

Karen Ignagni  
President &  
Chief Executive Officer



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March 8, 2007

Andrew C. von Eschenbach, M.D.  
Commissioner  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, MD 20857-0001

Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane  
Room 1061  
Rockville, MD 20852

Re: Notice of Proposed Rule Making Addressing Expanded Access to Investigational Drugs  
for Treatment Use (71 Fed. Reg. 75147)  
Docket No. 2006N-0062/RIN 0910-AF14

Notice of Proposed Rule Making Regarding Charging for Investigational Drugs (71 Fed.  
Reg. 75168)  
Docket No. 2006N-0061/RIN 0910-AF13

Dear Commissioner von Eschenbach:

On behalf of America's Health Insurance Plans (AHIP), I am writing to offer comments in response to two Notices of Proposed Rule Making (NPRMs) that were issued by the Food and Drug Administration (FDA) in the *Federal Register* on December 14, 2006. One NPRM addressed Expanded Access to Investigational Drugs for Treatment Use (71 Fed. Reg. 75147) and the second NPRM addressed Charging for Investigational Drugs (71 Fed. Reg. 75168).

AHIP is the national association representing nearly 1,300 health insurance plans providing coverage to more than 200 million Americans. Our members offer a broad range of products in the commercial marketplace including health, long-term care, dental, vision, disability, and supplemental coverage. Our members also have a strong track record of participation in Medicare, Medicaid, and other public programs.

AHIP strongly supports the FDA's overall goal of ensuring that critically-ill patients, their caregivers, and treating providers explore and evaluate medically appropriate and potentially lifesaving treatments. In these situations, we recognize that it is vital for patients to receive accurate information about the risks and benefits of experimental and investigational treatments or therapies to understand and evaluate their treatment options and decide whether to participate in such treatments or therapies.

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While the FDA's proposed regulations attempt to establish specific criteria for expanding access to experimental or investigational treatments and therapies, our members have significant concerns that several elements of the proposals could inadvertently undermine the goal of building the scientific research that is necessary for understanding the risks and benefits of these treatments and therapies. We are concerned that, if adopted, the proposals could have unintended consequences that create unnecessary risks for patients, cause additional difficulties for patients who want to enroll in clinical trials, and significantly increase costs for drugs whose benefits are unknown.

Our specific comments and concerns about the proposed regulations are outlined in the attached document (Attachment A). Our recommendations include alternative approaches that could achieve the agency's goals and implement regulatory requirements without creating significant risks and unintended consequences for patients and health care entities.

We appreciate the opportunity to comment on these important issues.

Sincerely,

A handwritten signature in black ink, appearing to read 'Karen Ignagni', with a long horizontal flourish extending to the right.

Karen Ignagni  
President and CEO

Enclosure