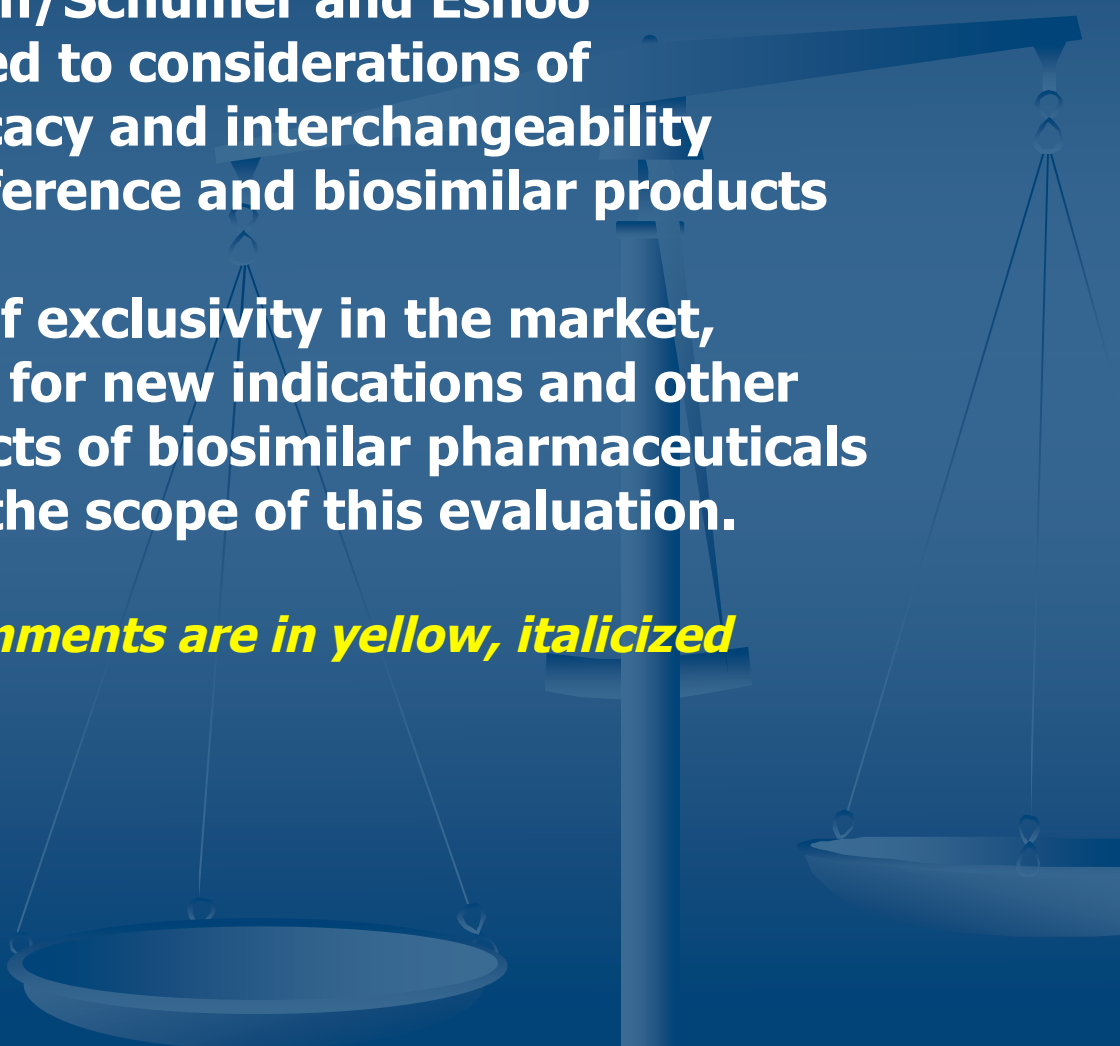


**Comparison of the Biosimilars Legislation  
Proposed by Henry Waxman and Anna Eshoo  
US House of Representatives**

**Charles Schumer  
US Senate**

**Waxman and Schumer bills are the same**



**Comparison of the Two Distinct Bills  
Waxman/Schumer and Eshoo  
is limited to considerations of  
safety, efficacy and interchangeability  
between the reference and biosimilar products**

**Questions of exclusivity in the market,  
and provisions for new indications and other  
commercial aspects of biosimilar pharmaceuticals  
are outside the scope of this evaluation.**

***Reviewer comments are in yellow, italicized***

# Comparison of the Biosimilars Legislation

	Waxman HR/Schumer S Bills	Eshoo HR Bill
Biosimilarity based on:	<p>Chemical, physical, biologic and other non-clinical laboratory studies.</p> <p><i>Definition of biosimilar is circular – suggested alternative creates an operational definition and criteria</i></p>	<p>Analytical studies to show that product is highly similar to the reference notwithstanding minor differences in clinically inactive components</p>
Animal studies	<p>Not specifically mentioned</p>	<p>Yes; including assessment of toxicity</p>
Clinical studies	<p>Yes; one or more studies sufficient to demonstrate safety, purity and potency. Applicant may use demonstration of similarity or interchangeability in one indication to support claims in other indications provided the same mechanism of action is involved in all conditions</p> <p><i>Abbreviated application, discretionary based on judgment of Secretary, HHS. “avoid duplicative” ... clinical studies is potentially very dangerous when it is a judgment call rather than evidence-based</i></p>	<p>Yes; one or more studies including immunogenicity and PK/PD to demonstrate safety, purity and potency in each condition of use approved for the reference product.</p> <p><i>Wording is less specific than in Waxman/Schumer bill, but studies may be more comprehensive</i></p>

## Comparison of the Biosimilars Legislation

	Waxman HR/Schumer S Bills	Eshoo HR Bill
Requested indications	Must be approved for the reference product	Same as Waxman bill
PK/PD	Route, dosage, strength must be the same as the reference product	Same as Waxman bill
Production	Appropriate facility must be used	Same as Waxman bill
Waiver of requirements	<i>FDA required to specify bases for rejection of an application. The burden on the FDA specifications here indicates that guidance will be key in determining the criteria by which some evidence or equivalence comparison can be decided</i>	FDA Secretary has the discretion to waive any analytical, animal or immunogenicity requirements determined to be unnecessary.
Interchangeability	Possible to get such a designation, though not required for biosimilarity  <i>Interchangeability should be required, not an option – if the biosimilar and the reference pharmaceutical are not interchangeable, the substance IS NOT biosimilar</i>	Same as Waxman bill  <i>Potentially stronger requirements</i>

# Comparison of the Biosimilars Legislation

	Waxman HR/Schumer S Bills	Eshoo HR Bill
Mechanism of action	Must be the same as that of the reference product	Same as Waxman bill
Product name	Secretary HHS shall designate the <u>same</u> official name for the biosimilar as for the reference drug  <i>EXTREMELY dangerous if any clinical differences exist</i>	HHS Secretary shall ensure that each biologic product approved under the bill bears a unique name that distinguishes it from the reference product and any subsequent biosimilars approved.
Guidance on requirements  <i>Guidance documents could be the basis for distinguishing class protein, glycol-protein, oligo and polysaccharide, etc. requirements</i>	<i>Not explicitly considered, except by a vague reference. Because comparison is the primary consideration, what to compare will be crucial to early identification of potential differences</i>	Secretary, HHS must issue guidance on requirements for licensure following a period of public comment/input. No products can be approved until such a time that final guidance has been issued.  <i>Secretary, HHS may indicate in guidance that certain products or product classes will not be licensed because current science or experience does not allow it.</i>