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Section D

Arsenical Drugs in Food Animal Production
Overview

- Arsenical drugs in animal production
- Human exposures and risks
- Regulatory and legislative efforts
- Successes, failures and progress
Arsenical Drugs

- Roxarsone
  - Also p-arsanilic acid, nitarsone, carbarsone, arsanilate sodium
- Additive in poultry and swine feed since the mid-1940s
- Approved for growth promotion, improved pigmentation, coccidiostat, treatment of swine dysentery
- In poultry production: 88 percent raised using roxarsone
  - 2010 estimate
  - 2012 to ?
- In swine and turkey production: unknown percentage
- Single domestic producer
Background and Historical Context

- 1944: FDA new animal drug (NADA) 7-891 approval for roxarsone

- 1951: Tolerance levels set by FDA for arsenic residues in meat products (21 CFR §556.60)
  - 2 ppm in liver
  - 0.5 ppm in uncooked meat

- 1981: Environmental impact analysis (for FDA)
  - “The only probable adverse effect on the human population arising from the use of 3-nitro premixes (roxarsone) in poultry and swine feeds is the residues of the compound which may be present in the food of man”

- 1983: NRC develops approach to chemical-risk assessment
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Inorganic Arsenic-Related Health Effects

- Arsenic is a well-characterized human carcinogen
  - Lung, bladder, skin
  - Other sites
  - Transplacental carcinogen

- Noncancer health effects
  - Cardiovascular disease
  - Diabetes mellitus
  - Dermal effects
  - Neurological effects/deficits
  - Immunologic effects
  - Fertility effects
  - Birth defects
  - Respiratory effects
  - Renal effects

- Acute toxicity
  - Irritation of lungs, throat, stomach, intestines, and skin

Source: CDC
Gaps in Knowledge/Remaining Questions

- Chicken meat
  - Arsenic type?

- Environmental impact
  - Approximately 11 tons per year, but where does it go?
The Roxarsone Story: 2011 and Beyond

- June 8: FDA announcement and Pfizer suspension also announced
  - Press and stakeholder calls

- July 8: Pfizer suspends marketing of roxarsone in the US

- August 29: Poultry industry trade groups send letter to Margaret Hamburg/FDA

- October 13: Zhejiang Rongyao Chemical Co. files a lawsuit ($20 million) against Pfizer over roxarsone
  - January 2011 contract
Use of roxarsone creates environmental public health issues that extend beyond the jurisdiction of any single federal agency

- Drugs, environmental exposures, food production, food safety, occupational exposures

Existing regulatory mechanisms that may address some of these issues are often inadequate
Regulatory Agencies/Mechanisms

- No existing standards addressing arsenic in animal waste
- No indication of further FDA action based on re-evaluation of arsenicals
- So, legislative intervention?
Federal and State Legislative Initiatives

- Federal bill (introduced by Rep. Steve Israel [D-NY])—the “Poison-free Poultry Act”
  - HR 3264 (2009-2010)
    - No vote
  - HR 1487 (2011-2012)
Federal and State Legislative Initiatives

- Maryland bills
  - 2010/2011
    - HB953/HB754 introduced by Del. Thomas Hucker
      - No vote/no decision
    - SB859/SB417 introduced by Sen. Paul Pinsky
      - No motion taken/no vote
  - 2012
    - HB167 introduced by Del. Thomas Hucker
    - SB207 introduced by Sen. Paul Pinsky
Why Was This Year Different?

- The state of knowledge has changed
  - FDA study
  - Harry Hughes Center for Agroecology’s December 2011 report

- State of public knowledge and intensity of advocacy coalition/organizing
2012: Success! (Sort of ... )

Maryland set to ban arsenic-containing drug in chicken feed
Article – Agriculture

6–107.3.

(A) Exempt as provided in subsection (B) of this section, a person may not use, sell, or distribute for use or sale within the State any commercial feed intended for use as poultry feed that contains:

(1) Roxarsone; or

(2) Any other additive that contains arsenic.

(B) A person may use, sell, or distribute for use or sale within the State any commercial feed intended for use as poultry feed that contains histostat.

SECTION 2. AND BE IT FURTHER ENACTED, That:
Loophole?

Roxarsone (BANNED)

Nitarsone (EXEMPTED)
AN ACT to amend the agriculture and markets law, in relation to the
manufacture, distribution, sale and use of commercial feed for poultry
containing roxarsone or any other substance that contains arsenic

THE PEOPLE OF THE STATE OF NEW YORK, REPRESENTED IN SENATE AND ASSEMBLY, DO ENACT AS FOLLOWS:

Section 1. The agriculture and markets law is amended by adding a new
section 131-a to read as follows:

S 131-A. COMMERCIAL FEED FOR POULTRY; ROXARSONE PROHIBITED. 1. NO PERSON IN THIS STATE SHALL MANUFACTURE, DISTRIBUTE, SELL OR USE ANY COMMERCIAL FEED FOR POULTRY, AS DEFINED IN SUBDIVISION SIXTEEN OF SECTION NINETY-B OF THIS CHAPTER, WHICH CONTAINS ROXARSONE OR ANY OTHER SUBSTANCE THAT CONTAINS ARSENIC.

2. ANY PERSON THAT VIOLATES SUBDIVISION ONE OF THIS SECTION SHALL BE GUILTY OF A CLASS A MISDEMEANOR AS DEFINED IN THE PENAL LAW.

S 2. This act shall take effect on the thirtieth day after it shall have become a law.

EXPLANATION—Matter in ITALICS (underscored) is new; matter in brackets [ ] is old law to be omitted.

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Conclusions

- A lack of meaningful regulatory action
- Maryland—a good first step, but we aren’t there
- Other states could follow through
- Eventual momentum for federal initiative
Wrap-Up

- Production of animals for food has changed drastically over the past fifty years

- Current production methods pose serious risks to humans and environmental quality

- Fence line communities and animal house workers bear the brunt of these risks