Getting to the Great Free-set: Tackling Drug Regulation and the Laws in General

Better Way Conference

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Table 1 | How the regulators compare

	Australia TGA	Europe EMA	UK MHRA	Japan PMDA	USA FDA	Canada HC
Budgets and fees						
Proportion of budget derived from industry	96%	89%	86%	85%	65%	50.5%
Total annual budget ↑	AU\$170m (£95m)	€386m (£331m)	£159m	¥29.1bn (£175m)	US\$6.1bn (£5bn)	C\$2.7bn (£1.7bn)
Transparency, COIs, and dat	ta					
Proportion of covid-19 vaccine committee members that declared financial COIs	50%	3%	32%	75%	<10%	0%
Declared COIs available as public information	No	Yes	Yes	Yes	Yes	No
Regulator routinely receives patient level datasets*	No	No	No	Yes	Yes	No
Drug approvals						
Proportion of decisions to approve new medicines (<i>v</i> not approve)	94%	88%	98.5%	Not disclosed	69%^ 29%#	83%
Proportion of new drugs approved through expedited pathways in 2020	20%	50%	36%₹	26%	68%	16%

https://www.bmj.com/content/bmj/377/bmj.o1538.full.pdf. BMJ June 2022. Maryanne Demasi

What we need to get rid of (1)

- Emergency Authorized Drugs and Vaccines—either you are in an experiment and receive full informed consent, or you receive a fully tested drug/vaccine. No gray area in between!
- Sleeper vaccine contracts—get rid of hidden government contracts to buy future vaccines whenever some emergency is designated
- All immunities for vaccine manufacturers and pharmaceuticals
- Expedited regulatory reviews (FDA gets paid extra to guarantee a shortened review, usually 6 months)
- "Other Transaction Authority" a sneaky way to bypass the system to buy pharma products without regulation
- Government agency 'deference' by courts—the gov't is assumed to be right

What we need to get rid of (2)

- Direct payments to agencies by drug manufacturers for drug reviews or other purposes
- Revolving doors between government and industry that allow industry insiders entry to rulemaking
- Revolving doors that allow government employees to get a 'payoff' job with industry if they regulated favorably
- Financial conflicts of interest—no waivers, no time limits
- Make the weaponization of government agencies a major crime with stiff penalties.
- Royalty payments to government employees and agencies

Some new laws that are needed

- 1. Enshrine bodily autonomy and informed consent to all medical procedures, including vaccines, as inalienable.
- 2. Criminalize the collection of private information (electronic or otherwise) without written informed consent.
- 3. Criminalize the collection and storage of human genomic data.
- 4. Prohibit all forms of government and industry interference in the doctor-patient relationship.

In order to turn our civilization around and make it work for people, we must do more than fix drug regulation

Just like Dorothy, we will have to overcome many hurdles before we get to the Emerald City. We need to anticipate and plan for them.



Here is a big hurdle: what happens when everyone figures out the enormity of the COVID crimes that have been committed? Our systems of law give most of the criminals extremely broad immunity.

- * How can we get justice?
- * How can we identify all the criminals?
- * How can we avoid a period of uncontrollable violence?

We will need new laws in place in a big hurry! So, let's start talking about them right now!

We are stuck with a bad body of law and compromised officials who misinterpret it, in government agencies, clinics and the courts

Under the current system, it is very hard to prosecute the government and any guilty parties we identify.

Clever laws like the US' 2005 Prep Act were designed to shield everyone involved with EUAs from all liability.

Government employment provides immunities also.

We don't even know who the real puppet-masters are.

We will still need doctors and hospitals as well as more natural forms of medicine.

Can we develop suggestions that our legislatures can adopt, once the cat is out of the bag, when even the woke are angry, and the pols want to get on the good side of the public?

Make all destruction of records (public/private) and computer hardware a crime with a stiff minimum sentence

Broaden freedom of information laws and make all government and contractor records fully transparent.

"Just following orders" will not be an acceptable defense.

Make judges elected. Impose short term-limits or make recalls or impeachments of judges relatively easy.

End all immunities: for drug companies, diplomats, government officials, private organizations such as the BIS, BMGF, World Bank employees. End the need for "standing" to charge public officials.

Since we cannot identify those at the top, we need a way to learn who they are

2. We must reorient our professionals The Truth and Reconciliation Commission idea is definitely worth considering.

People must tell everything they know, and if completely truthful they are not punished, or receive a reduced sentence.

Doctors, scientists, lawyers, etc. must be held to a strict ethical standard.

We should consider requiring them to undergo a period of retraining, like the continuing education or internships of today

Subsidiarity– a word that Dr. Wolfgang Wodarg taught me, which will help free us from centralization of power

Subsidiarity is a principle of social organization that holds that social and political issues should be dealt with at the most immediate or local level that is consistent with their resolution. The <u>Oxford English</u> <u>Dictionary</u> defines subsidiarity as "the principle that a central authority should have a subsidiary function, performing only those tasks which cannot be performed at a more local level."

You enshrine in law that every task is managed at the lowest level of government possible, so that it can be overseen by the people. The goal is for national governments to do as little as possible.

Bibliography for improved drug regulation

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Thanks for your attention and for caring!

Let's help others turn on the lights!

