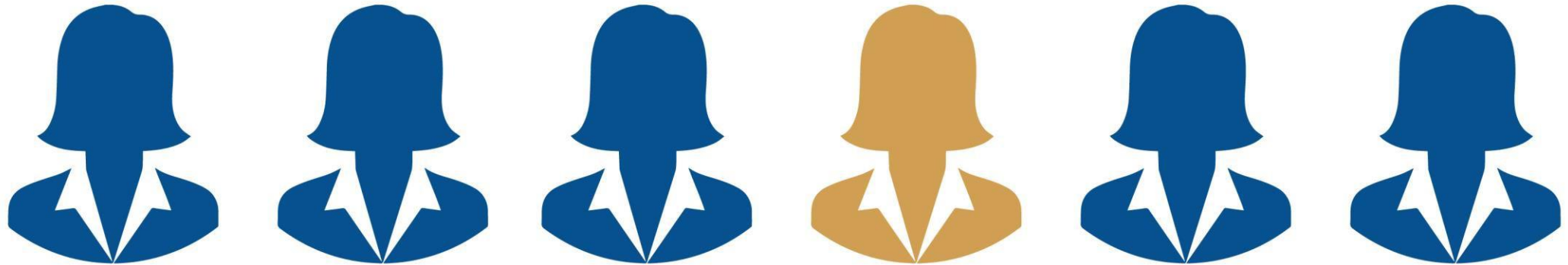




Transformations in
Donor IVF 1980s to Present:

One Woman's Journey

One Of 6 Women Worldwide Met The Definition
Of **Infertile** In The Early 1980s



This **New** Technique



This **New** Group
Of Medicines



This **New** Protocol





The Doctor Telling My Then Husband And I
That He Had **“Big Headed Sperm”**
And I Probably Had **Endometriosis.**

I Thought, **Was ‘Big Headed Sperm’**
A Good Thing Or A Bad Thing?

A large, stylized orange question mark graphic that occupies the right side of the slide. It has a thick, rounded top and a long, curved tail that ends in a small hook.

**What Do We
Need To Do
Next?**

1980s

Numerous Surgical **Laparoscopies**.

6 Month Bouts Of A Drug Called **Danazol** (androgenic hormone).

Which Has Been Removed From The Market Due To **Adverse Side Effects**.

Next Came **9 Monthly IUIs** (intrauterine inseminations).

While Taking An Ovulation Stimulating Drug Named **Clomid**.
Which Created Emotional Side Effects, And By Many
Accounts, Has Been Called The **Clomid Crazyies**.

1990s





By The 1990's, It Was Time To Switch Careers And Move Back To My Place Of Birth,
**The Booming Desert Metropolis Of
Phoenix, Arizona.**

At That Time, Labs Could Only **'Mix'**
The Sperm In A Petri Dish, Called
Conventional Insemination,
And Hope They Would Fertilize The
Eggs.



3

Intramuscular Shots Of
Gonadotropins A Day
To Stimulate My Ovaries
To Mature More Eggs

Daily Shots Of **Lupron**
And Slow, Very Painful Intramuscular
Shots Of **Progesterone** In Sesame
Seed Oil And Finally An
Intramuscular HCG Trigger Shot.

Anesthesiologists Were Virtually **Unused** In The U.S. For
Many IVF Procedures Until Nearly **20 Years Ago.**



The strange story of a fertility drug made with the Pope's blessing and gallons of nun urine



Get thee to a nunnery.

Image: Reuters/Stefano Rellandini

As Oliver Staley Cites In His Article,

“Soon, Tanker Trucks Were Hauling The Urine Of **Hundreds** Of Nuns From Catholic Retirement Homes Across Italy To Serono’s Headquarters In Rome. It Took About **10 Nuns 10 Days** To Produce Enough Urine For One Treatment.”



The **Three** IVF Cycles With My Own Eggs Failed, And
Now My Infertility Was Labeled **“Unexplained.”**
Fifteen Years Had Passed Since I Began, And I Felt Like A
Poster Child For Emerging IVF Treatments, Without The
Baby.

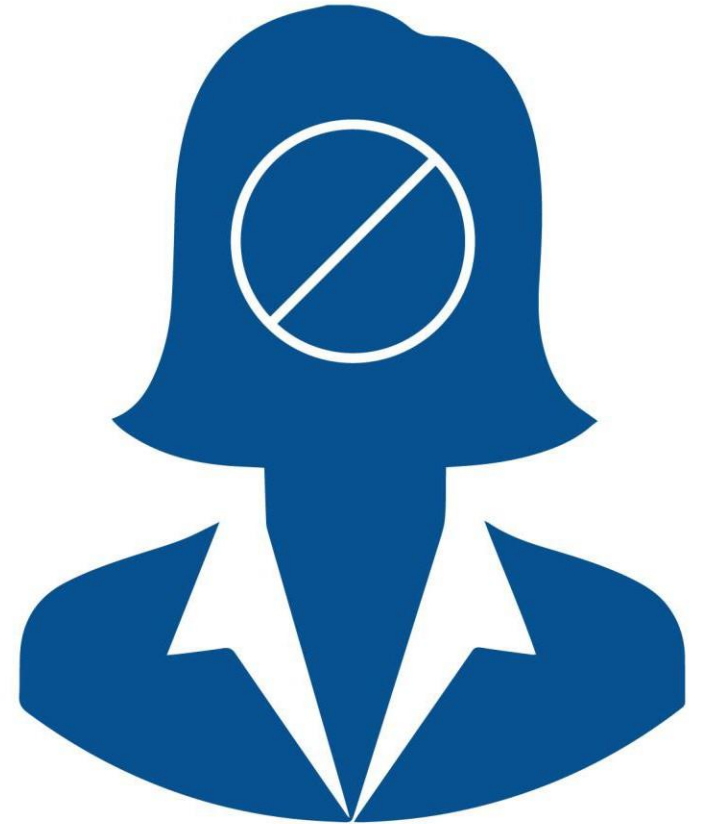
What Options Remained For Us?

1994

I Was Told There Was This **New** Treatment

"It Is New And You Use Another, Younger Woman's, Egg For About A **12%** Chance To Become Pregnant."

Then She Said, We Only Have **One Donor** And You Can't See Her Picture Or Know Who She Is, But Only Information About Her Such As **Height, Eye Color** And **Hair Color.**



What Would I Tell Our Child
About How They **Came To Be?**

Answer Questions About **Who**
Their Donor Was?



PRESS

I Took Matters Into **My Own**
Hands, And Decided I Would
Recruit My Own Donor
Through The **Arizona State**
University Press.

Just How Was I Going To Recruit My Own Donor?

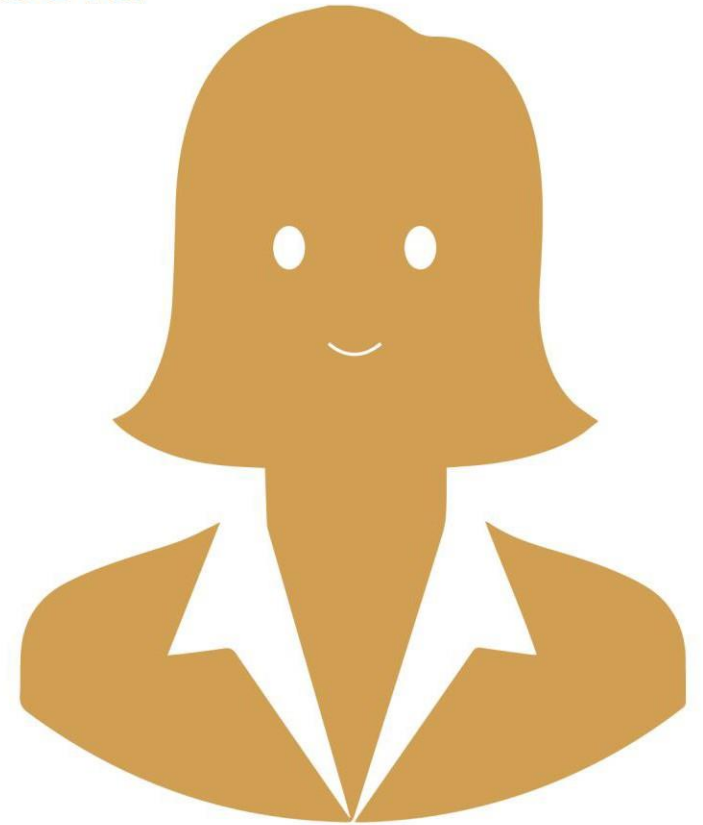


There Were No:

- Guidelines
- Australian Laws Were In Their Infancy
- No US Food And Drug Administrative Oversight Of Human Cells And Tissues

I Developed A Profile So That My Child Could Know:

- Donor's Ethnicity
- Family Medical History
- Interests
- **No Secrets**





I Then Wrote A Simple Contract Which Basically Said The Donor Had **No Rights Or Obligations** To A Child That May Result From Her Donation, And That We Will Retain An **Open Identity Relationship** Unless One Of Us Decides They No Longer Want That Later In Life.

1995

I Conceived My **First Son** In 1995
With Fresh Donor Eggs.

On Record Then, I Had One Of The
First 100 Babies From Donor Eggs In
The United States.





X and Y consulting, inc.

"The Centralized Egg Donor Registry For The Southwest U.S."

"Our highly personalized, thorough and anonymous service provides a non-clinical approach to egg donation that reduces a donor's natural concerns with the screening process and removes uncertainty from the selection process for our clients."

- egg donors
- recipients
- frequently asked questions
- fertility resources
- testimonials

Webpage, graphics and HTML © 2000 eggdonorsnow.com
All Rights Reserved



As A Result In **1996**,
I Started **X And Y Consulting**,
Which Was A Donor Agency To
Match Donors And Recipients For
Fresh Only Donor Cycles.

X And Y Consulting Located Donors
For **Local Doctors**, And Then
National Doctors And Eventually
For **Canadian Recipients** As
Well.

Four Years After Having My First Son, I Became **Pregnant** A Second Time In 1999 With Donor Eggs From A Second, Wonderful Egg Donor, And My **Twin Sons** Were Born September Of **2000**.

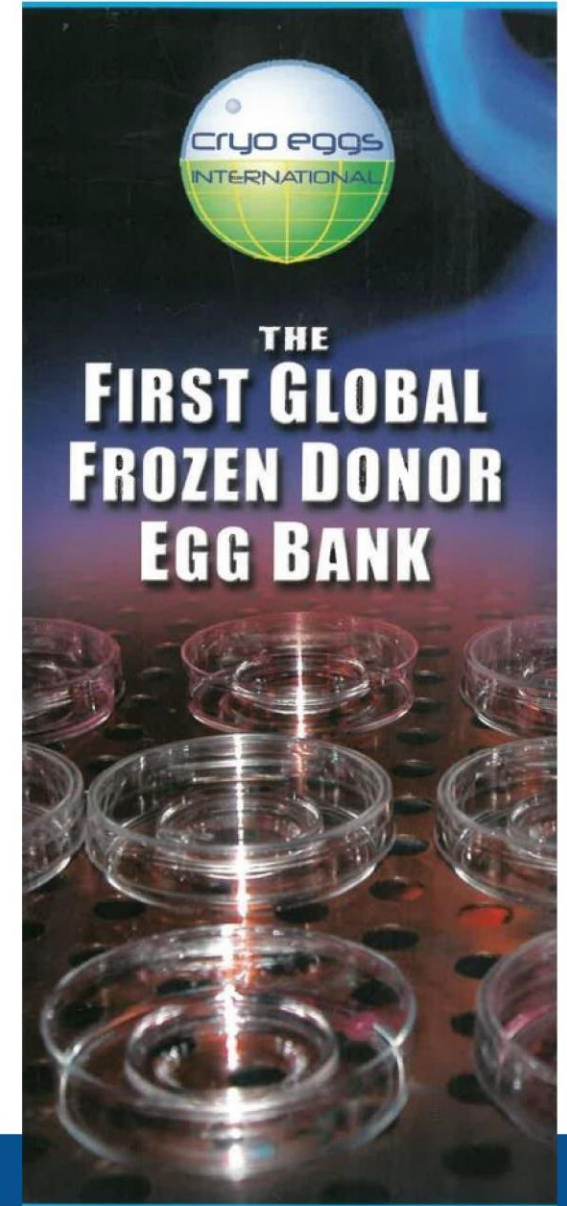
They Were Also Born At **29 ½** Weeks, And Less Than **3 lbs**, And Here They Are Today. With My Own Three Children, **Our Family Was Complete**.



In 2003, I Was Approached By
Dr. Jeffrey Boldt (Scientific Director In Indiana)
And **Dr. James Akin** (And REI In Kentucky) To
Start **The First Commercial Egg Bank**
In **North America.**



We Called The First Commercial Egg Bank,
Cryo Eggs International. I Then Became
CEO For Both **X And Y Consulting**, Which
Matched Recipients For Fresh Donor Cycles,
And Simultaneously Started And Operated
The Business Of **CEI** To Bank Donor Eggs.



Kentucky child, now 5, is first one born from frozen egg, live sperm

By Cheryl Truman — ctruman@herald-leader.com

Posted: 12:00am on Oct 25, 2011; Modified: 7:23am on Oct 25, 2011



Our **First Baby** From Our Frozen Donor Eggs Was Conceived In Kentucky In **2004**, And Born In January **2005**.



Cryo Eggs International Utilized **Slow Freeze Technology**.

Pregnancy Rates With Slow Freeze Technology Were Around **30%** At The Time.

In 2004, ASRM Then Promptly Decided That Egg Freezing Was **“Experimental”**

In An Article Published By Dr. Boldt, He Asked **Why Egg Freezing Was Considered Experimental**, When Other New And Unproven Techniques, Like ICSI Was Not.

We Obtained **International Review Board Oversight** And Continued To Sporadically Work In The U.S. But Also, Provided Our Frozen Egg Offerings In Australia.

We Became **The First** Egg Bank To Export Banked Eggs To These Countries Before 2011 And **The First** To Institute A Verification Program To Ensure End Users Had The Skills And Equipment To Follow Our Egg Warming Protocols.



The World Egg Bank Expands in Australia to Help Women and Couples Wanting Children

The World Egg Bank Hopes to Stop the Five-Year Waiting Gap for Women and Couples Seeking Eggs. TWEB's CEO & Founder Builds International Connections at The 14th World Congress on Human Reproduction in Melbourne, Australia.

Melbourne, Australia ([PRWEB](#)) December 20, 2011 – The CEO & Founder of [The World Egg Bank](#), in Phoenix, Arizona meets with top fertility specialists in Australia to expand availability of fresh and frozen donor eggs for infertile women at the 14th World Congress on Human Reproduction in Melbourne, held earlier this month.

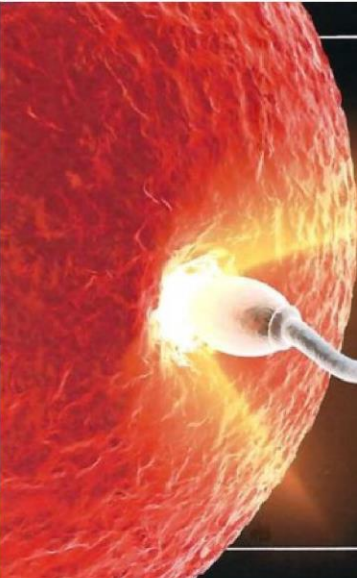
Childless British couples turn to eggs imported from America amid donor shortage

By JO MACFARLANE FOR MAILONLINE


UPDATED: 08:17 EDT, 17 April 2011

In 2009, **Cryo Eggs** International Moved From Slow Freeze Technology To **Vitrification**.

A Decision Was Made To Change Our Name To **The World Egg Bank**.



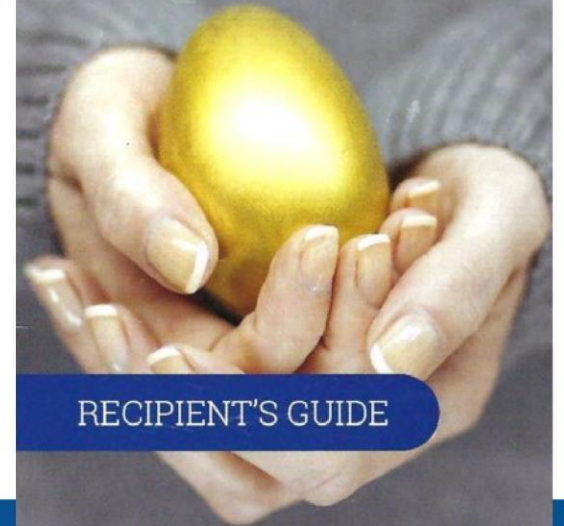
The World Egg Bank is the first global Donor Egg Bank with vitrified eggs ready for immediate use. TWEB is a merger of X and Y Consulting, an international egg donor recruitment agency with 12 years experience, and Cryo Eggs International, with 5 years of oocyte cryopreservation expertise developed by U.S. pioneers in the field: Dr. Jeffery Boldt and Dr. Michael Tucker.



THE WORLD
EGG
BANK



Setting the **GOLD**
STANDARD for Quality.



RECIPIENT'S GUIDE

- Regulations
- Guidelines
- Improved Technologies

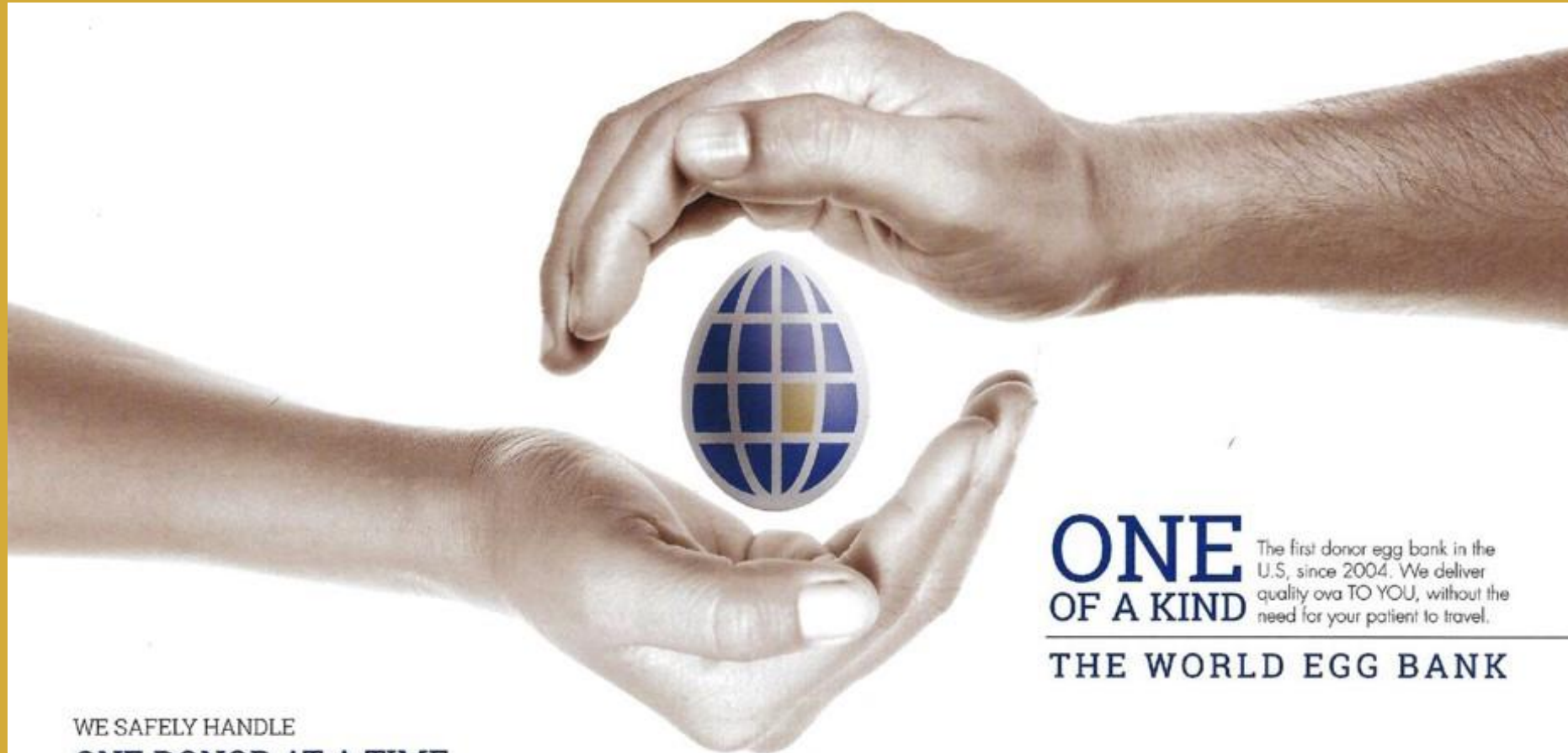
The **Acceptance** Of Frozen Donor Eggs Had Finally Begun To Coalesce, And A Broader Based Egg Banking Industry Began To Unfold.

By 2014, We Realized This Model Hampered **True Quality Control** Measures From Donor Screening To Egg Vitriification.

In The Early Days Of Donor Sperm.

The **General Attitude** Was, And Still Is In Some Instances, That Anyone Who Can Learn To Freeze Eggs Could Start An Egg Bank.

However, Clinics Quickly Learned That Freezing Eggs And Operating An Egg Bank Are Two Very Different Skill Sets.



ONE OF A KIND

The first donor egg bank in the U.S. since 2004. We deliver quality ova TO YOU, without the need for your patient to travel.

THE WORLD EGG BANK

WE SAFELY HANDLE

ONE DONOR AT A TIME

ONE PHYSICAL LOCATION.

Every ONE of our U.S. based donors walks through our clinic doors. All donor eggs are procured from ONE state of the art location.

ONE REAL EGG BANK.

We do not outsource with any other clinic locations and then post donor information on a virtual website.

ONE FOCUS ON QUALITY MANAGEMENT

ONE MEDICAL AND SCIENTIFIC TEAM

of experienced professionals

ONE SHIPMENT HANDLING DIRECTLY FROM OUR LAB TO YOU

We reduce variables with One team, One location, One consistent sets of protocols for Superior Egg Quality and Accountability.

ONE SOURCE

of information for all patients and clinics

ONE FREE ONLINE ACCESS

to all donors medical/genetic history

THREE THOUSAND

Eggs already banked and immediately available

Complies with EU Tissue and Cell Directives 2004, 2015, U.S. Food and Drug Administration (FDA), Australian RITAC and State regulators, Canadian Primary Establishment license, California State Department of Health Tissue Bank license, New York State Department of Health Tissue Bank license.

In 2015, We Chose **A Different** Path From The Networking Model.

We **Built** Our Own Egg Bank For The Sole Purpose Of Screening, Stimulating And Freezing Donor Eggs.

We Managed:

- All Protocols Consistently
- Donor Screening Protocols
- Stimulation Protocols
- Vitrification
- Storage
- Shipping Protocols

In The Decade That Followed From 2012 To 2022

The Internet Is Continuously Being Flooded With **Half-Truths**
And **Misrepresentations**.

“Claims That The Bank Is The:”

- Best
- Largest
- The Highest Caliber Donors
- Most Stringent Quality Control
- Highest Pregnancy Rates
- 25 – 40 Years Of Experience Banking Donor Eggs

This Would Indicate They Began Banking Eggs Between
1983 – 1998, Which Is Simply **Not** An Accurate Statement.

Donor Concierge:

Access to 25,000 donors

We find egg donors and surrogates by searching from the best egg donor and surrogacy agencies in the United States*

*Yet Their Roster Of Donors Is Largely From Eggs Imported Into The U.S.

However, One Of The Most **Disturbing** Trends That Has Emerged Since Around 2018-19, Is The Hidden Reality That Most Egg Banks Are **Importing Eggs From Developing Countries.**

New Life Network Staff only speaks Russian, Georgian and English.

- New Life in Ukraine
- New Life in Georgia
- New Life in Mexico
- New Life in Colombia
- New Life in India
- New Life in Poland
- New Life in South Africa
- New Life Latin America
- New Life Latin America

One Egg Bank Says That All The Vitrification Of Eggs Is Carried Out By The **Same Experienced Team** In California, Yet They Also Display This Map On Their Website, Which Clearly Presents Another Story.



How Eggs Are Procured And Handled **Impacts** The Donor, The Recipient And The Clinic.

It Is A **Huge Responsibility** As Doctors Who Wish To Help Patients Build Their Families With **Safe, Transparent** And **Morally Acceptable** Treatments.

Shouldn't We **Ask Ourselves** If It Is Acceptable To Agree To Using Imported Eggs, When A Patient Is **Unaware** Of The Risks, But Wants The Eggs?

Cyprus human egg trade market returns to spotlight

Young female students on the island are emerging as prime targets that are approached and persuaded to sell off their eggs in exchange for cash

18 JUNE 2020 - 14:17



Poor legal regulation threatens health of Ukraine's egg donors

Paid surrogacy and the practice of egg donation remain unresolved regulatory issues in both Poland and Ukraine.

FIRST THINGS

EGG DONORS AND HUMAN TRAFFICKING

by
Michele Clark
4.1.08

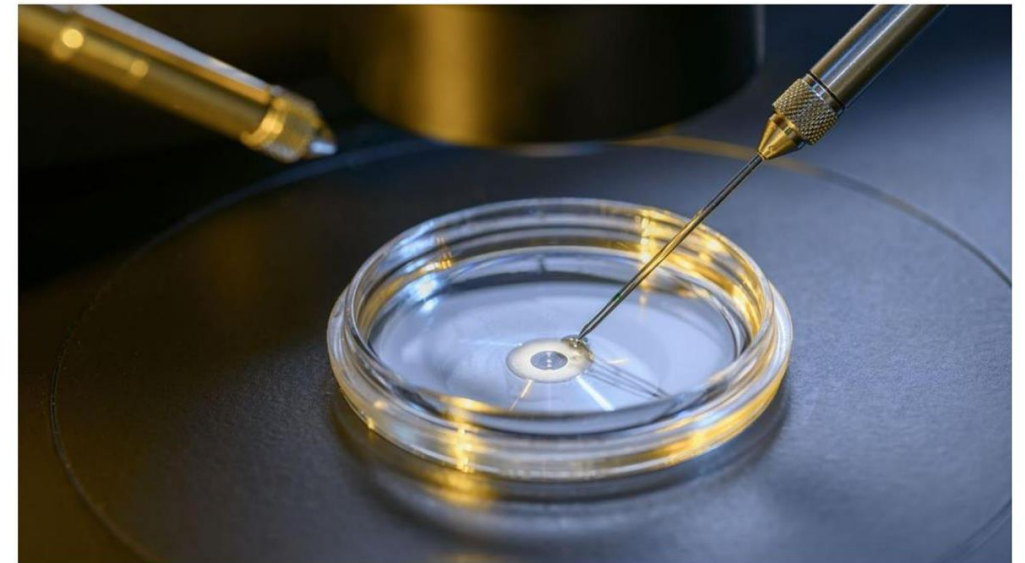
THECENTERFORBIOETHICS
ANDCULTURENETWORK

CBC

IS EGG “DONATION” AND SURROGACY THE NEWEST FORM OF HUMAN TRAFFICKING?

Posted by Jennifer Lahl, CBC President | Sep 18, 2019 | #BigFertility, Blog,

Egg donor IVF programme halts over concerns at Ukraine clinic



Human trafficking: the fastest growing crime

By CM Guest Columnist · July 31, 2022 · 0 comments · 1606 views

SHARE



0



US Secretary of State Antony Blinken speaks during the 2022 Trafficking in Persons (TIP) Report launch ceremony at the State Department, in Washington DC

More than 60 arrested in £500,000 European human egg trafficking and illegal adoption ring

► Doctors, medical staff and lawyers among those arrested in raids



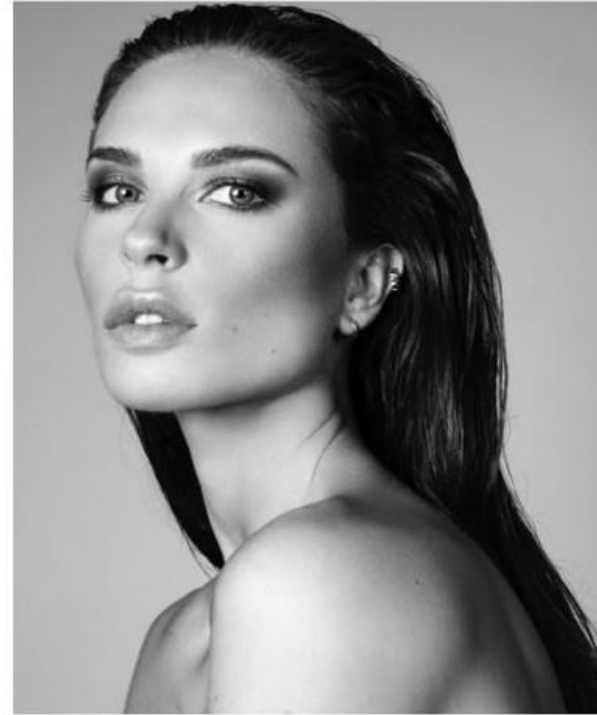


Donor Snapshot

Location	London
Ethnicity	Caucasian
Maternal Heritage	Latvian, Lithuanian, Russian
Paternal Heritage	German, Polish, Northwestern European
Year of Birth	1997
Height	5'11"
Weight	134 pounds
Natural Hair Color	Blonde
Eye Color	Green
Fertility Testing	AMH: 4.45 ng/mL

What are your hobbies?	I am a trained classical and jazz pianist. So music is definitely a hobby that preserved
Please list any special skills, talents, or abilities you have:	I am fluent in German, Latvian, Russian, French and English and know ancient Latin as well

ID PHOTO:



DONOR SNAPSHOT:

Location

Florida

Are you a US Citizen or have permanent residency? Green Card is pending

Level of Education: Graduate School

Name of College Currently Attending or Attended: University in Ukraine

Degree(s) Received : N/A

Major(s) or Emphasis: Economics: Management and Administration

Current Occupation: Model, DJ and Electronic Music Producer



Location	Illinois
Ethnicity	Caucasian
Maternal Heritage	Ukrainian
Paternal Heritage	Ukrainian
Year of Birth	1994
Height	5'5"
Weight	131 pounds
Natural Hair Color	Brown
Eye Color	Blue
Fertility Testing	AMH: 4.04 ng/mL

Name of College Currently Attending or Attended	College in Ukraine
Degree(s) Received	1 year apart from BA
Major(s) or Emphasis	Philology and accounting
Are you a US Citizen or have permanent residency?	No
If no, then what type of visa are you on?	Asylum

Form 1

Alias:
Julia 910

Country:
Outside of USA

Age:
24

Height:
5'3"

Weight:
103 lb

BMI:
18.2

Eye Color:
Brown

Natural Hair Color:
Black

Blood Type:
O+

What is your highest level of education?:
College in progress or equivalent

Racial Background:
Chinese,

Racial Description:
Chinese

Form 1

Alias:
UG-40164

Country:
Outside of USA

Age:
25

Height:
5'6.4"

Weight:
154.3 lb

BMI:
24.6

Eye Color:
Blue

Natural Hair Color:
Brown

Blood Type:
O

What is your highest level of education?:
College completed or equivalent

Racial Background:
White,

Racial Description:
Ukrainian

DONOR ID	SPERM BANK	DONOR TYPE ?	ETHNICITY	ETHNIC ORIGIN	DONOR ID	SPERM BANK	DONOR TYPE ?	ETHNICITY	ETHNIC ORIGIN
472973	Aphrodite Egg Bank	Identity options	Caucasian	Greek/Greek	OV0AR86691	Global Gamete Bank	Identity options	Caucasian	Venezuela
488615	Aphrodite Egg Bank	Identity options	Caucasian	Romania/Romania	OV0AR86806	Global Gamete Bank	Identity options	Caucasian	Argentina
489340	Aphrodite Egg Bank	Identity options	Caucasian	Romanian	OV0AR86829	Global Gamete Bank	Identity options	Caucasian	Argentina
490450	Aphrodite Egg Bank	Identity options	Caucasian	Albanian/Albanian	OV0AR86911	Global Gamete Bank	Identity options	Caucasian	Argentina
494043	Aphrodite Egg Bank	Identity options	Caucasian	Serbian/Serbian	OV0AR86948	Global Gamete Bank	Identity options	Caucasian	Argentina
500695	Aphrodite Egg Bank	Identity options	Caucasian	Serbian/Serbian	OV0AR86957	Global Gamete Bank	Identity options	Caucasian	Argentina
501458	Aphrodite Egg Bank	Identity options	Caucasian	Serbian/Serbian	OV0G002082	Global Gamete Bank	Anonymous	Asian	Kazakhstan
511726	Aphrodite Egg Bank	Identity options	Caucasian	Serbian/Serbian	OV0G002083	Global Gamete Bank	Anonymous	Asian	Kazakhstan
512289	Aphrodite Egg Bank	Identity options	Caucasian	Greek/Greek	OV0G002084	Global Gamete Bank	Anonymous	Asian	Kazakhstan
519865	Aphrodite Egg Bank	Identity options	Caucasian	Greek/Greek	OV0G002085	Global Gamete Bank	Anonymous	Asian	Kazakhstan
531499	Aphrodite Egg Bank	Identity options	Caucasian	Ukrainian/Ukrainian	OV0G002088	Global Gamete Bank	Anonymous	Asian	Kazakhstan
532755	Aphrodite Egg Bank	Identity options	Caucasian	Greek/Greek	OV0G002089	Global Gamete Bank	Anonymous	Asian	Kazakhstan
533250	Aphrodite Egg Bank	Identity options	Caucasian	Bosnian/Serbian	OV0G020810	Global Gamete Bank	Anonymous	Asian	Kazakhstan
538593	Aphrodite Egg Bank	Identity options	Caucasian	Ukrainian/Ukrainian	OV0G020811	Global Gamete Bank	Anonymous	Asian	Kazakhstan
543049	Aphrodite Egg Bank	Identity options	Caucasian	Serbian/Serbian					
543890	Aphrodite Egg Bank	Identity options	Caucasian	Ukrainian/Ukrainian					
546402	Aphrodite Egg Bank	Identity options	Black / African American	Cameroon/Cameroon					
548966	Aphrodite Egg Bank	Identity options	Caucasian	Ukrainian/Ukrainian					
549479	Aphrodite Egg Bank	Identity options	Caucasian	Mother: Ukrainian, Father: Russian					
551226	Aphrodite Egg Bank	Identity options	Caucasian	Bulgarian/Bulgarian					

OV0G020812	Global Gamete Bank	Anonymous	Asian	Kazakhstan
OV0G020813	Global Gamete Bank	Anonymous	Asian	Kazakhstan
OV0G020815	Global Gamete Bank	Anonymous	Asian	Kazakhstan
OV0K001648	Global Gamete Bank	Anonymous	Caucasian	Ukraine
OV0K005657	Global Gamete Bank	Anonymous	Caucasian	Ukraine
OV0K006878	Global Gamete Bank	Anonymous	Caucasian	Ukraine

Hundreds Of Imported Donor Eggs, Which Can Be Purchased And Shipped To The U.S.

These Imported Eggs Are Openly Distributed By A Company Calling Itself **"Global Gametes,"** Which Is Another Company Name For The **OvoBank** That Also Directly Exports Eggs From **Ukraine To The U.S.**

GLOBAL CIRCUITS OF FERTILITY:
THE POLITICAL ECONOMY OF THE UKRAINIAN OVA MARKET

Polina Vlasenko

Submitted to the faculty of the University Graduate School
in partial fulfillment of the requirements for the degree
Doctor of Philosophy
in the Department of Anthropology,
Indiana University
August 2021

Polina Vlasenko Wrote Her Ph.D. Dissertation Called
**“Global Circuits Of Fertility: The Political
Economy Of The Ukrainian Ova Market.”**

“My Fieldwork Took Place Between 2015 And 2018 And Included More Than **100 Interviews** With **Egg Donors, Surrogates, Medical Professionals,** And **Fertility Brokers,** And 15 Months Of Participant Observation In A Ukrainian Egg Bank, That Delivers Frozen Eggs To Any Destination Worldwide.

Most Western Wouples And Clinics Are More Likely To Aspire To Have A **Middle-Class Egg Donor** Or **Surrogate Mother**, Because Her Class, As Well As Education Level, Has Become Proxy For Her Strong Intellectual Abilities And Healthy Lifestyle That They Desire, And Can Free Them From The Ethical Concerns That They Are “**Exploiting Poor Third World Women**”. As A Result, Some Doctors Try To **Portray** Their Donors And Surrogate Mothers As Not Belonging To The Lowest Classes, But Rather Representing A National Average In Terms Of Income. This Also Allows Doctors To Avoid The Accusation Of “**Exploiting**” Donors Because Of Their Poor Material Conditions And Marketing Them To Foreign Couples.”

You Can Go Online And See Widely Advertised Ukrainian Eggs For **\$5,000 Per Cohort Of 6**. Yet U.S. Clinics Are Still Charging **17,000 To 22,000** For The Same Cohort Of 6 Eggs.

My Staff Also Had A Doctor In The U.K Recently Ask Them, **‘Why Would We Use Your Egg Bank When I Can Make So Much Profit Off These Imported Eggs?’**

As Long As These **‘Lead Firms’** Continue To Be Motivated By Money, **As They Are Not Passing The Savings On To The Patients**, The Eggs Will Continue To Be Procured Under Questionable Circumstances.



The Transportation Of Vitrified Eggs Is **Equally Precarious.**

Transportation Takes:

- **Undocumented** Or Only **Partially Documented** Paths From Various Locations Such As Ukraine To Spain And Then To Canada.

OR

- Eggs Are Transported To A Location In The EU, And Then To The U.S To Egg Banks

OR

- Eggs Are Shipped From Eastern Europe To Spain To The U.K, Where They Are Redistributed Either Directly Or Indirectly To U.K And U.S.

Does The Patient, The Doctor Or The Embryologist Know The **True Egg Retrieval Source**?

Do U.s. Patients Think They Are **Obtaining** Eggs From Donors In The U.K Or Spain, When The Eggs Are Collected In Many Other Countries But Distributed Through The U.K Or Spain?

How Many Times Were The Eggs **In And Out** Of Cryo Tanks At Locations That May Or May Not Be Qualified To Repackage Them For Shipment Again?

How Many Times Can Single Vitrified Cells Be Transported Around Without **Damage**?

Are Patients Being Made Aware Of These Risks?



The Donor's Health

How Many Times Are These Donors Being **Stimulated And Retrieved?**

Who Is Watching Family **Limits?**

How Are They Being **Stimulated?**

What Kind Of **Care** Or **Fair Treatment** Do These Women Have Access To In Countries With **Little To No Health Care** Or **Legal Rights For Women?**

The Websites That Advertise Imported Eggs Are Aware Of The Potential Criticisms And Have Statements Such As:

We are proud to declare that our company fully complies with European IVF standards as well as with the FDA, Health Canada, HFEA, ANVIZA, ANZICA and other requirements. We ensure compliance with the highest world IVF standards in every step of our activities.



FDA regulatory compliance

- FDA registered egg donor bank (Ovogene, IVMED)
- All donors approved by an FDA certified laboratory

INTERNATIONAL DONOR EGGS: WHAT PROVIDERS SHOULD KNOW

Many intended parents opt for international donor eggs as an affordable way to gain access to a large and diverse selection of donors, many of whom will reflect the physical, ethnic, religious, or social characteristics of an intended parent or their family. Although sourcing donor eggs internationally can be safe, compliant, and successful (see our article on pages 6-7, "International Donor FAQs"), not all countries or programs can provide eligible, legal, or ethically sourced donor eggs for your patients. As you support your patients in finding the right donors for them, there are many considerations for sourcing international donor eggs:



REGULATORY COMPLIANCE

Although a facility may be registered with the FDA to complete donor oocyte screening and eligibility activities, the registration alone does not ensure compliance. Here are some additional factors to consider:

A DONOR'S RESIDENCE AND TRAVEL

- FDA regulations prohibit donation from individuals who have spent a prolonged time or received specific medical treatment in 30 European countries, including the United Kingdom and Spain.¹²
- The FDA^{1,3} and Health Canada⁴ prohibit donation from any donors who reside in an area with an increased risk for Zika virus. Additionally, these entities prohibit donation from individuals who have traveled to (or had sexual contact with a partner who has traveled to) an area with an increased risk for Zika virus within a set time frame.

ADHERENCE TO STRONG STANDARD OPERATING PROCEDURES

- It's one thing to have standard operating procedures (SOPs) in place, and it's another to follow them. While registration for the FDA takes mere minutes, the real substance of the work lies in following strong SOPs and including risk factor questionnaires and thorough screening. In this way we can truly focus on the intent of FDA requirements: putting practices in place throughout our process to further mitigate risk. At Donor Egg Bank USA, we understand that it's not about pushing through donors, but rather relying on comprehensive processes to put forth well-screened candidates who are FDA compliant.

INFECTIOUS DISEASE TESTING

- The FDA¹ and Health Canada⁴ require that infectious disease tests for donors must be licensed, approved, or cleared by the FDA (or equivalent Canadian accreditation for Canadian donors). Testing from a non-registered or non-accredited laboratory is not compliant.
- West Nile virus testing⁵ is to be completed on all gametes that come from international countries, whereas here in the U.S., one may opt to test for only a portion of the year.



INDUSTRY AND THE AMERICAN SOCIETY OF REPRODUCTIVE MEDICINE (ASRM) STANDARDS

DONATION LIMITATIONS

- The ASRM recommends limiting oocyte donors to no more than six retrievals.⁶ While countries are not bound by this guidance, Donor Egg Bank USA ensures that oocyte donors participate in no more than six retrievals.

PSYCHOLOGICAL EVALUATION

- The ASRM has established criteria for completing psychological evaluation⁷ and counseling for donor candidates. Many international programs have not implemented a psychological evaluation screening process. Additionally, many fail to work with mental health professionals who use appropriate testing tools (such as PAI or MMPI) in the donor candidate's primary language, or who have completed training as recommended by the ASRM.

Sources:

1. Title 21 Code of Federal Regulations, part 1271, subpart C
2. FDA Guidance for Industry Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/TPs) - <https://www.fda.gov/media/73072/download>
3. FDA Guidance for Industry - Donor Screening Recommendations to Reduce the Risk of Transmission of Zika Virus by Human Cells, Tissues, and Cellular and Tissue-Based Products - <https://www.fda.gov/media/96528/download>
4. Health Canada Directive: Technical Requirements for Conducting the Suitability Assessment of Sperm and Ova Donors
5. FDA Guidance for Industry - Use of Nucleic Acid Tests to Reduce the Risk of Transmission of West Nile Virus from Living Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/TPs) - <https://www.fda.gov/media/87050/download>

LEGAL AND ETHICAL

LOCAL LAWS FOR DONATION, COMPENSATION, AND REIMBURSEMENT

- Although intended parents may receive treatment in a country where the use of donor eggs is legal and regulated, the eggs should also be collected in compliance with local laws. International donation laws vary significantly. Without thorough research or consulting, it may be difficult to identify or comply with the requirements for international donation. For example, Ukrainian legislation requires that all donor candidates must have a child of their own prior to donating.⁸
- Many countries regulate the compensation or reimbursement received for a donation. Canada prohibits compensation⁹ for Canadian donors but permits importation of eggs from donors who receive compensation. Australia prohibits the use of donor gametes in Australia if the donor received compensation.¹⁰

DONOR RECRUITING, CONSENTING, AND CARE PRACTICES

- If an international program is unregulated, there is no absolute assurance that they are using ethical practices for donor recruitment. Additionally (without the safeguards of regulations), these programs are not legally bound to provide adequate informed consent for screening, testing, retrieval process, and other processes associated with being a donor. That would include providing sufficient monitoring and ambulatory care, or proper treatment in the event of an adverse reaction to donation.
- Donor Egg Bank USA is committed to compliant and ethically sourced donor eggs. As part of our qualification process, we review the recruiting, compensation, consenting, and care processes for donors at our international partner clinics. We take steps to help ensure the safety and care of all donors and the reputation of those clinics with which we partner. We are committed to helping provide you with donor eggs that meet federal and local regulations.



We Need To Ask, Where Is The **Accountability**?

FDA Regulation of Human Cells and Tissues

<https://www.fda.gov/media/133837/download>

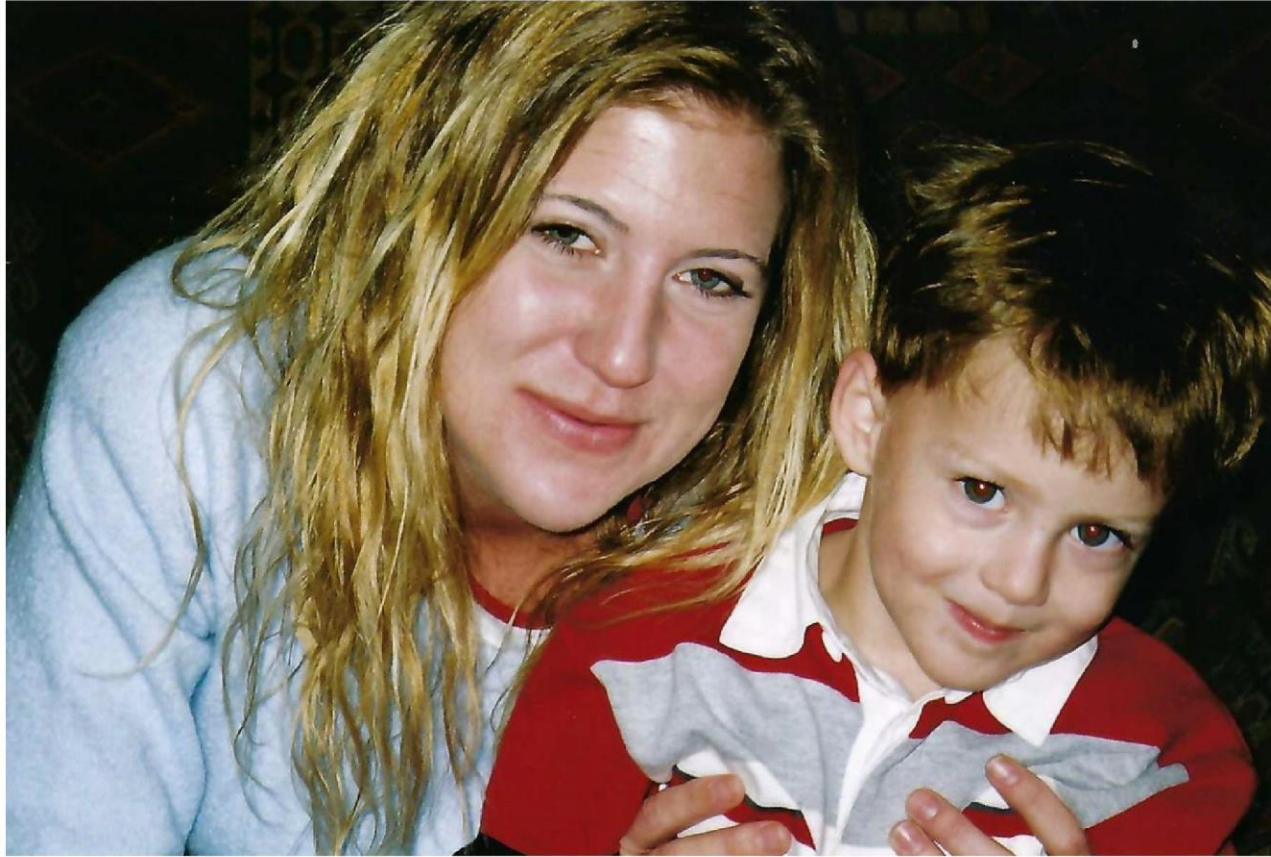
“Foreign establishments that offer HCT/Ps for import into the United States must register and list. They must identify a U.S. agent who is located in the U.S. and has a U.S. address and phone number.

“The **expectation** is that all HCT/Ps distributed in the U.S. are manufactured in accordance with FDA regulations. FDA will assign each location a permanent registration number. It is important to emphasize that registration is not the same as a pre-market review, **nor does it ensure an establishment is in compliance** with all regulations.”

These Donors Are Anonymous, Despite What A '**Consent**' May Imply.

“According to We are Donor Conceived, 65% of respondents agree with the statement “My donor is half of who I am”. 94% indicated they often wonder what personality traits, skills, and/or physical similarities they share with their donor. 96% of respondents said they would like to know how many donor siblings they have, and a strong majority indicated they are open to forming a relationship with their donor (87%) or donor siblings (96%).”



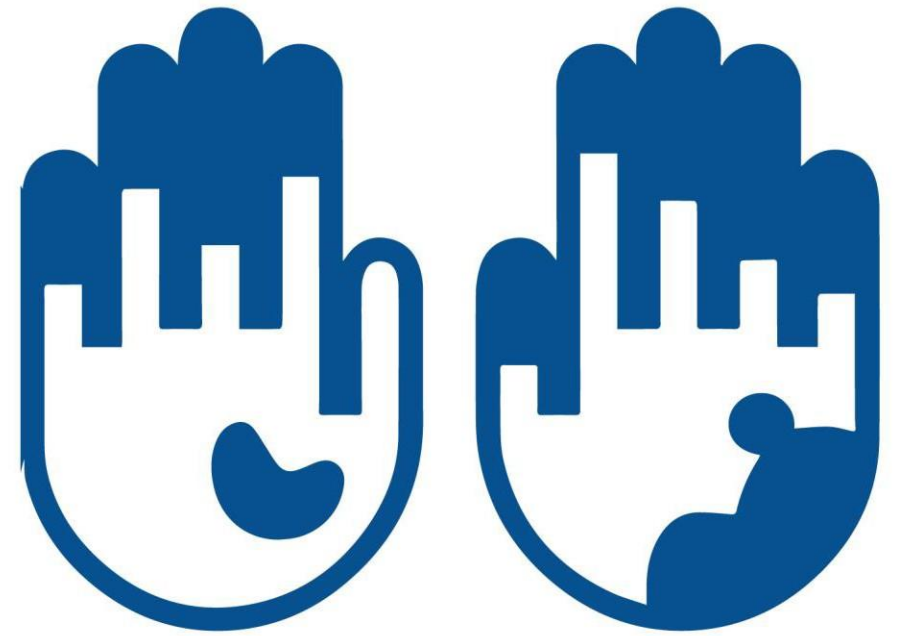


I **Knew** My Donors, My Children **Knew** Their Donors, And Legislation Around The World Has For Decades Acknowledged And Enforced Open Identity Donors.

In Australia, We Began A Donor Open Identity Policy In 2011 That Grew From **10% Of Our Donors To 95% Of Our Donors Today.**

Colorado Already Has An Open Identity Only Donor Law That Will Come Into Effect In A Few Years.

Banks And Clinics Say There Aren't Enough U.S. Donors, As Further Rationalization That We "**Need**" These Imported Eggs For Patients. We Also '**Need**' Human Organs For Transplant, But We Don't Justify Obtaining Them From Unethical Sources.



It Is Time We Start To Separate **Fact From Fiction**

I Have Been Told In Writing By The NASS Data Management Contractors For The CDC, That **No Foreign Egg Data Is Entered** On ART Cycles That Occur Outside Of The U.S.

In Fact, In An Informal Survey Via Email And Linkedin I Conducted With Over A Hundred Responses, Indicates That **51%** Of Clinics Responded That **They Do Not Know The Original Retrieval Location Of The Eggs They Warm.**



When Asked Where The Donor Eggs They Warm Originate From (When They Do Know), This Was The Response:

45% Are From The U.S., **45%** Are From Spain, **4%** Are From The U.K, And **6%** Are Directly From Eastern Europe.

Note: The Eggs From Spain Are Eastern European Eggs Relocated To Spain And Then Shipped Out Again To The U.S. The Eggs From The U.K Are Imported Eggs First Shipped To The U.K And Then Re-shipped To The U.S.

Furthermore, **67%** Replied That They Enter Data On Foreign Egg Retrievals Into SART.



In 2021, I Relocated And Expanded My Company From A 7,500 To A 14,000 Square Foot Custom Built Egg Bank And Added Our Sperm Bank.





Much Has Changed In Egg Donation Over **40 Years**.

We All Want To Be **Aware, Informed, Diligent** And Maintain Our Heartfelt Desire To **Put Patients First**, And Provide Them With The Information They Need To Make Informed Choices.

If We Do Not Wish To Be Legislated On How To Behave, Our Current Ability To Largely '**Self-regulate**' Will Require All Of Us To Ask Question And Take Responsibility For Patient Choices When Those Choices Are Unduly Influenced By Misleading Marketing Efforts And Subterfuge.

We Cannot Expect Non-profit Organizations To **Police The Worldwide Industry** - It Is Incumbent On Each Of Us To Avoid Assumptions And Accept That **Ethical Decisions Must Be Made By Every One Of Us.**

Change Is **Imminent** And When It Occurs, My Hope Is That We Can Inform Our Future Vision For IVF From Our Own Humanity, For The Humanity Of Others Who **Trust Us To Do So.**



Transformations in
Donor IVF 1980s to Present:
One Woman's Journey

THANK YOU