A CASE STUDY OF REGULATORY INNOVATION

Bartley J. Madden
www.LearningWhatWorks.com
www.FreeToChooseMedicine.com

HOW CAN WE LIVE LONGER, HEALTHIER, MORE PRODUCTIVE LIVES?

Answer: High-performance drugs-to-patients regulatory system (FDA in US) attuned to rapid medical advancements

- Conventional FDA purpose – safe and effective drugs
- Appropriate FDA purpose – better drugs, sooner, at lower costs
- Key Constraint – FDA clinical testing process takes a decade and costs billions

Who benefits from regulatory innovation?

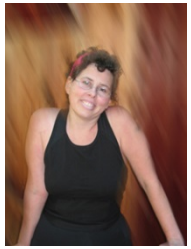
DRUGS APPROVED BUT TOO LATE FOR THESE PATIENTS











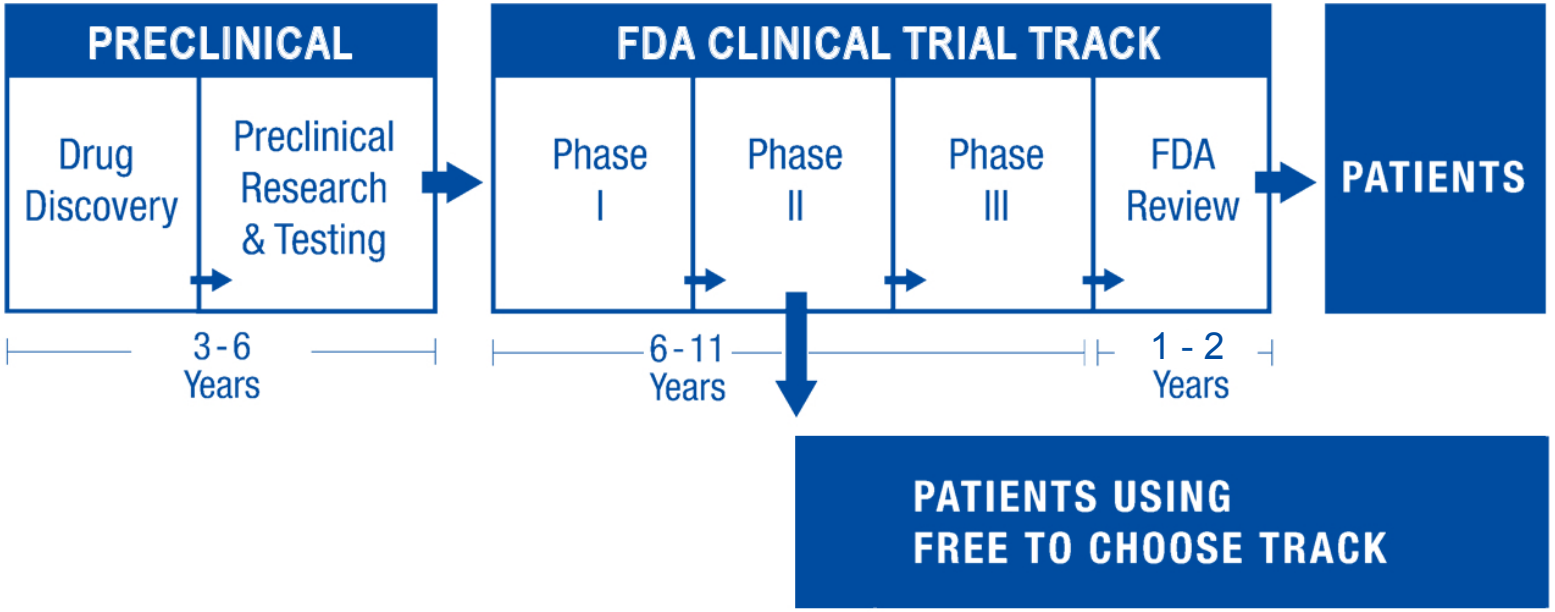
Photos provided by the Abigail Alliance for Better Access to Developmental Drugs. Abigail Burroughs (middle photo) was valedictorian of her high school class. On two occasions she was unable to access an especially promising developmental drug that specifically targeted her type of cancer and may have saved her life. **During the last 16 years, every drug that the Abigail Alliance has pushed for early access was subsequently approved by the FDA.**

MARKET-BASED SOLUTION … FUNDAMENTALLY BIPARTISAN

"Madden's market-based solution appeals to economists like me who are keenly aware of the critical importance of institutional design for a **system to promote decentralized responses close to the local knowledge that is available to physicians and their patients, but not to the FDA. This book is fundamentally bipartisan and should be read in that spirit.**"

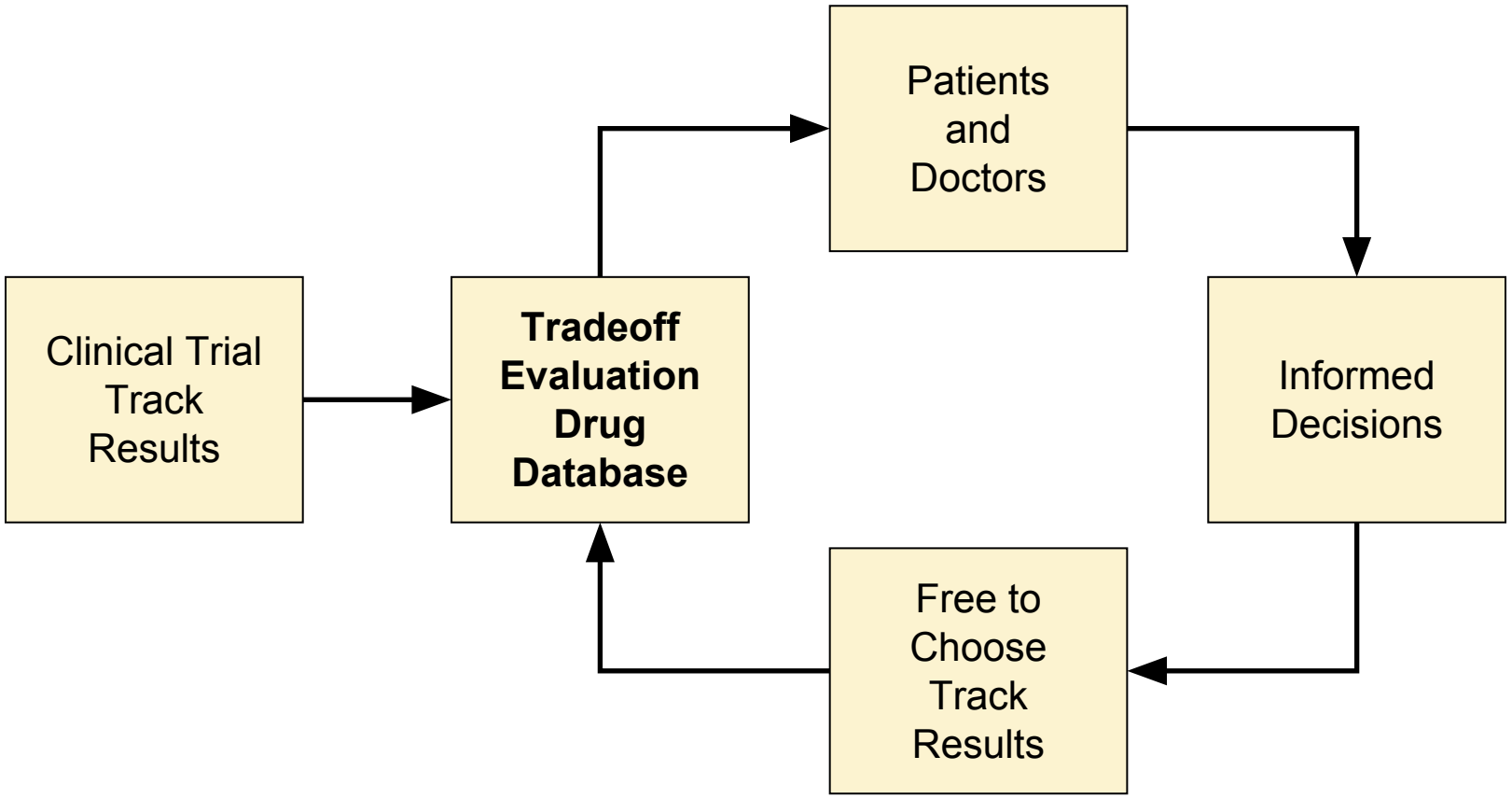
Vernon L. Smith
Chapman University
Nobel Laureate in Economics, 2002

FREE TO CHOOSE MEDICINE (FTCM)



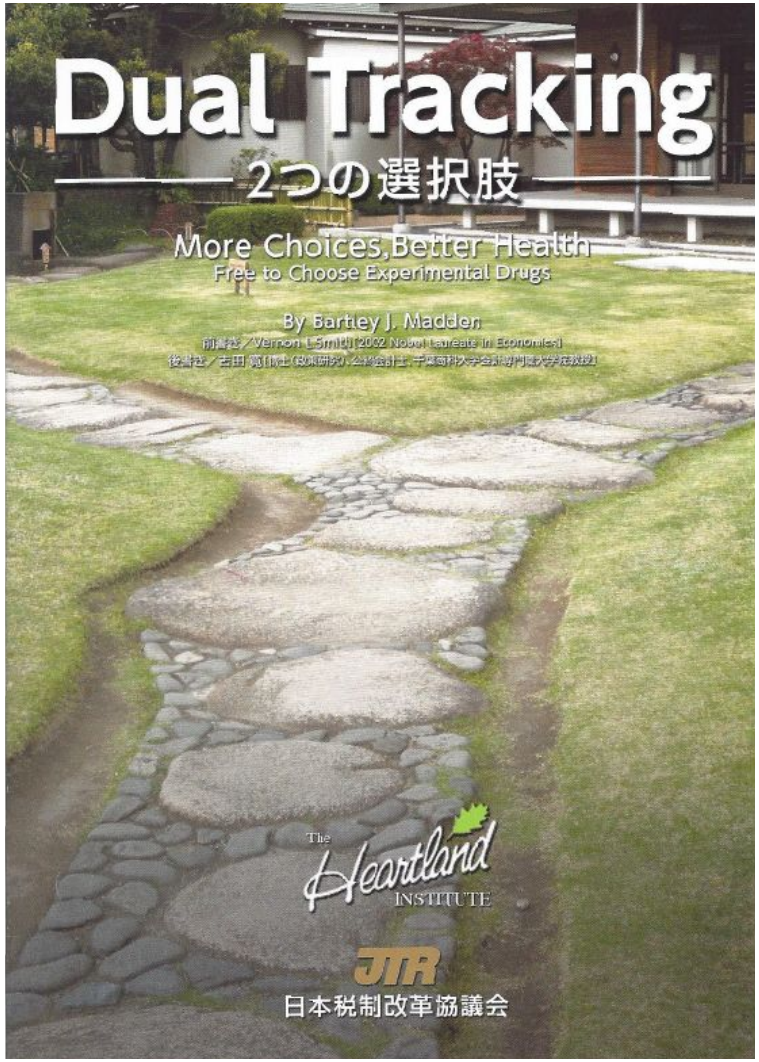
Patients, advised by their doctors, make informed decisions based on what they believe is in their best interest.

TRADEOFF EVALUATION DRUG DATABASE (TEDD)



- Evaluate Approved versus Not-Yet-Approved Drugs
- Treatment Results and Side Effects
- Patients' Genetic Data and Biomarkers
- Identification of Subsets Patients That Do Exceptionally Well or Poorly
- Self-Adjusting System
- Boost Innovation

FREE TO CHOOSE MEDICINE IN JAPAN

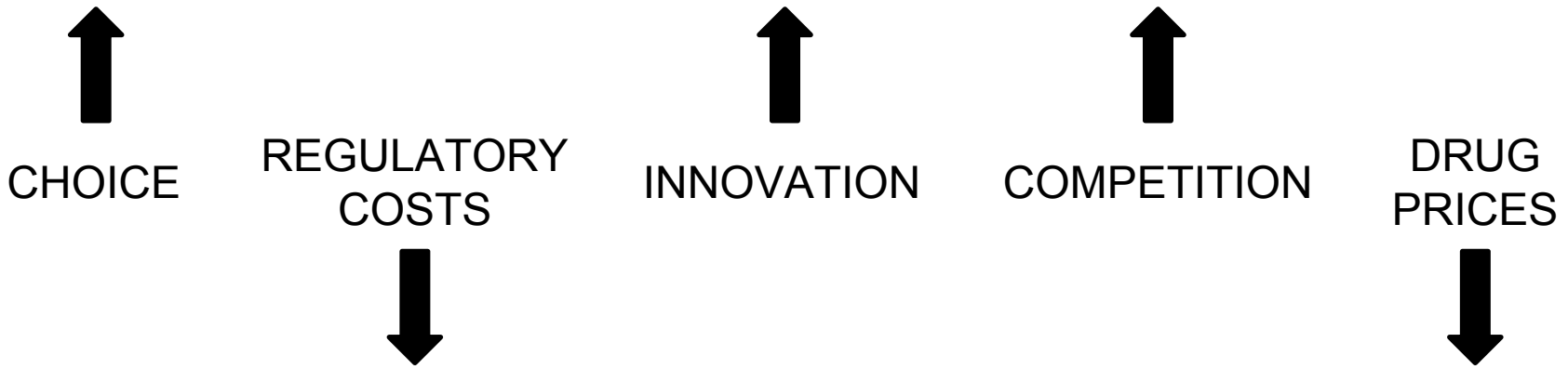


Japanese translation of an early FTCM booklet was heavily promoted to key players in Japan's biopharmaceutical industry by Masaru Uchiyama (Mr. You), President of the Japanese for Tax Reform.

He achieved consensus that FTCM is in the patients' best interest.

FTCM principles were instrumental in passage in 2014 of Japanese legislation permitting early access to regenerative medicine drugs.

SYSTEM GOAL
BETTER DRUGS, SOONER, AT LOWER COST



PROMISING PATHWAY ACT

- Introduced in U.S. Congress May 2021
- Contains all of the elements of FTCM
- Immediate benefit to patients
- Successful implementation would provide a unique, easy-to-understand demonstration of the value of freedom of choice
- Expect other countries to then duplicate the U.S. regulatory innovation