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Professional Boundaries in Nursing

A Look at the Health Insurance Portability and Accountability Act (HIPAA)
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Boundary issues are everywhere for nurses. Issues on the continuum range from stopping to buy a few groceries for a home-bound client, to accepting a personal gift from a client, to having a friendship with a former client, to having a sexual relationship with a current client. Although there is more gray area than black and white when studying boundaries, nurses can make thoughtful decisions when provided with information about the fundamentals of boundaries. This article is intended to highlight some of the basics. Nurses are encouraged to read additional information and have discussions with colleagues to broaden their understanding of the topic.

Boundaries are defined as limits that protect the space between the professional's power and the client's vulnerability. Maintaining appropriate boundaries controls this power differential and allows for a safe connection between the professional and client based on the client's needs.

The need for maintaining appropriate boundaries arises from the nature of the nurse-client relationship. Like other professional relationships, the client places his or her confidence in the nurse who possesses special knowledge, expertise, and authority. In addition, the client is vulnerable in so far as he or she has a nursing care need which the nurse has the ability to meet. It is imperative that the nurse be aware of this power differential and ensure that the nurse's actions are intended to meet the nursing care needs of the client.

The maintenance of boundaries need not be seen as an impediment to the professional relationship, but rather as facilitating it. Maintaining professional boundaries protects the safe space in the relationship and thereby enhances the building of the trust which is essential to enable clients to reveal their needs.

A boundary violation occurs when a nurse, consciously or unconsciously, uses the nurse-client relationship to meet personal needs rather than client needs. This violation breaches the fundamental nature of care that obligates the professional to place clients' needs first. It is helpful to view this as a process or a "slippery slope" rather than an end result or a "crossing the line." This provides an opportunity for the nurse to heed warning signs which will allow the nurse to take steps to reevaluate the relationship with the client and to reestablish appropriate professional boundaries. It also prevents ignoring, normalizing or dismissing relatively minor or less visible boundary violations. The minor violations may be damaging to the relationship and left unexamined, the minor violations can be repeated and expanded.

Four elements characteristically appear in boundary violations: role reversal, secrecy, double-bind, and indulgence of professional privilege.

- Role Reversal
Role reversal occurs when the client takes care of the nurse as the nurse looks to the client for satisfaction and gratification, rather than the nurse placing client needs first. The nurse may not be consciously aware of this role reversal or may attempt to justify it by contending his or her actions are for the client's benefit. Example: A client becomes a nurse's chemical dependency.

- Secrecy
Secrecy involves the nurse keeping critical knowledge or behavior from the client and/or others or selectively sharing information. Example: A nurse takes a client into his or her home and tells the client the nurse's employer cannot know about this or the nurse will lose his or her job.

- Double-Bind
A double-bind consists of two sets of messages which contradict each other while they discourage the receiver of the messages from noticing the inconsistency. The client is left feeling caught in a conflict of interest: any attempt at resolution places the client at risk of loss. The client is torn between the desire to terminate the relationship and the realization that this will end any form of help from the professional. The double-bind contains an implied threat. A sense of guilt and fear of possible abandonment by the professional blocks the client from taking action. The double-bind constrains the client from using all available options and thus limits growth.

Examples: 1) A nurse makes negative comments about other nurses caring for a client who has development of trust as a therapeutic goal. 2) A nurse tells a therapy client that they may begin a personal relationship when the client is no longer in therapy.

- Indulgence of Professional Privilege
Indulgence involves using information obtained in the relationship with a client for the benefit of the professional. Because the professional has authority over the client's situation, that professional is susceptible to extending the privilege of his or her position to intrude on the client. However, access to information does not constitute a right to it. This access is a professional privilege; it is not a professional right to use the information for one's own benefit. Example: Using proximity to post-partum mothers to locate a baby for adoption by the nurse.
To avoid boundary violations, it may be helpful to be aware of “warning signs”. In isolation these do not necessarily indicate a problem, but if repeated or if several warning signs are present, the nurse should reevaluate his or her actions.

- Perception: The nurse should ask: Is this what other nurses would do? How would this appear to others (peers, family, superiors)? How does this appear to the client?
- Time: The nurse should consider the quality and quantity of time spent with the client. Does it vary from that spent with other clients? Is the nurse spending “off duty” time with the client?
- Meeting time and place: Is the location of the interaction appropriate to the relationship? Would you provide nursing service to other clients in this location? If there is a legitimate, therapeutic need to meet at an unusual time, has it been made known to others and documented?
- Gifts: Does the gift giving create a sense of obligation on the part of the recipient? Is this a routine part of your practice regardless of the age or gender of the client? Is the gift of a personal nature, given to one nurse or a general gift given to a group of caregivers? Does the facility have a policy regarding gifts?
- Forms of address: Has there been a change in the way the client is addressed or how this client is addressed in relation to others?
- Personal attire: Has the nurse’s style of dress changed with more attention paid to personal appearance?
- Making exceptions: In general the nurse should carefully consider the therapeutic purpose in making exceptions in helping a client or family member. Another type of exception to note would be the nurse who changes assignments to care for a particular client.
- Internal cues: Learning to recognize and trust internal cues is important. A nurse should seek guidance if he or she is in a situation which raises questions in the nurse’s mind. When in doubt, check it out. Nonverbal behavior, the nurse’s or the client’s, may provide helpful insight. Does the nurse become defensive if questioned about the interaction with the client?
- Meeting personal needs: In addition to recognizing that the client’s needs must come first, the nurse should be aware of his or her own social and emotional needs and take affirmative steps to have those needs met away from work. Thoughts such as “I only feel appreciated at work” or “Only I can help this client” indicate the nurse may be meeting his or her needs through clients.
- Dual relationships: The nurse enters a nurse-client relationship in order to provide the client with nursing services. Nursing services would not include, for example, dating, baby-sitting or entering a business relationship with clients.
- Confidentiality: The nurse should maintain confidentiality by not using or sharing confidential information unless it is for a legitimate therapeutic purpose.
- Choosing sides: Is the nurse taking sides with the client against the client’s significant others? The nurse should ask: “What is the value in taking sides?” How can the nurse assist the client in looking at all sides of the issue to utilize his or her own problem solving skills?
- Self-disclosure: While professionals want to be perceived as caring, self-disclosure is rarely helpful or necessary. The nurse should consider the client need served by the self-disclosure and determine whether personal issues shared with the client are brief, resolved and related to what the client is experiencing.
- Touch: Touching is an integral part of many nursing interventions. Touch may be a component of another action, e.g., checking a blood pressure, or may be therapeutic in and of itself. Touch, however, should not be used indiscriminately. The nurse should be clear in his or her own mind why touch is called for and communicate this to the client.
- Communication: It is the responsibility of the nurse to establish and maintain boundaries and to communicate this to the client. In addition, the nurse should be able to communicate to others the nature of the relationship with the client. Is the nurse keeping secrets with or about the client? Does the nurse fail to document or report negative information about the client?

This is not an exhaustive list but should be instructional for all nurses. A nurse in any practice setting will encounter boundary issues. With forethought, planning, communication, and evaluation, the nurse can take steps to ensure a boundary issue does not progress to a boundary violation.

BIBLIOGRAPHY


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The Health Insurance Portability and Accountability Act (HIPAA) was passed by Congress on August 21, 1996 to address major problems in health care, including job lock, which occurs when an individual will not change jobs for fear of losing health benefits, and improper access to individuals’ personally identifiable health information. The noble purpose that Congress stated for HIPAA was: To amend the Internal Revenue Code of 1986 to improve portability and continuity of health insurance coverage in the group and individual markets, to combat waste, fraud, and abuse in health insurance and health care delivery, to promote the use of medical savings accounts, to improve access to long-term care services and coverage, to simplify the administration of health insurance, and for other purposes.

HIPAA is a broad and expansive statute covering many aspects of health care. The five titles of HIPAA are: Health Care Access, Portability, and Renewability; Preventing Health Care Fraud and Abuse; Administrative Simplification; Medical Liability Reform; Tax Related Health Provisions; Application and Enforcement of Group Health Plan Requirements; and Revenue Offsets. This piece will address Title I of HIPAA, which was to deal with job lock among other things. There will be an additional HIPAA piece in the March issue of the Wyoming Lawyer.

Recognizing the problems with health care coverage in the U.S., Congress attempted to remedy some of those problems through the passage of this act. The General Accounting Office (GAO) noted in a Letter Report to Congress:

Millions of Americans face discontinuity in their health care coverage when they change employers, and others do not change jobs because of concerns about losing health care coverage. In fact, individuals with health problems may face extended periods in which their new health plan does not cover their medical conditions because

of exclusions for preexisting conditions.

We estimate that up to 21 million Americans a year would benefit from federal legislation that would waive preexisting condition exclusions for individuals who have had continuous health care coverage. In addition, perhaps as many as 4 million Americans who at some time have been unwilling to leave their jobs because of concern about losing their health care coverage would benefit from national portability standards. Such a change, however, could possibly increase premiums, according to insurers.

This piece focuses on sections of Title I of HIPAA, which addresses “Health Care Access, Portability, and Renewability.” While HIPAA has a noble purpose and a seemingly sincere backdrop, Title I of HIPAA does not go far enough to protect individuals. A major problem with HIPAA is that practitioners do not fully understand HIPAA mandates and individuals have no way of understanding their rights and responsibilities under the act. This article is meant to provide a basic understanding of HIPAA’s preexisting condition exclusion and the prohibition on discrimination based on health status, both of which are found in Title I of HIPAA.

Title I deals specifically with portability, access, and renewability in group health plans. Group health plan is defined as “an employee welfare benefit plan to the extent that the plan provides medical care to employees and their dependents directly or through insurance, reimbursement, or otherwise.” If an individual is a member of a health insurance plan continued on Page 10.
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through that individual's employer, he or she is deemed to be in a group health plan.

**Preexisting Condition Exclusions**

One aim of HIPAA is to increase portability through limitations on "preexisting condition exclusions," defined as "a limitation or exclusion of benefits relating to a condition based on the fact that the condition was present before the date of enrollment for such coverage, whether or not any medical advice, diagnosis, care, or treatment was recommended or received before such date." 10

HIPAA limits when insurance companies can impose exclusions. Insurers can only impose an exclusion if:

1. such exclusion relates to a condition (whether physical or mental), regardless of the cause of the condition, for which medical advice, diagnosis, care, or treatment was recommended or received within the 6-month period ending on the enrollment date;
2. such exclusion extends for a period of not more than 12 months (or 18 months in the case of a late enrollee) after the enrollment date; and
3. the period of any such preexisting condition exclusion is reduced by the aggregate of the periods of creditable coverage . . . applicable to the participant or beneficiary enrollment date. 11

Essentially, the first point establishes a 6-month look-back period for the insurance provider to inquire about preexisting conditions. If an individual received "medical advice, diagnosis, care, or treatment" or if any of those were recommended within a 6-month time frame before enrolling for coverage, the insurance provider can impose an exclusion and not cover that condition. 12 Any conditions that were not diagnosed, cared for, or treated (or recommended to be diagnosed, cared for, or treated) within that 6-month window, the insurance provider cannot impose an exclusion on that specific condition. However, all of these restrictions are still subject to the terms of the provider's policy. If a condition is excluded from coverage for all individuals, then the provider can make that exclusion across the board.

The 6-month look-back period ends with the enrollment date. The enrollment date is "the date of enrollment of the individual in the plan or coverage or, if earlier, the first day of the waiting period for such enrollment." 13 This provision allows the look-back period to stop when the individual is enrolled in the health insurance plan. However, if there is a waiting period before an individual is actually eligible for coverage, the look-back period starts on the first day of that waiting period. "The term 'waiting period' means . . . the period that must pass with respect to the individual before the individual is eligible to be covered for benefits under the terms of the plan." 14

The second limitation allows the insurance provider to deny coverage for an acknowledged preexisting condition but only for twelve (12) months, or eighteen (18) months for a late enrollee. After that 12-month period, even the preexisting condition should be covered, unless the policy excludes it for other valid reasons. If that condition would be covered under the normal policy, it will only be covered to extent the policy allows. Just because the condition was preexisting, does not give it preferential or less coverage than any other covered condition.

"The term 'late enrollee' means . . . a participant or beneficiary who enrolls under the plan other than during-(A) the first period in which the individual is eligible to enroll under the plan, or (B) a special enrollment period . . . " 15 This section allows an insurer to extend the time it can exclude coverage for a preexisting condition if the individual does not enroll in the plan the first chance that individual gets or if that person falls into a category that puts him or her in a "special enrollment period." 16

The third limitation reduces the amount of time the preexisting condition exclusion can be in effect by the amount of time the individual had creditable coverage. Basically, if an individual has had any sort of health care coverage, that coverage will count to reduce the length of time the preexisting condition exclusion can be in effect. 17

However, there is a caveat to creditable coverage. "A period of creditable coverage shall not be counted, with respect to enrollment of an individual under any group health plan, if, after such period and before the enrollment date, there was a 63-day period during all of which the individual was not covered under any creditable coverage." 18 If there is a 63-day or more gap between the last day of previous coverage and the enrollment date, an individual will not get any credit for that previous coverage. However, "any period that an individual is in a waiting period for any coverage under a group health plan (or for group health insurance coverage) or is in an affiliation period . . . shall not be taken into account in determining the continuous period . . . " 19 The waiting period before an individual actually gets coverage will not count as a gap coverage. For example, if an individual's last day of coverage under a previous employer was December 31, and that individual started a new job on January 15, but had to wait 60 days for coverage under the new employer, there would be a 75-day span where the individual is not technically covered. However, as the 60-day wait is not counted towards a break in coverage, the individual will not be subject to preexisting condition exclusions.

There are exceptions to the requirement that there not be a gap in coverage.

Newborns cannot have exclusions imposed on them if the newborn is covered under creditable coverage within 30 days of birth. 20 Additionally, no exclusion can be imposed for an adopted child, who is under 18 years old, if that child has creditable coverage as of the 30th day after the date of adoption or placement of adoption. 21

After a newborn or adopted child has had 63 days without creditable coverage, the exception will not protect them from an exclusion. 22 This provision prevents the exception from being applied after a newborn or adopted child could have obtained coverage, but then the coverage lapses for at least 63 days. However, this provision does not add much to HIPAA since the exception can only be invoked if the newborns or adopted children obtain coverage within 30 days of birth or adoption, respectively. It appears that the lawmakers were simply making it clear that the exception only applies when the newborn or adopted child becomes eligible for coverage.

An exclusion cannot be imposed based on pregnancy. 23 This provision is very important as the cost of prenatal care and childbirth care is relatively high. It would be bad policy to tie an individual expecting to have a child to a particular job because the next employee's insurance company or provider could exclude coverage for prenatal care or childbirth based on a preexisting condition exclusion.

For an individual to get credit for creditable coverage, that individual has to be able to prove that he or she had such health care coverage. Therefore, HIPAA requires a group health insurer to provide the individual with a certificate of cred-
The insurance company or provider must provide this certificate - (i) at the time an individual ceases to be covered under the plan or otherwise becomes covered under a COBRA continuation provision, (ii) in the case of an individual becoming covered under such a provision, at the time the individual ceases to be covered under such provision, and (iii) on the request on behalf of an individual made not later than 24 months after the date of cessation of the coverage described in clause (i) or (ii), whichever is later.16

Basically, this certificate is to be given to the individual when some sort of coverage ends. It could be the entire plan under (i), or just a specific provision, as in (ii). If the insurance company or provider for whatever reason does not provide a certificate of creditable coverage to the individual at the end of the coverage, that individual can request the certificate. The provider is required to provide a certificate if the request is made by the individual within 24 months of the cessation of coverage.27

The time frame in which the insurance provider must provide the certificate is not specifically stated in HIPAA. The certification under clause (i) may be provided, to the extent practicable, at a time consistent with notices required under any applicable COBRA continuation provision.30 If COBRA applies, the time the certificate should be furnished should comply with the deadlines set out in COBRA, but only "to the extent practicable."31 There are no specific requirements for either subsections (ii) or (iii), either. Insurance providers are not on a set timeline, which could be a problem for someone who seeks to apply for coverage immediately after the cessation of previous coverage. While HIPAA does not require a turn-around time for previous insurance providers to produce a certificate of creditable coverage, the law does allow for the Secretary of Health and Human Services to establish some rules to protect individuals from being harmed by long turn-around times.32

HIPAA does establish some information required to be on the certificate of coverage. The certificate must be written verification of "(i) the period of creditable coverage of the individual under such plan and the coverage (if any) under such COBRA continuation provision, and (ii) the waiting period (if any) (and affiliation period, if applicable) imposed with respect to the individual for any coverage under such plan."33 The dates are generally what is important for creditable coverage, and the certificate is to address dates.

If the extent of the previous coverage is an issue for specific provisions or conditions in the new coverage, the certificate will not suffice. However, "to the extent that medical care under a group health plan consists of group health insurance coverage, the plan is deemed to have satisfied the certification requirement under this paragraph if the health insurance issuer offering the coverage provides such certification in accordance with this paragraph."33� It appears that a certificate of creditable coverage does not need to meet the date and waiting period requirements if the previous insurance issuer provides a certificate explaining that "medical care" was provided by the previous insurer.

Occasionally an individual does not sign up for, or include a dependent on, insurance coverage at the first opportunity because the individual and/or dependents already have other coverage. Therefore, HIPAA allows individuals and dependents who previously had other coverage and are eligible for the "new" plan but are losing that other coverage to enroll under the "new" group plan. HIPAA conditions enrollment on the following:

(A) The employee or dependent was covered under a group health plan or had health insurance coverage at the time coverage was previously offered to the employee or dependent. (B) The employee stated in writing at such time that coverage under a group health plan or health insurance coverage was the reason for declining enrollment, but only if the plan sponsor or issuer (if applicable) required such a statement at such time and provided the employee with notice of such requirement (and the consequences of such requirement) at such time. (C) The employee's or dependents' coverage described in subparagraph (A)—(i) was under a COBRA continuation provision and the coverage under such provision was exhausted; or (ii) was not under such a provision and either the coverage was terminated as a result of loss of eligibility for the coverage (including as a result of legal separation, divorce, death, termination of employment, or reduction in the number of hours of employment) or employer contributions toward such coverage were terminated. (D) Under the terms of the plan, the employee requests such enrollment not later than 30 days after the date of exhaustion of coverage described in subparagraph (C)(i) or termination of coverage or employer contribution described in subparagraph (C)(ii).13

HIPAA has additional requirements before mandating coverage for dependents.34 The dependents must be given a special enrollment period if "a group health plan makes coverage available with respect to a dependent of an individual"35 and "the individual is a participant under the plan."36 The dependent qualifies "through marriage, birth, or adoption or placement for adoption."37 A dependent special enrollment period under this subparagraph shall be a period of not less than 30 days and shall begin on the later of—(i) the date dependent coverage is made available, or (ii) the date of the marriage, birth, or adoption or placement for adoption (as the case may be).38

This provision gives an individual 30 days after a marriage, birth, or adoption to enroll his or her dependent in the group health care plan. After that 30-day window has passed, the dependents no longer get special treatment for enrollment.

If dependents are enrolled within the 30-day period, a traditional waiting period cannot be imposed on the dependent.39

The coverage of the dependent shall become effective—(i) in the case of marriage, not later than the first day of the first month beginning after the date the completed request for enrollment is received; (ii) in the case of a dependent's birth, as of such birth; or (iii) in the case of a dependent's adoption or placement for adoption, the date of such adoption or placement for adoption.40

This provision obviously shortens any waiting period that insurance providers generally require. In fact, birth and adoption trigger immediate coverage, which is certainly beneficial. The marriage trigger may require some wait time, but no more than a month. Once again, HIPAA protects newborns and newly adopted children.

Nondiscrimination based on health status

HIPAA also deals with prohibiting discrimination against individual participants and beneficiaries based on health status.41

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The Board Meeting dates for 2005 – 2006 are listed below:
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July 11 – 14, 2005 – Cheyenne
October 10 – 13, 2005 – Cheyenne
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The above stated factors could not be the basis for a health plan, based on very indicative factors. Therefore, this provision limits the insurers’ ability to exclude individuals from the health plan, based on very indicative factors. This provision of HIPAA provides some protection to individuals applying and participating in group health care plans. However, HIPAA does not require that insurers provide certain benefits, that insurers provide certain coverage, or coverage that insurers provide coverage at certain restricted prices. HIPAA requires that “similarly situated individuals” are treated similarly for receiving coverage or not. The above stated factors could not be incorporated in determining who is similarly situated. For example, it would seem that age, familial status and type of work performed would be acceptable factors to consider. Like in other anti-discrimination statutes, individuals must be classified by factors other than those factors which are prohibited. HIPAA goes further and also restricts longer waiting periods for individuals with protected health status-related factors. "Rules for eligibility to enroll under a plan include rules defining any applicable waiting period for such enrollment." Therefore, any rules or requirements by the statute for eligibility are to be similarly applied to waiting periods. This equal treatment or anti-discrimination language also applies to the health care premiums required by the group health plan. An individual cannot be required to pay higher premiums than other similarly situated individuals because of a protected health status-related factor. While this provision requires equal treatment of similarly situated individuals, there is no limit on the amount of contribution the insurer can require. The only limit is that all similarly situated individuals are required to pay comparable premiums. Those premiums could be quite exorbitant, but as long as they are applied across the board to individuals in similar situations, the premiums will not violate HIPAA. Specifically, HIPAA states, nothing in this provision shall be construed—(A) to restrict the amount than an employer may be charged for coverage under a group health plan; or (B) to prevent a group health plan, and a health insurance issuer offering group health coverage, from establishing premium discounts or rebates or modifying otherwise applicable copayments or deductibles in return for adherence to programs of health promotion and disease prevention. While HIPAA sets a federal bar for group health plans that states must meet or exceed, in this writer’s opinion HIPAA does not provide enough protection for individuals. Any individual rights under HIPAA are so convoluted and hard to access and understand that those rights are not likely to be exercised, and the remedies available are few and unsatisfying. The enforcement of HIPAA is the joint responsibility of the Secretary of Health and Human Services and the individual states. HIPAA allows states to regulate insurers, but it does not mandate that states monitor and regulate. If the Secretary finds that states are not enforcing HIPAA, the Secretary can step in and enforce the law. If liability is found, "The maximum . . . penalty imposed . . . is $100 for each day for each individual with respect to which such failure occurs." However, [in determining the amount of any penalty to be assessed . . . the Secretary shall take into account the previous record of compliance of the entity being assessed . . . and the gravity of the violation. The Secretary is limited in the imposition of penalties. "No civil money penalty shall be imposed under this paragraph on any failure during any period for which it is established to the satisfaction of the Secretary that none of the entities against whom the penalty would be imposed knew, or exercising reasonable diligence would have known, that such failure existed." Additionally, "No civil money penalty shall be imposed . . . on any failure if such failure was due to reasonable cause and not to willful neglect, and such failure is corrected during the 30-day period beginning on the first day any of the entities against whom the penalty would be imposed knew, or exercising reasonable diligence would have known, that such failure existed." The penalties for HIPAA violations seem weak, and again seem to let the individual down. While HIPAA is a good attempt to help protect individuals in the health care insurance arena, the law itself is inaccessible to individuals and painful and time-consuming for professionals. The ideas behind HIPAA are valuable and admirable; however, the law must be modified to achieve the goals and purpose HIPAA was designed to accomplish.
Get Educated On Your Medications!

by Roxanne Homar, R.Ph., Wyoming State Pharmacist

Overview:
Recently there has been some controversy over the Food and Drug Administration's (FDA) approval process for new drugs and the tracking of safety information. This was prompted by the recent removal of Vioxx (rofecoxib), a medication used to treat pain and inflammation. Concerns about the increased risk of heart attack and stroke caused the drug manufacturer to remove Vioxx from the market. This has led to questions regarding similar products as well as several other medications, and increased scrutiny of the FDA's process for drug approvals and safety tracking in general.

The Food and Drug Administration (FDA) has processes in place to review drug entities for both effectiveness and safety. A brief description of the new drug approval (NDA) process and post approval safety monitoring follows:

New Drug Approval (NDA) Process:
All new drugs marketed in the United States are approved through the FDA. It is an extensive process and the FDA estimates it takes approximately 8.5 years to study and test a new drug before it is approved for general use and marketing.

The initial stage of the new drug approval (NDA) process is called "pre-clinical" research and involves animal testing. The purpose is to develop adequate data to support a decision to move forward with human trials.

If a drug entity makes it past the pre-clinical stage it will enter the next step, the "clinical studies" phase. During the clinical studies phase the NDA must provide sufficient information for the FDA reviewers to believe that the drug is safe and effective for proposed use. The FDA reviewers want to know that the benefits of the medication outweigh the risks and that it is reasonably safe to proceed with human trials.

According to the FDA website the results of this testing comprise the single most important factor in approval or disapproval of a new drug.

Post Approval Safety Monitoring:
The FDA maintains post-marketing surveillance and risk assessment programs to identify adverse events that did not appear during the clinical trial period. The clinical trial period involves smaller numbers of individuals than those who would be exposed when the medication is available to the general public. In addition, the people chosen to participate in clinical trials must meet specific criteria and those with other underlying conditions are normally excluded. Therefore, other side effects and/or adverse events may appear when a medication is available to more people who may have other underlying conditions.

The FDA uses the Adverse Events Reporting System (AERS) and the Medwatch program for tracking and communicating safety problems and adverse events to the medical community.

The most recent controversy involving the removal of Vioxx, brought into question the FDA's processes for approving and monitoring the safety of medications. Dr. David Graham, a 20 year veteran of the FDA, testified to the Congressional Senate Finance Committee that "the FDA as currently configured is incapable of protecting America against another Vioxx". Graham contends the FDA has an inherent conflict of interest that triggers "denial, rejection and heat" when safety questions emerge about products it has approved. Dr. Graham's testimony ignited a firestorm of speculation about the FDA and its medication safety monitoring.

New information has surfaced regarding a survey conducted by the Department of Health & Human Services Office of Inspector General. The survey was conducted two years ago but was recently released after two public interest groups filed a freedom of information act to obtain it. The survey's results echo the concerns of Dr. David Graham.

The survey indicates that more than one third of FDA scientists have some doubts about the process for approving new drugs.

In addition, two-thirds of the FDA scientists surveyed were not highly confident that the FDA "adequately monitors safety of prescription drugs" once on the market. One in five said they'd been "pressed to approve" a drug "despite reservations about its safety" or other concerns, according to a CBS report.

According to Dr. Graham the five worst worrisome drugs that demand action include:

- Meridia - A medication moderately effective for weight-loss. Do the benefits outweigh the risks of higher blood pressure and stroke among people taking it? "I don't think Meridia passes that test," Graham said.
- Crestor - An anti-cholesterol medication. Dr. Graham believes the government should evaluate the occurrence of renal failure and other serious side effects among people taking Crestor.
- Accutane - A medication used to treat severe acne. It is a very effective medication, but can cause birth defects. The problem is that pregnancies continue to occur despite strict registration programs and mandatory pregnancy blood tests. Graham said the drug represents a 20-year "regulatory failure" by the FDA and sales should be restricted immediately.
- Bextra - An anti-inflammatory medication used mainly for arthritis or other joint pain. Graham said the drug posed the same heart attack and stroke risk as Vioxx. He recommended designing studies to look at the drug's cardiovascular risks.
- Serevent - An asthma treatment which can lead to increased risks when used improperly. Dr. Graham said that Serevent was shown, with 90 percent certainty in a long-term trial in England, to cause deaths due to asthma. "We've got case reports of people dying, clutching their Serevent inhaler," Graham said. "But Serevent is still on the market."

The comments from Dr. Graham raise some issues of concern for consumers. All medications carry some level of risk associated with their use. It is up to the patient and his health care team (physicians, pharmacists, etc.) to evaluate this risk and decide what is best for the patient. Ideally, the patient should play an active role in treatment decisions, including medication usage. At a minimum an educated consumer should know the following about his/her medication regimen:

- The name and strength of all medications;
- How to take the medication and for what length of time;
- What the medication is prescribed for;
- AND
- Potential side effects of the medication and what to do if a side effect occurs.

Wyoming has developed an innovative program called the WY PharmAssist program to help educate consumers about their medications. Many people take five or more medications, increasing their risk of side effects, and have difficulty paying for their prescriptions. Circuit pharmacists are in place throughout the state to conduct comprehensive assessments for qualified individuals. The program is available for a nominal fee of $5.00 and is not restricted by age, insurance status or income. Consumers may access the program by calling 877-246-4114.

In addition, Wyoming's AARP program's website has a terrific resource for medication information called the "Rx Resource Center". The information can be found at http://www.aarp.org/states/wy/. An educated consumer or caregiver provides one of the best defenses against medication problems. Get educated!
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