Interoperability is an important issue for FDA and CDRH because it presents the potential to improve patient safety and clinical efficiency, but it comes with some unique regulatory challenges. Part of CDRH's mission is to ***protect*** the health of the public by ensuring the safety and effectiveness of medical devices. How can we be assured that a system of interconnected medical devices — in a potentially unknown configuration and possibly from different manufacturers — performs safely and effectively? Who is responsible when the system fails? With clinical users demanding increased capability to configure these complex systems, where does one draw the line between systems engineering and the practice of medicine (for example, can a bedside physician install an arbitrary clinical protocol)? How will we review devices that claim interoperability with others as part of their intended use? What criteria will we use for such reviews?

CDRH has the tools to resolve the issues that will inevitably arise. Our principal tool is the medical device law, which embraces fundamental principles rather than prescriptive practices. Our regulatory tools are based on a systems engineering approach, focusing on how well a given system satisfies a medical intended use. This systems approach, which works well for complex systems provided by one manufacturer, can be extended to systems of interconnected devices from multiple manufacturers.

One indication we are interested in patient safety and interoperability is the Center's recent efforts to work toward a unique device identification system. There is no such system universally recognized and we see this as a hindrance to interoperability and also a hindrance to patient safety in many other ways. We are working toward such a system enforced by our regulatory process.

Another part of CDRH's mission is to ***promote*** the public health. Public health promotion means a lot of different things, but fundamentally, to us, it means being prepared to review innovative new medical products rapidly as well as thoroughly. This requires anticipating emerging technologies and developing an understanding of their clinical impact before they arrive on our doorstep. FDA has demonstrated a commitment to interoperability by hosting meetings and making resources available [committed personnel & OSEL has some projects in this area), supporting standards development]. Our efforts have been to improve our understanding of the background clinical requirements and underlying technologies to implement such systems. FDA has been proactive in trying to prepare for regulatory submissions by raising issues of safety early and often.

By participating with industry in standards development activities, we can facilitate interoperability and make sure safety gets discussed as a primary requirement early in the development process. By discussing our regulatory concerns with manufacturers during product development, the salient issues concerning safety and effectiveness can be addressed in the first submission, reducing the need for extra review cycles. By teaming with other Federal agencies and coordinating our efforts, we can create a road map to efficiently and safely develop a successful, open-source based interoperability framework.

So our role is not just to sit back and wait for the submissions to be submitted, but rather to actively engage with academia, industry, and clinicians in deciding how future medical device users might benefit from increased automation and information sharing. The CDRH staff who are here today participating in this meeting are one overt indication of our commitment. They are representing those of us who, for one reason or another, were not able to attend. You may be assured that there are a lot of us in CDRH who are vitally interested, on behalf of the American people, in the work you are doing.

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