## Howard Dean -- for hire

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Salon has an article today with this title: The seduction of Howard Dean, by Justin Elliot.

The Salon article details several of Howard Dean's advocacy efforts, for clients of the lobbying firm McKenna Long & Aldridge. Mentioned in the Salon article is Dean's work for drug companies, on issues such as the fight over the number of years of regulatory test data protection for biologic drugs (Dean wanted 16 years), as well as other apparently well heeled clients, such as Mujahedin-e Khalq (MEK), which Salon described as "an obscure and controversial Iranian militant group that is aggressively lobbying the Obama administration to remove it from the official list of terrorist organizations," and a group lobbying to liberalize the rules for foreign trained doctors to practice medicine in New York.

There have been several comments about the article on the Salon web site. These are a few.

I posted a letter on Dean's comments to the Gerson Lehrman Group

If you want some data points on Dean, look at this from Pharma Exec. On the issue on generics, Dean takes positions that seem to be the opposite of those he backed as a Governor. You tell me what changed his mind.

## http://blog.pharmexec.com/2011/04/06/governor-howard-dean-financing-the-future-of-us-drug-innovation/

Perhaps due to his new role as an adviser toMcKenna's biotech clients, Dean professed some views that are anathema to his own party caucus. These included support for the 12-year period of data exclusivity agreed by the Administration, PhRMA and BIO to advance the registration of follow-on biologics. Dean predicted that despite some backtracking from congressional Democrats to push the protection period down to seven years, the pledge will be kept – at 12 years. Next, while noting the financial impact of malpractice on providers has been overstated, Dean said he parts with his caucus by supporting tort reform, the centerpiece of which should be allowance for arbitration panels as an alternative to the constitutional right of victims to trial.

Finally, Dean pushed for actions to raise the "certainty index" for investors in big pharma and biotech. This includes mediating more directly between the FDA and Congress, the agency's most hostile stakeholder. "Pressures from Congress against the FDA have created an overly politicized decision-making chain on the licensing of new therapies, to the detriment of the industry's long-term future in the US," Dean said. Other actions he suggested industry pursue focused squarely on educating around the following issues: that medicines actually save money, when assessed in comparison to most other health interventions; explaining how the average price tag of financing a clinical trial has doubled over the past five years; drug companies, not academia or the NIH, do the heavy lifting in bringing new treatments to market; that manufacturing the next generation of large biologics is complex, risky and expensive; and why tax incentives in the US emphasize less productive short-term objectives rather than the long-term payout responsive to biotech's development cycle of more than a decade. That education should begin with Congress, which is "increasingly anti-science and ignorant about what is needed to seed drug innovation."

A defense of Howard Dean was later offered by Karen Finney, a former DNC Communications Director, and a self described "Friend and Adviser to Howard Dean." <u>What Justin Didn't Tell You About Howard Dean</u>. The Finney comment focused on several issues. On the biologics debate, she said this:

On the issue of biologics, one that he's known and had an opinion on long before he was DNC Chairman. For example, Justin did not mention Gov. Dean spent most of his time during the healthcare debate working with DFA and other grassroots organizations advocating for the public option as one of the most outspoken advocates. During that debate he was very transparent about his position on and support for biologics legislation sponsored by Reps. Anna Eshoo (D-Calif.), Jay Inslee (D-Wash.) and Joe Barton (R-Texas) in the House (H.R. 1548) and in The Biologics Price Competition and Innovation Act introduced by Sens. Edward Kennedy (D-Mass.) and Mike Enzi (R-Wyo.).

Here's the rest of what he said at the time about a commonsense and fair approach:

"A commonsense and fair approach, similar to the process and timeline currently in place for generic versions of chemical-based medicines, would allow the original developer of the biologic to protect the proprietary data used to develop the medicine for at least 12 years. A shorter exclusivity period would prematurely rob biotech innovators of their intellectual property and destroy incentives to develop new cures. Most firms would be unable to recoup their investments in new medicines, which ordinarily top \$1 billion and involve 15 years of research and development. If we discourage investment, we jeopardize the development of the next generation of breakthrough medicines and cures. "

This motivated me to post a comment on Karen Finney's defense

Karen Finney, a former DNC Communications Director and a "Friend and Adviser to Howard Dean," defends Dean for lobbying for the 12 year monopoly on test data for biologic drugs (he actually advocated for longer periods, but BIO only got 12). The period of exclusivity for pharmaceutical drug test data is 5 years, and in general, there is little or no practical difference in R&D costs between the two. Ms Finney suggests this was an old position by Dean, before he was paid to have it. If that is true, I would like to some evidence. We have never found anything from Dean on test data exclusivity periods before he was hired by BIO, but you can find him railing against longer patent exclusivity periods. For example, there is this from a 2002 Forbes Article:

## http://www.forbes.com/forbes/2002/0513/199\_print.html

"It's unconscionable how they're exploiting patent-extension loopholes," says Vermont Governor Howard Dean. He is a founder of Business for Affordable Medicine, an unlikely coalition of ten states, three labor unions and ten companies (such as General Motors, Wal-Mart and Motorola) now lobbying for Congress to outlaw some of the tactics used to stretch out drug patents.

Later there was this comment, signed Sarah\_2012 -- the user name for Sarah Rimmington, a lawyer who formerly worked for Essential Action in opposition to the BIO proposal on test data exclusivity. Rimmington's comment was: <u>Fair criticism of Dean</u>

I followed health care reform closely, and was incredibly disappointed by Howard Dean's lobbying activities on behalf of the biopharmaceutical industry. It was an incredibly cynical move, and very under-reported in the mainstream media. I appreciate Justin Elliot's work in raising the issue.

This was no small issue - Dean was advocating that price lowering generic competition for an incredibly expensive class of important drugs (most new cancer treatments fall in this category for example) be delayed more than twice the amount of time regular drugs receive. And we all know how expensive regular medicines are and how the pharma industry is price-gouging sick people.

These drugs cost tens of thousands of dollars a year and are a lynchpin of Big Pharma's big profits. They didn't need additional monopoly, but they got it. And Dean helped them get it. He is not the liberal many of us thought he was. Disappointing.

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