THE biodesign INSTITUTE at Arizona State University

Synthetic Biology: Charting Rational Public Policies For the Oversight and Regulation of Vanguard Technologies

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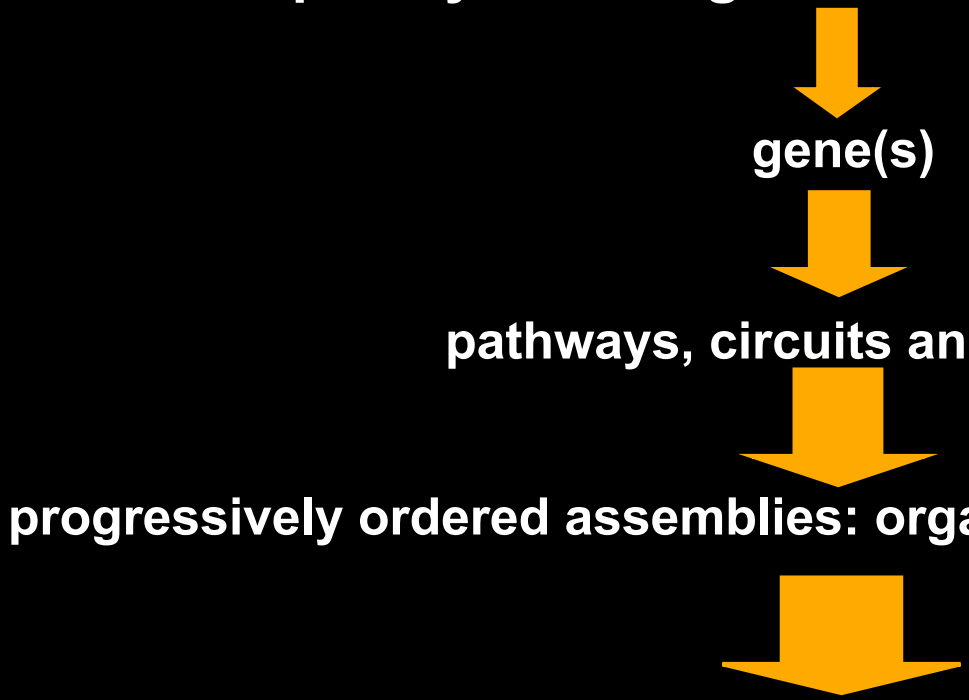
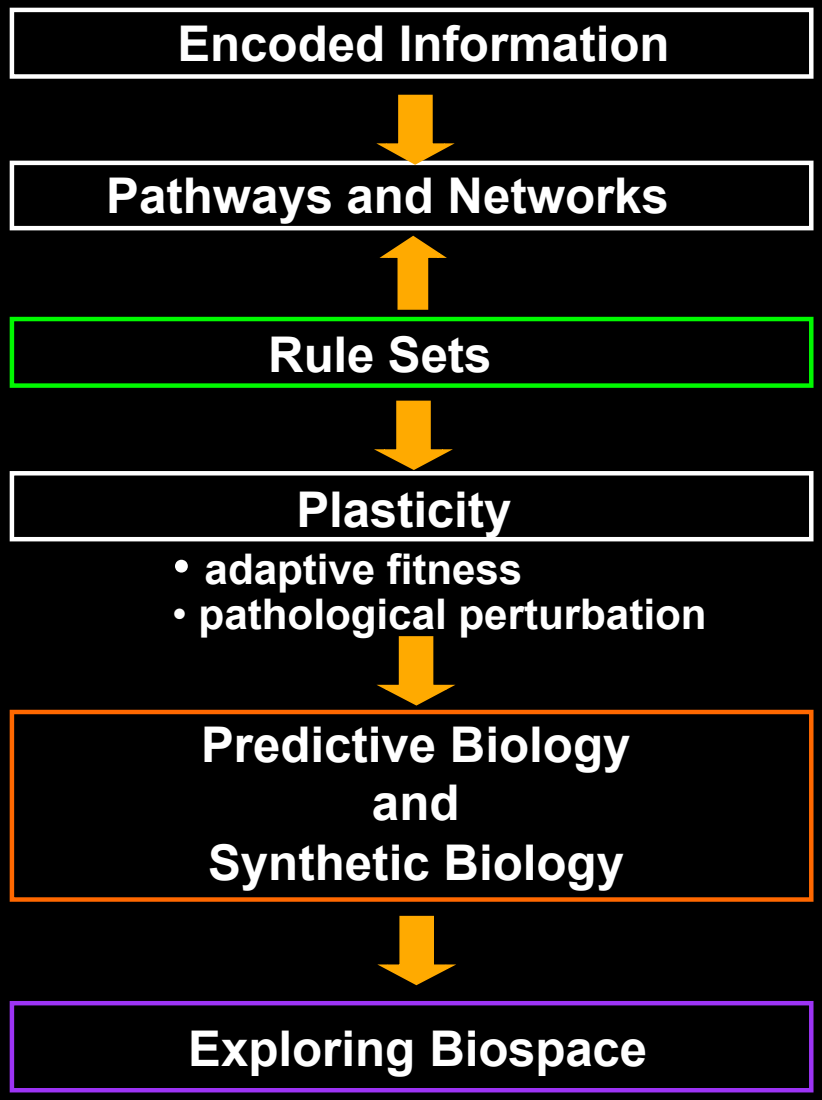
ASU

From Reductionism to Integrated Systems Biology

- understanding the information content encoded in biological networks
- mapping the design rules for progressively greater complexity of biological order



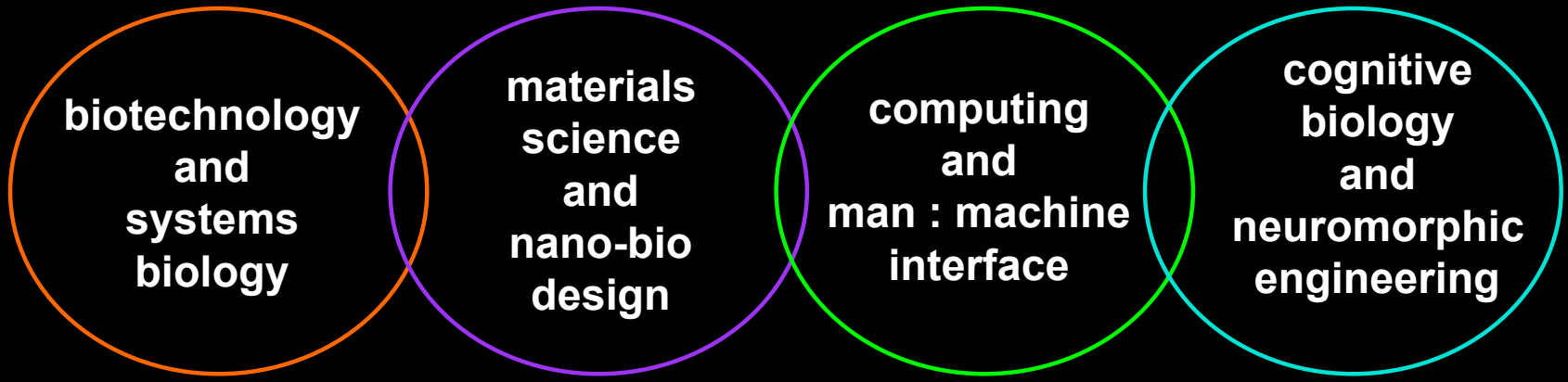
High Level Abstraction of Biological Pathways and Network Systems



“Bio-Inspired” Materials and Synthetic Biology

- recapitulation and extension of self-assembly properties in biological systems
  - nano-, micro- and macro-assemblies
  - non-linear spatiotemporal patterns of synthesis, degeneration and repair
- genesis of novel multifunctional materials
- self-generation and repair
  - tissue engineering
  - hybrid biological : biomaterials devices
- exploring ‘biospace’
  - optimizing biological fitness
  - synthetic genomics, novel functions and novel organisms
  - biomimetic robotics

Technology Convergence



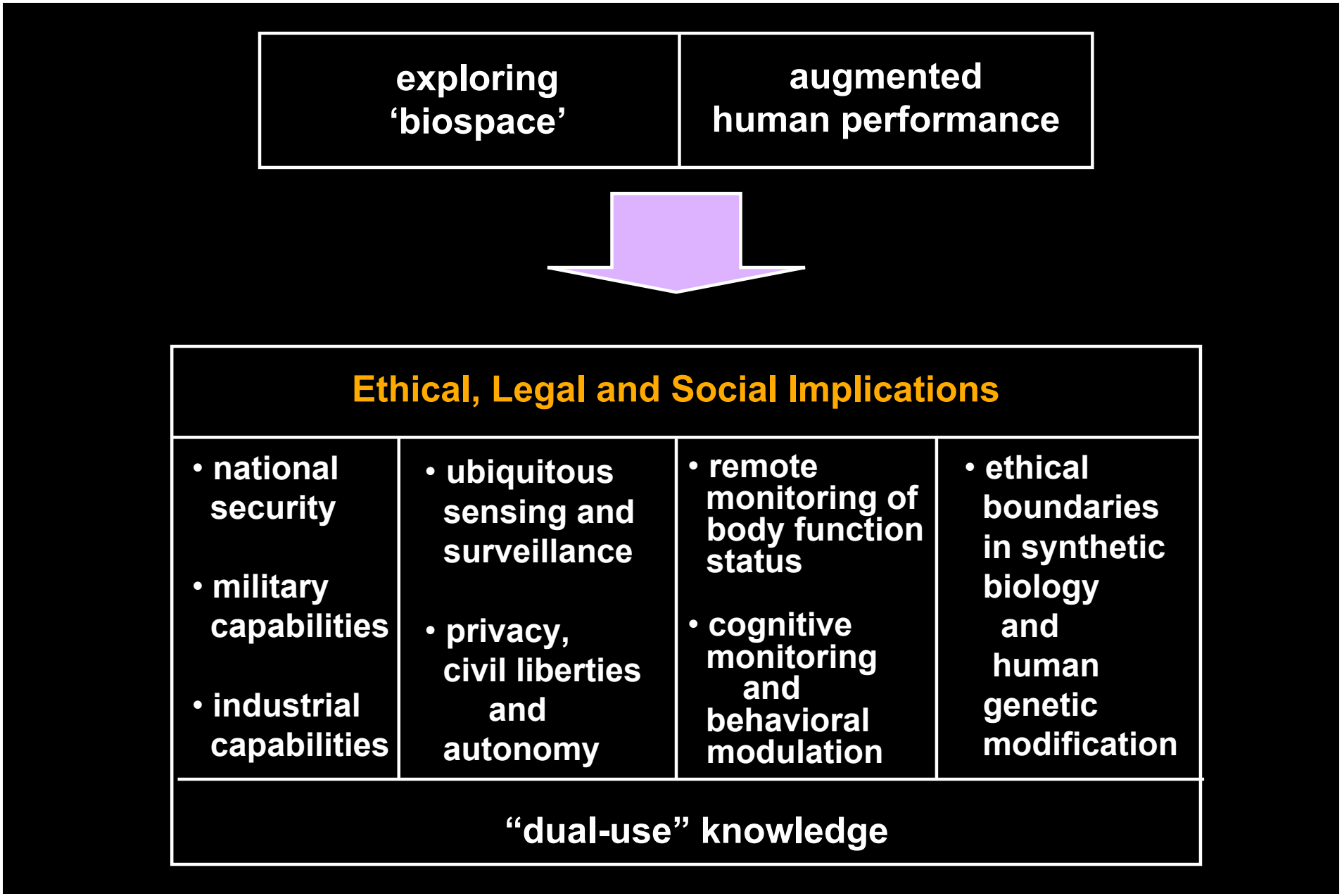
- mapping biological networks
- synthetic biology
- bio-inspired design

- novel biomimetic materials/devices
- tissue engineering

- ubiquitous sensing
- embedded networks

- carbon : silicon union
- external devices
- implants

exploring 'biospace'	augmented human performance


exploring 'biospace'
augmented human performance
Ethical, Legal and Social Implications
• national security
• military capabilities
• industrial capabilities
• ubiquitous sensing and surveillance
• privacy, civil liberties and autonomy
• remote monitoring of body function status
• cognitive monitoring and behavioral modulation
• ethical boundaries in synthetic biology and human genetic modification
"dual-use" knowledge

The Trajectory of Contemporary Science and Technology

- innovative solutions to global challenges and progressive distributive equity in access to benefits?

or

- technological dystopia?

Biotechnology:
Polarizing Societal Attitudes About the Direction and Control of Contemporary Science and Technology

- unique resonance of 'healthcare' and "genetics" in public imagination
- dizzying pace of change
- media sensationalism and anti-technology activism
- "playing God": Promethean excess, hubris and arrogance
- genetic determinism, behavioral genetics and free will
- Genetic profiling and discrimination in healthcare/employment
- fear: the law of unintended consequences
- alienation and retreat to false security of fundamentalism, cults and related psychological sanctuaries

Changing The Nature of Human Identity

- post-genome, post-human, trans-human
- genetic modification of humans
  - enhancement and eugenics
- carbon: silicon union
  - cyborgs
  - fyborgs

Charting Rational Public Policies for the Oversight and Regulation of Vanguard Technologies

- risk assessment and evaluation
- evidentiary standards
- public participation
- international harmonization
- adaptive flexibility to accommodate change and unforeseen outcomes
- accountability and enforcement
- compliance incentives and penalties

Public Policies for Risk Regulation

- regulatory systems embrace both rational and irrational decision frameworks
- regulators and politicians are increasingly paralyzed by the pace of change
  - widespread technical illiteracy in legislative bodies
  - intrusion of political populism
  - propagation of myth that zero-risk is attainable
- sophisticated anti-technology lobbies playing on public fear will become increasingly emboldened
  - GM plants, cloning, “nano” (loc.cit.)

Public Policies for Risk Regulation

- lack of transparent rationale for how and why risk regulation varies between policy domains
  - tobacco, alcohol, nutritional and herbal supplements versus highly regulated medicines
- public concern focuses on extreme, catastrophic and rare events
  - distorted perception of 'risk scale'
  - perception of voluntary versus imposed risks
- 'tombstone' policies in response to highly emotive tragedy/disaster
  - flawed, irrational 'kneejerk' legislation
- 'policy windows'
  - exploitation of public and media attention

“The era of big government may be over
but the era of regulation through litigation
has just begun”

Former US Labor Secretary Robert Reich
Vital Speeches 1 Oct. 2003 p. 764

“We are being propelled into this new century
with no plan,
no control,
no brakes”

Bill Joy,
The Future Doesn’t Need Us
Wired, 2002

The Six Principles Shaping the Evolution of Policies for Risk Regulation

- the paradoxical principle
  - public dependence vs distrust
- the polarizing principle
  - activist and media portrayal of catastrophic risk versus balanced assessment of risk plus benefit
- political correctness and political populism
  - spin, celebrity endorsement and political expediency versus evidence-based policies
- the precautionary principle
  - succumbing to intrinsic complexity, uncertainty and ambiguity with paralyzing inertia
- the ‘pass-the-buck’ principle

Activism

- emergence of NGO's as powerful anti-technology lobbies
  - well funded and sophisticated media relations
  - sound bites and spin sell!
- broadening coalitions of opposition
  - NGO's, organized labor and religious lobbies
- inadequate response of technical and commercial sectors in countering distortion and untruths
- increased distrust of S & T and "bio"-based industries
  - greed, genetics and globalism

“There is no great invention,
from fire to flying,
which has not been hailed
as an insult to some god.”

J.B.S. Haldane (1923)
Daedalus, or Science and the Future

“There is far too much regulation.
If nobody is hurt, then what is going to far?
The idea that there is some fundamental order arranged by God
is the origin of the whole fuck-up.”

James Watson
Financial Times 1 Feb. 2004

". . . . and in the end,
all the bioethical agonizing was largely beside the point.
The scientists kept working quietly,
deliberately working away
incrementally improving the technology.
What seemed scary to people
slowly started to seem interesting, and maybe useful.
Looking back over the years, its hard to find a case
in which the unthinkable remained unthinkable for long"

New York Times. 7 Dec. 1997 p. 6

What is Natural?

What is Natural?

- historical constancy of alarm and dismay about transforming technologies
  - transport, manufacturing, communication, health and entertainment
- S&T as powerful catalysts of change in institutional and cultural norms
  - military technologies and imperialism
  - public health, medicine and productivity
  - capitalism, consumerism and technological leisure (globalization)

What is Natural?

- romanticism, neo-Luddism and Rousseau concept of the 'noble savage'

versus

- the enlightenment model of equitable progression of the human condition via rational enquiry
  - infinite perfectability, freedom, individualism utilitarianism
  - breaking the Hobbesian yoke of life as "nasty, brutish and short

What is Natural?

- increasingly negative public perceptions of science and technology
  - unintended consequences
  - portrayed as destroying traditional worlds via multinational corporatism
- concerns over lack of equity in access to benefits
  - a 'Bladerunner' world
- "the endangered human": US Presidential Council on Bioethics
  - "Beyond Therapy": rejection of cosmetic/lifestyle related advances in healthcare

Shaping Rational Policies
and
Legal Frameworks for Regulating Risk

Risk Regulation

- how safe is safe enough?
- who bears the risk?
- who reaps the benefits?
- what is the cost and who pays?
- how are complexity, uncertainty and ambiguity addressed?
- what are the trade-offs in favoring one option over another?
- should voluntary risk(s) be regulated less stringently than imposed risk(s)?
- how will moral and ethical issues of distributive justice and equity be addressed?

Expertise and Analysis in Risk Regulation

- effectiveness
  - confidence that actions will produce desired outcomes
- efficiency
  - extent to which societal resources are used to reach the stated goal
- legitimacy
  - composite term
  - compatibility with scientific method, legal requirements, due process
- social acceptance
  - compatibility with values/lifestyles of pluralist societies

The "Pathologies" of Seeking Public Participation in Regulation of Technically Complex Risks

- regulatory imprecision
- predisposition to over-regulation
  - precaution
  - political populism
- unrealistic public expectations
- disproportionate role of activist groups
- new sources of conflict

The Obligate Need for Adaptive Flexibility in Policies and Regulations for Risk Management

- framework for ‘navigation’ rather than ‘prescriptive controls’
  - unforeseen consequences (benefits as well as risks!)
- proscribed interim reviews of effectiveness and sunset clauses
- accountability for regulators as well as the regulated
- the challenge of international harmonization

Dual-Use Knowledge

"Dual Use" Technologies

- simultaneous use of same knowledge for beneficent and malevolent ends
- historically, biology remote from the process
- biology poised to lose its innocence
  - shift from big bang, big metal weapons (physics-based) to bio-inspired systems
- bioterrorism
  - low probability, high consequence (today)
  - tomorrow with ubiquitous biotech skills (?)
- 'bio'-threat becomes more than bugs
  - from microorganisms to biological circuit disruptors and synthetic genomics

“Synthetic Genomics”

Dual Use Technologies : Civilian and Military Applications of New Knowledge

	Motive	Method	Management
CIVILIAN	• public good	• unfettered enquiry • transparency • widespread knowledge dissemination	• distributive equity • minimize regulatory/legal oversight • free market principles
MILITARY	• national and international security • power projection	• controlled enquiry • secrecy • restricted distribution	• highly controlled access • complex legal obligations • defense industry : military-industrial economic interdependence

Science, Censorship and Public Health :
Editorial by A. Salyers, President, ASM (2002) Science 296, 617

There remains an undercurrent of public discomfort with what is seen by some, however, wrongly as freedom without responsibility.

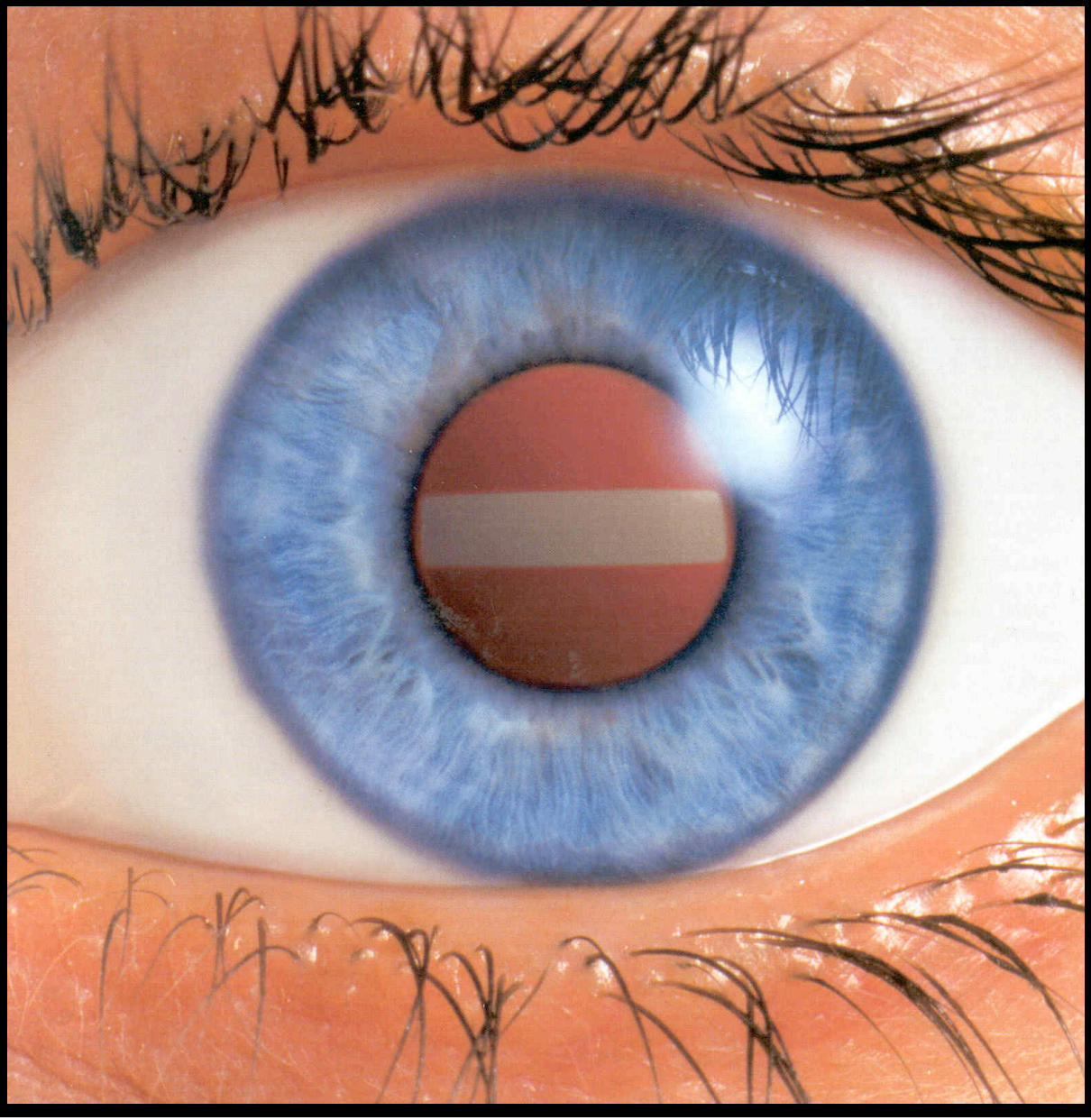
…… It is no on longer sufficient to tell the public:
"Trust us, we know what is good for you".
We need to be able to explain why our position is in the public interest".

"Because science is both a public and social enterprise,
and its application can have a profound impact,
society recognizes that the freedom of scientific enquiry
is not an absolute right
and scientists are expected to conduct their research
according to widely held ethical principles"

(US) National Bioethics Advisory Commission
1997 p. 6

"There are times when limits on scientific freedom
must be imposed, even if such limits
are perceived as an impediment
by an individual scientist"

Ibid. 1997 p. 6



Defining Boundaries for Scientific Enquiry and the Public Dissemination of Knowledge

- ‘forbidden’ knowledge
- ‘public’ knowledge
- ‘constrained’ knowledge

Defining Boundaries for Scientific Enquiry and the Public Dissemination of Knowledge

Category	Outcome
• forbidden knowledge	• doomed to failure
• public knowledge	• straightforward until abused -shifting societal definitions of abuse
• constrained knowledge	• classified data • 'sensitive' but not classified - ill-defined and unworkable • proprietary commercial data/trade secrets • fee-based access to data • codes of conduct

Scientific Method

- science is not neutral
- obligation of scientists and science-based industries to comprehend and communicate
  - benefit and risks
  - contribute to risk mitigation/elimination
- the ‘posturing’ of science
  - exploit public fear/generosity

Codes of Practice

- Francis Bacon (The New Atlantis: "constrained knowledge")
- guilds (proprietary art)
- trade secret and state secrets
- Asilomar
- robotics (I, Robot: Isaac Asimov)
- nanotechnology

Potential Shortcomings in Self-Policing Actions by the S&T Community

- the omnipresent ‘surprise’ factor in research
- lack of understanding of potential malevolent/illicit applications
- risk denial and/or lack of acceptance of responsibility/culpability in creating opportunities for malevolent abuse
- non-compliance by research investigators for varied motives
- lack of oversight and/or enforcement by funding agencies/regulators/IC
- difficulty of shaping consensus over control and publication formats
  - international harmonization
  - varied enforcement by publishers

The Calculus of Risk Assessment for Open Access to Dual Use Information and Materials

scale of new threat capability posed by malevolent use(s)	X	projected timeframe to convert to malevolent use(s)	X	technical complexity and cost to convert to malevolent use(s)	X	availability of robust mechanisms to monitor and detect malevolent use(s)	=	risk scale for anticipated conversion to malevolent use(s)

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scale of new threat capability posed by malevolent use(s)	X	projected timeframe to convert to malevolent use(s)	X	technical complexity and cost to convert to malevolent use(s)	X	availability of robust mechanisms to monitor and detect malevolent use(s)	=	risk scale for anticipated conversion to malevolent use(s)
• extreme • disruptive • counter-measures available • low to nil		• < 2 yrs • 2-5 yrs • > 5 yrs • > 10 yrs		• scales for T and $ - very high - medium - low		• high confidence • emerging • unavailable	=	χ= Threshold Trigger

Sustaining a Supportive Environment for Vanguard Science and Technology

- advocacy of S&T community and corporate leaders
  - proactive and transparent ID of applications, implications and limitations
  - cogent strategy for risk mitigation
  - counter distortions of anti-technology lobbies and media sensationalism
  - puncture the myth that zero-risk is attainable
  - active engagement in policy formulation
  - obligate demand for evidence-based policies versus expedient political populism

“Politics is the art of the possible,
the calculated science of survival”

Prince Otto von Bismarck

"Politics is the art of the possible,
the calculated science of survival"

Prince Otto von Bismarck

"Survival owes little to the art of politics,
but everything to the calculated application
of science".

Professor Rudolph Virchow
(in reply)