

### PART III

## The Shape of the Elephant for Digital Home Diagnostics

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### INTRODUCTION

In the famous parable that originates in India of the blind men and the elephant, six blind men lived in a village and experienced the world by hearing stories about it. They learned about many things but become particularly fascinated by the elephant which (in stories they are told) tramples forests, carries huge burdens, and makes a loud trumpet call. But they also hear that the Rajah's daughter would ride the elephant when she travels around her father's kingdom. How could this thing be dangerous, if the Rajah lets his daughter ride it, and also be so loud? They would argue about what it was – a powerful giant, a large cow, a graceful ride for a princess, and so on. The villagers grew tired of the argument and arranged to have the blind men examine a real elephant. One touched its side and decided it was smooth and powerful like a wall, as he had believed. Another touched the tusk and announced it was like a sharp spear, as he had believed. Another touched the leg and decided it was nothing more than a large cow, as he had believed. Another touched its trunk and concluded it was a very large snake, as he had believed. And so on. They bickered until the Rajah overheard them. He chastised them for being so certain that they knew what an elephant was – they had each only felt a part of the elephant. Only by putting together all of the pieces could they understand what an elephant was.

The chapters in this part are far from the blind men; they are quite illuminating, indeed, and are very self-aware as to what each of their parts are doing and not doing. But if the elephant represents the legal issues with the way at-home diagnostic devices are actually put on the market, it remains true that each of the first three