

October 2025

Consultation on safety and regulatory oversight of unapproved medicinal cannabis products

AMA Queensland welcomes the TGA's review of the safety and regulatory oversight of unapproved medicinal cannabis products.

We have been advocating for improved regulation of medicinal cannabis since 2023 given Queensland's disproportionately high rates of prescribing, dispensing and adverse outcomes in comparison to other Australian jurisdictions.¹ Our advocacy has included collaborating with similarly concerned health organisations to raise the issue at a national level, including with the TGA, Minister Butler, Queensland Health and Minister Nicholls.

We and our members are therefore pleased to see this Queensland-led advocacy now resulting in meaningful support from the TGA and health ministers Australia-wide, noting the issue was sponsored by Queensland's health minister for discussion at last month's Health Ministers' Meeting. Queensland Health also developed a [medicinal cannabis action plan in July 2024](#) to improve prescribing, dispensing and use of medicinal cannabis after we raised our concerns. The TGA's current review is a valuable addition to that work.

Holistic consideration of broader reform

Responsibility for medicinal cannabis regulation is inter-dependent, with multiple agencies and all state, territory and federal jurisdictions holding different levers. As such, we acknowledge there are key reforms that lie outside the scope of the TGA's current review and the agency's legislative remit.

Nonetheless, it is essential that the TGA consider the full range of reforms needed during its review to ensure any final recommendations will support, and not conflict with, these broader reforms. We urge the TGA to take a holistic approach to the present review to ensure it is effective in the broader framework of medicinal cannabis regulation. Some of the crucial issues requiring reform include:

- Restriction of vertically integrated and telehealth business models that risk exploitation of patients, prescribers and dispensers
- Requirement for prescribers to hold fellowship with a specialist medical college
- Mandating face-to-face consultations for initial prescriptions of medicinal cannabis products
- Imposition of time-dependence dispensing volume limits per patient (e.g. a reduction from 90 grams to 30 grams per week)
- Improved labelling of products (we welcome the TGA's confirmation in its paper that this issue will be examined as part of the current review)
- Real-time prescription monitoring (noting there are currently no ARTG-registered products)

¹ Refer attachments and [our webpage](#) which we also submit as part of our input to this consultation).

- Restriction of prescribing of medicinal cannabis for conditions for which it is not indicated while simultaneously not disadvantaging patients currently dependent on medicinal cannabis:
 - Addiction psychiatrists have advised they are aware of Queensland Opioid Treatment Program (QOTP) patients who are now addicted to medicinal cannabis and fear these patients may:
 - revert to opioid use if they could no longer access medicinal cannabis
 - seek illegal supply of cannabis if they could no longer access prescription forms
 - drop out of the QOTP if forced to choose between QOTP and medicinal cannabis (e.g. if a restriction/requirement for authorisation was brought in for concurrent prescribing for QOTP patients).

These clinicians were emphatic that any solution must ensure these patients are not placed at increased risk of harm.
- Training and eligibility requirements for prescribers, including safeguards for telehealth consultations.

Special Access and Authorised Prescriber Schemes

AMA Queensland has previously raised concerns about the use of the SAS and AP schemes for medicinal cannabis products. Those concerns are shared by the Royal Australian and New Zealand College of Psychiatrists (RANZCP), Royal Australian College of General Practitioners (RACGP) and the Pharmacy Guild of Australia (PGA) and documented in the attached correspondence.

As stated in the TGA's consultation paper, these schemes were not designed to support the ongoing and widespread access to medicines like we have seen with medicinal cannabis. We also note doctors state they believe there is very low compliance with data and reporting requirements of adverse events. We urge the TGA to remove access to these products from the SAS and establish an interim, suitable and safe alternative arrangement for a short period (e.g. maximum 2 years) by the end of which, products must have obtained ARTG registration.

We also urge the TGA to review the current requirements for authorised prescribers of medicinal cannabis under the schemes and consider restriction to medical practitioners with specialist registration only. Doctors are aware of exploitative business models that prey on more vulnerable practitioners, including pre-vocational doctors. Restricting prescribers to those who have completed specialist training through a medical college would greatly assist in protecting these practitioners and, subsequently, patients.

THC concentrations

We have heard consistently from our members, other health practitioners and patients that current controls on delta 9-tetrahydrocannabinol (THC) concentrations in medicinal cannabis products are woefully inadequate. Highly potent concentrations are common and clinicians, patients and their families have attributed these levels to episodes of patient harm, including psychosis and emergency department presentations.

AMA Queensland acknowledges the TGA's consultation paper states that a maximum upper allowable limit for THC was not established when there was an opportunity to do so via related amendments to

the governing legislation. AMA Queensland urges the TGA to set such a limit based on careful evaluation of existing evidence of the harms of THC and consultation with clinicians.

Our organisation, alongside RANZCP, RACGP and PGA, have noted that Category 5 products, where THC concentration is highest at $\geq 98\%$, have the greatest potential to cause harm. We have also advised the TGA that there is limited clinical evidence to support the use of THC at any strength. As such, we urge the TGA to carefully examine the appropriateness of current THC concentrations in medicinal cannabis products. Clear, robust evidence must exist for maintaining access to products with THC, especially potent formulations that are higher than that found naturally in cannabis plants.



Queensland Branch

21 November 2024

Prof Tony Lawler
Deputy Secretary
Therapeutic Goods Administration

By email: [REDACTED]

Subject: Medicinal cannabis concerns

Dear Prof Lawler

AMA Queensland, the Royal Australian and New Zealand College of Psychiatrists (RANZCP, Queensland Branch) and the Pharmacy Guild of Australia, Queensland hold serious concerns about the rapid increase in medicinal cannabis use across our state.

A 2023 RANZCP report has shown Queensland's rate of prescribing of medicinal cannabis products is higher than that of all other jurisdictions combined, with 167,000 scripts issued since licensing began in 2016 compared with 156,000 combined across Victoria, New South Wales, Western Australia and South Australia over the same period.

Patients, particularly those with psychotic illnesses, are suffering significant adverse health outcomes from inappropriate prescribing and use of products with highly potent concentrations of tetrahydrocannabinol (THC).

Even patients without previous histories of mental illness are presenting to our emergency departments with psychosis after using these substances.

It is our view that current controls are inadequate, including the TGA's standards for regulating medicinal cannabis products and their THC concentrations.

We are particularly concerned about medicinal cannabis business models that do not appear to have appropriate clinical governance and regulatory oversight to maintain professional standards for clinicians, do not meet the Medical Board of Australia's telehealth guidelines and engage in direct consumer marketing.

We also remain alarmed that these products continue to be prescribed for conditions for which there is no evidence, including anxiety, insomnia and chronic pain and for patients with comorbidities or who are taking other medicines where use of medicinal cannabis is contraindicated.

We are aware the TGA is discussing these issues with many agencies including Ahpra and different practitioner boards, but doctors and pharmacists remain largely unaware of this work or the issues with medicinal cannabis use.

Our organisations ask you to provide more information to health practitioners about appropriate prescribing of medicinal cannabis products and take action to improve its regulation, particularly the concentrations of THC allowable under relevant legislation.

The inclusion of medicinal cannabis in the TGA's Special Access Scheme (SAS) is also contributing to inappropriate use and we likewise recommend it be removed from the SAS and regulated in the same manner as all other drugs of dependence.

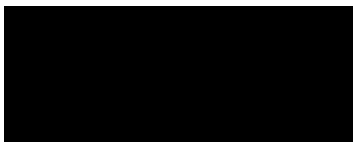
We would welcome an opportunity to meet with you to discuss this issue further.

Yours sincerely




Dr Nick Yim
President
AMA Queensland

Prof Brett Emmerson
Chair, Queensland Branch
The Royal Australian and New Zealand College of Psychiatrists



Chris Owen
President,
The Pharmacy Guild of Australia,
Queensland

Copied to:
Adj Prof Robyn Langham, Chief Medical Advisor, TGA: 



31 January 2025

The Hon Mark Butler MP
Minister for Health and Aged Care
Canberra

The Hon Tim Nicholls MP
Minister for Health and Ambulance Services
Brisbane

By email: [REDACTED] | [REDACTED]

Subject: Medicinal cannabis national approach

Dear Ministers

AMA Queensland, the Royal Australian and New Zealand College of Psychiatrists (RANZCP, Queensland Branch), the Royal Australian College of General Practitioners, Queensland (RACGP) and the Pharmacy Guild of Australia, Queensland, continue to be alarmed by the rapid increase in medicinal cannabis use across Queensland. Our interstate colleagues advise this is also becoming serious issue across the country.

Psychiatrists, emergency physicians, general practitioners and pharmacists are distressed by increasing patient harms, particularly psychotic illnesses and associated adverse outcomes, resulting from inappropriate prescribing and use of medicinal cannabis products. This is especially acute in patients using products with highly potent concentrations of tetrahydrocannabinol (THC). They are witnessing patients without previous histories of mental illness presenting to our emergency departments with psychosis after using these substances.

We wrote to the Therapeutic Goods Administration (TGA) in November 2024 (see enclosed) and subsequently met with key TGA representatives on 29 January 2025 to raise

our concerns. In particular, we advocated for improved regulatory controls and standards for medicinal cannabis products and associated THC concentrations.

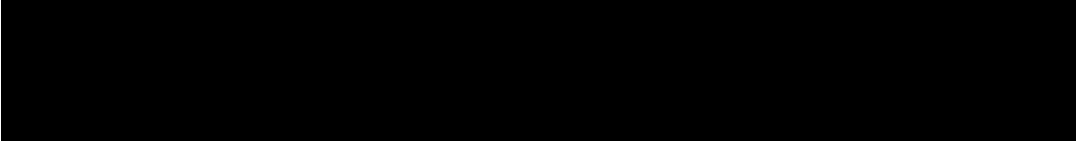
This meeting affirmed that the TGA and other regulatory agencies are acutely aware of this issue and have been trying to use different avenues to address patient harms. But their ability to improve medicinal cannabis regulation has been severely limited since the power to effect change does not sit with one agency nor one jurisdiction.

Given the complexities and significant vested interests in the medicinal cannabis market, we view this as a national issue requiring coordinated effort by all Australian jurisdictions. We respectfully suggest medicinal cannabis regulation be added to the agenda of the next Health Ministers' Meeting. Key issues for consideration by Health Ministers would include:

- impacts on public hospitals, including presentations, resourcing and occupational violence
- exclusion and/or reduction of THC concentrations
- time-dependent dispensing volume limits per patient (e.g. a reduction from 90 grams to 30 grams per week)
- removal from the Special Access Scheme
- improved labelling of medicinal cannabis products
- real-time prescription monitoring (noting there are currently no registered products)
- limiting authorised prescribers to medical practitioners with specialist registration only
- banning vertical integration and other aspects of medicinal cannabis business models that risk patient safety and clinical independence
- training and eligibility requirements for prescribers, including safeguards for telehealth consultations.

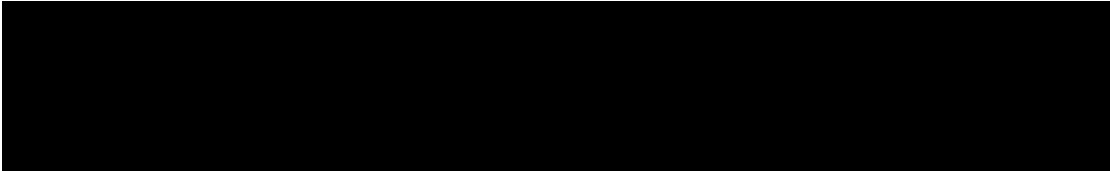
We would like to meet to discuss our concerns and possible solutions Health Ministers can take to protect patients from unnecessary and avoidable harms.

Yours sincerely



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The Royal Australian and New Zealand College of Psychiatrists



Chris Owen
President,
The Pharmacy Guild of Australia, Queensland

Dr Cath Hester FRACGP
Chair, RACGP Queensland



31 March 2025

Dr David Rosengren
Director-General
Queensland Health

By email: [REDACTED]

Subject: Restriction of medicinal cannabis prescribers to fellows

Dear David

As you know, our organisations have been strongly advocating for increased regulation of medicinal cannabis. Doctors and pharmacists are seeing too many patients harmed by highly concentrated products and inappropriate prescribing, including ED presentations for psychosis.

We have held several meetings with Queensland Health and the Therapeutic Goods Administration to seek sensible solutions. We also wrote to Ministers Nicholls and Butler urging them to act, as have our medical and pharmacy colleagues in other jurisdictions. These efforts have confirmed that current medicinal cannabis business models are exploiting vulnerable health practitioners, particularly early-career doctors and pharmacists with less financial and employment security.

To prevent continued exploitation and harms to patients, our organisations propose medicinal cannabis prescribers be limited to more senior and experienced practitioners who have completed specialist training through a medical college. Queensland Health has advised that this is readily achievable via amendment of the *Medicines and Poisons (Medicines) Regulation 2021* (Qld), similar to existing restrictions for high-risk medicines such as isotretinoin.

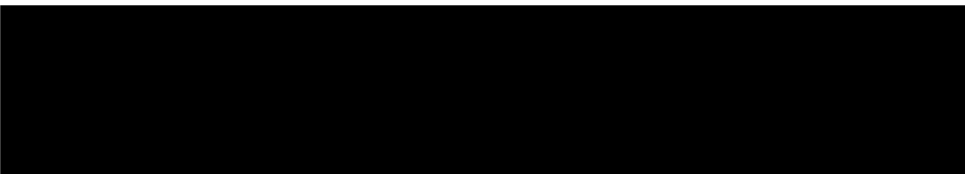
We think this is a sensible and efficient approach to improving medicinal cannabis regulation and seek a meeting with you and appropriate Queensland Health representatives to discuss further.

Yours sincerely



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Chris Owen
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Dr Cath Hester FRACGP
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Queensland Branch



22 July 2025

The Hon Mark Butler MP
Minister for Health and Ageing
Canberra

The Hon Tim Nicholls MP
Minister for Health and Ambulance Services
Brisbane

By email: [REDACTED]

Subject: Urgent reform of medicinal cannabis regulation

Dear Ministers

Pharmacists and doctors have observed, with concern, the rapid proliferation of business models focused solely on prescribing and dispensing medicinal cannabis since it was legalised in Australia. Our members have seen firsthand the exponential rise in medicinal cannabis prescriptions, often written for patients for whom it is inappropriate, if not completely contraindicated. They have also had to treat patients harmed by its use.

In Queensland, our organisations have forged a positive collaborative working relationship to coordinate efforts and raise concerns about this issue with the [Therapeutic Goods Administration and directly with you as our state and federal health ministers](#). Unfortunately, these efforts have yet to yield any meaningful outcomes.

In July, the Australian Health Practitioner Regulation Agency (Ahpra) released [guidance for prescribers who prescribe medicinal cannabis](#). This was developed in response to 'evidence of poor practice in prescribing medicinal cannabis that is leading to significant patient harm'.

Ahpra has also committed to act on reports and evidence of inappropriate, high-volume prescribing, even in the absence of a complaint. We warmly welcome this action as a positive step towards a nationally coordinated approach to tackling the complex issues associated with medicinal cannabis, but further action is needed.

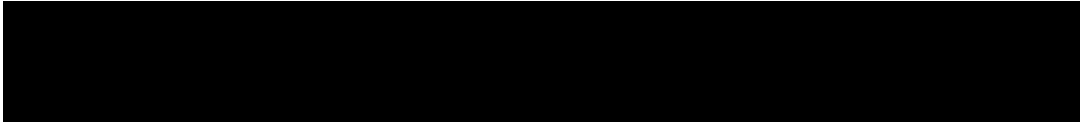
We recognise regulatory action is often slow and retrospective by nature, but immediate, nationally consistent action is needed urgently. Patients must receive safe, high quality care from qualified health professionals who prioritise patient outcomes over commercial interests. We propose that:

- **Prescribing of medicinal cannabis should be limited, by regulation, to more senior and experienced medical practitioners who have completed specialist training through a medical college.**
 - We understand many current medicinal cannabis business models rely on the employment of early-career doctors who have not been accepted onto a specialist training pathway. Restricting prescribers to those with medical college specialist training would improve patient safety by ensuring prescribers have the necessary expertise to manage complex health needs.
- **State and federal governments establish a joint review of the access to and availability of medicinal cannabis products within Category 5, where THC concentration is highest at $\geq 98\%$.**
 - These products have the highest potential to cause patient harm and the fact there exists limited clinical evidence to support the use of medicinal cannabis at any strength means the justification for their availability should be strongly questioned.
- **Medicinal cannabis regulation be added to the agenda of the next Health Ministers' Meeting.**
 - We strongly believe that a coordinated national approach, with the constructive input of all Australian jurisdictions, is the only way to tackle this increasingly troublesome area of practice that is, without doubt, causing significant patient harm.
 - We note this was the subject of our joint letter to you of 31 January ([available here](#)) and including the following issues for consideration by health ministers:
 - impacts on public hospitals, including presentations, resourcing and occupational violence
 - exclusion and/or reduction of THC concentrations
 - time-dependent dispensing volume limits per patient (e.g. a reduction from 90 grams to 30 grams per week)
 - removal from the Special Access Scheme
 - improved labelling of medicinal cannabis products
 - real-time prescription monitoring (noting there are currently no registered products)
 - limiting authorised prescribers to medical practitioners with specialist registration only
 - banning vertical integration and other aspects of medicinal cannabis business models that risk patient safety and clinical independence
 - training and eligibility requirements for prescribers, including safeguards for telehealth consultations.

This is a priority for all our organisations and our members. We would welcome an opportunity to meet with you to discuss our concerns and provide further detail on our

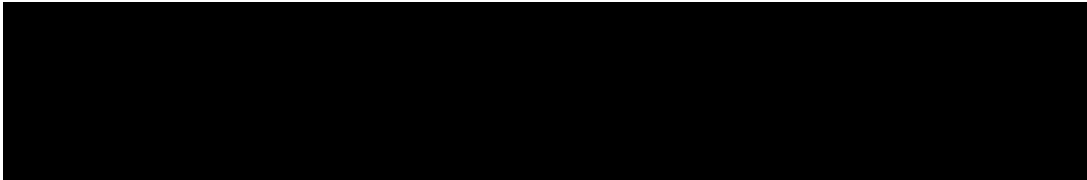
proposed actions. We believe that, with a coordinated approach, we can take positive steps to regulate medicinal cannabis and protect our patients from unnecessary and avoidable harms.

Yours sincerely



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Queensland Branch



10 September 2025

The Hon Tim Nicholls MP
Minister for Health and Ambulance Services

By email: [REDACTED]

Subject: Medicinal cannabis adverse outcomes: case examples for HMM

Dear Minister

Thank you again for meeting with our organisations last Monday to discuss medicinal cannabis reform. We are particularly grateful for your sponsorship of a briefing paper, alongside the Commonwealth Government, to have the issue tabled at this Friday's Health Ministers' Meeting (HMM).

As requested, we have compiled some deidentified case examples of adverse patient outcomes from medicinal cannabis use (refer attachment). We trust these will assist you in illustrating the concerns clinicians, patients and their families have with current regulatory settings for your fellow health ministers during the HMM.

Should you have any questions about the case examples or need further information, please don't hesitate to contact us.

Yours sincerely



Dr Nick Yim
President
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Dr Cath Hester FRACGP
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Copied to:

Dr David Rosengren, Director-General, Queensland Health

Dr Catherine McDougall, Acting Chief Health Officer, Queensland Health

Dr David Walker, Acting Chief Medical Officer, Queensland Health

ATTACHMENT



Queensland Branch



Medicinal cannabis adverse patient outcomes: case examples for Health Ministers' Meeting 12 September 2025

Please note: Our members, including psychiatrists, emergency physicians, general practitioners and pharmacists, advise the following case examples are commonly seen in the relevant patient cohorts represented, particularly in presentations to Queensland public hospital emergency departments and psychiatric inpatient units.

Case example 1: 15 year old male with autism

A young male aged 15 years with diagnosed autism was prescribed medicinal cannabis for anxiety. This is not a condition for which medicinal cannabis is indicated and there is currently no evidence to support the safe prescribing of medicinal cannabis with psychostimulants, especially for paediatric patients and those with autism. The interactions of the medicines are unknown, including whether medicinal cannabis interferes with the efficacy of psychostimulant medications and associated complications.

Case example 2: 16 year old male with no history of mental illness

A young male aged 16 years was prescribed medicinal cannabis without parental knowledge. He experienced several psychotic episodes and was admitted to a psychiatric inpatient unit.

Case example 3: 17 year old male with no history of mental illness or criminal offending

A young male aged 17 years was prescribed medicinal cannabis without parental knowledge. He experienced several psychotic episodes and, during one such episode, was arrested and charged with a criminal offence.

Case example 4: Adult with history of psychosis but under care of a treating psychiatrist

An adult with an existing psychotic illness that had been successfully managed for the previous 10+ years under the care of a treating psychiatrist. They were prescribed medicinal cannabis without the knowledge of their treating psychiatrist (e.g. via QScript recording or other mechanism) or family and relapsed. This required hospitalisation for prolonged periods and resulted in adverse social outcomes including homelessness and interaction with the police for associated criminal offending.

Case example 5: Adult male with history of psychosis

An adult male with an existing psychotic illness was prescribed medicinal cannabis on a regular basis despite it being contraindicated. The man passed away and the medicinal cannabis supplier continued to send multiple repeats to his home address, despite his family trying to cancel the supply. This caused significant distress to the patient's family.

Case example 6 (provided by elderly parent-guardian): Adult male aged 53 years with history of psychosis

A man aged 53 with diagnosed resistant paranoid schizophrenia and drug and alcohol dependency was prescribed medicinal cannabis oil (containing THC) after 'doctor shopping', despite being treated with prescription antipsychotics through a public mental health unit. The medicinal cannabis adversely interacted with his anti-psychotic medication (clozapine) and the parent-guardian was seeking assistance to ensure his son's medical records were updated to prevent further prescriptions and psychotic episodes.

Case example 7: Same day dispensing of medicinal cannabis for patient on psychostimulants

A patient's QScript history recorded multiple same day dispensing of medicinal cannabis products (up to three per day) for a patient who was also prescribed and dispensed psychostimulant medication. The medicinal cannabis prescriber was different from the psychostimulant prescriber and the former had authorised a dispensing interval of '1 day, staged supply if requested' on the prescription.

Case example 8: Oversupply and too frequent supply of medicinal cannabis

A patient's QScript history recorded an oversupply and too frequent supply (including same day dispensing) of medicinal cannabis along with various nomenclature for the product in different systems. The entries also noted an attempt by clinicians to rectify the confusion which was unsuccessful.

Case example 9: Purported umbrella substitution of medicinal cannabis products for all patients

A pharmacist identified inappropriate prescribing practices in a medical clinic where generic letters were sent to pharmacies authorising umbrella substitutions of medicinal cannabis products. The letters purported to be 'on behalf of Dr xxxx' and authorised the dispensing pharmacist to substitute (for any patient) out of stock or discontinued medicinal cannabis THC flower indica products with sativa products and with THC oil (instead of flower) products.

Case example 10: Emergency physician experience in metropolitan ED

An ED physician in a major South East Queensland public hospital raised concerns about 'daily' presentations associated with medicinal cannabis use. They were particularly concerned about increasing detection of medicinal cannabis as a factor in trauma cases.

Case example 11: Addiction psychiatrist in Queensland Health public mental health unit

An addiction psychiatrist in a Queensland Health public mental health unit raised concerns about a significant increase in patients presenting to Queensland Health alcohol and drug services requesting assistance for addiction to medicinal cannabis. They also reported a significant increase in patients presenting to acute mental health services with cannabis induced psychotic illnesses and in patients with severe mental illnesses presenting with acute exacerbations triggered by medicinal cannabis use.

Case example 12: Psychiatrist in Queensland Health public mental health unit

A psychiatrist in a Queensland Health public mental health unit raised concerns about increasing rates of psychotic presentations to mental health units because of medicinal cannabis prescribing. They were alarmed at the speed of the increase upon the passage of the legislation.

Case example 13: Compounding pharmacist and long-time medicinal cannabis consultant

A compounding pharmacist and long-time medicinal cannabis consultant raised concerns about unethical and illegal practices in the medicinal cannabis industry that were exploiting vulnerable patients and clinicians and causing patient harms. They urged advocacy for increased regulation.