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PATIENT AND CONSUMER COALITION

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Statement on Wound-Healing Combination Products

The Patient and Consumer Coalition recognizes the great importance of these products to millions of patients with severe burns, diabetic skin lesions, work and accident-related injuries, and decubitus ulcers. This is an important issue for consumers, and the implications for how the FDA functions as a scientific and regulatory agency is also important. We consider it imperative that any new wound-healing combination product undergo a thorough and comprehensive evaluation for safety and efficacy before coming to market. In addition, any Center with jurisdiction over these products must ensure that adequate post-marketing surveillance is performed to monitor adverse events. In determining jurisdiction over these combination products, we believe patient safety must have priority over all other considerations.

Jurisdictional Assignment Based on Individual Product Characteristics

The Patient and Consumer Coalition believes that assignment of jurisdiction over new wound-healing combination products should be based on the unique characteristics of each product. The traditional assignment of these combination products to the Center for Devices and Radiological Health should play no significant role in determining jurisdiction over future products. Jurisdiction should be assigned instead to the Center that is best equipped to evaluate the safety and efficacy of each new combination product.

Primary Mode of Action

The primary mode of action of a new combination product serves as a useful guide in assigning jurisdiction. In evaluating the primary mode of action, the following questions must be asked:

- Which component provides the greatest therapeutic benefit for the patient?
- Which component, if it fails or is defective, poses the greatest risk to patient health and safety?
- Which component has the longest-lasting impact on patient health?
- Which component interacts most closely with the patient's own tissues and cells?
- Which component, if any, is permanently implanted into a patient?
- Which component must be discussed in order to obtain true informed patient consent?

In evaluating the primary mode of action of any new combination product, the patient's perspective must be given the highest priority.

Patient Safety above Rapid Approval

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In assigning jurisdiction over new combination products, priority must always be given to patient safety over rapid product approval. The Patient and Consumer Coalition believes that thorough pre-market evaluation of combination product safety and efficacy benefits patients far more than rapid approval of new products. The Center that is assigned jurisdiction over a new combination product should commit to placing patient safety above industry demands for rapid evaluation and approval.

In-House Expertise vs. Outside Consultation

The Patient and Consumer Coalition believes that the Center assigned jurisdiction over a new combination product should have adequate in-house expertise to evaluate the product based on its primary mode of action. For example, if the primary mode of action is through the combination product's biologic component, the Center assigned jurisdiction should have adequate in-house expertise in the biological sciences. Not only would such in-house expertise permit a more thorough evaluation of new products, it would also allow a Center to more readily address such public safety concerns as bovine spongiform encephalopathy ("mad cow disease").

The Coalition opposes the use of any outside consultant in the evaluation of new combination products if these consultants are chosen and/or paid for by industry. Such outside consultants are subject to intolerable financial and professional conflicts of interest. Adequate staffing with in-house experts should minimize or even eliminate the need for such outside consultants.

Post-Market Surveillance

Once a new combination product is approved for market, the Center assigned jurisdiction should require manufacturers to perform comprehensive post-market surveillance activities. The Center should devote sufficient resources and personnel to closely monitor adverse events. Ideally, the Center assigned jurisdiction should have sufficient regulatory authority to compel manufacturers to complete all required post-marketing surveillance activities. All Centers with jurisdiction over combination products should be required to report to Congress, on an annual basis, the rate of completion and status of required post-market surveillance activities and any action taken by the Center against companies that failed to fulfill these requirements.

In summary, the Patient and Consumer Coalition believes that patient safety should have priority above all other considerations when assigning regulatory jurisdiction over new combination products.

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National Women's Health Network
National Center for Policy Research for Women & Families
Center for Medical Consumers
TMJ Association
The Title II Community AIDS National Network