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Testimony in SUPPORT of HB767
RELATING TO PRESCRIPTIVE AUTHORITY FOR CERTAIN CLINICAL PSYCHOLOGISTS.

REPRESENTATIVE DELLA BELATTI, CHAIR
HOUSE COMMITTEE ON HEALTH
Hearing Date: February 2, 2017 Room Number: 329

Fiscal Implications: None for Department of Health.

Department Testimony: As a population health management strategy, authorizing licensed clinical psychologists with specialized education and training for limited prescriptive authority may alleviate patient access barriers caused by the statewide shortage of behavioral health and other providers.

However, the Department of Health, in its capacity as a provider of direct health care and behavioral health care services, requires the following criteria as part of any enabling legislation: HB767:

1. A requirement for collaborative agreements with a patient's primary care provider;
2. A requirement for concurrence by a Department of Health psychiatrist for patients in the care of the department, to include those who are forensically encumbered or diagnosed with a serious and persistent mental illness; and
3. Restrictions on off-label use of medication for patients under seventeen years old.

The department defers to the Department of Commerce and Consumer Affairs on matters of professional licensure.

Offered Amendments: N/A

PRESENTATION OF THE
BOARD OF PSYCHOLOGY

TO THE HOUSE COMMITTEE ON HEALTH

TWENTY-NINTH LEGISLATURE
Regular Session of 2017

Thursday, February 2, 2017
9:30 a.m.

TESTIMONY ON HOUSE BILL NO. 767, RELATING TO PRESCRIPTIVE AUTHORITY FOR CERTAIN CLINICAL PSYCHOLOGISTS.

TO THE HONORABLE DELLA AU BELATTI, CHAIR,
AND MEMBERS OF THE COMMITTEE:

My name is May Ferrer, Executive Officer of the Hawaii Board of Psychology ("Board"). Thank you for the opportunity to provide comments on House Bill No. 767, Relating to Prescriptive Authority for Certain Clinical Psychologists.

The purpose of House Bill No. 767 is to authorize the Board to grant prescriptive authority to prescribing psychologists who meet specific education, training, and registration requirements.

While the Board has not yet reviewed House Bill No. 767, it was noted that the language in the bill closely mirrors House Bill No. 1072, H.D. 1, S.D. 1 from 2016, to which the Board expressed its support at its meeting on April 15, 2016.

The Board will discuss House Bill No. 767 at its next scheduled meeting on February 17, 2017.

Thank you for opportunity to provide comments regarding House Bill No. 767.

Psychologists Opposed to Prescription Privileges for Psychologists
www.poppp.org

Petition-Testimony OPPOSE HB767

A REQUEST **FROM PSYCHOLOGISTS** TO **OPPOSE** LEGISLATION GRANTING PRESCRIPTION PRIVILEGES FOR PSYCHOLOGISTS through non-traditional means (HB767)
31 January 2017

We, the undersigned **psychologists** and all others concerned about quality healthcare **OPPOSE** any efforts to allow psychologists to prescribe medications through **non-traditional means and substandard training.**

We consider prescribing by psychologists to be controversial, even among psychologists. The movement for prescriptive privileges originated within the Psychology profession, rather than being championed by other stakeholders, such as patient advocacy or public health groups. As psychologists, we oppose this proposal because we believe that it poses unnecessary risks to the public and would be an inappropriate and inefficient mechanism of addressing mental health needs of the population. We are a diverse group of psychologists, including clinicians, educators, and researchers.

Psychologists have made major contributions to human health and wellbeing and will continue to do so. The profession of Psychology has made major contributions to understanding human development throughout the life cycle and to a multitude of dimensions of human functioning as individuals, groups, communities, societies and cultures. Despite these contributions, there are limits to the practices that psychologists can undertake responsibly as professionals. We believe that prescribing medications goes beyond psychologists' competence…even if they obtain the additional training advocated by the American Psychological Association.

Psychotropic drugs are medications that have multiple effects on the human body. These effects are complex and result from the interaction among patients' unique health status, their other prescribed medications, as well as their diets, lifestyles, and other factors. Although the therapeutic effects of prescribed medications can be very positive, unintended adverse drug reactions are common. To minimize the risk of potential adverse effects, that can even have life-threatening consequences, we believe that medications should be prescribed only by professionals who have undergone suitable medical training that prepared them to manage these medications within the context of patients' overall health conditions. Patients have a right to expect that their medications will be managed by

professionals whose education adequately trains them to understand their health history, and assess their current health status, and the potential broad systemic effects of their medications. Unlike the training of current prescribers in other professions, the doctoral training of psychologists historically does not equip them to prescribe and manage medications safely.

Unfortunately, the American Psychological Association's (APA) model for training doctoral psychologists to obtain limited training in psychopharmacology, after they complete graduate school, does not match the levels required of other prescribing professionals (e.g., physicians, nurse practitioners, physician's assistants, optometrists) in terms of their overall training in matters directly related to managing medications. **The APA model is substantially less rigorous and comprehensive than the training required for all other prescribing disciplines.** Whereas the training of psychologists in certain professional activities, such as psychotherapy and psychological assessment, is generally more comprehensive than that of practitioners in other fields, this is not the case for training in clinical psychopharmacology**. The APA training model for prescribing even fails to meet the recommendations of APA's own experts** in its Ad Hoc Task Force of Psychopharmacology (e.g., in terms of undergraduate prerequisites in biology and other sciences) and has other inadequacies (e.g., lack of explicit requirements for supervision; no accreditation of programs).

It is noteworthy that the APA training model is substantively less rigorous than the training that the 10 psychologists undertook in the experimental program of the Department of Defense (DoD). Despite the alarmingly small sample of that pilot program, which precludes generalizing from it, the fact that the current training model is far less comprehensive, and the fact that inadequacies were noted in some of the graduates of the DoD program, proponents of psychologist prescribing make the dubious claim that the DoD program justifies prescribing by psychologists. It does not! In fact, the final report on the DoD project revealed that the psychologists were "**weaker medically"** than psychiatrists and compared their medical knowledge to students rather than physicians. We oppose psychologist prescribing because citizens who require medication deserve to be treated by fully trained and qualified health professionals rather than by individuals whose expertise and qualifications have been independently and objectively assessed to be at the student level. At this point, the training is less rigorous, with most of the training occurring online.

Proponents of psychologist prescribing also have misleadingly invoked a range of unrelated issues to advocate for their agenda. An article in the *American Journal of Law & Medicine* entitled, "Fool's Gold: Psychologists Using Disingenuous Reasoning To Mislead Legislatures Into Granting Psychologists Prescriptive Authority" critiques the rationales that advocates of prescription privileges use to promote their cause. Proponents point to problems in the healthcare system, such as the rural and other populations that are underserved. Whereas such problems are indeed serious and warrant changes in the healthcare system, allowing psychologists to prescribe is neither an appropriate nor an effective response. Permitting relatively marginally trained providers to provide services is not an acceptable way to increase access to healthcare services where high quality health care is needed. Rather than relying on under-trained psychologists to prescribe, it would be much more sensible to develop mechanisms to facilitate psychologists' providing those services that they are highly qualified to provide (e.g., counseling) to those populations and to innovate other approaches for medically-qualified providers (for example, collaboration, telehealth) to leverage available services. It should be noted that most psychologists practice in urban and suburban areas: There is no reason to expect that prescribing psychologists would have a significant impact on compensating for the shortages of psychiatrists in rural and economically disadvantaged areas, where relatively few actually work. Other remedies are needed to address such problems that would not compromise the quality of care.

Other health professionals, including nurses and physicians, are also concerned about psychologist prescribing. However, this should not be seen as a simple turf battle: It is because of legitimate concerns that the proposals for training psychologists to prescribe are too narrow and abbreviated. The International Society of Psychiatric-Mental Health Nurses position statement asserts, "nurses have an ***ethical responsibility*** to oppose the extension of the psychologist's role into the prescription of medications'" due to concern about psychologists' inadequate preparation, even if they were to get *some* additional training, in accordance with the APA model. When it comes to prescribing psychoactive medications that have a range of potential therapeutic and adverse effects on the human body, including interactions with other medications, shortcuts to training are ill advised. Some psychoactive drugs come with black box warnings about their potential risks.

Another concern is the limited expertise of psychology regulatory boards to effectively regulate prescriptive practicing. Given the similar limits in medication-related training of most psychologists who serve on these boards to that of other psychologists, and the fact that psychology boards historically have not overseen prescribing, we question whether regulatory boards have the expertise, resources and systems to provide effective oversight of psychologist prescribing.

Before supporting this controversial cause, we urge legislators, the media, and all concerned with the public health to take a closer look at this issue. Rather than permitting psychologists to prescribe medications, we advocate enhancement of currently available collaborative models in the delivery of mental health care, in which licensed psychologists work collaboratively with fully qualified prescribers to provide safe and effective services for those individuals who may benefit from psychoactive medications.

There are better and safer alternatives to psychologists prescribing that we believe will have a greater positive impact on mental health services. A more promising means for enhancing the mental health services available to all citizens than to allow psychologists to prescribe would be to dedicate efforts to better integrating mental health professionals, including psychologists, into the healthcare system, such as in primary care settings, where they could collaborate with other providers (who are prescribers) in the care of people who may need medications and psychological services. The barriers to such care have been detailed in a recent report by the U. S. Department of Health and Human Services, *Reimbursement of Mental Health Services in Primary Care Settings*. Overcoming the barriers to such care is an objective upon which psychologists agree with each other, and with other health professionals, and is clearly in the public interest. It would improve the quality of mental health care available in urban and rural areas.

We respectfully request that you OPPOSE HB767 that would allow psychologists to prescribe through non-traditional means.

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ROMAN CATHOLIC CHURCH IN THE STATE OF HAWAII

Hawaii Catholic Conference
The Public Policy Voice of the Roman Catholic Church in the State of Hawaii

TO: House Health Committee
DATE: February 2, 2017 at 9:30 a.m. in room 329
SUBMITTED BY: Walter Yoshimitsu, Executive Director
POSITION: **Support for HB 767**

The Hawaii Catholic Conference is the official public policy voice for the Roman Catholic Church in the State of Hawaii. The above-referenced bill would authorize and establish procedures and criteria for prescriptive authority for clinical psychologists who meet specific education, training, and registration requirements, including requiring prescribing psychologists to adhere to all applicable statutory regulations.

We support HB 767 because it would significantly address the lack of professionals to serve patients with mental illness and drug abuse disorders. There is no doubt that there is a need for additional providers for mental health and addiction treatment as we seek more efficient integrated health care services.

According to Mental Health Hawaii website, our state "has a significant rate of youth who suffer from depression and manifest suicidal behavior, and of college students whose mental health problems are not being treated." Sadly, gaps in mental health services remain. In fact, Hawaii has no secure residential treatment facilities and only two psychiatric hospitals for teens, both on Oahu. This is a travesty to people in our community who need services.

The current opiate epidemic also makes it clear that we need more trained professionals who can assist young people and adults avoid addiction in the first place and recover if they have become addicted. This bill would add specialized psychologists with authority to prescribe medication for their patients who need them.

While we understand that there are some concerns expressed by the American Psychiatric Association, we simply want to address the need for mental health services in the rural areas – and we all acknowledge that the need is great! While we agree that caution should be exercised moving forward, it does make sense for Psychologists to be able to prescribe psychiatric medicines if they are properly trained and licensed to do so. This bill attempts to do just that and it is a step in the right direction.

Mahalo for the opportunity to testify.

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ISLAND SUBSTANCE ABUSE COUNCIL
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lives by utilizing innovative resources and harnessing the strengths within each person."

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Outpatient Treatment
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Kealakekua, Hawai'i 96750
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Dr. Hannah Preston-Pita
Chief Executive Officer

Aloha,

I am writing this letter as a provider and concerned community member in support of HB767, Prescriptive Authority for Psychologists With Advanced Training. I am the current Chief Executive Officer of the Big Island Substance Abuse Council (BISAC). BISAC has been providing behavioral health services to the island of Hawaii for well over 50 years. As a resident and provider of the Island of Hawaii we see firsthand how physician and/or provider shortage, lack of resources and gaps in services impact our clients and the communities that we serve. Staff who work in rural underserved areas of the island share their frustration about not having services available to their clients in areas such as Pahoa, Kau, Kohala, Hamakua coast and Oceanview.

I am clearly aware that this bill has been introduced several times in previous legislative sessions with no success. The opposition's argument is basically that they will be able to take care of these issues and provide this well needed service. It has been years and we are back at the legislative session again trying to convince all of you that our communities are still suffering with no end in sight. This bill of course, with rigorous training requirements will help address the needs in our community and be another option of care for our clients. I invite you to walk the streets with us, listen to the concerns of our providers and spend a day in the life of the individuals that we treat so that you can experience firsthand how the lack of prescribing providers has impacted our communities. I kindly ask that you allow this bill to get scheduled for a hearing.

Sincerely,

Hannah Preston-Pita, Psy.D. CSAC
Chief Executive Officer

Mental Health America of Hawai`i

1124 Fort Street Mall, Suite 205
Honolulu, Hawaii 96813
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Helping Hawai'i Live Well

To: Representative Della Au Belatti, Chair, Representative Bertrand Kobayashi, Vice Chair, and members of the House Committee on Health
From: Trisha Kajimura, Executive Director

Re: **Testimony in support of HB 767**, Relating to Prescriptive Authority for Certain Clinical Psychologists

Hearing: Thursday, February 2, 2017, 9:30 am, Conference Room 329

Thank you for hearing HB 767, which authorizes the Board of Psychology to grant prescriptive authority to psychologists who meet specific education, training, and registration requirements. We strongly support this measure because it will help to alleviate the difficulty that people suffering from mental health problems have in accessing proper treatment and care.

Not everyone dealing with mental health issues needs medication, but when someone who needs it is not able to get it in a timely manner, they can end up in a crisis that could have avoided. This type of crisis takes a terrible toll on the individual, their support system, and their overall health. Hawai'i has been dealing with a physician shortage for years and it is not getting better. Prescriptive authority for psychologists with advanced training is one of the solutions that will help to alleviate this dangerous prescriber shortage.

Psychologists have had prescriptive authority since 1974 through the Department of Defense, and later in the Public Health Service, Indian Health Service, Guam, New Mexico, Louisiana, Illinois, and Iowa. There have been no reported adverse outcomes or malpractice complaints related to prescriptive authority for psychologists.

The language in this measure will provide the necessary safeguards to ensure only those psychologists with appropriate education, clinical training and registration will be authorized to prescribe from a limited formulary of psychiatric medications.

Passing HB 767 will give properly trained and approved psychologists the ability to help consumers that otherwise would be unable to access the medication they need and should have a right to access. Please help us improve mental health in Hawaii by passing HB 767.

Thank you for the opportunity to submit this testimony. You can reach me at trisha@mentalhealthhawaii.org or (808)521-1846 if you have any questions.

1/31/17

To: Representative Della Au Belatti, Chair, Representative Bertrand Kobayashi, Vice Chair, and members of the House Committee on Health

From: Ward M. Lawson, PhD, ABMP, ABPP
President, Academy of Medical Psychology
Tri-County Psychological Services, Inc.
Marshfield, MO. 65706

Re: Testimony in strong support of HB 767, Relating to Prescriptive Authority for Certain Clinical Psychologists

Hearing: Thursday, February 2, 2017, 9:30 am, Conference Room 329

Thank you for hearing HB 767, which authorizes the Board of Psychology to grant prescriptive authority to psychologists who meet specific education, training, and registration requirements. I and the Academy of Medical Psychology strongly support this measure because it will help to alleviate the difficulty that people suffering from mental health problems have in accessing proper treatment and care.

Psychologists have had prescriptive authority since 1990's through the Department of Defense, and later in the Public Health Service, Indian Health Service, Guam, New Mexico, Louisiana, Illinois, and Iowa. There have been no reported adverse outcomes or malpractice complaints related to prescriptive authority for psychologists. Malpractice insurance through the APA Insurance Trust is only a few hundred dollars more for Prescribing Psychologists, which says a lot about the safe care Prescribing Psychologists offer.

The language in this measure will provide the necessary safeguards to ensure only those psychologists with appropriate education, clinical training and registration will be authorized to prescribe from a limited formulary of psychiatric medications.

Passing HB 767 will give properly trained and approved psychologists the ability to help consumers that otherwise would be unable to access the medication they need and should have a right to access. Please help us improve mental health in Hawaii by passing HB 767.

Thank you for the opportunity to submit this testimony.

To: Chairperson Della Bellati, Vice Chair Bertrand Kobayashi, and members of the House Committee on Health

From: Brian Smith
State Affairs Director
American Psychiatric Association

Subject: HB 767: Relating to Prescriptive Authority for Certain Psychologists

Hearing Date: 9:30 a.m., Thursday, February 2, 2017

Dear Chairperson Bellati and all of the Members of the House Committee on Health:

I am writing on behalf of the American Psychiatric Association, the national medical specialty society representing more than 36,000 psychiatric physicians as well as their patients and families, to urge you to vote "No/Do Not Pass" on HB 767.

This legislation is a proposal that puts the health and safety of the citizens of Hawaii with mental illness, including substance use disorders, in serious jeopardy. HB 767 proposes to allow clinical psychologists, who are experts in important behavioral interventions but who have no medical training, the permission to prescribe extremely powerful psychotropic drugs for patients with psychiatric disorders as well as heart, lung, liver and other serious physical conditions. While we understand the intention of this legislation is to increase access to needed mental health care, HB 767 puts Hawaii's most vulnerable patients at risk while failing to promote *available evidence-based solutions* to mental health access challenges. We urge you to look at safer models already up and functioning in Hawaii, as there are better alternatives to supporting patients with mental health needs.

These alternatives include:

Project Echo: A program Hawaii began in 2017 that is helping deliver **quality** mental health care to patients in rural areas of the state. To go along with this, this past December Congress overwhelmingly passed the Expanding Capacity for Health Outcomes Act (Public Law No. 114-270). The legislation, sponsored by Hawaii Senator Brian Schatz, will help better integrate the Project ECHO model originating out of the University of New Mexico into health systems across the country. Senator Schatz's legislation directs the federal Secretary of Health and Human Services to prioritize analysis of the model and examine its impact on addressing mental health and substance use disorders.

Collaborative Care: A specific type of integrated care that improves access to evidence based mental health care for primary care patients. Working with a patient's primary care provider and a "care managers", a medically trained psychiatric consultant" (i.e. psychiatrist, nurse practitioner, or clinical nurse specialist or physician assistant with psychiatric training) deliver

care to a population of patients needing care. This "care team" shares a defined group of patients tracked in a registry to ensure no one falls through the cracks. Practices track and reach out to patients who are not improving and mental health specialists provide caseload-focused consultation, not just ad-hoc advice.

HPMA is also currently working with members of the Hawaii Legislature to implement the "Improving Access to Psychiatric Care by Patients on Medicaid" bill, which directs Medicaid in Hawaii to pay for Collaborative Care Services as paid for by Medicare since January 2, 2017.

As you know, HB 767 would permit psychologists to obtain a prescription pad by acquiring an online master's degree in psychopharmacology or "equivalent", as determined by the Hawaii Board of Psychology - a professional regulatory group that has no specific medical expertise or medical background. HB 767 would require little clinical experience to prescribe medications including controlled substances, antipsychotics, and an almost unlimited range of non-psychotropic medications. Under HB 767, only 400 contact hours with 100 patients is suggested, not required, as part of this training. Consider for a moment that psychiatric resident physicians, who complete a four-year medical residency program following graduation from medical school, **will generally see 100 patients in just two weeks.**

HB 767 would require passage of an exam created and administered by the same national organization that accredits these haphazard postdoctoral degree programs and that stands to directly benefit from this new certification. No other voluntary, dues-paying membership organization in any medical specialty (e.g., cardiology, obstetrics and gynecology, psychiatry) has created such an exam – nor do national professional advocacy associations for nurses and physician assistants accredit their graduate programs. These dangerously low and inadequate requirements must be taken into consideration, and any proposed training standards must be compared to the 12 or more years of medical education and training psychiatrists and other physicians receive to be able to safely care for any patient that is suffering physical, mental, or substance use disorders. We have included a chart for your reference that lays out the differences in training between psychiatrists, nurse practitioners, physician assistants, and the proposed training psychologists would be required to undergo under HB 767.

As you review HB 767, please consider:

- Proponents of HB 767 state that this will increase access to mental health care in Hawaii and cite both Louisiana and New Mexico as examples. The facts in New Mexico and Louisiana illustrate that psychologists' claims about increased access have not materialized. Specifically, after having gained prescriptive privileges, few psychologists in either New Mexico or Louisiana have become certified to prescribe psychotropic drugs, let alone practice in a rural or underserved area.

- Prescriptive authority for psychologists has not solved the mental health needs of the rural communities in those very few states that implemented such laws. Despite promises made in New Mexico and Louisiana, psychologists did not and do not move their practices to serve the rural communities.

- Powerful psychotropic medications do not stop at the patient's brain; they affect many systems of the body such as the heart, lungs, stomach, and kidneys. There can be seriously disabling or deadly side-effects of the medications if improperly prescribed and managed.

- Patients needing more than one drug at a time for other physical conditions, such as both heart disease or diabetes and mental illness, are at risk for potentially serious drug interactions. More than half of all patients that have a mental disorder also have one or more physical ailments. The medical providers who treat these patients must be trained to understand and treat all systems of the body in order to recognize the warning signs of adverse effects. The proposed bill would not require the scientific education and training necessary to safely treat all such patients. We have included a chart that will give the Committee an idea of some of the side effects and potential complications that could occur. In short, there are medications that should only be prescribed by clinicians with significant medical training and broad understanding of all systems of the body. Furthermore, we have included a chart that details some of the medications Louisiana and New Mexico psychologists have prescribed to patients under their care. These are not psychotropic medications, and all have serious side effects that must be managed by physicians.

- Fragmentation of Hawaii's health care system will increase by limiting the availability of behavioral therapy that integrated mental health care teams have come to rely on from psychologists. Coordinated, team-based care in which every member is relied on for their training and expertise is the model of practice and reimbursement the nation is moving toward. We would be happy to serve as a resource to this Committee on programs like Project Echo and collaborative care models already underway in Hawaii and in other states that would be more sustainable alternatives to solving significant access problems. HB 767 would seriously undermine this movement.

In summary, the practice of medicine is a serious responsibility that requires years of thorough and relevant medical education and training. Allowing psychologists to prescribe after dramatically short-cutting the medical education and training necessary presents a serious and avoidable danger to Hawaii's most vulnerable patients. Again, we urge you to vote No/Do Not Pass on HB 767 and would welcome the opportunity to work with you through our partners - the Hawaii Psychiatric Medical Association and the Hawaii Medical Association – in order to facilitate evidence-based, proven programs that can truly assist citizens of Hawaii suffering from mental illness, including substance use disorders.

Thank you for the opportunity to share our concerns. If you have any questions regarding this information, please contact Brian Smith, Director, State Government Affairs at bsmith@psych.org or (703) 907-7800.

An Independent Licensee of the Blue Cross and Blue Shield Association

February 2, 2017

The Honorable Della Au Belatti, Chair
The Honorable Bertrand Kobayashi, Vice Chair
House Committee on Health

Re: HB 767 – Relating to Prescriptive Authority for Certain Clinical Psychologists

Dear Chair Au Belatti, Vice Chair Kobayashi, and Members of the Committee:

The Hawaii Medical Service Association (HMSA) appreciates the opportunity to testify on HB 767, which would provide prescriptive authority for qualified psychologists. HMSA supports this Bill.

HMSA is dedicated to ensuring that all of our members are able to access the care they need, when they need it. This not only includes services for their physical health and wellbeing, but their mental health as well.

We believe that the language contained within this measure will provide the necessary safeguards to ensure only those psychologists with the appropriate education, clinical training, and registration will be authorized to prescribe the medications our members need. This will afford our members greater and wider access to care.

Thank you for the opportunity to testify on this measure.

Sincerely,

Mark K. Oto
Director, Government Relations

LATE

AONE Hawaii

Written Testimony Presented Before the
House Committee on Health
February 02, 2017 at 9:30AM
by
Laura Westphal RN, MBA, CPHQ

Past President AONE Hawaii

H.B. 767 RELATING TO PRESCRIPTIVE AUTHORITY FOR CERTAIN CLINICAL PSYCHOLOGISTS

Chair Belatti, Vice Chair Kobayashi and members of the House Committee on Health, thank you for hearing testimony today related to H.B. 767 Relating To Prescriptive Authority For Certain Clinical Psychologists.

AONE (American Organization of Nurse Executives) Hawaii is in support of this measure. Research indicates that 25% of the adult population in the United States has a mental disorder, and that 68% of this population has a comorbid medical condition. This is 10% higher than the population without mental disorders. Further, research indicates that a person with a mental disorder diagnosis is more likely to develop a chronic medical condition, more likely to have elevated symptom burden and may have difficulties managing their chronic condition[1]. This population is vulnerable due to the unique nature of their mental and medical conditions.

Hawai'i has a widespread shortage of Mental Health Care Professionals as a subset of our overall Health Provider workforce shortage. The U.S. Department of Health and Human Services Health Resources and Services Administration (HRSA) estimates that only 50.91% of the need nationally, and 64% of the need in Hawai'i is currently met by the existing psychiatric workforce[2]. Increasing access to qualified health care professionals trained in mental disorder diagnosis and pharmacotherapy treatment, and counseling is of dire need for this population and for our state.

AONE Hawaii is in favor of this measure and the recognition of Advanced Practice Registered Nurses in their role as primary care providers and interprofessional collaborators in care. Thank you for your support of equitable and safe health care access in Hawai'i.

---

[1] Policy Brief: Mental Disorders and Medical Comorbidity. Robert Wood Johnson Foundation. 2011. http://www.rwjf.org/content/dam/farm/reports/issue_briefs/2011/rwjf69438

[2] Mental Health Care Health Professional Shortage Areas (HPSAs). Kaiser Family Foundation. 2016. http://kff.org/other/state-indicator/mental-health-care-health-professional-shortage-areas-hpsas/

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LATE

From: mailinglist@capitol.hawaii.gov
To: HLTtestimony
Cc: julie.takishima@yahoo.com
Subject: Submitted testimony for HB767 on Feb 2, 2017 09:30AM
Date: Thursday, February 2, 2017 11:01:43 AM

HB767
Submitted on: 2/2/2017
Testimony for HLT on Feb 2, 2017 09:30AM in Conference Room 329

Submitted By	Organization	Testifier Position	Present at Hearing
Julie Yurie Takishima-Lacasa	Hawai'i Psychological Association	Support	Yes

Comments: Testimony in SUPPORT of HB767 RELATING TO PRESCRIPTIVE AUTHORITY FOR CERTAIN CLINICAL PSYCHOLOGISTS REPRESENTATIVE DELLA AU BELATTI, CHAIR, REPRESENTATIVE BERTRAND KOBAYASHI, VICE CHAIR HOUSE COMMITTEE ON HEALTH Hearing Date: Thursday Feb. 2, 2016, 9:30 a.m. Room Number: 329 2/2/17 I am writing in SUPPORT of HB 767. As a clinical psychologist who has worked in various rural communities across Hawai‘i, I have experienced first-hand the devastating consequences of the lack of basic access to psychiatric services on my patients – the suffering of your constituents caused by this crisis is very real. As such, we need all solutions being put forth to address this critical and growing problem, not just one or two solutions, or only those that will spread thin an already severely limited pool of psychiatrists serving those in need in our state. Across all of our islands psychologists outnumber psychiatrists by approximately 20% and therefore offer a substantial potential pool of prescribers. This represents one significant solution to address this access to care crisis that should not be overlooked. Thank you for the opportunity to submit this testimony. Respectfully submitted, Julie Takishima-Lacasa Julie Y. Takishima-Lacasa, Ph.D. Licensed Clinical Psychologist Chair, Legislative Committee, Hawai‘i Psychological Association

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HAWAI'I STATE CENTER FOR NURSING
Connecting Nurses. Transforming Healthcare.

Written Testimony Presented Before the
House Committee on Health
February 02, 2017 at 9:30AM
by
Laura Reichhardt, NP-C, APRN, Director
Hawai'i State Center for Nursing
University of Hawai'i at Mānoa

H.B. 767 RELATING TO PRESCRIPTIVE AUTHORITY FOR CERTAIN CLINICAL PSYCHOLOGISTS

Chair Belatti, Vice Chair Kobayashi and members of the House Committee on Health, thank you for hearing testimony today related to H.B. 767 Relating To Prescriptive Authority For Certain Clinical Psychologists.

The Hawai'i State Center for Nursing (HSCN) is in support of this measure. Research indicates that 25% of the adult population in the United States has a mental disorder, and that 68% of this population has a comorbid medical condition. This is 10% higher than the population without mental disorders. Further, research indicates that a person with a mental disorder diagnosis is more likely to develop a chronic medical condition, more likely to have elevated symptom burden and may have difficulties managing their chronic condition[1]. This population is vulnerable due to the unique nature of their mental and medical conditions.

Hawai'i has a widespread shortage of Mental Health Care Professionals as a subset of our overall Health Provider workforce shortage. The U.S. Department of Health and Human Services Health Resources and Services Administration (HRSA) estimates that only 50.91% of the need nationally, and 64% of the need in Hawai'i is currently met by the existing psychiatric workforce[2]. Increasing access to qualified health care professionals trained in mental disorder diagnosis and pharmacotherapy treatment, and counseling is of dire need for this population and for our state.

The HSCN is in favor of this measure and the recognition of Advanced Practice Registered Nurses in their role as primary care providers and interprofessional collaborators in care. Thank you for your support of equitable and safe health care access in Hawai'i.

[1] Policy Brief: Mental Disorders and Medical Comorbidity. Robert Wood Johnson Foundation. 2011. http://www.rwjf.org/content/dam/farm/reports/issue_briefs/2011/rwjf69438

[2] Mental Health Care Health Professional Shortage Areas (HPSAs). Kaiser Family Foundation. 2016. http://kff.org/other/state-indicator/mental-health-care-health-professional-shortage-areas-hpsas/

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LATE

Hawai‘i Psychological Association

For a Healthy Hawai‘i

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Testimony in Support of HB 767
Relating to Prescriptive Authority for Certain Clinical Psychologists
February 2, 2017

Honorable Chair Belatti, Honorable Vice-Chair Kobayashi, and Members of the Committee,

My name is Dr. Raymond Folen. I am the Executive Director of the Hawaii Psychological Association and I would like to provide testimony in strong support of HB 767 that will allow prescriptive authority for appropriately trained clinical psychologists:

1. There is a huge need for mental health services in rural and underserved areas in Hawaii. This need has now turned into a crisis.
2. For years, many community groups, community organizations and professional organizations have proposed a no-cost, safe and effective means to help address this pressing need. Providing appropriately trained psychologists, many of whom already live and work in underserved areas, the authority to prescribe will have a significant positive impact on these communities. This is the intent of HB 767.
3. The training requirements in HB 767 are consistent with current U. S. Navy, U. S. Air Force and U. S. Army standards for psychologists credentialed to prescribe. They are also consistent with training requirements in other states where psychologists prescribe. The training requirements that HB 767 proposes will insure patient safety and quality care. This has been documented, studied and clearly demonstrated in the practices of prescribing psychologists.
4. Clinical psychologists are licensed health professionals with an average of seven years of post-baccalaureate study and three thousand hours of post-graduate supervised practice. Prescribing psychologists will receive, at a minimum, an additional two years of training and supervised practice in an accredited program and they will be required to pass a national examination. The intensive didactic portion of their program includes instruction in anatomy and physiology, biochemistry, neuroanatomy, neurophysiology, neurochemistry, physical assessment and laboratory examinations, clinical medicine and pathophysiology, clinical and research pharmacology and psychopharmacology, clinical pharmacotherapeutics, research, and professional, ethical, and legal issues.
5. Unfortunately, organized psychiatry continues to distort the solid foundation and appropriateness of HB 767 and they continue to mischaracterize the extensive training requirements in the bill.
6. There are simply not enough psychiatrists to meet the overwhelming mental health needs in our state. Individuals in need are being forced to wait three months – a quarter of a year – to get an appointment. It is difficult to find an available psychiatrist in downtown Honolulu, let alone in rural communities on the neighbor islands.

Rather than relying on psychiatry to spread - even more thinly - their very limited resources, we are offering a solution based on demonstrated success. Hawaii's psychologists are well represented throughout the Islands and can provide the needed psychopharmacology services at no additional cost to the State. HB 767 will relieve many in desperate need from the needless suffering and damage that results when treatment is unnecessarily delayed for months. Please support your community in their efforts to improve access to mental health services and pass HB 767 so we can deliver the full range of mental health services to the people who need them.

Raymond A. Folen, Ph.D., ABPP
Executive Director

LATE

kobayashi2 - Jessi

From: mailinglist@capitol.hawaii.gov
Sent: Thursday, February 2, 2017 5:11 AM
To: HLTtestimony
Cc: hlusk@CHOWPRoject.org
Subject: Submitted testimony for HB767 on Feb 2, 2017 09:30AM

HB767
Submitted on: 2/2/2017
Testimony for HLT on Feb 2, 2017 09:30AM in Conference Room 329

Submitted By	Organization	Testifier Position	Present at Hearing
Heather Lusk	The CHOW Project	Support	No

Comments: Thank you for hearing HB 767, which authorizes the Board of Psychology to grant prescriptive authority to psychologists who meet specific education, training, and registration requirements. I strongly support this measure because it will help to alleviate the difficulty that people suffering from mental health problems have in accessing proper treatment and care. Psychologists have had prescriptive authority since 1974 through the Department of Defense, and later in the Public Health Service, Indian Health Service, Guam, New Mexico, Louisiana, Illinois, and Iowa. There have been no reported adverse outcomes or malpractice complaints related to prescriptive authority for psychologists. The language in this measure will provide the necessary safeguards to ensure only those psychologists with appropriate education, clinical training and registration will be authorized to prescribe from a limited formulary of psychiatric medications.

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Testimony in SUPPORT of HB767
RELATING TO PRESCRIPTIVE AUTHORITY FOR CERTAIN CLINICAL PSYCHOLOGISTS

REPRESENTATIVE DELLA AU BELATTI, CHAIR,
REPRESENTATIVE BERTRAND KOBAYASHI, VICE CHAIR
HOUSE COMMITTEE ON HEALTH

Hearing Date:
Thursday Feb. 2, 2016, 9:30 a.m. Room Number: 329

2/2/17

I am writing in SUPPORT of HB 767. As a clinical psychologist who has worked in various rural communities across Hawai'i, I have experienced first-hand the devastating consequences of the lack of basic access to psychiatric services on my patients – the suffering of your constituents caused by this crisis is very real.

As such, we need all solutions being put forth to address this critical and growing problem, not just one or two solutions, or only those that will spread thin an already severely limited pool of psychiatrists serving those in need in our state. Across all of our islands psychologists outnumber psychiatrists by approximately 20% and therefore offer a substantial potential pool of prescribers. This represents one significant solution to address this access to care crisis that should not be overlooked.

Thank you for the opportunity to submit this testimony.
Respectfully submitted,

Julie Takishima-Lacasa

Julie Y. Takishima-Lacasa, Ph.D.
Licensed Clinical Psychologist
Chair, Legislative Committee, Hawai'i Psychological Association

LATE

PHOCUSED

PROTECTING HAWAII'S OHANA, CHILDREN, UNDER SERVED, ELDERLY AND DISABLED

February 02, 2017

TO: Representative Della Au Belatti, Chair
Representative Bertand Kobayashi, Vice Chair
Members of the House Committee on Health

FROM: Natalie Okeson, Interim Executive Director

SUBJECT: Testimony in Support of HB767, RELATING TO PRESECRIPTIVE AUTHORITY FOR CERTAIN CLINICAL PSYCHOLOGISTS

Hearing: February 02, 2017 at 9:30am
Conference Room 329

My name is Natalie Okeson, and I am serving as the Interim Executive Director of PHOCUSED. PHOCUSED is a nonprofit, nonpartisan organization dedicated to increasing the safety for, visibility of, and investment in the children and adults in Hawaii who are marginalized, impoverished, and under-served.

PHOCUSED remains extremely concerned by our state's lack of access to psychiatrists and the medications they are able to prescribe to their patients, especially on the Neighbor Islands. The passage of HB767 will give properly trained and approved psychologists the ability to help consumers who would be otherwise unable to access the medication they need.

Our organization fully supports granting prescriptive authority to those psychologists who have fulfilled a number of additional qualifications, ensuring such professionals can responsibly and safely work to meet the mental health needs of our state's population.

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Among others, those additional qualifications include completing a post-doctoral Master of Science degree in Clinical Psychopharmacology or an equivalent, which follows a model curriculum as determined the American Psychological Association.

As an active community partner in the effort to address the homelessness issue, PHOCUSED understands the close ties between certain individuals experiencing homelessness and mental health problems. Although prescribing psychologists will only be able to prescribe only for patients with a primary care physician, this increased access to proper treatment and care could prove to be crucial in helping prevent homelessness among certain at-risk individuals.

Thank you for the opportunity to submit testimony in support of HB767.

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HAWAII MEDICAL ASSOCIATION
1360 S. Beretania Street, Suite 200, Honolulu, Hawaii 96814
Phone (808) 536-7702 Fax (808) 528-2376
www.hawaiimedicalassociation.org

TO: House Committee on Health

DATE: Thursday, February 2, 2017
TIME: 9:30 A.M.
PLACE: Conference Room 329

FROM: Hawaii Medical Association
Dr. Christopher Flanders, DO, Executive Director
Lauren Zirbel, Community and Government Relations

Re: HB 767 RELATING TO PRESCRIPTIVE AUTHORITY FOR CERTAIN CLINICAL PSYCHOLOGISTS

Position: OPPOSE

Chairs & Committee Members:

The Hawaii Medical Association (HMA) opposes HB 767. We believe it is important that professionals playing different roles coordinate and collaborate in delivering high quality and safe clinical care.

We believe the state should focus its limited resources on reducing stigma, increasing mental health parity, increasing funding for effective programs, and increasing support for recruitment of physicians to Hawaii's rural areas.

State monies could be better spent making Hawaii an attractive and competitive place to practice medicine. In each of the last seven years the Hawaii Physician Workforce Assessment study, funded through a special tax on physicians, has documented a deterioration of the physician workforce. Strides to shore up our physician shortage can be better achieved by funding an expansion of JABSOM to train more resident physicians, providing loan repayment to physicians practicing in rural areas, reducing administrative burdens, reducing malpractice insurance costs, and working to increase payment by altering Hawaii's Medicare geographic adjustment to truly account for the cost of living and practicing medicine in the State of Hawaii. Until we fix the underlying problems causing our provider shortage the people of Hawaii will continue to suffer due to lack of access.

The addition of prescriptive authority to psychologists will not serve to improve the access issues of care in our rural areas. Distribution studies performed in the two states with a history of allowing for psychologist prescription authority, New Mexico and Louisiana, show that psychologists do not go to areas with an underserved mental health population, but rather to the same areas currently served by psychiatrists and primary care physicians! In essence, **passing this bill would not improve access to mental healthcare, but would simply increase the**

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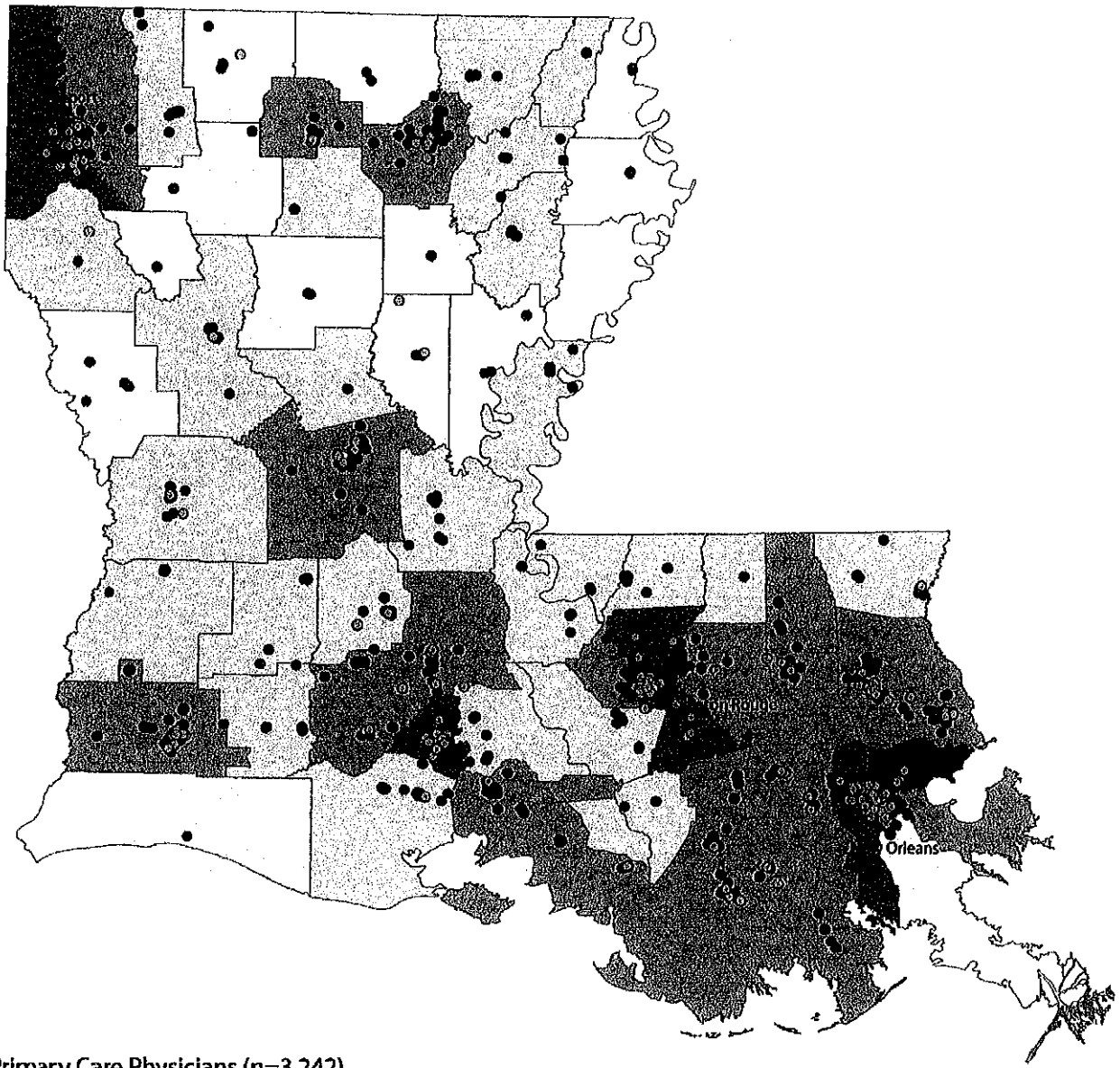
number of prescribers, with no net increase in access.

Current programs underway will more effectively improve access to mental health care in the rural areas of the state. For the past two years physicians have been working to develop a mental health collaborative care program for rural Hawaii. Using a two-pronged approach, telemedicine is being used to expand a diminished workforce. Project ECHO serves to link experienced psychiatrists with primary care providers, psychologists, and other rural providers in guiding and collaborating on care decisions for mentally ill patients. Similarly, telemedicine is being used to link experienced psychiatrists with care managers in rural Hawaii as a consult source of care, allowing for a more efficient system, serving more patients at a lower cost.

Let's be honest with ourselves and focus the states limited resources in a direction that is meaningful and effective. Psychologist prescriptive authority will not help Hawaii, only the psychologists. Instead, let's focus on methodologies that make a difference.

AMA
AMERICAN MEDICAL ASSOCIATION

Primary Care Physicians and Psychiatrists
Louisiana



- Primary Care Physicians (n=3,242)
- Psychiatrists (n=442)

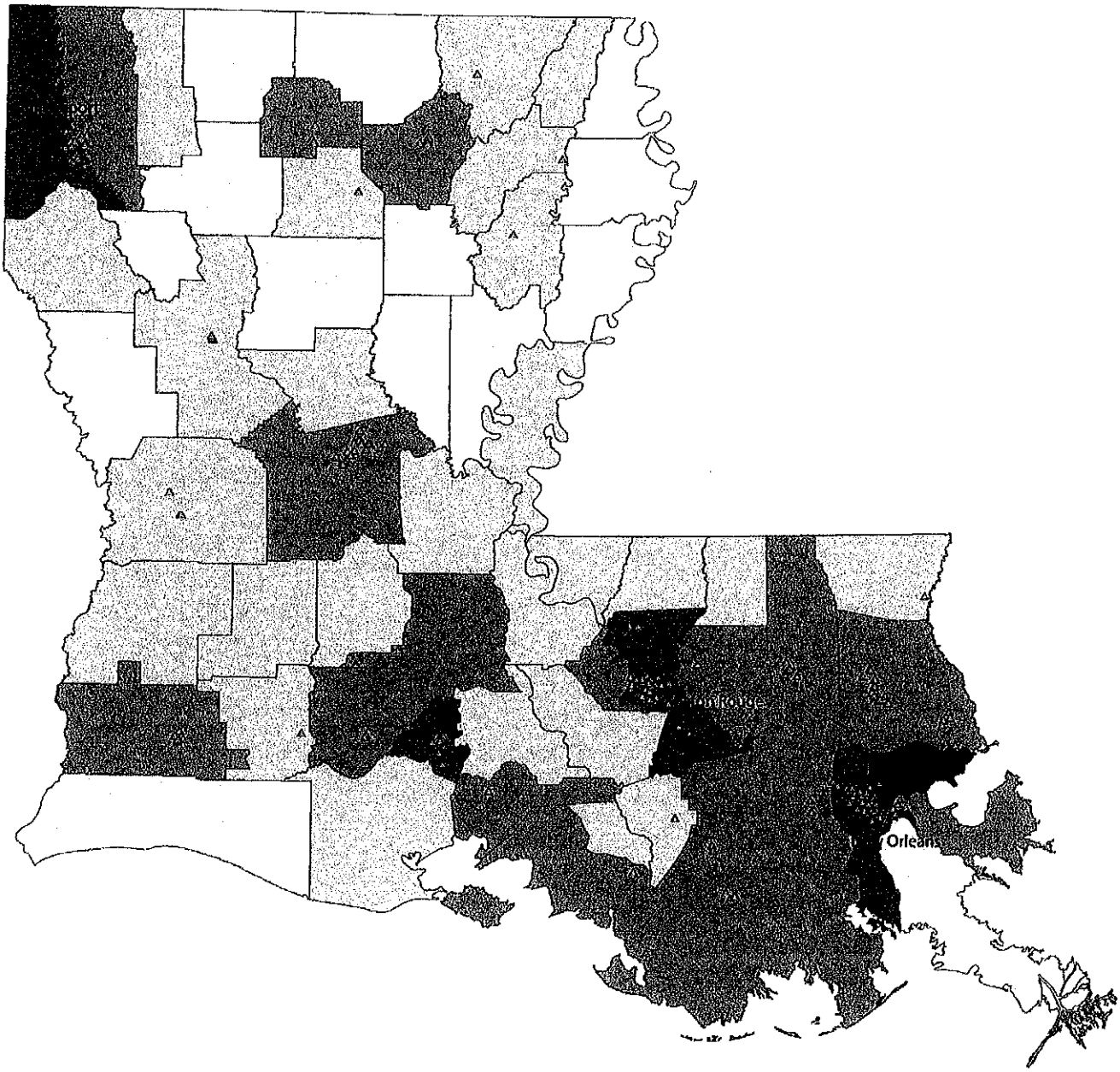
Population per square mile
Source: 2012 American Community Survey

<=25 | 26 - 75 | 76 - 250 | 251 - 1,000 | >1,000

Source Notes: AMA Physician Master6le 2012; US Census county and state shape6les 2010

AMA
AMERICAN MEDICAL ASSOCIATION

Psychologists
Louisiana



▲ Psychologists (n=507)

Population per square mile
Source: 2012 American Community Survey

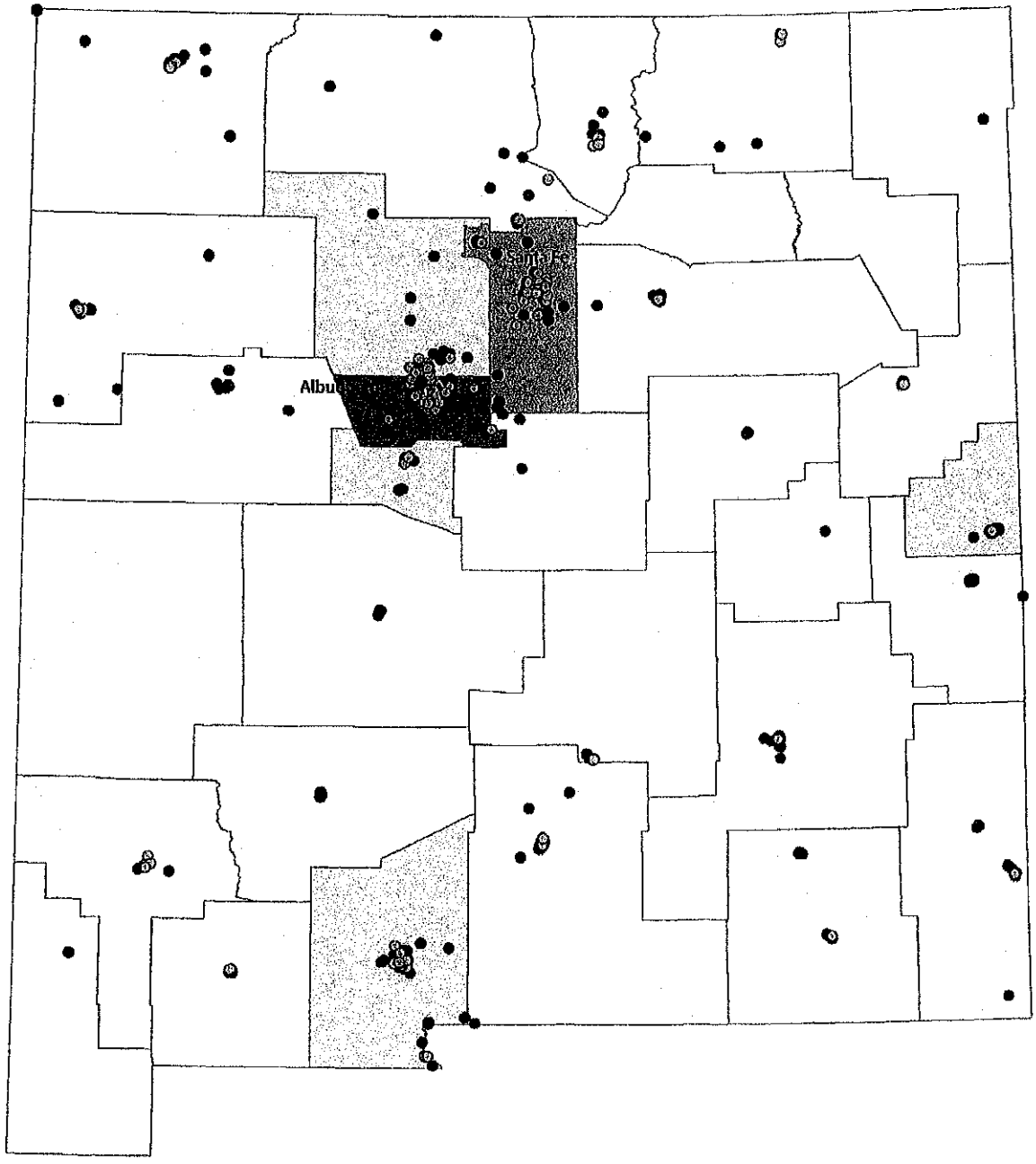
<=25 | 26 - 75 | 76 - 250 | 251 - 1,000 | >1,000

Source Notes: Centers for Medicare and Medicaid Services' National Plan and Provider Enumeration System 2013; US Census county and

AMA
AMERICAN MEDICAL ASSOCIATION

Primary Care Physicians and Psychiatrists

New Mexico



0 20 40 80 Miles

- Primary Care Physicians (n=1,671)
- Psychiatrists (n=267)

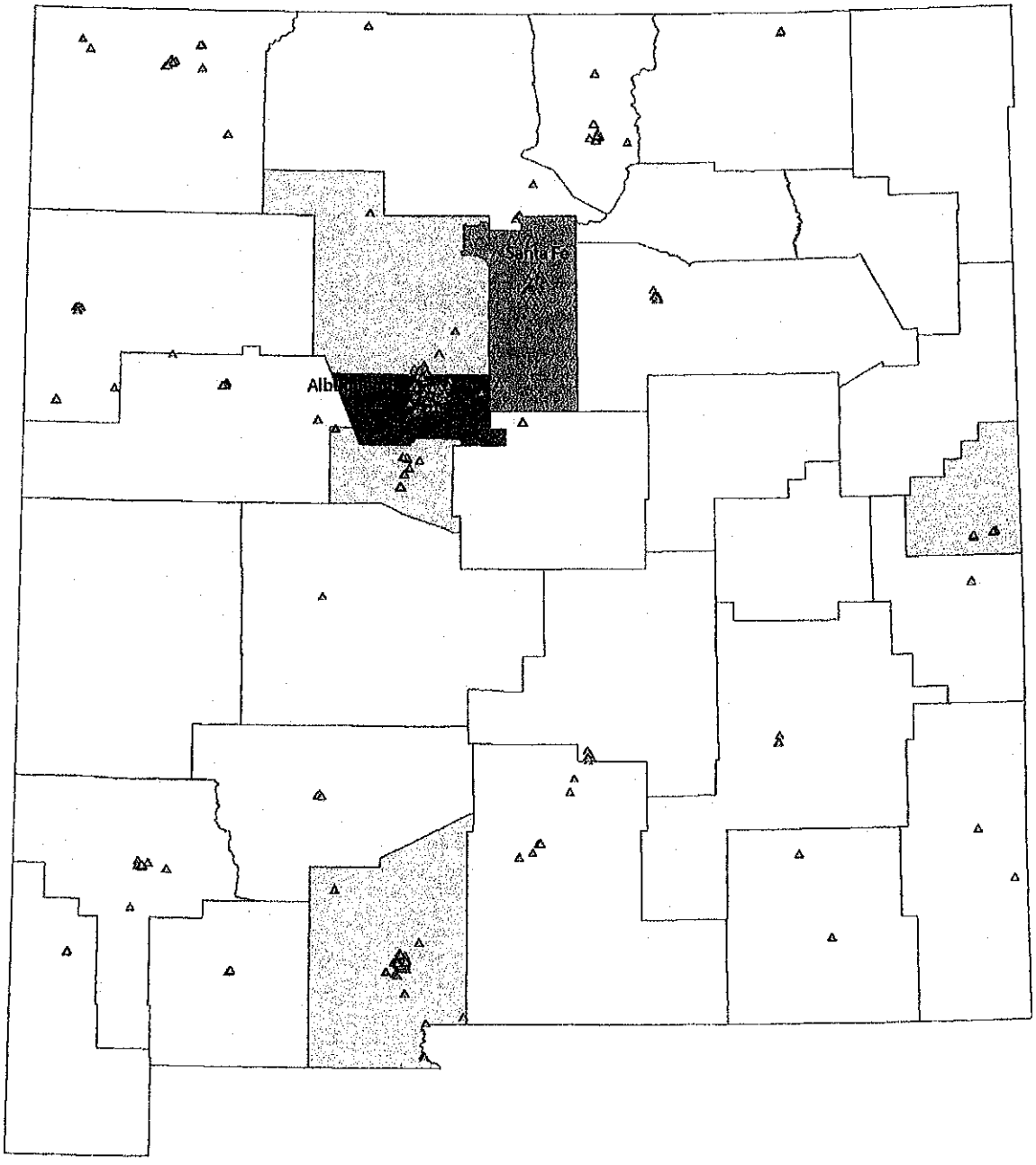
Population per square mile

Source: 2012 American Community Survey

<=25 | 26 - 75 | 76 - 250 | 251 - 1,000 | >1,000

AMA
AMERICAN MEDICAL ASSOCIATION

Psychologists
New Mexico



0 20 40 80 Miles

△ Psychologists (n=690)

Population per square mile

Source: 2012 American Community Survey

<=25 | 26 - 75 | 76 - 250 | 251 - 1,000 | >1,000

Source Notes: Centers for Medicare and Medicaid Services' National Plan and Provider Enumeration System 2013; US Census county and

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Government Relations

Testimony of
Jonathan Ching
Government Relations Specialist

Before:
House Committee on Health
The Honorable Della Au Belatti, Chair
The Honorable Bertrand Kobayashi, Vice Chair

February 2, 2017
9:30 a.m.
Conference Room 329

Re: HB767 Relating to Prescriptive Authority for Certain Clinical Psychologists

Chair Belatti, Vice Chair Kobayashi, and committee members, thank you for this opportunity to provide testimony on HB767, which authorizes the board of psychology to grant prescriptive authority to prescribing psychologists who meet specific education, training, and registration requirements.

Kaiser Permanente Hawaii OPPOSES HB767.

We recognize that the purpose of this measure is to address the shortage of prescribing mental health care providers in the State; however, Kaiser Permanente Hawaii finds the educational and clinical training requirements under HB767 are insufficient from both a safety and scope of practice perspective. We are not convinced that these requirements adequately prepare a psychologist to be able to prescribe psychotropic medications, which can cause serious harm to patients. Furthermore, Kaiser Permanente Hawaii notes that the complexities of the interaction between the mind and body cannot be adequately understood at the level of training currently required under HB767 for any psychologist seeking prescriptive authority.

During residency, psychiatrists must complete a minimum of 8,320 hours of clinical training in psychiatry/child psychiatry (four years). These clinical training hours, which involve seeing patients under supervision, do not include the additional four years of medical school, where psychiatrists learn anatomy, physiology, pharmacology, biochemistry, histology, neurology, neuroanatomy, and cell and molecular biology. These courses are also supplemented by two full years of clinical experience, which includes two months in each of the following areas: Internal Medicine, Obstetrics & Gynecology, Family Practice, General Surgery, and Pediatrics, Psychiatry, plus training in radiology, interpretation of EKGs, and understanding of labs and significance of those labs. This comprehensive training for psychiatrists allows them to determine when they need to look at a medical, pharmacological, or psychological cause of a patient's symptoms.

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In contrast, according to Alliant International University's Postdoctoral Master of Science Program in Clinical Psychopharmacology, which is one of the clinical pharmacology programs designated by the American Psychological Association,[1] a psychologist must complete 462 class hours.[2] If the minimum 400 clinical hours required under HB767 are also included, the minimum requirement to eligible for prescriptive authority is 862 hours, which is 10% of the hours a psychiatrist is required to complete just during their residency.[3] Kaiser Permanente Hawaii highlights this difference in hours because it holds that prescriptive authority requires appropriate interpretation of symptoms *and* the appropriate medical acumen and clinical knowledge, which can only be acquired through the completion of medical school and extensive clinical training.

As an alternative to HB767, Kaiser Permanente Hawaii suggests the committee consider exploring ways to address the shortages of specialty health providers in rural and remote areas of our State. One such approach is the funding of Project ECHO (Extension for Community Healthcare Outcomes), a partnership between the University of Hawai'i and the Hawai'i State Rural Health Association, which is a knowledge-on-demand model of telehealth care that educates, trains, and supports rural general practitioners and other available healthcare representatives on the best practice treatment protocols for complex diseases. Funding of SB1045, which makes an appropriation to the department of health to implement and administer an ECHO program, will help train primary care physicians and other healthcare representatives who live in rural and remote areas and who currently care for members of the public where there is the most need. This could include training of primary care providers in the areas of psychotic and substance abuse disorders, which can help better facilitate mental health care via telemedicine between a primary care provider and a psychiatrist.

Therefore, Kaiser Permanente Hawaii urges the committee to **HOLD** HB767. Mahalo for the opportunity to testify on this important measure.

[1] See http://www.apa.org/education/grad/designation.aspx.
[2] See http://catalog.alliant.edu/preview_program.php?catoid=28&poid=3703&returnto=1%20096.
[3] An psychologist seeking prescriptive authority under HB767 would be required to complete a minimum of 862 hours, which includes classroom and clinical hours versus a psychiatrists' 8,320 clinical hours required during a 4-year residency.

To: Rep Della Belatti, Chair, Rep Bertrand Kobayashi, Vice Chair, and members of the House Committee on Health

From: Julienne Aulwes, MD, Chair, Hawaii Psychiatric Medical Association Task Force on Improving Access to Psychiatric Care

Jeffrey Akaka, MD, Chair, Legislative Committee, Hawaii Psychiatric Medical Association (HPMA) - testifying

Hearing Date: February 2, 2017
Hearing Time: 9:30am

Re: HB 767 - Relating to Prescriptive Authority for Certain Clinical Psychologists

Position: OPPOSED

Dear Chairperson Belatti, Vice Chairperson Kobayashi, and Members of the House Committee on Health:

On behalf of the Hawaii Psychiatric Medical Association, I am testifying today to ask that the committee please **vote NO on HB 767.**

Last session the prescriptive authority for psychologists bill was defeated, but the legislature asked HPMA for help in addressing the difficulties patient's in rural areas have in accessing psychiatric care. In response, the Hawaii Psychiatric Medical Association, the American Psychiatric Association, and the Hawaii Medical Association, have been working on multiple fronts to try to solve this problem – I will briefly cover them in my testimony today.

First off I would like to point out that the proponents of psychologist prescribing and HB 767 have introduced the essentially the same bill that was defeated last session making no changes and bringing no additional feedback or solutions to the discussion. This legislation gives psychologists prescriptive authority not taking into account the new and innovative methods of bringing mental health care to our communities. There are several reasons for why this bill should not be passed, including certain statements in the bill which appear to be less than 100% accurate as well as the progress that HPMA and others have made toward viable solutions.

The good news is that since last session HPMA, HMA and others have been working to solve rural access to psychiatric care problems by methods proven to work safely in other states, and we have started to implement those methods here.

The first of the 3 better alternatives we have been working on is HB1272 (SB1155), Collaborative Care. Numerous evidence based studies show that by keeping the psychiatric patients with mild to moderate psychiatric conditions in their family

doctors office, embedding a care manager there, and the family practice contracting with an off-site psychiatric consultant, Collaborative Care results in better medical care as well as better psychiatric care. It provides improved patient outcomes, better patient and provider satisfaction, and saves money, up to $600-1000 per patient per year.

Instead of a psychiatrist taking care of only three or four patients in a morning, Collaborative Care allows a psychiatrist to oversee the care of 10-15 patients in a morning – meaning an increase in access to care for our community. The data on this program has been so positive that Medicare started paying for Collaborative Care in January. But we need your leadership as this proven solution is not covered by Medicaid. What we need is for Medicaid to cover the same service that Medicare started paying for – bringing a VIABLE solution to our state. This is why HPMA has worked with some of your colleagues on HB1272 to accomplish this. The time is now to abandon the same old so-called solutions and work to promote programs that move Hawaii healthcare in the direction of better medical (including psychiatric) care for more people at less cost.

Second, Network Adequacy is major contributor to difficulties accessing psychiatrists, but this also has a potential solution in the network adequacy bills HB914 and SB387. HPMA and it's members have been working with your colleagues to ensure when patients need mental health care, their insurers are providing trained medical professionals to help.

Finally, the Hawai'i ECHO (Extension for Community Healthcare Outcomes) Project, a partnership between the Hawai'i State Rural Health Association and the University of Hawai'i, helps primary care doctors to get help on challenging cases through videoconferences with specialist physicians. It started in January 2016 with Psychiatry as the first specialty covered, and included members of HPMA holding faculty positions at the University of Hawaii Department of Psychiatry in the School of Medicine. Current research shows this method improves the care of patients of participating rural family docs up to the level of care at city academic medical centers.

Our critics will say that "nothing has been done" in the short 6 months since last session. As you can see from my testimony today, HPMA has been actively pushing efforts in the community to bring increased mental health care to the community. The entire healthcare field is moving in the direction of more collaborative, team based, integrated care. HPMA is working hard to help Hawaii move forward in a way that provides better outcomes and better satisfaction and lower cost. There is no comparable valid evidence that a bill like HB767 would accomplish this.

Therefore, I ask you to all please vote NO on HB767. The alternatives are here, growing, proven to work on large scales, and are far safer.

HPMA and its members welcome this opportunity to inform you about these solutions and ask for your support.

Aloha and mahalo,

Jeffrey Akaka, MD
Chair, Legislative Committee, Hawaii Psychiatric Medical Association

From: Wild Rose Communications
To: HLTtestimony
Subject: Mental Health
Date: Tuesday, January 31, 2017 11:54:59 AM

1/31/17

To: Representative Della Au Belatti, Chair, Representative Bertrand Kobayashi, Vice Chair, and members of the House Committee on Health
From: (your name and organization)

Re: Testimony in support of HB 767, Relating to Prescriptive Authority for Certain Clinical Psychologists
Hearing: Thursday, February 2, 2017, 9:30 am, Conference Room 329

Thank you for hearing HB 767, which authorizes the Board of Psychology to grant prescriptive authority to psychologists who meet specific education, training, and registration requirements. I strongly support this measure because it will help to alleviate the difficulty that people suffering from mental health problems have in accessing proper treatment and care.

Psychologists have had prescriptive authority since 1974 through the Department of Defense, and later in the Public Health Service, Indian Health Service, Guam, New Mexico, Louisiana, Illinois, and Iowa. There have been no reported adverse outcomes or malpractice complaints related to prescriptive authority for psychologists.

The language in this measure will provide the necessary safeguards to ensure only those psychologists with appropriate education, clinical training and registration will be authorized to prescribe from a limited formulary of psychiatric medications.

Passing HB 767 will give properly trained and approved psychologists the ability to help consumers that otherwise would be unable to access the medication they need and should have a right to access. Please help us improve mental health in Hawaii by passing HB 767.

Thank you for the opportunity to submit this testimony.

Kayla Rosenfeld, Wild Rose Communications
808-230-5960 tel/text
www.wildrosecommunications.wordpress.com

Please excuse any typos. Sent with good intention from mobile phone

PHOCUSED

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PROTECTING HAWAII'S OHANA, CHILDREN, UNDER SERVED, ELDERLY AND DISABLED

February 02, 2017

TO: Representative Della Au Belatti, Chair
Representative Bertand Kobayashi, Vice Chair
Members of the House Committee on Health

FROM: Natalie Okeson, Interim Executive Director

SUBJECT: Testimony in Support of HB767, RELATING TO PRESECRIPTIVE AUTHORITY FOR CERTAIN CLINICAL PSYCHOLOGISTS

Hearing: February 02, 2017 at 9:30am
Conference Room 329

My name is Natalie Okeson, and I am serving as the Interim Executive Director of PHOCUSED. PHOCUSED is a nonprofit, nonpartisan organization dedicated to increasing the safety for, visibility of, and investment in the children and adults in Hawaii who are marginalized, impoverished, and under-served.

PHOCUSED remains extremely concerned by our state's lack of access to psychiatrists and the medications they are able to prescribe to their patients, especially on the Neighbor Islands. The passage of HB767 will give properly trained and approved psychologists the ability to help consumers who would be otherwise unable to access the medication they need.

Our organization fully supports granting prescriptive authority to those psychologists who have fulfilled a number of additional qualifications, ensuring such professionals can responsibly and safely work to meet the mental health needs of our state's population.

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Among others, those additional qualifications include completing a post-doctoral Master of Science degree in Clinical Psychopharmacology or an equivalent, which follows a model curriculum as determined the American Psychological Association.

As an active community partner in the effort to address the homelessness issue, PHOCUSED understands the close ties between certain individuals experiencing homelessness and mental health problems. Although prescribing psychologists will only be able to prescribe only for patients with a primary care physician, this increased access to proper treatment and care could prove to be crucial in helping prevent homelessness among certain at-risk individuals.

Thank you for the opportunity to submit testimony in support of HB767.

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www.phocused-hawaii.org admin@phocused-hawaii.org

From: Kelly_A_Stern/LEEDO/HIDOE@notes.k12.hi.us
To: HLTtestimony
Subject: HB 767
Date: Tuesday, January 31, 2017 12:14:46 PM

To: Representative Della Au Belatti, Chair, Representative Bertrand Kobayashi, Vice Chair, and members of the House Committee on Health
From: (your name and organization)

Re: Testimony in support of HB 767, Relating to Prescriptive Authority for Certain Clinical Psychologists
Hearing: Thursday, February 2, 2017, 9:30 am, Conference Room 329

Thank you for hearing HB 767, which authorizes the Board of Psychology to grant prescriptive authority to psychologists who meet specific education, training, and registration requirements. I have been working with children and adolescents in Hawaii since Felix, and have brought funding to Hawaii for access to more services, but at the end of the day if there are no providers, how can we get more services? In the schools much of our concerns have to do with the limited resources we have for those children. I propose that you allow us to expand our resources to include properly trained psychologists, as long as they meet minimum requirements to practice.

The language in this measure will provide the necessary safeguards to ensure only those psychologists with appropriate education, clinical training and registration will be authorized to prescribe from a limited formulary of psychiatric medications. Passing HB 767 will give properly trained and approved psychologists the ability to help consumers that otherwise would be unable to access the medication they need and should have a right to access. Please help us improve mental health in Hawaii by passing HB 767.

Thank you for the opportunity to submit this testimony.

Kelly A. Stern
School Climate Transformation Coordinator
Website: Project HI AWARE
Nanakuli Elementary School P-4
89-778 Haleakala Ave
Waianae, HI 96792
808-829-5202 (new number)

"We celebrate the tinkerers and dreamers whose talent and drive have brought new ideas to life, and we recommit to cultivating the next generation of problem solvers." President Barack Obama

Elaine M. Heiby, Ph.D.
Licensed Psychologist and Professor Emerita of Psychology
2542 Date St., Apt. 702, Honolulu, HI 96826
Phone: (808) 497-0929 Email: heiby@hawaii.edu

31 January 2017

Hawaii State Legislature House Health Committee

Re: OPPOSITION to HB767 Relating to prescription privileges for psychologists

Dear Honorable Representatives:

This is individual testimony that is informed from my experience as a doctoral level psychologist since 1980. My experience includes being a Professor of Psychology at the University of Hawaii at Manoa from 1981 to 2014, a Hawaii Licensed Psychologist since 1982, and a former member of the Board of Psychology. My opinions do not represent the University or the Board. My opinions are consistent with testimony submitted by Psychologists Opposed to Prescriptions Privileges for Psychologists (POPPP) and I am on the Board of Advisors of POPPP (https://www.poppp.org).

Purpose of HB767

This bill aims to expand the scope of practice of psychologists to that of psychiatrists based on only 10% of the medical training completed by psychiatrists. This expansion of scope of practice crosses disciplinary boundaries. It is not accurate to compare this expansion of scope of practice to permitting other health professionals, such as dentists and nurses, to prescribe as the training of these other allied health professionals is already premedical and medical in nature. In contrast, the training of psychologists is not related to the practice of medicine. Therefore, **this bill proposes a radical reduction of required medical training in order to practice medicine in Hawaii**.

Cost Implications

Some will have testified that this is a no-cost bill. This is not true. In order to offer the substandard medical training specified in this bill, it would cost the University of Hawaii-Hilo College of Pharmacy at least $250,000 per year (http://www.hawaii.edu/offices/app/aa/cms/MSCP_proposal_5-12-11_final_rev3.pdf).

Reasons for Opposition involve Risk to the Consumer

- Since 1996, bills similar to this one have been rejected at least 193 times in 26 states owing to substandard medical training (see 2016 map attached)

- Training for a doctorate in clinical psychology does not include pre-medical or medical training. Therefore, as stated above, comparison to expansion of scope of practice for dentists and nurses is erroneous because the training of these other professionals is already medical in nature.

- There is virtually no evidence that reducing medical training to about 10% of that required for physicians and about 20% of that required for advanced practice nurses (advanced nurse practitioners) will protect the consumer. This bill suggests there is solid evidence that licensing requirements for physicians and nurses is extremely excessive. Yet no such evidence exists and no bills to reduce the training required for physicians and nurses are being entertained.

- 89.2% of about 1000 members of the psychological Association for Behavioral and Cognitive Therapies (ABCT) argue the medical training for psychologists to prescribe should be equivalent to other non-physician prescribers (*the Behavior Therapist, September 2014)*. A survey of Illinois psychologist yielded similar findings (78.6%) (Baird, K. A. (2007). A survey of clinical psychologists in Illinois regarding prescription privileges. *Professional Psychology: Research and Practice, 38*, 196-202. doi:10/1037/0735-7028.38.2.196).

- Only 5.8% endorsed the effectiveness of online medical training, which is permitted in this bill (ABCT survey)

- Only 10.9% would refer a patient to a prescribing psychologist whose medical training is what is required in this bill (ABCT survey).

- 88.7% agreed that there should be a moratorium on bills like this one until there is objective evidence that the training involved protects the consumer (ABCT survey).

- The impact of prescribing privileges in New Mexico and Louisiana should be objectively evaluated for consumer safety before this experiment is repeated in Hawaii. Consumer safety outcome in the military is difficult to evaluate owing to the Feres Doctrine (barring lawsuits involving injuries to members of the armed forces) and the small number of prescribing psychologists (e.g., 2 in the Navy and 4 in the Air Force).

- Proponents claim that the lack of a reported death or serious harm by prescribing psychologists somehow provides evidence of safety. It does not. It only provides evidence that any harm done by these psychologists was not

identified and reported by the psychologists themselves or their patients. A **lack of evidence of safety does not constitute evidence for safety.**

- There have been malpractice lawsuits filed against prescribing psychologists in New Mexico and Louisiana, so some problems in their practice have been asserted.

- Given proponents spent over $500,000 to pass a prescribing bill in Louisiana alone speaks to the availability of funds to conduct such a consumer safety study for the amount of medical training required in this bill.

- The choice by the APA to not conduct a consumer safety outcome study suggests a lack of concern about consumer safety. There has been erosion in the ethics of the APA in the past decades. The ethics of the APA has changed from professional ethics designed to protect the consumer to guild ethics, designed to increase the income of psychologists regardless of the impact upon the consumer (http://kspope.com/PsychologyEthics.php#contentarea).

- Evidence of this erosion is apparent in the disregard for consumer safety in prescribing and in other areas, such as the APA's explicit support of doing harm by endorsing psychologists to conduct torture and the APA's admitted deception of the membership by presenting voluntary contributions as mandatory.

  <u>The State of Illinois has set the standard for prescription privileges for psychologists</u>

  - Illinois Model for psychologists prescribing is not controversial

  - In 2014, the State of Illinois enacted a law to permit psychologists to prescribe some psychotropic medications (e.g., excluding narcotics and benzodiazepines) to a limited population (excluding youth, the elderly, pregnant women, the physically ill, and those with developmental disabilities). http://ilga.gov/legislation/ilcs/ilcs3.asp?ActID=1294&ChapAct=225%26nbsp%3BILCS%26nbsp%3B15%2F&ChapterID=24&ChapterName=PROFESSIONS+AND+OCCUPATIONS&ActName=Clinical+Psychologist+Licensing+Act%2E

  - The training requirement is similar to what is required of Physician Assistants, including undergraduate pre-medical training. This training includes 7 undergraduate and 20 graduate courses along with a 14-month practicum in multiple medical rotations.

- The Illinois Psychological Association and Nursing and Medical associations supported the Illinois law, as it requires the same medical training as other non-physician prescribers. Psychologists Opposed to Prescription Privileges for Psychologists (POPPP) does not oppose the Illinois Model because of the standard medical training required.

Solutions to access to psychoactive drugs while protecting the consumer

1. Collaboration between psychologists and physicians. The University of Hawaii-Hilo's College of Pharmacy provides training for such collaboration if needed (http://hilo.hawaii.edu/catalog/ms-clinincal-psychopharmacology.html).

2. Completion of medical or nursing school by psychologists. Encouraging medical and nursing schools to offer executive track programs for psychologists and social workers.

3. Use of Tele-psychiatry, which is promoted by the Department of Veterans Affairs and the U.S. Bureau of Prisons and **enabled by HB1272**

4. Modify this bill to meet the required training and scope of practice limitations in the Illinois law enabling psychologists to prescribe.

5. Encouraging all professionals to serve rural areas. The prescribing laws in New Mexico and Louisiana did not result in psychologists moving their practices to rural areas as they had declared would happen (see attached chart; Source: Prof. T. Tompkins, 2010; used with permission; no prescribing psychologists in Guam identified despite enabling legislation in 1999).

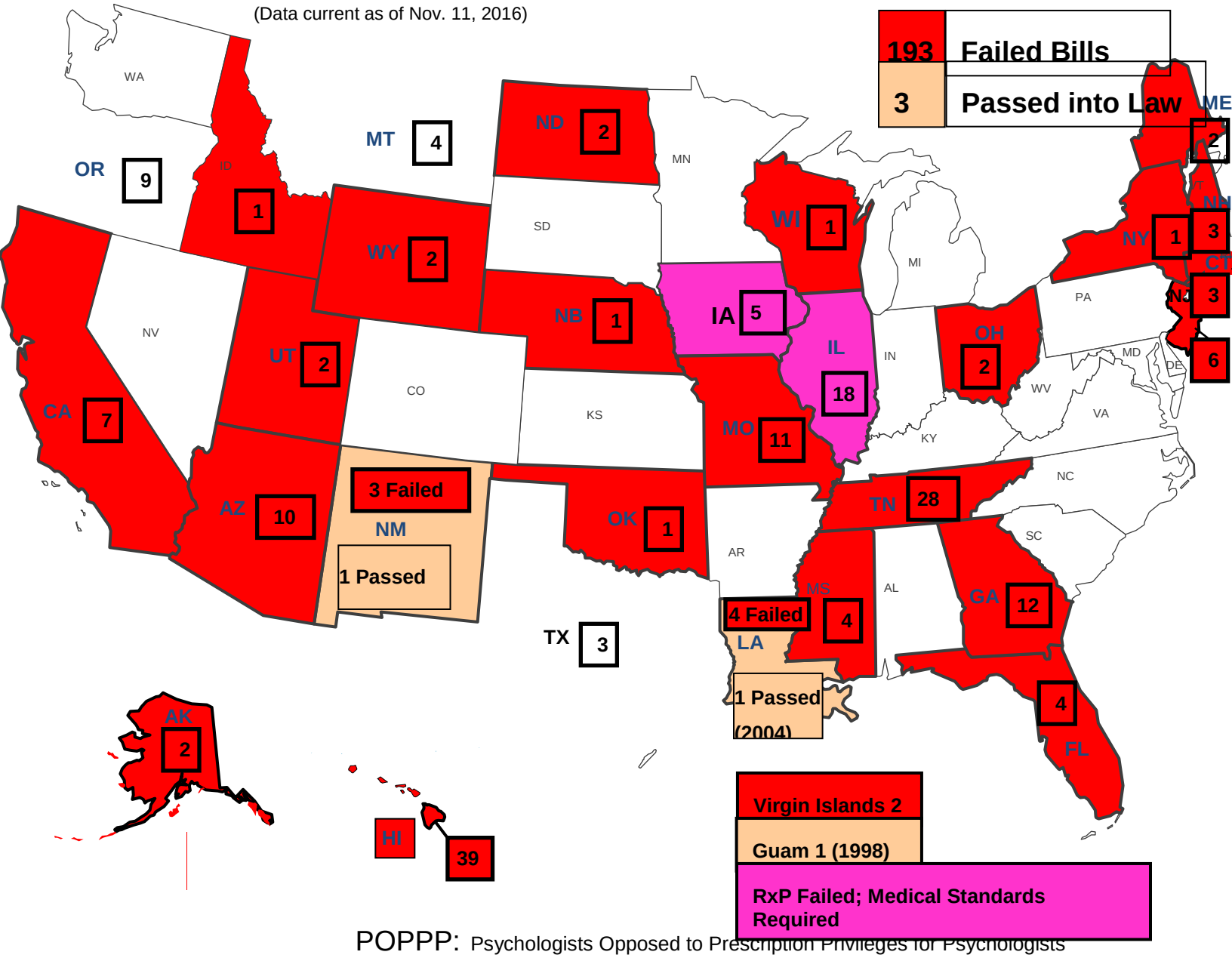
Thank you for your kind consideration of this opinion.

Respectfully,

Elaine M. Heiby, Ph.D.
Psychologist (HI license 242)
Professor Emerita of Psychology, UH-Manoa

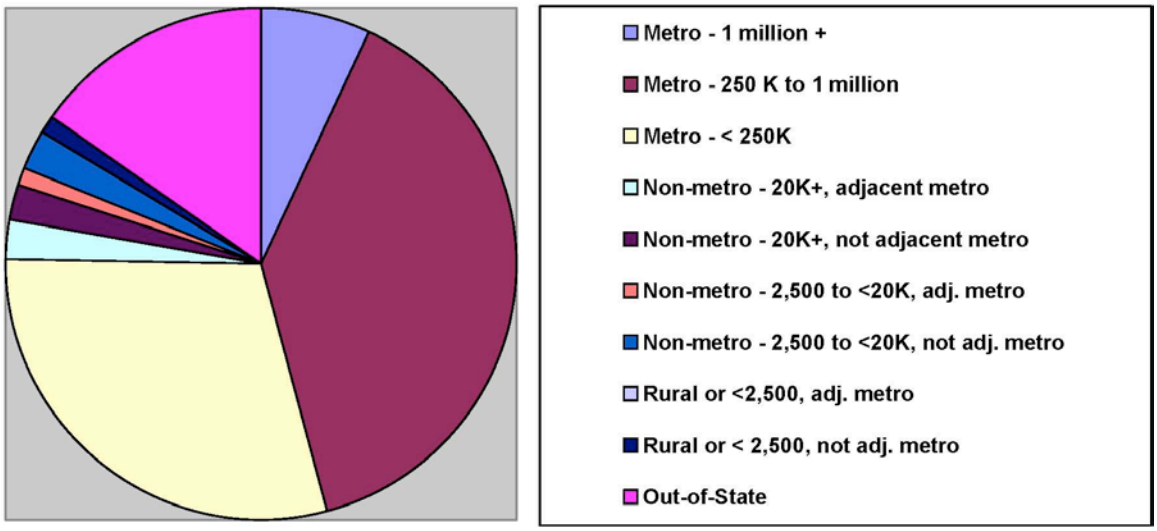
Psychologist Prescriptive Authority Legislative Bills 1995-2016

(Data current as of Nov. 11, 2016)



POPPP: Psychologists Opposed to Prescription Privileges for Psychologists

Combined Distribution of Psychologists Authorized to Prescribe Medications in NM, LA, and Guam



HOUSE COMMITTEE ON HEALTH
Representative Della Au Belatti, Chair
Representative Bertrand Kobayashi, Vice Chair

NOTICE OF HEARING
Thursday, February 2, 2017 at 9:30 AM
Conference Room 329
State Capitol
415 South Beretania Street

TESTIMONY IN SUPPORT OF HB 767
RELATING TO PRESCRIPTIVE AUTHORITY FOR CERTAIN CLINICAL PSYCHOLOGISTS

Honorable Chair Belatti, Vice-Chair Kobayashi and members of the Committee on Health, I am Robin Miyamoto, a Clinical Psychologist and Assistant Professor with the Departments of Native Hawaiian Health and Family Medicine and Community Health at the John A. Burns School of Medicine. I serve the Medicare/Medicaid community of Wahiawa and Mililani and I wish to submit this testimony in strong support of HB 767. This bill would allow advanced trained medical psychologists to prescribe and dispense medication within the scope of practice of psychology as defined by Hawai‘i Law.

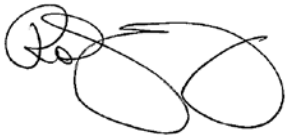
I support this bill for numerous reasons:

- In Hawai‘i, there is a substantial gap in mental health care that can be safely filled by granting prescription privileges to medical psychologists with advanced training in clinical psychopharmacology.
- Psychologists have been prescribing medications since 1974. They have done so in state systems, in the Indian Health Service, and in the Department of Defense.
- The education and training outlined in this bill, based in part on the already proven training of the U.S. Department of Defense Psychopharmacology Demonstration Project, and consistent with the American Psychological Association's Recommended Post-Doctoral Training in Psychopharmacology for Prescription Privileges, will provide psychologists with the core knowledge in medicine and psychopharmacology they will need to prescribe psychotropic medications safely and effectively.
- The training is part of a Post-Doctoral degree, the cost of which would be covered by the individual psychologist. These programs do not cost the state a single penny.

Psychiatry's arguments are the same ones that have been used for decades against nurses, podiatrists, optometrists, dentists and doctors of osteopathy. The organizers of the psychiatry guild disregard the overwhelming evidence that belies their position and they continue to distort and mislead. It is most disheartening that, for psychiatry, the goal is to keep us from prescribing even at the cost of the communities we serve.

What is the motivation behind our efforts? If you look at testimony provided over the years, psychology's message is consistent: to provide a full range of mental health services to those unserved and underserved communities. HB 767 will expand on our ability to do exactly that.

Thank you for your consideration.



Respectfully submitted by,
Robin E. S. Miyamoto, Psy.D.
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From: mailinglist@capitol.hawaii.gov
To: HLTtestimony
Cc: mpoirier808@gmail.com
Subject: Submitted testimony for HB767 on Feb 2, 2017 09:30AM
Date: Tuesday, January 31, 2017 4:41:05 PM

HB767
Submitted on: 1/31/2017
Testimony for HLT on Feb 2, 2017 09:30AM in Conference Room 329

Submitted By	Organization	Testifier Position	Present at Hearing
Marion Poirier	Individual	Oppose	No

Comments: Dear Representative Belatti and Members, I oppose H.B. 767. NAMI national opposes all state efforts to move this type of legislation forward because it does not solve the problems presenting. As a former Executive Director of our local NAMI, I became convinced by their arguments against. I attended numerous meetings and conferences on this subject, and feel more than comfortable in alerting you to the inadvisability of moving this bill out of committee. Please hold. Aloha, Marion Poirier, M.A.,R.N.

Lesley A. Slavin, Ph.d

317C Olomana Street, Kailua, HI

Licensed Clinical Psychologist,
Hawaii #864

Email: lalikipaulo@yahoo.com
Phone: (808) 393-9110

Testimony in SUPPORT of HB767
RELATING TO PRESCRIPTIVE AUTHORITY FOR CERTAIN CLINICAL PSYCHOLOGISTS

REPRESENTATIVE DELLA AU BELATTI, CHAIR,
REPRESENTATIVE BERTRAND KOBAYASHI, VICE CHAIR
HOUSE COMMITTEE ON HEALTH

Hearing Date:
Thursday Feb. 2, 2016, 9:30 a.m. Room Number: 329

1/31/17

Thank you for hearing HB 767, which authorizes the Board of Psychology to grant prescriptive authority to psychologists who meet specific education, training, and registration requirements. Licensed psychologists are doctoral level professionals with extensive training in psycho-diagnostics and psychotherapy. With the addition of specialized training in pharmacology and medicine, prescribing psychologists would be very well-equipped to provide excellent care that would integrated the use of medication with behavioral and talk-therapy approaches. I strongly support this measure because it will help to alleviate the difficulty that people suffering from mental health problems have in accessing proper treatment and care.

Passing HB 767 will give properly trained and approved psychologists the ability to help consumers that otherwise would be unable to access the medication they need and should have a right to access. Please help us improve mental health in Hawaii by passing HB 767. I also believe that having more prescribing professionals available to help provide more routine medication management will free up our precious and scarce psychiatrists to work with those patients whose mental and physical health needs are particularly complex.

Psychologists have had prescriptive authority since 1974 through the Department of Defense, and later in the Public Health Service, Indian Health Service, Guam, New Mexico, Louisiana, Illinois, and Iowa. There have been no reported adverse outcomes or malpractice complaints related to prescriptive authority for psychologists.

The language in this measure will provide the necessary safeguards to ensure only those psychologists with appropriate education, clinical training and registration will be authorized to prescribe from a limited formulary of psychiatric medications.

Thank you for the opportunity to submit this testimony.
Respectfully submitted,

Lesley Slavin

Lesley A Slavin, Ph. D.
Past President, Hawaii Psychological Association

To: Representative Della Au Belatti, Chair, Representative Bertrand Kobayashi, Vice Chair, and members of the House Committee on Health
From: Pedro Haro

February 2, 2016

Testimony in support of HB 767, Relating to Prescriptive Authority for Certain Clinical Psychologists

Hearing: Thursday, February 2, 2017, 9:30 am, Conference Room 329

Mahalo for hearing HB 767, which authorizes the Board of Psychology to grant prescriptive authority to psychologists who meet specific education, training, and registration requirements. I strongly support this measure because it will help to alleviate the difficulty that people suffering from mental health problems have in accessing proper treatment and care.

As a public health professional, I am deeply concerned about the shortage of psychiatric physicians, particularly on neighbor islands. I have experienced personally trying to seek psychiatric care for a loved one only to learn that several of psychiatrists I reached out to are not taking new patients because of an already overloaded patient schedule. This is not the fault of our physicians, they are trying the best they can to fulfill their duties. This bill would help lessen their load so that more people can receive access to proper care.

Psychologists have had prescriptive authority since 1974 through the Department of Defense, and later in the Public Health Service, Indian Health Service, Guam, New Mexico, Louisiana, Illinois, and Iowa. There have been no reported adverse outcomes or malpractice complaints related to prescriptive authority for psychologists.

The language in this measure will provide the necessary safeguards to ensure only those psychologists with appropriate education, clinical training and registration will be authorized to prescribe from a limited formulary of psychiatric medications.

Passing HB 767 will give properly trained and approved psychologists the ability to help consumers that otherwise would be unable to access the medication they need and should have a right to access. Please help us improve mental health in Hawaii by passing HB 767.

Thank you for the opportunity to submit this testimony.

Pedro Haro
204 Koalele St.
Honolulu, HI 96813

THE TWENTY-NINTH LEGISLATURE
REGULAR SESSION OF 2017

TO: **COMMITTEE ON HEALTH**
Rep Della Au Belatti, Chair
Rep Bertrand Kobayashi, Vice Chair

FROM: **Jill Oliveira Gray, Ph.D.**
Hawaii Licensed Clinical Psychologist

RE: **TESTIMONY IN SUPPORT OF HB 767**
RELATING TO PRESCRIPTIVE AUTHORITY FOR CERTAIN CLINICAL PSYCHOLOGISTS

Honorable Chairs, Vice-Chairs and members of the Committee on Health, my name is Dr. Jill Oliveira Gray and I am a licensed Clinical Psychologist who has worked in rural, medically underserved areas for the past 16 years to include Hana, Maui, Molokai, and Waimānalo. I am also a past President of the Hawai'i Psychological Association and current Training Director at I Ola Lāhui, an American Psychological Association accredited pre-doctoral internship and post-doctoral fellowship that has trained and placed psychologists in rural, medically underserved areas across our state since 2007. Because of my years of clinical experience serving rural, medically underserved areas, and first hand knowledge of what the severe needs of these communities are and the profound impact that mental health provider shortages have on the psychological well being of these communities, **I would like to submit this testimony in strong support of HB 767.**

The mental health needs of individuals across our state continue to outweigh the capacity of our mental health system. I have been advocating in support of this measure for 14 years and during this time have not witnessed significant improvements in patients being able to access timely psychiatric care, particularly in rural areas of our state, but also on O'ahu where repeated referrals to multiple psychiatrists are made due to many who do not accept new patients and/or Medicaid/Medicare patients. The psychiatrists that I do know who have made themselves available in rural areas are ***severely overbooked*** and unable to provide patients the attention and connectedness they need and require in order to benefit from their services.

According to a Report on Findings from the Hawai'i Physician Workforce Assessment Project (December, 2014), physician shortages, including psychiatry, are highest in Hawai'i's rural areas. Across the different counties, in ranking order, the greatest shortage of psychiatrists is found on Maui at 41.2%, followed by Hawai'i island 39.2%, and, Kaua'i at 29.5%. According to this report, there is a 0% shortage for psychiatry on O'ahu but this doesn't take into account other aspects of accessibility including, availability (i.e., how soon and how often can a patient be seen?) and acceptability (i.e., quality of the relationship). I have witnessed all too often the suffering that persists due to individuals not being able to receive adequate psychiatric care on an outpatient basis. Psychiatrists practice in various types of health care settings, to include hospitals and residential treatment programs where the larger portion of our population does not require care, however, they do face access difficulties to receive appropriate outpatient medication management in order to maintain functioning and prevent worsening of psychological problems.

Prescriptive authority for advanced trained clinical psychologists is a *long term*, *no-cost solution* to addressing the mental health provider shortages in our state. In Hawai'i, more

people die from suicides than from motor vehicle accidents, drownings, falls, poisonings, suffocations, and homicides. From 2008-2012, there was an increasing trend in number of suicides and attempts in Hawai'i with an average of 170 deaths and 852 attempts per year. The highest reported number of deaths in a 21-year period was a mere 5 years ago in 2010 with 195 deaths (Hawai'i State Department of Health, Hawai'i Injury Prevention Plan, 2012-2017). According to this report, the most common negative life events that precede suicide are relationship issues (34%) (i.e., break up or divorce), or serious illness or medical issues (26%). Many studies show that people who commit suicide receive little or no treatment for their mental health problems due to the multiple barriers that exist (i.e., access, availability, acceptability, cost). It is not to be taken lightly that despite a 0% documented shortage of psychiatrists on O'ahu, "…65% of the O'ahu [suicide] victims had a documented history of mental illness" (Hawai'i State Department of Health, Hawai'i Injury Prevention Plan, 2012-2017, p. 34). Something does not add up here. We need any and all solutions to address the problems of accessing timely, accessible, and acceptable care across our State.

The basic argument from those who oppose this measure is that patient safety will be seriously compromised by allowing psychologists to prescribe—but after 20 years of psychologists' prescribing, this has not proven to be true. Psychologists have been prescribing in the Indian Health Service and Department of Defense for the past 2 decades. There are now **130** prescribing psychologists licensed through New Mexico and Louisiana, many of whom are serving in rural, medically underserved areas and medically underserved populations. For example, the prescribing psychologists in New Mexico have increased the number of doctoral-level trained prescribers by 100%, and increased access to care among Medicaid patients by 60%. Via personal communication with a prescribing Medical Psychologist (MP) in Louisiana, after 10 years of practice, there have been NO complaints against MP's regarding prescribing and one of the benefits of MP's is that they are able to fill in positions that have been left vacant by psychiatrists for years.

The post-doctoral, master's level clinical psychopharmacology (MSCP) training sequence proposed in HB 767 is equivalent to that of the American Psychological Association's recommendations for obtaining the requisite sequence of training and certification specific to the practice of prescribing psychotropic medication.

There are multiple safeguards imbedded in this legislation to include:

- 2 years of course work culminating in a master's degree that covers content areas essential to prescribing psychotropic medication; 400 supervised (2 hours/week), direct face-to-face hours treating a diverse population of no less than 100 patients in either inpatient or outpatient settings;
- Passing a rigorous national exam, the Psychopharmacology Exam for Psychologists (PEP);
- Required to obtain Federal DEA license;
- Required to maintain malpractice insurance;
- Required to prescribe only in consultation and collaboration with a patient's physician of record and only after a written collaborative agreement has been

signed; will not be allowed to prescribe for any patient who does not have a primary or attending physician;

- For forensically encumbered or severely mentally ill patients, a prescribing psychologist must work with the department of health psychiatrist and/or enter into a collaborative agreement with the department of health;
- Exclusionary formulary prohibiting the prescribing of schedule I-III drugs to include opiates and narcotics and no off-label prescribing for patients 17 years of age and younger; and,
- Annual continuing education requirements specific to psychopharmacology and in addition to the existing continuation requirements for licensed clinical psychologists.

For all these reasons, and most importantly, to improve the health care system for Hawaii's medically underserved areas and most vulnerable populations, I humbly ask for your support of HB 767.

Respectfully submitted,

Jill Oliveira Gray, Ph.D.
Licensed Clinical Psychologist
Direct of Training
I Ola Lāhui, Inc

kobayashi2 - Jessi

From: ralph casazza <ralphcasazza@sbcglobal.net>
Sent: Wednesday, February 1, 2017 4:26 AM
To: HLTtestimony
Subject: Psychologists RX

2/1/17

To: Representative Della Au Belatti, Chair, Representative Bertrand Kobayashi, Vice Chair, and members of the House Committee on Health
From: (your name and organization)

Re: Testimony in strong support of HB 767, Relating to Prescriptive Authority for Certain Clinical Psychologists
Hearing: Thursday, February 2, 2017, 9:30 am, Conference Room 329

Thank you for hearing HB 767, which authorizes the Board of Psychology to grant prescriptive authority to psychologists who meet specific education, training, and registration requirements. I strongly support this measure because it will help to alleviate the difficulty that people suffering from mental health problems have in accessing proper treatment and care.

Psychologists have had prescriptive authority since 1990's through the Department of Defense, and later in the Public Health Service, Indian Health Service, Guam, New Mexico, Louisiana, Illinois, and Iowa. There have been no reported adverse outcomes or malpractice complaints related to prescriptive authority for psychologists. Malpractice insurance through the APA Insurance Trust is only a few hundred dollars more for Prescribing Psychologists, which says a lot about the safe care Prescribing Psychologists offer.

The language in this measure will provide the necessary safeguards to ensure only those psychologists with appropriate education, clinical training and registration will be authorized to prescribe from a limited formulary of psychiatric medications.
Passing HB 767 will give properly trained and approved psychologists the ability to help consumers that otherwise would be unable to access the medication they need and should have a right to access. Please help us improve mental health in Hawaii by passing HB 767.

Thank you for the opportunity to submit this testimony.

Ralph E. Casazza, Ph.D.
Clinical Psychology

kobayashi2 - Jessi

From: Sharon K. Usagawa <skulcsw@aol.com>
Sent: Tuesday, January 31, 2017 10:14 PM
To: HLTtestimony
Subject: HB 767

1/31/17

To: Representative Della Au Belatti, Chair, Representative Bertrand Kobayashi, Vice Chair, and members of the House Committee on Health
From: Sharon Usagawa, LCSW (Licensed Clinical Social Worker)

Re: Testimony in support of HB 767, Relating to Prescriptive Authority for Certain Clinical Psychologists
Hearing: Thursday, February 2, 2017, 9:30 am, Conference Room 329

Thank you for hearing HB 767, which authorizes the Board of Psychology to grant prescriptive authority to psychologists who meet specific education, training, and registration requirements. I strongly support this measure because it will help to alleviate the difficulty that people suffering from mental health problems have in accessing proper treatment and care.

Over the years, it has been becoming increasingly difficult to find referrals for clients who need a proper assessment/evaluation and oversight of psychotropic medication. Due to a shortage of Psychiatrists, I am in full support of this Bill for appropriately trained Psychologists to provide this much needed service for some of our clients.

Passing HB 767 will give properly trained and approved psychologists the ability to help consumers that otherwise would be unable to access the medication they need and should have a right to access. Please help us improve mental health in Hawaii by passing HB 767.

Thank you for the opportunity to submit this testimony.

To: Representative Della Au Belatti, Chair, Representative Bertrand Kobayashi, Vice Chair, and members of the House Committee on Health

From: Charley Ice, interested citizen

Supporting HB 767 - Prescriptive Authority for Certain Clinical Psychologists
Hearing: Thursday, February 2, 2017, 9:30 am, Conference Room 329

This bill authorizes the Board of Psychology to grant prescriptive authority to psychologists who meet specific education, training, and registration requirements. Thank you for hearing the bill; I strongly support it, as it will help to alleviate difficult access to proper treatment and care for people suffering from mental health problems. It is a successful program across the country with no reported adverse outcomes related to prescriptive authority for qualified psychologists.

Psychologists have had prescriptive authority since 1974 through the Department of Defense, and later in the Public Health Service, Indian Health Service, Guam, New Mexico, Louisiana, Illinois, and Iowa. The language in this measure will provide the necessary safeguards: only those psychologists with appropriate education, clinical training and registration will be authorized to prescribe from a limited formulary of psychiatric medications.

Passing HB 767 will give properly trained and approved psychologists the ability to help consumers that otherwise would be unable to access the medication they need and should have a right to access. Please help us improve mental health in Hawaii by passing HB 767.

Thank you for the opportunity to submit this testimony.

kobayashi2 - Jessi

From: mailinglist@capitol.hawaii.gov
Sent: Tuesday, January 31, 2017 9:35 PM
To: HLTtestimony
Cc: Drshell@hawaii.rr.com
Subject: Submitted testimony for HB767 on Feb 2, 2017 09:30AM

HB767
Submitted on: 1/31/2017
Testimony for HLT on Feb 2, 2017 09:30AM in Conference Room 329

Submitted By	Organization	Testifier Position	Present at Hearing
Shelley Ham	Individual	Oppose	No

Comments: Clinical psychologists are not trained in medicine, physiology, neuroanatomy, etc and thus cannot safely prescribe medications. If they want to prescribe, they should attend medical school rather than specialize in psychology.

Please note that testimony submitted less than 24 hours prior to the hearing, improperly identified, or directed to the incorrect office, may not be posted online or distributed to the committee prior to the convening of the public hearing.

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kobayashi2 - Jessi

From: Steve Katz <steve41550@yahoo.com>
Sent: Tuesday, January 31, 2017 8:15 PM
To: HLTtestimony
Subject: Regarding prescribing psychologists

I believe that this bill should be passed because:

1. As proposed these psychologists will have far more training than most PCPs as far as prescribing drugs for mental health issues.

2. Most psychologists spend 45 minutes- one hour every time a patient visits, compared to 10-15 minutes most psychiatrists spend - more time to talk about issues effecting medication and to see how medication is working.

3. The way it is now it makes it much more difficult and expensive for a patient to see both a psychiatrist and a psychologist, when many times if the psychologist could prescribe the psychiatrist visit would not be necessary.

4. Most psychiatrists in Hawaii will not accept Medicaid; so it is very difficult for poorer patients to get the treatment they need.

Aloha, Steven P. Katz, Licensed Marriage and Family Therapist, Hawaii Kai

Steven Katz, LMFT 808-220-3625

kobayashi2 - Jessi

From: mailinglist@capitol.hawaii.gov
Sent: Tuesday, January 31, 2017 6:50 PM
To: HLTtestimony
Cc: dshoup@iolalahui.org
Subject: Submitted testimony for HB767 on Feb 2, 2017 09:30AM

HB767
Submitted on: 1/31/2017
Testimony for HLT on Feb 2, 2017 09:30AM in Conference Room 329

Submitted By	Organization	Testifier Position	Present at Hearing
David Shoup	Individual	Support	No

Comments: 1/31/17 To: Representative Della Au Belatti, Chair, Representative Bertrand Kobayashi, Vice Chair, and members of the House Committee on Health From: (your name and organization) Re: Testimony in support of HB 767, Relating to Prescriptive Authority for Certain Clinical Psychologists Hearing: Thursday, February 2, 2017, 9:30 am, Conference Room 329 Thank you for hearing HB 767, which authorizes the Board of Psychology to grant prescriptive authority to psychologists who meet specific education, training, and registration requirements. I strongly support this measure because it will help to alleviate the difficulty that people suffering from mental health problems have in accessing proper treatment and care particularly in remote areas of Hawai'l Psychologists have had prescriptive authority since 1974 through the Department of Defense, and later in the Public Health Service, Indian Health Service, Guam, New Mexico, Louisiana, Illinois, and Iowa. There have been no reported adverse outcomes or malpractice complaints related to prescriptive authority for psychologists. The language in this measure will provide the necessary safeguards to ensure only those psychologists with appropriate education, clinical training and registration will be authorized to prescribe from a limited formulary of psychiatric medications. Passing HB 767 will give properly trained and approved psychologists the ability to help consumers that otherwise would be unable to access the medication they need and should have a right to access. Please help us improve mental health in Hawaii by passing HB 767. Thank you for the opportunity to submit this testimony. David Shoup

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kobayashi2 - Jessi

From: mailinglist@capitol.hawaii.gov
Sent: Wednesday, February 1, 2017 7:07 AM
To: HLTtestimony
Cc: wrlittleford@qwestoffice.net
Subject: Submitted testimony for HB767 on Feb 2, 2017 09:30AM

HB767
Submitted on: 2/1/2017
Testimony for HLT on Feb 2, 2017 09:30AM in Conference Room 329

Submitted By	Organization	Testifier Position	Present at Hearing
Warren R. Littleford, PhD	Individual	Support	No

Comments: To: Representative Della Au Belatti, Chair, Representative Bertrand Kobayashi, Vice Chair, and members of the House Committee on Health From: Warren R. Littleford, PhD Thank you for hearing HB 767, which authorizes the Board of Psychology to grant prescriptive authority to psychologists who meet specific education, training, and registration requirements. I strongly support this measure because it will help to alleviate the difficulty that people suffering from mental health problems have in accessing proper treatment and care. I teach psychopharmacology to doctoral students in the Doctor of Behavioral Health Program at Arizona State University, and the graduates of this program are prepared to work in integrated clinics which provide mental health and primary medical care under the same roof. This represents significant progress in the delivery of comprehensive treatment services to patients. HB 767 will enable specially trained psychologists to work in these integrated settings in Hawaii. By treating mental health and medical illnesses in a coordinated fashion, patients will be healthier and they will require less expensive health care in the future. Psychologists have had prescriptive authority since 1990's through the Department of Defense, and later in the Public Health Service, Indian Health Service, Guam, New Mexico, Louisiana, Illinois, and Iowa. There have been no reported adverse outcomes or malpractice complaints related to prescriptive authority for psychologists. Malpractice insurance through the APA Insurance Trust is only a few hundred dollars more for Prescribing Psychologists, which says a lot about the safe care Prescribing Psychologists offer. The language in this measure will provide the necessary safeguards to ensure only those psychologists with appropriate education, clinical training and registration will be authorized to prescribe from a limited formulary of psychiatric medications. Passing HB 767 will give properly trained and approved psychologists the ability to help consumers that otherwise would be unable to access the medication they need and should have a right to access. Please help us improve mental health in Hawaii by passing HB 767. Thank you for the opportunity to submit this testimony.

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January 31, 2017

Hawaii State Legislature
Committee on Health
Re: Psychologist who OPPOSES HB 767 relating to granting prescriptive authority Hawaii psychologists

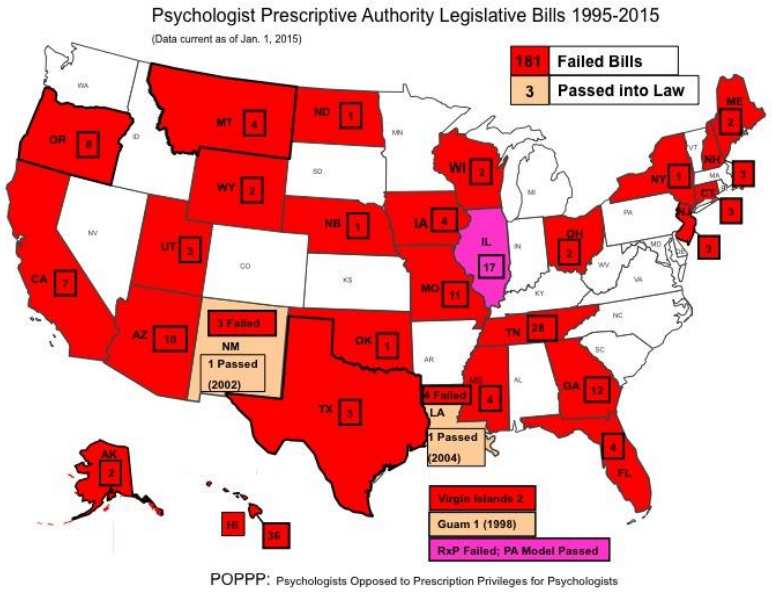
Dear Honorable Representatives:

This is individual testimony that is informed from my experience as a doctoral-level psychologist since 2002. My experience includes being a Professor of Psychology at Linfield College since 2002 and conducting research on this issue to try to understand psychologists' knowledge and views of prescriptive authority as well as psychologists' likelihood of training to pursue prescriptive authority. My opinions do not represent the College. My opinions are consistent with testimony submitted by Psychologists Opposed to Prescriptions Privileges for Psychologists (POPPP) and I am on the Board of Advisors of POPPP.

I am writing to request that you oppose HB 767 and any future initiatives that would allow psychologists to prescribe medications in Hawaii. I have been active in opposing legislation in Oregon and was a part of the team that convinced our Governor to veto a bill in 2010 that was pushed through both the house and senate in a short special session. Governor Kulongoski cited concerns about the lack of evidence to support both the safety and efficacy of such a drastic change in scope of practice. Hawaii's Governor Lingle, echoing worries about safety, cited consumer protection concerns in her rationale for vetoing Hawaii's bill nearly a decade ago. Below I detail my most serious concerns. I also reference two recent peer-reviewed articles as they contain figures demonstrating several key points of concern: failed efforts across many states that drain time and money away from real solutions to mental health problems; vast discrepancy between psychologists' preparation relative to other non-physician prescribers; lack of evidence to support arguments of improved access. I strongly believe that the stigma that surrounds mental illness serves as a more formidable barrier to accessing care than any other factor and is one that would not be addressed by establishing a lesser-trained class of psychologist prescribers. In fact, I would suggest that bills like HB 767 promulgate the stigma that those suffering from mental health problems currently face. During the legislative process, there is typically wrangling over the bare minimum training acceptable to medically treat the mentally ill. This race to the bottom echoes the message that is acceptable to provide sub-standard care to folks who suffer from mental illness. It is not. They deserve better care.

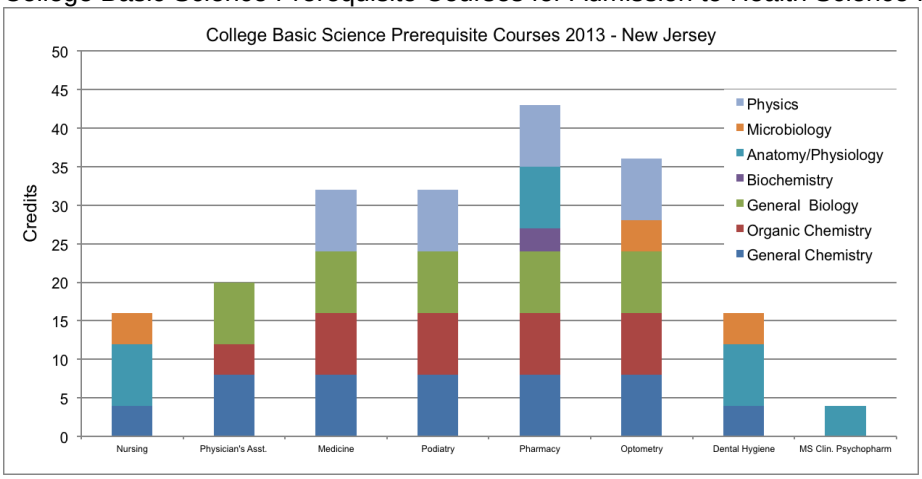
Reasons for Opposition involve Risk to the Consumer

- Bills similar to this one have been rejected over 180 times in 26 states over the past 20 years owing to substandard medical training (see Figure 1 from Tompkins & Johnson, 2016 presented below)



- Training for a doctorate in clinical psychology does not include pre-medical or medical training (see Figure 1 from Robiner et al., 2013 - psychologists are not prepared with even the most basic science courses prior to entering graduate school).

Figure 1
College Basic Science Prerequisite Courses for Admission to Health Science Programs



Note: Multiply credits by 10 for estimated hours of instruction. These data were derived by 2013 survey of admission requirements to the largest programs in New Jersey (e.g., Farleigh Dickinson University, University of Medicine and Dentistry of New Jersey, Rutgers University). Although there were no physical or health sciences prerequisites for entry into the Ph.D. programs in Clinical Psychology, both the FDU and Rutgers curriculum included one course in biopsychology or behavioral neuroscience.

- There is virtually no evidence that reducing medical training to about 10% of that required for physicians and about 20% of that required for advanced practice nurses (advanced nurse practitioners) will protect the consumer.
- 89.2% of members of the multi-disciplinary Association for Behavioral and Cognitive Therapies (ABCT) argue that medical training for psychologists to prescribe **should be equivalent to other non-physician prescribers** (*The Behavior Therapist,* September 2014). A survey of Illinois psychologists and Oregon psychologists yielded similar findings (78.6%; Baird, K. A. [2007]. A survey of clinical psychologists in Illinois regarding prescription privileges. *Professional Psychology: Research and Practice, 38*, 196-202. doi:10/1037/0735-7028.38.2.196; 69.2%; Tompkins & Johnson [2016]. What Oregon psychologists think and know about prescriptive authority: Divided views and data-driven change. *Journal of Applied Biobehavioral Research*).
- The 2014 ABCT survey found only 5.8% endorsed the effectiveness of online medical training, which is permitted in this bill and only 10.9% would refer a patient to a prescribing psychologist whose medical training is what is required in similar bills.
- Proponents claim that the lack of a reported death or serious harm by prescribing psychologists somehow provides evidence of safety. It does not! It only provides evidence that any harm done by these psychologists was not identified and reported by the psychologists themselves or their patients. A lack of evaluation of safety, and the absence of any credible, comprehensive system to identify problems, does not constitute evidence for safety. Psychologists' meager training to diagnose physical problems suggests that psychologists probably would not even know if their prescribing had caused medical problems.
- Recent data from the Part D Prescriber Public Use File (PUF) from the Centers for Medicare and Medicaid Service (CMS) suggests that some medical psychologists from Louisiana and prescribing psychologists from New Mexico have been prescribing beyond the legislative bounds of their licenses. For example, not only have they been prescribing powerful psychotropic medications (e.g., antipsychotics), but also anti-Parkinsonian agents like benztropine mesylate, likely to help control extrapyramidal disorders associated with anti-psychotic use. In addition, several classes of drugs used to treat cardiovascular disease (e.g., metropol succinate, lisinopril), neurological problems (e.g., memantine) and other systems (e.g., potassium chloride) reflect prescribing practices well beyond the competence of training (and in some cases the statutory limits of the prescribing license). Given that these data are only available for two years (2013, 2014) and only include prescriptions provided to approximately 70% of all Medicare beneficiaries it is unclear to what degree these instances of inappropriate prescribing may reflect more widespread problems with prescribing psychologists prescribing outside their bounds of competence.
- The 2014 ABCT survey found that 88.7% of psychologists agreed that there should be a moratorium on bills like this one until there is objective evidence that the training involved adequately protects consumers.
- The impact of prescribing privileges in New Mexico and Louisiana should be objectively evaluated for consumer safety before any experiment in psychologist prescribing is allowed in Idaho. Consumer safety outcome in the military is difficult to evaluate owing to the Feres Doctrine and the small number of prescribing psychologists (e.g., 2 in the Navy and 4 in the Air Force).

- Given proponents of prescriptive authority for psychologists (RxP) spent over $500,000 to pass a prescribing bill in Louisiana alone speaks to the availability of funds to conduct such a consumer safety study for the amount of medical training required in this bill.

<u>The State of Illinois has set a new and more appropriate standard for prescription privileges for psychologists</u>

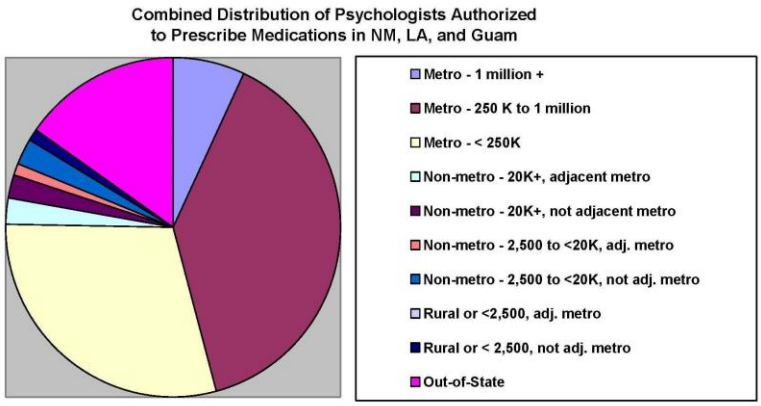
- In 2014, the State of Illinois enacted a law to permit psychologists to prescribe some psychotropic medications (e.g., excluding narcotics and benzodiazepines) to a limited population (excluding youth, the elderly, pregnant women, the physically ill, and those with developmental disabilities).
- The training requirement is similar to what is required of Physician Assistants, including completing undergraduate pre-medical science training before studying post-degree psychopharmacology. This training includes 7 undergraduate and 20 graduate courses along with a 14-month practicum in multiple medical rotations. The training program must be accredited by the Accreditation Review Commission on Education for the Physician Assistant (ARC-PA).
- No online medical training is acceptable.
- The Illinois Psychological Association, Nursing and Medical associations, and POPPP support the Illinois law, as it requires, at minimum, the same medical training as other non-physician prescribers. This is more appropriate than the APA model in that it meets an existing standard for healthcare providers, rather than establishing a new lower standard.

<u>Solutions to Access to Psychoactive Drugs</u>

<u>The stated rationale for proposing such bills is to improve access. There is NO EVIDENCE to suggest that allowing psychologists to prescribe will improve access in any meaningful way. Additionally, there are many alternatives to psychologists prescribing that more appropriately enhance access to the prescription of psychoactive medications in those individuals who would benefit from them.</u>

1. Collaboration between psychologists and physicians.
2. Completion of medical or nurse practitioner or physician assistant education by psychologists. Encouraging medical and nursing schools to offer executive track programs for psychologists.
3. Use of tele-psychiatry, which is promoted by the Department of Veterans Affairs, the military, and the U.S. Bureau of Prisons, and rural health centers, is an effective means of transcending distance between psychiatrists and patients. It is a mechanism for providing direct patient care by psychiatrists as well as a technology for providing primary care providers with appropriate consultation to develop appropriate treatment regimens, thereby extending the reach and impact of psychiatrists.
4. Encouraging all professionals to serve rural areas. The prescribing laws in New Mexico and Louisiana did not result in psychologists moving their practices to rural areas as they had declared would happen (see attached chart from Tompkins & Johnson, 2016; used with permission; no prescribing psychologists in Guam identified despite enabling legislation in 1999). A recent survey in Oregon is consistent with prior studies (94% - Baird, 2007) in showing

that the vast majority of psychologists sampled (96%) practiced in metropolitan areas and those practicing in non-metro areas were no more likely than urban psychologists to express an interest in pursuing prescriptive authority. Additionally, few (less than 7%) Oregon psychologists expressed an interest in pursuing training to become prescribers; in fact, results support prior survey results of both Oregon (Campbell et al., 2006) and Illinois (Baird, 2007) psychologists in suggesting that few have an interest in pursuing training and even fewer plan to prescribe.



*Note: There are no prescribing psychologists practicing in Guam despite legislation being passed granting prescriptive authority to psychologists in 1999.

Thank you for your kind consideration of this opinion.

Respectfully,

Tanya L. Tompkins, Ph.D.
Professor of Psychology
Linfield College

kobayashi2 - Jessi

From: Shawna Jan Allen <shawnaja@hotmail.com>
Sent: Wednesday, February 1, 2017 12:24 AM
To: HLTtestimony
Subject: Testimony from Jan Allen, MSCP

Please support HB 767! It makes sense & will provide help to those who may not otherwise receive it.Sincerely, Jan Allen, MSCP

Sent from my Virgin Mobile Android-Powered Device

kobayashi2 - Jessi

From: jcwhite54@gmail.com
Sent: Tuesday, January 31, 2017 10:35 PM
To: HLTtestimony
Subject: Prescriptive authority for psychologists

I am strongly in favor of the Hawaii legislature granti ng prescriptive authority to psychologists with advanced Rx training. There is a shortage of prescribing mental health providers statewide, but especially in the rural areas of our state, such as Kauai, where I practice.

Please pass this important piece of legislation so that all Hawaii residents can have adequate access to prescribing mental health providers.

Mahalo,

Judith C. White, Psy.D.
Clinical Psychologist, Kauai

Sent from my iPad

THE TWENTY-NINTH LEGISLATURE
REGULAR SESSION OF 2017

HOUSE COMMITTEE ON HEALTH
REP. DELLA AU BELLATI, CHAIR
REP. BERTRAND KOBAYASHI, VICE CHAIR

Re: Testimony **in support** of HB 767, Relating to Prescriptive Authority for Certain Clinical Psychologists

Hearing: Thursday, February 2, 2017, 9:30 am, Conference Room 329

February 1, 2017

Honorable Chair Bellati, Vice-Chair Kobayashi, and members of the State House Committee on Health, I am Jeffrey D. Stern, Ph.D. and I wish to submit this testimony in **strong support** of HB 767 1. This bill would allow advanced trained psychologists to prescribe and dispense medication within the scope of practice of psychology as defined by Hawai'i Law.

I support this bill for a number of reasons. In Hawai'i, there is a substantial gap in mental health care that can be safely filled by granting prescriptive authority to medical psychologists with advanced training in clinical psychopharmacology.

Psychologists have had prescriptive authority since 1974 through the Department of Defense, and later in the Public Health Service, Indian Health Service, Guam, New Mexico, Louisiana, Illinois, and Iowa. There have been no reported adverse outcomes or malpractice complaints related to prescriptive authority for psychologists.

The language in this measure will provide the necessary safeguards to ensure only those psychologists with appropriate education, clinical training and registration will be authorized to prescribe from a limited formulary of psychiatric medications.

The key issue, in my mind is access to care. This bill, if it becomes law, will increase access to care for all mentally ill and infirm patients, including those with Medicaid who have long been underserved, particularly in areas where access has been and continues to be a serious concern. Psychologists seek to provide a full range of mental health services to those unserved and underserved communities. HB 767 will expand on our ability to do exactly that, with necessary safeguards in the areas of education, training, and formulary of medications.

Thank you for the opportunity to submit this testimony.

Respectfully,

Jeffrey D. Stern, Ph.D.
Past President, Hawai'i Psychological Association

2/01/17

To: Representative Della Au Belatti, Chair, Representative Bertrand Kobayashi, Vice Chair, and members of the House Committee on Health
From: Monica Tatekawa-Chen, PsyD

Re: Testimony in support of HB 767, Relating to Prescriptive Authority for Certain Clinical Psychologists

Hearing: Thursday, February 2, 2017, 9:30 am, Conference Room 329

Thank you for hearing HB 767, which authorizes the Board of Psychology to grant prescriptive authority to psychologists who meet specific education, training, and registration requirements. I strongly support this measure because it will help to alleviate the difficulty that people suffering from mental health problems have in accessing proper treatment and care.

Psychologists have had prescriptive authority since 1974 through the Department of Defense, and later in the Public Health Service, Indian Health Service, Guam, New Mexico, Louisiana, Illinois, and Iowa. There have been no reported adverse outcomes or malpractice complaints related to prescriptive authority for psychologists.

The language in this measure will provide the necessary safeguards to ensure only those psychologists with appropriate education, clinical training and registration will be authorized to prescribe from a limited formulary of psychiatric medications.

Passing HB 767 will give properly trained and approved psychologists the ability to help consumers that otherwise would be unable to access the medication they need and should have a right to access. Please help us improve mental health in Hawaii by passing HB 767.

Thank you for the opportunity to submit this testimony.

kobayashi2 - Jessi

From: mailinglist@capitol.hawaii.gov
Sent: Wednesday, February 1, 2017 9:50 AM
To: HLTtestimony
Cc: asad@hawaii.edu
Subject: Submitted testimony for HB767 on Feb 2, 2017 09:30AM

HB767
Submitted on: 2/1/2017
Testimony for HLT on Feb 2, 2017 09:30AM in Conference Room 329

Submitted By	Organization	Testifier Position	Present at Hearing
asad ghiasuddin	Individual	Oppose	No

Comments: Dear Representative Belatti and Members, I oppose H.B. 767. As an advocate of safe patient care for everyone, especially vulnerable populations such as those with mental health concerns, I am strongly opposed to this bill as it would put patient safety at risk. Aloha, Asad Ghiasuddin MD, FAAP, FAPA

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HB767
Submitted on: 2/1/2017
Testimony for HLT on Feb 2, 2017 09:30AM in Conference Room 329

Submitted By	Organization	Testifier Position	Present at Hearing
Kenneth Hirsch, MD, PhD	Individual	Oppose	No

Dear Representative Belatti and Members

I oppose this bill because of the following three points, all referencing the requirements for the granting of prescriptive authority ("**§465- Prescriptive authority privilege; requirements.**"):

1. The justification for the bill as stated in its first line, is "…there is an insufficient number of prescribing mental health care providers available to serve the needs of Hawaii's people." The clear implication is that primary care providers lack the expertise to prescribe psychotropic medications. Yet, the requirements for supervision during the clinical training experience include specifically the same primary care providers who presumably lack the expertise to provide the care themselves.
2. The bill requires a minimum of 400 hours of clinical experience in a period of no less than twelve and no more than forty-eight months. 400 hours of clinical experience is ten weeks full time. By comparison, in Hawaii, electrician and plumber journeyman licenses require 10,000 hours experience. The Department of Defense Psychopharmacology demonstration Project, whose policies and conclusions I support, required one full year of full time clinical experience (~2,000 hours allowing for leave) under the supervision of board-certified psychiatrists.
3. The bill requires supervision of 100 patients in those 400 hours. There is no requirement that any of these patients be prescribed psychotropic or other medications. One could meet this requirement *without any prescribing experience whatever*.

Thank you for your consideration,

kobayashi1- Oshiro

From: Chuck Lepkowsky <clepkowsky@gmail.com>
Sent: Tuesday, January 31, 2017 3:16 PM
To: HLTtestimony
Subject: HB 767

1/31/17

To: Representative Della Au Belatti, Chair, Representative Bertrand Kobayashi, Vice Chair, and members of the House Committee on Health
From: Charles M. Lepkowsky, Ph.D.
Re: Testimony in support of HB 767, Relating to Prescriptive Authority for Certain Clinical Psychologists
Hearing: Thursday, February 2, 2017, 9:30 am, Conference Room 329

Thank you for hearing HB 767, which authorizes the Board of Psychology to grant prescriptive authority to psychologists who meet specific education, training, and registration requirements.

I am a licensed psychologist in private practice. Rural areas of Hawai'i are critically underserved by psychiatrists. HB 767 will provide access to psychiatric medical care for many people living in these rural areas, and increase access to care for people in suburban and urban areas.

There is precedent for psychologists prescribing psychoactive medications. Psychologists have had prescriptive authority since 1974 through the Department of Defense, and since then have been granted prescriptive authority by the Public Health Service and the Indian Health Service, the U.S. territory of Guam, and the states of New Mexico, Louisiana, Illinois, and Iowa.

There have been no reported adverse outcomes or malpractice complaints related to prescriptive authority for psychologists.

The language in this measure will provide the necessary safeguards to ensure only those psychologists with appropriate education, clinical training and registration will be authorized to prescribe from a limited formulary of psychiatric medications.

Passing HB 767 will give properly trained and approved psychologists the ability to help consumers that otherwise would be unable to access the medication they need and should have a right to access. Please help us improve mental health in Hawaii by passing HB 767.

Thank you for the opportunity to submit this testimony.

kobayashi2 - Jessi

From: mailinglist@capitol.hawaii.gov
Sent: Wednesday, February 1, 2017 11:15 AM
To: HLTtestimony
Cc: aseales@iolalahui.org
Subject: Submitted testimony for HB767 on Feb 2, 2017 09:30AM

HB767
Submitted on: 2/1/2017
Testimony for HLT on Feb 2, 2017 09:30AM in Conference Room 329

Submitted By	Organization	Testifier Position	Present at Hearing
Allison Seales	Individual	Support	No

Comments: 2/1/17 To: Representative Della Au Belatti, Chair, Representative Bertrand Kobayashi, Vice Chair, and members of the House Committee on Health From: Allison Seales, Ph.D. Re: Testimony in strong support of HB 767, Relating to Prescriptive Authority for Certain Clinical Psychologists Hearing: Thursday, February 2, 2017, 9:30 am, Conference Room 329 Mahalo for hearing HB 767, which authorizes the Board of Psychology to grant prescriptive authority to psychologists who meet specific education, training, and registration requirements. I strongly support this measure because it will help to alleviate the difficulty that people suffering from mental health problems have in accessing proper treatment and care. Psychologists have had prescriptive authority since 1990's through the Department of Defense, and later in the Public Health Service, Indian Health Service, Guam, New Mexico, Louisiana, Illinois, and Iowa. There have been no reported adverse outcomes or malpractice complaints related to prescriptive authority for psychologists. Malpractice insurance through the APA Insurance Trust is only a few hundred dollars more for Prescribing Psychologists, which says a lot about the safe care Prescribing Psychologists offer. The language in this measure will provide the necessary safeguards to ensure only those psychologists with appropriate education, clinical training and registration will be authorized to prescribe from a limited formulary of psychiatric medications. Passing HB 767 will give properly trained and approved psychologists the ability to help consumers that otherwise would be unable to access the medication they need and should have a right to access. Please help us improve mental health in Hawaii by passing HB 767. Mahalo for the opportunity to submit this testimony.

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To: Representative Della Au Belatti, Chair, Representative Bertrand Kobayashi, Vice Chair, and members of the House Committee on Health

From: Joseph E. Comaty, PhD, MP

Re: Testimony in strong support of HB 767, Relating to Prescriptive Authority for Certain Clinical Psychologists

Hearing: Thursday, February 2, 2017, 9:30 am, Conference Room 329

Thank you for hearing HB 767, which authorizes the Board of Psychology to grant prescriptive authority to psychologists who meet specific education, training, and registration requirements. I strongly support this measure because it will help to alleviate the difficulty that people suffering from mental health problems have in accessing proper treatment and care.

Psychologists have had prescriptive authority since 1990's through the Department of Defense, and later in the Public Health Service, Indian Health Service, Guam, New Mexico, Louisiana, Illinois, and Iowa. There have been no reported adverse outcomes or malpractice complaints related to prescriptive authority for psychologists. Malpractice insurance through the APA Insurance Trust is only a few hundred dollars more for Prescribing Psychologists, which says a lot about the safe care Prescribing Psychologists offer. I have personal experience in this area as I am a Medical Psychologist (prescribing) in Louisiana. The people of Louisiana have experienced increased access to much needed behavioral healthcare, especially in rural areas of the state, that was not possible 12 years ago when the prescribing law for psychologists was passed in our legislature. No one here in Louisiana has been harmed as a result of properly trained psychologists being given the authority to prescribe. Given the extensive experience with prescribing psychologists in both New Mexico and Louisiana, there is no question that these psychologists are highly trained and provide quality care with low to no risk to the public.

The language in HB 767 will provide the similar safeguards to ensure only those psychologists with appropriate education, clinical training and registration will be authorized to prescribe from a limited formulary of psychiatric medications.

Passing HB 767 will give properly trained and approved psychologists the ability to help consumers that otherwise would be unable to access the medication they need and should have a right to access. Please help us improve mental health in Hawaii by passing HB 767.

Thank you for the opportunity to submit this testimony.

LATE

kobayashi2 - Jessi

From: mailinglist@capitol.hawaii.gov
Sent: Wednesday, February 1, 2017 5:38 PM
To: HLTtestimony
Cc: michaeljlucido@yahoo.com
Subject: Submitted testimony for HB767 on Feb 2, 2017 09:30AM

HB767
Submitted on: 2/1/2017
Testimony for HLT on Feb 2, 2017 09:30AM in Conference Room 329

Submitted By	Organization	Testifier Position	Present at Hearing
Dr. Michael Lucido	Individual	Support	No

Comments: Please support this measure and consider places like Hana where there is a great need for help in psychiatric care. As a clinical psychologist with a postdoctoral degree in clinical psychopharmacology, I have over 12 years of psychological and psychiatric didactic and clinical experience, which is more education than all other professions prescribing psychotropic medications with the exception of psychiatrists. I believe Expanding the scope to specialized psychologists would lead to more psychologists to fill the need. Please support this important move for mental health access.

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LATE

kobayashi2 - Jessi

From: Michael Hand <mphand@msn.com>
Sent: Wednesday, February 1, 2017 6:04 PM
To: HLTtestimony
Subject: Prescriptive authority for apparently trained psychologists

To: Representative Della Au Belatti, Chair, Representative Bertrand Kobayashi, Vice Chair, and members of the House Committee on Health

From: Michael Hand, Ph.D., Clinical Psychologist

600 Sunland Park Drive, Building 6, Suite 100, El Paso, Texas 79912

Re: Testimony in strong support of HB 767, Relating to Prescriptive Authority for Certain Clinical Psychologists

Hearing: Thursday, February 2, 2017, 9:30 am, Conference Room 329

Thank you for hearing HB 767, which authorizes the Board of Psychology to grant prescriptive authority to psychologists who meet specific education, training, and registration requirements. I strongly support this measure because it will help to alleviate the difficulty that people suff ering from mental health problems have in accessing proper treatment and care.

Psychologists have had prescriptive authority since 1990's through the Department of Defense, and later in the Public Health Service, Indian Health Service, Guam, New Mexico, Louisiana, Illinois, and Iowa. There have been no reported adverse outcomes or malpractice complaints related to prescriptive authority for psychologists. Malpractice insurance through the APA Insurance Trust is only a few hundred dollars more for Prescribing Psychologists, which says a lot about the safe care Prescribing Psychologists offer.

The language in this measure will provide the necessary safeguards to ensure only those psychologists with appropriate education, clinical training and registration will be authorized to prescribe from a limited formulary of psychiatric medications.

Passing HB 767 will give properly trained and approved psychologists the ability to help consumers that otherwise would be unable to access the medication they need and should have a right to access. Please help us improve mental health in Hawaii by passing HB 767.

Thank you for the opportunity to submit this testimony.

LATE

My name is Zachary Callaghan and I have worked at Kahi Mohala Behavioral Health for the past six years and will graduate from the MSW program at UH Manoa. I am for H.B. No. 767, "RELATING TO PRESCRIPTIVE AUTHORITY FOR CERTAIN CLINICAL PSYCHOLOGISTS".

I recommend:

-Providing financial incentive for psychologists practicing psychopharmacology in rural communities in the State of Hawaii.

-Beginning a Post-graduate psychopharmacology program for psychologists within the University of Hawaii system.

I have several concerns regarding the bill. First, there is a dear need for mental health services to the severely mentally ill in rural communities. I have met people required by conditional release to travel far, daily, for services. Not all with these illnesses are capable of using public transportation, so that population receives no help. Versions of this bill have worked elsewhere, so it behooves us to try it here in Hawaii.

At present, there are no colleges in the Hawaii that offer the education required to obtain this license. This means that psychologists in Hawaii would need to leave the state to obtain education. Otherwise, prescribers from other states would have to relocate to Hawaii. One wonders how many current residents would leave the state for elsewhere to achieve licensure. Some also worry that those not familiar with our culture will be ineffective. However, this does not preclude that effective practitioners from other states could learn about Hawaii's cultures and history and gain an understanding of the generational trauma that tends to surround our rural communities.

Another concern is that psychiatrists are largely unwilling to relocate their services to rural communities and subsequently stay in Honolulu. So, one worries that the psychologists are also unwilling. It seems reasonable that offering similar incentives that were once offered to psychiatrists for the same end be offered to psychologists as well.

H.B. No. 1272 is a coy way of reacting to H.B. No. 767 by allowing psychiatric services be offered via telehealth. A worry I have is that one may not be able to observe all that is going on with the client. If the client cannot access video means of conferencing with a psychiatrist, much can be missed in assessing the client's current state. It is a way to compensate for a lack of care, but short-changes the clients served. Physical presence is more reliable for the client, especially if they are hallucinating and/or paranoid. Many clients are untrusting of technology, let alone knowing how to use it. Person-to-person contact is preferable, and this bill offers a means to provide that.

Although there are loose ends to mend, I agree with approving this bill, as those loose ends are not fatal to it. In the future, programs can be started to improve delivery, like having education in Hawaii for prescribing rights. For now, there are psychologists in the country that have licensure to prescribe psychotropic medication that could utilize this bill's passing. Psychiatrists have not answered this need, and psychologists, doctors in their own right, are capable of delivering this service.

Thank you for your time and consideration,

Sincerely,

Zachary Callaghan

kobayashi2 - Jessi

From: mailinglist@capitol.hawaii.gov
Sent: Thursday, February 2, 2017 12:19 AM
To: HLTtestimony
Cc: rkmasa@gmail.com
Subject: Submitted testimony for HB767 on Feb 2, 2017 09:30AM

LATE

HB767
Submitted on: 2/2/2017
Testimony for HLT on Feb 2, 2017 09:30AM in Conference Room 329

Submitted By	Organization	Testifier Position	Present at Hearing
rika suzuki	Individual	Oppose	No

Comments: Dear Representative Belatti and Members, I oppose H.B. 767. As an adult and geriatric psychiatrist, I strongly believe that prescribing expertise is a responsibility that requires a medical training (MD). Improved access to mental health care can be achieved by implementing telepsychiatry in and across more of our clinics and via collaborative care models in which primary care MDs consult psychiatrists, for example. These have been proven to be effective, efficient, and most importantly, SAFE strategies to assist more patients more quickly. Please vote NO on a bill that puts our patients at any unnecessary medical risk.

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LATE

kobayashi2 - Jessi

From: Peter Smith <psyd0905@gmail.com>
Sent: Wednesday, February 1, 2017 9:22 PM
To: HLTtestimony
Subject: Mental Health of America of Hawaii's RxP bill (HB 767)

02/02/17
To: Representative Della Au Belatti, Chair, Representative Bertrand Kobayashi, Vice Chair, and members of the House Committee on Health

Peter Smith Psy.D. - Maryland Academy of Medical Psychologists

Re: Testimony in strong support of HB 767, Relating to Prescriptive Authority for Certain Clinical Psychologists

Hearing: Thursday, February 2, 2017, 9:30 am, Conference Room 329

Thank you for hearing HB 767, which authorizes the Board of Psychology to grant prescriptive authority to psychologists who meet specific education, training, and registration requirements. I strongly support this measure because it will help to alleviate the difficulty that people suffering from mental health problems have in accessing proper treatment and care.

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The language in this measure will provide the necessary safeguards to ensure only those psychologists with appropriate education, clinical training and registration will be authorized to prescribe from a limited formulary of psychiatric medications.

Passing HB 767 will give properly trained and approved psychologists the ability to help consumers that otherwise would be unable to access the medication they need and should have a right to access. Please help us improve mental health in Hawaii by passing HB 767.

Thank you for the opportunity to submit this testimony.

Peter Smith PsyD - President MAMP
Marla Sanzone Ph.D. MP - Dean MAMP
Samuel Dutton Ph.D. MP - Provost MAMP

LATE

kobayashi2 - Jessi

From: mailinglist@capitol.hawaii.gov
Sent: Wednesday, February 1, 2017 10:11 PM
To: HLTtestimony
Cc: lenora@hawaii.edu
Subject: Submitted testimony for HB767 on Feb 2, 2017 09:30AM

HB767
Submitted on: 2/1/2017
Testimony for HLT on Feb 2, 2017 09:30AM in Conference Room 329

Submitted By	Organization	Testifier Position	Present at Hearing
Dr. Lenora Lorenzo	Individual	Support	No

Comments: I speak in support of HB 767 regarding Psychologists Prescribing Authority. Our ohana in our islands, particularly the neighbor islands and rural areas are unable to see psychiatric prescribers due to insufficient psychiatrist providers and or psychiatrist who do not accept Medicaid/Quest insurance. This is very problematic access issue. The trained and educated psychologist can help us to meet this access issue in a safe, cost effective and timely manner. The education, training, certification examination and supervisory period with the primary care provider (PCP) or psychiatric specialist (physician or APRN) and ongoing collaborative agreement with primary care provider will support our psychologist to deliver both the psychotherapy and pharmacology therapy safely and effectively. I am not in favor of using a prescribing psychologist for supervision, because the medical health care clinical supervision would be missing and could pose concerns for best care and public safety. Health care is changing such that all health care providers should be collaborating and working together for best practice and best outcomes. An ongoing collaborative agreement with the PCP is imperative to support the prescribing psychologist and ensure best practice care for our ohana. Mahalo for your support of this important measure, O au me ka ha`a (I am humbly yours), Lenora Lorenzo DNP, APRN, BC FNP, GNP, ADM, CDE, FAANP University of Hawai'i SONDH Faculty Hawai'i Association of Professional Nurses Treasurer American Association of Nurse Practitioners Hawai'i State Representative

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kobayashi2 - Jessi

From: mailinglist@capitol.hawaii.gov
Sent: Thursday, February 2, 2017 4:04 AM
To: HLTtestimony
Cc: drkeith1@verizon.net
Subject: Submitted testimony for HB767 on Feb 2, 2017 09:30AM

LATE

HB767
Submitted on: 2/2/2017
Testimony for HLT on Feb 2, 2017 09:30AM in Conference Room 329

Submitted By	Organization	Testifier Position	Present at Hearing
Keith Petrosky PHD	Individual	Support	No

Comments: HB767 will give properly trained psychologists the ability to help consumers that otherwise would be unable to access the medications they need and should have a right to access. Please help improve mental health in Hawaii by passing HB767. Properly trained psychologists have been safely prescribing medication for more than 17 years. During this time not a single patient has been harmed and many millions of patients have been helped. Despite these wonderful results psychologists need approval to do this on a state by state basis. This is your chance to add the state of Hawaii to the list of United States states and territories that have already passed this legislation. This legislation was already passed in your state before but was then vetoed by the politically motivated governor of your state at that time. Please put politics aside and do what is right for the people. The people are fed up with government gridlock. Please DO WHAT IS RIGHT FOR THE UNITED STATES CITIZENS WHO OCCUPY YOUR STATE!

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D. DOUGLAS SMITH, M.D.
229 Aiokoa Street
Kailua, Hawaii 96734

LATE

February 2, 2016 at 9:30 AM

Room 329

To: COMMITTEE ON HEALTH
Chair Della Au Belatti
Vice Chair Bertrand Kobayashi

From: D. Douglas Smith, M.D.

Re: HB 767, Relating to Prescriptive Authority for Certain Psychologists

IN OPPOSITION

I would like to thank Chair Belatti, Vice Chair Kobayashi , and members of the House Committee on Health for the opportunity to submit comments on HB767.

I am a physician who specializes in psychiatry and have spent my career practicing in Hawaii. For 11 years I was on the faculty of the JABSOM department of psychiatry and much of that time I coordinated psychopharmacology training for resident physicians.

I am opposed to this bill, urge you to either overhaul it with extensive amendments to include all reasonable safeguards, or to vote to defer this bill.

There are several reasons why this bill, however well intended would be bad law. Few doubt that Hawaii's health plan networks lack adequate access to mental health professionals, both psychologists and psychiatric physicians, in rural and underserved communities across the state. This has limited access to safe and effective care, particularly on the outer islands. The stated purpose of HB767 is to fix this.

Unfortunately, The bill's primary impact would be on Oahu, not the neighbor islands. The bill's low training standards are unsafe given the broad formulary and scope of practice it would allow. The bill would place considerable logistical and liability burdens on the Department of Health, exposing the State to forseeably large claims. The bill is dismissive of the extensive medical education and training of psychiatric physicians. Its passage would demoralize this critical part of the healthcare workforce, making it harder to recruit and retain psychiatrists in Hawaii. HB767 would disrupt, distract and divide the mental health community at a time when teamwork and collaboration are desperately needed to adopt proven solutions to improving access to safe mental health care. The controversial nature of HB767 poses significant political risks if those who vote for its passage are later held to account for any failure to fix the access to care problem, any new problems it creates, any harms to patients and any liabilities to the state or other entities.

For committee members hoping to be better informed about these matters, I have expanded upon this testimony at length, and attached relevant reports and documentation. Please contact me if I can be of assistance.

1. HB767 IS NOT A NEIGHBOR ISLAND BILL

Star Advertiser reporter, Kevin Dayton, described this proposal as "a measure that will allow specially trained psychologists to prescribe certain medications for people with mental illnesses on the neighbor islands." This is a basic misunderstanding of where in the islands this bill would have the most impact. This proposal is not in any way limited to the neighbor islands, and available evidence suggests its primary impact will be on Oahu. For example, out of the 78 prescribing psychologists practicing in Louisiana, between 91% and 97% practice in urban and suburban areas. The same pattern is seen in New Mexico, the only other state with experience of prescribing psychologists. HB1072 is not primarily an outer island bill. Even though supporters admit there is no shortage of psychiatric physicians on Oahu, this is where this bill will have the greatest impacts, for better or worse.

2. HB767 IS NOT A SAFE SOLUTION

The small number of influential psychologists who have been supporting this bill have made misleading claims about safety. First, they have argued that since a Department of Defense (DoD) pilot program was found to be safe in the 1990's, what is being proposed will be safe too. Second, they have misrepresented the MSCP training as rigorous, high quality and on par with other prescribers such as APRN's. Third, they have repeatedly claimed that there have been no adverse events or complaints against the psychologists who have prescribed drugs in Louisiana and New Mexico. The first two claims are misleading, and the second claim is clearly false.

The first misleading safety claim is that the MSCP training allowed under HB767 would be safe because "the DoD-PDP training model and standards were studied and shown to be safe and effective". This safety claim provides a superficial veneer of legitimacy by failing to point out that HB767 lacks the formulary and scope of practice limitations applied to prescribing psychologists by the DoD-PDP program, as well as its required minimum classroom and clinical training requirements and rigor. The DoD-PDP standards and safeguards are well documented the published data about the program. Concerns about crash course prescribing bills that omit these important standards and safeguards and have been raised repeatedly for over a decade. For example, after and extensive review of this issue in 2007, the Hawaii Legislative Reference Bureau's 104 page report concluded:

> *If the Legislature deems it appropriate to authorize prescriptive authority for qualified clinical psychologists who practice in community health centers, the Legislature may wish to consider requiring a training model that requires minimum classroom and clinical training requirements no less rigorous than the PDP program training model and a scope of practice and formulary for graduates that is no broader than limitations applied to PDP program graduates.*
>
> *Regardless of the approach or solutions adopted to increase access to mental health services for the medically underserved population, it is clear that patient safety cannot be compromised. Patient safety should guide the Legislature's decision on the issue of prescriptive authority for qualified clinical psychologists under limited circumstances.*

By any objective measure, HB767 and similar bills over many years have not met the LRB's common-sense safety standard, nor its more detailed recommendations (see attachment). For example, HB767 would allow psychologists with no clinical experience evaluating or treateing children with psychological or pharmacologic interventions to prescribe drugs to children. The same goes for prescribing drugs to teens, elderly, the medically-ill and the severely mentally-ill.

The bill's lack of so many common-sense safeguards is of great concern and is it has been referred to as "crash course prescribing". Whatever one calls it, one thing is clear. It is not fair, modest or accurate to glossing over the omission of these critical standards and safeguards in comparing the requirements of HB767 to those of the more rigorous and cautious DoD-PDP program.

The second safety claim is that the MSCP training endorsed by HB767 would be on par with other prescribers such as APRN's with prescriptive authority. This is not true because HB767 allows a broader formulary than for APRN-Rx, and its required minimum classroom and clinical training requirements are much less rigorous. Compared to the APRN-Rx standards for faculty, admission requirements, curriculum, and supervision, the MSCP program falls woefully short (see attachment for details).

For example, consider the basic and preclinical science curriculum of 9 semester hours allowed for a prescribing psychologist vs 27 semester hours required for an APRN-Rx. MSCP psychologists are provided just 6 semester-hours of recorded lectures on biochemistry and a 3 semester-hour taped class on human anatomy and physiology combined with microbiology ('1' = one semester-hour):

111111111 – MSCP psychologist (9)

111111111111111111 – BSN-RN (21 non-prescribing)

111111111111111111111111 – APRN-Rx (27)

111111111111111111111111111111111111111111 – MD (45)

In terms of the formulary, APRN-Rx are prohibited from prescribing controlled drugs, but under HB767 would allow psychologists to prescribe amphetamines and other stimulants for the treatment of attention deficit hyperactivity disorder (ADHD).

The third false claim is perhaps the boldest of all, and it's right there in the preamble of HB767, "There are approximately one hundred thirty psychologists with prescriptive authority in Louisiana and New Mexico. Furthermore, there have been no adverse events or complaints brought against any of these prescribing psychologists regarding their practice." This is a startling claim to make for any medical provider who has prescribed medications for any length of time, especially psychiatric drugs that carry significant risks for side-effects and serious adverse events even in the best of hands. It is baffling that psychologists would spread such a rosy sounding falsehood. This suggests either a worrisome naivete and lack of clinical judgment or a conscious desire to mislead others.

In the two states that have allowed psychologists to prescribe, have there been adverse events and complaints? Yes, of course. Undoubtedly, there have been many, many such adverse outcomes and complaints, many more that get reported formally. This is the case with all prescribers, particularly those who treat individuals who may be mentally vulnerable and unable to advocate for themselves. Absent a formal study of the matter, it is difficult to quantify the number and severity of these incidents. There have, however, been anecdotal reports of severe incidents, including a 2014 firearm tragedy that made national news involving a young district attorney in New Mexico, with no apparent history of mental illness, who developed severe side-effects and psychosis from a mixture of a stimulating antidepressant and an amphetamine given to him by a prescribing psychologist for the treatment of ADHD. Available information suggests that as the adverse event slowly escalated over a 3-4 month period, the psychologist was unable to recognize it and safely manage the patient's condition and medications (see attachment).

3. HB767 WOULD PUT THE DEPARTMENT OF HEALTH AT RISK

The main "safeguards" in bill is that psychologists who are granted prescriptive authority would have to work in collaboration and consultation with licensed physicians, and with employed physicians at the Department of Health for patients who are forensically encumbered or diagnosed with serious mental illness. These would be the most complex, vulnerable and highest risk patients.

The fact is, collaborating physicians, employers, health facilities, credentialing bodies and health plans would shoulder the burden of ensuring that prescribing psychologists have had sufficient education, training and supervised clinical experience for their practice activities. This is likely to increase medical liability and malpractice costs for these collaborating physicians and entities. If any of them to perform its due diligence in providing clinical oversight or in reviewing a prescribing psychologist's qualifications for the practice being approved, facilitated or permitted, they will be liable for any harms.

The State's assumption of this shared risk with community practitioners would be an unprecedented arrangement, creating a risk-management minefield in which DOH physicians would be expected to collaborate with these poorly trained psychologists in the care of the highest risk patients and to guard both patient and public safety.

The lack of safeguards in HB767 regarding proper standards for education, training and clinical supervision standards, combined with its reliance on collaboration, would make it a ticking risk-management time-bomb for the state's budget and reputation. It will expose the deep pockets of the self-indemnified DOH (i.e. taxpayers of Hawaii) to any plaintiff with severe mental illness who is harmed under HB767's reckless scheme. Last year alone, the legislature had to approve $11 million to resolve claims against the state. Just think what one tragedy like the FSU shooting could cost.

The only way to reduce these risks to amend HB767 to include higher training standards, a narrower drug list and limited range of patients similar to the Department of Defense program, and as recommended by the Hawaii Legislative Reference Bureau back in 2007 (see attachment). Supporters of psychologist prescribing in Hawaii have had 10 years to adopt these common-sense safeguards, but have failed to do so.

4. HB767 WOULD MAKE IT HARDER TO RECRUIT AND RETAIN WELL-TRAINED PSYCHIATRIC PHYSICIANS IN HAWAII

Rather than responding to the many genuine concerns about their reckless proposal with reason and facts, the few Hawaii psychologists pushing for crash course prescribing have focused primarily on discrediting and marginalizing opponents. Over many years, detailed criticisms and inconvenient facts about this reckless proposal have been repeatedly brought to their attention, and they have have doubled down with the misleading claims that "organized medicine (has) conjured up as many misleading and false arguments as possible to block this proven initiative."

They have insisted that psychiatric physicians are responsible to for the failure to improve access to care over the years, and have repeatedly disparaged psychiatric physicians as dishonest and unconcerned about patient suffering. Misleading legislators, concerned advocates and the general public with demonstrably false and misleading claims, ignoring valid concerns and unfairly blaming physicians may be good political strategy, but it has done great damage our mental health community over the past 30 years. It should be pointed out that this conduct is strictly prohibited under Hawaii Law:

> *Modesty, scientific caution, and due regard for the limits of present knowledge shall characterize all statements of psychologists who supply information to the public, either directly or indirectly. Psychologists who interpret the science of psychology or the services of psychologists to clients or to the general public have an obligation to report fairly and accurately. Exaggeration, sensationalism, superficiality, and other kinds of misrepresentation shall be avoided.*
>
> *(Hawaii Administrative Rules TITLE 16 - CHAPTER 98 - PSYCHOLOGISTS).*

The fact is, "organized psychiatry" is not the problem. Hundreds of dedicated psychiatric physicians are working hard every day helping individuals across the state who struggle with our most complex and challenging biopsychosocial problems. HB767 would communicate, loud and clear, to psychiatric physicians that their years of medical education, training, and supervised practice are not respected or valued here in Hawaii. It is possible that the net impact on qualified prescribers will be negative by pushing more medical students to choose other careers, and practicing psychiatrists to take jobs elsewhere, leave the state or retire. Continuing to marginalize and exclude the state's largest and most qualified resource when we are facing a shortage is not a winning strategy. HB767 would drive a permanent wedge between psychologists and psychiatrists when their cooperation is needed more than ever.

5. HB767 DISRUPTS & DISTRACTS FROM SAFE AND EFFECTIVE SOLUTIONS

The supporters of psychologist prescribing have convinced lawmakers and advocates that "organized psychiatry" has shirked their duty to fix the access to care problem. As the state psychological association's executive director said last year:

Organized psychiatry has promised - primarily in years when a psychology prescribing bill is introduced in the legislature - to address the access to care problem in Hawai'i's rural, medically underserved areas, but they have ignored their promises or have come up with short-lived solutions that have ended in failure.

It is misleading to claim that Hawaii's psychiatric physicians, beyond their own clinical practice, are responsible for adopting needed mental health policy reforms and for providing the necessary funding, oversight, enforcement to implement them. Let's be clear: psychiatric physicians have received no special funding or legal authority to make the types of system reforms necessary to improve access to care.

The sad irony is that putting the blame on psychiatric physicians for the repeated failure of crash course psychologist prescribing and for the failure to implement safe and effective reforms to improve access to care has tended to marginalize them further. This is seen in the way lawmakers, state agencies, private organizations, committees and task forces focused on improving access to care have not reached out to partner with state psychiatric association or community psychiatrists. This stigma is demoralizing to many psychiatric physicians, especially when they are then painted as responsible for solving the access problem all by themselves and failing to do so.

The important question is this. If "organized psychiatry" is not responsible for fixing the access problem on their own, is there anyone who is? The answer is yes.

Within our fragmented, privatized healthcare system, neither doctors, patients, nor lawmakers are responsible for ensuring access to care in underserved areas, nor have they been given the resources or authority to do so. In fact, Hawaii's regulated health plans are legally responsible for maintaining adequate provider networks, and for the apparent failure to do so. These plans have the sophisticated state-wide systems of command and control, expertise in health care operations necessary to improve access to care, and ample resources to do so, including combined revenues in excess of $6 billion per year.

For example, Optum-UnitedHealthCare and Ohana-Wellcare, for-profit corporations based in Minnesota and Florida, took in over $177 million more in combined annual revenue here in Hawaii than claims paid in 2013. This could have paid for over 800 more psychiatrists for Hawaii, more than four times the number currently in practice, and that is for just two of our Medicaid plans.

Managed health care plans in Hawaii can greatly improve the adequacy their provider networks, including psychiatric physicians and APRNs. There are numerous and opportunities to increase participation rates, to recruit and retain qualified providers, to properly train more providers, to improve the efficiency of care, and to improve member health and reduce unnecessary demand for services (see attachment). Unlike HB767, most of these approaches will not just improve access to psychiatrists, but also to primary and other medical specialty care.

Let's be clear about who is responsible for ensuring access to mental health care in Hawaii. All health plans in the state have made legal promises to provide an adequate network of clinicians to properly care for all members assigned to them and for whom they have received and accepted payments – including members with mental health

needs in rural and underserved areas. For example, all MedQuest plans are required to provide access to behavioral health care:

> HAR 17-1735.2-4 (b)
>
> *[MedQuest plans shall include] development and maintenance of a sufficient network of health care providers to ensure the provision of required health services are provide to an eligible individual in a timely manner.*

> RFP–MQD–2014-005
>
> *The health plan shall have an established provider network that meets the requirements of this RFP at the time of proposal submission for all primary care, acute care, behavioral health and long-term care services including nursing facilities and home and community-based services providers. The health plan is solely responsible for ensuring it: (1) has the network capacity to serve the expected enrollment in the service area; (2) offers an appropriate range of services and access to preventive, primary, acute, behavioral health, and long-term services and supports (LTSS); and (3) maintains a sufficient number, mix, and geographic distribution of providers of covered services.*

Similar requirements are also present in other State and Federal laws governing commercial health plans and Medicare Advantage plans (HRS 432-F(2), 42 C.F.R. 438.206, CMS Medicare Managed Care Manual, etc...)

The common-sense policy solution to the lack of access problem is to compel our health plans to finally dedicate themselves to meeting their obligations rather than blaming others and making excuses. To make this happen, advocates and officials need to stop turning a blind eye to start insisting on proper monitoring and enforcement of existing laws and contracts.

There are two Network Adequacy bills before the legislature this year (HB914 and SB387) that promise to help Hawaii better focus on who is responsible and what needs to be done to improve access to mental health care.

There are also two other legislative options for providing to the same level of healthcare to rural patients with chronic diseases as can be obtained in an urban setting. Both involve educating, training, and supporting rural primary care practices. HB1272 would expand Medicare's recent support for Psychiatric Collaborative Care to the state's MedQuest program. SB1045 would allow the department of health to implement and administer an ECHO program.

We need to pass these measures rather than blaming "organized psychiatry" and being distracted by risky, divisive and inadequate proposals.

6. HB767 POSES SIGNIFICANT POLITICAL RISKS

Given the controversial nature of HB767, its passage will not go unnoticed. Both supporters and opponents are tracking the votes of legislators are being noted for future account-

ability. The risk of voting against this bill yet again are that 10-20% of psychologists will be upset, along with Senator Baker and other supporters, but they are unlikely to retaliate because of the need for support for future passage. The risks of voting to pass the bill include being held responsible, perhaps for years, for any resulting harms to individual patients, any lawsuits against state agencies, any worsening of the split in the mental health community, any exodus of psychiatric physicians, or any failure to solve the access crisis, the suffering on outer islands and the many $millions in costs shifted on to the state budget. If HB767 is passed as is, there will be no way undo having voted for a bad law and any fallout that comes with it, making avoidance of long-term political risk very unlikely.

RECOMMENDATIONS

Lawmakers can reduce these six areas of risk by avoiding taking sides and by minimizing future harms to public health and the state budget:

1. Insist that HB767 be amended to adopt the LRB's recommended safeguards from the best studied prescribing psychologist regime – the DoD-PDP (see attachment). If this is not agreeable to supporters, the bill should be deferred.
2. Commit to support the monitoring and enforcement of legal standards for health plan network adequacy so that health plans are compelled to begin using their massive resources to implement safe, effective and sustainable strategies to improve access to care.
3. Support collaborative approaches that are non-divisive and that have been proven to be safe in published studies.

Thank you for allowing me to testify on HB 767, and your consideration of these concerns is appreciated.

Sincerely,

D. Douglas Smith, M.D.

PRESCRIPTIVE AUTHORITY FOR PSYCHOLOGISTS: ISSUES AND CONSIDERATIONS

LYNN MERRICK
Research Attorney

Report No. 2, 2007

Legislative Reference Bureau
State Capitol
Honolulu, Hawaii 96813

http://www.hawaii.gov/lrb/

FINDINGS AND SUMMARY

A need to increase access to mental health services statewide, particularly for the medically underserved population, is acknowledged by clinical psychologists, psychiatrists, community health centers, other health care providers, state agencies, and consumers. After a two year study, SHPDA will submit its final report to the 2007 regular session of the Legislature, identifying barriers and offering solutions to increase access to specialty health care, including mental health services, to those in medically underserved areas. Given SHPDA's expertise as the State's health planning agency, their suggestions to increase access to health care deserve serious consideration by the Legislature.

Whether prescriptive authority for certain qualified psychologists who practice in community health centers is an appropriate approach to increasing mental health services for medically underserved areas and populations is a policy decision for the Legislature. The Bureau makes no recommendation on the issue, but notes that only one training model has been evaluated and found to have successfully trained postdoctoral clinical psychologists to prescribe psychotropic drugs for patients with mental illness, the PDP program. The PDP program included the following requirements or factors:

1. A one year full time classroom training at a university that included medical science courses and courses tailored to participants needs;
2. A one year full time clinical training at a medical center that included inpatient and outpatient experience and supervision by psychiatrists, and a wide range of health care professionals, labs, and other equipment available in close proximity;
3. All participants had doctoral degrees in psychology and at least some years of clinical experience before entering the PDP program;
4. Development of the PDP training model and curriculum had input from psychologists, psychiatrists, representatives of American Association of Medical Colleges, the Accreditation Council for Graduate Medical Education, the medical school of the Uniformed Services University of Health Sciences, and the Walter Reed Army Medical Center;
5. The success of PDP graduates suggested that candidates for any similar training program, whether military or civilian, should be held to high selection standards; several years of clinical experience was also suggested;
6. Patients treated were generally limited to outpatients between the ages of 18 to 65, without serious medical conditions or serious mental illnesses;
7. Drugs prescribed were limited to psychotropic medications and adjunctive drugs;
8. Graduates received supervision by psychiatrists during their initial postgraduate medical facility assignment; and
9. Health care in military medical facilities is reported to be an open, collaborative practice that permits ready access to patient information and consultation with other health care providers.

In addition, in any deliberation of whether to authorize prescriptive authority for qualified psychologists who practice in community health centers, legislators also should include consideration of the following caveats:

10. Only two states have authorized certain psychologists to prescribe and little evaluative data from these states has been reported because those laws are very new;
11. Prescribing psychologists in New Mexico and Louisiana are in private practice in the civilian sector which does not provide the collaborative approach to medicine in which PDP participants trained and practiced; patient safety has not been established for this type of practice for which there is no "safety net;"
12. In contrast to patients treated by PDP graduates, clients who need mental health services at Hawaii community health centers include children and seniors and persons having both a serious mental illness and a serious medical condition;
13. There is no program that authorizes psychologists to prescribe psychoactive medications for children or seniors that has been evaluated or determined to be safe;
14. Unlike the development of the PDP training model and curriculum, the American Psychological Association training recommendations were developed solely by psychologists;
15. Current psychopharmacology training programs that authorize online learning, weekend classes, and optional clinical experience are considerably less rigorous than the PDP training model, and there are significant variations between the various programs;
16. No current psychopharmacology training programs appear to offer specialized training on the effects of medication on children and seniors;
17. Admission into current postdoctoral psychopharmacology programs require only a doctoral degree in psychology and a current state license to practice psychology; these minimal requirements do not establish the high selection standards suggested by the ACNP evaluation panel or the minimum two year clinical experience recommended by the Advisory Council;
18. In contrast to admission requirements for psychopharmacology training programs, an applicant to a psychiatry residency is subject to stricter scrutiny; a personal statement, recommendation letters, transcripts from undergraduate and medical school, and a personal interview are minimum requirements;
19. The Advisory Council to the PDP program recommended that applicants to the program should have a minimum of 2 years experience as a clinical psychologist;
20. No postdoctoral training program in psychopharmacology that meets the APA training recommendations has been externally evaluated and deemed successful; and

21. There is no postdoctoral training in psychopharmacology for clinical psychologists in Hawaii that has high selection standards to choose participants or that meets the classroom and clinical training requirements of the PDP program.

If the Legislature deems it appropriate to authorize prescriptive authority for qualified clinical psychologists who practice in community health centers, the Legislature may wish to consider requiring a training model that requires minimum classroom and clinical training requirements no less rigorous than the PDP program training model and a scope of practice and formulary for graduates that is no broader than limitations applied to PDP program graduates.

Regardless of the approach or solutions adopted to increase access to mental health services for the medically underserved population, it is clear that patient safety cannot be compromised. Patient safety should guide the Legislature's decision on the issue of prescriptive authority for qualified clinical psychologists under limited circumstances.

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HB767 - ANALYSIS OF PROPOSED STANDARDS & SAFEGUARDS

In 2006-2007, the Hawaii Legislative Reference Bureau (LRB) conducted an impartial review of the psychologist prescribing issue. The LRB's detailed 100 page report made no recommendation on the final question, but noted that only one training model has been evaluated and found to have successfully trained postdoctoral clinical psychologists to prescribe psychotropic drugs for patients with mental illness, the 1990-1997 Department of Defense PDP program (DoD-PDP). The Bureau's final recommendation was:

> If the Legislature deems it appropriate to authorize prescriptive authority for qualified clinical psychologists who practice in community health centers, the Legislature may wish to consider requiring a training model that requires minimum classroom and clinical training requirements no less rigorous than the PDP program training model and a scope of practice and formulary for graduates that is no broader than limitations applied to PDP program graduates.
>
> Regardless of the approach or solutions adopted to increase access to mental health services for the medically underserved population, it is clear that patient safety cannot be compromised. Patient safety should guide the Legislature's decision on the issue of prescriptive authority for qualified clinical psychologists under limited circumstances.

The primary question for policy makers should be, "How close does the process proposed under HB767 come to meeting the LRB's recommended requirements for (A) clinical training, (B) scope of practice, (C) medication formulary and (D) patient safety?" Another question of importance is (E) "Does HB767 have any budgetary implications or other risks?"

A. PROPOSED TRAINING AND SUPERVISION REQUIREMENTS ARE INADEQUATE

The LRB recommended that the Legislature require a training model with minimum classroom and clinical training requirements no less rigorous than the PDP program training model. How close does the process proposed under HB767 come to meeting the LRB's recommended requirements for clinical training?

As noted by the LRB, the Department of Defense PDP training program included the following four requirements or factors:

1. Curriculum: PDP students had one to two full-time years of classroom training in the basic and preclinical biomedical sciences, and one year of full-time clinical training at a medical center that included inpatient and outpatient experience. This totaled 2-3 calendar years of

full-time study. The PDP training model and curriculum was designed and approved not just by psychologists, but also by psychiatric physicians, representatives of American Association of Medical Colleges, the Accreditation Council for Graduate Medical Education, the medical school of the Uniformed Services University of Health Sciences, and the Walter Reed Army Medical Center.

Graduates of the apparently defunct University of Hawaii at Hilo Masters of Science in Clinical Psychopharmacology (UHH-MSCP) and Argosy University MSCP programs did not require applicants to demonstrate passing grades in any of the usual prerequisite courses or labs in basic foundational sciences, and instead claimed to provide students with equivalent basic science and preclinical biomedical education in a fraction of the time. At the UHH-MSCP program, listening to recorded lectures was the primary teaching method. The program told applicants, "As a distance learning online program, we offer flexible scheduling to ensure that your education does not impair your current work schedule."

In terms of biomedical science, UHH-MSCP applicants were not required to have completed any of the standard courses or labs for science majors. Instead, the psychologists were provided 6 semester-hours of recorded lectures on biochemistry, as opposed to the standard 21 semester-hours of general, organic and biochemistry required for other students at the College of Pharmacy. The psychologists received just a 3 semester-hour taped class combining human anatomy & physiology and microbiology, material that normally spans 24 semester-hours for other students at the University of Hawaii. Taken together, the basic and preclinical science provided to MSCP psychologists totaled just 9 credit-hours, compared to 21 credit-hours for non-prescribing nursing students, at least 27 credit-hours for APRN students, and 46 credit-hours for pharmacists and physicians. The following represents the amount of required basic and preclinical coursework ('1' = one semester-hour):

11111111 – MSCP psychologist at UHH (9)

1111111111111111111 – BSN-RN (non-prescribing) at UHH (21)

111111111111111111111111 –APRN at UH Manoa (27)

11111111111111111111111111111111111111111111 – Pharmacist at UHH (46)

11111111111111111111111111111111111111111111 – MD at JABSOM (46)

UHH-MSCP program provided a total of 33 credit-hours education. This is equivalent to a one year, two semester graduate program, though it is spread over 6 semesters with a 1/4 - 1/3 time student schedule. The Argosy University MSCP program offered graduates only a 22 semester credit hour cur-

riculum. For comparison, nursing students enrolled in the U.H. Hilo Bachelor of Science in Nursing program (BSN) receive a total of 123 credit-hours over 4 years, and APRN's with prescriptive authority receive even more.

As the LRB concluded, "Current psychopharmacology training programs that authorize online learning, weekend classes, and optional clinical experience are considerably less rigorous than the PDP training model." HB767 permits these low standards and lacks reasonable safeguards regarding quality and duration of the DoD-PDP curriculum.

2. Selective Admission: The PDP had a selective admission process and the LRB concluded that "candidates for any similar training program, whether military or civilian, should be held to high selection standards; several years of clinical experience was also suggested… The Advisory Council to the PDP program recommended that applicants to the program should have a minimum of 2 years experience as a licensed clinical psychologist."

There is no evidence that the criteria used by the UHH-MSCP program to select applicants recognized the challenges of its accelerated curriculum. It required no entrance examination or other evidence to ensure that its psychologists were sufficiently gifted or exceptionally qualified to allow them to safely bypass so much of the standard biomedical science coursework. In fact, its program coordinator admitted that her students were often "scared by biochemistry". The program did not require applicants to have 2 years or more of experience as a licensed clinical psychologist. The MSCP student selection process basically takes all comers.

Advising against this, the LRB cautioned, "Admission into current postdoctoral psychopharmacology programs require only a doctoral degree in psychology and a current state license to practice psychology; these minimal requirements do not establish the high selection standards suggested by the ACNP evaluation panel or the minimum two year clinical experience recommended by the Advisory Council." HB767 lacks these reasonable safeguards regarding the quality and experience of MSCP applicants.

3. Expert Clinical Supervision: PDP students were supervised by physicians specialized in psychiatry, and a wide range of health care professionals, labs, and other equipment available in close proximity.

The UHH-MSCP program's first director was a pharmacist with no experience treating patients with psychiatric drugs, or even on the pharmacy aspects of psychiatric drugs. This is also the case for the next program director, Supakit Wongwiwatthananukit, PharmD, a veterinary pharmacist whose main contribution since transferring to the School of Pharmacy from the U.H. Cancer Center, was designing a curriculum for pharmacy students to treat animals. As he described this, "The curriculum was designed to expose students to a veterinary clinical setting."

The basic science portion of the UHH-MSCP curriculum was not taught by qualified faculty with relevant degrees in these respective fields. Chemistry material was not taught by chemists. Biology material was not taught by biologists. This does not even meet community college standards.

According to current program listings, the only UHH-MSCP faculty who were trained to prescribe medications are Allen Novak, APRN-Rx and Kristine McCoy, MD, a family doctor. Both were listed as "guest lecturers".

The UHH-MSCP program had no other faculty or clinical training sites to provide the necessary supervised clinical experience. Instead, students were required to find their own clinical training sites and volunteer supervisors. Generally this meant a primary care doctors at a community health center. It is notable that even though the program's director advocated for psychologist prescribing by insisting that primary care doctors are not qualified to treat mental illness, the program relied on these same doctors as the primary supervisors for its psychologist trainees.

HB767 lacks reasonable safeguards regarding the quality of program faculty and clinical supervisors.

4. Post-graduate Collaboration: PDP graduates received close supervision by psychiatric physicians during their initial postgraduate medical facility assignment, and an ongoing open, collaborative practice that permitted ready access consultation with physicians who were on-site or readily available.

The process proposed under HB767 requires psychologists to maintain documented "collaborative agreements" and "treatment protocols" with DOH psychiatrists for patients with serious mental illness, and with the primary care physician for all other patients. These required collaborations, protocols and agreements would be the primary safeguards in the bill, but it is difficult to assess exactly what they would entail, how they will be meaningful, and their medico-legal implications. One thing is clear, these are likely to be the primary focus of scrutiny in event of adverse outcomes.

B. PROPOSED SCOPE OF PRACTICE LACKS SAFEGUARDS

How close does the process proposed under HB767 come to meeting the LRB's recommended requirements for scope of practice?

The LRB recommended that the Legislature require a scope of practice that is no broader than limitations applied to PDP program graduates. It also noted, "There is no program that authorizes psychologists to prescribe psychoactive medications for children or seniors that has been evaluated or determined to be safe."

The PDP scope of practice was limited to outpatients between the ages of 18 to 65, without serious medical conditions or serious mental illnesses. HB767 does not have this safeguard, would allow psychologists to prescribe risky drugs to children, teens, elderly, the medically-ill and the severely mentally-ill. Most people don't understand that there are no requirements for adequate supervised clinical experience for each of these specialized areas of practice, either during MSCP training or even in psychology doctorate programs.

HB767 does not require psychologists to meet the usual standards American Psychological Association (APA) for specialized training in child psychology or for proficiency in assessment and treatment of serious mental illness before prescribing drugs to in these higher risk cases. There is no evidence that any MSCP program offers the specialized biomedical, clinical and psychopharmacologic training required to safely treat children, seniors and other higher risk patient populations with drugs.

This bears repeating, HB767 would allow psychologists who have no clinical experience evaluating or treated children with psychological or pharmacologic interventions to prescribe drugs to children. The same goes for prescribing drugs to teens, elderly, the medically-ill and the severely mentally-ill. The bill's lack of such a common-sense safeguard is of great concern.

C. PROPOSED MEDICATION FORMULARY LACKS SAFEGUARDS

The LRB recommended that the Legislature require a formulary that is no broader than the limitations applied to PDP program graduates. How close does the process proposed under HB767 come to meeting the LRB's recommended requirements for the medication formulary?

Because PDP psychologists did not treat patients with severe mental illness, their medication formulary was limited to the lower risk drugs prescribed for less serious conditions. HB767 lacks this reasonable safeguard, and would permit psychologists use all psychiatric medications, a formulary that is nearly equivalent to that used by psychiatric physicians.

D. HB767 LACKS MULTIPLE DoD-PDP SAFEGUARDS

The LRB recommended that patient safety should guide the Legislature's decision on the issue of prescriptive authority for clinical psychologists. All agree that psychiatric drugs are no less complex and no less risky when prescribed by a Hawaii psychologist than by others. Once they are in someone's body, the chemicals will do what they do. Nevertheless, HB767 lacks the safeguards of the PDP:

- 2-3 years of quality, full-time biomedical training? *PDP -yes, HB767–no*
- Selective applicant process? *PDP -yes, HB767–no*
- Qualified preclinical and clinical faculty? *PDP -yes, HB767–no*
- Supervisors expert in the use of psychiatric drugs? *PDP -yes, HB767-no*
- Limited to the lowest risk medications? *PDP -yes, HB767–no*
- Videotaped lectures as primary teaching method? *PDP-no, HB767-yes*
- Prescribe drugs to children? *PDP-no, HB767-yes*
- Prescribe drugs to teens? *PDP-no, HB767-yes*
- Prescribe drugs to pregnant women? *PDP-no, HB767-yes*
- Prescribe drugs to the elderly? *PDP-no, HB767-yes*
- Prescribe drugs to the medically-ill? *PDP-no, HB767-yes*
- Prescribe drugs for severe mental illness? *PDP-no, HB767-yes*
- Psychology training in treating children? *PDP-n/a, HB767-no*
- Psychology training in treating teens? *PDP-n/a, HB767-no*
- Psychology training in treating pregnant women? *PDP-n/a, HB767-no*
- Psychology training in treating the elderly? *PDP-n/a, HB767-no*
- Psychology training in treating the medically-ill? *PDP-n/a, HB767-no*
- Psychology training in treating severe mental illness? *PDP-n/a, HB767-no*
- Training in treating children with drugs? *PDP-n/a, HB767-no*
- Training in treating teens with drugs? *PDP-n/a, HB767-no*
- Training in treating children with drugs? *PDP-n/a, HB767-no*
- Training in treating pregnant women with drugs? *PDP-n/a, HB767-no*
- Training in treating the elderly with drugs? *PDP-n/a, HB767-no*
- Training in treating severe mental illness with drugs? *PDP-n/a, HB767-no*
- Does HB767 mention any of this in its preamble? *No.*

SUMMARY

The available evidence continues to support the LRB's conclusion that, "There is no postdoctoral training in psychopharmacology for clinical psychologists in Hawaii that has high selection standards to choose participants or that meets the classroom and clinical training requirements of the PDP program."

The PDP only allowed psychologists to prescribe only after a 2-3 year, full-time biomedical training program, taught and supervised by qualified medical school faculty at Walter Reed. When finished, these military psychologists were only allowed to use a limited list of the safest psychiatric drugs to treat healthy adults aged 18-65, but not children, teens, elderly, the medically-ill or the severely mentally-ill.

HB767 does not compare favorably to an objective examination of the PDP training program safeguards for the admission process, curriculum and training content, duration, faculty and supervisor qualifications, and required clinical settings. This is alarming given that the bill also fails to require and the important PDP safeguards of a narrow scope of practice and limited formulary. This risk is compounded by the fact that neither conventional clinical psychology training nor MSCP programs require any significant education or supervised clinical experience for children, seniors or other specialized patient populations.

Another safeguard missing from HB767 involves psychologists who may have completed MSCP training years ago, perhaps 10-15 years ago or more, and who have no evidence of substantial relevant prescriptive practice or continuing education since then. Allowing these individuals to begin prescribing after such a long gap, especially given the sketchy quality of the training being considered, is yet another concern.

It is clear, according to the LRB's independent and objective analysis of this controversial issue, that HB767 does not require adequate education and training and poses significant risks to patient safety. The bill's primary safeguard, consultation and collaboration with physicians, will push these risks down to the level of those responsible for oversight the prescribing psychologists. For the highest risk cases, this would include department of health psychiatrists. Any future claims of inadequate training and negligent supervision would be very difficult to defend given the findings of the LRB and other independent experts. All of these risks and costs can be avoided by voting against HB767, and instead implementing initiatives that are safe and proven to work.

HOW HEALTH PLANS CREATE ADEQUATE PROVIDER NETWORKS

A`ohe hana nui ka alu`ia

No task is too big when done together.

Over the long run, and often in the short run as well, the most effective and affordable way to protect the Right to an Adequate Provider Network is to strengthen our health care workforce with adequate numbers of committed, culturally competent and well-trained doctors, and to maximize community health through prevention and early detection, thereby reducing need for medical and other health care. Some visionary leaders have planted seeds for these changes that can grow into long term solutions if the conditions are favorable. So, let's roll up our sleeves and start to help out, because cultivating those conditions will not be easy at the outset. Throughout our healthcare community, many will have to reprioritize, restructure or retrain to be able to fully contribute to a better way of keeping as many of our people healthy, and wisely caring for those who become ill. Make no mistake - given the direct-care manpower demands, we all need to do our part.

Many already realize that we must head in this direction; they see the destination in their mind's eye or have been lucky enough to get glimpses of it taking place. What is less clear is which policy initiatives will help move all of Hawai`i over to the health care Promised Land. In policy debates thus far, it has been said that no single entity can fix what ails the system, nor can one organization solely address the widespread change needed. This conclusion should be examined.

While it is true that no one person or entity can fix things, it is worth considering, "Is there is an organization, or group of organizations, that has the primary authority, ability and responsibility for ensuring that the necessary widespread change is effectively carried out?" If there is a top candidate group for this role, it is the health plans doing business in Hawai`i. These health plans operate in all of our communities, and the insurance companies that run them have over $6 billion of combined annual revenue. They are the only entities with the authority, expertise and resources to select, design and implement reforms on the scale necessary to be successful.

There is debate about whether or not health plans are responsible for more than token preventive and wellness activities, and they have largely kept provider recruitment and retention at arms length. Plans may avoid involvement in such activities for fear that the interventions are too nonspecific, or have no clear endpoints. How do you know when someone has enough health? Should every beneficiary be given their own personal coach, trainer and chef?

A. Supply and Demand

Under the traditional insurance model, health plans are only responsible for providing "medically-necessary" services once illness occurs, but not before. Technically and legally this is correct, and if plans choose to stop there it seems they can. Under this model, health plans have devoted resources to such tools and practices as utilization management (UM), quality improvement, and claims scrutiny, even though this has weakened provider relations and their ability to maintain adequate provider networks.

Some health plans may be less interested in initiatives to increase the overall supply of providers (though they should) and more with the practice mix (how many of specific specialties vs primary care), geographic distribution and plan participation levels of doctors. If there is a statewide shortage, but a particular plan has enough of the right kind of doctors in the right places who are willing to see enough members, maybe it doesn't matter what is happening with other plans.

As discussed, Network Adequacy regulations only require that the supply of providers is equal or greater than members needs for necessary services. This can be expressed as: Supply ≥ Demand. Unfortunately, health plans are able to give the appearance of adequate provider networks by a combination of:

- Inflating provider directories (false Supply ≥ Demand).
- Hiding complaints and other evidence of lack of access (Supply ≥ false Demand).

Across the country, there is growing awareness that proper regulation is necessary to ensure a supply of providers equal or greater than members' needs for necessary services: true Supply ≥ true Demand. The remedies for inadequate provider networks include some combination of:

- Increased provider Supply by recruitment, retention and workforce development.
- Increased Efficiency by coordinated care and reduced utilization management.
- Reduced beneficiary Demand by prevention, wellness, and early illness detection.

Policy makers and State regulators must realize that health plans remain legally responsible for adequate provider networks, and that true network adequacy should be the primary focus of regulation. Plans should otherwise be given as much freedom as possible to pursue from the many tested strategies available to improve specialty and primary care provider network recruitment and retention.

Before considering these specific strategies, let's take a moment to acknowledge one of the challenges of sustaining a system of adequate health plan provider networks. Once plans achieve adequate provider networks, the notorious "free rider" or "carpetbagger" problem emerges. A "free rider" health plan could then be able to achieve an adequate provider network without doing much at all, and profit from the efforts and investments of the other plans. This would be particularly true for late-comers, and for-profit insurance companies. Compared to the current situation, this would be a welcomed

problem - one that policy-makers may have to find a solution for through innovative contracting, legislation or enforcement. Hawai`i health plans have a shared interest in increasing overall supply and distribution of our providers, as well in reducing service demands through prevention, primary care and wellness. Efforts should be made to encourage cooperation and to discourage opportunistic selfish profiting. Plans should keep this in mind as they consider their options.

B. Increasing Supply: Provider Recruitment and Retention and Training

1. Traditional Recruitment Efforts – the Quick Fix:

- Marketing.
- "Head hunters".
- Locum Tenens.
- Relocation assistance.
- Help with practice start-up expenses.
- Retention challenges (distorted expectations, do not adjust to our culture, lack deep social ties, less committed to staying in Hawai`i).

2. Strengthen Hawai'i-based incentives and supports – the Long Game:

- Local students and residents have family and friends here, are culturally sophisticated regarding our people and more committed to their communities over the long haul - retention is high.
- The Native Hawai`ian Health Scholarship Program (NHHSP) tuition for tuition, books, other educational costs, and a monthly stipend.
- Targeted training exposure - rural medical student rotations.
- 'Imi Ho'ōla helps 12 college seniors from disadvantaged backgrounds to JABSOM.
- JABSOM summer programs for high school students.
- Visits by doctors and medical school students to high school classrooms, career fairs.
- Neighbor Island Residency Training (Hilo Family Residency Program established in 2014 with health plan funding).
- Rural, Recruitment and Retention Network (3R Net) for posting jobs in Hawai`i.
- The Department of Health's Office of Primary Care and Rural Health (OPCRH).
- The Hawai`i Primary Care Office (PCO).
- Expansion of the Hawai`i /Pacific Basin Area Health Education Center (AHEC).

3. Increase use of National Health Service Corps (NHSC) incentives by CHC's:

- The Hawai`i Loan Repayment Program (HLRP) up to $40,000 a year.

- NHSC Students to Service Loan Repayment Program (S2S LRP) up to $120,000.
- NHSC Loan Repayment Program (NHSC LRP) up to $50,000.
- NHSC Faculty Loan Repayment Program, up to $40,000.
- Conrad 30 (J-1 Visa) program for foreign medical graduates who trained in the U.S.
- NHSC Medical Students Scholarship Program, tuition, fees, other educational costs, and provides a living stipend.

4. Payment Reforms and other Incentives and Assistance:

- Pay bonuses to PCPs to meet care targets (quality, wellness, prevention).
- Pay providers higher rates for services delivered in rural and underserved areas.
- General Excise Tax breaks for services delivered in rural and underserved areas.
- Coordinate with our congressional delegation to secure a fair increase in the Hawai`i Medicare provider payment Geographic Adjustment Factor (1.003 = average) based on our high taxes and living costs (172% above average).
- Seek to prohibit non-compete clauses in provider employment contracts.
- Reduce risk and cost of part-time practice to retain competent older doctors
    - Medical fraud enforcement reform.
    - Malpractice and disciplinary reform (Hawai`i rate of 3.53 severe disciplinary actions per 1000 physicians is well above average).
    - Make unnecessary technical changes optional (electronic medical records).
    - Keep maintenance of certification (MOC) voluntary.

5. Improve Communication – the Cornerstone of Provider Relations:

- Written information about changes to administrative procedures, clinical break-throughs, quality measures, and legal updates.
- Provider relations shift from the telephone to in-person meetings at provider offices.
- Placed representatives in the communities that they serve.
- Routine provider site visits, with the frequency of such visits depending on member volume (monthly at sites with 500 or more members, every six weeks or once per quarter for those with less).
- For downloads that replace direct mailings (newsletters), send email with the newsletter in the body or a link that takes the user to the desired information.
- Conduct annual provider satisfaction surveys and share the results and the Plan's corrective actions.
- Mixed-mode survey (mail survey, e-mail reminders and Web-based option) higher response rates.

- Survey announcement letter or an e-mail about the upcoming survey, estimated timeline for arrival and deadline, when and how results will be made available, and encouraging participation.
- Supplement written or online satisfaction surveys, interview providers and take notes.
- For identified areas of poor performance, use provider focus groups to gain further information and insight and to hear about specific scenarios and examples of provider issues.
- Target areas needing performance improvement, determine interventions, implement and re-measure provider satisfaction at a later date.

6. Improve the Provider Recognition Practices:

- Highlight local examples of provider best practices in office administration, clinical practices, and quality measures in its provider newsletter and public forums.
- Recognize providers with dedication, expertise to encourage and retain them and as models for others.
- Thank network providers who provide uncompensated care to the uninsured in addition to care of plan members.
- Thank providers with personal letters from the medical director, newspaper radio and television spots.
- Annual county provider dinner with Quality awards (trophy and gift) to the most outstanding provider.

7. Strengthen the Provider Outreach Practices:

- Identify potential recruits by tracking claims submitted by nonparticipating specialists, and encourage them to join the network.
- Ask their contracted PCPs in rural communities to identify which specialists accepted their referrals based on informal collegial relations.

C. Increasing Efficiency: Help Doctors Focus on Patient Care not Paperwork

1. New Models of Care: Coordination and Technology

- Increased use of available AV technology for telehealth (Zoom) for direct care.
- Increased use of AV technology for collaborative care and consultation between primary care providers and specialists.
- Reimbursement and support for collaborative and team-based care models.
- Initiatives that educate, train, and support rural general practitioners or other available healthcare representatives on the best practice treatment protocols for complex diseases (project ECHO).

2. Improve UM practices and Reduce Administrative Burdens:

- Improve in UM customer service.
- Use technology tools to facilitate authorizations and referrals.
- Web-based search engines so that providers can search by diagnosis code for conditions that require authorization.
- No referral/authorization requirements for office-based services of in-network specialists.
- No referral/authorization requirements for services that have a high approval rate.
- No authorizations that specialists are required to obtain from PCPs.
- Replace authorizations based on dollar thresholds or number of visits, with more meaningful categories like:
    - Serious or complex medical conditions.
    - High-cost conditions.
    - Conditions with a history of overutilization or inappropriate utilization.
    - Conditions with corresponding legal requirements (e.g., hysterectomies and sterilizations).
- Have knowledgeable representatives, available to providers during regular Hawai`i working hours.
- Identify and evaluate outlier provider participation (high or low volume) assess for quality and reasons for participation rates, and incorporate into QI process.
- Correct errors in provider directories.

3. Simplify the Health Care Encounter Data Submission Process:

- Contract with a central clearinghouse, (e.g., WebMD) for providers to submit encounter data,
- Offer providers a coach to review current coding methods and teach strategies that could improve encounter data accuracy and reimbursement levels.

4. Simplify the Process for Verifying Member Eligibility:

- Medicaid status changes frequently for members.
- Contracting providers require a simple and dependable access to member eligibility status.
- Online lookup system through a secure Web application.
- Interactive voice response (IVR) option that verifies eligibility by telephone.
- Card swipe system can help high-volume practices to verify eligibility.

- Facilitate printing verification of eligibility, and honor claims for retroactively terminated members.

5. Simplifying the Provider Credentialing Process:

- Reduce the amount of documentation that providers must submit.
- Enabling electronic submission of credentialing documents.
- Extend re-credentialing from every two to every three years.
- Contract with a central clearinghouse to reduce submissions to multiple health plans (Council for Quality Affordable Health Care).
- Implement fair use of "board certification" and educate members about this.

6. Assist with Practice Operations (enabling service practices):

- Support use of Telemedicine in areas with shortages of health care professionals and services.
- Case management and other services aimed at patients who have trouble keeping appointments.
- Address the social barriers that may prevent or interfere with members' ability to receive medical services:
    - Transportation services.
    - Child care arrangements.
    - Interpreter services.
    - Cell phones so case managers can contact them.
- Private practice education and outreach of residents, non-participating area doctors.
- Assist with CME, MOC, credentialing with focus on plan priorities, population needs.
- Providing practical assistance to providers interested in starting a private practice.
- Provide access to free, open source, user friendly and certified electronic medical record billing and prescribing software that is interoperable with plan systems.

D. Reducing Demand: Focus on Wellness, Prevention, and Early Detection

Providers and Health Plans should increasingly focus on helping members become healthier and avoid getting sick or injured in the first place. Network Adequacy will benefit from a multi-pronged campaign that provides advocacy materials focused alcohol, obesity, public safety, safe vaccination, tobacco use, and wellness and prevention. Some plans might choose to adjust premiums or use other incentives for healthy behaviors. With their expertise in designing and implementing effective strategies to modify human behavior, Health Psychologists will be central to these efforts.

1. Advocate for Healthy choices, Habits and Behaviors:

- Getting 7-8 hours of sleep each day.
- Avoiding intake of tobacco, alcohol and other intoxicants, and excessive caffeine
- Learning proper Mindfulness based Stress Reduction.
- Regular physical activity, gentle movement throughout the day and periodic exercise.
- Avoiding prolonged sedentary activities.
- Avoid excessive "screen time".
- Paying attention to posture, body position and movement.
- Adequate intake of fresh water, avoiding drinks with sugar and caffeine.
- Good bowel habits, with adequate fiber intake.
- Eating fresh whole fruits, vegetables, starches and fish – culturally and geographically appropriate.
- Involvement with fishing, gardening or community supported agriculture.
- Avoid intake of processed foods with high content of fats, oils, sugars and simple starches.
- Regular kindness with each other, including physical touch when appropriate.
- Wearing helmets and safety belts and following work place safety rules.
- Avoiding risky sexual behaviors.
- Washing hands, and practicing good hygiene.
- Properly preparing and storing food.
- Recognizing the value of good health and making it a top priority.
- Practicing water safety.
- Take steps in youth activities to reduce and detect concussions and head injury.

2. Individual and Organization Health Measurement:

Gallup-Healthways Well-Being 5: Validated survey instrument measures, tracks and reports on the well-being of individuals and organizations.

- Physical - having good health and enough energy to get things done daily.
- Community - liking where you live, feeling safe and having pride in your community.
- Financial - managing your economic life to reduce stress and increase security.
- Social - having supportive relationships and love in your life.
- Purpose - liking what you do each day and being motivated to achieve your goals.

3. Other Health Plan Wellness and Prevention Initiatives:

- Facilitate participation from online consumer support communities.
- Assist members seeking to make healthy lifestyle changes (HMSA365 Discounts costs for gym memberships, yoga classes, healthy food and vitamins, health books and magazines, discounts on hearing aids, eye exams, frames, lenses, LASIK, non-emergency medical transportation, acupuncture, hypnotherapy, massage…).
- Health Education Workshops for members teaching about aspects of health and well-being.
- Support community wellness initiatives (Blue Zones).
- Provide coverage for evidence-based wellness services (Ornish Institute, ‘Ekahi health).

4. Health Coaching for improving well-being and managing diseases:

- Hawai`i-based Coaching Team includes registered nurses, exercise physiologists, health educators, registered dietitians, and other health care professionals.
- Teach strategies for dealing with unhealthy impulses, habits and situations.
- Guidance and support in setting realistic goals.
- Member chooses how to get support and how often, over the phone or online.
- Examples: asthma and obstructive pulmonary disease; heart failure and coronary artery disease; diabetes; and stress, depression, substance abuse, smoking (QuitNet® tobacco cessation program).
- Provides referrals to other services that might help with diet, exercise, and nutrition.

5. CE Focus for Providers, Nurses, Health Psychologists and other counselors:

- Providing motivation and encouragement for healthy lifestyle changes.
- Providing education to all age groups, especially young adults how to stay healthy, in a form they can understand, and based on needs and interests.
- Improve Motivational Interviewing skills.
- Provide preventive services such as cancer screenings, preventive visits and vaccinations.
- Providing family planning to prevent early and unplanned pregnancy.
- Programs to effectively prevent violence, sexual assault and bullying.
- Providing housing support to individuals who are homeless or at risk.
- Providing those recovering from chronic illness with jobs and volunteer opportunities.
- Providing counseling to support prudent financial decisions and money management.

- Providing representative payee services when necessary.
- Providing transportation or outreach services when necessary.
- Prescribing use of lowest effective doses of medications in all age groups, especially kupuna.
- Improve communication about end of life care and use of advance directives and hospice (Having the Conversation).
- Minimize use of narcotic analgesics outside of hospice-palliative care.

E. Summary

The 18 approaches and 137 practices listed above are just some of the many available to health plans for reducing unnecessary demands on provider networks and increasing their supply of participating providers. Our large state-wide and national insurance companies are best able to implement coherent plans to achieve and maintain adequate provider networks. Insurers may choose to cooperate on shared initiatives with one another, with provider groups and individual doctors, and/or with state officials and policy makers. Several of these strategies have already been implemented by Hawai`i health plans and been proven to work here in the islands.

Medications Frequently Used for Psychiatric Indications

The classification of psychotropic medication is fairly standard but medications can be used for treatment of illnesses that would be considered listed under a different classification. For example, some medications listed under antipsychotics maybe used as a mood stabilizer.

Antidepressants
amitriptyline (Elavil)
amoxapine (Asendin)
bupropion (Wellbutrin, Wellbutrin SR)
bupropion (Wellbutrin XL)
citalopram (Celexa)
desipramine (Norpramin)
desvenlafaxine (Pristiq, Khedezla)
doxepin (Sinequan)
duloxetine (Cymbalta)
escitalopram (Lexapro)
fluoxetine (Prozac)
imipramine (Tofranil)
levomilnacipran (Fetzima)
maprotiline (Ludiomil)
mirtazapine (Remeron, Remeron SolTab)
nefazodone (Serzone)
nortriptyline (Pamelor, Aventyl)
paroxetine (Paxil, Paxil CR)
protriptyline (Vivactil)
sertraline (Zoloft)
trazodone (Desyrel)
trimipramine (Surmontil)
venlafaxine (Effexor, Effexor XR)
vilazodone (Viibryd)
vortioxetine (Brintellix)

Anxiolytics/Sedatives/Hypnotics
alprazolam (Xanax, Xanax XR)
buspirone (BuSpar)
chlordiazepoxide (Librium)
clonazepam (Klonopin)
clorazepate (Tranxene)
diazepam (Valium)
diphenhydramine (Benadryl)
eszopiclone (Lunesta)
flurazepam (Dalmane)
hydroxyzine (Atarax, Vistaril)
lorazepam (Ativan)
oxazepam (Serax)
pentobarbital (Nembutal)
ramelteon (Rozerem)
suvorexant (Belsomra)

temazepam (Restoril)
triazolam (Halcion)
zaleplon (Sonata)
zolpidem (Ambien)
zolpidem (Ambien CR)

Antipsychotics
aripiprazole (Abilify, Abilify Discmelt)
aripiprazole (Abilify Maintena)
Aripiprazole lauroxil (Aristada)
asenapine (Saphris)
brexpiprazole (Rexulti®)
chlorpromazine (Thorazine)
clozapine (Clozaril, Fazaclo, Versacloz) **** see sample toxicity profile (below)***
droperidol (Inapsine)
fluphenazine (Prolixin)
fluphenazine decanoate (Prolixin D)
haloperidol (Haldol)
haloperidol decanoate (Haldol D)
iloperidone (Fanapt)
loxapine (Loxitane)
loxapine inhalant (Adasuve)
lurasidone (Latuda)
molindone
olanzapine (Zyprexa, Zyprexa Zydis)
olanzapine pamoate (Zyprexa Relprevv)
paliperidone (Invega)
paliperidone palmitate (Invega Sustenna)
paliperidone palmitate (Invega Trinza)
perphenazine (Trilafon)
pimozide (Orap)
quetiapine (Seroquel)
quetiapine (Seroquel XR)
risperidone (Risperdal, Risperdal M-Tab)
risperidone (Risperdal Consta)
thioridazine (Mellaril)
thiothixene (Navane)
trifluoperazine (Stelazine)
ziprasidone (Geodon)

Chemical Dependency Adjuncts
acamprosate (Campral)
disulfiram (Antabuse)
naltrexone (ReVia, Vivitrol)
topiramate (Topamax)

Monoamine Oxidase Inhibitors
isocarboxazid (Marplan)
phenelzine (Nardil)

selegiline (Emsam)
tranylcypromine (Parnate)

Mood Stabilizers
carbamazepine (Tegretol, Tegretol XR, Carbatrol, Equetro)
divaiproex sodium (Depakote, Depakote ER, Depakote Sprinkles)
lithium (Eskalith, Eskalith CR, Lithobid)
valproic acid (Depakene)
oxcarbazepine (Trileptal)
lamotrigine (Lamictal)

Stimulants
amphetamine/dextroamphetamine mixture (Adderall, Adderall XR)
dexmethylphenidate (Focalin, Focalin XR)
dextroamphetamine (Dexedrine, Dexedrine ER-)
lisdexamfetamine (Vyvanse)
methamphetamine (Desoxyn)
methylphenidate (Ritalin, Ritalin SR, Concerta, Metadate, Metadate CD)
methylphenidate patch (Daytrana)
methylphenidate solution (Quillivant XR)

CLOZAPINE ORAL

Clozapine is used for the symptomatic management of psychotic disorders. Drug therapy is integral to the management of acute psychotic episodes and accompanying violent behavior in patients with schizophrenia and generally is required for long-term stabilization to improve symptoms between episodes and to minimize the risk of recurrent acute episodes. Antipsychotic agents are the principal class of drugs used for the management of all phases of schizophrenia and generally are effective in all subtypes of the disorder and subgroups of patients. Patient response and tolerance to antipsychotic agents are variable, and patients who do not respond to or tolerate one drug may be successfully treated with an agent from a different class or with a different adverse effect profile.

Labeled Uses
SCHIZOPHRENIA, NOS

Uses DI™
Psychotic Disorders

CLOZAPINE
Adverse Effects List

Incidence more frequent
CARDIOVASCULAR EFFECTS
FEVER
HYPOTENSION
ORTHOSTATIC HYPOTENSION
TACHYCARDIA
CONSTIPATION
DIZZINESS
HEADACHE
HYPERSALIVATION
NAUSEA
VOMITING
WEIGHT GAIN

Incidence less frequent
AGITATED STATES
AKATHISIA
BLURRED VISION
CONFUSION, DRUG INDUCED
EKG CHANGES
FAINTING

HYPERTENSION
DRY MOUTH
GI IRRITATION
HEARTBURN
HYPERHIDROSIS
AGRANULOCYTOSIS
BLOOD DYSCRASIAS
DEPRESSION
DIFFICULT URINATION
EOSINOPHILIA
EXTRAPYRAMIDAL EFFECTS
GRANULOCYTOPENIA
IMPOTENCE
INSOMNIA
LEUKOPENIA
MUSCLE RIGIDITY
NEUROLEPTIC MALIGNANT SYNDROME
SEIZURES
TARDIVE DYSKINESIA
THROMBOCYTOPENIA
TREMORS

CLOZAPINE
Precautions

Label Warnings from First DataBank:

May cause drowsiness. Alcohol may intensify this effect. Use care when operating a car or dangerous machines.
It is very important that you take or use this exactly as directed. Do not skip doses or discontinue unless directed by your doctor.
Obtain medical advice before taking non-prescription drugs as some may affect the action of this medication.

Drug Disease Contraindications from First DataBank:

Most Significant
For these conditions, action to reduce the risk of adverse interaction is usually required

AGRANULOCYTOSIS
APLASTIC ANEMIA
BLOOD DYSCRASIAS
BONE MARROW DEPRESSION
NEUROLEPTIC MALIGNANT SYNDROME
SEVERE CNS DEPRESSION

Significant
For these conditions, assess risk to patient and take action as needed

NARROW ANGLE GLAUCOMA
PROSTATIC HYPERTROPHY
SEIZURE DISORDER

Possibly Significant
For these conditions, conservative measures are recommended until more is known.

CARDIOVASCULAR DISEASE
GASTROINTESTINAL DISORDERS
HEPATIC FUNCTION IMPAIRMENT
RENAL FUNCTION IMPAIRMENT

Fever:

Fever or transient temperature elevations exceeding 38°C generally have been reported in 5% or more of patients receiving clozapine. The peak incidence of fever occurs within the first 3 weeks of therapy, usually between days 5—20 of treatment. Fever generally is benign and self-limiting and usually diminishes within a few (4—8) days despite continued clozapine therapy; however, it may necessitate discontinuance of the drug. Fever occasionally may be associated with an increase or decrease in leukocyte count, in which case patients should be evaluated for underlying infection or development of agranulocytosis. (See Cautions: Hematologic Effects.) In the presence of high fever, the possibility of neuroleptic malignant syndrome also must be considered. (See Extrapyramidal Reactions under Cautions: Nervous System Effects.)

The mechanism of clozapine-induced fever (other than that occurring secondary to some other factor such as infection) is not yet known. It may result from the drug's pronounced anticholinergic activity (see Anticholinergic Effects under Pharmacology: Nervous System Effects) or a direct effect on the hypothalamic thermoregulatory center. Clozapine-induced hyperthermia may be a hypersensitivity reaction, a common mechanism underlying drug fevers. It has been suggested that decreasing the dosage of clozapine and then gradually increasing it to the previous level may reverse the hyperthermia and not be accompanied by a recurrence of elevated temperature; however, recurrence is possible despite such dosage adjustment.

Precautions and Contraindications:

Clozapine shares many of the toxic potentials of other antipsychotic agents (e.g., phenothiazines), and the usual precautions associated with therapy with these agents should be observed. (See Cautions, in the Phenothiazines General Statement 28:16.08.)

Because of the substantial risk of agranulocytosis and seizures, both of which present a continuing risk over time, extended treatment of patients failing to respond adequately to clozapine generally should be avoided. (See Uses: Schizophrenia.) In addition, the need for continued treatment in patients exhibiting a beneficial clinical response to clozapine should be reevaluated periodically. Patients receiving clozapine should be warned about the substantial risk of developing agranulocytosis andinformed that frequent, regular blood tests are required to monitor for the occurrence of this effect; the manufacturer currently recommends weekly monitoring. Patients should be advised to report immediately the development of lethargy, malaise, weakness, fever, sore throat, mucous membrane ulceration, or any other potential manifestation of infection. Particular attention should be paid to any flu-like symptoms or other complaints that might suggest infection. Patients who develop agranulocytosis or severe leukopenia/granulocytopenia (leukocyte less than 2000/mm3 and ANC less than 1000/mm3) while receiving clozapine should not be rechallenged with the drug. Although it is not known whether the risk of agranulocytosis is increased, clozapine generally should be avoided or used with caution in patients with a history of agranulocytosis induced by other drugs.

Patients in whom clozapine therapy has been abruptly discontinued (e.g., because of leukopenia or agranulocytosis) should be observed carefully for recurrence of psychotic manifestations. (See Other Nervous System Effects under Cautions: Nervous SystemEffects.)

Clozapine should be administered with extreme caution to patients having a history of seizure disorder or other factors possibly predisposing to seizure (e.g., abnormal EEG without a history of epilepsy, preexisting CNS pathology, history of electroconvulsive therapy or of perinatal or birth difficulties, family history of seizure or febrile convulsion). Generalized tonic-clonic (grand mal) seizures have occurred in patients receiving clozapine, particularly in patients receiving high dosages (greater than 600 mg daily) and/or in whom plasma clozapine concentrations were elevated. (See Seizures under Cautions: Nervous System Effects.) Because of the substantial risk of seizures associated with clozapine use, patients should be advised not to engage in any activity where sudden loss of consciousness could cause serious risk to themselves or others (e.g., operating heavy machinery, driving an automobile, swimming, climbing).

Clozapine should be used with caution in patients with cardiovascular disorders because the drug may cause tachycardia, hypotension, and cardiac and/or respiratory arrest. Patients receiving clozapine should be advised of the risk of orthostatic hypotension, especially during the period of initial dosage titration. (See Cautions: Cardiovascular Effects.) In patients with known cardiovascular disease, the recommendation for gradual dosage titration following a low initial dose should be observed carefully. (See Dosage and Administration: Dosage.) Occasionally, severe hypotension or orthostatic collapse may necessitate a temporary reduction in dose or interruption of therapy. Severe hypotensive effects may be alleviated with standard measures (e.g., IV fluids, placing patient in Trendelenburg's position) and, if required, by the administration of norepinephrine or phenylephrine; epinephrine should not be used since a further lowering

of blood pressure may occur. (See Drug Interactions: Other Drugs.) Patients should be informed of the risk of orthostatic hypotension associated with use of clozapine, especially during the period of initial dosage titration. In addition, if clozapine therapy has been discontinued for more than 2 days, patientsshould be advised to contact their clinician for dosing instructions. (See Cautions: Cardiovascular Effects.)

Because of the likelihood that a proportion of patients receiving long-term therapy with an antipsychotic agent will develop tardive dyskinesia, patients in whom long-term clozapine therapy is considered and/or their family or guardians should be fully informed, if possible, about the potential risk of developing this syndrome. The manner in which the patient and/or their family or guardians are informed should take into account the clinical circumstances and the competency of the patient to understand the information. The manufacturer states that, because of the potential risk of tardive dyskinesia, long-term clozapine therapy generally should be reserved for patients whose disorder is responsive to the drug; in addition, clozapine shouldbe prescribed in a manner that is most likely to minimize the occurrence of tardive dyskinesia.As with any antipsychotic agent, the smallest effective dosage and shortest duration of therapy producing an adequate clinical response should be employed. Patients receiving clozapine should be evaluated periodically to determine whether maintenance dosage could be decreased or the drug discontinued. If manifestations of tardive dyskinesia appear in a patient receiving clozapine, drug discontinuance should be considered. However, some patients may require treatment with clozapine despite the presence of the syndrome.

During clozapine therapy, patients may experience transient temperature elevations exceeding 38°C, with the peak incidence within the first 3 weeks of therapy. (See Cautions: Fever.) While this fever generally is benign and self-limiting, it may necessitate discontinuance of therapy. Occasionally, there may be an associated increase or decrease in leukocyte count, and patients with fever should be carefully monitored to rule out the possibility of infection or the development of agranulocytosis. In the presence of high fever, the possibility of neuroleptic malignant syndrome also must be considered.(See Extrapyramidal Reactions under Cautions: Nervous System Effects.)

Fatal pulmonary embolism has been reported with clozapine therapy. The possibility of pulmonary embolism should be considered in patients presenting with deep-vein thrombosis, acute dyspnea, chest pain, or other respiratory signs and symptoms.

Since clozapine has potent anticholinergic activity, the drug should be used with caution in individuals whose condition may be aggravated by anticholinergic effects (e.g., patients with prostatic hypertrophy, ileus, urinary retention, angle-closure [obstructive, narrow-angle] glaucoma). In addition, clozapine therapy has been associated with varying degrees of impairment of intestinal peristalsis, ranging from constipation to intestinal obstruction, fecal impaction, and paralytic ileus, that rarely have been fatal. The manufacturers state that constipation may be treated initially by maintaining adequate hydration and by using bulk-forming laxatives. Consultation with a gastroenterologist may be necessary in more severe cases.

Severe hyperglycemia, sometimes leading to ketoacidosis, has been reported in patients without a prior history of hyperglycemia who received clozapine therapy. The possibility of impaired glucose tolerance should be considered in patients presentingwith symptoms of hyperglycemia, including polydipsia, polyuria, polyphagia, and weakness. The manufacturers state that discontinuance of therapy should be considered in patients who develop severe hyperglycemia.

Because there have been reports of hepatic dysfunction, including hepatitis, in patients receiving clozapine, the drug should be used with caution in patients with preexisting liver disease. Liver function tests should be performed immediately in patients who develop nausea, vomiting, and/or anorexia during clozapine therapy. The manufacturers state that clozapine therapy should be discontinued in patients with marked elevations in serum aminotransferase concentrations or in those presenting with manifestations of jaundice.

Patients should be warned that clozapine may impair their ability to perform activities requiring mental alertness or physical coordination (e.g., operating machinery, driving a motor vehicle), especially during the first few days of therapy. The recommendation for gradual dosage escalation should be closely followed. Although some clinicians recommend that clozapine not be prescribed on an outpatient basis until the patient has developed tolerance to the drug's sedative effects, others state thattherapy with the drug can be started in many patients on an outpatient basis. Patients receiving clozapine should notify their physician if they are taking, or plan to take, any nonprescription or prescription medication or alcohol-containing beverage or product.

Because of the adverse CNS effects associated with clozapine therapy, the manufacturers state that an anesthesiologist should be consulted regarding continuation of clozapine therapy in patients undergoing surgery involving general anesthesia.

Clinical experience with clozapine in patients with concomitant systemic diseases is limited. Therefore, the manufacturer states that caution is advisable if the drug is used in patients with hepatic, renal, or cardiac disease.

Clozapine is contraindicated in patients with myeloproliferative disorders, uncontrolled epilepsy, preexisting bone marrow depression, or a history of clozapine-induced agranulocytosis or severe granulocytopenia. The drug also is contraindicated in patients receiving other agents that may cause agranulocytosis or suppress bone marrow function and in those with severe CNS depression or comatose states from any cause. Although the manufacturer does not mention it as a specific contraindication toclozapine therapy, the American Psychiatric Association recommends that clozapine therapy be avoided in schizophrenic patients who are unable or unwilling to comply with the close monitoring that is necessary to detect possible adverse hematologic effects associated with the drug.

Clozapine is contraindicated in patients with a history of hypersensitivity to the drug or any ingredient in the formulation.

Pediatric Precautions:

Safety and efficacy of clozapine in pediatric patients in children younger than 16 years of age have not been established.

Geriatric Precautions:

Clinical studies of clozapine did not include sufficient numbers of patients 65 years of age and older to determine whether geriatric patients respond differently than younger patients. Because geriatric patients may be at increased risk for certaincardiovascular (e.g., orthostatic hypotension, tachycardia) and anticholinergic effects of the drug (e.g., constipation, urinary retention in the presence of prostatic hypertrophy, extrapyramidal manifestations), clozapine should be used cautiously in this age group. In addition, geriatric patients generally are more sensitive than younger patients to drugs that affect the CNS; data from clinical studies indicate that the incidence of tardive dyskinesia appears to be highest among geriatric patients, especially women. In general, dosage should be titrated carefully in geriatric patients, usually initiating therapy at the low end of the dosage range; the greater frequency of decreased hepatic, renal, and/or cardiac function and of concomitant disease and drug therapy observed in the elderly also should be considered.

Pregnancy, Fertility, and Lactation:

Reproduction studies in rats and rabbits using clozapine dosages approximately 2—4 times the usual human dosage have not revealed evidence of harm to the fetus or impaired fertility. There are no adequate and controlled studies to date using clozapine in pregnant women, and the drug should be used during pregnancy only when clearly needed. Patients receiving clozapine should notify their physician if they become or plan to become pregnant during therapy.

Studies in animals suggest that clozapine may be distributed into milk. Because of the potential for serious adverse reactions to clozapine in nursing infants, a decision should be made whether to discontinue nursing or the drug, taking into accountthe importance of the drug to the woman.

Clozapine Adverse Effects Discussion

Hematologic Effects:

Granulocytopenia and Agranulocytosis

Agranulocytosis, defined as an absolute neutrophil count (ANC) less than 500/mm3 and characterized by leukopenia (leukocyte count less than 2000/mm3) and relative lymphopenia, has an estimated cumulative incidence of 1—2% after 1 year of clozapine therapy, as compared with an estimated incidence of 0.1—1% for phenothiazine-induced agranulocytosis. The rate of clozapine-induced agranulocytosis is based on the occurrence of 15 cases out of 1743 patients who received clozapine during clinical trials in the US. Some evidence suggests that the incidence of clozapine-induced agranulocytosis is at least 10 times greater than that of other antipsychotic agents, although it also has been suggested that the incidence of clozapine-induced agranulocytosis may be no higher than that associated with phenothiazines. ***Of the 149 cases of clozapine-induced agranulocytosis reported worldwide as of December 31, 1989, 32% were fatal.*** Few of these fatalities have occurred since 1977 when the knowledge of clozapine-induced agranulocytosis became widespread and close monitoring of leukocyte count became widely practiced. In the US, under a weekly leukocyte monitoring system in premarketing studies and in postmarketing experience with clozapine, 585 cases of agranulocytosis, including 19 fatalities, had occurred as of August 21, 1997; one patient receiving concomitant therapy with carbamazepine and clozapine died following development of an unusual hypoplastic anemia with agranulocytosis, a pancytopenic condition not usually characteristic of clozapine-induced hematologic effects. Based on analysis of data pooled from a confidential National master file of information (the Clozaril® National Registry), the incidence of agranulocytosis appears to rise steeply during the first 2 months of therapy and peaks in the third month. The incidence gradually declines with continued therapy and reaches a rate of 3 per 1000 person-years by 6 months of therapy. After 6 months, the incidence of agranulocytosis declines still further. However, the manufacturer cautions that a reduction in the frequency of leukocyte monitoring may result in an increase in incidence of agranulocytosis.

The precise mechanism by which clozapine induces agranulocytosis is not known, but both immunologic and toxic mechanisms (including a direct myelotoxic effect) have been implicated. Some evidence suggests that granulocyte antibodies may be involved. Except for the evidence of marked bone marrow depression during initial clozapine therapy and a disproportionate number of females, there are no established risk factors, based on worldwide experience, for developing clozapine-induced agranulocytosis.However, a disproportionate number of US cases have occurred in patients of Eastern European Jewish heritage compared with the overall proportion of such patients exposed to clozapine during domestic trials. Results of genetic typing indicate that genetic factors marked by a major histocompatibility complex haplotype (HLA-B38, DR4, DQw3) may be associated with the susceptibility of certain Jewish patients with schizophrenia to

develop agranulocytosis when treated with clozapine; the incidence of some phenotypes common among Ashkenazi Jews has been found to be greatly increased in patients with clozapine-induced agranulocytosis.

Most cases of clozapine-induced agranulocytosis in the US have occurred within 4—16 weeks of exposure to the drug. Although no patient characteristics predictive of an increased risk of agranulocytosis with clozapine have been identified conclusively, agranulocytosis associated with the use of other antipsychotic agents has been reported to occur more frequently in women, geriatric patients, and patients who are cachectic or have serious underlying medical conditions (e.g., immunocompromised patients, patients with human immunodeficiency virus [HIV] infection); such patients also may be at increased risk for developing agranulocytosis with clozapine therapy.

Investigation of 16 cases of clozapine-associated granulocytopenia occurring within a 2-month period in 1975 in southwest Finland, including 13 cases of agranulocytosis, revealed characteristics similar to those of phenothiazine-induced agranulocytosis. In all of these cases, the reaction occurred during first exposure to the drug and followed a latent period of 17—109 days at a cumulative dose of 4.5—42 g; reduced values for hemoglobin and peripheral erythrocyte and thrombocyte counts were foundinfrequently, and granulopoiesis in sternal marrow usually was severely depressed or absent. Erythropoiesis was below normal in only one case, and thrombopoiesis was normal or even increased. Hematologic values returned to baseline within 1—3 weeks after withdrawal of clozapine. All fatalities were attributed to secondary infection in patients in whom granulocytopenia was not diagnosed early or clozapine discontinued promptly. In patients who died, the clinical course typically consisted of fever with tonsillitis, which progressed to pneumonia and septicemia; the immediate cause of death usually was renal or cardiac failure. The frequency of clozapine-induced agranulocytosis or granulocytopenia in the Finnish experience was 7.1 per thousand—approximately 21 times higher than that reported in other countries. Although it has been suggested that a local genetic or environmental factor or factors may have been involved in the Finnish cases, the existence of such a factor has not been documented.

The most likely time of occurrence of granulocytopenia appears to be 4—16 weeks after initiation of treatment with clozapine. However, neither dose nor duration of therapy is a reliable predictor of agranulocytosis. Most patients develop agranulocytosis within the first 10 weeks of therapy, but a latent period of up to 1 year or longer also has been reported. Within the first 18 weeks of therapy, 77—90% of all cases of granulocytopenia and agranulocytosis have been reported and 85% of fatalities secondary to agranulocytosis have occurred. The latent period between the fall in leukocyte count and the development of a secondary infection usually is moderately long. Leukocyte count usually declines gradually (e.g., over a period of weeks), but italso may decline precipitously. Patients receiving clozapine may have a transient and benign reduction in leukocyte count without progression to agranulocytosis, and may or may not develop manifestations of infection (e.g., fever, sore throat).

Patients in whom granulocytopenia is diagnosed and clozapine therapy discontinued before the occurrence of infection generally have a favorable prognosis. Early diagnosis of granulocytopenia and appropriate medical management can forestall serious consequences and reduce morbidity and mortality substantially since the condition generally is reversible if clozapine is discontinued promptly. In contrast, agranulocytosis is more likely to be fatal in patients in whom clozapine therapy is not halted before the development of infection.

Because of the substantial, persistent risk of agranulocytosis associated with clozapine use, patients must have a leukocyte count performed before initiation of therapy with the drug. Clozapine therapy should not be initiated if the baseline leukocyte count is less than 3500/mm3. While some clinicians suggest that leukocyte counts be done weekly during the first 4—12 months of therapy and then less frequently (e.g., every 2 weeks or monthly) thereafter, most clinicians state that patients must have weekly leukocyte counts for the duration of therapy. However, the manufacturers suggest that the frequency of monitoring depends in part on the duration of therapy, adherence to therapy, and development of adverse hematologic effects. The manufacturers state that patients must have leukocyte counts done at least weekly for the first 6 months of continuous treatment and then every other week thereafter if leukocyte counts remain acceptable (leukocyte equal to or exceeding 3000/mm3, ANC equal toor exceeding 1500/mm3). Less frequent (i.e., every other week) of leukocyte counts also may be considered in patients who had a brief interruption in therapy (i.e., 1 month or less) before completion of 6 months, exhibited no adverse hematologic effects,and continued weekly leukocyte counts upon reinstitution of therapy. In patients receiving therapy for more than 6 months without adverse hematologic effects who have had an interruption in therapy of 1 year or less, monitoring of leukocyte counts also can be done every other week when therapy is reinstituted. However, in patients receiving therapy for less than 6 months who had an interruption in therapy for more than 1 month and exhibited no adverse hematologic effects, weekly leukocyte counts should be continued for an additional 6 months before reducing the frequency to every other week. In addition, leukocyte counts must be monitored weekly for an additional 6 months before reducing monitoring to every other week in all patients in whom the leukocyte count has fallen below acceptable limits (leukocyte less than 3000/mm3, ANC less than 1500/mm3), but who remain rechallengeable (i.e., leukocyte equal to or exceeding 2000/mm3 and ANC equal to or exceeding 1000/mm3) 1500/mm3). In addition, patients must have weekly leukocyte counts for at least 4 weeks following discontinuance of the drug. The manufacturer states that the distribution of clozapine is contingent upon the results of the required blood tests.

Although some clinicians suggest that body temperature be measured at least once daily for the first 18 weeks of clozapine therapy, others state that such monitoring is not an adequate means of assessing infection in clozapine-treated patients because of the drug's pharmacologic potential for causing temperature elevation. Patients should be advised to report immediately the appearance of lethargy, weakness, fever, sore throat, or any other potential manifestation of infection. The leukocyte count and differential should be repeated if, after initial clozapine therapy, the leukocyte count decreases to less than

3500/mm3; if it decreases by a substantial amount (defined as a single decrease of 3000 or more in the leukocyte count or a cumulative decrease of 3000 or more within 3 weeks) from baseline (even if it remains greater than 3500/mm3); or if immature leukocytes are present. If subsequent determinations of leukocyte count and differential reveal a total leukocyte count between 3000—3500/mm3 (mild leukopenia) and an ANC exceeding 1500/mm3, such determinations should be performed twice weekly.

If the total leukocyte count falls to less than 3000/mm3 or the ANC to less than 1500/mm3, clozapine therapy should be interrupted, leukocyte count and differential should be performed daily, and the patient should be monitored for flu-like symptomsor other manifestations of infection. Therapy may be resumed if symptoms of infection do not develop and if the leukocyte and ANC exceed 3000 and 1500/mm3, respectively. However, twice-weekly leukocyte and differential counts should then be performed until the leukocyte count exceeds 3500/mm3. If the leukocyte count decreases to less than 2000/mm3 or the ANC to less than 1000/mm3 (i.e., agranulocytosis), bone marrow aspiration should be considered to determine granulopoietic status. Protective isolation of the patient with close observation may be indicated if granulopoiesis is determined to be deficient. leukocyte and differential counts should be monitored daily or every other day until these values return to normal, which usually takes about 2 weeks. If infection develops, appropriate cultures should be performed and anti-infective regimens instituted, and the patient should be monitored closely. Supportive therapy with biosynthetic hematopoietic agents, including filgrastim, a recombinant human granulocyte colony-stimulating factor (G-CSF), and sargramostim, a recombinant human granulocyte-macrophage colony-stimulating factor (GM-CSF), has been effective in a limited number of patients with clozapine-induced neutropenia and agranulocytosis. Consultation with a hematologist and infectious disease expert is recommended.

During recovery, when the patient no longer has signs of infection and has a leukocyte count exceeding 4000/mm3 and an ANC exceeding 2000/mm3, determinations of leukocyte count with differential should be performed weekly until results show 4 consecutive weeks of normal values.

When granulocytopenia is diagnosed and clozapine therapy is discontinued, patients usually recover in 7—28 days. Most of these patients require further antipsychotic therapy because of a recurrence of psychotic symptoms. (See Other Nervous System Effects under Cautions: Nervous System Effects.) Since there appears to be no cross-sensitivity between clozapine and other antipsychotics in terms of hematologic toxicity, other antipsychotic drugs generally may be used without causing further hematologic complications in patients who develop clozapine-induced agranulocytosis. However, patients who develop clozapine-induced agranulocytosis (or those in whom the total leukocyte and ANC decrease to less than 2000/mm3 and less than 1000/mm3, respectively) should not be rechallenged with clozapine. Patients in whom clozapine therapy has been discontinued due to substantial leukocyte suppression have been found to develop agranulocytosis upon rechallenge with the drug, often with a shorter latency on reexposure. To reduce the chance of rechallenge in patients who have experienced

substantial bone marrow suppression with clozapine therapy, the manufacturer maintains a confidential national master file of information (the Clozaril® National Registry) on all such patients.

Eosinophilia
Eosinophilia has been reported in approximately 1% of patients who received clozapine therapy in clinical trials. The manufacturers state that if the total eosinophil count exceeds 4000/mm3, clozapine therapy should be temporarily discontinued untilthe count falls below 3000/mm3.

Other Hematologic Effects
Other hematologic effects reported with clozapine therapy include leukopenia, neutropenia, and thrombocytopenia, which have been reported in 1—3% of patients. Anemia, leukocytosis, and increased platelet count have been reported in less than 1% of patients receiving clozapine. Other clozapine-induced hematologic effects reportedly include basophilia, a substantial reduction in B cells, and an increase in hemoglobin concentration. Elevated erythrocyte sedimentation rate (ESR) and sepsis have been reported in patients receiving clozapine during postmarketing surveillance; however, a causal relationship to the drug has not been established.

Nervous System Effects:

Seizures
Clozapine lowers the seizure threshold, and ***seizures reportedly occurred in approximately 3.5% of patients*** exposed to the drug during clinical trials in the US (cumulative annual incidence of approximately 5%). In contrast, a seizure incidence of approximately 1% has been reported in patients treated with other antipsychotic agents. The risk of seizures with clozapine therapy appears to be related to dosage and/or plasma concentrations of the drug, with a reported incidence of approximately 0.6—2% at dosages less than 300 mg daily, 1.4—5% at 300—600 mg daily, and 5—14% at high dosages (600—900 mg daily). Clozapine-induced seizures may be associated with rapid dosage escalations or the influence of drugs or disease on clozapine metabolism, which maylead to increased plasma concentrations of the drug.

One patient receiving clozapine experienced a generalized tonic-clonic (grand mal) seizure following accidental ingestion of an extra dose (total dose ingested within 24 hours: 1050 mg); the same patient had another seizure several weeks later, 2 hours after a usual 450-mg morning dose. Results of plasma clozapine determinations obtained at the time of the seizures revealed plasma clozapine concentrations of approximately 2000 ng/mL in each case. Another patient who had been taking clozapine for 27months had a generalized tonic-clonic seizure following an apparent intentional overdosage (total dose ingested within 24 hours: approximately 3 g), after which the patient made an uneventful recovery. One hour after the seizure, the patient’s plasma clozapine concentration was 1313 ng/mL.

Discontinuance of clozapine therapy, at least temporarily, should be seriously considered in patients who experience seizures while receiving the drug; however, some clinicians state that reduced clozapine dosage and/or, occasionally, addition of anticonvulsant therapy may adequately ameliorate this effect. If clozapine therapy is to be continued in such patients, many clinicians recommend obtaining additional informed consent from the patient. In patients in whom clozapine is withheld, it has been suggested that therapy with the drug can be reinitiated at one-half the previous dosage. Clozapine dosage may then be increased gradually, if clinically indicated, and the need for concomitant anticonvulsant therapy should be considered. Some clinicians recommend that patients who have experienced a clozapine-induced seizure not be given clozapine dosages exceeding 600 mg daily unless the results of an EEG performed prior to the anticipated dosage increase are normal; others suggest addition of anticonvulsant therapy and/or consultation with a neurologist in managing such patients. In patients with preexisting seizure disorders who are treated concomitantly with certain anticonvulsants and clozapine, the anticonvulsant dosage may need to be increased. However, clozapine should not be used concomitantly with anticonvulsants (e.g., carbamazepine) or other drugs that potentially may cause bone marrow suppression. (See Drug Interactions: Myelosuppressive Agents.)

Extrapyramidal Reactions

In contrast to other antipsychotic agents, clozapine has a low potential for causing certain acute extrapyramidal effects (e.g., dystonias). Such effects, when they occur, have been limited principally to tremor, restlessness, rigidity, and akathisia; these manifestations generally are milder and less persistent than those produced by other antipsychotic drugs. In addition, marked or total remission of such manifestations induced by other antipsychotics has occurred during treatment with clozapine in some patients.

Neuroleptic malignant syndrome (NMS), a ***potentially fatal symptom complex****,* has been reported in patients receiving phenothiazines or other antipsychotic therapy. NMS attributable to clozapine therapy alone has been reported in a few patients, and there also have been several reports of NMS in patients treated concomitantly with clozapine and lithium or other CNS drugs; some clinicians suggest that NMS may be more likely to occur when clozapine or other antipsychotic agents are used concomitantly with lithium. Manifestations of NMS (e.g., muscle rigidity, hyperpyrexia, tachycardia, increased serum creatine kinase [CK, creatine phosphokinase, CPK], diaphoresis, somnolence), all of which may not occur in all patients with the condition, have occurred in a few patients treated with clozapine alone or combined with lithium or carbamazepine; resolution of the syndrome occurred following discontinuance of clozapine. However, clozapine also has been used successfully and apparently without recurrence of NMS in at least one patient who developed the syndrome while receiving chlorpromazine.

For additional information on NMS, see Extrapyramidal Reactions in Cautions: Nervous System Effects, in the Phenothiazines General Statement 28:16.08.

Tardive Dyskinesia
A syndrome consisting of potentially ***irreversible, involuntary, dyskinetic movements*** may develop in patients treated with antipsychotic agents. However, results of clinical trials in which clozapine was used have demonstrated a virtual absence of acute extrapyramidal reactions (e.g., dystonia), and there reportedly have been no confirmed cases of tardive dyskinesia associated with clozapine therapy alone. Nevertheless, a few cases of tardive dyskinesia have been reported in patients receiving clozapine who had been treated previously with other antipsychotic agents. Although current evidence suggests that clozapine may be less likely than other antipsychotic agents to cause tardive dyskinesia, it cannot yet be concluded, based on current limited experience, that the drug is incapable of causing this syndrome. The possibility of clozapine-induced tardive dyskinesia should be considered in patients receiving long-term therapy with the drug or in those starting clozapine therapy after discontinuance of other antipsychotic agents.

For additional information on tardive dyskinesia, see Tardive Dyskinesia in Cautions: Nervous System Effects in the Phenothiazines General Statement 28:16.08.

Other Nervous System Effects
Drowsiness and/or sedation occur frequently in patients receiving clozapine. (See Effects on Sleep under Pharmacology: Nervous System Effects.) The sedative-hypnotic effect of clozapine is most pronounced initially, diminishes after 1—4 weeks, and thengenerally, but not always, disappears during continued therapy. Daytime sleepiness may be minimized by administration of clozapine at bedtime. (See Dosage and Administration: Dosage.)

Dizziness and vertigo, headache, syncope, disturbed sleep (e.g., insomnia) or nightmares, hypokinesia or akinesia, and agitation have been reported with clozapine therapy. Clozapine also may cause confusion or delirium, which may be related to centralanticholinergic effects, and has been ameliorated in some cases by IV administration of physostigmine. Depression, fatigue, hyperkinesia, weakness or lethargy, and slurred speech also have been reported. Other adverse nervous system effects associated with clozapine therapy include ***ataxia, epileptiform movements or myoclonic jerks, and anxiety***.

Adverse nervous system effects reported in less than 1% of clozapine-treated patients include ***loss of speech, amentia (deterioration in cognitive function), tics, poor coordination, delusions or hallucinations, stuttering, dysarthria, amnesia, histrionic movements, increased or decreased libido, paranoia, shakiness, parkinsonian syndrome, and irritability.*** Difficulty in writing, residual daytime effects such as impairment of mental performance, and periodic cataplexy, which is characterized by sudden episodes of dropping objects and may or may not be accompanied by knee buckling, also have been reported infrequently with clozapine therapy**.** ***Exacerbation of psychosis, myoclonus, paresthesia, and status epilepticus*** have been reported in patients receiving clozapine during postmarketing surveillance; however, a causal relationship to the drug has not been established.

Abrupt discontinuance of clozapine (e.g., because of leukopenia or agranulocytosis) may result in recurrence of psychotic symptoms or behavior, including autism, auditory hallucinations, suicide attempts, development of parkinsonian symptoms, anxiety,insomnia, delusions, and violent behavior. It has been suggested that this "rebound psychosis" may result, at least in part, from clozapine-induced supersensitivity of mesolimbic dopamine receptors (see Behavioral Effects in Animals under Pharmacology:Nervous System Effects) and that the essential feature of this phenomenon appears to be recurrence of positive symptoms of schizophrenia. Patients who develop rebound psychosis following discontinuance of clozapine may improve with initiation of other antipsychotic therapy; however, clozapine should not be reinstituted in patients in whom severe leukopenia/granulocytopenia or agranulocytosis has occurred.(See Cautions: Hematologic Effects.)

Fever:

Fever or transient temperature elevations exceeding 38°C generally have been reported in 5% or more of patients receiving clozapine. The peak incidence of fever occurs within the first 3 weeks of therapy, usually between days 5—20 of treatment. Fever generally is benign and self-limiting and usually diminishes within a few (4—8) days despite continued clozapine therapy; however, it may necessitate discontinuance of the drug. ***Fever occasionally may be associated with an increase or decrease in leukocyte count, in which case patients should be evaluated for underlying infection or development of agranulocytosis.*** (See Cautions: Hematologic Effects.) In the presence of high fever, the possibility of neuroleptic malignant syndrome also must be considered. (See Extrapyramidal Reactions under Cautions: Nervous System Effects.)

The mechanism of clozapine-induced fever (other than that occurring secondary to some other factor such as infection) is not yet known. It may result from the drug's pronounced anticholinergic activity (see Anticholinergic Effects under Pharmacology: Nervous System Effects) or a direct effect on the hypothalamic thermoregulatory center. Clozapine-induced hyperthermia may be a hypersensitivity reaction, a common mechanism underlying drug fevers. It has been suggested that decreasing the dosage of clozapine and then gradually increasing it to the previous level may reverse the hyperthermia and not be accompanied by a recurrence of elevated temperature; however, recurrence is possible despite such dosage adjustment.

Cardiovascular Effects:

Hypotension and hypertension reportedly occur in less than 10% of patients receiving clozapine. When they occur, changes in blood pressure, principally reductions in systolic pressure, appear soon after initiation of clozapine therapy and may be associated with rapid dosage increases. A decrease in arterial blood pressure below 90 mm Hg was reported in 18% of male patients and 33% of female patients receiving clozapine in one retrospective study. Hypotension may result from clozapine's antiadrenergic effects (see

Adrenergic Effects under Pharmacology: Nervous System Effects) and may pose a serious risk for individuals with compromised cardiac function. However, tolerance to the hypotensive effects of clozapine often develops with continued therapy.

Orthostatic hypotension, with or without syncope, has been reported, particularly during initial titration or rapid escalation of clozapine dosage; however, this effect may represent a continuing risk in some patients. Rarely (approximately 1 case per 3000 patients), ***orthostatic hypotension has been accompanied by profound collapse and respiratory and/or cardiac arrest*** in patients receiving initial doses as low as 12.5 mg. If clozapine therapy is temporarily discontinued (i.e., for 2 or more days),the manufacturers recommend that the drug be reinitiated at a lower dosage (12.5 mg once or twice daily). In some cases when collapse and cardiac and/or respiratory arrest developed during initial therapy, benzodiazepines or other psychotropic agents were used concomitantly, suggesting a possible adverse interaction between clozapine and these agents. (See Drug Interactions: Benzodiazepines.) Although the clinical importance of this interaction has not been fully established, the manufacturers state that clozapine should be initiated with caution in patients receiving benzodiazepines or other psychotropic agents. Collapse and respiratory and/or cardiac arrest also have been reported in patients receiving initial therapy with clozapine alone. The risk of orthostatic hypotension may be reduced by initiating therapy at lower dosages, followed by only gradual, modest increases as necessary.(See Dosage and Administration: Dosage.) In some cases, withholding the drug for 24 hours and then restarting at a lower dosage has been accomplished without recurrence of orthostatic hypotension.

Tachycardia, which may persist throughout therapy in some cases, reportedly has been observed in 25% of patients receiving clozapine. Patients who experience clozapine-induced tachycardia demonstrate an average increase in pulse rate of 10—15 beats per minute (bpm); with aggressive dosage increases, the mean increase in heart rate ranges from 20—25 bpm. Persistent tachycardia associated with clozapine therapy is not simply a reflex response to hypotension and is present in all positions monitored. Although this effect may lessen once a plateau dosage level is reached, ***tachycardia may pose a serious risk for individuals with compromised cardiac function.***

Some clozapine-treated patients experience ECG repolarization changes, including ST-segment depression, shortening of the PQ interval, and/or flattening, depression, or inversion of T waves. These changes usually normalize after discontinuance of clozapine and are similar to those seen with other antipsychotic agents. The clinical importance of these changes currently is unclear, but some clinicians suggest that they occur infrequently and usually are not serious.

In clinical trials of clozapine, ***some patients experienced serious cardiovascular events, including ischemic changes, chest pain and angina, hypertension, myocardial infarction, nonfatal arrhythmias, or sudden, unexplained death.*** Causality assessment was difficult because of serious preexisting cardiac disease in many of the patients and plausible alternative causes.

Congestive heart failure and myocarditis (with or without eosinophilia), and pericarditis/pericardial effusions reportedly have occurred in clozapine-treated patients. Postexercise decreases in left ventricular output, which may indicate left ventricular failure, also have been reported in patients receiving the drug. Edema, palpitation, phlebitis or thrombophlebitis, cyanosis, ventricular premature complexes, and bradycardia have been reported in less than 1% of clozapine-treated patients. Although a causal relationship has not been established, atrial or ventricular fibrillation also has been reported in patients receiving the drug.

Deep-vein thrombosis and pulmonary embolism have been reported in patients receiving clozapine during postmarketing surveillance. As of December 31, 1993, 18 cases of fatal pulmonary embolism were reported in patients 10—54 years of age receiving clozapine therapy. Based on the extent of use observed in the Clozaril National Registry, the mortality rate associated with pulmonary embolism were 1 death per 3450 person-years of use; this incidence is approximately 27.5 times higher than that in thegeneral population. Although a causal relationship between clozapine and these adverse cardiovascular effects has not been established, the possibility of pulmonary embolism should be considered in patients presenting with deep-vein thrombosis or respiratory symptomatology. (See Cautions: Precautions and Contraindications.)

Rare instances of sudden, unexplained death have been reported in psychiatric patients, with or without associated antipsychotic drug treatment, and the relationship between sudden death and antipsychotic drug use is unknown. Some autopsy results have suggested that clozapine-treated patients have died from cardiac arrest and uncompensated cardiac disease, or from other causes such as renal insufficiency or severe alcohol abuse. A causal relationship between clozapine use and sudden death has not been established.

Autonomic Nervous System Effects:

Adverse autonomic nervous system effects occur in more than 5% of patients receiving clozapine. Dry mouth occurs frequently, but hypersalivation, an apparently paradoxical effect considering the drug's potent anticholinergic activity, is more common. (See Cautions: GI Effects.)

Other autonomic nervous system effects of clozapine include ***hyperhidrosis, decreased sweating, visual disturbances, nasal congestion, and pallor. Numbness, polydipsia, hot flushes (flashes), dry throat, and mydriasis*** have been reported in less than 1%of clozapine-treated patients.

Hepatic Effects:

Transient increases in liver function test results, including serum aminotransferases (transaminases), LDH, and alkaline phosphatase, may occur with clozapine therapy,

usually with no accompanying physical signs or symptoms. Clozapine-induced changes in liver function test results may be more pronounced than those with other tricyclic antipsychotic agents. Clozapine causes slight ***liver hyperplasia*** in rats; hyperplasia was reversible and no histologic changes were detectable. Clozapine occasionally causes slight elevations of bilirubin concentration. ***Cholestasis, hepatitis, and jaundice have been reported in patients receiving clozapine*** during postmarketing surveillance; however, a causal relationship to the drug has not been established.

Endocrine and Metabolic Effects:

Clozapine causes only a brief, transient ***elevation of prolactin concentration***. (See Pharmacology: Neuroendocrine Effects.) Because the drug's effects on prolactin are only minor, prolactin-dependent effects such as galactorrhea and amenorrhea usually are not associated with clozapine therapy. Breast pain or discomfort has been reported in less than 1% of clozapine-treated patients.

Clozapine may cause increased appetite, polyphagia, and weight gain in a substantial proportion (approximately one-third) of patients. Some clinicians suggest that the potential for weight gain with clozapine therapy may be similar to that with other antipsychotic therapy; others state that they have observed greater weight gain with clozapine in some patients. Some clozapine-treated patients reportedly have gained up to 1 kg weekly for 6 weeks. Weight gain may result from the drug's serotonergic-, histaminergic-, and adrenergic-blocking properties. Weight gain has been reported to be a problem for some patients during long-term therapy with clozapine and may be a major cause of outpatient noncompliance. Some clinicians suggest using exerciseand active measures (e.g., dietary counseling) to control dietary intake in clozapine-treated patients.

Severe hyperglycemia, sometimes leading to ketoacidosis, has been reported in patients without a prior history of hyperglycemia who received clozapine therapy. While a causal relationship to clozapine has not been established, blood glucose concentrations reportedly returned to normal following discontinuance of the drug in most patients but recurred in at least one patient upon subsequent rechallenge with clozapine. The effect of clozapine on glucose metabolism in patients with diabetes mellitus has not been studied.

Hyperuricemia, hyponatremia, weight loss, and decreased serum cholesterol concentrations also have been reported in patients receiving clozapine, although a causal relationship to the drug has not been established.

Small ***decreases in protein-bound iodine or thyroxine concentrations*** have been reported in some patients receiving clozapine, but these values remained within normal limits.

GI Effects:

Increased salivation may occur in approximately one-third of patients receiving clozapine; in some studies, hypersalivation was reported in up to 75—85% of clozapine-treated patients. Salivation may be profuse, very fluid, and particularly troublesome during sleep because of decreased swallowing. Since clozapine exhibits intrinsic anticholinergic properties, hypersalivation is an unexpected paradoxical effect. A muscle-relaxant effect of the drug may contribute to hypersalivation, but the cause has not been fully elucidated. Difficulty in swallowing has been reported in a few clozapine-treated patients, and it has been suggested that the drug may cause esophageal dysfunction, which may contribute to or exacerbate the nocturnal hypersalivation associated with clozapine therapy. Some clozapine-treated patients develop tolerance to increased salivation within a few weeks. Occasionally, hypersalivation may be ameliorated by reduction of clozapine dosage or cautious use of a peripherally acting anticholinergic drug; however, some clinicians generally advise against the use of anticholinergic therapy for this adverse effect because of possible potentiation of clozapine's anticholinergic activity.

Other GI effects associated with clozapine therapy include ***constipation, diarrhea, nausea and vomiting, heartburn, abdominal discomfort, and anorexia***; some of these effects have been reported in more than 5% of patients. Although some clinicians advocate the use of metoclopramide (e.g., in doses less than 30 mg daily) for the treatment of clozapine-induced nausea, other clinicians suggest that metoclopramide or other dopamine antagonists not be used or be used with extreme caution for the treatment of clozapine-induced nausea because of their potential for causing parkinsonian manifestations and tardive dyskinesia.

Abdominal distention, gastroenteritis, rectal bleeding, nervous stomach, abnormal stools, hematemesis, gastric ulcer, bitter taste, and eructation have been reported in less than 1% of patients receiving clozapine. Although a causal relationship to the drug has not been established, salivary gland swelling and paralytic ileus also have been reported in patients receiving clozapine.

Genitourinary Effects:

Genitourinary effects reported with clozapine therapy include ***polyuria, incontinence, urinary urgency or frequency, urinary retention, or other urinary abnormalities; enuresis; impotence; abnormal ejaculation; dysmenorrhea; and vaginal itch or infection. Priapism and acute interstitial nephritis also have been reported with clozapine therapy***, although a causal relationship to the drug has not been established.

Respiratory Effects:

Clozapine-induced respiratory effects include ***throat discomfort, dyspnea or shortness of breath, coughing, pneumonia or pneumonia-like symptoms, rhinorrhea,***

hyperventilation, wheezing, bronchitis, laryngitis, and sneezing. Although a causal relationship to the drug has not been established, aspiration and pleural effusion also have been reported with clozapine therapy during postmarketing surveillance.

Respiratory depression or failure, including arrest requiring resuscitation, also has been reported in patients receiving clozapine, usually at initiation of therapy and particularly in patients receiving concomitant benzodiazepine therapy or in those with a history of recent benzodiazepine use. Some evidence indicates that the incidence of respiratory arrest and vascular collapse is about 1—2% of patients receiving clozapine concomitantly with a benzodiazepine. For additional precautionary information about this potential effect, see Drug Interactions: Benzodiazepines.

Dermatologic and Sensitivity Reactions:

Rash has been reported in 2% of patients receiving clozapine. ***Pruritus, eczema, erythema, bruising, dermatitis, petechiae, and urticaria have occurred*** in less than 1% of patients.

Hypersensitivity reactions, including photosensitivity, vasculitis, erythema multiforme, and Stevens-Johnson syndrome, have been reported with clozapine during postmarketing surveillance; however, a causal relationship to the drug has not been established.

Musculoskeletal Effects:

Adverse musculoskeletal effects reported in 1% of clozapine-treated patients include ***muscular weakness (myasthenic syndrome); back, neck, and leg pain; and muscle ache or spasm. Muscle twitching and joint pain have been reported less frequently. Rhabdomyolysis has been reported with clozapine*** during postmarketing surveillance; however, a causal relationship to the drug has not been established.

Other Adverse Effects:

Numb or sore tongue, chills (with or without fever), malaise, ear or eyelid disorder, ocular hyperemia, epistaxis, and nystagmus have been reported in 1% or less of patients receiving clozapine. ***Periorbital edema*** also has been reported in clozapine-treated patients, although a causal relationship to the drug has not been established.

Mutagenicity and Carcinogenicity:

Clozapine did not exhibit carcinogenic potential in long-term studies in mice and rats receiving dosages approximately 7 times (on a mg/kg basis) the usual human dosage. Clozapine also did not exhibit genotoxic or mutagenic effects when assayed in appropriate bacterial and mammalian tests.

CLOZAPINE
Drug Interactions

Drug-Drug Interactions from First DataBank

These drug interactions are reviewed by an editorial panel at First DataBank and determined to be clinically significant.The list does not include every interaction ever reported.

Contraindicated
RITONAVIR/CLOZAPINE

Severe
CLOZAPINE/CARBAMAZEPINE

Moderate
CLOZAPINE/SELECT SSRI'S

Drug Interactions:

The manufacturer states that the potential risks of using clozapine in combination with other drugs have not been evaluated systematically. However, clinical experience and/or theoretical considerations indicate that certain potential drug interactions exist.

Myelosuppressive Agents
The mechanism of clozapine-induced agranulocytosis is unknown; however, the possibility that causative factors may interact synergistically to increase the risk and/or severity of bone marrow suppression warrants consideration. (See Cautions: Hematologic Effects.) Therefore, clozapine should not be used with other agents having a well-known potential to suppress bone marrow function. That clozapine may be directly myelotoxic has been suggested by in vitro study of the serum and bone marrow of a patient who died during multidrug therapy that included clozapine and carbamazepine.

Drugs Affecting the Seizure Threshold
Clozapine may lower the seizure threshold and has caused seizures in some patients (see Seizures under Cautions: Nervous System Effects); therefore, concomitant therapy with other agents that lower the seizure threshold generally should be avoided if possible. If such combined therapy is required, caution should be exercised (e.g., using low initial dosages of clozapine with slow upward titration) and the possible need for anticonvulsant therapy considered.

Benzodiazepines
Severe hypotension (including absence of measurable blood pressure), respiratory or cardiac arrest, and loss of consciousness have been reported in several patients who received clozapine concomitantly with or following benzodiazepine (i.e., flurazepam, lorazepam, diazepam) therapy. Such effects occurred following administration of 12.5—150 mg of clozapine concurrently with or within 24 hours of the benzodiazepine, but patients generally have recovered within a few minutes to hours, usually spontaneously; the reactions usually developed on the first or second day of clozapine therapy. Although a causal relationship has not definitely been established and such effects also have been observed in clozapine-treated patients who were not receiving abenzodiazepine concomitantly (see Cautions: Cardiovascular Effects), death resulting from respiratory arrest reportedly has occurred in at least one patient receiving clozapine concomitantly with a benzodiazepine. An increased incidence of dizziness and sedation and greater increases in liver enzyme test results also have been reported with this drug combination.

The manufacturer of clozapine recommends caution when the drug is initiated in patients receiving benzodiazepine therapy. However, some clinicians advise that, pending further accumulation of data, greater precaution should be exercised. These clinicians recommend that since initial titration of clozapine may cause respiratory arrest requiring resuscitation, which may be potentiated by recent benzodiazepine therapy, these latter drugs should be discontinued for at least 1 week prior to initiating clozapine therapy. In addition, these clinicians recommend that clozapine therapy be initiated in a setting where facilities for resuscitation are immediately available for the first few hours after administration of the first dose. Other clinicians, however, state that institutional initiation of clozapine therapy may not be necessary or practical, although they recommend slow and cautious initiation of the drug at low dosages.

Other CNS Depressants
Clozapine may be additive with, or may potentiate the action of, other CNS depressants such as opiates or other analgesics, barbiturates or other sedative/hypnotics, general anesthetics, or alcohol. When clozapine is used concomitantly with other CNS-depressant drugs, caution should be exercised to avoid excessive sedation.

Other CNS-active Agents
Although a causal relationship has not been established, at least one death has been reported with concomitant clozapine and haloperidol therapy. A 31-year-old woman with schizophrenia developed respiratory arrest, became comatose, and died 4 days after receiving 10 mg of haloperidol orally and a single 100-mg dose of clozapine IM. The patient had been maintained on oral clozapine 200 mg daily for 2 years and also had received smaller doses of haloperidol concomitantly with clozapine therapy without unusual adverse effect.

Neuroleptic malignant syndrome has been reported rarely with clozapine therapy alone and during concomitant therapy with clozapine and carbamazepine, lithium, or other

CNS-active agents. (See Extrapyramidal Reactions under Cautions: Nervous System Effects.)

Orthostatic hypotension, sometimes accompanied by profound collapse and respiratory and/or cardiac arrest, has been reported rarely with clozapine therapy alone and during concomitant therapy with other psychotropic agents. Although the clinical importance of this interaction has not been fully established, the manufacturers of clozapine state that the drug should be initiated with caution in patients receiving other psychotropic agents.

Drugs Undergoing Hepatic Metabolism or Affecting Hepatic Microsomal Enzymes
Metabolism of clozapine is mediated by the cytochrome P-450 (CYP) microsomal enzyme system, mainly by the isoenzyme 1A2 (CYP1A2), and possibly by other isoenzymes (e.g., CYP2D6). Concomitant use of clozapine with drugs that inhibit the CYP enzyme system (e.g., cimetidine, erythromycin, quinidine, certain antidepressants, phenothiazines, type 1C antiarrhythmics [e.g., propafenone, flecainide, encainide]) may result in increased plasma concentrations of clozapine. Conversely, concomitant use of clozapine with drugs that induce the CYP enzyme system (e.g., carbamazepine, phenytoin) may result in decreased plasma concentrations of clozapine. Caution should be observed if clozapine is used concomitantly with these drugs. Dosage adjustments of clozapine and/or other drugs may be necessary in patients receiving concomitant therapy with drugs that inhibit or induce the CYP enzyme system.

Phenytoin
Substantial reductions in plasma clozapine concentrations and exacerbation of psychosis have been reported in patients receiving concomitant therapy with clozapine and phenytoin, and an increase in clozapine dosage may be required to reestablish antipsychotic efficacy in patients receiving such combined therapy. In 2 patients stabilized for 1—2 weeks on a given dosage of clozapine, addition of phenytoin for prevention of clozapine-induced seizures resulted in a 65—85% decrease in steady-state plasma clozapine concentrations. Control of psychotic manifestations was regained in both patients by gradually increasing clozapine dosage. Although the mechanism of this potential interaction has not been established, it has been suggested that phenytoin may increase clozapine metabolism via stimulation of the hepatic cytochrome P-450 (microsomal) enzyme system and/or displacement of clozapine from protein binding sites, or that phenytoin may decrease absorption of clozapine from the GI tract. Pending further study, clozapine-treated patients in whom phenytoin therapy is initiated should be monitored carefully for reemergence of psychotic manifestations and clozapine dosage adjusted accordingly.

Carbamazepine
Concomitant use of clozapine and carbamazepine has been shown to decrease clozapine concentrations by about 40—50%. In addition, neuroleptic malignant syndrome has been reported rarely with clozapine therapy alone and during concomitant therapy with carbamazepine. (See Extrapyramidal Reactions under Cautions: Nervous System Effects.) Therefore, the manufacturers of clozapine state that concomitant use of these

agents generally is not recommended. However, if clozapine and carbamazepine are used concomitantly, it should be considered that discontinuance of carbamazepine may result in increased plasma concentrations of clozapine.

Selective Serotonin-reuptake Inhibitors
Concomitant use of clozapine with certain selective serotonin-reuptake inhibitors (SSRIs) can increase plasma concentrations of clozapine and enhance clozapine's pharmacologic effects secondary to suspected inhibition of clozapine metabolism by SSRIs. Modest (less than twofold) elevations in plasma clozapine concentrations have been reported in patients receiving clozapine concomitantly with certain SSRIs (i.e., fluoxetine, paroxetine, sertraline), although substantial (threefold) increases in trough plasma clozapine concentrations have occurred in patients receiving concomitant therapy with clozapine and fluvoxamine. The manufacturers of clozapine state that caution should be exercised and patients should be closely monitored when clozapine is used in patients receiving SSRIs, and a reduction in clozapine dosage should be considered.

Protein-bound Drugs
Because clozapine is highly protein bound, it theoretically could be displaced from binding sites by, or it could displace from binding sites, other protein-bound drugs such as oral anticoagulants (e.g., warfarin). Although no clinically important drug interactions have been reported to date, patients receiving clozapine with drugs that are highly protein bound should be observed closely for adverse effects.

Other Drugs
Clozapine has potent anticholinergic effects and may potentiate the actions of other drugs possessing such activity (e.g., antimuscarinics).

Clozapine may be additive with or potentiate the actions of hypotensive agents. In addition, the administration of epinephrine should be avoided in the treatment of clozapine-induced hypotension because of a possible reversal of epinephrine's vasopressor effects and subsequent further lowering of blood pressure.

Smoking
Some evidence indicates that cigarette smoking may substantially reduce plasma clozapine concentrations. Limited data indicate that average plasma clozapine concentrations following a given dose in smokers average 60—82% of those in nonsmokers. Changes in liver enzyme activity and/or the GI tract induced by nicotine or other substances present in cigarette smoke may explain these reduced concentrations. These effects should be considered when adjusting clozapine dosage in patients who smoke cigarettes.

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CLOZAPINE
Overdose & Toxicity

Chronic Toxicity:

Physical and/or psychological dependence have not been reported in patients receiving clozapine.

Chronic toxicity studies in mice, rats, dogs, and monkeys have revealed no specific organ toxicity. After 1 year of treatment with clozapine, a brown discoloration caused by increased lipopigment was observed in various organs in rats; this change normally appears with increasing age. Discoloration was noted in the thyroid, brain, liver, kidney, heart, spleen, and skeletal muscle of rats, but such increased pigmentation was not associated with deleterious changes. The liver did show slight, dose-dependent changes, including centrolobular vacuolation, hepatocyte swelling, and increased weight.

Acute Toxicity:

Pathogenesis
Acute toxicity studies in animals revealed that the LD50s for clozapine administered orally, IV, or intraperitoneally are approximately 145—325, 58—61, and 90 mg/kg, respectively.

Although the acute lethal dose of clozapine in humans remains to be established, fatal overdoses with the drug generally have been associated with doses exceeding 2.5 g. However, there also have been reports of patients surviving overdoses that substantially exceeded 4 g of the drug.

Manifestations
In general, overdosage of clozapine may be expected to produce effects that are extensions of pharmacologic and adverse effects. The most commonly reported signs and symptoms of clozapine overdosage have been altered states of consciousness and CNS depression (e.g., drowsiness, delirium, coma), tachycardia, cardiac arrhythmias, hypotension, respiratory depression or failure, aspiration pneumonia, and hypersalivation. Seizures have occurred with overdosage in some patients. (See Seizures under Cautions: Nervous System Effects.)

A 24-year-old woman who ingested 2 g in excess of her prescribed daily dosage (i.e., total ingestion approximately 3 g within a 24-hour period) had a tonic-clonic (grand mal) seizure; her plasma clozapine concentration 1 hour after the seizure (1313 ng/mL) was 500 ng/mL higher than usual, but she recovered uneventfully. In a 50-year-old woman who ingested 1 g of clozapine, the only manifestations were confusion and hallucinations lasting about 48 hours. A 26-year-old man who ingested approximately 3 g of clozapine became drowsy, agitated, and disoriented; he also had visual hallucinations, dysarthria, tachycardia, and hypersalivation. The patient was treated with gastric lavage and also received diazepam, digitalis, and anti-infectives, but continued to exhibit manifestations of severe central anticholinergic toxicity. Administration of physostigmine salicylate 2 mg by slow IV injection resulted in improvement in the patient's mental status within minutes; however, symptoms recurred after approximately 1 hour. Symptoms finally remitted 18—24 hours later with no further treatment.

Treatment

Treatment of clozapine overdosage generally requires symptomatic and supportive care, including monitoring of cardiac and vital signs. There is no specific antidote for the management of clozapine overdosage.

The manufacturer recommends establishing and maintaining an airway and ensuring adequate ventilation and oxygenation. Activated charcoal, which may be used with sorbitol, may be as or more effective than emesis or gastric lavage and should be considered in the treatment of clozapine overdosage. Electrolyte and acid-base balance should be monitored and adjusted accordingly. Peritoneal dialysis or hemodialysis is of limited value in the treatment of clozapine overdosage because the drug is almosttotally bound to serum protein. Forced diuresis, hemoperfusion, and exchange transfusion also are unlikely to be of benefit. While physostigmine salicylate may be useful as adjunctive treatment if severe anticholinergic toxicity is present, the drugshould not be used routinely because of its potential adverse effects.

Epinephrine should not be used for treating clozapine-induced hypotension, since clozapine can reverse epinephrine's vasopressor effects and cause a further lowering of blood pressure. Because of potential additive anticholinergic effects, quinidine or procainamide should be avoided when treating clozapine-induced arrhythmias. Surveillance of the patient should be continued for several days following overdosage because of the risk of delayed effects. In managing clozapine overdosage, the clinician should consider the possibility of multiple drug involvement.

CLOZAPINE
Pharmacology & Chemistry

Chemistry and Stability:

Chemistry
Clozapine is a dibenzodiazepine-derivative antipsychotic agent. The drug is a piperazine-substituted tricyclic antipsychotic agent that is structurally similar to loxapine but that differs pharmacologically from this and other currently available antipsychotic agents (e.g., phenothiazines, butyrophenones). Because of these pharmacologic differences, clozapine is considered an atypical antipsychotic agent.

While the structure-activity relationships of phenothiazine antipsychotic agents have been well described, these relationships for heterocyclic antipsychotic agents, including clozapine, have not been as fully characterized. Generally, the unsubstituted benzene ring seems to be important for interactions at dopamine receptors, while the chloro-substituted benzene ring seems more important for action at muscarinic receptors. In addition, an open carbon side chain replacing the piperazine moietyof clozapine generally leads to loss of activity.

Clozapine differs structurally from most currently available antipsychotic agents by the presence of a seven- rather than a six-membered central ring and the spatial relationship between the piperazine moiety and the chloro-substituted benzene ring.The core tricyclic ring system of clozapine is nonplanar and allows the piperazine moiety limited freedom of rotation.

Clozapine differs structurally from loxapine by the presence of a diazepine rather than an oxazepine central ring in the tricyclic nucleus and by the presence of a chlorine atom at position 8 rather than 2 of the tricyclic nucleus. The presence of a chlorine atom at position 8 of the tricyclic nucleus of clozapine appears to be associated with its distinct pharmacologic profile and may be responsible for the drug's antimuscarinic activity.

Clozapine occurs as a yellow, crystalline powder and is very slightly soluble in water.

Stability
Commercially available clozapine tablets should be stored in tight containers at a temperature not exceeding 30°C.

Pharmacology:

Clozapine is a dibenzodiazepine-derivative antipsychotic agent. While clozapine shares some of the pharmacologic actions of other antipsychotic agents, the drug has been described as an atypical antipsychotic agent since many of its CNS effects differ from

those of typical agents (e.g., butyrophenones, phenothiazines). In fact, these apparent differences in actions on neostriatal dopaminergic receptors have led some investigators to question the importance of the dopaminergic system in mediatingthe therapeutic effects of neuroleptic drugs. The exact mechanism of antipsychotic action of clozapine has not been fully elucidated but appears to be more complex than that of other antipsychotic agents and may involve serotonergic, adrenergic, and cholinergic neurotransmitter systems in addition to more selective, regionally specific effects on the mesolimbic dopaminergic system. Because of differences in the neurologic effects of clozapine, the drug is not considered a classic neuroleptic agent.

Nervous System Effects

Although the precise mechanism of action of antipsychotic drugs has not been fully elucidated, current data suggest that the therapeutic effects of these agents involve antagonism of dopaminergic systems in the CNS. In animals, classic neuroleptic agents increase muscle tone or induce postural abnormalities (catalepsy), antagonize stereotyped behaviors induced by the dopamine agonists apomorphine and amphetamine, accelerate dopamine turnover in various areas of the brain, increase serum prolactinconcentrations, and produce dopamine receptor hypersensitivity on repeated administration. These effects, many of which have been attributed to blockade of dopamine receptors in the neostriatum, form the basis for the hypothesis that idiopathic psychoses result from overactivity of dopamine in neostriatal and mesolimbic systems.

Unlike typical antipsychotic agents, clozapine exerts relatively weak antidopaminergic action within the neostriatum and has a low propensity to produce extrapyramidal effects or stimulate prolactin secretion. While some studies have demonstrated that relatively high doses of clozapine suppress the conditioned avoidance response in animals, which is a characteristic of typical antipsychotic agents, this response is not completely blocked by clozapine, and tolerance to this effect develops rapidly with repeated dosing, suggesting that it is not specifically related to clozapine's antipsychotic action. Further research is needed to elucidate fully clozapine's antipsychotic action in terms of the drug's serotonergic, adrenergic, muscarinic, and peptidergic effects and their influences on functional alterations in dopamine receptor systems.

Antidopaminergic Effects

The therapeutic effects of antipsychotic drugs are thought to be mediated by dopaminergic blockade in the mesolimbic and mesocortical areas of the CNS, while antidopaminergic effects in the neostriatum appear to be associated with extrapyramidal effects. Several (at least 5) different types or subtypes of dopamine receptors have been identified in animals and humans. The relative densities of these receptors and their distribution and function vary for different neuroanatomical regions, and clozapine's unique effects may be secondary to regionally specific receptor interactions and/or other effects on dopaminergic neurons. Results obtained from receptor binding, behavioral, metabolic, and electrophysiologic studies of clozapine as well as theapparently low incidence of extrapyramidal effects associated with clozapine therapy suggest that the drug is more active in the mesolimbic than the neostriatal dopaminergic system. Results

of some studies suggest that clozapine is more effective inincreasing dopamine turnover and release in the nucleus accumbens or olfactory tubercle than in the neostriatum with acute administration and that it reduces dopamine release in the accumbens but not in the neostriatum during prolonged administration, which suggests preferential effects on dopaminergic function in the limbic system. However, conflicting data (i.e., no preferential limbic effects) also have been reported with both acute and repeated administration of the drug, which may reflect differences in analytical techniques, regional differences in drug distribution or receptor affinity, or other variables.

Some evidence suggests that the effects of clozapine on dopamine metabolism in the neostriatum are dose related; unlike typical antipsychotic drugs, clozapine appears to increase striatal dopamine turnover only at supratherapeutic doses. Single highdoses (80 mg/kg intraperitoneally) of clozapine in rats interfere with dopaminergic transmission by blocking postsynaptic dopamine receptors and causing a compensatory increase in dopaminergic neuronal firing, while lower doses retard dopamine release. Clozapine appears to increase striatal dopamine content when given either in single high doses or repeated low doses, and low doses of the drug reportedly decrease the degradation of dopamine to 3-methoxy-4-hydroxyphenylacetic acid (homovanillic acid, HVA) in the neostriatum. In a rodent model of tardive dyskinesia, single low doses (up to 1.2 mg/kg intraperitoneally) of clozapine suppressed ketamine-induced linguopharyngeal movements, which resemble symptoms of tardive dyskinesia (e.g., tongue protrusions, retrusions, and swallows), by 15—75% compared with baseline measures. At clozapine doses of 4.8 mg/kg or higher, clozapine caused total suppression of these movements, and duration of suppression became dose dependent. Since suppression of abnormal linguopharyngeal movements occurred at doses substantially lower than those reported to alter dopamine turnover, it has been suggested that doses of the drug lower than those required for antipsychotic activity may be useful for treating antipsychotic-induced tardive dyskinesia. (See Uses: Other Uses.)

Current evidence suggests that the clinical potency and antipsychotic efficacy of both typical and atypical antipsychotic drugs generally are related to their affinity for and blockade of central dopamine D2 receptors; however, antagonism at D2 receptors does not appear to account fully for the antipsychotic effects of clozapine.

In in vitro studies, clozapine is a comparatively weak antagonist at D2 receptors. Clozapine's affinity for the D2 receptor on a weight basis reportedly is approximately one-third (33%) that of loxapine, one-tenth (10%) that of chlorpromazine, and one-fiftieth (2%) that of haloperidol. In oral dosages of 300 mg daily, clozapine produces a 40—65% occupancy of D1 and D2 receptors. During long-term clozapine therapy, the relative occupancy of D1 receptors may become greater than that of D2 receptors, or the long-term effects of the drug on D2 receptors may be antagonized by its nondopaminergic properties. Although the in vitro affinity of clozapine for D1 and D2 receptors in brain tissue of animals appears to be similar, the drug's in vivo effects in many animals resemble those of D1 receptor-specific antagonists. Compared with typical antipsychotic agents, clozapine shows greater affinity for and appears to produce greater

blockade of neostriatal dopamine D1 receptors; other data suggest that clozapine preferentially but not selectively antagonizes D1 receptor-mediated functions. At clinically effective dosages, however, the drug produces comparable blockade of D1 and D2 receptors and less D2 blockade than typical antipsychotic drugs. Long-term administration of clozapine leads to a 35—50% "up-regulation" of D1 receptors, which is comparable to that observed with administration of selective D1 antagonists; however, the number of D2 receptors is not changed, possibly because the proportionof occupied receptors required to elicit a response is less for D1 than for D2 receptors. Limited evidence suggests that D1 receptors may exist either coupled to adenylate cyclase or in uncoupled form. Clozapine appears to be a potent, competitive inhibitor of dopamine-stimulated adenylate cyclase in vitro, and the adenylate cyclase-coupled state of the D1 receptor binds clozapine with high affinity; in contrast, typical antipsychotic agents bind preferentially to the uncoupled D1 receptor.

Although their role in eliciting the pharmacologic effects of antipsychotic agents remains to be fully elucidated, dopamine D3, D4, and D5 receptors also have been identified; clozapine appears to have a much higher affinity for the D4 receptor thanfor D2 or D3 receptors. Current information on D3-receptor affinity for antipsychotic drugs suggests that most antipsychotics probably bind to both D2 and D3 receptors, although with higher affinity to D2 receptors; however, the magnitude of the difference in D3- versus D2-receptor binding is much less with atypical antipsychotics such as clozapine, suggesting that effects on D3 receptors may play a more important role in the pharmacologic actions of atypical versus typical antipsychotic drugs.The high affinity of the D4 receptor for clozapine and its preferential distribution in cortical and limbic areas in animals may explain, in part, the relative lack of tardive dyskinesia and extrapyramidal effects during clozapine therapy. The cloning of a gene for a neuron-specific dopamine D5 receptor, which binds antipsychotic drugs with similar affinity as the D1 receptor but has a tenfold higher affinity for dopamine, also has been reported.

Clozapine's clinical potency appears to be twice that of chlorpromazine on a weight basis, although the drug demonstrates considerably weaker D2-receptor binding affinity than chlorpromazine and appears to be much less potent in elevating dopamine metabolite concentrations in the brain. Clozapine produces a more potent blockade of central serotonergic, adrenergic, histamine H1, and muscarinic receptors than typical antipsychotic agents; also, long-term administration of clozapine enhances striatal D1-receptor function in animals and results in "down-regulation" of cortical, type 2 serotonergic (5-HT2) receptors, suggesting that an interaction between these central neurotransmitter systems may be important for the drug's antipsychotic efficacy. Antagonism at cholinergic and alpha1-adrenergic receptors in the mesolimbic system, compensating for dopaminergic blockade in the neostriatum, may explain the apparent selectivity and low incidence of extrapyramidal effects seen with clozapine. The amygdala also may be a site of action for clozapine, since repeated administration of the drug selectively induces supersensitivity to locally applied dopamine in the amygdala, and amygdaloid neurons are excited by clozapine but generally unresponsive to other antipsychotic agents (e.g., haloperidol).

Further studies are needed to elucidate the mechanism of clozapine's antipsychotic effects in various areas of the CNS.

Neurophysiologic Effects

In vitro and in vivo electrophysiologic studies in animals demonstrate different sensitivities of various brain areas to clozapine-mediated postsynaptic receptor blockade. While clozapine increases firing rates of both nigrostriatal (A9 pathway) and mesolimbic (A10 pathway) dopaminergic neurons after acute administration, only mesolimbic dopaminergic neurons exhibit prolonged depolarization blockade following repeated exposure to the drug. Repeated administration of typical antipsychotic agents (e.g., haloperidol) concomitantly with an anticholinergic agent (trihexyphenidyl) or an alpha1-adrenergic blocking drug (prazosin) mimicked these selective effects of clozapine on mesolimbic versus nigrostriatal dopaminergic neurons, suggesting that alpha1-adrenergic blocking and/or anticholinergic effects may be responsible, in part, for the differential effects of clozapine in these midbrain areas. Some evidence suggests that the nucleus accumbens has greater sensitivity for clozapine than do other regions, which may explain why the drug appears to produce depolarization blockade of dopaminergic neurons only in the mesolimbic area. However, some studies have shown that neurons in the neostriatum also may be responsive to clozapine. Clozapine reportedly produces an increase in dopamine metabolites in the neostriatum comparable to or even greater than that in the nucleus accumbens. Demonstrable dopamine-receptor supersensitivity in both striatal and limbic forebrain regions also has been reported with prolonged clozapine administration. Therefore, it has been suggested that there may be a dissociation between the effects of clozapine on synthesis and metabolism of dopamine within nigrostriatal neurons and the drug's effects on neuronal firing rate and dopamine release.

Adrenergic Effects

Clozapine has adrenergic-blocking activity, which may be partially responsible for the sedation, muscle relaxation, and cardiac effects observed in patients receiving the drug. (See Cautions: Cardiovascular Effects.) Although the drug appears to have relatively weak alpha-adrenergic blocking effects compared with typical antipsychotic drugs such as chlorpromazine, clozapine's in vitro affinity (relative to dopamine D2-receptor affinity) for alpha1- and alpha2-adrenergic receptors is much higher than that of other antipsychotics, including chlorpromazine, haloperidol, loxapine, and thioridazine. Clozapine increases the number and sensitivity of alpha1-adrenergic, but not dopamine D2, receptors. The turnover rate of epinephrine and norepinephrine also may be increased by clozapine, but to a lesser extent than that of dopamine. Substantial increases in plasma norepinephrine concentrations, which decreased following discontinuance of the drug but remained above basal levels, have been noted in both schizophrenic and healthy individuals receiving clozapine; such increases may be the result of feedback mechanisms activated by adrenergic blockade.

Clozapine's central alpha1-adrenergic blocking activity also may be responsible for the dose-related hypothermia observed in mice given the drug. Clozapine also induces ataxia

and blocks amphetamine-induced hyperactivity in mice, although repeated administration of the drug results in almost complete tolerance to these effects. It has been suggested that clozapine's alpha1-adrenergic blocking properties may, in part, mediate its differential effects on midbrain dopamine receptors and be responsible for itsrelative lack of extrapyramidal effects. However, the clinical importance of the drug's alpha1-adrenergic effects has not been fully elucidated.

Anticholinergic Effects

Clozapine possesses potent anticholinergic activity in vitro; the drug's affinity for muscarinic receptors substantially exceeds that of other antipsychotic agents (e.g., 39—50 times greater than that of chlorpromazine and 100 times that of loxapine) and may be similar to that of tricyclic antidepressants and antimuscarinic antiparkinsonian agents (e.g., benztropine, trihexyphenidyl). It has been suggested that clozapine's anticholinergic effects may be more potent centrally than peripherally and thatadverse anticholinergic effects generally are not dose limiting; however, peripheral anticholinergic effects such as dry mouth are common and may be troublesome. Clozapine-induced delirium, which reportedly has occurred with rapid dosage escalation,has been reversed by physostigmine; this suggests that clozapine has central antimuscarinic activity. Some evidence also suggests that clozapine's anticholinergic properties may counteract the effects of dopamine receptor blockade in the neostriatum and thus prevent extrapyramidal reactions. Limited data suggest that the propensity of antipsychotic drugs to cause extrapyramidal effects varies inversely with anticholinergic potency and antimuscarinic activity; however, the relatively potent anticholinergic activity of clozapine does not appear to account adequately for its atypical actions.

Serotonergic Effects

It has been suggested that schizophrenia may involve a dysregulation of serotonin- and dopamine-mediated neurotransmission, and clozapine may at least partially restore a normal balance of neurotransmitter function, possibly through serotonergic regulation of dopaminergic tone. Clozapine blocks central type 2 serotonergic (5-HT2) receptors; the drug also antagonizes central and peripheral type 3 serotonergic (5-HT3) receptors. Long-termand acute administration of clozapine has produced down-regulation of 5-HT2 receptors in the frontal cortex and neostriatum of male rats; single or repeated daily injections of clozapine also reduced the number of cortical 5-HT2 receptors but did not change receptor affinity. In contrast to effects caused by typical antipsychotic agents, an increase in brain tryptophan, serotonin, and 5-hydroxyindoleacetic acid (5-HIAA) concentrations generally has been reported with clozapine administration in animals. It has been suggested that these effects might contribute to the pronounced sedative effects of clozapine, although increases in blood serotonin concentrations occurring during clozapine treatment in humans have been inconsistent and variable. (See Effects on Sleep under Pharmacology: Nervous System Effects.) Clozapine's serotonergic effects also reportedly may contribute to the drug's efficacy against negative symptoms of schizophrenia and to the weight gain observed during clozapine therapy. (See Cautions: Endocrine and Metabolic Effects.)

Effects on Other Central Neurotransmitters
Clozapine appears to have important activity on the metabolism of Gamma-aminobutyric acid (GABA), which has inhibitory effects on dopaminergic neurons. In contrast to the effects of typical antipsychotic drugs, clozapine apparently augments GABA turnover in both the neostriatum and nucleus accumbens. Increases in neostriatal GABA turnover and release may attenuate extrapyramidal reactions, while a similar action in the nucleus accumbens may be related to antipsychotic efficacy.

Clozapine appears to have central histamine H1-receptor blocking activity; such activity reportedly may be associated with sedation, hypotension, and weight gain. The drug's affinity (relative to dopamine D2-receptor affinity) for histamine H1-receptors is approximately 30 times that of chlorpromazine and 4 times that of loxapine.

Behavioral Effects in Animals
Studies of the effects of clozapine on animal behavior routinely used to detect antipsychotic activity support its classification as an atypical antipsychotic drug. Such studies suggest that the neostriatum is relatively unresponsive to clozapine. Since the drug does not induce catalepsy or inhibit apomorphine-induced stereotypy, which are thought to be mediated principally by the nigrostriatal dopamine system, clozapine's antipsychotic activity appears to result from the drug's activity in otherareas. Clozapine also does not block amphetamine-induced hyperactivity or apomorphine-induced emesis in animals as the typical antipsychotic agents do. Long-term administration of clozapine causes supersensitization of behaviors mediated by mesolimbic dopaminergic pathways (e.g., dopamine-induced locomotion) but not those mediated via neostriatal systems (e.g., dopamine-induced stereotypy). Long-term administration of clozapine in male rats caused a marked supersensitivity (of the same magnitude andduration as that of haloperidol) in the mesolimbic but not the nigrostriatal system. It has been suggested that supersensitivity of mesolimbic dopamine receptors may be associated with the apparent rebound psychosis that has been reported following clozapine therapy. (See Cautions: Other Nervous System Effects.)

EEG Effects
Clozapine may produce dose-related changes in the EEG, including increased discharge patterns similar to those associated with seizure disorders, and may lower the seizure threshold; seizures have occurred in patients receiving the drug, particularly with high dosages (greater than 600 mg daily), rapid dosage increases, and/or in the presence of high plasma concentrations. (See Seizures in Cautions: Nervous System Effects.) Some EEG changes associated with clozapine administration are atypical of those generally seen with other antipsychotic agents, resembling more closely those produced by antidepressants. Like other drugs with antipsychotic activity, clozapine increases beta-, delta-, and theta-band amplitudes and slows dominant alpha frequencies in clinical EEG studies. However, in patients with severe, treatment-resistant schizophrenia, increases in delta and theta band frequencies are more pronounced with clozapine than with haloperidol or chlorpromazine therapy, a finding that appears to parallel the drugs' relative antiserotonergic, antihistaminic, and anticholinergic activities. Enhanced EEG

synchronization, paroxysmal sharp-wave activity, and spike and wave complexes also may develop during clozapine therapy. Clozapine-induced EEG changes generally appear soon after initiation of the drug and return to baseline upon cessation of therapy.In one study, the EEG showed slight general changes or slight diffuse slowing in 75% of patients receiving clozapine; in another study, clozapine caused marked EEG changes, including a slowing of basal activity, in 5% of patients.

Effects on Sleep

Clozapine causes a shift in the sleep-wake pattern toward dozing in animals, with marked reductions in both slow-wave and paradoxical sleep times. However, tolerance to the drug's sedative effect usually occurs, although slowly in some patients, during continuous administration of clozapine. In a controlled study of short-term (3-day) administration in healthy young men, clozapine in dosages of 25 mg nightly substantially increased total sleep time on the first night of administration, but the duration of sleep returned to baseline by the third night. Clozapine did not substantially affect the time spent in stage 1, 2, 3, or slow-wave sleep, nor did it affect latency to the rapid eye movement (REM) period or the percentage of time spent in REM sleep. However, the percentage of time spent in stage 4 sleep was reduced substantially on the second and third nights of drug administration, while a variety of REM indices were increased on the third night of the study.

In a few patients receiving clozapine dosages of 150—800 mg daily, REM sleep increased to 85—100% of total sleep time after several days of drug therapy, with the onset of REM sleep occurring almost immediately after patients fell asleep. Intensification of dream activity also has been reported during clozapine therapy. Some clinicians have suggested that a correlation may exist between increases in body temperature and REM sleep and clozapine-induced improvement in psychosis. Cataplexy has been reported in some patients receiving clozapine.

Neuroendocrine Effects

In contrast to typical antipsychotic drugs, clozapine therapy in usual dosages generally produces little or no elevation of prolactin concentration in humans. Administration of clozapine to rats has produced a transient, dose-related increase in prolactin concentrations that is of much shorter duration than that caused by other antipsychotic agents. Prolactin normally is inhibited by dopamine released from tuberoinfundibular (TIDA) neurons into the pituitary portal circulation. In rats, clozapineacutely increases the activity of TIDA neurons, which inhibit the release of prolactin; activation of TIDA neurons may be mediated by an enhanced release of neurotensin. Clozapine's effect on prolactin appears to be transient, possibly because the drug appears to dissociate from dopamine receptors more rapidly than typical antipsychotic agents and is therefore eliminated from the brain more rapidly.

Clozapine has an effect on corticotropin (ACTH) and corticosterone, possibly through its effects on dopamine metabolism in the hypothalamus. Short-term administration of clozapine (cumulative dose: 200 mg) to a few patients with schizophrenia resulted in

marked inhibition of apomorphine-induced somatotropin (growth hormone) response, suggesting that clozapine may block the dopamine receptors responsible for eliciting this response. In contrast to typical antipsychotic agents, clozapine decreases or has no effect on basal cortisol levels. Clozapine markedly increases corticosterone concentrations in a dose-dependent fashion; other antipsychotic agents appear to increase corticosterone concentrations only at doses producing substantial D2-receptorblockade. Clozapine-induced stimulation of corticosterone secretion may result from stimulation, rather than blockade, of dopamine receptors, but the exact mechanism has not been fully elucidated.

Other Effects
Clozapine produced a dose-dependent delay in initiation of copulation in male rats, which may be related to blockade of mesolimbic dopamine receptors; however, the drug had no effect on copulatory behavior once the behavior had started. Fertility inmale and female rats reportedly is not adversely affected by clozapine. (See Cautions: Pregnancy, Fertility, and Lactation.)

In animals, even small oral doses of clozapine cause ptosis, relaxation, and a reduction in spontaneous activity, effects that are consistent with the drug's sedative activity. Inhibition of locomotor activity induced by clozapine diminishes with repeated administration. With increasing doses of the drug, reactions to acoustic and tactile stimuli decline, and disturbances in equilibrium have been reported. Clozapine also inhibits isolation-induced aggression in mice at doses lower than those affecting motor function, suggesting a specific antiaggressive effect.

Studies in animals suggest that clozapine has a weak and variable diuretic effect; the clinical importance of this effect has not been established. In both rats and dogs, low doses of clozapine tend to increase the elimination of water and electrolytes, while higher doses are associated with increases in potassium excretion and sodium retention.

Pharmacokinetics:

Absorption
Clozapine is rapidly and almost completely absorbed following oral administration. However, because of extensive hepatic first-pass metabolism, only about 27—50% of an orally administered dose reaches systemic circulation unchanged. Some, but not all, evidence suggests that clozapine may exhibit nonlinear, dose-dependent pharmacokinetics, with oral bioavailability being approximately 30% less following a single 75-mg dose than at steady state following multiple dosing. GI absorption appears to occur principally in the small intestine and is approximately 90—95% complete within 3.5 hours after an oral dose. Food does not appear to affect the rate or extent of GI absorption of the drug. The relative oral bioavailability of commercially available 25- and 100-mg clozapine tablets reportedly is equivalent, as is the relative oral bioavailability of tablets and capsules of the drug.

Following oral administration of a single 25- or 100-mg oral dose of clozapine as tablets in healthy adults, the drug is detectable in plasma within 25 minutes, and peak plasma clozapine concentrations occur at about 1.5 hours. Peak plasma concentrations may be delayed with higher single doses and with multiple dosing of the drug. In one multiple-dose study, peak plasma clozapine concentrations at steady state averaged 319 ng/mL (range: 102—771 ng/mL) and occurred on average at 2.5 hours (range: 1—6hours) after a dose with 100 mg twice daily as tablets in healthy adults; minimum plasma concentrations at steady state averaged 122 ng/mL (range: 41—343 ng/mL). Steady-state plasma concentrations ranging from 200—600 ng/mL generally are achieved with oral dosages of 300 mg daily, and steady-state peak plasma concentrations generally occur within 2—4 hours after a dose. Steady-state plasma concentrations of clozapine are achieved after 7—10 days of continuous dosing.

Considerable interindividual variation in plasma clozapine concentrations has been observed in patients receiving the drug, and some patients may exhibit either extremely high or extremely low plasma concentrations with a given dosage. Such variability may be particularly likely at relatively high dosages (e.g., 400 mg daily) of the drug. In one study, a sixfold interindividual variation in steady-state plasma clozapine concentration was observed in patients receiving such dosages. In addition, considerable intraindividual variation, particularly from week to week, may occur in some patients. However, substantial intraindividual variations in pharmacokinetic parameters typically are not observed from day to day. Although the interindividual variability in plasma clozapine concentrations is consistent with that reported for other antipsychotic drugs and may be secondary to differences in absorption, distribution, metabolism, or clearance of the drug, further study is needed to clarify whether such variation results principally from variable pharmacokinetics or other variables.

There is some evidence that interindividual differences in pharmacokinetic parameters for clozapine may result, at least in part, from nonlinear, dose- dependent pharmacokinetics of the drug. However, a linear dose-concentration relationship also has been reported. Results of a study in patients with chronic schizophrenia revealed a correlation between oral clozapine dosages of 100—800 mg daily and steady-state plasma concentrations of the drug. In addition, linearly dose-proportional changes inarea under the plasma concentration-time curve (AUC) and in peak and trough plasma concentrations have been observed with oral dosages of 37.5, 75, and 150 mg twice daily in other studies.

Smokers appear to achieve plasma clozapine concentrations that are approximately 60—80% of those achieved by nonsmokers following oral administration of the drug, possibly because of alterations in hepatic metabolism and/or GI absorption of the drug caused by nicotine or other substances (e.g., polycyclic aromatic hydrocarbons) present in cigarette smoke. (See Drug Interactions: Smoking.) There also is limited evidence that gender may affect plasma clozapine concentrations, with concentrations beingsomewhat reduced, perhaps by as much as 20—30%, in males compared with females. In addition, smoking has a greater effect on clozapine plasma concentrations in men than in women, although this difference could result simply from gender differences insmoking behavior. Plasma

concentrations may be increased in geriatric individuals compared with relatively young (e.g., 18—35 years old) individuals, possibly secondary to age-related decreases in hepatic elimination of clozapine.

Pharmacologic effects of clozapine (e.g., sedation) reportedly are apparent within 15 minutes and become clinically important within 1—6 hours. The duration of action of clozapine reportedly ranges from 4—12 hours following a single oral dose. In one study in patients with schizophrenia, the sedative effect was apparent within hours of the first dose of the drug and was maximal within 7 days. (See Effects on Sleep under Pharmacology: Nervous System Effects.) However, antipsychotic activity generally is delayed for one to several weeks after initiation of clozapine therapy, and maximal activity may require several months of therapy with the drug.

Correlations between steady-state plasma concentrations of clozapine and therapeutic efficacy have not been established, and some evidence suggests that the degree of clinical improvement is independent of plasma concentrations ranging from 100—800 ng/mL. However, it also has been suggested that serum clozapine concentrations less than 600 ng/mL may be adequate for therapeutic effect in most patients. Results of one study of 29 patients treated with clozapine 400 mg daily for 4 weeks showed thatpatients were most likely to respond to therapy when their plasma clozapine concentrations were at least 350 ng/mL and/or when plasma concentrations of clozapine plus norclozapine (an active metabolite) totaled at least 450 ng/mL. Further study is needed to determine whether nonresponding patients with plasma clozapine concentrations less than 350 ng/mL will benefit from increasing their dosage in an attempt to achieve higher concentrations.

Although a relationship between clozapine plasma concentrations and the risk of seizures has been suggested (see Seizures under Cautions: Nervous System Effects), most clinicians believe that a relationship between plasma concentrations of the drug and the risk of adverse effects has not been established.

Distribution

Distribution of clozapine into human body tissues is rapid and extensive; distribution of metabolites of the drug also appears to be extensive. In mice and rats, clozapine distributes principally into the lung, spleen, liver, kidney, gallbladder, and brain, achieving concentrations in these tissues up to 50 times those in blood. At 8 hours after IV injection, clozapine was still detectable in these organs but not in blood. There is limited evidence in animals that clozapine and its metabolitesmay be preferentially retained in the lungs by an energy-dependent, carrier-mediated process and by cellular binding. Evidence in animals also suggests that competition between clozapine and other drugs (e.g., chlorpromazine, imipramine, certain tetracycline antibiotics) for pulmonary binding sites may potentially affect plasma and tissue concentrations of clozapine, but the clinical importance, if any, of such an effect has not been established.

The volume of distribution of clozapine has been reported to be approximately 4.65 L/kg. In one study, the volume of distribution at steady state averaged 1.6 L/kg (range: 0.4—

3.6 L/kg) in schizophrenic patients. Because the volume of distribution of clozapine is smaller than that of other antipsychotic agents, it has been suggested that clozapine is less sequestered in tissues than the other drugs. Clozapine is approximately 97% bound to serum proteins.

Results of receptor-binding studies in monkeys indicate that clozapine rapidly crosses the blood-brain barrier following IV injection. The highest brain uptake of the drug was in the striatum in these animals; lesser concentrations were achieved in the thalamus and mesencephalon, although they exceeded those in the cerebellum. The pharmacokinetic characteristics of the drug in the CNS paralleled those in plasma in these monkeys, with an elimination half-life from CNS of about 5 hours. Evidence from other animal studies indicates that CNS concentrations of the drug exceed those in blood. Distribution of the drug into the CNS in humans has not been characterized.

Clozapine reportedly is present in low concentrations in the placenta in animals; information on placental transfer of the drug in humans currently is unavailable. Results of animal studies indicate that clozapine distributes into milk. (See Cautions: Pregnancy, Fertility, and Lactation.)

Elimination

The decline of plasma clozapine concentrations in humans is biphasic. The elimination half-life of clozapine following a single 75-mg oral dose reportedly averages 8 hours (range: 4—12 hours); that after a 100-mg oral dose appears to be similar. The elimination half-life of clozapine at steady state following administration of 100 mg twice daily reportedly averages 12 hours (range: 4—66 hours). The rapid elimination phase may represent redistribution and is followed by a slower apparent mean terminal elimination half-life of 10.3—38 hours. Although a study comparing single and multiple dosing of clozapine demonstrated an increase in elimination half-life with multiple dosing, other evidence suggests this finding is not attributable to concentration-dependent pharmacokinetics.

Clozapine is metabolized in the liver prior to excretion. Clozapine may undergo N-demethylation, N-oxidation, 3-carbon oxidation, epoxidation of the chlorine-containing aromatic ring, substitution of chlorine by hydroxyl or thiomethyl groups, and sulfur oxidation. A glucuronide metabolite, tentatively identified as a quaternary ammoniumN-glucuronide of clozapine, also has been identified. Metabolism of clozapine may occur by one or more of these routes.

The rate of formation and biologic activity of clozapine metabolites have not been fully elucidated. The desmethyl metabolite of clozapine (norclozapine) has limited activity while the hydroxylated and N-oxide derivatives are inactive. The N-oxide anddesmethyl derivatives are found in urine and plasma of humans in a proportion of 2:1.

Approximately 32% of a single oral dose of clozapine is found in plasma as the parent compound after 3 hours, 20% in 8 hours, and 10% up to 48 hours following the dose.

Only limited amounts (approximately 2—5%) of unchanged drug are detected in urine and feces. Approximately 50% of an administered dose is excreted in urine and 30% in feces; maximum fecal excretion has been estimated at 38%.Approximately 46% of an oral dose of clozapine is excreted in urine within 120 hours.

Total plasma and blood clearance of clozapine reportedly average 217 and 250 mL/minute, respectively, but show considerable interindividual variation.

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use Vyvanse safely and effectively. See full prescribing information for Vyvanse.

Vyvanse (lisdexamfetamine dimesylate) Capsules, CII

Initial U.S. Approval: 2007

WARNING: POTENTIAL FOR ABUSE
See full prescribing information for complete boxed warning

- Amphetamines have a high potential for abuse; prolonged administration may lead to dependence (9)
- Misuse of amphetamines may cause sudden death and serious cardiovascular adverse events

-----RECENT MAJOR CHANGES-----

Indications and Usage, Adult (1.1)	04/2008
Dosage and Administration, Adult (2)	04/2008

-----INDICATIONS AND USAGE-----

Vyvanse is a prodrug of dextroamphetamine, a stimulant, and is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD). (1)

-----DOSAGE AND ADMINISTRATION-----

- Recommended dose: Adults and pediatric patients ages 6-12; 30 mg once daily in the morning (2)
- Maximum dose: 70 mg once daily in the morning (2)

-----DOSAGE FORM AND STRENGTHS-----

- Capsules: 20 mg, 30 mg, 40 mg, 50 mg, 60 mg, 70 mg (3)

-----CONTRAINDICATIONS-----

- Advanced arteriosclerosis (4)
- Symptomatic cardiovascular disease (4)
- Moderate to severe hypertension (4)
- Hyperthyroidism (4)
- Known hypersensitivity or idiosyncrasy to sympathomimetic amines (4)
- Glaucoma (4)
- Agitated states (4)
- History of drug abuse (4)
- During or within 14 days following the administration of monoamine oxidase inhibitors (MAOI) (4, 7.2)

-----WARNINGS AND PRECAUTIONS-----

- Serious Cardiovascular Events: Sudden death has been reported in association with CNS stimulant treatment at usual doses in children and adolescents with structural cardiac abnormalities or other serious heart problems. Sudden death, stroke and myocardial infarction have been reported in adults taking stimulant drugs at usual doses for ADHD. Stimulant products generally should not be used in patients with known structural cardiac abnormalities, cardiomyopathy, serious heart rhythm abnormalities, coronary artery disease or other serious heart problems. (5.1)
- Increase in Blood Pressure: Monitor blood pressure and pulse at appropriate intervals in patients taking Vyvanse. Use with caution in patients for whom blood pressure increases may be problematic. (5.1)
- Psychiatric Adverse Events: Use of stimulants may cause treatment-emergent psychotic or manic symptoms in patients with no prior history, or exacerbation of symptoms in patients with pre-existing psychosis. Clinical evaluation for bipolar disorder is recommended prior to stimulant use. Monitor for aggressive behavior. (5.2)
- Seizures: may lower the convulsive threshold, and in the presence of seizures, should be discontinued. (5.3)
- Visual Disturbance: difficulties with accommodation and blurring of vision have been reported with stimulant treatment. (5.4)
- Tics: may exacerbate tics. Clinical evaluation for tics and Tourette's syndrome is recommended prior to stimulant administration. (5.5)
- Long-Term Suppression of Growth: monitor height and weight at appropriate intervals in pediatric patients taking Vyvanse. (5.6)

-----ADVERSE REACTIONS-----

- Children ages 6 to 12: Most common adverse reactions (incidence ≥5% and at a rate at least twice placebo) were decreased appetite, dizziness, dry mouth, irritability, insomnia, upper abdominal pain, nausea, vomiting and decreased weight. (6.2)
- Adults: Most common adverse reactions (incidence ≥5% and at a rate at least twice placebo) were upper abdominal pain, diarrhea, nausea, fatigue, feeling jittery, irritability, anorexia, decreased appetite, headaches, anxiety, and insomnia. (6.2)

To report SUSPECTED ADVERSE REACTIONS, contact Shire US Inc. at 1-800-828-2088 or FDA at 1-800-FDA-1088 or www.fda.gov./medwatch

-----DRUG INTERACTIONS-----

- Urinary acidifying agents may reduce blood levels of amphetamine. (7.1)
- Urinary alkalinizing agents may increase blood levels of amphetamine. (7.2)
- MAOI antidepressants are contraindicated. (4; 7.2)
- The effects of adrenergic blockers, antihistamines, antihypertensives, phenobarbital, and phenytoin may be reduced by amphetamines. (7.3)
- The effects of tricyclic antidepressants, meperidine, phenobarbital and phenytoin may be potentiated by amphetamines. (7.4)
- Norepinephrine may potentiate the effects of amphetamines. (7.6)

-----USE IN SPECIFIC POPULATIONS-----

- Pregnancy: Use only if the potential benefit justifies the potential risk to the fetus. Based on animal data, may cause fetal harm. (8.1)
- Nursing Mothers: should refrain from breastfeeding. (8.3)
- Pediatric Use: has not been studied in children under 6 years of age or in adolescents over 12 years of age. (8.4)
- Geriatric Use: has not been studied in geriatric patients. (8.5)

See 17 for PATIENT COUNSELING INFORMATION and Medication Guide.

Revised: XX/2008

FULL PRESCRIBING INFORMATION: CONTENTS*

*Sections or subsections omitted from full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

WARNING: POTENTIAL FOR ABUSE

AMPHETAMINES HAVE A HIGH POTENTIAL FOR ABUSE. ADMINISTRATION OF AMPHETAMINES FOR PROLONGED PERIODS OF TIME MAY LEAD TO DRUG DEPENDENCE. PARTICULAR ATTENTION SHOULD BE PAID TO THE POSSIBILITY OF SUBJECTS OBTAINING AMPHETAMINES FOR NON-THERAPEUTIC USE OR DISTRIBUTION TO OTHERS AND THE DRUGS SHOULD BE PRESCRIBED OR DISPENSED SPARINGLY.

MISUSE OF AMPHETAMINES MAY CAUSE SUDDEN DEATH AND SERIOUS CARDIOVASCULAR ADVERSE EVENTS.

1 INDICATIONS AND USAGE

1.1 Attention Deficit Hyperactivity Disorder

Vyvanse™ is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD).

The efficacy of Vyvanse in the treatment of ADHD was established on the basis of two controlled trials in children aged 6 to 12 and one controlled trial in adults who met DSM-IV-TR®) criteria for ADHD *[see CLINICAL STUDIES (14)]*.

A diagnosis of Attention Deficit Hyperactivity Disorder (ADHD; DSM-IV®) implies the presence of hyperactive-impulsive and/or inattentive symptoms that cause impairment and were present before the age of 7 years. The symptoms must cause clinically significant impairment, e.g. in social, academic, or occupational functioning, and be present in two or more settings, e.g. school (or work) and at home. The symptoms must not be better accounted for by another mental disorder. For the Inattentive Type, at least 6 of the following symptoms must have persisted for at least 6 months: lack of attention to details/careless mistakes; lack of sustained attention; poor listener; failure to follow through on tasks; poor organization; avoids tasks requiring sustained mental effort; loses things; easily distracted; forgetful. For the Hyperactive-Impulsive Type, at least 6 of the following symptoms (or adult equivalent symptoms) must have persisted for at least 6 months: fidgeting/squirming; leaving seat; inappropriate running/climbing; difficulty with quiet activities; “on the go”; excessive talking; blurting answers; can’t wait turn; intrusive. The Combined Type requires both inattentive and hyperactive-impulsive criteria to be met.

Special Diagnostic Considerations

Specific etiology of this syndrome is unknown, and there is no single diagnostic test. Adequate diagnosis requires the use not only of medical but also of special psychological, educational, and social resources. Learning may or may not be impaired. The diagnosis must be based upon a complete history and evaluation of the patient and not solely on the presence of the required number of DSM-IV characteristics.

Need for Comprehensive Treatment Program

Vyvanse is indicated as an integral part of a total treatment program for ADHD that may include other measures (psychological, educational, social) for patients with this syndrome. Drug treatment may not be indicated for all patients with this syndrome. Stimulants are not intended for use in patients who exhibit symptoms secondary to environmental factors and/or other primary psychiatric disorders, including psychosis. Appropriate educational/vocational placement is essential and psychosocial intervention is often helpful. When remedial measures alone are insufficient, the decision to prescribe stimulant medication will depend upon the physician's assessment of the chronicity and severity of the patient's symptoms and on the level of functional impairment.

Long-Term Use

The effectiveness of Vyvanse for long-term use, i.e., for more than 4 weeks, has not been systematically evaluated in controlled trials. Therefore, the physician who elects to use Vyvanse for extended periods should periodically re-evaluate the long-term usefulness of the drug for the individual patient.

2 DOSAGE AND ADMINISTRATION

Dosage should be individualized according to the therapeutic needs and response of the patient. Vyvanse should be administered at the lowest effective dosage.

In children 6 to12 years of age or adults who are either starting treatment for the first time or switching from another medication, 30 mg once daily in the morning is the recommended dose. If the decision is made in the judgment of the clinician to increase the dose beyond 30 mg/day, daily dosage may be adjusted in increments of 10 mg or 20 mg at approximately weekly intervals. The maximum recommended dose is 70 mg/day; doses greater than 70 mg/day of Vyvanse have not been studied. Amphetamines are not recommended for children under 3 years of age. Vyvanse has not been studied in children under 6 years of age or over 12 years of age.

Vyvanse should be taken in the morning. Afternoon doses should be avoided because of the potential for insomnia.

Vyvanse may be taken with or without food.

Vyvanse capsules may be taken whole, or the capsule may be opened and the entire contents dissolved in a glass of water. The solution should be consumed immediately and should not be stored. The dose of a single capsule should not be divided. The contents of the entire capsule should be taken, and patients should not take anything less than one capsule per day.

Where possible, drug administration should be interrupted occasionally to determine if there is a recurrence of behavioral symptoms sufficient to require continued treatment.

3 DOSAGE FORM AND STRENGTHS

Vyvanse capsules 20 mg: ivory body/ivory cap (imprinted NRP104 20 mg)

Vyvanse capsules 30 mg: white body/orange cap (imprinted NRP104 30 mg)

Vyvanse capsules 40 mg: white body/blue green cap (imprinted NRP104 40 mg)

Vyvanse capsules 50 mg: white body/blue cap (imprinted NRP104 50 mg)

Vyvanse capsules 60 mg: aqua blue body/aqua blue cap (imprinted NRP104 60 mg)

Vyvanse capsules 70 mg: blue body/orange cap (imprinted NRP104 70 mg)

4 CONTRAINDICATIONS

- Advanced arteriosclerosis, symptomatic cardiovascular disease, moderate to severe hypertension, hyperthyroidism, known hypersensitivity or idiosyncratic reaction to sympathomimetic amines, glaucoma
- Agitated states
- Patients with a history of drug abuse
- During or within 14 days following the administration of monoamine oxidase inhibitors (hypertensive crises may result)*[See Drug Interactions (7.2)]*

5 WARNINGS AND PRECAUTIONS

5.1 Serious Cardiovascular Events

Sudden Death and Pre-existing Structural Cardiac Abnormalities or Other Serious Heart Problems

Children and Adolescents

Sudden death has been reported in association with CNS stimulant treatment at usual doses in children and adolescents with structural cardiac abnormalities or other serious heart problems. Although some serious heart problems alone carry an increased risk of sudden death, stimulant products generally should not be used in children or adolescents with known serious structural cardiac abnormalities, cardiomyopathy, serious heart rhythm abnormalities, or other serious cardiac problems that may place them at increased vulnerability to the sympathomimetic effects of a stimulant drug *[see CONTRAINDICATIONS (4)]*.

Adults

Sudden death, stroke, and myocardial infarction have been reported in adults taking stimulant drugs at usual doses for ADHD. Although the role of stimulants in these adult cases is unknown, adults have a greater likelihood than children of having serious structural cardiac abnormalities, cardiomyopathy, serious heart rhythm abnormalities, coronary artery disease, or other serious cardiac problems. Adults with such abnormalities should also generally not be treated with stimulant drugs *[see CONTRAINDICATIONS (4)]*.

Hypertension and Other Cardiovascular Conditions

Stimulant medications cause a modest increase in average blood pressure (about 2-4 mm Hg) and average heart rate (about 3-6 bpm) and individuals may have larger increases. While the mean changes alone would not be expected to have short-term consequences, all patients should be monitored for larger changes in heart rate and blood pressure. Caution is indicated in treating patients whose underlying medical conditions might be compromised by increases in blood pressure or heart rate, e.g. those with pre-existing hypertension, heart failure, recent myocardial infarction, or ventricular arrhythmia *[see CONTRAINDICATIONS 4)]*.

Assessing Cardiovascular Status in Patients Being Treated with Stimulant Medications

Children, adolescents, or adults who are being considered for treatment with stimulant medications should have a careful history (including assessment for a family history of sudden death or ventricular arrhythmia) and physical exam to assess for the presence of cardiac disease, and should receive further cardiac evaluation if findings suggest such disease (e.g. electrocardiogram and echocardiogram). Patients who develop symptoms such as exertional chest pain, unexplained syncope, or other symptoms suggestive of cardiac disease during stimulant treatment should undergo a prompt cardiac evaluation.

5.2 Psychiatric Adverse Events

Pre-existing Psychosis

Administration of stimulants may exacerbate symptoms of behavior disturbance and thought disorder in patients with a pre-existing psychotic disorder.

Bipolar Illness

Particular care should be taken in using stimulants to treat ADHD in patients with comorbid bipolar disorder because of concern for possible induction of a mixed/manic episode in such patients. Prior to initiating treatment with a stimulant, patients with comorbid depressive symptoms should be adequately screened to determine if they are at risk for bipolar disorder. Such screening should include a detailed psychiatric history, including a family history of suicide, bipolar disorder and depression.

Emergence of New Psychotic or Manic Symptoms

Treatment-emergent psychotic or manic symptoms, e.g. hallucinations, delusional thinking, or mania in children and adolescents without a prior history of psychotic illness or mania can be caused by stimulants at usual doses. If such symptoms occur consideration should be given to a possible causal role of the stimulant, and discontinuation of treatment may be appropriate. In a pooled analysis of multiple short-term, placebo-controlled studies, such symptoms occurred in about 0.1% (4 patients with events out of 3482 exposed to methylphenidate or amphetamine for several weeks at usual doses) of stimulant-treated patients compared to 0 in placebo-treated patients.

Aggression

Aggressive behavior or hostility is often observed in children and adolescents with ADHD, and has been reported in clinical trials and the post marketing experience of some medications indicated for the treatment of ADHD. Although there is no systematic evidence that stimulants cause aggressive behavior or hostility, patients beginning treatment of ADHD should be monitored for the appearance of, or worsening of, aggressive behavior or hostility.

5.3 Seizures

There is some clinical evidence that stimulants may lower the convulsive threshold in patients with prior history of seizures, in patients with prior EEG abnormalities in absence of seizures, and, very rarely, in patients without a history of seizures and no prior EEG evidence of seizures. In the presence of seizures, the drug should be discontinued.

5.4 Visual Disturbance

Difficulties with accommodation and blurring of vision have been reported with stimulant treatment.

5.5 Tics

Amphetamines have been reported to exacerbate motor and phonic tics and Tourette's syndrome. Therefore, clinical evaluation for tics and Tourette's syndrome should precede use of stimulant medications.

5.6 Long-Term Suppression of Growth

Careful follow-up of weight and height in children ages 7 to 10 years who were randomized to either methylphenidate or non-medication treatment groups over 14 months, as well as in naturalistic subgroups of newly methylphenidate-treated and non-medication treated children over 36 months (to the ages of 10 to 13 years), suggests that consistently medicated children (i.e. treatment for 7 days per week throughout the year) have a temporary slowing in growth rate (on average, a total of about 2 cm less growth in height and 2.7 kg less growth in weight over 3 years), without evidence of growth rebound during this period of development. In a controlled trial of amphetamine (d- to l-enantiomer ratio of 3:1) in adolescents, mean weight change from baseline within the initial 4 weeks of therapy was –1.1 lbs. and –2.8 lbs., respectively, for patients receiving 10 mg and 20 mg of amphetamine. Higher doses were associated with greater weight loss within the initial 4 weeks of treatment. In a controlled trial of Vyvanse in children ages 6 to 12 years, mean weight loss from baseline after 4 weeks of therapy was -0.9, -1.9, and -2.5 lb, respectively, for patients receiving 30 mg, 50 mg, and 70 mg of Vyvanse, compared to a 1 lb weight gain for patients receiving placebo. Higher doses were associated with greater weight loss with 4 weeks of treatment. Careful follow-up for weight in children ages 6 to 12 years who received Vyvanse over 12 months suggests that consistently medicated children (i.e. treatment for 7 days per week throughout the year) have a slowing in growth rate, measured by body weight as demonstrated by an age- and sex-normalized mean change from baseline in percentile, of -13.4 over 1 year (average percentiles at baseline and 12 months, were 60.6 and 47.2, respectively). Therefore growth should be monitored during treatment with stimulants, and patients who are not growing or gaining weight as expected may need to have their treatment interrupted.

5.7 Prescribing and Dispensing

The least amount of amphetamine feasible should be prescribed or dispensed at one time in order to minimize the possibility of overdosage. Vyvanse should be used with caution in patients who use other sympathomimetic drugs.

6 ADVERSE REACTIONS

6.1 Clinical Studies Experience

The premarketing development program for Vyvanse included exposures in a total of 762 participants in clinical trials (348 pediatric patients, 358 adult patients and 56 healthy adult subjects). Of these, 348 pediatric (aged 6 to 12) patients were evaluated in two controlled clinical studies (one parallel-group and one crossover), one open-label extension study, one single-dose clinical pharmacology study, and 358 adult patients were evaluated in one controlled clinical study and one open-label extension study. The information included in this section is based on data from the 4-week parallel-group controlled clinical studies in pediatric and adult patients with ADHD. Adverse reactions were assessed by collecting adverse events, results of physical examinations, vital signs, weights, laboratory analyses, and ECGs.

Adverse reactions during exposure were obtained primarily by general inquiry and recorded by clinical investigators using terminology of their own choosing. Consequently, it is not possible to provide a meaningful estimate of the proportion of individuals experiencing adverse reactions without first grouping similar types of reactions into a smaller number of standardized reactions categories. In the tables and listings that follow, MedDRA terminology has been used to classify reported adverse reactions.

The stated frequencies of adverse reactions represent the proportion of individuals who experienced a treatment-emergent adverse reaction of the type listed at least once.

<u>Adverse Reactions Associated with Discontinuation of Treatment in Clinical Trials</u>

In the controlled pediatric (aged 6 to 12) trial, 10% (21/218) of Vyvanse-treated patients discontinued due to adverse reactions compared to 1% (1/72) who received placebo. The most frequent adverse events leading to discontinuation and considered to be drug-related (i.e. leading to discontinuation in at least 1% of Vyvanse-treated patients and at a rate at least twice that of placebo) were ECG voltage criteria for ventricular hypertrophy, tic, vomiting, psychomotor hyperactivity, insomnia, and rash (2/218 each; 1%).

In the controlled adult trial, 6% (21/358) of Vyvanse-treated patients discontinued due to adverse events compared to 2% (1/62) who received placebo. The most frequent adverse events leading to discontinuation and considered to be drug-related (i.e. leading to discontinuation in at least 1% of Vyvanse-treated patients and at a rate at least twice that of placebo) were insomnia (8/358; 2%), tachycardia (3/358; 1%), irritability (2/358; 1%), hypertension (4/358; 1%), headache (2/358; 1%), anxiety (2/358; 1%), and dyspnea (3/358; 1%).

Adverse Reactions Occurring at an Incidence of 2% or more Among Vyvanse Treated Patients in Clinical Trials

Adverse reactions reported in the controlled trials in pediatric and adult patients treated with Vyvanse or placebo are presented in the Tables 1 and 2 below. The prescriber should be aware that these figures cannot be used to predict the incidence of adverse reactions in the course of usual medical practice where patient characteristics and other factors differ from those which prevailed in the clinical trials. Similarly, the cited frequencies cannot be compared with figures obtained from other clinical investigations involving different treatment uses and investigators. The cited figures, however, do provide the prescribing physician with some basis for estimating the relative contribution of drug and non-drug factors to the adverse reaction incidence rate in the population studied.

Pediatric

Table 1 Adverse Reactions Reported by 2% or More of Pediatric Patients Taking Vyvanse in a 4-Week Clinical Trial

Body System	Preferred Term	Vyvanse (n=218)	Placebo (n=72)
Gastrointestinal Disorders	Abdominal Pain Upper	12%	6%
	Vomiting	9%	4%
	Nausea	6%	3%
	Dry Mouth	5%	0%
General Disorder and Administration Site Conditions	Pyrexia	2%	1%
Investigations	Weight Decreased	9%	1%
Metabolism and Nutrition	Decreased Appetite	39%	4%
Nervous System Disorders	Dizziness	5%	0%
	Somnolence	2%	1%
Psychiatric Disorders	Insomnia	19%	3%
	Irritability	10%	0%
	Initial Insomnia	4%	0%
	Affect lability	3%	0%
	Tic	2%	0%
Skin and Subcutaneous Tissue Disorders	Rash	3%	0%

Note: This table includes those reactions for which the incidence in patients taking Vyvanse is at least twice the incidence in patients taking placebo.

Adult

Table 2 Adverse Reactions Reported by 2% or More of Adult Patients Taking Vyvanse in a 4-Week Clinical Trial

Body System	Preferred Term	Vyvanse (n=358)	Placebo (n=62)
Gastrointestinal Disorders	Dry Mouth	26%	3%
	Diarrhea	7%	0%
	Nausea	7%	0%

Table 2 Adverse Reactions Reported by 2% or More of Adult Patients Taking Vyvanse in a 4-Week Clinical Trial

Body System	Preferred Term	Vyvanse (n=358)	Placebo (n=62)
General Disorder and Administration Site Conditions	Feeling Jittery	4%	0%
Investigations	Blood Pressure Increased	3%	0%
	Heart Rate Increased	2%	0%
Metabolism and Nutrition Disorders	Anorexia	5%	0%
	Decreased Appetite	27%	3%
Nervous System Disorders	Tremor	2%	0%
Psychiatric Disorders	Insomnia	27%	8%
	Anxiety	6%	0%
	Agitation	3%	0%
	Restlessness	3%	0%
Respiratory Thoracic and Mediastinal Disorders	Dyspnea	2%	0%
Skin and Subcutaneous Tissue Disorders	Hyperhidrosis	3%	0%

Note: This table includes those events for which the incidence in patients taking Vyvanse is at least twice the incidence in patients taking placebo.

Vital Signs

Weight Loss – In the controlled adult trial, mean weight loss after 4 weeks of therapy was 2.8 lbs, 3.1 lbs, 4.3 lbs, for patients receiving final doses of 30 mg, 50 mg and 70 mg of Vyvanse, respectively, compared to a mean weight gain of 0.5 lbs for patients receiving placebo.

6.2 Adverse Reactions Associated with the Use of Amphetamine

Cardiovascular

Palpitations, tachycardia, elevation of blood pressure, sudden death, myocardial infarction. There have been isolated reports of cardiomyopathy associated with chronic amphetamine use.

Central Nervous System

Psychotic episodes at recommended doses, overstimulation, restlessness, dizziness, insomnia, euphoria, dyskinesia, dysphoria, depression, tremor, headache, exacerbation of motor and phonic tics and Tourette's syndrome, seizures, stroke.

Gastrointestinal

Dryness of the mouth, unpleasant taste, diarrhea, constipation, other gastrointestinal disturbances.

Allergic

Urticaria, rashes, and hypersensitivity reactions, including angioedema and anaphylaxis. Serious skin reactions, including Stevens Johnson Syndrome and Toxic Epidermal Necrolysis have been reported.

Endocrine

Impotence, changes in libido.

7 DRUG INTERACTIONS

7.1 Agents that Lower Blood Levels of Amphetamines

Urinary Acidifying Agents
These agents (ammonium chloride, sodium acid phosphate, etc.) increase the concentration of the ionized species of the amphetamine molecule, thereby increasing urinary excretion.

Methenamine Therapy
Urinary excretion of amphetamines is increased, and efficacy is reduced, by acidifying agents used in methenamine therapy.

7.2 Agents that Increase Blood Levels of Amphetamines

Urinary Alkalinizing Agents
These agents (acetazolamide, some thiazides) increase the concentration of the non-ionized species of the amphetamine molecule, thereby decreasing urinary excretion.

Monoamine Oxidase Inhibitors
MAOI antidepressants, as well as a metabolite of furazolidone, slow amphetamine metabolism. This slowing potentiates amphetamines, increasing their effect on the release of norepinephrine and other monoamines from adrenergic nerve endings; this can cause headaches and other signs of hypertensive crisis. A variety of toxic neurological effects and malignant hyperpyrexia can occur, sometimes with fatal results.

7.3 Agents Whose Effects May be Reduced by Amphetamines

Adrenergic Blockers
Adrenergic blockers are inhibited by amphetamines.

Antihistamines
Amphetamines may counteract the sedative effect of antihistamines.

Antihypertensives
Amphetamines may antagonize the hypotensive effects of antihypertensives.

Veratrum Alkaloids
Amphetamines inhibit the hypotensive effect of veratrum alkaloids.

Ethosuximide
Amphetamines may delay intestinal absorption of ethosuximide.

7.4 Agents Whose Effects May be Potentiated by Amphetamines

Antidepressants, Tricyclic
Amphetamines may enhance the activity of tricyclic antidepressants or sympathomimetic agents; d-amphetamine with desipramine or protriptyline and possibly other tricyclics cause striking and sustained increases in the concentration of d-amphetamine in the brain; cardiovascular effects can be potentiated.

Meperidine
Amphetamines potentiate the analgesic effect of meperidine.

Phenobarbital
Amphetamines may delay intestinal absorption of phenobarbital; co-administration of phenobarbital may produce a synergistic anticonvulsant action.

Phenytoin
Amphetamines may delay intestinal absorption of phenytoin; co-administration of phenytoin may produce a synergistic anticonvulsant action.

7.5 Agents that May Reduce the Effects of Amphetamines

Chlorpromazine
Chlorpromazine blocks dopamine and norepinephrine receptors, thus inhibiting the central stimulant effects of amphetamines, and can be used to treat amphetamine poisoning.

Haloperidol
Haloperidol blocks dopamine receptors, thus inhibiting the central stimulant effects of amphetamines.

Lithium Carbonate
The anorectic and stimulatory effects of amphetamines may be inhibited by lithium carbonate.

7.6 Agents that May Potentiate the Effects of Amphetamines

Norepinephrine
Amphetamines enhance the adrenergic effect of norepinephrine.

Propoxyphene Overdosage
In cases of propoxyphene overdosage, amphetamine CNS stimulation is potentiated and fatal convulsions can occur.

7.7 Drug/Laboratory Test Interactions

Amphetamines can cause a significant elevation in plasma corticosteroid levels. This increase is greatest in the evening. Amphetamine may interfere with urinary steroid determinations.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Animal reproduction studies of lisdexamfetamine dimesylate have not been performed. Studies have been performed with the active metabolite of lisdexamfetamine, d-amphetamine, either alone or in combination with l-amphetamine, as noted below.

Teratogenic Effects

Pregnancy Category C

Amphetamine (d- to l-enantiomer ratio of 3:1) had no apparent effects on embryofetal morphological development or survival when orally administered to pregnant rats and rabbits throughout the period of organogenesis at doses of up to 6 and 16 mg/kg/day, respectively. Fetal malformations and death have been reported in mice following parenteral administration of d-amphetamine doses of 50 mg/kg/day or greater to pregnant animals. Administration of these doses was also associated with severe maternal toxicity.

A number of studies in rodents indicate that prenatal or early postnatal exposure to amphetamine (d- or d,l-) at doses similar to those used clinically can result in long term neurochemical and behavioral alterations. Reported behavioral effects include learning and memory deficits, altered locomotor activity, and changes in sexual function.

There are no adequate and well-controlled studies in pregnant women. There has been one report of severe congenital bony deformity, tracheo-esophageal fistula, and anal atresia (vater association) in a baby born to a woman who took dextroamphetamine sulfate with lovastatin during the first trimester of pregnancy. Amphetamines should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nonteratogenic Effects

Infants born to mothers dependent on amphetamines have an increased risk of premature delivery and low birth weight. Also, these infants may experience symptoms of withdrawal as demonstrated by dysphoria, including agitation, and significant lassitude.

8.2 Labor and Delivery

The effects of Vyvanse on labor and delivery in humans is unknown.

8.3 Nursing Mothers

Amphetamines are excreted into human milk. Mothers taking amphetamines should be advised to refrain from nursing.

8.4 Pediatric Use

Vyvanse is indicated for use in children with ADHD aged 6 to 12 years. Vyvanse has not been studied in children under 6 years of age or adolescents. Long-term effects of

amphetamines in children have not been well established. Amphetamines are not recommended for use in children under 3 years of age.

A study was conducted in which juvenile rats received oral doses of 4, 10, or 40 mg/kg/day of lisdexamfetamine dimesylate from day 7 to day 63 of age. These doses are approximately 0.3, 0.7, and 3 times the maximum recommended human daily dose of 70 mg on a mg/m^2 basis. Dose-related decreases in food consumption, bodyweight gain, and crown-rump length were seen; after a four week drug-free recovery period bodyweights and crown-rump lengths had significantly recovered in females but were still substantially reduced in males. Time to vaginal opening was delayed in females at the highest dose, but there were no drug effects on fertility when the animals were mated beginning on day 85 of age.

In a study in which juvenile dogs received lisdexamfetamine dimesylate for 6 months beginning at 10 weeks of age, decreased bodyweight gain was seen at all doses tested (2, 5, and 12 mg/kg/day, which are approximately 0.5, 1, and 3 times the maximum recommended human daily dose on a mg/m^2 basis). This effect partially or fully reversed during a four week drug-free recovery period.

8.5 Geriatric Use

Vyvanse has not been studied in the geriatric population.

9 DRUG ABUSE AND DEPENDENCE

9.1 Controlled Substance

Vyvanse is classified as a Schedule II controlled substance.

9.2 Abuse and Dependence

Amphetamines have been extensively abused. Tolerance, extreme psychological dependence, and severe social disability have occurred. There are reports of patients who have increased the dosage to levels many times higher than recommended. Abrupt cessation following prolonged high dosage administration results in extreme fatigue and mental depression; changes are also noted on the sleep EEG. Manifestations of chronic intoxication with amphetamines may include severe dermatoses, marked insomnia, irritability, hyperactivity, and personality changes. The most severe manifestation of chronic intoxication is psychosis, often clinically indistinguishable from schizophrenia.

Human Studies

In a human abuse liability study, when equivalent oral doses of 100 mg lisdexamfetamine dimesylate and 40 mg immediate release d-amphetamine sulfate were administered to individuals with a history of drug abuse, lisdexamfetamine dimesylate 100 mg produced subjective responses on a scale of “Drug Liking Effects” "Amphetamine Effects", and "Stimulant Effects" that were significantly less than d-amphetamine immediate release 40 mg. However, oral administration of 150 mg lisdexamfetamine dimesylate produced increases in positive subjective responses on these scales that were statistically indistinguishable from the positive subjective responses produced by 40 mg of oral immediate-release d-amphetamine and 200 mg of diethylpropion (C-IV).

Intravenous administration of 50 mg lisdexamfetamine dimesylate to individuals with a history of drug abuse produced positive subjective responses on scales measuring "Drug Liking", "Euphoria", "Amphetamine Effects", and "Benzedrine Effects" that were greater than placebo but less than those produced by an equivalent dose (20 mg) of intravenous d-amphetamine.

Animal Studies

In animal studies, lisdexamfetamine dimesylate produced behavioral effects qualitatively similar to those of the CNS stimulant d-amphetamine. In monkeys trained to self-administer cocaine, intravenous lisdexamfetamine dimesylate maintained self-administration at a rate that was statistically less than that for cocaine, but greater than that of placebo.

10 OVERDOSAGE

Individual patient response to amphetamines varies widely. Toxic symptoms may occur idiosyncratically at low doses.

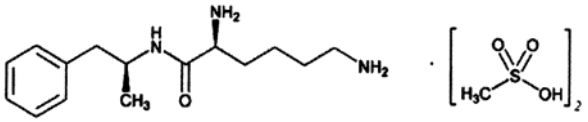
Symptoms: Manifestations of acute overdosage with amphetamines include restlessness, tremor, hyperreflexia, rapid respiration, confusion, assaultiveness, hallucinations, panic states, hyperpyrexia, and rhabdomyolysis. Fatigue and depression usually follow the central nervous system stimulation. Cardiovascular effects include arrhythmias, hypertension or hypotension, and circulatory collapse. Gastrointestinal symptoms include nausea, vomiting, diarrhea, and abdominal cramps. Fatal poisoning is usually preceded by convulsions and coma.

Treatment: Consult with a Certified Poison Control Center for up-to-date guidance and advice. Management of acute amphetamine intoxication is largely symptomatic and includes gastric lavage, administration of activated charcoal, administration of a cathartic, and sedation. Experience with hemodialysis or peritoneal dialysis is inadequate to permit recommendation in this regard. Acidification of the urine increases amphetamine excretion but is believed to increase risk of acute renal failure if myoglobinuria is present. If acute severe hypertension complicates amphetamine overdosage, administration of intravenous phentolamine has been suggested. However, a gradual drop in blood pressure will usually result when sufficient sedation has been achieved. Chlorpromazine antagonizes the central stimulant effects of amphetamines and can be used to treat amphetamine intoxication.

The prolonged release of Vyvanse in the body should be considered when treating patients with overdose.

11 DESCRIPTION

Vyvanse (lisdexamfetamine dimesylate) is designed as a capsule for once-a-day oral administration. The chemical designation for lisdexamfetamine dimesylate is (2S)-2,6-diamino-*N*-[(1*S*)-1-methyl-2-phenylethyl] hexanamide dimethanesulfonate. The molecular formula is $C_{15}H_{25}N_3O\bullet(CH_4O_3S)_2$, which corresponds to a molecular weight of 455.60. The chemical structure is:



Lisdexamfetamine dimesylate is a white to off-white powder that is soluble in water (792 mg/ml). Vyvanse capsules contain 20 mg, 30 mg, 40 mg, 50 mg, 60 mg, and 70 mg of lisdexamfetamine dimesylate and the following inactive ingredients: microcrystalline cellulose, croscarmellose sodium, and magnesium stearate. The capsule shells contain gelatin, titanium dioxide, and one or more of the following: D&C Red #28, D&C Yellow #10, FD&C Blue #1, FD&C Green #3, and FD&C Red #40.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Lisdexamfetamine is a prodrug of dextroamphetamine. After oral administration, lisdexamfetamine is rapidly absorbed from the gastrointestinal tract and converted to dextroamphetamine, which is responsible for the drug's activity. Amphetamines are non-catecholamine sympathomimetic amines with CNS stimulant activity. The mode of therapeutic action in Attention Deficit Hyperactivity Disorder (ADHD) is not known. Amphetamines are thought to block the reuptake of norepinephrine and dopamine into the presynaptic neuron and increase the release of these monoamines into the extraneuronal space. The parent drug, lisdexamfetamine, does not bind to the sites responsible for the reuptake of norepinephrine and dopamine *in vitro*.

12.3 Pharmacokinetics

Pharmacokinetic studies of dextroamphetamine after oral administration of lisdexamfetamine have been conducted in healthy adult and pediatric (aged 6 to 12) patients with ADHD.

In 18 pediatric patients (aged 6 to 12) with ADHD, the T_{max} of dextroamphetamine was approximately 3.5 hours following single-dose oral administration of lisdexamfetamine dimesylate either 30 mg, 50 mg, or 70 mg after an 8-hour overnight fast. The T_{max} of lisdexamfetamine was approximately 1 hour. Linear pharmacokinetics of dextroamphetamine after single-dose oral administration of lisdexamfetamine dimesylate was established over the dose range of 30 mg to 70 mg in children aged 6 to 12 years.

There is no unexpected accumulation of dextroamphetamine AUC at steady state in healthy adults and no accumulation of lisdexamfetamine after once-daily dosing for 7 consecutive days.

Food does not affect the observed AUC and C_{max} of dextroamphetamine in healthy adults after single-dose oral administration of 70 mg of Vyvanse capsules but prolongs T_{max} by approximately 1 hour (from 3.8 hrs at fasted state to 4.7 hrs after a high fat meal). After an 8-hour fast, the AUC for dextroamphetamine following oral administration of lisdexamfetamine dimesylate in solution and as intact capsules were equivalent.

Weight/Dose normalized AUC and C_{max} were 22% and 12% lower, respectively, in adult females than in males on day 7 following a 70 mg/day dose of lisdexamfetamine dimesylate

for 7 days. Weight/Dose normalized AUC and C_{max} values were the same in girls and boys following single doses of 30-70 mg.

Metabolism and Excretion

After oral administration, lisdexamfetamine is rapidly absorbed from the gastrointestinal tract. Lisdexamfetamine is converted to dextroamphetamine and l-lysine, which is believed to occur by first-pass intestinal and/or hepatic metabolism. Lisdexamfetamine is not metabolized by cytochrome P450 enzymes. Following the oral administration of a 70 mg dose of radiolabeled lisdexamfetamine dimesylate to 6 healthy subjects, approximately 96% of the oral dose radioactivity was recovered in the urine and only 0.3% recovered in the feces over a period of 120 hours. Of the radioactivity recovered in the urine 42% of the dose was related to amphetamine, 25% to hippuric acid, and 2% intact lisdexamfetamine. Plasma concentrations of unconverted lisdexamfetamine are low and transient, generally becoming non-quantifiable by 8 hours after administration. The plasma elimination half-life of lisdexamfetamine typically averaged less than one hour in studies of lisdexamfetamine dimesylate in volunteers.

Dextroamphetamine is known to inhibit monoamine oxidase. The ability of dextroamphetamine and its metabolites to inhibit various P450 isozymes and other enzymes has not been adequately elucidated. *In vitro* experiments with human microsomes indicate minor inhibition of CYP2D6 by amphetamine and minor inhibition of CYP1A2, 2D6, and 3A4 by one or more metabolites, but there are no *in vivo* studies of p450 enzyme inhibition.

Special Populations

Age

The pharmacokinetics of dextroamphetamine is similar in pediatric (aged 6 to 12) and adolescent (aged 13 to 17) ADHD patients, and healthy adult volunteers. Any differences in kinetics seen after oral administration are a result of differences in mg/kg dosing.

Gender

Systemic exposure to dextroamphetamine is similar for men and women given the same mg/kg dose.

Race

Formal pharmacokinetic studies for race have not been conducted.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis/ Mutagenesis and Impairment of Fertility

Carcinogenicity studies of lisdexamfetamine dimesylate have not been performed.

No evidence of carcinogenicity was found in studies in which d-, l-amphetamine (enantiomer ratio of 1:1) was administered to mice and rats in the diet for 2 years at doses of up to 30

mg/kg/day in male mice, 19 mg/kg/day in female mice, and 5 mg/kg/day in male and female rats.

Lisdexamfetamine dimesylate was not clastogenic in the mouse bone marrow micronucleus test *in vivo* and was negative when tested in the *E. coli* and *S. typhimurium* components of the Ames test and in the L5178Y/TK^{+-} mouse lymphoma assay *in vitro*.

Amphetamine (d- to l-enantiomer ratio of 3:1) did not adversely affect fertility or early embryonic development in the rat at doses of up to 20 mg/kg/day.

13.2 Animal Toxicology

Acute administration of high doses of amphetamine (d- or d,l-) has been shown to produce long-lasting neurotoxic effects, including irreversible nerve fiber damage, in rodents. The significance of these findings to humans is unknown.

14 CLINICAL STUDIES

The efficacy of Vyvanse in the treatment of ADHD was established on the basis of two controlled trials in children aged 6 to 12 and one controlled trial in adults who met Diagnostic and Statistical Manual of Mental Disorders, 4th edition (DSM-IV-TR) criteria for ADHD *[see INDICATIONS AND USAGE (1)]*.

Pediatric

A double-blind, randomized, placebo-controlled, parallel-group study was conducted in children aged 6 to12 (N=290) who met DSM-IV criteria for ADHD (either the combined type or the hyperactive-impulsive type). Patients were randomized to fixed dose treatment groups receiving final doses of 30, 50, or 70 mg of Vyvanse or placebo once daily in the morning for four weeks. All subjects receiving Vyvanse were initiated on 30 mg for the first week of treatment. Subjects assigned to the 50 and 70 mg dose groups were titrated by 20 mg per week until they achieved their assigned dose. Significant improvements in ADHD symptoms, based upon investigator ratings on the ADHD Rating Scale (ADHD-RS), were observed at endpoint for all Vyvanse™doses compared to patients who received placebo. Mean effects at all doses were fairly similar, although the highest dose (70 mg/day) was numerically superior to both lower doses (30 and 50 mg/day). The effects were maintained throughout the day based on parent ratings (Conner's Parent Rating Scale) in the morning (approximately 10 am), afternoon (approximately 2 pm), and early evening (approximately 6 pm).

A double-blind, placebo-controlled, randomized, crossover design, analog classroom study was conducted in children aged 6 to 12 (N=52) who met DSM-IV criteria for ADHD (either the combined type or the hyperactive-impulsive type). Following a 3-week open-label dose titration with Adderall XR®, patients were randomly assigned to continue the same dose of Adderall XR (10, 20, or 30 mg), Vyvanse (30, 50, and 70 mg), or placebo once daily in the morning for 1 week each treatment. A significant difference in patient behavior, based upon the average of investigator ratings on the Swanson, Kotkin, Agler, M.Flynn and Pelham (SKAMP)-Deportment scores across the 8 sessions of a 12 hour treatment day, was observed between patients who received Vyvanse compared to patients who received placebo. The drug effect was similar for all 8 sessions.

Adult

A double-blind, randomized, placebo-controlled, parallel-group, study was conducted in adults (N=420) who met DSM-IV criteria for ADHD. In this four-week study, patients were randomized to fixed dose treatment groups receiving final doses of 30, 50, or 70 mg of Vyvanse or placebo. All subjects receiving Vyvanse were initiated on 30 mg for the first week of treatment. Subjects assigned to the 50 and 70 mg dose groups were titrated by 20 mg per week until they achieved their assigned dose. Significant improvements in ADHD symptoms, based upon investigator ratings on the ADHD Rating Scale (ADHD-RS), were observed at end point for all Vyvanse doses compared to placebo.

16 HOW SUPPLIED/STORAGE AND HANDLING

Vyvanse capsules 20 mg: ivory body/ivory cap (imprinted NRP104 20 mg), bottles of 100, NDC 59417-102-10

Vyvanse capsules 30 mg: white body/orange cap (imprinted NRP104 30 mg), bottles of 100, NDC 59417-103-10

Vyvanse capsules 40 mg: white body/blue green cap (imprinted NRP104 40 mg), bottles of 100, NDC 59417-104-10

Vyvanse capsules 50 mg: white body/blue cap (imprinted NRP104 50 mg), bottles of 100, NDC 59417-105-10

Vyvanse capsules 60 mg: aqua blue body/aqua blue cap (imprinted NRP104 60 mg), bottles of 100, NDC 59417-106-10

Vyvanse capsules 70 mg: blue body/orange cap (imprinted NRP104 70 mg), bottles of 100, NDC 59417-107-10

Dispense in a tight, light-resistant container as defined in the USP.

Store at 25º C (77º F). Excursions permitted to 15-30º C (59-86º F) [see USP Controlled Room Temperature]

17 PATIENT COUNSELING INFORMATION

See Medication Guide

17.1 Information on Medication Guide

Prescribers or other health professionals should inform patients, their families, and their caregivers about the benefits and risks associated with treatment with Vyvanse and should counsel them in its appropriate use. A patient Medication Guide is available for Vyvanse. The prescriber or health professional should instruct patients, their families, and their caregivers to read the Medication Guide and should assist them in understanding its contents. Patients should be given the opportunity to discuss the contents of the Medication Guide and to obtain answers to any questions they may have. The complete text of the Medication Guide is attached to the package insert.

17.2 Controlled Substance Status/Potential for Abuse, Misuse, and Dependence

Patients should be advised that Vyvanse is a federally controlled substance because it can be abused or lead to dependence. Additionally, it should be emphasized that Vyvanse should be stored in a safe place to prevent misuse and/or abuse. Patient history (including family history) of abuse or dependence on alcohol, prescription medicines, or illicit drugs should be evaluated *[See Drug Abuse and Dependence (9)]*.

17.3 Serious Cardiovascular Risks

Patients should be advised of serious cardiovascular risk (including sudden death, myocardial infarction, stroke and hypertension) with Vyvanse. Patients who develop symptoms such as exertional chest pain, unexplained syncope, or other symptoms suggestive of cardiac disease during treatment should undergo a prompt cardiac evaluation *[See Warning and Precautions (5.1)]*.

17.4 Psychiatric Risks

Prior to initiating treatment with a stimulant, patients with comorbid depressive symptoms should be adequately screened to determine if they are at risk for bipolar disorder. Such screening should include a detailed psychiatric history, including a family history of suicide, bipolar disorder, and/or depression. Additionally, stimulant therapy at usual doses may cause treatment-emergent psychotic or manic symptoms in patients without prior history of psychotic symptoms or mania *[See Warnings and Precautions (5.2)]*.

17.5 Growth

Growth should be monitored during treatment with stimulants, and patients who are not growing or gaining weight as expected may need to have their treatment interrupted. *[See Warnings and Precautions (5.6)]*.

17.6 Pregnancy

Patients should be advised to notify their physicians if they become pregnant or intend to become pregnant during treatment *[see Dosage and Administration (2) and Use in Specific Populations (8.1)]*.

17.7 Nursing

Patients should be advised not to breast feed if they are taking Vyvanse *[see Use in Specific Populations (8.3)]*.

17.8 Impairment in Ability to Operate Machinery or Vehicles

Amphetamines may impair the ability of the patient to engage in potentially hazardous activities such as operating machinery or vehicles; the patient should therefore be cautioned accordingly.

Pharmacist: Medication Guide to be dispensed to patients

Manufactured for: Shire US Inc., Wayne, PA 19087

Made in USA

For more information call 1-800-828-2088

Vyvanse is a trademark of Shire LLC

Last Modified: mm/dd/2008

MEDICATION GUIDE
VYVANSE™
(lisdexamfetamine dimesylate) CII

Read the Medication Guide that comes with Vyvanse before you or your child starts taking it and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking to your doctor about you or your child's treatment with Vyvanse.

What is the most important information I should know about Vyvanse?

Vyvanse is a stimulant medicine. The following have been reported with use of stimulant medicines.

1. Heart-related problems:

- **sudden death in patients who have heart problems or heart defects**
- **stroke and heart attack in adults**
- **increased blood pressure and heart rate**

Tell your doctor if you or your child have any heart problems, heart defects, high blood pressure, or a family history of these problems.

Your doctor should check you or your child carefully for heart problems before starting Vyvanse.

Your doctor should check you or your child's blood pressure and heart rate regularly during treatment with Vyvanse.

Call your doctor right away if you or your child has any signs of heart problems such as chest pain, shortness of breath, or fainting while taking Vyvanse.

2. Mental (Psychiatric) problems:

All Patients

- **new or worse behavior and thought problems**
- **new or worse bipolar illness**
- **new or worse aggressive behavior or hostility**

Children and Teenagers

- **new psychotic symptoms (such as hearing voices, believing things that are not true, are suspicious) or new manic symptoms**

Tell your doctor about any mental problems you or your child have, or about a family history of suicide, bipolar illness, or depression.

Call your doctor right away if you or your child have any new or worsening mental symptoms or problems while taking Vyvanse, especially seeing or hearing things that are not real, believing things that are not real, or are suspicious.

What Is Vyvanse?

Vyvanse is a central nervous system stimulant prescription medicine. **It is used for the treatment of Attention-Deficit Hyperactivity Disorder (ADHD).** Vyvanse may help increase attention and decrease impulsiveness and hyperactivity in patients with ADHD.

Vyvanse should be used as a part of a total treatment program for ADHD that may include counseling or other therapies.

Vyvanse is a federally controlled substance (CII) because it can be abused or lead to dependence. Keep Vyvanse in a safe place to prevent misuse and abuse. Selling or giving away Vyvanse may harm others, and is against the law.

Tell your doctor if you or your child have (or have a family history of) ever abused or been dependent on alcohol, prescription medicines or street drugs.

Who should not take Vyvanse?

Vyvanse should not be taken if you or your child:

- have heart disease or hardening of the arteries
- have moderate to severe high blood pressure
- have hyperthyroidism
- have an eye problem called glaucoma
- are very anxious, tense, or agitated
- have a history of drug abuse
- are taking or have taken within the past 14 days an anti-depression medicine called a monoamine oxidase inhibitor or MAOI.
- is sensitive to, allergic to, or had a reaction to other stimulant medicines

Vyvanse has not been studied in children less than 6 years old. Vyvanse is not recommended for use in children less than 3 years old.

Vyvanse may not be right for you or your child. Before starting Vyvanse tell your or your child's doctor about all health conditions (or a family history of) including:

- heart problems, heart defects, high blood pressure
- mental problems including psychosis, mania, bipolar illness, or depression
- tics or Tourette's syndrome
- liver or kidney problems
- thyroid problems
- seizures or have had an abnormal brain wave test (EEG)

Tell your doctor if you or your child is pregnant, planning to become pregnant, or breastfeeding.

Can Vyvanse be taken with other medicines?

Tell your doctor about all of the medicines that you or your child take including prescription and nonprescription medicines, vitamins, and herbal supplements. Vyvanse and some medicines may interact with each other and cause serious side effects. Sometimes the doses of other medicines will need to be adjusted while taking Vyvanse.

Your doctor will decide whether Vyvanse can be taken with other medicines.

Especially tell your doctor if you or your child takes:

- anti-depression medicines including MAOIs
- anti-psychotic medicines
- lithium
- blood pressure medicines
- seizure medicines
- narcotic pain medicines

Know the medicines that you or your child takes. Keep a list of your medicines with you to show your doctor and pharmacist.

Do not start any new medicine while taking Vyvanse without talking to your doctor first.

How should Vyvanse be taken?

- **Take Vyvanse exactly as prescribed.** Vyvanse comes in 6 different strength capsules. Your doctor may adjust the dose until it is right for you or your child.
- Take Vyvanse once a day in the morning.
- Vyvanse can be taken with or without food.
- From time to time, your doctor may stop Vyvanse treatment for awhile to check ADHD symptoms.
- Your doctor may do regular checks of the blood, heart, and blood pressure while taking Vyvanse. Children should have their height and weight checked often while taking Vyvanse. Vyvanse treatment may be stopped if a problem is found during these check-ups.
- **If you or your child takes too much Vyvanse or overdoses, call your doctor or poison control center right away, or get emergency treatment.**

What are possible side effects of Vyvanse?

See **"What is the most important information I should know about Vyvanse?"** for information on reported heart and mental problems.

Other serious side effects include:

- slowing of growth (height and weight) in children
- seizures, mainly in patients with a history of seizures
- eyesight changes or blurred vision

Common side effects include:

- upper belly pain
- decreased appetite
- dizziness
- dry mouth
- irritability
- trouble sleeping
- nausea
- vomiting
- weight loss

Vyvanse may affect your or your child's ability to drive or do other dangerous activities.

Talk to your doctor if you or your child has side effects that are bothersome or do not go away.

This is not a complete list of possible side effects. Ask your doctor or pharmacist for more information

How should I store Vyvanse?

- Store Vyvanse in a safe place at room temperature, 59 to 86° F (15 to 30° C). Protect from light.
- **Keep Vyvanse and all medicines out of the reach of children.**

General information about Vyvanse

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use Vyvanse for a condition for which it was not prescribed. Do not give Vyvanse to other people, even if they have the same condition. It may harm them and it is against the law.

This Medication Guide summarizes the most important information about Vyvanse. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about Vyvanse that was written for healthcare professionals. For more information about Vyvanse, please contact Shire US Inc. at 1-800-828-2088.

What are the ingredients in Vyvanse?

Active Ingredient: lisdexamfetamine dimesylate
Inactive Ingredients: microcrystalline cellulose, croscarmellose sodium, and magnesium stearate. The capsule shells contain gelatin, titanium dioxide, and one or more of the following: D&C Red #28, D&C Yellow #10, FD&C Blue #1, FD&C Green #3, and FD&C Red #40.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

Last Modified: 04/dd/2008

Assistant District Attorney killed in shootout after being prescribed Antidepressants and Stimulants by New Mexico psychologist

On November 20, 2014, 31-year-old New Mexico attorney Myron May opened fire on students and employees in and around Strozier Library at Florida State University (FSU) before being shot and killed by police. His autopsy showed that he had Amphetamine in his blood and urine, likely the Amphetamine prescribed for him by his psychologist for several months.

Myron May was a popular student at his alma mater, having been elected as a student senator at FSU. After graduating from FSU with honors, May attended Texas Tech law school, where he obtained his juris doctorate.

At first recruited into at a national law firm, May later opted to join a smaller firm in Houston, representing employees instead of management. Leaving behind employment law and Houston, he moved to Las Cruces, New Mexico in January 2014, where he worked first as a Public Defender and then as an Assistant District Attorney in Dona Ana county. In New Mexico, May first practiced under a "limited license" before passing that state's Bar exam and being sworn in May 2014. He was well liked and respected.

With a heavier case load as a prosecutor, May sought help over the summer from a prescribing psychologist to focus better at work. The psychologist prescribed him Wellbutrin, an antidepressant, and Vyvanse, an amphetamine drug approved for Attention Deficit Hyperactivity Disorder (ADHD). New Mexico was one of only three states in the U.S. that allowed some psychologists to prescribe medications.

After taking these drugs for three weeks, May suffered a panic attack at work. After a second panic attack, May returned to the prescribing psychologist for an adjustment to his medications. At one point, he also went to a hospital emergency room due to panic and anxiety.

May reportedly became increasingly paranoid and delusional, believing that he was being targeted by a secret government program. On September 7, May's girlfriend called the police. May told the officers that someone was watching him through a camera hidden in his apartment, but the police laughed at him. He complained of hearing voices coming in through the walls as he bathed. He complained that he wasn't sleeping because of his neighbors' constant spying and that their voices kept him up. May said he wanted to buy a gun and take revenge on his neighbors. At one point, May documented these psychotic experiences on YouTube and his belief he was the target of a far-flung and intricate government conspiracy. (See: www.youtube.com/watch?v=a1vIkUZjRl4)

The 2008 FDA-approved label for Vyvanse (lisdexamfetamine) warns of treatment emergent or worsening psychosis, mania, hallucinations and delusional thinking. An FDA review of pediatric postmarketing adverse events involving Vyvanse further revealed that the drug regulatory agency has received other reports of homicidal ideation in children, an unlabeled event.

(See: www.accessdata.fda.gov/drugsatfda_docs/label/2008/021977s001lbl.pdf)

Frightened and concerned about his medications, May's friends contacted his prescribing psychologist who reportedly met with May and declared him to be fine. Within a few days, May had voluntarily checked himself into Mesilla Valley Hospital, a mental health center. He was released four days later to the care of his prescribing psychologist.

On October 5, May drove to Denver and back, making frantic phone calls to his friends from the road. He reportedly said that the police were on to him, that his hotel room was bugged, that he was being followed, and that he would be a millionaire when he brought justice to the crooked cops who were persecuting him. Unable to get help from his prescribing psychologist, May's friends contacted the facility he had been to the month before, Mesilla Valley Hospital, but were told he would have to come there voluntarily, be brought by the police or committed by his psychologist.

Two days later, May went to the County sheriff's office because he couldn't take it anymore and was going to turn himself in. He was turned away. That evening, May's girlfriend called police when he came to her home and appeared psychotic. He had left before they arrived. It is not clear why his prescribing psychologist did not intervene.

(See: www.scribd.com/document/252093571/Myron-May-Police-Report-Oct-7)

After abruptly quit his job with the Distric Attorney, weeks later May walked into Florida State's Strozier Library with a gun, wounded three students, and was gunned down by police. Nathan Scott and Farhan "Ronny" Ahmed were hospitalized after being shot by May. Mr. Scott recovered, but Mr. Ahmed was paralyzed. The tragedy could have been much worse. Student Jason Derfuss, who found a bullet in his backpack upon returning home, was saved by his books and a high-impact plastic water bottle. Bullets also reportedly grazed or narrowly missed students Elijay Velez and Robert Cohen. May's gun also malfunctioned as he attempted to shoot library security employee Paige McPhadden.

Toxicology results showed that assistant District Attorney May had amphetamine in his system at the time of his death, likely the Vyvance given to him from his prescribing psychologist.

(See: page 16 www.scribd.com/document/252095421/Myron-May-s-autopsy-report)

LATE

kobayashi2 - Jessi

From: mailinglist@capitol.hawaii.gov
Sent: Wednesday, February 1, 2017 8:01 PM
To: HLTtestimony
Cc: brian.laughs@gmail.com
Subject: Submitted testimony for HB767 on Feb 2, 2017 09:30AM

HB767
Submitted on: 2/1/2017
Testimony for HLT on Feb 2, 2017 09:30AM in Conference Room 329

Submitted By	Organization	Testifier Position	Present at Hearing
Brian Schultz	Individual	Oppose	No

Comments: Please vote "NO" on HB767. I am a board certified psychiatrist practicing in the State of Hawaii. I applaud efforts to expand access to safe mental health care. However, this bill does not ensure a reasonable level of training for prescription privileges. This bill does not require the same level of training as other states such as Illinois and Iowa. To prescribe chemicals that affect multiple organ systems, without appropriate biological and medical training, would be irresponsible. Thank you for your consideration into this matter.

Please note that testimony submitted less than 24 hours prior to the hearing, improperly identified, or directed to the incorrect office, may not be posted online or distributed to the committee prior to the convening of the public hearing.

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LATE

To: Chair Della Au Bellati & Members of the House Committee on Health

From: Amber Lea Rohner Sakuda, MD

Subject: **HB 767, Relating to Prescriptive Authority for Certain Psychologists**

Hearing Date: Thursday 2/2/17, 9:30 AM

Position: **OPPOSED**

Aloha Representative Della Au Bellati & Members of the House Committee on Health,

Mahalo for this opportunity to testify in opposition to HB 767. I am a medical doctor specializing in adult psychiatry with 2 years of sub-specialty training in child & adolescent psychiatry. This is my 6th year back home on Maui practicing psychiatry since I finished my 13 years of supervised training on thousands of patients. I'm very concerned about the lack of safety in HB 767 which would allow psychologists with no medical background to do substantially less training (400 hours over 1-4 years on 100 patients) to be able to prescribe many of the same medications I do. That means they could potentially prescribe addicting substances for ADHD like Desoxyn (methamphetamine) & Adderall (amphetamine salts) with minimal training & supervision.

I continue to be heavily involved in mental health integration/collaborative care efforts on Maui, helped with a case on Kaua'i, & formerly helped on the Big Island as well, to train primary care physicians (PCPs) to manage psychiatric conditions better, which seems a much safer & cost effective way to improve access to mental health treatment. It would require a significant amount of time & money, and new legislation, to train a psychologist with absolutely no medical background how to try to function as a medical doctor specializing in psychiatry.

If your parent or child was depressed & suicidal & in need of medication, would you want them to see a psychiatrist with 12+ years of medical training, or a psychologist with 1-4 years of medical training? Let's do what is pono & protect patient safety.

Please support patient safety & **VOTE NO on HB 767**!

Mahalo nui loa for your consideration of my testimony.

Much Aloha,

Amber Lea Rohner Sakuda, MD

(808) 870-1093