

# COMPLIANCE TODAY

MAGAZINE

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What compliance professionals  
should know about  
the unthinkable (P18)

Controlling mobile devices in  
an academic medical center:  
Unique challenges (P22)

Compliance tips for implementing  
an electronic medical  
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Tried and true survey readiness  
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**GREG RADINSKY**

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## SEEING ENFORCEMENT ISSUES FROM ALL SIDES

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“ I do recall some of the physicians I interacted with being a bit perplexed and saying, “You worked for the OIG and you now do marketing?” ”

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# Remembering Jesse

by Kelly M. Willenberg

In 1999, Paul Gelsinger's 17-year-old son Jesse was suffering from a genetic disease called ornithine transcarbamylase deficiency. A buildup of ammonia was making Jesse very sick from dietary choices, including a strict non-protein diet. A carefully followed diet and medication controlled the disease. Given an opportunity to participate in a gene therapy trial designed to test possible treatments for his disease, Jesse decided that when he turned 18, he would give consent. The trial would use gene therapy or an adenovirus to transport a normal gene into his liver. For the most part, Jesse was informed that subjects who had received the adenovirus had not had serious complications. But a mere four days after the gene therapy, Jesse suffered an immune reaction and died.

Last fall, I met Jesse's dad at a conference where we were both speakers. Listening to this father describe what his family went through inspired me to consider the research compliance profession and where we are today. Jesse's family felt that Jesse had not been properly informed. Later they discovered that adverse reactions were not reported or communicated. There were questions of conflicts of interest and data not being reported properly. Today we are moving from

gene therapy and proton therapy to customized molecular profiling for treatment — all of which began in a clinical trial. Oversight, safety concerns, and evaluation are top priorities in the planning and carrying out of clinical research and must not be taken for granted. Research compliance is needed and should be first and foremost in all settings.

Remembering the ethical side of why patients consider participating in a clinical trial, and how compliance oversight protects that sacred agreement, is the reason we are in the careers we are in today. Clinical research has changed over the nearly 20 years that have gone by since Jesse Gelsinger's death. But we must remain diligent in the role of a research compliance professional and not take for granted why that role is important.

In corresponding with Mr. Gelsinger since the day I met him, I asked him what one thing he would like all research professionals to consider in the important role they play. He said, "Keeping everyone as safe as possible in research can only be accomplished through protocol compliance and by adapting what Jesse demonstrated: Do what you do, not for recognition, nor for money, but only to help. Only then will you get research right, and have a blameless prosperity." <sup>CT</sup>



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