

The Abell Report

What we think about, and what we'd like you to think about

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Abell Salutes: "Parent Aides Nurturing and Discovering with Adolescents" (PANDA)

Volunteers Are Helping to Break the Cycle of Child Abuse

At about 10:00 o'clock on a Wednesday morning, a young woman, Sara Walters, knocks on the door of a row house on Fremont Avenue in West Baltimore. Responding, 17-year-old Tanya Smith answers; folded in her arms is her son—one-month old Tony. Mother and son are both crying.

Sara will soon discover that each is crying for a different reason: Tony is hungry; his mother is overwhelmed—and angry. A victim of child abuse herself, she is on the edge of abusing her own child.

Sara is a volunteer for Parents Aides Nurturing and Discovering with Adolescents (PANDA). PANDA is a program created by Parents Anonymous of Maryland. It is a statewide nonprofit organization of parents, children and family care professionals who have joined together to find answers to the problems of child abuse.

Finding answers begins with questions. Sara asks Tanya, "Do you hold the baby when you feed him?"

"Sometimes I just prop the bottle in the crib."

"You have to remember that Tony is still very little. He can't call out to you if the bottle falls, or if he gets too much and he chokes. Also it's soothing and comforting to him if you hold him."

"But I get so upset with him. When he wakes up at night I'm tired. So I just prop the bottle. He's just bad and he makes me mad!"

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Maryland's New Bioprocessing Facility

Maryland Takes the First Step In a Leap of Faith; At the Far End of It Could be Ten Times the Jobs and Tax Revenues

The biotechnology industry in Maryland, according to the North Carolina Biotechnology Information Center, currently employs 4,000 and generates an estimated \$10 million in state, county and local taxes. The Maryland Department of Economic and Employment Development asserts that this could grow to 40,000 jobs and \$100 million in taxes by year 2000—if Maryland can maintain its share of the market and if sales within the industry grow 20-fold in 10 years, as anticipated by Ernst & Young in its 1990 report, "Biotech 91: The Changing Environment."

In order to reach that potential, however, Maryland must make a leap of faith: it must develop the infrastructure to foster the growth of biotechnology companies, including financial and technical assistance. One particularly important element that is needed is production or "scale-up" assistance, to help small firms move from the lab to the marketplace. Because Maryland's biotech industry is made up of companies that are young and small, their resources are limited; they are not prepared to meet the costly and complex manufacturing and marketing demands associated with anticipated growth in the industry. The consequence is that in order for these young, small Maryland companies to move their products into the market they may have to enter into joint ventures with or be acquired by larger biotechnology or pharmaceutical companies, or hire expensive contract manufacturing firms. Either case is problematic for Maryland because it results in the export of money, jobs and future revenues to companies located in other states and

limits the growth of the industry within the state.

But in June 1991, the state legislature took the first step toward that long leap of faith; it voted to fund the design of a bioprocessing plant here in Maryland.

The facility will provide Maryland's mostly small biotech companies with access to the physical manufacturing facilities they need but can't afford, and the technical expertise they have not yet developed; it will provide, too, incentive for Maryland's biotech companies to remain here and for others outside of the state to locate here.

All in all, the facility opens the door of opportunity for the state to help realize the full and bright promise of its own, fledgling biotechnology industry.

The opportunity could not come at a better time.

Maryland already has a head start on the venture; the state, through the National Institutes of Health and Johns Hopkins University, is already in the forefront of receiving federal dollars for life sciences/biotech research. In addition, Maryland is home to the Federal Drug Administration (FDA) and the University of Maryland Medical System, the two major agencies affecting the future of the biotech industry. And, according to the Ernst & Young study, Maryland ranks in the top five states in terms of number of firms, sales and employees in the industry nationwide. But the flying start Maryland enjoys grinds to a slow stop: Maryland's biotech firms are for the most part small ones; for them to grow into the size where they make a difference in the Maryland economy they

need support. That is where the bioprocessing facility recently authorized by the legislature comes in.

Why Is It Needed?

Most small-scale Maryland firms cannot afford their own scale-up facilities and may be forced to do manufacturing outside of the state, either through being acquired or joint venture, or through very costly contract manufacturing which will inhibit profitability.

A small-scale, research-oriented firm facing the need to scale up a product in sufficient quantity for FDA clinical trials is unlikely to have the capital to build its own pilot plant and will, therefore, be forced to either contract out manufacturing or sell out to out-of-state pharmaceutical companies. In such cases, the manufacturing of products based on Maryland research and the jobs and taxes that go with them are likely to go out of state. Additionally, future profits resulting from the development of these newly manufactured products will have to be shared by these other players, limiting the growth and profitability of the Maryland companies.

What Is It?

It is a 30,000 square-foot, FDA-licensed, shared-use light manufacturing facility which will make available highly specialized and controlled equipment, procedures and technical assistance. The facility is to be built in Baltimore City or Baltimore County and will offer pilot-scale manufacturing capabilities for several biotech firms at one time. Individual suites will provide confidentiality and control cross-contamination. A technical staff is available to provide a range of assistance, including guidance with product development, resource referral for business development issues, linkages and networking with other biotech companies, staff training, and assistance with a variety of FDA

regulations. It will be governed by a board of directors consisting of leaders from the public and private sectors. First preference for usage will go to Maryland firms; out-of-state firms, when space is available, will be permitted to rent space but at a higher rate than local firms.

How Much Is It Costing the State and Where Will the Money Come From to Pay For it?

The facility, which will cost \$22 million to build and equip, requires a highly specialized and regulated building of which equipment is an essential feature. The source of funds is the following:

- \$17 million from Maryland for design (\$1.5 million), construction (\$10 million) and equipment (\$5.5 million)
- \$5 million from federal and private sources for start-up costs (including FDA-required trial runs on all equipment)
- \$900,000 in donated land
- \$2 million from users and industry for annual operating costs. User fees, like space charges in an industrial incubator, would represent a subsidized rate below what the company would have to pay on the open market.

What Are the Alternatives?

Recognizing the need for such a facility, many private sector firms have attempted to capitalize on the demand but have had limited success. Because the costs of building a bioprocessing facility are exorbitant (due to stringent FDA regulations), the private sector has not been able to recoup both capital and operating costs in addition to turning a profit.

The few contract bioprocessing opportunities that are available for small companies are actually excess space and equipment in existing biotechnology manufacturing plants of larger pharmaceutical companies. Unfortunately, it is difficult to identify and schedule time at these facilities. Smaller biotech companies are often "bumped" if the host firm needs to use the

scale-up facility, and the smaller companies must often share highly proprietary information at great cost.

The Maryland Bioprocessing Facility will be unique in the country in that it will be the first nonprofit, contract manufacturing facility available exclusively to small biotech companies. Because the facility does not need to pay for capital costs or turn a profit, it will only need to charge as rent an amount needed to cover its operating costs. The only similar facility in the world is located in Montreal.

What Can Maryland (and Marylanders) Expect From It?

Initially, the facility will provide an opportunity for Maryland's emerging biotechnology firms to manufacture limited amounts of their product for testing and clinical trials. Over the longer term, the effort will provide a critical piece of a larger biotechnology infrastructure within Maryland that will help to retain, develop and attract a significant biotechnology industry into the state.

In return for its investment, the state will be retaining firms; additionally, it is likely that the facility will attract other firms from across the country and globe. If the biotech industry in Maryland can grow as anticipated, its companies will have the opportunity to produce up to \$4.5 billion in sales, 40,000 jobs and close to \$100 million in state, county and city taxes in the next decade.

How Do Entrepreneurs In the Business Feel About the New Bioprocessing Facility?

Henry Linsert is chairman of the Martek Corporation in Columbia, Maryland. His fledgling company is in the business of manufacturing oil from micro algae that provide certain key fatty acids found in breast milk and not contained in infant formula today. The potential for the company's product worldwide is highly promising.

"In this project we have had to allocate a couple of million dollars out of a budget of maybe \$5 million to scale up—and providing facilities for an economical

scale-up is what this new bioprocessing plant is all about. That is a lot of money for us to raise and spend. We require large fermenters (stainless steel 'pots' with controls used to grow microbes by fermenting them) and if we had them we would not have to go out and find the funding to build them. The difference between having the bioprocessing plant here in Maryland and our having to go out of town to avail ourselves of the facilities comes down to something like this. If a bioprocessing facility were, say, at University of Maryland Baltimore County 15 minutes away, our people could go back and forth easily. It would be convenient, more economical, and would allow us to produce in large amounts in compliance with the government's standards of good manufacturing practices sufficient to meet FDA requirements for marketing. We would be up and running faster."

Dr. M. James Barrett is president and CEO of Genetic Therapy, Inc. in Gaithersburg, Maryland. The company is still in its research and development stage but hopes to develop products for commercial use. Dr. Barrett's perspective on the value of the facility is that it lies within the state's overall and growing biotech infrastructure. "It's another but a large piece of the whole. I think if the state does a good job and gets the facility running well it is going to get decent use, and that usage is certainly helpful to those doing the using. Would Genetic Therapy as a user of the new facility stay in Maryland when and if we get a successful commercial product to market? I can't really say that just because the facility is here in Maryland that circumstance by itself would make us stay in Maryland. I will say that if it is here and meets our needs we would use it, and if that arrangement worked out well the good experience would have a positive influence on our decision to stay. The state is doing a lot for biotech companies, and we would look with strong interest at that hospitable environment."

Christopher Price is vice president of business development at Nova Pharmaceutical Corporation in Baltimore. He views the bioprocessing facility as not only keeping Maryland's biotech compa-

nies in Maryland but attracting others from out-of-state to locate in Maryland.

"Both things are going to happen, I believe, not only as a result of a combination of the bioprocessing facility's being in place here but also because of Maryland's improving biotechnology infrastructure. And among those out-of-state companies that may be interested in coming to Maryland are those in Europe and Japan as well. A recent example of how this is already happening is Otsuka Pharmaceutical, which has set up a research facility in Maryland. I think that when these companies get up and running there will be a great deal of 'value addition' occurring. There will be improvements in fermentation; there will be problems solved in purifying compounds; there will be relationships built up with biotech personnel and with other parts of the Maryland infrastructure such as packaging. All that familiarity is not likely to be abandoned. These Maryland companies are going to develop comfort levels with respect to people and service opportunities, which will act to bind them to Maryland.

"And the truth of it is, Maryland's facility will have no competition. Arkansas and New Jersey have tried to do it, but failed. We in Maryland are alone, unique. For Maryland, the way is wide open."

What Are the Problems? What Do the Program's Critics Say?

In the euphoria, there are concerns. Linger- ing questions remain.

Is the program welfare dressed up for the rich—as some of the program's detractors would have it? Does it take monies that might be used for the poor and the disadvantaged and use it to finance the rich? If a business cannot make it on its own in the very same free market that business clamors for, why should public money rescue private enterprise?

An answer is that effective and efficient efforts that promise to create jobs within a community are in fact helping every sector of the community.

A more pressing question, and one that would appear to be more easily answered, is the fragility of the program's objective: if in fact the program is being set

up to grow small companies into big ones in the hope that they will remain in Maryland as a payback, what assurances are there that the recipients will in fact carry out their end of the "understanding"? Opinions are mixed.

Henry Linsert, answers the question this way. "If we got on the road because Maryland helped us get there, would we stay in Maryland? It's hard to say. We would hope to, but we'd have to go where we could to get access to a fermenter large enough to meet our needs as they grew. A bioprocessing plant here in Maryland would surely keep more start-up companies in Maryland than if the state didn't have the plant. It should certainly help. Look, if that processing plant were up and running here in Maryland today, I would be looking to cut a deal with the state to do a scale-up. That deal would keep me close to Maryland today, and in my plans tomorrow. In the end, it's hard to say."

But Dr. Hans Mueller, president and CEO of Nova Pharmaceutical Corporation, is quite positive about the program's potential as an incentive for companies to remain in the state. "The physical proximity of the key assets of a company is important since the arrangement it allows improves operational efficiency. The interaction of the bench scientists with the scale-up team is frequent and intensive—and on-the-spot. This interaction is crucial for product development. While the facility provides no guarantee that the state will retain its biotech firms, and equally important, attract new firms, it nevertheless is an important step in the competitive race against other states with equally determined efforts to win 'industries of the mind'."

The question cannot really be answered at all because only time will tell. But knowledgeable observers in the business are confident that bread-on-the-waters comes back. And Maryland legislators clearly hope that Maryland's biotech businesses, entrenched in Maryland and enjoying the benefits of that entrenchment, will stay in Maryland.

And lastly, and perhaps peripherally, is the question of whether the state, in building the bioprocessing facility out of the public sector, is in fact competing with

private industry—which might be looking for the same business but would be eliminated from doing so.

The answer to the third question is academic; there is, in the country, no precedent for private sector success in building bioprocessing facilities. Private sector economics simply don't work in this area; small-scale biotech companies can't afford the fees private firms require to cover their operating and capital costs, and still make a profit.

The Window of Opportunity

Maryland, among the top three states in number of biotechnology companies along with California and Massachusetts, has the potential of becoming the Silicon Valley of the biotechnology industry. The presence of the National Institutes of Health, the Johns Hopkins Medical Institutions, the Maryland Biotechnology Institute, the Federal Drug Administration, the University of Maryland Medical System and over 100 corporations related to this industry provide the expertise that continues to draw the industry to this area. Today, however, biotechnology has matured from its research stage and stands at a critical crossroads in its development. In order for Maryland's investment to pay off in the long term, it must provide the infrastructure and support systems necessary to insure the industry's smooth transition from research to manufacturing.

According to the report by Ernst & Young, biotechnology scale-up manufacturing is considered the most important issue facing biotechnology firms today. Additionally, 75 percent of the companies represented in the report plan construction of new, full-scale manufacturing facilities within five years while the industry projects that the number of marketing personnel will triple.

The Maryland bioprocessing facility is undoubtedly going to provide the ideal medium for introducing a variety of biotechnology firms to the merits of locating and/or expanding Maryland. Immediately, it is going to help Maryland firms grow into international leaders; in the long term, at the far side of the leap of faith, could be the new jobs, the additional revenues, the diversified economic base—and the State of Maryland in the position as the nation's biotechnology manufacturing center.

Abell Salutes: PANDA

(continued from page 1)

It is the Tanyas of the world—bewildered and frustrated at the circumstances they suddenly find themselves in and taking out that anger on what (more often “who”) they perceive as the source of their frustration that PANDA seeks to reach, with one-on-one, in-home counseling, support groups and a special emphasis on nurturing. Executive director for Parents Anonymous is Elaine Fisher; program coordinator for PANDA is Bonnie Elward. Long term, the program, which is modeled after similar Parents Anonymous programs around the country, seeks to prevent repeat pregnancies, promote academic achievement and parenting skills, and improve the level of self-esteem among adolescent parents.

Historically, while not everyone who was abused becomes abusive, most parents who abuse their children have had difficult childhoods; they respond to their children's cries for help in a destructive way—as their own parents did. It is at this point that PANDA intervenes—looking to break the cycle.

Society is just beginning to recognize that many negative social behaviors of children—delinquency, substance abuse, poor school performance, learning and emotional disabilities, running away, dropping out of school, pregnancy out of wedlock—may be the consequences of having been abused.

How well does the PANDA program work? During its three years in operation, a similar program in Prince George's County has served 100 teens and their children. Among these teens, there are only two repeat pregnancies. The majority of these teens returned to school, finished school, or completed their GED, and several went on to enroll in college or job training programs. It costs Parents Anonymous approximately \$1,000 to provide its services to each child; it costs approximately \$30,000 to house one prisoner.

By providing care to Tanya, the PANDA volunteers are helping to assure that her baby son, Tony, will never need them.

Some Recent Grants By The Abell Foundation

Associated Black Charities \$58,750
Challenge grant for a study of the operational and organizational structure, philosophy and performance of the Administration of the Baltimore City Public Schools.

Baltimore Mental Health Systems, Inc. \$16,957
To support the enhancement of the Client Information System, a computerized data base that collects information on children, adolescents and adults served by the public mental health system in Baltimore City.

Appalachian Trail Conference \$12,500
Challenge grant toward the cost of an inventory of land abutting the 40-mile section of the Appalachian Trail in Maryland to be used for a strategic plan to protect a greenway corridor.

Magic Me \$14,850
For production costs of a pilot video to introduce black role models to students in Baltimore City Public Schools.

Morgan State University \$150,000
To provide second-year funding for the Center for Educating African-American Males. The center's program is designed to recruit and train teachers to take their places in experimental schools. In the schools, an exclusively African-American male faculty and an all-African-American male student body will have the mission of demonstrating that such an educational environment works to keep young African-American males in school and in the workplace.

Planned Parenthood \$73,357
Matching grant for the development and implementation of a pregnancy prevention program for teens who have received a negative pregnancy test.

**Baltimore City Public Schools/
Samuel F. B. Morse Elementary School** \$50,080
To supply computer equipment needed to test the educational impact on a computer lab based on the Digicard network and philosophy. Using the lab, the teachers will have more control over the use of the computers and will be able to more closely coordinate computer time with regular classroom instruction.

**Maryland Department of Health
and Mental Hygiene** \$93,455
To cover costs of training staff to introduce Norplant contraceptive technology to the Maryland public health system.

Marylanders Against Handgun Abuse \$8,180
For the production of one radio and one television public service announcement to educate Marylanders about the impact of handgun abuse on children and to discredit the notion that handguns are for “self-defense.”

Towson State University \$76,334
To supply a support and training program for 25 returning Peace Corp volunteers in preparation for teaching in Baltimore City Public Schools.