



Working Together for an Affordable Future

PRESS STATEMENT

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NCHC, Stakeholders Counter Attempt to Cripple Competition from Generic Biologic Drugs

WASHINGTON, D.C. (JUNE 5, 2012) – In a letter to U.S. Food and Drug Administration Commissioner Margaret Hamburg, health care advocates, seniors groups, unions, pension funds, consumer advocates, and health plans joined with the National Coalition on Health Care to urge the FDA to reject recent efforts to limit generic competition to high-cost biologic prescription drugs.

The letter was a response to comments from several pharmaceutical manufacturers submitted to the FDA that call for assigning generic biologic drugs a different International Nonproprietary Name (INN) from that belonging to the original brand name drug. The impact of this regulatory change could extend beyond FDA rules; several state prescribing laws require that generics can only be substituted for a brand name drug if they have the same name.

“This seemingly obscure regulatory decision could seriously impact the affordability of prescription drugs. In these states, consumers and health plans would continue to face costs that can exceed \$100,000 a year per person for a single brand-name drug,” explains NCHC President and CEO John Rother.

The letter also stressed significant negative implications for patient safety.

“Requiring different INNs for biologics and biosimilars could lead to patient and prescriber confusion, increasing the possibility of medication errors, and would also effectively separate the biosimilar from existing safety information about the underlying molecule,” the letter states. “In addition, since adverse events and product recalls for small-molecule and biologic drugs are already successfully identified using the national drug code and lot number, there is no compelling evidence that biosimilars should be handled differently.”

"With high drug costs, driven by the high price of biologics, burdening consumers, businesses and public institutions alike, a competitive market for these drugs is vital for both our health system and the national economy," said Rother.

Signatories to the letter included the National Coalition on Health Care, Health Care for America Now, AARP, Aerospace and Agricultural Implement Workers of America (UAW), Alliance for Retired Americans, AFL-CIO, American Federation of Federal, State, County and Municipal Employees (AFSCME), American Federation of Teachers (AFT), American Medical Students Association, Blue Cross and Blue Shield Association, California Public Employees Retirement System, Community Catalyst, Consumer Federation of America (CFA), International Brotherhood of Teamsters, National Association of Chain Drug Stores (NACDS), National Committee to Preserve Social Security and Medicare, Older Women's League, Service Employees International Union (SEIU), United Automobile, UAW Retiree Medical Benefits Trust, United Steelworkers (USW), US Action, and US PIRG.

The text of the letter can be found [here](#).

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The National Coalition on Health Care, the oldest and most diverse group working to achieve comprehensive health system reform, is a 501(c)(3) organization representing more than 80 participating organizations, including medical societies, businesses, unions, health care providers, faith-based associations, pension and health funds, insurers and groups representing consumers, patients women, minorities and persons with disabilities. Member organizations collectively represent – as employees, members, or congregants – over 100 million Americans.

Some members of the National Coalition Health Care (NCHC) do not, or cannot, take positions either on specific legislation, strategies or on any policies outside their respective mission areas. However, all that can, do endorse broad policy positions in support of comprehensive health system change.