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Pleasure to be with you tonight and to have the opportunity to talk informally about challenges and opportunities in health policy as viewed from a ^{at Hopkins} ~~perspective~~ ^{perspective} which is so very different from ~~being~~ that of a ~~Dean~~ ^{Dean} ~~so many ways~~ and so similar at the same time.

Those who imagine that an office in the White House conveys unusual power to ~~direct~~ ^{guide} the mighty ship of state - to direct that programs be changed / advocated / stopped or started // that people be hired / fired // that new ~~programs~~ ^{programs} be implemented tomorrow, etc. etc.

^{however,} A colleague suggested that his job, as he perceived it, was not unlike that of herding a roomful of cats from point A to point B. That seemed reasonably apt to me until I discovered he was discussing his previous jobs - as a Dean.

I have come to ^{discover} ~~learn~~ that a job such as mine is characterized by learning more and more about less and less. // And this under ^{an} unusual degree of scrutiny.

i. Genome patenting issue emerging.

ii. Certain of our Hopkins colleagues rec'd the notice ^{of the notice} / noted the price tag / and immediately concluded that ~~the~~ one of the White House staff was engaged in some sort of entrepreneurial venture. In due ^{course}, I was queried about this. Why this didn't get in the Washington Post, I have no idea. Rest assured I'm not even permitted to be reimbursed for parking.

^{set the stage by saying} Important first that I ~~say~~ ^{word} about the Office of Science as I must confess that when first asked to serve, my own notion of the Office was fuzzy at best and for good reason.

~~Concept of~~ ^{Concept of} science adviser - germinated with the development of the atomic bomb and matured during the Eisenhower ~~years~~ and Kennedy years ^{concerns}

- E the launching of Sputnik, the scope expanded from nuclear to space.
- Pres. Nixon's ^{Office} was
- 1976 - ~~enacted~~ ^{enacted} enshrined in Fed. legislation -

provided for a Presidentally nominated / Senate confirmed Science Advisor + 4 Associated Directors

Carters + Pres
Reagan years

Book Administration - Science was once again ^{perceived} to be central to ~~and~~ formulation of national policy.

Asst to Proxy

Assoc. Dir's - 1st line and first line Assoc. Dir. for life sciences! ^{Jim Wyngarden}

Office 15 → 50

(still heavily physics, space, electronics)

PCAST

FCCSET.

Presidential initiative

My own initiation to the office was unexpected for me - and ^{indeed} many of my colleagues.

Resigned deanship for 14 years. (who needs more)

~~Chair~~

Substantial / Edgar Berneer Chair / International vaccine program -
CVA - heads of state

Asked by Allen Browley - background

Phone calls from Bennett / Posen / Thur.

Principles: Science / education - key to future of the country

Need for interagency planning

Key that the best of science inform policy

What I am not engaged with is domestic policy - e.g.

• reform of health care ^{depriving} ~~referring~~ and financing med. such as abortion policies

Two M.D.'s in W.H. - Brut Lee + Whit

Whether ^{role} ~~then~~ will change, remains to be seen.

Our agenda is constantly changing + may be different by nightfall from A.M.

Sworn in on 1 April - symbolic day perhaps - ^{many critical} ~~issues in sciences~~ ^{life} ~~promptly~~ engaged

Two problems which I brought → With a staff of exactly 2 professionals (Ritz + WK - credentials) enough to say grace over

① Stanford → indirect costs

Arcane A-21 - Thought I ~~but~~ could for get this piece.

Feeling hungry / desire for Exec. decision.

Link to academic community - interim rep.

Task Force created - OMB / OST / Agencies + liaison group.

② Difficult issue

David Baltimore & Bob Gallo - ^{allegation of} ~~misconduct~~ in science

IAU examines

NAS Committee

Interagency Task ^{Force} ~~Force~~ created = ^{objective} ~~purpose~~ of developing common principles

③ Biotechnology - Presidential initiative for the FY 94 budget.

Defined - techniques that use living organisms to make or modify products, to improve plants or animals and to improve microorganisms for specific use.

Ancient techniques - yeast to make beer and bread
plant and animal breeding.

With understanding of the genetic nature of organisms and new techniques such as

DNA cloning and sequencing

DNA synthesis and application

Monoclonal antibody

Macromolecular structure analysis

A whole new world of possibilities ^{suddenly} opened ~~with~~ explosive growth over the past 10 years.

Drugs and vaccines - once developed by trial and error and massive screening techniques of libraries of different products now can be tailor made to attach to a modify ^{the} key part of a cell.

Plant breeding - once a cumbersome hit and miss operation involving the cross of two plants with ~~the~~ certain useful characteristics now changing to permit just one gene to be changed to make the plant taller, more resistant to drought or insects.

During the late 1980's 7100 new U.S. companies created annually.

New drugs and vaccines are already in use

Vaccines vs. hepatitis and hemophilus influenza

Drugs such as insulin and white blood cell stimulators

In 1991 ^{alone} nearly 300 new biotech. products submitted to FDA as (INDs)

Invest. New Drugs - ready for trial in humans.

~~For the past ten years~~ ^{For the past} 5 years - biotechnology INDs have outnumbered non-biotech. INDs

In agriculture - more nutritious, higher yielding, pest resistant plants
Animals which themselves can serve to manufacture specific proteins useful as drugs

Environmental remediation - use of microbes for degrading toxic chem.

Manufacture of unique products using renewable resources.

(49)

The agenda is all but infinite. ^{Almost to the point of being} If it can be imagined, it can be executed

C VI

Twelve agencies were brought together to take the first steps for the creation of a government wide initiative

note: "Biotechnology for the 21st Century"

President's budget proposes \$4.0 billion be devoted to the basic science underpinning - an increase of nearly \$250 million

Planning effort continues this year.

Other issues of immediate concern to us

④ Genome patenting -

Can / should genetic fragments of the genome be patented and if they can, what should govt. policies be regarding licensee access.

Immensely complex subject - subject NAB on May 21-22

⑤ HIV vaccine testing - Why?

Some 13 different progs. produced ind / govt / acad.

Phase 1 / and what testing in humans in U.S.

How and when do we test for efficacy?

No animal model - must put in humans

Not spreading fast enough in U.S. ∴ international

Problems of testing: 12-20 yrs olds -

ethical issues

international sensitivities

? litigation

Need to proceed ASAP & must be done in concert w/ intl bodies (WHO)

This does not exhaust the list which includes issues such as biological warfare concerns, risk assessment, and international relationships with Eastern Europe and international organizations.

Dr. Bransley, with the perspective of 40 years in physics field speculates that the next 40 years will witness a comparable growth in our understanding of the fundamental processes of life itself.

Reflects past prudent investment in NIH and NSF (5)

The groundwork is ^{well} ~~being~~ prepared. U.S. ~~leadership~~ ^{program} for outdistances that of any other country. ~~the~~ We need to sustain this momentum in the interests of the economy, of humanitarian concern and of global health.

It's a challenge participating in the role ~~I have~~ ^{I have} It is deemed to be an arena of less ^{interest to} ~~interest~~ ^{current} in the political turmoil of an election year — and for this I am grateful!

Thus far, it has been both creative and productive. For whatever reasons, however,