

Approved: January 25, 1996  
date

MINUTES OF THE SENATE COMMITTEE ON COMMERCE.

The meeting was called to order by Chairperson Alicia Salisbury at 8:00 a.m. on January 24, , 1996 in Room 123-S of the Capitol.

Members present: Senators Salisbury, Burke, Downey, Feleciano, Gooch, Harris, Jordan, Petty, Reynolds, Steffes and Vidricksen.

Committee staff present: Lynne Holt, Legislative Research Department  
Jerry Donaldson, Legislative Research Department  
Bob Nugent, Revisor of Statutes  
Betty Bomar, Committee Secretary

Conferees appearing before the committee:  
Rich Bendis, President, KTEC  
Val J. Stella, Director, Center for Drug Delivery Research, Overland Park  
Timothy Newell, Office of Science & Technology Policy, Washington, D.C.

Others attending: See attached list

The Chair informed the Committee she was referring **SB 501 - concerning municipalities; relating to tax increment financing** to the TIF Subcommittee chaired by Senator Ranson for consideration and recommendations to the full committee.

Dr. Val J. Stella, Professor of Pharmaceutical Chemistry, University of Kansas Medical School, Director for Drug Research, Higuchi Biosciences Center, and Director, Center for Drug Delivery Research. Professor Stella told the Committee of his experience in delivering a drug product from research to a commercial product and the 15 years it has taken which has resulted in a low monetary return. Professor Stella advised the Committee that with the assistance of KTEC and its expertise in investment and commercialization of products, the prospective return of investment, both monetary and creation of jobs, is greatly enhanced. Professor Stella informed the Committee of one particular pharmaceutical product, Cyclodextrin, whose potential to the University, KTEC and the State of Kansas is at least \$100 - 200 million. Professor Stella stated that the assistance of KTEC and the expertise it offers to the science and technology fields, has assisted in creating new products, hi-tech jobs and economic development in the state. Attachment 1.

Timothy Newell, Office of Science & Technology Policy, Washington, D. C. advised in light of new realities, both domestic and international, it is vital the federal government, private industry, and the states, restructure their support of science and technology. Believing that science and technology are central to the nation's economic well-being, John Gibbons, Assistant to the President for Science and Technology, asked former governors Richard Celeste of Ohio and Dick Thornburgh of Pennsylvania in 1995 to work with the National Governors' Association, the National Conference of State Legislatures, and the Carnegie Commission on Science, Technology, and Government, and the American Society of Mechanical Engineers, to address these issues. In response to this request, Gov. Celeste and Gov. Thornburgh formed the 20-member State-Federal Technology Partnership Task Force, which included sitting governors and state legislators, academic leaders and industrial executives. Senator Dave Kerr was a member of the Task Force and Rich Bendis, was an alternate for Senator Kerr.

The Task Force recommended: 1) a joint high-level state-federal policy mechanism should be established to improve the coordinated development and implementation of science and technology policies. 2) each governor is encouraged to establish, with the help of industry, academia, and local economic development authorities, a state science and technology strategy. 3) take full advantage of the capabilities of states in ensuring that the benefits of research and development reach the market by stimulating research and technology commercialization in the private sector through coordination of state and federal public-private technology partnerships; and 4) federal-state-industry jointly undertake a national manufacturing excellence initiative, to increase small and medium-sized manufacturers' access to the technology and expertise necessary

CONTINUATION SHEET

MINUTES OF THE SENATE COMMITTEE ON COMMERCE, Room 123-S Statehouse, at 8:00 a.m.  
on January 24, 1996.

for American industry to compete internationally. A copy of *The State-Federal Technology Partnership Task Force final report* is on file in the office of Legislative Research.

Upon motion by Senator Reynolds, seconded by Senator Jordan, the Minutes of the January 23, 1996 meeting were approved.

The meeting adjourned at 9:00 a.m.

The next meeting is scheduled for January 25, 1996.

# SENATE COMMERCE COMMITTEE GUEST LIST

DATE: January 24, 1996

| NAME             | REPRESENTING |
|------------------|--------------|
| MIKE WOSCICKI    | KTEC         |
| DYO GRAYD        | KCC          |
| HARCO STONES     | ICBA         |
| Janni Rutherford | KTEC         |
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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**

*Senate Commerce Committee  
January 24, 1996*

January 24, 1996

*Attachment 1 thru 1-12*

## **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  
mgn., tech. transfer)

**Program Manager**  
Kathy E. Porsch  
(Operations mgn.,  
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

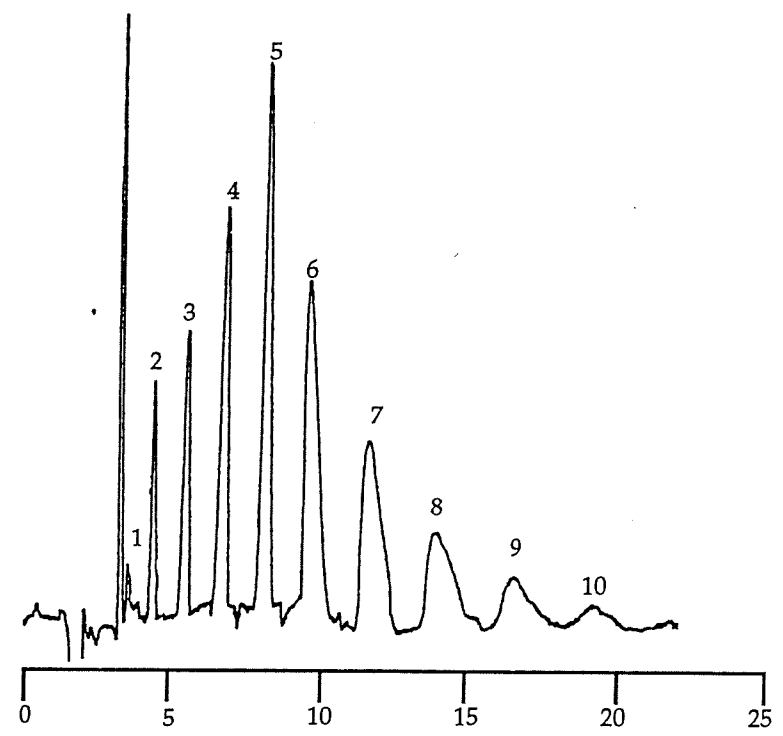
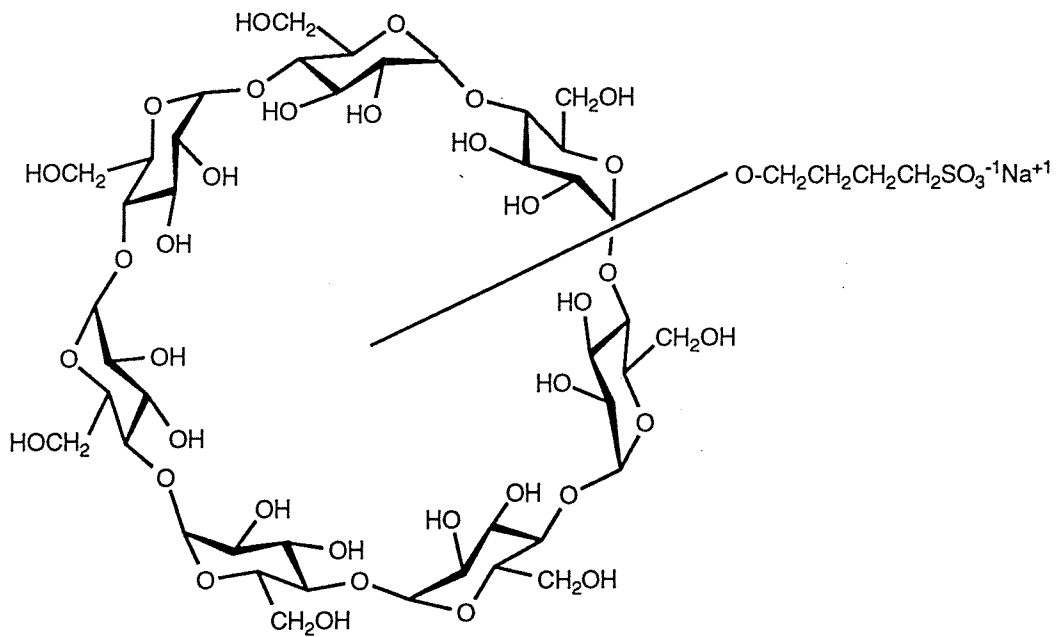
\$ Industrial  
Partners

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**

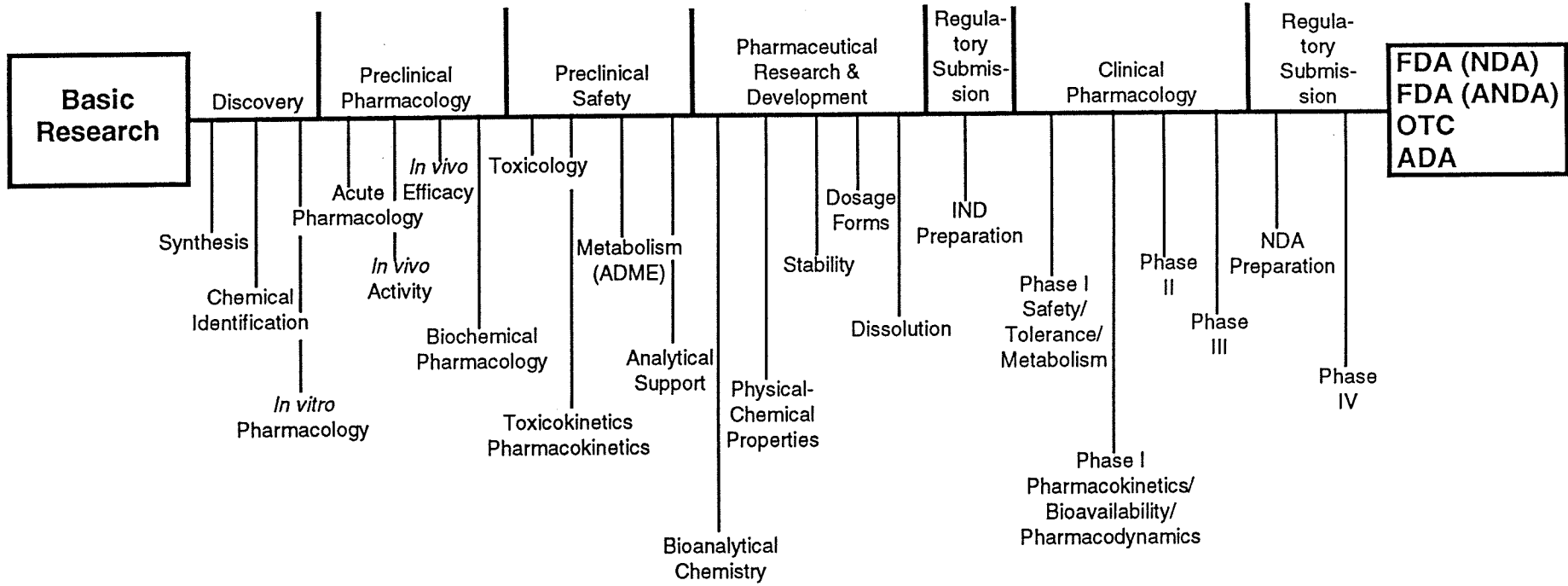
**Kansas Alliance Company**

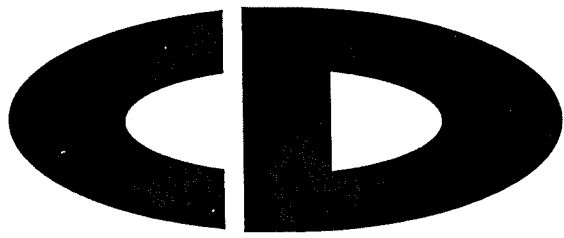
# Center for Drug Delivery Research (CDDR)

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

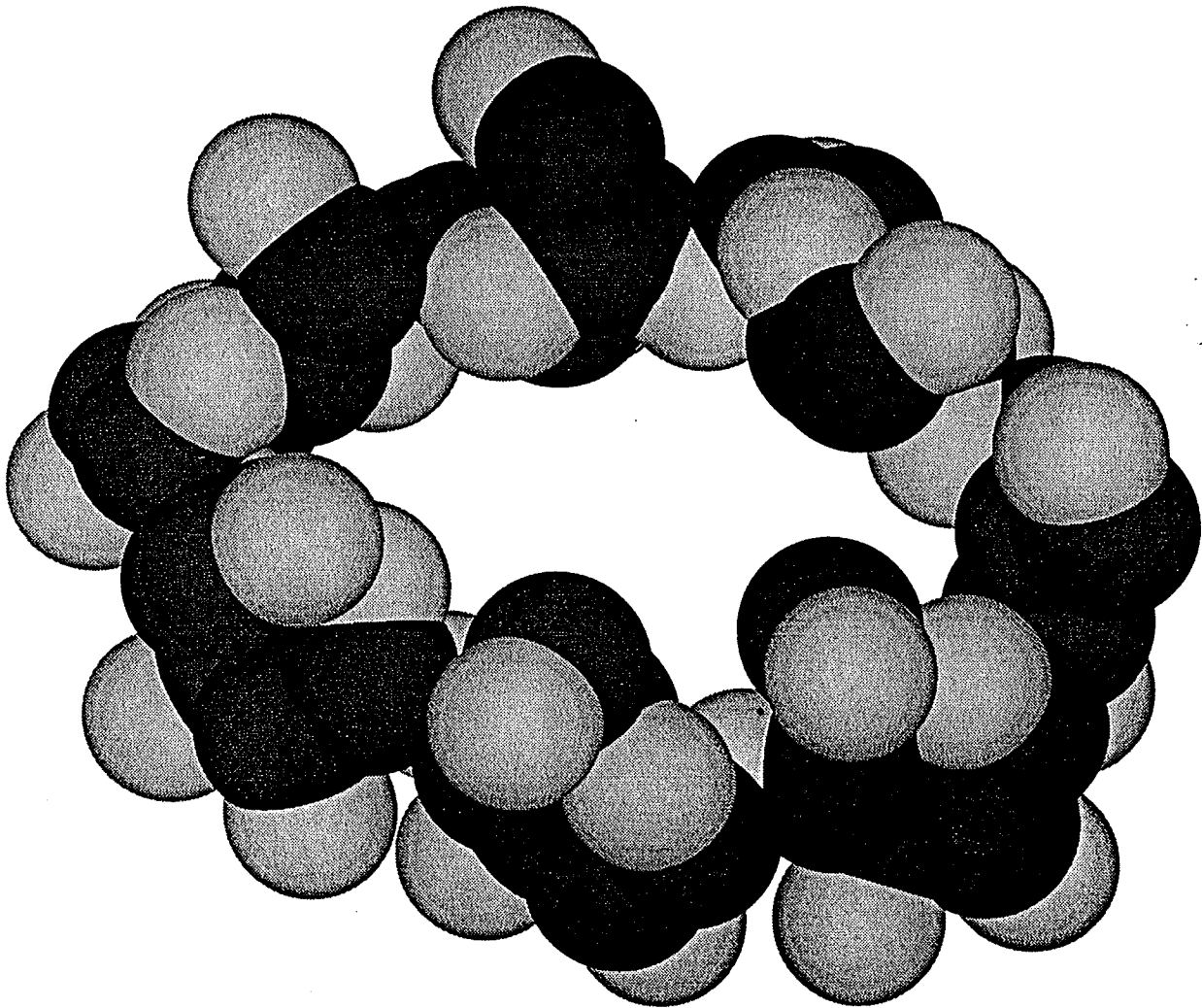
# Center for Drug Delivery Research (CDDR)

## Pharmaceutical Development





**CyDex, L.C.**



**SBE Cyclodextrins**

Delivering  
Solution  
Opportunities

# KU/CyDex Historical Background

- US Patent issued to KU claiming its sulfobutylether  $\beta$ -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