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**FEDERAL DEMONSTRATION PARTNERSHIP
FACULTY PANEL ON COUPLING AND DECOUPLING RESEARCH:
Friday, December 4, 1998
Orlando, Florida**

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Presentation by Susan Braunhut, University of Massachusetts at Lowell, Chair of the Faculty Committee.

CHAIR SIEGEL: I'd like to welcome Susan Braunhut, University of Massachusetts at Lowell, Chair of the Faculty Committee.

MS. BRAUNHUT: Thank you Barbara. We are already implementing new aspects of faculty participation. We've decided we're going to implement a regular faculty break-out lunch for the first day of FDP meetings. This worked well for the September meeting of the Steering Committee, and the intention is so that faculty can then participate in all the afternoon working group meetings. For all faculty, I encourage you to join these lunches.

I'm also pleased to note that at this FDP meeting we have the introduction of mixed working group panels with faculty representation - the cost-sharing panel included Carol Lietdke, who did an excellent job representing the faculty. Faculty participation in work groups will strengthen our faculty base, help identify interest and expertise within particular work groups, and will contribute I'm sure in a substantive way to these work groups.

Today our faculty panel will focus on the single theme or topic of "Coupling and Decoupling of Education and Research." Later at our faculty break-out lunch we're inviting federal agency representatives to meet with us to identify and talk about funding issues - and we've generously agreed to let them eat, too! This also will become a regular feature of future FDP meetings - faculty having an opportunity to meet and talk to federal agency representatives. (Shows viewgraph number 1 - Fig. 1 - "New Aspects of Faculty Participation")(Attachment 1 to this appendix, p. A-79).

And now I'd like to introduce our faculty panel: John Hildebrand, Professor of Neurobiology at the University of Arizona, who will talk from the perspective of undergraduate education; Robin Leach, Associate Professor of Cellular and Structural Biology, University of Texas Health Science Center at San Antonio, who will address graduate education issues; bob Decker, Associate Dean for Research and Graduate Studies at Northwestern University Medical School who will talk on medical education; and finally Steve Dahms, Professor of Chemistry at San Diego State, who will let us know what lies ahead for graduates in the life sciences.

I'd like to begin our panel discussion with a few remarks about what I call the "black box of academic research." My second viewgraph, Fig. 2, "Black Box of Academic Research"(attachment 2, p. A-80)is a schematic prototype box showing all the personnel who work within the typical lab: the PI shown here coordinates the efforts of professional staff, postdocs, and teaching/research assistants. The PI is also able to draw upon other external expertise and support staff represented schematically outside the box. This picture shows the productivity stream out of the lab measured as: the graduate, patents, and publications.

Each figure in the schematic shown represents a position within the laboratory, which might actually be filled by between one and ten individuals holding that type of position within a typical research lab.

In the middle of the black box schematically drawn is a lab bench. Across the bench from the PI, post-doc and technical staff are shown three figures representing medical students, teaching assistants, and research assistants. These individuals represent a part of the work force that is uncompensated by the funded grant yet contribute to the research endeavor. They are supported through the institution by indirect cost allocations. They also represent an overlap in the conduct of research with educational instruction, mentoring, and training. This will be discussed further by this panel.

Many institutions have different ways of filling these positions of teaching and research assistants, but in the laboratory, they're contributing to the research endeavor in a simultaneous moment in which they're obtaining training.

Now, these individuals are what we'd consider the unpaid voluntary or volunteer component of a laboratory. These people are during either part or all of their career working in a laboratory being supported by federal funds but are themselves unpaid by the grant. Their effort and output, as we'll discuss in a minute, has clear benefit to the grant-supported research program that is on-going in this laboratory because as will be evident through our discussion, anyone connected with a laboratory engages in activity that is ultimately going to benefit the output of the grant-supported work.

Why? Because the research a PI is conducting, whether it's multiple-funded supported all has as a central theme work that reflects the interests the PI is supported to research. So to satisfy those goals that the PI has on their grants there's not one individual working in this laboratory who is not contributing in some way to the research program. At the same time, you cannot uncouple - and we'll hear more evidence of this - teaching from the activity of that research.

I have indicated by the arrows on the schematic the flow of what I call "instruction" and that is occurring while exercising research activity within the laboratory. For example, shown by this arrow, the PI is instructing all of the teaching and research associates.

There is cross-pollination between the post-doctoral fellow and the principal investigator. The main post-doctoral fellow is usually someone who has been funded by the research proposal to bring some expertise into the laboratory. So there is cross-teaching that goes on between the post-doctoral fellow and the principal investigator.

And then there is professional staff that is being trained by the PI. The post-doctoral fellow and the professional staff are also participating in a teaching component as they instruct the teaching, and research assistants and medical students how do conduct research.

So the instructional component is very strong in the research environment, but the impact of the teaching and mentoring going on will ultimately benefit the funded research.

Now, before I turn this over to John, let me just mention two questions that we're attempting to deal with and grapple with the faculty at this meeting. First of all, who is funded on a grant and who contributes to the grant? What is the educational component, and really the question for us is, can you separate those two things?

In light of the presentations yesterday, I also wanted to point out that frequently, the teaching and research assistants are being supported, at least for part of their time, by the very indirect costs that are

coming into the institution. If their uncompensated effort was named in a grant application as cost-sharing it's being accounted for in the proposed research support which would in turn lower the indirect costs to the institution. If this happens these volunteer uncompensated people will disappear from our schematic because that support will no longer be coming to the institution and the number of teaching assistants and research assistants will shrink.

In light of our discussion yesterday, that's something that the faculty is trying to grapple with, how acknowledging uncompensated efforts, volunteer effort, a major contribution to the grant output, will lead to a decrease in the support for that research component/contribution.

This is the last thing I'm going to say, but I wanted to address this last separate issue -- the faculty have been hearing a lot about output, and what I've been hearing is that these items on the right: publications, disclosures, and graduates of a lab will be used as potential measures of output when a grant or program has completed. (Shows Fig. 2 again, "Black Box of Academic Research") (Attachment 2, p. A-80).

What I would like to point out is that in dealing with the faculty these are perceived as very short-term indicators. I would recommend for publications, if you looked later, what you might expect to see is invited symposia and increased citations as a true indicator of the impact of the research completed, a year or two after the grant is concluded.

Even later, real indicators of what the value of that research program has been might be something like the development of a new avenue of research, a spawning of a new field.

With regard to patent disclosures, you should consider monitoring whether or not patents materialized. And later, licensing and actual applications of the invention. That is the only way you can really assess that stream of outcome and its value. And lastly, with regard to graduates, you would like to see them move into either post-doctoral positions, into clinician scientist positions, into industry, assistant professor positions, and eventually you'd like to see the creation of a new lab or black box, as shown here.

So the long-term impact of these outcomes are really much more far-reaching than I think we've heard them discussed. Now with that, I'd like to conclude with this diagram. (Shows Fig. 3.) (Attachment 3, p. A-81) This is one of the major things that has concerned the faculty given our discussions of yesterday. How is it that uncompensated effort, voluntary cost-sharing and other activities that faculty participate in, use, et cetera, how is it that these contributed efforts are lowering negotiated indirect costs at our institutions?

We see this precisely as illustration, as a paradox. It is counter-intuitive to us and simply underscores the principle that research cannot be fit into formulas designed for business; that this is just plain puzzling to us as represented by the question mark on the diagram shown.

Now I'd like to introduce my panel. (Shows

Fig. 4 "List of panelists" (Attachment 4, p. A-82). John Hildebrand is going to talk first about the contributions of undergraduates and also some of the dilemmas he has faced with the role of undergraduates in laboratories. This model represents a large fraction of labs supervised by the faculty. Robin Leach is going to discuss the role of graduate students and the contribution of graduate students to research. Bob Decker will discuss the uncompensated contribution of medical students and residents to research. And then finally, Steve Dahms will discuss with us where these newly-trained scientists are going to end up in the new millennium. What will they do and what are the prospects for their future.

Presentation by Bob Decker, Associate Dean for Research and Graduate Studies at Northwestern University Medical School

I'm going to give you a private university perspective. I'm going to give it to you from a position of the fact that I spend my time between administration and the laboratory. Presumably 75 percent is associated with research and 25% is as a faculty faculty member. The only problem is when I count my hours - there's no such thing as a 75 percent job; there's no such thing as a 25 percent job.

I want to talk about what goes on in my lab and the relationships between what I do in my laboratory vis-a-vis how these people are supported by the institution, by the medical school, and by my funding agencies. Presently I'm funded by NIH and by the American Heart Association.

My laboratory is composed of what I consider to be an interesting cross-section of people. Now, I'm at a medical school that's 15 miles away from our major institution, but I act as a PI in this laboratory and I get part of my funding, a certain percentage of it, from NIH, which reflects the percentage effort that I put down on my grant.

At Northwestern, we do a dollar-per-hour payment for research, so whatever percent of time I put toward research is paid for by the NIH in this particular instance. The American Heart Association is just now beginning to allow funding off of _____ salaries. So my 25 percent comes off my grant; my 75 percent comes out of the institution as a research PI.

Now, I have a senior research associate in my laboratory who's the principal director of the lab, for obvious reasons, and she is funded from AHA and from NIH and her time is proportioned based upon her effort for each of these grant activities.

I have an NIH-supported research technician who spends 100 percent of her time on the NIH-funded grant. I have a Russian Fellow in my laboratory who's been in my laboratory two years. I don't know where his rubles come from, but they don't come from Northwestern and they don't come from the United States. He's funded by some extraneous source of dollars.

But he is functioning in a training environment to learn how to do research in the United States. And his research effort is posted on the NIH grant. He has a specific line in my research grant.

I have an NRSA post-doctoral fellow in my lab who's funded by NIH. He's funded for a project that isn't directly related to my own NIH grant, but is a _____.

This past year, I had a graduate student who just came into the lab. That graduate student, I think -- well, his first 18 months is supported by a complicated formula from the university and the medical school. Once this particular individual acquires Ph.D. candidacy, it will be incumbent upon me to find resources to support him. That individual will probably be supported by my NIH grant.

This past year, I've had a medical student in my lab. This medical student is required by our specifications for degree to spend six months in a research laboratory doing research. This activity is a training and education component, yet this individual is doing research. It is required by my university that a student spend six months in the lab. This is part of the degree requirements.

They've got to do research, but defining it or coupling it or decoupling it from a training, a mentoring, or

an educational perspective is difficult to do. We feel it's absolutely crucial for medical students to spend time in a biomedical research lab because we want them to know how the therapies and the interventions they ultimately use on patients are developed.

We feel it's a crucial part for them to treat a diabetic, for example, in the 21st century where they're going to have to know something about gene therapy, for example.

I also have an undergraduate in my laboratory which is not typically -- not typically what one would find in a medical school, but we get more and more undergraduates coming down to spend time in the summer. I had a student who came down. This student was funded by the university as well as the medical school.

That student will be back in next summer. The student turned out to be an exceptional student. She's bright, she works hard. She probably works more hours than John. These people are indispensable to the laboratory.

Lastly, I have a resident in my lab and graduate medical education, more and more frequently, is asking residents to spend time doing research, once again to reinforce their medical education to make them better physicians. In this particular instance, that resident was supported by a hospital in our partnership.

So I have nine people in my laboratory coming and going at various times for a year. Of those nine people, probably 40 to 50 percent of their salary is donated, quote-unquote, by various components of the medical center and Northwestern University. However, all of the expenses that these people incur in their training and mentoring is coming right out of my pocket, and that means it's coming out of my NIH dollars and it's coming out of my American Heart Association dollars to do research.

I can't train these people. Okay? I can't educate them or mentor them unless I have things to do it with. These things are the consumable supplies that a researcher does research with. So to try to couple or uncouple the two is virtually impossible.

And so, when it comes down to that particular point in time that I have to fill out my time and effort report and have to define exactly what I'm doing, it's particularly difficult to do. Furthermore, what I'm saying is that if you look at this teeter-totter that Susan's going to put up and show you first, I can tell you that 40 percent of what I do in the laboratory is donated cost-sharing, if you want to use that term, or voluntary cost-sharing.

It's my plea to all of you, and this is particularly true to the agencies and the federal government, that they're getting a tremendous bang for their buck. We do far more research, we make far more discoveries on the limited budget that we get from our funding agencies because these people are always available.

I want to reiterate what John Hildebrand had to say and what Robin Leach had to say and that is that young people have tremendous ideas. They're willing to say things that we might not normally or ordinarily say or do.

Students aren't encumbered by that kind of knowledge or that bias, and as a result, I listen to students very, very closely because in actuality, students break the ice. It's a two-way street and I think that that's something that everyone needs to know.

Presentation by Steve Dahms, Professor of Chemistry at San Diego State

A presentation was made on the nature of graduate student-based university research and research-training programs and challenges facing the placement of future PhD's in the life sciences, relative to the recent National Academy of Sciences report, "Trends in the Early Careers of Life Scientists" and as alluded to in the September formal Congressional report (Representative Ehler) on US science policy. The nature of the bioscience industry was discussed, specifically regarding employment of future life scientists at the PhD and MS levels. The possible effect of both: 1) the doubling of the NIH budget on the production numbers of future scientists and 2) the anticipated consolidations of biotechnology companies on the nation's biotechnology industry workforce were discussed, as well as their combined effect on employability of future life science PhD's in industry. It is suggested that graduate PhD training be less coupled to basic research funding in lieu of more amplified dependency on professional PhD-level research associates. A demonstration project under the Federal Demonstration Partnership was proposed.

Data from the recent National Academy of Sciences (NAS) report was presented. The time to PhD degree for life scientists is currently 8.5 years (for reference purposes, 6.5 years biochemistry and 6.4 years for chemistry). The average age of a person now completing a life science PhD is 31.5 years and the corresponding age for placement into an academic position is ~37 years. 20 years ago, 40% of PhD's in the life sciences went into academic positions in PhD institutions, as compared to 20% in 1995. Importantly, the numbers of PhD's entering the bioscience industry in recent years has been lower than expected, and in fact the NAS report shows a reduction in numbers entering the industry 5-6 years after the PhD (a 25% reduction over the 1989-95 period). The NAS report provides an initial indication that justification of new PhD programs in the life sciences based upon the needs of the bioscience industry is ill-advised. Significantly, the trends reported in the NAS report are based upon entry of PhD's into industry in general, without regard to the exact specification of whether it refers to the biotechnology, medical device, pharmaceutical, other sub-categories, or even peripherally-related industries.

Similar to the NAS COSEPUP/Griffiths report of 1995 and the Ehlers report, it is suggested by the NAS report that in many cases the horizons of PhD students be expanded to include "alternate careers", including expansion of their repertoire into some aspects of business relatedness .

The nature of the biotechnology industry was discussed, with particular reference to the fact that it generically represents a melange of overlapping endeavors covering the biopharmaceutical, agricultural, environmental, bioprocessing and even aspects of the pharmaceutical industry. The biotech, pharmaceutical and medical device industries were contrasted.

With over 1300 companies, \$20b in revenues, \$4.1b loss in 1997, 160,000 employees, a \$100b market cap and about 100 products, the biotechnology industry is in the shadow of the pharmaceutical industry with 75 major companies, 260,000 employees, \$400b market cap, and \$31b in projected 1998 profits. The entire biotechnology industry is about the size of Merck, a profitable company which has \$20b in revenues and a \$126b market cap. The size scope and scale of the biotechnology industry was covered, as well as the number of proto-products under development, currently ~1100. The hope is that about 140 of these proto-products will break out into commercialization in the next 3-6 years.

The 1500 company, \$200b market cap medical device industry with \$65b in revenues and a \$4b R&D budget has 310,000 employees but it is expected to contract with loss of ~50,000 employees off-shore, although expansions of the industry can be expected in certain hot-spot regions of the U.S.

The biotechnology industry is the most regulated industry in the world and biotech drug development is

a 10-14 year process, costing \$450m-\$700m. Last year only ten of the top 30 biotech companies were profitable, but this is up from seven the year before. Although the industry is operating at a loss, the loss of \$4.1b in 1997 was 9% less than the previous year. In the first half of 1998, the top 30 biotech companies had a net profit of \$600m, a 57% increase from the previous period in 1997. For reference purposes, it was pointed out that the earnings of the pharmaceutical industry is growing at about 18% a year. The current product pipeline was discussed and that 42% of all biotech companies are focusing on human therapeutics.

The R&D budget of the biotech industry is over 50% of their revenues (\$10b R&D) vs. the \$13b R&D budget of the 4-fold greater market cap U.S. pharmaceutical industry. The current forces driving the industry movement towards consolidation, mergers, and acquisitions were discussed and that the ~1300 companies must "reassemble" into ~700 companies in order to attract funding from the capital markets, which notably do not find companies attractive unless their market cap is over \$500m; comparatively, the average market cap of a U.S. biotechnology company is currently under \$100m, making capital acquisition in our current environment extraordinarily difficult. The relationships between the pharmaceutical industry and the biotech industry were discussed, in particular the fact the former consumes companies and technologies from the latter with its annual \$30b war chest.

The nature of the current workforce was discussed, with prospects for its growth over the next 12 years with an average growth rate of 9%, resulting in a workforce of over 500,000 in 2010. Currently the workforce has the following characteristics: 70% technical with 50% BS, 17% MS, 19% PhD, and 14% pre-baccalaureate. Growth in the workforce in the past two years were 19 and 14% respectively. The projected annual 9% growth rate over the next decade may be conservative relative to the number of proto-products in the industry and its head-over-heels movement from research boutiques into production and manufacturing. On the other hand, the impacts on capital market-induced consolidation of the ~1300 biotechnology companies into ~700 on the ultimate size of the 2010 workforce is totally unknown, as was discussed last week in Washington at the Council of Biotechnology Centers Board of Directors meeting with the Biotechnology Industry Organization leadership. Regardless, graduate training activities of U.S. universities should take into account the needs of the biotechnology industry as it transitions not only into profitability, but also into a greater dependency of a workforce in the applied sector. Notably, the 1995 COSEPUP report showed that 65% of chemistry PhD's entered "industry" in 1991, in contrast to ~20% for life scientists. Some view the possibility that in 2020, the entry of life science PhD's into "industry" may reflect that of the chemistry PhD in 1991 (i.e., an increase from ~20% to a level of ~65%), and if this is indeed a possibility, then the degree to which this transition is successful may be dependent upon the focus and special nature of their graduate training beyond their basic research experiences. It is not clear that graduate life science PhD training programs understand these dynamics.

Of course, although the number of biotechnology companies has been in steady state over the past three years, it can be argued that completion of the various genome projects will uncover so many new drug and device targets, that the industry will expand in size. Another unknown in the quadratic calculus of workforce analysis and projections.

There is an intimate relationship between the U.S. basic biomedical and related life science research budget and the numbers of graduate PhD scientists produced annually. The U.S. scientific basic research enterprise in all universities is largely dependent upon and associated with the training of PhD graduate students. This Yin and Yang relationship has served U.S. science extraordinarily well in the past-Sputnik area. Importantly, the doubling of the NIH budget over the next five years and Varmus's intent to increase new and competing grants will certainly result in an increase in the annual production of PhD life scientists due to the long associated coupling of PhD production to basic research funding, in particular R01 funding. The biotechnology industry is facing contrasting, diametrically opposing

situations: capital market forces leading towards potential workforce reduction and on the other hand new product approvals by the FDA leading to commercialization and manufacturing, resulting in needs for an expanded and perhaps slightly different graduate workforce. The ability of the industry to handle the current production of graduate life scientists is uncertain, but clearly the industry's ability to handle the increased numbers of graduate PhD's associated with doubling of the NIH budget is problematical.

It is suggested that graduate PhD student training should be uncoupled or less coupled to NIH basic research expansion. Perhaps it is time to consider a change in the nature of our basic research enterprise, with an emphasis on producing PhD-level, permanent career-tracked research associates to conduct the expanded NIH agenda, rather than employing and relying so exclusively upon PhD graduate students as in the past. It is proposed that a Federal demonstration project may be warranted, one that evaluates reliance upon permanent PhD research associates rather than graduate students. It would be a different type of demonstration project and a longer term project, but a necessary one. The bottom line is that such an approach would rather innocuously reduce the number of PhD's produced, while creating additional career slots for existing and future, new life science PhD's, without compromising the nation's basic research enterprise that has, especially evident in the case of the biotechnology industry, been so extraordinarily productive. We will revisit this matter at the June FDP Committee of the Whole meeting in DC. Most certainly it will be a topic of discussion amongst the Council of Biotechnology Centers/BIO in the next six months, comprising 105 biotechnology centers which stride the industry-academic interface of which over 75% are academically-based and most of which are associated with PhD institutions.

Faculty Panel "Issues" Document

1] The Faculty strongly recommends that academic and medical research outcomes not be measured by short term indicators. It is the view of the faculty that accurate measures of the impact of a particular research project at its conclusion may have a latency of 20 years or more. As an example, it has been suggested that indicators of a research project could be 1] the number of resulting publications, 2] the number of graduate students trained in the laboratory and/ or 3] the number of patent disclosures resulting from the research project. It is the assertion of the Faculty that these indicators may or may not accurately reflect the value of the research conducted. Taking each of the above measurement tools and applying a longer range view, the numbers of publications could instead be the number of citations of the published work and even later, an assessment of whether a new field or discipline developed from the initial publication(s). This may prove to be a more accurate reflection of the value of the work. In support of this contention, examples abound where a single publication has had a profound influence on science for years to come. The short term indicator of number of patent disclosures would, in keeping with this view, convert to the long term indicator of actual licensing agreements, and still later, the realization of a new tool, application, drug, or therapy, etc in science or medicine. Lastly, the short term indicator of number of graduates would, in this model, convert to an assessment of the fate of these graduates. The career progress of these individuals to become Postdoctoral Fellows, Clinical Scientists, Assistant Professors and to create their own new independent research programs could be a more accurate appraisal of the quality of the training they received during the grant period.

The latency of the impact of scientific research may not permit accurate assessment at the conclusion of the grant period.

2] In medical and academic research laboratories around the country, when a principal investigator is discussing research experiments to be performed with a Postdoctoral Fellow, medical student, teaching or research assistant in that laboratory, in that simultaneous moment, the PI is conducting research but

also educating a developing scientist. The conduct of science is imparted to today's young scientist within today's research lab largely by a one-on-one Socratic method. At the same moment that a young scientist is planning an experiment with their mentor which will ultimately benefit the research program by answering a scientific question, that individual is simultaneously being taught how to conduct research.

It is the assertion of the Faculty that Research and Education are inextricably coupled.

3] Within medical and academic research laboratories around the country, voluntary effort, and uncompensated effort is expended by personnel at many levels. One primary example is that effort exerted by medical students, teaching and research assistants active within the laboratories. These individuals conduct research, which benefits the grant program, yet they are supported by the institution, usually by institutional indirect cost allocations. The justification for this expenditure on the part of the institution is in part due to the view that these individuals are simultaneously being trained or educated in the conduct of research (see point 2 above). This is a part of the mandate of the instructional institution. the dilemma that faces us now however is that uncompensated effort reporting would have a negative impact on the negotiated indirect cost. It is the assertion of the Faculty that the institution, the research and the teaching endeavor would be negatively impacted by allowing this to happen.

Donated/gifted, voluntary or uncompensated effort should not impact on indirect cost negotiations in a negative way.