



FRALIN

BIOTECHNOLOGY  
CENTER

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## CLEAR SUPPORT FOR GENETIC TESTING AMIDST CONCERNS FOR PRIVACY

A VCU Survey of Virginians

### IN THIS ISSUE:

*Clear Support for Genetic Testing Amidst Concerns for Privacy* ..... 1

*Virginia Advisory Committee on Ethical, Legal, and Social Issues in Genetic Research* ..... 3

*Fralin Biotech Center Faculty and Staff Contact Information* ..... 3

*Ethics Case Study and Commentaries on Genetics of Nicotine Addiction and Lung Cancer* ..... 4

*Institutional Review Boards* ..... 5

*2004-2005 Biotech-in-a-Box*..... 6

*Genetics Mentor Network*..... 7

*Biotechnology 2004 Conference: Ethics and Genetic Screening Workshop* ..... 8

Through decades of research in human genetics and even some recent developments from the Human Genome Project, genetic testing has become a reality. Would you ever consider having a genetic test done? Regardless of your own choices about whether to have a genetic test, do you think such tests should be available to those who want them? Such questions were asked in a survey on genetic testing conducted by Virginia Commonwealth University with sponsorship from the Virginia Advisory Committee on Ethical, Legal, and Social Issues in Genetic Research (VAC). The survey was conducted by telephone November 14-25, 2003, with 804 adult Virginians and has a margin of error of +/- 4 percentage points.

Virginians express clear support for the idea of genetic testing and most maintain that the benefits of genetic testing outweigh any risks. At the same time, a majority of Virginians are very concerned about the privacy of genetic testing results and, more generally, the privacy of health and medical information.

#### Support for Genetic Testing

About nine in ten Virginians (89%) say that genetic testing for disease risk is a very good or a good idea (see Table 1). Just 8% think it is a bad or very bad idea. Why would anyone want to have a genetic test? Nearly six in ten (58%) say it would be very helpful to know more about one's risk for disease in order to take better care of one's

Continued on page 2

Table 1. What is the importance of... ..in your decision to get genetic testing?

	Very important	Important	Not too important	Not at all important	Don't know	No answer
Privacy of the testing results	69%	19%	8%	4%	0%	0%
Family medical history	62%	29%	6%	3%	0%	1%
Availability of treatments	57%	30%	7%	4%	1%	0%
Cost of the test	52%	32%	10%	3%	1%	1%
Your current age	28%	33%	25%	11%	2%	1%

*This special issue of the Biotech Times is co-authored and co-sponsored by the Institute for Practical Ethics and Public Life at the University of Virginia and the Virginia Advisory Committee on Ethical, Legal, and Social Issues in Genetic Research.*



**Table 2. How often do you think... would deny coverage/jobs because of genetic testing results?**

	Almost always	More than half the time	About half the time	Less than half the time	Almost never	Don't know	No answer
Life insurance companies	48%	22%	16%	5%	3%	5%	2%
Health insurance companies	46%	21%	17%	7%	3%	5%	1%
Employers	20%	21%	23%	21%	10%	4%	1%

**How often do you think other people would treat you differently if they knew about your genetic testing results?**

	Almost always	More than half the time	About half the time	Less than half the time	Almost never	Don't know	No answer
Other people	11%	13%	13%	21%	31%	2%	1%

Continued from page 1

health. Another 31% say this would be somewhat helpful and just 9% say it would be not too or not at all helpful.

Similarly, clear majorities support the idea of making genetic testing easily available to all who want it; four in ten strongly favor, 44% somewhat favor and 13% somewhat or strongly oppose this idea. About three in ten (at 29%) consider themselves likely to get tested if genetic testing were easily available. Ten percent of Virginians say someone in their household has had genetic testing.

**Privacy Concerns Factor in the Decision to Get Tested**

The fact that genetic testing is available for individuals presents a risk that this information will become available to other audiences, for example, health insurance companies or employers. When asked to rate a series of factors that might influence personal decisions to get genetic testing, more people considered the privacy of the testing results to be very important than any other factor. Sixty-nine percent said the privacy of the testing results would be very important in their decision to get genetic testing. Another 19% said it would be important and 12% thought it would be not too or not at all important in their decision.

Similarly, 54% said they were very concerned, in general, about their ability to keep health and medical information private; 26% were somewhat concerned while one in five were not too or not all concerned with this. Similar portions say they would be very concerned about keeping genetic testing results private (58%); 24% would be somewhat concerned and 17% would be not too or not at all concerned.

**Expectations of Discrimination**

Although privacy of health information is intrinsically valued, of more practical concern is the possibility for discrimination by insurers and employers on the basis of genetic testing information. Respondents were asked to rate how often they thought such discrimination would occur (see Table 2). Insurance companies were expected to deny people coverage because of ge-

netic testing results “almost always” by 48% and 46% for life and health insurance companies, respectively.

By comparison, 20% thought that employers would deny people jobs because of genetic testing results “almost always.” More optimism was expressed for how people would treat each other outside of these settings. Only 11% thought that other people would “almost always” treat you differently if they knew about your genetic testing results.

**Groups Trusted with Genetic Testing Information**

Privacy of genetic testing results is valued, especially for the purpose of avoiding discrimination.

Then, who can be trusted with these results? Respondents were asked how much they would trust each of five groups to safeguard their genetic testing information. A majority of Virginians said they would trust physicians with this information, while fewer expressed such trust of laboratories, scientists doing genetic research, hospitals or health insurance companies (see Table 3). Only 20% of those surveyed trusted health insurance companies with this information.

Despite any concerns over protecting the privacy of genetic testing results and potential consequences when those results are known, support for genetic testing is clear. When asked to weigh the risks and benefits of genetic testing, 63% said the benefits outweigh the risks while only a quarter said the risks

Continued on page 3

**Table 3. How much would you trust... to safeguard your genetic testing information?**

	A great deal	Somewhat	Not much	Not at all	Don't know
Physicians	55%	34%	5%	4%	1%
Laboratories that provide testing	40%	41%	11%	7%	2%
Scientists who do genetic research	40%	40%	10%	7%	3%
Hospitals	37%	43%	12%	7%	1%
Health insurance companies	20%	35%	21%	22%	1%

## The Virginia Advisory Committee on Ethical, Legal, and Social Issues in Genetic Research

Virginia Advisory Committee on Ethical, Legal, and Social Issues in Genetic Research (VAC) was established to serve as a resource for researchers in Virginia universities and others who want to explore and address the ethical and social issues associated with genetic information. Of particular interest are issues arising with genetic research on tobacco-related morbidity and youth tobacco use. Established with support from the Tobacco Settlement Fund, VAC is comprised of three faculty members from each of the six Virginia universities collaborating on tobacco-related research. The collaborating universities are: College of William and Mary, George Mason University, James Madison University, University of Virginia, Virginia Commonwealth University, and Virginia Polytechnic Institute and State University. Coordinated by James Childress, Ph.D., and Ruth Gaare Bernheim, J.D., M.P.H., of the University of Virginia Institute for Practical Ethics and Public Life, VAC brings together experts in ethics, law, social sciences, and public policy, as well as researchers in genetics.

Continued from page 2

outweigh the benefits.

### **Policy Needed for Privacy Protection**

What are the next steps in the public discussion of genetic testing? Obviously, more research must be done to determine the role of genes in specific diseases and to develop genetic tests where appropriate. In the meantime, policy can be put in place to protect individuals and information.

Virginians expressed strong agreement with the notion that better enforcement of current laws was needed to protect the privacy of genetic testing information. Eight in ten Virginians agreed with a statement to that effect. Forty-four percent of Virginians agree that current laws are adequate for protecting the privacy of genetic testing in-

formation. These results suggest that Virginians may be open to new laws that would better protect the privacy of genetic testing information and tend to support better enforcement of current laws.

More people thought the federal government would be best able to enforce safeguards on the privacy of genetic information compared to state or local government. However, two thirds of Virginians agreed with the idea that "government safeguards aren't enough; we need citizen watchdog groups to make sure that the privacy of genetic testing information is protected."

*Cary Funk*  
*Director of the Commonwealth Poll*  
*Virginia Commonwealth University*

## Learn About Genetic Testing: Biotech-in-a-Box

If you would like to teach students about how genetic testing is done, as well as the underlying biological concepts, check out Fralin's **DNA Biotechnology Kit** or borrow a **Thermal Cycler** to conduct a mock genetic test. More information about these and other Fralin **Biotech-in-a-Box** kits is provided on page 6.

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# GENETICS OF NICOTINE ADDICTION AND LUNG CANCER

## A Case Study and Commentaries on Ethical, Legal, and Social Issues

### The Case

A physician-investigator is developing a research project. He wants to study tissue samples from clinic patients who have lung cancer and who have also been long-time cigarette smokers. His goal is to identify a gene that contributes to nicotine addiction and/or another gene that, in combination with cigarette smoking, contributes to lung cancer. If it is possible to identify either gene, the physician-investigator plans to tell the patients the results. Then they or other family members could choose to have their children tested to determine whether the children are at high risk for nicotine addiction or lung cancer from smoking. Armed with this information, parents could use a variety of techniques to ensure that their high-risk children do not smoke. The physician-investigator believes that he has adequate consent from the clinic patients for the use of their tissue in research. When the patients had tissue removed as part of diagnostic and therapeutic procedures, he also asked them for permission to use their tissue samples in future research.

What ethical, legal, and social concerns does this proposed study raise? Are there significant risks? If so, do the potential benefits of the research outweigh those risks? If the research is successful, what issues will arise from the clinical use of these genetic tests?

#### Commentary by Doris Zallen, Ph.D., Professor Science and Technology in Society, Virginia Tech

Despite his good intentions, this physician-investigator has failed to take three issues into account.

1. A single research project is insufficient to establish the connection of any gene (or gene variant) to a particular illness. The pages of scientific journals are littered with studies that have not held up. Until any genetic finding is validated in other studies, it would be irresponsible to present it to the research subjects as medical fact.

2. Even if, eventually, genes are found that indicate a heightened likelihood for nicotine addiction or lung cancer, it would still be inappropriate to automatically inform individuals of their genetic status. Genetic information comes laden with a host of burdens. Many people - for perfectly good reasons - do not want to know their genetic makeup. Experience has shown that such information could make them feel tainted, might cause strife among family members, and could call health or life insurance coverage into question. Keep in mind that the majority of individuals at risk for inheriting the gene leading to Huntington disease have *not* sought genetic testing. People have to be given the opportunity to decide for themselves about whether or not to obtain genetic information.

3. Testing of children to inform them of their genetic status raises further red flags. The American Society of Human Genetics and the American College of Medical Genetics have recommended that genetic testing not be done on children unless there are immediate and tangible benefits for that child. It is hard to see what medical benefits would accrue here. Quite the opposite, children found to have the problem gene may end up feeling stigmatized or labeled - in the absence of any smoking activity on their part. And children found *not* to have the gene may incorrectly assume that they are somehow resistant to harm and turn deaf ears to warnings about the dangers of tobacco use. Genetic testing is no substitute for programs of education for all of our children and the institution of meaningful penalties for the sale of tobacco products to minors.

#### Commentary by Margaret Foster Riley, J.D. Associate Professor University of Virginia School of Law

This research may be subject to federal or state laws that control what the researcher can do. In many cases, the researcher may have to present the plan to an institutional review board (IRB; for additional information, see the panel on Institutional Review Boards on page 5). The IRB would review the research and determine whether it would be conducted ethically.

The first question raised by this scenario is whether the patients consented to allow the researcher to do this kind of research. To have valid consent, the patients must be able to understand what the consequences of participating are. In this instance, the consent that the patients signed may have been so ambiguous that the patients could not have appreciated that their tissue could be used for genetic research and that this kind of research may pose risks to them.

If someone were known to have a gene that predisposed them to nicotine addiction or lung cancer, they might have greater difficulty getting insurance or may be exposed to discrimination in the workplace. Also, knowing that one has a gene that may predispose one to lung cancer or addiction may have psychological consequences. It is not clear that everyone would want to have that information. It is even more difficult when parents are making decisions for their children since it is hard to know what the children might prefer in the future or what the consequences may be for them. On the other hand, knowing a genetic predisposition

Continued on page 5



Continued from page 4

to either nicotine addiction or lung cancer would help an individual take preventive action and could help society find treatment solutions that could benefit many people. The IRB would need to balance all of these issues, assure that valid consent is obtained, minimize the risks to patients, and insist on strong confidentiality measures.

### Institutional Review Boards

Most studies involving human or animal (primarily vertebrate) subjects are approved by an Institutional Review Board (IRB), an independent group within each research organization that is comprised of medical, scientific, and non-scientific members. The IRB must ensure the protection of rights, safety, and well-being of human and animal subjects. Although IRBs are established to monitor such efforts, all researchers who participate in projects funded by the National Institutes of Health (NIH) and other federal agencies are required to participate in training on scientific ethics, especially related to human and animal testing. To view the computer based training available for researchers through the NIH, see: <http://cme.nci.nih.gov>.

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#### Commentary by William J. FitzPatrick, Ph.D., Assistant Professor Department of Philosophy, Virginia Tech

Medical research depends crucially on broad access to tissue samples and health data. Many researchers worry, however, that a lack of public understanding of this fact, together with increasing emphasis on patient control over health information, may hinder research in ways that the public would not in fact welcome. At the same time, considerations of social utility must be weighed against legitimate personal concerns - in an age where information flows with unparalleled ease and health care is increasingly tied to big business - over the potential abuse of personal health information by employers or insurers.

One way of addressing such concerns is to allow use of archived tissue or information without consent only where it is de-identified, and to require consent in other cases. The obvious limitation of de-identifying the data is that it precludes the possibility of directly benefiting the particular patients with potential discoveries. In the present case study, there must at least be encoded or encrypted identifiers to allow for re-identification, and presumably the consent form specifies the terms for the handling of those identifiers, as well as the risk of misuse. Did it also specify the terms under which the patient would wish to be contacted later with the new information, and what kinds of information the patient would want to receive? This is important: consent to allow researchers to *use* tissue samples does not itself imply consent *to be recontacted* with various forms of information. Some, for example, may wish *not* to be told about any untreatable diseases they may be found to have. In the present case, the focus is on information that may prove useful to the healthcare of their children, but patients must be given the chance to specify whether the information they receive will be restricted to that or might include more.

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#### Commentary by Chris Moskaluk, M.D., Ph.D., Associate Professor Departments of Pathology and Biochemistry & Molecular Genetics, University of Virginia

Some very important points of genetic predisposition are relevant to this case study: having a disease predisposition does not necessarily mean you have a 100% risk of developing that disease, there can be (and often are) minor degrees of risk, and the degree of risk may not be able to be determined precisely in each affected individual (variable disease penetrance). It is a common misconception that genetic traits are 100% penetrant and autosomal dominant (if I have this gene, I will get this disease and so will my children). Such diseases do occur, are rare, and are self-evident in family histories. So even before we perform the research proposed in this case study, we already know that this is probably not the case for tobacco related cancers.

If the hypothesis is proven true, the data will probably look more like this: smokers without disease allele(s) have an 8% lifetime risk of developing lung cancer, and smokers with the disease allele(s) (15% of the population) have a 16% lifetime risk of developing lung cancer. I will leave the dire consequences of what society will do with genetic pre-determinism to others, and offer this question: what do we do with a disease in which genetic predisposition may be a component but is less of a factor than the environment (the personal choice to begin smoking) or society (the legal protection of a known addicting and disease-causing substance)? In this particular case, my belief is that the need to eliminate the use of a disease-causing substance (tobacco) by the general population will remain a much greater public and personal health priority than the need to focus on a minority of individuals with relative, but not absolute, inherited disease susceptibility.

In my judgment, the research in this case has sufficient scientific and medical relevance to be allowed to proceed. However, the risks involved are above the 'minimal risk' threshold and therefore require that the patients be recontacted prior to the study to obtain their specific informed consent. The major risks to an individual in a genetic study are personal and societal perceptions of genetic heredity - perceptions that often fail to recognize the variable degree of penetrance of genetic traits or the profound influence of the environment on the health states of an individual. Only continued research and education will remedy this situation.

# FRALIN BIOTECHNOLOGY CENTER

## 2004-2005 EQUIPMENT LOAN PROGRAM

### BIOTECH-IN-A-BOX

For the 11<sup>th</sup> year, the Fralin Biotechnology Center will offer Biotech-in-a-Box, an equipment loan program that provides complete kits for bringing biotechnology to Virginia high school and community college classrooms. These kits contain all the equipment needed for the experiments, and the Center pays round-trip shipping between Virginia Tech and your school. Extensive manuals, full of potentially useful information, are sent to borrowers in advance of the equipment loan.

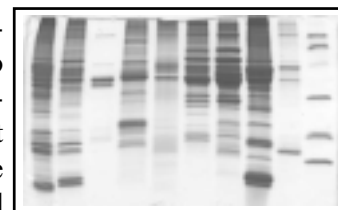
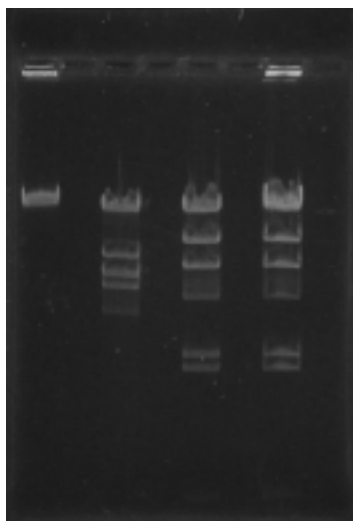


#### **DNA BIOTECHNOLOGY KIT- *Who is eating Fluffy's cat food?***

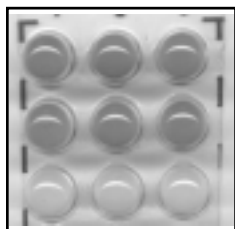
The DNA Biotechnology Kit contains the equipment and materials needed for students to perform a DNA fingerprinting experiment. The kit manual offers crime scene scenarios for your students to solve, such as who is stealing Fluffy's cat food or who murdered the delivery person. Included in the kit are electrophoresis chambers, power supplies, a microcentrifuge, light boxes for viewing stained gels, and micropipettors, as well as all the expendables needed to run the experiment. This kit is available for a 2-week loan period, and multiple borrowers from the same school are asked to coordinate their loan requests.

#### **PROTEIN ELECTROPHORESIS KIT- *Is it really crabmeat?***

The Protein Electrophoresis Kit contains all the material needed to perform polyacrylamide gel electrophoresis (SDS-PAGE) of proteins in the classroom. Several approaches (described in the kit manual) can be used to present the experiment to students, for example, an evolutionary approach in which the proteins from closely-related and distantly-related fish are compared, and a forensic approach, in which students are asked to determine the identity of a seafood sample by comparing the proteins in the unknown sample to those of known species. Included in the kit are gel boxes, power supply, and other equipment and materials needed to prepare samples for electrophoresis. Instructions in the kit explain how to prepare protein samples from fish and other seafood (*not* included). The Center will provide 5 gels with the kit. This kit is available for a 2-week loan period, and multiple borrowers from the same school are asked to coordinate their loan requests.



#### **IMMUNOLOGY KIT- *Investigate a classroom epidemic!***



In the Introduction to Immunology Kit, students share "bodily fluids" to simulate the spread of disease through intimate contact and then test their samples using an ELISA assay to see if they have been "infected." The kit contains all materials needed except for hydrogen peroxide and distilled water. Background information with the kit emphasizes using antibodies as tools in research and in diagnostic tests. The kit was adapted from one developed by Ken Kubo at the BIOTECH Project at the University of Arizona; no bodily fluids or infectious agents are used in this experiment! The Introduction to Immunology Kit is available for a 3-week loan period.

## COLUMN CHROMATOGRAPHY KIT

Column chromatography is a technique commonly used to purify proteins, both in research labs and in the biotechnology industry. The Column Chromatography Kit contains materials for running three types of chromatographic columns: gel filtration, which separates molecules by size; ion exchange, which separates based on charge; and reverse phase, which separates molecules based on polarity. The kit contains all materials needed for running the columns, except for rubbing alcohol and grape soda. This kit is available for a 2-week loan period.

## THERMAL CYCLER- *PCR in your classroom!*

Thermal cyclers are available from the Fralin Biotechnology Center for 2-week loans. Unlike the other equipment loans, this is **not** a complete kit; it includes only the thermal cycler and is intended for those teachers who are able to supply their own materials for Polymerase Chain Reaction experiments. A number of companies, including Bio-Rad, Carolina Biological Supply Company, Edvotek, Fotodyne, and Modern Biology, Inc., have PCR kits available. The thermal cycler will hold twenty-four 0.2 ml thin-wall PCR tubes.

## TO SCHEDULE AN EQUIPMENT LOAN

For an equipment request form for one of the kits listed above for the 2004-2005 school year:

**Download** pdf forms at: [http://www.biotech.vt.edu/outreach/biotech\\_box.html](http://www.biotech.vt.edu/outreach/biotech_box.html)

**Request** forms as Word documents that may be returned as attachments or by mail or fax by contacting:

Dr. Kristi DeCourcy, Lab Manager  
Fralin Biotechnology Center, Virginia Tech  
Blacksburg, VA 24061  
(540) 231-7959 phone, (540) 231-7126 fax  
email: [decourcy@vt.edu](mailto:decourcy@vt.edu)

Please specify in which kit(s) you are interested. Scheduling of equipment requests for the 2004-2005 school year will be completed by August 14, 2004. To have your equipment loan scheduled at that time, please return your request form **no later than August 2, 2004**. Requests received after that time will be filled on a space-available basis, but to be considered for the most desirable loan periods, applications should be returned by August 2<sup>nd</sup>.

**Please note: Equipment loans are available only to Virginia educators.**

## The Genetics Mentor Network

*The American Society of Human Genetics, The National Human Genome Research Institute,  
The Genetic Alliance, and the Genetics Society of America Mentorship Program*

Given the extremely rapid pace of genomics research, and the many medical, social, and ethical implications of human genetics, it is imperative that the genetics community provides as many in-depth and personal learning opportunities for students as possible. The American Society of Human Genetics (ASHG) has a long history of providing educational opportunities for students and teachers, at the ASHG annual meeting, at national teacher conferences, and through individual efforts of hundreds of ASHG members. It is hoped that nearly every member of ASHG (students and faculty, practitioners and researchers), Genetic Society of America (GSA) members, and Alliance Advocates will be willing to participate at least once during each year.

Nearly 900 members of the ASHG have already volunteered to be a part of the Genetics Mentor Network, a unique resource for K-12 students and teachers in Canada and the US. Now this opportunity is being extended to advocates in the Genetic Alliance as well as members of the GSA. These human genetics professionals and advocates will volunteer their time on National DNA Day as well as throughout the year to assist science teachers in increasing understanding and awareness of the Human Genome Project and genetics among students and the general public.

Genetics and genomics professionals and advocates can participate in the mentorship network program by visiting ASHG's Outreach to Teach website at: <http://genetics.faseb.org/genetics/ashg/educ/003.shtml>. Students interested in finding mentors can do so by visiting this same website and searching for mentors within their locality. For additional information, please email: [jboughman@ashg.org](mailto:jboughman@ashg.org).

# BIOTECHNOLOGY 2004 CONFERENCE

## JULY 14-17, 2004

### FRALIN BIOTECHNOLOGY CENTER

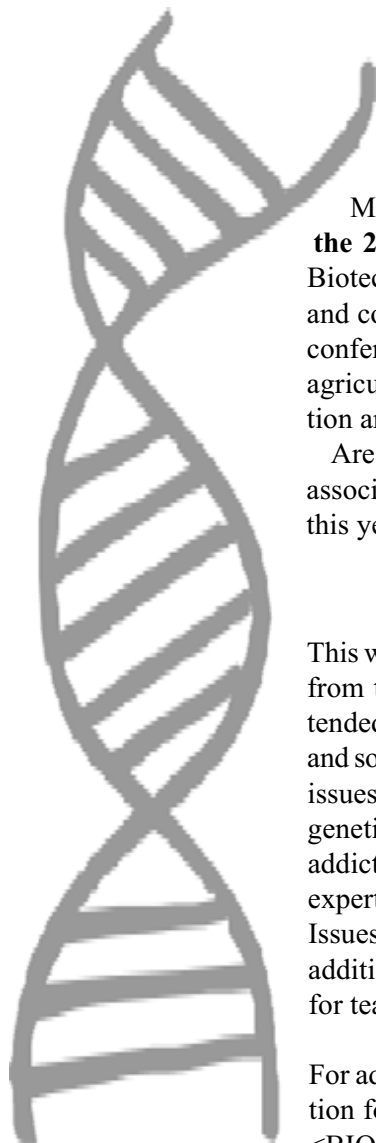
Mark your calendar for this summer's **Biotechnology 2004: Updating Educators for the 21st Century** at the Donaldson-Brown Hotel and Conference Center and the Fralin Biotechnology Center on the Virginia Tech campus. Biotechnology 2004 provides technical and content updates for high school and college biology faculty. Now in its ninth year, the conference draws educators from across the nation to discuss new applications in medicine, agriculture, informatics, and environmental science. The conference program and registration are available on the Fralin website at: <http://www.biotech.vt.edu>.

Are you and your students interested in investigating the ethical, legal, and social issues associated with human genetics? The following workshop is being offered for the first time this year:

### Ethics and Genetic Screening

This workshop, presented by James Childress, Ph.D., and Ruth Gaare Bernheim, J.D., M.P.H., from the Institute for Practical Ethics and Public Life at the University of Virginia, is intended to enable teachers to address in rigorous and creative ways some of the ethical, legal, and social issues associated with applied human genetics. Following an examination of broader issues and frameworks of ethical analysis, the workshop will pay particular attention to genetic screening and testing associated with predispositions to conditions such as nicotine addiction and to diseases such as cancer. The workshop, which will draw on experiences and expertise of members of the Virginia Advisory Committee on Ethical, Legal, and Social Issues in Genetic Research, will be highly interactive, and will focus on concrete cases. In addition, materials will be provided along with information about various other resources for teaching ethical, legal, and social issues in genetics. <http://www.virginia.edu/ipe/>

For additional information or to receive a hard copy of the conference brochure and registration form, please contact the Center outreach coordinator, Erin Dolan, at 540/231-2692 or <[BIOoutreach@vt.edu](mailto:BIOoutreach@vt.edu)>.



Virginia



Tech

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