Alemtuzumab

The Eagle has landed...in Europe

Alemtuzumab was compared against the most widely used class of medications in the world. It was not compared against a placebo as in most other studies. At the end of the day, a reasonable person would conclude that alemtuzumab is better than the medications used in first line therapy for reducing relapses and reducing the rate of worsening disability.

Can the FDA justify a rejection of a transformational medication such as Alemtuzumab based on safety considerations?

Perspective on Safety From a Multiple Sclerosis Patient

Five Year Follow up Data on CAMMS223 Trial

Withdrawal From Therapy Due to Adverse Events:

Alemtuzumab=3.25%

Rebif=12.1%

THE PROOF IS IN THE PUDDING!

R

Summary of All Clinical Trials

Thyroid Disorders
alemtuzumab=39%
Rebif=28%

Regulators:

" There is concern about life long risk of hypothyroidism resulting from alemtuzumab"

Prevalence and Impact of Thyroid Disease

An estimated 20 million Americans have some form of thyroid disease.

One woman in eight will develop a thyroid disorder during her lifetime.

Most thyroid diseases are life-long conditions that can be managed with medication.

In fact, both of my sisters and my mother have hypothyroidism and will be on synthroid for the rest of their lives.

Generic synthroid was prescribed 70.5 million times last year in the United States

It would be absurd to reject Lemtrada based on concerns of thyroid disease.

I would gladly trade my life long MS for life long hypothyroidism.

You can replace thyroid but you cannot replace neurons!

Regulators:
There is concern for increased incidence of thyroid cancer.

CARE MSI and CARE MSII
Thyroid Cancer

Alemtuzumab=6
Rebif=0

Perspective:
PROGNOSTIC FEATURES — Most patients with thyroid cancer do not die of their disease.
(From Up To Date)

Follow up on All Phase II and Phase III Trials

ITP
Alemtuzumab=1.8%
Rebif=0.9%

ITP is treatable and curable
There is no cure for MS.

Regulators:
There is concern for increased rate of infections.

CARE MS I and CARE MS II Infections:

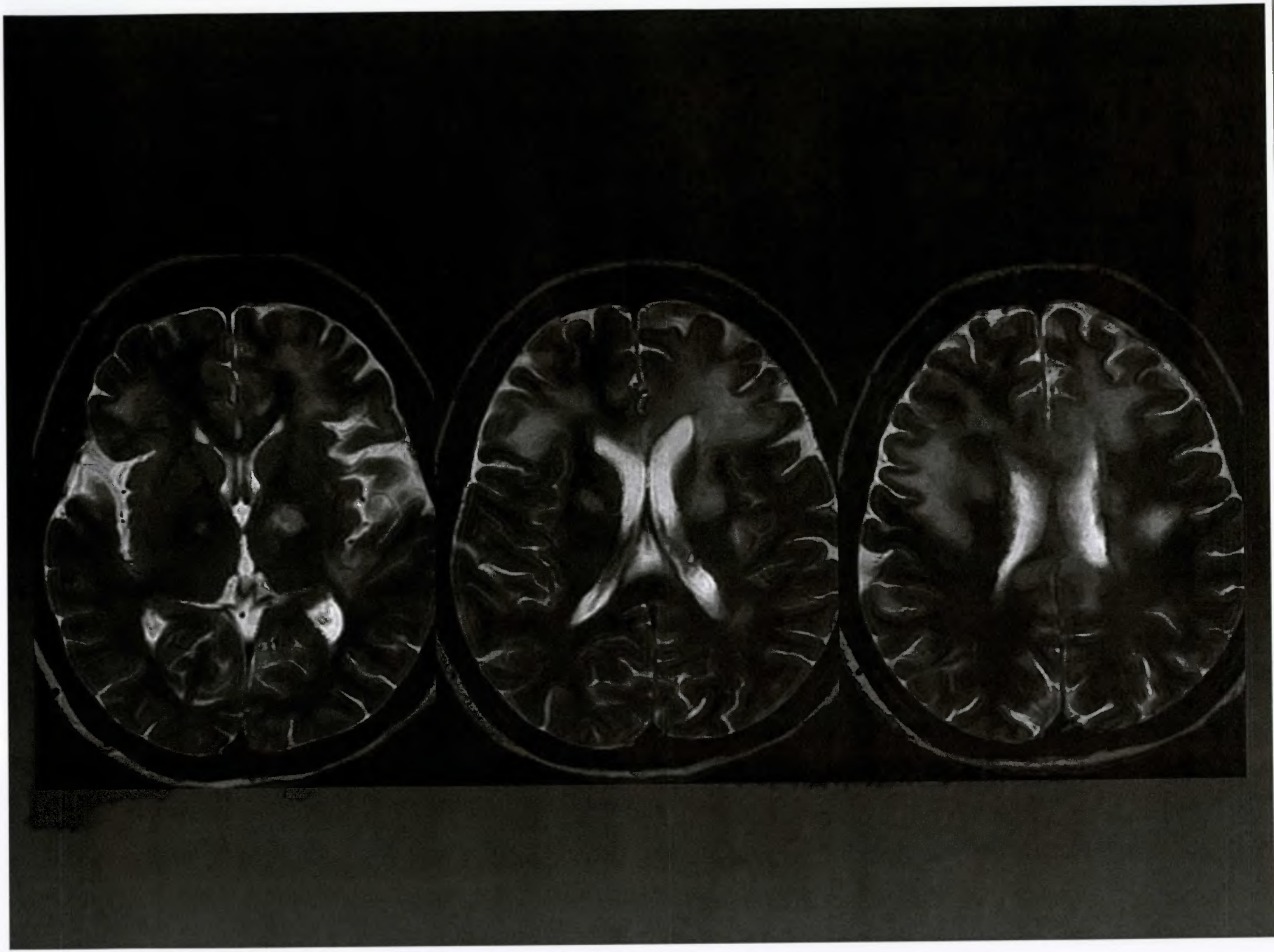
Alemtuzumab=67%-77%

Rebif=45%-66%

The reported infections were mild in both groups of patients. No infection led to a withdrawal from therapy. The most frequent reported infections in order of frequency:

- Nasopharyngitis (common cold)
- Urinary tract infection
- Herpes Simplex (mouth sores)
- Sinusitis
- Influenza

Risk of PML for a Patient on Tysabri From the Perspective of a Multiple Sclerosis Patient and Why the MS Population Needs Alternative Therapies



Status of PML Cases

- As of 2nd July 2013:
  - 88 patients have died (23%)
  - 289 patients are alive (77%)
    - It is too early to draw conclusions about the outcomes of patients who develop PML while on natalizumab treatment

- PML may be fatal or result in severe disability[1]

The median time to death was 2.2 months (range, 0.1 to 15.2 months) for 44 deaths as of 29th February 2012.

1. TYSABRI Summary of Product Characteristics
2. Biogen Idec, data on file.

biogen idec

PML Reported Cases While on Disease Modifying Therapy as of Oct 2013

Alemtuzumab=0

Tysabri=401

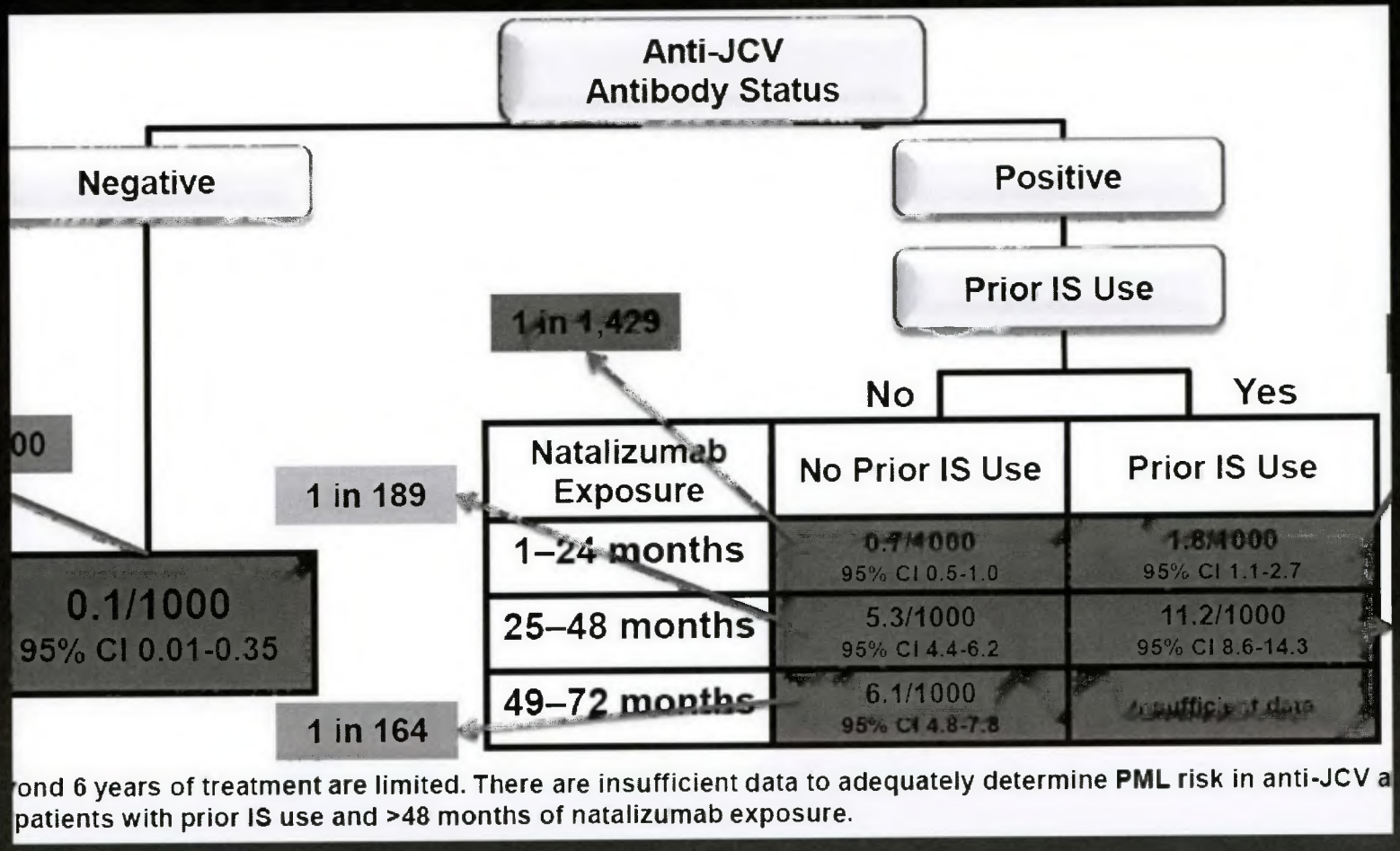
How can you justify a rejection of Lemtrada due to "potentially lethal complications" when Tysabri has already resulted in 88 lethal complications and hundreds of patients with severe disability due to PML?

Death as a Complication of Disease Modifying Therapy

Alemtuzumab=1 (unrecognized ITP in phase II trial)
Tysabri=88

After adopting a risk management strategy for Lemtrada and comparing it to the risks of Tysabri, a reasonable person would conclude that Lemtrada is safer than Tysabri.

Risk of PML



ond 6 years of treatment are limited. There are insufficient data to adequately determine **PML** risk in anti-JCV a patients with prior IS use and >48 months of natalizumab exposure.

If your risk of PML was 1 in 164, would you choose to stay on Tysabri?

Patients like me were started on Tysabri after we failed or could not tolerate the other available therapies.

Seventy percent of patients who start on Tysabri, withdraw from therapy by 48 months due to fear of PML.

The patients who failed the injectables, who then switched to Tysabri, who now fear PML, can choose to go to an oral therapy. What happens if these patients can't tolerate the oral therapies or relapse?

An alternative therapy, such as Lemtrada is needed for these people.

EscalateTherapy Slowly as Disease Worsens

vs

Treat Disease at the Earliest Presentation With the Most Effective Therapy

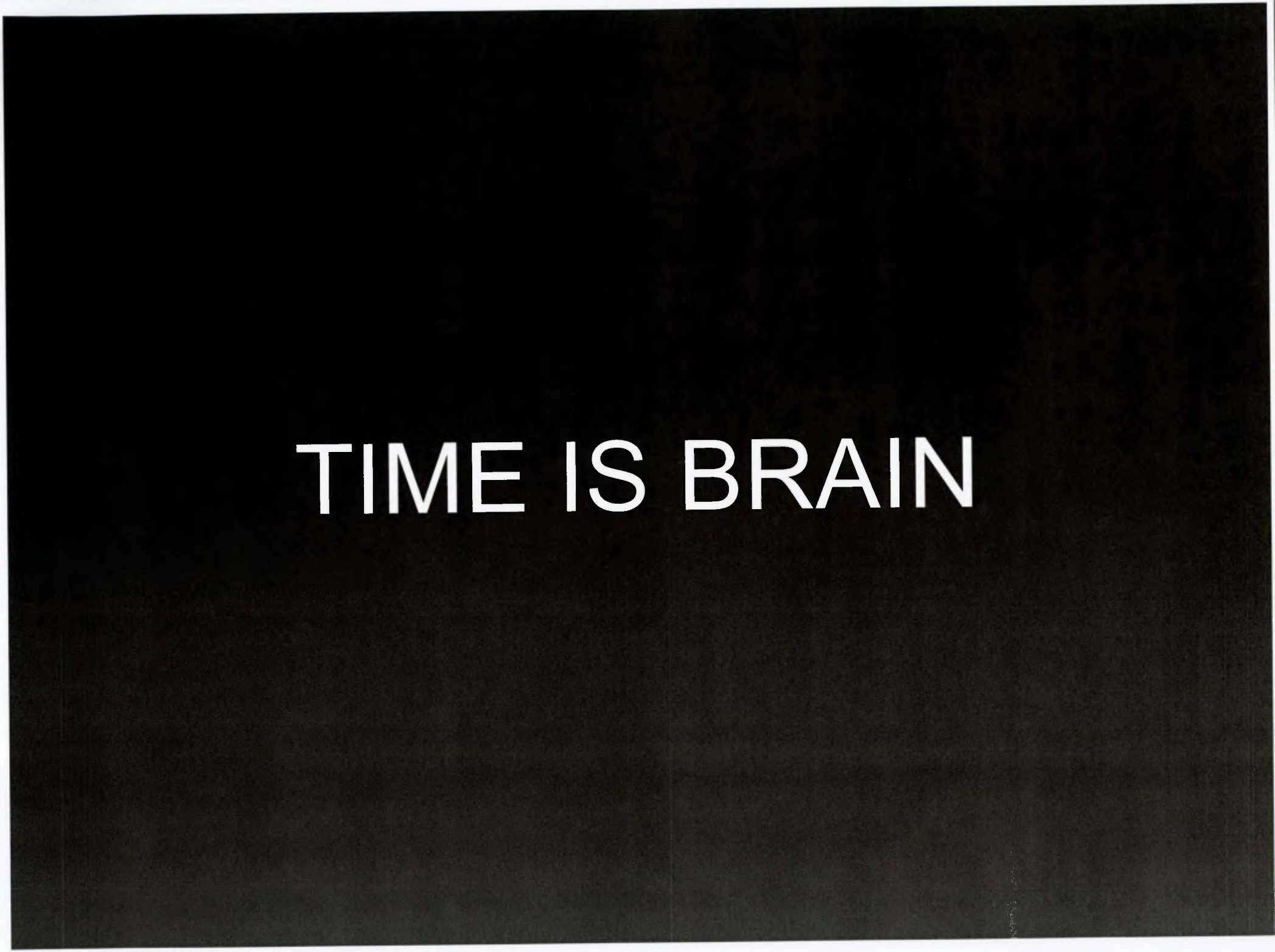
Maintenance Therapy
vs
Induction Therapy

Who should make these choices? In the new era of personalized medicine, the regulators should enable the patients and neurologists to make these choices.

Alemtuzumab:
Durable remission?
Cure for some patients?
Both outcomes are beneficial.
Do we need to wait twenty years to find out?
Or...can we manage the risks and offer this option now?

Alemtuzumab offers the MS patient a 50-60% chance of durable remission or cure in exchange for a 30% chance of thyroid disease and a 2% chance of ITP.

I call that a
"No Brainer"


TIME IS BRAIN

If one of your family members had MS, wouldn't you want them to have a choice? We, as patients, deserve the right to have a choice of therapy.


Control
Multiple sclerosis