



NIH Scientific Management Review Board



NIH Intramural Research Program Working Group

Recommendations Recap

December 7, 2010

Arthur Rubenstein, M.B.B.Ch.

Executive Vice President of the University of Pennsylvania for Health System and Dean of the University of Pennsylvania School of Medicine

IRP Working Group Charge

“... to recommend whether any change in the organization and/or management of NIH intramural research could further optimize the opportunities available in a central research program at NIH and maximize human health and/or patient well being.”

IRP Working Group Membership

Non-Federal

Arthur Rubenstein, MBBCh
(Chair)

Gail Cassell, PhD

Solomon Snyder, MD

Norman Augustine
(ad hoc)

Federal

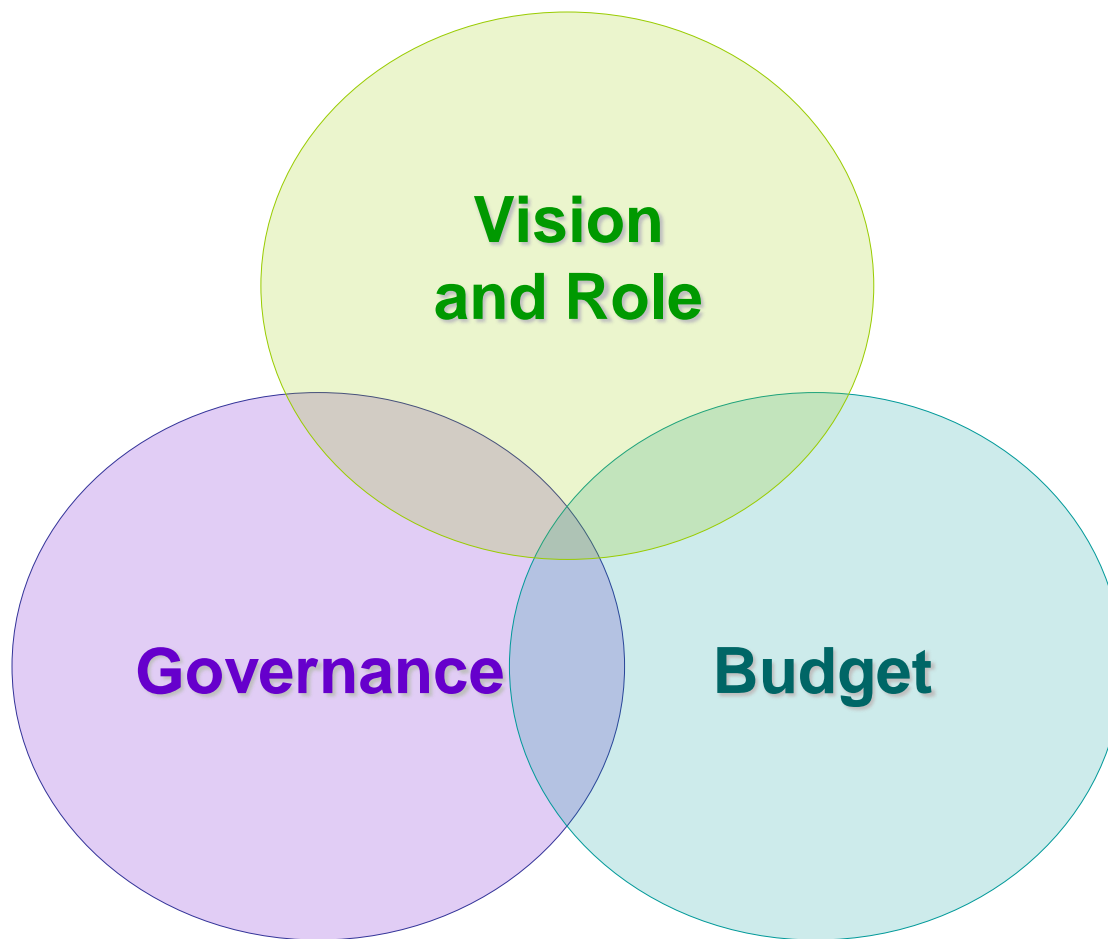
Anthony Fauci, MD

Stephen Katz, MD, PhD

Susan B. Shurin, MD

Francis Collins, MD, PhD
(ex officio)

Summary of Findings: CC Challenges



CC Challenges: Vision and Role



Vision and Role

Challenges

- **Perceived lack of prioritization of and commitment to funding clinical research at the CC**
- **Barriers to partnerships and leveraging resources (e.g., barriers to intra-/extramural collaborations, intellectual property)**
- **Barriers to recruitment, mentorship, and retention of investigators**

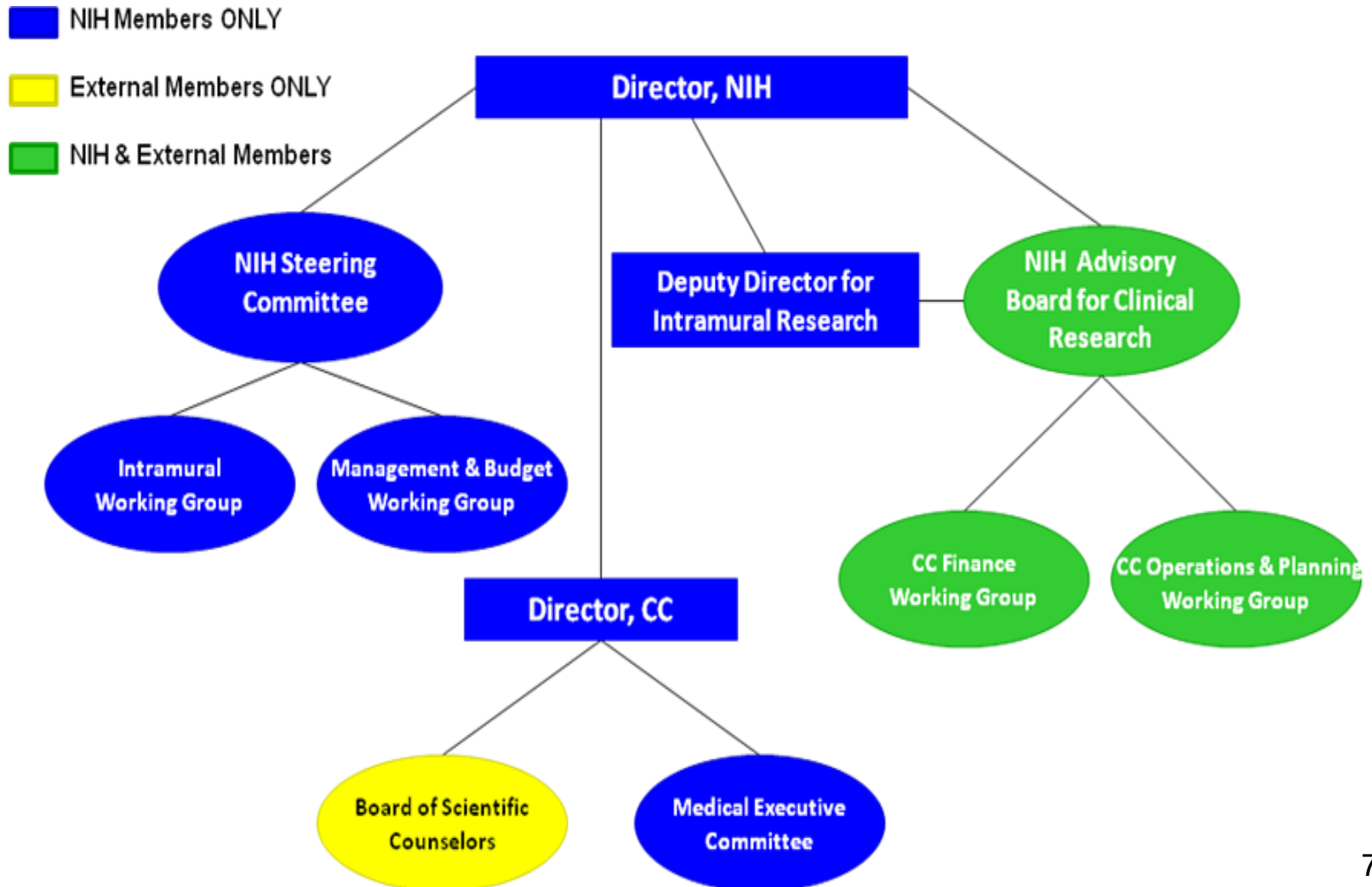
CC Challenges: Governance



Challenges

- **Lack of trans-NIH vision for priority setting in clinical research**
- **Complexity in administrative approval processes**

Governance: Current Oversight Structure



CC Challenges: Budget

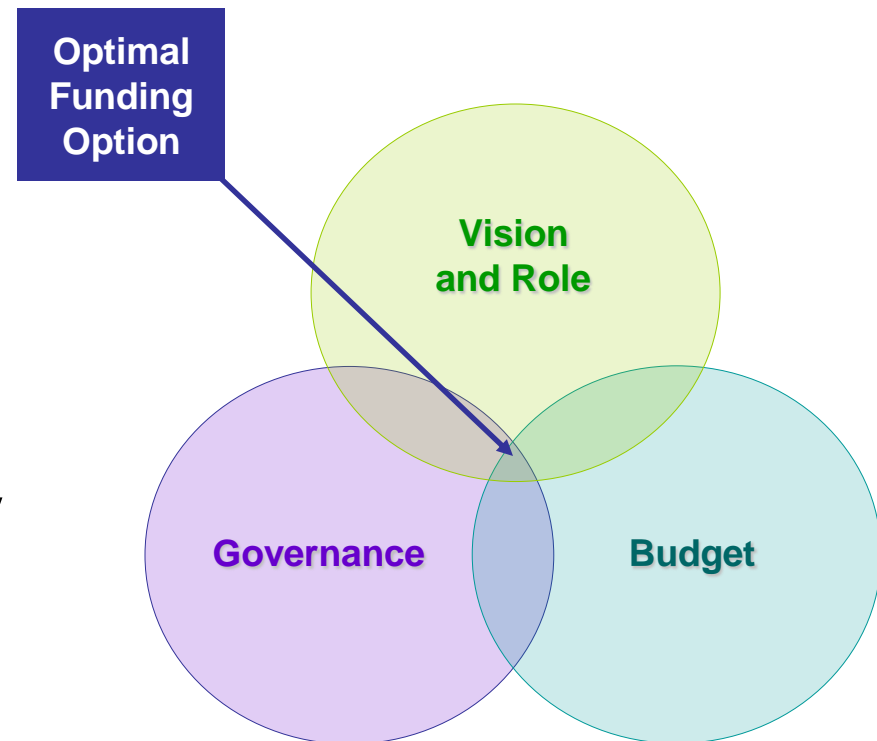


Challenges

- **Increasing costs of CC associated with healthcare inflation - current “School tax” method does not keep up with inflation**
- **Cost shifts have had unintended and undesirable consequences (e.g., significantly reduce use of CC use by ICs)**
- **Budget mechanism does not support outside investigators’ use of CC**

Overcoming CC Challenges: Attributes of Optimal Funding Option

- **Positions CC as a national resource**
- **Prioritizes clinical research at NIH**
- **Streamlines governance**
- **Ensures fiscal sustainability - stable, responsive budget**
- **Enhances programmatic planning**



RECOMMENDATIONS



Recommendation # 1



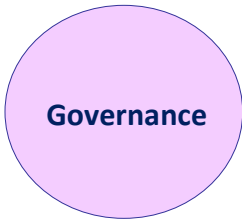
Clinical Center as a National Resource

Role of the CC should be to serve as a state-of-the-art national resource, with resources optimally managed to enable both internal and external investigator use

Examples of Potential Use by External Investigators



CATEGORY	EXAMPLE	
Patient Cohorts	Unique Populations	Undiagnosed Diseases Program
Services	Special Laboratory	Metabolic chambers
	Candidate Drug Development	GMP Facility
	Repositories	Research Blood Products
	Imaging	Positron Emission Tomography
	Clinical Trials Infrastructure	First in Human Studies
	Databases/IT Tools	Biomedical Translational Information System
Clinical Research Training	Clinical Research Training Programs	Long distance and on site training
	Fellowships	Bioethics Fellowship
	Exchange Programs	Partnerships with foundations
Bench-to-Bedside Program	Intramural/Extramural Partnerships	Intramural/extramural awards ¹²



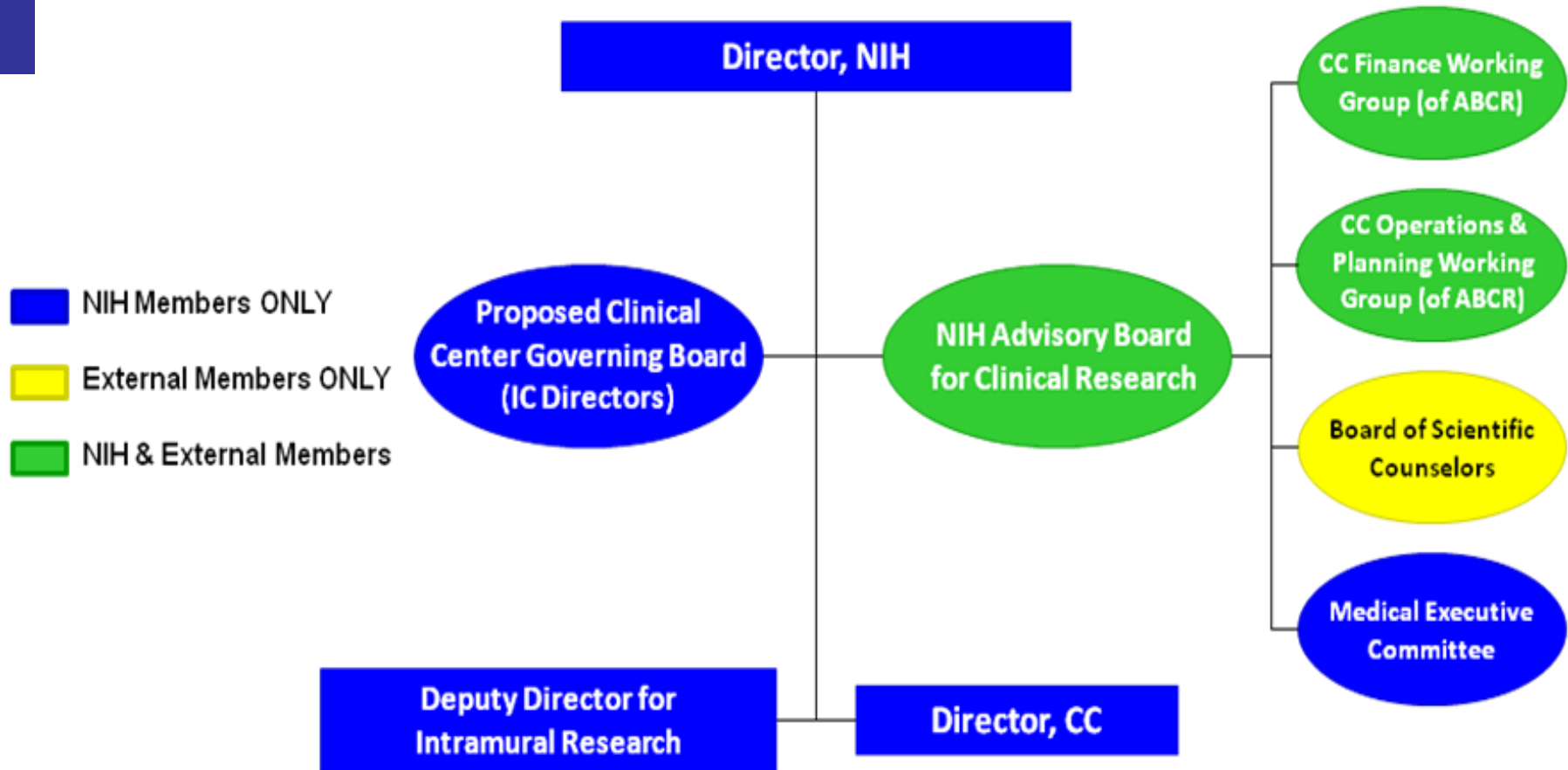
Recommendation # 2



Streamlined Governance Structure

Governance should have a simplified structure, capable of developing and overseeing a clear, coherent plan for clinical research.

Recommended Oversight Structure



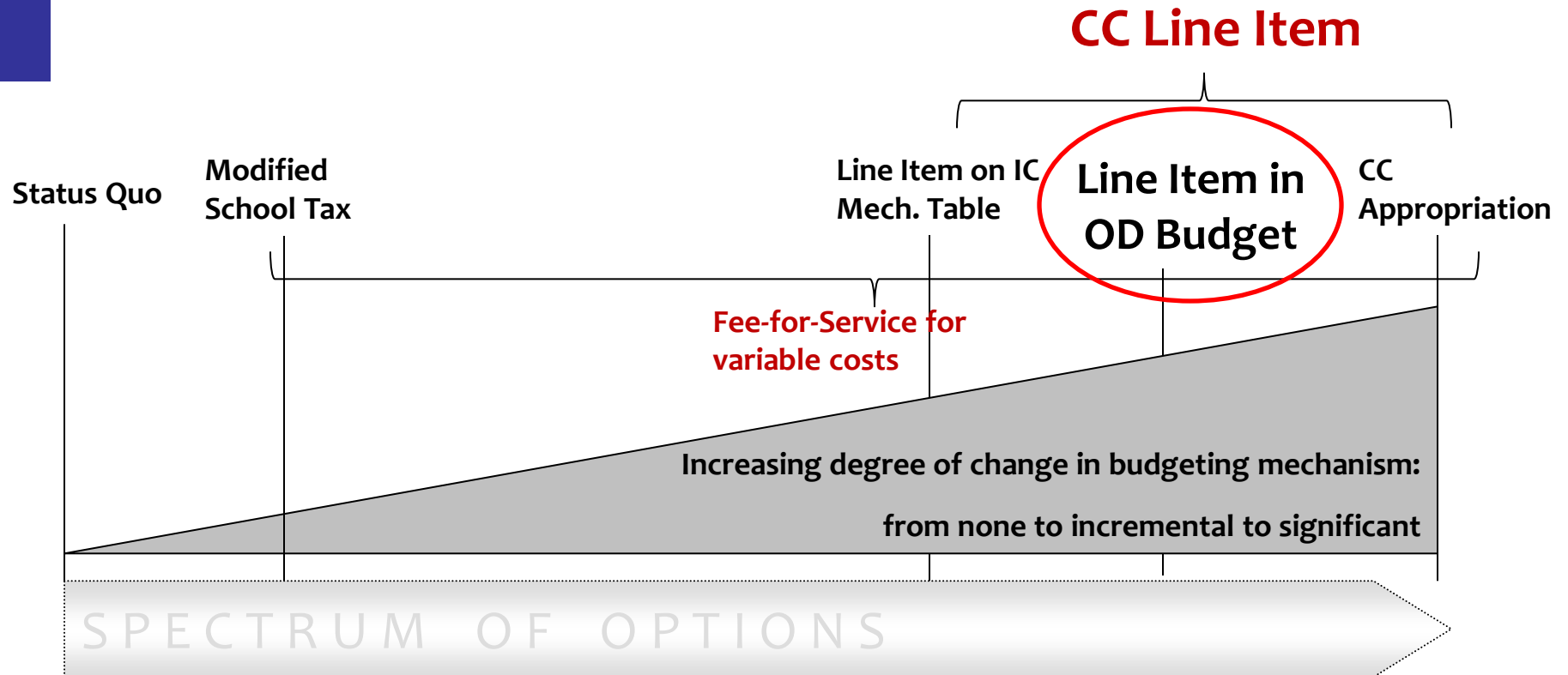
Recommendation # 3



Stable, Responsive Budget Underpinned by Priority Setting

Budget should be linked to a strong planning process, remain stable (in source) and equitable (in distribution), be effective in attracting and supporting a high quality workforce, and assure efficient use.

Recommended Funding Option



DISCUSSION



Hypothetical Model for Meeting Escalating CC Costs

FY	Budget (MILLIONS)	ABCR Recom. Increase for Following Year	NIH Oversight Group Recom. Increase	Increase in NIH Budget	\$ Required from Total NIH Budget (MILLIONS)	NIH Budget (BILLIONS)	Cum. Total Needed from NIH Budget (MILLIONS)	% NIH Budget in Current Year Not Coming from IRP	Cum. % NIH Budget for CC Not Coming from IRP
10	\$362.0	5%	3%	3%	\$7.24	\$31.26	\$7.24	0.023%	0.023%
11	\$380.1	3%	1%	1%	\$7.60	\$31.57	\$14.84	0.024%	0.047%
12	\$391.5	4%	3%	3%	\$3.92	\$32.55	\$18.76	0.012%	0.058%
13	\$403.2	3%	3%	3%	\$0.00	\$33.53	\$18.76	0.000	0.056%
14	\$415.3	4%	2%	2%	\$8.31	\$34.20	\$27.07	0.024%	0.079%