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Bio industry hopes for help from Obama

Silicon Valley / San Jose Business Journal - by Lisa Sibley

President-elect Barack Obama hasn't outlined details of his administration's biotechnology agenda yet, but industry leaders in Silicon Valley are closely watching what he will do with the U.S. Food and Drug Administration and stem cell research.

The industry has fallen into a "comfort zone" with the FDA and could be in for a shock, suggested John Manthei, a partner and global co-chair of Latham & Watkins LLP life sciences practice group in Washington, D.C.

The FDA is likely to be more aggressive next year, he said, because Democrats believe the agency hasn't enforced laws as well as it could.

He said there will probably be more investigations with an increased emphasis on product safety issues, which could ultimately slow approvals of new drugs and therapies.

Matthew Gardner, chief executive of BayBio — a trade association serving the Northern California life science industry — said the industry is always concerned about regulation.

"At the end of the day, it comes down to whether there could be too much regulation," he said.

Edison Pharmaceuticals Inc. CEO Dr. Guy Miller worries that the FDA has become a pseudo-legislative body. While it's good that the FDA is increasing regulatory requirements for drugs that are better than previous generations, he said a regulatory body shouldn't be legislating.

The San Jose biotechnology company has diversified its funding to prepare for economic uncertainties, Miller said. The company has raised funds through alternative financing such as private, wealthy individuals, development deals and the National Institutes of Health.

The company focuses on drug development for rare diseases that impair energy metabolism.

Edison and other biotechs will probably need more funds, Manthei said, because Democrats are likely to use facility inspections and user fees to raise money to get the FDA more resources.

"Asking industry to bear that burden makes drug development more expensive and limits the amount of people who can participate," he said.

Gardner said he's not hearing concerns yet over an increase in user fees.

On the positive side, Gardner said he's pleased with Obama's promise to overturn the Bush administration's position on federal funding of stem cell research and the new president's commitment to double research funding.

Jim Greenwood, chief executive officer and president of the Biotechnology Industry Organization, said his group is planning to support and work with the Obama administration and leaders in Congress to get as many votes as possible in support of stem cell research. However, he said they are also planning to use it as “a teaching tool.”

“It’s important for us to make clear to the administration and Congress that funding stem cell research through the NIH, while important, [only] provides for academic research, but it doesn’t produce new therapies,” he said. “It is companies — biopharmaceutical companies — that produce those products.”

The BIO is the world’s largest biotechnology organization, offering services to more than 1,200 members worldwide, including those in the Bay Area.

In addition, Manthei said biotech executives should also expect to see legislation in creating a regulatory pathway for the FDA to approve new versions of drugs whose patents have expired known as “biosimilars.” He also mentioned that Obama has indicated support for legislation that allows drugs sold overseas to be reimported into this country.

While it’s too early to tell who might be appointed as the new FDA commissioner and chief counsel, Gardner indicated a need for long-term FDA leadership. Greenwood stressed the importance of getting that commissioner confirmed early and ensuring it’s someone who is not hostile toward the industry or biased.

Gardner said BayBio leaders will be watching how the new administration addresses job creation as part of its stimulus program. He’s also looking for Obama to increase the capital gains tax period as it relates to early stage entrepreneurs.

He said that changing the capital gains rules would help early stage companies deal with the growing “Valley of Death,” a reference to the stage between research and commercialization, where a company’s drug or product can die without funding.

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