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Federal Trade Commission
Office of the Secretary
Room H-135 (Annex F)
600 Pennsylvania Avenue, N.W.
Washington, D.C. 20580

Re: Emerging Health Care Competition and Consumer Issues – Comment, Project No. P083901

Dear Federal Trade Commission:

Wyeth Pharmaceuticals would like to thank the Federal Trade Commission (FTC) for the opportunity to participate in the November 21, 2008, Roundtable on Follow-On Biologic Drugs: Framework for Competition and Continued Innovation. Wyeth Pharmaceuticals, a division of Wyeth, is one of the world's largest research driven pharmaceutical and health care products companies with leading products in the areas of women's health care, infectious disease, gastrointestinal health, central nervous system, inflammation, transplantation, hemophilia, oncology, vaccines and nutritional products.

Wyeth appreciates FTC's interest in the topic of "follow-on biologics" or biosimilars[1] and the competitive issues that could arise upon the market availability of these types of products. As the fourth largest biotechnology manufacturer in the world, Wyeth shares FTC's interest in this topic and has been actively engaged in the global debate on appropriate regulatory approval mechanisms.

Wyeth submitted initial comments to the docket on September 30; the following comments are intended to supplement that initial submission and address specific issues that arose during the Roundtable.

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[1] As we pointed out during our presentation at the November Workshop, Wyeth believes the term "biosimilars" is the most appropriate to describe these types of products. Accordingly, that is the term used throughout this document.

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I. Certainty of an Adequate Return on Investment Is Crucial to Pharmaceutical and Biotechnology Innovation

The pharmaceutical/biotechnology industries are among the most risk intensive in the world. It is well documented that only a miniscule percent of research projects ever result in an FDA approved and marketed drug product, and that only one in three of such approved and marketed products provides even a break-even return on investment. It is these very few successful products that provide the profit and funding that enables the development of innovative medicines and therapies for patients in need. To undertake this risk, pharmaceutical and biotechnology companies must have a high degree of certainty that, in those few instances where a product does reach the market, they will recoup their tremendous research and development investment, and profit beyond that investment. This certainty is critical to continued medical innovation and the benefits to patients and society as a whole that such innovation yields.

A. Patent Protection Does Not Provide Adequate Certainty to Spur Pharmaceutical and Biotechnology Investment and Innovation

Just as certainty spurs innovation and advances that benefit patients, lack of certainty in the pharmaceutical and biotechnology industries hinders innovation. Although patent protection has been assumed to provide such certainty to the pharmaceutical industry, in fact, it no longer provides the certainty needed to spur innovation and to undertake the enormous costs of developing pharmaceuticals. And, patent protection provides no more certainty to the biotechnology industry.

The value of patent rights to the pharmaceutical and biotechnology industries is less today than it has ever been in the past. Changes to the law, as well as to the tactics adopted by the generic industry, are largely responsible for this shift. These changes have rendered the patent system an extremely uncertain spur to innovation. Although the United States Constitution states that the law should secure for inventors the exclusive rights to their inventions for a limited time, today, that Constitutional guarantee has been eroded as never before. Judicial changes in the law concerning the granting of permanent injunctions, obviousness, declaratory judgment jurisdiction, and the doctrine of equivalents have all contributed to this erosion. Patent law reform by Congress threatens further erosion to the patent system.

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B. The Current Hatch-Waxman Environment and Its Impact on Innovation

Tactical shifts by the generic industry have further eroded the value of patents as an incentive to innovation to the pharmaceutical industry. As a result, the historical assumptions and balances that underlay the Hatch-Waxman system for small molecule drugs have now become irrelevant, and the system unbalanced. In the years leading up to the Hatch-Waxman Act, patent owners and others began highlighting the erosion of effective patent life to less than 17 years caused by delays in regulatory approval, and predicted that a declining effective patent life would result in decreased expenditures for research and development and, eventually, in a decline in the introduction of new drugs. H.R.Rep. No. 98-857(I), at 17 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2650. First voiced formally by President Carter's Advisory Committee on Industrial Innovation, the issue of declining effective patent life was studied by the Office of Technology Assessment before the passage of the Act, and several committees held extensive hearings. H.R. Report No. 98-857 (II), at 3, *reprinted in* 1984 U.S.C.C.A.N. 2686, 2687. The result of these analyses was the creation of the Patent Term Extension provisions of the Act. Those provisions provided for an effective patent life of 14 years for new pharmaceutical products. Yet today, pharmaceutical companies can realistically expect no more than 6 to 7 years of de facto market/patent exclusivity in which to obtain an adequate return on investment. Not surprisingly, the number of new drugs, as measured by New Chemical Entity (NCE) approvals by FDA, has also consistently declined over the last 10 years.[2]

Among the assumptions underlying the Hatch-Waxman balance was that there would be basic compound patent protection for a period approximating 14 years (the maximum period of extended patent life under the Act). It was assumed that this 14-year period of patent exclusivity would provide the necessary spur to pharmaceutical innovation and the corresponding public benefits, while at the same time, balancing the need of the public for lower cost generic medicines.

However, the 14-year maximum effective patent life accorded (most often) to basic compound patents no longer provides sufficient certainty to ensure the kinds of investment that must be made to bring a new drug to the market. Although there was a time when generic companies virtually never challenged basic compound patents, today such challenges have become routine. Moreover, it is

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[2] B. Hughes, 2007 FDA Drug Approvals, A Year of Flux, Nature Reviews Drug Discovery 7, 107-109 (Feb 2008).

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the rare NCE today that is not faced with multiple patent challenges at the first possible instance, namely four years following initial FDA approval.

This trend, and the inherent uncertainty in any litigation, let alone litigation as scientifically and legally complex as patent litigation, has reduced the period of certainty on which a pharmaceutical company can count to obtain an adequate return on investment to a fraction of that 14 years. Considered together with the erosion of the value of patent rights due to changes in the law, as well as the now common occurrence of "at-risk" launches (see, e.g., Protonix, Lotrel, Famvir, Accupril, Zithromax, Plavix, Prilosec, and Pulmicort), the reduction in certainty is remarkable. Today, as noted above, pharmaceutical companies can count on no more than 6 to 7 years of de facto market/patent exclusivity in which to obtain an adequate return on investment (to recoup their massive research and development investment and profit sufficiently to justify that investment).

This dramatic shift in the landscape, taken together with a number of different factors, including the following, has resulted in an environment that discourages pharmaceutical innovation:

- The high cost of drug development, now in excess of one billion dollars and continuing to climb;
- The length of time it takes to bring the rare successful product to the market, typically in excess of 12 years;
- The growing odds against successfully gaining FDA approval, with a dramatic increase in the number of late stage clinical failures and ever more stringent approval requirements, including Phase IV commitments; and
- The increased risk of an "early" generic entry and the impact of such an entry into the marketplace, with the virtual overnight collapse of the innovator's market share and price caused by mandatory substitution laws and the impact of the "little section 8" mechanism.

As a result, it should come as no surprise that there has been a decrease in traditional pharmaceutical innovation in the last ten years. With so much at risk, pharmaceutical companies must try to shorten the odds against success by concentrating R&D resources in areas likely to yield higher success rates, such as enantiomers, active metabolites, and new formulations of already approved molecules. Such areas provide a lower risk of return on investment. By lowering these odds, and increasing the rate of return on at least some of their investment,

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pharmaceutical companies may be able to fund riskier and more expensive projects in far less certain areas such as Alzheimer's disease.

The shorter period of certainty in today's environment has also decreased exploration by innovator companies of new uses for their already approved small molecule drugs. Once it was common for a drug to see multiple clinical trials for new indications following approval. Today, given the time and expense of doing such trials, the even shorter time for a certain return on investment, and the "little section 8" mechanism and mandatory substitution, there is virtually no certainty of return, and therefore, little incentive to explore these new uses. Decisions are routinely made to forego such clinical trials today simply because there is no certainty of an adequate time for a return on investment.

The increasingly aggressive tactics of the generic industry are a direct outgrowth of the need of all companies to show sales and earnings growth to their investors. As the generic industry has matured, there are fewer targets of opportunity for generic companies than ever before. Multiple companies challenge every large target, and many smaller targets, at the first opportunity (4 years post approval) in order to enjoy the potential benefits of 180-day generic exclusivity. Generic companies are now pursuing even the smallest of opportunities on products once thought too small to justify the time or investment. And consolidation in the generic industry has accelerated as large companies continue to acquire smaller ones to obtain access to markets and targets. The end result has been a spiral in which the need of generic companies to continue to show earnings growth has led directly to a decrease in innovator productivity. In the end, there will simply not be enough targets to support the generic industry.

As already discussed, today's Hatch-Waxman environment has made innovator R&D more risky and more costly than ever before. Certainty of an adequate ROI is a key driver for investment, and without such certainty, some products are not developed, some research areas are not explored, and decisions are made to invest in "safer" opportunities. In the end, the public health suffers, as a lack of new treatment options for unmet medical needs results. Moreover, this increased risk, and the early loss of key products, has also driven cost control measures by the innovator industry. This has resulted in a loss of U.S. jobs, the relocation of R&D to ex-US locales (mainly India and China), and outsourcing of manufacturing and other jobs to India and China. The U.S. economy bears the brunt of this impact. The impact of the current environment will also result in decreased competition between innovators, as companies are forced to make decisions about what kind of R&D they are willing to fund. The direct result of this is that fewer innovative

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therapies are available to the public, and patients have fewer options and face higher costs.

C. The Need for Substantial Data Exclusivity

This new environment for small molecule pharmaceuticals is not sustainable in the long run, for either generic or innovator companies. More importantly, the impact on the public health is being felt today with the dramatic decrease in NCE approvals. Despite claims by the generic industry that the Hatch-Waxman system has been a boon to pharmaceutical innovation by forcing constant innovation, the facts do not support that claim. This might be true where the time lines of innovation and generic competition are roughly equal in length (e.g., 14 years), but cannot function where these timelines are so dramatically out of balance as today.

Patents, due to their inherent uncertainty, are insufficient as the primary motivating factor for innovation. A substantial period of data/market exclusivity for new chemical and biological entities can provide that incentive. However, the data exclusivity period provided by the Hatch-Waxman Act is too short to provide the necessary certainty of an adequate return on investment to justify the incredible time, cost, and risk involved in developing a new drug product. To ensure that sufficient incentive exists to provide the kind of treatments and therapies to meet the unmet medical needs of the public, in all disease areas, it is necessary to restore the original balance between generics and innovators.

II. Data Exclusivity, Patents, and Biotechnology

A. De Facto Data Exclusivity Has Spurred Innovation in Biotechnology

Biologic drug products have development timelines equal to or longer than for small molecule drugs, success rates equal to or lower than for small molecule drugs, and very high R&D costs. There are very few successful biotech companies. Most lose money and very few survive over time. The cost of manufacturing facilities is staggering, and this large investment must be made long before a product is approved by the regulatory agencies. Yet, the U.S. biotechnology industry is among the most vibrant industries in the world, and a remarkable innovation engine in the United States.

Until very recently there was no mechanism for approval of a biosimilar product anywhere in the world. Today, no such system exists in the United States, and only a limited system for such approvals exists in the EU and in a few other

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jurisdictions around the world. As a result of this historical inability of others to rely on an innovator's data, we have seen the biotechnology industry and innovation within that industry thrive, while traditional small molecule pharmaceutical innovation has suffered. Although there is no specific provision in the law for data exclusivity for biologic drugs, there has been no need for one. Instead, biologics have enjoyed de facto data exclusivity, due to the absence of a mechanism by which a competitor can rely on data provided to FDA. This exclusivity has greatly contributed to the thriving biotechnology industry in the United States, and to the development of innovative, life-changing medicines by that industry.

B. Patents in the Biotechnology Area

Although competition in the biologics area can be intense (see, e.g., human growth hormone, anti-TNF biologics), such competition has not discouraged innovation in this area. The public has enjoyed the benefits of such competition with new products, product improvements, and price competition. Moreover, patent protection for innovator molecules has not discouraged competition by other innovators. Indeed, patent protection on biologic products has spurred attempts to innovate around competitor patents, resulting in additional advancements. Patent protection for biologic drugs has, to date, been less important to product development than for small molecule pharmaceuticals in the Hatch-Waxman context. This is directly due to the lack of a biosimilar mechanism. As with traditional pharmaceuticals, patent litigation between innovators concerning biological drug products is relatively rare.

Moreover, patents relating to biologic drug products provide no more certainty to innovator companies than do patents for small molecule drugs. Indeed, due to the current uncertainty regarding regulatory requirements for a biosimilar product, there is far less certainty today that patents will provide robust protection and therefore incentive to invest, to innovator companies. However, it is likely that patents relevant to biosimilars will provide less certainty than even that provided by patents for small molecule drugs.

Unlike with small molecule drugs, with which a generic product must show sameness, it is anticipated that a follow-on biologic product will only have to meet a "similarity" requirement."[3] A generic small molecule product will, by

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[3] As we stated in our earlier submission, biosimilars cannot be rated for interchangeability in the same way as chemical generic compounds. While most traditional chemical molecules can be exactly replicated, allowing products that incorporate the molecules to be found

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definition, infringe at least some of the core patents relating to a small molecule pharmaceutical, such as the patent on the active ingredient itself, typically referred to as the "compound patent." Under a "similarity" standard for follow-on biologics, infringement can not be assumed, as it may be possible to design around patents relating to the active molecule itself. It is unknown today by how much a biosimilar may differ from an innovator biologic product. Nucleotide, amino acid, and glycosylation differences between biosimilars and innovator products, and the patents thereon, may have an impact on infringement. And, where there is no literal infringement, the recent reduction in the scope and application of the doctrine of equivalents will make it less likely that innovator patents will be infringed after even minor changes.

Moreover, as the biotechnology industry has matured, it has become far harder to obtain broad patents relating to biologic drug products. While some currently marketed biologic products enjoy broad patent protection, this is far less likely to occur today or in the future. Therefore, the patent portfolios of today's marketed biologic products do not form a good model for predicting the future impact of patents in a biosimilar context. As a legislative approach for biosimilars is developed, an important balance must be struck between the desire to ease access for biosimilars to today's marketed products, and the need to ensure that adequate incentives exist to ensure the innovation and investment needed to produce tomorrow's products. Transition provisions that differentiate between today's already marketed products and those not yet approved should be drawn carefully to ensure this balance.

"bioequivalent" - and therefore potentially eligible to be rated as interchangeable - if they meet applicable data requirements, it is not possible to make an exact copy of a biological product due to its derivation from cell culture or whole living organisms and the complex manufacturing processes involved. As such, there is bound to be a degree of variability in any attempt to copy a biologic, which is why biosimilars cannot automatically be deemed interchangeable with approved innovator products.

Questions of biosimilar interchangeability are inherently scientific and require careful consideration of the short and long term effects of the biosimilar product's safety, efficacy, and immunological profile. These considerations are most appropriately made by the Food and Drug Administration (FDA) in its capacity as a science-based governmental agency. To demonstrate interchangeability, applicants should be required to provide additional clinical data clearly establishing the safety of interchangeable use of the innovator and biosimilar, including immunological safety, as applicable, as well as head-to-head clinical trial data demonstrating the equivalent clinical efficacy of the products.

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Finally, the development of the law relative to the biologic drug industry is still in its relative infancy. Historically, the few cases in this area have tended to focus on the enablement and written description requirements of 35 U.S.C. § 112. There have been even fewer cases regarding invalidity for anticipation and obviousness under 35 U.S.C. §§ 102 and 103. None of these cases have been decided in the context of biosimilars. The development of the case law in this area will clearly play an important role moving forward. As of now, and for the foreseeable future, it simply presents more uncertainty. Given the level of uncertainty surrounding the value and role of patents in today's Hatch-Waxman environment, it is safe to say that patents in the biotechnology arena provide innovator companies with no more certainty, and likely less.

C. Less Than Adequate Data Exclusivity Would Stifle Innovation and Harm the Public

As with traditional small molecule pharmaceuticals then, in the biotechnology field there is both competition between innovators, and the threat and promise of patents. Missing from the biologics area, however, is the intense pressure and uncertainty provided for small molecule drugs by overly short data exclusivity periods. The result is an area that enjoys substantial innovation and competition in which investment and innovation are driven in large measure by the certainty that, if a product does gain regulatory approval, others will not be able to rely on the data obtained by the innovator at such great expense.

It is thus vital that any legislation on biosimilars provide adequate data/market exclusivity. Anything less would threaten this vibrant U.S. industry, and would exacerbate the R&D shift and outsourcing to India and China already seen in the traditional small molecule pharmaceutical industry. More importantly, a system that allows reliance on innovator data without adequate protection for that data would result in decreased innovation. R&D would shift away from new treatments for new diseases, thus depriving the public of much needed treatments for unmet medical needs, toward "safer" bets such as new formulations or second generation molecules. The number of post-approval clinical trials testing new uses of already approved biologics would drastically decrease due to the lack of certainty of an adequate return on investment. Instead of anti-cancer biologics being tested in a dozen or more indications in large scale, "phase IV" clinical trials, no attempt would be made to broaden the use of approved biologic drugs. Patients and the public health would lose out.

Lack of adequate data/market exclusivity for biologics would have a significant, negative impact on investment in biotechnology. Investment in small and mid-

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size biotechnology companies, already suffering due to the current economic conditions, would further dry up. And, almost certainly, the biotechnology industry would be transformed by consolidation in much the same way that the pharmaceutical industry was in the 1980s and 1990s.

Finally, if there is not an adequate balance between innovators and biosimilars, in the long run there will be a decrease in the number of "targets of opportunity" for copying. In the short run, there will certainly be a flurry of activity in the area. But, over time, as with small molecule pharmaceuticals, an imbalance between innovation and copying will result in a decrease in the number of targets available to biosimilar companies and increased consolidation.

D. An Adequate Data Exclusivity Period Would Properly Balance Innovation and Competition

Any legislation regarding biosimilars should provide for a minimum term of data/market exclusivity of 14 years. As discussed above, the legislative history of the Hatch-Waxman Act makes it clear Congress recognized that the decline in effective patent life to less than 17 years would result in decreased expenditures for R&D and eventually a decline in new drugs. Yet today, under the current Hatch-Waxman environment, effective patent life for small molecule pharmaceuticals is now far less than that target. The harmful results of this environment have been discussed above. An adequate data/market exclusivity term must ensure an adequate return on investment for innovators in view of the enormous risk, time and cost of developing a biologic product for regulatory approval. Patents simply do not provide the necessary certainty to provide this incentive. Moreover, data/market exclusivity and patents serve different functions. Data exclusivity provides a reward for the investment of time and money needed to generate data for regulatory approval. Patents provide a reward for invention, regardless of the time or money underlying the invention. The two rewards are not co-extensive. An inventor need not undertake the time and expense to develop her invention. Yet, that inventor may still assert the patent against others. Likewise, a company investing time and money in pre-clinical and clinical trials need not obtain a patent. It should, however, be entitled to separate and strong protection against unauthorized use of that data.

Adequate data/market exclusivity of at least 14 years would enhance competition between innovator companies by encouraging the investment of time and resources in bringing alternative innovative treatments forward. Data exclusivity does not prevent innovative competition. It simply prevents unauthorized use of data. Patients and the public health will benefit from the increased health care

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options and price competition resulting from innovator vs. innovator competition.

Adequate data/market exclusivity would also spur secondary innovation. In particular, a period of at least 14 years would provide the necessary assurance of an adequate return on investment to permit innovators to conduct clinical research to explore alternative uses of their already approved biologic products. These lengthy, costly, large-scale clinical trials can only be undertaken if there is sufficient time and incentive. The benefits of new uses for patients and the public have been amply demonstrated by the examples of anti-cancer antibodies and anti-TNF biologics. Such advances would not have been made if innovators were concerned about early "generic" entry. Moreover, adequate data/market exclusivity allows sufficient time for advances in product and process improvement. The new technology arising there from benefits everyone.

Finally, there will be no negative impact on competition from an adequate data/market exclusivity period of at least 14 years. Transition provisions in any legislation can ensure that existing products do not unfairly benefit from such a period. Therefore, a sufficiently long data/market exclusivity period will have little to no short-term impact on competition. Thus, the complexity, length, and cost of patent litigation will be reduced by an adequate data/market exclusivity period. Patents still existing at the end of this data/market exclusivity period are likely to be those relating to product or process improvements or new uses. Companies wishing to rely on the data of an innovator should not need to use such technology to produce a biosimilar product, as such a product, by definition, will not be an exact copy.

E. Economic Theories of Competition

During the November Workshop, FTC staff presented a slide offering assumptions of market effects based on competition among various types of market entrants. Based on our interpretation of this graphic, Wyeth believes the methodology used for the FTC suggested goal and economic target curve is inadequate. An appropriate break-even analysis must allow for a large mature portfolio or industry, include the risk of failure (both product development and marketing risks), and include an appropriate return on invested capital.

Wyeth agrees with Grabowski that the appropriate period of data exclusivity for biologics should be 12.9 to 16.2 years. Wyeth believes that the economic break-

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even analysis provided by Grabowski uses an appropriate methodology. As the FTC is aware, Grabowski's NPV analysis[4] incorporates:

- A portfolio of biologics marketed by a mature company;
- The average risk adjusted cost of research and development needed to bring a new biologic to market;
- Other sources of risk related to cost and value; and
- The required return on capital for investors.

However, the FTC curve does not appear to consider these essential elements.

In addition, the FTC's analysis does not appear to consider the external benefits to society when considering the trade-off between innovation and price competition. As Grabowski noted: "when the output of innovation has important external benefits to society — as in the case of new medicines and new indications for existing medicines — this also supports a longer exclusivity period."[2]

Even if the FTC analysis were based on an appropriate break-even methodology, it would have a detrimental impact on the incentives for innovation. The FTC suggested curve (as well as the Grabowski and Brill analyses) is based on a net present value or NPV calculation. NPV is equal to the difference between the initial investment or cash outflows and the present value of the future cash flows generated by the investment. The NPV rule states that only investments that generate positive net present values (i.e., the cash inflows exceed the cash outflows) should be undertaken. Similar to the NPV rule, the rate of return rule states that only investments that generate a rate of return that exceeds the cost of capital should be undertaken. The FTC analysis flies in the face of these fundamental rules of finance because it would result in investments that could only generate an NPV of $0 or slightly negative, which means that the rate of return would not exceed the cost of capital. Since, as Mr. Brill states in his paper, "[a] positively valued portfolio is one that will be funded by investors,"[5] the FTC analysis would, if it formed the basis for legislation, clearly make it more difficult, if not impossible, to attract capital needed to fund innovative new projects.

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4 H. Grabowski, "Follow-on biologics: data exclusivity and the balance between innovation and competition," Nature Reviews Drug Discovery | AOP, published online 12 May 2008; doi:10.1038/nrd2532.

5 A. Brill, Proper Duration of Data Exclusivity for Generic Biologics: A Critique, available online at www.tevadc.com/Brill_Exclusivity_in_Biogenerics.pdf , (November 2008).

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III. An Early Patent Resolution Mechanism Must Be Paired With Adequate Data Exclusivity

In order to ensure an adequate balance between innovation and competition that benefits the public, an early patent resolution mechanism must be paired with adequate data exclusivity. Such a mechanism would allow for certainty on the part of all interested parties, including innovator companies, biosimilar manufacturers, third party payers, and most importantly, patients. The foundations of such a system are relatively few:

- Assurance for all interested parties that upon a date certain, there could be biosimilar competition. This will permit reasoned decision making by innovators, biosimilar manufacturers, third party payers, healthcare providers, and patients.
- Full disclosure by all participants in the early patent resolution mechanism. For patentees, this would require full disclosure of the patents at issue in any dispute. For biosimilar applicants, this would require full disclosure of their application for regulatory approval, including all manufacturing process details. There should be a mechanism for enforcing these obligations in order to discourage gamesmanship by all participants, consistent with traditional principles of fairness and the interests of justice.
- Sufficient time to fully resolve patent disputes. Any patent resolution mechanism must provide for the initiation of patent disputes early enough that there is an opportunity for consideration through the Court of Appeals prior to the expiration of data/market exclusivity. At the same time, a patent resolution proceeding should not be initiated at a point in time that is too early, when the details of the biosimilar product are not yet fully defined or manufacturing processes are still subject to change.
- Linkage of patent resolution to regulatory approval. In order to provide certainty to all parties concerning the outcome of any patent resolution mechanism, a linkage mechanism is required. Such a mechanism need not be overly burdensome on any party, and should be based on notice and full disclosure by biosimilar applicants and full identification of patents at issue by innovator patent holders.

Wyeth would be pleased to participate in any discussion with the FTC staff or any others regarding the specific requirements and components of a patent resolution mechanism.

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Conclusion

Again, Wyeth appreciates the opportunity to comment on the important issues raised at the FTC's Roundtable on Follow-On Biologic Drugs. We look forward to engaging with the FTC on the elements of a meaningful and appropriate regulatory approval mechanism for biosimilars. If you have any questions about Wyeth's comments, please do not hesitate to contact me.

Sincerely,

Matthew D. Eyles
Vice President, Public Policy
Wyeth Pharmaceuticals