

Beware of Foreign Entanglements

The first article in our series discussed so-called “Black Swans”—unanticipated events with a hugely significant impact. The concept of a Black Swan was popularized by Nasim Taleb in his recent bestseller of the same name.

The unseen, unthought-of ways and means of persons going suddenly out of the world are innumerable and inconceivable...

— Sinners in the Hands of an Angry God, puritan sermon ca. 1740

Some Black Swan events (think meteor-induced mass extinctions) are sudden and relatively unexpected. Others, such as Hitler’s “surprise” invasion of Poland or the collapse of the US mortgage-backed securities markets, are slow-motion disasters, widely acknowledged as “obvious” in retrospect. This is due to an important Black Swan characteristic: retrospective distortion, which is the rationalization that occurs in the aftermath of an “unexpected” adverse event. This effect explains why, only after a catastrophic event, do we learn of all the reasons that made it more-or-less inevitable. Hindsight is 20/20 and, thanks to the peculiarities of human psychology, hazardous circumstances appear much more obvious and predictable in retrospect.

A foolish consistency is the hobgoblin of little minds.

— Ralph Waldo Emerson,
Self-Reliance



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The current series of articles originally was conceived as professional conversations with risk management experts. While that original plan has been fulfilled to some extent, events, as they say, have overtaken us. A journalistic column dedicated to medical device risk management would be sadly remiss if it did not comment on broad-based changes to the fundamental risk management landscape. May’s discussion

(see “Risk Management,” available in the archives section of www.mpo-mag.com) of changes to supplier qualification is an example of one such tectonic change. Current proposed legislation, the Food and Drug Administration Globalization Act of 2008, is another. (For more information about this proposal, also see “On the Hill” on page 20.)

Q: What do the medical device industry, big oil and Barry Bonds have in common?

Recently, representatives of the medical device industry had the unwelcome distinction of joining others appearing before Congress to discuss dubious professional practices. Now, in response to a spate of public health threats, including adulterated heparin, Congress is preparing a new round of regulation for imported food, drugs and medical devices. Among the proposals contained in the FDA Globalization Act of 2008 is a “corps of inspectors dedicated to inspections of foreign food, drug, device and cosmetics facilities and establishments.” Proposed penalties include “...\$100,000 per violation. Each day during which a violation continues shall be considered a separate violation.”

Outsourcing’s Chickens: Home to Roost?

Conversations with congressional aides of the sponsoring legislators indicate a very real legislative commitment to increased regulation—based on a number of high-profile incidents and a groundswell of public concern around the safety of imported products. For medical device manufacturers, this import concern extends not only to finished devices, but also to components used in the manufacture of finished devices.

Speaking on the condition of anonymity, one congressional staffer working directly

on the proposed legislation explained, “We understand that a device is essentially an assembly of subcomponents—so, component suppliers are not exempt from the proposed overseas inspections... Manufacturers enjoy the benefit of offshoring, so they should share in the costs of ensuring that those suppliers are safe and compliant.”

A third-party system, much like the notified body approach employed by the European Union, has been suggested as one means of overcoming an anticipated resource shortage. The FDA’s own (often delayed) third-party certification effort could serve as the point of departure in this regard.

A Perilous Process

However, a dedicated overseas medical device inspectorate is not the only source of elevated risk to a global outsourcing model. Dennis M. Moore, a former senior investigator for the State of California (Department of Health Services), FDA-credentialed investigator and current president of consulting firm Auk Technical Ltd., also pointed to the FDA’s import detention program. According to the agency:

The Food, Drug, and Cosmetic Act (the Act) authorizes FDA to detain a regulated product that appears to be out of compliance with the Act... If the owner fails to submit evidence that the product is in compliance... The product then has to be exported or destroyed within 90 days.

Straightforward in theory, import detention can be extremely problematic in practice. Explained Moore, “The level of risk to manufacturers is immense—if your foreign suppliers are on detention, the product doesn’t get through at all.” While the legislation requiring overseas inspections winds its way through Congress, the FDA is using import detention as a risk management tool to guard against potential public health threats and to bring overseas manufacturing sites into compliance. In May alone, nearly 100 medical device products were placed on import detention (a monthly



listing of detention actions is available at: www.fda.gov/ora/oasis/ora_ref_prod.html).

Although Moore characterized import detention as a “perilous process” without clear guidelines for detention removal, he also noted that administrative means to achieve risk management ends may be the shape of things to come: “Right now, we have an activist Congress, so it’s no surprise we have aggressive proposed legislation [FDA Globalization Act]. Come November, we very well may have an activist executive branch—in which case we will get aggressive passed legislation... not to mention many important branch appointments [the President appoints the director of Health and Human Services, which leads the FDA].”

A Perfect Globalization Storm?

In May’s column, we discussed how increased FDA pressure on large manufacturers was leading to more rigorous supplier control. In fact, one manufacturer was forced to staff and train a dedicated 14-person supplier audit group. Now, increased emphasis on supplier control (in general), combined with increased emphasis on overseas supplier control (specifically), has produced something of a “perfect storm” in global outsourcing. And, as with the conditions leading to in-

creased global energy prices, these changes most likely are structural and permanent.

The June “Risk Management” column (available at www.mpo-mag.com) discussed the connection between value and risk: What we value generates risk, and risk must be managed. Using a quality systems model, medical device manufacturers can be defined as a collection of processes designed to convert inputs (requirements, components, human resources, intellectual property) into outputs. Therefore, elevated input risk is especially hazardous to a manufacturer’s effective function. Because of recent concerns with supplier quality—especially overseas suppliers—certain inputs carry an increasing risk of disruption. George Washington, in his farewell address, cautioned his fellow countrymen to “beware of foreign entanglements”:

The great rule of conduct for us in regard to foreign nations is, in extending our commercial relations, to have with them as little political connection as possible. So far as we have already formed engagements, let them be fulfilled with perfect good faith. Here let us stop.

An aging worldwide population and relatively weak US dollar mean that overseas markets will remain extremely attractive as sales regions for medical device manufacturers. However, given recent regulatory developments and the changing risk management landscape, Washington’s caution may be applied, with equal advantage, to overseas suppliers. ❖

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