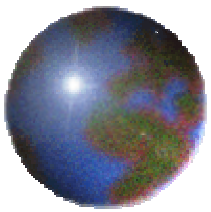

The Impact of Global Development: a US FDA Perspective

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Common Mission

- To promote and to protect the public health of our citizens – in a science lead manner – when it comes to the products for which we are responsible within our jurisdictions

FDA's Special International Statutory Mission

- (3) … participate through appropriate processes with representatives of other countries to reduce the burden of regulation, harmonize regulatory requirements, and achieve appropriate reciprocal arrangements…

GLOBALIZATION

- ***Promote and protect public health*** in the **globalized** world, rather than the traditional domestic world, in which our regulated products are discovered, developed, manufactured, authorized, promoted, marketed, purchased, and ultimately used by consumers, practitioners and patients.

GLOBALIZATION

- ***Promote and protect public health*** in the **globalized** world in which technology makes mass production of products possible, but also makes mass production of counterfeit products a reality and the growing currency of organized crime.

GLOBALIZATION

- ***Promote and protect public health*** in the **globalized** world in which Internet technology makes instantaneous communication of important safety information possible around the world, but also facilitates instantaneous access to illicit “pharmacies” that disappear with the push of a “delete” button when a regulator investigates

GLOBALIZATION

- ***Promote and protect public health*** in the **globalized** world in which new scientific disciplines are taking us swiftly into the molecular world of genetics-based personalized medicine, but also we remain in a world in which most people still die of infections for which we have not yet produced simple, effective, available vaccines.

GLOBALIZATION

- ***Promote and protect public health*** in the **globalized** world in which dubious purveyors of “information” with their own agendas are innumerable and immediately available, but a world in which we are called upon to be ***trusted*** purveyors, not of information, but ***knowledge*** that people can use in their daily lives to better their health

GLOBALIZATION

- ***Promote and protect public health*** in the **globalized** world in which we can travel around the world in ways our grandparents only dreamed, but also a world in which any microorganism, any radiation emitting device, or any intentionally contaminated product can be almost anywhere in the world in 24 hours.

GLOBALIZATION

- ***Promote and protect public health*** in the **globalized** world in which the products for which competent regulatory authorities are responsible within their borders are no longer predominantly domestic products; bur rather they are international commodities that at any given point in time could be under – or not under - the control of another competent regulatory authority.

Response to these Challenges

- Cannot meet mission by only looking within one's own borders

- Regulatory cooperation must become the standard operating procedure of the 21st century

Response to these Challenges

- Much framework and confidence building has been accomplished

- Now we must flesh out the framework and demonstrate that our interactions add real value to the lives of our fellow citizens

Response to these Challenges

- No agency is a “gold” standard – that is a moniker each of us must earn everyday, and it is only as valid as the last decision an Agency makes

Response to these Challenges

- No nation or no national or regional regulatory authority has a monopoly on good science or good regulatory practices.

- The sum of our parts is clearly superior to their individual value.

Response to these Challenges

- No regulatory agency has the resources to meet the expectations of its parliament and people

- Leveraging our scientific, human, and financial resources has to be the first step

- We must be scrupulously based in and lead by the best science possible – *wherever in the world it is found*

- We must be always vigilant in the independence, the integrity, and the transparency of our regulatory decisions and willing to have them evaluated by our regulatory peers.

- We must recognize that we have many *stakeholders* at home and abroad with genuine equities in what happens at our agencies, but we have only one ***customer*** – our fellow citizens - who daily bet their health on our faithfully fulfilling the public responsibilities with which they have entrusted us.

- We must acknowledge the fact that public health diplomacy is now a non-discretionary part of all of our regulatory agencies' 21st century too kit to meet our common public health mission

- We must embrace the fact that being an integral, active, leading part of the 21st century international community of medical product regulators is a marvelous opportunity

Thank You