INVESTIGATOR PERSPECTIVE

Ronald Atlas, Ph.D., **Professor of Arts and Sciences, Department of Biology, University of Louisville**

The topic of personnel reliability and developing the culture of responsibility is extremely difficult and it is not failsafe. A layered approach will be necessary to try and achieve the security of potentially dangerous pathogens, as well as potential dual use or dangerous knowledge that may be generated from research.

Ultimately it comes down to "who do you trust." We have numerous examples in other fields where trusted individuals have misled us and after a period of time have been exposed, whether it was in the financial area or researchers who have falsified data and later been discovered and had to retract publications. There are those other areas where we see a number of years often of trusting an individual, of following them to various ends, only to later discover by various means that we should not have trusted them.

Let me suggest that when we talk about government oversight of personnel reliability and various mandated systems which are not being recommended by the NSABB, they have tended to be entry point oversight mechanisms, hiring practices. Do we trust the individual the day they begin in the laboratory? I would suggest this is not really the point often of concern. It tends to be a longer term concern and, therefore, requires continuous monitoring and guidance at multiple levels. Within the laboratory, the principal investigator must set a standard, must be the observer, must be the ears to listen to what is going on and to observe what's going on in the laboratory, and exercise a policy of zero tolerance. Particularly when it comes to select agents where there are legal requirements regarding biosecurity there can be no exceptions or variations.

Now, that in itself represents a problem, because not all PIs--in fact, maybe most PIs--do not agree with all the security requirements that have been imposed around select agents. Particularly when it comes to some of the inspections and the requirements of various agencies, questions always arise: why do I have to do this, why am I auditing this, why am I counting this. It doesn't make any sense to me. Whether or not it makes sense to the principal investigator, when it's a legal requirement there can be zero tolerance. There are severe penalties for the investigators and for the institutions that have to be taken into account. And that is problematic when the person who is carrying out the compliance does not agree with the measures to which they are being held accountable.

In other areas, either individuals within the laboratory or the principal investigator may detect a problem and the question is who do they turn to? Who are the leaders within the institution, not only who are charged with implementation of various policies, but who can actually help? The National Academies looked at this issue of personnel reliability. They found that institutions worked best when they had true ombudsmen, individuals you could turn to who knew how to handle specific issues, whether they were financial issues that individuals within the lab might face or mental health issues or alcohol or drug abuse issues that might arise; such individuals knew how to help the individuals and to move things forward where, in fact, security and safety could be ensured.

In my former life as a graduate dean I often had individuals come and say, "This graduate student is having problems. They are mental health problems. They are financial problems." And knowing where to turn to gain the help, which sometimes meant bringing in true professionals from outside, was in fact the critical path to resolving those issues. I have seen too many of my colleagues faced with problems who raise their hands and say, "I don't know what to do about that," so they turned a blind eye to it and

that does not, in fact, help at all.

Certainly, in this multilayered approach, the responsible official and the biosafety officer are absolutely critical for select agent oversight. I think it is easier actually when we talk about select agents and personnel reliability and biosecurity because there are legal requirements. There are mandates. When we get to the broader term "culture of responsibility" referring to dual usage where we're talking about the security of knowledge that's generated within the laboratory, it's much more difficult to define, much broader, and I think we have a long way to go before we really know what to do about that.

There are some institutions that offer excellent training and exercises for raising awareness of dual use issues, but in the end that is more nebulous and more difficult. Where there is clear buy-in to the rules and regulations, where they are clearly defined, where you can have layers of responsible oversight, it becomes easier.

But, as I said at the onset, ultimately it is not failsafe and it requires multiple eyes and it requires multiple places to be able to go with the knowledge of what to do with the information and the concerns that are being raised.