TYLENOL® Continues Its Battle for Success

Introduction

When it comes to a corporate crisis, Johnson & Johnson (J&J) and its subsidiary Tylenol demonstrate what a company should do in responding to stakeholder concerns. With its handling of the Tylenol tampering in the early ‘80s, J&J secured its status in the history books for effective crisis management. Since then, J&J has won numerous accolades for consumer safety and for its social responsibility initiatives. In 2010, Barron’s magazine named Johnson & Johnson #2 among the World’s Most Respected Companies. Targeted at top investors, the survey ranked winners according to their strength of management, business strategy, ethical business practices, competitive edge, shareholder orientation, and consistent revenue/profit growth. J&J also ranked eleventh place in DiversityInc magazine’s “2012 DiversityInc Top 50 Companies for Diversity” list.

As with most major companies, however, J&J has received its share of criticism in regards to Tylenol. Recent waves of Tylenol recalls and other over-the-counter medications, resulting from bacterial contamination, nauseating smells, and metallic flakes, have cost the company financially. It has also elicited criticism from the Food & Drug Administration (FDA) on Johnson & Johnson’s slow response time. The problems escalated so much that the House Committee on Oversight, Government Reform, and the Justice Department began investigating the company. Health officials are also concerned about the chemical acetaminophen found in Tylenol, which can cause injury or death if too much is consumed. This case will therefore analyze some of these crucial issues as well as how Johnson & Johnson maintains its industry-leading reputation through its day-to-day operations and commitment to its Credo of Values.

Company Background

In order to discuss the story of Tylenol, two companies must first be examined: McNeil Consumer Healthcare, a subsidiary of Johnson & Johnson and the producer of TYLENOL, and Johnson & Johnson itself. The first to be founded was McNeil Laboratories, founded by Robert McNeil in 1879 when he acquired a drugstore. Johnson & Johnson was founded seven years later in 1886. Its founders, Robert Wood Johnson and his two brothers James Wood and Edward Mead Johnson, created the partnership to develop sterile dressings for hospitals.

In 1955, the Tylenol brand was created with the development of TYLENOL Elixir for children. The name TYLENOL was created by the McNeil sales team using letters from the product’s main ingredient, acetaminophen. Tylenol was marketed as an effective painkiller but without the side effects of aspirin. It was marketed specifically to physicians and pharmacists as a safer alternative...
to aspirin. In 1959, McNeil Laboratories was purchased by Johnson & Johnson. Under Johnson &
Johnson’s leadership, McNeil Laboratories sold the first non-prescription bottle of TYLENOL in
1960. It was not long before Tylenol became one of Johnson & Johnson’s most popular over-the-
counter drugs. Today with the help of Tylenol, along with several other popular brands, Johnson &
Johnson has become the world’s largest maker of healthcare products.

Despite its immense success, however, even Johnson & Johnson could not avoid the deep economic
losses stemming from the 2009-2010 global recession. In 2009, J&J generated $61.9 billion in
revenue, a decline of 3 percent from 2008 and the first revenue decline in J&J’s history since the
Great Depression. In November of the same year, J&J announced its plans to reduce its workforce by
8,000 employees to approximately 110,000 employees worldwide. J&J also announced an overhaul
in its bonus program. Under the overhaul, thousands of employees received lower bonuses in an
attempt to create a more uniform payment program across the company. According to J&J officials,
employee bonuses will also be tied more to performance.

ABOUT TYLENOL PRODUCTS

Tylenol sells a variety of self-healthcare products to tackle some of the most common issues of a
cold or flu, including relieving pain, reducing fevers, and relieving the symptoms of allergies and
coughs. Tylenol’s goal is to become the leader in over-the-counter (OTC) products worldwide. The
Tylenol product line consists of hundreds of products that fit into categories such as Head & Body
(back pain, headaches, muscle aches, and cramps); Arthritis; Sinus and Allergy; Cold and Flu
(coughs, sore throats, congestion, and multi-symptoms); Pain and Sleeplessness; and Children
(fever, aches, cold, cough, flu, and non-medicated). In addition to tablets, J&J has come out with
Tylenol chewables, drops, and meltaways.

JOHNSON & JOHNSON CREDO

While many organizations have developed ethics initiatives only recently, J&J was a pioneer in
developing a sound code of ethics. Robert Wood Johnson, who acted as chairman of J&J from 1932
to 1963, developed the Johnson & Johnson Credo of values in 1943. Before stakeholder orientation
became a major business concept, J&J recognized that a set of company morals would not only
maintain an ethical corporate culture but also help to ensure business success. The J&J Credo
emphasizes putting the consumer first—a concept that would make all the difference during the
mass Tylenol recalls in the early ‘80s. The Credo identifies four primary stakeholders and addresses
the company’s duty to each group. These groups include consumers, employees, communities, and
stockholders.

CONSUMERS

The J&J Credo begins by addressing the groups it sees as its most important stakeholder:

“We believe our first responsibility is to the doctors, nurses and patients, to mothers and fathers
and all others who use our products and services. In meeting their needs everything we do must be
of high quality...”
The Credo seeks to serve consumers by (1) keeping costs low so reasonable prices can be maintained and (2) promptly and accurately servicing customer orders. Access to medicines and medical care is also an issue that J&J is addressing with its Access2wellness program. This program was created to help those without medical insurance to get the care that they need. J&J claims to have provided over 1.7 million units of medicine to over 300,000 patients within a two-year time span.

**EMPLOYEES**

The second section of the Credo addresses J&J employees:

“We are responsible to our employees, the men and women who work with us throughout the world. Everyone must be considered as an individual. We must respect their dignity and recognize their merit...”

To address the needs of its employees, the Credo maintains that J&J will provide (1) a sense of job security, (2) fair and adequate compensation, and (3) clean and safe working conditions. Job security became more problematic in light of the recent global recession, but J&J believes its bonus overhaul will make the pay system more equitable by tying in bonuses to performance. To create a more open workplace environment, employee suggestions and complaints are encouraged. Internally, J&J operates numerous programs that seek to help the physical and mental well-being of its employees. For example, J&J offers the Mental Well-Being employee assistance program, which helps employees in matters pertaining to mental health. Under this program, employees have access to resiliency training; employee assistance programs, which include counseling and intervention; and work-life programs including flexible schedules, compressed work weeks, telecommuting, and flextime.

**COMMUNITIES**

After addressing consumers and employees as individuals, J&J’s Credo goes on to address itself within the community:

“We are responsible to the communities in which we live and work and to the world community as well. We must be good citizens...”

J&J defines good citizens as those who “support good works/charities and who accept their fair share of taxes, with the belief that these will encourage civic improvement and lead to better health and education within each community.” Included within this stakeholder group are the following environmental and disaster relief initiatives:

*Environmental Goals*

Reviewed and updated every five years since 1990, J&J's environmental goals seek to reduce the company's environmental footprint. J&J works with various stakeholders, including government officials, environmental groups, and academic leaders, to achieve its environmental goals. These goals are organized into ten categories, such as energy use, product stewardship, and external
manufacturing. Thus far, the program has seen positive results for the many of its goals. For example, when the program first began in 1990, J&J set a goal of reducing its carbon dioxide emissions by 7 percent within the next twenty years. By 2007, the company had already surpassed its goal and reduced their emissions by 12.7 percent. To mark its 100th anniversary, J&J launched Healthy Future 2015 goals for the next five years. Among its many goals, J&J plans to increase fleet emissions efficiency by 20%, reduce water usage by 10%, and reduce waste disposal by 10%.

Disaster Relief

As part of its Credo, Johnson & Johnson also works to provide disaster relief, both domestically and internationally. Within one month of Hurricane Katrina, J&J had contributed $5 million in cash and $250,000 in disaster relief products. After the 2010 earthquakes in Haiti and Chile, J&J leveraged its international connections and partnered with several nonprofit companies to quickly transport resources to victims. The company has pledged to support long-term efforts to provide health care services for women and children within these countries. The company also donated money to Japan after the 2011 earthquake and tsunami. Additionally, Johnson & Johnson maintains its U.S. Matching Gifts Program, in which employee's personal contributions are double matched by the company.

STOCKHOLDERS

The last section of the J&J Credo addresses stockholders:

“Our final responsibility is to our stockholders. Business must make a sound profit...We must experiment with new ideas...”

Johnson & Johnson emphasizes the importance of innovation in generating a fair return for stockholders. To develop new ideas, J&J is committed to (1) conducting research and developing new programs, (2) purchasing new equipment and facilities to aid in launching new products, and (3) creating reserves for protection in adverse climates. A small, but significant, section of the Credo states that mistakes must be paid for. This was widely demonstrated during the 1982 Tylenol recalls that will be discussed later in the case.

Despite Johnson & Johnson’s recent problems, the company’s long-term and consistent returns have continued to maintain the positive relationship it has with stockholders. Combined with its Credo of Values and its actions during the 1982 product recalls, J&J has earned a stellar reputation that is demonstrated through stockholder returns.

CRISES AND REPUTATION MANAGEMENT

While it isn’t unusual for pharmaceutical companies to experience crisis situations, it is highly unusual and frightening for firms to experience the type of crisis that Johnson & Johnson faced during the 1980s. Despite the fear that gripped the nation, Johnson & Johnson tried to maintain a sense of calm and concern for consumer well-being that reassured its customers. While Johnson & Johnson certainly lost money in the short-run, its quick actions served to create a favorable reputation as a firm that pursued the right course even when it cost it financially. Indeed, Johnson &
Johnson’s effective crisis management likely increased its market share in the long-term as customers could feel confident that the company had their best interests at heart.

THE TYLENOL POISONINGS

Johnson & Johnson’s Credo took on prime importance during the crisis of the 1982 Tylenol recalls. The crisis started on September 29, 1982, in the Chicago area when 12-year-old Mary Kellerman was pronounced dead at a hospital after her parents found her on the bathroom floor. Adam Janus was later found collapsed on his living room floor in another part of town and died in the hospital shortly thereafter. Afterward, Adam’s brother Stanley and sister-in-law Theresa gathered at his house. Suffering from a headache, they found a bottle of Extra-Strength Tylenol on the kitchen counter and took some capsules. They collapsed soon afterward and died later in the hospital. Three more deaths were reported the next day. All of these deaths occurred after the victims had consumed Tylenol. The news of the incident spread quickly, causing a nationwide panic.

Investigations revealed that the sudden deaths were a result of cyanide poison discovered in the Tylenol capsules. The capsules had been opened and filled with 65 mg of cyanide—up to 10,000 times that which was needed to kill a person. Since the tampered bottles came from different factories and the seven deaths had all occurred in the Chicago area, the possibility of sabotage during production was eliminated. Instead, the culprit was believed to have entered various supermarkets and drug stores over a period of weeks, pilfered packages of Tylenol from the shelves, poisoned their contents with cyanide at another location, and then replaced the bottles. In addition to the five bottles which led to the victims’ deaths, three other tampered bottles were discovered. These poisoned bottles were discovered at different stores in the Chicago area.

JOHNSON & JOHNSON’S REACTION

The crisis was every company’s worst nightmare. Some predicted that Tylenol would never sell again. What followed, however, is one of the most often used examples of effective crisis management. J&J took its consumer responsibility outlined in its Credo seriously. It immediately recalled 31 million bottles of Extra-Strength Tylenol worth over $100 million from all retail stores across the United States. In addition, the company offered to exchange all Tylenol capsules already purchased by the public with solid tablets. Johnson & Johnson also distributed warnings to hospitals and distributors that Tylenol production and advertising would be halted until further notice. According to an analyst, Johnson & Johnson suffered a loss of $1.24 billion due to the depreciation of the company’s brand value. Immediately after the crisis, Tylenol’s share fell from 37% of the U.S. over-the-counter pain reliever market to just 7% by late 1982. Yet rather than drop the brand as a lost cause, J&J President James Burke poured millions into reviving the struggling brand. Within six months, its share was back up to 30 percent.

Tylenol managed the crisis in two steps: public relations (reacting to the crisis) and its comeback stage. Even though the deaths were not a fault of the company, it took responsibility and, unlike many companies in similar crises, put consumer safety over profit. In addition to its country-wide recall, J&J partnered with the FBI, the Chicago Police, and the FDA to track down the culprit, even
offering a $100,000 reward for anyone who could volunteer information about the killer. Perhaps most importantly, J&J did not deny the link between the deaths and its products, a mistake that many companies make immediately following a product crisis.

In Tylenol’s comeback stage, Johnson & Johnson needed to find a way to restore consumers’ trust in the brand. The company took several actions to demonstrate Tylenol’s safety. Tylenol products were introduced with new triple-seal tamper resistant packaging. It also offered a $2.50 off coupon on the purchase of its Tylenol products, which could be found in newspapers or by calling a toll-free number. A new pricing program was introduced that provided discounts of up to 25 percent.

Additionally, more than 2,250 salespeople made presentations to members of the medical community. Johnson & Johnson’s actions effectively restored customer goodwill toward the company. In fact, in a survey taken shortly after the crisis, 90 percent of respondents stated that J&J was not to blame for the situation.

Unfortunately, product tampering did not stop with the 1982 Tylenol poisonings. In 1986, the company faced another crisis after a woman died after taking Extra-Strength Tylenol capsules. Once more, cyanide was to blame. This time Tylenol was not alone. The incidence of product tampering appeared to rise after the 1982 Tylenol murders, including incidents of poisoned chocolate milk, orange juice, Excedrin, and Sudafed. J&J responded with another recall and a promise to only release Tylenol in caplet or tablet form.

CONTROVERSY SURROUNDING ACETAMINOPHEN

In 1989, Johnson & Johnson faced another problem when deaths were reported due to overdoses on Tylenol. It was later revealed that hundreds of deaths and severe liver damages could be attributed to acetaminophen, the main ingredient in Tylenol. Many analysts feel that Johnson & Johnson’s labeling should have been clearer, with explicit warnings about the dangers of overdose. At least 100 suits were filed against Johnson & Johnson over acetaminophen poisonings between 1990 and 1997. In 2006, J&J was ordered to pay damages in the wrongful death suit of a young boy. Although the FDA did not require strong warnings regarding the dangers of acetaminophen overdose until later that year, the judge determined that J&J knew about the risks and did not actively work to mitigate them with clear labeling. Perhaps one of the reasons for the verdict was the fact that advisory panels as early as 1977 were warning about the dangers of acetaminophen. When the lawsuit was still pending, J&J began running advertisements warning against Tylenol overdose and stressing the importance of reading the labels of OTC drugs.

Despite the extensive campaign, one must wonder why Johnson & Johnson did not seem as dedicated toward consumer safety as it did with the 1982 Tylenol recalls. Even though Tylenol was found guilty, it was not violating FDA warning guidelines. This clearly brings up the question of how much responsibility companies must take when marketing products, particularly ones that have such a strong possibility to be misused such as drugs. Another ethical consideration is whether the fault should rest on companies alone. Should the FDA also receive part of the blame for Tylenol overdoses since its laws did not require more explicit labeling? The right to be informed and the right to safety are two rights that consumers have when purchasing products, and it is the
business’s responsibility to observe these rights. However, there is a blurry line between where a
business’s responsibility for consumer safety ends and the consumer's responsibility begins. Should
consumers themselves be held responsible for choosing to take more than what is on the label?
How much do they need to have explained to them about the dangers of overdosing to know that
taking above the recommended amount is dangerous? These questions make ethical dilemmas like
this one harder for J&J to navigate.

**FDA RESPONSE TO ACETAMINOPHEN**

In 2009, the FDA released a formal report which found that a lack of consumer awareness may lead
consumers to take acetaminophen without realizing that certain amounts can cause liver damage or
death. Previous reports have revealed that many people take more than the recommended dose of
acetaminophen-based, over-the-counter painkillers with the false notion that higher dosages will
be more effective against pain without severe side effects. A lack of knowledge of these dangers, as
well as the belief that drugs like Tylenol are relatively safe, can make it easy to exceed the
recommended dose. Another danger is that consumers often mix other medications with
acetaminophen drugs, which can cause dangerously high levels of acetaminophen in their system.

Such news does not bode well for Tylenol. An FDA panel began recommending lowering the daily
dose of nonprescription acetaminophen, which will in turn affect drugs like Tylenol. It also
suggests banning pain relievers that combine acetaminophen with other painkilling
ingredients from the market. Johnson & Johnson, along with other drug manufacturers such as
Procter & Gamble, tried to persuade U.S. regulators to allow the pain reliever acetaminophen to stay
in the marketplace. The panel did end up rejecting a proposal to pull drugs such as Nyquil from
shelves. Panelists also recommended that Tylenol’s dosage amounts be decreased and that the
extra strength version be given by prescription only.

After the panel came out, J&J took quick actions to maintain Tylenol’s reputation as a safe
medication. Three days after the panel’s announcement, J&J ran full-page ads in *USA Today, The
New Times*, and *The Wall Street Journal* to assure the public that Tylenol is still “the safest brand of
pain reliever you can choose” as long as consumers take the proper amount. The ads also directly
addressed the panel’s results and, through careful wording, denied culpability in any wrongdoing.
J&J maintains that it is up to consumers to monitor the intake of the medications they take. J&J's
reaction was quick to counteract the negative effects of the FDA report by addressing consumer
corns. However, its denial of any negligence on its part reiterates the ethical question of who
holds primary responsibility for how a product is used: the business or consumers themselves.

In 2011 the FDA decided to limit prescription acetaminophen products to 325 milligrams per unit,
but this did not impact Tylenol because it is an over-the-counter drug. However, due to pressure
and safety concerns, J&J announced later that year that it was lowering the maximum daily dosage
of Extra Strength Tylenol from eight pills to six pills to cut back on the chance of overdosing.
Johnson & Johnson also released less concentrated acetaminophen products for infants with new
instructions to help parents avoid confusion on how much to give their infants.
Despite being praised for its quick actions during the Tylenol poisoning crisis of 1982, Johnson & Johnson has faced criticism for not reacting quickly enough to another crisis. In 2009, Johnson & Johnson recalled many of its children’s Tylenol common cold and allergy medications. Nearly two dozen varieties of its children’s Tylenol were voluntarily pulled off the shelves because of a bacterial contamination in its Fort Washington, Pennsylvania facility. Johnson & Johnson took precautionary steps to voluntarily recall some of the Tylenol product line after an internal lab test found bacteria in the raw material that went unused in the making of its product. Although the bacteria *Burkholderia cepacia* was found in a portion of the raw material that went unused, none of the bacteria was found in finished products. As a precaution, however, all products were recalled that had used any of the raw material manufactured at the same time as the raw material that tested positive for the bacteria. The effects of the bacteria can be dangerous for those with weakened immune systems or chronic lung diseases, with symptoms ranging from none at all to serious respiratory infections.

Unfortunately, the bacterial contamination didn’t stop there. In addition to the previous recalls, Johnson & Johnson also recalled millions of bottles of Tylenol, Benadryl, Zyrtec, and Motrin on April 30, 2010. The recall was issued because of possible safety violations in the medications, including too much of an active drug, metal specks, or ingredients that had failed testing requirements. Due to the massive amounts of recalls and seeming lack of oversight on the part of J&J’s subsidiary McNeil Healthcare, the issue was investigated by a Congressional committee. Documents were also recovered which revealed that in 2009, McNeil Consumer Healthcare hired private companies to buy defective Motrin products from stores, without reporting it to the FDA. A McNeil spokeswoman said that since the products did not prove to be a safety risk (they were defective in other ways), it was not a recall and thus did not have to be reported to the FDA. With accusations of rampant misconduct by governmental agencies, McNeil Laboratories and its executives (VP of Quality and VP of Operations) were charged with failure to comply with federally mandated manufacturing practices. In March of 2011, the FDA gave McNeil two options: to agree to a “consent decree” or to succumb to a lawsuit. McNeil chose the consent decree, which requires adherence to a strict timetable for bringing its facilities into compliance. It must also retain an independent expert to inspect the plants to determine whether the violations have been corrected, and to ensure that adequate manufacturing processes are in place. The Justice Department is conducting its own investigation, and the FDA is also monitoring two other manufacturing plants.

Additionally, Tylenol Arthritis Pain was recalled due to complaints of moldy odors, nausea, vomiting, and diarrhea. The scent was found to be a result of 2,4,6-tribromoanisole, a component of pesticides and flame retardants which were used to treat wooden storage pallets at McNeil’s plant in Las Piedras, Puerto Rico. These are only a few examples of 50 products that were recalled in a matter of 50 weeks. In addition, it was found that J&J had known of the odors for more than a year, but only recalled the product after an FDA investigation. The investigation also uncovered unsanitary conditions at the Fort Washington, Pennsylvania, facility. Thick dust and grime was found covering certain equipment. There was also a hole in the ceiling and duct tape-covered pipes.
Johnson & Johnson traced many of the problems to the Tylenol plant in Fort Washington, Pennsylvania. The company responded by shutting down the plant and submitting a plan to regulators addressing how it will fix the problems. Some of the proposed solutions included installing new equipment and revamping its operations to reduce the opportunity for product contamination. J&J stressed its commitment to upgrading the plant, which will remain closed until then. Such changes have caused an elimination of 300 jobs at the plant, and analysts suspect that the plant’s closure and its renovation may cost J&J upwards of $500 million in lost revenue. To prevent future recalls—and the resulting negative publicity—J&J has also made changes in its management, hired an outside expert to help in redoing the plant, and improved its employee training and operational processes.

ORGANIZATIONAL ISSUES

As the recalls demonstrate, despite J&J’s early reputation of effective crisis handling the last ten years have presented the firm with a myriad of costly issues. Some analysts say the causes of these issues lie in three possible areas: heavy profit focus, decentralization, and lapses in leadership oversight. Critics propose that each division of J&J has its own separate culture, indicating that there is no sense of coherence in leadership or operations. Analysts also propose that J&J is cutting too many costs to increase profits, thus sacrificing customer safety and increasing risk in this area. Then CEO of Johnson & Johnson William Weldon disagreed. Weldon claimed that the company has not placed profits over the customer, and he also discounted the idea that decentralization is the problem. He says that if decentralization was the issue, all of the divisions would be experiencing problems and not just McNeil.

Other accusations levied against J&J include paying kickbacks, using financial incentives to encourage unauthorized use of drugs and devices, and taking actions to avoid a recall by sending employees into stores to buy up tainted products. J&J has also created a strain on its relationship with FDA regulators throughout their investigations by not being immediately compliant. J&J denies claims regarding a lack of oversight. However, its annual report for 2010 details government criminal and civil investigations as well as thousands of private lawsuits covering a wide range of drugs, devices, and business practices. While lawsuits are not uncommon for a company dealing in sensitive products like pharmaceutical drugs, a large number of lawsuits and complaints could seriously undermine the credibility of Johnson & Johnson.

CONCLUSION

As the nation’s best-selling pain-relieving brand, Tylenol is one of hundreds of brands in the J&J portfolio. Each year, McNeil Laboratories seeks to strengthen the Tylenol brand by adding new products and maintaining the high quality of current products. Using the Credo of Values as a decision-making guide, McNeil Laboratories and J&J strive to maintain and further develop key stakeholder relationships. After its successful handling of the 1982 Chicago Tylenol murder crises, Johnson & Johnson was largely acknowledged as an industry leader in business and ethics.
Until recently, Johnson & Johnson's reputation management has been highly effective. However, the company's massive product recalls of Tylenol and other medications brought into question the high quality of its products. It would appear that J&J has slipped some in its careful handling of product development and consumer safety. This demonstrates that ethics is an ongoing process necessary for all companies, even those who have gained a reputation for ethically-sound management. In light of the recalls, Johnson & Johnson must work hard to defend the integrity of its products and operations. No longer can it rely upon its reputation as an industry leader as a means for continued success. The company must commit its resources to rebuilding the Tylenol brand as it tries to regain the trust of consumers, government regulatory agencies, and other stakeholders.

Even though Tylenol has developed an ethical culture with a Credo and identified key stakeholders, it is still important to translate these abstractions into daily actions. While the culture of an organization provides the values and assumptions about why things happen the way they do in the organization, the climate of the organization refers to specific behaviors and the coordination of efforts to determine the 'what' that happens on an everyday basis. It is important that Tylenol continue to maintain high standards and communicate all the signals that go with an ethical culture. However, based on the recent shortcomings and safety issues, it is important also to focus on the climate that designates specific behaviors and inter-functional coordination between marketing, production, and other areas to make sure that quality products and ethical behavior drive Tylenol's reputation.

QUESTIONS

1. Johnson & Johnson was a leader in recognizing key stakeholders and in developing a credo for appropriate conduct. Why do you think that there have been a number of failures in product safety even though the company has tried to be responsible?

2. Even though Johnson & Johnson has received many awards for ethically and socially responsible conduct, why do you think that they are being investigated for responding too slowly to the most recent product recall crisis?

3. Johnson & Johnson's over-the-counter drugs such as Tylenol products have many risks associated with them in product quality and safety. How would you suggest Johnson & Johnson gain more control and decrease the possibility of misuse, safety defects, and other harmful consequences?

Sources: