YOUNG RESEARCH SUBJECTS, OLD PROBLEMS

Prof dr I.D. de Beaufort

Department of Medical Ethics and Philospohy


BBC
监控录像显示
BBC NEWS

- “To experiment on children in ways that are not related to them as patients is already a **sanitized form of barbarism** which pays no attention to the faithfulness-claims which a child, simply by being a normal or a sick or a dying child, places upon us and medical care.”


ETHICS

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Balancing between non-maleficence, dignity, beneficence and solidarity

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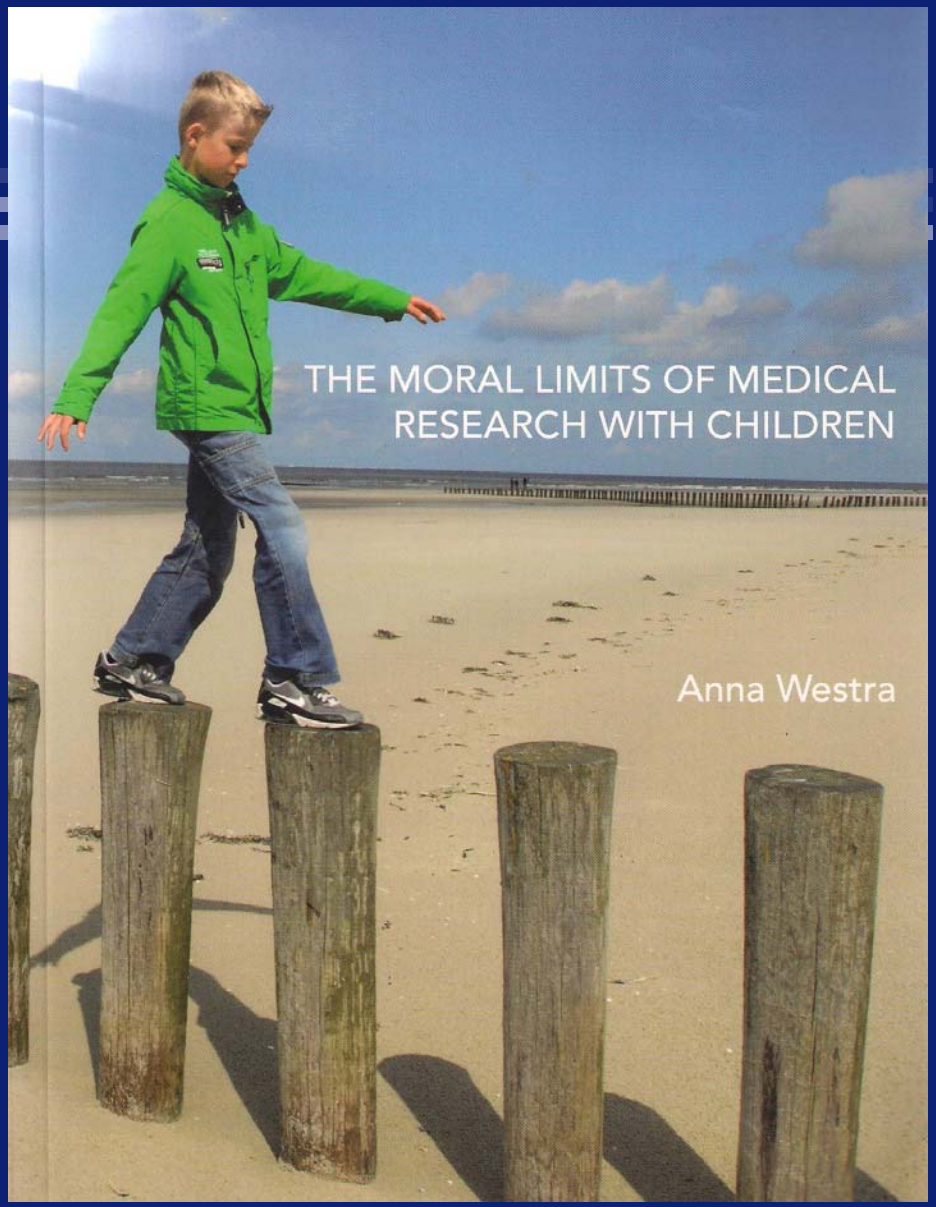
To use (off-label) treatments on children that have not been subject of research is, prima facie, unethical.


THE MORAL LIMITS OF MEDICAL RESEARCH WITH CHILDREN
Anna Westra

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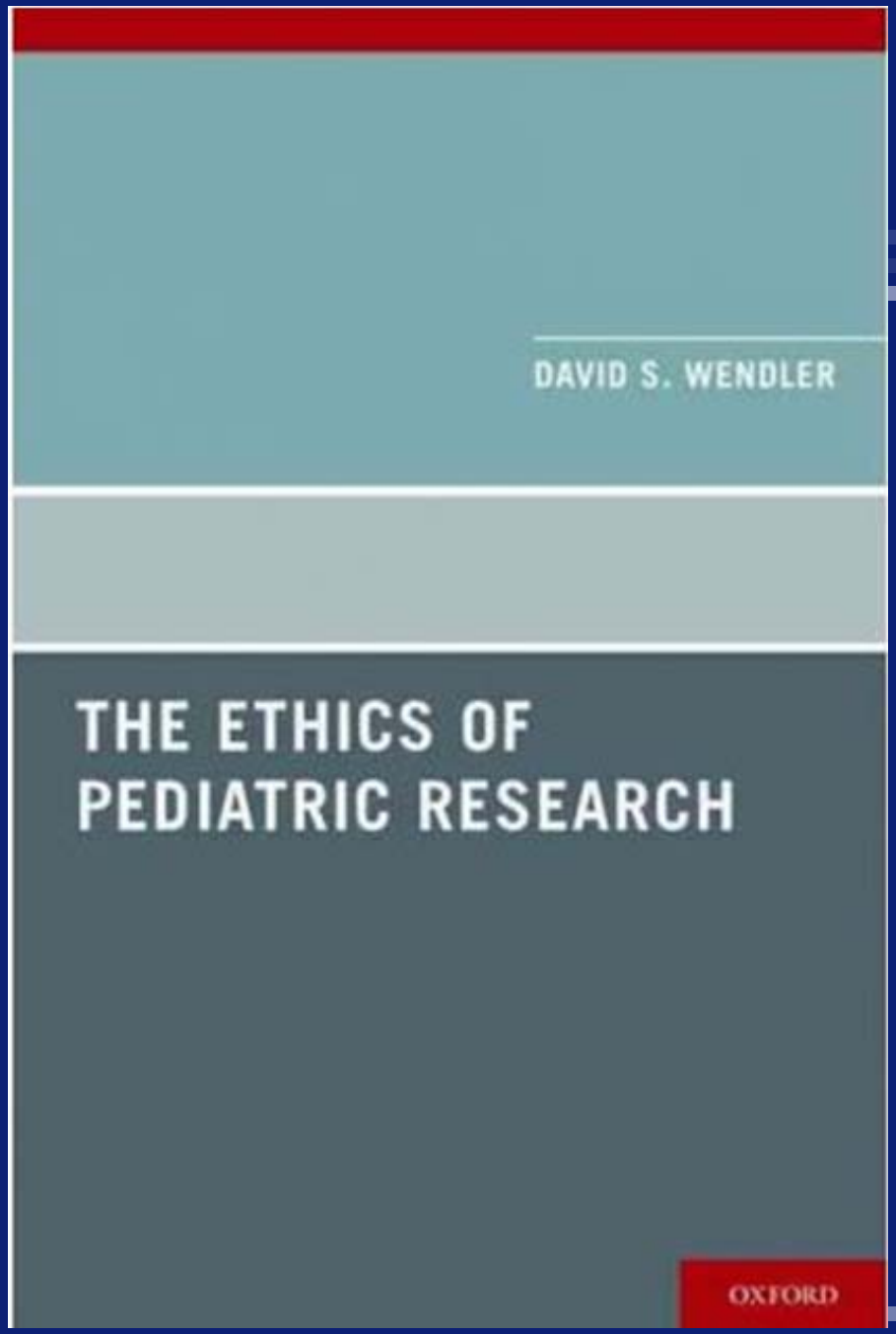

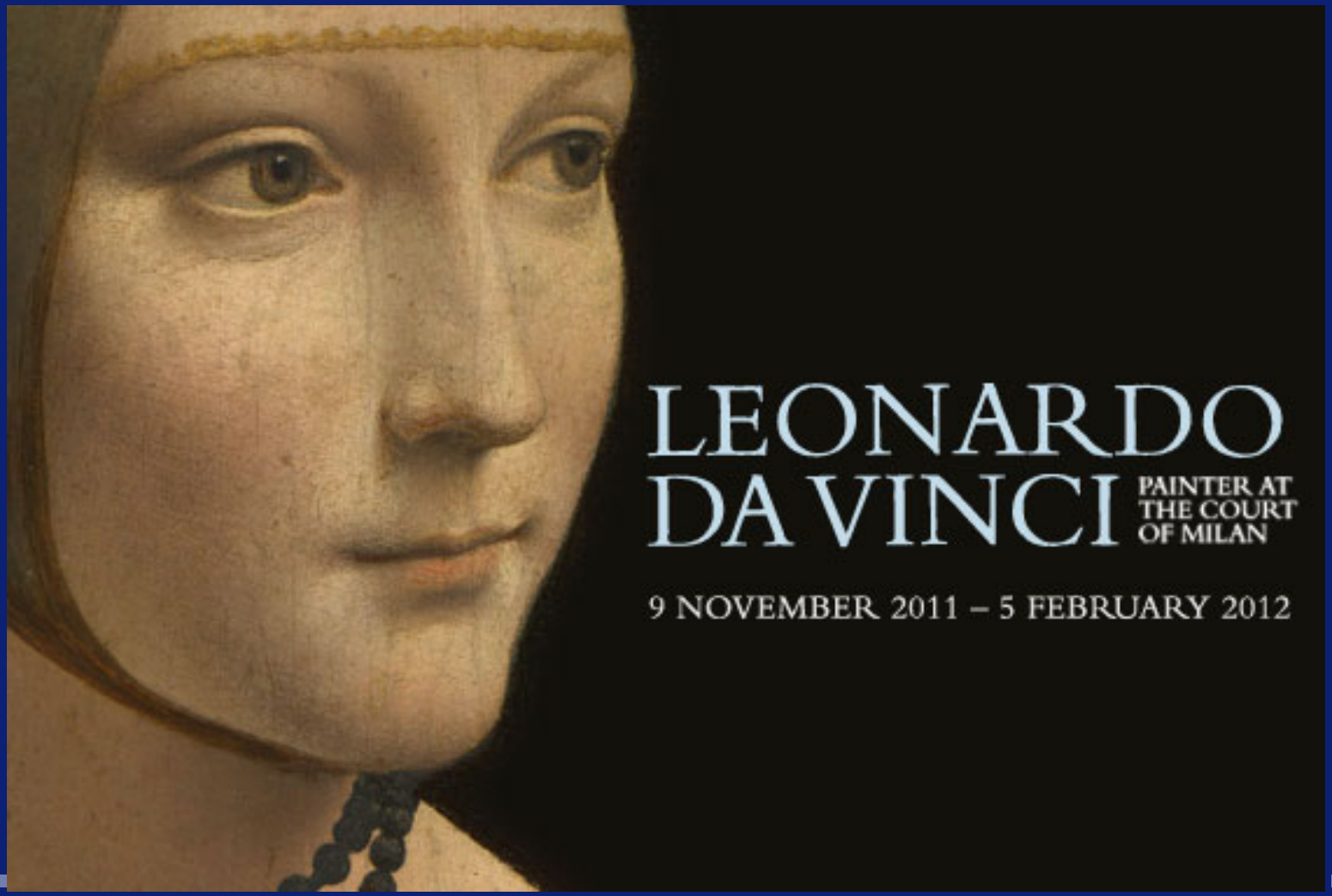
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9 NOVEMBER 2011 – 5 FEBRUARY 2012

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Systemic Administration of PRO051 in Duchenne's Muscular Dystrophy

Nathalie M. Goemans, M.D., Mar Tulinius, M.D., Ph.D., Johanna T. van den Akker, Ph.D., Brigitte E. Burm, Ph.D., Peter F. Ekhart, M.Sc., Niki Heuvelmans, Tjadine Holling, Ph.D., Anneke A. Janson, Gerard J. Platenburg, M.Sc., Jessica A. Sipkens, M.Sc., J.M. Ad Sitsen, M.D., Ph.D., Annemieke Aartsma-Rus, Ph.D., Gert-Jan B. van Ommen, Ph.D., Gunnar Buyse, M.D., Ph.D., Niklas Darin, M.D., Ph.D., Jan J. Verschuuren, M.D., Ph.D., Giles V. Campion, M.D., Sjef J. de Kimpe, Ph.D., and Judith C. van Deutekom, Ph.D.

ABSTRACT

BACKGROUND

Local intramuscular administration of the antisense oligonucleotide PRO051 in patients with Duchenne's muscular dystrophy with relevant mutations was previously reported to induce the skipping of exon 51 during pre–messenger RNA splicing of the dystrophin gene and to facilitate new dystrophin expression in muscle-fiber membranes. The present phase 1–2a study aimed to assess the safety, pharmacokinetics, and molecular and clinical effects of systemically administered PRO051.

From the Department of Pediatric Neurology, University Hospitals Leuven, Leuven, Belgium (N.M.G., G.B.); the Department of Pediatrics, University of Gothenburg, Queen Silvia Children's Hospital, Gothenburg, Sweden (M.T., N.D.); ClinPharMed, Ermelo (J.M.A.S.); Prosensa Therapeutics, Leiden (J.T.A.,

NON-THERAPEUTIC PROCEDURES OR TRIALS

MINIMAL RISK AND MINIMAL BURDEN

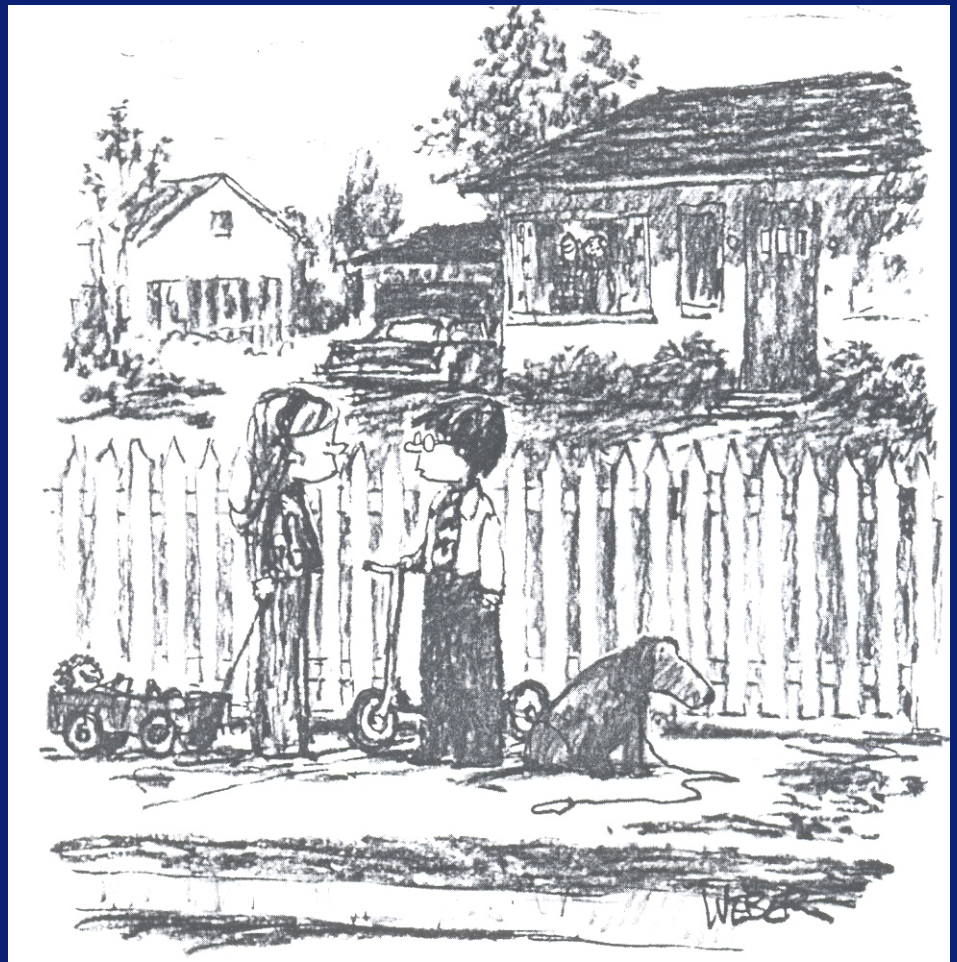
- What is minimal risk and minimal inconvenience/ burden
- Should exceptions be allowed and when?
- No exceptions should be allowed as a matter of principle
- Too difficult to decide when and which exceptions should be allowed
- A slippery slope

A minor increase over minimal risk

Stretching the notion of benefit and therapeutic

It is therapeutic in a moral sense.

- It is taking a rain check on the future
- It may justify too much!
- Children need not be ‘mini Samaritans’



"I find there's a lot of pressure to be good."

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JOHN HARRIS' ARGUMENT FOR A DUTY TO RESEARCH

IAIN BRASSINGTON

Keywords
duty,
Harris,
obligation,
research,
rescue

ABSTRACT
John Harris suggests that participation in or support for research, particularly medical research, is a moral duty. One kind of defence of this position rests on an appeal to the past, and produces two arguments. The first of these arguments is that it is unfair to accept the benefits of research without contributing something back in the form of support for, or participation in, research. A second argument is that we have a social duty to maintain those practices and institutions that sustain us, such as those which contribute to medical knowledge. This argument is related to the first, but it does not rely so heavily on fairness. Another kind of defence of the duty to research rests on an appeal to the future benefits of research: research is an effective way to discharge a duty to rescue others from serious illness or death, therefore we have a duty to research. I suggest that all three of Harris' lines fail to provide a compelling duty to research and spell out why. Moreover, not only do the lines of argument fail in their own terms: in combination, they turn out to be antagonistic to the very position that Harris wants to defend. While it is not my intention here to deny that there might be a duty to research, I claim that Harris' argument for the existence of such a duty is not the best way to establish it.

Is there a duty for us to participate in and support research – specifically medical research? John Harris, in a recent paper in the *Journal of Medical Ethics*, claims that there is.[1] To establish his point, he makes use of two strategies that are quite different from each other in terms of their emphasis. The first strategy concentrates on how it is that I or we got into our present situation and what obligations are generated thus: in a nutshell, Harris' claim is that obligations to participate in and support ongoing medical research derive from the benefits of past research that we currently enjoy. However imprecise the term, I shall call the arguments produced by this sort of strategy 'past-based arguments'. The second concentrates on benefits that are yet to be produced, which I shall call 'future-based arguments'. The point of this paper is to destabilise Harris' position. I want to suggest that the

[1] J. Harris. Scientific Research is a Moral Duty. J Med Ethics 2005; 31: 242–248.

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- We recommend Europe to adopt a policy that is more closely related to the two factors that determine when exceptions to the minimal risk and burden can be justified: the assent of the research subjects and the value of the study.

VIR
Very Important Research

For a study to be exceptionally valuable, the desired data much be truly indispensable for improving medical care for children.

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Home

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Please contact Kim Wever at info@patientpartner-europe.eu if you need any other information

Welcome to the PatientPartner website

Although the project has come to an end, you can still use this website to access the many resources linked with the project.

- **About PatientPartner**

Here you will find details about the project, its funding and objectives, and the four partners involved.

- **The Project**

This section contains all the work that was undertaken during the course of the three years of this project. You will be able to access reports, detailed results, programmes and presentations.

- **Project Outcomes**

Directly to

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A ‘NATIONAL’ APPROACH

ATTENTION FOR ETHICAL REVIEW TOURISM

CHILDRENS VIEWS AND EXPERIENCES

Focus groups with pediatricians, parents and children may be helpful.

AWARENESS OF OTHER GROUPS OF PATIENTS