

# RetireSafe

Standing Up For America's Seniors!

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## **RetireSafe Comments for the May 11, 2012 FDA Draft Guidance Hearing Relating to the Development of Biosimilar Products**

Thank you for the opportunity to comment today. My name is Al Cors, and I serve as the Vice President, Public Affairs for RetireSafe, a non-profit, non-partisan organization that educates and advocates on behalf of 400,000 older Americans we count as supporters across our great Nation. Our President, Thair Phillips, had hoped to be here; however he is in Denver today participating in the Colorado Gerontological Society's 23<sup>rd</sup> Annual "Salute to Seniors." I am pleased to represent both him and RetireSafe at this important hearing to add additional comments on this critical Food and Drug Administration (FDA) draft biosimilar guidance.

### **First, I'd like to cite three recent events:**

- **Lab Mistakes Regarding Cancer Cells**

According to an April 21, 2012 *Wall Street Journal (WSJ)* article, "In hundreds of documented cases that undermine a broad swath of research, cancer samples that were supposed to be one type of tumor have turned out to be another, through either careless laboratory handling, mislabeling or other mistakes."

- **Fake Avastin Possible in 13 States**

A different article in the same April 21 *WSJ* newspaper cited above, reports an FDA warning to doctors and medical practices in 13 states regarding the fact that they may have purchased a fake version of the cancer drug Avastin, an injectable biologic. All told, at least 76 physicians and medical practices have received letters from FDA warning about using counterfeit Avastin of one form or another. The story notes; "By purchasing cheaper foreign drugs, doctors can increase their profits, say investigators probing the purchases. If doctors buy cheaper price-controlled drugs from other countries, but bill managed-care companies and

government health programs for the full price of FDA-approved drugs, the difference goes to their bottom lines, the investigators say.”

- **Avastin/Lucentis AMD Controversy**

On April 24<sup>th</sup>, several news stories noted that in the United Kingdom, the drug company Novartis had taken legal action to stop a National Health Service (NHS) effort to encourage the use of the approved cancer drug Avastin to treat wet age-related macular degeneration or wet AMD, rather than a more expensive drug, Lucentis, a drug approved and licensed for use in the treatment of AMD. A *Daily Mail* story noted that the Royal college of Ophthalmologists “supports the continued use of Lucentis,” and also noted that “fears over side-effects” had led the U.S. Department of Veterans Affairs to stop using off-label Avastin for the treatment of AMD.

These three recent events are important because they highlight just how critical the FDA Biosimilar Guidance is for all Americans, and especially for “seniors.” Please remember that there are roughly 10,000 new retirees every day, and that older Americans will soon comprise some 20 percent of our population. They will no doubt be the largest users of biologics and biosimilars. We want them to be safe. In the first instance above, scientists made major mistakes in the lab, endangering both research and patients. In the second instance, we know that fake biologics of uncertain provenance are enriching some greedy individuals while putting perhaps thousands of cancer patients at risk. In the third and final instance we know that governments on both sides of the Atlantic Ocean have tried to favor the use of one unapproved and unlicensed injectable biologic for the treatment of AMD over the use of an approved and licensed injectable biologic designed to treat AMD, just to

save money. In the last case, we know that infections and side-effects have been reported, probably because of this substitution.

There can be no short-cuts. Both original biologics and their biosimilars must be rigorously tested, including full clinical trials. Biologics are complex organisms and as we have seen, even scientists can make mistakes. Every drug destined for the market must be fully proven to be safe, with no exceptions. The biosimilar system must absolutely guard against the use of cheaper imported drugs that may bring the plague of counterfeit foreign drugs here. The complete surveillance system for biosimilar manufacture, marketing, and distribution must be in place before a single patient is put at risk. Finally, there can be no forced government or third-party payer substitution because one biologic drug is simply cheaper than another. The choice between two biologic drugs should be a patient/physician decision, made after both drugs are fully approved to treat the respective illness. Biosimilar drugs are not innovator drugs, and thus have a large time (and cost) advantage over the developers of new, innovative treatments and cures. These drugs should certainly come to market sooner, and cost less. But, biosimilar drugs are also not generics, and they must all be required to prove their safety and effectiveness just as the reference drug to which they are similar did earlier. There should be no “flexibility” (intentionally introducing differences to the molecule or the finished product) allowed in the manufacture of biosimilars. That would clearly open the door to unintended or unanticipated risk. Biosimilar drugs should each be labeled distinctively, and a strong track and trace system for them should be fully in place before they come to market. That’s what patients want as guidance for this important new class of drug. Thank you for your consideration.