

United States:

The Entrepreneur

You have invented a Gizmo and you are convinced that it has an application in the developing world. The FDA just told you that it would cost around \$650,000 to get it approved for use in America. Unfortunately, you only have about \$100,000 left after you paid for the R&D required to launch your device. You are hoping to be able to sell it at a reduced, but sustainable price in a low-resource setting where your product has its maximum impact. In your first voyage outside Kansas, you are off to Brazil to convince the local authorities to let you distribute 100 prototypes that you can sell to an interested doctor that you met from Brazil. Part of the \$100,000 paid for a small scale set of trials at the University of Wheat that show your machine works the way it's supposed to. You are in Brazil to get more data and hope to make some sales while you are at it.

American IRB Officer

You are the clinical trial police. Your job is to ensure full compliance of ethical and clinical standards so that that the University doesn't get in trouble. This means long hours drafting 20 page IRB proposals that involve multiple parties. Your office just suffered a series of cutbacks so you are overwhelmed with proposals.

Brazil:

Regulatory

You are a medical device approval officer at ANVISA, the local medical device regulatory agency. By default your main job is protect the Brazilian population and ensure a good standard of health.

In order for products to be accepted in Brazilian customs, it is a legal requirement for the products to have directions for use in Portuguese and to have Portuguese product labels. Each of the following items must be included:

- Product name and intended use.
- Manufacturing and sterilization date.
- Method of sterilization.
- Expiration date.
- MOH registration number.
- Name and registration number of responsible technical person at the Brazilian distributor's office.
- Manufacturer and distributor names (the distributor holding the registration) and addresses.

If a clinical trial is involved you want the terms of the IRB, and you demand that the IRB is authored and harmonized locally in Portuguese. It's a medical device that is not FDA approved, you want to clinical trial data that doesn't begin with Brazilians because they aren't Guinea Pigs.

If a clinical device will be used in Brazil you need to company to become a Brazilian company with local distributors and local manufacturing.

Your job will typically take about 6 months, but in reality, things take about 12 months. You should not disclose that though, because it will make sound like your office is too slow and you may get fired.

One of the things you need to control is the overabundance of imported medical devices. The reason for this is that you want to control the national trade deficit as mandated by a central federal

government. If presented with a foreign company that presents you with an excellent device and a local company with an okay device, you prefer to go with a local company for approval. Intellectual property is less of a concern to you. In fact and should be the company's problem. Access to care is your mandate.

If you're careful, and your slick, you can earn some extra money by greasing the wheels on the process. Be creative, the country seems to be very lax on corruption enforcement standards.

You are extremely wary of foreign imports. This is in part due to your upbringing in an oil services town where the foreign multinational polluted the local water system throughout the years. technology was brought in from Switzerland to provide accessible chlorination to the town, but he just resulted in inexpensive purchase of hardware. Moreover an extra tax was levied on your family and the rest of the town to pay for the failed project. The engineers that came in from the capital hired by the company look down on your neighbors because they didn't have as much education as they did. Since then he seem to have a chip on your shoulder to try to true foreigners and Brazilians can do it better.

Consultant to Regulatory

You are the head of biomedical engineering at the University of Manaus. You have invented three different devices that are used to combat inflammation resulting from snakebites. Furthermore you've offered about 500 papers involving different types of uses for these devices. They have all been papers published in Brazilian journals. You have made the footnote of an article in Nature and you are very proud of that.

The reason you consult with ANVISA is to supplement your income because a professor salary in Brazil doesn't go very far. ANVISA pays by the hour and passes on the cost to the applicant, so the longer it takes the better it is for you.

Generally you're on the fence about foreigners. On one hand you really want impressive them because you never really got into a very good university outside Brazil. On the other hand, you know Brazil and they don't. You really get annoyed when they tell you that something is the way it is supposed to be after they have just arrived into town.

Your primary job is to review the technical details a device and make sure that they match the IRB. If they don't match, then the company has to start all over again.

Local Entrepreneur and Medical Device Factory

Your family has a small pharmaceutical factory in the heart of Brazil that supplies mostly over the counter painkillers in topical medications to the Brazilian market. Five years ago you graduated from the University of Window with a degree in Chemical Engineering and a minor in business. In your fourth year, you saw a medical device company go public and your dream is to follow in their footsteps. Your parents have given you some freedom in running a portion of the company. You want to move things into the medical device arena, because you think aspirin is boring.

You like Brazil, you are a king in that country, but you feel a little stifled. On the other hand, you didn't like any of the regular business rules or intellectual property rights that the US had to offer when you lived there. At the end of the day, you know that pursuing a patent in Brazil will take years for the litigant to get anything done any seen most of your friends violate IP protections and make a lot of money. Everyone sleeps at night because they know that at the end of the day patients are getting treated. Depending on the person he basically flip a coin and decide how to get to that juncture in the road if it ever comes to you.

Republic of Tocoa

Doctor

Your patients are dying all around because they don't have access to X. Your training in the US included a class at MIT that taught students how to design appropriate medical technology. You know that there's a better way to address the lack of this technology but no one listens to you. You are trying to find the right partners that share your vision. Your cousin is the director of the local FDA, but he/she isn't very knowledgeable about these matters and will generally be bi-polar about these decisions. You work in a country hospital because you like the people that you treat but hope to come back to the capital eventually. In the meantime, you are a bit frustrated with the local authorities because the procurement process is endless and you never seem to get any of the equipment or instruments that you request.

Tocoan Regulatory Ministry

You are a medical device approval officer at TRM, the local medical device regulatory agency. By default your main job is protect the TRM population and ensure a good standard of health. You have never approved a medical device in your life. Your main job is to ensure that fake pharmaceuticals don't get into the country.

In order for products to be accepted in Tocoan customs, it is a legal requirement for the products to have directions for use in Portuguese and to have Portuguese product labels. Each of the following items must be included:

- Product name and intended use.
- Manufacturing and sterilization date.
- Method of sterilization.
- Expiration date.
- MOH registration number.
- Name and registration number of responsible technical person at the Brazilian distributor's office.
- Manufacturer and distributor names (the distributor holding the registration) and addresses.

If a clinical trial is involved you want the terms of the IRB, and you demand that the IRB is authored and harmonized locally in Tocoan. It's a medical device that is not FDA approved, you want to clinical trial data that doesn't begin with Tocoans because they aren't Guinea Pigs.

Your job will typically take about 6 months, but in reality, things take about 12 months. You should not disclose that though, because it will make sound like your office is too slow and you may get fired.

You are totally in awe of foreign technology and love American and German brands. Tocoa just got invited to be part of the Central American Free Trade Organization. This has implications in the regulatory affairs of the country because the United States wants to make sure that any products getting exported out of Tocoa and into the US do not harm Americans. They have just given you a free 2-week seminar on FDA best practices and you have determined that it is the gold standard for approving products. You wish that your agency had the capacity to do that rigorous amount of work, but you don't get paid enough to do it, so you always start by demanding FDA approval.

If you're careful, and your slick, you can earn some extra money by greasing the wheels on the process. Be creative, the country seems to be very lax on corruption enforcement standards. On the other hand, if patients get hurt on your watch they will fire you and because our appointment is a political one, they will lay off other members of your family. Risk is not of your favorite pastimes.

Local Entrepreneur and Medical Device Factory

Your family in the small pharmaceutical factory in the heart of Tocoa supplies mostly over-the-counter painkillers in topical medications to the Tocoan market. Five years ago you graduated from the University of Window with a degree in Chemical Engineering and a minor in business. In your fourth year, you saw a medical device company go public and your dream is to follow in their footsteps. Your parents have given you some freedom in running a portion of the company. You want to move things into the medical device arena, because you think aspirin is boring.

You like Tocoa, you are a king in that country, but you feel a little stifled. On the other hand, you didn't like any of the regular business rules or intellectual property rights that the US had to offer when you lived there. At the end of the day you know that pursuing a patent in Brazil will take years for the litigant to get anything done any seen most of your friends violate IP protections and make a lot of money. Everyone sleeps at night because they know that at the end of the day patients are getting treated. Depending on the person, he basically flips a coin and decides how to get to that juncture in the road if it ever comes to you.

Director of Physicians College

Your regulatory body is in charge of advising the TRM to make sure they know what types of therapies they should be approving. You recognize that approval is basically a rubber stamp, and you are concerned about the power and relevance of your organization. Your mandate is to keep the 500 new MD graduates of the country employed. If something hinders that, then you take action. You think American doctors are too much in love with technology, so you take a lot of pride in the fact that you can do things by pure skill. That makes a true measure of a doctor. You are tired of gizmos that break down an in general look down on new ones. Your power is based on the recommendations that you make to TRM on whether to pursue something or not. You generally try to supplement your income by finding business opportunities with your friends. Most recently, you became a part time medical officer for a pharmaceutical company and that has paid off handsomely. That ended in Christmas and you are open to new side gigs.

Doctor

You are a gadget freak. Even though you studied medicine you really wanted to study engineering but it really didn't pay that well. Instead you became an internist and are now handsomely being paid by your private practice. You are really good friends with XXXXXXXXX and offer advice whenever you guys get together. Most of the XXXXXXXXX to serve as a de facto consultant whenever they can't figure it out. You were born in the capital, had a fairly privileged upbringing, and know very little about the countryside except that it's full of poor people that you rarely see because your patients are mostly part of the professional class. You are a subscriber to Technology Review and keep a framed picture of the MIT dome from when you got invited to a conference on Physics with your High School.

Ministry of Health Finance Officer

Your job entails (1) getting money from donors, and (2) spending money from donors.

In the last 10 years, you have gotten very good at getting donations of medical equipment. You also manage medical supply procurement. Your financing arms (World Bank and IADB) only allow for medicines to be bought, so 90% of your purchases are drugs. You basically get to decide whether a hospital gets to buy something or not.

The Bank

Your job is to provide venture loans to promising companies. You have to assess risk which includes:

- Soundness of business plan
- Country risk
- Intellectual property protection
- Market size

Big Multinational Organization Financier

You have an MBA from the University of Monee and you are an expert at making loans. You have learned to calculate risk and get most of your money back from countries in the developing world who usually default on all their loans. Recently you put in place a very specialized dating system that I'll only approved an established manufacturers of medical supplies to make it into the procurement process. Your dream system is one in which you will two main groups of items for purchase: Medications which are usually recommendation by international bodies and Equipment. For equipment, the MBA inside you wants to harmonize everything so that there are about 250 essential medical devices around the world that every country must purchase as part of their aid package. Whenever there's a new manufacturer generally rely on your network of friends who went to really cool universities to find out if they are legitimate or not. Your friends are now all in banking however it's been a long time since he worked in the lab so they generally go by name association.

Patient

You are really poor. The last time you ever went to the doctor was because you couldn't stand the pain from a broken tooth and it almost got your fired. When health is concerned, affordability is paramount. You basically only go to the doctor when things hurt. You have three children and you make no exceptions when it comes to their health.

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