

targeted completion date of November 27, 2023. Excuse me for asking, but are we going down the same path as ePedigree and the Affordable Care Act or Obamacare? Why in the world would anybody be building a new system when so many technologies are proven and available in the marketplace?

The complexities of such a system to provide only the appropriate information to the appropriate individuals may or may not go far beyond the FDA's current capabilities. With a collective system, each user must be provisioned to have only certain information at his or her disposal, depending on his or her role in the supply chain. If the FDA intends a one-size-fits-all, master-collective system, it is inviting a free-for-all.

For example, let's say a disgruntled employee of a major distributor has just made friends with some less-than-reputable members of society. This employee, under a one-size-fits-all approach, may grab a few serial numbers he or she sees on some packaging and create shipment patterns of some drugs for these less-than-reputable folks. If the drugs are controlled substances with a convertible street value, they may only be at risk of being stolen from the supply chain. What if the less-than-reputable individual has plans to resell the product back into legitimate channels?

Remember, if the product is particularly temperature sensitive or has specialized handling guidelines, the criminals aren't playing by the rules. They won't care about whom they hurt, since they are already playing outside of the rules. It then only takes a shady pharmacy looking to boost its profits to fabricate the pedigree in the system and pay less than market rates. Sure, it might be discoverable, but with the sheer size of all the data the FDA is likely to encounter, will it find out in time? At risk in this potential free-for-all are the ultimate consumers—patients.

WHERE DO WE GO FROM HERE?

We live in a world of distributed computing and cloud computing. The sharing of technology infrastructures on a secure, permissions-based basis would allow for people within a pharmaceutical drug supply chain network to track and trace pharmaceutical drugs in a cost-efficient manner. It would also allow the private marketplace to leverage existing capabilities and not have to bear the expense of migrating to a new centralized system.

My suggestion is to develop two side-by-side feasibility studies. One study would use 2D barcodes and the other would use RFID tags. These