U. S. Ocean Commission on Ocean Policy

Marine Biotechnology Panel

Date: **April 18, 2002**

Region: **Southwest (San Pedro, California)**

Distinguished Commissioners, Fellow Panel Members, and Fellow Citizens:

Thank you for allowing me the opportunity to present my experience and recommendations to the commission. My perspective relative to the charges presented to the Commission in the Oceans Act of January, 2000, is that of marine biotechnology small business owner and aquatic-systems innovator. I worked in the field of oceanography for 8 years, and then in aquaculture for almost 30 years, designing and implementing high-yield closed-systems, and pond culture systems for fish, shrimp and also ecological sewage treatment. For the past 11 years I have managed CalBioMarine Technologies, Inc., which was founded on the question posed by a pharmaceutical company executive: "is it's possible to grow drugs-from-the sea?" Our business concept is to apply modern aquaculture and bioprocess techniques, together with knowledge of the life cycles of marine invertebrates and marine algae to high-yield culture for eventual extraction of desired bioactive chemical constituents.

Given the high-risk nature of our business concept, and the relatively long-term projections for returns on investment, we were unable to obtain private venture funding to seed the company's growth. For proof of concept funding we turned to the U.S. Government's Small Business Innovation Research (SBIR) programs. Our initial SBIR contract was funded in 1990 by Dr. Newman's division at the National Cancer Institute to develop mariculture systems for production of the Pacific coast colonial bryozoan *Bugula neritina* (see slide #1), the source of the promising anticancer compound bryostatin 1. Bryostatin 1 was at that time just entering human clinical development sponsored by the NCI. The Phase I project was successful in that it proved the feasibility of the concept, and a 2-year Phase II contract was awarded to scale-up the tank-based component of the process (slide #2). A companion 2-year contract with the DOC /NCRI allowed us to test a prototype of an in-sea growout module (slide #3). The in-sea growout proved highly successful, in that commercially-viable yields of bryozoan biomass and drug compound were obtained in multiple growout trials (slide #4).

This *Bugula neritina*/bryostatin mariculture technology should (hopefully) be adopted for commercial scale-up in approximately 2 years by the pharmaceutical company that has partnered with the NCI to completing the human clinical trials. The eventual market for the drug has been conservatively estimated to be in the half-billion dollar per year range. A supply contract for CalBioMarine, coupled with a residual royalty on drug sales would provide for a significant return on the government's and the company's investments in the development of the process — albeit after more than 10 years of process development and clinical trials of the drug.

Standing in the path of commercialization of this and other similar ocean-dependent technologies (bio-or otherwise) are the almost insurmountable hurdles of obtaining all the necessary permits from local, state and national agencies with jurisdictions over coastal ocean environments and marine resources, and the seed funding required to launch new marine bio-businesses. Precedents for this ambitious a marine bio-business concept in California, can be found only in the few private marine fish and shellfish hatcheries which have received permits within the State. Permitting for the more than 200 individual in-sea culture components that would be required for full commercialization of this technology is unprecedented in the State of California, or in the nation at large. Expenditures of $1.0-2.0 million and from 1-2 years have been estimated to complete the permitting process alone, and over $10 million would need to be invested in capital costs to implement a commercial-scale system for economical bryostatin mariculture.

This example illustrates the inherent high-risk nature, long development times required, and some of the challenges that face current and future development of new marine biotechnology businesses that require access to our common marine resources of the United States.

Recommendations to the Commission:

Given that "Marine Bio-Medicine" R&D (and other emerging areas of marine biotechnology such as marine bio-materials, and marine-derived enzymes) are at relatively early stages of research and technology development; and, given that the United States is endowed with significant marine resources under its stewardship; and given that the U. S. does see it to be in its best national interest to become a world leader in the new and emerging field of marine biotechnology; and, given that funding, either governmental or private is difficult to obtain, and has not as yet been specifically ear-marked for R&D in marine bio-medicine and marine bio-technology, I hereby propose and suggest to the commission that a new national effort be mounted, and recommendations made to the President and to the Congress, to fund a new national program in marine biotechnology. I further suggest this program could be named the ***"Ocean Technology Partnerships"*** program, whose purpose would be to foster innovation and seed investment in new marine biotechnologies, in order to advance the nation into a world leadership position in these important and new emerging field of technology.

I have envisioned that the ***"OTP"*** program would be administered by the DOC/NOAA in a similar programmatic manner to the extant "Advanced Technology Program" (ATP) which is currently administered by the DOC/NIST. ***"OTPs"*** would be formed as a consortium between a small U.S.-based business (or businesses), a university (or universities), and/or a National Government laboratory group. Together the consortium would propose individual, innovative R&D projects which possess attainable commercial endpoints, for Federal funding through a 4-Phase program of research, development and eventual commercialization. As with the SBIR programs, the small business partner would be required (in the third phase) to develop a commercialization plan (Phase IV) that includes a commitment for follow-on funding from either an industrial partner or venture capital sources. The terms for award and the specific criteria would need to be customized to suit the new program overall.

To underscore the importance of this proposed initiative to the U.S. Commission on Ocean Policy's charge relative to the Oceans Act of 2000, I respectfully recommend that the commission recommends to the U. S. Congress, an amendment to the wording of the Act in Section 2, sub-section (6) to read: ***"... including investments and technologies designed to promote national energy, food security, and new marine-derived healthcare technologies."***

This ***"OTP"*** program has been envisioned as a means to address the number-one, over-riding issue for eventual commercialization of new marine biotechnologies in the U.S., namely how to fund such early-stage, and high-risk projects in order to stimulate industry to enter into this new and potentially huge new field of national endeavor. The foregoing is offered as a starting concept for discussion, and is not intended to be a completely developed proposal.

Respectfully Submitted By:

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