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ASSISTANT VICE PRESIDENT
BIOLOGICS AND BIOTECHNOLOGY

PhRMA

April 1, 1998

Honorable Thomas P. Gannon
Chairman
House Judiciary Committee
49 East Wing
Main Capitol
House of Representatives
Harrisburg, PA 17120

Dear Chairman Gannon:

As a follow-up to a telephone conversation Kristin Geisler of the PhRMA staff had with James Mann yesterday, I regret to inform you that I will be unable to testify at the April 2, 1998 public hearing on House Bill 2128 (Banning Human Cloning) due to an untimely conflict out of my control.

I will however submit a statement regarding the bill on behalf of PhRMA for the House Judiciary Committee's review. Again, I do apologize for any inconvenience this may cause the Committee.

Thank you for your understanding.

Sincerely,

Gillian Woollett

Gillian Woollett, Ph.D.

Enclosure

cc: Honorable Jerry Birmelin, Chairman, Subcommittee on Crime and Corrections
Honorable Harold James, Minority Chairman, Subcommittee on Crime and Corrections
Mr. James Mann, Research Analysis, Judiciary Committee
Mr. David W. Sweet, Esquire
Ms. Eloise J. Frazier, Esquire
Mr. John O'Connor, Senior Regional Director, PhRMA

Statement PhRMA

POSITION OF THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA ON PENNSYLVANIA HB 2128

- **The Pharmaceutical Research and Manufacturers of America (PhRMA) believes that state legislation to ban cloning is unnecessary, since the federal Food and Drug Administration (FDA) has announced its authority to regulate – and prohibit – the cloning of entire human beings.** PhRMA is concerned that state legislation intending to duplicate FDA's ban on the cloning of entire human beings could end up banning all cloning technology – a technology that has been used to meet medical needs globally for 20 years. Well-intended proposals could unintentionally slow or stop biomedical research advances that help patients.

- **FDA's recent statement of its regulatory authority over cloning of entire human beings will safeguard biomedical advances and, at the same time, afford the opportunity for a thoughtful scientific, ethical, and legal debate on this important issue.** With the FDA's recent announcement, a scientist seeking to create a genetic replica of a person will have to submit an investigational new drug application (IND) to FDA. The FDA has indicated that approval of such an IND would be out of the question, thus effectively prohibiting the cloning of entire human beings.

- **PhRMA and its member companies neither support nor engage in the cloning of entire human beings.** PhRMA member companies develop medicines to prevent and cure disease, and voluntarily subscribe to the President's call for a ban on the cloning of entire human beings. Scientists at PhRMA member companies, however, do conduct biomedical research that employs cloning technology with human cells, genes, tissues and organs. This research already has proved a powerful tool in the search for cures, leading to effective medicines to treat HIV/AIDS, cystic fibrosis, diabetes, heart attack and stroke, and hemophilia.

- **Uniform national standards are best suited to preventing the cloning of entire human beings.** Federal FDA regulation and related Congressional oversight provides a uniform national prohibition against cloning of entire human beings, and avoids the development of a patchwork of inconsistent and potentially conflicting state-level requirements. Uniformity also will help ensure compliance.

- **If the Pennsylvania legislature determines that it must enact a legislative ban on the cloning of entire human beings, any bill must:**

  - prohibit the ***act*** of cloning an entire human being (i.e., creation of a human being genetically identical to an existing, or previously existing, individual), rather than

prohibit biomedical research or base a prohibition on a researcher's intent or purpose.

- include a section that specifically states that the prohibition does not apply to biomedical research that does not involve cloning of an entire human being. This narrow prohibition would help protect research that uses cloning technology to develop cells, tissues, and organs to benefit patients. The Pennsylvania legislation includes a statement that its proposed prohibition would not apply to the cloning of human cells, human tissues and human organs that do not result in the cloning of an entire human being.

- establish civil monetary penalties as the enforcement mechanism, not criminal penalties. Civil penalties are more appropriate for scientific institutions. Moreover, the risk of criminal penalties may deter legitimate researchers, eager to avoid even the appearance of engaging in prohibited activities, from undertaking promising research unrelated to cloning entire human beings, yet integral to the development of needed medicines. The Pennsylvania bill wisely includes this enforcement mechanism.

- bar a private right-of-action (private lawsuits). This measure would protect legitimate biomedical researchers from lawsuits filed by individuals or groups who believe that certain research activities that do not involve the cloning of entire human beings also should be prohibited.

- include a sunset (perhaps five years, as recommended by the National Bioethics Advisory Commission). This measure would ensure a deliberate review of the ethical and safety issues.