

PRESENTATION SUMMARY

Models and Mentors: Models from Human Health and Their Potential Applicability to Contraception in Cats and Dogs

Katherine Moldave, MBA, AlcheraBio

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– Seth Berkley, President and CEO of International AIDFS Vaccine Initiative¹

... the NNRI has the ability to form joint ventures and partnerships with companies.... Even if a particular company is not interested in developing a promising compound, the NNRI may be able to license and develop the drug independently. Conversely, companies wishing to develop drugs on their own may still benefit from NNRI or FFB resources...

– Gordon Gund, founder of the Foundation Fighting Blindness, from which the National Neurovision Research Institute was spun off²

Introduction

Among the issues confronting the pet population community have been whether there are permanent and/or long-term ways to control fertility in cats and dogs by methods other than surgical intervention and, if there are such methods, how to turn the technologies into commercializable (i.e., “real”) products.

Historically, the large animal-health companies have not been as active in this area as in other areas of companion animal health, and scientists have not necessarily received the level of funding needed to support development activities. How, then, can the need for permanent or long-term solutions be addressed?

At the 2004 Alliance for Contraception in Cats and Dogs Symposium in Breckenridge, Colorado, **Dr. Linda Rhodes** of AlcheraBio introduced the audience to the Population Council. The council is a nonprofit organization that has successfully developed and achieved regulatory approval for human contraceptives since its inception in the 1950s. The success of the council and numerous subsequent nonprofits devoted to addressing underserved needs in human health demonstrate that a nonprofit entity can successfully move research from the lab through various stages of the drug development process.

Following the 2004 symposium, **Katherine Moldave** and Dr. Rhodes volunteered to develop a white paper exploring the options for a nonprofit organization to spearhead development, regulatory approval, and commercialization³ and distribution of products intended to provide long-term or permanent fertility control in cats and dogs.

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In June of 2005, a group of 15 people met to discuss the potential of ACC&D to become a nonprofit organization charged with advancing the development, approval, and commercialization of nonsurgical fertility control products for cats and dogs. (For more information on the outcome of the meeting as well as a variety of other information, see the ACC&D website: www.acc-d.org.)

As ACC&D has continued to evolve, the organization's leadership has been considering how to move forward as a nonprofit organization whose mission is making permanent and/or long-term nonsurgical fertility control in cats and dogs a reality.

Nonprofit Drug Development Models

As noted, a number of nonprofits exist that are dedicated to developing and commercializing products to meet unmet or underserved needs in human health. They have been conceived by people who recognize an unmet need and have an interest in seeing that need met. They are aware of the limitations of the traditional drug development and commercialization process and are comfortable with the concept of entrepreneurship – or at least they learn to be comfortable with it.

Several models for nonprofit involvement in drug development have emerged in the human health sector. This summary reviews these models briefly and lists some of the challenges and opportunities presented by pursuing a nonprofit-oriented drug development strategy. The summary is intended as a take-off point for the talk that will be given at the third ACC&D symposium in November 2006.

There are three interesting models that could be embraced by a nonprofit devoted to permanent and/or long-term fertility control in cats and dogs:

- The nonprofit Population Council model applied to an Animal Population Council
- A model that entails creating a nonprofit umbrella organization with certain characteristics of public-private partnerships (PPPs) and venture philanthropy (VP)
- A model by which the nonprofit makes a commitment to purchase a specific amount of an appropriate product developed by a pharmaceutical company and approved by the appropriate regulatory agency

Keep in mind that hybrids of these models exist.

The first two models have demonstrated the potential to have a significant impact on drug development in the human-health arena. The third is a more recent type of strategy. These models are presented to serve as a basis for generating discussion and enthusiasm as ACC&D moves forward to create its own paradigm. The three models are summarized below and will be discussed in greater detail at the November 2006 ACC&D symposium.

Model 1. Under the nonprofit “animal population council” model, a new nonprofit organization would be responsible for putting a drug-development infrastructure in place

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and then developing a contraceptive product. This infrastructure would consist of a combination of internal and externally sourced resources.

Examples: The Population Council (www.popcouncil.org)
 One World Health (www.oneworldhealth.org)

Model 2. Under the public-private partnership/venture philanthropy (PPP/VP) model, a new, nonprofit umbrella organization would solicit and provide funding, provide oversight, and undertake risk reduction and other management activities that would enable “big pharma” to develop nonsurgical animal contraceptives for the mutual benefit of the collaborating pharmaceutical company (and its veterinary customers and their clients) and the nonprofit organization (and its animal-population-control stakeholders).

Examples: Medicine for Malaria Venture (www.mmv.org)
 Institute for the Study of Aging (www.aging-institute.org)
 Juvenile Diabetes Research Foundation (www.jdrf.org)
 Cystic Fibrosis Foundation/Cystic Fibrosis Therapeutics, Inc.
 (www.cff.org/home)
 Cure Autism Now (www.cureautismnow.org)

Model 3. Under a “pull” scenario, a new nonprofit umbrella organization would commit to soliciting funding and purchasing a specified number of doses of a long-acting, permanent animal-population-control product, thus providing an incentive – in the form of a guaranteed market – to the first company to achieve regulatory approval of such a product. The private company would pick the approach (i.e., technology); the nonprofit would simply purchase the specified number of units of the product at a specified price/unit and distribute the product as the organization sees fit.

Examples: While there are examples of programs designed to increase the value of markets for pharmaceuticals to spur R&D (e.g., Orphan Drug Act and Vaccines for Children), there do not yet appear to be clear-cut examples of instances in which pull strategies have been implemented by nonprofits.

Vaccines for Children (www.cdc.gov/nip/vfc/default.htm) was established by the U.S. government to provide vaccines to needy children free of charge. An advisory committee makes recommendations to the Department of Health and Human Services regarding which vaccines should be included in the program, thus providing a reasonably large market to the producer(s) of those vaccines.

In short, in terms of nonsurgical contraception in cats and dogs:

- Under Model 1, a nonprofit would develop the product and then may use proceeds for development of others (perhaps for other species, or with longer action).
- Under Model 2, a nonprofit would provide financing, incentive, and oversight for a pharmaceutical company to develop the product, and the nonprofit is given remuneration in the form of payments that could be applied to further development or “free” product to be used for pet population control.

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- Under Model 3, a nonprofit pledges to raise funds to be used to purchase a pre-specified number of doses of the first long-term, permanent pet-population-control product. The nonprofit therefore has no oversight or development responsibilities.

How Do Nonprofits Do It?

Inspiration and Creativity in Response to Need. It is probably true that just about every nonprofit involved in developing and/or commercializing products for unmet or underserved health-related needs has been conceived out of a certain amount of frustration on the part of people with an inherent interest in having that need met or a belief that the need should be met.

For example:

- “The Institute for OneWorld Health will serve as a positive agent for change by saving lives, improving health, and fulfilling the promise of medicine for those most in need.”
- “Founded by parents of children with type 1 juvenile diabetes, the Juvenile Diabetes Research Foundation has always focused on a single goal – accelerating research progress to cure diabetes and its complications. To that end, our research management process is unique – we’re organized as a diabetes cure enterprise. We take informed risks, continuously monitor the global diabetes research landscape, and make research investments strategically, to ensure that resources are effectively directed to research with the greatest impact leading to a cure as soon as possible.”
- “The Institute for the Study of Aging is a biomedical venture philanthropy whose mission is to catalyze and fund the discovery and development of new therapies to prevent and treat Alzheimer’s disease.”
- “Medicines for Malaria Venture is a nonprofit organization created to discover, develop and deliver new antimalarial drugs through effective public-private partnerships.”
- “To speed the flow of new cystic fibrosis drugs through the development pipeline, the CF Foundation has created an aggressive clinical research program. Building upon the success of decades of clinical studies through its extensive CF Foundation-accredited network of care centers, the CF Foundation created another network that includes some of these centers, which have received specialized training in how to design and conduct clinical trials.”
- “To foster collaborative efforts to research and develop nonsurgical technologies for the humane control of cat and dog overpopulation.” (Alliance for Contraception in Cats and Dogs – ACC&D)

Planning. Once the inspiration to become a nonprofit happens, there are a number of things to think about at the outset, including the following:

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- Defining the mission clearly (i.e., setting the context for the organization)
- Identifying something to develop, acquire or license, and commercialize (e.g., research, technology, existing product, intellectual property)
- Raising the funding needed to characterize the market, evaluate technologies, support the most promising technologies, conduct key development activities, license intellectual property and/or rights to products, distribute products to key targets, and raise public awareness and support
- Identifying key stakeholders, collaborators, and partners, such as universities with promising science, leaders in animal welfare sectors, outsourcers of the activities required to develop, distribute and/or market products, and pharmaceutical companies

Generating Enthusiasm, Confidence, and Funding. How have nonprofits with drug-development missions generated enthusiasm and confidence on the part of stakeholder groups and funders? They have:⁴

- Developed a business plan that includes clear statement of mission, objectives and related strategies and tactics (action plans), timelines, benchmarks at key stages, and risk/benefit analysis. In the case of a nonprofit related to veterinary drugs, the gaps in the veterinary drug development and delivery process as it exists today would be defined, along with the ways in which the nonprofit will address the gap. Typically, the business plan will include a financial plan that (1) characterizes the potential outcomes of investing in the nonprofit, (2) provides a menu of options for investing, and (3) describes a system to measure the return on investment – that is, the outcomes at key stages of a given development and/or commercialization project. Of course, this means each stage has predefined outcome objectives.
- Continued to build a network of key stakeholders in multiple disciplines to streamline the development and commercialization process. Note that the disciplines may not have been related previously, other than having a common interest in some aspect of nonsurgical fertility control, so it will be important to ensure that each type of stakeholder understands the importance of what the other stakeholders bring to the table. This entails a number of activities, including but not limited to:
 - Identifying key stakeholders and relating their objectives to those of the nonprofit to create a shared sense of purpose, accountability, and potential (i.e., creating a “win-win” situation for each key stakeholder and the nonprofit)
 - Ensuring rigorous evaluation of development and/or commercialization candidates and the status of intellectual property that may be involved
 - Developing a consistent method for reporting, publishing, and disseminating research results
- Kept a balance. While it seems trite to say that partnership strategy depends on reconciling what partners are most desirable and what partners are most available,

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the nonprofit's overall structure, mission, priorities, funding and specific products and/or development candidates at any given time will dictate, at least in part, who the partners will be as well as the nature of a given partnership.

Ongoing Challenges

Challenges (or, as big corporations call them, “opportunities”) a nonprofit can be expected to encounter as it evolves include, but are not limited to:

- Maintaining the flexibility to revise strategy and direction within the overall context of the organization.
- Identifying and courting funders; focusing on funders most likely to be amenable to “social philanthropy” (i.e., traditional venture capital unlikely).
- Managing key stakeholder, collaborator, and partner relationships.
- Reducing perceived “threats” to key stakeholders (e.g., potential of streamlining to reduce the importance and/or value of a given stakeholder's activities).
- Coming up with ways to increase the productivity of key stakeholders engaged in activities that will benefit the nonprofit – letting them do what they do best (e.g., it is estimated that researchers spend between 33% and 50% of their time seeking funding). This could include incorporating emerging entrepreneurial research models.
- Collecting, synthesizing, and disseminating information that ACC&D and its stakeholders need in order to support the organization's mission and objectives. This is among the activities that could be “outsourced” to an appropriate stakeholder.

ACC&D has been working with key stakeholders to generate a model of nonprofit drug development and commercialization that should be capable of meeting the need for nonsurgical fertility control in cats and dogs. The nonprofit experience in human health is demonstrating that this concept is feasible.

¹ *Investing in Innovation: Accelerating Disease Research Through Philanthropy and Business*, 2005, p. 32.

² *Ibid*, p. 41.

³ “Commercialization” refers to the act of developing something for public or private sector use. Generally it is assumed that this activity is undertaken for a monetary profit, but in this context “profit” can also refer to accomplishing an objective (e.g., cure for juvenile diabetes, alleviating disease in underdeveloped areas, bringing products for fertility control in cats and dogs to market).

⁴ Thanks to FasterCures for its November-December 2005 meeting report, *Investing in Innovation: Accelerating Disease Research Through Philanthropy and Business*, in which some of the ideas presented here were discussed in the human health context.

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Nonprofit Models from Human Health and their Potential Applicability to Contraception in Cats and Dogs

Katherine Moldave
Alchera Bio
Third ACC&D Symposium
Alexandria, Virginia
November 2006

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Ongoing Issues Facing the Pet Population Control Community

- Are there viable permanent and/or long-term ways to control fertility in cats and dogs by methods other than surgical intervention?
- How can we turn those technologies into products that are available to the pet population control community?

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Historical Barriers

- Large animal health companies have not been as active in this area as in other areas of companion animal health
- Researchers have not necessarily received the level of funding needed to support development activities
- Funders have not necessarily had a clear context in which to distribute grants and/or contributions

How, then, can the need for permanent or long-term solutions be addressed?

ACC&D Breckenridge 2004

- Introduction of the concept of nonprofit organizations bringing pharmaceutical products to market
 - Population Council
 - A nonprofit organization that has successfully developed and achieved regulatory approval for human contraceptives since its inception in the 1950s

Proof of Concept

The success of the Population Council and subsequent nonprofits devoted to addressing underserved needs in human health demonstrate that a nonprofit entity can move research from the lab through various stages of the drug development process.

Types of Human Health Nonprofits

- Nonprofit creates infrastructure and develops products – “do it yourself”
- Nonprofit partners with public entities, private entities and/or venture philanthropists – “fund and oversee”
- Nonprofit encourages development by profit-making enterprise by agreeing to purchase a predetermined amount of the product – “guarantee a market”

Example: OneWorld Health

- Self-described “nonprofit pharmaceutical company”
- Founded in 1998
- Objective: Uncover, research, and develop new medicines for neglected infectious diseases
- Created an infrastructure to develop products

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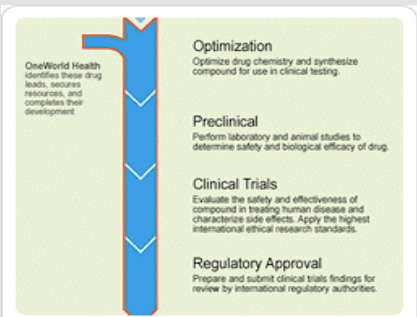
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OneWorld Health: Strategy

- Identify the most promising drug and vaccine candidates
- Develop them into safe, effective and affordable medicines
- Partner with companies, nonprofit hospitals and organizations in the developing world to conduct medical research on new cures, and manufacture and distribute newly approved therapies



A Nonprofit Model for Drug Development
Many promising drug candidates are discarded for lack of a viable market. OneWorld Health embraces the opportunity and responsibility of bringing these new medicines to light.

[Click here to view the OneWorld Health Drug Development Process](#)

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OneWorld Health: Results

- Indian government approved first OWH drug, Paromomycin IM Injection, to cure visceral leishmaniasis, August 2006
 - Collaboration among OneWorld Health, Gland Pharma Limited, the International Dispensary Association (IDA), IDA Solutions, the World Health Organization's Special Programme for Research and Training in Tropical Diseases (WHO/TDR) and the Government of India
 - "Approval of this drug represents a critically important milestone for OneWorld Health. It proves that a nonprofit pharmaceutical company can successfully develop, and be granted approval of, an important new medicine."

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OneWorld Health: Results

- Three other products in the current pipeline
- Collaborations with WHO and NIH
- Alliances with biotech (e.g., Celera and Amyris Biotechnologies)
- Funding sources include Gates and Chiron foundations
- Received innovation award from *The Economist*

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Example: Cure Autism Now

- Founded at a kitchen table in 1995
- Objective: Fund essential innovative research directed at identifying the causes of autism and preventing, treating and curing autism and related disorders
 - 90% of funds are allocated to research

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Cure Autism Now: Strategy

- Fund research from basic research to clinical applications
- Five types of grants
 - Young Investigator Awards
 - encourage young scientists to enter the field
 - Pilot Research Awards
 - target innovative approaches and technologies
 - Treatment-Related Awards
 - encourage development of therapies that range from intervention strategies to clinical trials
 - Innovative Technology for Autism Grants/ITA Initiative
 - encourage development of products that provide “real world” improvements to the daily lives of people with autism
 - merge technology, design, engineering, social science and neuroscience
 - Innovative Technology Bridge Grants
 - support projects lacking traditional funding due to project timeline, area of investigation, or the nature of the need

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Cure Autism Now: Results

- Tripled the number of scientists
- Established first collaborative gene bank
 - Autism Genetic Resource Exchange (AGRE), a biomaterials bank with a large collection of cell lines and DNA samples from families with more than one child with autism
 - Samples and the accompanying clinical data are available to the entire scientific community

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Cure Autism Now: Results

- Biomarker identification initiative
 - Metabolic profiling using lipid and urine analyses
 - Early physiologic markers such as motor function
- Driver of increase in autism-related NIH spending on autism from \$5m in 1995 to >\$30m in 2006
- >30 initiatives funded at least in part by CAN in 2006

Example: Cystic Fibrosis Foundation

- Founded 1955
- Objective: to continue to develop therapies that will extend and enhance the lives of those with cystic fibrosis and ultimately to find a cure or control for CF

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Cystic Fibrosis Foundation: Strategy

- Primary catalyst and sponsor of critical research
- An innovative business approach to drug discovery and development
 - Virtually every approved cystic fibrosis drug therapy available today was made possible because of the Foundation and its supporters
 - Since the 1980s, the Foundation has played an integral role in the development and FDA approval of four therapies used for cystic fibrosis: Pulmozyme®, TOBI®, azithromycin and hypertonic saline
 - Collaborators include CominatoRx, Predix Pharmaceuticals, Vertex Pharmaceuticals

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Cystic Fibrosis Foundation: Results

- In 1989, CF Foundation-supported scientists discovered the cystic fibrosis gene
- More than 25 potential new therapies are in the CFF-supported drug discovery and development pipeline
- Foundation funds and accredits more than 115 cystic fibrosis care centers nationwide
 - Also serve as clinical study sites
- Cystic Fibrosis Services Pharmacy (a wholly owned subsidiary of the Foundation) provides easy access to specialized cystic fibrosis medications, helps families with insurance reimbursement process and refers families to social services organizations that can help obtain medicines

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Example: British Government

- Pledge to purchase malaria and HIV/AIDS vaccines for developing countries
 - “Rewards” developers for creating the desired product (aka “pull” program)
 - No payments until a successful product is developed
 - Provides developers with strong incentives to “self-select” projects that have the best chance of success
 - Helps ensure that if products are developed, they will reach those who need them
 - More info: *Strong Medicine*, Kremer and Glennerster, Princeton University Press, 2004

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What Is the Common Thread?

- *Inspiration and Creativity in Response to Unmet Needs*
 - Turning frustration into motivation

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“ . . . the NNRI has the ability to form joint ventures and partnerships with companies . . . Even if a particular company is not interested in developing a promising compound, the NNRI may be able to license and develop the drug independently. Conversely, companies wishing to develop drugs on their own may still benefit from NNRI or FFB resources . . .”

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Lesson:
Convert Inspiration and Creativity into a Credible Organization

- ***Set the context***
 - Define the mission clearly
 - Identify a technology or product to develop, codevelop, acquire, license, and/or commercialize
 - Identify key stakeholders, collaborators, and partners

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- ***Generate Enthusiasm, Confidence, and Funding***
 - Develop, implement, and adjust a business plan
 - Continue to build a network of key stakeholders in relevant disciplines
 - Monitor progress against predefined benchmarks
 - Identify and court funders
 - Focus on funders most likely to be amenable to “social philanthropy” (i.e., traditional venture capital unlikely)
 - Don’t be shy

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Lesson:
Anticipate and Meet Ongoing Challenges

- Maintain the flexibility to revise strategy and direction within the overall context of the organization
- Manage key stakeholder, collaborator, and partner relationships

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- Reduce perceived “threats” to key stakeholders
- Increase the productivity of key stakeholders engaged in activities that will benefit the organization

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- Collect, synthesize, and disseminate information that the organization and its stakeholders need in order to support the organization's mission and objectives
- Keep a balance

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Possible Applications of These Models to a Pet Overpopulation Nonprofit

- Do It Yourself
 - Identify, assess the potential of, and develop long-term or permanent nonsurgical approach/es to cat and dog contraception
 - Partner for manufacturing and distribution
 - Serve as a clearinghouse to evaluate the impact of nonsurgical approaches to pet population

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Possible Applications of These Models to a Pet Overpopulation Nonprofit

- Raise funds and oversee
 - Assess the potential of technologies
 - Fund and oversee development by one or more companies of long-term or permanent nonsurgical approach/es to cat and dog contraception
 - Share the revenue of marketed drugs for the purpose of providing the product to the low-cost/high-volume, and shelter communities
 - Collect and monitor data re: how use of the product affects population dynamics

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Possible Applications of These Models to a Pet Overpopulation Nonprofit

- “Guarantee” a market
 - Solicit and manage funding to be used to purchase a prespecified number of doses of an approved permanent/long-term pet population control product with predefined characteristics at a prespecified price/dose
- Hybrid

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June 2005

- ACC&D retreat
 - Small group charged with discussing the potential of ACC&D to become a nonprofit organization charged with advancing the development, approval, and commercialization of long-term and/or permanent nonsurgical fertility control products for cats and dogs

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**What Does All This Mean
to Today's ACC&D?**

Joyce Briggs will tell us now!

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