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Comments on the *Therapeutic Goods Amendment (2016 Measures No. 1) Bill 2016* & comments on the Therapeutic Goods Administration (TGA) approval and review process more generally

Joint submission of the Australian Taxpayers' Alliance (ATA) and MyChoice (MC)

Introduction

1. The Australian Taxpayers' Alliance (ATA) and MyChoice (MC) thank the Federal government for the opportunity to present our submission on the *Therapeutic Goods Amendment (2016 Measures No. 1) Bill 2016 ('the Bill')*. We would also like to thank the committee for the extension granted. We note that for the purpose of this review, we will be focusing mainly on reform to the TGA's process for reviewing and/or approving the scheduling or rescheduling of substances as well as their guidelines for publishing their findings and/or justifications for these decisions.

2. We commend the government for seeking to improve the operations and functionality of the TGA through *The Bill*. Enabling priority approval of medical devices and medicines will facilitate consumer access and increase efficiency as will amendments to the powers to approve unapproved goods in the event of a shortage. We also commend the requirement that the secretary must specify timeframes for the processing of an application as this fosters confidence and transparency in the TGA process.

3. However, we also note that under the current status quo, a number of additional amendments are necessary to ensure that these processes are adequately transparent, connote efficacy, public information and public safety, maintain reasonably high standards of comprehensiveness and scientific rigour and are ultimately conducted in the public interest with adequate addressal of the concerns and submissions of relevant stakeholders.

4. The ATA is an Australia-based grassroots, free-market advocacy group, consisting of over 25,000 members. The ATA stands for the principles of limited government, personal responsibility and rolling back the regulatory state. MC is an autonomous affiliate of the ATA dedicated to promoting individual freedom and personal

responsibility in the community.

5. The ATA and MC take note of the following statements made by Sussan Ley MP for Farrer and (then) Minister for Spot and Minister for Health and Aged Care in her 2nd reading speech for *the Bill*:[1]

   "*The purpose of this bill is to make a number of such changes that will enable members of the public to have access to medicines and medical devices more quickly, while continuing to maintain high standards of safety and efficacy which the public expects, as well as decrease the regulatory burden on industry and on medical practitioners.*"

   "*A number of minor amendments in the bill aim principally to achieve greater consistency between the regulation of different types of therapeutic goods and to reduce health risks to the public*."

6. The ATA and MC submit that present TGA protocols as reflected in their recent review of the scheduling of nicotine solutions under the Australian Poisons Standard and their subsequently published interim decision the matter connote deep flaws and a lack of transparency that is antithetical to these desired outcomes. This is especially so in relation to the objectives of reducing health risks and harm to the public, providing a regulation system for goods that is consistent, decreasing regulatory burden, fostering public access to harm reduction and addiction-reducing tools and maintaining a high standard of efficacy. That particular review by the TGA was characterised by a denial of procedural fairness, selective redaction and selective use of evidence which must be remedied by amendments to the TGA's guidelines.

7. The ATA and MC provide the following recommendations which, if adopted into the proposed bill, would foster a transparent, consistent, high scientific rigour TGA process which is in the public interest and connotes public health outcomes.

Priority approval pathways

8. The ATA and MyChoice endorse the implementation of eight key recommendations of the Expert Panel Review of Medicines and Medical Devices Regulation (the Review), which aimed to identify areas of the regulation of medicines and medical devices which could be streamlined, while maintaining the safety and quality of therapeutic goods.

9. The recommendation for the creation of more priority approval pathways for new treatments, goods and devices is especially commendable as it will foster patient access to much-needed and rapidly evolving medical technology, treatments and medicines.

[1] Commonwealth, *Parliamentary Debates*, House of Representatives, 1 December 2016, 5113 (Sussan Ley, Minister for Sport and Minister for Health and Aged Care).

10. We note that *The Bill* attempts to implement this recommendation by designating to the TGA a regulatory power to introduce new pathways as well as guidelines for applying for these pathways and the criteria to be considered. Though this is certainly a very welcome step, we submit that the amendment could go further by including or specifying its own grounds for a priority approval whereby the exact detail of how these would be implemented or assessed can be designated to the TGA following consultation with experts and relevant stakeholders. Further grounds for future priority approval pathways can be introduced by the TGA as well through the regulatory process already stipulated in *The Bill.*

Priority Approval Criteria – Existing approval/certificate from a comparable foreign jurisdiction

11. The ATA and MyChoice recommend that *The Bill* is amended to specify a priority approval pathway for devices, treatments, goods and technology which has already been approved in a comparable foreign jurisdiction.

12. Foreign jurisdictions including the UK and USA have similar stringent standards of public safety and welfare reflected by their own government agencies such as the British Healthcare Products Regulatory Agency (MHRA) which is the UK equivalent of the TGA. It therefore makes sense to avoid a duplication of functions which has already taken place overseas. This will save the TGA significant time and expense whilst prioritising consumer access to new treatments.

13. Issues of independence, sovereignty and maintaining the TGA's role in reflecting specific Australian interests are still addressed as the TGA will continue to hold a fast-tracked version of its own review process.

14. The process can be further sped up by the institution of a guideline that the TGA must consider reports from foreign TGA-equivalent bodies which have granted the equivalent license/certification for the product in question. In this manner, the TGA's decision and policy making process can benefit from research and reviews conducted by other countries with comparable healthcare standards to ours.

Provisional Approval

15. Alternatively, the ATA and MyChoice submit that The Bill should be amended to include a new 'provisional approval' mechanism for the TGA whereby the provision of an equivalent license/certificate from a foreign TGA-equivalent body from a country with comparable standards to Australia will confer a 'provisional approval' allowing for the legal sale and use of that product in the Australian market subject to potential revocation in the event that the TGA's own review determines that there are valid reasons for doing so.

16. This will ensure that the Australian public is not denied access to new, rapidly evolving treatments that citizens of other nations are benefiting from due to unnecessary regulatory burden.

17. Where there are concerns about the potential dangers of a provisionally approved product, these can be mitigated by narrowing the scope of a provisional approval grant to exclude treatments, medicines, technology, goods and devices with demonstrated side effects. This will ensure that there is a fair balance between fostering access to new treatments and taking precautions relevant to promoting public safety at a high standard.

18. The need for this reform is highlighted by the recent Federal Court ruling against the TGA regarding its approval process for a nicotine inhaler quit smoking device intended for over-the-counter sale whereby the TGA declined to even assess the application despite the product's approval/certification for over-the-counter sale in the UK by the UK's British Healthcare Products Regulatory Agency.[2] [3] [4]

Variations to product by notification

19. The ATA and MyChoice commend the amendment which will require the TGA to implement regulations allowing immediate changes to variations of details on the register which do not impact product safety.

20. This measure is important as it connotes a pragmatic and efficient approach which cuts regulatory burden for sponsors of products.

Conformity assessments – private bodies

21. The ATA and MyChoice also supports the amendment to allow private Australian bodies to undertake conformity assessments of products on the TGA's behalf. As private entities, these bodies are likely to be specialised in the field of their testing and therefore able to provide a high level of scientific accuracy and vigour if properly vetted for independence and standards.

22. This measure can be further enhanced if the qualification that these bodies must be 'based in Australia' is removed. Independent bodies in foreign countries with stringent standards are equally capable of undertaking conformity assessments and could possibly do so in a more cost-effective way or with even better facilities than bodies in Australia. Furthermore, this will force Australian bodies to constantly update their facilities to conform with the latest International standards in order to

[2] http://www.judgments.fedcourt.gov.au/judgments/Judgments/fca/single/2016/2016fca0394
[3] http://www.vapingpost.com/2015/12/07/uk-an-e-cigarette-to-be-made-available-on-the-nhs/ ;
[4] http://www.smh.com.au/federal-politics/political-news/federal-court-forces-drug-regulator-to-consider-nicotine-inhaler-case-20160421-goc3kx.html

gain contracts from the TGA thus improving our global competitiveness. This option, if left open to the TGA, will still leave the possibility of an Australia-based body being selected.

Confidentiality & Redaction Policy

23. The ATA and MyChoice note that the TGA provides a confidentiality option when taking submissions from stakeholders or the public. Similarly, a party can consent to its full submission and the names of its authors being published once the review reaches an outcome or interim decision by ticking a box. Though some parties may seek confidentiality, many parties including academics, think tanks, social/medical researchers and others may deliberately intend for their work and names to be published in order to reach the public who have a stake in the inquiry and to spur debate about the relevant issues of the inquiry.

24. The ATA and MyChoice note that disappointingly, the interim decision on nicotine reclassification by the TGA featured heavily redacted submissions from several parties who had consented to full publication. The redactions often included not only names but large sections of research and points, sometimes to the extent of being virtually unrecognisable by the authors themselves.

25. One of the heavily redacted submissions was a major work signed by 40 eminent public health authorities. Both the names of the authorities and much of their argument have been redacted and are not a matter of public record despite their explicit request for their submission to be wholly published.

26. Furthermore, the ATA and MC believe that confidentiality ought to be granted only in special circumstances. It is a general principle of transparent and accountable policy-making that who and what interests support or oppose an application for scheduling should be a matter of public record. Their motives and intentions should be subject to scrutiny especially where they influence the inquiry's outcome. Those who put submissions to the inquiry ought to be prepared to defend their submissions publicly. The current process is secretive. It is impossible for 3rd parties, the media and the public at large to evaluate or examine the quality of their evidence or merits of a submission where the identities of submitters and even their key arguments and/or research are redacted. The TGA hence cannot be held fully accountable as its decision-making process is rendered opaque. This is contrary to the public interest which the TGA is supposed to uphold and it is imperative to the intended objectives of *The Bill* that measures be put in place to address this problem.

27. It is highly concerning that much of the material or submissions which were not redacted or were redacted to a lesser degree, were in support of the conclusion that the TGA reached. Notably, when elaborating on the reasoning for its interim decision, the TGA failed to address many arguments and much evidence which contradicted or appeared to counter their justification. A lot of this material has been redacted. There

is therefore a strong appearance of deliberate and/or inadvertent bias whereby the TGA seems to have engaged in selective redaction to support its ultimate decision rather than engage in a truly objective and critical process.

28. The ATA and MyChoice are happy for our submissions to be published in full. We submit that confidentiality ought to be waived in lieu of special or exceptional circumstances where parties submit to future TGA inquiries.

29. In the alternative, the ATA and MyChoice submit that at the very least, the TGA should not engage in redactions of submitted material or submitters' identities where these individuals or organisations have provided consent for full publication.

30. These reforms to the TGA's inquiry process will greatly enhance transparency as well as the wider public debate surrounding issues of the public interest. This is especially pertinent for the TGA as the TGA is responsible for important decisions concerning public health and access to both beneficial and detrimental goods.

Disclosure requirements

31. The ATA and MyChoice note that in coming to its decision at the end of an inquiry, the TGA peruses stakeholder submissions, engages in consultations and even resorts to commissioning (paying for) its own expert opinions and engaging in its own deliberations.

32. It is a matter of public interest that consulted individuals and organisations, the budget for their consultation, the terms of reference provided to these individuals/parties and any declared conflicts of interest be disclosed to the public. The failure to implement this disclosure requirement greatly undermines public confidence in the TGA's decision-making and connotes potential bias.

33. The ATA considers this as an especially pertinent matter of concern as it concerns expenditure of public funds for the ostensible purpose of public safety and harm reduction conducted in a non-verifiable manner.

Scientific Rigour

34. The ATA and MyChoice submit that the TGA ought to adopt higher standards of scientific rigour. We understand that this may come across as a bold assertion, we believe that its substance is attested by the TGA's interim decision on the scheduling of nicotine.

35. As an example, the abovementioned interim decision was supported by the following statement: "*There is little evidence regarding the safety of long term nicotine exposure via ENDS. Exposure to nicotine in adolescents may have long-term consequences for brain development, potentially leading to learning and anxiety*

disorders. The toxicity of long term exposure to nicotine delivered by ENDS is unknown. Long-term exposure to excipients via the ENDS route of exposure is uncertain."

36. In making this statement and providing elaboration on its reasoning, the TGA did not deal in any significant detail with the available evidence and studies that indicate that nicotine delivered through vaping is non-toxic and that ENDS (Electronic Nicotine Delivery System) is proven to be safer than nicotine delivered through cigarettes which remain legal. Much of this evidence was outlined in the heavily redacted submissions provided to the TGA. For example, the ATA in our own submission (Attached with citations: Appendix A) at points 14-16 noted:

"*14. A recent study conducted by 15 of the world's leading Tobacco Control experts through Georgetown University's Comprehensive Cancer Centre found that found that e-cigarettes are likely to provide public health benefits based on "conservative estimates" of the likely uptake of vaping and smoking by adolescents and young adults and that "recent claims by some scientists that e-cigarettes are likely to act as a gateway to the use of tobacco products are overstated". The team that developed the model, which included researches from the United States, Australia, and Canada, projected a reduction of 21 percent in smoking attributable deaths and 20 percent in life years lost as a result of use of e-cigarettes in people born in 1997 or after, compared to what would have happened if e-cigarettes were not an option.* 5

15. An further study published in August 2016 in Nicotine & Tobacco Research found that after switching from tobacco to e-cigarettes, nicotine exposure remains unchanged, while exposure to selected carcinogens and toxicants is substantially reduced.6

16. There is considerable research into the addictive nature and toxicity of nicotine, and the ATA wishes to draw the Committee's attention to several pertinent facts. Firstly, while the tobacco in the average cigarette contains 10mg of nicotine, only about 1mg of nicotine is absorbed per cigarette, as a result of loss in sidestream smoke. 7 Secondly, the rate of absorption of nicotine is fastest when it is delivered via oral inhalation, compared to the progressively slower rates of absorption observed via skin, mouth, or nose and finally and least efficiently, by oral consumption and digestion. It is further noted that current pharmaceutical NRT options including nicotinated gum, nasal spray, and patches. As such it is concluded therefore from these points that ENDS can therefore mimic the effects of smoking most closely, making it the ideal substitute product."

The ATA and MyChoice submit that the TGA should be required to respond to or at least acknowledge academic evidence from peer-reviewed sources that contradicts or appears to contradict their determinations. This will ensure that potential bias in the decision/policy making process is reduced insofar as practicable.

37. It is further noted that a number of policy grounds supported by numerous stakeholders were not addressed or considered at all by the TGA despite their importance as policy considerations pertinent to the issue being determined as well as the number of stakeholders and amount of scholarly evidence in support for them. For example, the ATA and MyChoice noted at points 11 and 21 of Appendix A the value of ENDS as a public harm reduction strategy as it is a smoking cessation tool and provides a smoking alternative which limits the exposure of smokers to carcinogenic chemicals and toxins. These points were further elaborated with peer-reviewed, long-term studies cited in our reply to the TGA interim decision (Attached: Appendix B). Despite the relevance of this policy ground to the TGA's work, it was not dealt with in any significant detail by the TGA in their interim decision.

38. The ATA and MyChoice submit that the TGA should be required to address all relevant policy grounds which significantly pertain to public health, risk and harm reduction. A failure to implement guidelines to this effect would connote the potential for the TGA to simply avoid addressing policy grounds which go against its decisions and policies rather than engaging in an objective policy-making process. It would therefore defeat the intended objectives of *the Bill*.

39. As a further general point, it is against the objectives of public policy for a product to be rejected or rendered illegal because its long-term risks are supposedly 'unknown' where there is evidence attesting to the non-existence of said risks, proof that it is safer than a currently legal, more harmful alternative and where there is no material evidence attesting to the inverse – that there are long-term risks. This further supports our suggestion that the TGA ought to respond to evidence that contradicts or counters the grounds for its decision.

Narrowing grounds for refusal to consider application

40. Under s 23 of the *Therapeutic Goods Act 1989 (Cth)*, applications can only be assessed if they are submitted 'in accordance with' the relevant form. As such s 25 of the same legislation specifies separate forms for assessment of medicines intended for over-the-counter sale and medicines intended for sale upon prescription.

41. In practice, this rule has been interpreted widely by the Secretary of the TGA to refuse to hear applications prior to any scientific or technical assessment of their merits by the TGA. For example, in the recent Federal Court case *Nicovations Australia Pty Ltd v Secretary of the Department of Health [2016] FCA 394*,[5] an application deliberately tendered for a product (nicotine inhaler anti-smoking aid) to be approved for over-the-counter sale was declined by the Secretary prior to any TGA assessment on its merits because the Secretary determined oh his own and based upon a bare technicality that the product could not be sold over the

[5] http://www.judgments.fedcourt.gov.au/judgments/Judgments/fca/single/2016/2016fca0394

counter.[6] The Court found that the Secretary had incorrectly interpreted the s23 rule and that the issue in question was a scientific one which ought to have been assessed by the TGA.

42. The ATA and MyChoice submit that refusals to hear an application on procedural or technical grounds should only be made in exceptional circumstances as it is in the public interest for new technologies and treatments to be assessed by the TGA in order to foster consumer access and public health outcomes.

43. We recommend that The Bill is amended to require TGA guidelines to this effect whereby the Secretary ought to err on the side of allowing a merits assessment where it is not completely obvious that an application fails to meet the stipulated procedural or technical grounds.

Electronic Nicotine Delivery Systems (ENDS) Scheduling

44. The ATA and MyChoice note that it is beyond the scope of this committee's present inquiry to make determinations on specific matters of policy outside TGA reform. However whilst recognising this, we believe that there is a policy imperative at present for a legislative (parliamentary) solution to the issue of tobacco harm reduction given the ill effects of smoking addiction for consumers and our health care system. We further note that this (despite being outside the scope of the present inquiry) would be in line with the objectives of *The Bill*. As such, we provide the committee members with the following evidence for your consideration as we believe that you are best placed to effect a reasonable solution in the public interest given the current transparency problems with the TGA's policy-making procedure.

45. The ATA and MyChoice note that extensive research and recommendations by international health experts and independent agencies have recognised consistently that e-cigarettes offer a safer alternative to tobacco smoking with no known carcinogenic effects. Indeed, switching from traditional cigarettes to nicotine vaping has consistently been recommended as an effective and proven smoking cessation tool for smokers attempting to resolve their addiction. Contrary to fears that e-cigarettes could result in the're-normalisation' of smoking by making smoking appear more attractive and fashionable, the studies have also found that they have not been taken up by previous non-smokers.[7]

46. Though E-cigarettes do not inherently come loaded with nicotine, their value as a smoking cessation tool is greatly enhanced by the use of nicotine. Nicotine itself is

[6] http://www.smh.com.au/federal-politics/political-news/federal-court-forces-drug-regulator-to-consider-nicotine-inhaler-case-20160421-goc3kx.html

[7] E-cigarettes: a developing public health consensus - Joint statement on e-cigarettes by Public Health England and other UK public health organisations: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/534708/Ecigarettes_joint_consensus_statement_2016.pdf

non-carcinogenic and not a pharmaceutical. It poses no significant long-term health risks when used in concentrations appropriate or commonly favoured by vapers and there are no reports of significant health risks from use of nicotine as a smoking cessation tool in the form of patches, gums or other means which have been legal in Australia and other nations for decades.

47. Notably, a recent long-term American study has found that inhaling nicotine vapours through an e-cigarette is far safer than tobacco smoking whereby it is the toxic combustion of tobacco and other additives rather than the nicotine itself which has been associated with the cancerous effects of cigarettes.[8] This finding is further supported by a study by 15 of the leading public health authorities in the UK which found that e-cigarettes are **at least 95% safer** for both active and passive smokers than tobacco smoking.[9] The same study recommended that smokers seeking to cease smoking switch to e-cigarettes as they are able to satiate their cravings of nicotine (which is not associated with any significant health risks) without inhaling toxic or cancerous chemicals and this has been confirmed by a significant reduction in the build-up of such chemicals in those who switched to e-cigarettes over time.

48. An academic study has found that over 6 million citizens of the European Union have successfully given up smoking cigarettes by switching to e-cigarettes.[10] The value of e-cigarettes as a smoking cessation and harm reduction aid with no significant health risks is hence not only recommended by research, but proven by it. It would hence be counter-intuitive for Taiwan to continue towards a ban on e-cigarettes based on public welfare concerns when the evidence strongly demonstrates that these are assuaged rather than negated by e-cigarettes.

49. Furthermore, the prohibition of e-cigarettes would support the black market trade of e-cigarettes and nicotine solutions which could fund criminal enterprises in a similar manner to the growth of the illicit tobacco trade. Notably, nicotine solutions easily available online for smuggling from China are unregulated and sometimes have extreme and dangerous concentrations of nicotine reaching over 90% far in excess of legal, safe nicotine solutions which are not available because of the TGA's current position.[11] Targeting and regulating this black market, especially when its sources are in geographic proximity to Australia, will connote a significant and increasing expense of time and resources by our government and there is no guarantee that any policing strategy of the black market will be effective.

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[8] Shahab L, Goniewicz ML, Blount BC, Brown J, McNeill A, Alwis KU, et al. Nicotine, Carcinogen, and Toxin Exposure in Long-Term E-Cigarette and Nicotine Replacement Therapy Users: A Cross-sectional Study. Ann Intern Med. [Epub ahead of print 7 February 2017] doi: 10.7326/M16-1107 http://annals.org/aim/article/2599869/nicotine-carcinogen-toxin-exposure-long-term-e-cigarette-nicotine-replacement

[9] https://www.gov.uk/government/news/e-cigarettes-around-95-less-harmful-than-tobacco-estimates-landmark-review

[10] https://www.ncbi.nlm.nih.gov/pubmed/24935441

[11] Bates C. Regulators and the compliance fallacy - buying 99% nicotine e-liquid from China, Counterfactual 4 May 2016.

50. The abovementioned ill effects also flow from the classification of nicotine solutions or e-cigarettes as products available upon medical prescription or permission as this makes the product difficult or even prohibitive for most people attempting to cease smoking whereby even black market solutions may be seen as more feasible.

51. A more elaborate analysis of the effects of e-cigarettes and nicotine vaping by the ATA and MyChoice with further scholarly sources, statistics and research has been attached as Appendix "C".

52. Similarly, currently illegal ENDS devices such as inhalers should be legalised for over-the-counter sale in order to facilitate consumer access to this harm reduction technology.

Recommendations (Amendments & Additions to *The Bill*)

53. That The Bill is amended to mandate that the TGA establish a provisional approval for products which have been granted certification, license or approval by the TGA-equivalent agency of a comparable jurisdiction.

54. In the alternative to 47., that *The Bill* is amended to mandate that the TGA establish a priority/fast-track approval process where a product has been certified as 'safe' by the TGA-equivalent agency of a comparable jurisdiction and that the reports or findings of these bodies be explicitly included as a criteria for determining approval by the TGA.

55. That the TGA is required to publish in full without redaction and with all sources, author identities and arguments included, all submissions put to it by parties consenting to full publication of their work.

56. That the TGA is required to amend its confidentiality policy so that confidentiality i.e. withholding of sections of a party's submission and/or their identities and potential conflicts of interest, is only granted in special circumstances in order to promote transparency and accountability.

57. That the TGA should be required to address all relevant policy grounds which significantly pertain to public health, risk and harm reduction. In order to support and ensure the scientific rigour of its review process.

58. That the TGA disclose the identities of its independent consultants and experts in order to ensure a fair, balanced and transparent review process free of conflicts of interest.

59. That *The Bill* is amended to require TGA guidelines to this effect whereby the Secretary ought to err on the side of allowing a merits assessment where it is not completely obvious that an application fails to meet the stipulated procedural or

technical grounds.

60. That legislation is expediently passed to legalise nicotine solutions for ENDS in Australia to enable consumers to access this proven smoking-cessation technology in order to reduce the serious health risks incurred by our smokers.

Conclusion

61. The ATA and MyChoice welcome *the Bill* as we consider it an important step in the right direction due to its facilitation of consumer access to new, rapidly evolving medicines, treatments and technology. We believe that the recommended additions and/or clarifications to the Bill's amendments outlined above will enhance its objectives of easing regulatory burden, fostering consumer access and remedying deep-seated deficiencies in the TGA's processes which connote a lack of transparency, potential bias and insufficient scientific rigour.

62. Unless these deficiencies highlighted in legal disputes such as *Nicovations Australia Pty Ltd v Secretary of the Department of Health [2016] FCA 394* and the TGA's review of nicotine scheduling are remedied through the implementation of effective guidelines to counter them, legislative solutions may be necessary to ensure that Australian consumers have access to vital technology and treatments which are accessible in comparable countries to Australia. It is imperative that the committee and its members act to ensure the public interest by upholding consumer access to effective harm reduction treatments such as ENDS in an era where Cancer and other smoking-related illnesses are the leading cause of death in the country. We therefore recommend that the committee members consider supporting a legislative solution to the ENDS issue even if it is outside the scope of the present inquiry as the abovementioned deficiencies of the TGA are likely to persist for some time until the amendments take full effect.

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