

THE IMPACT OF LAWS AND REGULATIONS ON THE INNOVATIVE PROCESS

Presentation by

Norman J. Latker
Patent Counsel

United States Department of Health, Education and Welfare

Before The

Second Annual Meeting of SUPA

February 9, 1977

Chicago, Illinois

(Disclaimer of Representing DHEW Policy)

In James K. Polk's inaugural speech of 1845 he stated:

"Our population has increased from 3 to 20 million, new communities and states are seeking protection under its aegis, and multitudes from the old world are flocking to our shores to participate in its blessings . . . Genius is free to announce its inventions and discoveries, and the hand is free to accomplish whatever the head conceives, not incompatible with the rights of a fellow being."

I would conjecture that President Polk was, in his own words, anticipating what others later would call the "American Dream." This was the spark in America that spawned the expression so often uttered by so many immigrants - "Only in America." The expression was full of meaning. It meant hope, and it meant promise. It meant a delightful sense of surprise. In America anything could happen. The rules said there were no rules. The dreams of dreamers were often fulfilled.

Now, part of Polk's American dream is forever foreclosed. Free or cheap land has all but disappeared. Although the rest of the dream is still there, it is under heavy attack from those who believe the discoveries of genius and dreamers are incompatible with their rights. In fact, many of us, if not the majority, have been overwhelmed by the sense of loss

of much that has made our country great. Ostensibly, the purveyors of fear have outweighed our sense of the American dream, knowing full well that every judgment in science stands on the edge of error.

The present is possibly a watershed in the history of our nation. New ideas have always had trouble gaining acceptance in the scientific community, but that fact did not foreclose the development of science in the past. Now, however, science has become so sophisticated that substantially all done in the fields of science require large financial resources. This, of course, means that the granting or sponsoring agencies which control such resources are able to exercise more control over the activities of scientists than in the past. I am of the opinion that this need for large sums of money to bring ideas to the point of completion, coupled with the fear that science is encumbering the rights of others, is clearly having a chilling effect on the innovative process.

Dr. Harry Meyer, Jr., the Director of the Bureau of Biologics, recently indicated that the pharmaceutical industry was deserting the vaccine business not only because of financial risk, but because of strict Federal regulations deemed necessary. He stated that "if Jenner and Pasteur and Walter Reed had to set up their clinical trials today to comply with

FDA regulations, I suspect that Jenner might stick to general practice, Pasteur to soil microbiology and Walter Reed to selling mosquito repellent." Many similar comments are appearing in other areas of regulation and science.

In addition to the FDA laws, many new laws and regulations have been recently promulgated without a clear understanding of or basis for how they would impact on the innovative process. Examples are portions of the Freedom of Information Act, the "Sunshine Laws," the Medical Device Act, the Toxic Substance Act, the Nuclear Regulatory Agency, enhanced anti-trust laws, and some still in the stage of introduction or passage, such as laws governing recombinant DNA research, the Consumer Protection Agency, and a proposed Patent Act which contains onerous filing obligations on the part of the inventor. This is by no means an all-inclusive list but is also not intended to imply that all regulation is counter-productive to the extent they are ^{useful} ^{to} ^{the} ^{public} useful in preserving the legitimate rights of the public.

The recent feeling that "regulation is the antithesis of innovation" finds support in Hayek's argument in his 1944 book "The Road to Serfdom" that all socialism is nationalistic and that socialists cannot achieve their goal - the total regulation of society through regulation of the economy - unless they insulate the nation from unregulated forces -

free trade, free movement of labor and capital, and eventually the free movement of disruptive ideas and dreams that complicate the construction of a "planned society."

No system can work for long, even if it seems to be rationally perfect, which ignores the forces of human nature and its dreams.

Adam Smith saw this very clearly 200 years ago. He put it this way:

"The man of system ... seems to imagine that he can arrange the different members of a great society with as much ease as the hand arranges the different pieces upon a chessboard. He does not consider that the pieces upon the chessboard have no other principle of motion besides that which the hand impresses upon them; but that, in the great chessboard of human society, every single piece has a principle of motion of its own, altogether different from that which the legislature might choose to impress upon it. If those two principles coincide and act in the same direction, the game of human society will go on easily and harmoniously, and is very likely to be happy and successful. If they are opposite or different, the game will go miserably, and human society must be at all times in the highest degree of disorder."

Now early in this century, the concept of human nature as essentially rational, responsible and autonomous was dominant. That notion was a fundamental tenet of classical liberalism, and thus supported the political view that Government's role should be severely limited. The administration and severity of the laws and regulations, which I've noted, in my mind rejects the concept of rational men and, therefore, negatively impacts on the innovative process.

The force behind most ideas is the need to provide the necessities and satisfactions of life. Thus, in my view, the motivation for creators to see their ideas through to utilization are:

1. The desire to serve others without regard to reward.
2. The search for truth.
3. The respect of his peers, or
4. Financial remuneration.

Probably all of these are involved in various degrees unknown even to the creator.

No matter what the motivation, if we are to remain a free and successful society, we must assure that the proper environment exists for dreams and ideas. This is in our best interest, since creation of useful results must occur prior to distribution to the public of its benefits. It

seems axiomatic that the needs of the creator come before the needs of his beneficiaries."

The mind of a single scientist can overnight make obsolete a 6 billion dollar defense system or a 100 billion dollar stockpile of nuclear weapons. The mind of a single citizen holds within it the potential of showing us how to cure cancer or feed the starving millions in the world. The human mind is the screen where man can project precisely how he can make his dreams come true and make his destiny secure. Of course, there will always be people who cannot be responsible. It happens in all walks of life and at all intellectual levels, but it is patently a denial of freedom to allow laws and regulations to develop in a way which withholds from an individual the opportunity of becoming a contributor to the community. History provides sufficient evidence that the irresponsible can flourish under any society. It is only through new dreams and ideas of the human intellect that the prospect of unification of the human race through their utilization that one can envision the process whereby man's destructive tendencies can ever be brought under control.

Dave Eden spoke earlier on your progress toward assuring that our creators will not be denied a role in advocacy of inventions they have made with the contribution of Federal support. Your job is not finished, nor may it ever be finished as long as the innovative process is endangered by

those who neither cherish nor understand it. But as long as knowledge is better than ignorance, no university can turn from the defense of the innovative process. This is especially important to note in light of the realization that innovators by their very nature do not band together due to the disparity of their ideas and dreams and their desires to pursue these ideas free from outside distraction. In other words, science's pluralistic nature/ ^{in this country,} which I believe to be its greatest strength, becomes its weakness when evaluating laws and regulations impacting on the innovative process.

In closing, a comment made by Oliver Wendell Holmes seems most appropriate to the age that we now live:

"Life is action and passion . . . It is required of a man that he should share the action and passion of his time at peril of being judged not to have lived."