

Solving the FDA Crisis

A guest article for the *Biotech Blog*

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News of the latest crisis under the FDA's watch – salmonella contamination and the peanut plant in Georgia – has all the usual suspects calling for increased inspections and hiring more inspectors. It won't work. With all the money from the US bailout, the FDA could permanently station inspectors at every single biotechnology building, food processing plant, pharmaceutical site, and medical device factory in the US. And we would still have the problems we have today...only at an \$800 billion price tag.

To solve the underlying issues we need an approach that will cost less, will strengthen our safety (especially as we enter the era of personalized medicines), and yet will still allow innovation and a level competitive playing field. This strategy will also need foresight – not only to expect that events will occur in the future that will challenge this solution – but to assume that without satisfying the public outcry when something does go wrong, the strategy will not last, and we will again be revisiting the “solution” when the next crisis *du jour* occurs. Put simply, we need a solution that can be applied with such tenor that it will “leave the people at once satisfied and stupefied” (Machiavelli, *The Prince*); we need stricter, harsher penalties.

The False Premise of More Inspections

As anyone with real-world experience in quality systems, information technology security, records management, or corporate espionage knows, you can have the best written rules in place, everyone trained, and auditors and inspectors in place, active, and auditing away, recording and documenting each transgression. So what? If the penalties are just a slap on the wrist – or in some places I've seen, a friendly chat – the transgressions will continue.

Malcontents and people who are ethically-challenged are always to be found. When I give talks and workshops on corporate espionage or quality systems compliance, I always review the four key reasons people do not follow rules: money, ego, ideology, or coercion. How does stationing an inspector at every building stop these motivators?

The reality is simple: for some people, just having the risk of getting caught is not enough. For these individuals, the risk of getting caught needs to be combined with the penalties for being caught, and together this must outweigh any perceived benefits to not abiding by the rules. And it is for these people that rules, regulations, policies and punishments are designed.

So if hiring more inspectors and increasing the frequency of inspections will not work, what will?

An Example that Works

All of us know the incredible annoyance of the telephone ring at dinner time as the telemarketers begin their evening onslaught. Thankfully, my children are growing up in a world where this does not occur. Is it because the telemarketing companies suddenly discovered that kindness and consideration preclude them from calling during family time?

Or is it to do with the National Do No Call registry? Think about it. By itself, the registry is just a big list. Again, so what? Just because you and I can put our names on a national Do Not Call registry does not really keep the telemarketing calls away, does it? Instead, the power of the registry has to do with the coupling of strict, harsh penalties associated with violating the rules.

And the penalties are simple and severe: \$11,000 (USD) per sales call.

Ultimately, this is why the Do Not Call registry works – its teeth are both satisfactory and stupefying. It is satisfactory that people who knowingly violate the law have to pay so much. It provides us, as the consumers, the impetus to gleefully file complaint paperwork. And the penalty is stupefying. Would you like to pay \$11,000 out of your pocket for a misplaced call? Or would that make you do everything within reason to avoid the misplaced call (and its associated penalty)?

So why is it that we're willing to take this approach to stop a few phone calls every evening, but for products that enable us to actually live – food and medicine – we only suggest increasing the number of monitors?

The Way Forward

The FDAAA of 2007 took tentative, baby steps in the right direction. As attendees of my January teleconference, [Bulletproof Yourself Against FDA Enforcement in 2009](http://www.ceruleanllc.com/seminars) (<http://www.ceruleanllc.com/seminars>), are quite well aware, the use of civil monetary penalties was expanded beyond just device makers, and the agency was given several powers of enforcement that it had long argued in the courts it required. Under the possible roadmap of the Do Not Call registry, however, the FDA is still sorely lacking in its ability to levy penalties against those executives and companies who do not produce safe products. And as we move from the one-size-fits-all medicines of

the 20th century into drugs tailored specifically to your or my genetic makeup, product safety needs to be much, much higher on our priority list than stopping a telemarketing call or two.

There are three steps we can take to ensure a more consistent degree of safety in the products we get from companies under FDA jurisdiction:

1. Increased Penalties. Penalties for violation of FDA regulations and laws need to rise to at least the level of Do No Call penalties. Today, a firm receiving a Form 483 inspectional observation has no real penalty; only if the observed deficiency is “grossly deficient” will the company even risk being temporarily shut down until the deficiency is resolved. How effective would the Do Not Call registry be if instead of the \$11,000 fine per call, it was only a “gross deficiency” of not following the registry that *might* cause the telemarketing firm to be temporarily stopped from making calls until they agreed to not call anyone on the registry? Instead, under a stricter approach modeled on the eminently functional Do No Call registry, a firm receiving a Form 483 inspectional observation might be assessed an \$11,000 fine per observation; this would not be immediately due – rather, the firm could have the same process that exists today to head off a warning letter (*e.g.*, fix the problem within a defined time period). If the firm does not fix the observation to the agency’s satisfaction (no different than today), then the warning letter is issued along with a penalty statement explaining that for each item listed on the letter, the firm is required to pay \$11,000 per day until resolved. The firm would also be required to hire an independent third-party to inspect and certify that the violations were resolved.

2. Increased Incentives. At minimum, incentives for whistleblowers, consumers, healthcare providers, and even other non-FDA inspectors (customs agents, state food inspectors, etc.) need to be

increased to encourage the filing of substantiated claims. For instance, we could look at the financial incentives from Sarbanes-Oxley as a possible model; a whistleblower of an FDA-regulated company whose allegations were proven correct could receive 10-30% of the levied fines as a thank-you for helping to protect the public.

Lest the incentives are all seemingly against firms, positive reinforcement should also be granted. At a minimum, rather than just publishing the list of firms who've demonstrated poor controls in its weekly enforcement reports, the agency can note firms who successfully passed inspections or otherwise adequately resolved previous issues. As shareholders increasingly agitate against executives who delay product launch because of FDA noncompliance, this type of public commendation can be a positive tool for executives seeking increased funding or new product approvals.

3. Strengthened Early Inspection Triggers. Today, the agency inspects firms for one of three main reasons: routine (also known as “surveillance”), for cause (such as a whistleblower complaint or adverse event or recall), and pre-approval. Pre-approvals are generally undertaken when a company files an application to sell a product in interstate commerce (pharmaceutical companies, for instance, file an NDA or ANDA). For medicines – including medical devices – a pre-approval inspection should also regularly occur when a company wants to start clinical trials. For foodstuffs, state agencies are the main inspectors, with the FDA chronically understaffed in this area. While state agencies should continue to play their role, the rules could be strengthened to force first-time manufacturers and processors to undergo a joint state-FDA inspection prior to allowing the product on the marketplace.

There are other items as well that would strengthen the incentives for making safe, efficacious and quality products while lowering taxpayer costs. Congress can encourage the FDA to expand the current joint inspection pilot programs with authorities in Canada, the EU and Australia to cover all medicinal products and foodstuffs. The agency can be more accepting of third-party and ISO-based inspections to stand in for nominal risk products (such as most Class I devices and foodstuffs).

Final Thoughts

Under this strategy, the FDA would need to publish a clearly defined baseline of inspectional criteria that will trigger the stricter penalties (much as the Federal Trade Commission publishes the clear list of criteria that will trigger the Do Not Call fines). Such a baseline would need to spell out that for the vast majority of – if not all – companies, inspectional observations such as “insufficient conveyor belt clearance” would not initiate a penalty unless other thresholds were also triggered; on the other hand, executives who decide to repeatedly test their product for the presence of contamination until they hit upon the “right” test and then pronounce their product “safe”, could be assured of painful consequences that would stupefy them and satisfy the public. The simpler and clearer the rules, and the stricter and swifter the penalties, the greater the adherence.

No regulatory schema or enforcement program is perfect; someone who values money, ego, ideology or coercion enough will eventually break the rules. But just as under the Do Not Call registry, this rule-breakage is extremely rare, so too should be the rule-breakage of FDA-supervised products. The question we face is ultimately one that asks us to choose between priorities: are good medicines and safe food more or less important than skipping a few telemarketing calls this evening?

Are you ready?

About the Author

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