

Fraud in SBIR Grant Results in Civil Settlement/Voluntary Exclusion



Suspension and Debarment Workshop
October 28, 2010

Introduction



- Advanced BioNutrition Corp. (ABN)= The company
- Company dynamics= Full of conflict
- SBIR awards
 - Phase I (Proof of principle)= \$99,523
 - Phase II (Scale-up)= \$467,000
 - Incorporate live probiotic bacteria in new food products, including baby formula
 - MicroMatrix technology

Intake of Complaint



- *A qui tam*
 - False Claims Act suit
- Relator (complainant) went to USAO in Baltimore, MD
- Allegations included:
 - Misuse of money to prop up business model
 - False certification of results
- Other agencies involved in complaint (DoD, Commerce, Agriculture)

Fraud Inducement in Phase II Proposal



- Phase I final report included in Phase II proposal
- Material false statements included:
 - Number of process runs
 - Particle viability and size
 - Claims concerning “robustness,” “replication,” and “validation”
- The *Longhi v. Lithium Power Technologies, Inc.* case
 - SBIRs awarded based on company’s potential to do work
 - Fraud can occur in inducement of award
 - Irrelevant whether research is productive

Process Run Claims



- Report claimed that six full-scale process runs were completed
 - “The system was then tested and **replicated** with six full-scale process runs.”
 - “Six sequential large-scale batch runs . . . were completed, thereby establishing the **robustness** of this continuous production system.”
 - “The system was then tested and **validated** with six full-scale process runs.”
- A few definitions
 - Replication= “The repetition of an experiment in order to test the validity of its conclusion.”
 - Robustness= “Strong enough to withstand intellectual challenge.”
 - Validate= “To make or confirm the validity of.”
 - ABN defined “validation” in its work plan: “A validation series will consist of three sequential operations that provide repeatable data.”

Process Run Laboratory Data



Date of Run	Throughput Rate Times Duration	Throughput Rate	Duration	Volume
Final Report Statements				
6 replicate runs	550 kg	1 kg/min	9 hours	Full scale is 200L
Actual Laboratory Data				
Dec. 7	Ok	Ok	Ok	60L
Dec. 12	Ok	Ok	Ok	60L
Dec. 14	Ok	Ok	Ok	60L
Dec. 16	Ok	Ok	Ok	Ok
Dec. 20	Ok	Ok	Ok	Ok
Dec. 22	No data	No data	No data	Ok

Viability Data (Reported to NSF)



- Report asserted “that there was little damage to the viability of the bacteria . . .”
- Viability loss of only 42%

Time (min)	Feed Tank (x10 ⁹ cfu/gdw)	Harvest Stream (x10 ⁹ cfu/gdw)	% Recovery
0	28.0	9.2	33%
30	33.7	25.2	75%
60	35.4	20.9	59%
90	29.2	18.1	62%
Mean	31.6	18.4	58%



Data presented in Phase I final report

Viability Data (Unreported)



Comparison of Lab Notebook Data from Two Bacterial Runs

Time (min)	Viabilities: Run 4 +E9 cfu/gdw	Viabilities: Run 5 +E9 cfu/gdw
0	33	8.7
30	75	56.5
60	59	45.7
90	62	27.2
Mean	58	21.6

NSF Final Report

Unreported Run

Particle Size Data



- Report asserted "Particles from the harvest tanks (large particles and small particles) both had about the same bacterial count on a dry weight basis."

Data Presented in Final Report (From Run 4 Only)

	Viability ($\times 10^9$ cfu/gdw)
Large particles	27.1
Small particles	16.9
Recycle tank particles	1.2
Recycle tank supernatant	0.01

Comparison of Laboratory Notebook Data
from Two Bacterial Runs

	Viability $\times 10^9$ cfu/gdw	
	Run 4	Run 5
Large Particles	27.1	267
Small Particles	16.9	88.5
Tank Particles	1.2	1.96
Tank Supernatant	0.01	0.01
Ratio Large to Small	1.6	3.02

Unreported

Phase I Conclusions



Run	Objective	Replicate?	Robust?	Validate?
1	“Establish how much the alginate particle formation affects the CaCl ₂ bath ionic concentration”	N/A	N/A	N/A
2	“Repeat Experiment 1 but with constant amendment of CaCl ₂ and a higher starting concentration”	NO	NO	NO
3	“Repeat Experiment 2, but with a full CaCl ₂ bath volume . . . to establish a full scale operation and see if Cl levels rise”	NO	NO	NO
4	“Repeat Experiment 3 with a full CaCl ₂ bath volume . . . but with removal of overflow and removal of CL with ion exchange resins”	NO	NO	NO
5	“Repeat of experiment 4 with a full CaCl ₂ bath volume . . . but including bacteria at the 2% load”	NO	NO	NO
6	“Repeat experiment 5 in all its glory”	NO DATA	NO DATA	NO DATA

Metric	Veracity of Final Report Statements	Acceptable?
Viability	Data from only one run. Misleading.	NO
Particle Size		

Phase II Reviewer False Impressions



- “In Phase I, the technical and economic viability of a continuous 1 kg/min-scale process was established.” **NOT TRUE**
- “This company has presented technology that allows the stabilization of live probactic [sic] bacteria for incorporating into food.” **NOT TRUE**
- “Initial studies using a prototype manufacturing system indicated that particles of the correct size and consistency were formed, and the viability of the on-board probiotic bacteria was acceptable.” **NOT TRUE**

Phase II Fraud



- Fraud continued into Phase II (“Fraud-plus”)
- Associated with individual elements of award
 - Clean room
 - Lid for tank
 - Fermentor
- Fraudulent claims of project success
- About 50% of award funds accounted for

Plan of Work for Phase II



<i>Project Tasks</i>	3	6	9	12	15	18	Total	<i>Milestone and Metrics</i>
	Mo	Mo	Mo	Mo	Mo	Mo	Funds	
TASK 1							\$ 114 K	
Conversion to GMP							total	
1.1 install clean room								Room functional
1.2 SIP equipment fabrication								Equipment operational
1.3 monitoring system								Protocol written/tested
1.4 validate for SIP								Process validated
TASK 2								
Process Optimization								
2.1 establish process							\$ 40 K	Process functional
2.2 fractionation							\$ 30 K	Process functional
2.3 Box-Cox							\$ 42 K	Process functional
2.4 data analysis							\$ 6 K	Process functional
TASK 3							\$ 167 K	
Downstream Processing							total	
3.1 lab trials							\$ 45 K	Process functional
3.2 establish process							\$ 25 K	Process functional
3.3 design							\$ 20 K	Process functional
3.4 validate process							\$ 10 K	Process functional
3.5 costing exercise							\$ 17 K	Process functional
TASK 4								
Validation of Final Report								
4.1 finalize SOPs								Process written
4.2 validate process								Process validated
4.3 validate data logging								Data logging validated
4.4 evaluate economics							\$ 5 K	Cost <\$6/kg dw
4.5 write final report							\$ 10 K	Final Report Complete
Expenditure (\$K)	\$104	\$ 83	\$ 76	\$ 68	\$108	\$ 61	\$500 K	

Clean Room



D. EQUIPMENT (LIST ITEM AND DOLLAR AMOUNT FOR EACH ITEM EXCEEDING \$5,000.)		
Clean Room	\$	15,000
Fermentor		20,000
Lid(2)		10,000
Others (See Budget Comments Page...)		14,000
TOTAL EQUIPMENT		59,000

General Scope Of Work: Fabricate and provide an official Servicor-CPI modular cleanroom. All Servicor-CPI cleanrooms feature modular components that can be easily reconfigured, relocated or expanded. The cleanroom wall and ceiling components will be constructed of polyurethane powder painted steel.

Fax #:

General cleanroom Specifications		
Room # 1 Dimension	10' x 12' x 12'	Dim. in Ft.
Room # 1 Air Class	100,000	Hardwall Cleanroom
Room # 2 Dimension	x x	Dim. in Ft.
Room # 2 Air Class		
Room # 3 Dimension	x x	Dim. in Ft.
Room # 3 Air Class		

We hereby propose to furnish a complete system in accordance with the above quantities, specifications and notes for the sum of:

\$ 20,950.00 ↙

The prices above represent only the quantities and products listed. The issuance of a purchase order shall serve as evidence of customer's agreement with Servicor's standard terms and conditions. This quotation is based on the meets 1994 UBC requirements. Seismic Zone 4 and other special and current UBC requirements including structural calculations may require a change in standard materials and fixtures that will cause a change in our quote/invoice.



Image from DomeHouse website.
Retail Price: \$700.00

Quote for clean room.

The Actual “Clean Room”



Figure 1. Clean room housing spray-capture unit and process tank. [From September 10, 2007 Interim Report]

Lid for Tank



D. EQUIPMENT (LIST ITEM AND DOLLAR AMOUNT FOR EACH ITEM EXCEEDING \$5,000.)

Clean Room	\$	15,000	
Fermentor		20,000	
Lid(2)		10,000	
Others (See Budget Comments Page...)		14,000	
TOTAL EQUIPMENT		59,000	



→ This is a lid.

← This is plastic and duct tape.

Picture 1. Cover assemblies over the process tank (left) and harvesting system (right) including piping, nozzle system assembly and vent port filter that prevents contamination of the inside content of the tank as well as probiotic aerosol from escaping outside the tank and the harvester.

Image from January 28, 2009 Final Report

What a Subpoena Can Do



- April 6, 2008 Interim Report: "Downstream drying is very critical to the overall success of the project. . . . Having succeeded with eliminating major losses and improving viability, **we consider this task almost completed.**"
- December 19, 2008 Subpoena
- January 28, 2009 Final Report: "**This task was not accomplished to our satisfaction.** The resulting product was not completely dried [W]e feel that industrial up-scaling of this drying process might be difficult."

Subject's Role in Case



- Designed and directed Phase I process runs
- Direction continued into Phase II
- Editorial control over written materials including:
 - Phase I proposal
 - Phase I final report
 - Phase II interim reports

Case Settlement



- No admission of wrongdoing
- ABN and subject each pay \$467,000
- Relator given \$105,275
- Five-year:
 - Compliance plan for ABN
 - Voluntary exclusion for subject

Definition of Voluntary Exclusion (2 C.F.R. 180.1020)



- “[A] person’s agreement to be excluded under the terms of a settlement between the person and one or more agencies. Voluntary exclusion must have governmentwide effect.”
- Suspension and debarment are an integral part of our considerations in case processing

Why Voluntary Exclusion?



- Subject's actions were so egregious that federal government's interests had to be protected
- Subject divorced himself from company during investigation
 - Would not have been affected by settlement agreement with company
 - Had history of starting up small companies
- Subject elected a five-year voluntary exclusion during civil settlement negotiations
- Faster administrative process than debarment

Process Employed



- During course of negotiation, subject asked us our intentions regarding debarment
- We intended to recommend debarment to NSF
- Subject wanted a global settlement; Offered to agree to voluntary exclusion
- Included in settlement agreement
- Provided settlement agreement to NSF Office of General Counsel, Eric Gold
- NSF lists Subject in EPLS (many thanks Eric!!)

Take-Away Points



- Evidence presentation is key
 - Created 12 posters that were used throughout case
- Get AUSA on-board ASAP
 - Special thanks to AUSA Thomas Corcoran
 - Case was technical, but not overwhelming
- Teamwork helps get the job done
 - Special thanks to AIGI Dr. Peggy Fischer, Special Agent Brian Hess, and Investigative Analyst Nick Macedonia
 - Collaboration of different investigative skills
 - Utilize expert in science-type cases, if needed

Questions?

