

Meeting Minutes
PhRMA/FDA
Pediatric Exclusivity Provisions of the FDA Modernization Act

February 11, 1998

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PhRMA Participants:

Jonathan Rosefsky, M.D., Wyeth-Ayerst
Williams Roberts, M.D., Merck
John Siegfried, M.D., PhRMA
Harry Laws, M.D., Lilly
Martin Teicher, Pfizer
Stephen Spielberg, M.D., Ph.D., J&J
Maria Kennedy, Hoffmann-LaRoche
Marjorie Powell, PhRMA
Thomas L. Copmann, Ph.D., Lilly
Robert T. McDonough, Pharmacia & Upjohn

FDA Participants:

Leanne Cusumano, Regulatory Policy Staff, CDER
Rosemary Roberts, M.D., Pediatric Subcommittee, CDER
Linda Carter, Office of Review Management, CDER
Elizabeth Dickinson, Office of the Chief Counsel, FDA
Ann Witt, Office of Policy, FDA
Murray Lumpkin, M.D., Deputy Director, CDER
Cecelia Parise, Office of Generic Drugs, CDER
Khyati Roberts, Executive Operations Staff, CDER

Type of Meeting: Information gathering meeting.

Meeting Chair: Murray Lumpkin

External Participant Lead: John Siegfried

Meeting Recorder: Khyati Roberts

Meeting Objectives and Discussion: This meeting was scheduled to discuss the pediatric exclusivity provisions of the FDA Modernization Act (FDAMA). The goal was to hear PhRMA's perspective on some specific topics. PhRMA's views follows each topic.

What is meant by "may produce a health benefits" as used in Section 111(b)?

- The definition should be broad and flexible to allow any medication currently used for a disease that occurs in children be placed on the list.

- A universal rather than a restrictive list should be prepared.
- A restrictive list would not advance the goal of pediatric drug development.
- Competition and the exclusivity incentives will ultimately encourage further development of drugs for children.

What is the interaction of submitting studies under Section 111(d) and the filing of an application or supplement?

- The FDAMA does not require filing of an application. The Agency is free to discuss filing issues with the sponsor.
- Exclusivity should be granted regardless of approval.
- A pending supplement that is currently under review should be granted exclusivity.
- The agency has options to make it uncomfortable for a sponsor should they wish not to submit an application. However, studies should be designed with the goal of revising the labeling.
- Completion of the study should trigger the exclusivity determination.

What should be included in the definition of pharmacokinetic studies as used in Section 111(g)?

- Pk studies should be designed with reasonable scientific principles from a pediatric point of view. Special considerations should be given to the formulation, sparse blood sampling, smaller patient numbers, etc.
- If the product is not formulatable, the product still should be given exclusivity.

What is the definition of "drug" as used in Section 111(h)?

- "Drug" should be defined as any drug product that contains the active ingredient that was studied.

What should the "written request," as used in Section 111(a) and (c), contain? and What should the format of the "written agreement," as used in Section 111(d) and (e), be? Should a disease that occurs in children be placed on the list.

- The written request should be any agreed upon protocol.
- The completion of the study described in the protocol should constitute entitlement.
- For approved products, once a protocol is agreed upon, it should automatically place it on the list.

What are “commonly accepted scientific principles and protocols” as used in Section 111(d)(3)?

- Flexibility, appropriate hypothesis, FDA/AAP standards, IRB approvals, use of patients rather than healthy volunteers, smaller numbers of patients, extrapolation of data when disease is similar in adults are some examples of “commonly accepted scientific principles.”

What is meant by “other requirements,” as described in Section 111(I)?

- “Other requirements” refers to the existence of the written agreement and requirements of regulations.

How should we anticipate use of a drug in a particular age group as described in Section 111(g)?

- For adult diseases/conditions that occur in pediatrics, it is easy to determine the anticipated use.

The following issues were raised by PhRMA. FDA’s response follows each topic.

How will off patent/exclusivity drugs be handled?

- FDAMA only allows FDA to grant pediatric exclusivity to drugs that have patent or exclusivity protection. Only Congress can expand the scope of FDAMA.

How do you get on the list and how will it be updated?

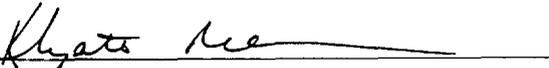
- A Federal Register Notice will publish in the near future outlining the process.

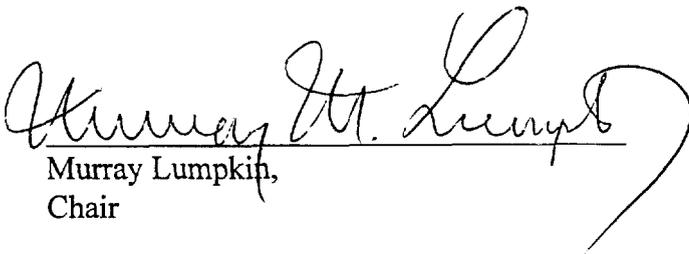
Will the Agency form some kind of committee to handle pediatric issues?

- The idea of forming a committee is currently under discussion in the Agency.

Will there be a public workshop?

- The agency has limited resources to implement FDAMA and a workshop is not planned. However, FDA would be willing to participate in workshops and conferences held by other organizations.


Khyati Roberts
Meeting Recorder


Murray Lumpkin,
Chair