

MINUTES OF THE HOUSE COMMITTEE ON ECONOMIC DEVELOPMENT.

The meeting was called to order by Chairperson Barbara P. Allen at 3:30 p.m. on January 24, 1996 in Room 423-S of the Capitol.

All members were present except: Rep. King - excused
Rep. Toplikar - excused

Committee staff present: Lynne Holt, Legislative Research Department
Bob Nugent, Revisor of Statutes
Nancy Kirkwood, Committee Secretary

Conferees appearing before the committee: Valentino J. Stella, Professor of Pharmaceutical Chemistry, Kansas University; Director, Center for Drug Delivery Research
Tim Newell, Deputy Director for Policy of the Office of Science and Technology Policy at the White House

Others attending: See attached list

Valentino Stella, Director, Center for Drug Delivery Research, has developed twelve patents accredited to him. He informed the committee of one patent he is working on known as *Cyclodextrins*. Mr. Stella stated how the support of KTEC has afforded Kansas University and him success. His relationship with KTEC is to create jobs in Kansas, as well as economic return for Kansas (Attachment 1).

Tim Newell, Deputy Director for Policy of the Office of Science & Technology Policy at the White House, briefed the committee about Science and Technology from a Federal perspective. He pointed out that state and federal government share the common goals of generating economic growth and jobs, and finding ways to protect the environment at a lower cost than before (Attachment 2).

The meeting adjourned 4:45 p.m.

The next meeting is scheduled for January 25, 1996.

A Presentation to the

Senate Commerce Committee

and the

House Economic Development Committee

By

Valentino J. Stella
Director

Center for Drug Delivery Research

*A Member Center of the
Higuchi Biosciences Center*

**A Kansas Technology Enterprise Corporation
Center of Excellence**

January 24, 1996

*Economic Development
January 24, 1996
Attachment 1*

Center for Drug Delivery Research (CDDR)

CDDR MISSION STATEMENT

The mission of The Center for Drug Delivery Research is to:

- **Conduct drug delivery research to develop life enhancing and life saving pharmaceutical products.**
- **Commercialize these products in ways that guarantee an economic return to Kansas.**
- **Provide training and appropriate technology assistance to Kansas companies.**

Center for Drug Delivery Research (CDDR)

CENTER FOR DRUG DELIVERY RESEARCH

**Core Faculty
Advisory
Board**

CDDR Director
Valentino J. Stella

**Industry
Advisory Board**

Assistant Director
Roger A. Rajewski
(Science/operations
mgm., tech. transfer)

Program Manager
Kathy E. Porsch
(Operations mgm.,
tech. transfer)

Product Development Laboratory
Director, David G. Kosednar

Focus Areas

Prodrugs

1. Water Soluble Prodrugs of Hindered Alcohols and Phenol Containing Drugs

Special Projects:

1. Development of New Antioxidants for Protein Formulations
2. Synthesis and Preliminary Evaluation of Novel Prodrug Technologies

Novel Excipients

1. Preparation of New Cyclodextrin Based Excipients with Enhanced Binding Capability
2. Application of Sulfobutylether Derivatives of Cyclodextrins as Osmotic and Solubilizing Agents in Novel Osmotic Pump Tablets

Pharmaceutical Technologies

1. Production of Submicron Drug Particles and Particle Coating Using Supercritical Antisolvents
2. Novel Production of Pharmaceutical Drug Products by Lyophobic Precipitation Using Near- and Supercritical Fluids

Center for Drug Delivery Research (CDDR)

BASIC UNIVERSITY RESEARCH

CDDR - KTEC CORE PROJECTS
(Applied Research)

\$
Royalty
and
other
income
flows
back to
renew
the
cycle

\$ Industrial
Partners

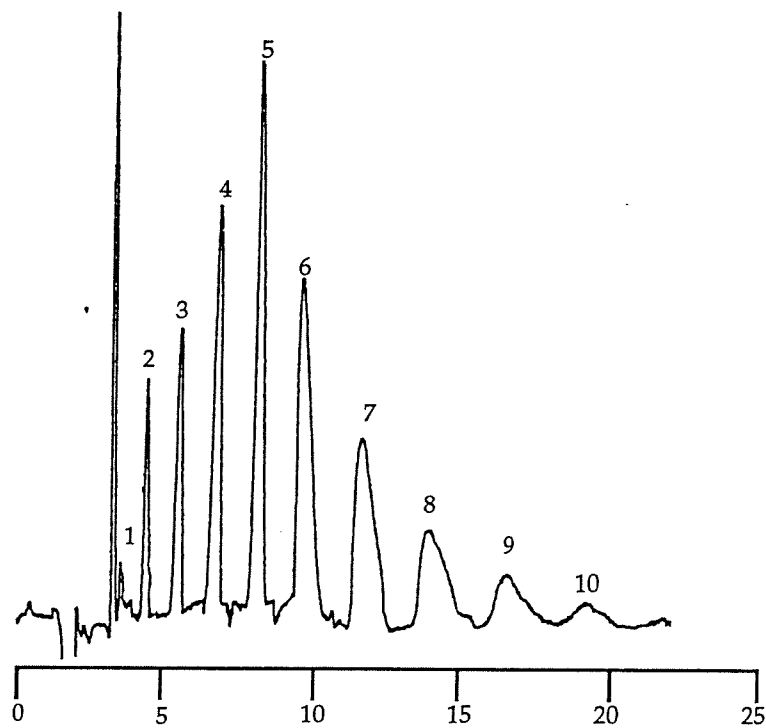
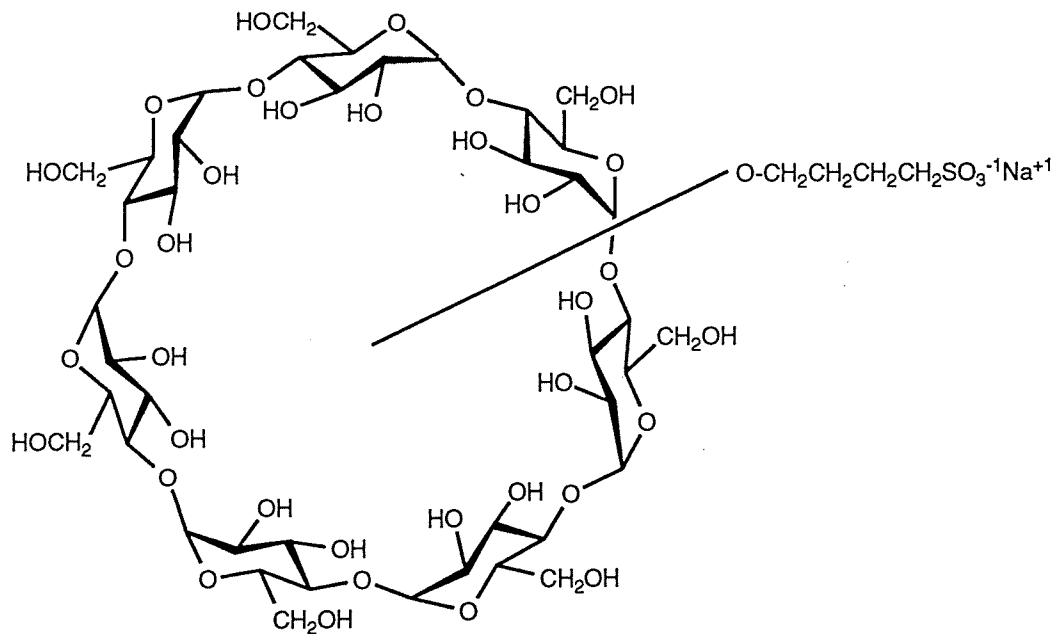
\$ Industrial
Partners

INVESTMENT
GRADE
TECHNOLOGY

COMMERCIAL
PRODUCTS

JOBS for
KANSAS

Center for Drug Delivery Research



Higuchi Seminar March 1993

Center for Drug Delivery Research (CDDR)

BASIC UNIVERSITY RESEARCH

Cyclodextrins

CDDR - KTEC CORE PROJECTS
(Applied Research)

Cyclodextrins

Pfizer, Inc.;
CyDex, L.C.

INVESTMENT
GRADE
TECHNOLOGY

Cyclodextrins

COMMERCIAL
PRODUCTS

Cyclodextrins

Center for Drug Delivery Research (CDDR)

Cyclodextrin Development Options

KU/HBC

KU Technology Transfer Office

Research Corporation

Kansas Company

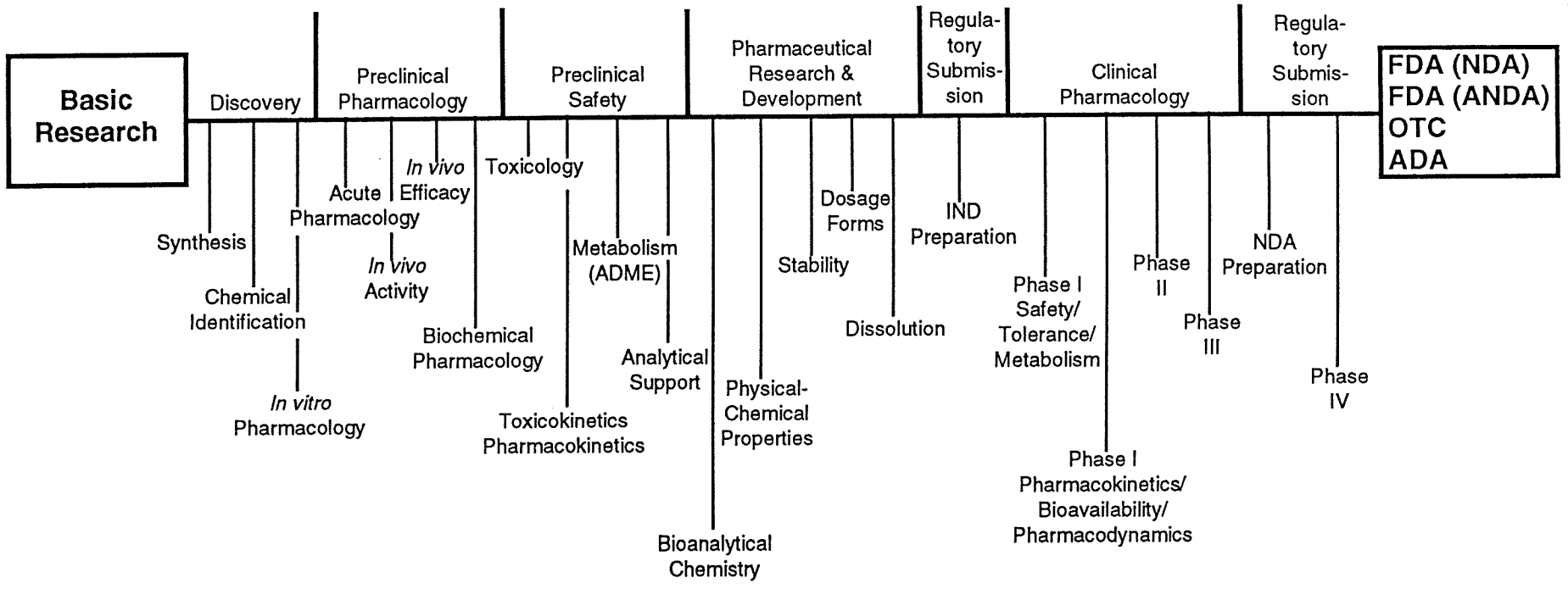
Kansas Alliance Company

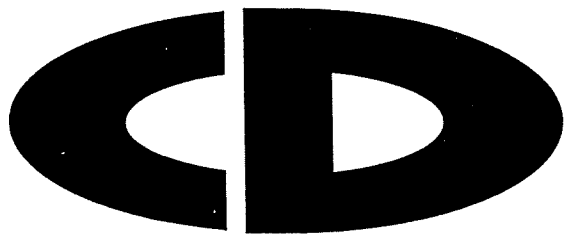
Center for Drug Delivery Research (CDDR)

OPTION	PROS	CONS
KU/HBC	100% Ownership Product champion Licensing	Personnel Product champion Product applications? Cost Expertise Kansas economic dev.?
KU Technology Transfer Office	100% Ownership Product champion Licensing	Timing to create/establish Product champion Product applications? Cost Personnel Expertise Kansas economic dev.?
Research Corporation	Easy to administer Experienced licensing	Loss of ownership 57% to Research Corp. Correct experience? Pharm. product dev.? Kansas economic dev. - No control
Kansas Company	>% Return to KU Equity for KU? Licensing & products? Kansas economic dev.	<% Return to KU Timing to create/establish offsets split to company Cost-product dev. Personnel Expertise
Kansas Alliance Company	Easy to administer Expertise >% Return than PC Equity for KU?	May have to give up some ownership <% Return than PC

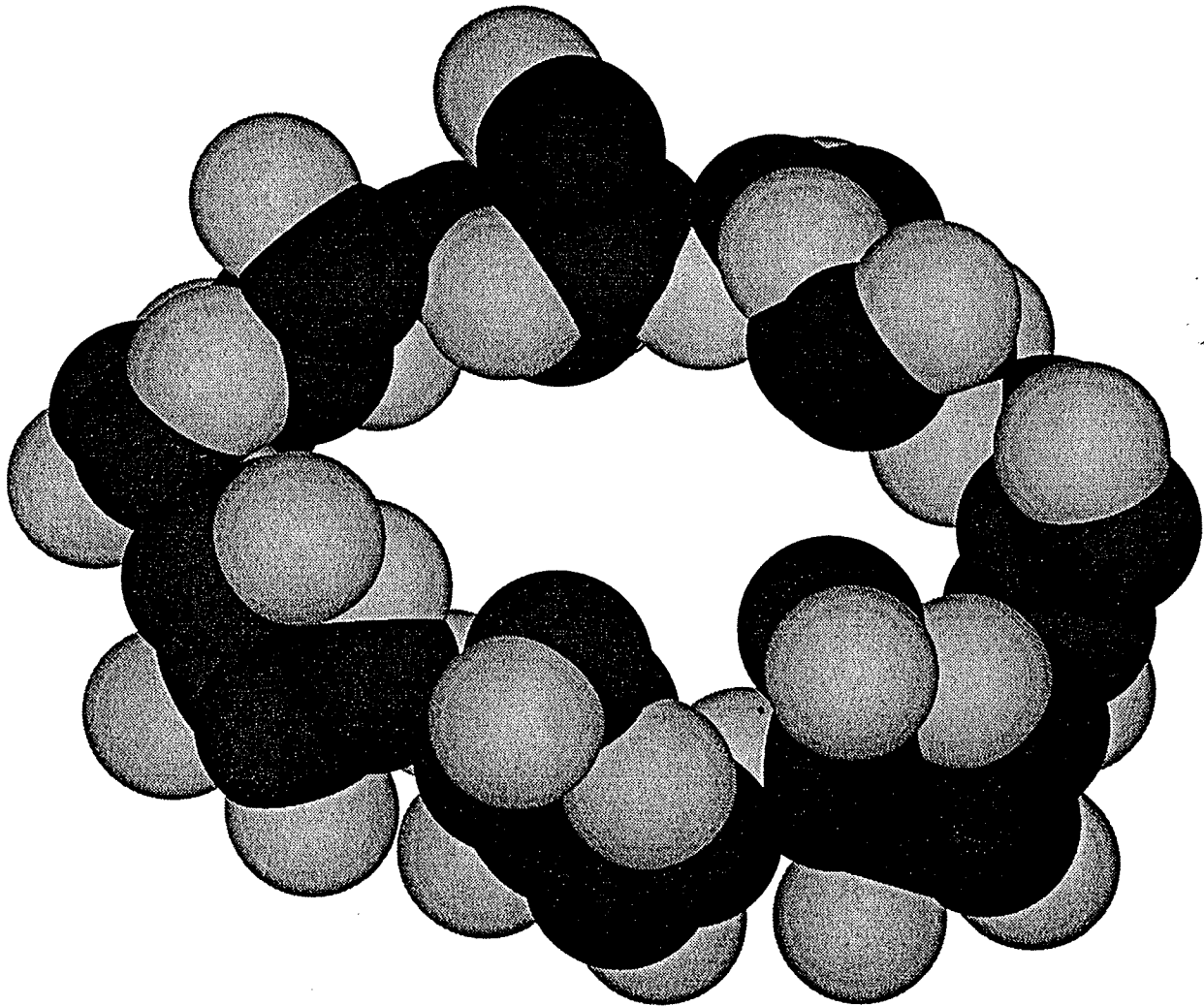
Center for Drug Delivery Research (CDDR)

Pharmaceutical Development





CyDex, L.C.



SBE Cyclodextrins

Delivering
Solution
Opportunities

KU/CyDex Historical Background

- US Patent issued to KU claiming its sulfobutylether β -cyclodextrin technology (“SBE-CD”) in July 1992
- CyDex established August 1993
- KU License agreement signed September 1993
- KU/Pfizer agreement signed December 1993 and immediately assigned to CyDex
- CyDex awarded the Silicon Prairie Technology Association’s 1994 Technology of the Year in Bioscience

CyDex Current Status

- Preclinical and clinical studies completed
- Manufacturing process scale up
- Regulatory submissions for two SBE-CD formulated products in 1995
- Perkin Elmer marketing SBE-CD as a chiral reagent for capillary electrophoresis
- SBE technology currently under evaluation in over 75 pharmaceutical companies

Biography for
Timothy Newell

Timothy Newell is the Deputy Director for Policy of the Office of Science & Technology Policy at the White House. He reports directly to Dr. John Gibbons the President's Science Advisor and is responsible for coordinating the development and implementation of Science and Technology within OSTP. He acts as the liaison between the White House and Congress on Science and Technology policy as well as overseeing Federal and State relations in Science and Technology Policy. In March 1993, he joined the White House with the Clinton administration.

Prior to joining the White House Staff, he served as the staff and legislative director for U.S. Representative Norman Mineta. While with Representative Mineta, he specialized in technology, trade, economic policy, and national security.

He is a member of the Science Space and Technology Committee of the US House of Representatives where he represents the Silicon Valley area of California. His private sector background includes strategic planning for U.S. high technology industries as an associate of Cambridge Research Institute in Cambridge, Mass.

*Economic Development
January 24
Attachment 2*