

## **BARR LABORATORIES, INC. SHAREHOLDERS' RESOLUTION**

This Proposal is submitted by \_\_\_\_\_ .

WHEREAS, statistics published by research oversight bodies in North America and Europe document that the vast majority of painful and distressing animal experiments are conducted to satisfy outdated, government-mandated testing requirements<sup>1</sup> and that such testing is on the rise;<sup>2</sup> and

WHEREAS nearly 60% of animals used in regulatory testing suffer pain ranging from moderate to severe, all the way to pain near, at, or above the pain tolerance threshold,<sup>3</sup> generally without any pain relief; and

WHEREAS non-animal test methods are generally less expensive,<sup>4</sup> more rapid, and always more humane, than animal-based tests; and

WHEREAS, unlike animal tests, non-animal methods have been scientifically validated and/or accepted as total replacements for the following five toxicity endpoints: skin corrosion (irreversible tissue damage), skin irritation (milder and reversible damage), skin absorption (the rate of chemical penetration), phototoxicity (an inflammatory reaction caused by the interaction of a chemical with sunlight), and pyrogenicity (a fever-like reaction that can occur when certain intravenous drugs interact with the immune system);

NOW THEREFORE BE IT RESOLVED, that the shareholders request that the Board:

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<sup>1</sup> CCAC Animal Use Survey – 2001: <http://www.ccac.ca/english/FACTS/Facframeaus2001.htm>

<sup>2</sup> Statistics of Scientific Procedures on Living Animals – Great Britain – 2002. <http://www.official-documents.co.uk/document/cm58/5886/5886.htm>

<sup>3</sup> CCAC Animal Use Survey – 2001

<sup>4</sup> Derelanko MJ and Hollinger MA (Eds.). (2002). *Handbook of Toxicology, Second Ed*, 1414 pp. Washington, DC: CRC Press.

1. Commit specifically to using only non-animal methods for assessing skin corrosion, irritation, absorption, phototoxicity and pyrogenicity.
2. Confirm that it is in the Company's best interest to commit to replacing animal-based tests with non-animal methods.
3. Petition the relevant regulatory agencies requiring safety testing for the Company's products to accept as total replacements for animal-based methods, those approved non-animal methods described above, along with any others currently used and accepted by the Organization for Economic Cooperation and Development (OECD) and other developed countries.

***Supporting Statement:*** This Resolution is designed to harmonize the interests of sound science with the elimination of animal-based test methods where non-animal methodologies exist. It seeks to encourage the relevant regulatory agencies to join their peers in accepting validated *in vitro* and other non-animal test methods. It will not compromise consumer safety or violate applicable statutes and regulations.

Further, this Resolution commits the Company to end animal testing for five specific endpoints in favor of valid non-animal methods. These include the 3T3 Neutral Red Uptake Phototoxicity Test, human skin equivalent tests for corrosivity, and a human blood-based test for pyrogenicity, all of which have been successfully validated through the European Centre for the Validation of Alternative Methods.<sup>5</sup> Several non-animal methods have also been adopted as Test Guidelines by the OECD<sup>6</sup> (an alliance of 30 member countries including the US, EU, Japan, Canada and Australia). Regulatory agencies in OECD member countries are not at liberty to

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<sup>5</sup> ECVAM website: <http://ecvam.jrc.it>

<sup>6</sup> OECD test guidelines: [http://www.oecd.org/document/22/0,2340,en\\_2649\\_34377\\_1916054\\_1\\_1\\_1\\_1,00.html](http://www.oecd.org/document/22/0,2340,en_2649_34377_1916054_1_1_1_1,00.html)

reject data from non-animal tests for skin corrosion, skin absorption and phototoxicity where such data have been generated in accordance with an OECD Test Guideline.

We urge shareholders to support this Resolution.