LACK OF APPROVED PHARMACEUTICS
RESTRAINS U.S. GOAT INDUSTRY

National Institute for Animal Agriculture
Small Ruminant Committee Meeting, March 27, 2012

Tom Boyer, President
American Goat Federation
WHAT IS THE GOAT “INDUSTRY”? 

It involves goats, goat producers, processors and companies that manufacture/sell goat-related goods and services.
GOAT INDUSTRY: THE GOATS

Meat Goats

KIKO

BOER

MYOTONIC

SPANISH
GOAT INDUSTRY: THE GOATS

Dairy Goats

Lamancha

Alpine

Nubian

Nigerian Dwarf
GOAT INDUSTRY: THE GOATS

Oberhasli

Dairy Goats

Sable

Toggenburg

Saanen
GOAT INDUSTRY: THE GOATS

Fiber Goats

Angora (produce mohair)

Cashmere
GOAT INDUSTRY: THE GOATS

Browsing (selective herbivory)

Any breed of goat can adapt to this function,
They should not be animals in production
GOAT INDUSTRY: THE GOATS

Companion Animals
GOAT INDUSTRY: THE GOATS

Companion Animals: Pack Goats
GOAT INDUSTRY: THE PEOPLE

Operate Commercial or Extensive Dairy, Meat or Fiber Herds
GOAT INDUSTRY: THE PEOPLE

Operate Intensively Managed Dairy or Meat Herds
GOAT INDUSTRY: THE PEOPLE

Operate Seedstock Operations
(usually smaller in scale)
GOAT INDUSTRY: THE PEOPLE

Biomedical Research

• Animal Model for human disease (Rheumatoid arthritis, HIV, Trauma, Orthopedics, etc.)
• Produce antibodies
• Goat Reagents
• Transgenic goats
Transgenic goats – used as bioreactors

- Anti-thrombin (Atryn) – TC Biotherapeutics, to treat deep vein thrombosis
- Spider silk – University of Utah, for bio-matrices and sutures
- Human butyrylcholinesterase – PharmAthene, for protection against nerve gas damage
- Human granulocyte colony stimulating factor – Brazil, stimulates white blood cells
- Human Lysozyme – UC Davis, has antimicrobial effect on gut flora
GOAT INDUSTRY: THE PEOPLE

Small flock producers:

- Sustainable
- Diversified
- Organic
- Homestead
Youth Projects:
- Family Hobby
- Science Literacy for youth
GOAT INDUSTRY: THE PEOPLE

Youth Show Projects:
- 4H
- FFA
- Youth Market Jackpot shows
GOAT INDUSTRY: THE PRODUCTS

Dairy Products: you can find any dairy product in a “goats milk” version
Goat Meat: Is popular for
- Ethnic markets
- Upscale restaurants
- Health conscious consumers

<table>
<thead>
<tr>
<th></th>
<th>3 OZ COOKED (roasted)</th>
<th>CALORIES (gm)</th>
<th>FAT (gm)</th>
<th>SAT'D FAT (gm)</th>
<th>PROTEIN (gm)</th>
<th>IRON (gm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Goat (1)</td>
<td>122</td>
<td>2.58</td>
<td>0.79</td>
<td>23</td>
<td>3.2</td>
<td></td>
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<tr>
<td>Beef (2)</td>
<td>245</td>
<td>16.00</td>
<td>6.80</td>
<td>23</td>
<td>2.9</td>
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<tr>
<td>Pork (2)</td>
<td>310</td>
<td>24.00</td>
<td>8.70</td>
<td>21</td>
<td>2.7</td>
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<tr>
<td>Lamb (2)</td>
<td>235</td>
<td>16.00</td>
<td>7.30</td>
<td>22</td>
<td>1.4</td>
<td></td>
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<tr>
<td>Chicken (2)</td>
<td>120</td>
<td>3.50</td>
<td>1.10</td>
<td>21</td>
<td>1.5</td>
<td></td>
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</tbody>
</table>
GOAT INDUSTRY: THE PRODUCTS

Beautiful, Natural Fibers:

Mohair, from Angora Goats

Cashmere, can be combed or shorn from Cashmere Goats
GOAT INDUSTRY: THE PRODUCTS

- Goat’s milk soap and skin care products

DIONIS

goat’s milk infused bath and body care products to moisturize, soothe and replenish all skin types.
GOAT INDUSTRY: THE PRODUCTS

- Fire Mitigation
- Noxious weeds
- Ecosystem Maintenance
- Habitat restoration
GOAT INDUSTRY: THE PRODUCTS

- International Development
GOAT INDUSTRY: THE PRODUCTS

Leather
GOAT INDUSTRY: THE CHALLENGE

There are only 15 approved drugs labeled for use in goats!

<table>
<thead>
<tr>
<th>Drug Category</th>
<th>Cattle</th>
<th>Swine</th>
<th>Chickens</th>
<th>Turkeys</th>
<th>Sheep</th>
<th>Goats</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anesthetics</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Antibiotics</td>
<td>139</td>
<td>46.50%</td>
<td>126</td>
<td>66.70%</td>
<td>31</td>
<td>15.20%</td>
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<tr>
<td>Antiinflammatory Agents</td>
<td>10</td>
<td>3.30%</td>
<td>1</td>
<td>0.50%</td>
<td>0</td>
<td>0</td>
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<tr>
<td>Antiparasitics</td>
<td>61</td>
<td>20.40%</td>
<td>30</td>
<td>15.90%</td>
<td>172</td>
<td>84.30%</td>
</tr>
<tr>
<td>Growth Promoter</td>
<td>11</td>
<td>3.70%</td>
<td>8</td>
<td>4.20%</td>
<td>21</td>
<td>19.30%</td>
</tr>
<tr>
<td>Hormonal Agents</td>
<td>48</td>
<td>16.10%</td>
<td>5</td>
<td>2.60%</td>
<td>2</td>
<td>4.20%</td>
</tr>
<tr>
<td>Minerals, Nutrients or Vitamins</td>
<td>4</td>
<td>1.30%</td>
<td>11</td>
<td>5.80%</td>
<td>2</td>
<td>4.20%</td>
</tr>
<tr>
<td>All Other Classes</td>
<td>26</td>
<td>8.70%</td>
<td>8</td>
<td>4.20%</td>
<td>1</td>
<td>0.50%</td>
</tr>
<tr>
<td>Total Approved (A)NADAs</td>
<td>299</td>
<td>100%</td>
<td>189</td>
<td>100%</td>
<td>109</td>
<td>100%</td>
</tr>
</tbody>
</table>

There are only 15 approved drugs labeled for use in goats!
GOAT INDUSTRY: THE CHALLENGE

Types of Drugs Needed:
- Antibiotics
- Antiparasitics (internal & external)
- Anti inflammmatories
- Analgesics
- Reproductive management
- Anesthetics
If there aren’t labeled drugs for goats, then what?

Extra-Label Drug Use (ELDU)

- Provides a means for use of many FDA approved drugs in goats
- Applies to both Over the Counter and Prescription Medications
- Not the gold standard (no dosing or human food safety studies)
- Legal responsibility lies within the veterinarian
- Not available for medicated feeds
Cannot be used for production purposes
NRSP-7 *MINOR USE ANIMAL DRUG PROGRAM*

- To identify animal drug needs for minor species and minor uses in major species
- To generate and disseminate data for safe and effective therapeutic applications
- To facilitate FDA/CVM approvals for drugs identified as a priority for a minor species or minor use

To accomplish these goals, MUADP coordinates the efforts of animal producers, pharmaceutical manufacturers, FDA/CVM, USDA-NIFA state Agricultural Experiment Stations and veterinary medical colleges throughout the country.
ROUTE TO VETERINARY DRUG APPROVAL

The FDA Drug Approval Process

- Very expensive and time consuming
- Sponsors must demonstrate:
  - Target Animal Safety**
  - Effectiveness**
  - Human Food Safety**
    (meat & milk residues)
  - Environmental and User Safety
  - Good Manufacturing Practices

**Study Portions Usually Performed by the Minor Use Animal Drug Program
MUMS Legislation:
- Public Law: Minor Use and Minor Species Animal Health Act of 2004
- MUMs office is based at FDA
- Intent of Legislation
  - Allow early marketing to recover investment costs
  - Provides alternative legal means to market drugs
  - Provides incentives to encourage drug approval** (this one most directly applies to minor species)
PROJECTS IN PROGRESS

- CIDRs
  - Target Animal Safety Packet Complete
  - Human Food Safety Packet Complete
  - Efficacy Studies Pending
- Tulathromycin (Draxxin)
  - Target Animal Safety Packet Complete
  - Human Food Safety Pending
  - Efficacy Protocol Pending
- Florfenicol (Nuflor)
- Ceftiofur Crystalline Free Acid Sterile Suspension (Excede®) for treating respiratory disease
WITHOUT THESE PROGRAMS, THE GOAT INDUSTRY IS AT A DISADVANTAGE

Trade Barriers:
Other countries have many more drugs approved for use in goats
Estrus Synchronization Products Distributed for Use on Goat Dairies in France (sponges);

CIDRs are available in NZ and other countries for small ruminants.

Without this tool, US producers cannot provide year-around products.
BUT, WAIT! IT GET’S WORSE

- There is no funding in the current budget for NRSP-7

MUADP [NRSP-7]
National Research Support Project No. 7

- There is no funding in the current budget for FARAD
HOW STAKEHOLDERS CAN HELP!

- Participate in research that supports getting FDA drug approval
- Contact your Congressional Member and let them know the importance of the Minor Use Animal Drug Program
  - Ask for agriculture appropriations in the 2013-2014 budget
  - Ask for MUADP authorization in the upcoming Farm Bill
- Contact your Agriculture Experiment Station Director and let them know about the importance of the Minor Use Animal Drug Program
KEY HOUSE MEMBERS FOR AGRICULTURE APPROPRIATIONS

Jack Kingston, GA
Tom Latham, IA
Jo Ann Emerson, MO
Robert Aderholt, AL
Cynthia Lummis, WY
Alan Nunnelee, MS
Tom Graves, GA

Sam Farr, CA
Rosa DeLauro, CT
Sanford Bishop, GA
Marcy Kaptur, OH
KEY SENATE MEMBERS FOR AGRICULTURE APPROPRIATIONS

Roy Blunt (MO)
Thad Cochran (MS)
Mitch McConnell (KY)
Susan Collins (ME)
Jerry Moran (KS)
John Hoeven (ND)

Herb Kohl (WI)
Tom Harkin (IA)
Dianne Feinstein (CA)
Tim Johnson (SD)
Ben Nelson (NE)
Mark Pryor (AR)
Sherrod Brown (OH)
KEY MEMBERS FOR THE FARM BILL

Senator John Barrasso, WY
Proposed Farm Bill Authorization for MUADP in 2007

Senator Debbie Stabenow
Chairwoman of the Senate Committee on Agriculture, Nutrition and Forestry
Chelsea Render (Veterinary Student in Senator Stabenow’s office)
OTHER MINOR SPECIES AFFECTED

- Sheep
- Deer
- Elk
- Bison
- Fish
- Other aquatic species
- Honey bees
- Llamas
- Alpacas
EVEN CATTLE WILL BE AFFECTED

- Minor Use in Major Species
  - Veal Calves
  - Southern Texas: Ivermectin MUADP project for eradication of cattle tick fever
THANK YOU FOR YOUR SUPPORT!