

# No More Animal Testing--President Biden signs the Bill meeting Professor Niazi's recommendations

*A Bill signed today allows waivers of animal testing for new drugs and biosimilars, a major shift in how the drug development with lower cost and better safety.*

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No More [Animal Testing](#)--President Biden signs the Bill meeting Professor Niazi's recommendations.

Professor Sarfaraz Niazi, a strong proponent of animal rights, won today big as President Biden signed the [FDA Modernization Act 2.0](#), which includes the Reducing Animal Testing Act removing the animal testing requirements in drug development, as proposed by Professor Niazi in a

Science magazine contribution that he had shared with every member of the US Senate and the House to convince them of the scientific rationale and merit behind avoiding animal testing.

The Bill amends 21 U.S.C. § 355(i) to substitute the term "nonclinical tests" for the current "preexisting clinical tests

(including tests on animals)" and also amends Section 351(k)(2)(A)(i)(I)(bb) of the [Biosimilars Price Competition and Innovation Act \(BPCIA\)](#) to substitute "animal studies (including the assessment of toxicity)" with "non-clinical" testing defined as: "a test conducted in vitro, in silico, or chemico, or a non-human in vivo test and may include animal tests, or non-animal or human biology-based test methods, such as cell-based assays, microphysiological systems, or bioprinted or computer models."

Professor Niazi stated, "this is a major shift in how drugs will be developed with better confidence in their safety, particularly the biological drugs that have no pharmacology in animals. Applied to biosimilars, this will expedite their market entry and at a more affordable



Leave Them Alone



No More Animal Testing of  
New Drugs and Biosimilars"

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cost; and with lesser safety risk by preventing developers from using animal toxicity studies to justify analytical differences that are more relevant."

The Reducing Animal Testing Act was first created by Senator Lujan of New Mexico, with whom Niazi had shared his writings; another Bill in the Senate is to remove the Interchangeability status of biosimilars by Senator Lee of Utah, where Professor Niazi had provided the supporting arguments.

"Now we have technologies that are more objective in testing the safety and efficacy of drugs; I am glad that our first milestone is achieved, and the other interchangeability redaction of biosimilars will arrive soon, leaving only the removal of clinical efficacy that has proven to be worthless. To make biological drugs affordable, we need to have a better understanding of science and not require testing, just for the abundance of caution," said Niazi

Professor Niazi is a member of the College of Pharmacy, University of Illinois, Chicago, IL. He has pioneered biosimilars with several FDA approvals.

Novel351k, Inc released this news.

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