



**White Paper – “Follow-On Biologics Regulatory Debate”
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Democratic Governors Association – Regional Life Science Public Policy Conference
June 2009**

Follow-on biologics (“FOBs”), also known as biosimilars or biogenerics, are copies of innovator biologic drugs.¹ Biologic drugs are protein-based and are manufactured using living cells or are derived from living matter.² They include such medicinal products as vaccines, allergenics, and gene therapies. Biologic drugs are isolated from natural sources and can be produced by biotechnology methods. Unlike the generic chemical drugs that are currently approved by the FDA, FOBs aren’t identical to the originator products and have no pathway for FDA approval.³

Congress, the FTC, and the biologics industry all seem to agree with President Obama’s call for a pathway for regulatory approval of FOBs by the FDA in order to provide consumer access to cheaper medication. However, the debate surrounding the regulation of FOBs is focused on two main issues. One, whether an extra period of data exclusivity is necessary to encourage the development of new drugs. Two, if data exclusivity is necessary, how long the exclusivity period should last.

The biologics industry argues that not only is an additional period of data exclusivity⁴ necessary, but it needs to be a longer period in order to encourage development of new drugs. The biologics industry also argues that regulation without such a period will reduce new drug development and consumer safety instead of cutting drug prices, but it doesn’t seem likely that consumer safety will be so impacted.

The FTC argues that an additional period of exclusivity is unnecessary because biologics manufacturers already have enough incentive to develop new drugs through patent protection and market-based pricing.

Two bills were introduced into the House of Representatives during the current Congress. H.R. 1427, the “Promoting Innovation and Access to Life-Saving Medicine Act,” was introduced March 11, 2009 and referred to the House Energy and Commerce committee and the House Judiciary committee. H.R. 1548, the “Pathway for Biosimilars Act,” was introduced March 12, 2009 and referred to the House Energy and Commerce committee and the House Judiciary committee. One big difference between the two bills is the length of the additional exclusivity periods; H.R. 1427 sets it at five years and H.R. 1548 for up to fourteen years.

¹ Roger, Simon D. and Ashraf Mikhail. “Biosimilars: Opportunity or Cause for Concern?” 10(3) J. PHARMACY & PHARM. SCI. 405-10 (2007), available at http://www.ualberta.ca/~csps/JPPS10_3/ReviewArticle_1308/R_1380.html.

² Center for Biologics Evaluation and Research. “What is a biological product?” U.S. Food and Drug Administration, available at <http://www.fda.gov/AboutFDA/CentersOffices/CBER/ucml33077.html>.

³ Roger, “Biosimilars.”

⁴ Data exclusivity is the period during which a potential generic drug supplier is prevented from using an innovator’s clinical trial and related data to substantiate the safety of the generic’s medically equivalent drug.

Summary, H.R. 1427 and S. 726

The purpose of H.R. 1427 and S. 726 is to amend the Public Health Service Act⁵ in order to establish a pathway to license biosimilar and biogeneric biological products (FOBs).

Definitions

Reference product is defined as a single licensed biological product against which a FOB is evaluated for demonstration of safety, potency, or purity.

Biosimilar is defined as a FOB with no clinically meaningful differences between the FOB and the reference product are expected in safety, potency, or purity during treatment.

Interchangeability with respect to a given condition of use is defined as that the FOB is biosimilar to the reference product and the patient can be switched one or more times between the FOB and the reference product without an expected increase in the risk of adverse effects, including a change in immunogenicity⁶, compared to the expected risks from continues to use the reference product without switching.

Applications

Abbreviated biological product applications (applications to license FOBs) must show:

- 1) Information that demonstrates the FOB and reference product contain highly similar molecular structural features, notwithstanding minor differences in heterogeneity profile, impurities, or degradation patterns;
- 2) Information that demonstrates the FOB is biosimilar to or interchangeable with the reference product for the condition or conditions of use prescribed in the proposed labeling based on
 - a. Information from chemical, physical, and biological assays, and other non-clinical laboratory studies, and
 - b. Information from any necessary clinical study sufficient to confirm safety, purity, and potency;
- 3) Information that demonstrates the FOB and reference product utilize the same mechanisms of action for the condition prescribed in the proposed labeling to the extent that the mechanisms are known for the reference product. However, if the application relies on a demonstration of biosimilarity or interchangeability for a single condition of use to support additional conditions of use that share the same mechanisms of action, the application must include information demonstrating such reliance is scientifically appropriate;
- 4) Information that shows the conditions of use prescribed for the FOB were previously approved for the reference product;

⁵ 42 U.S.C. 262

⁶ Immunogenicity is the property that enables a substance to provoke an immune response, or the degree to which a substance possesses that property.

- 5) Information that shows the route of administration, dosage form, and strength of the FOB are the same as the reference product; and
- 6) Information that demonstrates the facility where the FOB is manufactured, processed, packed, or held meets standards designed to ensure the product continues to be safe, pure, and potent.

Interchangeability Determinations

When issuing a license to a FOB, the Secretary⁷ must make and publish one of the following determinations:

- 1) The FOB is interchangeable with the reference product for one or more specified conditions of use prescribed in the labeling of the FOB, or
- 2) Interchangeability isn't established but the FOB is as safe and effective for its approved uses as the reference product.

If the Secretary approves a license for a FOB, and prior to issuing the license, makes a determination of the interchangeability between a separate FOB and the same reference product which is still under an exclusivity period, the Secretary will issue the license to the subsequent FOB and defer the determination of interchangeability for the subsequent FOB and the shared reference product until the exclusivity period expires.

Official Name Designation

If the Secretary determines the designation of an official name for a FOB is necessary or desirable for usefulness or simplicity, the Secretary can designate the same official name for the FOB as was designated for the reference product.

No later than 5 years after the date of the enactment of this subsection, the Comptroller General of the United States shall submit a report to the Congress on public health and economic impacts associated with the practices for designation official names of FOBs in the U.S. and other countries that approve FOBs.

Establishing Interchangeability

Applicants can submit information to demonstrate the interchangeability of a FOB and the reference product. A request for an interchangeability determination submitted after an application is filed is considered a major amendment to the application and can be withdrawn at any time.

Within 2 years of enactment of this subsection, the Secretary must issue guidance regarding the standards and requirements for interchangeability.

Upon a determination of interchangeability, the Secretary can provide a label of the FOB to include a statement that the FOB is interchangeable with the reference product for the conditions of use prescribed in the labeling.

⁷ The Secretary of Health and Human Services

Exclusivity Period

Approval for applications for licenses of biological products must be delayed for 5 years after the product's approval date when these conditions apply:

- 1) No major substance of the product or any highly similar major substance has been approved in any other application;
- 2) The submitted application is approved after the enactment of this subsection; and
- 3) The application could not and did not rely on any clinical safety, purity, or potency study in any other approved application or any clinical safety or effectiveness study in any application approved under section 505 of the Federal Food, Drug, and Cosmetic Act.

Biological products excluded from this delay include:

- 1) Protein biological products that differ in structure solely due to post-translation events, infidelity of translation or transcription, or minor differences in amino acid sequence;
- 2) Polysaccharide biological products with similar saccharide repeating units, even if the number of units different and there are differences in post-polymerization modifications;
- 3) Glycosylated protein products that different in structure solely due to post-translational events, infidelity of translation or transcription, or minor differences in amino acid sequence, and if they had similar saccharide repeating units, even if the number of units differ and even if there were differences in post-polymerization modifications;
- 4) Polynucleotide biological products with identical sequence of purine and pyrimidine bases, or their derivatives, bound to an identical sugar backbone (ribose, deoxyribose, or modifications of these sugars); and
- 5) Closely related, complex partly definable biological products with similar therapeutic intent, such as live viral products for the same indication.

Approval for applications for licenses of biological products must be delayed for 3 years after the product's approval date when these conditions apply:

- 1) The product includes a major substance approved in another application, or any highly similar major substance;
- 2) The application is approved after the date after the date of enactment of this subsection;
- 3) The application contains reports of new clinical investigations, other than pharmacokinetic or pharmacodynamic studies, essential to the approval of the application and conducted or sponsored by the application; and
- 4) The product represents a significant therapeutic advance, which may include the demonstration of safety, purity, and potency for a significant new indication or subpopulation, other than a pediatric subpopulation.

When a supplement to an application is approved more than 1 year before the expiration of a exclusivity period, that period will be extended 6 months if:

- 1) The supplement contains reports of new clinical investigations (other than pharmacokinetic or pharmacodynamic studies) essential to the approval of the supplement and conducted or sponsored by the person submitting the supplement; and
- 2) The change provides a significant therapeutic advance, which can include the demonstration of safety, purity, and potency for a significant new indication or subpopulation, other than a pediatric subpopulation.

The 6 month extension to the exclusivity period will be reduced to 3 months if an organization, other than the FDA, designated by the Secretary, notifies the Secretary that the combined annual gross sales in the U.S. for all biological products containing any major substance contained in the biological product in question and owned or marketed by the applicant or its affiliates exceeds \$1 billion in the calendar year preceding approval of the supplement.

Only one 6-month extension to the exclusivity period under this subsection will be granted for any biological product.

If the Secretary determines that information relating to the use of a new biological product in the pediatric population may produce health benefits in that population, makes a request for pediatric studies, the applicant agrees to the request, such studies are completed, and the reports are submitted and accepted in accordance with section 505A(d)(3) of the Federal Food, Drug, and Cosmetic Act, the exclusivity period will be extended by 6 months.

The Secretary must not make a determination of interchangeability for a subsequent FOB and a shared reference product until the earlier of:

- 1) 180 days after the first commercial marketing of the first interchangeable FOB;
- 2) 1 year after
 - a. A final court decision⁸ in favor of the applicant on all patents in suit in an action against the applicant for the first approved interchangeable product, or
 - b. The dismissal with or without prejudice of an action against the applicant for the first approved interchangeable FOB;
- 3) 36 months after approval of the first interchangeable FOB if the applicant has been sued and such litigation is still ongoing within the 36-month period; or
- 4) 1 year after approval of the first interchangeable FOB if the applicant has not been sued.

Patents

An applicant or prospective applicant can send a written request for patent information to the holder of an approved application for the reference product. The holder must provide to the applicant a list of all patents owned by, licensed to, or under the control of the holder within 60

⁸ Defined for the subparagraph as a final decision of a court from which no appeal has been or can be taken, except an appeal to the Supreme Court for a writ of certiorari.

days of receiving the request. For 2 years from the date the holder receives the request for information, the holder must send updates of its response by identifying all relevant patents issued or licensed to the holder after the initial response.

Any time after submitting an application, the applicant may provide notice of the application to the holders of patents identified in information requests which include a detailed statement of the factual and legal bases for the applicant's belief that the patents included in the notice are invalid, unenforceable, or not infringed by the commercial sale of the product for which approval is being sought. This information must also be submitted to the Federal Trade Commission, which will treat this notice as confidential.

Summary, H.R. 1548

The purpose of H.R. 1548 is to amend the Public Health Service Act in order to establish a pathway to license biosimilar biological products (FOBs).

Applications

Applications to license FOBs must show that:

- 1) The FOB is biosimilar to the original biologic (the reference product) through the following:
 - a. Analytical studies demonstrate the FOB is highly similar to the reference product notwithstanding minor differences in clinically inactive components,
 - b. Animal studies, and
 - c. Clinical studies (including, but not limited to, the assessment of immunogenicity and pharmacokinetics⁹ or pharmacodynamics¹⁰) sufficient to demonstrate safety, purity, and potency for each condition of use for which the FOB is approved;
- 2) The FOB and the reference product utilize the same mechanisms of action for the conditions prescribed in the proposed labeling to the extent the mechanisms are known for the reference product;
- 3) The conditions prescribed in the labeling proposed for the FOB were previously approved for the reference product;
- 4) The administration dosage form, and strength of the FOB are the same as for the reference product;
- 5) The facility where the FOB is manufactured, processed, packed, or held meets standards designed to assure the FOB continues to be safe, pure, and potent.

⁹ Pharmacokinetics is the action of a drug in the body over a period of time, including the process of absorption, distribution, localization in tissues, biotransformation, and excretion.

¹⁰ Pharmacodynamics is the study of the biochemical and physiological effects of drugs as well as the mechanisms of their actions, including the correlation of their actions and effects with their chemical structure.

The Secretary may determine that the analytical studies, animal studies, or clinical studies are unnecessary and waive the requirement that information be included with the application. The Secretary may also determine that an assessment of clinical studies covering immunogenicity is unnecessary and waive the requirement to include information with the application so long as the Secretary published a final guidance, following receipt and consideration of public comments on a draft guidance, which advises that it's feasible to make determinations on immunogenicity with respect to products in the product class to which the FOB belongs and that explains the data required to support such a determination.

The Secretary will determine the FOB is interchangeable with the reference product if the information submitted in the application or supplement to the application shows:

- 1) The FOB is biosimilar to the reference product and any FOB already licensed was determined to be interchangeable with the reference product;
- 2) The FOB is expected to produce the same clinical result as the reference product in any given patient for each condition of use prescribed in the labeling of the reference product; and
- 3) If the FOB is administered more than once to a patient, the risk of switching between the FOB and the reference product is no greater than the risk of using the reference product without switching.

The Secretary can't determine the FOB is interchangeable with the reference product unless the Secretary has published a final guidance, following receipt and consideration of public comments on a draft guidance, that advises it's feasible to determine interchangeability with respect to products in the product class to which the FOB belongs and that explains what data will be required to support such a determination.

The bill preserves state authority to require or regulate prescriptions.

The bill limits a FOB to only be evaluated against one reference product in an application.

Applications will be reviewed by the FDA division responsible for the review and approval of the application under which the reference product is licensed. The Secretary's authority respecting risk evaluation and mitigation strategies under the Federal Food, Drug, and Cosmetic Act¹¹ will apply to licensed FOBs in the same way it applies to reference products.

If FOBs contain a select agent or toxin listed in the Code of Federal Regulations or contains a controlled substance in the Controlled Substances Act, the Secretary won't license them unless the Secretary determines there is no increased risk to the security or health of the public from licensing them.

Exclusivity for the first FOB

The Secretary won't determine that a subsequent FOB is interchangeable with the same reference product until 24 months after the later of the date of the first commercial marketing of the first FOB or the date the product is determined to be interchangeable.

¹¹ 21 U.S.C. 355

Exclusivity for Reference Product

The Secretary can't approve the license of a FOB until 12 years after the date the reference product was first licensed. An application for a license of a FOB can't be filed until the later of the date of commencement of a proceeding for issuance of guidance with respect to the product class in which the FOB falls or the date that is 4 years after the reference product was first licensed. The date on which the reference product was first licensed doesn't include the date of approval of a supplement or of a subsequent application for a new indication, route of administration, dosage form, or strength for a previously licensed product.

If, within 8 years following the licensure of the reference product, the Secretary approves a supplement to the application for the reference product for a new indication that would be a significant improvement, when compared to marketed products, in the treatment, diagnosis, or prevention of a disease, an application to license a FOB can't be approved for 14 years after the reference product was first licensed.

If the Secretary determines that use of the reference product may produce health benefits in the pediatric population, makes a written request for pediatric studies to the applicant/holder of the application or license of the reference product, and the studies are submitted and accepted in accordance with 505A(d)(3) of the Federal Food, Drug, and Cosmetic Act, the exclusivity period includes an addition 6 months, so 12 years 6 months or 14 years and 6 months. If the determination under 505A(d)(3) of the Federal Food, Drug, and Cosmetic Act is made less than 9 months prior to the expiration of the exclusivity period, the additional 6 months will not be added to the exclusivity period.

Patents

Within 30 days of acceptance of the application, the applicant must provide a copy of the application and information concerning the FOB to the reference product sponsor. Within 60 days of receiving the information, the reference product sponsor must provide a list of relevant sponsor-owned patents, or patents to which the sponsor has the right to commence an action of infringement, relevant to the FOB. If the reference sponsor is issued or acquires an interest in a relevant patent after the date of supplying the patent information, the sponsor shall identify the patent to the FOB applicant within 30 days of being issued or acquiring the patent.

Any time after the Superintendent publishes a notice for a FOB application, an interested third party may provide notice of ownership of or rights to a relevant patent. Within 30 days of receiving notice, the FOB applicant shall send the application and information concern the FOB to the interested third party. Within 90 days of receiving the FOB information, the interested third party shall provide to the FOB applicant a list of relevant patents to which the third party has rights or owns. If the third party is issued or acquires an interest in a relevant patent after the date of supplying the patent information, the third party shall identify the patent to the FOB applicant within 30 days.

Products Previously Approved Under Section 505

An application for a biological product must be submitted under section 351 of the Public Health Service Act, as amended by this act. If the biological product is in a product class for

which a biological product in such product class is the subject of an application approved under section 505 no later than the date of enactment of this act and the application for the biological product was submitted to the Secretary before the date of enactment of this act or no later than 10 years after the enactment of the act, the application can be submitted under section 505 of the Federal Food, Drug, and Cosmetic Act instead. However, an application for a biological product can't be submitted under section 505 of the Federal Food, Drug, and Cosmetic Act if a biological product has already been approved under section 351(a) of the Public Health Service Act that could be a reference product for the application if it were submitted under 351(k). An application approved under section 505 will be deemed a license for a biological product under section 351 10 years after the date of enactment of this act.

Two bills were introduced into the Senate during the current Congress. S. 726, the "Promoting Innovation and Access to Life-Saving Medicine Act," was introduced March 26, 2009 and referred to the Senate Health, Education, Labor, and Pensions committee. This is a companion bill to H.R. 1427. S. 613, the "Bill to Prohibit the Use of Federal Funds to Approve Certain Biologics License Applications by the Food and Drug Administration," was introduced March 17, 2009 and referred to the Senate Health, Education, Labor, and Pensions committee.

VIEWS ON THE REGULATION OF FOLLOW-ON BIOLOGICS

President Obama

In his June 2009 speech, President Obama stressed the need to introduce FOBs into the marketplace via a pathway for Food and Drug Administration (“FDA”) approval.¹²

Medicare Payment Advisory Commission

In its June 2009 report to Congress, “Improving Incentives in the Medicare Program,” the Medicare Payment Advisory Commission (“MedPAC”) said that establishing a regulatory pathway for FOBs approval is necessary to provide more competition among biologics and to generate savings for those paying for the drugs.¹³

Federal Trade Commission

In June 2009, the Federal Trade Commission (the “Commission”) put out a report on FOBs, “Emerging Health Care Issues: Follow-On Biologic Drug Competition.” In it, the Commission addressed whether the price of biologics could be reduced by competition from FOBs and concluded that providing the FDA with the authority to approve FOBs is an efficient way to bring lower-priced drugs to market without needing the extra data exclusivity period biologics manufacturers request.¹⁴

The Commission discussed the Hatch-Waxman Act (“Hatch-Waxman”) through which the Food and Drug Administration (the “FDA”) approves sales of generic small molecule chemical drugs. Hatch-Waxman doesn’t apply to biologics; instead, the FDA approves biologics through the Public Health Safety Act (“PHS Act”).¹⁵ Hatch-Waxman allows competition from generic drugs to reduce prescription drug prices, increase access by Americans to prescription drugs, and encourage innovation.¹⁶ Hatch-Waxman doesn’t require generic applicants to duplicate clinical testing of chemical drugs already shown to be safe and effective.¹⁷ Instead, an applicant must show that the generic is the bioequivalent to the branded drug, which is a much less expensive test.¹⁸ A bioequivalent drug can be safely substituted for and is as effective as the branded drug.¹⁹

FOBs differ from generic chemical drugs; the pioneer biologic drug product can’t be exactly replicated and technology can’t determine whether FOBs are interchangeable with the

¹² President Obama, Speech on health reform to the American Medical Association. (June 15, 2009), available at http://www.usatoday.com/news/washington/2009-06-15-obama-speech-text_N.htm.

¹³ Medicare Payment Advisory Commission. “Releases Report On Medicare Payment Policy.” (2009), available at <http://www.medpac.gov/documents/June09NewsReleaseFINAL.pdf>.

¹⁴ Federal Trade Commission. “FTC Releases Report on ‘Follow-On Biologic Drug Competition.’” (2009), available at <http://www.ftc.gov/opa/2009/06/biologics.shtm>.

¹⁵ Federal Trade Commission. “Emerging Health Care Issues: Follow-On Biologic Drug Competition.” 1, 3 (2009), available at <http://ftc.gov/os/2009/06/P083901biologicsreport.pdf>.

¹⁶ *Id.*

¹⁷ *Id.* at 4.

¹⁸ *Id.* at 4.

¹⁹ *Id.* at 4.

pioneer products.²⁰ Current legislative proposals would allow the FDA to approve FOBs that are similar to the pioneer biologics without being exact replicas.²¹

In order to determine whether legislation of FOBs approval should follow the same model as Hatch-Waxman, regulators must first determine whether the competition between pioneer biologics and FOBs is similar to the competition between branded and generic chemical drugs.²² The Commission determined that competition between biologic drugs and FOBs is more likely to resemble brand-to-brand competition than the brand-generic competition under Hatch-Waxman.²³

The Commission also determined that existing incentives such as patent protection and market-based pricing are sufficient to support FOBs competition and biologic innovation because pioneer biologics already compete against other branded entrants and FOBs competition will develop without special legislative incentives.²⁴ FOBs are unlikely to be discounted more than ten to thirty percent and will have difficulty growing their market shares, so branded biologics will maintain their market advantages for years after FOBs enter the market.²⁵ In addition, there is little data that suggests biologics under development would be unpatentable or that patents claiming biologics have been designed around more frequently than those claiming chemical drugs.²⁶ A twelve to fourteen year exclusivity period is unnecessary to encourage the creation of new biologics, which have already been incentivized through patent protection and market-based pricing.²⁷

Biotechnology Industry Organization

Biotechnology Industry Organization (“BIO”) President and CEO Greenwood released a statement following H.R.1427 that condemned the bill for jeopardizing the continued development of breakthrough drugs and the safety of consumers.²⁸ Instead he suggested the correct regulatory pathway should recognize that biologics are more complex than chemical drugs and because the regulatory standard of approval of FOBs must be based on similarity rather than sameness, as it is with generic chemical drugs, regulators must ensure that any pathway for regulation focuses on patient safety and doesn’t require manufacturers to cut corners in order to meet price cut demands.²⁹

PROPOSED LEGISLATION OF FOLLOW-ON BIOLOGICS

H.R. 1427/S. 726

²⁰ *Id.* at 4.

²¹ *Id.* at 4.

²² *Id.* at 4.

²³ *Id.* at 5.

²⁴ *Id.* at 7.

²⁵ *Id.* at 8.

²⁶ *Id.* at 8.

²⁷ *Id.* at 9.

²⁸ Biotechnology Industry Organization. “New Proposed Biosimilars Pathway Filled with Potholes.” (March 11, 2009), available at http://www.bio.org/news/pressreleases/newsitem.asp?id=2009_0311_02.

²⁹ *Id.*

In March 2009, Energy and Commerce Committee Chairman Waxman (D-CA) and Representatives Pallone (D-NJ), Deal (R-GA), and Emerson (R-MO) introduced H.R. 1427, the “Promoting Innovation and Access to Life-Saving Medicine Act,” which allows the FDA to approve FOBs.³⁰ The bill was endorsed by the Consumers Union, AARP, the National Organization of Rare Disorders, the Coalition for a Competitive Pharmaceutical Market, General Motors, Express Scripts, Inc., the National Business Group on Health, the AFL-CIO, and the SEIU, among others.³¹ Companion legislation, S. 726, was introduced in the Senate by Senators Schumer (D-NY), Brown (D-OH), Collins (R-ME), Vitter (R-LA), Stabenow (D-MI), Shaheen (D-NH), and Martinez (R-FL). H.R. 1427/S. 726 gives brand-name biologics five years of exclusivity before generic versions can enter the market.³² Generic Pharmaceutical Association (“GPhA”) President and CEO Jaeger issued a press release supporting the bill’s balance between encouraging pharmaceutical innovation and making affordable medicines available to consumers.³³

H.R. 1548

In March 2009, Representatives Eschoo (D-CA), Inslee (D-WA), and Barton (R-TX) introduced the “Pathway to Biosimilars Act” which creates a regulatory path for FDA approval of FOBs and gives brand-name biologics twelve years of data exclusivity with provisions for an additional two years for medically significant new indications and six months for pediatric studies.³⁴ BIO President and CEO Greenwood issued a press release supporting the bill.³⁵

S. 613

In March 2009, Senator Brownback (R-KS) introduced the “Bill to Prohibit the Use of Federal Funds to Approve Certain Biologics License Applications by the Food and Drug Administration.”³⁶ The bill prohibits the use of funds provided under any Appropriations Act enabled before the date of enactment of this bill for any product which contains an agent or toxin from among listed agents and toxins and when the applying entity sold, marketed, or distributed the product in Iran, provided select agents or toxins to institutions in Iran, violated US laws governing handling of select agents or toxins, or has been the subject of an investigation by the listed organizations.³⁷ The purpose seems to be to exclude biologics that rely on Iranian products

³⁰ Committee on Energy and Commerce. “Bipartisan Group of Members Introduces ‘Promotion Innovation and Access to Life-Saving Medicines Act.’” (2009), available at http://energycommerce.house.gov/index.php?option=com_content&task=view&id=1528&Itemid=1.

³¹ *Id.*

³² Noonan, Kevin E. “Uncertain Future for Waxman Follow-On Biologics Bill.” (June 9, 2009), available at <http://www.patentdocs.org/2009/06/uncertain-future-for-waxman-followon-biologics-bill.html>.

³³ Zuhn, Donald. “Waxman Introduces Follow-On Biologics Bill.” (March 11, 2009), available at <http://www.patentdocs.org/2009/03/waxman-introduces-followon-biologics-bill.html>.

³⁴ “Eshoo, Inslee, and Barton Introduce Pathway for Biosimilars Act.” (March 17, 2009), available at http://eshoo.house.gov/index.php?option=com_content&task=view&id=581&Itemid=79.

³⁵ Zuhn, Donald. “Second Follow-On Biologics Bill is Introduced in House.” (March 18, 2009), available at <http://www.patentdocs.org/2009/03/second-followon-biologics-bill-is-introduced-in-house.html>.

³⁶ Brownback, Samuel. “Bill to Prohibit the Use of Federal Funds to Approve Certain Biologics License Applications by the Food and Drug Administration.” (March 17, 2009), available at <http://www.govtrack.us/congress/bill.xpd?bill=s111-613>.

³⁷ *Id.*

or on funds that come from companies that support Iranian institutions in order to keep Iranian institutions from developing products.

CONCLUSION

The debate surrounding the regulation of FOBs is focused on whether an extra period of data exclusivity is necessary to encourage the development of new drugs and provide adequate consumer protection and, if so, how long the exclusivity period should last. The biologics industry emphasizes the need to encourage the development of new drugs and claims the current patent protection and market-based pricing incentives aren't enough when it comes to biologics. The other side of the argument focuses on the need to provide cheaper and wider-spread access to biologics for consumers and claims patent protection and market-based pricing are enough incentives to encourage the development of new drugs. Current legislation introduced to Congress includes an additional exclusivity period, but different bills have different lengths of time for such periods.