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THE LAW OF BIOLOGIC MEDICINE

HEARING BEFORE THE COMMITTEE ON THE JUDICIARY UNITED STATES SENATE ONE HUNDRED EIGHTH CONGRESS

SECOND SESSION

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

AUG 1 8 2004

The Honorable Orrin Hatch
Chairman
Committee on the Judiciary
United States Senate
Washington, D.C. 20510-6275

Dear Mr. Chairman:

Thank you for the letters of July 6, 2004, containing follow-up questions for the Food and Drug Administration (FDA or the Agency) from the June 23, 2004, hearing entitled, "The Law of Biologic Medicine." We have restated your questions below with our response for the record.

Questions from Senator Orrin G. Hatch

To Dr. Crawford

1. Please comment on trade secrets, and any other major factors that will be discussion points on how to regulate follow-on proteins, especially considering issues of safety and effectiveness of these products.

The "major factors" that should be discussed in determining how to regulate follow-on proteins fall into two general categories: First, there are numerous scientific issues relating to how and to what degree one can assess the "sameness" of two proteins. We mention these scientific issues first, because they are the ones that relate most directly to assessing the safety and effectiveness of follow-on proteins. Second, there are legal and policy issues that need to be considered in a comprehensive discussion of follow-on proteins. Among these issues, and in no particular order, we believe it is necessary to be cognizant of: protecting trade secrets and confidential commercial information; making sure that nothing we do amounts to an unconstitutional taking of property without due process of law; assuring that patent rights are protected; maintaining incentives for industry to innovate, while appropriately balancing the need for lower cost follow-on products; and minimizing, to the extent compatible with assuring product safety and effectiveness, the regulatory burden.

2. You testified that under section 505(b)(2) of the FDCA, the agency may approve a new drug application (NDA) based, at least in part, on FDA's earlier finding that a drug is safe and effective. In doing so, is the agency using the data that supports the earlier approval to support the approval of the 505(b)(2)

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application, or is the agency only relying on the final finding of safety and effectiveness for the earlier approval? Or is it both?

Under the 505(b)(2) approval mechanism, FDA may approve a new drug application (NDA) by relying on the finding of safety and effectiveness for the earlier approval.

- 3. Does the FDA consider there to be a distinction between reliance on a prior finding of safety and effectiveness and reliance on the underlying proprietary data that supported the finding of safety and effectiveness. Is there a legally significant difference?**

When FDA approves a 505(b)(2) application that relies on the Agency's previous finding of safety and effectiveness for a drug product, it does so to the same extent as is contemplated by the abbreviated new drug application (ANDA) approval process. That is, the applicant seeking approval for the new product must show that its proposed product is sufficiently similar to the approved product to be able to rely on the conclusions the Agency has made regarding the approved product's safety and effectiveness. The Agency's finding of safety and effectiveness is, of course, based on studies conducted by the sponsor. However, a subsequent ANDA or 505(b)(2) applicant does not rely on the study data directly, but rather on whatever findings FDA has already made about that data to support a drug approval. This is important because the data in an NDA may go well beyond what was needed to support the earlier approval. Therefore, FDA has determined that there is a legally significant distinction between reliance on a prior finding of safety and effectiveness and reliance on the underlying proprietary data that supported the finding of safety and effectiveness.

- 4. As you mentioned in your testimony, the agency is prohibited from disclosing trade secret and confidential information to the public. What guidance does FDA provide to its medical review staff with respect to the need to protect such information from disclosure? Is the review staff permitted to review, for example, manufacturing specifications in one sponsor's marketing application before providing comments on another applicant's manufacturing specifications?**

All staff, including medical review staff, are sensitized to their obligation to protect trade secret and confidential commercial information from inappropriate disclosure. All new employees are trained early in their employment on this obligation and are required to acknowledge it in writing. The Agency periodically reminds staff of the need to safeguard protected information.

For example, FDA's Center for Drug Evaluation and Research reviewers who work on NDAs, including applications covered by section 505(b)(2) of the Act, are apprised of policies relevant to their reviews. Reviewers are advised, for example, that they can rely on prior Agency findings of safety and effectiveness for approved drugs in reviewing generic drug applications. This reliance is, however, distinct from using specific data owned by one sponsor, which underlies a prior Agency finding, to fill a "gap" in another sponsor's application that needs to be filled in order for the application to be approved. We prohibit the latter type of reliance unless authorized by the relevant sponsor. Consistent with the above,

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reviewers can and do consult previously approved applications for background or other purposes not related to unauthorized "gap filling," including in scenarios such as the one you describe. (In fact, reviewers are sometimes unavoidably conscious of information in a prior application, even without physically consulting the application, simply because they recall the information from having worked on the earlier review.)

Questions from Senator Richard J. Durbin

To Dr. Crawford and Mr. Troy

The FDA has promised a guidance document for an approval process for "follow on biologics" by Fall, 2004. In addition to addressing the biological, medical and technical aspects of producing generic equivalents, will the document address the legal issues associated with (a.) the regulation of biologics under the Food, Drug and Cosmetic Act and the Public Health Service Act; (b.) how both of these laws might apply to "follow on biologics"; and (c.) recommendation for changes to each of these laws?

No. The draft guidance that FDA will prepare is not expected to address legal issues; it is intended to address the science of follow-on proteins.

Questions from Senator Charles E. Schumer

To Dr. Crawford

1. In March of this year Dr. Mark McClellan, then Commissioner of the FDA, said "we do believe the science may be adequate now to proceed on several relatively simple biologics that were approved as NDAs, and hence are subject to Hatch-Waxman laws." It was my understanding that the FDA planned to issue draft guidance this summer to clarify FDA's current thinking on this issue and to lay out the scientific parameters relevant to the creation of follow-on biologics. Now it seems this guidance is being delayed. I understand you plan to hold a public symposium first, but that it isn't expected to take place until the fall. FDA has tremendous scientific expertise here, and you have said you have the authority to approve follow-on versions of products regulated as drugs under section 505 of the Food, Drug & Cosmetic Act (FD&C Act). We may not be able to approach this with a one-size-fits-all solution. If the science and the regulatory pathway are both there for some products, what is the reason for the delay? Why not issue guidance now, based on FDA's own scientific knowledge base, and get the discussion going, so that we can at least begin to move forward on the products we do know something about?

FDA shares your desire to accelerate the discussion on this topic, and it is precisely our commitment to fostering a meaningful public discussion that has driven our anticipated schedule. Since the June 23, 2004, Judiciary Committee hearing, we have further solidified

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our plans. FDA will hold a two part workshop exploring science issues relating to follow-on proteins: the first will be a public meeting in early fall at which the Agency will solicit public input on the numerous scientific issues relating to follow-on proteins (regardless of their legal approval mechanism); the second part is a cosponsored workshop with the Drug Information Association that will solicit the views of experts in a public forum. Given the fast-changing state of the science and the precedent-setting nature of the questions presented, FDA desires to make the anticipated scientific guidance as accurate as possible, and we need the public discussion to make this happen. There may well be certain "relatively simple" proteins for which it is appropriate to proceed with some form of follow-on. However, because the issues raised by these relatively simple products also implicate more complex products, FDA believes it makes sense to proceed with the benefit of public and expert input.

2. In 1996, and in an updated version issued in 2003, the FDA issued guidance which allowed brand companies who have made manufacturing changes to show their new product is "comparable" to the one that was originally approved. Don't these documents provide a good framework for how a generic company might be able to do the same? Doesn't the guidance show- at the very least- that it's scientifically possible to show "comparability"?

The 1996 guidance document is entitled, "FDA Guidance Concerning Demonstration of Comparability of Human Biological Products, Including Therapeutic Biotechnology-Derived Products." This guidance document has not been updated. FDA has issued subsequent guidance concerning comparability protocols. FDA issued the 1996 guidance to address the situation in which a single manufacturer makes changes to its own manufacturing process and must demonstrate comparability between the "old" and the "new" products. For scientific and legal reasons FDA limited the guidance to a single manufacturer. This guidance document could, in theory, provide a starting point for developing a scientific framework to demonstrate comparability between two products from two different companies. The general concept of comparability may be applicable to follow-on biologics if a number of additional factors are taken into account, as outlined below:

- 1) To demonstrate comparability between a commercially available innovator product and a follow-on product, the follow-on manufacturer would need to determine whether or not the formulation of the innovator's product contains components that would interfere with a thorough analysis of the characteristics of that product's active ingredient. In such cases, the innovator's active ingredient would need to be purified away from the interfering substances, without altering the qualities of the active ingredient, prior to being subject to a thorough characterization.
- 2) Some biotechnology products are more complex than others; for the most complex, the details of how the manufacturing process is performed can have a significant (and, in some cases, unpredictable) impact on the product's characteristics. Therefore, initial forays into the world of follow-on biologics will be most successful for those who work with relatively simple proteins (e.g., highly purified proteins that are not complex mixtures of variants).

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- 3) The innovator company may have a very specific, proprietary assay method that it uses to evaluate the potency of its product. The follow-on manufacturer would need to develop its own assay method to compare its product to the innovator's. It would also need to ensure that the assay method used for this comparison and for routine product quality testing is relevant to the clinical activity of the product.

3. Did the FDA conduct a widespread public symposium prior to issuing the initial draft of the 1996 comparability guidance for brand companies?

The concept of biochemical comparability was publicly discussed at public forums such as scientific meetings and conferences prior to issuing the draft. FDA did not hold a public symposium prior to issuing the draft 1996 Comparability Guidance, to our knowledge.

4. FDA has stated publicly that certain biotechnology products, for example Human Growth Hormone, may be approved based on limited clinical studies. I can only assume that FDA's saying this indicates that the Agency believes this can be done with no ill-effect on the public health. Is that the case? Does the Agency still believe this, and if so, why has the Agency chosen to delay issuance of the scientific guidance which might flush out this position?

As you indicate, we continue to believe that applications for human growth hormone (hGH) can be approved based on less clinical data than would be required for other products whose clinical effects are not as well understood. We are delaying the issuance of a scientific guidance (which will be applicable to therapeutic proteins and peptides beyond just hGH) because additional time is needed to prepare the guidance. In substantial part, a delay is necessary because we are committed to ensuring that a full public discourse takes place before the guidance is completed. We believe that engaging in an open discussion before proceeding with the guidance is critical given the complexity of issues and controversy surrounding our work on this document. As you have noted, we are convening a public workshop this fall. We will solicit public input on key scientific issues during this workshop. The fall workshop will be followed by a second scientific workshop in early 2005. To help enhance the discussion at the second workshop, we will issue a concept paper in advance that is based on our consideration of the public input we receive during the fall session. We believe this multi-step public process will best ensure that our guidance is robust and addresses all pertinent issues.

5. Some have argued that it is not possible to determine that two biologics are "interchangeable". However, it is my understanding that the FDA already has some experience making such a determination. Specifically, the package insert for a hepatitis-B vaccine, Engerix-B, describes studies which indicate that Engerix-B, which is yeast-derived, is interchangeable with other manufacturers' plasma-derived vaccines. How did the FDA make the determination that these vaccines were in fact interchangeable? On what science did FDA base its approval of this statement? Did the Agency require the companies to do

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additional tests? What from this experience is transferable to the determination of interchangeability of follow-on biologics? Doesn't this action by the FDA clearly indicate that science exists to allow for similar determinations for other follow-on products?

It is true that the package insert for Engerix-B contains a subsection, in the Clinical Pharmacology section, concerning the vaccine's interchangeability with other hepatitis B vaccines. This subsection states that, based on *in vitro* and *in vivo* studies, "it should be possible to interchange the use of Engerix and plasma-derived vaccines (but see CONTRAINDICATIONS)." However, as described below, interchangeability in this vaccine context is largely based on antibody response, and is thus separate and distinct from any notion of demonstrating sameness between follow-on therapeutic protein products.

Serum antibodies against the surface protein of the hepatitis B virus (the hepatitis B surface antigen, abbreviated as "HBsAg") are a well-accepted correlate of human protection against hepatitis B disease; there is general agreement that 10 milli-International units/mL (mIU/mL) of such antibodies are protective. Currently, there are two hepatitis B vaccines in use in the United States, Recombivax HB from Merck and Engerix-B from Glaxo Smith Kline (GSK). Each is a recombinant DNA-produced version of the HbsAg; both recombinant vaccines are produced in yeast. Although similar, there are differences in the vaccines and vaccine formulations. For example, the Merck vaccine is formaldehyde-treated (thus modifying the HbsAg protein), whereas the GSK vaccine is not. The pediatric dose (for children born to mothers who are not positive to the HBsAg) of Recombivax HB, administered on a 0, 1, and 6 months schedule (i.e., the second and third doses are administered at one and six months, respectively, after the first dose), is 5 µg; the pediatric dose of Engerix-B, administered on the same schedule, is 10 µg.

Both vaccines are comparable in sero-conversion rates to the 10mIU/mL level - essentially 100 percent for healthy infants and in excess of 95 percent for healthy adolescents and young adults (< 40 years of age); there is an age-dependent waning of vaccine response that is observed with both vaccines. The antibody responses that are seen with the two vaccines are highly similar in nature (not just in level) in that no differences were seen between them and the previously licensed plasma-derived hepatitis B vaccine. Both vaccines demonstrated clinical efficacy, among other things, in preventing disease in neonates born to hepatitis B infected mothers.

Both recombinant vaccines demonstrated interchangeability with the then-licensed plasma derived vaccine (the plasma-derived vaccine is no longer manufactured, having been replaced by the recombinant DNA derived vaccines). This interchangeability was evidenced by the similar nature of the antibody responses to the respective vaccines (see P. Hauer *et al.*, *Postgrad. Med. J.*, 63 (Suppl 2), 83 - 91 (1987); cf., West, D.J.; Calandra, G.B.: Vaccine induced immunologic memory for hepatitis B surface antigen; implications for policy on booster vaccination, *Vaccine*, 14(11): 1019-1927, 1996. Ermini, E.A.; Ellis, R.W.; Miller, W.J.; McAleer, W.J.; Scolnick, E.M. and Gerety, R.J.: Production and immunological analysis of recombinant hepatitis B vaccine, *J. of Infection*, 13(Sup. A): 3-9, 1986; Brown,

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S.E.; Stanley, C.; Howard, C.R.; Zuckerman, A.J.; Steward, M.W.: Antibody responses to recombinant and plasma derived hepatitis B vaccines, *Brit. Med. J.*, 292: 159-161, (1986). In an additional clinical study (L.M. Bush et al., Evaluation of initiating a hepatitis B vaccination schedule with one vaccine and completing it with another, *Vaccine*, 9, 807 - 809 (1991)), it was shown that Engerix-B could be used to complete a course of immunization begun with Recombivax HB (serological responses to two doses of Recombivax HB followed by one dose of Engerix-B were similar to three doses of Recombivax HB).

In summary, the licensure of each vaccine was separately based on (1) clinical studies of efficacy against a disease end-point and (2) very high rates of seroconversion in vaccine recipients to a well-established correlate of immunity (i.e. anti-hepatitis B surface antigen serum antibody levels in excess of 10 mIU/mL). The given interchangeabilities of the vaccines, which are limited (vide infra), were based on clinical studies in human vaccine recipients demonstrating that comparable antibody responses were achieved. The interchangeability that is allowed is limited to those instances that were studied clinically; for example, Engerix-B may not be used interchangeably with Recombivax HB for the accelerated adolescent schedule.

6. Is it the case that, in the interest of public health, the FDA has assigned certain therapeutic proteins to be reviewed under the NDA route in the FD&C Act as opposed to under the BLA route in the Public Health Service Act (PHSA)? Doesn't FDA have the ability to select the legal mechanism under which a product will be approved, when it is in the interest of the public health? Are there any limitations on this authority? If so, what are they?

Whether a particular approval mechanism is "in the interest of public health" is not the standard that FDA uses in determining how a product will be regulated; rather, since our approval authority derives from statute that determination is made by reference to statutory language and definitions. If a product fits the definition of a biologic under section 351(i) of the Public Health Services Act, it is regulated using a biologic license application (BLA). If a product does not fit the definition in the Public Health Services Act, its intended use will nonetheless make it a drug, subject to regulation under an NDA (or in some cases, a device, subject to regulation under the device authorities). You are correct that because of the interpretation of the definition in the Public Health Services Act, there are a limited number of protein products regulated as drugs under section 505 of the FD&C Act. These include products such as insulin and human growth hormones.

7. I have heard from industry sources that for certain classes for which FDA has approved multiple similar biologics, the Agency has been able to refine the clinical requirements for applicants after the first. Is this the case?

It is common to refine clinical requirements after some experience with products in a class. This phenomenon is not limited just to biologics. FDA frequently learns things from the first product applications in a class that can help refine study design issues for subsequent products, either in terms of safety or efficacy.

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For instance, pre and post approval (or licensure) experience with a product as well as increased knowledge about the disease or condition that a product is intended to treat, may aid in refining subsequent clinical studies with similar products. Such information might, for example, lead to the establishment of surrogates such as a correlate of protection that can subsequently be used as the basis for demonstrating efficacy for product licensure or approval. Similarly, information about safety problems encountered with members of a class may lead to the need for specific safety monitoring during clinical trials of new members of the class.

Question from Senator Joseph R. Biden, Jr.

To Dr. Crawford

1. Many biologics are quite complex and are used to treat very specialized segments of the population. These will not be so-called "blockbuster" products. Do you think that some biologics lend themselves more to "follow on" versions than others? How do you think we should deal with more complex biologics that may be more difficult to replicate? What about products that are akin to "orphan drugs" only aimed at a limited group of patients?

Proteins vary in complexity. Many highly sophisticated analytical methods have been developed permitting more accurate characterization of complex proteins, and as science improves, more advances can be expected. In general, some proteins clearly lend themselves more to "follow-on" versions than others. Larger, more complex (e.g., with varying degrees of post-translational modifications or consisting of multiple sub-units) are more difficult to evaluate and handle than smaller, less complex molecules.

While market demand is likely to drive development of follow-on products, limited use products may only have one manufacturer. Orphan designation is available for products regulated under a BLA.

Thank you again for contacting us concerning this matter. FDA appreciated the opportunity to testify before the Subcommittee. Please let us know if there are further questions.

Sincerely



Patrick Ronan
Assistant Commissioner
for Legislation