Contraceptive Research

Perspectives on Laboratory and Field Research Considerations

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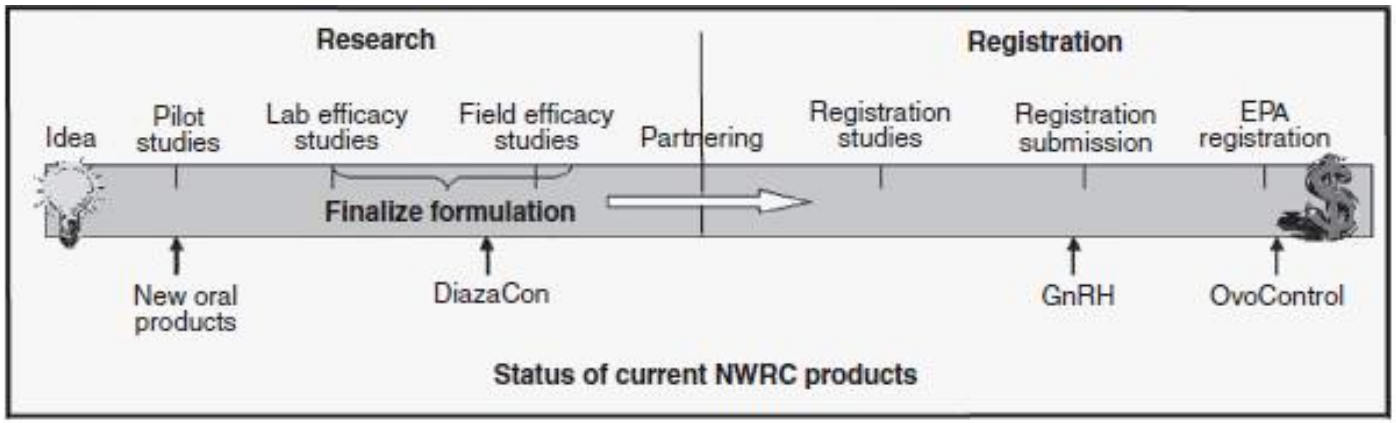
Clinical Trials of Sterilants/Contraceptives

- **Build a data file for registration**
- **Depends on agency that oversees: in USA**
  - **FDA (companion animal – dog & cat products)**
  - **USDA (food animal products)**
  - **EPA ("pesticides" - 2006 et seq. – "wild" animals)**
    - **wild horses & deer – pZP and Gonacon**
    - **Contrapest for rodents**
    - **Ovocontrol for birds**
    - **Feral cat sterilant??**

Development Process

- **Product development**



From Fagerstone et al, 2008 Wildlife Res 35:586-592

Animal studies – minimize harms

- EPA did not require the pZP registration application to provide formal (GLP) efficacy studies.
- So, we were able to use the results from our "efficacy" research (i.e. Assateague, NIST, etc) that was conducted to address various unknowns related to field application. These studies produced a positive outcome for the animals in the trials (Assateague female pony average lifespan increased from 7 years to 21!) and provided data acceptable to EPA.

Studies on pets or on animals that become pets

- If one has to register with FDA, I suspect that GLP efficacy trials will be required.
- Perhaps one could take a page out of pet food trials where studies are being done with owner consent in pets or in animals that are adopted out afterwards and that experience minimally invasive procedures (e.g. no bone biopsies).

Replacement alternatives

- **Non-animal studies**
  - Toxicology is undergoing a revolution at the moment with high-throughput techniques, organs-on-a-chip, human iPSCs, powerful new computer algorithms for read-across and IATA (integrated approaches to testing and assessment)
  - Netherlands expert group predicted non-animal testing by 2025 as did Francis Collins in testimony to a Senate committee in 2016.
  - But not sure these will apply to efficacy and safety tests for animal products by then.

Conclusions

- Real potential to use “clinical” animal trials and studies in which animals are not harmed and adopted out at end of study in place of standard GLP tox and efficacy trials;
- Similar approaches are being used in pet food studies and in wildlife fertility control.
- We have the ability to do the studies in ways that will minimize harm but not sure if regulatory agencies will loosen guidelines sufficiently to allow such approaches.