



## THE INFLUENCE GAME: Biotech Drug Lobbying War

By: Alan Fram, Associated Press Writer

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(AP) With the nation's \$46 billion biological drug market at stake, the war between makers of the pricey biotech medicines and their would-be generic competitors has involved millions of dollars in lobbying, thousands in campaign contributions and uncounted visits to members of Congress. And one noteworthy letter.

The note from the private National Health Council, sent to House leaders drafting health overhaul legislation, said the plea was on behalf of "the more than 133 million Americans living with chronic diseases and disabilities and their family caregivers." It urged lawmakers to protect the makers of high-technology biological medicines against early competition from lower-cost generic copycats.

The letter did not mention that nearly \$1.2 million of the council's \$2.3 million budget in 2007 came from the pharmaceutical industry's chief trade group and 16 companies that sell or are developing the brand-name biotech drugs.

The July 20 letter is an example of a favored lobbying tactic \_ special interests quietly financing private groups that may take their side as respected, seemingly independent allies without obvious financial interests in the outcome. It also underscores how both sides are using every weapon at their disposal as they battle over an issue that will affect millions of Americans but has been overshadowed by Congress' larger struggle over reshaping the nation's health care system.

Biotech drugs, made from living cells that treat diseases from cancer to psoriasis, can cost a patient tens of thousands of dollars per year. Amgen Inc. and the other companies that make them want their products protected from generic products for at least 12 years, and have won early congressional votes on the issue, due in part to a lopsided edge in lobbying resources. Their generic rivals want to cut that waiting period to five years.

In its letter to House Energy and Commerce Committee Chairman Henry Waxman, D-Calif., and other leading legislators, the council argued for at least 10 years of exclusivity, saying the longer protection would encourage biotech companies to keep developing products. The generic drug industry sees that as supporting the biotech companies, but council vice president Marc Boutin says its position is a balance of the views of the 50 patient advocacy groups, like the March of Dimes, that comprise the heart of his organization.

"The sponsors have no control or input" into council projects, Boutin said.

Manufacturers say they need the longer protection to earn a profit on biotech drugs, which can take over \$1 billion and a decade to bring to market. Generic companies say waiting that long would discourage

them from developing competing products and would keep drug prices high \_ just when President Barack Obama is trying to lower medical costs as part of his reshaping of health care.

The White House has proposed seven years of protected marketing for brand-name drug makers.

The health council's letter lists its board members, which include the drug makers Amgen and Pfizer Inc., along with patient groups and other companies and medical industry organizations. The council's Web site lists many of the contributions it receives from these groups, another rarity.

"Is all their work bad? No," Steven Findlay, health analyst for Consumers Union, which backs the shorter five-year period, said of the council and other patients' groups that accept medical companies' financing. "But when it comes to health care reform and biogenerics, are they going to oppose the industry on that? No."

Billy Tauzin, president of the industry group Pharmaceutical Research and Manufacturers of America, which gave the health council \$290,000 in 2007, called them "a great organization" with unchallenged credibility.

"We'll stand by them whether or not they agree with us, any day," said Tauzin, who is also on the council's board.

The lobbying battle has so far been one-sided. The Senate health committee voted 16-7 for a 12-year protection period last month, while Waxman's House energy panel voted 47-11 for 12 years of protection last Friday on an amendment by Rep. Anna Eshoo, D-Calif., who has numerous biotech firms in or near her Silicon Valley district.

That dominance is partly due to a huge disparity in money, according to the nonpartisan Center for Responsive Politics and the Senate Office of Public Records.

Representing biotech companies, the Biotechnology Industry Organization has spent \$3.7 million lobbying so far this year. Their ally, Tauzin's association of drug makers, has spent \$13.1 million \_ the second most of any group that lobbies in Washington.

The main group opposing them, the Generic Pharmaceutical Association, has spent \$1.1 million lobbying this year. Another group, a coalition of generic drug companies, insurers and large employers, has spent another \$180,000, though most of its members \_ like AARP and the General Motors Corp. \_ are more focused on the overall bill and are devoting few resources to the generic fight.

Individual biotech companies like Amgen are also easily outspending their generic rivals such as Teva Pharmaceuticals USA, Inc.

The one-sidedness extends to campaign contributions, too. The biotech organization contributed \$192,000 to federal candidates in the two-year 2008 election cycle, the pharmaceutical association \$155,000. The generic association: \$51,000.

All that money has let the biotech industry launch a lobbying blitz, with targets including lawmakers from biotech-heavy states like California, Maryland, Massachusetts, New Jersey and North Carolina.

The biotech organization has brought its CEOs to Washington, and has run print and radio ads in the states of pivotal lawmakers. The pharmaceutical association has helped organize lobbying by universities that conduct biotech research and venture capitalists who invest in such firms, and paid for a Duke University study that concluded biotech firms need 12 to 16 years of protection from generic competitors to break even.

With Democrats controlling Congress, doctor and former national Democratic Party Chairman Howard Dean has spoken out for the biotechs \_ though initially he did not reveal he worked for a law firm advising the biotechnology organization. Former Rep. Ron Klink, D-Pa., and Charles Brain, a former top House Democratic health aide, are lobbying on the biotech side.

"They don't do one thing, they do everything," said a frustrated Katie Huffard, a GOP lobbyist leading the generic coalition. "They are a very formidable, powerful presence."

Other big pharmaceutical contributors to the health council included Pfizer, \$184,000; Wyeth Pharmaceuticals, \$141,000; and Eli Lilly and Co., \$131,000.

***Company Codes:*** NASDAQ-NMS:AMGN, NYSE:PFE, NYSE:WYE, NYSE:LLY

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*National Health Council response, Tuesday, August 4, 2009:*

The National Health Council has advocated for a regulatory pathway for biosimiliars that improves access to existing drug therapies while simultaneously promoting the development of new treatments. Our most [recent letter to Congress](#) was posted on the NHC website in June, and the Associated Press reporter acknowledged seeing it.

Unfortunately, the reporter described only part of our position – the part that calls for 10 years of data exclusivity similar to other international standards. The reporter did not address our call to use data exclusivity to encourage the development of treatments for conditions with limited or no treatments such as ALS or lupus. In doing so he implied that the NHC's position had been inappropriately influenced by drug manufacturers. Our [policy on corporate relations](#) publicly defines our relationship with business and industry.

Throughout the debate, the NHC has been clear in its cause to foster research and development in a way that leads to breakthrough treatments so desperately needed by patients.