic drug legislation. The Administration commends Senators Grassley, Snowe, Breaux, Jeffords, Landrieu and Hatch for working across party lines to provide effective drug coverage for seniors. The Administration supports a Medicare drug benefit that protects seniors against high expenses, allows them to choose a plan that provides the drug coverage they and their doctors prefer, and provides them with access to lower prices. Employers, unions, private plans, and other sources provide some prescription drug coverage to almost three-fourths of Medicare beneficiaries today and the Administration believes that a Medicare drug benefit should strengthen and complement these private sources of coverage, not replace them with

an expensive government program. Most importantly, the Medicare drug benefit should continue to encourage the life-saving and life-improving innovation in prescription drugs that holds so much promise for improving the health of seniors in the twenty-first century. S. 2 reflects these principles.

The Administration supports other features of S. 2. The bill takes a step toward fair and effective competition in the Medicare program. The bill also gives seniors the option of a more rational and up-to-date Medicare benefit package, which provides free preventive care, better protection against high expenses, and more affordable coverage. In addition, in contrast to other Medicare bills, S. 2 appropriately targets all new spending to improving Medicare's benefits for seniors.

The Administration urges further improvements in Medicare legislation to make the program more efficient and secure for the Baby Boom generation while increasing value for seniors today. These improvements include providing seniors with: a wide range of choice options and further steps toward effective competition that saves money for beneficiaries in the Medicare program in the years ahead; a more efficient improved benefit option in the traditional medicare plan; and, competitive bidding for more products and services in the traditional Medicare plan. The Administration also supports allowing current beneficiaries to have the option of continuing their existing Medicare benefits exactly as they are now.

If additional, sensible steps like these to improve Medicare cannot be enacted, then it is important to consider alternative, less costly drug benefit proposals that put a comprehensive drug benefit in place for beneficiaries with limited means and protect all beneficiaries against high expenses. The Administration commends Senators Hagel, Ensign, Gramm, Lugar and Inhofe for developing a more sustainable drug benefit proposal. S. 2736, the Medicare Rx Drug Discount and Security Act, represents an important first step toward bringing the Medicare program up to date.

The Administration opposes S. 2625, the Graham-Daschle-Kennedy-Miller bill. This bill would require seniors to purchase government-controlled drug coverage with few or no choices, with the government having unprecedented control over which drugs seniors do not have access to. Not only is the flat-rate drug benefit an untested benefit design which will prevent seniors from sharing in the savings of choosing less costly drugs, but it will also eliminate virtually all incentives for the drug benefit plans to keep their costs down. As the Congressional Budget Office (CBO) has noted, this kind of drug benefit will actually increase drug prices, especially on the drugs that seniors use most. This benefit design will also make it difficult for existing employer plans and other private plans to qualify for subsidies, resulting in millions of seniors having no choice but to join the new government plan in order to get subsidized coverage. Because of higher drug prices and a widespread replacement of private drug financing, hundreds of billions of dollars in new spending under the bill would simply go toward purchasing the drugs that are currently financed through existing private coverage.

As a recent Health and Human Services report concluded, all countries that have adopted government-controlled drug coverage use delays, restrictions, and denials of new drug coverage to control costs. This bill would impose similar burdens on seniors in the United States. For example, seniors may have no choice other than joining their State Medicaid drug plan, or joining a single plan controlled by the

Federal government. Now is not the time to restrict access to life-saving breakthrough treatments through a one-size-fits-all, government-controlled drug benefit.

Further, the supporters of the Graham-Daschle-Kennedy-Miller proposal have not proposed any way to pay for the bill=s unsustainable costs. In fact, the drug benefit is a temporary proposal that ends in 2010, only seven years or less after it is implemented. (Even though the bill is scheduled to go into effect in 2003, independent experts have noted that such a major government run drug benefit program could not possibly be implemented until at least 2005.) The cost of making this drug benefit permanent would require cutting all other government programs by more than 10 percent, draining the Medicare Trust Fund by 2019 or earlier (if only half of the costs of the benefit are paid for by using Part A surpluses), or increasing taxes on all working Americans by an amount equal to a 1 to 2 percentage point, or greater, increase in the payroll tax. These tax increases would be equivalent to a tax of around $1,500 in today=s dollars on every working American in 2025. The President believes that a Medicare drug benefit should be a permanent and secure part of Medicare; this proposal is neither.

Further, the bill does nothing to improve existing Medicare benefits, which are out of date and inadequate for seniors. For example, the bill provides no stop-loss protection for non-pharmaceutical medical expenses so that even with this costly benefit, seniors still would not have financial security in the event of a major illness. In addition, the bill does nothing to correct the years of unfair and inadequate payment updates to the private Medicare+Choice depended on by over 5 million seniors, especially those with limited means or from minority groups.

Finally, the Administration understands that the Graham-Daschle-Kennedy-Miller bill may have provisions providing billions of dollars in additional payments to providers. These provisions would add to an already unsustainable financing burden, as well as take away funds that are badly needed to provide better drug coverage and other benefit improvements. The Administration supports improvements in provider payment rules to address unexpected reductions, such as those facing physicians. Under current law, provider payments are scheduled to increase by over 5 percent per year, and this amount is sufficient to provide adequate reimbursement for all Medicare providers. Higher priorities for new health care spending should be addressed before spending more money on providers, including improving Medicare coverage, reducing the uninsured, and making health care more affordable for all Americans.

While passage of a bipartisan bill to provide permanent prescription drug coverage is clearly the most important action needed by the Senate now, the Administration urges the Senate to act on effective proposals to lower drug costs for seniors immediately. These proposals are needed because a full drug benefit will take several years to implement. The President has proposed a Medicare-endorsed prescription drug card to give seniors the ability to use bulk purchasing to negotiate lower prices from drug manufacturers. The President supports additional payments for Medicare+Choice plans that keep up with Medicare cost increases, so that seniors can have wider access to modern benefits like drug coverage, and to services to help them avoid disease complications and costly medical care. The President also supports additional Medigap options to provide more affordable drug coverage. Moreover, the President has proposed immediate Federal funding to provide prescription drug assistance for seniors who can least afford drugs and do not have coverage now, through the Medicare

drug card or existing State programs. Combined with the APharmacy Plus@ wavier program that the President implemented this year, these proposals would allow up to 5 million seniors who do not have drug coverage now to get help before the full drug benefit is available. All of these measures have passed the House, and the Administration urges Senate passage quickly.

Drug Reimportation Amendment

Amendments related to drug reimportation have also been offered to S. 812. While the Administration supports measures to reduce drug costs for seniors, the Administration is concerned that these amendments will compromise drug safety. The Secretary of Health and Human Services believes that the drug reimportation proposals introduced this year and in previous years would create unacceptable risks of adulterated, outdated, mislabeled, or otherwise unsafe medications. This same view was also shared by the Secretary of Health and Human Services in the previous Administration. The Dorgan reimportation scheme related to Canadian imports only runs the risk of transshipment and adulteration, because the FDA cannot guarantee the safety of such imported drugs. In addition, this reimportation proposal does not provide for the substantial costs of administering the extensive new tracking, inspection, and testing processes for reimported drugs. The Customs Service and FDA officials are already facing substantial new responsibilities for maintaining the safety and security of legal imports; this is not the time to add immensely to that burden, especially when the public health is at risk.

Pay-As-You-Go Scoring

Any law that would reduce receipts or increase direct spending is subject to the PAYGO requirements of the Balanced Budget and Emergency Deficit Control Act and could cause a sequester of mandatory programs in any fiscal year through 2006. The requirement to score PAYGO costs expires on September 30, 2002, and there are no discretionary caps beyond 2002. Although S. 812 is not subject to PAYGO scoring, many of the amendments that may be considered by the Senate related to Medicare reform and a prescription drug plan would increase direct spending over the next ten years. The Administration will work with Congress to ensure fiscal discipline consistent with the President=s Budget and a quick return to a balanced budget. The Administration also will work with Congress to ensure that any unintended sequester of spending does not occur.

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