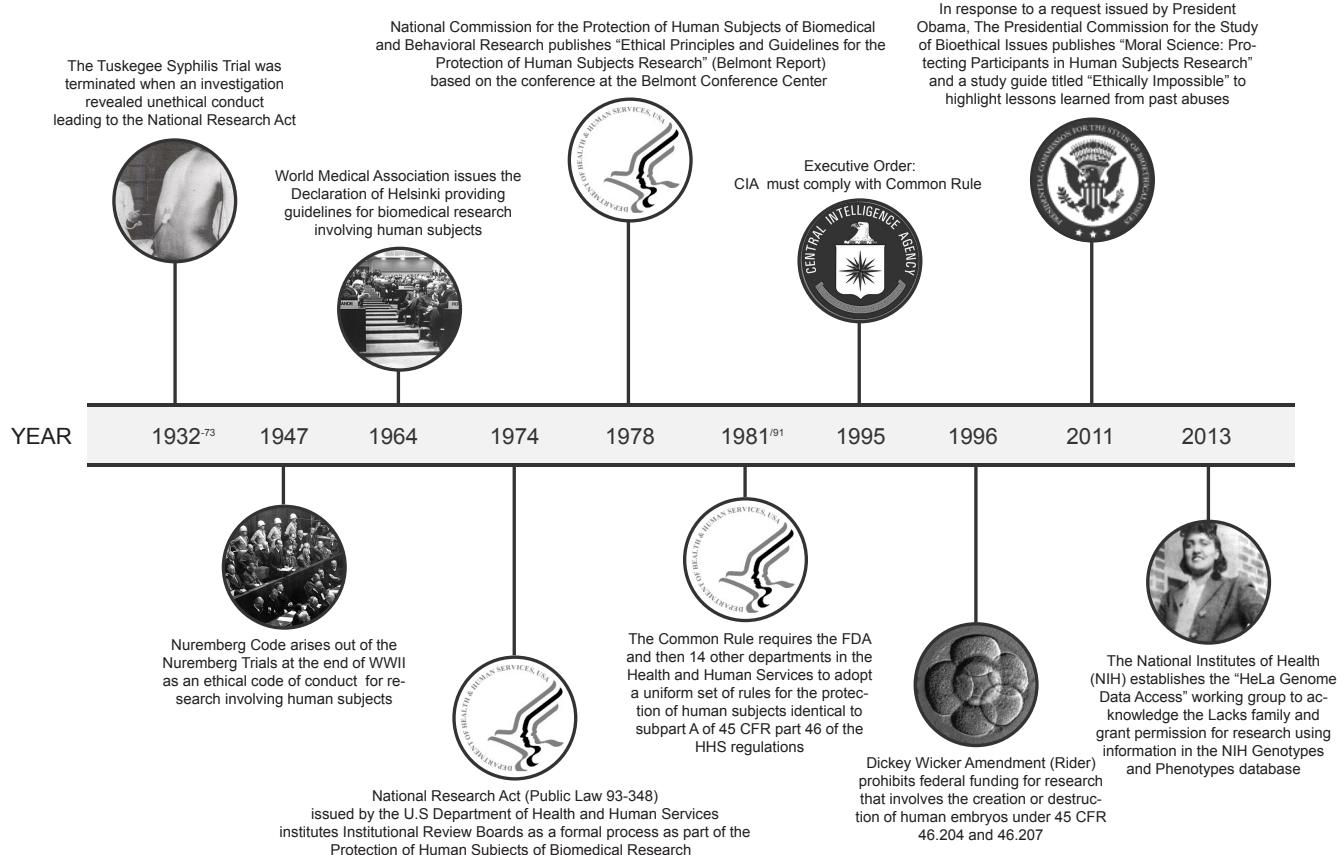


## HISTORY OF HUMAN SUBJECTS RESEARCH



### References:

1. Annonymous. 2012. Justice for all. *The Lancet*. 484, 287.
2. Vandewalle, A. and Kurban S. 2011. Paying human subjects in research: Where are we, how did we get here, and now what? *Journal of Law, Medicine, and Ethics*, 39(3), 543-558.
3. Emanuel, E., et al. 2011. Reforming the regulations governing research with human subjects. *New England Journal of Medicine*, 365, 1145-1150.
4. Callaway, E. Aug 2013. Done deal over HeLa cell line. *Nature*, 500, 132-133. (Podcast available).
5. Tuskegee syphilis trial photo courtesy of The National Archives.
6. Photo of Henrietta Lacks courtesy of the Lacks family.

# The human genome, HeLa, and Mo

Bioengineering 100  
Fall 2016

Who owns the human genome?

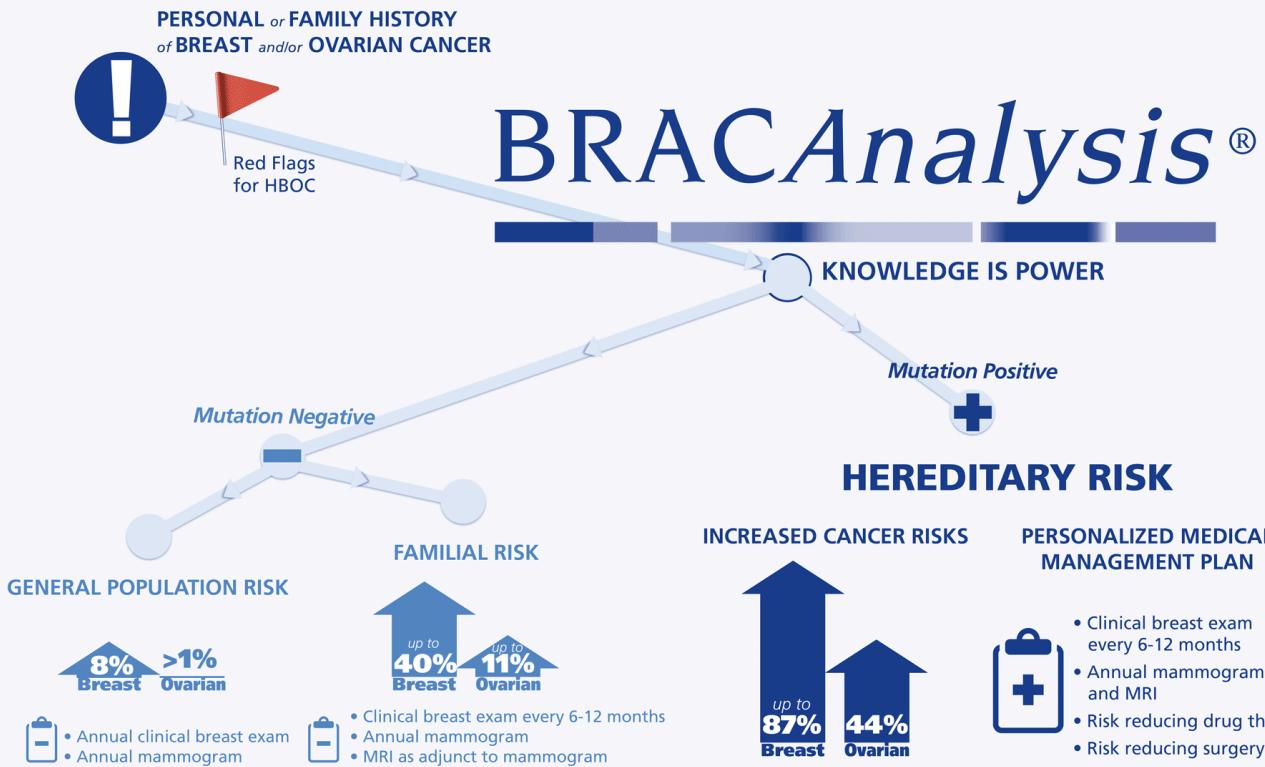


Tom Williams/Roll Call/Getty Images



The Value of

# Hereditary Cancer Testing



# Myriad Genetics

- 7% of all breast cancer cases are caused by mutations in BRCA1 and BRCA2 genes
- Carrying a mutation in BRCA1 or BRCA2 means a much higher risk of breast cancer
- Myriad developed a genetic test to identify whether patients have mutations in BRCA1, BRCA2, and other genes with higher risk for breast cancer.
- 1997, 1998 patented BRCA1, BRCA2 genes
- In 2013: charging \$4000 for the BRCA1/BRCA2 test

# SUPREME COURT OF THE UNITED STATES

## Syllabus

### ASSOCIATION FOR MOLECULAR PATHOLOGY ET AL. *v.* MYRIAD GENETICS, INC., ET AL.

### CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

No. 12–398. Argued April 15, 2013—Decided June 13, 2013

Each human gene is encoded as deoxyribonucleic acid (DNA), which takes the shape of a “double helix.” Each “cross-bar” in that helix consists of two chemically joined nucleotides. Sequences of DNA nucleotides contain the information necessary to create strings of amino acids used to build proteins in the body. The nucleotides that code for amino acids are “exons,” and those that do not are “introns.” Scientists can extract DNA from cells to isolate specific segments for study. They can also synthetically create exons-only strands of nucleotides known as complementary DNA (cDNA). cDNA contains only the exons that occur in DNA, omitting the intervening introns.

# 2013 Supreme Court Decision 9-0

*“A naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated but cDNA is patent eligible because it is not naturally occurring.”*

-Justice Clarence Thomas for the Court

If I have family history of a genetic disease, I would get tested.

# Debates begin next week!

- Tuesday: The free market sale of human organs should be allowed
- Thursday: The cost of drugs and medical devices should be regulated

# Who is Henrietta Lacks?

# HeLa Cells

- How have HeLa cells changed basic biology research?
- What are some of the bioethics questions that human cell and tissue research raises?



<http://www.radiolab.org/2010/may/17/henriettas-tumor/>

# The HeLa cell line

- On Oct. 4, 1951, Henrietta Lacks died of cervical cancer at Johns Hopkins University Hospital
- Part of the cancer was broken down into individual cells and cultured
- An epithelial-like subset of these cells grew in culture, and became the first human cells shown to divide endlessly *in vitro*



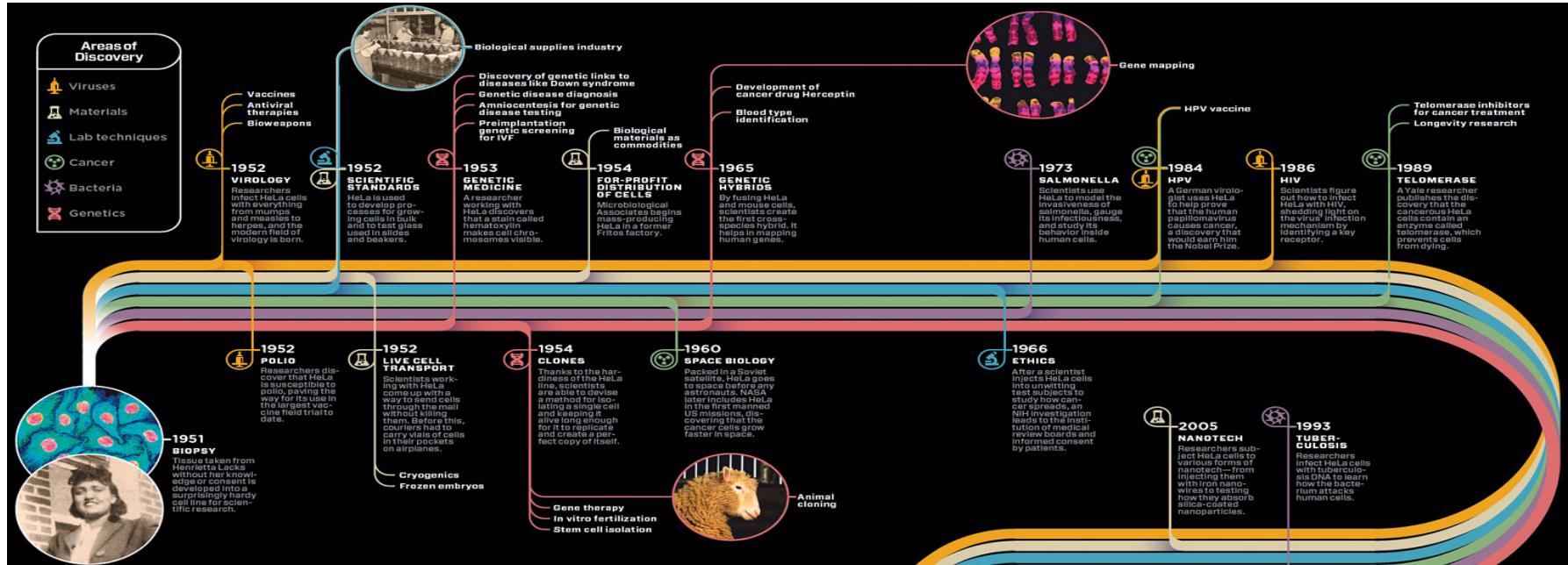
# Cell Culture in the 1950s



Cell Culture in George Gey's Lab; Photo courtesy of Mary Kubieck



# Impact of HeLa Cells on Science



[http://www.wired.com/magazine/2010/01/st\\_henrietta/](http://www.wired.com/magazine/2010/01/st_henrietta/)

## UNIT AT TUSKEGEE HELPS POLIO FIGHT

**Corps of Negro Scientists  
Has Key Role in Evaluating  
of Dr. Salk's Vaccine**

### HELA CELLS ARE GROWN

**These Are Used in Assaying  
Blood Taken From Children  
in Country-Wide Drive**

Special to The New York Times.

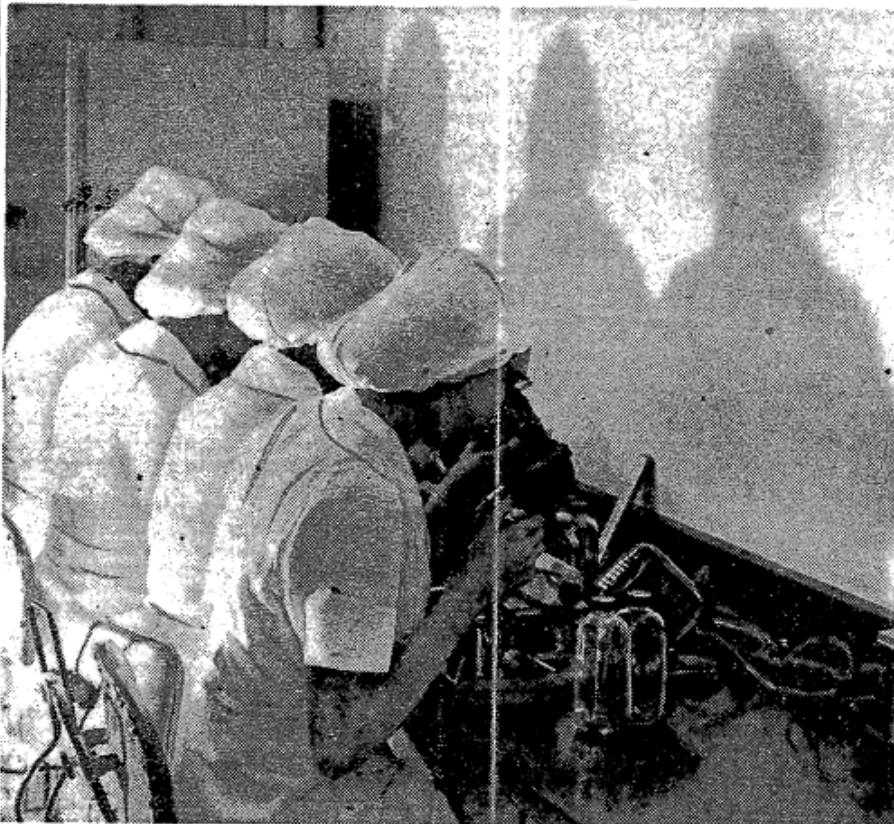
TUSKEGEE, Ala., Jan. 5—Tuskegee Institute's George Washington Carver Foundation is the central source in this country of HeLa cells, currently being used in the evaluation tests of the Salk polio vaccine.

HeLa cells are living human cancer cells. They are all descendants of cells from a single human cancer which resulted in the death of a woman in Baltimore in 1951.

The cells were first grown in tissue culture by Dr. George Gey of Johns Hopkins University.

About twenty-five Negro scientists and technicians are participating in the production of HeLa cells under the direction of Dr. Russell Brown. It is a highly specialized operation for which the Tuskegee unit is said to have more HeLa cell tubes and bottles

## Tuskegee Has a Key Role in Testing Polio Vaccine



The George Washington Carver Foundation at Tuskegee (Ala.) Institute is the nation's central source of supply for the HeLa cells currently being used in evaluation tests of Salk polio vaccine. Here four technicians examine cancer cells growing on walls of glass bottles.

## LAW SCHOOLS GET \$4,650,000 GRANTS

### Ford Foundation Would Spur Training and Research in International Problems

The Ford Foundation announced yesterday grants totalling \$4,650,000 to spur training and research in international legal problems and issues of foreign policy.

The grants went to four of the many law schools that have increased their courses in these fields since World War II. Harvard received \$2,050,000, Columbia \$1,500,000, Stanford \$600,000 and Michigan \$500,000. The funds, both capital and income, are to be used or committed over a ten-year period.

The foundation's primary purpose in making the grants, its announcement said, was "to develop greater understanding of international affairs among Americans trained in the law."

The four schools being assisted, the foundation continued, "have sought in recent years to make their international training programs more relevant to their students' future roles as lawyers and leaders in government, business and community life."

While the programs of the schools vary, "each has these three objectives: to make training in international and foreign problems an integral part of their undergraduate legal studies; to provide training for able students from foreign countries; and to conduct research."

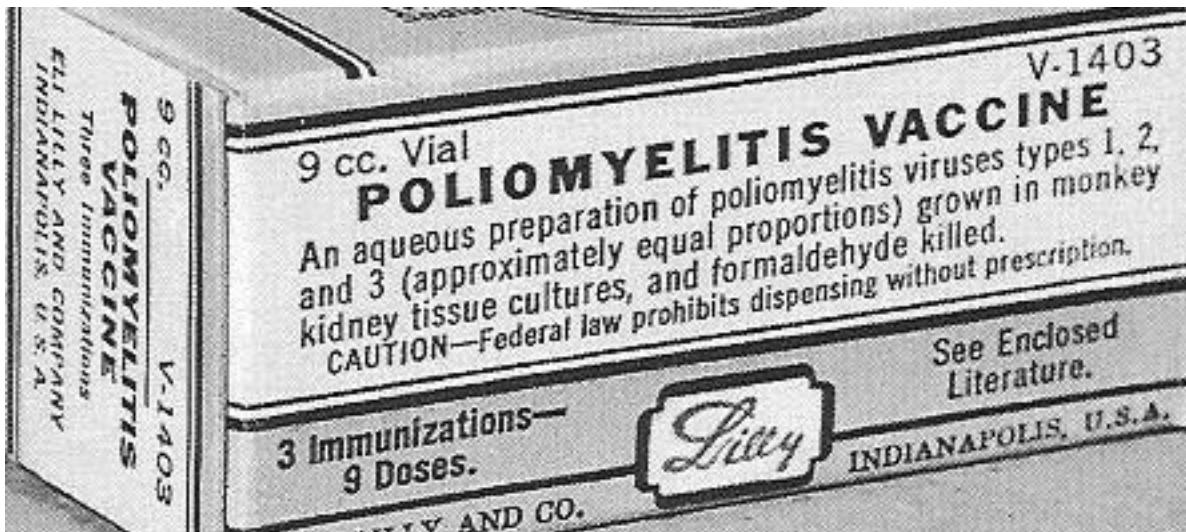
# HeLa Mass Production Center

Technician Working  
With HeLa Cells at the  
Tuskegee Institute

Courtesy of the March  
of Dimes



# Polio Vaccine



The Lacks family should receive financial compensation for the ‘donation’ of HeLa cells.

Agree or Disagree?

The ownership of cells and tissues should belong to the people from which they originally came from.

Agree or Disagree?

Mo

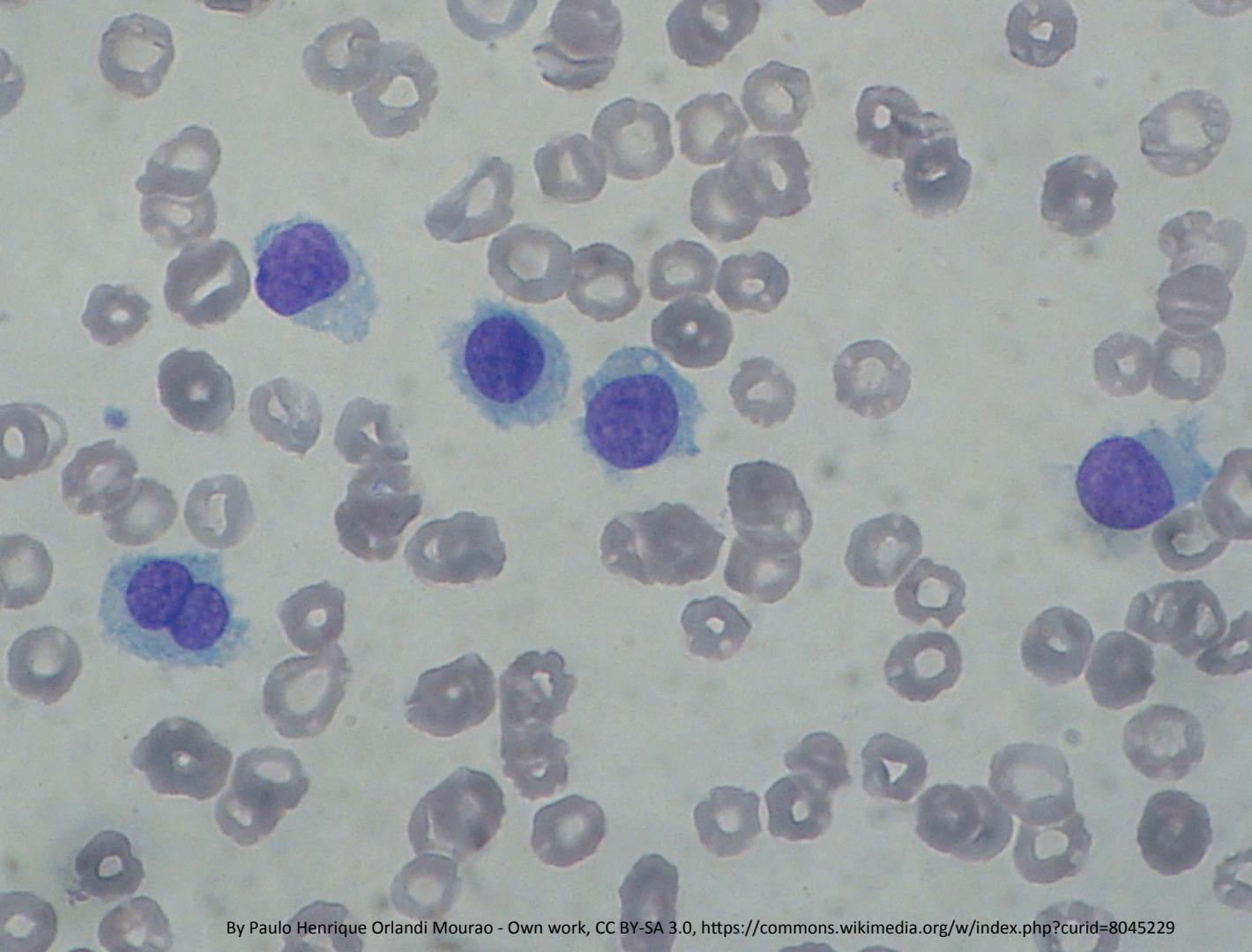


<https://www.youtube.com/watch?v=ZzBAoE9W3yc>

CBC

# John Moore

- 1976: Diagnosed with rare leukemia, had surgery at UCLA to remove spleen on recommendation from Dr. David Golde
- 1976-1983: Moved to Seattle, returned to UCLA for follow-up visits with Golde.
- 1983: Moore became suspicious of new consent form, discovered new patent was filed for 'Mo' cells.



Hairy cell leukemia: abnormal B cells look "hairy" under a microscope because of radial projections from their surface.

UNITED STATES PATENT AND TRADEMARK OFFICE  
CERTIFICATE OF CORRECTION

PATENT NO. : 4,438,032

DATED : March 20, 1984

INVENTOR(S) : David W. Golde et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

On the title page of the patent add as a second paragraph to the ABSTRACT:

--The Mo line has been deposited at the A.T.C.C. on June 3, 1981, with the Accession No. CRL 8066.--

Signed and Sealed this

Nineteenth Day of March 1985

[SEAL]

Attest:

DONALD J. QUIGG

Attesting Officer

Acting Commissioner of Patents and Trademarks



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## Mo [Mo T] (ATCC® CRL-8066™)

Organism: [Homo sapiens, human](#) / Cell Type: [T lymphocyte](#) / Disease: [hairy cell leukemia](#)

[GENERAL INFORMATION](#) [CHARACTERISTICS](#) [CULTURE METHOD](#) [SPECIFICATIONS](#) [HISTORY](#) [DOCUMENTATION](#) [SHARE](#) [EMAIL](#) [PRINT](#)

Name of Depositor Genetics Institute, Inc., Regents of the University of California

U.S. Patent Number [4,438,032](#)

Disclosure This material is cited in a US or other Patent and may not be used to infringe the claims. Depending on the wishes of the Depositor, ATCC may be required to inform the Patent Depositor of the party to which the material was furnished. This material may not have been produced or characterized by ATCC.

References Golde DW, Quan SG. Unique T-lymphocyte line and products derived therefrom. US Patent 4,438,032 dated Mar 20 1984

Mo [Mo T]  
ATCC® CRL-8066™

frozen

For-Profit: \$551.00

Non-Profit: \$459.15

Qty:

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RECOMMENDED FOR THIS PRODUCT



John Moore should receive financial compensation for the ‘donation’ of spleen cells.

Agree or Disagree?

The ownership of cells and tissues should belong to the people from which they originally came from.

Agree or Disagree?