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pro bono humani generis

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Dr. David J. Galas ↙
Department of Energy
Washington DC 20585

Dear David

Thank you for sending me "Biotechnology for the 21st Century", and for inviting my comment. I apologize, I had a very heavy travel schedule just now and could not get my comments back to you in time.

The report is excellent, and I have very few comments to make beyond that. It certainly is an accurate representation of the importance of biotechnology for the public benefit, and for the national economy in particular. It is also a field where the contributions of academic research have flowed promptly and efficiently into practical application. Seeing that the foundations are well-maintained is crucial. I can think of no field that needs *less* fixing to assure the interconnections!

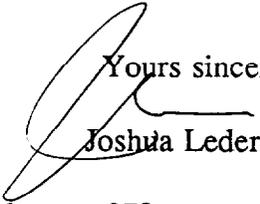
There are more general issues, going far beyond the budget, about measures to assure continued encouragement of investment. For example a higher tax on short-term capital gains, coupled with, say a ten year declining scale for longer term would help stem the flow of funds into speculative takeovers in favor of the longer term commitment needed to encourage the really exciting innovations in the field. But I know such domains of policy were beyond the purview of your committee.

Your priority ordering was just right; it needs to include more coordination between, e.g. HHS and AID to allow for the most effective amelioration of global health problems. The "environment" section could have used more emphasis on mechanistic understanding of toxicity (mutagenesis, etc) as the underpinning of remediation, and of risk-based policy analysis.

The reference to manufacturing is confusing. The government does not need to intervene in proprietary manufacturing technology for the production of salable products of biotechnology: that is entirely the province of private enterprise. And a close reading of text shows it is not inconsistent with that doctrine.

The industry does need help in the "drug validation" process, viz. its relationships with FDA. Most importantly, the staffing of FDA needs to be enlarged and enhanced, to enable clearer and prompter surveillance of NDA's. In related vein, the criteria and procedures of validation need to be rationalized and made thoroughly clear to prevent the tragic and costly

late stage failures and postponements that have bedevilled the industry. I am not suggesting any relaxation of objectives in what is obviously needed to protect public health.


Yours sincerely,
Joshua Lederberg

PS Can you give me a reference for the picture of bugs eating coal: page 27?