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Medicare Reform Must Precede A Prescription Drug Benefit:

Testimony of Mitchell E. Daniels, Jr., Senior Vice President Of Corporate Strategy and Policy, Eli Lilly and Company before the

U.S. Senate's Special Committee on Aging Washington, D.C.
Tuesday, February 8, 2000

Usually the Independence Institute only publishes documents written by Independence Institute authors. We made an exception here because this material is an excellent explanation of the tremendous public health problems that would be created by President Clinton's proposal for price controls on prescription medicines. Thus, even though we have no position on the author's proposal to expand Medicare to include out-patients, we think that the author's description of disaster that price caps would create is very much worth reading.

Testimony of Mitchell E. Daniels, Jr., Senior Vice-President of Corporate Strategy and Policy, Eli Lilly and Company, before the Special Committee on Aging of the U.S. Senate, Room 562, Dirksen Senate Office Building, Washington, D.C., 9:30 a.m., Tuesday, Feb. 8, 2000:

Thank you, Mr. Chairman and Senator Breaux, for your invitation to be part of this forum. I wish to commend the Committee for engaging in these critically important issues.

Your decisions about the future of Medicare and the addition of a prescription drug benefit will affect millions of Americans.

We at Eli Lilly and Company applaud Senator Breaux's efforts to bring the outdated Medicare program into the twenty-first century. A great deal has changed since Lyndon Johnson signed Medicare into law 35 years ago, and the challenge is immense.

Our basic goal, however, is relatively simple: we must focus on the best interests of the patient. While tremendous strides have been made in medical technology over the past 30 years, comparable progress has not been made in the Medicare benefit structure. When Medicare began in the 1960s, pharmaceutical cures were the exception, not the rule. Long hospital stays were much more common, and outpatient surgery was generally unimaginable. Many conditions easily managed today were largely untreatable then. Preventive care was virtually nonexistent.

Medical advances of all kinds have allowed seniors to live significantly longer and healthier lives. Yet, as dramatic as these advances have been, we are on the brink of new discoveries that will bring even greater benefits. Fueled by advances in our understanding of the life sciences, these discoveries will dramatically improve doctors' abilities to prevent illness and to heal and comfort those who suffer. It is imperative that we have in place a system that provides the benefit of these discoveries to the patients who need them.

If Congress were enacting Medicare anew today, the program would bear no resemblance to its current form. Medicare was designed to guarantee quality health care for our senior citizens, but it is now disconnected, uncoordinated, inadequate, expensive, and unresponsive. The program has numerous design flaws and perverse incentives that would be unthinkable to someone designing a modern-day health plan. And Medicare beneficiaries suffer as a result.

In many ways, Medicare fails seniors when they need protection the most. It does not include catastrophic coverage, hospital coverage decreases with length of stay, there are no long-term care benefits, it does not pay for most preventive care and its cost-sharing requirements are disjointed. And the first dollar coverage provided by supplemental insurance creates incentives for seniors to utilize care inappropriately. The claims review and appeals process for denied claims is interminable — 524 days on average — and its regulatory burden is absurd. Unbelievably, Medicare's rules and regulations are more voluminous than the tax code and pervade every sector of the medical system. For Medicare providers, innovation, efficiency, and quality are discouraged. Mastering the bureaucratic system is the more essential skill.

One glaring deficiency is the lack of coverage for outpatient prescription drugs. Pharmaceuticals play a central role in the modern-day practice of medicine. With the promise of future discoveries clearly in sight, pharmaceuticals may soon become the single most necessary component of health care, especially for seniors. Indeed, they may already be.

Medicare's lack of prescription drug coverage is bad health care, bad public policy, and, apparently, bad politics. The absence of coverage for prescription drugs often creates perverse incentives that favor more costly and invasive treatments. While many seniors have prescription drug coverage from other sources, for some the financial burden of paying for their medicines is significant. This issue presents a significant challenge to both government and industry: we must find a way to ensure access for all our citizens to the breakthrough medicines that enhance and extend life, while at the same time maintaining today's momentum and American leadership in the discovery and development of new cures.

At its very core, Medicare is a government-run health system that relies on the failed strategy of bureaucratic controls instead of private competition. Despite all its rules and price controls, the program is moving toward bankruptcy. Although our currently robust economy may give the system some breathing room, simply adding additional benefits to the existing program without other basic reforms will only accelerate its financial demise and perpetuate a structure that impedes quality, efficiency, coordination, and innovation. Because of its complexity and controversy, we cannot wait until the last minute to shape the solutions.

In light of this urgent agenda for reform, we believe the reinvention of Medicare should be guided by our national experience over the past 35 years:

We should pursue a comprehensive solution that addresses seniors' total health care needs.

We should approach health care not piece by piece, but as an integrated whole that helps us learn what improves quality, communication, and convenience, what provides the best results for patients, and what delivers the best economic value.

We should offer seniors choices of health plans that best fit their particular needs.

We should stress competition – which fosters innovation and quality. And, above all, we must prevent any possibility of government-imposed price controls that delay and deny care for today's patients – and impede innovation for tomorrow's patients. Price controls would derail medical progress and, insidiously, we would never know what miracles we had missed.

Eli Lilly and Company strongly supports the establishment of an outpatient drug benefit within Medicare. To succeed, however, it must be enacted as part of comprehensive reform and be based on competition among private sector options where beneficiaries can choose the plan they want. We believe that coverage must be provided through market-based insurance that spreads and shares the costs, not through government-imposed price controls, which are doomed to fail to meet any of the key policy goals. In addition, drug coverage must be integrated so that choices are made with the right incentives in mind, beginning with what is best for the patient. A market-based system can ensure a fiscally sound Medicare program that provides seniors the care they need now and in the future.

Although drug benefits, in isolation, may be more politically attractive in this campaign season, a viable, sustainable senior drug benefit ultimately requires comprehensive reform. Congress must decide on the pace of that reform. If Congress decides to adopt a drug benefit as a stop-gap, incremental step, it must at the very least ensure that the drug benefit will work as part of an eventual comprehensive overhaul.

As you undertake these deliberations, we urge the Congress to consider several basic factors that emerge from this country's recent experience. First, few forces have proven more powerful or more beneficial than genuine consumer choice. People desire and deserve to make the best decisions for themselves. Second, the recent surge of medical innovation which has improved and saved so many lives is just beginning. Under positive conditions, health care progress will continue to accelerate. Lastly, progress here as everywhere is best driven by the incredible fertility of effective competition among private sector entities.

I. Importance of the National Bipartisan Commission on the Future of Medicare

The National Bipartisan Commission on the Future of Medicare, which began its deliberations on March 6, 1998, is the latest and most significant attempt by Congress and the Administration to address the critical issues facing the Medicare program. As we all are aware, beginning in the year 2011, the Baby Boom Generation (77 million Americans) starts to enter the Medicare program, presenting significant challenges to the solvency of the program. Clearly, issue number one faced by the Commission was how to devise a set of policies to ensure the continuation of the program while providing high-quality medical care to the elderly and disabled.

An equally important and interrelated issue was how to modernize the Medicare benefit package and the delivery of medical services. The Medicare program currently has an outdated benefit design that has not significantly changed since its inception in 1965. One key omission is the absence of an outpatient prescription drug benefit. As Senator Breaux stated last year, "Prescription drugs are as important today as a hospital bed was in 1965." President Clinton agrees: "Since Medicare's founding in 1965, a medical revolution has transformed health care in America. Once the cure for many illnesses was a scalpel; now just as likely it's a pharmaceutical."

Yet, approaching this problem as a drug-only issue is unwise. Past experience with a drug-only benefit is telling. Let us all recall that in the Medicare Catastrophic Coverage Act of 1988, a prescription drug-only benefit along with protection from catastrophic costs was enacted into law. Because of unsound structure and financing of the benefit, it was repealed, amid great public outcry, approximately one year later. As the Commission recognized, true success can only come from comprehensive modernization of the system.

As we are all aware, Medicare today is still predominantly a fee-for-service delivery system administered by the Health Care Financing Administration (HCFA) through the use of administered pricing. For many Medicare beneficiaries, particularly in rural areas, there still is very little choice of comprehensive health plans that are tailored to their needs rather than those of government.

After more than 12 months of deliberation, a majority of the Commission issued its report on March 16, 1999. The Commission majority recommended a transition from the current antiquated 1960s Medicare delivery system to one that looked similar to the Federal Employees Health Benefits Program (FEHBP), which is currently offered to all Members of Congress and approximately nine million Federal employees, retirees, and their dependents. In this system, health care plans offer a defined minimum set of benefits and compete for beneficiaries who choose the plan which best suits their personal needs. This model, based on market competition and innovation, has proven its ability to offer innovative benefit designs and quality health care at competitive prices. In the FEHBP program, private sector insurers compete for patients, rather than government contracts.

Eli Lilly and Company strongly supports the Commission's majority view that prescription drugs should be provided as an integrated benefit as part of a system that offers seniors a choice of competing private health plans. Lilly also endorses the principles for comprehensive Medicare reform articulated by the pharmaceutical industry in February 1999. Integrated health care is critical because, today, pharmaceuticals are an indispensable part of modern medicine. When a health plan offers an integrated benefit package, it is in a

position to make rational and efficient allocations of resource trade-offs to provide the best health care at the lowest possible price. When providers focus on the cost of only a single component, such as drugs, they seek to reduce the cost of that item without proper regard for the effects on patient welfare or costs elsewhere in the system.

For example, atypical antipsychotic medications are revolutionary new medicines for the treatment of schizophrenia. These drugs, however, are considerably more expensive than the old technology, 1960s-era therapies that they replaced. Although costly when considered in isolation, the drugs prove to be a significant value when considered in the greater context. Total annual health care spending drops an average of \$10,300 when patients are prescribed atypical antipsychotic medicines rather than older, conventional schizophrenia therapies.1[1] Simply put, these drugs pay for themselves by savings in other health care costs, including hospitalization. This lesson is lost on the administrator who is only focused on his compartmentalized costs and not the savings to the overall system. In this case, both the system and the patient suffer.

II. "Medicare Preservation and Improvement Act of 1999"

On November 9, 1999, Senators Breaux, Frist, Kerrey, and Hagel introduced S. 1895, the "Medicare Preservation and Improvement Act of 1999," which establishes a Medicare competitive premium system for all Medicare recipients based on the principles endorsed by a majority of the Commissioners. This bill provides both for the creation of a system that offers beneficiaries a choice of competing health plans and for continuation of the traditional HCFA-sponsored Medicare plan. In each system, there are provisions for both standard and high-option plans. The standard plan offers only the core Medicare benefits available under existing Parts A and B of the traditional program. The high-option plan adds outpatient prescription drugs and stop-loss coverage, although the stop-loss coverage applies only to the core benefits and not the drug benefit.

Under the Breaux-Frist bill, the high-option drug benefit will be offered in the private marketplace either directly by private health plans (e.g., private insurance companies, HMOs, etc.) receiving a premium payment from the Federal government for each individual Medicare beneficiary they directly enroll or indirectly by HCFA contracts with private entities to provide the drug benefit to beneficiaries enrolled in a HCFA-sponsored high-option plan. These private entities include insurers, PBMs, and pharmacy networks. They will bear full financial risk for the provision of outpatient prescription drug benefits under the HCFA-sponsored high option plan. The Federal government will pay each private entity a premium for each enrollee and the private entity is solely and exclusively responsible for delivering the benefit.

We at Lilly want to congratulate you, Senator Breaux, and your bipartisan co-sponsors on what we believe is a highly successful legislative translation of the principles embraced by a majority of the Commission members. In particular, we believe that the competitive premium system concept is the right structure for Medicare generally and, with respect to the drug benefit specifically, permits delivery as an integrated benefit within competing health care plans.

We strongly support the overall structure of the competitive premium system model envisioned by your bill; we also believe it is a breakthrough step in addressing Medicare reform. However, as you move through the legislative process, it is very important to make a number of changes if this approach is to work.

We believe the bill should offer stronger incentives for patients to move from traditional Medicare into the competitive premium system. While we recognize the need for a transition period, permanent retention of the current system perpetuates existing deficiencies.

^{1[1]} Obenchain, R.L., Johnstone, B.M. "Mixed-Model Imputation of Cost Date for Early Discontinuers from a Randomized Clinical Trial," *Drug Information Journal* 33, Jan.-Mar. 1999, 191-209.

The HCFA stand-alone, high option drug benefit provides incentives that run counter to high quality patient care. Because these HCFA contractors will bear full financial risk for the provision of the drug benefit but not other health care costs, they will be under enormous pressure to limit drug expenditures without regard for patient welfare of savings in other treatment areas. The only way they profit under a drug-only contract is to provide fewer or cheaper drugs. As a result, it can be expected that patients will be required by the system (not by their doctors) to fail on older, cheaper medicines before the latest, most effective drugs are made available to them. While new drugs often reduce hospital, surgical, and other costs, HCFA contractors will see no benefit from these savings and will not bother to use the new drugs or seek those savings. Perversely, their incentive under a drug-only risk contract will be to restrain drug spending whatever the consequences.

The concept of updating the actuarial value of the prescription drug benefit by the increase in the "reasonable cost" of outpatient drugs during the previous years is troublesome. This is an open invitation for the Medicare Board to substitute an arbitrary administrative determination of "reasonableness" for the reality of the medical marketplace.

In addition, the way the bill is currently structured, its stop-loss coverage excludes pharmaceuticals. Because of the importance of pharmaceuticals, and the fact that a few patients require very expensive drug therapies, we believe that medicines should be included in the stop-loss coverage.

Finally, other than authorizing the use of formularies and related cost control mechanisms, the bill is silent on what drugs have to be covered. It is important to ensure that formulary design is based on appropriate clinical guidelines and that patients have access to medicines their doctors believe are medically necessary.

III. Clinton Administration Proposal

In an effort to highlight the need for a drug benefit, the Clinton Administration issued a proposal in July of 1999. This is currently a proposal without any legislative language, but its intended direction is clear. The Administration's proposal would create a new, voluntary Part D Medicare drug benefit, administered by the HCFA through private-sector contractors (eligible PBMs, insurers, and other private entities, which, according to the Administration's proposal, includes State Medicaid systems), with one contractor chosen per region.

Beneficiaries would pay a monthly premium of \$24 per month in 2002, rising to \$44 per month in 2008. Under the program, Medicare would pay 50 percent of enrollees' drug costs, capping the government's contribution at \$1,000 in 2002 (\$2,000 in drug costs) and increasing to a cap of \$2,500 in 2008. After reaching the cap, beneficiaries would receive no further government assistance, but HCFA by law would require that government contractors sell drugs to the beneficiary at prices HCFA and the contractors agreed on for coverage. Beneficiaries below 135 percent of poverty would pay neither premiums nor cost-sharing, and beneficiaries between 135 and 150 percent of poverty would receive assistance with their premiums on a sliding scale.

As initially outlined, this proposal does not embrace comprehensive reform. It simply adds a burden to the current price-administered, antiquated system, without taking steps to make the system more viable.

Consumer choice also disappears under the Administration's current plan. With a single geographic provider, dissatisfied Medicare beneficiaries have no other options. They cannot shop for a PBM with a different formulary or one that offers better care. Furthermore, because there is no competition, benefit managers have little incentive to respond to customer complaints or make decisions based upon anything but cost.

As an approach to insurance, this plan is upside down. Ironically, it will help seniors with modest, predictable expenses while leaving them vulnerable to large, unexpected costs.

In addition, the proposed benefits are seriously limited. Not only is the benefit capped at \$2000, the protection it provides is weak. Under the Administration's proposal, a senior whose annual drug costs are \$600 would receive a \$12 benefit. The senior will pay \$288 in premiums and be required to pay one-half of the drug costs in coinsurance. So \$600 worth of drugs will cost \$588 -- an expensive way to get a \$12 benefit. For those with drug costs of less than \$600, the benefit begins to make seniors worse off. For example, for \$200 worth of drugs, a senior will pay \$288 in premiums and \$100 in coinsurance. So \$200 worth of drugs will cost \$388, a \$188 added cost. By 2008, a senior with annual drug costs of \$1,000 will pay \$1,028 -- \$528 in premiums plus \$500 coinsurance.

The Clinton plan sets up a monopoly purchasing system, which will quickly translate into price controls on pharmaceuticals.

As the Progressive Policy Institute, a centrist Democratic think tank noted, "price controls have four key problems: [they] perpetuate the fallacy that bureaucrats and legislators can allocate resources better than consumers and providers in the marketplace; [they] would discourage the development of drugs and biotechnology products for older and disabled Americans; [they] would undermine competition by substituting federally mandated discounts for the hard work of negotiating prices that regularly occurs in the marketplace; and price controls on drugs for seniors would be difficult to implement so that they in fact lower prices for seniors."

Market-based health care reforms like the competitive premium system model would ensure that more people enjoy the benefits of strong competition in the pharmaceutical industry and that we have the resources necessary to continue researching and developing a constant stream of innovative new medicines.

The Administration states that it did not intend to propose a system of price controls. However, we believe that price controls are the inevitable outcome of the Administration's current proposal. We urge the Congress to ensure that any legislation sent to the President's desk does not include or lead to price controls.

Finally, there is no real competition here. There is no "competitive, market-based approach" if the individual beneficiary does not have a choice among competing plans. And a single government contractor cannot offer beneficiaries "market-based alternatives."

IV. Potential Interim Steps

We believe that comprehensive reform of the Medicare system is the only lasting answer to the shortcomings of the present system. We would be greatly disappointed if this Congress and Administration are unable to enact comprehensive reform.

However, we recognize that Congress may prove able to deal only with an especially urgent subset of the overall Medicare problem; namely, those seniors who are unable to pay for their prescription drugs. No matter what policy changes we favor, we all agree it is intolerable that any elderly Americans go without needed medicines for financial reasons.

As mentioned above, Lilly believes that in any stop-gap approach to Medicare reform the prescription drug benefit must be delivered only through the private sector utilizing market-based principles. Only this approach is consistent with a subsequent transition to a competitive premium system.

In delivering an outpatient prescription drug benefit, there are a limited number of practical options. One option considered by the Commission is to expand Medicaid eligibility. We object to expanding eligibility for Medicaid because that program is based on direct price controls in the form of the Medicaid rebate, best price provisions, and CPI caps. Such a system of price controls is a direct threat to the ability of our industry to

invest in the research and development efforts necessary to discover and develop new drugs. Moreover, expanding the Medicaid fee-for-service entitlement would erect a substantial barrier to moving to a competitive premium system based on private competing health plans. The two systems are incompatible.

V. Conclusion

In light of the urgent need for reform, the reinvention of Medicare should be guided by our national experience over the past 35 years. Congress should:

Pursue a comprehensive solution that addresses seniors' total health care needs.

Approach health care not according to its various parts, but as an integrated whole which allows us to improve overall quality, communication, and convenience; a system that provides the best results for patients and delivers the best economic value.

Offer seniors choices of health plans that best fit their particular needs.

Ensure competition – which fosters innovation and quality. Congress should reject any form of government-imposed price controls which delay and deny care for today's patients and impede innovation for tomorrow's patients. Price controls would derail medical progress and – insidiously – we would never know what miracles we had missed.

The next generation of seniors will live longer and healthier lives, and they can be assured of affordable, effective health care if the Congress succeeds in a comprehensive Medicare overhaul. If the Congress and the Administration decide on a short-term approach, we would be disappointed but still strongly urge that these same principles be followed.

Finally, it is important to note that Medicare reform will pose major challenges and require major changes by our company and our industry. At the same time that we are facing dramatic increases in competition in the laboratory and in the marketplace, we would face immense new pressures from the implementation of Medicare reforms. The Breaux-Frist approach, for example, would allow millions of seniors to join large, integrated health plans with strong leverage over suppliers – including pharmaceutical companies.

Our challenge will be to maintain and accelerate our pace of innovation while confronting greatly intensified marketplace pressures. We are committed to adapt, adjust, and succeed. In an environment of private sector competition, we will stay focused on our mission of delivering pharmaceutical advances to patients with heart disease... cancer... Alzheimer's...diabetes...and other urgent health problems. At Lilly we will do our part to ensure that America continues to lead a global medical revolution.

Thank you for this opportunity to present our views.

Nothing written here is to be construed as necessarily representing the views of the Independence Institute or as an attempt to influence any election or legislative action.

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