

BIO chief: FDA needs to create chief innovation officer position

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To keep up with the rapidly changing pace of science and technology, the U.S. Food and Drug Administration needs to create the new position of chief innovation officer, says the CEO of the biotechnology industry's leading trade group.

Adding the new position would help shape the FDA as “not an application cop, but an agency that works to try to inspire and encourage innovation,” said [Jim Greenwood](#), CEO of the [Biotechnology Industry Organization](#) (BIO).

The position's duties would include working more closely with external, nongovernment groups such as private industry and academia to stay on top of technological advances and keep the FDA informed of the latest science, Greenwood said.

Here's how BIO's managing director for science and regulatory affairs, Andrew Emmett, described the position, according to [Genetic Engineering & Biotechnology News](#): “For example, as new clinical trial designs or new biomarkers or new ways to develop or use electronic medical records are developed, the chief innovation officer would work with their developers to see that they are validated and tested in the FDA's centers, to increase the FDA's comfort level with these innovations.”

Of course, government regulators always have been and always will be popular targets of criticism from the industries they regulate, as hungry shareholders demand companies push for any advantage they can to maximize profits. But at least give BIO credit for tempering its criticism of the FDA with suggestions for how it believes the agency can improve. How responsive the FDA will be to those suggestions is another matter.

Among the FDA's greatest needs is increased funding to help it better fulfill its regulatory mission, Greenwood said. That's one point BIO and the FDA would likely agree on.

“They're still underfunded and still have chronic problems in keeping up with the science,” he said. “Given their pay scales and the length of time it takes to hire, that's always a challenge.”

If increased FDA funding is the industry's policy, it may want to [rethink](#) its political donation strategy. Since 1990, pharmaceutical manufacturers (a group that admittedly includes more than just biotech companies) have donated more money to Republicans than Democrats in 11 of the last 12 two-year federal election cycles, according to the [Center for Responsive Politics](#).

Republicans — the party of small government [rhetoric](#), if [not action](#) — would seem to be ideologically bound to opposing more funding to the FDA, and thus opposed to one of BIO's top policy priorities. That's something for biotech executives to consider next time a politician of any party calls and asks them to pull out their checkbooks.

Here are a few other suggestions from BIO and Greenwood on FDA reform:

Establish the FDA as an independent agency: The FDA is currently housed within the U.S. Department of Health and Human Services, but BIO would like to see the agency stand on its own. “We think that it would allow the FDA to be bolder in its budget requests and would speed up the regulatory process by eliminating bureaucracy,” Greenwood said.

Create “progressive approvals”: Under the FDA’s current guidelines, a drug can’t be prescribed to patients until it’s gone through a lengthy FDA review process that results in approval. Greenwood described the approach as “nobody gets access until everybody gets access.” He’d like to see that change for drugs that are “highly innovative and filling unmet needs.” BIO advocates allowing patients with such unmet medical needs access to promising drugs after they’ve been established to be safe for human consumption in early clinical trials, but before the drugs have been formally approved for commercialization by the FDA.

Update the mission statement: The FDA is “clearly mandated” to protect the public from products that are unsafe, and that mission obviously needs to stay in place, but “we also think it needs a new mandate that includes encouraging the development of innovative products,” Greenwood said.