



ARE NO RULES BETTER THAN BAD RULES?

THE DANGERS OF THOUGHTLESS COMPLIANCE

by Martin Lush

Like many of you I've been following the coroner's inquest into the tragic death of 15-year-old Natasha Ednan-Laperouse with interest.

For me it was personal. Both my children, like Natasha, have severe anaphylactic, life threatening food allergies. Natasha purchased a baguette from Pret a Manger (at Heathrow airport) and scrutinized the label for allergens. It's what every allergy sufferer habitually does... always check. Since sesame seeds (her anaphylactic trigger) weren't listed, she purchased and ate the baguette. Hours later she died from an allergic reaction.

The inquest exposed how Natasha had been let down by both law makers and Pret:

- > EU regulations state that sesame is one of 14 allergens consumers must be made aware of when used as a food ingredient.
- > However, EU regulations allow member states to decide how information about "non-pre-packaged food" (the baguette) is provided.
- > The UK's Food Regulation Agency allows "freshly handmade, non-pre-packaged food" to not be individually labeled. Why? To make life easier for food producers rather than protect allergy sufferers!
- > So, although Pret listed allergy warnings around its shops, packaging on individual products did not list allergen advice on the item, where allergy sufferers expect to find it. So, Pret was in compliance with the law. A bad law. They focused on meeting the rules, not the needs of allergic consumers making a potentially life-or-death decision on whether something is safe to eat?



To make this tragedy worse, Pret knew its practices were risky. There had been nine sesame-related allergic reactions in the previous year. Despite these warnings, Pret didn't act.

WHAT CAN WE ALL LEARN FROM THIS TRAGEDY?

- > Bad rules can be worse than no rules because those they seek to protect are lulled into a false sense of security. No sesame on the label means no sesame in the baguette, right?
- > Complex rules are bad rules. Rules must provide immediate clarity. Rules that meet complexity with complexity are worse than no rules at all. Complex rules lead to confusion, shortcuts and rule breaking. For rules to be effective, they must be simple.



- > Once written, rules are obsolete. The world has changed. To remain effective, rules must continue to evolve in light of new evidence, shifting objectives, changing conditions and real-life experience.
- > Rules that try to satisfy everyone are bad rules. Good rules focus only on who and what matters most.
- > Bad rules stifle the innovation we need to improve and grow. Remember, rules describe the minimum requirements. It's amazing how many companies include "to stay in regulatory compliance" in their mission statement. Aiming to comply with minimal requirements is hardly aspirational for an industry built on innovation and smart risk-taking.
- > Bad rules try to cover every eventuality. Good rules focus on the 20 percent that matters most.
- > Bad rules are written in isolation, without the participation of those who understand the situations in which they will be used. Our regulations would be so much better if patients and their advocate groups were sitting at the head of the rule-making table.
- > Have a high trust environment that actively encourages people to challenge rules without fear?
- > Have confidence to challenge regulators when we're asked to comply with bad rules?
- > Have methods of trending failures to tell us the rule is not being followed or is just plain bad?
- > Use failures to encourage people to rip up the rule (even the whole book) and start again?
- > Make compliance easy? Pret's excuse (for not labeling products) was that allergy advice was posted in the shop. Next time you pass through Heathrow airport, go to Pret. It's noisy and crazy busy. Customers need simple, easy access to allergen advice. Listed on the product, not on a shelf meters away, obscured by other customers. Remember, if you want people to follow rules, you must keep them simple. If you don't, people take shortcuts.
- > Involve our patients and their advocate groups when we write our corporate policies?
- > Annually review how good our rules are based on performance and feedback?
- > Educate our people in the why (the rules matter) before the how (to follow)?

Pharma and med device companies have thousands of rules. From corporate and site policies to SOPs and work instructions and everything in between. One company I recently visited had over 14,000 of them. Mostly bad, some dangerous. All were overcomplex and written without user involvement, and provided the dangerous illusion of control and order...when there was none.

DO YOU HAVE GOOD RULES OR BAD RULES? HOW TO FIND OUT

Ask as many of your colleagues as possible. Do we...

- > Apply a "less is more" approach to our rules? After all, smaller rules are simple rules and simple rules work.

QUESTIONS FOR OUR REGULATORS

- > When will you start writing rules with patient representation, because if you don't, how do you know they're fit for purpose?
- > When will you start reviewing rules that are no longer fit for purpose? For example, the rules governing post-approval changes discourage the improvements and innovation patients desperately need. This is a bad rule where everyone loses.



- > When will you change the rule-making process to keep up with the speed of science and technology? This must start sooner and involve all stakeholders including patients and their advocate groups.
- > Do we have too many rules? Has the (almost) exponential growth in number resulted in safer, better quality and more cost-effective medicines? Is it time for a mass culling?

SOME VERY IMPORTANT QUESTIONS FOR YOU

Are your rules good or bad? Do they benefit the patient, or are they just a tick box exercise to satisfy the box checkers? Do you focus on meeting rules or meeting genuine needs of those who matter most?

I LOVE THE FOLLOWING QUOTES:

"There are no rules here. We're trying to accomplish something." Edison

"Rules are for obedience of fools and for the guidance of wise men." Day

Don't get me wrong, I'm not saying we don't need rules. We do, but we only need good ones.

Follow Martin on [LinkedIn](#) and get involved with the debate.

ABOUT THE AUTHOR



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