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AMERICA'S MOST IMPORTANT SPECIALTY

To the Editor:

During the 30 years I have devoted to the education and training of family physicians, I have witnessed our struggle for family medicine not only to be recognized and survive but also to grow and develop. While there have been federal subsidies to promote primary care, they have not made a difference because the academic medical community has not given family medicine its due respect and specialists have been remunerated disproportionately in comparison to primary care physicians.

The result is now well known to all. Instead of 50% to 75% of our graduates choosing primary care, it is now less than one-third allopathic and decreasing numbers of osteopathic. Fewer than 33% of all practicing physicians are in primary care when the proportion should exceed 50%.^{1,2} When family practice was declared a specialty in 1969, the goal was to have 25% of all graduates in family practice. Since then, we have increased the number of medical schools and physician graduates, but we have never had more than 15% enter the specialty.

Managed care programs have been advocated by many policymakers both in government and within the medical community. Where managed care has been in place for some time, costs have decreased.³ The value of the primary care physician has increased while the need for the other specialists has decreased. The results have been dramatic in some cases. We are already beginning to see layoffs of specialists in various parts of the country where managed care now dominates the medical marketplace. It is anticipated that this trend will continue over the next 5 years and, as a result, some physicians may not be able to find work. There is a growing movement to develop retraining and education programs to fill the need for physicians in primary care and to utilize this potential resource of medical manpower.

We now have specialists arguing that they provide primary care services. Perhaps they do, if primary care means continuous care of one organ or sex. Although the argument can be made that the definition of primary care should be

liberalized to embrace a wider number of the specialties because of the need for more primary care physicians, doing so will not correct the problem. On the other hand, one can also argue that the delivery of comprehensive health care is enhanced when a primary care physician can manage all members of the family. We simply need more family physicians. Family medicine is the only specialty that provides accessible, coordinated, continuous, and comprehensive health care for a community of people and cares for the patient from birth until death regardless of age and of sex.

A well-trained, well-educated, board-certified family physician can competently manage at least 85% of the health and medical care problems a person faces in a lifetime. That makes it possible for such a physician to practice in any geographic area, whether in urban, suburban, semi-rural, or rural America. Of course, that also means they can practice in any remote or underserved area as well. Since the 1950s, every report addressing the issue of physician manpower indicates a need for physicians with this capacity.^{4,5} That is what makes family practice America's most important specialty.

Including other specialties in primary care would do little to promote family medicine or affect physician workforce reform. All health care policies should promote the academic and practice environments of family medicine to enable us to train and educate not 25%, but 50% of our graduates into competent, well-compensated family physicians.

Nikitas J. Zervanos, MD
Lancaster, Pennsylvania

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1. US Department of Health and Human Services. 4th Report of the Council on Graduate Medical Education Executive Summary. Improving access to health care through physician manpower reform: directions for the 21st century. Washington, DC: US Department of Health and Human Services, Public Health Service, Health Resources and Services Administration, April 1994.
2. Kahn NB, Schmittling G, et al. Results of the 1994 National Resident Matching Program: Family Practice. *Fam Med* 1994; 26: 487-91.

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4. American Medical Association Report of the Ad Hoc Committee for Family Practice of the Council on Medical Education. Meeting the challenge of family practice. Chicago, Ill: American Medical Association, 1966.
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To the Editor:

I have been outraged by the plans for the "retraining of other specialists for family practice." Family practice is a board-certified specialty with a 3-year residency requirement.

Other specialists need to complete a family practice residency and pass the family practice boards. Credit should then be given for board-certified specialists in their area of expertise *only*.

Any other plans would demean all board-certified family practitioners and send out a hoard of physicians incompetent to practice primary care. Such a development would damage our reputation as family practitioners as well as risk our patients' well-being.

Nayvin Gordon, MD
Oakland, California

ALIEN LIFE FORMS

To the Editor:

Thank goodness Dr Bennett had the courage to speak up regarding his alien child. (*Bennett HJ. My daughter is a Klingon. J Fam Pract* 1994; 39:295-6). Up until now, my husband and I thought we were alone.

At 30 weeks' gestation now, we have had a multitude of ultrasounds. Once she no longer appeared to be a salamander, it became clear from the AP facial views that we, too, had a Klingon daughter. There were no Klingon male donors at the fertility clinic that day, so a semen specimen mix-up does not explain her appearance. Although I admit that Worf's appearance has improved each season, I swear we have never seen each other.

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See complete prescribing information in SmithKline Beecham Pharmaceuticals literature or PDR. The following is a brief summary.

INDICATIONS AND USAGE: Paxil is indicated for the treatment of depression.

CONTRAINDICATIONS: Concomitant use in patients taking monoamine oxidase inhibitors (MAOIs) is contraindicated. (See WARNINGS.)

WARNINGS: Interactions with MAOIs may occur. Given the fatal interactions reported with concomitant or immediately consecutive administration of MAOIs and other SSRIs, do not use Paxil in combination with a MAOI or within 2 weeks of discontinuing MAOI treatment. Allow at least 2 weeks after stopping Paxil before starting a MAOI. **PRECAUTIONS:** As with all antidepressants, use Paxil cautiously in patients with a history of mania.

Use Paxil cautiously in patients with a history of seizures. Discontinue it in any patient who develops seizures.

The possibility of suicide attempt is inherent in depression and may persist until significant remission occurs. Close supervision of high-risk patients should accompany initial drug therapy. Write Paxil prescriptions for the smallest quantity of tablets consistent with good patient management in order to reduce the risk of overdose.

Reversible hyponatremia has been reported, mainly in elderly patients, patients taking diuretics or those who were otherwise volume depleted.

Clinical experience with Paxil in patients with concomitant systemic illness is limited. Use cautiously in patients with diseases or conditions that could affect metabolism or hemodynamic responses. Observe the usual cautions in cardiac patients. In patients with severe renal impairment (creatinine clearance <30 mL/min) or severe hepatic impairment, a lower starting dose (10 mg) should be used.

Caution patients about operating hazardous machinery, including automobiles, until they are reasonably sure that Paxil therapy does not affect their ability to engage in such activities. Tell patients 1) to continue therapy as directed; 2) to inform physicians about other medications they are taking or plan to take; 3) to avoid alcohol while taking Paxil; 4) to notify their physicians if they become pregnant or intend to become pregnant during therapy, or if they're nursing.

Concomitant use of Paxil with tryptophan is not recommended. Use cautiously with warfarin. When administering Paxil with cimetidine, dosage adjustment of Paxil after the 20 mg starting dose should be guided by clinical effect. When co-administering Paxil with phenobarbital or phenytoin, no initial Paxil dosage adjustment is needed; base subsequent changes on clinical effect. Concomitant use of Paxil with drugs metabolized by cytochrome P₄₅₀1D₂ (antidepressants such as nortriptyline, amitriptyline, imipramine, desipramine and fluoxetine; phenothiazines such as thioridazine; Type 1C antiarrhythmics such as propafenone, flecainide and encainide) or with drugs that inhibit this enzyme (e.g., quinidine) may require lower doses than usually prescribed for either Paxil or the other drug; approach concomitant use cautiously. Administration of Paxil with another tightly protein-bound drug may shift plasma concentrations, resulting in adverse effects from either drug. Concomitant use of Paxil and alcohol in depressed patients is not advised. Undertake concomitant use of Paxil and lithium or digoxin cautiously. If adverse effects are seen when co-administering Paxil with procyclidine, reduce the procyclidine dose.

In 2-year studies, a significantly greater number of male rats in the 20 mg/kg/day group developed reticular cell sarcomas vs. animals given doses of 1 or 5 mg/kg/day. There was also a significantly increased linear trend across dose groups for the occurrence of lymphoreticular tumors in male rats. Although there was a dose-related increase in the number of tumors in mice, there was no drug-related increase in the number of mice with tumors. The clinical significance of these findings is unknown. There is no evidence of mutagenicity with Paxil. Serotonergic compounds are known to affect reproductive function in animals. Impaired reproductive function in rats (i.e., reduced pregnancy rate, increased pre- and post-implantation losses, decreased viability of pups) was found at Paxil doses 15 or more times the highest recommended human dose.

Pregnancy Category B. Reproduction studies performed in rats and rabbits at doses up to 50 and 6 times the maximum recommended human dose have revealed no evidence of teratogenic effects or of selective toxicity to the fetus. However, there are no adequate and well-controlled studies in pregnant women. Paxil should be used in pregnancy only if the benefits outweigh the risks. The effect of Paxil on labor and delivery in humans is unknown. Paroxetine is secreted in human milk; exercise caution when administering Paxil to a nursing woman.

Safety and effectiveness in children have not been established.

In worldwide Paxil clinical trials, 17% of Paxil-treated patients were ≥65 years of age. Pharmacokinetic studies revealed a decreased clearance in the elderly; however, there were no overall differences in the adverse event profile between older and younger patients.

ADVERSE REACTIONS: Incidence in Controlled Trials—Commonly Observed Adverse Events in Controlled Clinical Trials:

The most commonly observed adverse events associated with the use of Paxil (incidence of 5% or greater and incidence for Paxil at least twice that for placebo) are: asthenia (15% vs. 6%), sweating (11% vs. 2%), nausea (26% vs. 9%), decreased appetite (6% vs. 2%), somnolence (23% vs. 9%), dizziness (13% vs. 6%), insomnia (13% vs. 6%), tremor (8% vs. 2%), nervousness (5% vs. 3%), ejaculatory disturbance (13% vs. 0%) and other male genital disorders (10% vs. 0%). Twenty-one percent (881/4,126) of Paxil patients in worldwide clinical trials discontinued treatment due to an adverse event. The most common events (≥1%) associated with discontinuation and considered to be drug related include: somnolence, insomnia, agitation, tremor, anxiety, nausea, diarrhea, dry mouth, vomiting, asthenia, abnormal ejaculation, sweating. The following adverse events occurred in 6-week placebo-controlled trials of similar design at a frequency of 1% or more.

Body as a Whole: headache, asthenia, abdominal pain, fever, chest pain, trauma, back pain. **Cardiovascular:** palpitation, vasodilation, postural hypotension. **Dermatologic:** sweating, rash. **Gastrointestinal:** nausea, dry mouth, constipation, diarrhea, decreased appetite, flatulence, vomiting, oropharynx

disorder, dyspepsia, increased appetite. **Musculoskeletal:** myopathy, myalgia, myasthenia. **Nervous System:** somnolence, dizziness, insomnia, tremor, nervousness, anxiety, paresthesia, libido decreased, agitation, drugged feeling, myoclonus, CNS stimulation, confusion. **Respiration:** respiratory disorder, yawn, pharyngitis. **Special Senses:** blurred vision, taste perversion. **Urogenital System:** ejaculatory disturbance, other male genital disorders, urinary frequency, urination disorder, female genital disorders.

Studies show a clear dose dependency for some of the more common adverse events associated with Paxil use. There was evidence of adaptation to some adverse events with continued Paxil therapy (e.g., nausea and dizziness). Significant weight loss may be an undesirable result of Paxil treatment for some patients but, on average, patients in controlled trials had minimal (about 1 lb) loss. In placebo-controlled clinical trials, Paxil-treated patients exhibited abnormal values on liver function tests no more frequently than placebo-treated patients.

Other Events Observed During the Premarketing Evaluation of Paxil: During premarketing assessment, multiple doses of Paxil were administered to 4,126 patients, and the following adverse events were reported. Note: "frequent" = events occurring in at least 1/100 patients; "infrequent" = 1/100 to 1/1,000 patients; "rare" = less than 1/1,000 patients. Events are classified within body system categories and enumerated in order of decreasing frequency using the following definitions. It is important to emphasize that although the events occurred during Paxil treatment, they were not necessarily caused by it.

Body as a Whole: frequent: chills, malaise; infrequent: allergic reaction, carcinoma, face edema, moniliasis, neck pain; rare: abscess, adrenergic syndrome, cellulitis, neck rigidity, pelvic pain, peritonitis, ulcer. **Cardiovascular System:** frequent: hypertension, syncope, tachycardia; infrequent: bradycardia, conduction abnormalities, electrocardiogram abnormal, hypotension, migraine, peripheral vascular disorder; rare: angina pectoris, arrhythmia, atrial fibrillation, bundle branch block, cerebral ischemia, cerebrovascular accident, congestive heart failure, low cardiac output, myocardial infarct, myocardial ischemia, pallor, phlebitis, pulmonary embolus, supraventricular extrasystoles, thrombosis, varicose vein, vascular headache, ventricular extrasystoles. **Digestive System:** infrequent: bruxism, dysphagia, eructation, glossitis, increased salivation, liver function tests abnormal, bloody ulceration, rectal hemorrhage; rare: aphthous stomatitis, mouth diarrhea, bulimia, colitis, duodenitis, esophagitis, fecal impactions, fecal incontinence, gastritis, gastroenteritis, gingivitis, hematemesis, hepatitis, ileus, jaundice, melena, peptic ulcer, salivary gland enlargement, stomach ulcer, stomatitis, tongue edema, tooth caries. **Endocrine System:** rare: diabetes mellitus, hyperthyroidism, hypothyroidism, thyroiditis. **Hemic and Lymphatic Systems:** infrequent: anemia, leukopenia, lymphadenopathy, purpura; rare: abnormal erythrocytes, eosinophilia, leukocytosis, lymphedema, abnormal lymphocytes, lymphocytosis, microcytic anemia, monocytosis, normocytic anemia. **Metabolic and Nutritional:** frequent: edema, weight gain, weight loss; infrequent: hyperglycemia, peripheral edema, thirst; rare: alkaline phosphatase increased, bilirubinemia, dehydration, gout, hypercholesterolemia, hypocalcemia, hypoglycemia, hypokalemia, hyponatremia, SGOT increased, SGPT increased. **Musculoskeletal System:** infrequent: arthralgia, arthritis; rare: arthrosis, bursitis, myositis, osteoporosis, tetany. **Nervous System:** frequent: amnesia, CNS stimulation, concentration impaired, depression, emotional lability, vertigo; infrequent: abnormal thinking, akinesia, alcohol abuse, ataxia, convulsions, depersonalization, hallucinations, hyperkinesia, hypertonia, incoordination, lack of emotion, manic reaction, paranoid reaction; rare: abnormal electroencephalogram, abnormal gait, antisocial reaction, choreoathetosis, delirium, delusions, diplopia, drug dependence, dysarthria, dyskinesia, dystonia, euphoria, fasciculations, grand mal convulsion, hostility, hyperalgesia, hypokinesia, hysteria, libido increased, manic-depressive reaction, meningitis, myelitis, neuralgia, neuropathy, nystagmus, paralysis, psychosis, psychotic depression, reflexes increased, stupor, withdrawal syndrome. **Respiratory System:** frequent: cough increased, rhinitis; infrequent: asthma, bronchitis, dyspnea, epistaxis, hyperventilation, pneumonia, respiratory flu, sinusitis; rare: carcinoma of lung, hiccups, lung fibrosis, sputum increased. **Skin and Appendages:** frequent: pruritus; infrequent: acne, alopecia, dry skin, ecchymosis, eczema, furunculosis, urticaria; rare: angioedema, contact dermatitis, erythema nodosum, maculopapular rash, photosensitivity, skin discoloration, skin melanoma. **Special Senses:** infrequent: abnormality of accommodation, ear pain, eye pain, mydriasis, otitis media, taste loss, tinnitus; rare: amblyopia, cataract, conjunctivitis, corneal ulcer, exophthalmos, eye hemorrhage, glaucoma, hyperacusis, otitis externa, photophobia. **Urogenital System:** infrequent: abortion, amenorrhea, breast pain, cystitis, dysmenorrhea, dysuria, menorrhagia, nocturia, polyuria, urethritis, urinary incontinence, urinary retention, urinary urgency, vaginitis; rare: breast atrophy, breast carcinoma, breast neoplasm, female lactation, hematuria, kidney calculus, kidney function abnormal, kidney pain, mastitis, nephritis, oliguria, prostatic carcinoma, vaginal moniliasis.

Non-U.S. Postmarketing Reports

Voluntary reports of adverse events that have been received since market introduction and may have no causal relationship with Paxil include elevated liver function tests (the most severe case was a death due to liver necrosis, and one other case involving grossly elevated transaminases associated with severe liver dysfunction) and toxic epidermal necrolysis.

DRUG ABUSE AND DEPENDENCE: Controlled Substance Class: Paxil is not a controlled substance. Evaluate patients carefully for history of drug abuse and observe such patients closely for signs of Paxil misuse or abuse (e.g., development of tolerance, increments of dose, drug-seeking behavior).

BRS-PX-L6

References:

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JANSSEN PHARMACEUTICAL RESEARCH FOUNDATION

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It is only through thorough and meticulous research on other families in our situation that we will ever be able to explain this. (Are Klingons actually spontaneous mutations of Earthers?)

Nicole A. Chauche, MD
San Diego, California

The preceding letter was forwarded to Dr. Howard J. Bennett, who responds as follows:

I appreciate Dr. Chauche's thoughtful response to my article. Although anecdotal reports are important, I agree that they are no substitute for carefully controlled, prospective research. As a start, I suggest we seek answers to the following questions:

- Should all pregnancies be screened for alien life forms?
- What percentage of Klingon fetuses will be picked up on a level-2 sonogram?
- At what age can physicians reliably diagnose a Klingon baby?
- What impact, if any, exists between the use of fertility drugs and giving birth to a Klingon infant?
- Given the choice, would most physicians prefer raising a Klingon, a Vulcan, or a Romulan infant?
- Is the Klingon influence stronger on the West Coast?
- Are Klingon babies equally represented in the general population or do they have a preference for medical families?
- Do most surgeons have Klingon ancestors in their family tree?
- Can I use a Klingon grant to help cover my orphan research projects?
- Should we establish a national clearinghouse for information on extraterrestrial births?

While all of this is being studied, my wife and I are writing a book for the general public. It's called *Klingon Babies and the Parents Who Love Them* (Milky Way Press).

Howard J. Bennett, MD
Washington, DC