Ronald A Rader, J Bioanal Biomed 2015, 7:5
http://dx.doi.org/10.4172/1948-593X.C1.017

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4th International Conference and Exhibition on
Biologics & Biosimilars
October 26-28, 2015 Baltimore, USA

# Impact of the biosimilars pipeline and nomenclature on market development

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The major factors that will most affect the evolution of the bio-similar markets, particularly, in the U.S. are the development pipeline and product nomenclature. There are more products, players and will be more competition than commonly presumed. As reported in the *BIOPHARMA: Biosimilars/Bio-betters Pipeline Database*, there are now nearly 700 biosimilars and 500 bio-betters in development worldwide. The market will be more like generic drugs, with many, often 10 or more, biosimilars competing with reference products and each other (along with bio-betters and other new me-too products). The U.S. market will be chaotic, with many players having different goals and approaches to competing in the marketplace. The nomenclature/names to be applied to biosimilars will be the primary driver shaping their market, particularly marketing, in the U.S. The names used will control underlying perceptions of these products – whether biosimilars are each unique high-tech biopharmaceuticals or are rather generic, all much the same. The official FDA-designated non-proprietary product name to be used in marketing and labeling will determine U.S. biosimilars marketing. Generic-type names indicate products are the same and reduce or even eliminate the need for marketing, as with most generic drugs. More unique names indicate products are each different, not comparable, and require biosimilars be proactively marketed, much like innovator products. The impact of ongoing nomenclature activities by the FDA and WHO/UN, with its INN nomenclature and proposed worldwide Biological Qualifier (BQ) manufacturing site identifiers, will be discussed.

## Biography

Ronald A Rader has been President of his own publishing/consulting company, the Biotechnology Information Institute, since late 1990. He has a BS in Microbiology, Master in Library Science, and over 30 years experience as a pharmaceutical and biotechnology information specialist, author, publisher and consultant. He is a world-class expert in biotechnology and pharmaceutical information, competitive intelligence, technology and market assessments and information resources development and concerning biopharmaceutical products and bio-processing. He is best known as the author and publisher of *BIOPHARMA: Biopharmaceutical Products in the US and European Markets*, the only information resource specializing in biopharmaceuticals. He is also the author and publisher of the *Biosimilars / Bio-betters Pipeline Database*. For 15 years, from 1988-2018, he was the author and publisher of the *Antiviral Agents Bulletin*, the only periodical specializing in antiviral and HIV drug and vaccine development. Prior to his own company he served as a chemical and biomedical information specialist with companies including the Gillette, MITRE Corp. and Computer Sciences Corp.

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