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**/THE FIRST WORD****Preserving Biotechnology**

**P**harmaceutical stocks are off. U.S. biotechnology executives are nervous as long-tailed cats in a roomful of rocking chairs. On the one hand, the incoming administration promises to create jobs, foster technology, and promote education—all goals that bode very well for biotech. On the other hand (the hand with the iron fist in the velvet glove), we've barely begun to learn how to biotechnology should play the existing marketing and regulatory game—and the new administration may rewrite the rules.

Biotechnology is one of the brightest spots in what may be the economic story of the decade: the U.S. high-technology turnaround. So along with our support for Bill Clinton's and Al Gore's policies of enlightened stewardship of the nation's land and economy, we enclose a message—a plea, really—to the new administration: Please don't louse up a good thing.

To begin a list of specifics that will continue next month:

*Look at costs...but look at benefits, too.* Across the board, big-company pharmaceutical research productivity is in a tailspin: The curve of new product sales per research dollar invested seems to be a hyperbola asymptotically approaching zero. Most big drug-makers rely on price increases on old products to keep sales up.

Against this background, it is tempting to denounce as profiteering a new drug (like the newly approved Genetics Institute-Baxter factor VIII) that costs, per year, three times what most families make.

But these biotechnology drugs don't fit into the picture. They are new, and offer hope where there may have been none before. They are expensive to discover. They are, moreover, very expensive to produce.

Production-cost studies for a leading peptide therapeutic show that the product's much-criticized price runs two or three times the cost of manufacture—a sight less than the five-times-manufacturing formula we used to set prices for trade books, back when. And that figure that doesn't even begin to amortize the costs of research and development.

There's another danger to cost-cutting schemes, especially those that codify current practice in tables of fixed prices for approved products: They fossilize the state of the art and keep badly needed new treatments out of the hands of patients.

Drugs are easy targets, but it would be supremely foolish to try to reduce the nation's healthcare bill solely by trimming the 7 percent or so devoted to pharmaceuticals.

*Don't abandon the Orphan Drug Act.* It's not just that research costs are spiraling and production is expensive. It now seems likely that many biotech drugs will be orphans. As we've noted before, clinicians and regulators are looking increasingly to narrow, molecular indications, especially for protein-based therapies. This trend seems destined to fragment large indications into hosts of smaller ones. Add to that the natural market limitations on injected formulations and you have a recipe for expensive research that must be recouped from ever smaller patient populations.

Be very careful about removing incentives to produce therapies for these patients, many of do not respond to conventional therapies. We'd save healthcare costs, certainly, but at what cost to the patients themselves?

More next time.

**The new look**

This month, we introduce a new graphic design to usher in our Jubilee Year (the March issue will mark our 10th anniversary; tin is the material of choice, say the tradition-mongers, so see your whitesmith today). To complement our increased editorial coverage, we've adopted a more open, easier-to-read presentation. Let us know what you think.

—DOUGLAS K. MCCORMICK