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June 2, 2008

The Honorable Nancy Pelosi
Capitol Building, H-232
U.S. House of Representatives
Washington DC 20515

Dear Speaker Pelosi:

On behalf of the California Healthcare Institute (CHI), whose more than 250 members include our state's leading biotech, pharmaceutical, and medical technology firms, along with premier research institutes and universities, I am writing to address the important issue of electronic drug pedigrees (e-pedigree). E-pedigree is the process of tagging prescription drugs with a standardized numerical identifier that will track and trace the product as it changes ownership through the supply chain from manufacturers down to patients.

As you may know, the state of California has been at the forefront of this issue, having enacted a requirement for an electronic drug pedigree, by 2011, to track each prescription drug at the item level through the distribution system. California's public and private stakeholders who have been involved in this process should be commended for the extensive work they have done towards establishment of a comprehensive system. Throughout this process, CHI member companies, who invest billions of dollars annually in the development of innovative, breakthrough medicines, have dedicated significant hours and resources, testing various technology applications internally and with other members of the supply chain to gain a stronger understanding of what suits their particular business models and product lines.

Despite the work that has been accomplished in California, counterfeiting of pharmaceuticals is a serious problem that transcends state and even national borders, and therefore requires a strong, single federal approach. For manufacturers and wholesalers, producing and distributing products to sell in a global economy, a patchwork of individual state mandates is not a viable solution. Without a strong national standard, significant inefficiencies will be introduced into the national drug distribution system that will impact patients' ability to access the therapies they require.

Specifically, CHI supports:

1. **One uniform federal pedigree standard** – In order to avoid confusion and differing standards, federal legislation should contain strong preemption language that would prohibit any state or locality from enacting requirements outside the scope of federal standards;

2. **A phased-in approach to serializing products and tracking them through the system** – Federal legislation should provide for the development of a system that prioritizes implementation based on risk of counterfeiting and that builds upon current Food and Drug Administration (FDA) efforts to develop standards;
3. **An interoperable, standards-based approach that is technologically neutral** – Federal legislation should give manufacturers the ability to apply product-appropriate anti-counterfeiting solutions and pedigree data carriers.

Thank you for considering our views regarding federal e-pedigree legislation. We would be pleased to discuss any aspects of this important issue at your convenience.

Sincerely

A handwritten signature in black ink that reads "Todd E. Gillenwater". The signature is written in a cursive style with a large, prominent "T" and "G".

Todd Gillenwater
Vice President-Public Policy