Side-by-Side Comparison of
Promoting Innovation and Access to Life-saving Medicines Act (H.R. 1427)
Pathway for Biosimilars Act of 2009 (H.R. 1548)

	H.R. 1427, "Promoting Innovation and Access to Life-saving Medicines Act" (Waxman/Deal/Pallone/Emerson) March 11, 2009	**H.R. 1548 "Pathway for Biosimilars Act of 2009 " (Eshoo/Inslee/Barton) March 17, 2009**
Scope	Establishes a pathway for approval of biosimilar and interchangeable biologics. Permits approvals of biosimilar products which reference previously approved biosimilars (i.e., copies of copies). Also provides for approval of 'other applications" under section (k)(4), which permits approval of a product that differs from the reference, or incorporates a change to the reference, including a change in molecular structure, mechanism of activity, conditions of use, rate of administration, dosage form, or strength. Product can be different in safety, purity, potency, -if there is sufficient information to establish the safety, purity, potency of the biosimilar. Comparative data is not required.	Establishes a pathway for biosimilar and interchangeable biologics. Prohibits approvals of biosimilar products which reference previously approved biosimilars (i.e,, copies of copies). No provision, such application would be approvable through the full BLA process however.
Market Exclusivity	Market Exclusivity is only available to reference biologics approved after enactment. Exclusivity is 5 years if new major substance, or highly similar major substance, has not been previously approved (this excludes products with minor amino acid differences, differences solely due to post-translational events, similar saccharide repeating units,	Provides for 12 years of market exclusivity for innovator products from the product's "first licensure. Provides an additional 2 years of exclusivity for a "medically significant new indication" (subject to FDA's determination) approved w/in 8 years after initial approval; and an additional 6 months of exclusivity for a pediatric indication. Clarifies that the date the reference

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Market Exclusivity continued	glycosolation, etc). 5 year exclusivity can be extended by 6 months for approval of a pediatric supplement, or approval of a supplement that represents a therapeutic advance, (e.g. new indication or subpopulation), and is supported by clinical studies, but will be reduced to 3 months if combined annual gross sales for any major substance contained in the product exceed $1 billion. Exclusivity is 3 years for biologics for which a major/similar substance has been approved. Biologic product must be approved after enactment and include reports new clinical investigations essential to the approval; and product must represent a "significant therapeutic advance" or subpopulation.	product was first licensed doesn't include date of approval of a subsequent or supplemental application for a new indication, route of administration, dosage form or strength.
Approval Standard	Requires biosimilar to have no clinically meaningful differences from reference product. No differences would be expected in terms of safety, purity, potency if treatment were to be initiated with the biosimilar instead of the reference. Definition same as above. Directs FDA to approve a product unless specific information enumerated in law is not provided by the applicant, thereby prohibiting the FDA from rejecting an application for reasons not specified in statute.	Requires biosimilar products to be proven safe, pure and potent, in accordance with data requirements established in product class-specific guidance. Does not define in statute. No provision.

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Filing and Review of Applications / Data Exclusivity	Applications may be filed at any time. (No data exclusivity). Directs FDA to seek to reach an approval decision on a biosimilar in advance of exclusivity expiration, and to consider exclusivity expiration in setting user fee goals. Requires the FDA to take a final action on an application within 10 months following submission, or 6 months from the time the FDA has accepted the application for filing, whichever is earlier.	Prohibits filing of a biosimilar application until 4 years after first licensure of reference product or initiation of product-specific guidance, whichever is later. (At least 4 years of data exclusivity).
Guidance Process	Directs FDA to issue a guidance addressing standards and requirements for interchangeability within two years, but permits interchangeability determinations prior to issuance of guidance. No other guidance requirements with respect to biosimilar products.	Requires FDA to issue product class-specific guidance, after opportunity for public comment, outlining criteria that will be used to determine whether a product is biosimilar to the reference product; criteria for making interchangeability determinations, if applicable; and criteria used to assess immunogenicity, if available. Prohibits FDA from approving a biosimilar product application until such guidance is complete. Allows for revision of guidance documents. Requires the FDA to establish a process through which the public may provide input regarding priorities for issuing guidance. Allows an applicant to petition the FDA to initiate the guidance process for any innovator product that was licensed 7 years prior to enactment. Requires the petitioner to describe scientific feasibility and rationale

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		behind request; and requires FDA to issue final guidance within 2 years (including guidance which states current science precludes approval of a biosimilar). Allows the FDA to issue guidance stating that current science and expertise preclude the approval of an application for a biosimilar.
Data Requirements for Approval of Biosimilar Products	FDA assessment of biosimilarity or interchangeability is based upon: data from non-clinical laboratory studies, and data from any necessary clinical studies sufficient to confirm safety, purity and potency; clinical studies shall be designed to avoid duplicative and unethical testing. Requires applications to include information demonstrating that the biological product and reference have: 1) highly similar molecular structures, notwithstanding minor differences in heterogeneity, impurities, degradation; 2) same mechanism(s) of action, if known or can be reasonably determined; 3) proposed condition(s) of use have been previously approved for reference product; 4) route of administration, dosage form, and strength are the same; and 5) the facility meets GMPs. Data to be submitted is in the discretion of the Secretary (i.e., FDA may waive any portion of the requirements where appropriate).	Requires biosimilar products: 1) be proven biosimilar to a reference product based on data from analytical studies demonstrating the product is "highly similar": animal studies; and clinical study or studies (including the assessment of immunogenicity) that are sufficient to demonstrate safety, purity, and potency in 1 or more appropriate conditions of use for the reference product; 2) utilize the same mechanism of action as the reference product, to the extent it is known; 3) the proposed condition(s) of use have been previously approved for the reference product; 4) use the same route of administration and dosage form; and 5) the facility meets GMPs. Allows the FDA discretion to waive analytical, animal and clinical studies; however, allows waiver of immunogenicity studies ***only*** after publishing guidance advising such waiver is scientifically feasible and

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	For a (k)(4) "other application" where there are differences from the reference, no data requirements are specified.	explaining the data required to support such determination. No such applications are permitted.
Post Marketing Clinical Studies & Post Marketing Safety Monitoring	Not addressed	Extends the FDA's authority regarding Risk Evaluation and Mitigation Strategies (REMS) to biosimilar products.
Conditions of Approval	Requires that the conditions of use of the biosimilar have been previously approved for the reference product, but does not require data or approval for each condition of use approved for the reference. Information submitted must show that the biologic product is biosimilar or interchangeable for the condition(s) of use in the proposed labeling. Also, permits data on one condition of use to support approval of additional conditions of use, if information provided shows that such reliance is scientifically appropriate.	Requires a product to be proven biosimilar for **each** condition of use for which the reference product is approved. Prohibits the approval of a biosimilar that contains select agents or toxins.
Therapeutic Equivalence/ Interchangeability	Allows the FDA to make a determination that a biologic product to be used only once is interchangeable if it is a biosimilar. For a product intended to be administered more than once, FDA can deem as interchangeable if it can be switched without an expected increase in the risk of adverse effects, including a clinically significant change in immunogenicity, or diminished effectiveness,	Allows the FDA to make a determination that a biosimilar product is interchangeable with the reference product if the product is shown to be biosimilar; can be expected to produce the same clinical result as the reference product; and the risk in terms of safety or diminished efficacy of alternating or switching the products is not greater than the risk of using the reference product without such alternation or

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	compared to continuing on reference drug without switching.	switching. ***However,*** prohibits the FDA from making a determination on interchangeability until it has published guidance advising it is scientifically feasible and explaining the data requirements necessary to support such a determination.
Therapeutic Equivalence/ Interchangeability continued	Requires that FDA reach and publish one of the following determinations: biosimilar is interchangeable with reference for one or more of the labeled indications; or interchangeability has not been established, but product is as safe and effective for approved uses as the reference. Provides minimum of 180 day exclusivity to the first approved interchangeable biosimilar after first commercial marketing of biosimilar, or up to 36 months of exclusivity if involved in ongoing patent litigation. (Exclusivity only blocks subsequent interchangeable biosimilars).	Not defined in statute. Provides a 2 year period of marketing exclusivity for the first biosimilar product deemed interchangeable w/a reference product. (Exclusivity only blocks subsequent interchangeable biosimilars).
Naming/Labeling	Permits FDA to designate an official name for a biosimilar if necessary or desirable for usefulness or simplicity. Requires that the name of the biosimilar be the same as for the reference biologic At the request of the applicant, requires the FDA to include a statement on the label that the product is interchangeable with the reference product.	Requires the FDA to ensure the labeling and packaging of each biosimilar bears a unique name that identifies the biosimilar and distinguishes it from the reference product and any other biosimilar.

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Patent Notification and 3rd Party Patents	A biosimilar applicant may, i.e., has discretion to, send a written request for patent information to the BLA holder. Within 60 days, the BLA holder must provide the applicant a list of all patents relating to the approved product. The BLA holder must update the patent list for two years after receiving the request. At any time thereafter, the biosimilar applicant may provide notice of the biosimilar application with respect to one or more patents, either listed by the BLA holder or not. This notice, which the applicant sends to the BLA holder, patent owner and the FTC, must include a detailed statement of the factual and legal basis for applicant's belief that the listed patents are invalid, unenforceable or not infringed. Within 45 days of receiving the biosimilar applicant's notice, the BLA holder or patent owner may sue for patent infringement, but only with regard to patents listed in the notice. If the BLA holder/patent owner does not file suit within 45 days, the biosimilar applicant may bring an action for declaratory judgment that the patent(s) are invalid or not infringed. If a the BLA holder/patent owner sues after the 45 days, they are entitled to damages only in the form of reasonable royalties in the event that a court finds infringement by the applicant. The bill also states that if a patent owner/licensee fails to timely disclose a patent in response to an applicant's request for patent information, the patent owner/licensee may not bring an	Requires the FDA to publish notice identifying the reference product identified in the application within 30 days of acceptance, thereby initiating a timely process that enables biosimilar applicants and patent holders to identify relevant patents in question. Ensures that owners of 3rd party or platform patents are notified, facilitating licensing of identified patents to biosimilar applicants. Requires reference product sponsor and 3rd party patent holders to identify all relevant patents to the biosimilar applicant, and an explanation of why patents are infringed; then requires applicant to explain why patents are not infringed or are unenforceable, or that it will not commence marketing of biosimilar until patent expiry. Allows patent holder to bring suit over any disputed patents. If successful, FDA approval of biosimilar is not effective until infringed patent expires. If patent holder does not bring suit, allows biosimilar applicant to seek declaratory judgment 3 years prior to expiration of data exclusivity period of reference product.

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	action "under this title" for patent infringement.	
Treatment of trade secrets and confidential commercial information	States that applications may rely in part on data from reference product application, and that FDA may review information in the reference product's application to reach a determination of biosimilarity.	No provision.
Transitional Provisions	No transition provisions. Market exclusivity provisions are prospective only.	Establishes clear transitional rules for products already approved by the FDA, allowing the FDA to immediately initiate guidance process relating to reference products approved more than 7 years prior to enactment.
User Fees	Establishes a user fee program and directs Secretary to revise PDUFA reauthorization goals and procedures for the review of applications within 6 months.	Establishes a user fee program for biosimilar product applicants by adding biosimilar products to PDUFA applicable products.