Research to Application through Multi-Sector Partnerships

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Innovation for Human & Environmental Health
It is difficult to find a black cat in a dark room...
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Especially if there is no cat.
Supporting Impactful Innovation

Flashlights & Focal Points
The HESI Model: Bridging Research to Application

INNOVATION THAT BENEFITS PUBLIC HEALTH

- Academic & basic research sector
- Foundations & NGOs
- Industry R&D
- Government Research & Regulation
HESI: Growing Innovation

- Safe and Effective Medicines
- Accurate & Efficient Risk Assessment
- Environmental Quality and Sustainability
- Food Safety
HESI: Health and Environmental Sciences Institute

- 90 Universities & Research Centers
- 33 Government Agencies
- 54 Corporate Sponsors
- 16 Scientific Committees
- 77 Distinct Projects
- IMPACT via Quality Science

From 14 Countries
From 12 Countries
Across multiple sectors (pharma, chem, agchem, consumer product)
FIRST: Defining critical health or environmental issues.

_then….._

Design Relevant & Fit for Purpose Frameworks & Studies

Engage Stakeholders in Evaluating, Applying & Communicating Results

Create Human or Environmental Health Impact

CROSS SECTOR ENGAGEMENT

HESI: Innovation from Research to Application
Seldane Risk Reported -- Fda Warns About Popular Antihistamine

By Rita Rubin
Times News Services: Dallas Morning News

The U.S. Food and Drug Administration warned yesterday that Seldane, the most widely prescribed antihistamine, can cause life-threatening heartbeat irregularities in a small number of patients.

The irregularities occur when excessive levels of Seldane build up in patients' blood, according to the FDA. Patients at risk include those who take more than the recommended two tablets a day or those who use Seldane with certain other drugs.

Those drugs are Nizoral - an anti-fungal medication commonly used by AIDS patients - and the antibiotic erythromycin. Nizoral and erythromycin appear to interfere with the body's ability to utilize Seldane, the FDA said.

"Use of Seldane together with ketoconazole (the generic name for Nizoral) and erythromycin must be
Seldane Issue Takes New Turn

By Rita Rubin
Times News Service

The U.S. Food and Drug Administration has launched an investigation into irregularities at the manufacturer of Seldane, an antihistamine, called Sandoz Inc.

The irregularities were discovered during a routine inspection of the company's Parma, Ohio, plant last week. The FDA has not disclosed why it took so long to complete the inspection, which began five days earlier.

Seldane, which is marketed under the names Actifed and Claritam, is a commonly prescribed antihistamine, called a non-sedating antihistamine, that blocks the effects of histamine in the body.

The FDA says that patients at risk include those who take more than the recommended two tablets a day or those who use Seldane with certain other drugs.

Those drugs are Nizoral - an anti-fungal medication commonly used by AIDS patients - and the antibiotic erythromycin. Nizoral and erythromycin appear to interfere with the body's ability to utilize Seldane, the FDA said.

"Use of Seldane together with ketoconazole (the generic name for Nizoral) and erythromycin must be
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Need for Improved Approach to Assess Patient Cardiac Risk from Medicines

- Academic & basic research sector
- Foundations & NGOs
- Industry R&D
- Government Research & Regulation
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Need for Improved Approach to Assess Patient Cardiac Risk from Medicines
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Clinical outcomes, Heart physiology

Foundations & NGOs

Industry R&D

Government Research & Regulation
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The HESI Model: Bridging Research to Application

Clinical outcomes, Heart physiology

Screening Models Clinical Trial Data

Foundations & NGOs

Government Research & Regulation
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Foundations & NGOs

Define Thresholds for Safety & Required Testing
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Clinical outcomes, Heart physiology

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Clinical outcomes, Heart physiology

Screening Models Clinical Trial Data

ICH help set global regulatory standards

Define Thresholds for Safety & Required Testing
The HESI Model: Bridging Research to Application

- Right Experts, Across Sectors & Disciplines
- Novel Data Generation
- Building Best Practice in Public Domain
- Consensus on Fit for Purpose Application

Clinical outcomes, Heart physiology
ICH help set global regulatory standards
Define Thresholds for Safety & Required Testing
Screening Models Clinical Trial Data
The HESI Model: Bridging Research to Application

Novel Approach to Assessing Risk for Cardiac Arrhythmia (TdP)

Clinical outcomes, Heart physiology

Screening Models Clinical Trial Data

Define Thresholds for Safety & Required Testing

Now the standard... TdP no longer a public health challenge

ICH help set global regulatory standards
The HESI Model: Bridging Research to Application

Innovation Continues...

Clinical outcomes, heart physiology

Screening Models
Clinical Trial Data

ICH help set global regulatory standards

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For more information

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