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THE STRUGGLE TO FIND A HOME IN REFORM

"The more sand that has escaped from the hourglass of our life, the clearer we shall see through."

--Jean Paul Sartre

When discussing the prospect of change to the structure of the American health care system, a little background is in order. Historically, the pharmaceutical industry has yielded to certain cyclical patterns that emerge when a new drug or treatment is introduced to the marketplace or new regulations come into effect, resulting in an initial surge followed in time by greater restraints imposed from both the federal and state level. Since its inception in 2010, the Affordable Care Act has in many ways preempted these cycles as it seeks to provide a nearly universal health care blanket by constructing a new foundation made of regulatory building blocks aimed at shifting emphasis from a cost based to a performance driven philosophy that it believes will reduce fraud and waste, thereby lowering costs across the board. Within its folds exist a number of pharmaceutical specific studies and programs designed to more accurately police the industry as the Federal Government attempts to curtail spending.

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With cost savings as not only its driving force, but also the effective public barometer gauging the plan's success or failure, the ACA has taken an aggressive stance toward what the Federal Government views as wasteful spending. With this in mind, the best course of action for those in the field of pharmaceuticals would be to learn from history and not fall victim to the mistakes of the past by underestimating the effects of well-enforced regulations. This is especially true under the changes set forth by the ACA in its bid to restructure reimbursements and prevent misuse of information.

Bundled within the core tenets of the ACA is the newly enacted Physician Payment Sunshine Act, which, despite its benign moniker, wields an impressive set of muscles as it seeks to promote transparency in the dealings between physicians and group purchasing organizations, as well as the pharmaceutical, medical device and biologic industries.

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With its assertive approach to cost savings and a decisively sink or swim mentality, it is but a matter of time before the ACA implements further changes aimed at the relationship between pharmaceutical companies and the patients and providers they serve. In fact, a recent study conducted by the Office of the Inspector General (OIG) for the fiscal year 2011 concluded that if Medicare had embraced a prescription drug rebate plan under Medicare Part B similar to the one held by Medicaid, the program would have netted an estimated $2.4 billion, excluding implementation costs.

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The boldness inherent at the core of the ACA has its positive side for the pharmaceutical industry as well, however. Along with its zealous approach to regulation, the ACA also brings with it a host of new opportunities that bode well for the makers of pharmaceuticals, not least of which is the ACA's acceptance of drug and alcohol addiction as chronic diseases that fall under the responsibility of modern health insurance plans. In classifying addiction as a disease rather than a lifestyle choice, this stance marks a significant reversal in government philosophy, and paves the way for a new industry-wide focus on the research, development, and distribution of addiction related treatment and medicines.

As history suggests, absence of accountability is the common thread in health care, and the moving target of regulatory focus is just as transient today in its approach to marijuana as it was in 1885 when Parke-Davis sold cocaine cigarettes, powder and injections as an alternative to food, or in 1895 when Bayer introduced diacetyl-morphine as an over-the-counter product more commonly known as Heroin. Even the "low-calorie martini," also known as MDMA, was the subject of scientific research in 1976 Berkeley, California, 69 years after the state banned marijuana as a poison.

In many ways, the ACA seems to have tucked itself between a rock and a hard place when attempting to differentiate between classes of treatment. At the same time, this $50 billion enterprise has begun to face state and federal scrutiny as the cause or solution for what has been described as epic distribution of marijuana on a national level, while small distributors continue to spread like weeds in pop up shacks along Venice Beach and in shopping malls across the country. And yet, if history has any say in the matter, the far reaching vision of the ACA could make it a matter of time before a patient is able to pick up both his anti-addiction meds and his weekend stash at the local CVS or Walgreens.

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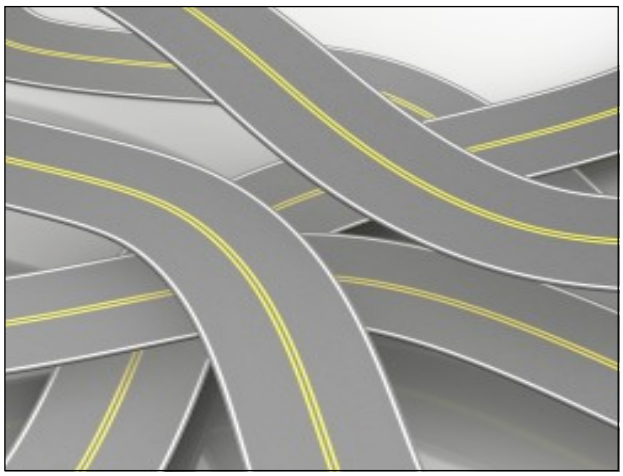
THE FAMILIAR PATH OF HEALTH CARE REFORM

Friedrich Nietzsche wrote: *"When we are tired, we are attacked by ideas we conquered long ago."*

More than three years deep into the Affordable Care Act, 13 months since the U.S. Supreme Court confirmed its constitutionality, and almost 10 months after the American public approved reform through the Electoral College, modern American health care is now poised to shine or make its claim as a historical disaster. As the nation prepares for the health insurance exchange, the next few months shall prove critical in determining the trajectory — and thus the fate — of our health care system, and we would be remiss not to notice the storm clouds forming overhead.



Despite the progress fueled by its recent success, the Affordable Care Act now finds itself in a holding pattern that to some eyes suggests turmoil in the months to come. As things now stand, at least one mandate has been delayed, Medicaid expansion has yet to blossom as fully as predicted, and Pioneer accountable care organizations, or ACOs, have begun to unravel.

Furthermore, the proposed reductions in Medicare disproportionate share payments are slated to commence on Oct. 1, the same day the next phase of the hospital value based purchasing program takes effect. Although the upcoming set of Medicare Shared Savings Program ACO selections may generate some reform-related momentum, something as trivial as a few poorly timed, misfired state exchanges could be enough for an injunction stopping them all in the name of equal protection. These seemingly contradictory elements force those in the industry to ask the question: Is modern American health care truly at a strange new crossroads, or have we as a nation traveled this path before?

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The uncertainties that accompany any historical reform such as the Affordable Care Act are of course to be expected, and our health care history is riddled with similar examples. Forty-two years ago the "debate on health care in the United States [was] of the first order of importance to the health professions, and of no less importance to the political future of the nation, for precedents [set then would] be applied to the rest of American society in the future."

The same can be seen when comparing industry reactions to some of health care's more prominent evolutionary markers. Historically speaking, certain structurally changing concepts such as ACOs and the patient centered medical home are not as dynamic as it would initially appear when viewed in the big picture. "A new concept of practice requires a new type of facility to replace, or perhaps to supplement, the hospital, which has become the center of health care but is now inadequate. The new concept of the community health center is needed. This should be combined with hospital-based group practice, which is undoubtedly the best way to bring health services to the people."

In this context, the present state of physicians should come as no surprise. Just as doctors abandoned the hospital setting almost 50 years ago in favor of Part B, today's physicians now find themselves exiting the Medicaid program en masse as they take aim at Medicare while battling this most recent round of imperialist hospital spending sprees. Caught in the resultant cross-fire, patient perception of the physician plummeted around the same time that Gregory House replaced Marcus Welby as the quintessential physician in American pop culture.

Structural uncertainties aside, there is comfort in knowing that the stakes remain largely unchanged since the introduction of Medicare. "The implementation of a law so extensive and complicated as Medicare will involve the private physician in a bureaucratic pattern perhaps more complex and frustrating than he has ever seen. The paperwork he now complains about will be inconsequential by comparison. Such is the nature of a bureaucracy, especially one implementing a program costing billions of dollars and affecting millions of people."

In times of flux, historical lessons often provide meaningful insight and offer much-needed clarity by showing a prior resolution in the form of its individual steps. The funds designated to flow into today's health care system will help to build a greater infrastructure, to be sure, while hospitals and insurance companies shall certainly benefit in this recent era of reform. The greatest value to be found in the influence of the Affordable Care Act, however, lies in the achievement of that all-important third step, when factors old and new combine to rebuild that continually tenuous bridge between doctors and their patients.

MEDICARE: THE PERPETUAL BALANCE BETWEEN PERFORMANCE AND PRESERVATION

"Confusion is a word we have invented for an order which is not understood."

-- Henry Miller

Since its introduction in 1965, Medicare has weathered innumerable storms within the ever-changing climate of American healthcare and grown to be the preeminent standard for health insurance in the United States. And yet, despite repeated attempts on the part of the Federal Government to fortify its foundation and ensure Medicare's longevity, the effects of such growing pains and structural changes felt by the program over the past 48 years continue to make losing Medicare as a vital public benefit the single greatest fear with which each passing generation of Americans must contend.

The most recent changes implemented by the Patient Protection and Affordable Care Act ("PPACA"), while laudable in their attempt to ensure coverage for a broader group of people, add additional layers of complexity to such an extent that it may be but a matter of time before the confusion experienced by today's providers impacts the coverage and well-being of our nation's seniors. While healthcare in America is an industry built upon decades of trial and error from the point of view of both physicians and lawmakers, it may soon be forced to witness firsthand how the information providers typically share with patients, including diagnosis and dialogue, may give way to confusion and disruption industry-wide as a result of newly enacted regulations.

Today, Medicare is the preeminent standard for America's health care industry, and the ways in which it has evolved to weather fluctuations in the economic, political and social climate over the past 50 years have been necessary components to ensure its survival. To this end, most of the substantive changes to Medicare over the decades have triggered a corresponding restructuring of the entire health care system. If nothing else, in its struggle toward sustainability, the Medicare Program must be mindful of the resulting consequences as it evolves and further distances itself from the simplicity under which it initially operated in 1965.

The industry's transition in the 1980s from an originally cost-based system to the prospective payment system ("PPS") takes another step under the PPACA, this time focusing on a system based primarily on performance. Such a formulaic approach to provider reimbursement under the Medicare program has drawn comparisons to *Finnegan's Wake* by James Joyce, a book which according to some critics is generally incomprehensible. While one may argue that the preeminate system for health care reimbursement in the United States should be understood by all hospitals and physicians providing medical care thereunder each day, concern over Medicare's potential insolvency has prevailed under the PPACA. As providers struggle to understand the new Medicare system under health care reform, there is little room to debate whether or not a balanced solution is even viable. Providers can no longer return to the PPS system as it existed before PPACA, but instead must familiarize themselves with Medicare's performance-based model or be forced to watch their Medicare revenue decrease by incremental percentage points with each transgression.

Enrolling 19 million elderly Americans within its first year, Medicare's initial goal was simple: It sought to provide coverage to all persons 65 years of age or older who could satisfy certain legal residency requirements. The program cornerstone was "Part A," which provided health insurance coverage for those qualified individuals requiring hospitalization. The more concessional "Part B" offered optional benefits addressing medically necessary services such as doctor visits, outpatient care, and home health services. Simultaneously, Medicaid provided similar access to heath care on a state level for qualifying low-income individuals, expanding the already-existing federal and state welfare structure in the United States.

With only two historical benchmarks forcing Medicare's structural evolution over the decades, the system of guaranteed health insurance for those 65 years of age or older has become quite the regulatory enigma. The first change occurred in the 1980s under the Reagan administration with the introduction of the prospective payment system and diagnosis-related groups ("DRGs"). Designed to reduce healthcare costs by shifting the burden of operational efficiency to the hospitals, to this day DRGs remain at the core of the Medicare system.

The ACA introduced the most recent fundamental change to the Medicare system, although its implementation has just begun and will continue over the next several years. If *efficiency* had in the past defined DRGs, *performance* now lies at the heart of Medicare's most recent structural upgrade. Separated by almost 30 years, each transition has nonetheless raised the threat of catastrophic operating losses for hospitals unable to meet or exceed the respective standards. To be sure, by holding hospitals to a higher level of efficiency, DRGs have been generally successful for Medicare Part A in accomplishing its fiscal objectives.

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