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The Next Decade: A Shifting Focus*

Henry Spira

Animal Rights International

This World Congress represents a sea change, a turn toward the practical -and the do-able. An added dimension is the focus on public policy, that is, developing optimal scenarios for regulatory agencies to accept viable alternatives as replacements for traditional animal tests. Congratulations to Alan Goldberg for bringing together global representatives from the corporate, regulatory, scientific, academic, high tech, and activist sectors, and for providing an environment conducive to sharing information and ideas.

This World Congress builds on earlier initiatives that legitimized and institutionalized the concept of alternatives. This mainstreaming of alternatives has already led, according to Dr. Andrew Rowan of Tufts University, to an estimated 38-50% reduction in animal use over the past decade. Major corporations such as Avon, Bristol-Myers Squibb, Colgate, Hoffman-LaRoche, Johnson & Johnson, L'Oreal, Mobil, Procter & Gamble, and Unilever are using *in vitro* systems for their inhouse research and development (R&D) and questioning routine traditional practices. The corporate sector, bioresearch entrepreneurs, and regulators are realizing the great promise in alternatives: that they are faster, cheaper, and more predictive. And now the focus is evolving from R&D to closures with timetables.

Enormous strides have been made in the new discipline of *in vitro* toxicology, but this success remains to be translated into regulatory policy decisions. Until recently, alternatives evolved in a regulatory vacuum, without the necessary involvement of the global regulatory sector, from the ground up. A workshop on alternatives to eye irritation testing sponsored by the Interagency Regulatory Alternatives Group (IRAG) and this Congress spotlights the increasing involvement of the regulatory community with alternatives.

The European Community recognizes that the validation of potential alternatives is the key to their application and use; Accordingly, they have established the European Center for the Validation of Alternative Methods (ECVAM) in Ispra, Italy, to coordinate the validation of alternatives. ECVAM, guided by Dr. Michael Balls, is becoming a center for information exchange, promoting dialogue among legislators, industry, scientists, consumer and animal advocates. Global commerce makes international harmonization crucial.

With their recent congressional mandate to implement alternatives, U.S. regulators and the National Institute for Environmental Health Sciences are also moving forward in joint efforts with both industry and the international regulatory community.

After a decade of brilliant science, now there is a need for aggressive implementation and global regulatory harmonization. And we must maintain the momentum and the energy that reduced the use of lab animals by as much as 50%. This massive reduction was made possible by the "three R's," methods, which Replace the use of animals, Reduce the number of animals used, or Refine procedures to reduce pain and distress; and by the "zero based" concept, which calls for all animal research/testing/ education programs to be re-examined from ground zero, so as not to repeat mindlessly tomorrow what was done yesterday. This is already being done by forward-looking researchers and it needs to become the norm throughout the corporate, academic, and governmental sectors.

The ability to be flexible and adapt to emerging and changing circumstances is what has made the difference to date. It should continue to make the difference in the future.

This World Congress has been dedicated to Gerhard Zbinden. We can pay no greater homage to this sensitive and brilliant scientist than to complete what he pioneered. It seems to me that to realize Gerhard Zbinden's vision we need clear goals, and blueprints with timeframes and benchmarks. In addition there must be an incentive. We must be as motivated about implementation as we have been about R&D. One of the motivations in this instance is to make our lives worthwhile. All of us want our lives to amount to more than consuming resources and generating garbage. All of us want to be able to look back and know that we have been able to help enhance the lives of others: to reduce substantially the pain and suffering of our fellow inhabitants.

*** Text of a speech to the World Congress on Alternatives and Animal Use in the Life Sciences: Education, Research and Testing. Nov. 14-19, 1994, Baltimore, MD.**

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