FUTURE INNOVATIONS AND STRUCTURAL CHANGES

DR. GREGORY K. BELL, Executive Vice President of CRA International, presents his view of the future.

What are some of the more significant structural changes that will shape our industry in the future?

I see three structural changes likely to have a fundamental impact on the way the industry operates. The first concerns the increasing consumerization of healthcare, particularly as we see more pharmaceuticals being introduced to address what some might term lifestyle conditions. Globally, consumers are going to become more attuned to the cost of pharmaceuticals as national and private payers continue to push more of the fiscal responsibility for care directly onto the patients. In the U.S., although Medicare Part D puts pharmaceutical benefits coverage within the reach of all senior citizens, the prevalence of co-insurance tiers means that most Part D recipients will continue to feel the cost of individual prescriptions. We are also seeing significant growth in consumer-directed health plans (CDHP).

Second, the potential to unite therapeutics and diagnostics is likely to change the way pharmaceutical companies develop drugs and bring them to market and the way that physicians use more specific therapies to treat their patients. Some of the promise of new biologics and gene-based therapies lies in customizing therapy. That ability, however, will likely be tied to a specific diagnostic. As a result, I expect that pharmaceutical companies are going to be investing in diagnostics, a part of the industry that many of them have not really addressed. The benefits of more targeted therapies could be substantial – greater efficacy and greater compliance justifying higher prices – but the consequently smaller patient group does not really fit with the "blockbuster" model that has dominated the industry.

The third significant structural change concerns physician-administered drugs, those that are given by injection or infusion in the physician's office. These products tend to be distributed using the "buy & bill" model; physicians, mostly oncologists, buy these products, dispense them in their offices, and then bill insurers for the administration and the product itself. In the U.S., Medicare Part B probably pays for one-third to one-half of these therapies and appears to be looking to change the business model, likely to one in which the physicians no longer profit from dispensing the products. The Competitive Acquisition Program has not been a particularly successful first step, but the writing appears to be on the wall. The days of "buy & bill" appear to be numbered and I expect private payers will be seeking to introduce similar reforms and subject product choice in the physician office to many of the same type of formulary and category management techniques used for the self-administered drugs purchased from the retail pharmacy.

Are pharmaceutical companies going to continue to be rewarded for innovation?

Obviously the rewards for innovation must be maintained; those rewards have driven the remarkable innovations that the industry has generated and supported the resulting significant gains in health and welfare. Nonetheless, budgets for healthcare are strapped, both among national payers and private insurers. New ways to price innovation must be developed or we run the risk of more stringent and invasive pharmaceutical price controls that will only cripple the opportunities to develop life-saving therapies in the future. A notable example is the recent announcement that two European governments agreed to allow GlaxoSmithKline to raise the price of some drugs once additional clinical data on their value is available. At-risk pricing and contracting options that will align the interests of the pharmaceutical company with the interests of the payer offer the opportunity to secure higher returns for innovation, but are likely to threaten the profit potential of less innovative product introductions and line extensions.

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