Ethics, Regulation and Public Policy in Cognitive Enhancement

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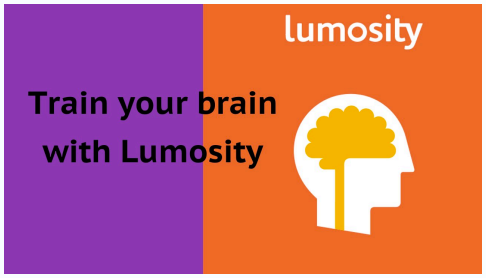
What is enhancement?

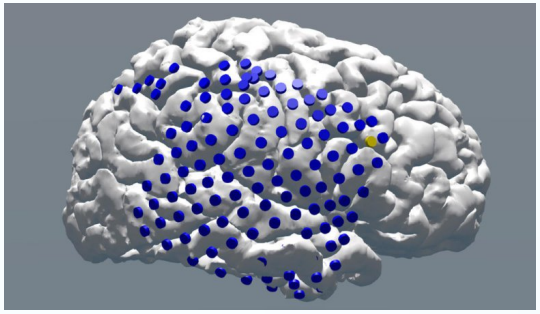
Treatment

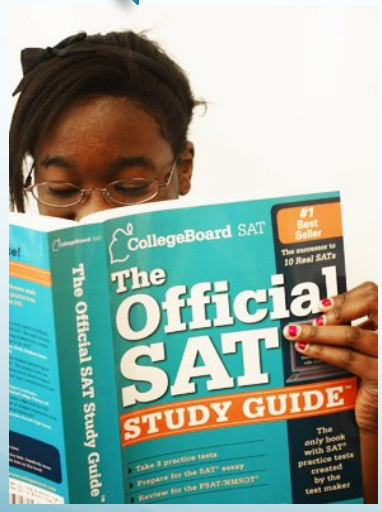
"Normal?"

Enhancement

What is *cognitive* enhancement?







Cognitive Enhancement: Ethical Issues

Safety (short and long-term)

Effects on personality/identity

Access

Authenticity

Coercion

*Commercialization of techniques

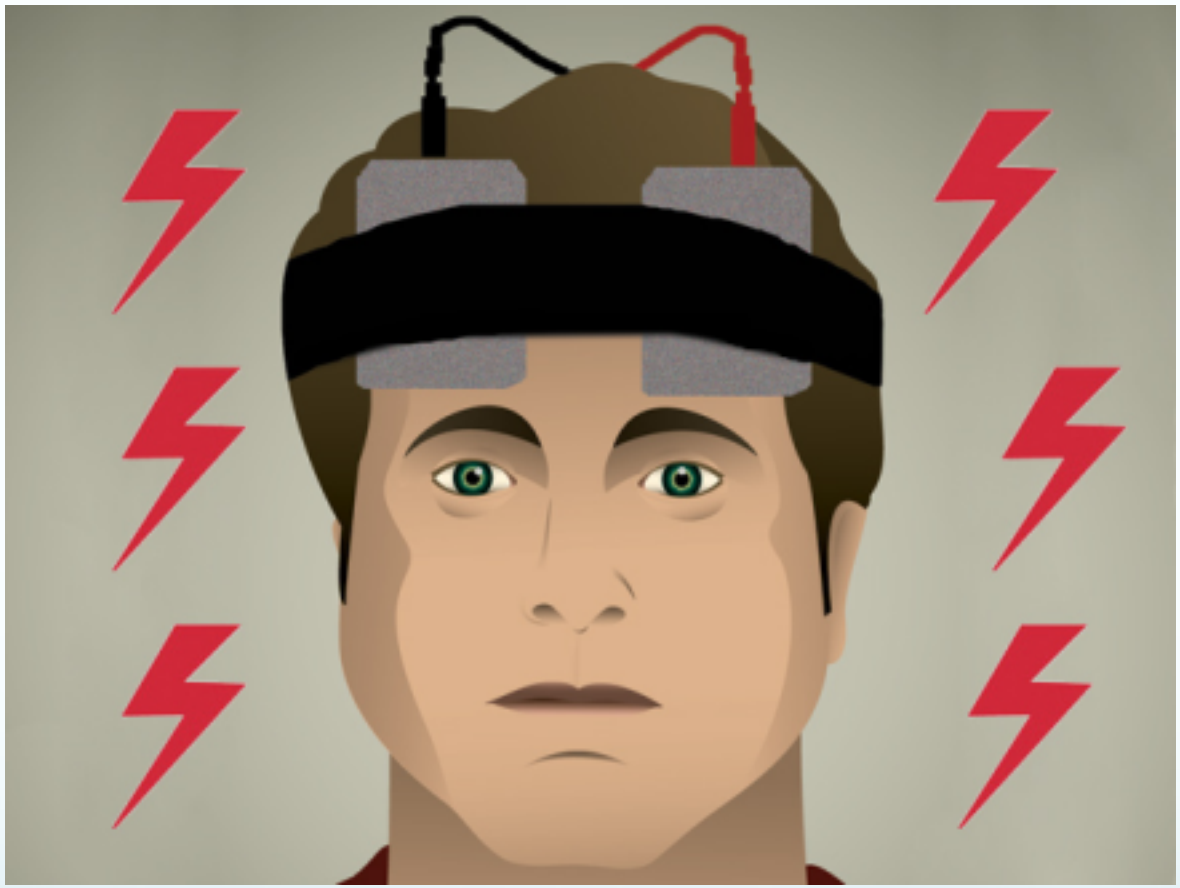
Safety: Side effects/short-term

Cognitive enhancement **drugs**: dizziness, insomnia, loss of appetite and depression on withdrawal

Cognitive enhancement **devices**: itching, tingling, headache, skin redness, burning sensation, and occasional skin burns

Safety: long-term/unknown risks

Effects of chronic use?



Use on children?

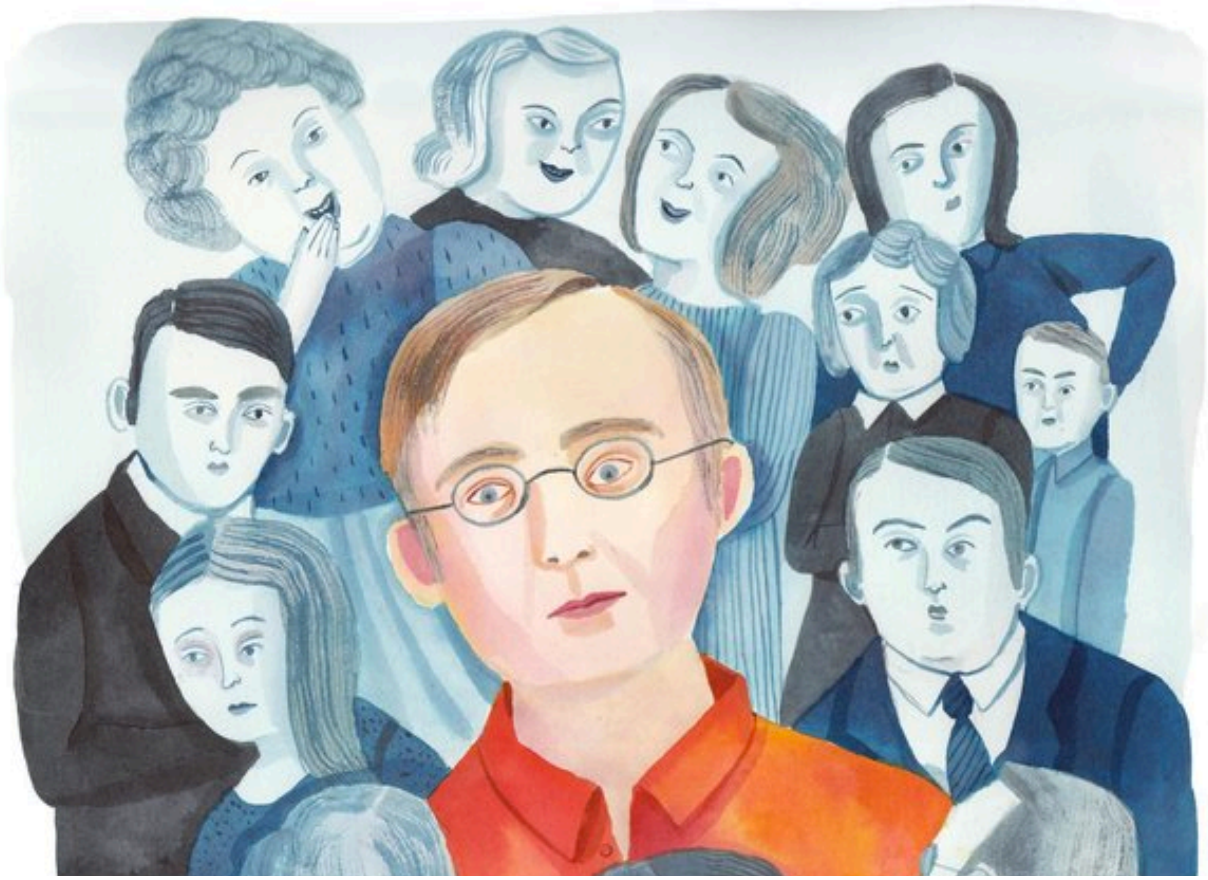
Interaction with drugs & pre-existing conditions

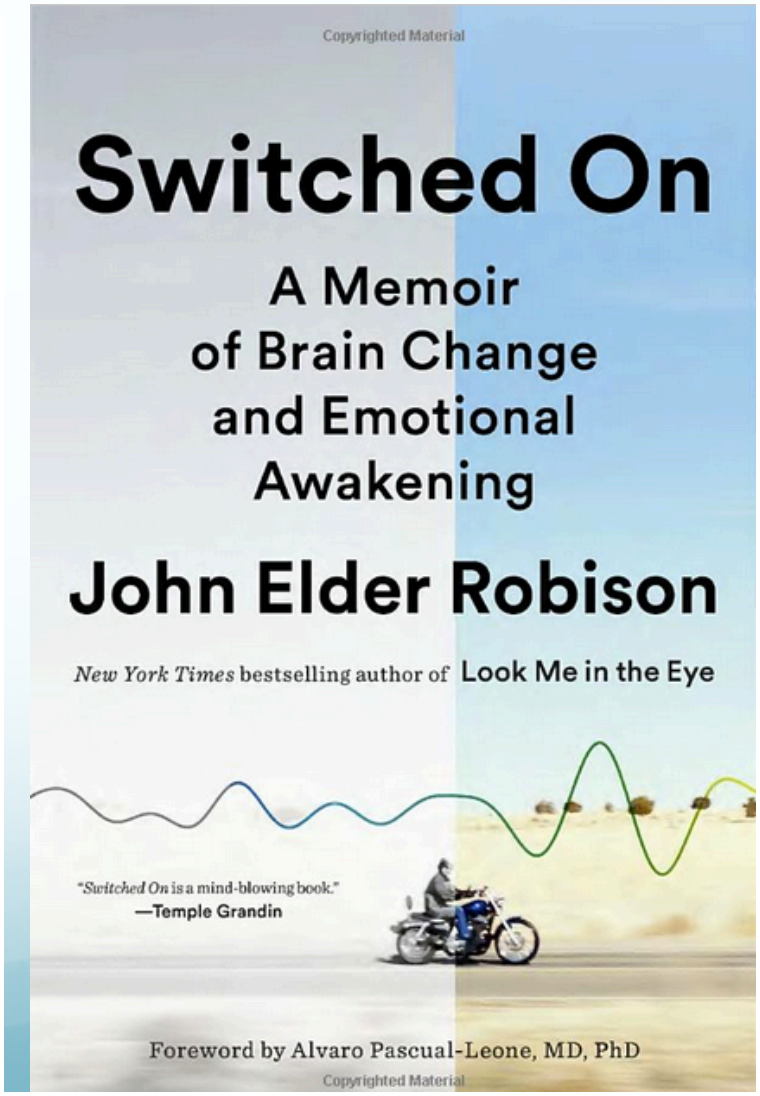
Effects on personality/identity

The New York Times

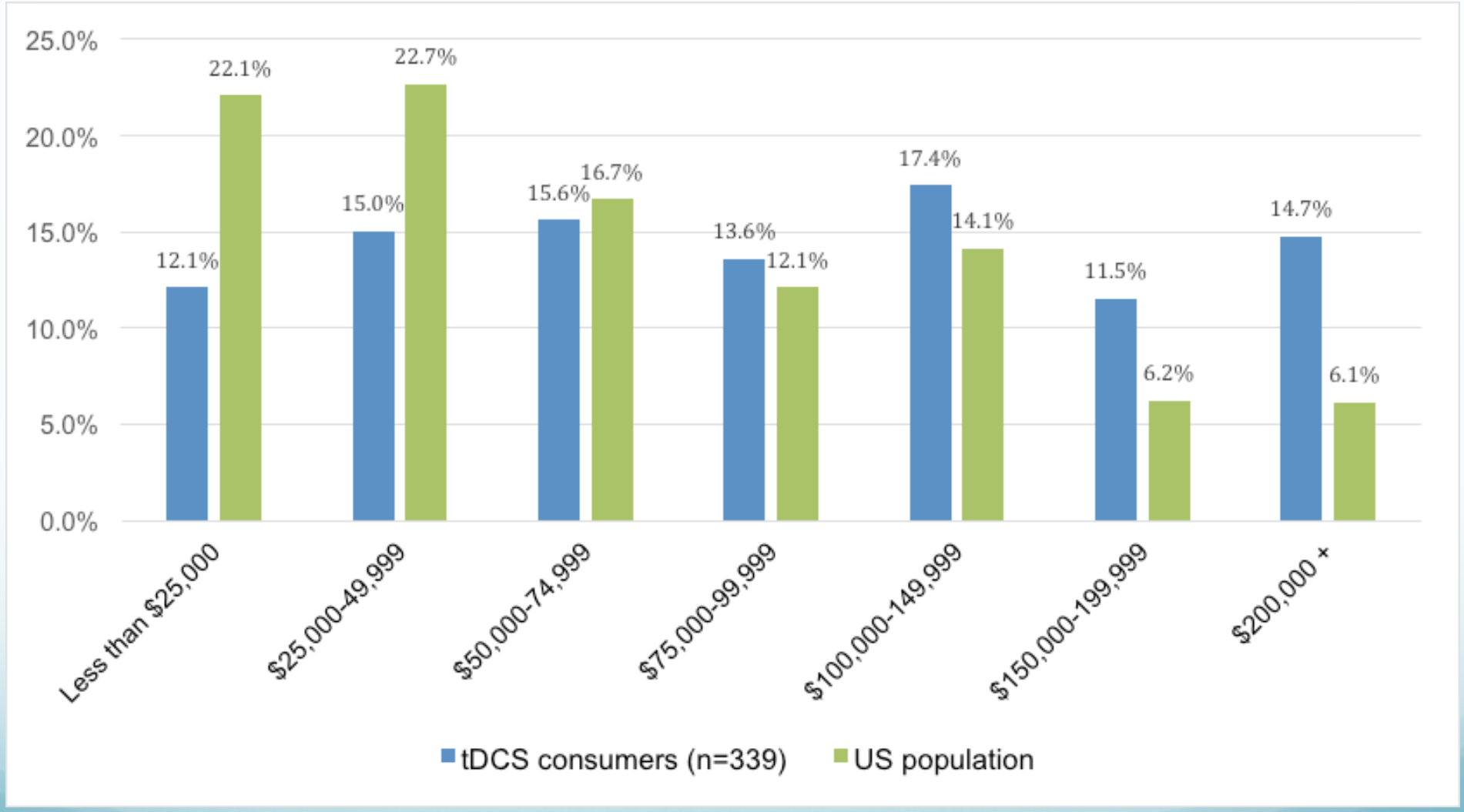
An Experimental Autism Treatment Cost Me My Marriage

By JOHN ELDER ROBISON MARCH 18, 2016 6:00 AM 357





Access and inequality



Household income distribution, tDCS consumers compared to U.S. population (2016 US census data).

Authenticity

Leon Kass: “personal achievements impersonally achieved are not truly the achievements of persons”

Coercion

Better brains, better society.

Nootropics for Everyone.

Commercialization of cognitive enhancement products

halo neuroscience

Thync

NERVANA: Changing the Way You Feel Music

The World's First Consumer Product to Stimulate the Body's Pleasure Center in Synchronicity to Music

Cognitive enhancement: regulatory issues

FDA (Food, Drug and Cosmetic Act)

FDA (Dietary Supplement Health and Education Act)

Cognitive enhancement: regulatory issues

Are products marketed for cognitive enhancement considered medical devices?

Definition of a Medical Device

According to Section 201(h) of the Food, Drug & Cosmetic (FD&C) Act, a medical device is:

an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

- recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
- **intended for** use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
- **intended to** affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes.

Regulated by the **Food and Drug Administration (FDA)**

Regulated by the **Consumer Product Safety Commission (CPSC)**

Direct-to-consumer tDCS Devices

Power Your Mind!

Reducing Depression

Reducing pain

tDCS Provides a Learning Boost

Increase your attention span and stimulate your neurons to improve math skills, language abilities, creativity, and visual association.

RECHARGE YOUR BRAIN

tDCS allows you to unlock your brain's true potential!

tDCS for Medical Use

tDCS had been widely applied to treat Depression, also in Chronic Pain, Amblyopia, Alzheimer's disease, Migraine, Parkinsonism, Tinnitus, Stroke and etc.

tDCS has also been documented as having impressive potential to treat depression, anxiety, PTSD, as well as chronic pain.

Finally, there is drug free (DIY) method to increase Concentration as well as relief for Depression, Anxiety and Migraines!

General Wellness:
Policy for Low Risk Devices

Guidance for Industry and
Food and Drug Administration Staff

Document issued on: July 29, 2016.

general wellness products presenting a low risk to safety will *not* be regulated as medical devices by the FDA

A **general wellness product** is one that makes claims related to "maintaining or encouraging a general state of health" without references to diseases or conditions

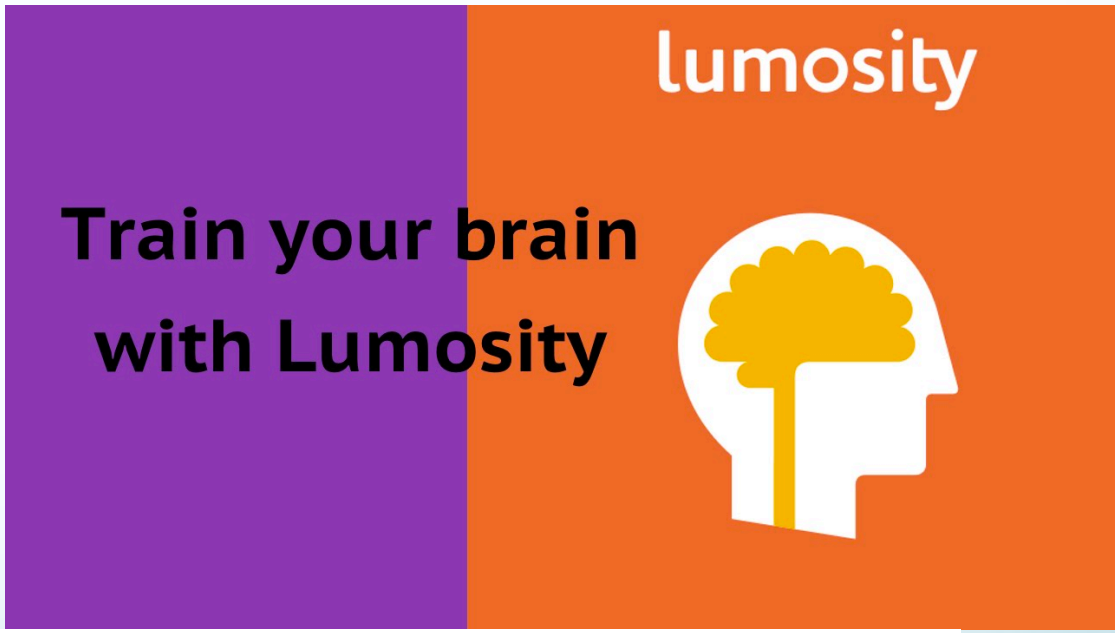
Examples of acceptable wellness claims are those relating to:

"mental acuity"
"concentration"
"problem-solving"
"relaxation and stress management"

FEDERAL TRADE COMMISSION
PROTECTING AMERICA'S CONSUMERS

Federal Trade Commission

Section 5 of the FTC Act prohibits **"unfair or deceptive acts or practices"** in commerce



FTC Charges Marketers of 'Vision Improvement' App With Deceptive Claims

Carrot Neurotechnology & Owners Agree to Stop Making False Claims That 'Ultimeyes' App Improves Users' Vision; To Pay $150,000 to Settle FTC's Allegations

Intersection of science and law

Frye v. United States (1923): court excluded polygraph evidence, noting that a scientific test "must be sufficiently established to have gained **general acceptance** in the particular field in which it belongs."

Frye standard of general acceptability… law defers to scientific opinion

Daubert vs. Merrell Dow Pharmaceuticals (1993): overturned Frye (in all federal cases)… judge can use multiple criteria when evaluating reliability of scientific evidence: (a) "whether it can be (and has been) tested;" (b) whether "the theory or technique has been subjected to peer review" and publication; (c) "its known or potential rate of error and the existence and maintenance of standards controlling its operation"; (d) "general acceptance."

Frye (deference to science) and *Daubert* (non-deference to science)

Thank you!

Faigman, David L. (2013). "The Daubert revolution and the birth of modernity: Managing scientific evidence in the age of science."

Wexler, Anna. (2016). "A Pragmatic Analysis of the Regulation of Consumer Transcranial Direct Current Stimulation (tDCS) Devices in the United States." *Journal of Law and the Biosciences*, doi:10.1093/jlb/lsv039

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