Stone Cottage,
Main Street,
Abthorpe,
Towcester,
NN12 8QN
United Kingdom

Dockets Management Branch,
Food and Drug Administration,
Department of Health and Human Services,
Room 1-23,
12420 Parklawn Drive,
Rockville,
MD 20857.
USA

June 10th, 2003

Dear Sir,

Please find enclosed a Citizen's Petition requesting the Commissioned of Food and Drugs to consider amending labelling on new drugs filing for approval with the FDA as to whether or not work involving human embryos, or material derived for human embryos, had been used in the research, production or testing processes.

I hope I have included everything that you need to file this petition. If you would like me to amend anything then you might find my email address (yngarthur@aol.com) more convenient than my mailing address above.

Thank you for your assistance in this matter.

Yours faithfully,

A.J.Young

Arthur Young

June 10th, 2003

Dockets Management Branch,
Food and Drug Administration,
Department of Health and Human Services,
Room 1-23,
12420 Parklawn Drive,
Rockville,
MD 20857.
USA

Citizen Petition

The undersigned submits this **petition** to request the Commissioner of Food and Drugs.

A. Action requested

To indicate to potential users of a drug by means of labelling whether any product had used human embryo or material derived from human embryos in its development, production or testing.

B. Statement of Grounds

In some jurisdictions, such as the UK, research involving human embryos has been sanctioned in principle. Such work may become more prevalent in the future. Many people are opposed to this work, believing that it shows extreme disrespect for the value and sanctity of human life and campaign that this work should not be done. I want to be able to avoid being an unwitting consumer of any of the products resulting from research in this area and therefore want to ensure that there is sufficient information available to allow me to ensure that I derive no personal benefit from such products. Additionally, I believe that many people who would welcome confirmation that the drugs they were taking did not rely on this sort of work and that this petition merits consideration by the FDA. The benefits of this would also be felt in other countries.

C. Environmental Impact

No significant impact expected.

D. Economic Impact

The proposed measure should not materially add to the cost of producing new drugs. If labelling did indicate whether or not human embryo research had played any part in its development, testing or production, there may be an incentive to duplicate a preparation in ways which did not involve reliance on this work. This would be filling an unmet need, producing a version acceptable to a significant section of the community, to whom the human embryo-derived version is unacceptable.

If developers and researchers knew they would have to indicate in filing to the FDA whether human embyros or material derived from human embryos had played any part in the research or production or testing of a product they could arrange their work accordingly. This would be less onerous if acknowledged at the start of a research program rather than trying to audit a research process some time after it commenced.

E. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this **petition** includes all information and views on which the **petition** relies, and that it includes representative data and information known to the petitioner which are unfavorable to the **petition**.

A J. Young

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