

## **The Price of a False Idea about Economic Growth** **Health Research Cuts and Uncontrolled Toxic Agents**

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### **Two Crises**

In ancient Ionia, the physician-philosopher Galen of Pergamos and Rome wrote, children would take pig bladders, “fill them with air, and then rub them with ashes near the fire ...and sing songs [in] an exhortation to the bladder to increase in size ... until the bladder seems to them to have become large enough.” <sup>2</sup> This describes with near perfection the beliefs and behavior of politicians and ‘experts’ who promote the false idea about economic growth prevailing in our nation’s centers of government. Promising new directions in disease prevention are being sidelined and the control of long-known environmental risks to life is obstructed. Their mistake has costs in sickness and death.

Professor Antonio Giordano, Director of Temple University’s Sbarro Institute, recently received an email<sup>3</sup> from Dr. Stephen J. Meltzer, a distinguished medical scientist of Johns Hopkins University. A crisis has struck the National Institutes for Health and Meltzer asked for help. Critical cuts continue to be made in the budget of the National Institutes of Health. In a conference call with Administration officials, during which research funding was discussed, the officials staunchly defended the proposed \$30.7 billion 2013 NIH budget as being perfectly adequate, remarking that “The NIH ... will continue to be strong; it will do just fine.” It seemed clear that these officials did not fully understand the central importance of NIH funding to our national research enterprise and local economies, or that the survival of our worldwide leadership in medical education and research is rapidly fading.

Unfortunately, Meltzer noted, the proposed NIH budget will severely exacerbate a catastrophic crisis that has been ongoing since 2003, when growth in NIH funding fell (and has continued to fall every subsequent year) behind the rate of inflation. As a consequence of this deeply flawed public policy, human resources are wasted and promising research projects have been aborted. Hundreds of laboratories nationwide have shrunk or been shut down, established and accomplished senior researchers have been forced to abandon their programs, young scientists have departed from research and left the country (after many years of productive training), thousands of ancillary jobs have been lost, our worldwide medical research dominance has been eroded (ceded to China, India, and other nations), and a large support network of laboratory supply and biotechnology companies has drastically shrunk.

The community of scientists has challenged this devastating political pattern. A petition to increase NIH funding garnered about four signatures per minute when circulated, resulting in some 25,000 petitioners. The scientists were responding to reductions in health research programs that translate into less control over the entire spectrum of disease, a diminished quality of life, and unacceptable changes in the direction of our evolving society.

The same political pattern affects other fields of critical research. Physicist Steven Weinberg writes that in 1992 the House of Representatives cancelled funding for the Superconducting Super Colliders. They poured down the drain \$2 billion already spent and raised the future cost of promising long-term research that already had given us the World Wide Web. “Congress,” Weinberg points out, “never supplied sufficient funds to keep to the planned rate of spending. This stretched out the time and hence the cost to complete the project.” <sup>4</sup>

Basic failures in the prevailing political discussion of “gross national product”, “budget deficits”, “disposable income” and other ways of viewing society divert attention from, and distort our ability to properly ask, the most important question facing every society. How do we protect human life?

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<sup>2</sup> Galen. *On the Natural Faculties*, Brock trans. London: Loeb Classical Library, Heinemann (1916) 27-29.

<sup>3</sup> Email: S.J. Meltzer to A. Giordano, March 22, 2012.

<sup>4</sup> Weinberg S. *The Crisis of Big Science*, NY Review of Books, May 10, 2012.

Fruitful ideas of economic growth consistent with the vision of a humane society are obscured by the mistaken belief that economic expression of growth is unique, e.g., separate from the ideas that shape and drive successful biomedical investigation. The true (most fruitful) idea of growth - a unifying concept basic to economic, social and biological theories and the positive discoveries that for millennia have flowed from them - is lost in political cackle on 'budgets and the economy'.

Our 'republic of the multitude' is being assaulted by politicians misguided by professionals whose lack of objectivity is uncovered by sociologists of science, as by the revered scientist Ludwik Fleck. "The 'accumulated experience – not only of an individual but of a well-trained<sup>5</sup> collective", he wrote, is one in which the members "teach others to see" 'facts'. The mechanism by which 'facts' are taught, Fleck notes, is the incestuous imprinting of thought during the migration of ideas throughout the collective, driven by the natural striving for the collective rewards of collective achievement.<sup>6</sup>

### The Rationalization of Failure

Policymakers need to rationalize their conclusions with methods that appear to be "scientific". They found one in the necromantic rite of cost-benefit analysis: an example of the collective abuse of science via the Arithmorphic Fallacy.<sup>7</sup>

Nearly a century ago economists were warned about an alarming trend in their profession: "the all too prevalent methodological fanaticism which prefers the accurate but superficial to the approximate but fundamental ...".<sup>8</sup> Practitioners of the fallacy demand precise quantification beyond the capacity of the subject matter to support precision and quantification. In both Republican and Democratic regimes, by setting necessarily arbitrary monetary values for a human life, we are forced to play absurd games of necromantic roulette, as illustrated by Table I.

Table I  
Setting the Value of a Human Life<sup>9</sup>

| Source                   | 2000          | 2004          | 2008                        | 2010                        | 2011        |
|--------------------------|---------------|---------------|-----------------------------|-----------------------------|-------------|
| EPA                      | \$7.8 million | \$7.3 million | \$6.8 <sup>10</sup> million | \$9.1 million <sup>11</sup> |             |
| FDA                      | 5.0 million   |               | 5.0 million <sup>12</sup>   | 7.9 million                 |             |
| DOT                      | 3.5 million   |               |                             | 6.1 million                 |             |
| OMB                      |               |               |                             | 8.7 million                 | 5.0 million |
| DHS                      |               |               |                             | 100 X average for terrorism |             |
| A Professor of Economics |               |               |                             | 8.7 million <sup>13</sup>   |             |

The bi-partisan guidance of the President's Office of Management and Budget to the regulators cited was simple: pick a number "\$1–10 million ... but not under \$5.0 million." Of course, the game is "based on the best available science", as judged by the politically-selected collective. With even relative objectivity compromised, their subjective judgment conceals the possibility of an agreed underlying reality seen in common by the regulatory agencies and their elected overseers on the eternal value of protecting a life.

The technique sometimes appears to work in society's favor, as in the recent case of reclaiming hazardous waste sites in the provinces of Caserta and Naples. There significant increases in malformation and the mortality of cancer and other diseases were occurring in

<sup>5</sup> To answer a peer reviewer's question, by "well-trained" Fleck meant the acquisition of high levels of non-rational habits of thought, as in conditioning laboratory rodents to respond to food-rewarded signals.

<sup>6</sup> Fleck L. *Genesis and Development of a Scientific Fact*, Forward by TS Kuhn. TJ Trenn and RK Merton, eds. Chicago: The University Press (1979) 118-119.

<sup>7</sup> Full explanation: Samuels SW. *The Fallacies of Risk/Benefit Analysis* in Hammond EC and Selikoff IJ. *Public Control of Environmental Health Hazards*. Annals NYAS 329 (1979) 267-273.

<sup>8</sup> Viner J. *The Utility Concept in Value Theory and Its Critics*. J. Polit. Economy (1925) 33:369.

<sup>9</sup> Source: Appelbaum B. *As U.S. Agencies Put More Value on a Life, Businesses Fret*. N.Y. Times (02/16/11). Numbers adjusted to 2011 values.

<sup>10</sup> During G.W. Bush administration, value was "as low as" this number.

<sup>11</sup> Death by cancer valued higher.

<sup>12</sup> "Might increase to 50% higher for cancer". In year 2009, value was \$7 million for the same rule.

<sup>13</sup> W.K. Viscussi's calculation of the "statistical value of life."

specific areas where the economic impact of improper waste management and illegal waste trafficking had been fully documented and could be remedied at minimal costs.<sup>14</sup> That case, in fact, demonstrates that the real costs in human life of environmental non-regulation also have an economic impact. That fact is not argued. Contention occurs when the method is manipulated to favor doing little or nothing while playing necromantic roulette.

"(A)fter a string of food-borne outbreaks shook consumer confidence in the nation's food," the Washington Post reports, "new food safety legislation was signed in January 2011. But no changes in food protection policy have taken place, "some experts" say, because OMB "has raised questions about the FDA's analysis of the provisions' cost and benefits."<sup>15</sup> Is a human life worth \$5 million or \$7.9 million?

It is not surprising to those of us who respect the Goddess of Truth to find that this respect helps us to 'un-conceal' that which is also morally good. Science and ethics are intertwined in rational decision-making processes.

The irrationality of cost/benefit analysis is cogently summarized by a great moral philosopher of The University of Chicago, the late Alan Gewirth in one of his final papers.<sup>16</sup> Cost/benefit analysis assumes that all the variables with which it deals are, or can be made commensurable with one another so that there is a common denominator into which the costs and benefits can be translated: a person's preferences in the allocation of resources, e.g., in allocation of money. He found five difficulties with this position:

- Knowledge. If risks are imposed with the consent of those impacted, are they informed and unforced?
- Distributive justice. The poor person will accept greater risks than those who are richer.
- Is human life a commodity to be bought and sold on the market? It has no market price.
- Those who set a price on human life are not the same persons as those whose lives are being valued.
- Market strategies, such as providing economic incentives in the tax system, permit polluters to pay to prolong the risk [and pass all or some of the cost on to its customers] making the risks "matters of bargaining or purchase rather than basic goods and rights."

In at least the workplace, the Congress did not pretend that they could or ought to resolve these difficulties. Wisely, they chose a different route for the setting of the standards that implement public health policy in writing the Occupational Safety and Health Act of 1970. In a tradition of thought at least as ancient as Aristotle, more recently expressed by a plurality of the Supreme Court in the 'benzene' case, the language and legislative history of the OSHAct make clear that the requirement to determine the priority of regulation, by determining the significant risk to be regulated, need not be "a mathematical straitjacket," but can be "based on policy considerations... risking error on the side of overprotection rather than underprotection."<sup>17</sup> This finding, that there is no requirement to commit the Arithmorphic Fallacy, coupled with a following decision on a cotton dust standard, should have ended cost-benefit analysis in workplace standard-setting.

### **The Majority Opinion and the Alternative**

Justice Brennan, writing for the majority, put to rest the debate as to whether cost-benefit analysis was required for OSHA regulations.<sup>18</sup> Any standard based on a balancing of costs and benefits by the Secretary that strikes a different balance than that struck by Congress would be inconsistent with the command set forth in the Act. Thus, cost-benefit analysis by OSHA is not required by the statute, but feasibility analysis is. The Court looked to

<sup>14</sup> Barba M. et al. *Wasting Lives: The Effects of Toxic Waste Exposure and Health. The Case of Campania, Southern Italy*. Cancer Biology & Therapy 12-2, (July 15, 2011) 106-111.

<sup>15</sup> ElBoghdady D. *White House delay on food-safety rules causes frustration*. Washington Post (May 3, 2012) A-13.

<sup>16</sup> Alan Gewirth. *Human Rights and the Workplace* in *The Environment of the Workplace and Human Values*. SW Samuels, Ed. Liss: NY 1986.

<sup>17</sup> *IUD (Industrial Union Department) vs. API (American Petroleum Institute)* (1980): 4480.5 607 Supreme Court, Washington, DC.

<sup>18</sup> *American Textile Manufacturers Institute v. Donovan*. SCOTUS 101 S.Ct. 2478 (1981).

the plain meaning of the word *feasible*, a comparison with other federal laws requiring cost-benefit analysis, and the legislative history of the Act in reaching its decision. The Court found that Congress uses specific language when intending that an agency engage in cost-benefit analysis. In the light of its ordinary meaning, the word *feasible* cannot be construed to articulate such congressional intent. The Court then found that the law merely requires that standards relating to toxic materials and harmful substances be issued to prevent material impairment of health “to the extent feasible.”

Couple this finding with the OSHA's mandate that the Secretary set a standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity by attainment of the highest degree of health and safety protection for the employee, considering the latest scientific data. The cotton dust decision did not eliminate the issue of costs: ventilation systems need not use platinum-plated sheet metal that will last for centuries. Yet the guidelines for the ethical consideration of costs ordered in these U.S. Supreme Court decisions have not stopped the misuse of economic analysis.

The Court argued that the legislative history showed that Congress did not intend to impose the unrealistic goal of a risk-free workplace. Nevertheless the Court recognized the paramount value, quoting Senator Yarborough: “We are talking about people's lives, not the indifference of some cost accountants.”

Albert Jonsen and Stephen Toulmin resurrect a time-tested alternative to cost-benefit analysis: moral judgment by the tradition of case studies. This fundament of legal, medical and pastoral practice is not held captive by deductions from universal abstract principles on which there is no or little agreement.<sup>19</sup> Judgment is drawn from something else on which there is or can be agreement. For this truth, the ‘something else’ is Aristotle's unconsciously and consciously held sense of *phronesis*: practical wisdom, which for most healthy humans is embedded in *conatus*: “the impulse by which each thing endeavors to persevere in its own being.”<sup>20</sup> Largely concealed at times, *conatus* perpetually uncovers itself enough to reveal an underlying presence useful in the systems of heuristically-held moral axioms that are the hallmark of the real world of ‘as if’ in which we un-godlike mortals live.

Yes, this method is blasted in histories that perpetuate Pascal's famous rant on the evils of the case method - ‘casuistry’ - practiced by Jesuits in mid-Seventeenth Century, who had been found guilty-by-association in the sometimes barbaric tumult of the French revolutions. Unfairly, they were blamed one-and-all for turning an ancient, tried Roman and Judeo-Christian method of setting moral rules for the identification of sin and remedy into a popular slur. Even when successfully employed by the *oecumenical* sophists of his era, Pascal's judgment recognized nothing more and nothing less than that there is nothing – no matter how virtuous in intent – that we humans do or say that is not corruptible. Whether practiced in Presidential Commissions on Human Experimentation or government-chartered committees of the National Academy of Science and its Institute of Medicine, the historical record in the United States, from the time of Lincoln [who founded the National Academy] to the present day, is replete with the success of the case method of judgment.

### **An Ethical Research-Based Future**

Professor Gian Giacomo Giordano, of blessed memory, recommended that this writer share with the Italian environmental health community the long American experience – more than 60 years of social failure based on cost-benefit analyses – in setting a workplace standard for toxic beryllium dust exposure, including the attempted abuse of genetic testing as part of the standard.<sup>21</sup> We documented a modern form of attempted cannibalism: the Department of Energy's ill-considered abuse of molecular biological research for identification of individuals to create a genetically-selected workforce, with effects which could occur in one or two generations. The long, bitter history of similar attempts in the United States and in Europe was begun by Darwin. He documented and publicized a practice he found abhorrent: racial selection by the murder of young Native American women in South America, providing him with an example of cultural selection as distinct from natural selection as a mechanism of

<sup>19</sup> Jonsen AR and Toulmin S. *The Abuse of Casuistry* Berkeley: University of California Press (1988) 19.

<sup>20</sup> Wolfson HA. *The Philosophy of Spinoza*, New York: Meridian (1958) ii, 195.

<sup>21</sup> Samuels SW. *The Masada Syndrome* in Romano C. and Grassano G. *Bioetica*, Torino: UTET (1995) 184-189.

evolution. This kind of threat persists, but is abated with public awareness, voluntarily [the case here] or by legislation. Thus, there is no reason to fear an important research initiative using similar methods.

Christopher Wild, Director of the International Agency for Research in Cancer in Lyon, has provided an organizing concept for identifying the course of environmental exposures and subsequent genetic changes retained over the natural history of the individual, thus sharpening molecular biology as the cutting edge of environmental health science today.<sup>22</sup>

The sequencing and mapping of the human genome, he writes, “provides a foundation for the elucidation of gene expression and protein function, and the identification of the biochemical pathways implicated in the natural history of chronic diseases, including cancer, diabetes, and vascular and neurodegenerative diseases. This knowledge may consequently offer opportunities for a more effective treatment and improved patient management.”

Genetic testing, ethically conducted, can identify individuals whose genes have been or may be damaged by environmental exposures and, thus, are susceptible to chronic diseases. Genetics in this application moves away from the clinic towards testing whole populations and enables reduced disease and death through preventive public health measures.

“It is well known,” Wild underlines, “that the majority of genetic variants ... in the human genome are of low penetrance, including genes implicated in metabolism of environmental chemicals ... .” Their “high prevalence ... means that despite their low penetrance, they may substantially contribute to population disease burden. Nevertheless, the majority will do so only in the presence of specific environmental exposures that in themselves are of low penetrance. Environmental exposures are acknowledged to play an overwhelmingly important role in [the] common chronic diseases mentioned above, which constitute the major health burden in economically developed countries. ... Despite this, many exposure-disease associations remain ill defined and the complex interplay with genetic susceptibility is only beginning to be addressed. ... .”

“The imbalance in measurement precision of genes and environment has consequences, most fundamentally in compromising the ability to fully derive public health benefits from expenditure on the human genome and the aforementioned cohort studies. There is a desperate need to develop methods with the same precision for an individual's environmental exposure as we have for the individual's genome. I would like to suggest that there is need for an “exposome” to match the “genome.” This concept of an exposome may be useful in drawing attention to the need for methodologic developments in exposure assessment,” Wild writes.

Dr. John Howard, Director of our National Institute for Occupational Safety and Health<sup>23</sup> has outlined the need in the United States for this new program “of mapping the “exposome,” an emerging issue for the 21st century.” He sees a promising new method to “measure all the exposures that an individual may experience over a lifetime in his or her environment, whether those exposures may affect the person's health, and if so, in what ways. ... [taking] into account the impact of exposures on health modified by factors such as lifestyle, physical condition, and genetics.”

But nothing will happen of significance to fast forward an exposome program without a change in national economic policy.

### **The Fruit of an Ancient Tradition**

The desecration of reason embodied in cost-benefit analysis prevails not only in United States regulatory policy, but also in setting priorities in the nation's budget [both income and expenditures]. Cutting budgets of NIH and other health research programs, ripping from the fabric of our society the highest human value: reduction of unnecessary death and suffering. This distortion is aided, we have claimed here, by accepting a mistaken meaning of ‘growth’, whether in sociological, biological or economic dialogue.

Successful traditions of thought include those who at crucial turns in the dialectic synthesize what was said in the past and what needs to be said for the future. In the tradition

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<sup>22</sup> Christopher Paul Wild, *Complementing the Genome with an “Exposome”: The Outstanding Challenge of Environmental Exposure Measurement in Molecular Epidemiology* Cancer Epidemiol Biomarkers Prev 14 (August 2005) 1847.

<sup>23</sup> NIOSH website, February eNews 2010.

initiated by Parmenides of Elea – over more than 2500 years of dialectic – there have been many who played that role.

In the Eleatic tradition, from the amendments of Aristotle and Galen to modern developmental biologists, growth of the kind we claim colors current political dialogue is simple growth in size alone that normally appears in the end stage of life. Before reaching that stage in life, organisms may require enlargement, but certainly tissue, organ and functional differentiation, in stage-by-stage changes in composition, structure and creative growth, a changing process. Galen empirically described a unity governed by nature, its chemistry and physics in constant interplay with its environment, a result of *genesis*: a faculty in which “something comes into existence which did not exist previously.”<sup>24</sup> By faculty, Galen meant the cause of an effect that “results from it, and of nothing else” ... “and so long as we are ignorant of the true essence of the cause which is operating, we call it a *faculty*. ... In an investigation of a faculty, we begin with the effect, each of which “comes from a certain activity, and each of these again is preceded by a cause.”<sup>25</sup> Biologists today incorporate these processes of change in the developmental concepts of *epigenesis* and *epigenetics*.

In modern times, one Eleatic had something to say not only relevant to developmental biology, but of all science: Eugenio Rignano of Livorno and Milan. He was dedicated to providing a unified vision: “...demonstrating the utility of ...the theorist [bringing a] synthetic and unifying vision [to specialized fields of biology, psychology and sociology].”<sup>26</sup> The object: “discovery of the hidden characteristics which may be possessed in common by phenomena apparently unrelated.” The fruit of this approach is illustrated in physics by Maxwell’s work on optical and electrical phenomena and Einstein’s special theory of relativity.<sup>27</sup> Pertinent to our issue here, it is illustrated also in human ecology. The evolving community does not simply expand, like blowing up a pig’s bladder, from a smaller preformed type. We develop new structures from the old, characterized by more than economics, to meet new and continuing challenges to an encompassing natural phenomenon: *conatus*.

Rignano, in an echo of Parmenides and Bruno of Nola, supposes a kind of memory in biological mechanisms: “Mnemic evocation”. This is a process of reproduction like that brought about “by internal causes of certain peculiar physiological states of the brain, constituting the ‘sensations,’ and also determined in the past by the external world.” This may be a useful model in the exploration of the ontogeny of acquired characters expressed in disease leading to the “suspicion” of a more general “mnemic property.”<sup>28</sup>

This “property” may explain a kind of DNA tattoo: methylation. This chemical alteration turns off genes, one of many epigenetic signals or chemical changes to DNA and its associated proteins that modify gene activity without altering the genetic information in the genes. Methylation, which may lead to cancer, is a kind of long-term memory, preserving detectable environmental effects on genes long after the environmental exposures themselves can no longer be detected, potentially a tool of exposome research.

Exploration of this and other processes are being pioneered by the Sbarro Health Research Organization in an unique way. Seeds - young scientists in modern laboratories - are being planted throughout Italy by Professor Antonio Giordano and his colleagues. This is justly done in the regions where the fruit of this ancient tradition was first grown and gathered. This initiative in inventive molecular biological research – a pathway for future biomedical research - ought to be duplicated directly by the people of all nations, and indirectly through national budgets. It is a bi-national demonstration of how to meet our fundamental shared need, to protect life itself.

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<sup>24</sup> Galen, op. cit., note 2, I viii.

<sup>25</sup> Ibid, I iv.

<sup>26</sup> Rignano E. *Essays in Scientific Synthesis*, Chicago: Open Court (1918) 5.

<sup>27</sup> Ibid, p10.

<sup>28</sup> Ibid, p21.