

FDA expert panels targeted in congressional hearing

Keith Darcé – San Diego Union Tribune
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For the second time in recent months, members of Congress gathered in San Diego on Monday to hear complaints about government drug and medical device regulation from representatives of the biotechnology industry.

The problems cited at the latest hearing were similar to those in mentioned in the April gather: Time-consuming reviews by the Food and Drug Administration and inconsistent policies are blocking patient access to innovative therapies, chasing away investors and pushing companies to test and commercialize their products overseas.

“While we are currently the global leader in the development of biotechnology treatments and therapies, intense competition from China and India means this is a position we have to fight to keep,” said Steven Mento, chief executive of Conatus Pharmaceuticals, who testified on behalf of the national Biotechnology Industry Organization.

The field hearing was held at The Scripps Institution of Oceanography by the House Committee on Energy and Commerce’s Subcommittee on Health. Rep. Brian Bilbray, R-San Diego, and Rep. Michael Burgess, R-Texas, were the only members to attend.

Several witnesses urged the lawmakers to revamp rules that ban people who have a potential conflict of interest from serving on FDA independent scientific advisory committees. The result has produced panels filled with doctors and other experts with little or no experience in the disease areas covered in their reviews, industry representatives said.

While panel decisions aren’t binding, it’s rare for the FDA to go against the recommendations.

Bilbray likened the policy to blocking teachers or parents of students from serving on school boards.

“It’s an acceptance of ignorance because of a perception of conflict,” he said.

Lawmakers will get a chance to reconsider the restrictions later this year when they vote on reauthorizing user fees charged to drug and medical device makers.