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GLOBALIZATION OF BIOSIMILARS

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With over 100 products currently available as potential biosimilar candidates, there is a dire need to develop a dossier that will be acceptable globally, if we are to make biosimilars accessible, available and affordable. Generally, if a product is approvable in US, the barrier to EU entry is lowered significantly, not the other way. I have filed citizen petitions to FDA to change its evaluation process to bring the EU and US requirements closer; this advise includes removing bridging studies, modifying the analytical similarity testing because of mistakes in the guideline, which the FDA withdrew after receiving my petition; change the PK testing protocols; adopt more *in vitro* immunogenicity testing and minimize in-patient studies. A few years ago, EMA would not consider any filing without testing in patients, now they do, just like the FDA does. Similar to how the International Conference on Harmonization (ICH), there is a dire need to develop global guidelines that will be acceptable to all development countries. I am presenting an outline of this guideline, as I have submitted to FDA and EMA for consideration.

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