PART III

Designing Medical Device Regulations Introduction

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In English, as in many (all?) languages there exists a grammatical category known as the "irrealis moods" – a set of grammatical categories that refer to a situation or action that is not known to have happened at the moment the speaker is talking. Andre Aciman has poetically described them as "verbal moods that indicate that certain events have not happened, may never happen, or should or must or are indeed desired to happen, but for which there is no indication that they will happen . . . the might be and the might have been."[1] Some of these are familiar in English like the subjunctive (for unlikely events) or conditional (for events that depend on another condition) mood. Others are more common in non-English languages like the optative (for events that are hoped for or expected),[2] the dubitative (events whose occurrence is doubted or dubious),[3] and jussive (events that are pleaded or asked for)[4] moods.

The irrealis mood is always an exercise in imagined alternatives, and the same is true in each of the chapters in this part – indeed all, in one way or another, imagine a counterfactual world where the FDA rethinks its regulatory approach. Each also has at its core a view that an FDA device regulatory approach that was good (or at least workable) in one context, is a failure as applied to a new set of technologies.

For Mateo Aboy and Jake S. Sherkow's chapter "IP and FDA Regulation of De Novo Medical Devices" the problem arises in the intersection of the FDA's recent policy clarifications on permitting a De Novo device as a "predicate" for a follow-on device application under the 510(k) pathway. While from a safety and efficacy perspective it makes sense to require the second applicant to show that the device is "substantially equivalent" to its predicate device including an assessment that it uses the "*same* technological characteristics" as the predicate, that requirement creates trouble when the relevant aspect of the predicate device is patented, creating

[1] Andre Aciman, Homo Irrealis: *Essays* 1 (2020).

[2] See Optative, Merriam-Webster Dictionary Online, https://www.merriam-webster.com/dictionary/optative.

[3] See Dubitative, Merriam-Webster Dictionary Online, https://www.merriam-webster.com/dictionary/dubitative.

[4] See Jussive, Merriam-Webster Dictionary Online, https://www.merriam-webster.com/dictionary/Jussive.

a tactic that is as clever as it is problematically anticompetitive: "device manufacturers use patents to protect the very controls required for regulatory approval."

For Sara Gerke's chapter, "Digital Home Health During the COVID-19 Pandemic: Challenges to Safety, Liability, and Informed Consent and the Way to Move Forward," the problem is the intersection with the Emergency Use Authorization (EUA) regime created by the PREP act and activated in COVID-19 and the only partial coverage of digital home health products within the FDA's regulatory review. Because many digital home health products do not require FDA review, they thus do not require authorization under an EUA (a benefit to the maker) but also do not qualify for the immunity protections of the PREP act (a drawback to the maker). From the perspective of the end user, though, the details of what the FDA reviews or not is at best mysterious and more likely totally unknown, such that their understanding of the liability ramifications are paltry at best. While Gerke discusses whether such gaps can be filled with more robust informed consent processes, in particular during the COVID-19 pandemic one wonders if this is an unlikely might have been!

In some of the chapters in this part, determining which irrealis mood the authors intend is trickier. Matthew Herder and Nathan Cortez offer a chapter on "A 'DESI' for Devices? Can a Pharmaceutical Program from the 1960s Improve FDA Oversight of Medical Devices?," but should we take those question marks and their framing as optative or dubitative? Their chapter takes inspiration from the history of the Drug Efficacy Study Implementation program (DESI) triggered by a major existential shift at the FDA to examine drug effectiveness more which required relying on third parties to examine the effectiveness of more than 3,000 drugs between 1963–84. They argue for a Desi 2.0, reasoning that "[i]f the FDA's inability to encourage high-quality evidence production are ultimately reflective of a kind of incumbency – *both* in terms of who is involved in producing and how it is appraised – then regulation may take as its inspiration DESI's disruptive move to bring outside actors into the regulatory fold." Perhaps in an attempt to move the reader from dubitative to optative they suggest precursors in the treatment of digital health technologies by the FDA at the moment, in particular the precert program and the involvement of the National Evaluation System for health Technology (NEST).

As a group these chapters also raise the interesting question about the role of the scholar and the irrealis moods. Legal and policy scholarship tends to focus on existing initiatives and regulatory processes, primarily concerned with the "here and now." Then again, if past is prologue, perhaps we should not be so dubitative about large changes to the FDA's approach to device regulation – these chapters chart both major sea changes in the past and strong tail winds in the present toward novel regulatory approaches.