

Medical Technology and the Future of Medical Care

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A. Introduction

[Overhead 1] Thank you very much. It is a pleasure to be here with you today.

You have asked me to address a very challenging topic: that is, an overall picture of the role and assessment of medical devices for hospital operation under managed care. As I do so during the next hour, my intent will be to share with you some of our experiences in the U.S. as we have struggled with the changes of a dynamic health care system -- particularly the restructuring it has undergone as part of managed care.

In sharing our experiences, my hope is that you can benefit from and gain insights from our mistakes and perhaps improve upon our experience. I want to stress, however, that I am not holding out the U.S. system as a model for Japan. Instead, I am holding out the lessons the U.S. is learning as relevant to any nation -- whatever its system.

To understand what we have gone through, and where we are today, we need to understand the many factors that come into play in the decentralized, market-driven U.S.

system. So for the next few minutes, let me provide you with an outline of some of the key factors affecting the U.S. experience.

B. Factors Affecting U.S. Experience

Context: U.S. Device Market

The place I want to start is with the U.S. device industry itself – and, specifically, with some of the unique aspects of the U.S. industry and the U.S. market. By examining and understanding them, I believe we will be better able to sort through the impact of recent changes in the United States.

[Overhead 2] As you know, medical devices emerge from a highly innovative and highly diverse industry. Some companies in the U.S. are large, international corporations, employing thousands of workers with facilities throughout the world. At the same time, our industry is dominated by small firms. According to the Food and Drug Administration, some 85-90 percent of the 18,000 medical device firms employ fewer than 100 workers -- and many of those fewer than 50. This "small company" aspect of our industry is something that I'll be returning to frequently.

One of the unique aspects of medical technology companies in the U.S. is their intensive commitment to R&D. In 1997, the U.S. device industry invested 6.8 percent of sales in R&D -- traditionally about double the R&D investment average of overall U.S. industry.

That puts medical device companies squarely at the top of the most research-intensive industrial sectors, surpassing R&D expenditures in the aerospace and defense, electronics, and telecommunications industries as a percentage of sales.

Much of that intensive R&D is in smaller firms -- traditionally the source of the most significant innovations. Data show that companies with sales of less than \$5 million invested a whopping percent of sales in R&D. Some estimates show well over 100 percent -- obviously reflecting the fact that venture capital and other assets were fueling innovation for products that may not yet have generated a cash flow. The intensive R&D that is going on within our industry can also be seen in individual industry sectors. For example, it has been reported that half of in vitro and in vivo diagnostics companies invest roughly 50 percent or more of their sales in R&D, while 25 percent invest more than 150 percent.

This robust commitment to R&D is a significant factor in the industry's continued growth in overall production and international trade. In 1997, U.S. production of medical technology totaled \$65.2 billion, a 6.5 percent increase from the previous year. The 1997 domestic consumption of medical technology grew to \$58.1 billion, also a 6.5 percent rise from the year before.

International markets continue to be critical outlets for U.S. production and a major contributor to U.S. production growth. In 1997, roughly 20 percent of industry

production was exported. The 1997 medical product exports reached \$13.7 billion, an increase of about 6 percent from the year before.

Thanks, in part, to strong trade and intensive R&D, the U.S. device industry has traditionally been a strong creator of new jobs. The medical technology industry employed about 300,000 people in 1997 -- and job growth for 1998 is projected to add up to 3 percent -- well ahead of U.S. industry overall.

Let me add one additional piece of background that I think is critical in understanding the U.S. industry -- and the challenges that lie before it. The U.S. device market is highly fragmented. That is, it is made of many niche product lines that are of relatively modest market size. As a result, the industry itself is highly fragmented, with segments as diverse as medical/surgical devices, imaging systems, monitoring equipment, lab tests, and health information systems.

Within these segments, there are some 900 product line groupings. These are groupings of products that naturally go together, such as syringes and needles; within these groupings are more than 3,000 distinct major product lines; and -- within them -- approximately 84,000 individual products. In any book, that's diversity.

In addition to this diversity, the markets for these products are relatively modest. Of the 900 product line groupings in 1993, about 11 had U.S. sales exceeding \$500 million; 33 were over \$300 million; and only about 65 were greater than \$150 million. That means

all the rest had U.S. sales of less than \$150 million. By way of context, keep in mind that the product categories in the pharmaceutical industry often exceed \$1 billion.

So as you contemplate the data on the U.S. industry, I want to underscore:

- that its markets are much smaller than is often thought;
- that the number of small companies in the industry are much greater than often thought;
- and that -- together -- these facts mean that finding the financial resources to meet the increasing demands of managed care -- as well as government payers -- is much harder than often thought.

But I'm getting ahead of my story. Let me first say a word about what all this innovation and robust R&D has created -- in human terms.

Context: Benefits of Technology

Despite the enormous economic strides of the device industry, I believe its real value is in the countless lives its products have helped improve and save during the past 30 years.

You know many of these kinds of examples from your own work -- examples like these:

- Implantable defibrillators that restore normal heart rhythms, saving the lives of some 10,000 patients annually;
- Pulse oximeters that detect low blood oxygen levels and have significantly cut down deaths and mishaps related to anesthesia;
- Hydrocephalus shunts that divert fluid away from the brains of newborns, saving some 2,000 lives annually and reducing other problems for some 40,000 infants annually.

In all, devices have contributed significantly to a demonstrable improvement in health and longevity in the U.S. population. **[Overhead 3]** As you can see from this slide, there has been significant progress during the past three decades in increasing life expectancy in the U.S. While some of these increases are clearly due to non-technology factors -- such as changes in lifestyle -- there is no doubt that medical technologies have contributed in many cases.

In and of themselves, I believe that such achievements are significant. But look behind them for a moment -- at their economic impact. Many technologies save money in direct, measurable terms:

- Fiberoptics allow physicians to look inside the knee and repair joint injuries -- without checking the patient into a hospital;

- MRI imaging has replaced exploratory surgery for detecting benign tumors;
- Balloon angioplasty is only a fraction of the cost of coronary bypass surgery.

Beyond direct economic effects, medical technology helps build what I call *human* infrastructure -- making patients more productive so they can return to their jobs and contribute to the economy. Though such economic benefits are not often measured, I believe they are critical in calculating the real value of this industry and in understanding why public policies that encourage its continued innovation are so critical. One study reported that the potential *indirect* benefits to the U.S. economy of three types of minimally invasive surgery totaled almost \$2 billion annually, with these potential gains tied to quicker recoveries and quicker returns to work.

Let me sum up this section of my comments with this overall point: The U.S. medical technology industry is vigorous and innovative. Its value can be measured both in dollars and lives, in the short term as well as over time. It is my belief that this kind of value deserves public-sector and private-sector payment policies that permit – indeed, encourage – continued and robust innovation.

Device Innovation Process

In providing this background, my intent is to set a context for you -- that is, a context for understanding what the U.S. device industry is and why we must construct policies that create conditions favorable for its continued vitality. Another element in providing that context is understanding how the kind of innovations I've just described come about. In effect, understanding the device innovation *process*. **[Overhead 4]**

Too few policymakers understand this. They assume it works like any other industry, particularly the pharmaceutical industry. Hence, the impulse is to create policies that are often short-sighted and ineffective -- and that would cause direct harm. More specifically, I think that understanding the device innovation process is especially critical in sorting through the impact of managed care.

Regardless of the type of device, most technologies proceed through similar stages of innovation:

- Invention, when new ideas are translated into prototypes;
- Development, when new products undergo testing and evaluation;
- Diffusion, when new products seek acceptance in the market; and

- Feedback, when users -- such as physicians -- put products to use, learn from their experiences, and provide suggestions and responses to the inventors... and then we start the cycle anew.

Feedback is Critical

Though each stage is important, the process of feedback is one of the defining characteristics of device innovation -- carrying with it many of the obstacles and opportunities inherent in the process.

Feedback usually occurs as devices are used by clinicians in real-life practice settings and as company R&D professionals continue to refine their products. These interactions reflect an ongoing "dialogue" of device innovation: manufacturers make incremental changes in response to user suggestions; users apply the new products and discover even more possibilities; and manufacturers refine products further.

From this interaction comes continuous, incremental improvements in existing medical technologies, leading to such examples as --

- The development of artificial hips, which reflects a long series of incremental changes during the past 30 years, including improvements in materials, design, and fixation.

- Another example is the endoscope, which has been transformed from a bulky, rigid tube to miniaturized devices that often employ flexible fiberoptics and video technology.

Changes like these make it difficult to predict the ultimate application of a medical device or the form that a device will eventually take. Thus, public policy may inadvertently block what would otherwise be a worthwhile innovation.

Smaller Companies

Another defining characteristic of U.S. device innovation is the key role played by small companies. Small start-up companies were responsible for such innovations as the heart bypass machine, flexible endoscopes, glucose monitors, ultrasound, IV pumps, and artificial hips and knees -- to name just a few.

Yet smaller firms often have difficulty in managing the uncertainty of device innovation, due to such factors as a lack of funding or lack of regulatory expertise. As a result, they are often vulnerable to shifts in the market and changes in government regulation.

Because of these challenges, small companies often align with larger companies to cope with the financial and regulatory uncertainties of innovation. In turn, larger companies are noted for incremental improvements and for bringing their financial clout and expertise to bear in steering products through the innovation process.

Regardless of which type of company innovates a new product, powerful audiences often remain skeptical -- thereby creating a significant deterrent. Such skepticism may be expressed by physicians, regulators, and investors, and can translate into a reluctance to accept or finance the innovation.

In short, device innovation is not automatic. It's not a guarantee. Without well-reasoned and well-focused policies among public and private payers, it can be snuffed out -- or, at the very least, made much less productive and valuable.

C. Government Role in U.S. Health Care

Let me step back now and say a word about the U.S. environment into which device innovations are born -- that is, the U.S. health care system.

The U.S. system is decentralized and pluralistic. The largest single payer -- and the largest single purchaser of managed care services -- is the Medicare program, which pays for care for the U.S. elderly and disabled.

The U.S. system also features a variety of private payers that provide health insurance for the working population. Some of these private payers appear, at times, to follow Medicare's lead, but there is no clear, unified pattern. In all, the U.S. system is marked by multiple decisions, made by multiple decisionmakers.

To give you a clearer context, let me share some introductory data with you about Medicare -- as well as about private insurers.

Medicare v. Private Insurance

[Overhead 5] As you see here, Medicare and private insurance spending per enrollee grew at similar average annual rates between 1970 and 1996 -- 10.8 percent and 11.3 percent, respectively, over the period.

I'll provide some more comparisons for you a little later. For now, though, my point is that the U.S. system is pluralistic: There is an important governmental health program, Medicare, but there is also a collection of dynamic private-sector programs.

Medicare Overview

Let's look more closely at Medicare. From the slide, you'll note the drop-off in spending growth in recent years. One key question now facing the U.S. is how long we can expect spending growth to moderate.

[Overhead 6] I say that because you can see on this slide that the U.S. population will age rapidly through the year 2030. This will create significant growth in the number of individuals eligible for Medicare.

[Overhead 7] The next slide translates this population growth into growth in the number of Medicare beneficiaries. As you can see, there will be an estimated doubling in this number between 1987 and 2017.

Medicare Spending

[Overhead 8] With the rise in the number of beneficiaries in mind, it is important to remember what Medicare pays out for each one. In federal fiscal year 1996, as this slide shows, Medicare paid – on average – \$5,012 in benefits per beneficiary. But as you can also clearly see, average spending per beneficiary varies on the basis of the patient's entitlement. By far, the greatest number of beneficiaries fall into the “aged” category – with a benefit payment level of just under \$5,000 per enrollee.

[Overhead 9] It is interesting to note that a small percentage of beneficiaries account for a disproportionate share of Medicare spending. In 1995, five percent of beneficiaries accounted for almost 50 percent of Medicare spending; 10 percent of beneficiaries accounted for more than 60 percent.

What Medicare Buys

Now let me focus a bit on where Medicare payments go -- that is, on what Medicare buys.

[Overhead 10] Medicare benefit spending in FY 1997 was \$207 billion. The largest share was for inpatient hospital services (43 percent) and physician services (20 percent). A growing share of Medicare benefits is paid to managed care plans -- 12 percent in FY 97. (Note that medical technology is not depicted as a share of spending in these official U.S. government statistics. That is because the government has traditionally calculated its spending in terms of those entities and individuals that directly provide care to beneficiaries. I'm not aware of any official data on Medicare spending for technology.)

[Overhead 11] Over the last 15 years or so, there have been significant shifts in how Medicare spends its budget. Because of both delivery system and payment system changes, inpatient hospital spending declined from two-thirds of Medicare benefit spending in 1980 to less than half of total Medicare benefits expenditures in FY 1996. Note also the significant increases in the share of spending attributable to skilled nursing facility and home health services.

[Overhead 12] Turning to physician rates, this slide says, basically, that Medicare pays less for physician services than do private insurers. In the early 1990s, cost containment policies caused Medicare's payments to physicians to drop, relative to private insurers' payments to physicians. More recently, though, higher annual updates of Medicare's fees -- combined with lower inflation in the private sector -- have begun to narrow the gap.

[Overhead 13] As a result of major changes contained in the 1997 Balanced Budget Act – an important law that changed many Medicare programs -- the average rate of growth in Medicare benefit payments per enrollee is expected to change significantly.

- First, let's look at the experience in the recent past. This slide shows Medicare spending from FY 1990 - FY 1996 by type of service. As you can see, the average annual rate of growth per enrollee was 8.5 percent. There were significant increases recorded for home health, skilled nursing, and hospice services.
- **[Overhead 14]** In contrast, this slide shows projections of the rate of growth in benefit payments after the Balanced Budget Act changes are taken into account. You see that the projected annual average rate of growth per enrollee is now estimated to be 3.8 percent -- down from 8.5 percent. You can also see that significantly lower increases are forecast for home health, skilled nursing, and hospice services.

So that's an overview of the system into which medical devices are born in the U.S.

As they try to enter this system, devices face two significant challenges. The first is, "Will Medicare adopt and pay appropriately for a new technology?" The second is, "Will private payers do so?" And both, I might add, are increasingly laden with issues involving managed care.

Let me now describe how the hurdles to device innovation occur in the Medicare program. I will concentrate on Medicare simply because it *is* the largest U.S. health care payer.

The Coverage Process

To be paid by the Medicare program, all services and products must be covered by the Health Care Financing Administration -- its acronym is HCFA -- which is the agency that administers Medicare. That is, the services or procedures where the products are used must be deemed to be reasonable and necessary for diagnosing or treating a patient. They must also fit into particular statutory categories, such as hospital services, surgical dressings, durable medical equipment, prosthetics and orthotics, or supplies incident to a physician's services.

Medicare coverage is carried out at three levels...local, regional, and national:

- *Local Coverage:* The vast majority of Medicare coverage decisions are made as a result of claims processing by Medicare contractors. These are private insurance companies, such as Blue Shield, which contract with HCFA to process claims from providers. In deciding whether to cover a medical service or technology, contractors review applicable manuals for specific product-related policies supplied by HCFA or apply general criteria such as:

- Is the product safe and effective?
- Is it appropriate?
- Is it experimental or investigational?

And, I might add, HCFA seems increasingly to be examining cost-effectiveness. That includes long-term value, impact on utilization, and effect on overall patient well-being. This is much, much more than the traditional Food and Drug Administration standards of whether a device is safe and effective. As one top HCFA official said of FDA review: "So it's safe. So it's effective. So what?"

National Coverage: A second kind of Medicare coverage occurs at the national level. Only about 10 to 20 treatments or technologies per year are "approved" by HCFA for national coverage determinations. Such decisions are issued when the treatment or technology might diffuse rapidly or when it represents a large expense or a significant technological advance. In making national decisions, Medicare generally uses the same criteria its carriers use in making local decisions.

Regional Coverage: Finally, some decisions are made by four regional carriers -- these are local contractors who process claims for durable medical equipment, prosthetics, orthotics, surgical dressings, and a wide array of supplies used in the patient's home. There is also a law -- not yet implemented -- requiring use of regional carriers to process claims for clinical laboratory tests.

As some of you may know, Medicare coverage policy has been one of the hottest health care issues in Washington recently, at least as far as federal device policy is concerned. Medicare's coverage policies have been marked by confusion and uncertainty, long delays, and a general sense of uncertainty over what Medicare wanted, what processes it would use, and what rights the public had to participate or appeal. One study found, for example, that, on average, just the technology assessment element of national coverage decisions took nearly two and a half years. In effect, Medicare coverage has been a slow, unresponsive, black box.

HIMA has been fighting hard to reform this process. We've issued many detailed recommendations, which I won't go into today. But our focus is clear: make Medicare more conducive to device innovation through clear procedures, reasonable criteria, and an open and participatory process.

So one of the primary lessons that *I draw* from the U.S. government policy on coverage is that it needs to be modified and adjusted from time-to-time to be sure that devices can continue to offer the enormous human and economic gains I described at the beginning of my remarks.

I am optimistic that we will see improvement in Medicare coverage policy in the not-too-distant future. HCFA has shown willingness to make changes, and I believe there is interest in Congress as well.

Medicare Payment Systems

Coverage, while important, is only the first step in adoption and use of a technology by Medicare. Once a product is covered, HCFA must then decide how much to pay for it. Medicare's payment methodologies and amounts vary, depending upon where the technology is used, who provides the care, and the kind of treatment or service that is provided. If the technology is used to care for hospital inpatients, for example, its payment is included in the Diagnosis Related Group or DRG payment rate. The overall DRG price is intended to cover all hospital costs associated with an inpatient stay.

If the product is used in a physician's office, the doctor's fee may be adjusted to account for the cost of the technology. Separate fee schedules apply to payments for technologies used in other settings, such as clinical laboratories and dialysis centers.

In addition to these traditional Medicare reimbursement systems, the 1997 Balanced Budget Act – which I mentioned a moment ago -- required HCFA to develop a number of other new prospective payment systems. These include systems for skilled nursing facilities, which is now being phased in, and for hospital outpatient department services, which will likely go into effect in 2000. Though each of these systems has unique features, each sets a defined price for a given set of services.

In all of Medicare's payment systems -- old and new -- challenges abound for technology. If the prices are too low or if they are updated too slowly to reflect new types of

technology -- or if the payment categories are too narrow -- technology will suffer, as will patients. Much as it did in the area of coverage, HIMA has offered U.S. policymakers a variety of detailed recommendations.

HIMA is calling for policies:

- that employ the best and most accurate procedure codes;
- that update payment levels and categories frequently
- that use the latest information about changes in technologies
- that employ temporary payment categories when needed
- and that work hand-in-glove with Medicare's coverage and coding policies.

All of this is focused on one goal: Creating a flexible, up-to-date payment system that incorporates new technologies promptly and speeds the access of patients to needed care.

Growth of Managed Care in Medicare

As you may know, the vast majority of Medicare beneficiaries rely on Medicare's traditional fee-for-service system. But managed care is playing an increasingly important role in the Medicare program. Let me spend just a moment on that.

[Overhead 15] Here you see that Medicare enrollment levels in HMOs are lower than non-Medicare levels -- roughly 13 percent of the Medicare population is in HMOs, versus 43 percent of the non-Medicare population.

[Overhead 16] But Medicare enrollment in risk HMO plans (those are plans paid on a pre-paid, capitated basis) has increased every year since the beginning of the risk program in 1985. As you can see, increases in enrollment have accelerated rapidly in recent years.

[Overhead 17] As a matter of fact, that growth has far exceeded non-Medicare HMO growth rates over the past several years: In 1996, you can see that growth in Medicare HMOs shot up 33 percent versus 13 percent in the non-Medicare population.

[Overhead 18] And, as you might guess, the number of Medicare risk contracts is at its highest historic levels.

[Overhead 19] Medicare's HMO enrollment growth has not occurred uniformly across the United States. As you can see from this slide, California, Florida, and Pennsylvania -- while accounting for only 23 percent of the total Medicare population -- account for nearly half of all Medicare risk enrollment.

[Overhead 20] Yet despite the growth in Medicare HMO enrollment, commercial penetration still exceeds Medicare HMO penetration. Much of this may be explained

simply by the fact that the two populations are different, with different medical needs. Commercial programs serve the working population, while Medicare serves (as we discussed earlier) the elderly and disabled.

Now let me outline a recent development in Medicare payment policy that may, over time, draw considerably more Medicare beneficiaries into managed care plans.

As part of the 1997 Balanced Budget Act, Congress enacted policies intended to increase the use of managed care within Medicare. In fact, the law attempts to make managed care one of Medicare's primary methods of health delivery. It does so by vastly expanding the types of managed care medical plans beneficiaries may choose from and by encouraging plans to spread into regions of the country traditionally underserved by managed care.

Frankly, the program has not been an unqualified success. In recent months, a number of Medicare managed care plans have decided not to continue participating in the Medicare program, citing low payment rates, among other things.

This has sent ripples of concern throughout Washington, which has placed so much hope on managed care as a vehicle for helping manage Medicare's costs. No one can know for sure how this issue will turn out. Some estimates have indicated that roughly 25 percent of seniors are expected to be enrolled in managed care plans by 2002. Today, the

specifics of this projection may be in doubt. That said, it seems quite likely that managed care's overall expansion within Medicare will continue.

Given the fact that Medicare spending constitutes roughly 20 percent of all health care spending in the U.S., the growth of managed care in Medicare will likely have a significant impact on devices. It will certainly influence how devices are used, purchased, and priced. But it will also influence how and if they are covered. Yet much of this coverage question remains an enigma. Little is known about the practical implications of the coverage process within the managed care part of Medicare.

For example, the law sheds little light on the criteria that managed plans should follow in making coverage decisions. HCFA's current policy is simply to oversee these plans in the same general, managerial fashion it oversees the traditional insurance carriers that serve as Medicare contractors.

At the very least, it appears that there needs to be some type of mechanism to ensure that national and local coverage decisions of these organizations are, in fact, in accord with those of Medicare's fee-for-service system. In addition, such decisions should be made openly, with an opportunity for public input, and an opportunity to appeal.

It seems to me that the worst possible outcome of Medicare's move to managed care would be the kind of closed and unresponsive decisionmaking that has defined mainstream Medicare for too long. As one small step to shed light on technology

adoption within managed care organizations, HIMA was recently awarded a contract by the State of California. Under this contract, we will be interviewing executives of both device companies and managed care organizations. Through these interviews, and subsequent follow-up activities, we will attempt to identify voluntary best practices for technology introduction and key impediments to such introduction.

In summary, let me re-emphasize that all of these government policies -- Medicare's coverage system, Medicare's many reimbursement systems, and now Medicare's increasing reliance on managed care -- represent hurdles that medical devices must overcome if they are to be adopted and utilized in the United States.

Now let me turn to yet another critical factor that medical technology faces in the U.S. -- and here you will see how the policies of government and the private sector are becoming increasingly similar.

D. Private Sector Managed Care Environment

I am referring specifically to the growth of managed care in private sector reimbursement, coupled with the cost-driven changes in the structure and delivery of health care in the United States. Let me begin again by setting the context.

Pressure on Costs

In the late 1980s, major employers in the U.S. began pursuing strategies to rein in rapidly increasing health care costs. One of the primary tools they turned to was managed care, which, in the beginning, was typically associated with "capitation" -- setting a fee to cover all costs associated with care. Over time, "managed care" has come to embrace a variety of payment arrangements, notably "PPOs" -- or preferred provider organizations. As it has evolved, managed care -- coupled with the overall drive to control costs -- has unleashed a range of changes that have begun reshaping the entire structure of U.S. health care delivery.

Consolidation of Providers: First, hospitals, physicians, and alternate site centers have increasingly consolidated and formed themselves into what are often called "integrated delivery systems." This permits them to realize new economies and efficiencies in the face of mounting cost pressures. Integration of this type provides one-stop shopping for purchasers, while it affords greater control of delivery and utilization. One survey showed that almost 30 percent of the hospitals in the U.S. were part of such systems and that almost half had begun developing them.

Purchasing Clout: Because of their substantial purchasing volume, integrated systems can exert significant leverage relative to suppliers. This includes prices --

we have witnessed significant price competition among firms in our industry and, as a result, price concessions. Integrated systems can also demand greater product standardization. What I mean is that these systems are limiting the number of product brands they will maintain and, as a result, the number of manufacturers from whom they will purchase products. Added to this, of course, is the fact that many purchasing decisions are not made by physicians, but by administrators -- focusing increasingly on price-related issues.

Alternate Delivery Systems: Cost factors are also directly influencing *where* care is delivered and that has meant rapid growth in alternate site delivery centers, such as surgery centers and walk-in clinics. Although the number of hospitals fell slightly from 1984 to 1993, the number of freestanding surgery centers increased sixfold and the number of diagnostic imaging centers jumped from 650 to 1,963. This trend is often facilitated by technologies -- such as lasers, fiberoptics, and ultrasound -- that permit treatments to be done quickly, safely, and at substantially reduced per-unit costs over the inpatient setting.

Purchasing Groups: Another element in the active cost-control push in the U.S. is the power of the group purchasing organization -- in essence, large, consolidated buyers of medical products and services. GPOs cover virtually every hospital in the U.S. and are rapidly incorporating a variety of alternative site providers into their membership. Paul Campbell, representing one of the largest such organizations in the U.S., will be telling you more about this.

Evidence and Outcomes: That brings me to one of the hallmarks of today's cost-conscious environment in the U.S. -- and that is the drive for value. Payers and purchasers want to be certain they are spending their resources on health care services that offer clear benefits, as measured by healthier patients, reduced morbidity, and longer lives. In essence, they want proof -- from device companies -- that devices do just that -- save lives, reduce complications, and make patients healthy. In turn, some purchasers are using outcomes data -- some of which they generate on their own, as well -- to help develop practice guidelines that aid physicians in providing optimal care. The goal is to gather the information and understand the elements necessary to manage disease in the most cost-effective manner possible.

Financial risk sharing: Finally, we are seeing a new phenomenon that blends this idea of integrated system with the desire for managing costs. It's called financial risk-sharing. To help manage their costs, some providers are seeking to enter into financial risk-sharing arrangements with suppliers. That is, the supplier assumes part of the provider's risk through capitated supply agreements or other means. That means the provider doesn't worry as much about utilization or per-unit costs -- that's up to the supplier. In turn, the supplier has to have the expertise, capacity, and financial where-with-all to take on what is often significant financial risk.

Impact on Devices

These changes -- and I have only touched on a handful of them -- have had a significant impact on medical technology. The trend toward managed care, integrated delivery systems, and reduced costs have intensified the competitive environment for our industry.

In recent years, we have witnessed slower growth of procedures and utilization of hospital services, as well as greater pressures on prices -- largely as a result of the impact of managed care. An early-1990s study HIMA commissioned by the Wilkerson Group found, for example, that the coronary angioplasty and orthopedic hip implant markets, both of which enjoyed annual historical rates of growth between 15 and 20 percent over the previous five years, were projected to grow at around 5 -7 percent annually through the year 2000. Similarly, prices have shifted dramatically. Between 1980 and 1992, price increases in the hospital supply industry were on the order of 4 percent annually. From 1993-1994, they were in the range of only one-half percent.

Managed care is also leading to changes in other key areas:

- The greater demands for outcomes data and technology assessment have raised costs for medical technology firms. Doing the studies and analyzing the data can require significant expenditures and years of research. This is especially hard for small companies.

- Such demands, in turn, mean that device companies will likely find it harder to continue the kind of incremental innovation that, as I mentioned earlier, is at the very heart of device development. It may simply be too expensive to develop the data necessary to prove to managed care firms that these improvements save money or otherwise improve cost-effectiveness. We may see fewer incremental improvements, and the continuous nature of device innovation will become considerably less fluid.
- The higher costs of demonstrating value to purchasers, in addition to offering purchasers the price discounts and standardization they demand, means that smaller companies will have a harder time innovating in the managed care environment. This will be exacerbated by the fact that they do not have the financial resources to share financial risks with purchasers and providers. In all likelihood, that will mean fewer breakthrough advances that are usually the domain of small firms.
- Complicating the course for innovation is the fact that managed care administrators, not physicians, are more often at the crossroads of device purchasing, adoption, and use. In effect, administrators are deciding what to buy and what not to buy. That means device firms are losing access to the active interchange with physicians that is so vital to healthy device innovation.
- Finally, one of the most unmistakable trends we see today is greater consolidation within the medical device industry. The reason is clear: To provide purchasers the broad product lines they seek, financial scale to permit risk sharing, and the extensive

data on the value of products, medical technology firms must be large enough and command sufficiently high market share. During 1993 and 1994, almost \$100 billion in merger and acquisition activity took place among health care companies overall, with medical device companies -- a small share of the health care market -- accounting for approximately \$9 billion, or nearly 10 percent, of this.

Consolidation has been particularly strong in the industry market segment involving small companies, as many larger companies are seeking to capture, through mergers and acquisitions, growth opportunities associated with innovative devices. This acquisition activity is expected to continue. In a survey of medical device companies, nearly 60 percent of companies responding reported a high likelihood that they would be involved in a merger or acquisition within five years.

One result of this increased merger activity is that the medical technology industry is becoming one of relatively large companies and relatively small ones, with fewer companies in the medium sized range -- i.e., \$50 million to \$250 million in sales.

E. Technology Assessment

Now let me pause for a moment and recap: I've gone through this detailed explanation because I wanted to give you a sense of the dynamic, diffuse, market-driven environment that medical devices face in the U.S. The recent changes I've outlined have had a

dramatic effect on how Americans receive care, how it is paid for, and the type of care they can expect.

In many ways, this is a very positive development. Health care providers are becoming more efficient and are managing themselves in a more cost effective manner. Providers, insurers, manufacturers, and consumers are much more focused on value. Consumers are increasingly receiving care in local, comfortable, and more convenient alternate treatment centers -- that also save money. And rapidly rising health care costs have certainly moderated -- some have even suggested they are under control.

But for these positives, there are also some negatives. As I mentioned earlier – including reduced innovation, threats to small companies, and reduced access to physicians.

A Template for Navigation

The question is: How do we balance the good qualities of a more cost-efficient health system with the need for continued innovation and improvements in the quality of care?

Now I am certainly no farther along on this question than anyone else. But I'd like to suggest a template for at least *thinking* about this question. Consider this template a navigational aid.

This template consists of 10 principles. And they represent what I believe is a set of approaches through which a health system -- any health system -- might thoughtfully address technology.

Now let me just add this: I am not suggesting that every principle can be applied to every nation's health system. That's certainly not the case because every nation will have its own history, its own culture, and therefore its own system.

But what I *am* saying is that every nation faces essentially the same fundamental challenge: providing high-quality health care to its citizens at reasonable cost. We believe technology can be helpful in meeting that challenge. And therefore we think a nation might benefit -- not from inflexibly adhering to our principles -- but from examining its system *in light of our* principles -- and looking for opportunities to mold the principles to its own circumstances

There are 10 principles in all. I'll not go into them in any great detail. I'll simply touch on the key concepts. And I'll begin with the principles that concern how we obtain good evidence and information on technology.

The conventional way U.S. payment policy thinks about information is to say we'll not pay for a new technology until its use has been validated, preferably by a randomized controlled clinical trial.

The problem is that we'll never have enough money or time to do all the trials the conventional technology assessors say we should. It would be particularly infeasible for smaller companies, which, as I indicated, represent a significant factor in the U.S. medical device industry. And even if we could do all these trials, the information would be from artificial, controlled settings -- and thereby less relevant to patients and providers generally.

Our first principle would suggest that one key source of evidence is information from "real-life" settings. **[Overhead 21]** And by "real-life," I mean the settings where technology is actually used in the day-to-day practice of medicine.

It is interesting to note that Paul Ellwood, M.D., one of our pre-eminent health policy thinkers -- who coined not only the term "HMO" but also the term "outcomes" -- emphasizes that we should view the health care delivery system as our own ready-made "clinical trials *machine*."

The point here is that the best information is generated *as* technology diffuses. That's when we learn about the proficiency of users, about the breadth of applications, and about longer-term outcomes. And it is how the next generation of devices is born as professionals provide feedback to innovators.

Given all this, there's growing interest in so-called "conditional coverage." That means paying for studies on a technology earlier in its life, then collecting information as it

diffuses, then using the information to make permanent decisions later. There's been more and more interest in doing this in the U.S.

Now let me move to a second aspect of *conventional* payment policy as often practiced by government policymakers and private sector payers. And that's the notion that we can freeze everything ... as we methodically assess technology ... and then review the results of that assessment ... and then finally act on those results.

Geligns and Their, writing for the U.S. Institute of Medicine, have documented a fact that innovators already know: Device life cycles are extremely short -- they're often measured in months. The speed of that innovation/feedback loop I mentioned earlier is, for many technologies, supersonic.

And so the time for any one technology is short. It seems to grow shorter still if you have to wait for an assessment. As I mentioned, one federally sponsored study found that Medicare assessments averaged almost two and a half years.

So our second principle calls for faster, more efficient reviews of technology.

[Overhead 22] It calls for doing a better job matching the availability of information to the time we need it. As you know, in baseball, it's not where the ball *is* that counts. It's where the ball *will be*.

In the same way, technology studies need to be less about history and more about foresight. They need to be more predictive, iterative, adaptive. Perhaps one day -- through electronic systems -- we'll assess technological change in something approaching "real time."

Now so far, we've talked about time and information. Conventional payment policy rarely teams the two creatively. And that's because conventional policy is focused immutably on yesterday: It relies on yesterday's information, with no real way to adjust to *new* information. And with device technology -- with its short life cycles -- there is a constant *flow* of new information.

Our third principle calls for rapid integration of new knowledge into a feedback loop -- one that fosters continuous improvement [**Overhead 23**].

At the center of this loop is the health care professional. For it is this person who actually uses the technology in a real-life setting...who sees ways the technology can be improved...and who then feeds suggestions back to the manufacturer.

Not incidentally, as I noted earlier, these same steps -- use, feedback, improvement -- are the key steps in device innovation. And so this principle would use innovation to *power* a new set of capabilities. This principle would hitch "real life"...to "real time"...to leapfrog us into a new kind of feedback system -- one that Ellwood and other acolytes of the market have long had in mind.

The system, in effect, would give us a camera lens that's always open. This lens would convert each "frame" of health care experience into a seamless moving picture -- one that could be constantly edited to reflect new knowledge. And as these "frames" of knowledge rolled constantly forward, we could use them as guides to continually improve quality and cost-effectiveness.

Now, *whose* quality? And *whose* cost-effectiveness?

Let me give you an example.

I heard a presentation recently by a fellow from a U.K.-based private health insurance company. He was talking about laparoscopic cholecystectomy...which, of course, is a minimally invasive technique for gall bladder removal and which I shall call, "lap coly."

The insurance fellow was decrying the fact that his firm was receiving increasing numbers of claims for gall bladder removal. And he blamed it on lap coly. He said that the ease of the procedure was causing physicians to use it when the indications for its use weren't clear. And that, he said, was driving up costs for his firm.

At which point someone in the audience stood up and said something like: "But what about the patients who now don't have to endure major surgery? And what about the

employers that get those patients back to work faster? And what about the health system as a whole -- aren't its costs *actually lower*?"

I don't recall precisely how the insurance fellow answered. But the gist of his response was: "That's not my compartment."

Well, this next principle says that kind of answer is not acceptable. **[Overhead 24]** It says we have to take into account *all* the compartments -- *all* the perspectives of the major stakeholders, including patients and employers.

The reasoning is that if we don't do this, we'll blind ourselves to the system-wide efficiencies that technologies -- like lap coly -- can make possible.

Now, just as no single compartment should be our vantage point on technology, neither should any single decisionmaker have the exclusive say.

The dream of a single, omniscient arbiter of technology is perhaps the most dangerous element of the conventional thinking. It's dangerous because it's so appealing. It *does* sound appealing to make a decision once and for all, to apply it across the board, and to then watch uniform little columns of health care fall into lockstep.

But the reality is less tidy. There are rarely single answers to complex medical questions -- and a top-down, centrally driven approach risks imposing a wrong answer for many

patients. One shudders to think how CT scanning might have fared under this thinking in, say, 1975.

Our fifth principle, then, calls for a pluralism of decisionmakers. **[Overhead 25]**

Providers, payers, and health plans know their own circumstances. They're closer to their own patients. And -- together -- they can act as checks and balances.

Happily, we're see growing recognition of these facts. One expert panel in the U.S. pointed out that national practice guidelines should serve as no more than departure points for local adaptation. And the Agency for Health Care Policy and Research -- the agency that, in the past, took nearly two and a half years to assess a technology -- has now turned its emphasis to a global clearinghouse on the World Wide Web -- a clearinghouse from which local decisionmakers can draw.

Now let me step back for just a moment. And I'll simply note that we've just been through the first five principles -- those that relate most directly to technology and information.

The second five deal with a little bit broader set of technology issues. I'll turn to them now -- beginning with what we call "flexible updating." **[Overhead 26]**

As I explained earlier, device innovation is a constant flow of technological change. Since a payment system can reflect only the information known at a particular point in

time, there should be a predictable, timely process to update the system to capture the ongoing changes in technology.

In the 1980s, for example, it became clear in the U.S. that mammography screening had the potential to save thousands of breast cancer victims. But it took years of debate, then an act of Congress, before we updated Medicare to reflect this important service.

The point is that a payment system should be supple, fluid, changeable. We should anticipate that there will be technologies we will not anticipate.

Principle #7 -- broad units of payment -- refers to the fact that technology needs room to spread its wings. **[Overhead 27]** If it is constrained -- if our lens defines what we're paying for too narrowly -- we will not see choices that technology can make possible.

Let me illustrate. Liver cancer can be treated in different ways. One way is to administer chemotherapy on an inpatient basis. A second way is to deliver these same chemotherapeutic agents by implantable infusion pump. The pump targets measured doses directly to the cancerous tissue, allowing the patient to lead a longer life -- free of many of the side effects of the conventional chemotherapy. In addition, the pump can be refilled simply by the patient visiting a doctor's office.

Despite the pump's advantages, the Medicare DRG system -- which reimburses hospitals for inpatient care -- actually discourages its use. That's because DRGs focus on

technology's consequences only within the inpatient episode of care... and thus -- through that particular lens -- can see only that it costs more to implant the pump than to administer conventional chemotherapy. The lens cannot adjust to see a "longer" payment unit -- it cannot see that the cost of repeated inpatient stays for chemotherapy will exceed the one-time cost of implanting the pump ...even after the follow-up doctor visits are added in.

What I am saying, in effect, is that we need this breadth of vision to see technology's substitutional effects -- one setting for another, one procedure for another. This is an important piece of the "value" of technology. But we also need "length" of vision to see what technology can do over time. **[Overhead 28]** You could say that our camera needs a time lapse feature -- it needs to be able to see technology's effects over a longer period.

Site-neutral incentives **[Overhead 29]** is a related principle. And I should add that I use the word "site" to mean *where* care is delivered -- that is, the hospital, the home, or some other health care setting.

Principle #9 stands for the point that we should let technology's substitutional effects -- one procedure for another, for example -- lead us to the settings where clinically appropriate care can be delivered most cost effectively.

Again, let me try to show how the U.S. system has not always done this very well.

Medicare is premised on a model of health care delivery that emphasizes acute hospital care. Now to be clear: acute care remains a vital element of U.S. health care delivery. But the current Medicare model needs to be refined and expanded to take advantage of treatments that are increasingly available in alternative, lower-cost settings, such as physicians' offices, freestanding ambulatory care centers, and the home.

For example, some home infusion technologies were long denied coverage because Medicare -- when first instituted in 1965 -- couldn't foresee that this kind of treatment would one day be available in the home.

The point is that a payment system should not favor use of technology in one setting over another. Instead, decisions on a technology's use should be based on clinical appropriateness and current medical practice.

And finally, we will not effectively implement the first 9 principles without a fair and open process for all the stakeholders. **[Overhead 30]** Let me use as my example, once again, the Medicare program's coverage process -- that is, the process for deciding whether a new technology will be eligible for reimbursement. But this issue is just as critical in private managed care plans -- especially those that enroll Medicare beneficiaries.

As I indicated earlier, this Medicare coverage process has been known for many years as the "Black Box." It acquired this title because, unless one were a Medicare program

official -- that is, already stationed in the box -- you could have little idea how the decisions would actually be made, when they would be made, and what they would be based on. Unfortunately, it took litigation before Medicare initiated steps toward reforming its process -- a development that, while positive, is by no means finished and remains a point of contention.

The point here is that decisions on technology should be the result of a process that is fair, that is predictable, and that is open to all affected parties. I want to underscore this point with regard to managed care -- especially managed care in Medicare.

Decisionmaking behind closed doors, with confusing or inappropriate criteria, breeds cynicism and resistance and will ultimately reduce availability of innovation, both for managed care plans and patients.

F. Conclusion

What I have presented is perhaps little more than the picture of a health care system undergoing change. It is, in many ways, messy. But it is bringing some needed improvements for all.

I cannot tell you whether or how to apply our experiences to your own system. I leave that to you. But let me offer you the conclusions that I draw from this dynamic, rapidly changing system that I have outlined today.

- First, medical technology offers some astounding benefits to our economy and our society. It offers improved efficiency, greater productivity, longer and healthier lives, and long-term savings for a nation's health care system.
- Second, the benefits of technology do not occur automatically. They evolve from a fragile innovation process that is heavily influenced and directed by the demands of public and private payers, increasingly dominated by managed care.
- Third, it is clear that some adjustments are necessary in the policies of those payers so that their demands are consistent with the realities of the device innovation process. Among other things, these policies must provide for clarity, openness, and promptness in assessing and adopting new medical technologies.
- Fourth, the rapid transformation of the U.S. delivery system -- through pluralistic, market-driven forces -- is bringing about many positive developments.
- Fifth -- and this is my final point -- despite the clear benefits of these market-driven changes, steps are sometimes necessary to ensure that the forces of managed care flow in concert with continued patient access, improved quality, and the continued innovation in medical technology.

I wish you the best in your efforts. And I hope that the U.S. experience is of help to you.