

Can the Food Drug and Cosmetic Act Survive the 21st Century?

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The underlying structure of the Food Drug and Cosmetic Act's regulation of therapeutic products goes back to 1906 or 1938. The FDCA uses regulatory approaches based on adulteration, misbranding, premarket review and post market oversight to satisfy its objective of providing patients with safe and effective products.

These "pillars" of the FDCA have worked well for many decades and have been flexible enough to handle changing technologies, medical practice and social expectations. We rarely think about whether the basic construct of the FDCA will be able to adapt to the 21st Century. However, emerging technologies, clinical practice and social expectations may well stress these pillars of the FDCA beyond the breaking point.

We will explore this question using examples such as artificial intelligence, 3D printing and evolving 1st Amendment jurisprudence. As these examples demonstrate, there may be fundamental and significant gaps in the core construct of the FDCA that may require basic changes to the FDCA.