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A SUBMISSION TO THE TASKFORCE ON REDUCING THE REGULATORY BURDEN ON BUSINESS - WITH SPECIAL REFERENCE THERAPEUTIC GOODS REGULATION

I would like to thank the Task Force for the opportunity to make a submission to the Taskforce and I sincerely hope that these few thoughts may help the task force achieve the aims the Government is trying, through this public consultation exercise.
I am very supportive of the Australian Government's determination to reduce the burden of regulatory activity. The Government has done its bit in successfully arranging mutual recognition agreements and opening doors to global markets.
It is time for the bureaucracy to strategically move along and provide advice.

Regulatory costs - Some facts from other countries

United States of America

Government is costing us more than the taxes we see, because it's difficult to see the extra cost of complying with government regulations. Complying with government regulations consumes $1.4 Trillion ($1,028 billion federal mandates, $343 billion state & local government mandates)

- 14.9% of the economy - $4,680 per man, woman and child -
- adding this regulation cost to $13,568 government spending per person equates to $18,248 per person of government impact -
- compliance costs small business more per employee than big business -
- federal expenditures on regulatory activity increased 2.7 times faster than economic growth since 1960 -
- at 14% per year compounded -

Government mandated regulatory compliance costs are huge amounts: as much as all spending by state & local governments (education, police, welfare, etc.), or twice as much as social security & Medicare spending, or 3 times more than national defense. And, government does not budget or account for these huge costs - although $100 hammers are accounted. Despite congressional mandates, government has been dragging its feet for years to account, measure & control - thereby placing the economics of our young generation at incalculable risk.

Of $1.371 trillion total regulatory costs, federal regulatory compliance costs are 1.028 trillion (incl. about $200 billion for paperwork just complying with tax codes, which is rapidly increasing); state & local government compliance costs are estimated at $343 billion.[1]

America's smallest firms bear the largest per employee burden of federal regulatory compliance costs, according to a recent study released by the Office of Advocacy of the U.S. Small Business Administration. Firms with fewer than 20 employees annually spend $7,647 per employee to comply with federal regulations, compared with the $5,282 spent by firms with more than 500 employees. The report measures disproportionate regulatory compliance impact on small business. The study finds that small business faces a 45 percent greater burden than their larger business counterparts. [2]

Smaller countries like smaller businesses bear greater burden of regulatory compliance and Australia even tough large in area is small in terms of population and consumer base.

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[1] Regulation Cost report part of the series of Grandfather Economic Reports

[2] The peer-reviewed study, The Impact of Regulatory Costs on Small Firms.

The Government has been extremely successful in reaching mutual recognition agreements with the European Community and the USA (FTA) in areas of therapeutic goods manufacture and distribution. These agreements have been reached with the aim of giving Australian manufacturers access to these markets.

Unfortunately increased quality controls and validation requirements imposed by local regulatory authorities gives the prospective entrepreneur the impression regulation in this country is an end in itself and not a means to an end which regulation is intended to be.

It is said that regulation is the fastest growing business in countries where the bureaucracy has the time and inclination to support studies intended to delay the release and marketing of products in the name of consumer safety. Much of the regulation manufactured by governments in Australia ignores or overlooks the economic and community costs of new red tape, or whether regulation already in place can do the job. Regulation is mainly reviewed by civil servants enjoying the comfort zones.

We are becoming more and more risk-averse, demanding regulation to anticipate each and every unforeseen contingency. We seem to have forgotten that therapeutic goods are handled by qualified professionals also interested in the consumer welfare.

At the same time our trading partners like the EC and USA are looking at risk based approach to therapeutic goods legislation and they are actively reviewing their existing regulation-making systems and culling unnecessary or outdated regulation. FDA Modernization Act has been enforced onto the fossilized FDA.[3]

As Tony Blair recently noted in a speech in which he committed Britain to systematically tackling its own regulatory blow-out in an acknowledgement that Western societies have become increasingly averse to risk.

The current systems must be overhauled to make sure all new regulation fully takes account of costs to business and avoids costly and undesirable overlap and duplication and impose a cultural change to reduce the “holier than thou” attitude of our legislators. Mutual recognition when it takes effect should have no or a minimum of exceptions. E.g. We have one of the most stringent disinfectant regulations in the world – a regulation which even though reviewed is still plagued with local requirements which our trade partners are unwilling to accept totally.

Apparently we review existing regulation but it is definitely not aimed to improve or eliminate regulation that is unnecessary, duplicated or outdated – sometimes is seems solely aimed to serve as an ‘alter ego’ to a pre retirement civil servant.

The problem is further compounded by the overlap and lack of co-ordination between the Commonwealth and states, and between the states themselves.

The system must allow for a regular review of red tape to adjust, modernise and streamline it to meet the needs of its business and community consumers and the opportunity is now as we proceed to move into Trans-Tasman regulatory body.

Hoping this is helpful

Yours sincerely

Olavo Cotta

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[3] **FOOD AND DRUG ADMINISTRATION MODERIZATION ACT OF 1997**