

## New Year's Remarks

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Last year began with the unprecedented and horrific tragedy of The Great East Japan Earthquake. Japan was further struck by various hardships – the rapid rise in the yen, the crisis in the European currency, and corporate governance problems. Turmoil continues in politics and it seems that the new year looks to be another unsettling one.

And though we expect this year to be the year when we begin to overcome these “hardships,” with the international environment drastically changing, it won't be enough to expend the same amount of energy and effort as before. It is clear “the tide has turned” and that with new ways of thinking and the creation of new systems, a new post-quake prosperity for Japan can be born.

In spite of all this, in our medical devices field, we see the emergence of several “seeds” pointing to new systems and new ways of thinking.

The first “seed” points to the creation of a new industry. Though it can be said that one of the finest aspects of Japan's healthcare system is its health insurance system, going forward this will not be enough to drive the medical device industry into further growth. The Ministry of Economy, Trade and Industry's “Framework for a Healthcare Industry Platform” moves beyond the bounds of the existing health insurance system and is a timely call for the internationalization of healthcare, health management checkups and examinations for healthy citizens, and the industrialization of home medical care. We will work in concert with the broader industrial community and generate innovations.

The next “seed” to grow is the medical device industry. With emerging nations continuing to grow larger, we are seeking a new framework to follow since the close of the GHTF's (Global Harmonization Task Force) and its goal to “advance the international harmonization of regulations and abolish non-tariff barriers.” Just as the regulatory authorities are seeking to work together through their own organization – IMDRF (International Medical Device Regulators Forum) – there are similar movements in industry. In the radiological systems industry, with the trio of Japan-U.S.-Europe at its center, we will strengthen activities in DITTA (Global Medical Imaging, Healthcare IT & Therapy Trade Association). We have great expectations for expanded international collaboration between regulators and related healthcare organizations.

The third “seed” I expect to emerge relates to movement in medical device regulatory reform. Even though medical devices are very different from drug products, they remain tied down by The Pharmaceutical Affairs Law-Japan and are thus at a disadvantage; we need a legal system that

takes into consideration their special characteristics. Also, regarding the IT software which has now become indispensable to medical devices, we need a system which takes into consideration both the special characteristics of the software and the speed of its technological evolution; where risks are low, we hope for bold reforms such as using private certifying bodies or introducing European-style self-verification/self-responsible quality control systems. The Ministry of Health, Labour, and Welfare's 'Working Group for Reforming the Pharmaceutical Products System' has taken up the handling of medical devices, and medical IT has been raised as an important issue by The Japan Federation of Medical Devices Associations. We are seeing new activity and look forward to reforms taking place at the earliest possible time.

The fourth "seed" relates to developments related to The Great East Japan Earthquake. An unintended result of the disaster was a reaffirmation of the importance of medical services and appeals are being made to link the promotion of healthcare industries to reconstruction plans. As we think about the future of healthcare, it will be important to develop regional medicine coalitions which have diagnostic and treatment support infrastructure systems equipped with next-generation information technologies. Work in this area funded by the government has begun to take shape, and we look forward to a "Tohoku Model bridge from earthquake disaster reconstruction to new development" to then lead to an All Japan Model for development.

I am confident that with industry, government, and healthcare institutions working as one, these "seeds" in the medical device field will grow into "mighty oaks" in the new world of our post-quake age.

JIRA is into the third year of its "Future Concept Project" aimed at "creating a new dynamism in the medical imaging systems industry." We plan to nurture these "seeds" and through the vitalization of our medical imaging systems industry contribute to the development of Japan's overall medical device industry and so do our part to increase the Quality of Life (QOL) of the world's people and its healthcare.

Finally, I offer my heartfelt prayer that we can put our "troubles" behind us and that this year will bring to all the very best.