May 2, 2008

The Honorable Frank Pallone, Chair
The Honorable Nathan Deal, Ranking Member
Subcommittee on Health
Committee on Energy and Commerce
Rayburn House Office Building
Washington, DC 20515

Dear Mr. Chairman and Congressman Deal:

Consumers Union, the independent, non-profit publisher of *Consumer Reports*, is pleased to submit these comments in response to your letter of April 3, 2008 to James Guest. Thank you for the opportunity. We applaud the Subcommittee's deliberations and leadership on this issue, and we appreciate the specificity of the questions posed in your letter. In the "Answers" section of this letter we respond to those items on which we have a perspective.

We believe there is an urgent need to develop a pathway for the FDA's approval of safe, effective generic biologics, or follow-on biologics (FOBs). Moreover, we believe last year's FDA Amendments Act provided an important foundation for FOB legislation. We also join the chorus of voices in recent months calling for a budget increase for the agency, for fiscal year 2009 and beyond. Clearly, an FOB pathway will require the agency to have additional resources. Now is the time to begin determining the magnitude of those resources.

We would take this opportunity to note that other actions will be necessary in the years ahead to encourage the development of new innovative medicines and improve access to them while constraining the growth in pharmaceutical costs. The advent of the Medicare Part D program now makes constraining costs a priority. In this regard, the 2008 Medicare Trustees Report signaled serious looming problems. The report estimated an average 11 percent annual increase in Part D expenditures through 2017, with average annual increases per beneficiary between 3 to 5 percent greater than for HI and SMI Part B. By 2017, the Part D out-of-pocket limit will climb to *$7,850.*

Thus, in addition to establishing an FOB pathway, we'd urge consideration of the following actions and policies:

1. Remove the Medicare Modernization Act's prohibition on Medicare direct negotiation of drug prices and create a standard Medicare-run plan that uses negotiated prices.

2. Enact the 2007 House-passed Comparative Effectiveness provisions of the CHAMP Act. The House bill provided about $3.7 billion over ten years for meaningful research into what medical procedures, drugs, and devices really work best. Today, we waste billions on medical services that are ineffective – or worse, harmful. We also waste billions of dollars on high-priced medicines when equally effective lower-cost ones are readily available. (See www.CRBestBuyDrugs.org.)

3. Phase-in a requirement that doctors use e-prescribing as a condition of receiving Medicare physician payment updates.

4. Direct FDA, and amend PDUFA, to require that, in some circumstances, drugs be tested not just against a placebo but against what is considered the current best treatment in the field.

5. Enact stronger laws to prevent brand and generic drug companies from colluding to delay the timely market entry of generics.

6. Enact legislation requiring the pharmaceutical and medical device industries to publicly report any and all gifts and payments to physicians, hospitals, health care companies, and health-related trade or interest groups. While industry support of some forms of continued medical education has positive value, it is now well understood that many targeted payments to providers and other entities are intended to promote the sale of products.

7. Reward Part D plans and state Medicaid programs for the use of generics and for the use of high quality formularies that promote the most cost-effective and safest drugs.

The pharmaceutical industry has invented wonderful medicines. Over the last decade, however, the industry has paralyzed public policy by arguing that without unlimited monopoly profits in the U.S it will not be able to develop new drugs. The plain fact is we have the world's highest pharmaceutical prices, and we are getting less and less innovation. Instead, the industry enhances profits through product line extensions, , and fighting generic entry. The high cost of medicines in the U.S. inhibits access to needed medicines for millions of Americans, insured and uninsured. Congress should enact policies to enhance innovation and access and constrain unjustifiably high costs. Thank you for consideration of our views and answers to your questions.

Sincerely,

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Health Care Analyst, Consumers Union
Managing Editor, *Consumer Reports Best Buy Drugs*
Consumer Representative, FDA Advisory Panel on Cardiovascular and Renal Drugs

ANSWERS TO QUESTIONS

Science/Safety

Q2 (and other questions). The FDA should be given scientific and regulatory discretion to review follow-on biologics (FOBs) on a case-by case basis within a scientific evaluation and approval framework and pathway. This includes evaluation of immunogenicity. Congress should provide close oversight of the FOB process in its initial years. Legislation that details the multiple complex steps along "the pathway" would be counter-productive.

Q3. The FDA should be given discretion.

Q4. As with non-biologics, there should be a primary indication. Beyond that, FDA must have flexibility and discretion to evaluate on a case-by-case basis the need for testing for other indications.

Q5. This question underscores a major reason we believe a pathway for FOBs can be established forthwith. FDAAA gives the FDA new tools and authority for follow-on studies, labeling changes, and DTC ad warnings that will help ensure the safe use of new medicines. The new system of active post market surveillance will help to more quickly detect problems with both original biologics and FOBs. The advent of more biologics and FOBs in the future also underscores the need for enhanced databases for safety monitoring. FDA is working to build such databases now and should be given the resources to maintain and enhance them in the future.

Q6. FOB names should maximize their uptake. Congress should monitor this naming issue carefully and consider legislative language pursuant to it. FOB makers may want flexibility with naming their products, something that serves a purpose among some categories of chemical drugs. FOBs should not be required to have varying names; that could confuse consumers.

Q7. Yes, should have same mechanism(s) of action. If the reference product's mechanism is unknown, there should be no requirement placed on the FOB applicant to determine the mechanism.

Q9. Clinical trials for an FOB should be the exception and not the rule, and only required in special circumstances at the discretion of the FDA. A requirement for clinical trials is too high a barrier for the FOB industry, would inhibit the development of that industry, and be costly.

Regulatory/Administrative

Q1. We can not speak with specificity on the 505 pathway. FOB legislation might require the FDA and other entities to render a judgment on the short-term applicability of the 505 pathway. In the long term, of course, a new FOB pathway and framework is needed, as the FDA has signaled loud and clear. Our most important criteria for that pathway is that it not set up a structure that fosters protracted litigation. Appropriate legal rights must be granted to both innovator companies and FOB companies, but it should not become a patent lawyer's full-employment act.

Q4. A new standard must be defined and set, with some built-in flexibility. But by and large, any FOB should be based on the same technology and use the same or very similar methods of production of the innovator product and be as similar to that product as technically and scientifically feasible, allowing for variance.

Q5. FDA should be empowered to issue guidance in advance for a specific FOB or class of FOBs, as appropriate to the science and for the purpose of expediting the application and approval process. Public comment on such guidance in advance should be at FDA's discretion but hopefully would be the exception, save for the normal give and take between FDA and outside scientific advisors, including the FDA's formal advisory panels.

Q6. We would strongly prefer to see FDA funded at a level that would not require additional user fees for a FOB process. However, we would not oppose an appropriate and reasonable user fee program should it be necessary to assure the timely establishment of a program.

Interchangeability

Q1. Yes, we believe current science will permit assessment of whether an FOB will yield the same biologic and clinical effect. Those methods will improve over time, and those improvements should be rapidly incorporated.

Q3 and Q4. Product-specific requirements for interchangeability are too cumbersome. General guidelines must be established that govern interchangeability, and the FDA should have the authority, with flexibility, to administer those guidelines. Again, the FDA has procedures for obtaining expert input on scientific issues. A formal public comment process, especially tied to individual products, strikes us as burdensome and unnecessary.

Q5. Interchangeability based on full access to the innovator company's methods and data will yield products that everyone should feel comfortable are fully substitutable. Careful post-marketing of that will shore up confidence.

Q6. Pathways to full interchangeability/substitutability will be critically important to a true competitive FOB marketplace, with multiple entries per product over time, and one that brings about substantial opportunity for cost savings.

Patents

Q1. The effective average patent life of most drugs today is in the neighborhood of 10 to 12 years. The current patent and market exclusivity laws are often abused by the exploitation of loopholes and excessive litigation by both brand and generic companies.

Q2. A hard-and-fast fixed patent-plus-exclusivity period should be granted for innovator biologics, to assure a *predictable period* of full market exclusivity. We believe the concept of broad data exclusivity protection should be re-evaluated and not used for biologics. The world is quickly moving to new standards of openness in scientific research. While we respect that businesses have a right to proprietary information around certain manufacturing practices, research on the safety and effectiveness of prescription drugs exists to serve a public health interest that, in our view, supersedes such proprietary rights. Thus, all studies and clinical trials on innovator biologics should be registered and publicly released. We would not oppose a limited exclusivity period on production and manufacturing methods, but *only* if this is tied to a requirement for *full and expedited* disclosure to FOB developers of all data and information on production and manufacturing methods..

Hatch-Waxman worked well to spur a robust generics industry but its framework still permits too much delay in generic entry and excessive litigation over patents. There's a better way, and that begins with firmer patent/exclusivity periods, with fewer add-on periods. Clearly, lessons will be learned in the years ahead about biologics, and FOBs, that may warrant changes in any pathway developed in the next year or two. Thus, legislation that mandates an FOB pathway and sets some rules of the road should build in flexibility for the future, and mandate tracking and research to inform that process.

Q3. We are quite sure patents on biologic-based medicines can be made relatively iron-clad with the right framework and regulatory language that encompasses a scope of scientific "sameness" for any FOB.

Q4. Strict penalties for patent violations should be employed to discourage patent infringement. Litigation pathways should not be overly complex.

Q6. We could be glib and say "someone has to do it, so it might as well be the FDA." But this is an excellent question. Debate should occur on this issue in Congress in the context of the FDA's budget and structure and the need for attention to both. That said, we can not at this time imagine this activity being housed anywhere else.

Incentives/Exclusivity/Investment

Q1. Addressed above.

Q2. Exclusivity periods for biologics that would exceed those currently operational for non-biologics should be a "non-starter." We can not specify a time period for absolute patent protection/exclusivity at this time. That's because no one has yet produced, to our knowledge, a full and accurate enough evaluation of the economic impact of varying protection periods. We would argue that there is a compelling need for such an evaluation and that a protection period can not be settled upon absent this analysis. Congress must weigh the need to support innovation with the reality that biologics will almost certainly become a larger and larger slice of the pharmaceutical market in coming years and that taxpayers will pay a large, and probably growing, share of that bill.

Q3. As with non-biologics, some exclusivity for a legitimate modification that improves a biologic would be warranted. However, we would recommend that Congress consider limiting the scope of modifications that are awarded with additional exclusivity. We believe the current system is routinely abused by drug makers.

Q4, 5, 6, 7. We believe we addressed these questions above (in Q2 under "patents)."

Economic Impact

Q1. We understand that estimates vary widely for this, depending on assumptions. In truth, it is not possible to make any kind of accurate assessment beyond the next five to seven years. That said, we believe that optimal system-wide saving will accrue only if interchangeability is sanctioned and multiple FOB firms are allowed to enter the market. Moreover, we do not believe the theory that FOBs will always "shadow" price the original product. Over time, new and more efficient production techniques will likely permit FOBs to be produced much more cheaply than will probably be the case in the next decade.

Q3. An exemplary pathway for FOBs in the U.S. will have worldwide consequences. The U.S. government should be assertive in fostering innovation in this field through the fair protection of intellectual property rights, but also in creating a system that *puts public health front and center*. The high cost of health care has eroded the U.S.'s competitiveness in world markets. We believe that providing a pathway for the approval of safe competitive biologics will improve American competitiveness.

European Model

All Qs. The EU model should be studied closely. However, FOB regulations in the EU have been adopted in the context of EU nations' health care systems and their more centralized control of drug prices. As such, the FOB provisions in Europe may not be appropriate in the U.S. In the U.S., we'll need to be more scrupulous about preventing excessive market monopolies that generate excessive profits.